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Faculty of Medicine Ramathibodi Hospital

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Introduction

งานวิจัยแพทย์ประจำบ้าน ถือเป็นส่วนหนึ่งของการอบรมเป็นแพทย์ผู้เชี่ยวชาญในศัลยศาสตร์สาขาต่างๆ ด้วยเหตุผลตรงไปตรงมาว่า การเป็นผู้เชี่ยวชาญในความรู้สาขาใดก็ตาม ย่อมรวมไปถึงการมีความสามารถผลิตความรู้ใหม่ในสาขานั้นๆด้วย และการทำวิจัยก็คือการผลิตความรู้ใหม่ในแง่มุมของวิทยาศาสตร์ นั่นเอง

แต่การทำวิจัย เป็นมากไปกว่ากิจกรรมที่ทำขึ้นเพื่อตอบสนองข้อกำหนดของหลักสูตรฝึกอบรมผู้ที่ทำวิจัยอย่างจริงจังอาจมีมุมมองหรือโลกทัศน์ที่เปลี่ยนไปหรือแตกต่างไปจากคนปกติได้ เนื่องเพราะการทำวิจัยจะเน้นให้ผู้อบรม เข้าใจถึงประโยชน์และคุณค่าที่แท้จริงของงานวิจัย เข้าถึงข้อจำกัดต่างๆของขั้นตอนการผลิตความรู้ใหม่ มีประสบการณ์ในการทบทวนความรู้ที่มีอยู่ในปัจจุบัน ที่เกี่ยวข้องกับศาสตร์หนึ่งๆ ทำให้ทราบถึงขอบเขตของความรู้ที่มีอยู่ และดังนั้นจึงทราบถึงความไม่รู้ของวิชาการที่เกี่ยวข้อง ว่าลึกและกว้างเพียงใด การประกอบวิชาชีพของผู้อบรม จะเป็นไปอย่างระมัดระวัง เพราะจะไม่ไว้ใจหรือเชื่อคำกล่าวที่ไม่มีหลักฐานสนับสนุนเพียงพอ โดยประเมินได้ว่าหลักฐานที่อ้างถึงนั้น อาจไม่มีน้ำหนักแต่อย่างใด

ในทางปฏิบัติ ผลประโยชน์ที่ได้จากงานวิจัยที่ทำสำเร็จลุล่วงอย่างงดงาม นอกเหนือจากประโยชน์ในแง่การปรับเปลี่ยนโลกทัศน์แล้ว ยังนำไปสู่ความภาคภูมิใจของผู้อบรม ที่ได้รู้ว่าตนมีส่วนร่วมในการพัฒนาวิชาชีพไม่ว่าจะเล็กน้อย (หรือยิ่งใหญ่) เพียงใด อาจนำไปสู่การตีพิมพ์เผยแพร่ผลงาน ที่จะจารึกชื่อของตนไว้เป็นเวลานานตราบที่โลกของเครือข่ายอิเล็กทรอนิกส์ยังคงมีอยู่ เป็นที่ชื่นชมของลูกหลานและเหลน หรืออย่างน้อยที่สุด ก็ใช้เป็นพื้นฐานของการเลื่อนเงินเดือนในอนาคต การตีพิมพ์ผลงานนั้น ถือว่าเป็นจุดจบของการเริ่มต้นชีวิตของงานวิจัยชิ้นหนึ่งๆ ถ้าหากไม่มีการตีพิมพ์ ก็ต้องถือว่างานวิจัยได้ตายไปแล้วตั้งแต่คลอด

งานวิจัยของแพทย์ประจำบ้าน ภาควิชาศัลยศาสตร์ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มีคุณภาพอยู่ในชั้นแนวหน้าของสถาบันฝึกอบรมทั้งประเทศ เป็นที่ภาคภูมิใจของภาควิชาและคณะฯ ทั้งนี้เป็นเพราะความอุตสาหะวิริยะ และความกระตือรือร้นของแพทย์ประจำบ้านทุกคน แต่ที่ขาดเสียมิได้ ก็คือการสนับสนุน ความร่วมมือ และความยินยอมของอาจารย์ในภาควิชาฯทุกท่าน ที่ให้การวิจัยดังกล่าวเกิดขึ้นได้ และในหลายกรณีให้แพทย์ประจำบ้านเข้าร่วมโครงการวิจัยของอาจารย์เอง อีกทั้งยังกำกับดูแล และสั่งสอนวิธีการวิจัยให้แก่แพทย์ประจำบ้านเป็นอย่างดี จึงต้องขอขอบคุณแพทย์ประจำบ้านและขอบพระคุณอาจารย์ในภาควิชาฯทุกท่าน ที่ทำให้งานวิจัยของแพทย์ประจำบ้านในแต่ละปีจบลงได้ และประสบความสำเร็จอย่างสูง จนปรากฏเป็นผลงานที่นำเสนอในหนังสือเล่มนี้

ท้ายที่สุด ที่สำคัญไม่ยิ่งหย่อนกว่ากัน ก็คือ การสนับสนุนของท่านหัวหน้าภาควิชาศัลยศาสตร์ รองศาสตราจารย์นายแพทย์เฉลิมพงษ์ ฉัตรดอกไม้ไพร ที่เห็นความสำคัญของงานวิจัยของภาควิชามาตลอด และอดีตหัวหน้าภาควิชาศัลยศาสตร์ ศาสตราจารย์นายแพทย์กฤษฎา รัตนโอฬาร อาจารย์นายแพทย์สาธิต กรเณศ และศาสตราจารย์นายแพทย์วชิร คชการ ที่ให้งานวิจัยเป็นหนึ่งในเป้าหมายหลักสำหรับงานพัฒนาของภาควิชาฯ โดยให้การสนับสนุน และให้กำลังใจแก่ผู้เขียนและคณะกรรมการสนับสนุนงานวิจัย ตลอดเวลาที่ทำงานสนับสนุนการวิจัยให้แก่ภาควิชาฯ

รองศาสตราจารย์ภาณุวัฒน์ เลิศสิทธิชัย
ผู้แทนคณะกรรมการสนับสนุนงานวิจัยภาควิชาศัลยศาสตร์

welcome message

สารจากหัวหน้าภาควิชาศัลยศาสตร์

การทำวิจัยและการสร้างนวัตกรรมเป็นกระบวนการทางวิทยาศาสตร์ที่มีความสำคัญอย่างยิ่งในการพัฒนาสิ่งใหม่ๆ องค์ความรู้ อุปกรณ์หรือกระบวนการรักษาพยาบาลในผู้ป่วยศัลยกรรม และเกิดประโยชน์ในวงกว้างหากมีการตีพิมพ์หรือถ่ายทอดสู่สาธารณะเพื่อนำไปสู่การใช้ความรู้นั้นๆได้จริง

การสร้างผลงานวิจัยจึงเป็นหนึ่งใน learning & training objectives ที่จะทำให้ผู้เข้ารับการฝึกอบรมสามารถนำทักษะดังกล่าวไปใช้ในพัฒนาการเรียนรู้ นวตกรรมได้ตลอดการทำงานในอนาคต จึงได้รับการบรรจุในหลักสูตร ทุกหลักสูตรของศัลยศาสตร์เพื่อให้แพทย์ประจำบ้าน และแพทย์ประจำบ้านต่อยอด การนำเสนอองค์ความรู้ให้ผู้ฟังเข้าใจ และเกิดปัญญาในการพัฒนาองค์ความรู้ในระดับสูงขึ้น

ขอแสดงความยินดีกับผู้วิจัยทุกท่านที่ประสบความสำเร็จในการศึกษาวิจัยและนำเสนอ ไม่ว่าจะได้รับรางวัลหรือไม่ก็ตาม และทุกผลงานดีๆจะได้รับประโยชน์ทวีคูณ หากได้รับการเผยแพร่ในเวทีนานาชาติ หรือตีพิมพ์ในวารสารนานาชาติ อย่าได้หยุดเพียงแต่การนำเสนอในเวทีภาควิชาศัลยศาสตร์คณะแพทยศาสตร์โรงพยาบาลรามาธิบดีเท่านั้น

รองศาสตราจารย์ นายแพทย์เฉลิมพงษ์ ฉัตรดอกไม้ไพร
หัวหน้าภาควิชาศัลยศาสตร์
มีนาคม 2568

ORGANISING COMMITTEE

คณะกรรมการสนับสนุนงานวิจัยภาควิชาศัลยศาสตร์

ปีการศึกษา 2567

• รศ.นพ.ภาณุวัฒน์	เลิศสิทธิชัย	ประธานกรรมการ
• ศ.นพ.จุมพล	วิลาศรัศมี	กรรมการ
• รศ.พญ.ปิยนุช	พูตระกูล	กรรมการ
• ผศ.นพ.คชินท์	วัฒนะวงษ์	กรรมการ
• ศ.นพ.เอก	หังสสูต	กรรมการ
• ผศ.พญ.พรศรี	ธนะฉัตรชัยรัตนะ	กรรมการ
• ผศ.นพ.ปรมินทร์	ม่วงแก้ว	กรรมการ
• ผศ.พญ.ปกเกศ	ศิริศรีตรีรักษ์	กรรมการ
• นพ.ปริญญา	ลีลายนะ	กรรมการ
• ดร.นพ.กรกช	เกษประเสริฐ	กรรมการ
• นพ.สามารถ	ภูวไพรศิริศาล	กรรมการ
• นพ.ชวินธีร์	พุทธธนะพิทักษ์	กรรมการ

เจ้าหน้าที่ประจำหน่วยสนับสนุนงานวิจัยภาควิชาศัลยศาสตร์

• นางวรภรณ์	ศรียอดเวียง	นักวิทยาศาสตร์
• นางสาวญาดา	เพ็งสะและ	ผู้ช่วยวิจัย
• นางสาวทิฆัมพร	เหลืองวัฒนวิไล	ผู้ช่วยวิจัย
• นางสาววิจิตรา	มาแตง	เจ้าหน้าที่วิจัยและเลขานุการ
• นางสาวนิภาพรรณ	ชูหนู	เจ้าหน้าที่วิจัย
• นางสาวสุไรด๊ะ	อีซอ	เจ้าหน้าที่วิจัย
• นางสาวปัตตาเวีย	ช้อยเครือ	เจ้าหน้าที่วิจัย
• นางสาวนภัสสร	สุวรรณเทวะคุปต์	เจ้าหน้าที่วิจัย
• นางสาวชุติมน	เติมขวัญเจริญ	เจ้าหน้าที่วิจัย

RESIDENTS AND FELLOW

แพทย์ประจำบ้านและแพทย์ประจำบ้านต่อยอด
ภาควิชาศัลยศาสตร์ ที่จบการฝึกอบรม ปีการศึกษา 2567

แพทย์ประจำบ้าน

สาขาศัลยศาสตร์

- นายแพทย์สหรัฐ ปองมงคล
- นายแพทย์นินนาท ฟองสุภา
- นายแพทย์ธีรภัทร ศรีนา
- นายแพทย์พัฒนภักดิ์ รักชอบ
- นายแพทย์ฐากูร กงเพชร
- นายแพทย์ภัทรพล โชติสันต์
- นายแพทย์ณัฐคมน์ แก้วเภตรา
- นายแพทย์ปฐมพงศ์ ชิตเลิศ
- แพทย์หญิงพัชภรณ์ เสริมสาสน์รัตน์
- แพทย์หญิงพิมพ์ชนก รุ่งวรโสภิต
- แพทย์หญิงปาณิสรา ศรีสุวรรณนิเวศ
- แพทย์หญิงอรณิชา มากเกษม

สาขาศัลยศาสตร์ยูโรวิทยา

- นายแพทย์วรากร จิระจันทร์
- นายแพทย์กัญจน์ ปัญญาพินิจนุกูร
- นายแพทย์ธนกร ปัทมาวไล
- นายแพทย์ธรพล เศรษฐวงศ์
- แพทย์หญิงอรณิชา เพราะสุนทร

สาขากุมารศัลยศาสตร์

- แพทย์หญิงภาวิตา ธรรมโสภิต
- แพทย์หญิงวรัญญา วรรณธนาเลิศ

สาขาประสาทศัลยศาสตร์

- นายแพทย์อานุภาพ ภูไชยแสง
- นายแพทย์ธนกร จตุรสุวรรณ
- แพทย์หญิงวีรยา จริยานุภาเดชา
- นายแพทย์ยศกร เลิศไกร

สาขาศัลยศาสตร์ทรวงอก

- นายแพทย์อภิภัทร์ ธีรกุล
- นายแพทย์กุลธร คดีธรรม

RESIDENTS AND FELLOW

แพทย์ประจำบ้านและแพทย์ประจำบ้านต่อยอด
ภาควิชาศัลยศาสตร์ ที่จบการฝึกอบรม ปีการศึกษา 2567

แพทย์ประจำบ้าน

สาขาศัลยศาสตร์ตกแต่ง

- แพทย์หญิงชวิศา มาลีวรรณ
- นายแพทย์ธนภัทร ศรีสุวัฒน์
- แพทย์หญิงอมลิน ภมะราภา
- แพทย์หญิงเพ็ญศิริ แสนสามารถ

แพทย์ประจำบ้านต่อยอดปี 1

อนุสาขาศัลยศาสตร์เต้านมและต่อมไร้ท่อ

- แพทย์หญิงมนสินี สงวนแก้ว
- แพทย์หญิงกัลย์กมล ตามใจจิตร
- แพทย์หญิงวศินี แดงผ่องศรี

อนุสาขาผ่าตัดผ่านการส่องกล่องศัลยศาสตรทั่วไป

- แพทย์หญิงกฤษตินา สุรชัยดังถวิล
- นายแพทย์วุฒิพงษ์ สุจินดามณีชัย

อนุสาขาศัลยศาสตร์ตับ ตับอ่อนและทางเดินน้ำดี

- นายแพทย์สุขุม กอบเดช
- นายแพทย์อติวิชญ์ อัศวชัยสุวิกรม

อนุสาขาประสาทศัลยศาสตร์กระดูกสันหลังและไขสันหลัง

- นายแพทย์ไซดาน หะยีสะมะแอ

อนุสาขาศัลยศาสตร์ปลูกถ่ายอวัยวะ

- แพทย์หญิงสาคเรศ ทางเรือ
- นายแพทย์ศุภเสกข์ ภัทรวงศ์ไพบูลย์

แพทย์ประจำบ้านต่อยอดปี 2

อนุสาขาศัลยศาสตร์มะเร็งวิทยา

- นายแพทย์รัฐพล ธวัชพงศ์ธร
- แพทย์หญิงกนิษฐา เพิกโสภณ

อนุสาขาศัลยศาสตร์หลอดเลือด

- แพทย์หญิงพจนวรรณ สินสุวงศ์วัฒน
- นายแพทย์ชวลิต ติรพัฑฒ์
- แพทย์หญิงธัชพร บุญเสก

Conference schedule

27 MARCH, 2025

Athasit Vejjajiva Room, Queen Sirikit Medical Center,
Faculty of Medicine Ramathibodi Hospital

07.30 - 08.00	Registration	
08.00 - 08.10	Open ceremony By Head of Surgery Dept.	
08.10 - 08.20	Early Identification of Middle Meningeal Artery in Modified Craniotomy Using Sphenoparietal Keyhole Comparing with Craniotomy Using MacCarty Keyhole in Routine Fronto-temporal Craniotomy, Randomized Controlled Trial	นพ.ยศกร เลิศไกร Neuro
08.20 - 08.30	Comparison of hospital stay between microscopic approach and endoscopic approach for discectomy and lateral recess decompression: A retrospective study.	พญ.วีรยา จริยานุภาเดชา Neuro
08.30 - 08.40	Gamma-glutamyl transferase predicts jaundice clearance following kasai operation – A thai multicentre study	พญ.วรัญญา วรรณธนาเลิศ Ped
08.40 - 08.50	The optimal flow rate for continuous bladder irrigation in patients with gross hematuria	นพ.วรากร จิระจันทร์ Uro
08.50 - 09.00	Evaluating Inferior Alveolar Nerve Injury After Bilateral Sagittal Split Osteotomy Using Bicortical Screw Vs Miniplate	นพ.ธนภัทร ศรีสุวัฒน์ Plastic
09.00 - 09.10	Comparative study of Overactive bladder symptoms management with High-intensity Focused Electromagnetic stimulation Chair therapy and Mirabegron	นพ.ธนกร ปัทมาวไล Uro
09.10 - 09.20	Outcome comparison between traditional curettage and cotton swab technique for endoscopic transsphenoidal surgery of pituitary adenoma.	นพ.ธนกร จตุรสุวรรณ Neuro
09.20 - 09.30	Association of the timing in performing ERCP and overall complication in acute cholangitis, Ramathibodi hospital.	นพ.ฐากูร กงเพชร Gen
09.30 - 09.40	Can sanitary napkin improve healing of chronic venous ulcer compared with conventional gauze covering? : A randomized controlled trial	นพ.ธีรภัทร ศรีนา Gen
09.40 - 09.50	Impact of prostate shape ratio on perioperative bleeding and other perioperative outcomes of robotic assisted laparoscopic radical prostatectomy	นพ.ธรพล เศรษฐวงศ์ Uro

Conference schedule

27 MARCH, 2025

Athasit Vejjajiva Room, Queen Sirikit Medical Center,
Faculty of Medicine Ramathibodi Hospital

09.50 - 10.00	Importance of anticoagulant in venous thromboembolism prophylaxis for surgical patients	นพ.สหรัฐ ปองมงคล Gen
10.00 - 10.10	Significant associated risk factors in venous thromboembolism for surgical patients in Ramathibodi Hospital	พญ.พิมพ์ชนก รุ่งวรโศภิต Gen
10.10 - 10.20	Donor-site morbidity of rectus sheath sparing tram flap in breast reconstruction: A retrospective review	พญ.เพ็ญศิริ แสนสามารถ Plastic
10.20 - 10.30	Factor associated with perioperative major adverse cardiovascular events (MACE) of patient undergone non-cardiac vascular surgery	นพ.ภัทรพล โชติสันต์ Gen
10.30 - 10.40	Short term outcome of laparoscopic vs open hepatectomy in Ramathibodi hospital	นพ.พัฒนภักดิ์ รักชอบ Gen
10.40 - 10.50	A study of quality of life in end-stage renal disease patients undergoing different types of vascular access procedures at the division of vascular surgery, Ramathibodi hospital	นพ.ปฐมพงศ์ ชิตเลิศ Gen
10.50 - 11.00	Role of indocyanine green assist laparoscopic cholecystectomy compared with conventional laparoscopic cholecystectomy in Ramathibodi hospital: Randomized controlled trial	พญ.พัชภรณ์ เสริมสาสน์รัตน์ Gen
11.00 - 11.10	Parathyroid surgery in patients with secondary and tertiary hyperparathyroidism	พญ.ปาณิสรา ศรีสุวรรณนิเวศ Gen
11.10 - 11.20	Prospective Randomized Controlled Trial to evaluate effectiveness of Tranexamic Acid Irrigation on Perioperative Blood Loss During Mini-Percutaneous Nephrolithotomy	พญ.อรณิชา เพราะสุนทร Uro
11.20 - 11.30	An in vitro study of Microencapsulation of Human Parathyroid Cell	พญ.อรณิชา มากเกษม Gen
11.30 - 11.40	Patient characteristic and outcome after second kidney transplantation, single center experience	นพ.ณัฐคมน์ แก้วเภตรา Gen
11.40 - 11.50	Prevalence of and factors associated with intraductal papillary lesion, both of benign and malignant, in patients with nipple discharge undergoing mammary duct excision	นพ.นินนาท ฟองสุภา Gen

Conference schedule

27 MARCH, 2025

Athasit Vejjajiva Room, Queen Sirikit Medical Center,
Faculty of Medicine Ramathibodi Hospital

11.50 - 12.00	Overall 5-year survival rate and disease-free survival after segmentectomy versus lobectomy in patients with non-small cell lung cancer	นพ.กุลธร คดีธรรม CVT
12.00 - 12.10	Comparison of Robotic vs Laparoscopic Radical Nephroureterectomy with bladder cuff excision in Upper Urinary Tract Urothelial Carcinoma: A Retrospective Cohort Study	นพ.กัญจน์ ปัญญาพินิจนุกูร Uro
12.10 - 12.20	In Search of Aesthetic Nasal Profile in East Asians	พญ.ชวิศา มาลีวรรณ Plastic
12.20 - 12.30	Association between image-defined risk factor and surgical outcome and complication in abdominal neuroblastoma in Ramathibodi hospital	พญ.ภาวิตา ธรรมโสภิต Ped
12.30 - 12.40	5-year survival rate of Pediatric pulmonary metastatic sarcoma , Post-pulmonary metastasectomy in Ramathibodi Hospital, A retrospective study	นพ.อภิภัทร์ ธีรกุล CVT
12.40 - 12.50	The anatomical relation between Transverse-Sigmoid sinus and skull landmarks in 3D imaging study	นพ.อานุภาพ ภูไชยแสง Neuro
12.50 - 13.00	Risk Factors of Bottoming-out Deformity in Primary Breast Augmentation Patients in Ramathibodi Hospital: A Retrospective Study	พญ.อมลิน ภมะราภา Plastic
13.00 - 14.30	ปิดการประชุมฯ และรับประทานอาหารกลางวัน	

Abstract

“Early Identification of Middle Meningeal Artery in Modified Craniotomy Using Sphenoparietal Keyhole Comparing with Craniotomy Using MacCarty Keyhole in Routine Fronto-temporal Craniotomy, Randomized Controlled Trial”

Yossakorn Lertkrai, MD

Yossakorn Lertkrai,[1] Ake Hansasuta,[1] Sorayouth Chumnanvej,[1] Kriangsak Saetia,[1] Siriwut Pokanan,[1] Atthaporn Boongird [1]

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Background: The MacCarty keyhole has been considered the traditional surgical landmark for pterional craniotomy. The middle meningeal artery (MMA) is often torn during bone flap elevation due to its characteristic of piercing the sphenoid wing. To avoid cutting through the sphenoid wing, the sphenoparietal suture, which is anatomically correlated with the MMA, may be a useful landmark for pterional craniotomy.

Objective: To compare between the application of the traditional MacCarty keyhole and the alternative sphenoparietal keyhole for fronto-temporal (pterional) craniotomy in terms of the identification of middle meningeal artery (MMA) through the keyholes, as well as its preservation, blood loss during craniotomy, duration of craniotomy and aesthetic effect.

Methods: A randomized controlled trial (TCTR20250117006) was conducted from January 2022 to January 2025 to compare the data and clinical outcomes between two surgical techniques. Data analysis was performed using Program STATA with the Two-sample t test or Wilcoxon rank-sum (Mann-Whitney) test for quantitative variables and the Chi-square test or Fisher's exact test for categorical variables.

Results: Out of a total of 49 patients, 23 used the MacCarty keyhole and 26 used the sphenoparietal keyhole. As anticipated based on anatomical considerations, MMA could not be identified in any of the cases using the MacCarty keyhole, whereas it was identified in 13 cases (50%) using the sphenoparietal keyhole prior to craniotomy flap elevation (P <0.001). Blood loss during craniotomy for the sphenoparietal group [median 50 mL (10-400 mL)] was slightly less than in the traditional MacCarty group [median 100 mL (30-500 mL)]; (P =0.137). Craniotomy could be performed more rapidly using the sphenoparietal keyhole [10 minutes (7–27 minutes)] compared to the MacCarty keyhole [13 minutes (8–20 minutes)]; (P = 0.018), which corresponds with trends toward a smaller number of burr hole requirements in the sphenoparietal group compared to the MacCarty group. There was higher number of cases with unpleasant aesthetic outcome from skull defect in the MacCarty group [17 cases (73.9%)] than in the sphenoparietal group [12 cases (46.1%)]; (P =0.048).

Conclusion: The sphenoparietal keyhole is superior to the traditional MacCarty keyhole for routine fronto-temporal craniotomy in terms of a higher chance of early MMA identification, avoiding cuts into the sphenoid wing, less blood loss during craniotomy, faster craniotomy performance, fewer burr hole requirements and better aesthetic outcome.

Keyword: Sphenoparietal keyhole; MacCarty keyhole; Pterional craniotomy; Fronto-temporal craniotomy; Middle meningeal artery; MMA

Early Identification of Middle Meningeal Artery in Modified Craniotomy Using Sphenoparietal Keyhole Comparing with Craniotomy Using MacCarty Keyhole in Routine Fronto-temporal Craniotomy, Randomized Controlled Trial

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COA. MURA2021/497

Title of Project (English)	Early Identification and Preservation of Middle Meningeal Artery in Modified Craniotomy Using Sphenoparietal Keyhole Comparing with Craniotomy Using MacCarty Keyhole in Routine Fronto-temporal Craniotomy, Randomized Control Trial
Title of Project (Thai)	การศึกษาเพื่อเปรียบเทียบการพบเจอและการเก็บรักษาหลอดเลือดแดงมิดเดิลมีนิน เจียลระหว่างการใช้สฟีโนบ่าไรทัลคีย์โฮลกับการใช้แมคคาร์ทีคีย์โฮลในการผ่าตัดเปิดกะโหลกศีรษะบริเวณฟรอนโตเทมปอรัล
Type of Review	Full Board
Principal Investigator	Yossakorn Lertkrai, M.D.
Official Address	Department of Surgery Medicine Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator(s)	1. Attaporn Boongird, M.D.
Approval includes	1. Submission Form Protocol Version 2 Date 17/6/2021 2. Patient Information Sheet Version 2 Date 17/6/2021 3. Informed Consent Form Version 1 Date 15/3/2021 4. Case Record Form Version 1 Date 15/3/2564 5. Certificate in Ethics Training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	June 24, 2021
Date of Expiration	June 23, 2022

Signature of Chair.....

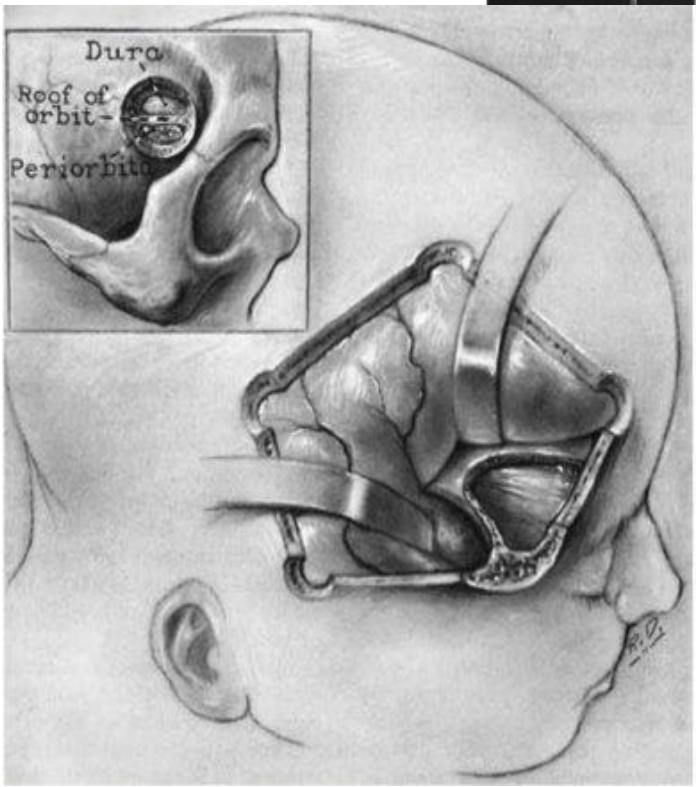
(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Introduction

- The MacCarty keyhole = the traditional surgical landmark for pterional craniotomy.

- Initially proposed by Collin Stewart MacCarty in 1950s . The inventor called it as “anterior inferior keyhole”

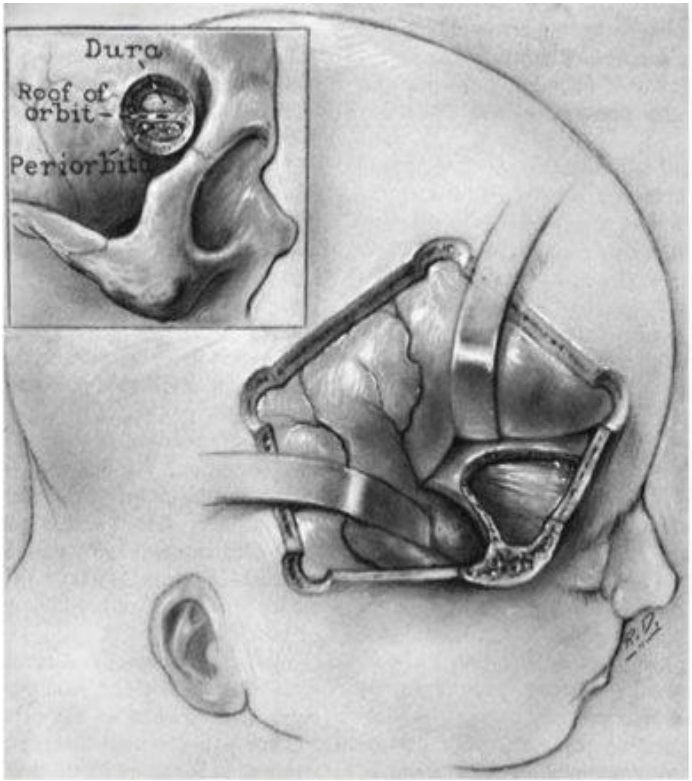


Orbitozygomatic Jumah F, Adeeb N, Dossani RH. Collin S. MacCarty (1915-2003): Inventor of the "MacCarty Keyhole" as the Starting Burr Hole for Craniotomy. World Neurosurg. 2018 Mar;111:269-274.

Introduction

- “the junction of the sphenoid ridge, lateral posterior portion of the orbit, and the anterior portion of the zygomatic arch”

- frontosphenoidal suture and 1 cm posterior to the frontozygomatic junction



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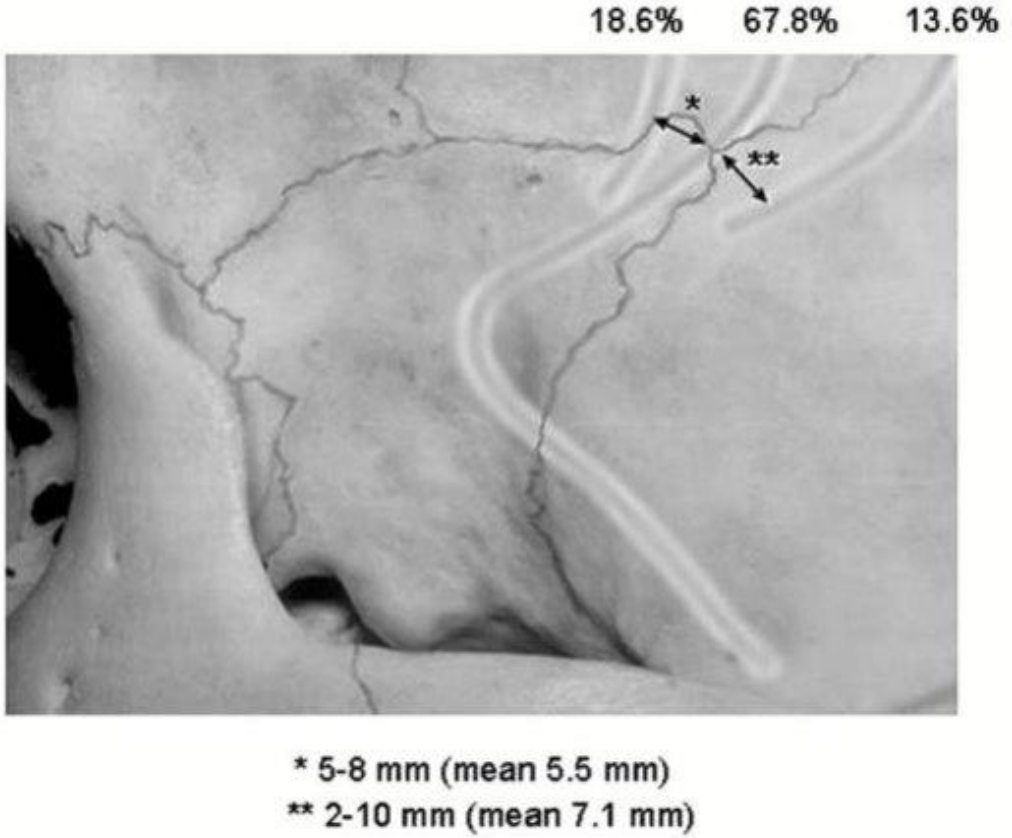
Introduction

- The prominent vascular structure passing by pterion is the middle meningeal artery (MMA).

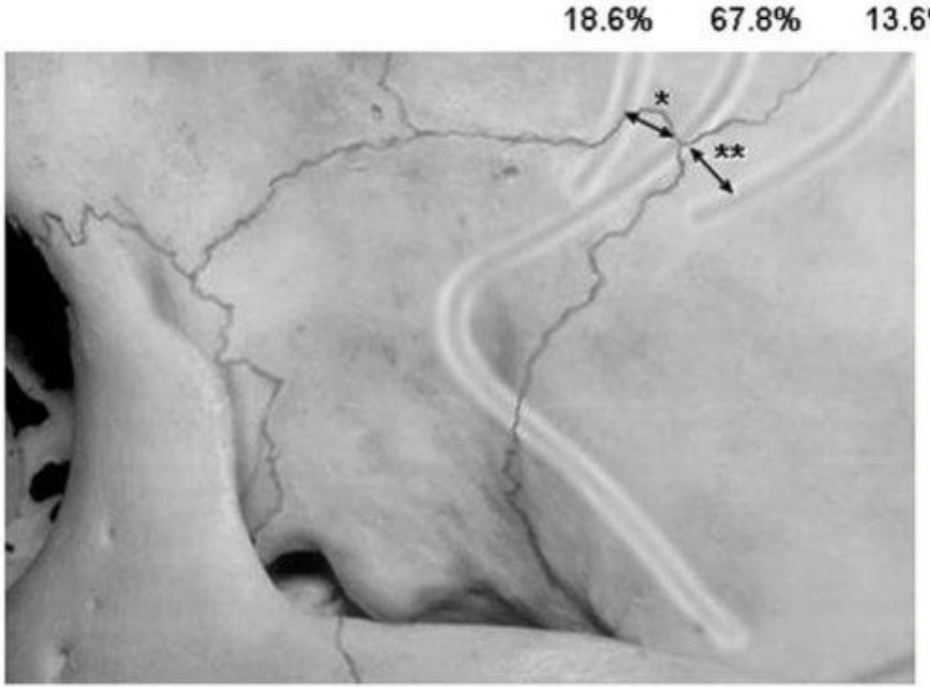
- anterior branch of MMA is found to be piercing through a ‘tunnel’ in the lesser wing of sphenoid bone just beneath the junction of the sphenoparietal, sphenosquamosal and squamosal sutures



Shimizu S, Hagiwara H, Utsuki S, Oka H, Nakayama K, Fujii K. Bony tunnel formation in the middle meningeal groove: an anatomic study for safer pterional craniotomy. Minim Invasive Neurosurg. 2008 Dec;51(6):329-32.

Introduction

- MMAs are often torn apart during bone flap lifting due to its characteristic of piercing into sphenoid bone. This is mostly due to fracture of the sphenoid bone during this process



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Objective

- To compare between the application of the traditional MacCarty keyhole and the alternative sphenoparietal keyhole for fronto-temporal (pterional) craniotomy in terms of the identification of middle meningeal artery (MMA) through the keyholes, as well as its preservation, blood loss during craniotomy, duration of craniotomy and aesthetic effect

Methods - Study design

- Patient Enrollment
  - Randomized controlled trial
  - experimental study in patients undergoing frontotemporal craniotomy in our institution from January 2022 to January 2025.

- Inclusion criteria
  - at the age of 18 or older
  - receiving fronto-temporal craniotomy

Methods - Study design

- Exclusion criteria
  - emergency cases
  - receiving prior craniotomy upon the same surgical site
  - intellectual disabilities or lack of awareness
  - below the age of 18
  - suspicious for previous tear of MMA
  - patients' own desire to terminate the enrollment.

Methods - Data collection and Follow-up

- separated into two groups :using the MacCarty’s keyhole or the sphenoparietal keyhole.
- a computerized program to create an order of randomized allocation between these two groups. A concealed envelope was assigned to each patient

Methods - Data collection and Follow-up

- The outcomes include:
  - identification of MMA through the keyhole
  - preservation of MMA
  - ability to coagulate MMA through the burr hole prior to craniotomy flap elevation
  - blood loss during craniotomy
  - change in hemoglobin concentration
  - duration of craniotomy
  - aesthetic effect.

Statistics and Data Analysis

- Data analysis was performed using Program STATA.
- Quantitative data was summarized as mean and SD or median and range as appropriate.
- Categorical data was summarized as counts and percentage.
- Comparison of quantitative variables between groups was done using the Two-sample t test or Wilcoxon rank-sum (Mann-Whitney) test as appropriate.
- Comparison of categorical variables between groups was done using the Chi-square test or Fisher's exact test as appropriate.
- P-value <0.05 was considered statistically significant.

Results

- We performed the surgeries in total of 49 patients.
- Twenty-three patients= MacCarty's keyhole
- 26 patients = sphenoparietal keyhole.

- None of the cases (0%) were those able to be identified MMA through the MacCarty keyhole
- 13 cases (50%) were those able to be identified with MMA through the sphenoparietal keyhole with statistical significance (P value <0.001)

Variables	MacCarty (n = 23)	Sphenoparietal (n = 26)	P-value
Age (year); median (min, max)	54 (27, 73)	49.5 (18, 74)	0.326
mean ± SD	52.3 ± 11.1	47.7 ± 16.2	0.256
Gender; n (%)			
Male	7 (30.4)	8 (30.8)	0.980
Female	16 (69.6)	18 (69.2)	
Identify MMA; n (%)	0 (0.0)	13 (50.0)	**< 0.001**
Preserve MMA; n (%)	0 (0.0)	1 (3.9)	> 0.999
Coagulate MMA; n (%)	0 (0.0)	12 (46.1)	**< 0.001**

Table 1: Primary outcomes data collection comparing between the MacCarty's keyhole group and the sphenoparietal keyhole group

Results

- Can preserve MMA in only one case (3.9%) of the sphenoparietal group (P value >0.999).
- 12 cases (46.1%) were those we successfully coagulated the MMA prior to craniotomy flap elevation in order to prevent much bleeding (P-value <0.001).

Results

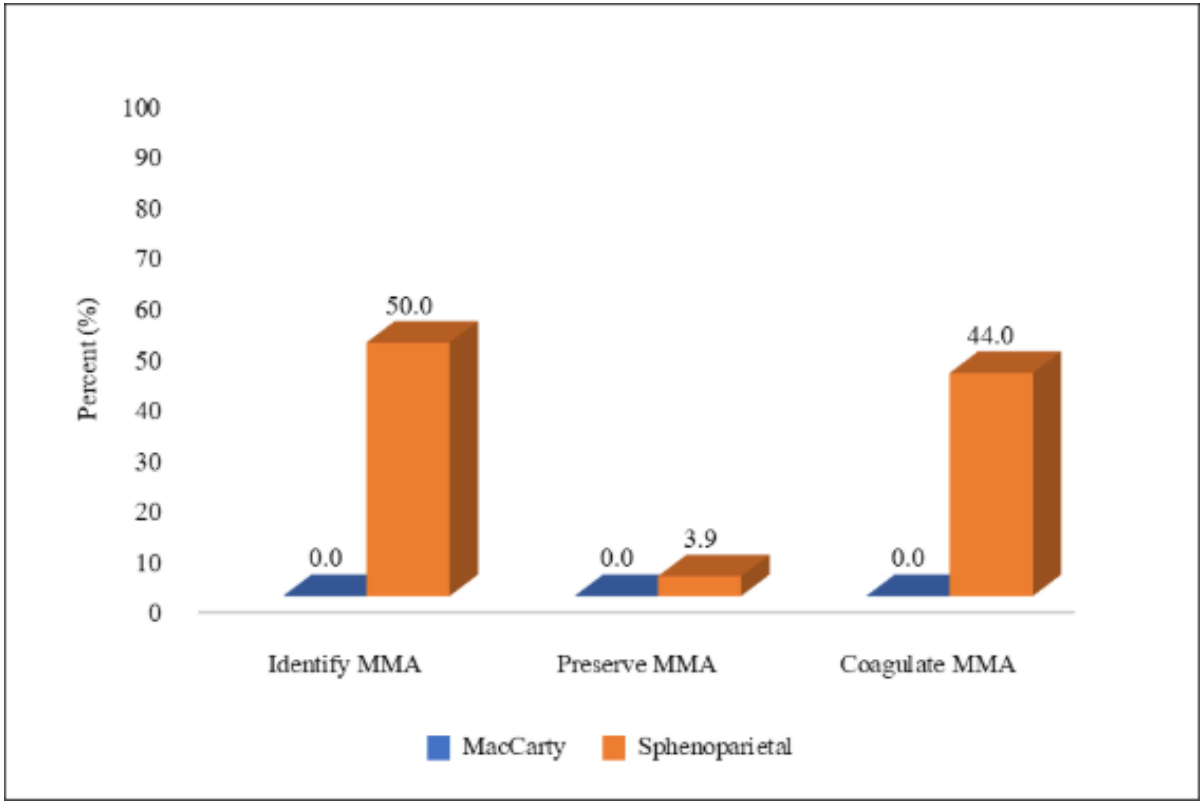

Figure 1: Primary outcomes bar charts comparing between the MacCarty's keyhole group and the sphenoparietal keyhole group

Results

- ‘obvious bleeding’ from MMA during craniotomy process
  - no difference between the MacCarty’s and the spenoparietal group [6 cases (26.1%) in the MacCarty’s group versus 7 cases (26.9%) in the sphenoparietal group, P-value =0.947].
- less blood loss during craniotomy period for the sphenoparietal group [median 50 mL (10-400 mL)] than in the MacCarty’s group [median 100 mL (30-500 mL)] even though without statistical significance (P-value=0.137)

Results

- A slightly smaller amount of overall blood loss was observed in the sphenoparietal group [median 500 mL (100-2,100mL)] than in the MacCarty's group [median 600 mL (100-2,500 mL)], but, again without statistical significance (P-value =0.093)

- 'no difference between two groups for the change of hemoglobin concentration before and after the operation. [MacCarty: mean -1.5 ± SD 1.2 (g/dL) versus sphenoparietal: mean -1.3 ± SD 1.3 (g/dL); P-value = 0.589].

Variables	MacCarty (n = 23)	Sphenoparietal (n = 26)	P-value
Obvious bleed from MMA; n (%)	6 (26.1)	7 (26.9)	0.947
Blood loss during craniotomy (mL); median (min, max) mean ± SD	100 (30, 500) 129.1 ± 118.5	50 (10, 400) 95.2 ± 92.3	0.137 0.266
Pre-op Hb (g/dL); median (min, max) mean ± SD	13.1 (10.3, 16.4) 13.2 ± 1.7	12.9 (9.3, 16.6) 12.9 ± 1.8	0.667 0.445
Post-op Hb (g/dL); median (min, max) mean ± SD	11.6 (9.4, 14.5) 11.7 ± 1.4	11.3 (9, 15.8) 11.5 ± 1.4)	0.483 0.658
Change of Hb (g/dL); median (min, max) mean ± SD	-1.4 (-4.4, 0.8) -1.5 ± 1.2	-1.3 (-4.7, 2.1) -1.3 ± 1.3	0.623 0.589

Table 2.1: Secondary outcomes data compares bleeding between the MacCarty's keyhole group and the sphenoparietal keyhole group

Variables	MacCarty (n = 23)	Sphenoparietal (n = 26)	P-value
Duration of Craniotomy (min);			
median (min, max)	13 (8, 20)	10 (7, 27)	**0.018**
mean ± SD	13.2 ± 3.5	11.2 ± 4.3	0.088
No. of burrholes; n (%)			
2	0 (0.0)	4 (15.4)	0.050
3	13 (56.5)	16 (61.5)	0.721
4	7 (30.4)	6 (23.1)	0.560
5	3 (13.0)	0 (0.0)	0.096

Table 2.2: Secondary outcomes data compares duration of craniotomy between the MacCarty's keyhole group and the sphenoparietal keyhole group

Variables	MacCarty (n = 23)	Sphenoparietal (n = 26)	P-value
Unpleasant Aesthetic outcome from skull defect			
Yes	17 (73.9)	12 (46.1)	**0.048**
No	6 (26.1)	14 (53.9)	
Skull defect type			
Obvious skull defect	13 (76.5)	6 (50.0)	0.236
Minimal skull defect (recognized only by palpation)	4 (23.5)	6 (50.0)	

Table 2.3: Secondary outcomes data compares aesthetic result between the MacCarty's keyhole group and the sphenoparietal keyhole group

Results

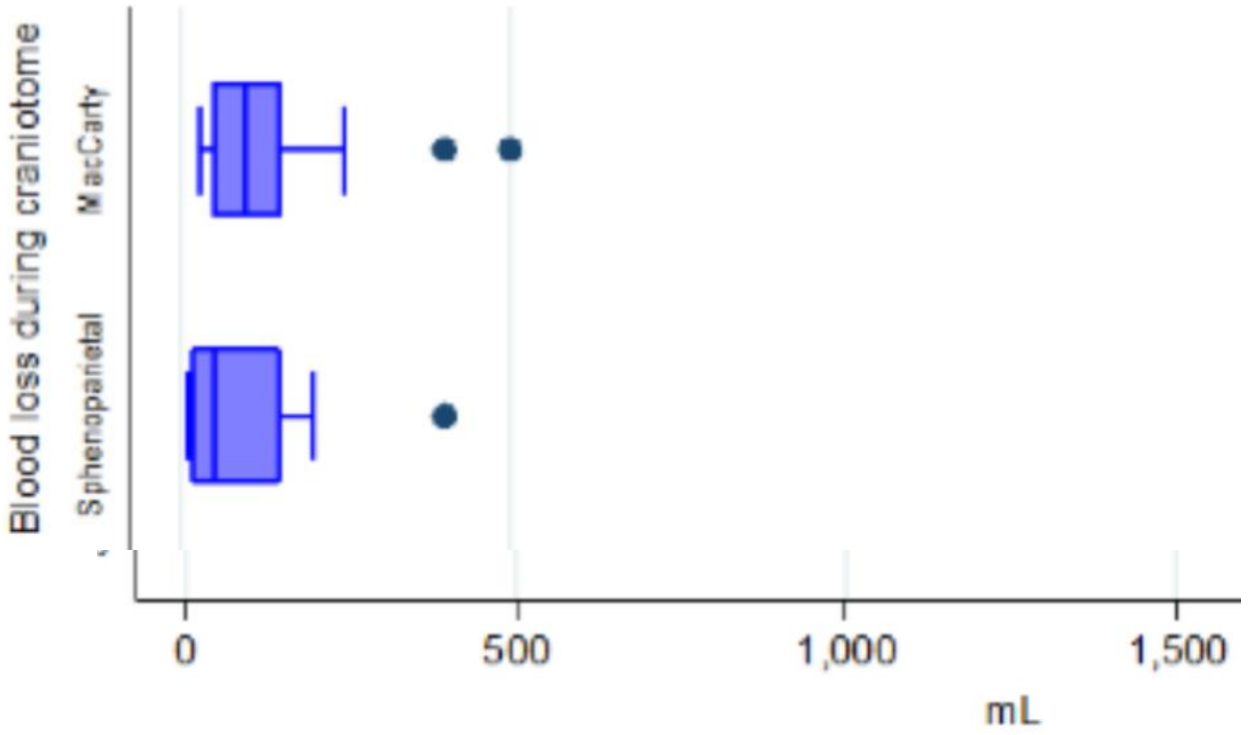

Figure 2: Box plots comparing blood loss during craniotomy and overall blood loss between the MacCarty's keyhole group and the sphenoparietal keyhole group

Results

- subgroup analysis for cases in the sphenoparietal group comparing between the group in which MMA was coagulated prior to craniotomy flap elevation and the group in which MMA was not coagulated. There was no difference in term of ‘obvious bleeding’ from MMA as subjective evaluation by the surgeon between the two groups [3 cases (25.0%) in coagulated MMA group versus 4 cases (28.6%) in non-coagulated MMA group; P-value >0.999]. There was also no difference between the two groups in terms of ‘blood loss during craniotomy’ [median 75 mL (20-200 mL) in coagulated MMA group versus 40 mL (10-400 mL) in non-coagulated MMA group; P-value =0.174], ‘overall blood loss’ [median 500 mL (200-2,100 mL) in coagulated MMA group versus 500 mL (100-1,500 mL) in non-coagulated MMA group; P-value =0.718] or ‘change of hemoglobin concentration’ [mean -0.95 ± 1.4 g/dL in coagulated MMA group versus mean -1.7 ± 1.2 g/dL in non-coagulated MMA group; P-value =0.180]

Variables	coagulation of MMA prior to craniotomy flap elevation (n = 12)	No coagulation of MMA (n = 14)	P-val
Obvious bleeding; n (%)	3 (25.0)	4 (28.6)	> 0.999
Blood loss during craniotomy;			
median (min, max)	75 (20, 200)	40 (10, 400)	0.236
mean ± SD	107.5 ± 76.6	84.6 ± 105.6	
Change of Hb (g/dL);			
median (min, max)	-1.2 (-2.5, 2.1)	-1.5 (-4.7, 0.5)	0.395
mean ± SD	-0.95 ± 1.4	-1.7 ± 1.2	0.180

Table 3: Subgroup analysis for sphenoparietal group cases

Results

- In term of the period used for craniotomy (start from first keyhole creation until craniotomy flap elevation was finished), we found that craniotomy might be performed faster using the sphenoparietal keyhole ([10 min (7-27 min)] than the MacCarty keyhole [13 min (8-20 min)] with statistical significance (P-value=0.018)

- Regarding the aesthetic effect, there was higher number of cases with concerning aesthetic problem from skull defect in the MacCarty's group [17 cases (73.9%)] than in the sphenoparietal group [12 cases (46.2%)] with statistical significance (P-value =0.048). Defining the defect type, there seemed to be more obvious defect in the MacCarty's group [13 cases (76.5%)] than in the sphenoparietal group [6 cases (50.0%)]; (P-value =0.236). There was no difference between two groups in numbers of bur-holes used before craniotomy was achieved.

Discussion

- The result of this trial confirmed our hypothesis that we would be able to early identify MMA through the bur-hole at sphenoparietal suture rather than through the original MacCarty's keyhole. The reason why we could identify MMA only about a half of the sphenoparietal group might be due to the variation of location at which point MMA passes near the sphenoparietal suture

- in our study, the surgeon would prefer coagulating the MMA to preserving it. From all the thirteen cases of the sphenoparietal group, which we were able to identify MMA through the bur-holes, we preserved MMA only in one case. In the other twelve cases, the surgeon coagulated the vessel prior to craniotomy process. Despite the statistical significance, there was a considerable bias among surgeons' decision to coagulate the vessel.

Discussion

- Although this study reported the propensity of less blood loss using the sphenoparietal keyhole, some biases during the data collection should not be overlooked. The subjective evaluation from the surgeon in term of ‘obvious bleeding from MMA’ was suspicious for measurement bias among surgeons. The estimation of blood loss during craniotomy and overall blood loss might also be subjected to the measurement bias by the estimation of the attending anesthesiologist. There were also some other factors which might be confounding intra-operative blood loss including variety of operations performed, difference in size of the tumor/lesion, difference in skull thickness, etc.

Discussion

- The result reported the tendency towards faster craniotomy process using the sphenoparietal keyhole than using the MacCarty's keyhole. This is an anatomical explanation about the issue. As we performed modified craniotomy using the sphenoparietal keyhole, the craniotomy flap was usually created in 'heart-shaped' leaving greater sphenoid wing with the rest of the cranium. On the other hand, during the craniotomy using the MacCarty's keyhole, cutting the bone flap through the greater wing of sphenoid bone was usually unavoidable, leading to longer craniotomy period in the MacCarty's group as the surgeon struggled to cut the skull through the thick sphenoid wing. The performance of each surgeon and each patient's anatomical variance somehow undeniably contributed towards biases.

Discussion

- The MacCarty's keyhole is located 1 cm posterior to frontozygomatic junction 23,24 which is more anterior than the location of sphenoparietal keyhole. This could explain the better aesthetic result in the sphenoparietal group as the sphenoparietal keyhole defect is located more posteriorly and more likely to be covered by the temporalis muscle.

Conclusion

- The sphenoparietal keyhole is superior to the traditional MacCarty keyhole for fronto-temporal craniotomy in terms of a higher chance of early MMA identification, avoiding cuts into the sphenoid wing, less blood loss during craniotomy, faster craniotomy performance, fewer burr hole requirements and improved aesthetic outcomes.

Abstract

> Comparison of hospital stay between microscopic approach and endoscopic approach for discectomy and lateral recess decompression: A retrospective study.

Weeraya Jariyanupadecha, MD

Weeraya Jariyanupadecha[1], Kriangsak Saetia[1]

[1]*Neurological surgery unit, Department of surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand*

Objective: For lateral recess stenosis or herniated nucleus pulposus (HNP), the traditional surgery is microscopic surgery, which requires an one to two inches incision. However, there is a alternative surgery that uses only small incision and an endoscope to perform the surgery. Because of smaller incision, resulting in fewer scars and allowing the patient to return to their daily activities faster. However, there is currently only some comparative studies to determine which method is better. The risks of both types of surgery include pain, blood loss, wound infection, the possibility of nerve and spinal cord injuries, and spinal instability requiring further spinal fixation.

Methods: A retrospective analysis of prospectively collected data was conducted on 180 consecutive patients with single level lateral recess stenosis or herniated nucleus pulposus. Patient demographics, operative details, complications, and recurrent disease were reviewed. Outcomes were quantified using hospital stay, the amount of pain medication that patients requested for additional injections after surgery, the intraoperative blood loss and operative time, the preoperative and postoperative leg motor power, the success of the surgery, the complications and recurrence of the disease at 1 year.

Results: A total of 95 patients underwent uniportal endoscopic and 85 underwent microscopic with a follow-up period of 12 months. The endoscopic group experienced a significantly fewer estimated blood loss ($p = 0.001$) and fewer complications ($p = 0.048$). Both groups experienced significant improvements in leg motor power ($p < 0.001$), but the endoscopic group required significantly more operative time ($p = 0.001$).

Conclusions: Uniportal endoscopic and microscopic result in similar improvement of leg motor power for single level lateral recess stenosis or herniated nucleus pulposus, while the endoscopic approach demonstrates fewer estimated blood loss and a favorable rate of complications.

Keywords: endoscopic spine surgery; lateral recess stenosis; herniated nucleus pulposus; microscopic spine surgery; discectomy; lateral recess decompression

Comparison of hospital stay and outcome between microscopic approach and endoscopic approach for discectomy and lateral recess decompression: A retrospective study.

Principal investigator: Weeraya Jariyanupadecha

Co-investigator Assoc. Prof. Kriangsak Saetia

EC

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COA No. MURA2024/231

Title of Project (English)	Comparison of hospital stay between microscopic approach and endoscopic approach for discectomy and lateral recess decompression: A retrospective study
Title of Project (Thai)	การศึกษาเปรียบเทียบระยะเวลาการนอนโรงพยาบาลของการผ่าตัดแบบใช้กล้องจุลทรรศน์และแบบส่องกล้องเอนโดสโคป ในผู้ป่วยหมอนรองกระดูกสันหลังเคลื่อนและผู้ป่วยช่องกระดูกสันหลังด้านข้างตีบ
Type of Review	Expedited
Principal Investigator	Weeraya Jariyanupadecha
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator	Kriangsak Saetia
Approval includes	1. Submission form protocol version 2 date 21/02/2024 2. Curriculum vitae 3. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	March 28, 2024
Date of Expiration	March 27, 2025

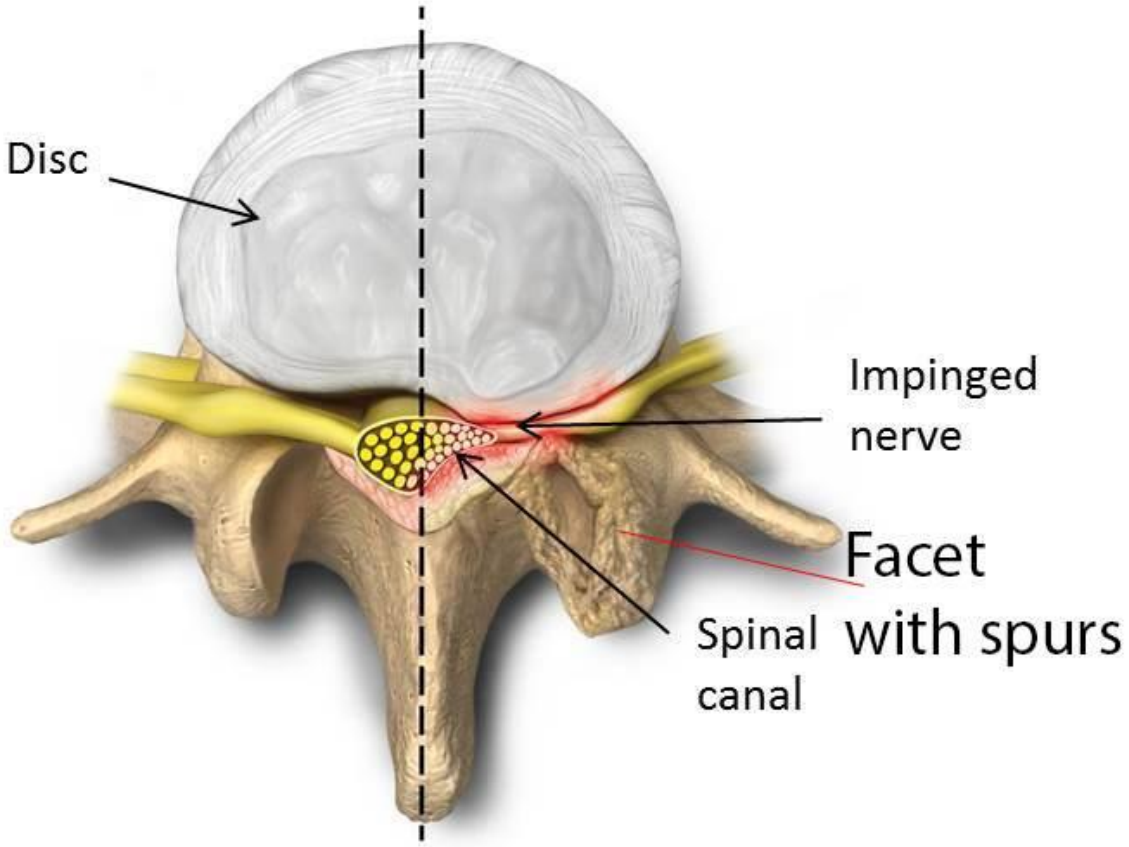
Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

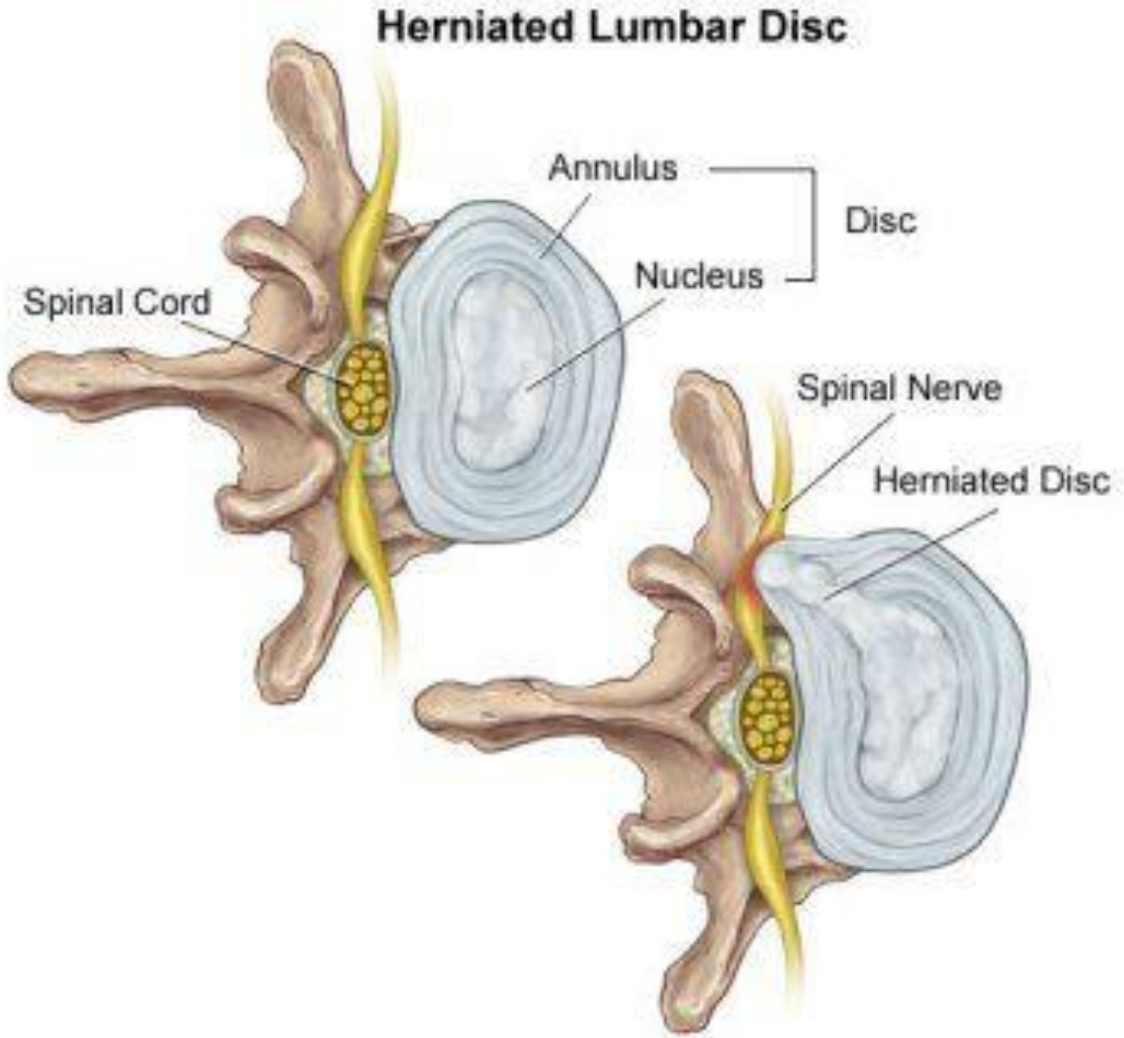
This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Introduction



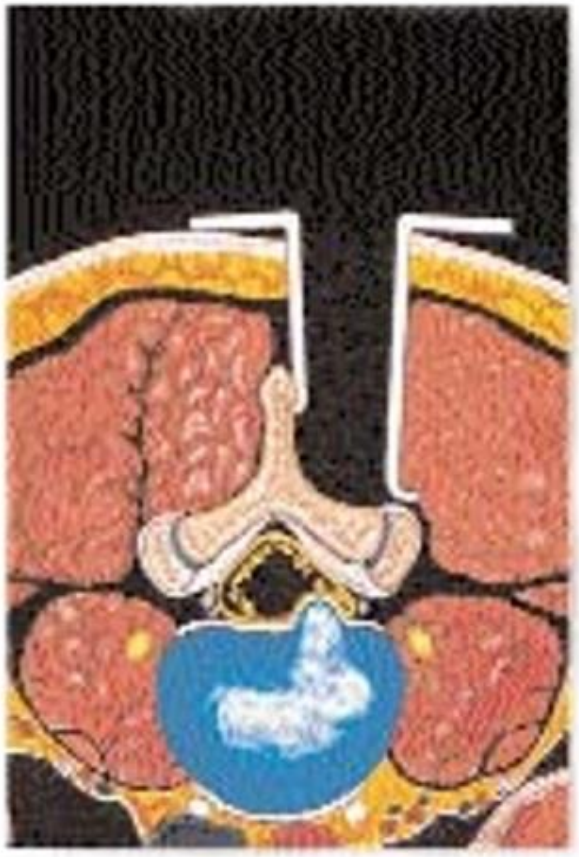
Lateral recess stenosis



Herniated nucleus pulposus

Traditional microscopic approach

Open (small incision)



Endoscopic : uniportal interlaminar approach

Material and methods

- A retrospective trial : 180 consecutive patients with single level lateral recess stenosis or herniated nucleus pulposus.
- Patient demographics, operative details, complications, and recurrent disease were reviewed.
- Outcomes were quantified using
  - hospital stay
  - amount of pain medication that patients requested for additional injections after surgery
  - intraoperative blood loss and operative time
  - preoperative and postoperative leg motor power
  - complications
  - recurrence of the disease at 1 year

Results

- Patient demographics and preoperative clinical data
- Outcome
- Adverse events

TABLE 1. Patient demographics and preoperative clinical data

N=180	Micro 0 n=85	Endo 1 n=95	Total n=180	P*
Age	58.03(14.31)	49.40(14.85)	53.47(15.18)	0.0001
Sex male	43(50.59)	48(50.53)	91(50.56)	0.993
female	42(49.41)	47(49.47)	89(49.44)	
BMI	25.52(5.32)	24.79(4.60)	25.13(4.95)	0.326
smoking	18(21.18)	11(11.58)	29(16.11)	0.080
bowel bladder involve	1(1.18)	0	1(0.56)	0.289

**Mann-Whitney U test for non-normally distributed data and t-test for normally distributed data.*
**Chi-square test for categorical data.*

TABLE 2. Outcome

N=180	Micro 0 n=85	Endo 1 n=95	Total n=180	P*
EBL (mL)	**109.47(103.66)**	**37.46(43.33)**	**71.46(85.60)**	**0.001**
op time (min)	**109.10(57.70)**	**138.2(56.58)**	**124.46(58.78)**	**0.001**
motor pre	4.38(0.939)	4.36(0.88)	4.37(0.91)	0.833
time to sx (mo)	16.79(23.73)	11.61(16.80)	14.05(20.47)	0.269
LOS (d)	3.41(2.32)	3.20(3.46)	3.30(2.97)	0.090
motor post	4.75(0.57)	4.72(0.73)	4.73(0.66)	0.388
recurrent	14(16.47)	11(11.58)	25(13.89)	0.343
Mo (mg)	11.08(4.81)	9.90(4.85)	10.46(4.85)	0.057

**Mann-Whitney U test for non-normally distributed data and t-test for normally distributed data.*
**Chi-square test for categorical data.*

TABLE 3. Adverse events

N=180		Micro 0 n=85	Endo 1 n=95	Total n=180	P*
Complication	**n%**	**8(9.41)**	**2(2.11)**	**10(5.56)**	**0.048**
Surgical site infection		2	0	2	
Dura tear		6	2	8	

**Mann-Whitney U test for non-normally distributed data and t-test for normally distributed data.*
**Chi-square test for categorical data.*

Conclusion

- Uniportal endoscopic and microscopic result in similar improvement of leg motor power for single level lateral recess stenosis or herniated nucleus pulposus.
- while the endoscopic approach demonstrates fewer estimated blood loss and a favorable rate of complications.

Thank you for your attention

Abstract

> Gamma-glutamyl transferase predicts jaundice clearance following kasai operation – A thai multicentre study

Varanya Wantanalert, MD

Varanya Wantanalert[1], Ampaipan Boonthai[1], Pornthep Tanpowpong[2], Dolrudee Aroonsang[3], Jiraporn Khorana[4], Paul D. Losty[1,5]

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Background: Gamma-glutamyl transferase (GGT) is a biomarker of liver function and may provide evidence of obstructive bile flow after Kasai Procedure (KP).

Objectives: We report the utility of GGT to monitor success of KP in a multicentre study

Methods: Medical records of Biliary Atresia (BA) patients undergoing Kasai operation during 2004 - 2022 in 3 Thailand hospitals were examined. Patient demographics, GGT level(s) at pre-operative and postoperative day(s) (POD) 7, 30, 60, 90, 120 were recorded. Total bilirubin (TB) , symptom(s) of liver cirrhosis 6 month after Kasai and number of patients needing liver transplant are analyzed.

Results: 56 BA patients (46% male: 54% female) had mean age diagnosis 71.7±26.8 days and mean age at operation 77.4±26.4 days. Pre-operative mean GGT was 887±822 mg/dL. Twenty three of 56 cases (41%) failed to become jaundice-free (TB≥2mg/dL) 6 months after Kasai. There was no difference(s) between age operation (76.4±22.9 days jaundice-free vs 78.7±31.2 days jaundice; p=0.75) or (76.4±22.9 days jaundice-free vs 78.7±31.2 days jaundice; p=0.75) steroid use (76.4% jaundice-free vs 73% jaundice; p=0.3) including post-operative complications (73.7% jaundice-free vs 68.2% jaundice; p=0.69) comparing groups. Jaundice patients had higher PELD score at 6 months (12.3±10.9 vs -0.2±6.5; p= 0.03) and cirrhosis vs jaundice-free cohort (100% vs 47.1%; p <0.05). Sixty eight percent BA jaundiced patients required early liver transplant vs 25% jaundice-free (p < 0.05). Those with jaundice at 6 months had higher percentage (%) difference(s) (ΔGGT) between pre-operative and 1-month GGT (61% jaundice vs 49% jaundice-free; p= 0.04), 2-month GGT (70% jaundice vs 50% jaundice-free; p <0.05), 3-month GGT (73% jaundice vs 61% jaundice-free; p <0.05) - (Figure 1) We found moderate correlation(s) between ΔGGT at 2 months and jaundice (TB≥2mg/dL) at 6 months (r =0.37; p= 0.05)

Conclusions: GGT profiling is predictive of jaundice clearance after Kasai operation. We recommend GGT biomonitoring to promote early referral to liver transplant centres.

Gamma-Glutamyl Transferase predicts jaundice Clearance Following Kasai Operation – A Thai Multicenter study

Varanya Wantanalert, M.D.

Advisor **: Ampaipan Boonthai,** M.D. FRCST FEBPS

Co-advisor **: Prof. Paul D. Losty, Prof. Pornthep Tanpowpong, Ass.Prof. Jiraporn Khorana, Dolrudee Aroonsang,** M.D.

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COA. MURA2022/441
Ref.2367

Title of Project (English)	Gamma-glutamyl Transpeptides (GGT) to predict outcome(s) after Kasai operation
Title of Project (Thai)	การใช้ค่าแกมม่า-กลูตามิลทรานสเปบทิเดส (GGT) เพื่อพยากรณ์ผลการผ่าตัด Kasai
Type of Review	Expedited
Principal Investigator	Varanya Wantanalert
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator (s)	1. Ampaipan Boonthai 2. Pornthep Tanpowpong 3. Jiraporn Khorana 4. Dolrudee Aroonsaeng 5. Surasak Sangkhathat Added date 26/8/2022
Approval includes	1. Submission form protocol version 4 date 22/8/2022 2. Amendment letter date 22/8/2022

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval of Amendment August 26, 2022

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:
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2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Background

- Gamma-glutamyl transferase (GGT) : biomarker of liver function
  - may provide evidence of obstructed bile flow after Kasai operation

- We observed ΔGGT pre- and post-operative Kasai during the first 6 months compare between 2 groups of patients
  1. Jaundice free (TB $\leq$ 2mg/dl)
  2. persistent jaundice (TB > 2 mg/dl).

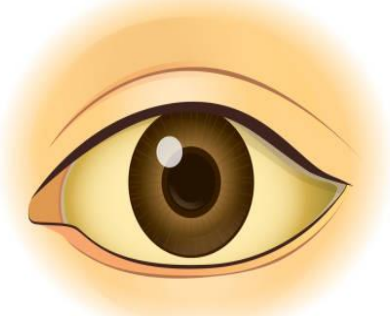
56 patients

71.7±26.8 days

77.4±26.4 days

37/56 (72.5%)

TB > 2mg/dl

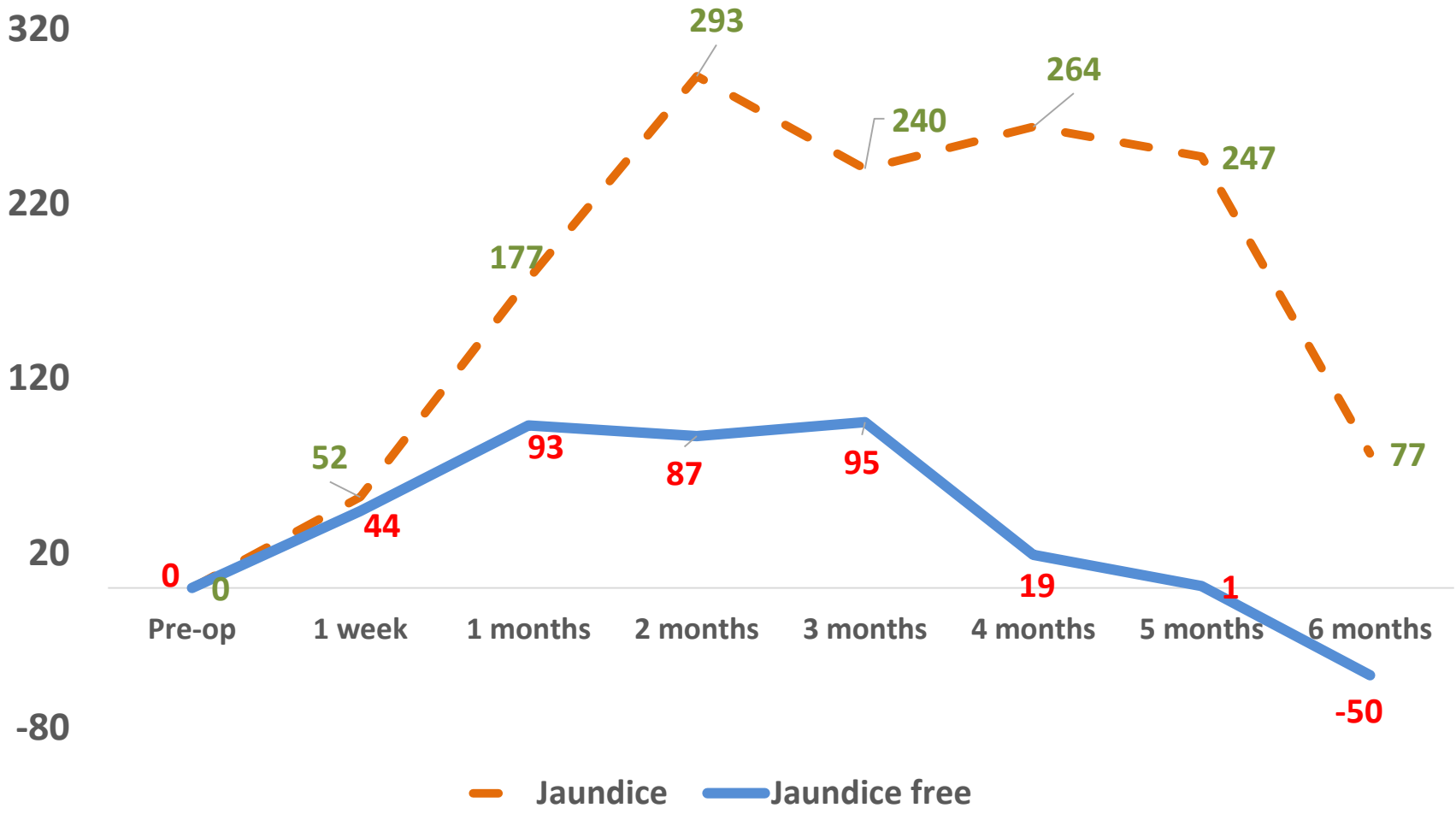


23/56 (41.1%)

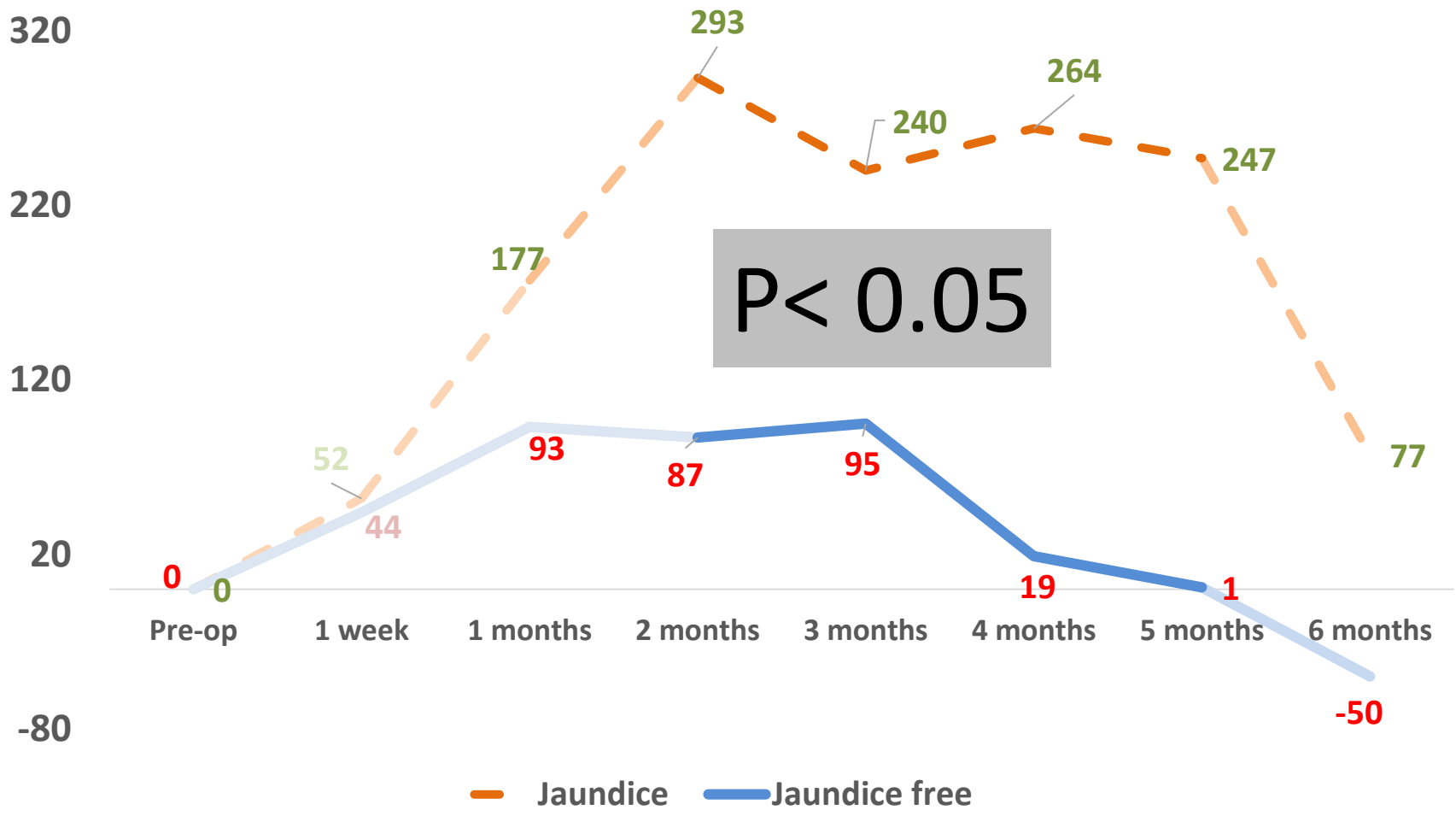
TB≤ 2mg/dl

33/56 (58.9%)

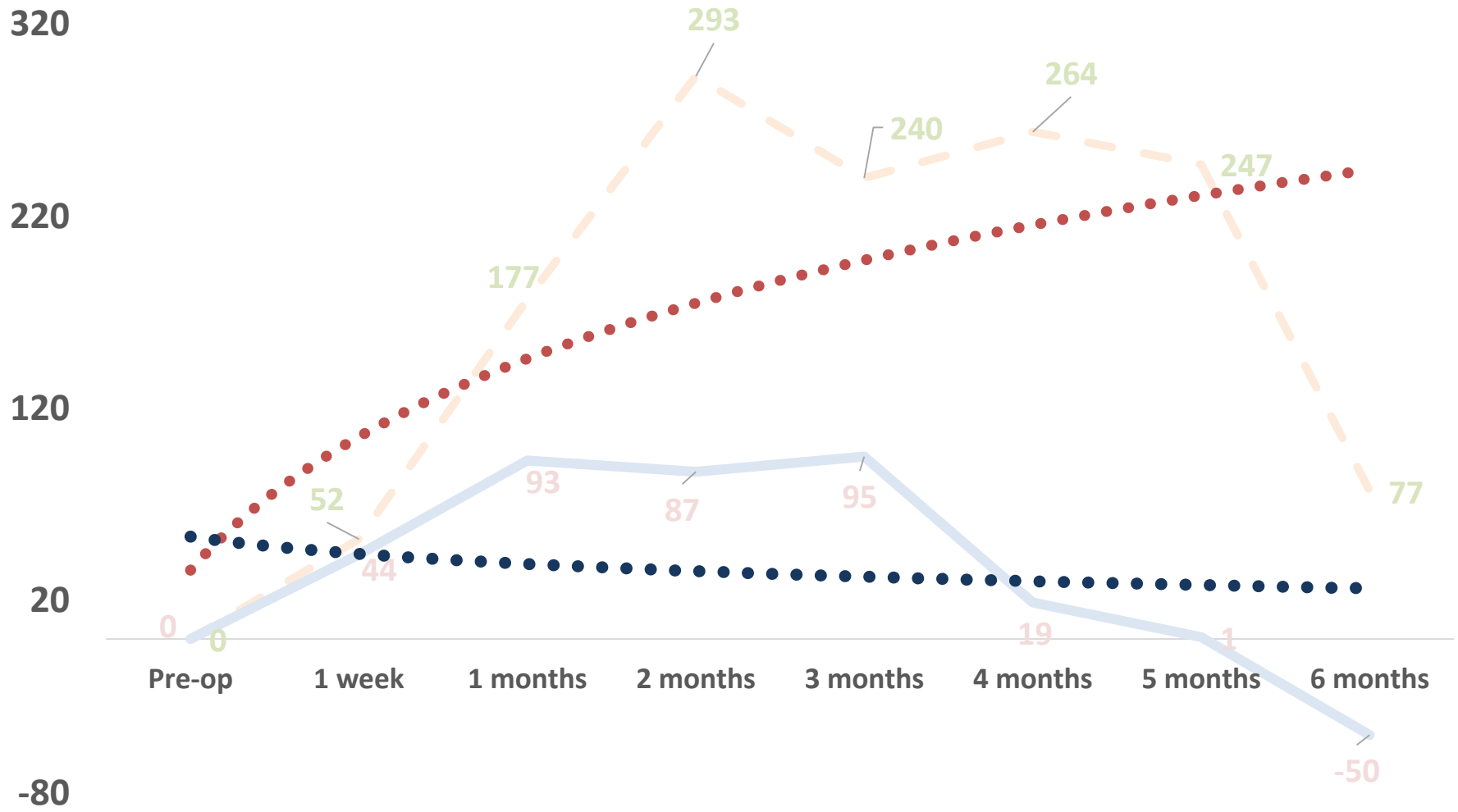
GGT raising percentage comparing to baseline GGT



GGT raising percentage compared to baseline

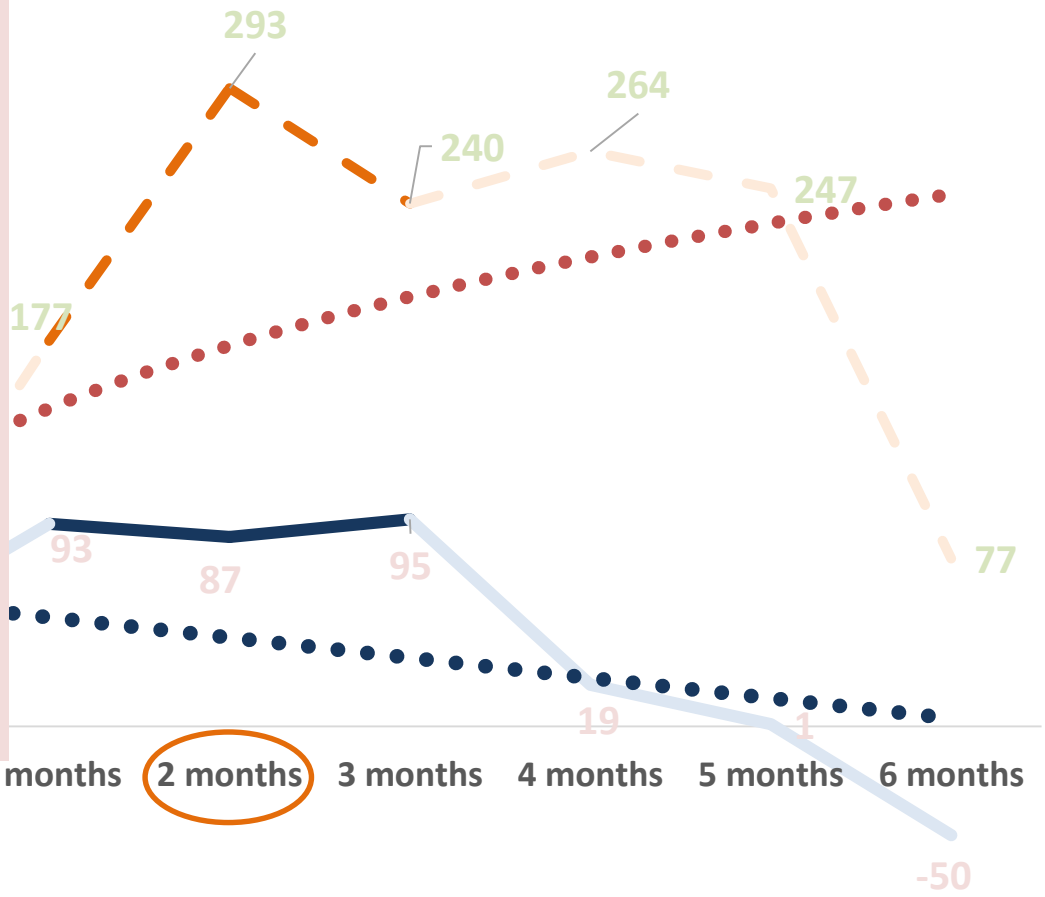


GGT raising percentage compared to baseline



GGT raising percentage compared to baseline

ΔGGT at 2 months shows moderate correlation with persistent jaundice at 6 months
(r =0.37; *p*= 0.05)



Conclusion

- GGT profile is predictive of jaundice clearance after Kasai operation

- We recommend GGT monitoring
  - to promote early referral to liver transplant center

Abstract

“The optimal flow rate for continuous bladder irrigation in patients with gross hematuria”

Varagorn Jirajan , MD

V. Jirajan, W. Viseshsindh

Division of Urology, Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

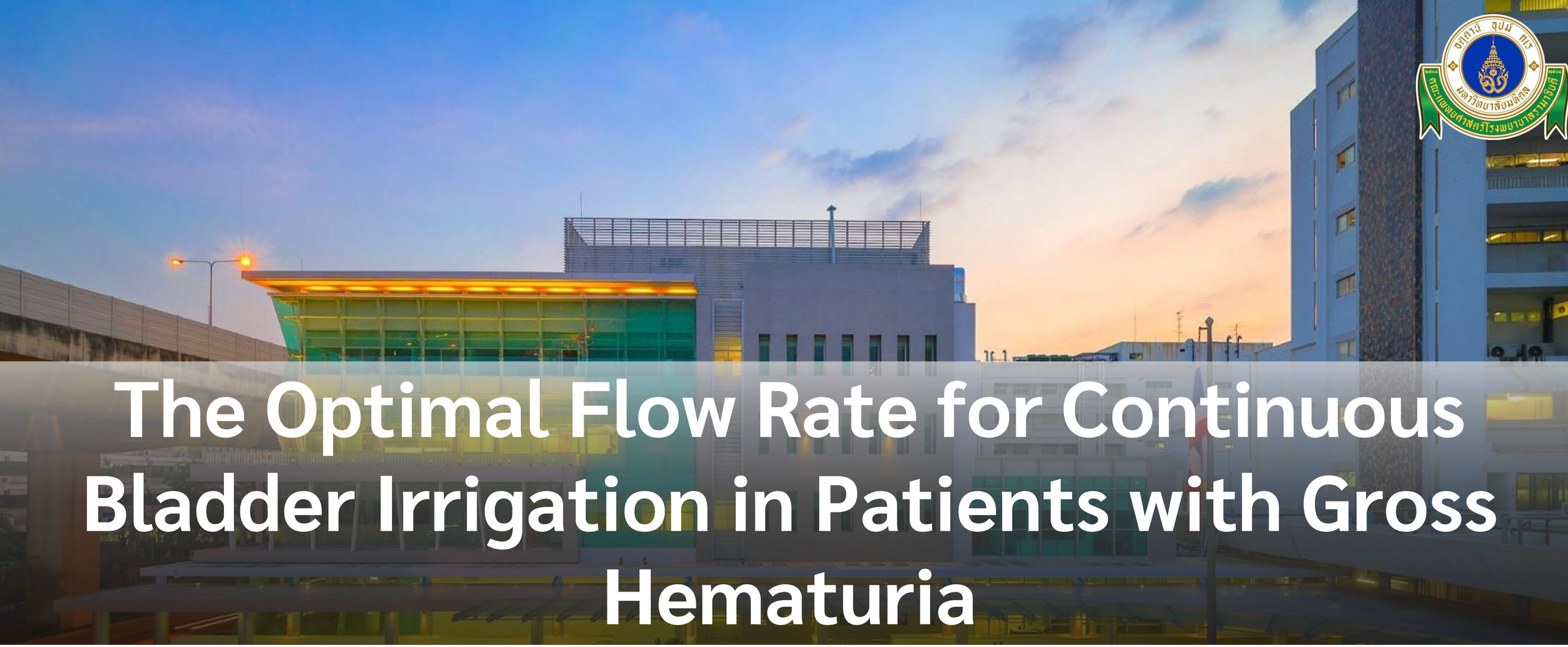
Introduction: Acute urinary retention (AUR) due to clot retention in the bladder is a common complication in patients with gross hematuria. Currently, the standard approach for preventing acute urinary retention caused by clot retention in the bladder is continuous bladder irrigation (CBI). However, there is no standardized protocol for determining the appropriate irrigation flow rate in patients with gross hematuria. Therefore, this study aims to investigate the effects of different flow rates of continuous bladder irrigation (CBI) on varying levels of urine color intensity in patients with gross hematuria.

Objective: This study aims to investigate the effects of different flow rates of continuous bladder irrigation (CBI) on varying levels of urine color intensity (hematuria grading) in patients with gross hematuria. Additionally, we want to evaluate the incidence of acute urinary retention, assess pain scores, and monitor changes in hemoglobin levels and blood electrolyte concentrations in these patients during continuous bladder irrigation (CBI). Furthermore, the study will compare urine hematocrit levels and urine dipstick analysis tests with varying degrees of urine color intensity.

Material and methods: This observational study enrolled 75 patients with gross hematuria undergoing continuous bladder irrigation (CBI) at Ramathibodi Hospital urology outpatient department and surgical ward from 1st May 2023 to 31st December 2024. Participants were assessed with hematuria grading, pain score, urinalysis, urine hematocrit, complete blood count, blood electrolytes, and coagulogram before CBI. A 22 Fr 3-way Foley catheter was inserted, and manual irrigation was performed to remove clots. CBI was administered for 2 hours at a fixed rate, based on the observed intensity of urine color and clinical judgment. Hematuria grading, pain scores, and complications such as acute urinary retention were monitored. Post-CBI evaluations included complete blood count and blood electrolytes.

Results: From the study of 75 participants that met inclusion and exclusion criteria, the average optimal continuous bladder irrigation rate was found to be 896.7 ± 582.8 mL/hr. (range: 100–3000). When analyzed according to hematuria grading before initiating continuous bladder irrigation, the average optimal continuous bladder irrigation rates for hematuria grading levels 1, 2, 3, 4, 5, 7, 8, and 10 were as follows: Level 1 (n=24): 667 ± 385.6 mL/hr. (range: 100–1500),Level 2 (n=14): 821.4 ± 699.1 mL/hr. (range: 100–2750),Level 3 (n=11): 1021.4 ± 765.8 mL/hr. (range: 235–3000),Level 4 (n=8): 1054.1 ± 532.2 mL/hr. (range: 450–2000),Level 5 (n=3): 1666.7 ± 763.8 mL/hr. (range: 1000–2500),Level 7 (n=2): 850 ± 495.0 mL/hr. (range: 500–1200),Level 8 (n=3): 916.7 ± 76.4 mL/hr. (range: 850–1000),Level 10 (n=2): 1550 ± 636.4 mL/hr. (range: 1100–2000).In this study, regardless of the continuous bladder irrigation rate used, none of the patients experienced acute urinary retention due to clot retention. There were slight changes in the hemoglobin level and electrolyte levels before and after continuous bladder irrigation. However, these alterations were not clinically significant. Regarding pain associated with the use of continuous bladder irrigation, the pain score showed no statistically significant correlation with the rate of continuous bladder irrigation (p-value = 0.730). The analysis of urine analysis and urine hematocrit in relation to urine color revealed several key findings. For urine analysis, finding >20 RBC/HPF was the most common result across all urine colors. Patients with lower hematuria grading (level 1–2) showed mixed findings in urine analysis. For higher hematuria grading (level 3–10), most patients had >20 RBCs/HPF. For urine hematocrit, the data shows a clear trend with higher hematuria grading is associated with higher urine hematocrit levels, while lower hematuria grading is associated with lower urine hematocrit levels. The Pearson Chi-Square Test revealed a chi-square value of 129.1648 with 56 degrees of freedom and a p-value of 0.000, indicating a statistically significant association between urine hematocrit levels and hematuria grading. Additionally, Cramer's V value of 0.4960 suggests a moderate to strong association between the two variables.

Conclusion and benefit: This study provides evidence-based guidance on optimal CBI rates for managing gross hematuria, tailored to hematuria severity. The findings suggest that higher hematuria grading requires higher CBI rates, but the absence of acute urinary retention in all patients raises questions about the necessity of high-rate CBI when manual irrigation is effective. Additionally, CBI is a well-tolerated, safe, and effective intervention for managing gross hematuria, with minimal pain and no clinically significant laboratory changes. The strong association between hematuria grading and urine hematocrit levels supports using visual analog scales and urine hematocrit as tools for objective assessment. These insights can enhance the efficacy, safety, and cost-effectiveness of CBI, ultimately improving patient outcomes.



The Optimal Flow Rate for Continuous Bladder Irrigation in Patients with Gross Hematuria

V. Jirajan, W. Viseshsindh

Division of Urology, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

27/3/68

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COA. MURA2023/391

Ref.2024/446

Title of Project (English)	The optimal flow rate for continuous bladder irrigation in patient with gross hematuria
Title of Project (Thai)	การศึกษาอัตราการไหลของสารน้ำที่เหมาะสมในการล้างกระเพาะปัสสาวะแบบต่อเนื่องในผู้ป่วยที่มีภาวะปัสสาวะเป็นเลือด
Type of Review	Full Board
Principal Investigator	Varagorn Jirajan
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 26/04/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	May 22, 2023
Renewal Date (1st)	May 22, 2024
Date of Expiration	May 21, 2025

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

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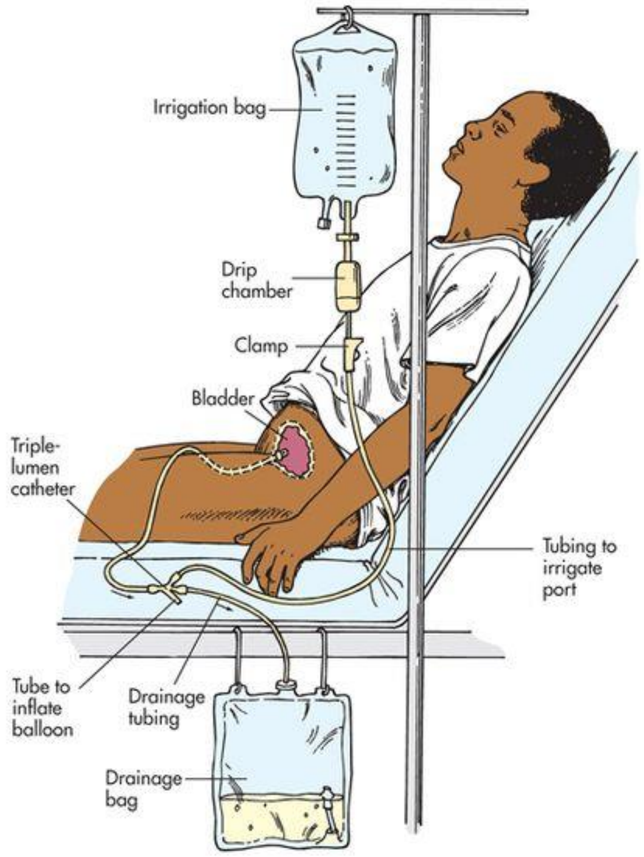
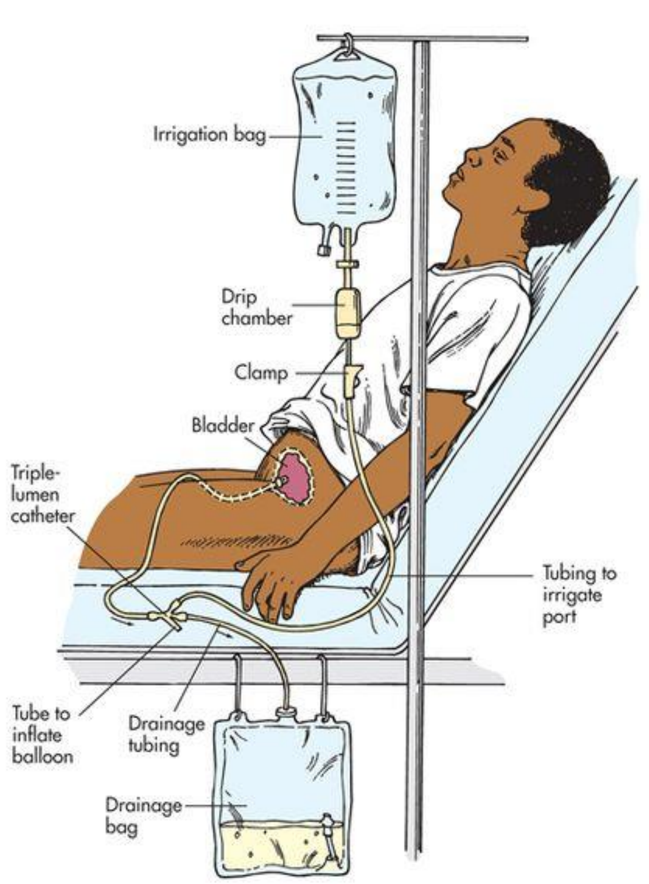
Introduction

- **Gross hematuria** is a common condition with various underlying causes, such as urolithiasis, urologic malignancies, or urinary tract infections (UTIs).
- Over time, blood clots can develop and lead to acute urinary retention due to clot retention.
- **Continuous bladder irrigation (CBI)** is a cornerstone treatment for patients with gross hematuria



Introduction: Continuous bladder irrigation

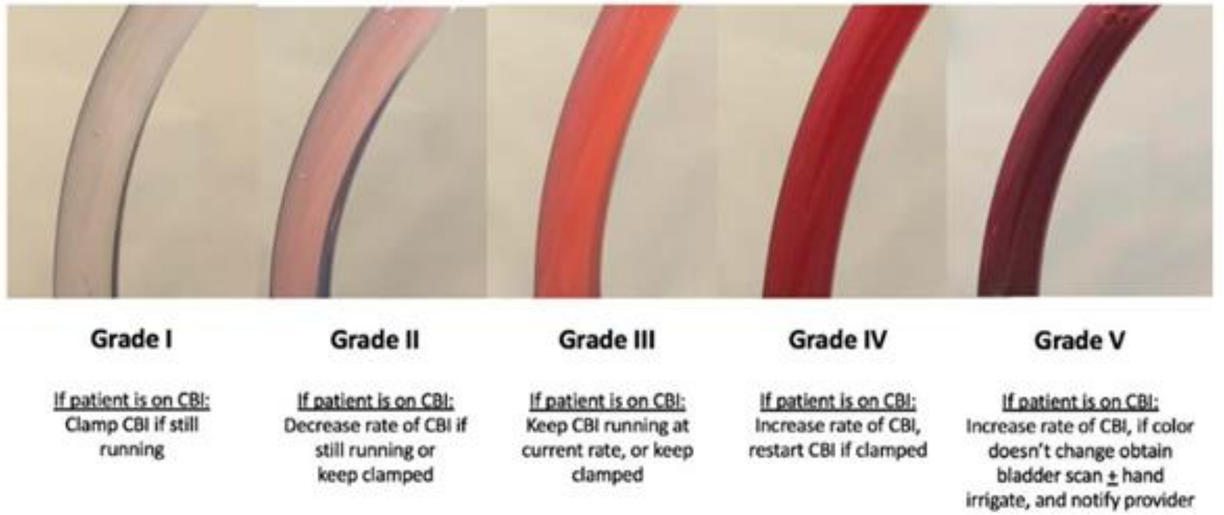
- There is currently *no standardized protocol* for **continuous bladder irrigation (CBI)**, particularly regarding [1]
  - **The flow rate** of the irrigation fluid
  - The **tools used to assess the severity of hematuria.**



[1]Lucas A, Ward CW. Manual and continuous bladder irrigation: Best practices. Nursing. 2022;52(7):31-6..

Introduction: CBI flow rate

- In clinical practice, **flow rate** of the irrigation fluid based on the *observed color* of the urine and *subjective judgment* of the clinician [1,2]
  - If the urine appears **dark red**, resembling the color of blood, the **flow rate** is *increased*.
  - If the urine is **pink**, the **flow rate** is *reduced*



Visual analog scale for hematuria grading by *Thomas Stout et al.* [2]

[1]Lucas A, Ward CW. Manual and continuous bladder irrigation: Best practices. Nursing. 2022;52(7):31-6.
[2]Stout TE, Borofsky M, Soubra A. A Visual Scale for Improving Communication When Describing Gross Hematuria. Urology. 2021; 148:32-6.

Introduction: Visual analog scale for hematuria grading

- **Thomas et al.** study found that grading the intensity of hematuria by healthcare providers was *highly variable* and *subjective* [2]

Hematuria Grade	I	II	III	IV	V
Different words used to describe urine color	Clear Clear pink Light Peach Pink lemonade Pigmentless	Clear Clear pink Light red Pale red Pink lemonade Peach Rosé Watermelon	Bloody Cherry Grapefruit Kool-Aid Pink lemonade Strawberry Pink Watermelon	Berry Bloody Cherry Fruit punch Kool-Aid Raspberry Red Strawberry Watermelon Wine	Bloody Cherry Red Frank blood Ketchup Magenta Mauve Sanguineous Strawberry Tomato Wine

Visual analog scale for hematuria grading by *Thomas Stout et al.* [2]

[2]Stout TE, Borofsky M, Soubra A. A Visual Scale for Improving Communication When Describing Gross Hematuria. Urology. 2021; 148:32-6.

Introduction: Visual analog scale for hematuria grading

- Study by **Joo Yong Lee et al.** [3] designed a visual analog scale for hematuria grading
  - **11 levels of severity** (ranging from 0 to 10) *like the visual analog scale* for *pain assessment*
  - Based on the **CMYK model** (cyan, magenta, yellow, and black), is suitable for *printing on paper* and *practical for use* in hospital wards
  - This scale served as a **standardized tool** for assessing the severity of hematuria **in this study**

Table 1. Composition of HGS using CMYK and RGB models

Preliminary Scale	Modified Scale (HGS)	Color	CMYK Model				RGB Model		
			C (%)	M (%)	Y (%)	K (%)	R	G	B
0	0W		0	0	0	0	255	255	255
–	0Y		0	0	10	0	255	255	230
–	1		0	10	10	0	255	230	230
1	2		0	20	20	0	255	204	204
2	3		0	40	40	0	255	153	153
3	4		0	60	60	0	255	102	102
4	5		0	80	80	0	255	51	51
5	6		0	100	100	0	255	0	0
6	7		0	100	100	20	204	0	0
7	8		0	100	100	40	153	0	0
8	9		0	100	100	60	102	0	0
9	10		0	100	100	80	51	0	0
10	–		0	100	100	100	0	0	0

CMYK, cyan, magenta, yellow, and key color model; HGS, Hematuria Grading Scale; RGB, red, green, and blue color model. (Color version available online.)

Visual analog scale for hematuria grading by Joo Yong Lee et al. [3]

[3] Lee JY, Chang JS, Koo KC, Lee SW, Choi YD, Cho KS. Hematuria grading scale: a new tool for gross hematuria. Urology. 2013;82(2):284-9

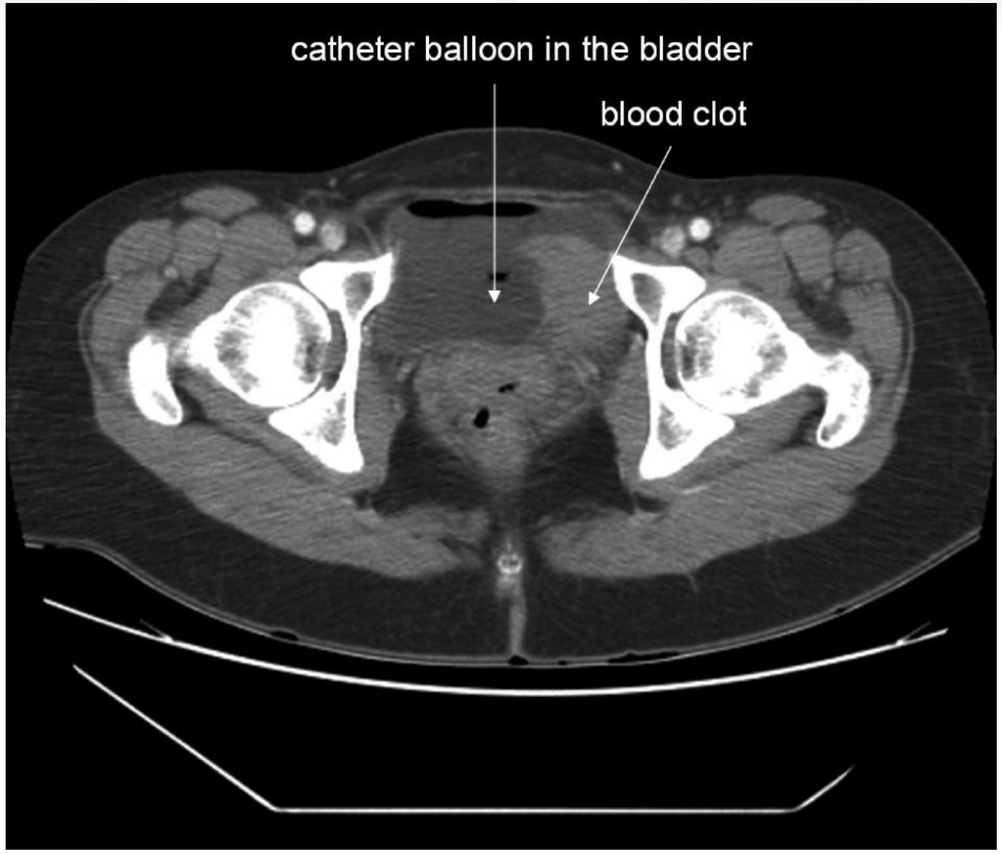
Introduction: Continuous bladder irrigation

- The **evaluation of urine color intensity** and the selection of the irrigation fluid **flow rate** relies heavily on the *subjective judgment* and experience of the clinician, leading to variability in treatment approaches and outcomes.
- **Excessively high flow rate**
  - Bladder spasms -> *pain* and *exacerbating bleeding*
  - Cause injury to the bladder urothelium -> promote the reabsorption of irrigation fluid into the bloodstream -> *pulmonary edema* [4]
  - *Increases the workload* for healthcare providers
  - *Increase the overall cost* of CBI

[4] Di Paolo M, Bugelli V, Di Luca A, Turillazzi E. Bladder irrigation and urothelium disruption: a reminder apropos of a case of fatal fluid absorption. BMC urology. 2014;14(1):91...

Introduction: Continuous bladder irrigation

- **Excessively low flow rate**
  - Fail to prevent the formation of new blood clots in the bladder -> *acute urinary retention due to clot retention* -> bladder spasms -> *exacerbating bleeding*
  - **“vicious cycle of bleeding ”**



Introduction: Objective

- Determine the **optimal flow rate** for **continuous bladder irrigation (CBI)** in patients with gross hematuria to improve the efficacy, safety, and cost-effectiveness of the treatment
- Evaluate **complications associated with CBI**: *acute urinary retention* from clot retention (AUR), *pain scores*, *hemoglobin levels and electrolyte changes*.
- Compare *urine hematocrit levels* and *dipstick analysis* with *hematuria* grading to develop a reliable way for **objective measurement of gross hematuria severity**.

Methods

- Observational prospective study of 75 patients with gross hematuria undergoing continuous bladder irrigation (CBI)
- Conducted at Ramathibodi hospital urology outpatient department and the surgical ward
- Between 1st May 2023 and 31st December 2024

Methods: Inclusion and exclusion criteria

The Inclusion criteria

- Patients with gross hematuria requiring continuous bladder irrigation (CBI)
- Age 18 years or older
- Willing to participate in the study by providing written informed consent

Exclusion criteria

- Patients with anuric end-stage renal disease
- Patients with abnormal urine color due to causes other than gross hematuria
- Patients with urethral disruption or severe urethral stricture preventing the placement of a urinary catheter
- Patients who refused to participate or withdrew consent during the study

Methods: Procedure

- **Baseline assessment:** complete blood count (CBC), serum electrolyte levels, and a coagulogram
- **Catheterization and Initial Bladder Irrigation:**
  - 22 Fr 3-way Foley catheter was inserted.
  - *Manual bladder irrigation* was then performed to remove any residual blood clots from the bladder.
  - The *intensity of urine color (hematuria grading)* was recorded and *compared to a visual analog scale* for hematuria grading, as developed by **Joo Yong Lee et al.** (printed on white paper) [14]
  - The urine specimen was sent for *urine dipstick analysis* and *urine hematocrit measurement*.

Intensity of urine color was compared to a visual analog scale for hematuria grading by *Joo Yong Lee et al.* [3]

[3] Lee JY, Chang JS, Koo KC, Lee SW, Choi YD, Cho KS. Hematuria grading scale: a new tool for gross hematuria. Urology. 2013;82(2):284-9

Methods: Procedure

- **Catheterization and Initial Bladder Irrigation:**
  - Patients underwent continuous bladder irrigation (CBI) at a *fixed flow rate for a duration of 2 hours* adjusted by the healthcare provider based on the observed intensity of urine color and *clinical judgment*.
  - The irrigation fluid was administered using an intravenous infusion set under gravity
  - The *intensity of urine color* was recorded and c*ompared against the visual analog scale for hematuria grading* [3] *at 2 hours* after initiating CBI
  - The *total volume of irrigation fluid* used during *the 2-hour CBI* was recorded to calculate the *average CBI rate (ml/hr.).*

Intensity of urine color was compared to a visual analog scale for hematuria grading by *Joo Yong Lee et al.* [3]

[3] Lee JY, Chang JS, Koo KC, Lee SW, Choi YD, Cho KS. Hematuria grading scale: a new tool for gross hematuria. Urology. 2013;82(2):284-9

Methods: Procedure

- **Post-Procedure Assessments:**
  - After completing 2 hours of CBI, patients were evaluated for the *incidence of acute urinary retention* and their *pain levels* (using a visual analog scale for pain) during the procedure.
  - Additional tests, including a *complete blood count (CBC) and serum electrolyte levels*
- **Standard Care:** All other diagnostic and treatment procedures followed standard clinical practices.

Intensity of urine color was compared to a visual analog scale for hematuria grading by *Joo Yong Lee et al.* [3]

[3] Lee JY, Chang JS, Koo KC, Lee SW, Choi YD, Cho KS. Hematuria grading scale: a new tool for gross hematuria. Urology. 2013;82(2):284-9

Methods: Outcome

- **The primary outcome:** the *optimal average CBI rate* for each varying degree of hematuria grading.
  - **Optimal average CBI rate** was defined as the *CBI rate* that resulted in a *reduction or no change in urine color intensity (hematuria grading) without causing acute urinary retention* from blood clot retention
  - Calculated by dividing the total volume of irrigation fluid used during the 2-hour CBI by 2
- **Secondary outcomes:** complications associated with CBI, including
  - *Incidence of acute urinary retention*
  - *Pain scores*
  - *Changes in hemoglobin levels and blood electrolyte concentrations* after CBI
  - *Compare the association between urine hematocrit levels and urine dipstick analysis test* with varying degrees of *hematuria grading*

Table 1.1: Baseline demographic and patient characteristics

Variable	Total (n=75)
Gender, n(%)	
Male	64(85.3)
Female	11(14.7)
Age(year), mean±SD	70±10.2
Weight (kg), mean±SD	65.0±12.5
Height (cm), mean±SD	163.6±6.3
BMI (kg/m^2), mean±SD	24.2±3.9
Comorbidity, n (%)	
DM	26(34.7)
HT	50(66.7)
DLP	41(54.7)
CKD	22(29.3)
Cause of hematuria, n (%)	
Tumor	23(30.7)
Radiation	5(6.7)
Infection	6(8.0)
Stone	21(28.0)
BPH	43(57.3)
Antiplatelet, n (%)	
No	67(89.3)
Yes	8(10.7)
Anticoagulant, n (%)	
No	66(88.0)
Yes	9(12.0)

Results: Baseline patient characteristics

- The study included a total of **75 patients**
- Most participants were male (85.3%, n=64).
- The mean age of the participants was 70 ± 10.2 years.
- The **primary causes of hematuria** were *benign prostatic hyperplasia* (57.3%, n=43), *tumors* (30.7%, n=23), urinary stones (28.0%, n=21), infection (8.0%, n=6), and radiation-induced hematuria (6.7%, n=5). 10.7% (n=8) of patients were on antiplatelet therapy, and 12.0% (n=9) were on anticoagulant therapy

Table 1.2: Factor associated with CBI rate

Variable	Univariate		Multivariate	
	Coef. (95%CI)	p-value	Coef. (95%CI)	p-value
Gender				
Male	base			
Female	374.5(-386 to 1135)	0.330		
Age(year)	-3.4(-30 to 23)	0.800		
Weight (kg)	-26.0(-47 to -5)	0.016		
Height (cm)	2.2(-41 to 45)	0.921		
BMI (kg/m^2)	-99.7(-165 to -34)	0.003	-82.9(-148 to -17)	0.014
Comorbidity				
DM	-179(-747 to 388)	0.531		
HT	-424(-990 to 143)	0.140		
DLP	-415(-951 to 120)	0.127		
CKD	38.4(-556 to 634)	0.898		
Cause of hematuria				
Tumor	638.8(70 to 1207)	0.028	782.0(275 to 1288)	0.003
Radiation	895.7(-170 to 1962)	0.098		
Infection	332.5(-663 to 1328)	0.508		
Stone	-528.3(-1119 to 63)	0.079		
BPH	-520.1(-1054 to 14)	0.056		
Antiplatelet				
No	base			
Yes	-196.2(-1073 to 681)	0.657		
Anticoagulant				
No	base			
Yes	398.2(-430 to 1227)	0.342		

Results: Baseline patient characteristics

- In the univariate analysis **lower body weight** (coefficient: -26.0, 95% CI: -47 to -5, p=0.016) and **lower BMI** (coefficient: -99.7, 95% CI: -165 to -34, p=0.003) were *associated with higher CBI volumes*.
- The presence of a **tumor** as the cause of hematuria was significantly *associated with increased CBI volume* (coefficient: 638.8, 95% CI: 70 to 1207, p=0.028).

Results: Optimal average CBI rate

Table 2.1: Distribution of Hematuria Grading (VAS) Before and After CBI

VAS 0	VAS 2, n (%)					Total
	0	1	2	3	4	
0	-	-	-	-	-	-
1	18 (64.3%)	6 (21.4%)	2 (7.1%)	2 (7.1%)	1 (3.6%)	28 (100%)
2	8 (47.1%)	4 (23.5%)	2 (11.8%)	2 (11.8%)	0 (0%)	17 (100%)
3	5 (41.7%)	3 (25.0%)	2 (16.7%)	1 (8.3%)	1 (8.3%)	12 (100%)
4	2 (25.0%)	4 (50.0%)	1 (12.5%)	1 (12.5%)	0 (0%)	8 (100%)
5	1 (33.3%)	0 (0%)	0 (0%)	1 (33.3%)	1 (33.3%)	3 (100%)
7	0 (0%)	0 (0%)	0 (0%)	2 (100%)	0 (0%)	2 (100%)
8	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0%)	0 (0%)	3 (100%)
10	0 (0%)	1 (50.0%)	0 (0%)	1 (50.0%)	0 (0%)	2 (100%)
Total	35 (46.7%)	19 (25.3%)	8 (10.7%)	10 (13.3%)	3 (4.0%)	75 (100%)

VAS 0 = Hematuria grading before CBI, VAS 2 Hematuria grading after CBI for 2 hrs.

- **67 out of 75** patients who underwent CBI achieved either a *reduction or no change in urine color intensity* (hematuria grading) *without experiencing acute urinary retention* from blood clot retention

Results: Optimal average CBI rate

Hematuria Grading	Number of Patients (n)	Mean Optimal Average CBI Rate (mL/hr.)	Standard Deviation (SD)	Range (mL/hr.)
Overall	67	896.7	582.8	100–3000
1	24	667	385.6	100–1500
2	14	821.4	699.1	100–2750
3	11	1021.4	765.8	235–3000
4	8	1054.1	532.2	450–2000
5	3	1666.7	763.8	1000–2500
7	2	850	495.0	500–1200
8	3	916.7	76.4	850–1000
10	2	1550	636.4	1100–2000

Table 2.2: Optimal Average CBI Rates by Hematuria Grading

- The **mean optimal average CBI rate across all patients** (n=67) was *896.7 ± 582.8 mL/hr*. (range: 100–3000)
- **Optimal average CBI rates** for all participants, **categorized by urine color intensity** (hematuria grading) before initiating CBI, are presented in **Table 2.2**

Results: Acute urinary retention from clot retention

- **None of the 75 participants** *experienced acute urinary retention* from clot retention, regardless of the CBI rate administered.

Results: Changes in hemoglobin levels and blood electrolyte concentrations

Table 3: Comparison of Laboratory Parameters Before and After CBI

Laboratory	Before CBI	After CBI	p -value
Hb (g/dL), mean±SD	12.5±2.3	12.1±2.2	0.000
Hct (%), mean±SD	40.5±21.6	36.1±6.3	0.099
Platelet x10^3 (/mm^3), mean±SD	229±83	215±77	0.002
Sodium, mean±SD	139.3±4.2	138.8±3.6	0.086
Potassium, mean±SD	4.1±0.5	4.0±0.4	0.123
Chloride, mean±SD	106±4	107±4	0.005
HCO3, mean±SD	23.7±2.8	22.6±2.4	0.002

Hemoglobin:

- *Decreased* from 12.5 ± 2.3 g/dL to 12.1 ± 2.2 g/dL *($p < 0.001$).*

Platelets:

- Declined 229 ± 83 x10^3/mm^3 to 215 ± 77 x10^3/mm^3 ($p = 0.002$).

Results: Changes in hemoglobin levels and blood electrolyte concentrations

Table 3: Comparison of Laboratory Parameters Before and After CBI

Laboratory	Before CBI	After CBI	p -value
Hb (g/dL), mean±SD	12.5±2.3	12.1±2.2	0.000
Hct (%), mean±SD	40.5±21.6	36.1±6.3	0.099
Platelet x10^3 (/mm^3), mean±SD	229±83	215±77	0.002
Sodium, mean±SD	139.3±4.2	138.8±3.6	0.086
Potassium, mean±SD	4.1±0.5	4.0±0.4	0.123
Chloride, mean±SD	106±4	107±4	0.005
HCO3, mean±SD	23.7±2.8	22.6±2.4	0.002

- Some changes were *statistically significant* but **not clinically significant.**

Electrolytes:

- *No significant changes* in **sodium and potassium**
- **Chloride** *increased* from 106 ± 4 mmol/L to 107 ± 4 mmol/L *(p = 0.005).*
- **Bicarbonate** *decreased* from 23.7 ± 2.8 mmol/L to 22.6 ± 2.4 mmol/L *(p = 0.002).*

Results: Pain score

Table 4.1: Distribution of Pain Scores Before and After CBI

Pain score Before CBI	Pain score after CBI, n								Total
	0	1	3	4	5	6	7	8	
0	21	1	0	0	0	0	0	0	22
1	2	1	0	0	0	0	0	0	3
2	4	2	0	0	0	0	0	0	6
3	1	1	1	0	1	1	0	1	6
4	1	0	0	0	1	0	0	0	2
5	1	0	0	0	0	0	1	0	2
6	0	0	1	1	0	0	0	0	2
7	0	0	0	0	0	0	1	0	1
8	0	0	0	0	0	0	1	0	1
Total	30	5	2	1	2	1	3	1	45

Table 4.2: Comparison of Average CBI Rates Between Patients with Reduced/Stable Pain and Increased Pain

	Reduced or stable pain (n=39)	Increased pain (n=6)	p-value
Average CBI rate., mean±SD	968±580	883±337	0.730

- 45 participants assessed for pain scores
  - **39 (86.7%)** reported either *reduced or stable pain* during CBI with **mean average CBI rate** was *968 ± 580 mL/hr*
  - **6 (13.3%)** reported *increased pain* with **mean average CBI rate** was *968 ± 580 mL/hr*
- These results suggest **no significant difference** in CBI volumes between the two groups *(p = 0.730).*

Results: Association Between Hematuria Grading and Urine Red Blood Cell Count

Table 5.1: Distribution of Urine Red Blood Cell Count by Hematuria Grading

Hematuria Grading / RBC count	0-1	1-2	2-3	5-10	10-15	15-20	>20	Total
1	2 (7.1%)	1 (3.6%)	1 (3.6%)	1 (3.6%)	1 (3.6%)	0 (0%)	22 (78.6%)	28 (100%)
2	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (23.5%)	12 (70.6%)	17 (100%)
3	1 (8.3%)	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	0 (0%)	10 (83.3%)	12 (100%)
4	0 (0%)	0 (0%)	0 (0%)	1 (12.5%)	0 (0%)	0 (0%)	7 (87.5%)	8 (100%)
5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (100%)	3 (100%)
7	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (100%)	2 (100%)
8	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (100%)	3 (100%)
10	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (100%)	2 (100%)
Total	4 (5.3%)	1 (1.3%)	1 (1.3%)	2 (2.7%)	2 (2.7%)	4 (5.3%)	61 (81.3%)	75 (100%)

- Most patients **(61 out of 75, 81.3%)** had *>20 RBCs/HPF*.
- Patients with **lower hematuria grading (level 1–2)** showed *mixed findings in urine analysis*
- Patients with **higher hematuria grading (level 3–10)**, *most patients had >20 RBCs/HPF*

Results: Association Between Hematuria Grading and Urine Hematocrit

Table 5.2: Distribution of Urine Hematocrit Levels by Hematuria Grading

Hematuria Grading /Urine hematocrit	0	0.5	>1	1	1.5	2	3	4.5	10	Total
1	16 (57.1%)	7 (25.0%)	1 (3.6%)	4 (14.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	28 (100%)
2	5 (29.4%)	5 (29.4%)	0 (0%)	5 (29.4%)	1 (5.9%)	1 (5.9%)	0 (0%)	0 (0%)	0 (0%)	17 (100%)
3	2 (16.7%)	2 (16.7%)	0 (0%)	7 (58.3%)	0 (0%)	1 (8.3%)	0 (0%)	0 (0%)	0 (0%)	12 (100%)
4	2 (25%)	1 (12.5%)	0 (0%)	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	0 (0%)	0 (0%)	8 (100%)
5	0 (0%)	1 (33.3%)	0 (0%)	2 (66.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (100%)
7	0 (0%)	1 (50.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (50.0%)	0 (0%)	0 (0%)	2 (100%)
8	0 (0%)	1 (33.3%)	0 (0%)	0 (0%)	0 (0%)	1 (33.3%)	1 (33.3%)	0 (0%)	0 (0%)	3 (100%)
10	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (50.0%)	1 (50.0%)	2 (100%)
Total	25 (33.3%)	18 (24.0%)	1 (1.3%)	20 (26.7%)	2 (2.7%)	4 (5.3%)	3 (4.0%)	1 (1.3%)	1 (1.3%)	75 (100%)

Pearson Chi-Square: 129.1648 (p = 0.000), Cramer's V: 0.4960

- **Lower hematuria grading (levels 1–2)** was predominantly *associated with low urine hematocrit levels*
- **Higher hematuria grading (levels 3–10)** correlated with increased proportions of *higher urine hematocrit levels*
- **Strong association between hematuria grading and hematocrit levels** (*p = 0.000*, *Pearson Chi-Square: 129.1648*, *Cramer's V: 0.4960* (moderate to strong association))

Discussion: Optimal CBI rate

- The **average optimal CBI rate** across all patients was *896.7 ± 582.8 mL/hr*. with a **wide range of CBI rates** used in this study *(100–3000 mL/hr.)* and varying significantly based on hematuria grading
    - Study results suggest that **higher hematuria severity necessitates more aggressive irrigation** to prevent clot retention and maintain clear urine output
    - **Variability of CBI rate** used suggests that healthcare providers adjust irrigation rates based on *their own experience and interpretation of urine color intensity*, which leads to *treatment inconsistencies* that may impact patient outcomes
- **Establishing evidence-based protocols** for CBI rate adjustment could *enhance treatment consistency* and optimize patient management.

Discussion: Acute urinary retention

- *None of the 75 patients* experienced **acute urinary retention from clot retention**, regardless of the CBI rate used.
- This raises the question of whether **high-rate CBI is always necessary**, especially when **manual irrigation is performed** beforehand to remove clots.
- Future studies could explore whether lower CBI rates, combined with effective manual irrigation, might suffice in preventing clot retention, thereby reducing resource use and potential complications.

Discussion: Laboratory changes

- **Hemoglobin** *decreased slightly* from 12.5 ± 2.3 g/dL to 12.1 ± 2.2 g/dL ($p < 0.001$),
  - *Statistically significant but not clinically significant* and likely reflect the dilution effect of irrigation fluid rather than significant blood loss.
- **Sodium** and **potassium** levels remaining *stable*, **chloride** levels *increased* from 106 ± 4 mmol/L to 107 ± 4 mmol/L ($p = 0.005$), while **bicarbonate** (HCO_3) *decreased* from 23.7 ± 2.8 mmol/L to 22.6 ± 2.4 mmol/L ($p = 0.002$)
  - *No clinically significant change* suggesting that *CBI is safe in terms of electrolyte balance*.
- However, it is important to note that **several confounding factors**, such as *intravenous fluid rates, blood transfusions,* or *underlying comorbidities*, could have influenced these laboratory changes.

Discussion: Pain score and other complications

- **Pain scores** during CBI showed *no significant correlation with the irrigation rate (p = 0.730)*
- However, the small proportion of **patients (13.3%)** who reported *increased pain* warrants *further investigation to identify potential causes*, such as bladder spasms or catheter-related discomfort
- **Absence of severe complications**, such as pulmonary edema or significant electrolyte imbalances, in this study.
- This suggests that CBI, even at higher rates, is a **safe intervention** and **well tolerated** when *appropriately managed and monitored regardless of the flow rate*.

Discussion: Association Between Hematuria Grading and Urine Red Blood Cell Count

- Patients with higher hematuria grading (levels 3–10), the vast majority (>80%) had >20 RBCs per high-power field (HPF) in their urine analysis. Conversely, in patients with **lower hematuria grading (levels 1–2)**, *RBC counts in urine varied*.
- This suggests that **lighter urine color does not always correspond to a low RBC count**, as factors like *urine dilution*, *hemoglobin release from lysed RBCs*, and *intermittent bleeding* can **affect RBC concentration**.
- These findings highlight that **urine color alone is not always a precise indicator of hematuria severity**, emphasizing the **need to use both visual grading and other objective measurements** for more accurate assessment.

Discussion: Association between hematuria grading and urine hematocrit levels

- The Pearson Chi-Square Test ($p = 0.000$) and Cramer's V (0.4960) confirmed a **statistically significant** and **moderate-to-strong association** between *hematuria grading* and *urine hematocrit levels*, reinforcing the validity of using visual grading scales to guide CBI rates

Discussion: Clinical implications

- This study is **one of the first** to systematically determine **optimal CBI rates** for **varying degrees of gross hematuria**.
    - Provides **evidence-based guidelines** for *adjusting CBI rates* based on hematuria severity.
    - Using a **visual analog scale** for hematuria grading can *standardize assessments* and g*uide CBI rate* adjustments.
- The **absence of acute urinary retention** in all patients highlights the effectiveness of manual irrigation in clot removal and question the *necessity of high-rate CBI* in all cases.
- **CBI is well-tolerated** with minimal risk of significant complications. No severe pain or clinically significant laboratory changes were observed in most patients.

Discussion: Clinical implications

- The correlation between hematuria grading and urine hematocrit levels suggests that **urine hematocrit can be a useful objective tool** for **assessing hematuria severity**.
  - It complements visual assessments and supports a more standardized approach to grading hematuria.

Discussion: Limitations

- **Small Sample Size:** *Limited data for higher hematuria grading categories* (levels 5, 7, 8, and 10) *reduces generalizability for these groups*.
- **Subjective Assessments:** Reliance on visual assessments for hematuria grading introduces potential *interobserver variability*, despite using a standardized scale.
- **Confounding Factors:** IV fluid administration, blood transfusions, or underlying bleeding disorders may have influenced laboratory findings

Discussion: Future direction

- Larger studies with more diverse cohorts are needed to validate findings.
- Use of objective measures, such as automated urine color analysis, could improve accuracy.
- Future studies could explore whether lower CBI rates, combined with effective manual irrigation, might suffice in preventing clot retention.
- Further investigation into the role of urine hematocrit as an objective tool for hematuria grading is recommended to determine its clinical utility in managing patients with gross hematuria

Conclusion

- This study provides evidence-based guidance on optimal CBI rates for managing gross hematuria, tailored to hematuria severity.
- CBI is a well-tolerated, safe, and effective intervention for managing gross hematuria, with minimal pain and no clinically significant laboratory changes
- The strong association between hematuria grading and urine hematocrit levels supports using visual analog scales and urine hematocrit as tools for objective assessment.
- Future studies could explore whether lower CBI rates, combined with effective manual irrigation, might suffice in preventing clot retention and investigate the role of urine hematocrit as an objective tool for hematuria grading to determine its clinical utility in managing patients with gross hematuria.

Thank you

Abstract

“Evaluating Inferior Alveolar Nerve Injury After Bilateral Sagittal Split Osteotomy Using Bicortical Screw Vs Miniplate”

Thanaphat Srisuwat, MD

Thanaphat Srisuwat, Kachin Wattanawong

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Background: Postoperative sensory disturbances are a common concern following bilateral sagittal split osteotomy (BSSO). The choice between miniplate and bicortical screw fixation may influence nerve recovery, but comparative data remain limited.

Objective: This study aimed to compare sensory recovery between miniplate and bicortical screw fixation after BSSO.

Methods: This randomized controlled trial included patients undergoing BSSO for mandibular advancement. Participants were randomly assigned to receive either miniplate fixation (Group M) or bicortical screw fixation (Group B). Sensory function was assessed using fine touch, cold, hot, pressure, visual analog scale (VAS) for subjective sensation, and two-point discrimination (2PD) at the lower lip and chin at multiple postoperative time points (1 week, 2 weeks, 1 month, 3 months, and 6 months). Statistical analysis was performed using appropriate tests, including independent t-tests and Fisher’s exact test for 2PD.

Results: A total of 26 patients (12 in Group M, 14 in Group B) completed the study. Across all sensory modalities, no statistically significant differences were observed between miniplate and bicortical screw fixation at 6 months:

- Fine touch: Lower lip (4.40 ± 0.82 [M] vs. 4.19 ± 1.05 [B], p = 0.45), chin (4.35 ± 0.88 [M] vs. 3.75 ± 1.06 [B], p = 0.07).
- Cold sensation: Lower lip (4.70 ± 0.57 [M] vs. 4.44 ± 0.89 [B], p = 0.29), chin (4.65 ± 0.67 [M] vs. 4.19 ± 0.83 [B], p = 0.07).
- Hot sensation: Lower lip (4.15 ± 1.26 [M] vs. 3.69 ± 1.45 [B], p = 0.31), chin (4.41 ± 1.17 [M] vs. 3.25 ± 1.53 [B], p = 0.11).
- Pressure sensation: Lower lip (4.45 ± 0.69 [M] vs. 4.44 ± 0.73 [B], p = 0.96), chin (4.43 ± 0.75 [M] vs. 4.00 ± 0.82 [B], p = 0.19).
- VAS scores: Lower lip (8.70 ± 1.24 [M] vs. 7.94 ± 2.59 [B], p = 0.40), chin (8.70 ± 1.34 [M] vs. 7.43 ± 2.19 [B], p = 0.04).
- Two-Point Discrimination (2PD): Lower lip (Median = 5, IQR: 4–5 [M] vs. Median = 4, IQR: 4–5 [B], p = 0.482), chin (Median = 5, IQR: 4–5 [M] vs. Median = 4, IQR: 4–5 [B], p = 0.134).

No patient experienced permanent complete sensation impairment. There is also no significant difference in hospital stay, operative time, blood loss, and total drain output.

Conclusion: Miniplate fixation demonstrated a trend toward better early sensory recovery, particularly in fine touch and temperature perception at the chin. However, none of the differences reached statistical significance, and long-term sensory outcomes were comparable between groups, reaching near normal sensation at 6 months. These findings suggest that fixation choice may have a limited impact on long-term sensory recovery in BSSO patients.

Evaluating Inferior Alveolar Nerve Injury After Bilateral Sagittal Split Osteotomy Using

Bicortical Screw Vs Miniplate

Thanaphat Srisuwat, M.D.

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Title of Project (English)	Evaluating Inferior Alveolar Nerve Injury after Bilateral Sagittal Split Osteotomy Using Bicortical Screw VS Monocortical Plate
Title of Project (Thai)	การศึกษาผลของการบาดเจ็บต่อเส้นประสาทอินฟีเรียร์อัลวีโอล่าร์ ภายหลังการผ่าตัดเลื่อนกระดูกขากรรไกรด้วยเทคนิคบีเอสเอสโอระหว่างการใช้หมุดยึดตามกระดูกเปรียบเทียบกับการใช้แผ่นโลหะยึดตามกระดูก
Type of Review	Full Board
Principal Investigator	Thanaphat Srisuwat
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Document reviewed	Annual Progress Report Date 20/06/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	October 17, 2020
Renewal Date (3rd)	July 04, 2024
Date of Expiration	July 03, 2025

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

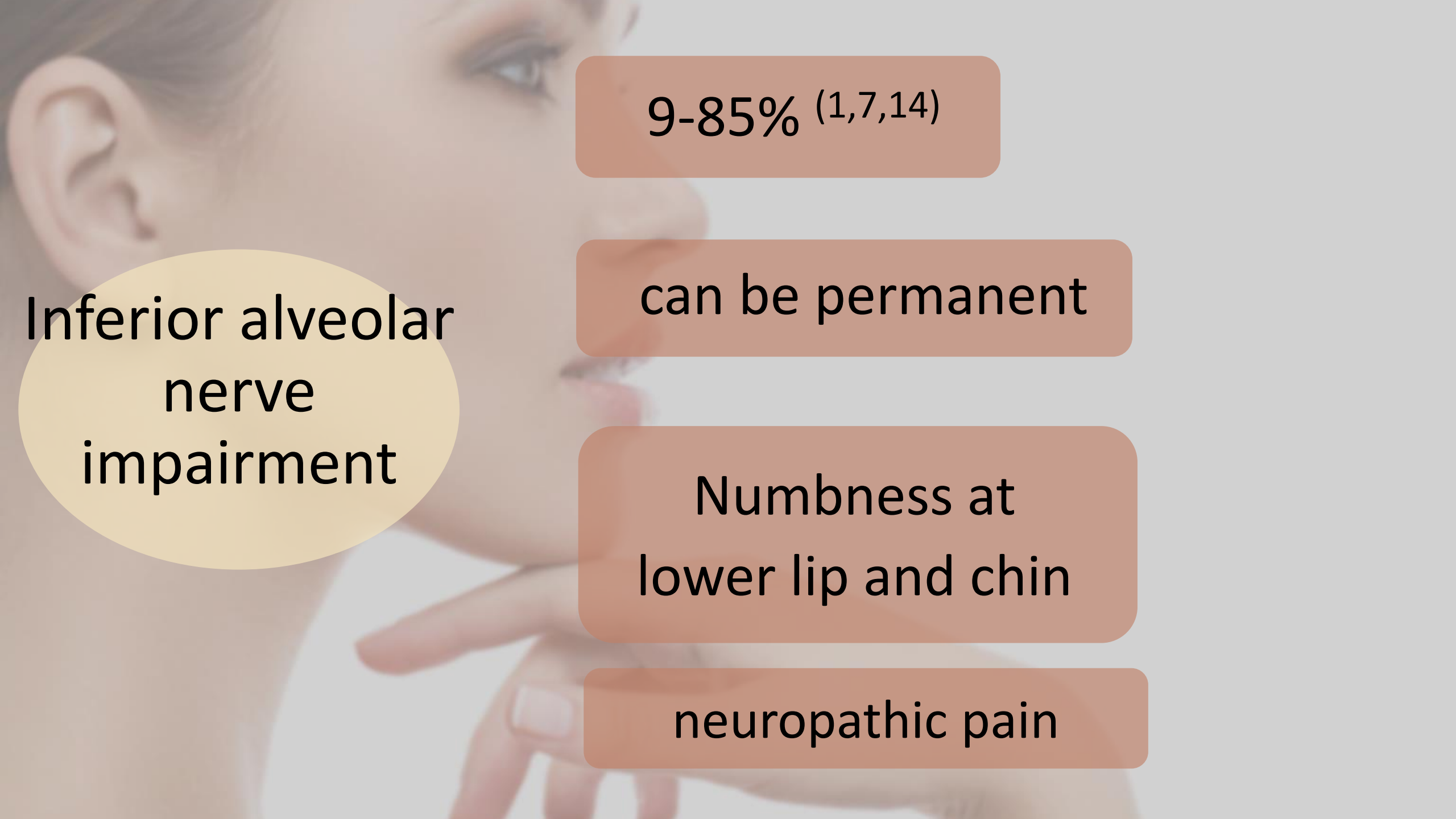
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Why is it important

Bilateral sagittal split osteotomy (BSSO)

Improves masticatory function[8,24] and facial aesthetic [5,28]

Well known operation for treating malocclusion[23]



Inferior alveolar nerve impairment

9-85% [1,7,14]

can be permanent

Numbness at lower lip and chin

neuropathic pain

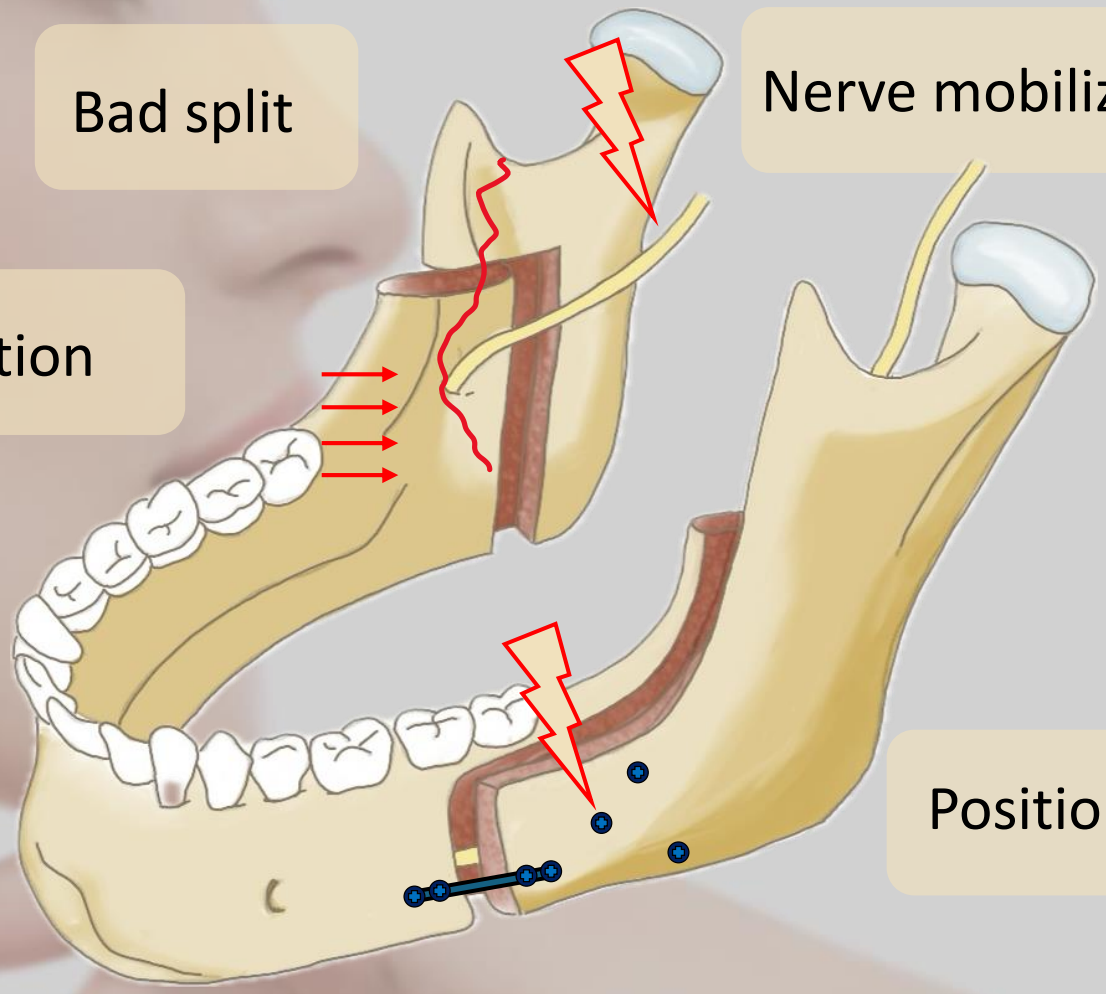
Risk factors

Bad split

Nerve mobilization or exposure

Medial ramus dissection

Large mandibular advancement

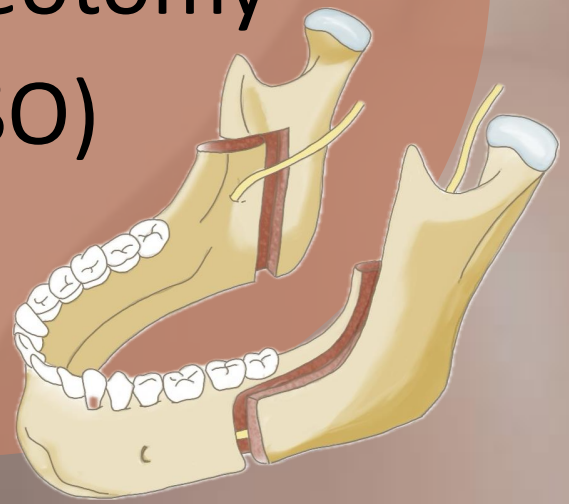


Position screw placement

Fixation technique

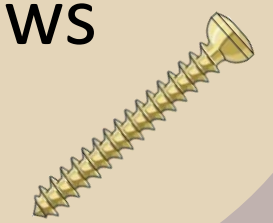
Fixation

Bilateral sagittal split osteotomy (BSSO)

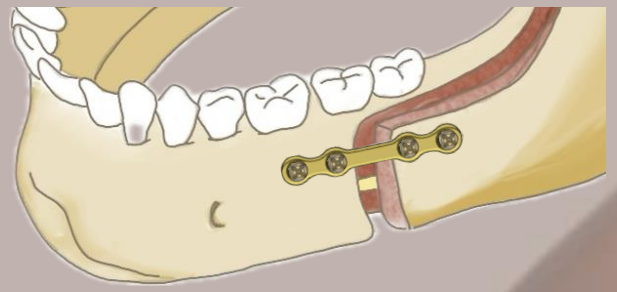


Miniplates

Bicortical screws

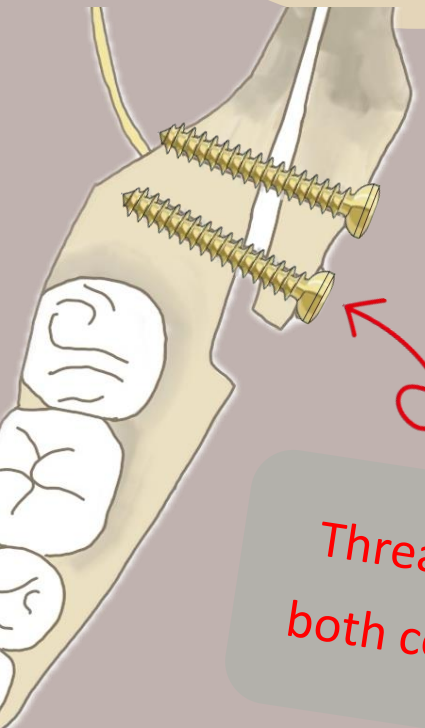


Miniplate



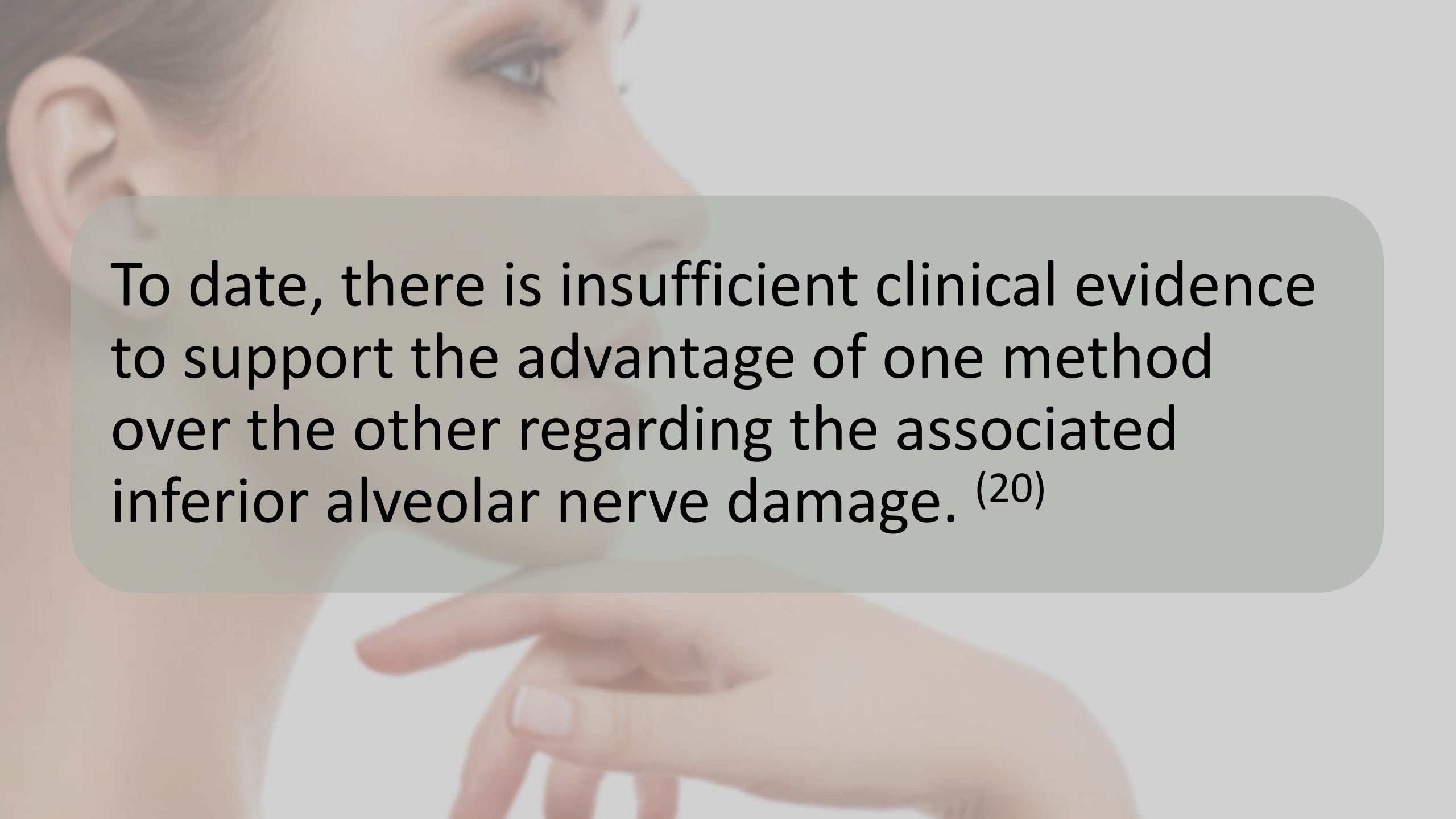
- Can be placed **transorally** (less scar)
- **Single cortex fixation (less nerve encountered)**
- Palpable hardware and chronic irritation
- Easy removal
- Less rigid in lateral vector (asymmetrical adjustment)
- More expensive

Bicortical screw



Threads on both cortices

- 2-mm diameter titanium **positioning** screws x3 screws on each side
- **Easier placement**
- Allows more bone recontouring after fixation
- More **cost effective**
- **Difficult to remove**
- Harder to readjust occlusion



To date, there is insufficient clinical evidence to support the advantage of one method over the other regarding the associated inferior alveolar nerve damage. [20]

To date, there is no RCT comparing sensation outcome between these two fixation.

VS

Study Design

P – Patient undergoing BSSO

I – Fixation with Bicortical Screw

C – Fixation with Miniplate

O – Labiomental sensation recovery

Study Design

Objective:

- To compare the rate of inferior alveolar nerve injury between miniplate fixation and bicortical screw fixation following bilateral sagittal split osteotomy (BSSO) by evaluating postoperative sensory outcomes over a six-month follow-up period.

Hypothesis:

- **Null Hypothesis (H_0):** There is no significant difference in the rate of inferior alveolar nerve injury between miniplate fixation and bicortical screw fixation after BSSO.

Study Design

- Single centered
- **Randomized controlled trial**
- From July 2022 to December 2024
- Primary Outcome
  - Subjective sensation, VAS and 2-point discrimination
- Secondary Outcome
  - Operative time, hospital stay, blood loss, and drain output

Outcome measurement

- Multimodality evaluation of patient's sensation
  - Temperature sensation — Hot, Cold
  - Light touch sensation
  - Pressure sensation
  - 2-point discrimination
  - VAS
- Evaluated at
  - Pre-operative
  - Post-operative ; 1 week, 2 weeks, 1 month, 3 months, 6 months

Patient and Methods: Inclusion criteria

Age 18 and above

Patient consent

Patients with malocclusion undergoing BSSO at Ramathibodi hospital

Patient and Methods: Exclusion criteria

Patient
denies consent

Craniofacial
syndrome

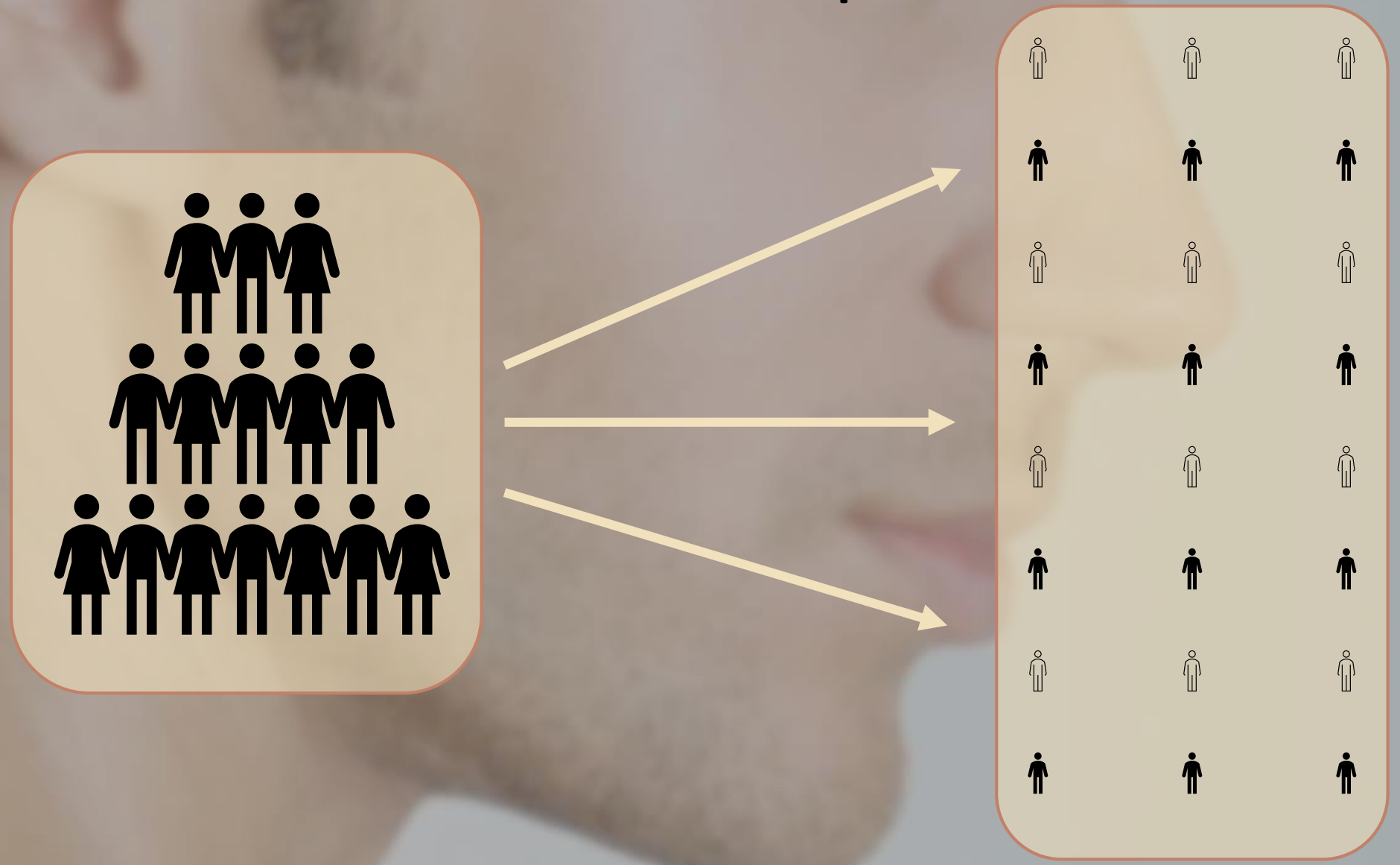
Underlying DM, Stroke and
neurological disease

Previous
craniofacial trauma

Previous genioplasty

Concurring sensory
deficit

Patient and Methods: Simple Randomization



Patient and Methods: Operation

- Operations were done by one senior surgeon at Department of plastic surgery, Faculty of Medicine, Ramathibodi Hospital
- Between July 2022 and December 2024

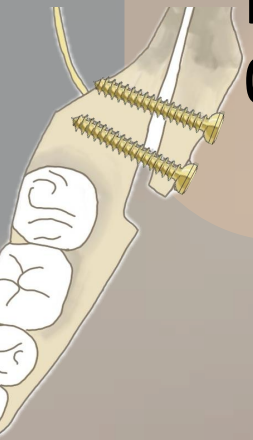
Operative details

- Osteotomy line was designed and horizontal corticotomy was done with reciprocating saw and then extends anterolaterally to the molar (**Hunsuck**)
- The osteotomy line was split using osteotome, dautry and mallet.
- **Prefabricated Occlusal splint** was placed and maxillomandibular fixation was applied with archbars and wires no.26

Operative details

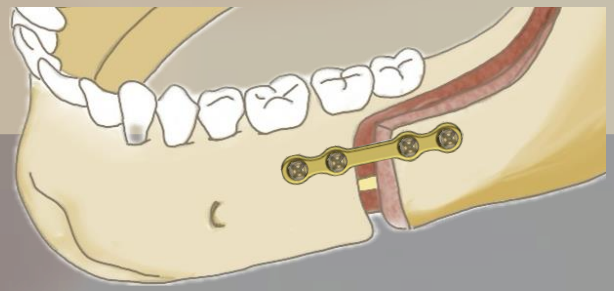
Bicortical screw

- Stab incision was made with blade. No.11 and trocar was used.
- 2-mm bicortical positioning screws were placed at upper and lower border of the mandible. 3 screws on each side, 0.5 cm from the edge.



Miniplate

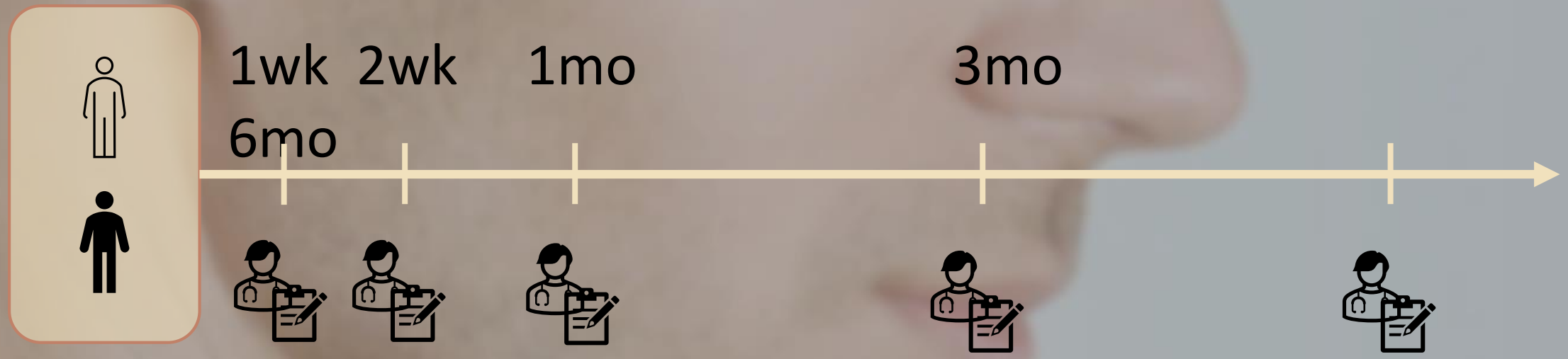
- 2-mm 4-hole miniplate was placed and fixed with 4 monocortical screws on each side
- Percutaneous screw placement with trocar may be used if exposure is inadequate.



Operative details

- 1 **silicone drain** no.10 was placed on each sides, removed post-operatively after content is less than 20ml for 24 hours
- Pressure dressing was applied (**Barton bandage**)
- **Rubber band MMF** was applied at ward after ETT was removed and airway was clear and removed 2 weeks post operatively

Patient and Methods: Follow up period



Patient and Methods: Sensation evaluation

Tested by trained assessor and patient reported score of 1(numb)-5(normal)

- Fine touch
  - Patient was tested with light touch with small filament of cotton ball and
- Hot, Cold
  - The end of a forceps submerged in hot water and cold water compared to sensation at cheek
- Pressure
  - The end of a forceps pressed against the tested area compared to sensation at cheek

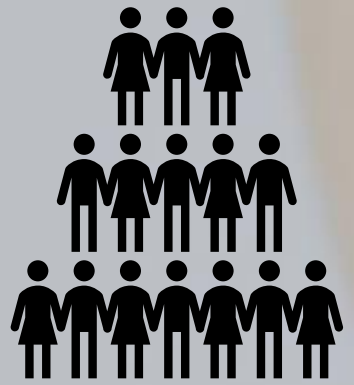
Patient and Methods: Sensation evaluation

- Self reported VAS score from 0 to 10
- 2-point discrimination
  - A **caliper** is lightly pressed against the tested area and the closest 2-point discrimination distance is recorded, repeated 2 times.
  - If the distance is more than 20mm, considered numb
  - Given the score based on the distance
    - 5= 2-5 mm
    - 4= 6-10 mm
    - 3= 11-15 mm
    - 2= 16-20 mm
    - 1= >20 mm or numb

Results

8

18



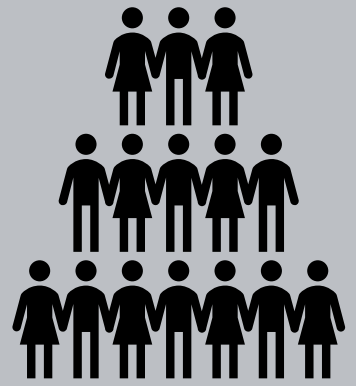
26 cases
52 fixations
- 1 bad split

27

24

Total
51 included fixations

Results



Total
51 included fixations

Variable	Miniplate (Mean ± SD)	Bicortical Screw (Mean ± SD)	p-value
Age (years)	27.33 ± 5.82	32.00 ± 8.01	0.1073
Gender (M/F)	4 / 8 (33.3% / 66.7%)	4 / 10 (28.6% / 71.4%)	0.793
Height (cm)	164.25 ± 6.92	166.03 ± 10.51	0.6217
Weight (kg)	53.13 ± 6.79	56.34 ± 12.58	0.4201
BMI (kg/m²)	19.66 ± 1.97	20.23 ± 2.73	0.5666

No significant demographic differences

Results

Diagnosis, n(%)	Total	Miniplate	Bicortical screws
Facial asymmetry	7(26.9)	5(41.7)	2(14.3)
Malocclusion	4(15.4)	0	4(28.6)
Prognathism	14(53.8)	7(58.4)	7(50.0)
Retroghathia	1(3.8)	0	1(7.1)
Operation, n(%)			
2-jaw	5(19.2)	3(25.0)	2(14.3)
2 jaw + genioplasty	1(3.9)	1(8.3)	0
BSSO	15(57.7)	7(58.3)	8(57.1)
BSSO + genioplasty	5(19.2)	1(8.3)	4(28.6)

Results:

Variable	**Miniplate** (Mean ± SD)	**Bicortical Screw** (Mean ± SD)	**p-value**
Operative Time (min)	204.17 ± 57.48	193.21 ± 57.93	0.63
Hospital Stay (days)	4.0± 1.1	4.0± 0.6	0.62
Total Drain Output (mL)	99.73 ± 42.53	91.08 ± 26.92	0.47
Blood Loss (mL)	Median = 350 (IQR: 200-500)	Median = 275 (IQR: 200-550)	1.00

No significant difference in post operative details

No reoperation cases due to fixation failure

Results

LL = lower lip
M=miniplate
B=bicortical screw

Timepoint	Cold (LL)	Cold (Chin)	Hot (LL)	Hot (Chin)	Pressure (LL)	Pressure (Chin)
1 Week	**2.25 ± 1.24** (M) **2.07 ± 1.21** (B) **p = 0.69**	**1.69 ± 1.25** (M) **1.64 ± 0.84** (B) **p = 0.91**	**1.81 ± 1.22** (M) **1.62 ± 1.12** (B) **p = 0.66**	**1.50 ± 1.10** (M) **1.29 ± 0.61** (B) **p = 0.51**	**2.25 ± 0.86** (M) **2.79 ± 1.12** (B) **p = 0.15**	**1.81 ± 0.83** (M) **2.50 ± 1.09** (B) **p = 0.06**
2 Weeks	**2.47 ± 1.50** (M) **2.67 ± 1.62** (B) **p = 0.70**	**2.22 ± 1.31** (M) **2.48 ± 1.36** (B) **p = 0.56**	**2.28 ± 1.56** (M) **2.57 ± 1.43** (B) **p = 0.54**	**1.94 ± 1.30** (M) **2.10 ± 1.34** (B) **p = 0.72**	**2.33 ± 1.37** (M) **3.10 ± 1.41** (B) **p = 0.09**	**2.33 ± 1.33** (M) **2.76 ± 1.48** (B) **p = 0.35**
1 Month	**2.46 ± 1.38** (M) **2.58 ± 1.43** (B) **p = 0.78**	**2.29 ± 1.30** (M) **2.68 ± 1.49** (B) **p = 0.36**	**2.42 ± 1.35** (M) **2.58 ± 1.57** (B) **p = 0.71**	**2.21 ± 1.14** (M) **2.58 ± 1.46** (B) **p = 0.36**	**2.92 ± 1.28** (M) **3.21 ± 1.32** (B) **p = 0.47**	**2.63 ± 1.09** (M) **2.95 ± 1.51** (B) **p = 0.42**

No patient with permanent sensation loss

Results

LL = lower lip
M=miniplate
B=bicortical screw

Timepoint	Fine (LL)	Fine (Chin)	VAS (LL)	VAS (Chin)	2-Point (LL)	2-Point (Chin)
1 Week	**2.19 ± 1.33** (M) **1.57 ± 0.65** (B) **p = 0.11**	**1.56 ± 0.89** (M) **1.36 ± 0.50** (B) **p = 0.44**	**4.43 ± 1.45** (M) **3.21 ± 2.72** (B) **p = 0.15**	**3.36 ± 2.41** (M) **3.57 ± 2.06** (B) **p = 0.80**	**2.70 ± 1.12** (M) **2.70 ± 1.12** (B) **p = 1.00**	**2.70 ± 1.12** (M) **2.70 ± 1.12** (B) **p = 1.00**
2 Weeks	**2.67 ± 1.78** (M) **2.67 ± 1.80** (B) **p = 1.00**	**2.39 ± 1.42** (M) **2.38 ± 1.50** (B) **p = 0.98**	**4.33 ± 3.36** (M) **4.95 ± 2.67** (B) **p = 0.53**	**4.33 ± 3.02** (M) **3.95 ± 2.20** (B) **p = 0.65**	**3.12 ± 1.33** (M) **2.56 ± 1.14** (B) **p = 0.31**	**3.12 ± 1.33** (M) **2.56 ± 1.14** (B) **p = 0.31**
1 Month	**2.83 ± 1.58** (M) **2.42 ± 1.54** (B) **p = 0.39**	**2.46 ± 1.25** (M) **2.32 ± 1.25** (B) **p = 0.71**	**5.33 ± 2.61** (M) **4.47 ± 2.67** (B) **p = 0.30**	**4.88 ± 2.40** (M) **4.37 ± 2.81** (B) **p = 0.53**	**3.56 ± 1.32** (M) **3.46 ± 1.32** (B) **p = 0.88**	**3.56 ± 1.32** (M) **3.46 ± 1.32** (B) **p = 0.88**

No patient with permanent sensation loss

Results

LL = lower lip
M=miniplate
B=bicortical screw

Timepoint	Cold (LL)	Cold (Chin)	Hot (LL)	Hot (Chin)	Pressure (LL)	Pressure (Chin)
3 Months	**4.31 ± 0.79** (M) **4.10 ± 1.26** (B) **p = 0.55**	**3.93 ± 1.12** (M) **4.04 ± 1.20** (B) **p = 0.78**	**3.69 ± 1.14** (M) **3.57 ± 1.54** (B) **p = 0.80**	**3.31 ± 1.30** (M) **2.97 ± 1.27** (B) **p = 0.44**	**4.25 ± 1.00** (M) **4.33 ± 0.91** (B) **p = 0.79**	**3.81 ± 1.05** (M) **3.95 ± 1.16** (B) **p = 0.71**
6 Months	**4.70 ± 0.57** (M) **4.44 ± 0.89** (B) **p = 0.29**	**4.65 ± 0.67** (M) **4.19 ± 0.83** (B) **p = 0.07**	**4.15 ± 1.26** (M) **3.69 ± 1.45** (B) **p = 0.31**	**4.41 ± 1.17** (M) **3.25 ± 1.53** (B) **p = 0.11**	**4.45 ± 0.69** (M) **4.44 ± 0.73** (B) **p =0.96**	**4.43 ± 0.75** (M) **4.00 ± 0.82** (B) **p = 0.19**

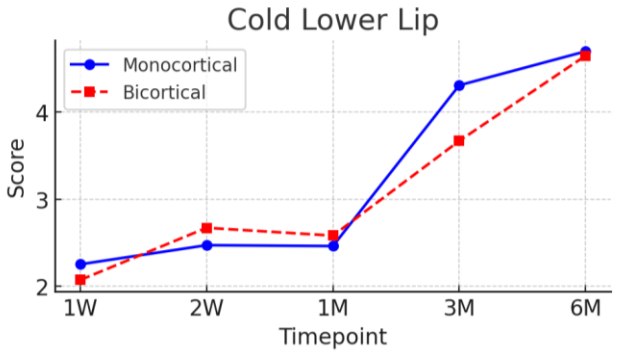
No patient with permanent sensation loss

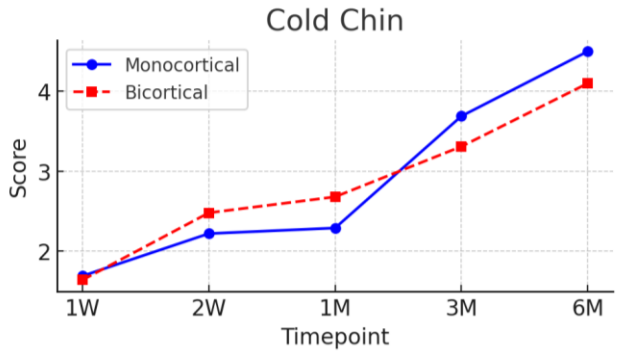
Results

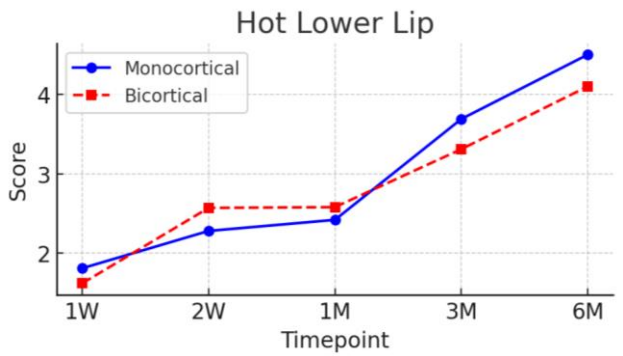
LL = lower lip
M=miniplate
B=bicortical screw

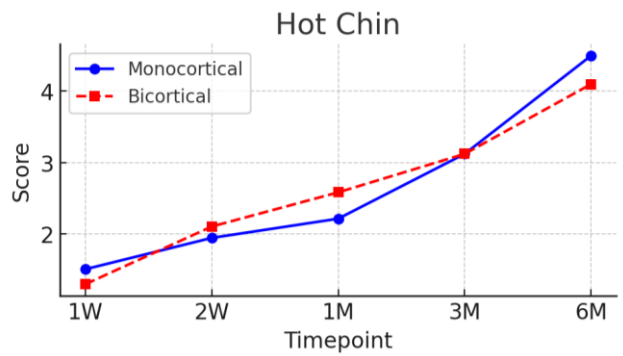
Timepoint	Fine (LL)	Fine (Chin)	VAS (LL)	VAS (Chin)	2-Point (LL)	2-Point (Chin)
3 Months	**3.88 ± 0.96** (M) **4.28 ± 0.90** (B) **p = 0.19**	**3.88 ± 1.02** (M) **4.33 ± 1.06** (B) **p =0.20**	**7.50 ± 1.59** (M) **7.38 ± 2.40** (B) **p = 0.86**	**7.38 ± 1.71** (M) **7.33 ± 2.18** (B) **p = 0.95**	**4.31 ± 1.18** (M) **3.62 ± 1.21** (B) **p = 0.09**	**3.62 ± 1.21** (M) **3.62 ± 1.21** (B) **p = 1.00**
6 Months	**4.40 ± 0.82** (M) **4.19 ± 1.05** (B) **p = 0.45**	**4.35 ± 0.88** (M) **3.75 ± 1.06** (B) **p = 0.07**	**8.50 ± 1.24** (M) **7.94 ± 2.59** (B) **p = 0.40**	**8.70 ± 1.34** (M) **7.43 ± 2.19** (B) **p = 0.04**	**4.83 ± 0.83** (M) **4.50 ± 0.95** (B) **p = 0.40**	**4.50 ± 0.95** (M) **4.50 ± 0.95** (B) **p = 1.00**

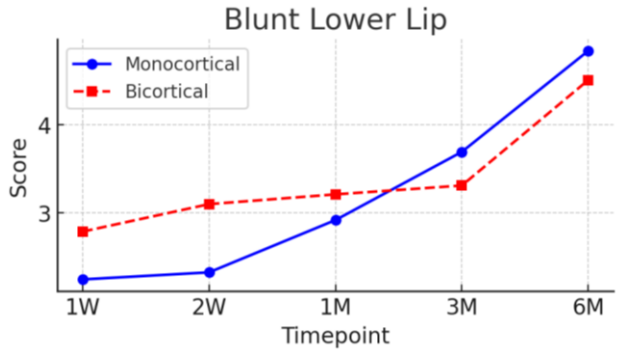
No patient with permanent sensation loss

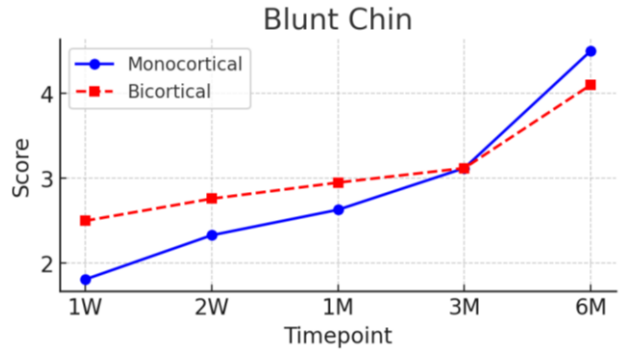


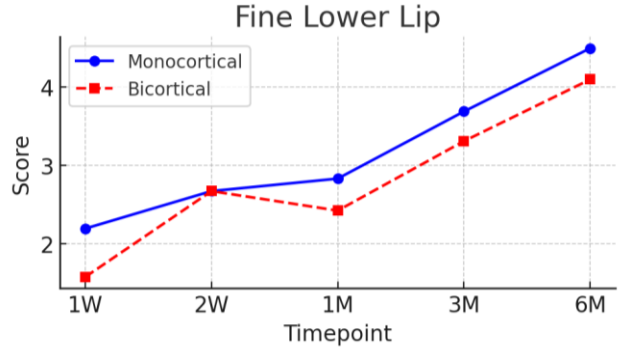


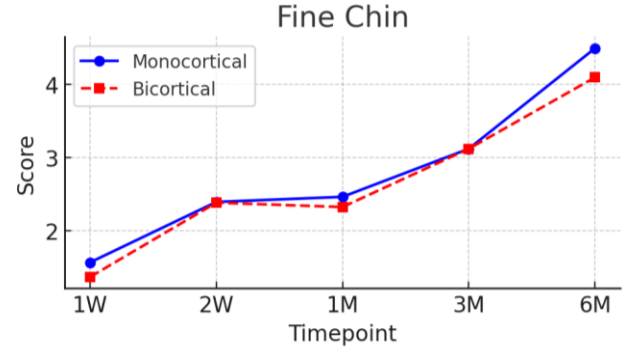


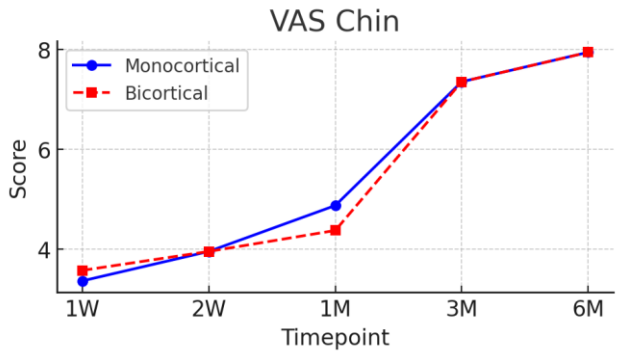


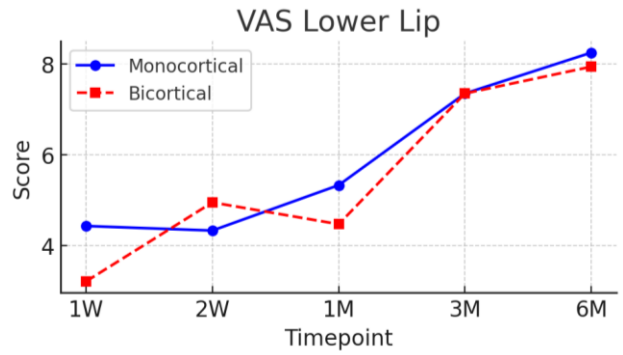


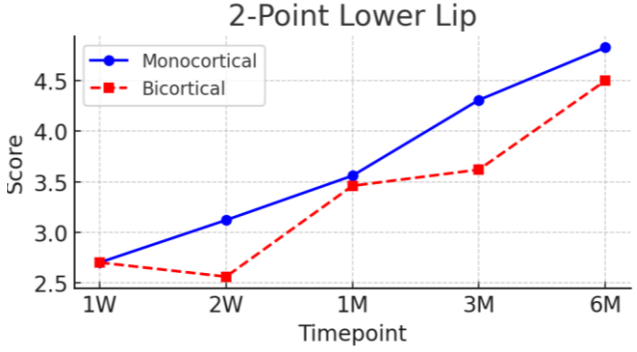


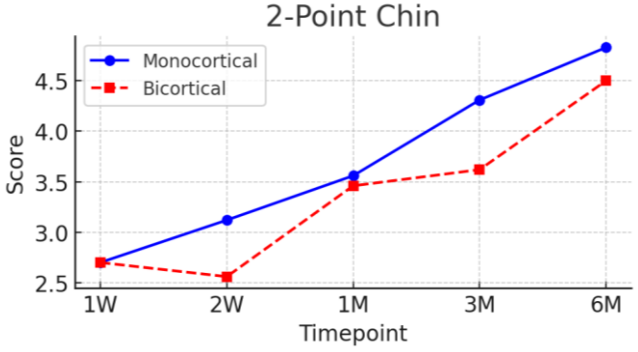












No patient with permanent sensation loss

Discussion

- Our study was done in a single center with single operating surgeon to exclude the difference in mandibular splitting technique.
- There is currently no standard for labiomental sensation assessment. Because EMG is not feasible for every patient in our center, most of the sensory evaluation are subjective, which is enough to assess impact on quality of life.
- There is no significant difference in sensation impairment between fixation method of bicortical screws and miniplate after BSSO.

Discussion

- At 6 month, there is a significant statistical difference in VAS at chin sensation (**8.70 ± 1.34** (M) **7.43 ± 2.19** (B) **p = 0.04**). However, there is no noticeable clinical difference between the two groups.
- We did not detect any permanent impairment of labiomental sensation. May be due to low number of sample size.
- There is no difference in operative time, hospital stay, total drain output and intraoperative blood loss.

Discussion

- Previously, miniplate fixation with monocortical placement is believed to holds lower risk of inferior alveolar nerve injury. Our study shows that there is no increased trend of nerve injury in bicortical screws also.
- Therefore, the concern of nerve injury may not be sufficient to switch between fixation method. All sensation modalities shows steady recovery, reaching near-normal sensation by 6 months.

Conclusion

- There are no significant difference in terms of sensation recovery for miniplate and bicortical screws fixation after BSSO
- Further multi-center study with, larger sample size may be required for more reliable results

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Abstract

“Comparative study of Overactive bladder symptoms management with High-intensity Focused Electromagnetic stimulation Chair therapy and Mirabegron”

Thanakorn Pattamawalai, MD

Thanakorn Pattamawalai, Pokket Sirisreetreerux

Division of Urology, Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Introduction: Overactive bladder is the clinical symptoms characterized by primary symptoms of urinary urgency, combined with urinary frequency and nocturia, with or without urge incontinence, without other pathology. This condition has widely impact on the patients and affects both health and quality of life. Management of overactive bladder symptoms are depend on severity of symptoms. However, medical therapy has some adverse effects and more medical cost.

Objective: The aim of this study was to evaluate the efficacy of High-intensity Focused Electromagnetic stimulation (HIFEMs) Chair therapy compare with mirabegron in treatment of overactive bladder.

Material and methods: From October 2023 to June 2024, we prospectively collected data from 39 Thai patients underwent treatment for overactive bladder in Ramathibodi Hospital. Individual patient were treated with HIFEMs therapy or mirabegron. Clinical outcome and questionnaire, including urinary symptoms of frequency, nocturia, urgency and urge incontinence and questionnaires of ICIQ-OAB and ICIQ-Qol, were quantifined with univariated analysis ($P<0.05$).

Results: There were 39 patients met the inclusion and exclusion criteria. The patients in both group had similar baseline characteristic and urinary symptoms (Table 1). At 2 month after treatment, the HIFEMs group significantly reduce storage symptoms (frequency symptom before treatment, 1 mo, 2 mo and after finishing treatment 3 mo: 14, 6, 6 and 6 respectively (Figure 1), frequency of nocturia before treatment, 1 mo, 2 mo and after finishing treatment 3 mo: 3, 2, 2 and respectively. (Figure 2) Urrgency and urinary incontinent stmptoms improvement. (Figure 3,4) Regarding quality of life, ICIQ-OAB qol score significantly decrease ICIQ OAB Qol Total score before treatment, 1 mo, 2 mo and after finishing treatment 3 mo: 111.3, 73.6, 70.2 and 63.4 respectively (Figure 5). HIFEMs has some report of minimal side effect of dizziness and muscle strain. The patients have no significant difference in complications between 2 groups. (Table 3)

Conclusion: HIFEMs chair has been proved to be an effective treatment modality for OAB patients with minimal adverse events. It provides alternative option for OAB patients who do not want to be treated with medication. However, further study with more number of patients is suggested.

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Comparative study of Overactive bladder symptoms management with High-intensity Focused Electromagnetic stimulation Chair therapy and Mirabegron

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Ref.2024/899

Title of Project (English)	Comparative study of Overactive bladder symptoms management with High-Intensity Focused Electromagnetic stimulation Chair therapy and Mirabegron
Title of Project (Thai)	การศึกษาเปรียบเทียบการรักษาผู้ป่วยกลุ่มอาการกระเพาะปัสสาวะบีบตัวไว ด้วยการใช้เก้าอี้กระตุ้นคลื่นแม่เหล็กไฟฟ้าเปรียบเทียบกับการใช้ยามิราบิกอน
Type of Review	Expedited
Principal Investigator	Thanakorn Pattamawalai
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 13/08/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	September 11, 2023
Renewal Date (1st)	September 11, 2024
Date of Expiration	September 10, 2025

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

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Introduction

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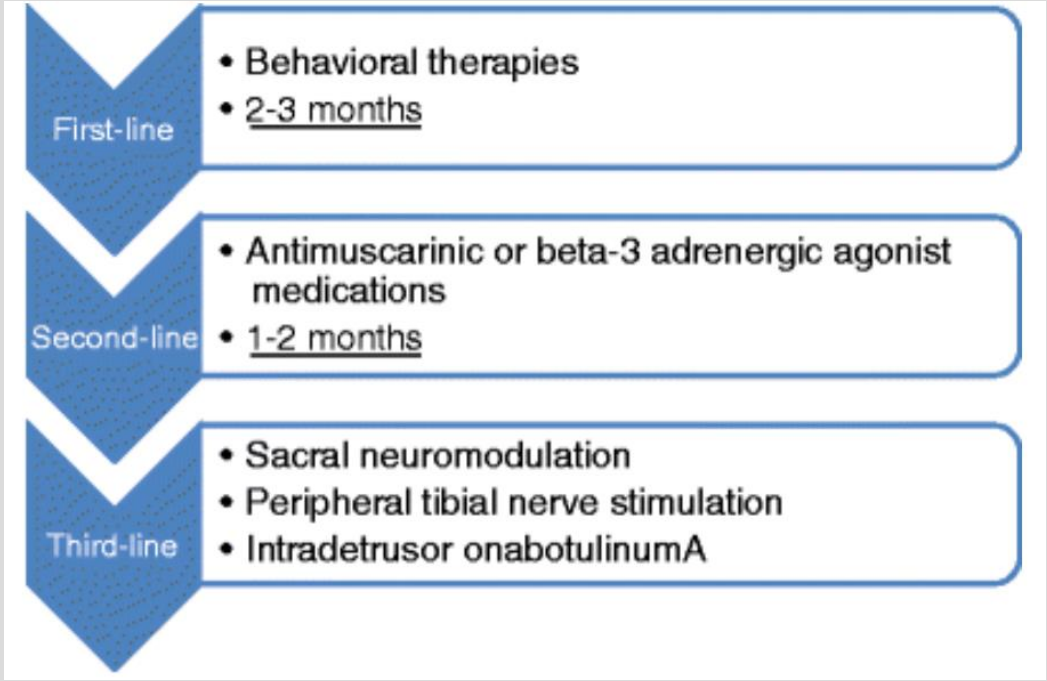
- **Overactive bladder (OAB)** characterized by primary symptoms of urinary urgency, combined with urinary frequency and nocturia ,with or without urge incontinence , without pathology .
- The prevalence of overactive bladder syndrome is 16.5% , increasing with aging society .
- Symptoms of OAB are usually bothersome affecting many health problems including physical health, mental health, quality of life, and social situations.

Introduction : Management of OAB

- The management of overactive bladder follows the AUA/SUFU Guideline 2019

Recommending behavioral modifications and the use of oral medications. : Beta 3-adrenoceptor agonists.

American Urological Association
Advancing Urology™



Mirabegron

- Beta 3-adrenoceptor agonists

- Increase bladder capacity

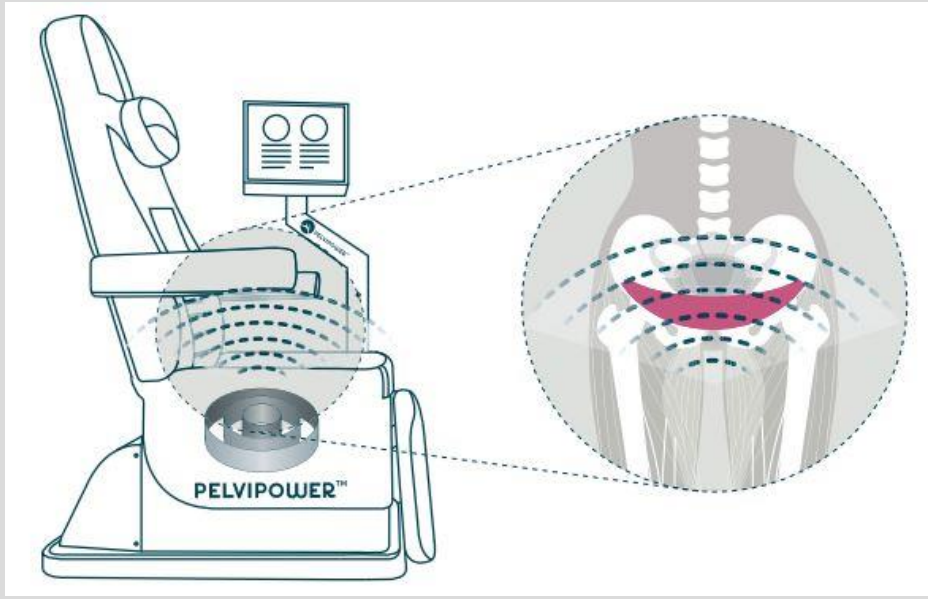
- Dose 50 mg / day

HIFEMs chair

High-intensity Focused Electromagnetic stimulation Chair

- **HIFEMs chair** (approved by the FDA since 1998) ,the modality of choices abnormal urinary incontinence comprising of stress, urge, and mixed incontinence.
- Magnetic chairs result in …

1. inhibition bladder contractions
2. increasing bladder capacity
3. strengthening pelvic floor muscle contractions
4. contraction of the internal urethral sphincter



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Research Question

Comparing with Mirabegron, dose the HIFEMs chair improve OAB urinary symptoms in OAB patients?

PICO

P : Patient with idiopathic OAB syndrome

I : HIFEMS chair

C : Mirabegron 50 mg

O : OAB symptoms improvement (Frequency, urgency and nocturia

Objective

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- **Primary objective** : To evaluate efficacy of HIFEMs chair compare with Mirabegron in treatment of OAB
  - Frequency of urination
  - Nocturia
  - Urgency symptoms
  - Urinary incontinence symptoms
- **Secondary objective** : To compare
  - Quality of life
  - Adverse events of the interventions

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Methods

Study design

- Prospective observational comparative study .
- Data collection between Oct 2023 to June 2024 .

Intervention

- Interventional group : HIFEMs chair for 6 treatments session (once a week)

  Setting : frequency 10 Hz ,moderate intensity duration 20 min/session
- Control group : Mirabegron 50 mg/day for 2 months

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HIFEMs chair

Population

Inclusion Criteria	Exclusion Criteria
1) Men or Women age older than 18 years old	1) Patients who had active urinary tract infection
2) Patients who were diagnosed as OAB by clinical urinary symptoms	2) Patients who were diagnosed as stress urinary incontinent
3) Having inform consent to participate the research	3) Contraindicated for HIFEMs chair including pacemaker insertion, had metallic implants, hadactive malignancy and pregnancy.
	4) Contraindicated for mirabegron including - uncontrolled hypertension - drug allergy - renal impairment (ESRD and GFR < 15 ml/min/1.73 m2) - hepatic cirrhosis Child-Pugh class B&C - cardiac arrythmia (QT prolongation)
	5) Patients who currently received antimuscarinic drug
	6) Patients who cannot communicate and inform for the information
	7) Patients who reject to participate the research .

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Data collection

- After treatment ,the patient follow up the clinical history, ICIQ-OAB and ICIQ-OAB Quality of life questionnaire at 1,2, 3, 6 after starting the treatment.

ICIQ- OAB

Self-reported questionnaire for evaluating overactive bladder symptoms

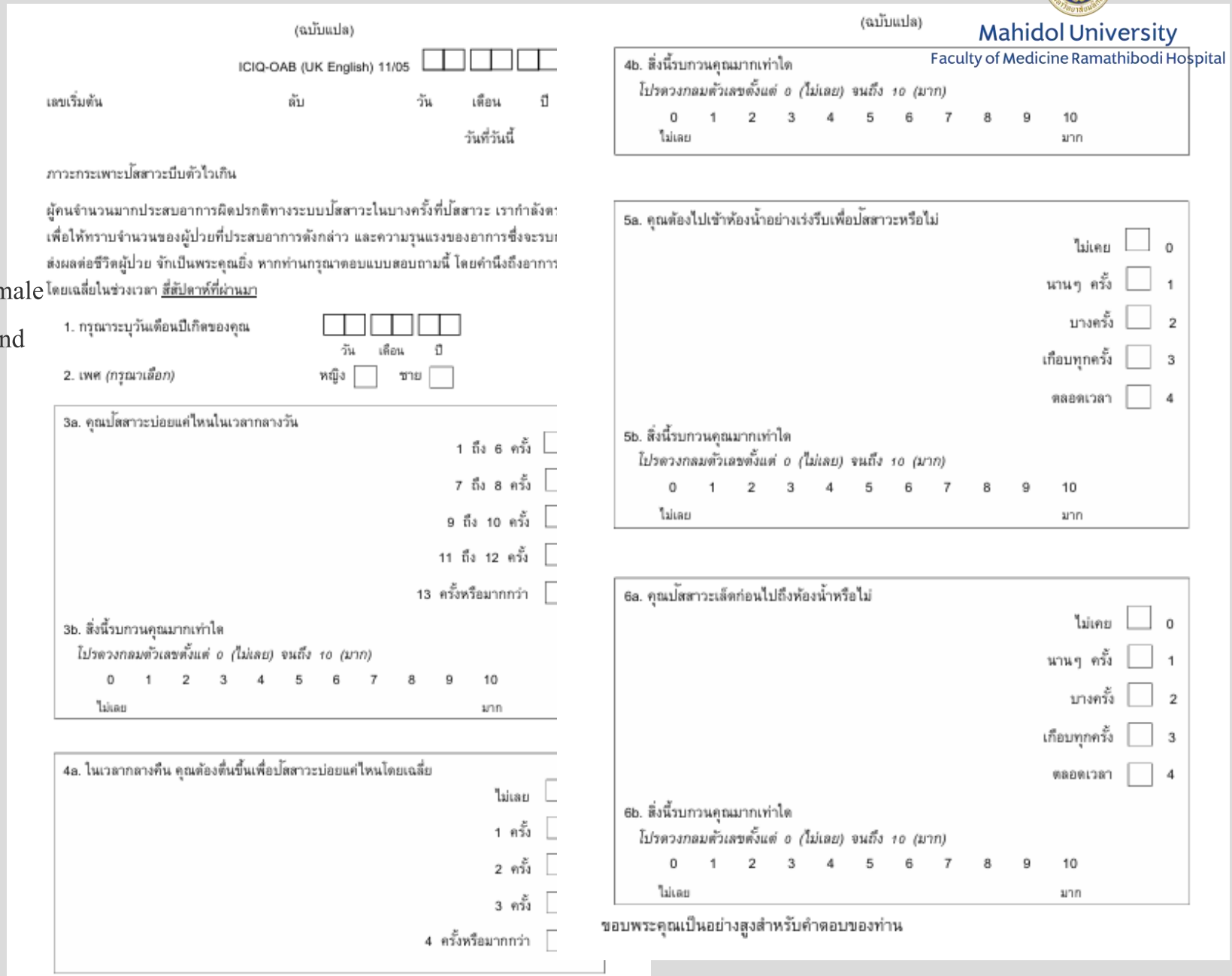
The ICIQ-OAB ,derived from the fully validated ICSmale and BFLUTS , use to eveluaate outcome in research and clinical practice across the world. questionnaires

Question items:

- Frequency
- Nocturia
- Urgency
- Urge urinary incontinence

Scoring:

- 0-16 overall score with greater values indicating increased symptom severity
-



(ฉบับแปล)

ICIQ-OAB (UK English) 11/05

เลขเริ่มต้น ลับ วัน เดือน ปี

วันที่วันนี้

ภาวะกระเพาะปัสสาวะบีบตัวไวเกิน

ผู้คนจำนวนมากประสบอาการผิดปรกติทางระบบปัสสาวะในบางครั้งที่ปัสสาวะ เรากำลังศ
เพื่อให้ทราบจำนวนของผู้ป่วยที่ประสบอาการดังกล่าว และความรุนแรงของอาการซึ่งจะรบก
ส่งผลต่อชีวิตผู้ป่วย จักเป็นพระคุณยิ่ง หากท่านกรุณาตอบแบบสอบถามนี้ โดยคำนึงถึงอาการ
โดยเฉลี่ยในช่วงเวลา สี่สัปดาห์ที่ผ่านมา

1. กรุณาระบุวันเดือนปีเกิดของคุณ วัน เดือน ปี

2. เพศ *(กรุณาเลือก)* หญิง ☐ ชาย ☐

3a. คุณปัสสาวะบ่อยแค่ไหนในเวลากลางวัน

1 ถึง 6 ครั้ง ☐
7 ถึง 8 ครั้ง ☐
9 ถึง 10 ครั้ง ☐
11 ถึง 12 ครั้ง ☐
13 ครั้งหรือมากกว่า ☐

3b. สิ่งนี้รบกวนคุณมากเท่าใด

โปรดวงกลมตัวเลขตั้งแต่ 0 (ไม่เลย) จนถึง 10 (มาก)

0 1 2 3 4 5 6 7 8 9 10

ไม่เลย มาก

4a. ในเวลากลางคืน คุณต้องตื่นขึ้นเพื่อปัสสาวะบ่อยแค่ไหนโดยเฉลี่ย

ไม่เลย ☐
1 ครั้ง ☐
2 ครั้ง ☐
3 ครั้ง ☐
4 ครั้งหรือมากกว่า ☐

(ฉบับแปล)

4b. สิ่งนี้รบกวนคุณมากเท่าใด

โปรดวงกลมตัวเลขตั้งแต่ 0 (ไม่เลย) จนถึง 10 (มาก)

0 1 2 3 4 5 6 7 8 9 10

ไม่เลย มาก

5a. คุณต้องไปเข้าห้องน้ำอย่างเร่งรีบเพื่อปัสสาวะหรือไม่

ไม่เคย ☐ 0
นานๆ ครั้ง ☐ 1
บางครั้ง ☐ 2
เกือบทุกครั้ง ☐ 3
ตลอดเวลา ☐ 4

5b. สิ่งนี้รบกวนคุณมากเท่าใด

โปรดวงกลมตัวเลขตั้งแต่ 0 (ไม่เลย) จนถึง 10 (มาก)

0 1 2 3 4 5 6 7 8 9 10

ไม่เลย มาก

6a. คุณปัสสาวะเล็ดก่อนไปถึงห้องน้ำหรือไม่

ไม่เคย ☐ 0
นานๆ ครั้ง ☐ 1
บางครั้ง ☐ 2
เกือบทุกครั้ง ☐ 3
ตลอดเวลา ☐ 4

6b. สิ่งนี้รบกวนคุณมากเท่าใด

โปรดวงกลมตัวเลขตั้งแต่ 0 (ไม่เลย) จนถึง 10 (มาก)

0 1 2 3 4 5 6 7 8 9 10

ไม่เลย มาก

ขอบพระคุณเป็นอย่างสูงสำหรับคำตอบของท่าน

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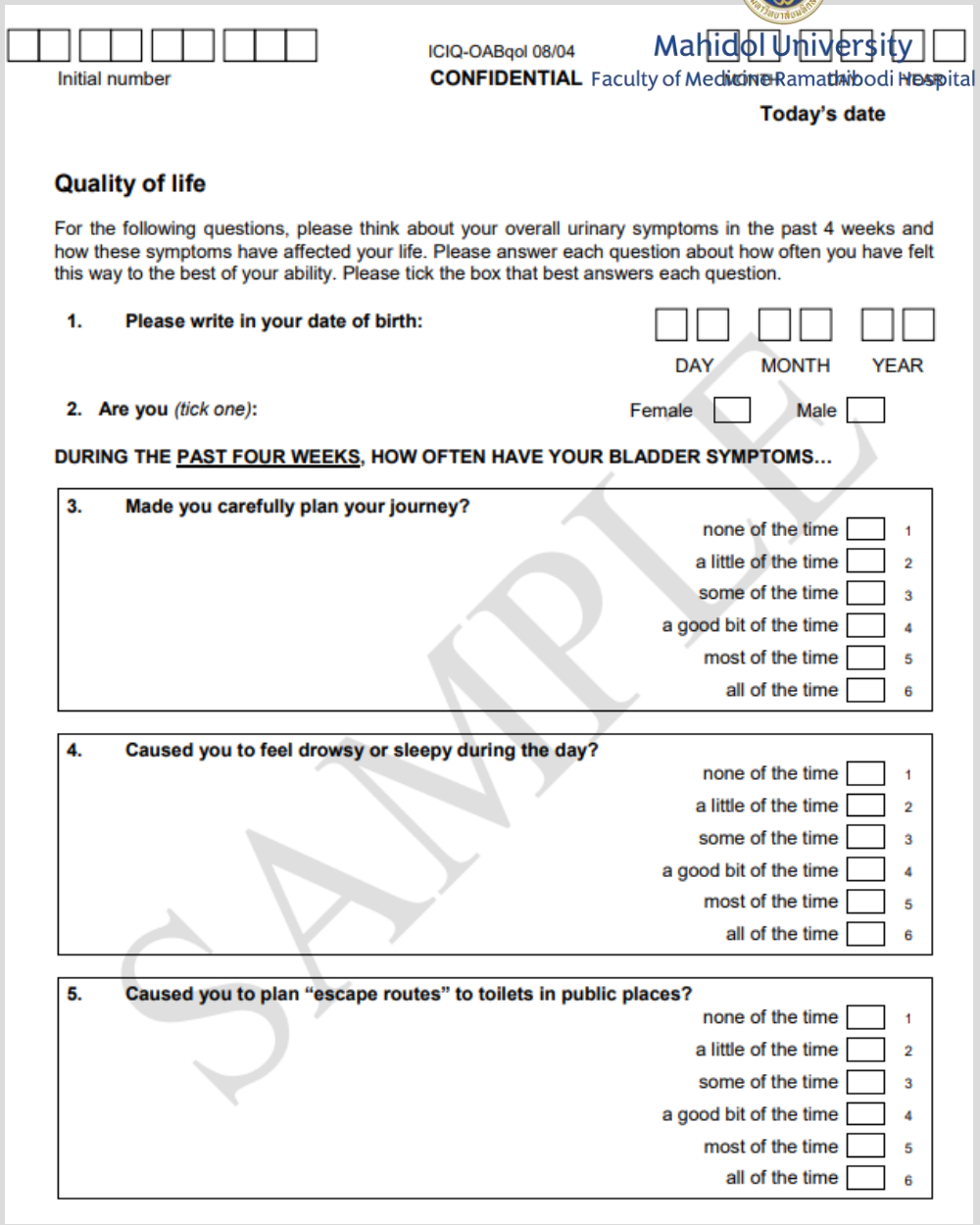
ICIQ- OAB qol

Self-reported questionnaire for evaluating impact of OAB on quality of life (QoL)

The patient-completed questionnaire evaluating quality of life (QoL) in patients with overactive bladder for use in research and clinical practice across the world.

Number of items: 26

25-160 overall score with greater values indicating increased bothersome symptom severity



Initial number

ICIQ-OABqol 08/04

CONFIDENTIAL

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Today's date

Quality of life

For the following questions, please think about your overall urinary symptoms in the past 4 weeks and how these symptoms have affected your life. Please answer each question about how often you have felt this way to the best of your ability. Please tick the box that best answers each question.

1. **Please write in your date of birth:** DAY MONTH YEAR

2. **Are you** *(tick one)*: Female ☐ Male ☐

DURING THE PAST FOUR WEEKS, HOW OFTEN HAVE YOUR BLADDER SYMPTOMS...

3. **Made you carefully plan your journey?**
   - none of the time ☐ 1
   - a little of the time ☐ 2
   - some of the time ☐ 3
   - a good bit of the time ☐ 4
   - most of the time ☐ 5
   - all of the time ☐ 6

4. **Caused you to feel drowsy or sleepy during the day?**
   - none of the time ☐ 1
   - a little of the time ☐ 2
   - some of the time ☐ 3
   - a good bit of the time ☐ 4
   - most of the time ☐ 5
   - all of the time ☐ 6

5. **Caused you to plan "escape routes" to toilets in public places?**
   - none of the time ☐ 1
   - a little of the time ☐ 2
   - some of the time ☐ 3
   - a good bit of the time ☐ 4
   - most of the time ☐ 5
   - all of the time ☐ 6

SAMPLE

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STAT analysis

Baseline characteristic and **clinical outcome** of each group were complared

- Continuous variable (frequency urination ,nocturia , ICIQ OAB score) >> t-test
- Categorical variable (urgency ,urinary incontinent) >> Chi-square test

Pre and Post treatment comparison

- Categorical variables > McNemar test
- Continuous variables > Paired t-test

STATA version 18 (STATA Corp., TX, USA) was used for all statistical analysis.

P-values < 0.05 were considered statistically significant.

Results: Baseline characteristic

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Variable	Total (n=39)	Mirabegron (n=19)	HIFEMs (n=20)	P-value
Gender, n(%)				
Male	13(33.3)	9(47.4)	4(20.0)	0.070
Female	26(66.7)	10(52.6)	16(80.0)	
Age(year), mean±SD	54.8±18.3	65.0±16.9	45.6±14.3	0.001*
Weight (kg), mean±SD	67.1±13.3	65.0±11.4	69.1±14.9	0.342
Height (cm), mean±SD	160.5+6.5	159.6+6.3	161.3+6.6	0.448
BMI(kg/m^2), mean±SD	25.9+4.4	25.4+3.5	26.5+5.2	0.448
Comorbidity, n(%)				
• **DM**	4(10.3)	2(10.5)	2(10.0)	0.999
• **HT**	10(25.6)	7(36.8)	3(15.0)	0.155
• **DLP**	13(33.3)	8(42.1)	5(25.0)	0.257
• **Stroke**	2(5.1)	2(10.5)	0	0.231
• **CKD**	2(5.1)	1(5.3)	1(5.0)	0.999
• **BPH**	6(15.4)	4(21.1)	2(10.0)	0.407
• **CAD**	1(2.6)	0	1(5.0)	0.999

* Statistical significance

Results: Baseline characteristic

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Variable	Total (n=39)	Mirabegron	HIFEMs	P-value
Frequency(pre-treatment), mean±SD	11±8	8±3	14±10	0.027
Nocturia(pre-treatment), mean±SD	4±2	4±2	3±2	0.122
Urgency(pre-treatment), n(%)				
• **No**	1(2.6)	0	1(5.0)	0.999
• **Yes**	37(97.4)	18(100)	19(95.0)	
Urinary incontinence(pre-treatment), n(%)				
• **No**	7(18.4)	2(11.1)	5(25.0)	0.410
• **Yes**	31(81.6)	16(88.9)	15(75.0)	
ICIQ-OAB score (pre-treatment), mean±SD	8±2	7±2	8±1	0.086
ICIQ-OABqol score (pre-treatment), mean±SD	97±26	90±23	103±27	0.116

Results

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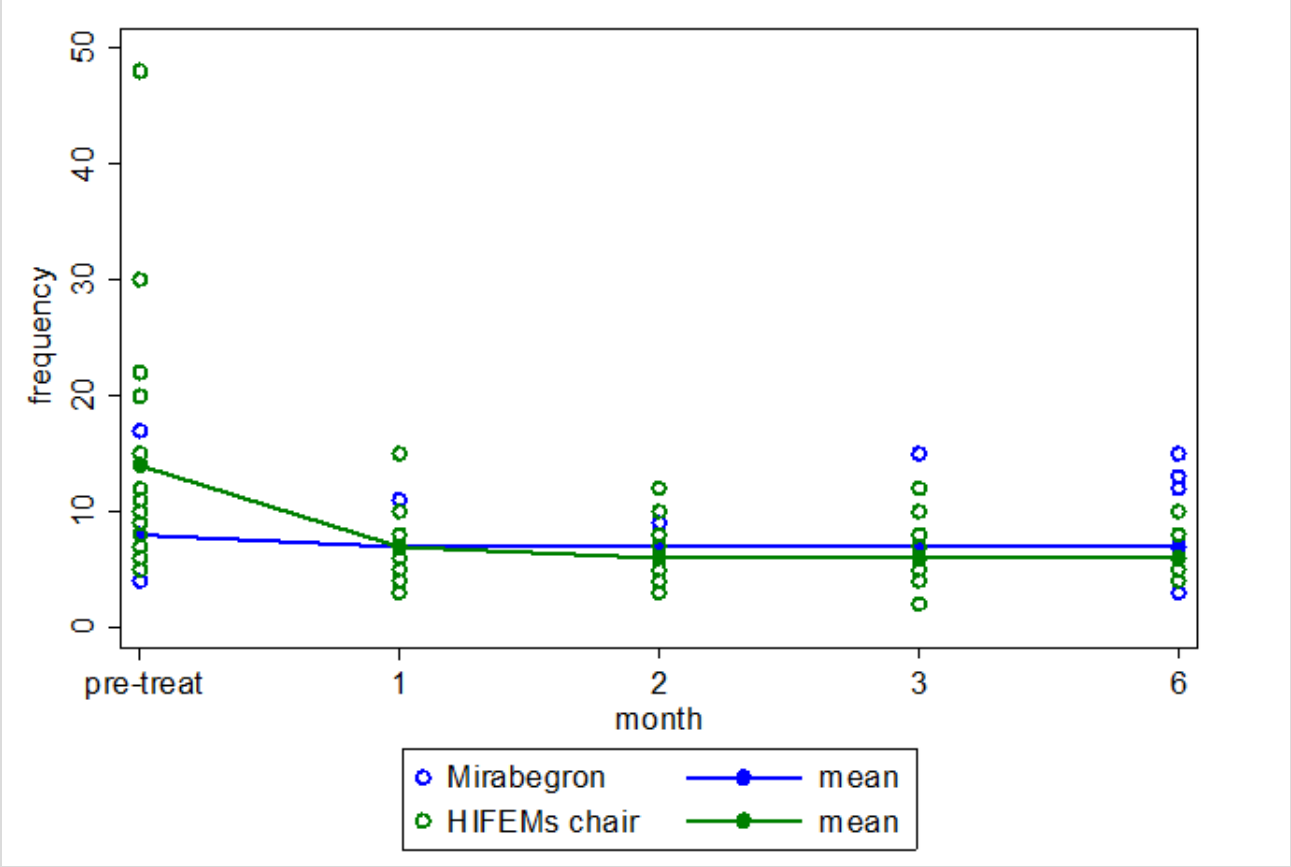
- Frequency urination during follow up 1,2,3,6 months



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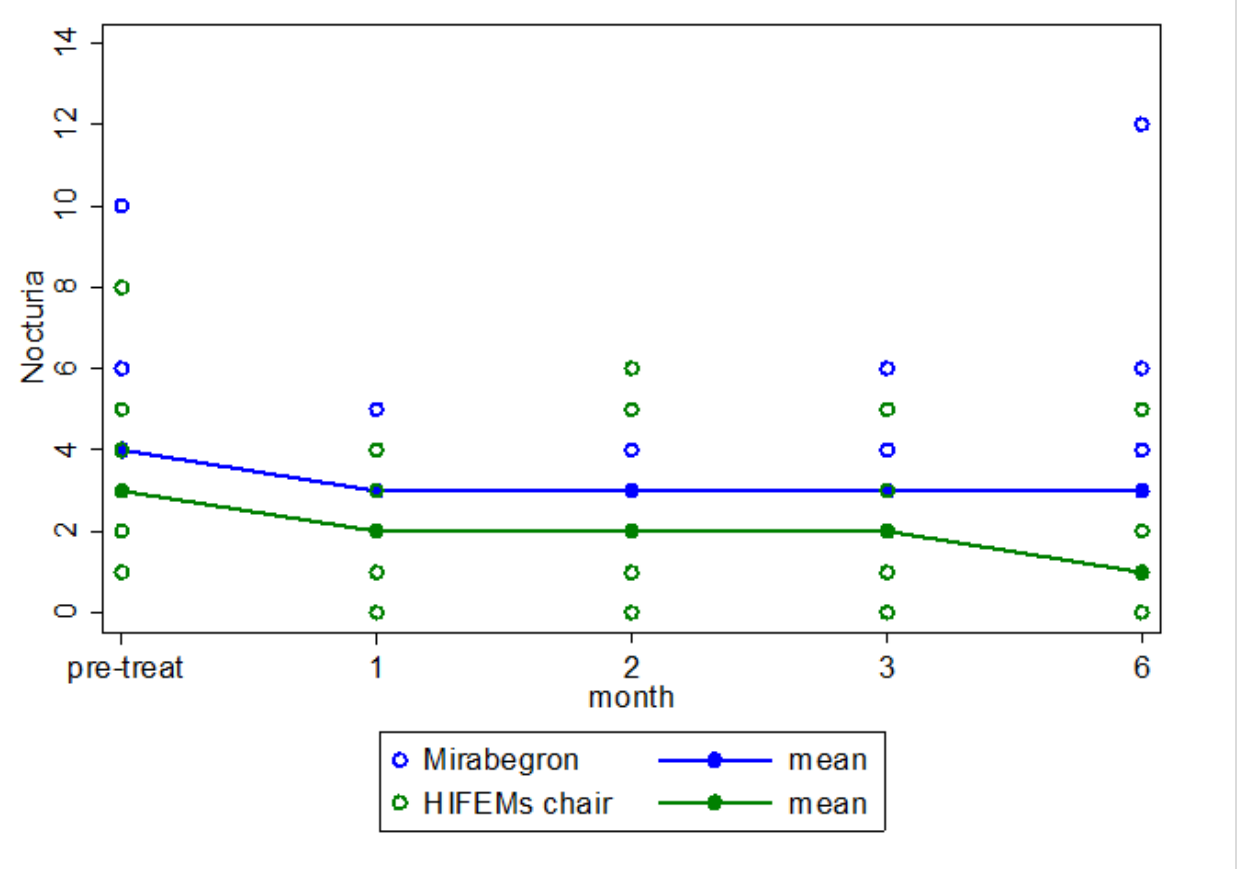
Results

- Nocturia during follow up 1,2,3,6 months



Results

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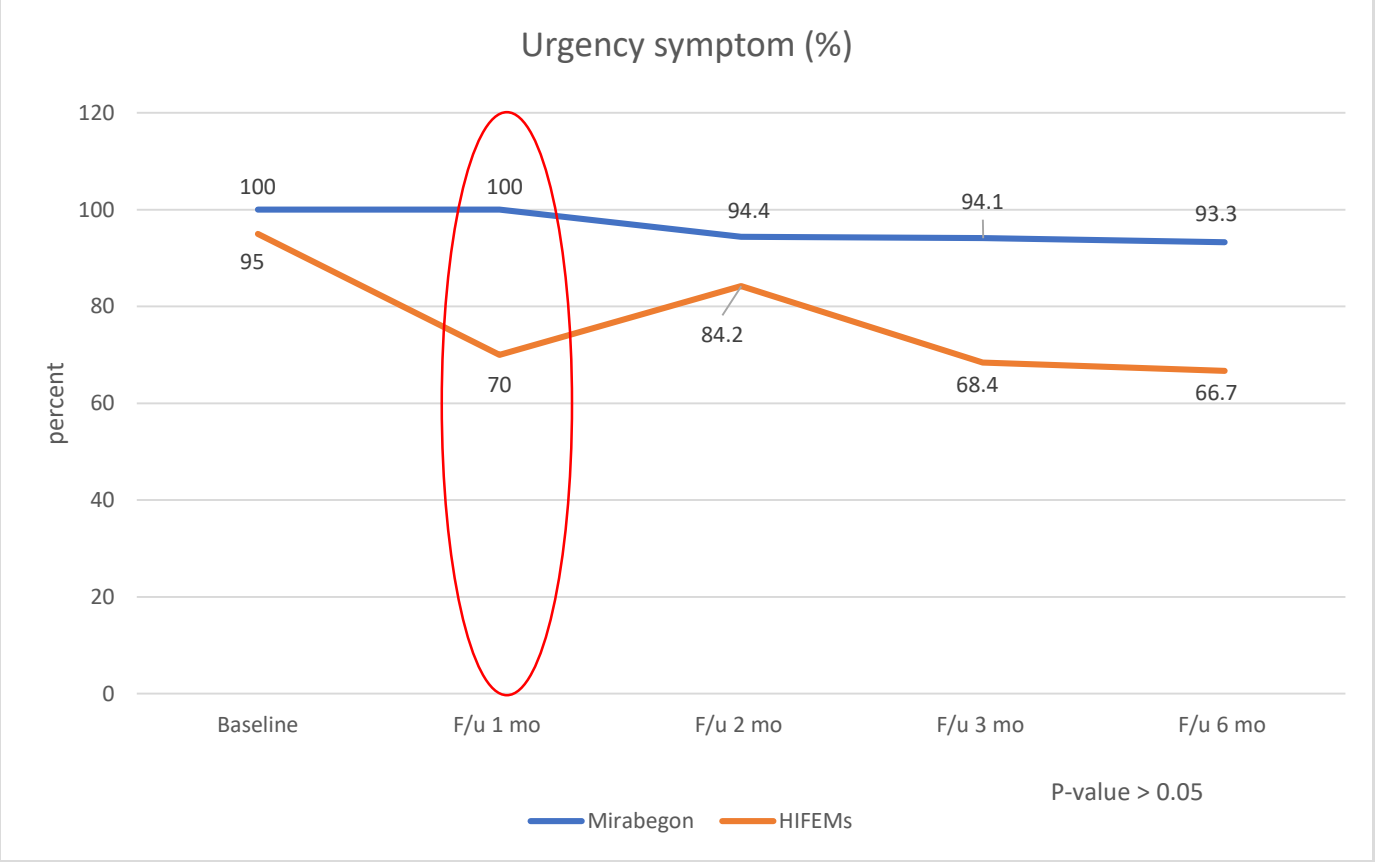
- **Primary outcome** : Percent urgency symptoms during follow up 1,2,3,6 months

  EMSELLAR has a significant effect of 30 % reduction urinary symptoms at 1 mo, P value <0.021



No statistical significance

Results

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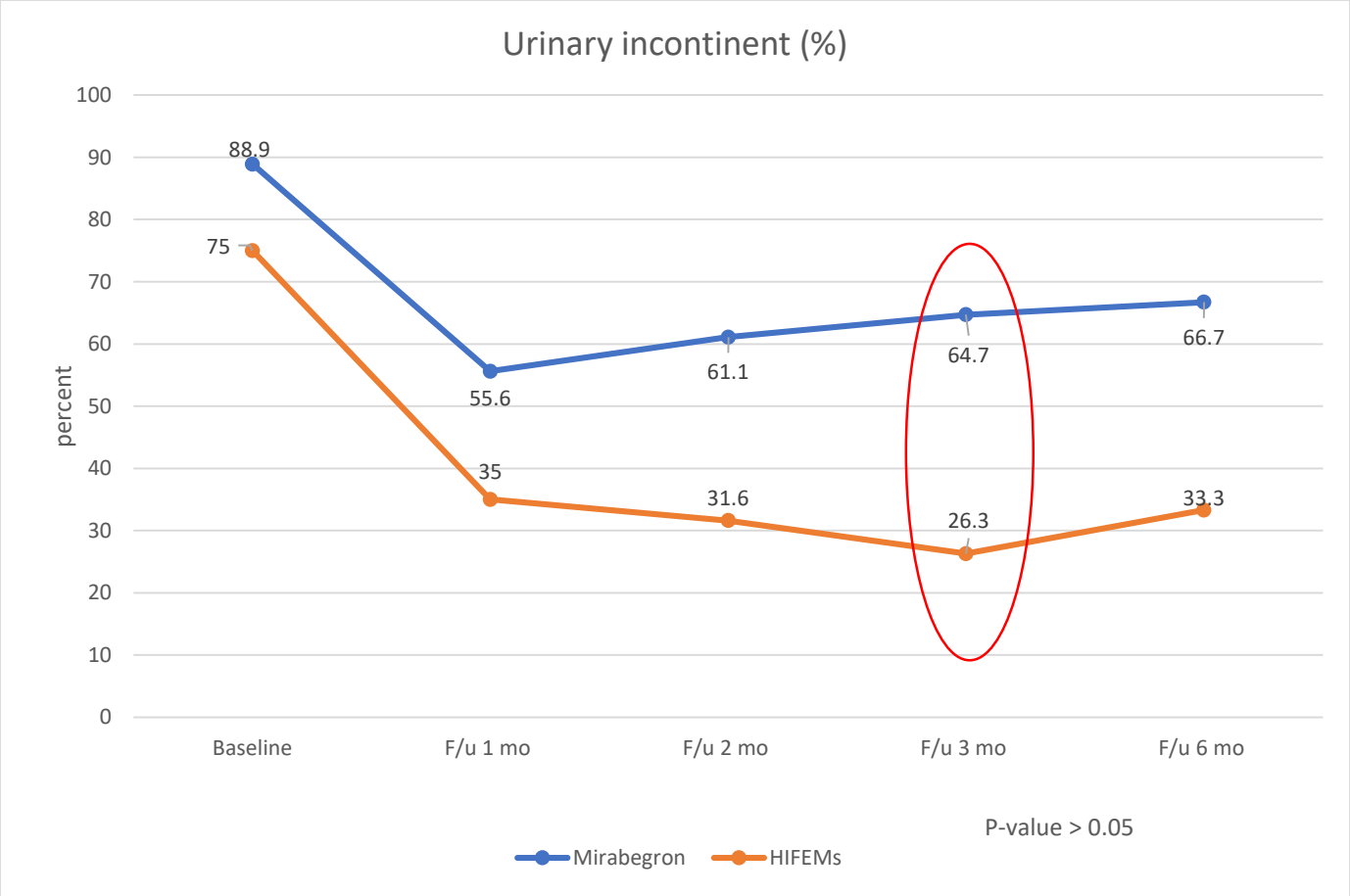
- Percent urinary incontinent symptoms during follow up 1,2,3,6 months

HIFEMs has a significant effect of 74 % reduction urinary incontinent symptoms at 3 mo, P value <0.042



No statistical significance

Results

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	n=19	Mirabegron mean±SD	p-value	n=20	HIFEMs chair mean±SD	p-value
ICIQ-OAB (Q26 score)						
Pre-treat		7.3±2.1			8.3±1.3	
F/u 1 month	n=18	5.9±2.2	0.003	n=19	4.7±2.5	<0.001
F/u 2 month	n=18	5.5±2.4	0.001	n=17	4.7±2.5	<0.001
F/u 3 month	n=17	5.0±2.5	0.002	n=16	4.2±2.3	<0.001
F/u 6 month	n=14	4.6±2.5	0.001	n=14	4.1±2.5	<0.001
ICIQ-OAB qol (Total score)						
Pre-treat		97.3±23.9			111.3±29.2	
F/u 1 month	n=18	83.6±24.4	0.004	n=19	73.6±32.6	<0.001
F/u 2 month	n=18	76.1±23.7	0.000	n=17	70.2±36.7	0.001
F/u 3 month	n=17	68.0±25.9	0.002	n=16	63.4±31.3	<0.001
F/u 6 month	n=15	60.1±33.3	0.002	n=15	60.1±35.9	<0.001

Results

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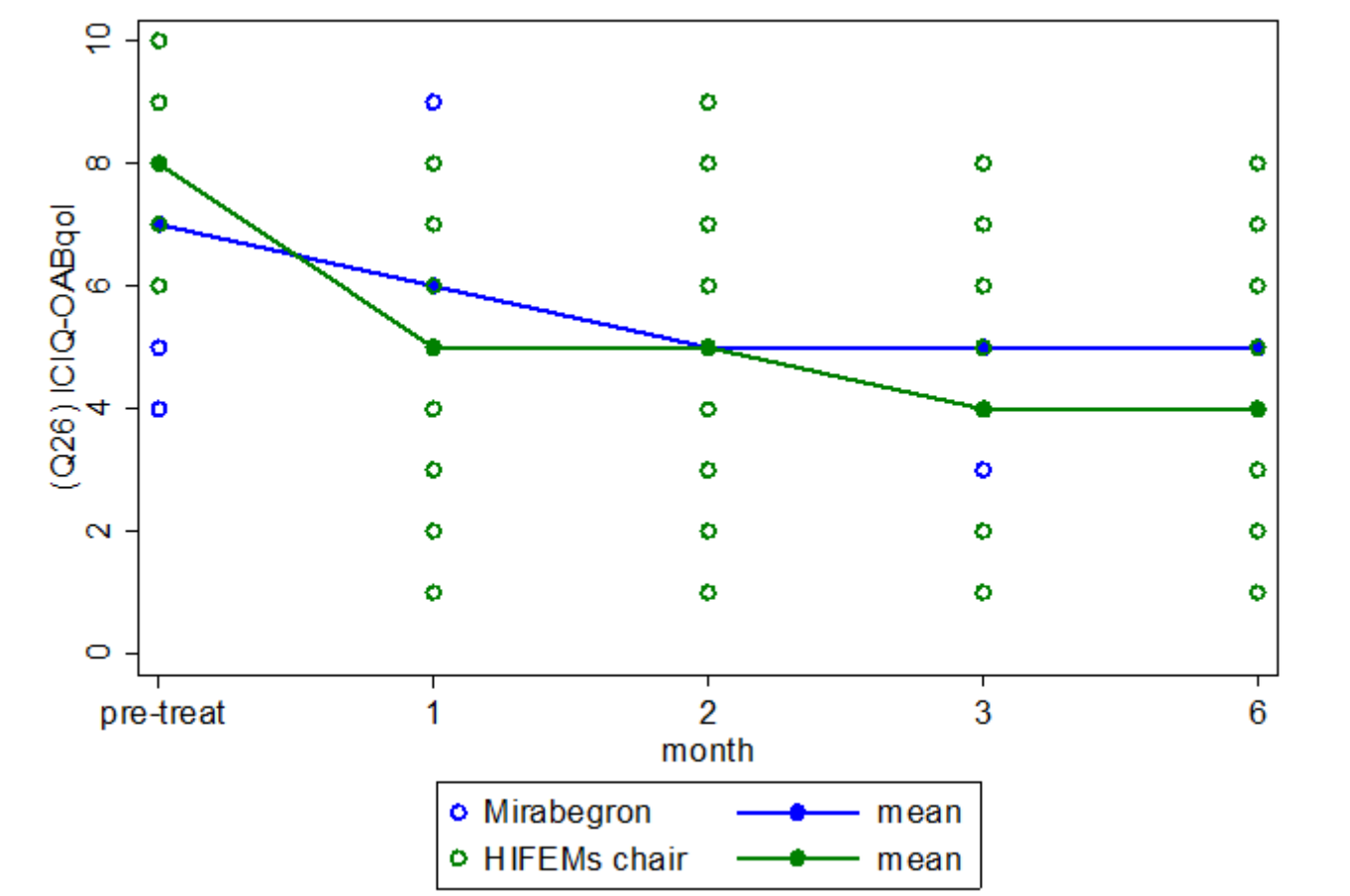
- Overall score impact on everyday life : ICIQ OAB Q26 during follow up 1,2,3,6 months



Statistical significance

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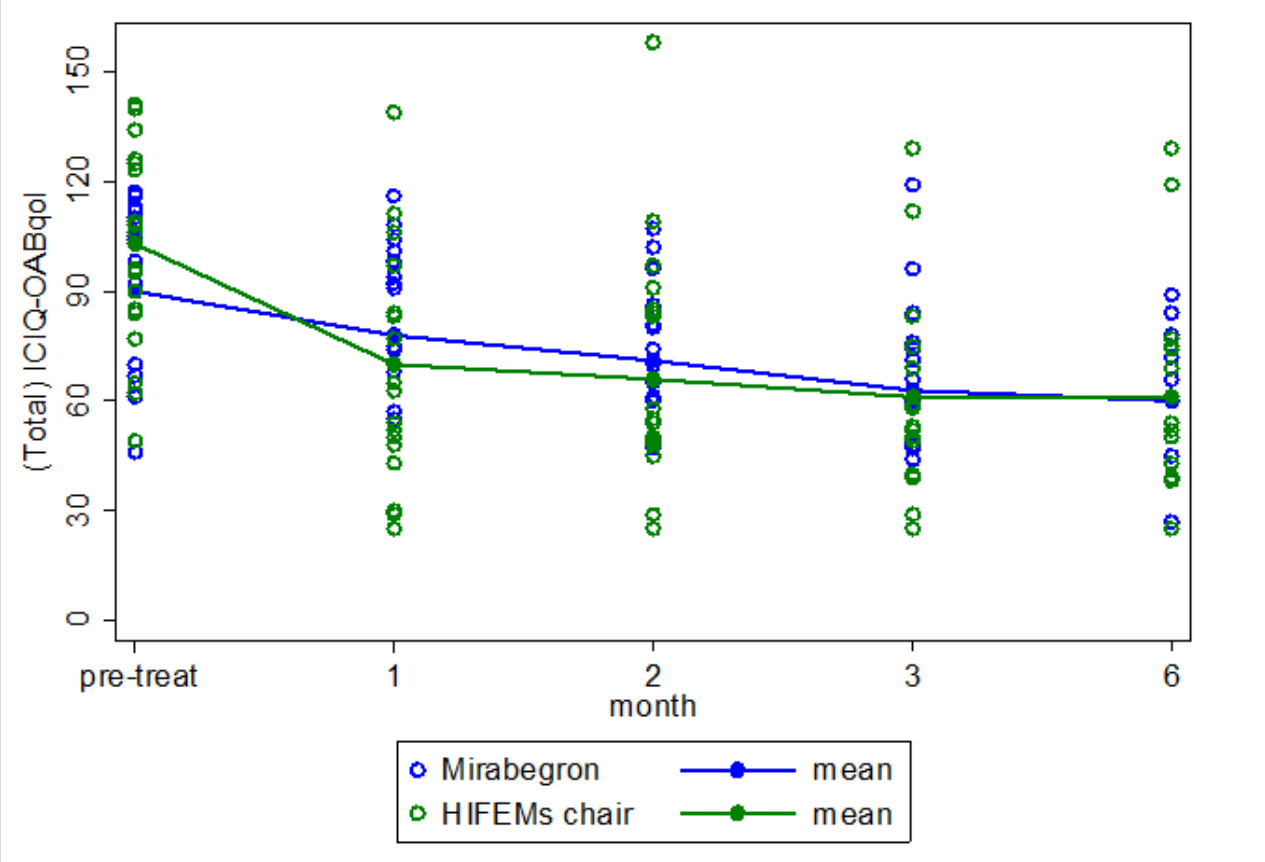
Results

- Total score impact on quality of life : ICIQ-OAB qol total score during follow up at 1,2,3,6 months



Statistical significance

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Results

- **Adverse events**
  - more GI disturbant (diarrhea and constipation) , muscle strain ,dizziness and voiding symptoms (LUTS) in Mirabegron group , but there are no statistic significant.
  - HIFEMs has some report of minimal side effect of dizziness and muscle strain
  - No serious side effect of EMSELLAR .

Adverse events

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Side effect	Total (N=39) ,%	Mirabegron(n=19),%	HIFEMs(n=20) ,%
Diarrhea			
• At 1 mo follow-up visit	2(5.1)	2(10.5)	0
• At 3 mo after finishing the treatment	4(10.8)	4(21.1)	0
Constipation			
• At 1 mo follow-up visit	3(7.7)	3(15.8)	0
• At 3 mo after finishing the treatment	1(2.7)	1(5.3)	0
Muscle strain			
• At 1 mo follow-up visit	6(15.4)	3(15.8)	3(15.0)
• At 3 mo after finishing the treatment	2(5.4)	1(5.3)	1(5.6)
Dizziness			
• At 1 mo follow-up visit	3(7.7)	3(15.8)	0
• At 3 mo after finishing the treatment	2(5.4)	1(5.3)	1(5.6)
Voding symptoms			
• At 1 mo follow-up visit	2(5.1)	2(10.5)	0
• At 3 mo after finishing the treatment	2(5.4)	2(10.5)	0
Palpaitation symptoms			
• At 1 mo follow-up visit	0	0	0
• At 3 mo after finishing the treatment	1(2.7)	1(5.3)	0

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Disscusion

- HIFEMs significantly provides treatment effect of reduction nocturia symptom and reduction of urinary frequency at 1 ,2 ,3 and 6 month.

- HIFEMs reduces frequency of urination, urgency symptoms and urinary incontinent symptoms but not statistic significance.
- HIFEMs also improves quality of life, assessment with ICIQ OAB questionaire.
- The patients have no significant difference in complications between 2 groups.

Limitations

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- This research was carried out in a single institution and relatively small sample size, this may complicate the accuracy of predicting efficacy of medical treatment leading to minor deviation from expected treatment effect .

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Conclusion

- HIFEMs chair has been proved to be an effective treatment modality for OAB patients with minimal adverse events.
- It provides alternative option for OAB patients who do not want to be treated with medication.
- However, further study with more number of patients is suggested.

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Thankyou

Abstract

> “Outcome comparison between traditional curettage and cotton swab technique for endoscopic transsphenoidal surgery of pituitary adenoma.”

Thanakorn Jaturasuwon, MD

Thanakorn Jaturasuwon, Ake Hansasuta, Wasawat Muninthorn,
Division of Neurosurgery, Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Objective: Endoscopic transsphenoidal surgery (ETSS) has become the standard approach for managing pituitary adenomas, including the extracapsular dissection technique. Recent meta-analyses and systematic reviews have evaluated the effectiveness and safety of using a cotton swab for extracapsular dissection in ETSS. However, no direct comparison has been made between the traditional curettage technique and the cotton swab technique. This study aims to address this gap.

Methods: A retrospective review was conducted on patients who underwent ETSS for pituitary adenomas between 2009 and 2020. Patients were divided into two groups: one operated on using the traditional curettage technique and the other using the cotton swab technique. Inclusion criteria included patients with histologically confirmed pituitary adenomas who had undergone ETSS with at least five years of follow-up. Data on preoperative, intraoperative, and postoperative clinical and radiographic assessments were collected and analyzed.

Results: A total of 314 patients underwent ETSS between 2009 and 2020, with 268 in the control group (traditional curettage) and 136 in the cotton swab group. Preoperative characteristics were similar between groups. Intraoperative CSF leaks were significantly higher in the cotton swab group (73.9%) than in the control group (38.2%) ($p<0.05$), but postoperative CSF leaks were slightly lower (3.7% vs. 8.1%), though not statistically significant. The cotton swab group had significantly fewer redo ETSS procedures and less left visual acuity worsening (20.7% vs. 30.7%). Postoperative MRI showed no residual tumor in 16.0% of the cotton swab group versus 5.9% in the control group ($p<0.05$). The percentage of tumor removed along the anterior-posterior axis was also higher in the cotton swab group (47% vs. 34%) ($p<0.05$). No deaths or vascular injuries occurred.

Conclusions: The cotton swab technique for extracapsular dissection in ETSS for pituitary adenomas demonstrated significant advantages over the traditional curettage technique. The cotton swab group had a lower rate of redo ETSS and less left visual acuity worsening, while achieving a higher rate of complete tumor removal and a greater percentage of tumor resection along the anterior-posterior axis. These findings suggest that the cotton swab technique is a viable alternative to the traditional curettage technique, offering potential benefits in surgical outcomes. However, a prospective randomized controlled trial would be the best way to confirm these results, but in practical terms, it would be difficult to conduct.

Outcome comparison between traditional curettage and cotton swab technique for endoscopic transsphenoidal surgery of pituitary adenoma.

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Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University
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COA. MURA2021/179
Ref. 2024/1403

Title of Project (English)	Outcome comparison between traditional curettage and cotton swab technique for endoscopic transsphenoidal surgery of pituitary adenoma
Title of Project (Thai)	การเปรียบเทียบผลการผ่าตัดเลาะเนื้องอกต่อมใต้สมองระหว่างวิธีโดยเทคนิคการใช้คิวเร็ทและเทคนิคไม้พันสำลีสำหรับการผ่าตัดส่องกล้องผ่านโพรงอากาศสฟีนอยด์
Type of Review	Expedited
Principal Investigator	Thanakorn Jaturasuwon
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 24/12/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval **February 27, 2021**

Project was suspended during February 27, 2022 to January 12, 2023 due to no annual renewal approval in the period

Renewal Date (3rd) **January 13, 2025**

Date of Expiration **January 12, 2026**

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

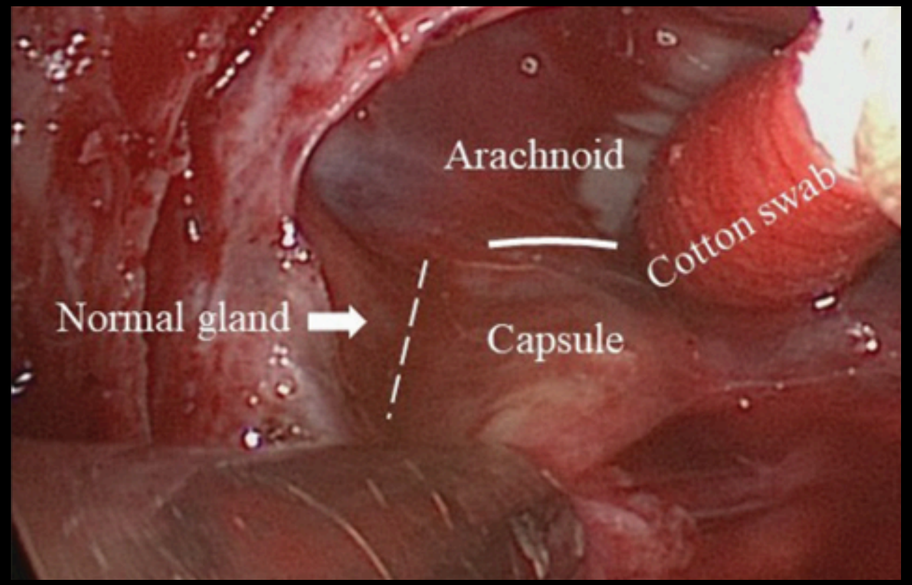
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Introduction

- Endoscopic transsphenoidal surgery (ETSS) has become the standard approach for managing pituitary adenomas.
- With gross total PA resection set as the preferred goal, extracapsular dissection is encouraged to identify a tissue plane or cleavage between tumor's pseudocapsule and normal pituitary gland, arachnoid, or diaphragma sellae.

Introduction

- Recent meta-analyses and systematic reviews have evaluated the effectiveness and safety of using a cotton swab for extracapsular dissection in ETSS.
- But no direct comparison has been made between the traditional curettage technique and the cotton swab technique.
- This is the reason why this research was conducted.

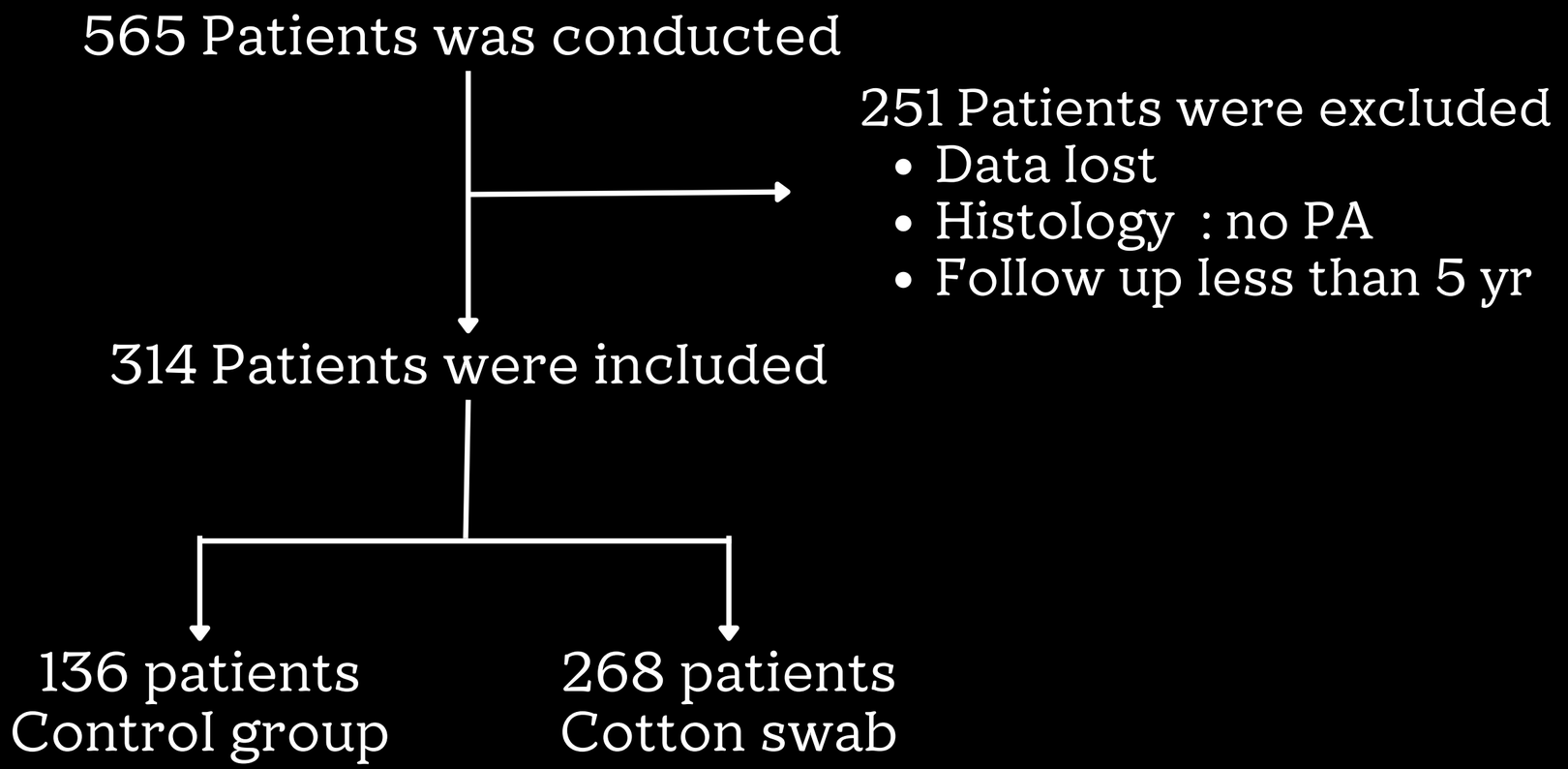


Materials and Methods

- Ethical approval Ramathibodi Hospital (COA. MURA2021/179)
- A retrospective study

Materials and Methods

- Patients who underwent ETSS for pituitary adenomas between 2009 and 2020.



Materials and Methods

- Inclusion criteria included patients with histologically confirmed pituitary adenomas who had undergone ETSS with at least five years of follow-up.
- Exclusion criteria included patients with data lost.

Materials and Methods

- Collect data on preoperative, intraoperative, and postoperative clinical and radiographic assessments were collected and analyzed.
- Primary outcome : Symptom (VA,VF), Lab hormone, Size tumor
- Secondary outcome : Post operative complication, Redo operation, Op time, Blood loss etc.

Statistical analysis

- Categorical variables :
report n, (%) > Fisher's exact test/ Chi-square test
- Continuous variables (normal distribution) :
report mean+SD > T-test
- Continuous variables (non-normal distribution) :
report median(IQR) > Mann–Whitney test

Results

Preoperative characteristics were similar between groups. (Table 1.1)

- no significant difference

variable	Total (n=404)	Control (n=136)	Cotton (n=268)	p-value
Age(year), mean SD	55±15	56±15	54±15	0.226
Gender, n(%)				0.442
Male	206(51.0)	73(53.7)	133(49.6)	
Female	198(49.0)	63(46.3)	135(50.4)	
Present, n(%)				0.507
0	169(41.8)	60(44.1)	109(40.7)	
1	235(58.2)	76(55.9)	159(59.3)	
VA, n(%) n=403				0.511
0	249(61.8)	81(59.6)	168(62.9)	
1	154(38.2)	55(40.4)	99(37.1)	
VA logMAR Rt, mean ± SD(cm)	0.684±0.988	0.754±0.970	0.649±0.997	0.309
VA logMAR Lt, mean ± SD(cm)	0.666±0.979	0.621±0.746	0.689±1.078	0.456
VF, n(%)				0.744
0	251(62.1)	86(63.2)	165(61.6)	
1	153(37.9)	50(36.8)	103(38.4)	
VF Rt, n(%)				0.391
0	220(54.5)	70(51.5)	150(56.0)	
1	184(45.5)	66(48.5)	118(44.0)	
VF Lt, n(%)				0.389
0	223(55.2)	71(52.2)	152(56.7)	
1	181(44.8)	65(47.8)	116(43.3)	
Non PA, n(%) n=391				0.645
0	56(14.3)	21(15.4)	35(13.7)	
1	335(85.7)	115(84.6)	220(86.3)	
Ghrowth hormone producing, n(%) n=36				-
1	36(100)	16(100)	20(100)	
Adrenocorticotropic hormone producing, n(%) n=21				-
1	21(100)	3(100)	18(100)	
Prolactinoma, n(%) n=12				-
1	12(100)	6(100)	6(100)	
Thyroid stimulating hormone producing, n(%) n=3				-
1	3(100)	1(100)	2(100)	
Hormorn deficit , n(%) n=401				0.524
0	233(58.1)	82(60.3)	151(57.0)	
1	168(41.9)	54(39.7)	114(43.0)	

variable	Total (n=404)	Control (n=136)	Cotton (n=268)	p-value
Apoplexy, n(%) 0				0.659
1	374(92.6)	127(93.4)	247(92.2)	
	30(7.4)	9(6.6)	21(7.8)	
Recur Growth, n(%)				0.557
0	310(76.7)	102(75.0)	208(77.6)	
1	94(23.3)	34(25.0)	60(22.4)	
Residual, n(%)				0.206
0	326(80.7)	105(77.2)	221(82.5)	
1	78(19.3)	31(22.8)	47(17.5)	
Asymptomatic, n(%)				0.916
0	248(61.4)	83(61.0)	165(61.6)	
1	156(38.6)	53(39.0)	103(38.4)	
Prior Sx, n(%)				0.220
0	231(57.2)	72(52.9)	159(59.3)	
1	173(42.8)	64(47.1)	109(40.7)	
No. Of Prior Sx, n(%)				
1	104(25.6)	37(27.2)	67(25.0)	
2	48(11.9)	22(16.2)	26(9.7)	
3	15(3.7)	5(3.7)	10(3.7)	
4	3(0.7)	0	3(1.1)	
5	1(0.3)	0	1(0.4)	
6	1(0.3)	0	1(0.4)	
8	1(0.3)	0	1(0.4)	
Prior RT, n(%)				0.999
0	397(98.3)	134(98.5)	263(98.1)	
1	7(1.7)	2(1.5)	5(1.9)	

Results

Preoperative radiographic were similar between groups. (Table 1.2)

- no significant difference

variable	Total (n=404)	Control (n=136)	Cotton (n=268)	p-value
Normal pituitary gland				
Rt gland, n(%) n=352				
0	149(42.3)	52(43.3)	97(41.8)	0.784
1	203(57.7)	68(56.7)	135(58.2)	
Lt gland, n(%) n=368				
0	193(52.5)	64(52.0)	129(52.7)	0.910
1	175(47.5)	59(48.0)	116(47.3)	
Midline gland, n(%) n=324				
0	298(92.0)	100(91.7)	198(92.1)	0.913
1	26(8.0)	9(8.3)	17(7.9)	
Tumor size, mean±SD				
Superior to inferior	2.4±1.2	2.4±1.1	2.4±1.3	0.859
Right to left	2.4±1.0	2.3±0.9	2.4±1.1	0.681
Anterior to posterior	2.2±0.9	2.1±0.8	2.2±1.0	0.418
Macroadenoma, n(%)				
0	17(4.2)	6(4.4)	11(4.1)	0.884
1	387(95.8)	130(95.6)	257(95.9)	
Hardy's classification				
Hardy0, n(%) n=320				
0	290(90.6)	100(92.6)	190(89.6)	0.389
1	30(9.4)	8(7.4)	22(10.4)	
Hardy a, n(%) n=333				
0	256(76.9)	84(75.7)	172(77.5)	0.713
1	77(23.1)	27(24.3)	50(22.5)	
Hardy b, n(%) n=343				
0	224(65.3)	76(65.5)	148(65.2)	0.953
1	119(34.7)	40(34.5)	79(34.8)	
Hardy c, n(%) n=362				
0	183(50.5)	65(52.0)	118(49.8)	0.689
1	179(49.5)	60(48.0)	119(50.2)	
Intra-ventricular, n(%) n=319				
0	316(99.1)	106(98.2)	210(99.5)	0.266
1	3(0.9)	2(1.8)	1(0.5)	
Knosp classification, n(%) n=403				
0	39(9.7)	7(5.1)	32(12.0)	0.086
1	126(31.3)	45(33.1)	81(30.3)	
2	102(25.3)	41(30.2)	61(22.8)	
3a	31(7.7)	8(5.9)	23(8.6)	
3b	49(12.1)	20(14.7)	29(10.9)	
4	56(13.9)	15(11.0)	41(15.4)	

Results

- Primary outcome :
  - Significant less left visual acuity worsening
  - Right visual acuity and both VF : differrence non significant

variable	Total (n=404)	Control (n=136)	Cotton (n=268)	p-value
Rt VA improve, n(%) n=341				
0	193(56.6)	65(52.8)	128(58.7)	0.294
1	148(43.4)	58(47.2)	90(41.3)	
Rt VA stable, n(%) n=337				
0	198(58.8)	70(62.5)	128(56.9)	0.324
1	139(41.2)	42(37.5)	97(43.1)	
Rt VA worsening, n(%) n=333				
0	245(73.6)	79(69.9)	166(75.5)	0.277
1	88(26.4)	34(30.1)	54(24.5)	
Lt VA improve, n(%) n=345				
0	162(47.0)	60(48.8)	102(45.9)	0.613
1	183(53.0)	63(51.2)	120(54.1)	
Lt VA stable, n(%) n=334				
0	221(66.2)	76(69.1)	145(64.7)	0.429
1	113(33.8)	34(30.9)	79(35.3)	
Lt VA worsening, n(%) n=331				
0	251(75.8)	79(69.3)	172(79.3)	0.044
1	80(24.2)	35(30.7)	45(20.7)	

Results

- Primary outcome :
  - Significant less left visual acuity worsening
  - Right visual acuity and both VF : differrence non significant

variable	Total (n=404)	Control (n=136)	Cotton (n=268)	p-value
Rt VF improve, n(%) n=339				
0	233(68.7)	81(69.8)	152(68.2)	0.754
1	106(31.3)	35(30.2)	71(31.8)	
Rt VF stable, n(%) n=379				
0	102(26.9)	35(28.0)	67(26.4)	0.738
1	277(73.1)	90(72.0)	187(73.6)	
Rt VF worsening, n(%) n=328				
0	307(93.6)	100(90.1)	207(95.4)	0.063
1	21(6.4)	11(9.9)	10(4.6)	
Lt VF improve, n(%) n=347				
0	220(63.4)	71(60.2)	149(65.1)	0.370
1	127(36.6)	47(39.8)	80(34.9)	
Lt VF stable, n(%) n=374				
0	116(31.0)	41(33.3)	75(29.9)	0.498
1	258(69.0)	82(66.7)	176(70.1)	
Lt VF worsening, n(%) n=325				
0	306(94.2)	104(93.7)	202(94.4)	0.799
1	19(5.8)	7(6.3)	12(5.6)	

Results

- Primary outcome :
  - Post-op improve or new hormone deficit : no significant difference

variable	Total (n=404)	Control (n=136)	Cotton (n=268)	p-value
HyperPituitaryCure, n(%) n=235				
0	216(91.9)	76(92.7)	140(91.5)	0.752
1	19(8.1)	6(7.3)	13(8.5)	
ImprovePostopHormone n(%) n=243				
0	211(86.8)	75(87.2)	136(86.6)	0.897
1	32(13.2)	11(12.8)	21(13.4)	
Stable_hormone, n(%) n=345				
0	79(22.9)	33(28.7)	46(20.0)	0.070
1	266(77.1)	82(71.3)	184(80.0)	
NewhormoneDEF, n(%) n=285				
0	181(63.5)	60(58.3)	121(66.5)	0.166
1	104(36.5)	43(41.7)	61(33.5)	
PoDI, n(%) n=331				
0	309(93.4)	110(96.5)	199(91.7)	0.097
1	22(6.6)	4(3.5)	18(8.3)	

Results

- Primary outcome :
  - No residual tumor in the cotton swab group less than the control group.
  - The percentage of tumor removed along the anterior-posterior axis was also higher in the cotton swab group.

variable	Total (n=404)	Control (n=136)	Cotton (n=268)	p-value
Percentage of tumor removal size, median(IQR) n=399				
Superior to inferior	53(25, 77)	53(31, 77)	52(25, 80)	0.362
Right to left	47(15, 75)	40(16, 69)	50(15, 77)	0.170
Anterior to posterior	41(13, 68)	34(11, 61)	47(19, 72)	0.024
No Residual tumor, n(%) n=272				
0	237(87.1)	79(94.1)	158(84.0)	0.023
1	35(12.9)	5(5.9)	30(16.0)	

Results

- Secondary outcome :
  - The cotton swab group had significantly fewer redo ETSS procedures. (Table 3.3)

variable	Total (n=404)	Control (n=136)	Cotton (n=268)	p-value
Redo craniotomy, n(%)				
0	387(95.8)	132(97.1)	255(95.2)	0.732
1	14(3.5)	3(2.2)	11(4.1)	
2	3(0.7)	1(0.7)	2(0.7)	
Redo ETSS, n(%)				
0	295(73.0)	75(55.1)	220(82.1)	0.000
1	91(22.5)	47(34.6)	44(16.4)	
2	16(4.0)	13(9.6)	3(1.1)	
3	2(0.5)	1(0.7)	1(0.4)	
Conv SRT, n(%)				
0	275(68.1)	85(62.5)	190(70.9)	0.087
1	129(31.9)	51(37.5)	78(29.1)	

Results

- Secondary outcome :
  - Intraoperative CSF leaks were significantly higher in the cotton swab group (73.9%) than in the control group (38.2%) ($p<0.05$), but postoperative CSF leaks were slightly lower (3.7% vs. 8.1%), though not statistically significant.
  - No deaths or vascular injuries occurred.

variable	Total (n=404)	Control (n=136)	Cotton (n=268)	p-value
Intra-op LEAK, n(%)				
0	154(38.1)	84(61.8)	70(26.1)	0.000
1	250(61.9)	52(38.2)	198(73.9)	
Grading of LEAK				
1	154(38.1)	22(16.2)	132(49.3)	
2	40(9.9)	4(2.9)	36(13.4)	
3	35(8.7)	10(7.4)	25(9.3)	
Post-Op leak, n(%)				
0	383(94.8)	125(91.9)	258(96.3)	0.062
1	21(5.2)	11(8.1)	10(3.7)	

Limitations

- A retrospective study
- However, a prospective randomized controlled trial would be the best way to confirm these results

Conclusion

- The cotton swab group had a lower rate of redo ETSS and less left visual acuity worsening, while achieving a higher rate of complete tumor removal and a greater percentage of tumor resection along the anterior-posterior axis.
- Retrospective study => prospective randomized controlled trial would be the best way to confirm these results.

Abstract

"Association of the timing in performing ERCP and overall complication in acute cholangitis, Ramathibodi hospital."

Thakul Kongpeth, MD

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Background: Cholangitis is an emergency condition which could become life-threatening. Mortality rate could be up to 10%. Early endoscopic retrograde cholangiopancreatography (ERCP) in 24 hours could decrease 30-day mortality, but early ERCP complications over different periods of time has remain unclear. This study aims to compare overall complications after performing ERCP at different periods of time(> 24 hours, 24-48 hours and >48 hours after diagnosed with acute cholangitis.

Method: This retrospective cohort study compared overall complications in patients diagnosed with acute cholangitis who had undergone ERCP at <24 hours, 24-48 hours and >48 hours group. Data from January 1, 2012 to January 1, 2022 at Ramathibodi Hospital were retrospectively reviewed. Patient demographics were compared using chi-square and Wilcoxon rank-sum tests. Overall complications, 30-day mortality, Re-admission in 30 days, Duration in ICU and LOS, Operation time and intra-operative findings(Cannulation attempts, CBD size, Cause of cholangitis)were analyzed by using standard deviation.

Results: Among 238 acute cholangitis patients who underwent early ERCP, complications occurred in 70 patients(29.4%). There was no significant difference between patient demographics, LOS and duration in ICU and CBD size in the three groups.The average time of complication is 38 hours after diagnosed. Complications were found in >48hr group 25 cases(28.4%), 24-48hr group 23 cases(33.33%) and <24hr group 22cases(27.2%). Thirty-nine patients(16.4%) had increase severity of cholangitis. Only 1 patient died in the 24-48hr group. There were 3 patients in 30-day mortality and 28 patients were re-admission in our study. Operation time in <24 hr group (65 min), 24-48hr group (60 min) and >48hr group (50 min)

Conclusion: Based on our study delaying ERCP more than 24 hours and severe grading of cholangitis were increases the risk of complications. However, early ERCP required more operative time than delay ERCP.

Keywords: Acute cholangitis; ERCP; Overall complication.

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Association of the timing in performing ERCP and overall complication in acute cholangitis, Ramathibodi hospital.

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Title of Project (English)	Association of the Timing in Performing ERCP and Post Operative Complication in Acute Cholangitis, Ramathibodi Hospital
Title of Project (Thai)	การศึกษาความสัมพันธ์ระหว่างผลการรักษาและระยะเวลาในการส่องกล้องท่อท่างเดินน้ำดีผู้ป่วยท่อทางเดินน้ำดีอักเสบฉับพลัน
Type of Review	Expedited
Principal Investigator	Thakul Kongpeth
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Date of Initial Approval	June 14, 2022
Renewal Date (2nd)	June 14, 2024
Date of Expiration	June 13, 2025

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Background

- Acute cholangitis is an emergency condition which could become life-threatening. Mortality rate could be up to 10%.
- Early endoscopic retrograde cholangiopancreatography(ERCP) in 24 hours could decrease 30-day mortality, but early ERCP complications over different periods of time has remain unclear.
- This study aims to compare overall complications after performing ERCP at different periods of time(*< 24 hours*, *24-48 hours* and *>48 hours* after diagnosed with acute cholangitis)

Methods

- Retrospective cohort study
- Include acute cholangitis patients who had undergone ERCP
- Data collected from January 1, 2012 to January 1, 2022 at Ramathibodi Hospital
- **Inclusion criteria**
  - Patients who diagnosis acute cholangitis age 18-90 years old and underwent ERCP
- **Exclusion criteria**
  - The patient other diagnosed after ERCP, ERCP not for therapeutic treatment.

Methods

- **Primary outcome**
  - Compare overall complications after performing ERCP at different periods of time(*< 24 hours*, *24-48 hours* and *>48 hours* after diagnosed with acute cholangitis)
- Statistical analysis : STATA version 17
- Clinical characteristics were used to compare different periods of time of ERCP
  - Group date : Analysed by *Chi-square test*
  - Continuous data : Analysed by *ANOVA in normal distribution* and *Kruskal-Wallis in non-normal distribution*
- Risk factors for overall complication were *Binary Logistic regression model*

Results

- Total of 238 acute cholangitis patients who underwent ERCP were included in this study
- Overall complications 70 patients (29.4%)

Results

Table 1 The characteristics of patients in interval group

variable	Total (n=238)	Time			p -value
		ERCP < 24 hr. (n=81)	ERCP 24-48 (n=69)	ERCP >48 hr. (n=88)	
Gender, n(%)					
Male	122(51.3)	45(55.6)	33(47.8)	44(50.0)	0.613
Female	116(48.7)	36(44.4)	36(52.2)	44(50.0)	
Age(year), mean±SD	66.4±15.2	66.1±15.2	66.6±16.1	66.6±14.7	0.740
Weight (kg), mean±SD	63.4±14.2	65.2±13.5	61.7±15.1	63.3±13.9	0.632
Height (cm), mean±SD	160.2±8.5	160.6±8.7	158.6±8.7	161.1±8.2	0.818
BMI(kg/m^2), mean±SD	24.6±4.6	25.2±4.5	24.3±4.6	24.2±4.6	0.986
LOS(day), median(IQR)	6(4, 9)	5(3, 8)	6(4, 9)	7(5, 11)	0.002
U/D, n(%)					
HT	151(63.4)	52(64.2)	44(63.8)	55(62.5)	0.972
DM	70(29.4)	27(33.3)	17(24.6)	26(29.5)	0.507
DLP	116(48.7)	44(54.3)	34(49.3)	38(43.2)	0.349
IHD	44(18.5)	11(13.6)	12(17.4)	21(23.9)	0.219
CVA	22(9.2)	7(8.6)	6(8.7)	9(10.2)	0.923
ASA score, n(%)					
I	57(24.0)	22(27.2)	11(15.9)	24(27.3)	0.326
II	140(58.8)	43(53.1)	48(69.6)	49(55.7)	
III	40(16.8)	16(19.7)	10(14.5)	14(15.9)	
Time to ERCP (hr.) median(IQR)	39(22, 70)	19(15, 22)	36(28, 44)	89(67, 119)	-
Preoperative laboratory					
WBC x10^3, mean+SD	13.8±6.3	14.0±6.6	14.3±7.0	13.2±5.2	0.483
AST, mean+SD	193(97, 363)	193(97, 368)	211(106, 375)	185(85, 324)	0.540
ALT, mean+SD	193(96, 343)	186(109, 343)	218(107, 330)	193(89, 339)	0.871
ALP, mean+SD	242(164, 396)	226(162, 341)	219(149, 396)	281(178, 484)	0.218
Albumin, mean+SD	31.2±7.2	31.1±8.5	31.2±7.1	31.2±6.2	0.998
TB, median(IQR)	4.7(2.8, 6.7)	4.9(3.0, 7.3)	4.6(2.8, 8.9)	4.5(2.8, 5.9)	0.647
Lactate, median(IQR) n=108	2.7(2.1, 4.1)	2.4(2.1, 3.9)	2.9(2.3, 4.3)	2.6(1.8, 3.2)	0.172
Operative time(min), median(IQR)	60(38, 105)	65(43, 145)	60(40, 105)	50(35, 80)	0.026

Results

Table 2 Comparison of outcomes base on interval groups

variable	Total (n=238)	Time			p -value
		ERCP < 24 hr. (n=81)	ERCP 24-48 (n=69)	ERCP >48 hr. (n=88)	
Severity, n(%)					
Mild	35(14.7)	12(14.8)	10(14.5)	13(14.8)	0.938
Moderate	168(70.6)	55(67.9)	49(71.0)	64(72.7)	
Severe	35(14.7)	14(17.3)	10(14.5)	11(12.5)	
Increase severity of cholangitis grading,n(%)	39(16.4)	11(13.6)	11(15.9)	17(19.3)	0.590
Complication, n(%)	70(29.4)	22(27.2)	23(33.3)	25(28.4)	0.687
Time(hr.), median(IQR)	38(23, 73)	24(14, 43)	36(24, 65)	56(34, 110)	0.006
Operation, n(%)					
ERCP	91(38.2)	23(28.4)	23(33.3)	45(51.1)	0.023
ERCP with stent	81(34.0)	26(32.1)	29(42.0)	26(29.6)	
ERCP with LC	57(24.0)	28(34.6)	13(18.9)	16(18.2)	
ERCP convert to CBDE	3(1.3)	1(1.2)	2(2.9)	0	
ERCP convert to CBDE with OC	6(2.5)	3(3.7)	2(2.9)	1(1.1)	
ERCP Success, n(%)	212(89.1)	74(91.4)	61(88.4)	77(87.5)	0.708
Cannulated attemp, mean+SD	3.4+3.4	3.8+4.3	3.1+2.6	3.1+3.1	0.265
Diagnosis, n(%)					
Acute cholangitis only	137(57.6)	42(51.8)	40(58.0)	55(62.5)	0.072
Cholangitis with Pancreatitis	42(17.6)	9(11.1)	16(23.2)	17(19.3)	
Cholangitis with Cholecystitis	52(21.8)	27(33.3)	11(15.9)	14(15.9)	
Acute cholangitis with cholecystitis with pancreatitis	6(2.5)	3(3.7)	2(2.9)	1(1.1)	
Other	1(1.1)	0	0	1(1.1)	
Ethiology, n(%)					
CBD stone	199(83.6)	68(83.9)	52(75.4)	79(89.8)	0.236
CBD stricture	12(5.0)	5(6.2)	5(7.3)	2(2.3)	
Malignancy	25(10.5)	8(9.9)	11(15.9)	6(6.8)	
Other	2(0.8)	0	1(1.5)	1(1.1)	

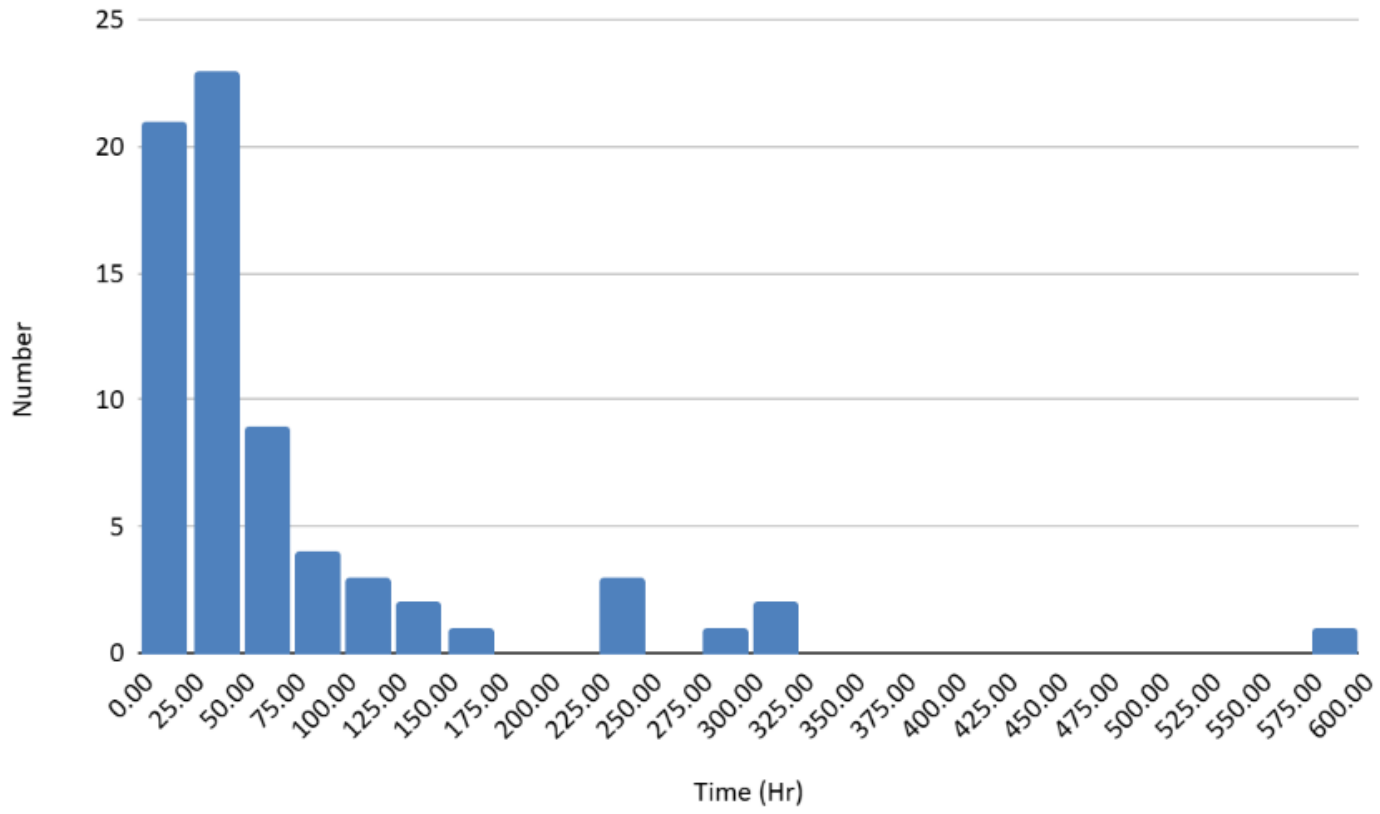
Results

Table 2 Comparison of outcomes base on interval groups

variable	Total (n=238)	Time			p -value
		ERCP < 24 hr. (n=81)	ERCP 24-48 (n=69)	ERCP >48 hr. (n=88)	
CBD size, mean±SD	10.8+4.5	10.9+4.8	10.9+4.1	10.7+4.6	0.434
GS presenting, n(%)	157(66.0)	62(76.5)	38(55.1)	57(64.8)	0.021
Overall complication, n(%)					
Sepsis	25(10.5)	7(8.6)	11(15.9)	7(7.9)	0.215
Post operative pancreatitis	15(6.3)	7(8.6)	4(5.8)	4(4.6)	0.538
UGIB	10(4.2)	3(3.7)	2(2.9)	5(5.7)	0.664
Duodenal perforation	2(0.8)	1(1.2)	1(1.5)	0	0.548
Septic shock	6(2.5)	3(3.7)	3(4.4)	0	0.517
Neurological dysfunction	1(0.4)	0	0	1(1.1)	
Respiratory failure	6(2.5)	2(2.5)	1(1.5)	3(3.4)	
AKI	2(0.8)	0	1(1.5)	1(1.1)	
Hepatic failure	1(0.4)	0	0	1(1.1)	
DIC	1(0.4)	0	1(1.5)	0	
Dead	1(0.4)	0	1(1.5)	0	0.292
Long term complication	6(2.5)	1(1.2)	2(2.9)	3(3.4)	0.648
30-day Rehospitalization	28(11.8)	7(8.6)	11(15.9)	10(11.4)	0.380
30-day Mortality	3(1.3)	1(1.2)	2(2.9)	0	0.271
ICU admission, n(%)	73(30.7)	26(32.1)	25(36.2)	22(25.0)	0.299
Length of ICU admission, day median (IQR)	4(2, 7)	3(2, 7)	4(2, 10)	4(3, 6)	0.820

Results

Figture1. Timing of overall complication



- The median complication time was 38 hours.

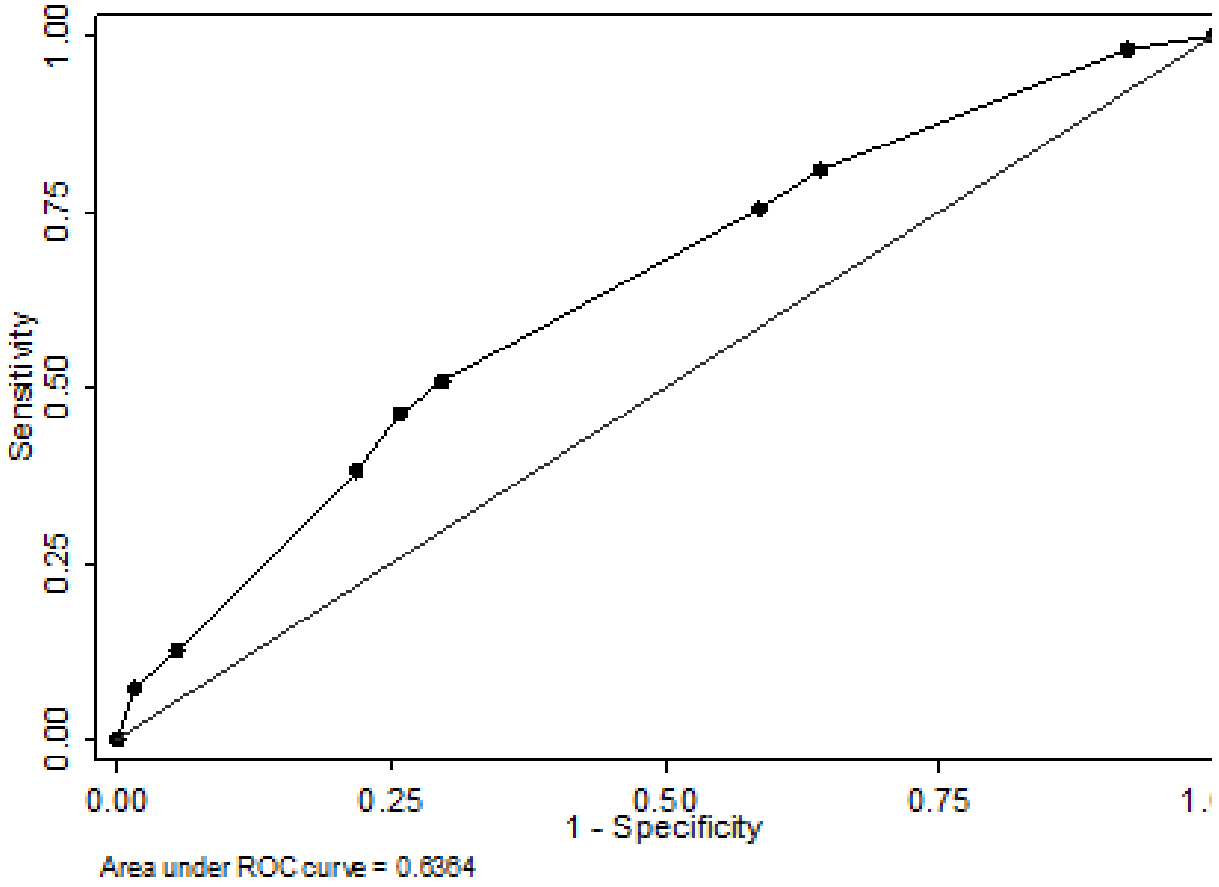
Results

Table 3 Risk of overall complication

variable	Univariate		Multivariate	
	OR(95%CI)	p-value	OR(95%CI)	p-value
Age(year)	1.01(0.98-1.02)	0.740		
ASA score				
I	base			
II	0.80(0.43-1.48)	0.478		
III	1.14(0.509-2.57)	0.743		
Severity				
Mild	base		base	
Moderate	1.33(0.63-2.82)	0.454	1.33(0.62-2.86)	0.460
Severe	3.24(1.22-8.63)	0.018	3.46(1.27-9.38)	0.015
Time to ERCP				
ERCP < 24 Hr	base		base	
ERCP 24-48	2.49(1.29-4.81)	0.007	2.63(1.34-5.16)	0.005
ERCP >48 Hr	1.35(0.73-2.51)	0.337	1.43(0.76-2.69)	0.262
Laboratory				
WBC	1.06(1.02-1.11)	0.009		
Albumin	0.95(0.91-0.98)	0.004		
TB	1.02(0.97-1.07)	0.351		
Lactate, n=108	1.58(1.15-2.17)	0.005		

Results

Figture2. ROC curve analyzed of severity and timing in overall complication



- The area under the curve (AUC) was 0.64

Discussion

- Performing ERCP within 24 hours is reducing complications. Delays ERCP between 24-48 hours significantly increase risks of overall complication.
- In delays ERCP > 48 hours group, the risk of complications was not significant. This is likely due to selection bias and patients in this group were often less critically ill.
- Delay ERCP > 48 hours may still be feasible for stable patients.
- In severe grade of cholangitis should early ERCP to decrease complication.

Conclusion

- Delaying ERCP >24 hours and severe grading of cholangitis were increases the risk of complications.
- Clinicians must carefully assess the severity of cholangitis, especially for patients requiring delayed procedures.
- Future studies with larger sample sizes and multicenter data are needed to validate these findings.
- Limitation
  - Single-center, retrospective study, which introduces selection bias.
  - The sample size was relatively small.

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Thank you

Abstract

Teerapat Srina, MD

“Can sanitary napkin improve healing of chronic venous ulcer compared with conventional gauze covering? : A randomized controlled trial”

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Background: Venous leg ulcers (VLUs) are the most common lower extremity ulcers which characterize by a long period of treatment, high recurrent rate, and interfere with the quality of life. The pathophysiologies of VLUs are venous hypertension and chronic inflammation. The active inflammatory cells produce proteolytic enzymes such as matrix metalloproteinases (MMPs), collagenase, and elastase, resulting in delayed wound healing. The sanitary napkin consists of super absorbent polymers (SAPs) which can reduce the concentration of proteinase, inhibit bacterial growth, and absorb excessive fluid. We aimed to evaluate whether the sanitary napkin improves wound healing.

Methods: A randomized controlled trial was conducted at vascular wound clinic, Ramathibodi hospital between January 2019 to December 2020 and between June 2022 to April 2024. The VLUs participants were randomized wound dressing into sterile sanitary napkin group (intervention) and gauze group (control). Wound healing rate, PUSH score, frequency of dressing change, pain, odor, patient satisfaction, and adverse events were compared between the two groups.

Results: There were 56 patients included in this study which 27 patients were in the sanitary group and 29 patients were in the control group. Baseline wound area in sanitary napkin group trended to be larger than gauze (6.39 vs 3.99 cm2, P=0.33). Overall complete healing in the sanitary napkin group and gauze group in 12 weeks were not significantly different (40.7% vs 37.9%, P=0.999). There was no statistically significant difference in wound area reduction, PUSH score, frequency of dressing change, pain, odor, patient satisfaction, and adverse events.

Conclusion: Sanitary napkins and gauze dressing were not different in wound healing of VLUs.

Can sanitary napkin improve healing of chronic venous ulcer compared with conventional gauze covering? : A randomized controlled trial

Teerapat srina, MD

Department of surgery, Faculty of Medicine, Ramathibodi Hospital

Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University
270 Rama 6 Rd. Phayatai Ratchathewi Bangkok 10400 Tel.(660)2012175, 2011544, 2010388
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COA. MURA2023/424

Title of Project (English)	Sanitary Napkins to Dressing Chronic Venous Leg Ulcer Compared with Sterile Gauze in Ramathibodi Hospital: A Randomized Controlled Trial
Title of Project (Thai)	การศึกษาการหายของแผลที่ขาจากโรคหลอดเลือดดำบกพร่องเรื้อรังเมื่อใช้ผ้าอนามัยปลอดเชื้อเปรียบเทียบกับการใช้ผ้าก๊อซเป็นวัสดุปิดแผล
Type of Review	Full Board
Principal Investigator	Teerapat Srina
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital, Mahidol University
Co-investigator	Suthas Horsirimanont
Approval includes	1. Submission Form Protocol Version 4 Date 23/5/2023 2. Information Sheet and Consent Form Version 2 Date 23/5/2023 3. Case Record Form Version 1 Date 7/5/2023 4. Curriculum Vitae 5. Certificate in Ethics Training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	June 2, 2023
Date of Expiration	June 1, 2024

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

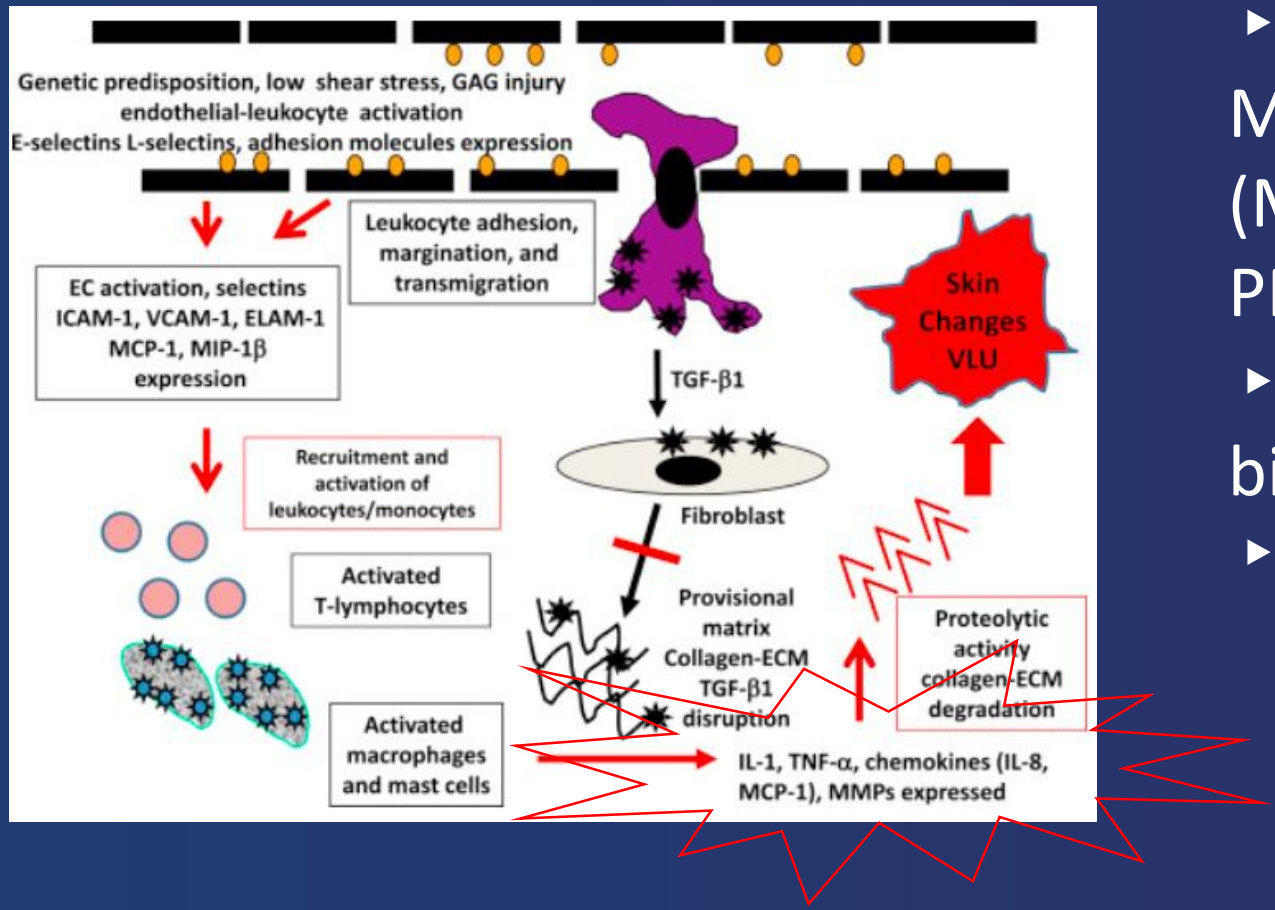
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

BACKGROUND

- Most common type of lower extremity ulcer
- Low healing rates and frequent recurrences
- Interfere to QoL

- High exudate
- Odor
- Pain
- Frequency of wound dressing change
- Hygiene problem
- Prone of infection

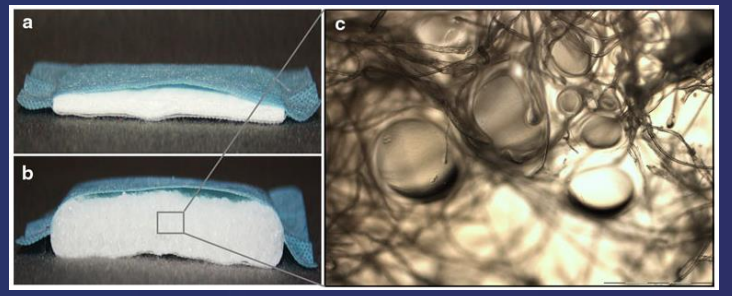
BACKGROUND



- Increased protease: Matrix Metalloproteinases (MMPs)
PMN-derived elastase
- High incidence of bacterial biofilms
- Excess moisture and exudate

Raffetto JD. Pathophysiology of chronic venous disease and venous ulcers. Surgical Clinics. 2018

SANITARY NAPKIN



- Main Material : Superabsorbent polymers (SAP) Pulp, nonwoven fabric

Previous study, SAPs containing dressing reducing concentration of

- Metalloproteinase : MMP-2 and MMP-9
- Collagenase, Elastase
- Inhibiting bacterial growth : Klebsiella pneumoniae and Pseudomonas aeruginosa growth and a significant inhibition of Staphylococcus aureus and Candida albicans
- Absorb excess fluid

1. Wiegand C, Abel M, Ruth P, Hipler UC. Superabsorbent polymer-containing wound dressings have a beneficial effect on wound healing by reducing PMN elastase concentration and inhibiting microbial growth. J Mater Sci Mater Med. 2011

2. Wiegand C, Hipler UC. A superabsorbent polymer-containing wound dressing efficiently sequesters MMPs and inhibits collagenase activity in vitro. J Mater Sci Mater Med. 2013

PREVIOUS USED

- Previous study of sanitary napkins for wound dressing

  - Hip and knee replacement wound *

  - Ludwig's angina **

* Shetty V, The Use Of Occlusive Sterile Sanitary Napkin Dressing In Hip And Knee Replacement Wounds. Orthopaedic Proceedings; 2010

** Waking P. Et al, Sterile feminine hygiene sanitary napkin dressing in the management of Ludwig's angina. World Journal of Dentistry, 2015

RESEARCH QUESTION

- Can sanitary napkin improved wound healing in venous leg ulcers compared with gauze?

RESEARCH DESIGN

- Open label randomized controlled trial, single center, non-inferiority trial.

OBJECTIVE

- Primary outcome:
  - Wound healing rate

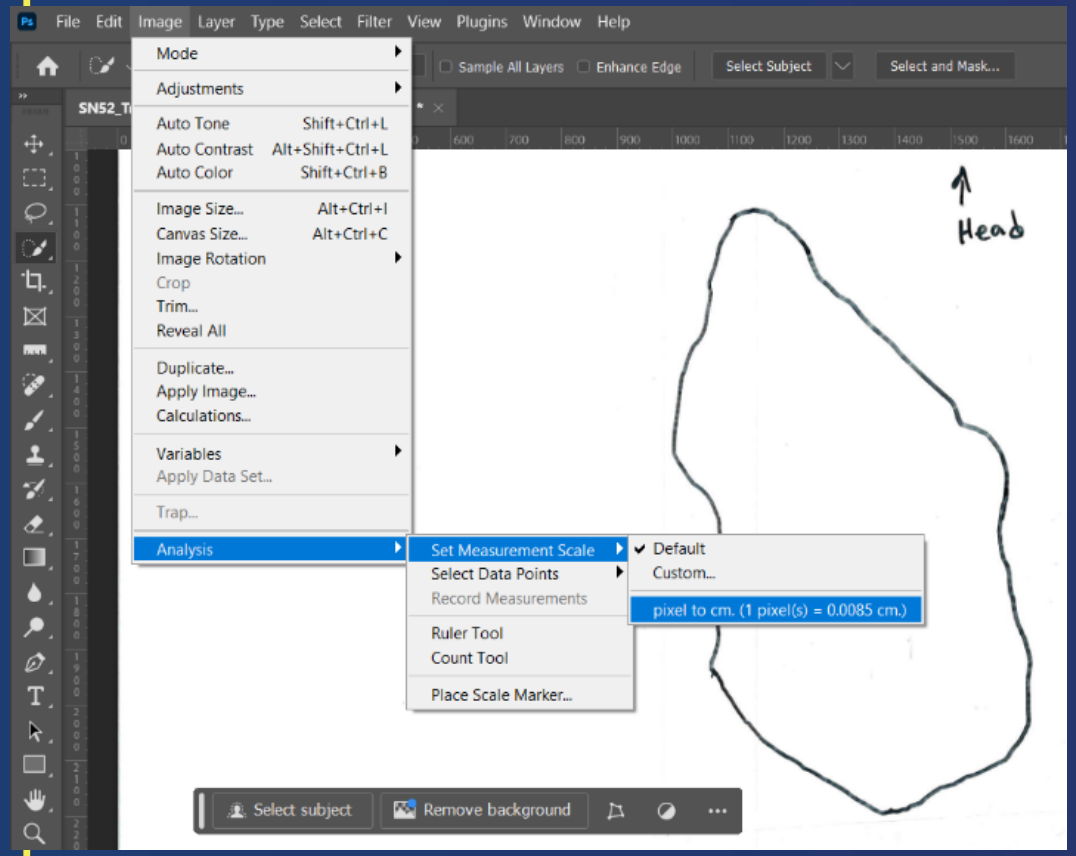
- Secondary outcomes:
  - Pressure Ulcer Scale of Healing (PUSH score)
  - Frequency of dressing change
  - Pain control
  - Odor control
  - Safety and Adverse Events
  - Patient satisfaction

OBJECTIVE

- Primary outcome:
  - Wound healing rate

Calculated wound area by Adobe Photoshop CC

- Secondary outcomes:
  - Pressure Ulcer Scale of Healing (PUSH score)
  - Frequency of dressing change
  - Pain control
  - Odor control
  - Safety and Adverse Events
  - Patient satisfaction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Mode
Adjustments
Auto Tone Shift+Ctrl+L
Auto Contrast Alt+Shift+Ctrl+L
Auto Color Shift+Ctrl+B
Image Size... Alt+Ctrl+I
Canvas Size... Alt+Ctrl+C
Image Rotation
Crop
Trim...
Reveal All
Duplicate...
Apply Image...
Calculations...
Variables
Apply Data Set...
Trap...
Analysis
Set Measurement Scale
Select Data Points
Record Measurements
Ruler Tool
Count Tool
Place Scale Marker...
Default
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pixel to cm. (1 pixel(s) = 0.0085 cm.)
Sample All Layers
Enhance Edge
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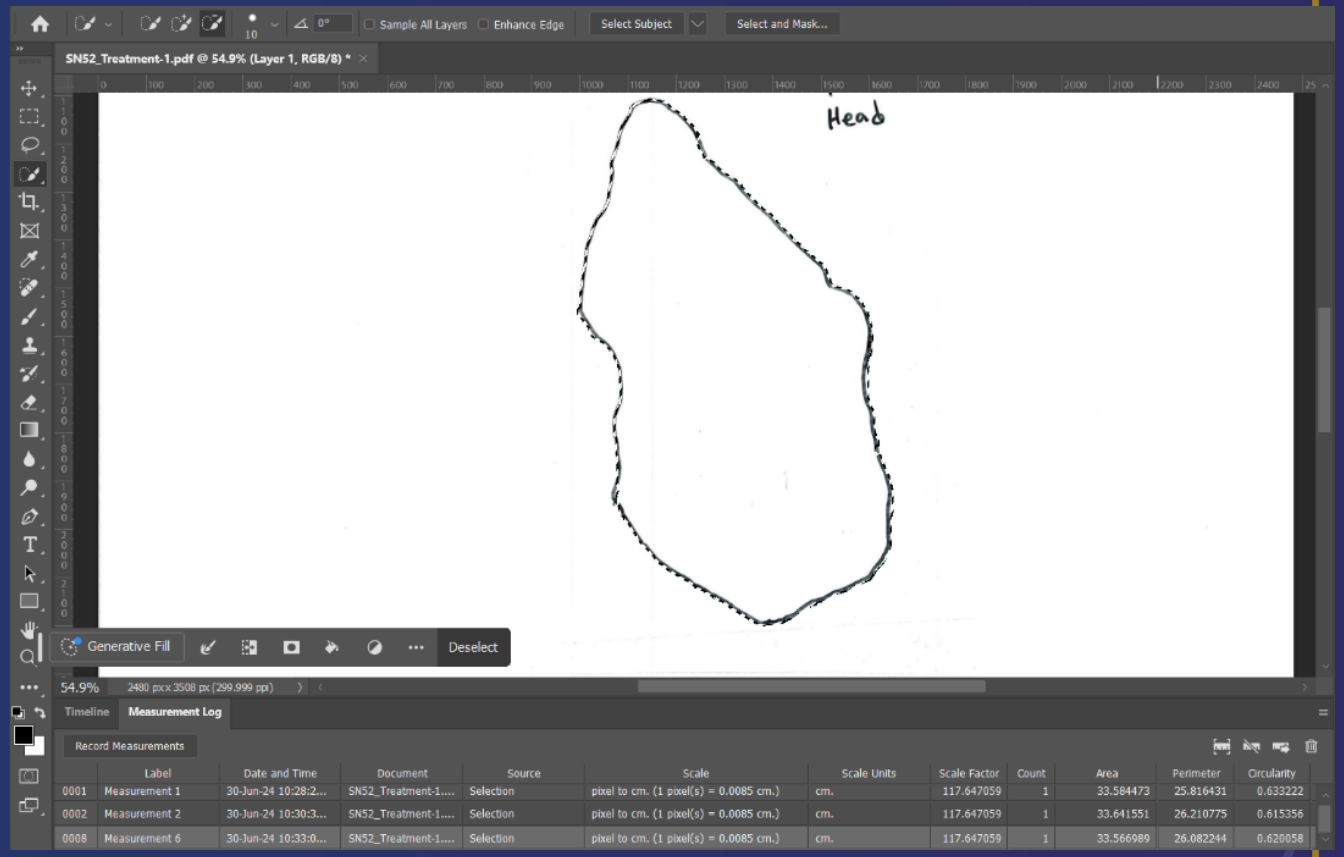
Select subject
Remove background


SN52_Treatment-1.pdf @ 54.9% (Layer 1, RGB/8) *
Head
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Timeline
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Record Measurements
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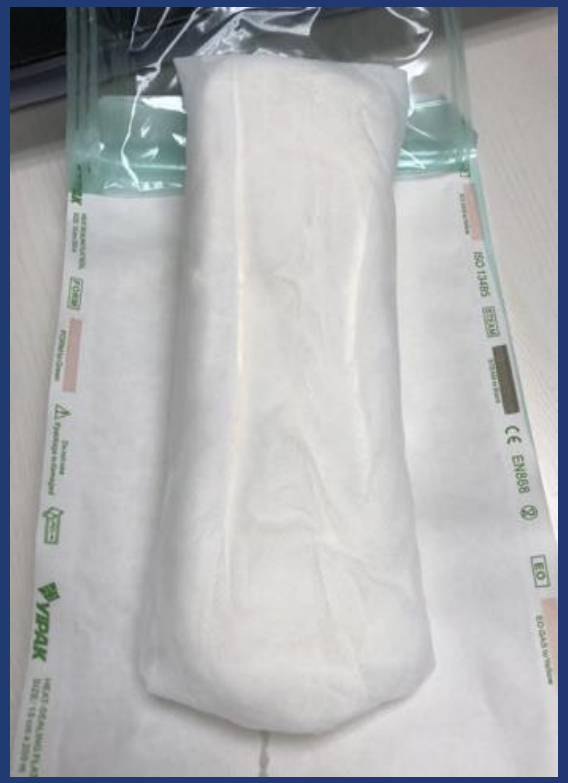
0001 | Measurement 1 | 30-Jun-24 10:28:2... | SN52_Treatment-1.... | Selection | pixel to cm. (1 pixel(s) = 0.0085 cm.) | cm. | 117.647059 | 1 | 33.584473 | 25.816431 | 0.633222
0002 | Measurement 2 | 30-Jun-24 10:30:3... | SN52_Treatment-1.... | Selection | pixel to cm. (1 pixel(s) = 0.0085 cm.) | cm. | 117.647059 | 1 | 33.641551 | 26.210775 | 0.615356
0008 | Measurement 6 | 30-Jun-24 10:33:0... | SN52_Treatment-1.... | Selection | pixel to cm. (1 pixel(s) = 0.0085 cm.) | cm. | 117.647059 | 1 | 33.566989 | 26.082244 | 0.620058

CRITERIA

- INCLUSION CRITERIA ☑
  - Age >18 years with venous leg ulcer
  - The wound area < 4x12 cm^2
- EXCLUSION CRITERIA ☒
  - Patient had any sign of infection
  - Evidence of significant arterial insufficiency (ABI < 70 mmHg)
  - Acute DVT
  - History of allergy to any of medical products used in the trial
  - Not willing to used sanitary napkin as wound dressing

MATERIAL AND METHODS

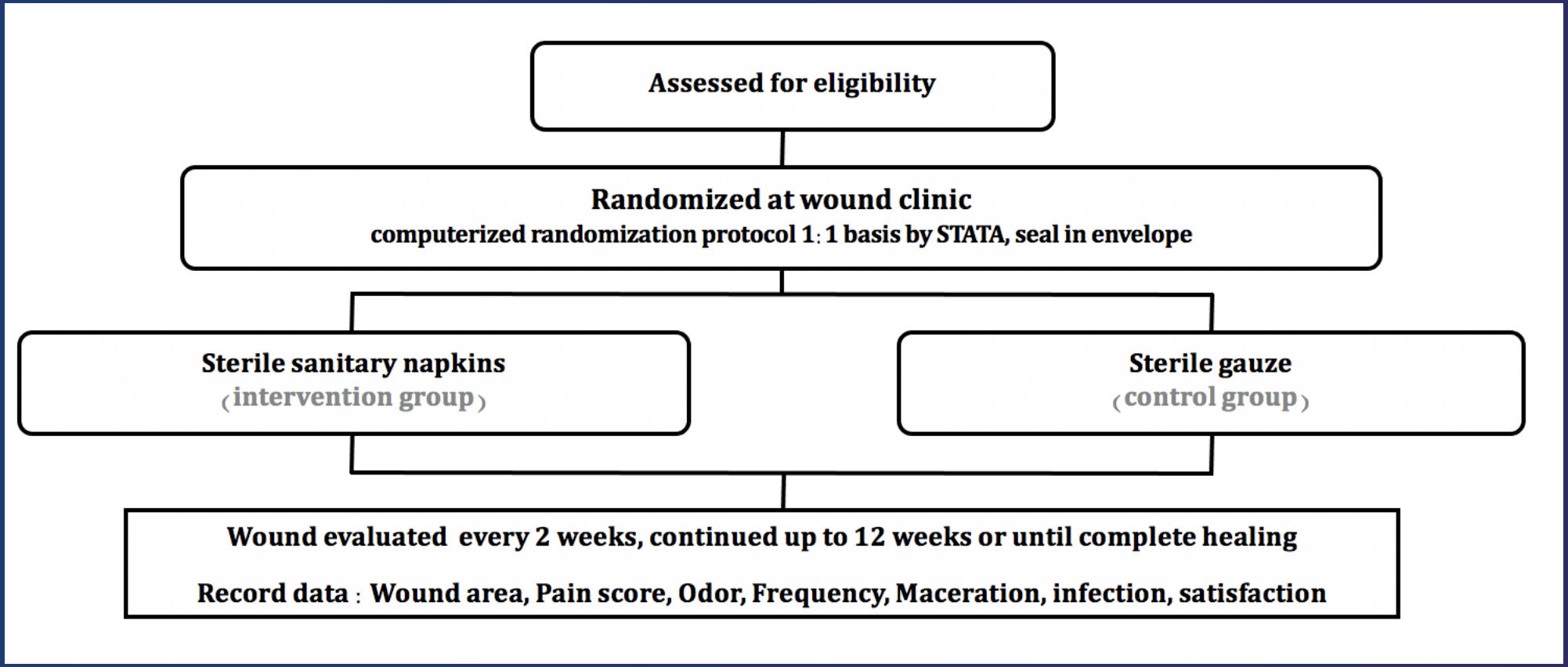
- Sanitary napkins : Postpartum pads with remove plastic sheath



Sterilization at Central Sterile Supply Unit, Ramathibodi hospital (ISO certification 9001:2015)

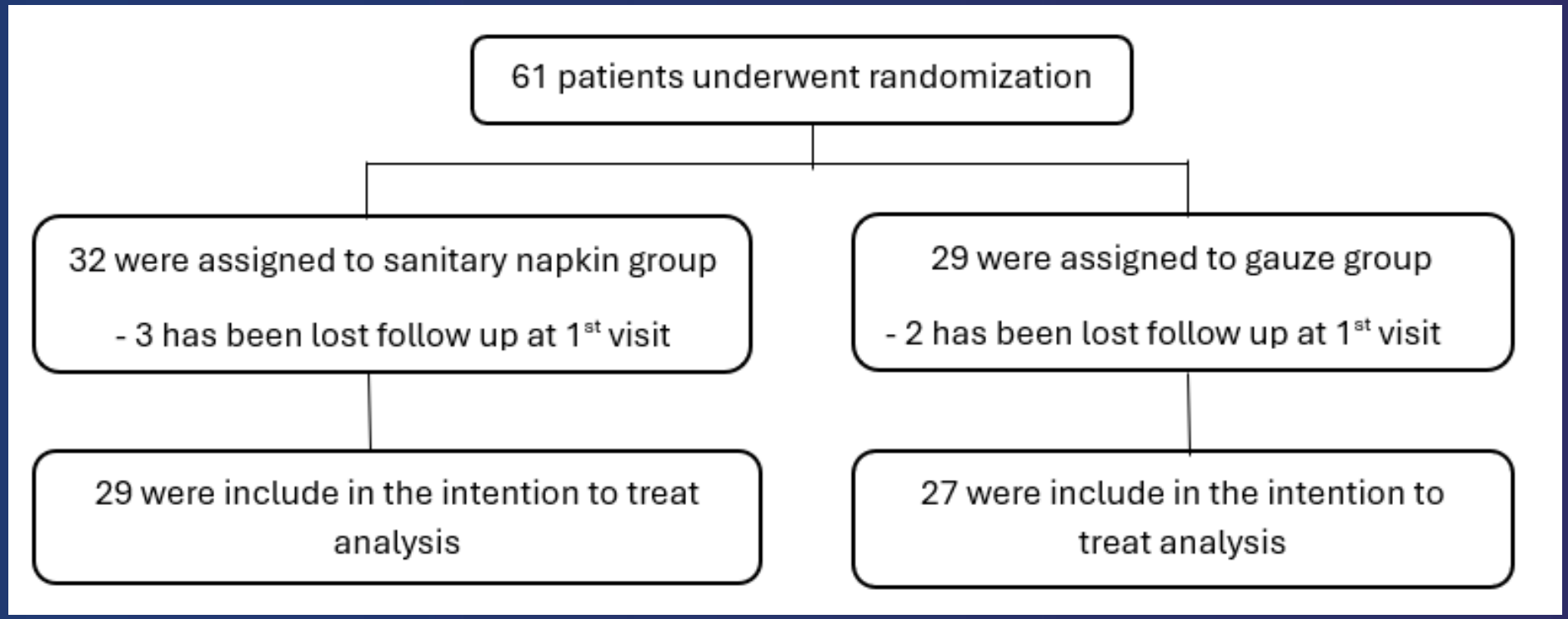
Pre-vacuum stream sterilizer : 135 c, 4 min

PROTOCOL


Assessed for eligibility
Randomized at wound clinic
computerized randomization protocol 1: 1 basis by STATA, seal in envelope
Sterile sanitary napkins
(intervention group)
Sterile gauze
(control group)
Wound evaluated every 2 weeks, continued up to 12 weeks or until complete healing
Record data : Wound area, Pain score, Odor, Frequency, Maceration, infection, satisfaction

RESULT

- From January 2019 through December 2020 and from June 2022 through April 2024



BASELINE CHARACTERISTIC

Table 1 Baseline demographic and clinical characteristics of the Trial Participants.				
Variables	Total (n=56)	Sterile napkins (n=29)	Gauze (n=27)	P-value
Age: Median (P25, P75(IQR))	65.5 (55,74.5(19.5))	65 (57,73 (16))	66 (53,76(23))	0.993
BMI: Median (P25, P75(IQR))	27.7(23.7, 31.18 (7.48))	27.8 (23.7,31.1(7.4))	27.4 (23.7,31.25(7.55))	0.883
- **Female**	37 (66.07)	18 (62.07)	19 (70.37)	0.512
Comorbidities: n (%)				
- **Hypertension**	32 (57.14)	16 (55.17)	16 (59.26)	0.757
- **Diabetes mellitus**	9 (14.75)	6(18.75)	3 (10.34)	0.329
- **Dyslipidemia**	17 (30.36)	10 (34.48)	7 (25.93)	0.487
- **Chronic kidney disease**	3 (5.36)	3 (10.34)	0 (0.00)	0.237
Current intake steroid: n (%)	4 (7.14)	1 (3.45)	3 (11.11)	0.343
Reference leg: n (%)				
- **Right**	24 (42.86)	12 (41.38)	12 (44.44)	0.630
- **Left**	30 (53.57)	15 (51.72)	15 (55.56)	
- **Both**	2 (3.57)	2 (6.90)	0 (0.00)	
- **No DUS**	7 (12.50)	5 (17.24)	2 (7.41)	

BASELINE CHARACTERISTIC

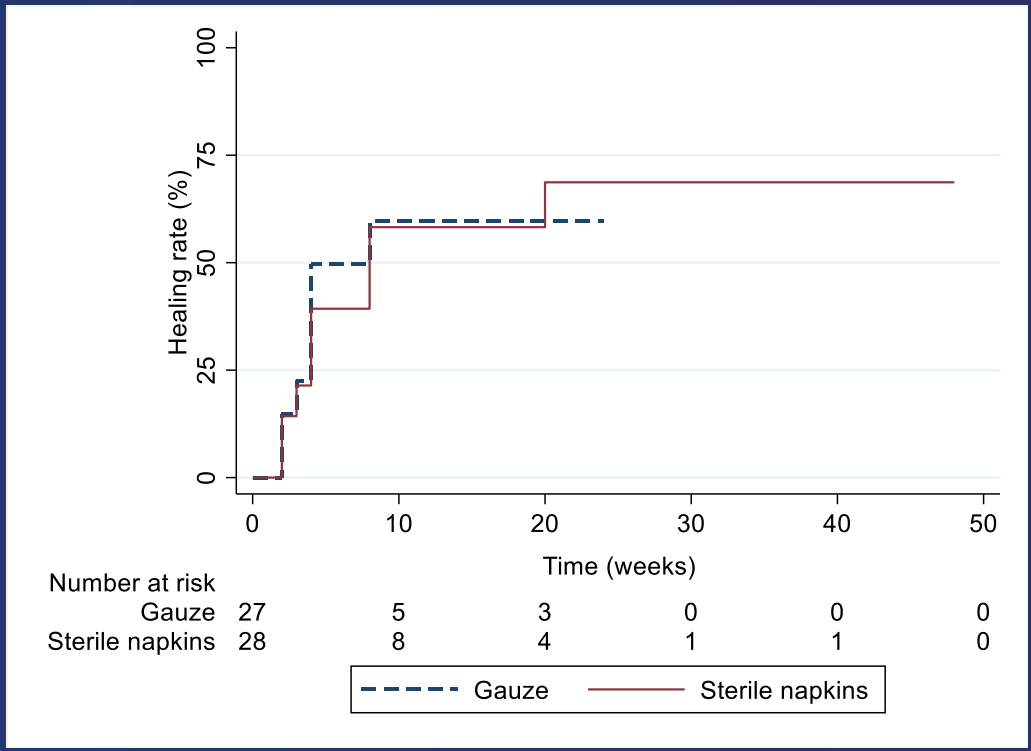
Variables	Total (n=56)	Sterile napkins (n=29)	Gauze (n=27)	P-value
Baseline wound area,cm^2: Median (P25, P75(IQR))	5.17 (2.16,14.36(2.2))	7.09 (3.09,15.72(12.63))	3.99 (1.76,12.63(10.87))	0.325
Wound base: n (%)				
- Slough	33 (58.93)	19 (65.52)	14 (51.85)	0.299
- Granulation	23 (41.07)	10 (34.48)	13 (48.15)	
Venous pathophysiology: n (%)				
- Venous reflux	37 (66.07)	16 (55.17)	21 (77.78)	0.242
- Venous obstruction	2 (3.57)	2 (6.90)	0 (0.00)	
- Venous reflux and obstruction	5 (8.93)	2 (6.90)	3 (11.11)	
- No venous pathophysiology identifiable	5 (8.93)	4 (13.79)	1 (3.70)	
Adequate compression therapy* : Median (P25, P75(IQR))	31.67(10,60(50))	30 (10,50(40))	33.33 (0,60(60))	0.598
Venotonic drug: n (%)	53 (94.64)	28 (96.55)	25 (92.59)	0.605
History of superficial venous treatment: n (%)	11 (19.64)	4 (13.79)	7 (25.93)	0.253

PRIMARY OUTCOME

Table 2 Wound healing rate				
Variables	Total (n=56)	Sterile napkins (n=29)	Gauze (n=27)	P-value
Complete healing: n (%)	22 (39.29)	11 (37.93)	11 (40.74)	0.999
Incomplete healing: n (%)	34 (60.71)	18 (62.07)	16 (59.26)	0.999
Percent of wound area reduction: Median (IQR)				
- **Baseline to 1st visit (n=56)**	11.41 (51.99)	18.57 (47.85)	-0.60 (67.28)	0.063
- **1st visit to 2nd visit (n=46)**	30.54 (88.60)	35.94 (61.23)	25.13 (98.78)	0.371
- **2nd visit to 3rd visit (n=36)**	9.56 (54.85)	12.28 (64.14)	9.20 (54.72)	0.919
- **3rd visit to 4th visit (n=30)**	29.42 (89.19)	29.42 (83.94)	30.79 (95.20)	0.726
- **4th visit to 5th visit (n=24)**	26.57 (100)	26.57 (96.80)	25.42 (63.64)	0.579
- **5th visit to 6th visit: (n=9)**	4.80 (49.92)	-4.74 (59.52)	4.80 (49.92)	0.999

PRIMARY OUTCOME

- Kaplan-Meier time to healing analysis between sterile sanitary napkin and gauze.



SECONDARY OUTCOME

Table 3 Secondary outcomes				
Variables	Total (N=56)	Sterile napkins (n=29)	Gauze (n=27)	P-value
PUSH 3.0 score average all visit: Median (IQR)	8 (5)	9 (4)	8 (6)	0.446
Pain score average all visit: Median (IQR)	1.75 (2.67)	1.67 (2.70)	2.00 (3.67)	0.399
Frequency of dressing change: Median (IQR)	1 (0)	1 (0)	1 (0)	0.684
Odor at last visit: n (%)	3 (5.36)	2 (6.90)	1 (3.70)	0.999
Satisfaction: n (%)				0.285
- Very satisfied	14 (25.00)	7 (24.14)	7 (25.93)	
- Just satisfied	27 (28.21)	11 (37.93)	16 (59.26)	
- Dissatisfied	10 (17.86)	7 (24.14)	3 (11.11)	
Adverse events: n (%)				
- Skin maceration	3 (5.36)	1 (3.45)	2 (7.41)	0.583
- Wound infection	0 (0.00)	0 (0.00)	0 (0.00)	-
- Allergy to wound dressing	4 (7.14)	2 (6.90)	2 (7.41)	0.999

SECONDARY OUTCOME

Variables	Univariate analysis			Multivariate analysis		
	Coef.	P	95%CI	Coef.	P	95%CI
Group						
- **Control**	0.92	0.455	-1.51 to 3.36			
- **Treatment**						
Gender: n (%)						
- **Male**	-4.00	0.002	-6.54 to -1.45	-2.99	0.279	-8.39 to 2.42
- **Female**						
BMI	1.86	0.030	0.02 to 0.35	0.30	0.122	-0.08 to 0.69
HT	3.63	0.003	1.22 to 6.05	8.92	0.001	3.54 to 14.29
DM	0.48	0.774	-2.79 to 3.74			
DLP	-4.47	0.001	-7.01 to -1.93	-10.24	0.001	-16.31 to -4.17
Steroid	-1.79	0.475	-6.72 to 3.14			
Visit (times)	-0.97	0.003	-1.61 to -0.32	-0.85	0.000	-1.31 to -0.40
Compression therapy	-3.67	0.000	-5.65 to -1.68	-2.83	0.000	-4.09 to -1.56

DISCUSSION

- No statistical significant difference in

  - Wound healing rate
  - Pressure Ulcer Scale of Healing (PUSH score)
  - Pain control
  - Odor control
  - Satisfaction
  - Safety and Adverse Events

DISCUSSION

- Hypothesis of this study : sanitary napkin can improve wound healing

- SAPs containing dressing reducing the concentration of MMPs **
  - Main cause of the pathogenesis of non-healing chronic venous ulceration was overexpressed of metalloproteinases (MMPs) *

* Bruno Amato, Role of matrix metalloproteinases in non-healing venous ulcers, International Wound Journal , 2015

** Wiegand C, A superabsorbent polymer-containing wound dressing efficiently sequesters MMPs and inhibits collagenase activity in vitro. J Mater Sci Mater Med. 2013

DISCUSSION

- Risk factors for delayed healing in venous leg ulcers*
  - Larger ulcer area, longer ulcer duration, a previous history of ulceration, venous abnormalities and lack of high compression
  - Large amount of exudate

- Early endovenous ablation of superficial venous reflux can improved healing**

* Parker CN, Finlayson KJ, Shuter P, Edwards HE. Risk factors for delayed healing in venous leg ulcers: a review of the literature. Int J Clin Pract. 2015

** Gohel MS, Heatley F, A randomized trial of early endovenous ablation in venous ulceration. New England Journal of Medicine. 2018

DISCUSSION

- Risk factors for delayed healing in venous leg ulcers*
  - **Larger ulcer area**, longer ulcer duration, a previous history of ulceration, venous abnormalities and lack of high compression
  - Large amount of exudate

- **Early endovenous ablation** of superficial venous reflux can improved healing**

* Parker CN, Finlayson KJ, Shuter P, Edwards HE. Risk factors for delayed healing in venous leg ulcers: a review of the literature. Int J Clin Pract. 2015

** Gohel MS, Heatley F, A randomized trial of early endovenous ablation in venous ulceration. New England Journal of Medicine. 2018

LIMITATION

- Small sample size
- Single center
- Small wound size
- The patient did not attend appointments regularly

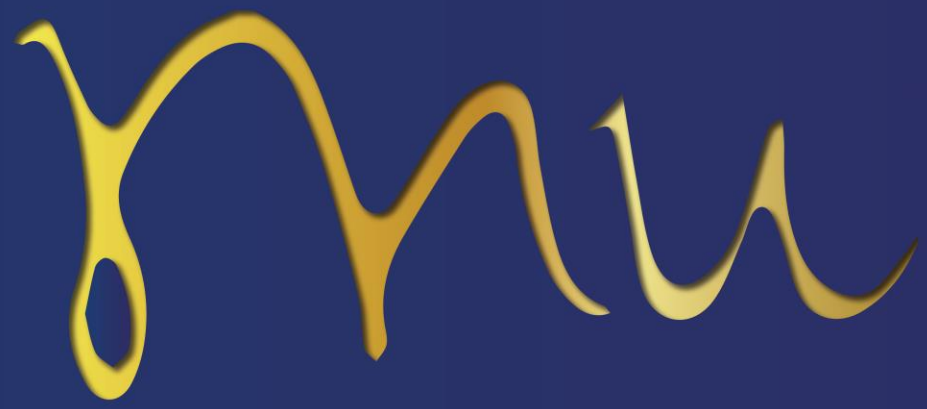
CONCLUSION

- Sanitary napkin and gauze dressing were **not difference** in wound healing of VLUs

Thank you.

Mahidol University
Wisdom of the Land

999 มหาวิทยาลัยมหิดล ถนน พุทธมณฑลสาย 4
ตำบล ศาลายา อำเภอพุทธมณฑล นครปฐม 73170
โทร : 02 849 6000



Mahidol University
Wisdom of the Land

Abstract

"Impact of prostate shape ratio on perioperative bleeding and other perioperative outcomes of robotic assisted laparoscopic radical prostatectomy"

Tarapon. Setthawong, MD

T. Setthawong, W. Kongchareonsombat

Division of Urology, Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Introduction: Robotic assisted laparoscopic radical prostatectomy (RARP) has been increasingly used for prostate cancer surgery in Thailand. There are studies compared the prostate volume and perioperative complications but in the detail of prostate shape ratio is tended to be one of the impact factors. Therefore, this study aimed to compare the prostate shape ratio and perioperative complications.

Objective: We determined the impact of prostate shape ratio on perioperative bleeding and other perioperative outcomes of robotic assisted laparoscopic radical prostatectomy.

Material and methods: From January 2017 to December 2022, we reviewed the records of 160 patients who have pre-operative MRI for measurement prostate shape ratio (Width/Length) and underwent robotic assisted laparoscopic radical prostatectomy at Ramathibodi hospital. The primary outcome was perioperative bleeding. The secondary outcomes included perioperative blood component used, perioperative injury and operative time.

Results: 160 patients met the inclusion criteria. Patients who have prostate width/length<1 (group 1) has 82 patients and who have prostate ratio width/length>1 (group 2) have 78 patients. Group 2 had higher intraoperative blood loss (median 300ml $p<0.001$). There was no significant in perioperative blood component used, perioperative injury and operative time between two groups.

Conclusion: In robotic assisted laparoscopic radical prostatectomy, higher prostate shape ratio (Width/Length>1) is associated with more intraoperative blood loss but not different in other perioperative outcomes.

Keywords: Prostate cancer, Robot assisted laparoscopic radical prostatectomy, Prostate shape ratio, Perioperative bleeding, Perioperative complications.

Impact of prostate shape ratio on perioperative bleeding and other perioperative outcomes of robotic assisted laparoscopic radical prostatectomy

T. Setthawong, W. Kongchareonsombat

Division of Urology, Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Ethic approval

Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University
270 Rama 6 Rd. Phayatai Ratchathewi Bangkok 10400 Tel.(660)2012175, 2011544, 2010388
Website: https://med.mahidol.ac.th/research/ethics
E-mail: raec.mahidol@gmail.com

COA. MURA2022/775

Title of Project (English)	Impact of prostate shape ratio on perioperative bleeding and others perioperative outcomes of robotic assisted laparoscopic radical prostatectomy
Title of Project (Thai)	การศึกษาความสัมพันธ์ของสัดส่วนความกว้างและยาวของต่อมลูกหมากของผู้ป่วยมะเร็งต่อมลูกหมากต่อปัญหาเลือดออกและปัญหาอื่น ๆ ในกระบวนการการผ่าตัดต่อมลูกหมากผ่านกล้องโดยใช้หุ่นยนต์ช่วยผ่าตัด
Type of Review	Expedited
Principal Investigator	Tarapon Setthawong
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator	Wisoot Kongchareonsombat
Approval includes	1. Submission form protocol version 2 date 30/11/2022 2. Curriculum vitae 3. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	December 15, 2022
Date of Expiration	December 14, 2023

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Introduction

- Prostate cancer is one of the most prevalent cancers in the Thai population, and its incidence continues to rise each year
- The treatments for prostate cancer depend on the stage and risk group, with some stage and risk groups being more preferred for radical prostatectomy
- Radical prostatectomy is a complex and difficult surgery that requires surgeon experience and has the risks for complications
- RARP has been shown to improve surgical outcomes and reduce both intraoperative and postoperative complications

Introduction

- Recent studies have reported that prostate volume and weight considerably affects estimated blood loss and post-operative outcomes
- From the observation when performing RARP in Ramathibodi hospital, not only the prostate size but also the shape of the prostate of the patient has an impact on the procedure.

Objectives

- This study aimed to investigate the impact of prostate shape ratio on perioperative bleeding and other perioperative outcomes in robotic-assisted laparoscopic radical prostatectomy.

Methods and materials

- **Patient population**

From January 2017 to December 2022, we collected the records of 160 patients who have pre-operative MRI for measurement prostate ratio (Width/Length) and underwent robotic assisted laparoscopic radical prostatectomy at Ramathibodi hospital in Thailand

Methods and materials

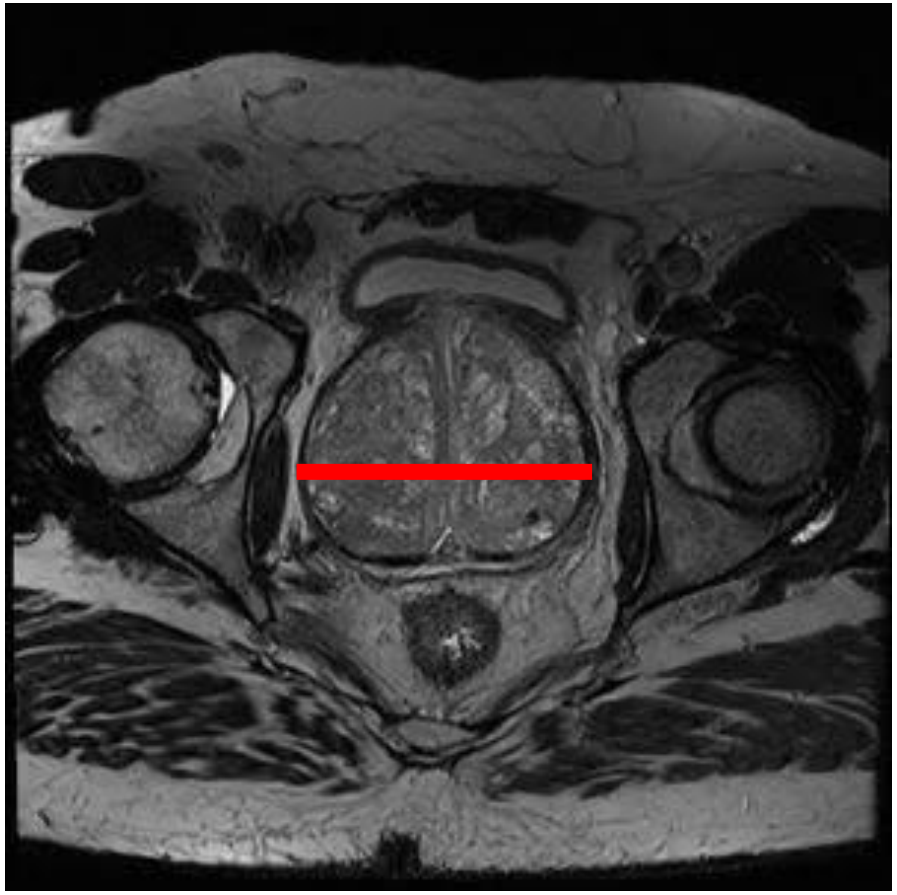
- **Inclusion Criteria**

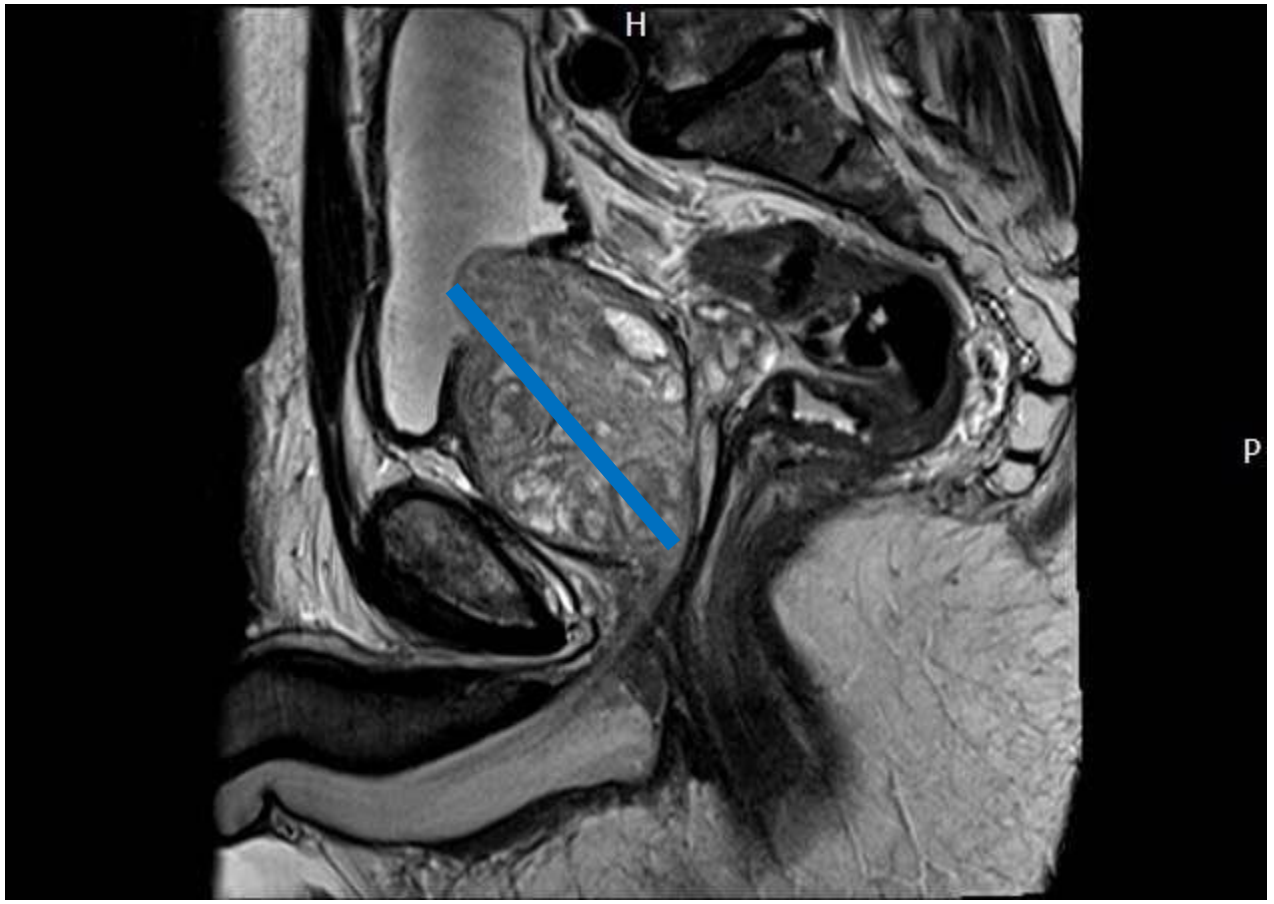
1) Patients who have diagnosis with prostate cancer
2) Prostate cancer patients have to underwent 4-arms robotic assisted laparoscopic radical prostatectomy and one assistant ports
3) The prostate have been measured by pre-operative MRI by radiologists
4) the operations have to record intraoperative blood loss
5) the operations have to record intraoperative blood component used, complication and operative times

Methods and materials

- **Exclusion Criteria**

1) Patients who underwent open or pure laparoscopic radical prostatectomy
2) No measurement on prostate shape (Width and length)
3) Incomplete operative record in blood loss, blood component used, complication and operative time.





Width

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Length

Statistical analysis

- **Quantitative data** was summarized as mean and SD or median and interquartile as appropriate.
- **Categorical data** was summarized as counts and percentage.
- **Comparison of quantitative variables between treatment groups** was done using the independent t-test or the Wilcoxon rank-sum (Mann-Whitney) test as appropriate.
- **Comparison of categorical variables between groups** was done using the chi-square test or Fisher's exact test as appropriate.
- **P-values < 0.05** were considered statistically significant.
- STATA version 14.1 (STATA Corp., TX, USA) was used for all statistical analysis.

Results

Results

- Comparison between groups of a prostate which have ratio width/length ≤1 and >1, both groups have the same characteristic in prostate volume, pre operative PSA, GS, T stage and pre operative neoadjuvant hormone.
- Patients with the prostate ratio width/length >1 have significant intraoperative blood loss (mean 300ml vs 150ml, P-value<0.001)

Comparison between ratio group (N = 160)

Variable	Ratio ≤ 1 (n = 82)	Ratio > 1 (n = 78)	P-value
Age (year); mean±SD	68.0 ± 6.2	67.9 ± 5.6	0.871
Weight (kg.); median (IQR)	67.2 (61.5, 76.3)	68.0 (61.9, 78.0)	0.663
Height (cm.); mean±SD	166.8 ± 6.9	167.5 ± 5.4	0.436
Body Mass Index (kg/m^2); median (IQR)	24.6 (22.6, 26.8)	24.4 (22.5, 27.2)	0.847
P volume; median (IQR)	37.8 (27.9, 58.7)	34.7 (25.2, 53.0)	0.091
PSA; median (IQR)	10.1 (7.3, 14.2)	10.4 (7.2, 15.5)	0.772
GS; mean±SD	7.1 ± 0.9	6.9 ± 0.8	0.246
T stage; n (%)			
T1a	-	-	0.255
T1b	2 (2.4)	1 (1.3)	
T1c	55 (67.1)	57 (73.1)	
T2a	2 (2.4)	3 (3.9)	
T2b	4 (4.9)	0 (0.0)	
T2c	-	-	
T3a	9 (11.0)	12 (15.4)	
T3b	10 (12.2)	5 (6.4)	
T4a	-	-	
T4b	-	-	
Neoadj H; n (%)	24 (29.3)	25 (32.5)	0.662
Intra op bleed; median (IQR)	150 (100, 200)	300 (200, 400)	<0.001
Intra blood com; n (%)	0 (0.0)	1 (1.3)	0.487
Injury; n (%)	-	-	-
Op time; median (IQR)	120 (120, 140)	120 (120, 150)	0.419

Results

- The higher intraoperative blood loss in the group of larger prostate volume (≥50g) (mean 300ml vs 200ml, P-value 0.004).

Comparison between P volume group (N = 160)

Variable	P volume < 50 (n = 112)	P volume ≥ 50 (n = 48)	P-value
Age (year); mean±SD	67.5 ± 6.1	68.9 ± 5.3	0.158
Weight (kg.); median (IQR)	66.7 (61.3, 74.0)	74.5 (62.6, 82.2)	0.020
Height (cm.); mean±SD	167.1 ± 5.6	167.3 ± 7.5	0.830
Body Mass Index (kg/m^2); median (IQR)	24.3 (22.3, 26.3)	25.9 (22.8, 27.9)	0.030
Ratio; mean±SD	1.1 ± 0.2	0.9 ± 0.2	0.082
PSA; median (IQR)	9.9 (7.2, 14.9)	10.9 (7.9, 15.1)	0.214
GS; mean±SD	7.1 ± 0.9	6.8 ± 0.8	0.052
T stage; n (%)			
T1a	-	-	0.506
T1b	2 (1.8)	1 (2.1)	
T1c	74 (66.1)	38 (79.2)	
T2a	3 (2.7)	2 (4.2)	
T2b	3 (2.7)	1 (2.1)	
T2c	-	-	
T3a	17 (15.2)	4 (8.3)	
T3b	13 (11.6)	2 (4.2)	
T4a	-	-	
T4b	-	-	
Neoadj H; n (%)	31 (27.9)	18 (37.5)	0.230
Intra op bleed; median (IQR)	200 (100, 300)	300 (150, 425)	0.004
Intra blood com; n (%)	0 (0.0)	1 (2.1)	0.300
Injury; n (%)	-	-	-
Op time; median (IQR)	120 (120, 140)	120 (120, 150)	0.355

Results

- In the prostate volume <50g groups, the prostate ratio >1 has significant in intraoperative blood loss compared to the prostate ration ≤ 1 (mean 300ml vs 100ml, p-value<0.001) but other impacts are not different.

Comparison between ratio group **of patients have P volume < 50g** (N = 112)

Variable	Ratio ≤ 1 (n = 55)	Ratio > 1 (n = 57)	P-value
Intra op bleed; median (IQR)	100 (100, 200)	300 (200, 400)	<0.001
Intra blood com; n (%)	-	-	-
Injury; n (%)	-	-	-
Op time; median (IQR)	120 (110, 130)	120 (120, 150)	0.065

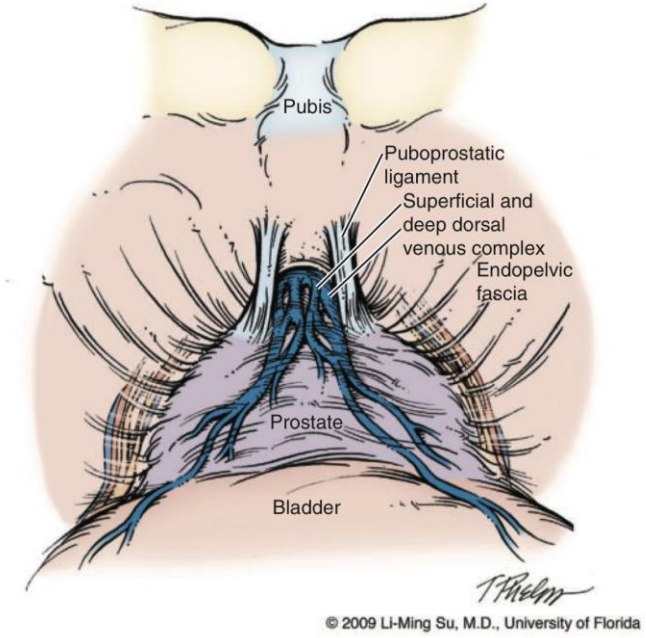
Comparison between ratio group **of patients have P volume ≥ 50g** (N = 48)

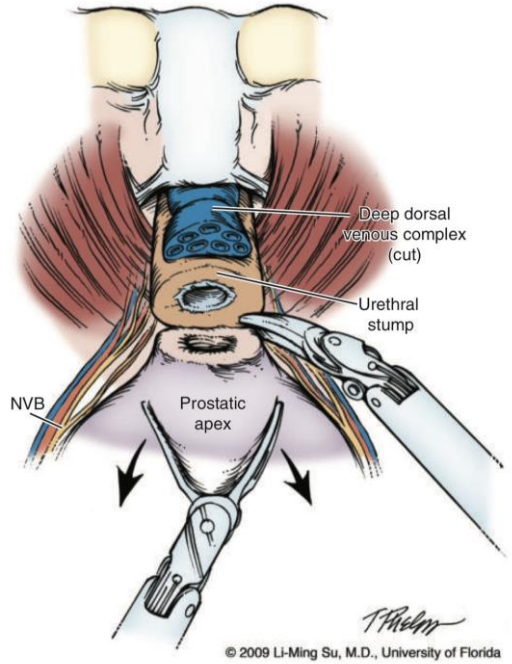
Variable	Ratio ≤ 1 (n = 27)	Ratio > 1 (n = 21)	P-value
Intra op bleed; median (IQR)	200 (150, 450)	300 (200, 400)	0.168
Intra blood com; n (%)	0 (0.0)	1 (4.8)	0.438
Injury; n (%)	-	-	-
Op time; median (IQR)	120 (120, 150)	120 (120, 132)	0.205

Discussions

Discussions

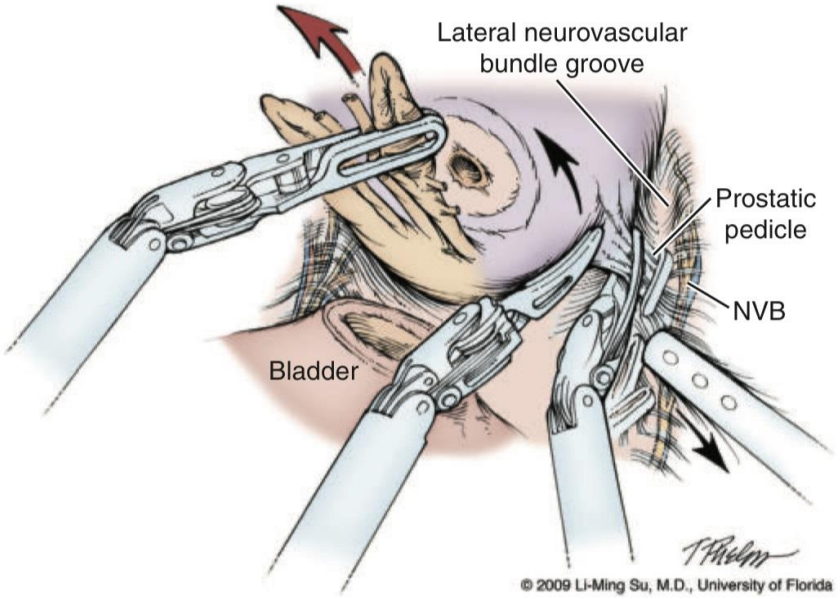
- A higher prostate shape ratio (>1) is associated with significantly increased intraoperative blood loss
  - A broad base and a wide vascular pedicle
  - Difficult to provide adequate exposure for dissection, especially at the apex.





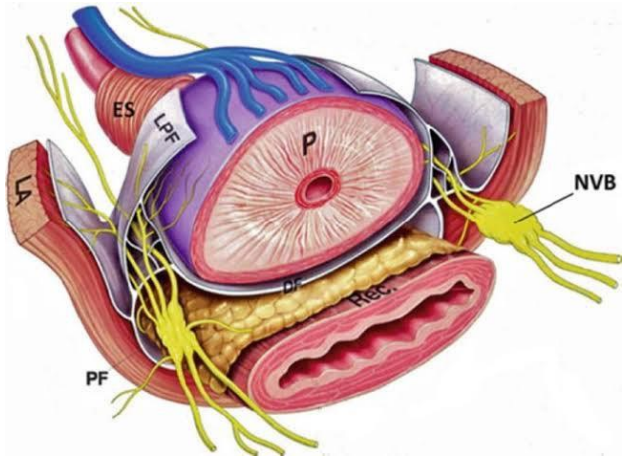
Discussions

- No significant differences in blood transfusion rates or intraoperative complications.
  - RARP improved hemostatic control and enhanced visualization in the surgical field and reduced overall perioperative complications compared to open or conventional laparoscopic radical prostatectomy



Discussions

- Higher prostate volume (≥50g) has significant intraoperative blood loss
- Analyzing subgroups
  - The increased intraoperative blood loss associated with a higher prostate shape ratio was significant only in patients with a prostate volume <50 g.
  - Larger prostates (>50 g), the overall gland size may tend to have technical difficulties, diminishing the isolated effect of the shape ratio on bleeding.



Discussions

- Our study can be applied for preoperative planning and surgical decision-making. Preoperative MRI measurements of prostate shape ratio may serve as a predictor of intraoperative bleeding risk.
- Surgeons, particularly those with less experience in RARP, should be aware of the increased bleeding risk in patients with a higher prostate shape ratio and take additional precautions
  - such as preparing intraoperative blood components,
  - carefully dissecting the prostate from surrounding tissue
  - preparing for potential hemostatic interventions.

Limitations

- A single institution with a relatively small sample size, which may limit the generalizability of the findings
- A retrospective study
- further study of this impact needs to be in a prospective cohort and done in multiple centers.

Conclusions

- A higher prostate ratio (width/length > 1) has an impact on intraoperative blood loss, especially in the small prostate size (<50 g),
- RARP in patients is feasible with patients with low intraoperative complications.
- the surgeon who may not have experience in RARP could be prepared to face more intraoperative blood loss in the small prostate with the higher prostate ratio group.

Q&A

Abstract

“Importance of anticoagulant in venous thromboembolism prophylaxis for surgical patients”

Saharath Pongmongkol, MD

Saharath Pongmongkol, Nutsiri Kittitirapong, Piyanut Pootracool, Wiwat Tirapanich, Sopon Jirasiritum, Surasak Leela-Udomlipi, Suthas Horsirimanont, ChaowanunPornwaragorn, Gorawee Tepsamritporn

Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Background: Venous thromboembolism (VTE) is a serious condition that can lead to significant morbidity and death. Despite the implementation of preventive measures, the Caprini risk stratification system, many high-risk surgical patients at Ramathibodi Hospital still do not receive adequate anticoagulation therapy due to concerns about bleeding complications.

Objectives: To address this issue, a retrospective cohort study was conducted to evaluate the effectiveness and safety of anticoagulation therapy in preventing VTE in high-risk surgical patients.

Method: This study analyzed surgical patients at Ramathibodi Hospital between September 2022 and September 2023 who were identified as high-risk for venous thromboembolism (VTE) based on a Caprini score equal or greater than 5. Patients were categorized into two groups: those not receiving pharmacological prophylaxis (934 cases) and receiving anticoagulant (82 cases). The primary outcome was the incidence of VTE, and the study also compared the rates of post-operative bleeding complications among the groups.

Result: This study found the incidence of VTE in high-risk patients was not significantly different between two groups, 12(1.28%) in non-anticoagulant group vs 0(0%) in the group receiving anticoagulant [p = 0.614]. Patients who received intraoperative heparinization had higher events of bleeding complication, major bleeding in 54/122 cases (44.2%). After excluding those with intraoperative heparinization, the bleeding complications were not significantly different between the two groups. Minor bleeding incidence is 83(8.89%) vs 8(9.76%) [p = 0.791] and major bleeding is 23(2.46%) vs 2 (2.44%) [p = 0.999]

Conclusion: This study demonstrates that using anticoagulants for VTE prophylaxis does not effectively reduce the incidence of VTE events and shows no significant increase in bleeding complications. However, the findings are limited in their generalizability due to the small sample size and low incidence of VTE observed. Further research with larger sample sizes is needed to determine the optimal VTE prevention strategies for individual patients.

IMPORTANCE OF ANTICOAGULANT IN VENOUS THROMBOEMBOLISM PROPHYLAXIS FOR SURGICAL PATIENTS

Saharath Pongmongkol, MD.

Assoc.Prof. Nutsiri Kittitirapong

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COA. No. MURA2023/764

Title of Project (English)	Importance of anticoagulant in venous thromboembolism prophylaxis for surgical patients
Title of Project (Thai)	ความสำคัญของการให้ยาต้านการแข็งตัวของเลือดในการป้องกันภาวะลิ่มเลือดอุดตัน หลอดเลือดดำในผู้ป่วยที่เข้ารับการผ่าตัด
Type of Review	Expedited
Principal Investigator	Saharath Pongmongkol
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator	1. Nutsiri Kittitirapong 2. Suthas Horsirimanont 3. Chaowanun Pornwaragorn 4. Gorawee Tepsamritporn
Approval includes	1. Submission form protocol version 1 date 20/7/2023 2. Case record form version 1 date 28/9/2023 3. Curriculum vitae 4. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	October 2, 2023
Date of Expiration	October 1, 2024

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University
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COA. No. MURA2023/764
Ref.2024/635

Title of Project (English)	Importance of anticoagulant in venous thromboembolism prophylaxis for surgical patients
Title of Project (Thai)	ความสำคัญของการให้ยาต้านการแข็งตัวของเลือดในการป้องกันภาวะลิ่มเลือดอุดตัน หลอดเลือดดำในผู้ป่วยที่เข้ารับการผ่าตัด
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Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator (s)	1. Nutsiri Kittitirapong 2. Suthas Horsirimanont 3. Chaowanun Pornwaragorn 4. Gorawee Tepsamritporn 5. Bundit Sakulchairungruang Added date 16/06/2024
Approval includes	1. Submission form protocol version 3 date 10/06/2024 2. Amendment letter date 11/06/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval of Amendment	June 16, 2024

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Mahidol University
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BACKGROUND

- Venous thromboembolism (VTE) is a serious condition that can lead to significant morbidity and death.

Table 4. Outcomes of Patients with Acute Pulmonary Embolism (n = 696).

Outcomes	Median (IQR) or n (%)
30-day all-cause mortality	133 (19.1)
30-day PE-related mortality	39 (5.6)
30-day non-PE-related mortality	94 (13.5)
Sepsis	37 (39.4)
Pneumonia	25 (26.6)
Cancer	11 (11.7)
Septic shock	10 (10.6)
Others	11 (10.7)
Major bleeding	57 (8.2%)
UGIH	34 (4.9)
ICH	11 (1.6)
LGIH	8 (1.1)
Hemoptysis	4 (0.6)
Recurrent PE within 14 days	2 (0.3)
Hemodynamic collapse	37 (5.3)
Mechanical ventilation (MV) support	158 (22.7)
MV days (median, IQR)	4 (2, 10)
Vasopressor	90 (12.9)
Turn to CTEPH	25 (3.6%)
Hospital stay (days) (median, IQR)	12 (6, 23)

Note: Data are median, IQR, or n (%). Abbreviations: CTEPH, chronic thromboembolic pulmonary hypertension; ICH, intracerebral hemorrhage; LGIH, lower gastrointestinal hemorrhage; PE, pulmonary embolism; UGIH, upper gastrointestinal hemorrhage.

The cumulative incidence of PTS was 47% after VTE event
Development of PTS is the principal determinant of health-related QOL 2 years after DVT

Table 3 Change in quality of life (QOL) from baseline to 2 years according to post-thrombotic syndrome (PTS) status

	Subjects with PTS		Subjects without PTS		
	n	Mean (SD) change score	n	Mean (SD) change score	P-value
Generic quality of life					
SF-36 PCS	134	3.8 (12.7)	154	8.9 (13.2)	0.001
SF-36 MCS	134	5.5 (12.0)	154	6.7 (12.9)	0.39, NS
Venous disease-specific QOL					
VEINES-QOL	137	3.6 (6.2)	155	5.9 (6.0)	0.002
VEINES-Sym	137	2.0 (7.2)	155	4.7 (6.1)	0.001

Chaiwat Bumroongkit, Clinical Characteristics, Risk Factors, and Outcomes of Acute Pulmonary Embolism in Asian Population, J. Clin. Med., 2022
S R Kahn, Determinants of health-related quality of life during the 2 years following deep vein thrombosis, JTH., 2008

Caprini Score for Venous Thromboembolism (2005)

stratifies VTE risk in surgical patients, guiding prophylaxis decisions

1 point	2 points
○ Age 41-60	○ Age 60-74
○ Minor surgery	○ Arthroscopic surgery
○ Prior major surgery (<1 mo)	○ Malignancy
○ Varicose veins	○ Major surgery >45 min
○ Inflammatory bowel disease	○ Laparoscopic surgery >45 min
○ Swollen legs	○ Confined to bed (>72 h)
○ Obesity	○ Immobilizing cast (<1 mo)
○ Congestive heart failure	○ Central venous access
○ Sepsis (<1 mo)	**3 points**
○ Lung disease, i.e., pneumonia (<1 mo)	○ Age > 75
○ Abnormal pulmonary function (COPD)	○ History of VTE
○ Medical patient in bed	○ Family history of VTE
○ Other _____	○ Factor V Leiden
○ On estrogen supplementation	○ Prothrombin gene mutation
○ Pregnant or puerperium	○ Elevated homocysteine
○ History of unexplained stillborn, recurrent abortions, premature birth with toxemia or growth-restricted infant	○ Lupus anticoagulant
5 points	○ Positive anticardiolipins
○ Elective lower extremity arthroplasty	○ Heparin induced thrombocytopenia
○ Hip, pelvis, or leg fracture (<1 mo)	○ Other thrombophilia
○ Stroke (<1 mo)	**Total score =**
○ Multiple trauma (<1 mo)	
○ Spinal cord injury (<1 mo)	

Figure 146.2 Validated 2005 Caprini Risk Score. *VTE*, Venous thromboembolism. (Adapted from Caprini JA. Thrombosis risk assessment as a guide to quality patient care. *Dis Mon*. 2005;51(2-3):70-78.)

TABLE 146.1 Boston University Algorithm for Prescribing Thrombosis Prophylaxis

Caprini Score	Risk	Recommendation	Duration
0	Lowest	Early ambulation only, OR Compression boots, OR Low dose Heparin; OR Low molecular weight heparin	Hospitalization
1-2	Low	Compression boots, OR Low dose Heparin, OR Low molecular weight heparin	Hospitalization
3-4	Moderate	Compression boots, AND Low dose Heparin, OR Low molecular weight heparin	Hospitalization
5-8	High	Compression boots, AND Low dose Heparin, OR Low molecular weight heparin	1-10 days
9 or more	Highest	Compression boots, AND Low dose Heparin, OR Low molecular weight heparin	30 days

Compliance was 100% in the low- and moderate-risk groups, 89% in the high-risk group, and 77% in the highest-risk group.
(Adapted from Cassidy MR, Rosenkranz P, McAneny D. Reducing postoperative venous thromboembolism complications: in reply to Lau and colleagues. *J Am Coll Surg*. 2014;219(5):1103-1104.)

Caprini JA. Thrombosis risk assessment as a guide to quality patient care. Dis Mon. 2005

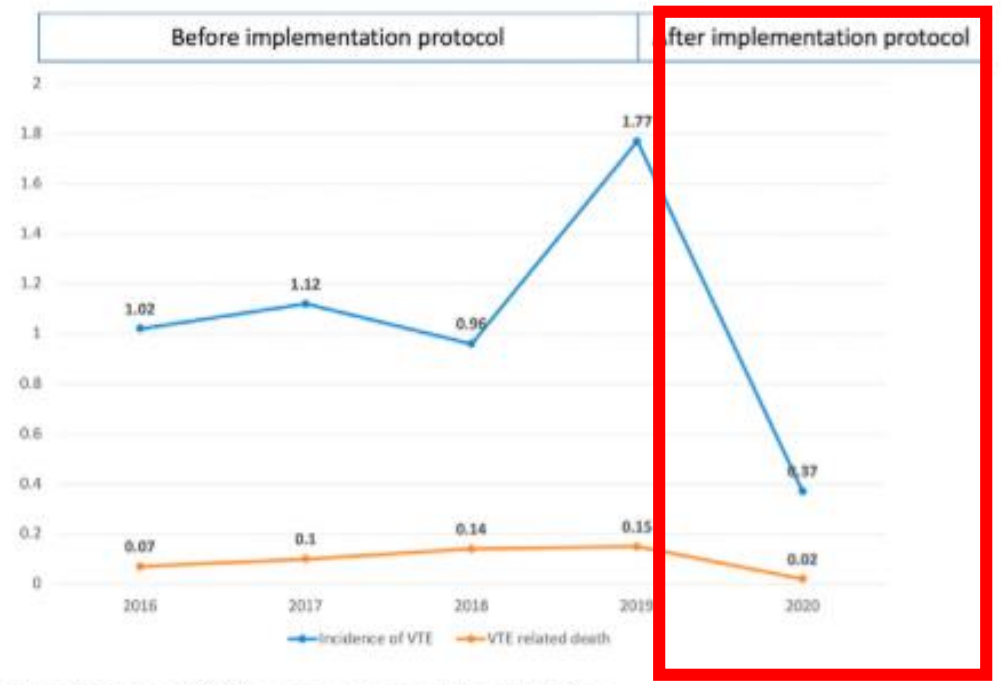
The prevalence of symptomatic VTE and VTE-related death decreased after protocol implementation

Table 2 – Rates of venous thromboembolism in pre- and post-intervention groups (n = 319).

Variable	Pre-intervention		Post-intervention		p value
	n	%	n	%	
Total					
VTE	13	6.2	1	0.9	0.04
DVT	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
PE	6	2.9	0	0.0	0.10
Postdischarge					
VTE	8	3.8	1	0.9	0.17
DVT	6	2.9	1	0.9	0.43
PE	5	2.4	0	0.0	0.17
Inpatient					
VTE	5	2.4	0	0.0	0.17
DVT	4	1.9	0	0.0	0.30
PE	1	0.5	0	0.0	1.00

DVT = deep venous thromboembolism; PE = pulmonary embolism; VTE = venous thromboembolism.

Caprini > 5, Mechanical prophylaxis + Pre-op to 28 days Post-op Anticoagulant



Abbreviations: VTE, venous thromboembolism

Fig. 2. Incidence of VTE and VTE-related death from 2016 to 2020
Abbreviations: VTE, venous thromboembolism.

Caprini > 5, Mechanical prophylaxis + Pre-op Anticoagulant

H. Abraham Chiang, Implementation of a Perioperative Venous Thromboembolism Prophylaxis Program for Patients Undergoing Radical Cystectomy, European Urology Focus, 2020
Nutsiri Kittitirapong, Outcomes after implementation of prophylactic protocol for venous thromboembolism in surgical patients, International Journal of Surgery, 2022

From the survey

Many high-risk surgical patients at Ramathibodi Hospital still do not receive adequate anticoagulation therapy due to concerns about bleeding complications.

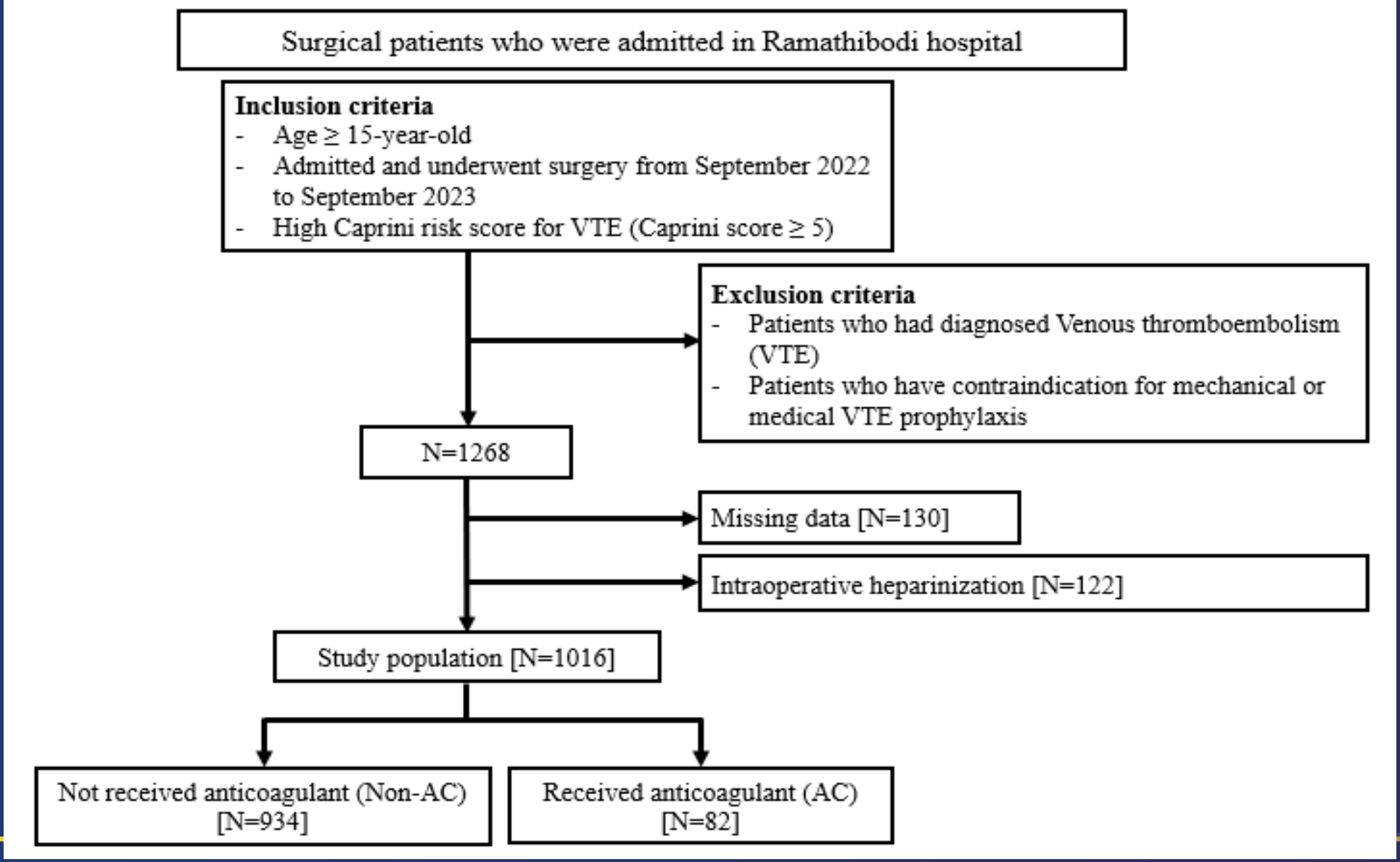
only 8.07% of high-risk patients received anticoagulants

This study was conducted to evaluate the effectiveness and safety of anticoagulation therapy in preventing VTE in high-risk surgical patients

Methods

STUDY DESIGN

- Retrospective cohort study



OUTCOMES

Primary outcome

- Incident of deep vein thrombosis (DVT) and pulmonary embolism (PE)
  diagnosed by CTPA and ultrasonographic imaging, respectively

Secondary outcome

- Bleeding complication
  - Minor bleeding complication
    Need blood transfusion (Red cell 2-4 units), Wound bleeding, Hematoma, Platelet count < 100,000
  - Major bleeding complication
    Need blood transfusion (Red cell > 4 units), Intra-cranial bleeding, Intra-ocular bleeding, Retroperitoneal bleeding
- 30-day VTE-related death

European Society for Vascular Surgery (ESVS) 2021 Clinical Practice Guidelines on the Management of Venous Thrombosis. Eur J Vasc Endovasc Surg. 2021
Shaieb MD, Bleeding complications with enoxaparin for deep venous thrombosis prophylaxis. J Arthroplasty. 1999

PROTOCOL

- The contraindications for mechanical and pharmacological prophylaxis were assessed

Mechanical prophylaxis

- Intermittent pneumatic compression (IPC) device was preferred over the graduated compression stockings (GCS)

Pharmacological prophylaxis

- Patient with normal kidney function
  - 40 mg of enoxaparin was subcutaneously injected every 24 hours stopped 12 hours before surgery
- Patients with impaired kidney function (CrCL <30 mL/min)
  - 5000 units of unfractionated heparin were subcutaneously injected every 8 hours stopped 8 hours before surgery

Matthew A, Perioperative Venous Thromboembolism Prophylaxis, Thematic review on perioperative medicine, 2020
Caprini JA. Thrombosis risk assessment as a guide to quality patient care. Dis Mon. 2005

DATA COLLECTION

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Age : _____ years

Sex ☐ Male ☐ Female

Height : _____cm Weight : _____ kg BMI : _____

Division ☐ General surgery ☐ ACS/Trauma ☐ Breast and endocrine surgery
☐ Vascular surgery ☐ Neurosurgery ☐ Cardiovascular thoracic surgery
☐ Urology surgery ☐ Plastic surgery

Caprini score Date : _____ Score : _____

Risk
☐ Minor surgery (< 45 min) ☐ Major surgery (> 45 min)
☐ Previous major surgery in 1 month ☐ Hip/Knee arthroplasty
☐ Overweight BMI (> 25 kg/m^2)
☐ Current or past malignancy ☐ Inflammatory bowel disease
☐ Lung disease (COPD/Asthma) ☐ MI within 1 month
☐ Congestive heart failure ☐ Serious infection in 1 month
☐ Immobilizing cast ☐ Broken hip/pelvic/leg in 1 month
☐ Serious trauma in 1 month ☐ Spinal cord injury in 1 month
☐ Stroke in 1 month
☐ Visible varicose vein ☐ Swollen legs
☐ Central venous catheter within 1 month
☐ History of VTE ☐ Family history of VTE
☐ Currently use OCP/HRT ☐ Pregnancy within 1 month
☐ History of unexplained stillborn infants ☐ Currently on chemotherapy
☐ Best rest ☐ Confined to bed > 72 hr

Mode of prophylaxis

☐ Intermittent pneumatic compression (IPC) ☐ Anticoagulant (AC)
☐ Intra-op heparinization

Pre-operative platelet : _____

Complication

VTE ☐ DVT ☐ PE (☐ Non-massive PE , ☐ Massive PE)

Minor bleeding
☐ PRC transfusion 2-4 unit ☐ Wound bleeding
☐ Hematoma ☐ Platelet < 100,000

Major bleeding
☐ PRC transfusion >4 unit ☐ Intracranial bleeding
☐ Intraocular bleeding ☐ Retroperitoneal bleeding

VTE related death in 30 days ☐ Yes Date : _____

STATISTICAL ANALYSIS

- Data was collected manually by two physicians and entered into spreadsheet (Microsoft Excel)
- Statistical analyses were performed using STATA version 15.1 (STATA Corp.)
- Continuous data are presented as mean ± standard deviation.
- Categorical variable were compared using the Chi-square test or Fisher's exact test as appropriate, and are presented as number (percentage)
- P-value of 0.05 was considered statistically significant.

RESULTS

Table 1 : Demographic data

Variable	Non-AC N=934	AC N=82	P-value
Age ,Mean(±SD)	67(±13.22)	64(±11.91)	0.079
Gender			
Male	411(44)	32(39.02)	0.383
Female	523(56)	50(60.98)	
BMI, Mean(±SD)	24.05(±5.26)	24.20(±4.46)	0.799
Pre-operative platelet count, Mean(±SD)	2539(±97.11)	252(±79.09)	0.903
Division			**<0.001**
Gastrointestinal surgery	203(21.73)	17(20.73)	
Acute care and trauma surgery	94(10.06)	3(3.66)	
Breast and endocrine surgery	198(21.20)	5(6.10)	
Hepatobiliary surgery	87(9.31)	1(1.22)	
Vascular surgery	73(7.82)	5(6.10)	
Neurosurgery	87(9.31)	1(1.22)	
Cardiovascular thoracic surgery	59(6.32)	49(59.76)	
Urology surgery	73(7.82)	0	
Plastic surgery	60(6.42)	1(1.22)	
Caprini score , Mean(±SD)	5.91(±1.18)	5.95(±1.13)	0.804
Intermittent pneumatic compression	810(86.72)	74(90.24)	0.363

Table 2 : Demographic data (Caprini risk factor)

Variable	Non-AC N=934	AC N=82	P-value
Minor surgery (less than 45 minutes)	62(6.64)	1(1.22)	0.051
Major surgery planned (longer than 45 minutes)	800(85.65)	75(91.46)	0.145
Past major surgery (more than 45 minutes) within the last month	67(7.17)	6(7.32)	0.961
Elective hip or knee joint Replacement surgery	1(0.11)	0	0.999*
Current or past malignancy (excluding skin cancer)	620(66.38)	65(79.27)	**0.017**
Present and history of Inflammatory Bowel Disease (IBD)	2(0.21)	1(1.22)	0.108
Present and history of obesity (BMI ≥ 25)	80(8.57)	5(6.10)	0.439
Present and history of lung disease	23(2.46)	6(7.32)	**0.024**
Recent event of heart attack (within 1 month)	5(0.54)	1(1.22)	0.397*
Recent event of congestive heart failure (within 1 month)	24(2.57)	4(4.88)	0.275
Recent event of serious infection (within 1 month)	21(2.25)	0	0.404*
Non-removable plaster cast (within 1 month)	0	0	-
Recent event of broken hips, pelvis or leg (within 1 month)	4(0.43)	3(3.66)	**0.014***
Recent event of serious trauma (within 1 month)	9(0.96)	0	0.999*
Recent event of spinal cord injury (within 1 month)	12(1.28)	0	0.614*
Visible varicose veins (current)	19(2.03)	0	0.392*
Swollen legs (current)	14(1.50)	1(1.22)	0.999*
Central venous access	12(1.28)	1(1.22)	0.999*
History of venous thromboembolism (VTE)	7(0.75)	1(1.22)	0.491*
Family history of blood clotting disease (thrombosis)]	1(0.11)	0	0.999*
Current use of birth control or Hormone therapy (HRT)	4(0.43)	0	0.999*
Pregnant or had a baby within the last month	0	0	-
History of unexplained recurrent spontaneous abortion	0	0	-
On bed rest or restricted mobility less than 72 hours	46(4.93)	3(3.66)	0.791*
Confined to a bed for 72 hours or more	103(11.03)	5(6.10)	0.193*

* Fisher's exact test

Table 3 : Result in VTE prophylaxis and bleeding complication

Variable	Non-AC N=934	AC N=82	P-value
Event of VTE	12(1.28)	0	0.614
DVT	10(1.07)	0	0.999*
PE	6(0.64)	0	0.999*
VTE related death within 30 days	0	0	0.999*
Minor bleeding			
Need blood transfusion (Red cell 2-4 units)	83(8.89)	8(9.76)	0.791
Wound bleeding	0	0	-
Hematoma	0	0	-
Platelet count < 100,000	19(2.03)	4(5.88)	0.107*
Major bleeding			
Need blood transfusion (Red cell > 4 units)	23(2.46)	2(2.44)	0.999*
Intra-cranial bleeding	4(0.43)	0	0.999*
Intra-ocular bleeding	0	0	-
Retroperitoneal bleeding	1(0.11)	0	0.999*

* Fisher's exact test

DISCUSSION

DISCUSSION

- This study found the incidence of VTE in high-risk patients (Caprini score ≥ 5) to be 1.28%, which is not significantly different from previous studies conducted in Asian populations

- Patients who received intraoperative heparinization had a higher incidence of bleeding complication [major bleeding in 54/122 (44.2%)]. The majority of these patients were from the CVT and vascular divisions.

- Patients with a diagnosis of cancer were prescribed anticoagulants more frequently than those without (66.38% vs 79.27%, P = 0.017), particularly patients with lung cancer

DISCUSSION

- Regarding the primary outcome, the incidence of VTE was not significantly different due to the low number of VTE events at Ramathibodi Hospital, with 90% of high-risk patients received mechanical prophylaxis (Intermittent pneumatic device)
- None of patient from AC group developed VTE
- No patient deceased from VTE

Variable	Non-AC N=934	AC N=82	P-value
Event of VTE	12(1.28)	0	0.614
DVT	10(1.07)	0	0.999*
PE	6(0.64)	0	0.999*
VTE related death within 30 days	0	0	0.999*

DISCUSSION

- Bleeding complication is not significantly different between the 2 groups

Minor bleeding			
Need blood transfusion (Red cell 2-4 units)	83(8.89)	8(9.76)	0.791
Wound bleeding	0	0	-
Hematoma	0	0	-
Platelet count < 100,000	19(2.03)	4(5.88)	0.107*
Major bleeding			
Need blood transfusion (Red cell > 4 units)	23(2.46)	2(2.44)	0.999*
Intra-cranial bleeding	4(0.43)	0	0.999*
Intra-ocular bleeding	0	0	-
Retroperitoneal bleeding	1(0.11)	0	0.999*

LIMITATION

- Small sample size
- Single study center
- Retrospective study
- Potential of missing data
- Low incidence of venous thromboembolism (VTE)
- Concentration of prescribing anticoagulants are dependent on individual physicians' judgement

CONCLUSION

CONCLUSION

- After excluding patients who received intraoperative heparinization, the bleeding results were not significantly different between the two groups

- In this study, the incidence of the disease showed no significant difference, likely due to the very low number of events. Further data collection is needed.

Thank you.

Mahidol University
Wisdom of the Land

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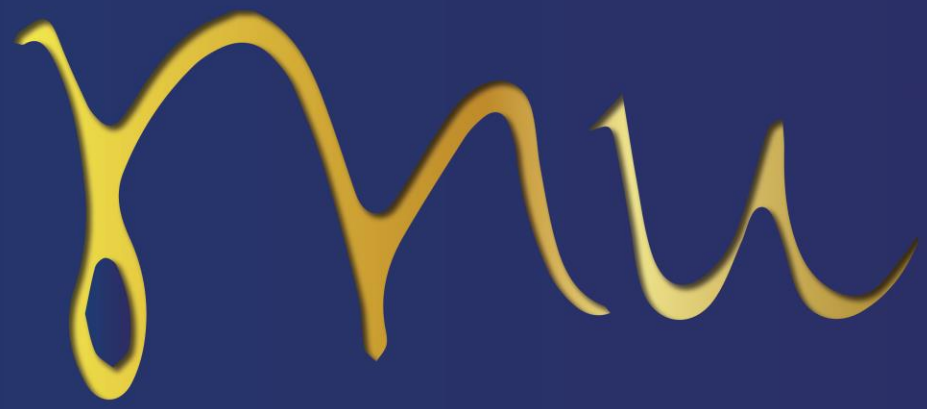

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Abstract

“Significant associated risk factors in venous thromboembolism for surgical patients in Ramathibodi Hospital”

Pimchanok Roongwarasopit, MD

Pimchanok Roongwarasopit, Nutsiri Kittitirapong
Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Background: Venous thromboembolism is a serious condition that may result in significant morbidity and mortality, especially in postoperative patient. Although VTE incidence following surgery in Thailand is low (3.6%), the associated in-hospital mortality remains high at 17%. To mitigate the risks of VTE, standardized risk assessment tools, such as the Caprini Risk Assessment Score are widely used to guide the implementation of prophylactic measures. However, the complexity of these tools often leads to inaccuracies in risk stratification.

Objective: The primary aim of this study is to identify key risk factors that are significantly associated with the development of symptomatic VTE in postoperative patients at Ramathibodi Hospital. Based on these findings, the study intends to propose a simplified effective risk assessment tool for clinical use.

Materials & Methods: A retrospective case-control study was conducted on surgical patients who underwent risk assessments using the Caprini score enrolling 82 participants in Ramathibodi hospital: 42 cases with a confirmed diagnosis of VTE (DVT and/or PE) and 42 controls matched by age, gender and operative time. Data on potential risk factors including patient demographics, surgical procedures, comorbidities, and postoperative outcomes were collected through medical records between November 2019 and July 2023. Multivariable logistic regression analysis was performed to determine specific risk factors contributed most significantly to the development of symptomatic VTE (DVT and PE).

Results: After propensity score matching, significant differences between cases and controls were observed in several risk factors. Patients with a history of obesity (BMI ≥ 25), and patients who were received PRC ≥ 2 units had a significantly higher risk of VTE (multivariate p-value = 0.020, and p = 0.041, respectively). Additionally, platelet count was significantly higher in VTE patients, as patients with platelet count > 100,000 were at higher risk to develop VTE. (multivariate p-value = 0.015)

Conclusions: The results of this study suggested that obesity, higher platelet counts and receiving more packed red cell components are significant risk factors for VTE. By these results leading to an improving revised VTE risk assessment scores of Ramathibodi hospital, which aims to reduce the incidence of imprecise evaluation in VTE risk contributing to decrease in VTE incidence and VTE related complications.

SIGNIFICANT ASSOCIATED RISK FACTORS IN VENOUS THROMBOEMBOLISM FOR SURGICAL PATIENTS IN RAMATHIBODI HOSPITAL

Pimchanok Roongwarasopit M.D.
Nutsiri Kittitirapong C.M.D.

มหาวิทยาลัยมหิดล
ปัญญาแห่งแผ่นดิน

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COA. No. MURA2023/735

Title of Project (English)	Significant associated risk factors in venous thromboembolism for surgical patients in Ramathibodi Hospital
Title of Project (Thai)	การศึกษาปัจจัยเสี่ยงสำคัญที่สัมพันธ์กับการเกิดภาวะลิ่มเลือดอุดตันหลอดเลือดดำในผู้ป่วยที่เข้ารับการผ่าตัดในภาควิชาศัลยศาสตร์ โรงพยาบาลรามาธิบดี
Type of Review	Expedited
Principal Investigator	Pimchanok Roongwarasopit
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-Investigator (s)	1. Nutsiri Kittitirapong 3. Chaowanun Pornwaragorn 2. Suthas Horsirimanont 4. Gorawee Tepsamritporn
Approval includes	1. Submission form protocol version 1 date 4/8/2023 2. Curriculum vitae 3. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	**September 22, 2023**
Date of Expiration	**September 21, 2024**

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

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Ref.2024/1149

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Type of Review	Expedited
Principal Investigator	Pimchanok Roongwarasopit
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 18/10/2024

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Date of Initial Approval	**September 22, 2023**
Renewal Date (1st)	**September 22, 2024**
Date of Expiration	**September 21, 2025**

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

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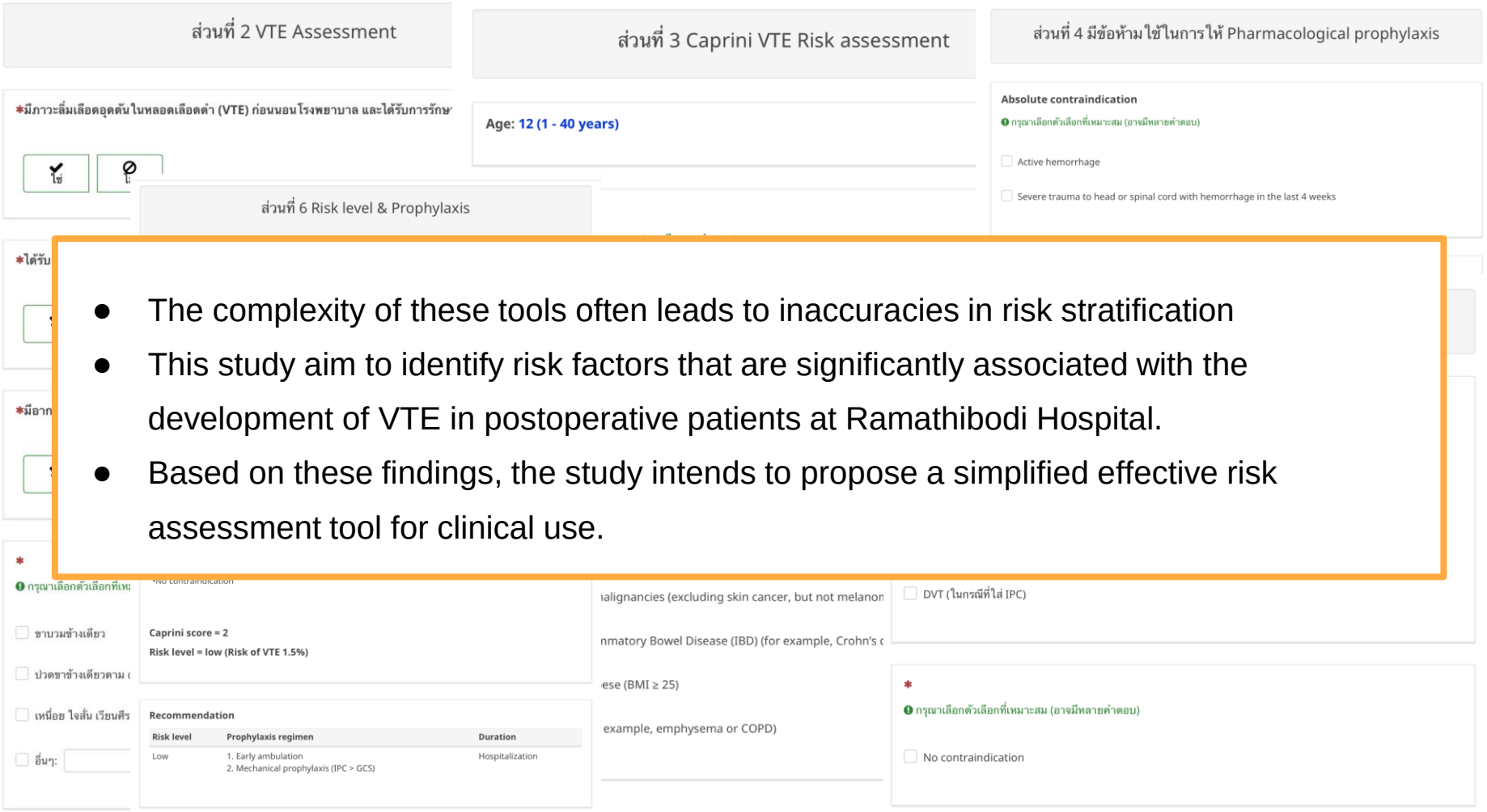
Introduction

- VTE is a serious condition that may result in significant morbidity and mortality, especially in postoperative patient.
- Although VTE incidence following surgery in Thailand is low (3.6%), the associated in-hospital mortality remains high at 17%.
- To mitigate the risks of VTE, standardized risk assessment tools, such as the Caprini Risk Assessment Score are used to guide the implementation of prophylactic measures.



- The complexity of these tools often leads to inaccuracies in risk stratification
- This study aim to identify risk factors that are significantly associated with the development of VTE in postoperative patients at Ramathibodi Hospital.
- Based on these findings, the study intends to propose a simplified effective risk assessment tool for clinical use.

Method

- A retrospective case-control study
- Study group : surgical patients in Ramathibodi hospital
- Matching Criteria = Matched for age, gender and operative time
- Standardized mean differences for matching
- Data on potential risk factors including patient demographics, surgical procedures, comorbidities, and postoperative outcomes were collected through medical records
- Duration : between November 2019 and July 2023
- Univariate and Multivariate logistic regression for analysis to determine specific risk factors contributed most significantly to the development of symptomatic VTE

Results

Table 1 : Variables before and after propensity score matching

	Before matching			After matching		
Variable	Study	Control	stddiff	Study	Control	stddiff
Age, Mean(±SD)	65(±16.36)	67(±13.04)	0.13	65(±16.36)	62(±14.07)	-0.17
Gender						
Male	17(40.5)	399(44.4)	0.07	17(40.5)	22(52.4)	0.24
Female	25(59.5)	500(55.6)		25(59.5)	20(47.6)	
Operative time, Mean(±SD)	223(±139.76)	142(±117.98)	-0.12	223(±139.76)	166(±157.8)	-0.18

*stddiff = standardized difference

Table 2 : Baseline characteristics of postoperative patients before and after propensity score matching

Variable	Before Matching		P-value	After Matching		P-value
	No VTE	VTE		No VTE	VTE	
	N = 899	N = 42		N = 42	N = 42	
Score, Mean(±SD)	6(±1.21)	6(±1.97)	0.230	6(±1.51)	6(±1.97)	0.210
BMI, Mean(±SD)	24.01(±4.94)	25(±5.66)	0.478	24.66(±5.17)	24.56(±5.66)	0.934
Platelet(K), Mean(±SD)	250(±95.41)	278(±116.31)	0.132	232(±94.57)	278(±116.31)	0.050
PRC >/= 2	111(12.35)	18(42.86)	<0.001	8(19.05)	18(42.86)	0.018
Platelet < 100k	30(3.34)	2(4.76)	0.650*	3(7.14)	2(4.76)	0.999*
Type of surgery [Minor surgery (less than 45 minutes) is planned]	56(6.23)	2(4.76)	0.999*	3(7.14)	2(4.76)	0.999*
Type of surgery [Planned major surgery lasting longer than 45 minutes (including laparoscopic and arthroscopic)]	743(82.65)	38(90.48)	0.187	34(80.95)	38(90.48)	0.212
Type of surgery [Past major surgery (more than 45 minutes) within the last month]	101(11.23)	0	0.018	4(9.52)	0	0.116
Type of surgery [Elective hip or knee joint replacement surgery]	1(0.11)	0	0.999*	0	0	-
Present and past history [Current or past malignancies (excluding skin cancer, but not melanoma)]	535(59.51)	28(66.67)	0.355	26(61.90)	28(66.67)	0.649

Variable	Before Matching		P-value	After Matching		P-value
	No VTE	VTE		No VTE	VTE	
	N = 899	N = 42		N = 42	N = 42	
Present and past history [A history of Inflammatory Bowel Disease (IBD) (for example, Crohn's disease or ulcerative colitis)]	2(0.22)	0	0.999*	0	0	-
Present and past history [Overweight or obese (BMI ≥ 25)]	86(9.57)	9(21.43)	0.030*	3(7.14)	9(21.43)	0.061
Present and past history [Lung disease (for example, emphysema or COPD)]	27(3.00)	4(9.52)	0.045*	2(4.76)	4(9.52)	0.676*
Recent Event (1 month) [Heart attack]	17(1.89)	0	0.999*	0	0	-
Recent Event (1 month) [Congestive heart failure]	55(6.12)	0	0.167*	2(4.76)	0	0.494*
Recent Event (1 month) [Serious infection (for example, pneumonia)]	21(2.34)	0	0.619*	1(2.38)	0	0.999*
Recent Event (1 month) [Broken hip, pelvis or leg]	4(0.44)	0	0.999*	0	0	-
Recent Event (1 month) [Serious trauma (for example, multiple broken bones due to a fall or car accident)]	8(0.89)	1(2.38)	0.338	0	1(2.38)	0.999*
Recent Event (1 month) [Spinal cord injury resulting in paralysis]	4(0.44)	0	0.999*	1(2.38)	0	0.999*
Recent Event (1 month) [Experienced a stroke]	14(1.56)	2(4.76)	0.157*	0	2(4.76)	0.494*
Venous disease or clotting disorder [Visible varicose veins]	18(2)	0	0.999*	2(4.76)	0	0.494*

Variable	Before Matching		P-value	After Matching		P-value
	No VTE	VTE		No VTE	VTE	
	N = 899	N = 42		N = 42	N = 42	
Venous disease or clotting disorder [Swollen legs (current)]	17(1.89)	0	0.999*	0	0	-
Venous disease or clotting disorder [Tube in blood vessel in neck or chest that delivers blood or medicine directly to heart within the last month (also called central venous access, PICC line, or port)]	33(3.67)	0	0.394	2(4.76)	0	0.494*
Venous disease or clotting disorder [History of blood clots, either Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE)]	6(0.67)	0	0.999*	1(2.38)	0	0.999*
Venous disease or clotting disorder [Family history of blood clots (thrombosis)]	1(0.11)	0	0.999*	0	0	-
Venous disease or clotting disorder [Personal or family history of positive blood test indicating an increased risk of blood clotting]	1(0.11)	0	0.999*	1(2.38)	0	0.999*
Mobility [On bed rest or restricted mobility, including a removable leg brace for less than 72 hours]	69(7.68)	4(9.52)	0.560*	6(14.29)	4(9.52)	0.500
Mobility [Confined to a bed for 72 hours or more]	108(12.01)	3(7.14)	0.339	7(16.67)	3(7.14)	0.178

Table 3 : Univariate and Multivariate Analysis of Risk Factors for Venous Thromboembolism (VTE) in postoperative patients

Variable	Univariate OR(95% CI)	P-Value	Multivariate OR(95% CI)	P-Value
Score, Mean(±SD)	1.19(0.89-1.58)	0.225		
BMI, Mean(±SD)	0.99(0.92-1.07)	0.933		
Platelet > 100K, Mean(±SD)	1.00(0.99-1.01)	0.050	1.00(1-1.01)	0.020
PRC >/= 2	3.18(1.19-8.51)	0.021	3.90(1.30-11.67)	0.015
Type of surgery [Minor surgery (less than 45 minutes) is planned]	0.65(0.10-4.10)	0.647		
Type of surgery [Planned major surgery lasting longer than 45 minutes (including laparoscopic and arthroscopic)]	2.23(0.61-8.08)	0.220		
Present and past history [Current or past malignancies (excluding skin cancer, but not melanoma)]	1.23(0.50-3.01)	0.649		
Present and past history [Overweight or obese (BMI ≥ 25)]	3.54(0.88-14.18)	0.044	4.51(0.94-21.59)	0.041
Present and past history [Lung disease (for example, emphysema or COPD)]	2.10(0.36-12.16)	0.406		
Mobility [On bed rest or restricted mobility, including a removable leg brace for less than 72 hours]	0.63(0.16-2.42)	0.503		
Mobility [Confined to a bed for 72 hours or more]	0.38(0.09-1.60)	0.190		

Table 3 : Univariate and Multivariate Analysis of Risk Factors for Venous Thromboembolism (VTE) in postoperative patients

Variable	Univariate OR(95% CI)	P-Value	Multivariate OR(95% CI)	P-Value
Score, Mean(±SD)	1.19(0.89-1.58)	0.225		
BMI, Mean(±SD)	0.99(0.92-1.07)	0.933		
Platelet > 100K, Mean(±SD)	1.00(0.99-1.01)	0.050	1.00(1-1.01)	0.020
PRC >/= 2	3.18(1.19-8.51)	0.021	3.90(1.30-11.67)	0.015
Type of surgery [Minor surgery (less than 45 minutes) is planned]	0.65(0.10-4.10)	0.647		
Type of surgery [Planned major surgery lasting longer than 45 minutes (including laparoscopic and arthroscopic)]	2.23(0.61-8.08)	0.220		
Present and past history [Current or past malignancies (excluding skin cancer, but not melanoma)]	1.23(0.50-3.01)	0.649		
Present and past history [Overweight or obese (BMI ≥ 25)]	3.54(0.88-14.18)	0.044	4.51(0.94-21.59)	0.041
Present and past history [Lung disease (for example, emphysema or COPD)]	2.10(0.36-12.16)	0.406		
Mobility [On bed rest or restricted mobility, including a removable leg brace for less than 72 hours]	0.63(0.16-2.42)	0.503		
Mobility [Confined to a bed for 72 hours or more]	0.38(0.09-1.60)	0.190		

Discussion

- Prior to matching, some key differences were observed between the study and control groups, particularly in terms of operative time, age, and gender. However, after matching, most of these differences were mitigated.
- These results highlight the importance of adjusting for confounders such as age, gender, and operative time in studies of this nature, to reduce potential biases and improve the reliability of the findings.

Discussion

- According to univariate and multivariate logistic regression analysis, we identified several key risk factors :
- 1. **PRC >/= 2 levels** were significantly higher in patients who developed VTE, both in univariate and multivariate analyses.
- 2. **Overweight and obesity (BMI ≥ 25)** were associated with a higher risk of VTE, although the results were borderline significant in univariate and multivariate analyses ($p = 0.044$ and $p = 0.041$, respectively).
- 3. **Platelet level** as higher platelet counts were associated with VTE in the multivariate analysis (OR=1.00, p=0.020), suggesting a potential role of platelet activation and aggregation in the pathogenesis of VTE.

Limitation

- **Retrospective Design** ; selection bias and information bias
- **Residual Confounding**
- **Sample Size and Power** ; the number of patients with VTE is relatively small for detecting subtle differences in risk factors
- **Single-Center Study** ; lack of diversity (both patient characteristics and treatment)

Conclusion

This study identifies significant factors, including **PRC ≥2, elevated platelet counts, and obesity**, as significant risk factors for venous thromboembolism (VTE), with both univariate and multivariate analyses supporting these associations.

However, the retrospective design and small sample size limit the generalizability of these findings.

Future research should focus on larger, prospective studies that include a wider range of variables to further elucidate VTE pathogenesis. Additionally, exploring the role of inflammatory and hematologic markers—like PRC and platelet count—could help develop more accurate predictive tools and targeted prevention strategies for VTE.

Thank you

Abstract

Pensiri Sansamart, MD

Donor-site morbidity of rectus sheath sparing tram flap in breast reconstruction: A retrospective review

Pensiri Sansamart, Sarayuth Damrongwongsiri

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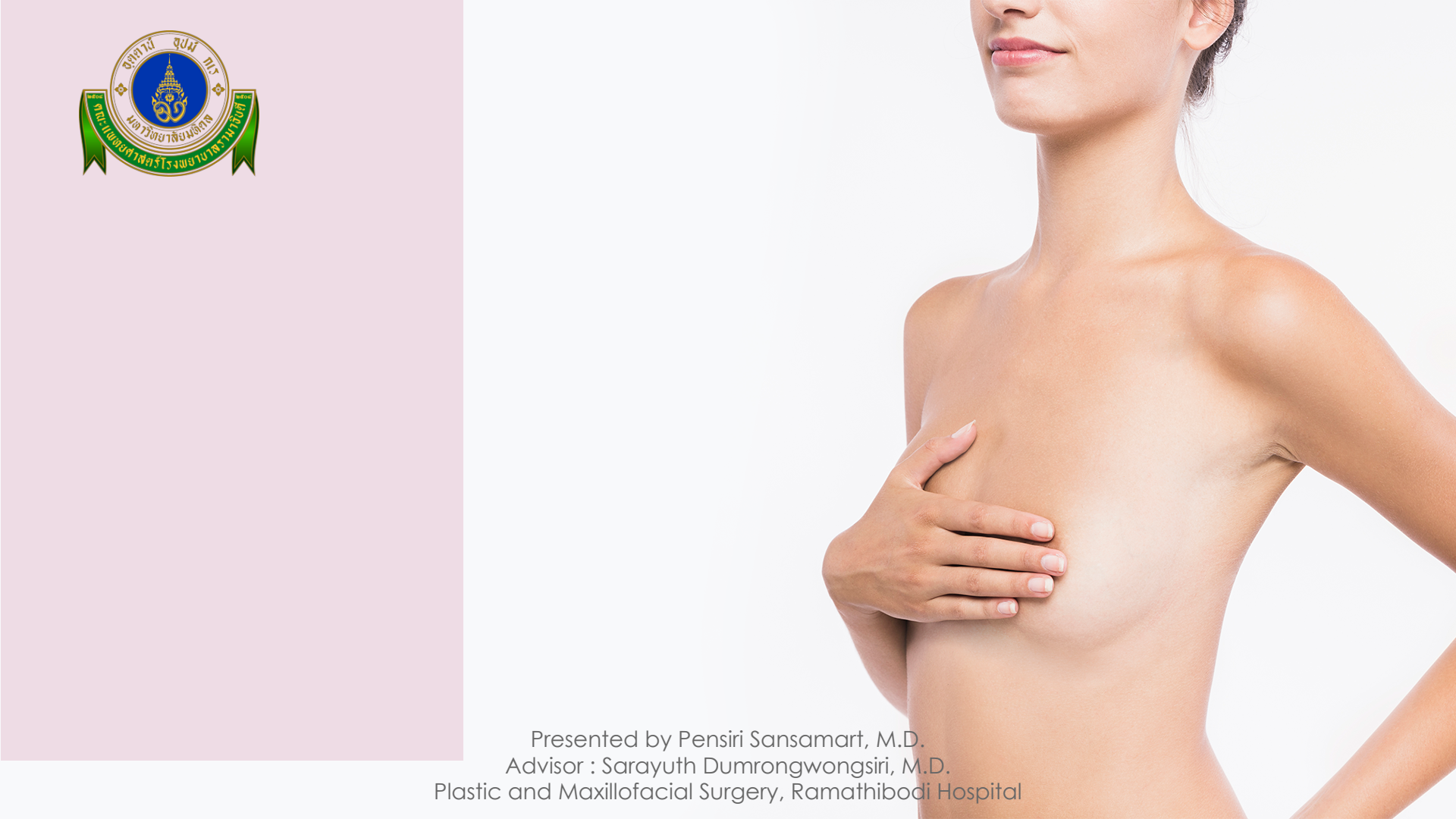
Background: The transverse rectus abdominis myocutaneous (TRAM) flap has been widely used for autologous breast reconstruction for over severaldecades. While it provides reliable soft tissue coverage, donor-site morbidity remains a significant concern, particularly regarding hernia formation, abdominal bulging, postoperative pain, and aesthetic outcomes. Conventional TRAM with mesh reinforcement aims to reduce these complications, while the rectus-sparing TRAM technique preserves muscle integrity to potentially improve functional and aesthetic results. This study compares the donor-site morbidity associated with these two techniques to guide surgical decision-making and optimize patient outcomes.

Methods: A retrospective cohort study was conducted on patients who underwent breast reconstruction using TRAM flaps at Ramathibodi Hospital between 2009 and 2020. Patients were categorized into two groups:
1.Conventional TRAM flap with mesh reinforcement
2.Rectus sheath sparingTRAM flap
Data were collected from electronic medical records, including demographic factors (age, BMI, comorbidities), oncologic details (cancer stage, radiation, and hormone replacement therapy) and postoperative outcomes. The primary outcome measures included the incidence of donor-site hernia and abdominal bulging.
Secondary outcomes assessed included pain, sensory deficits, and aesthetic concerns based on clinical evaluations and patient-reported outcomes. Statistical analyses were performed to compare complication rates and identifypotential risk factors.

Results: Atotal of 49 patients were included, with 17 in the conventional TRAM with mesh group and 32 in the Rectus sheath sparing TRAM. The incidence of hernia was 17.7% (3 from 17) in the mesh group versus0% in the rectus-sparing group(p= 0.022). Abdominal bulging occurred in 23.5% (4 from 17) of patients with mesh reinforcement compared to 6.3% (2 from 32) in Rectus sheath sparing(p = 0.037). Patients in the rectus-sparing group reported lower postoperative pain scores and higher satisfaction with abdominal contour.No significant differences were observed in surgical site infections or seroma formation between groups**.**

Conclusion: The Rectus sheath sparing TRAM technique without mesh demonstrates comparable or reduced donor-site morbidity relative to conventional TRAM with mesh, particularly in reducing hernia risk and improving abdominalaesthetics. These findings suggest that preserving rectus sheath integrity may enhance postoperative recovery while maintaining reconstructive efficacy. Further prospective studies are warranted to validate these findings and refine reconstructive approaches in breast cancer patients.



Presented by Pensiri Sansamart, M.D.
Advisor : Sarayuth Dumrongwongsiri, M.D.
Plastic and Maxillofacial Surgery, Ramathibodi Hospital

Ethic Approval

Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University
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COA. MURA2022/653

Title of Project (English)	Donor-site morbidity of rectus sheath sparing TRAM flap in breast reconstruction
Title of Project (Thai)	การศึกษาเปรียบเทียบอัตราการเกิดภาวะแทรกซ้อนของผนังหน้าท้องหลังผ่าตัดเสริมสร้างเต้านมด้วยเนื้อเยื่อบริเวณหน้าท้อง
Type of Review	Expedited
Principal Investigator	Pensiri Sansamart
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator	Sarayuth Dumrongwongsiri
Approval includes	1. Submission form protocol version 1 date 28/10/2022 2. Case record form 3. Curriculum vitae 4. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

DONOR- SITE MORBIDITY OF
RECTUS SHEATH SPARING TRAM FLAP IN BREAST RECONSTRUCTION

BACKGROUND

Overview

- The transverse rectus abdominis myocutaneous flap was introduced more than 40 years
- The TRAM flap provide a large volume of skin and fat for breast reconstruction , especially valuable in delayed reconstruction and post - mastectomy radiation.

Rationale

- ✦ Donor-site issues
  - ✦ Abdominal bulge and hernia
  - ✦ Weakness -> interference with activities of daily living
- ✦ Additional muscle sacrifice
  - ✦Decrease sensation
  - ✦Diminish function strength

Research Question

Primary Endpoint

- Incidence of abdominal wall morbidity : hernia & bulging after TRAM flap reconstruction in Ramathibodi hospital

Secondary Endpoint

- Satisfaction
- Other abdominal symptoms
  - Pain
  - Discomforts

METHOD

DONOR- SITE MORBIDITY OF
RECTUS SHEATH SPARING TRAM FLAP IN BREAST RECONSTRUCTION

P

Patients who underwent breast reconstruction

I

Rectus sheath sparing technique

C

Pedicled TRAM flap
(with MESH)

O

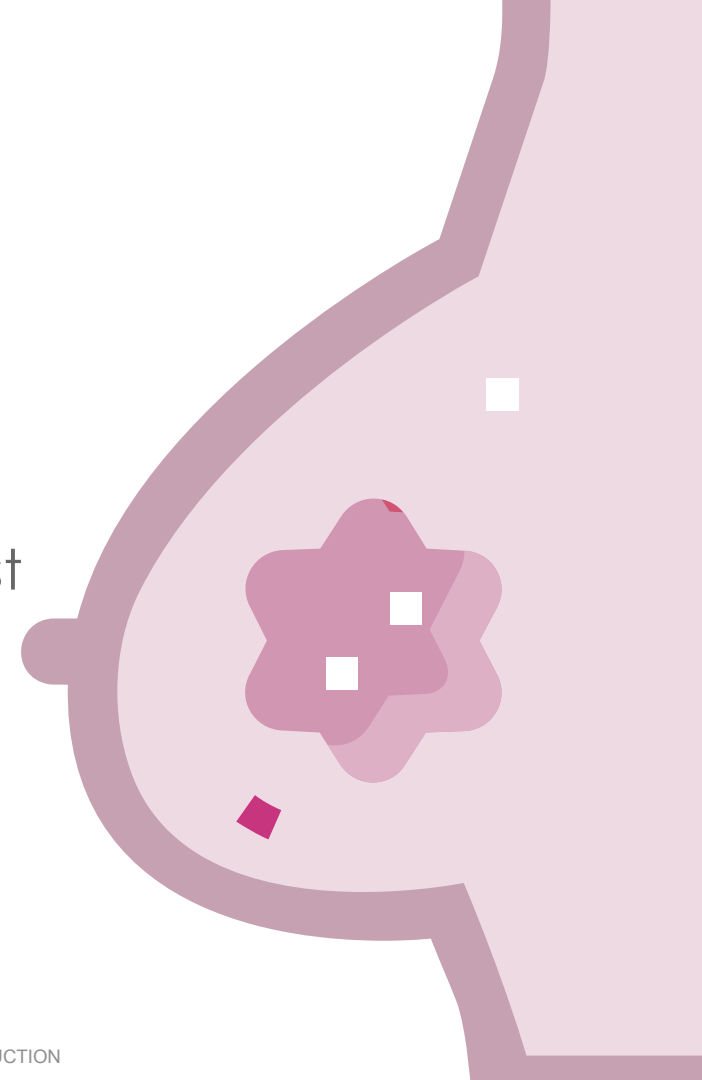
Donor site morbidity rate
(bulging / hernia)

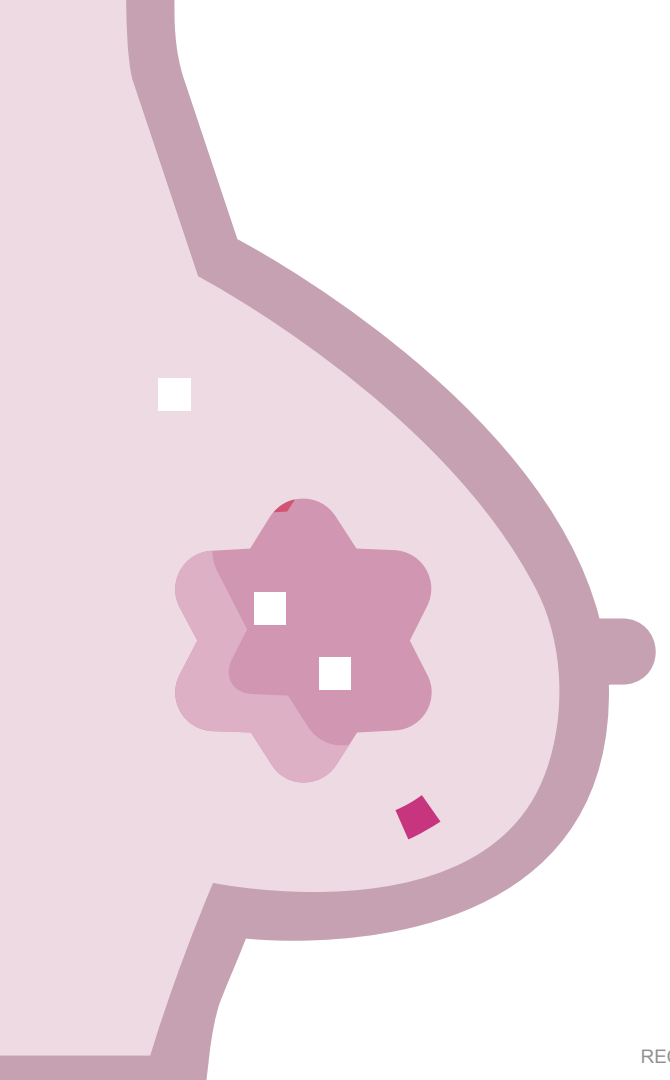
- Study Design -

Retrospective Cohort Study

Inclusion Criteria

- Patients who underwent TRAM flap breast reconstruction in Ramathibodi hospital

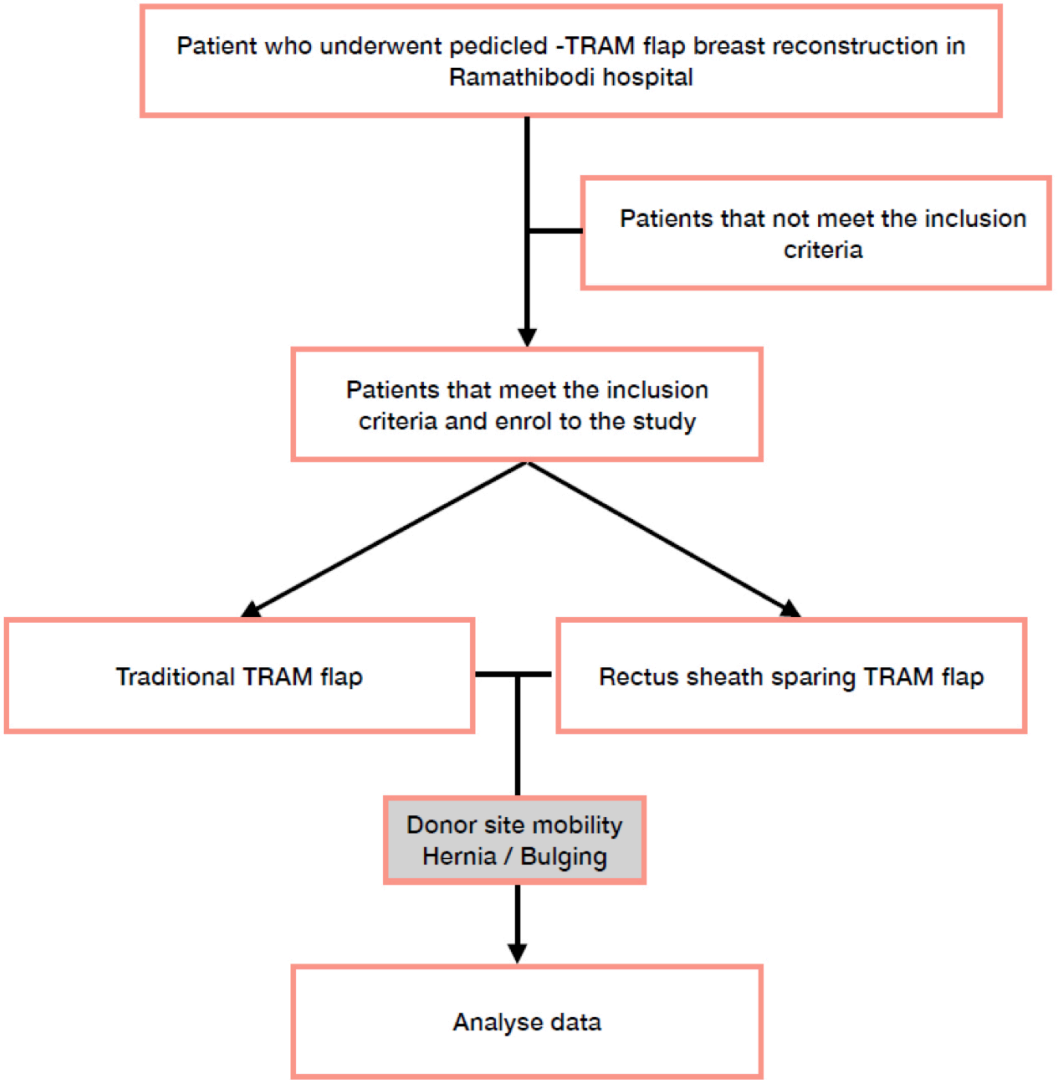




Exclusion Criteria

- Patients with multiple abdominal surgical intervention or procedure prior to the study
- Patient disease that might influence abdominal wall function
- Previously diagnosed hernia
- Connective tissue disease
- Remote area , loss F/U

Protocol Flow chart



Sample Size = 49

$$n_1 = \left[\frac{z_{1-\frac{\alpha}{2}} \sqrt{\bar{p}\bar{q}\left(1+\frac{1}{r}\right)} + z_{1-\beta} \sqrt{p_1 q_1 + \frac{p_2 q_2}{r}}}{\Delta} \right]^2$$

$$r = \frac{n_2}{n_1}, q_1 = 1 - p_1, q_2 = 1 - p_2$$

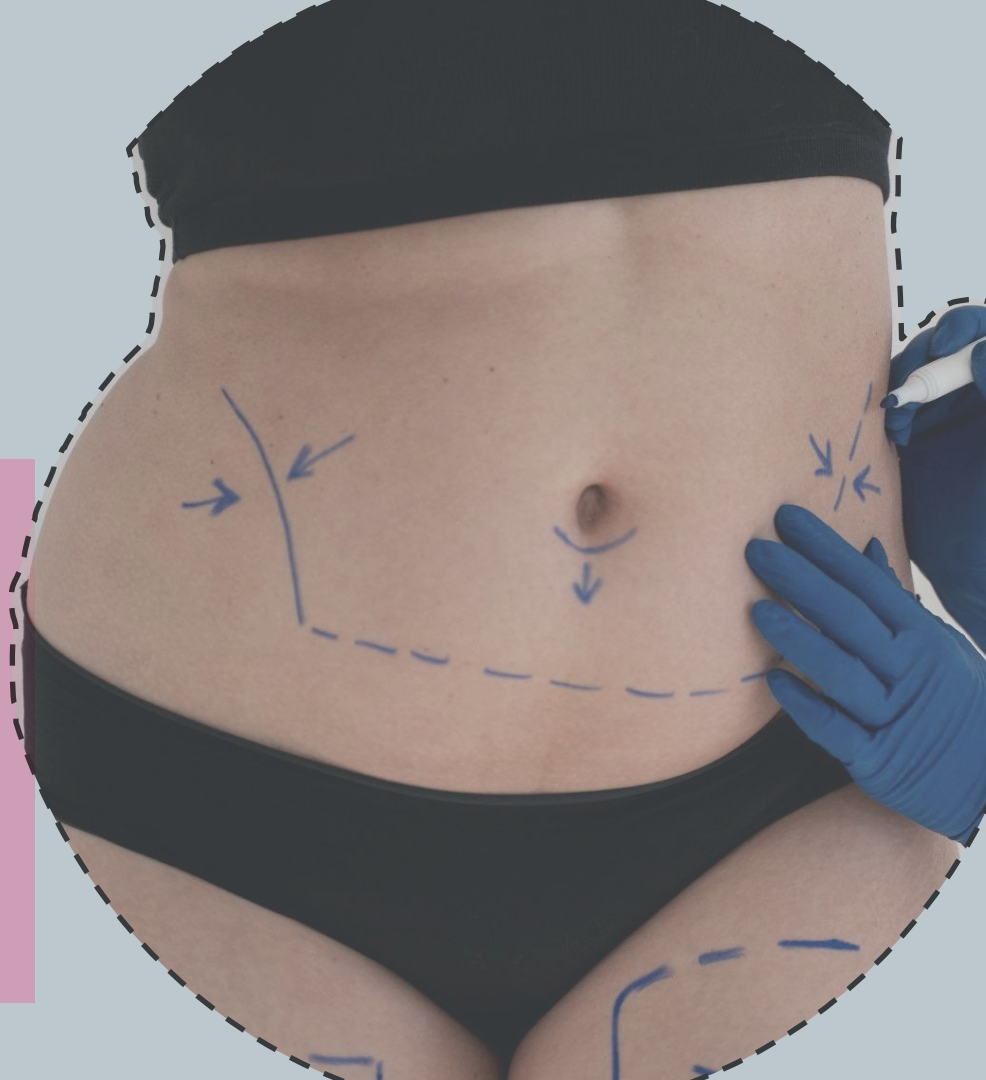
$$\bar{p} = \frac{p_1 + p_2 r}{1+r}, \bar{q} = 1 - \bar{p}$$

$$m_1 = \frac{n_1}{4} \left(1 + \sqrt{1 + \frac{2(r+1)}{n_1 r |p_2 - p_1|}} \right)^2$$

การคำนวณขนาดตัวอย่างของงานวิจัยนี้มาจากการศึกษาภาวะแทรกซ้อน และการเกิดไส้เลื่อนหลังผ่าตัดเสริมสร้างเต้านมด้วยเนื้อเยื่อหน้าท้องที่ตีพิมพ์ในปี พ.ศ. 2557 โดยเก็บข้อมูลจากผู้ป่วย 7,929 คนใน 6 ปี

RESULTS

DONER-SITE MORBIDITY OF
RECTUS SHEATH SPARING TRAM FLAP IN BREAST RECONSTRUCTION



Demographic Data

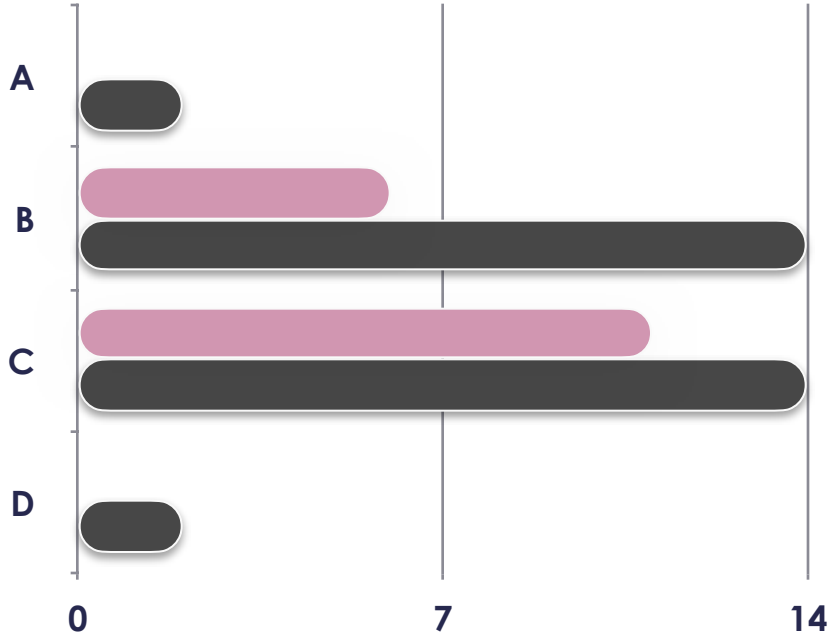
Variable	Pedicled TRAM (n = 17)	Rectus Sheath Sparing TRAM (n = 32)	P-value
Age (year); mean ± SD	57.5 ± 10.3	54.1 ± 10.2	0.263
Body Wight (kg.); mean ± SD	59.6 ± 9.2	59.6 ± 13.2	0.999
Height (cm.); mean ± SD	155.8 ± 4.8	152.8 ± 4.8	0.051
BMI (kg/m^2); mean ± SD	24.5 ± 3.5	25.5 ± 4.9	0.476
Underlying disease; n (%)			
DM	4 (25.0)	4 (12.9)	0.416
HT	7 (43.8)	10 (32.3)	0.437
DLP	8 (50.0)	13 (41.9)	0.598
Steroid usage	2 (11.8)	1 (3.1)	0.273

Demographic Data

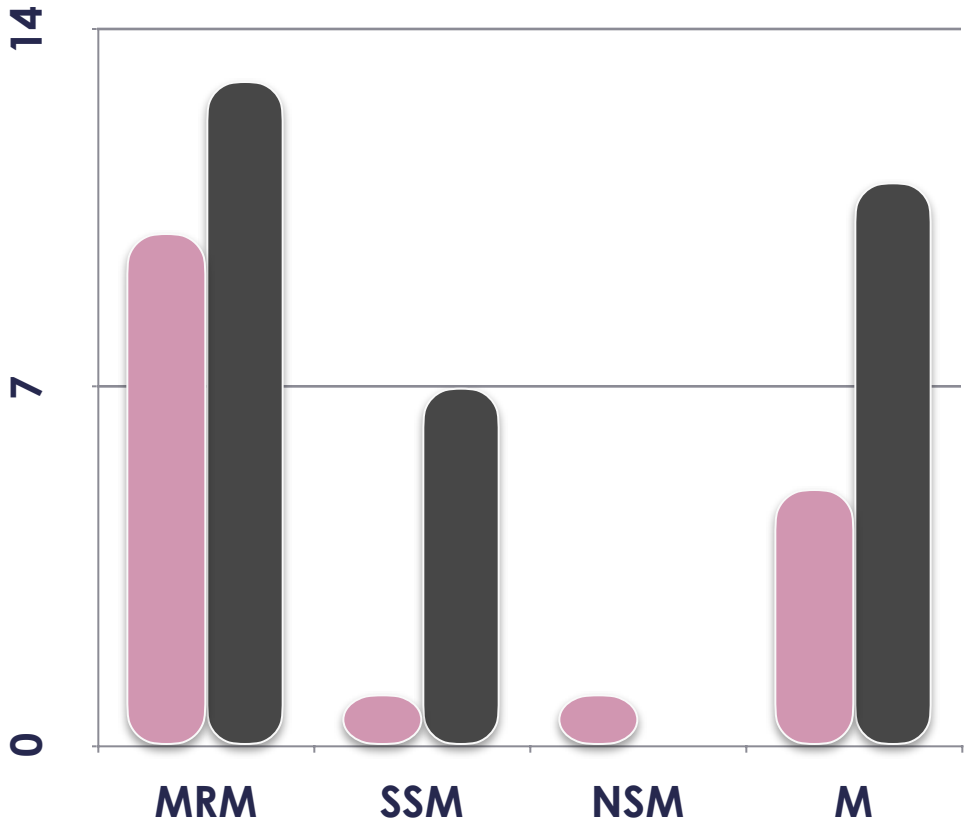
Variable	Pedicled TRAM (n = 17)	Rectus Sheath Sparing TRAM (n = 32)	P-value
CMT; n (%)	13 (81.3)	24 (80.0)	> 0.999
HRT; n (%)	15 (100.0)	26 (83.9)	0.157
RT; n (%)	13 (81.3)	22 (71.0)	0.505
Previous Surgery ; n (%)	2 (11.8)	3 (9.7)	> 0.999
Smoking; n (%)	-	-	-
Alcohol drinking; n (%)	2 (11.8)	2 (6.3)	0.602

Demographic Data

Variable	Pedicled TRAM (n = 17)	Rectus Sheath Sparing TRAM (n = 32)	P-value
Bra Cup (Before Reconstruction)			
A	0 (0.0)	2 (6.3)	0.465
B	6 (35.3)	14 (43.8)	
C	11 (64.7)	14 (43.8)	
D	0 (0.0)	2 (6.3)	



Breast Procedure

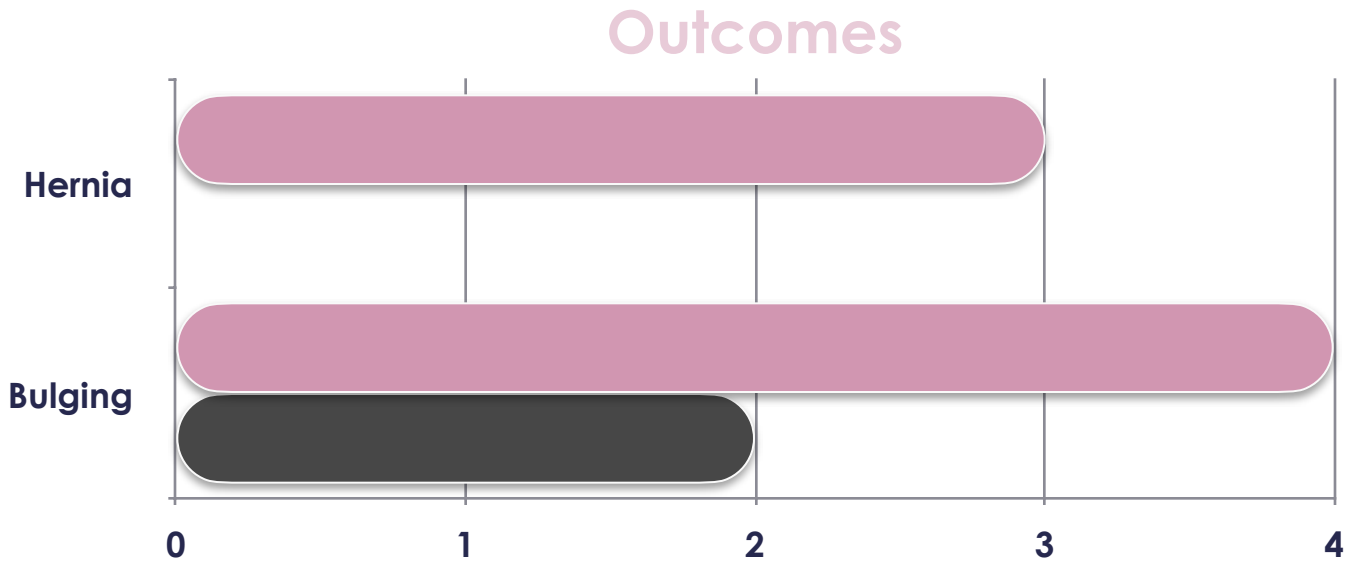


Variable	Pedicled TRAM (n = 17)	Rectus Sheath Sparing TRAM (n = 32)	P-value
Breast Procedure			
MRM	10 (58.8)	13 (41.9)	0.204
SSM	1 (5.9)	7 (22.6)	
NSM	1 (5.9)	0 (0.0)	
Mastectomy	5 (29.4)	11 (35.5)	

Demographic Data

Variable	Pedicled TRAM (n = 17)	Rectus Sheath Sparing TRAM (n = 32)	P-value
Bra Cup (Before Reconstruction)			
A	0 (0.0)	2 (6.3)	0.465
B	6 (35.3)	14 (43.8)	
C	11 (64.7)	14 (43.8)	
D	0 (0.0)	2 (6.3)	

Donor Site Morbidity



Variable	Pedicled TRAM (n = 17)	Rectus Sheath Sparing TRAM (n = 32)	P-value
Hernia; n (%)	3 (17.7)	0 (0.0)	**0.037**
Bulging; n (%)	4 (23.5)	2 (6.3)	0.164

Complications

Variable	Pedicled TRAM (n = 17)	Rectus Sheath Sparing TRAM (n = 32)	P-value
Immediate complication; n (%)	2 (11.8)	9 (28.1)	0.287
Trans-abdominal surgery ; n (%)	7 (41.2)	3 (9.7)	**0.022**

Donor Site Morbidity

Outcomes

Variable	Pedicled TRAM (n = 17)	Rectus Sheath Sparing TRAM (n = 32)	P-value
Hernia; n (%)	3 (17.7)	0 (0.0)	**0.037**
Bulging; n (%)	4 (23.5)	2 (6.3)	0.164
Aesthetic concern; n (%)	3 (17.7)	4 (12.5)	0.681

Discussion

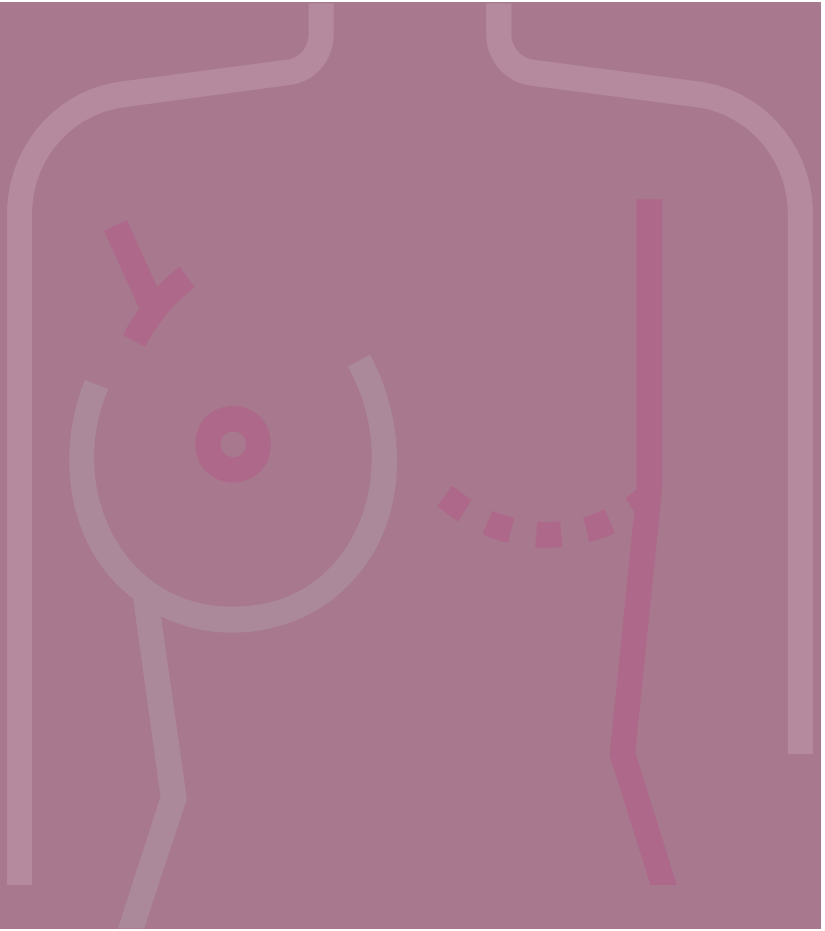
- Rectus-sparing TRAM m demonstrated a lower incidence of donor-site morbidity in hernia and bulging
- Postoperative pain and sensory disturbances were reduced in the rectus-sparing group
- Aesthetic outcomes favored the rectus-sparing technique, with improved abdominal contour and fewer complaints of donor-site deformity.
- No significant differences were noted in surgical site infection or seroma rates
    - Mesh does not increase wound-related complications.

Clinical Implication

- Our findings suggest that rectus-sparing techniques may **provide equivalent or superior abdominal wall integrity without the need for prosthetic material.**

- The rectus-sparing approach preserves the myofascial unit, potentially improving core strength and reducing long-term physical impairment.

- Flap selection must be patient-specific
    - The conventional TRAM may still be warranted in patients requiring larger flap volumes, where vascular supply is a limiting factor.



Strength

- Longitudinal data spanning over a decade of TRAM-based reconstructions.
- Direct comparison of two commonly used abdominal flap techniques.
- Multidimensional outcome assessment including functional, aesthetic, and pain-related endpoints.

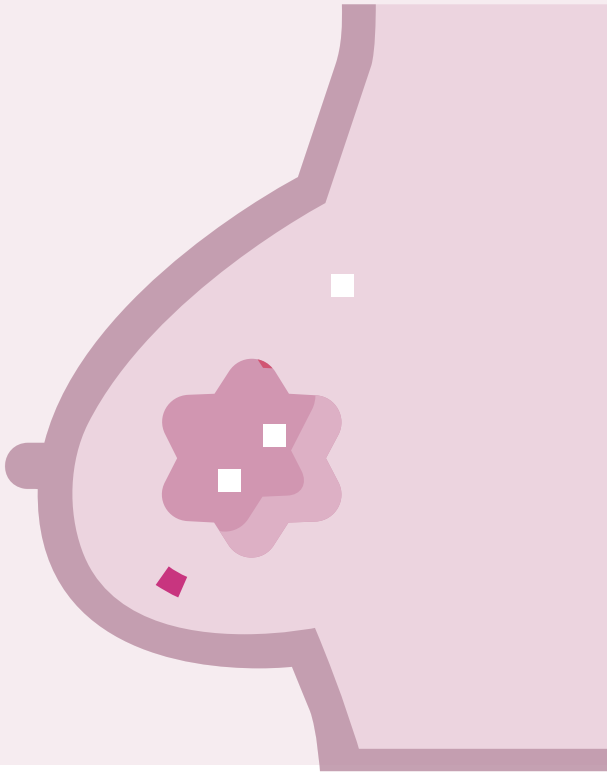
Limitation

- Retrospective design, subject to selection bias.
- Heterogeneity in mesh types and variations in surgical technique may impact outcomes.

Future Direction

- Objective assessment of core strength and physical function postoperatively to quantify long-term impact.
- Development of an evidence-based reconstructive algorithm integrating patient factors, oncologic considerations, and donor-site morbidity risk.

Q & A



THANK YOU

DONER-SITE MORBIDITY OF
RECTUS SHEATH SPARING TRAM FLAP IN BREAST RECONSTRUCTION

Abstract

"Factor associated with perioperative major adverse cardiovascular events (MACE) of patient undergone non-cardiac vascular surgery"

Pattarapon Chotisun, MD

Pattarapon Chotisun, Piyanut Pootracool, Suthas Horsirimanont, Nutsiri Kittitirapong, Chaowanun Pornwaragorn, Gorawee Tepsamrithporn

Division of Vascular Surgery, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, 10400, Thailand

Background: Perioperative major adverse cardiovascular events (MACEs) are associated with the morbidity and mortality of patients undergoing noncardiac vascular surgery. It is thus essential to understand the risk factors associated with such complications to aid the preoperative and postoperative care of such patients.

Objectives: To identify factors associated with perioperative major adverse cardiovascular events in patients undergoing noncardiac vascular surgery of Ramathibodi hospital.

Materials and Methods: This work involved a retrospective study of patients who underwent noncardiac vascular surgery at the Department of Vascular Surgery, Faculty of Medicine, Ramathibodi Hospital, Bangkok, Thailand from 2011 to 2020, aimed at analysing the risk factors associated with MACEs perioperatively and within 30 days postoperatively after undergoing noncardiac vascular surgery (perioperative MACEs). The patients were classified into two groups: those with and those without perioperative MACEs. The obtained data were subjected to univariate and multivariate analyses.

Results: The study findings were as follows. There were 1,169 patients, 740 (63.3%) of whom were male, with a mean age of 69.59 years. Overall, 152 patients (13%) had perioperative MACEs. The risk factors identified by univariate analysis as being associated with such complications included age [odds ratio (OR), 1.02 (95% CI, 1.01–1.04); P<0.001], history of congestive heart failure (4.1, 2.03–8.28; P<0.001), atrial fibrillation (1.67, 1.03–2.70; P=0.035), chronic kidney disease stage 4 (3.47, 1.71–7.02; P<0.001), white blood cell count (1.06, 1.03–1.09; P<0.001), albumin level (0.92, 0.9–0.95; P<0.001), left ventricular ejection fraction (0.96, 0.94–0.97; P<0.001), American Society of Anesthesiologists risk classification (ASARC) 4 (2.59, 1.74–3.85; P<0.001), intraoperative red blood cell transfusion (2.6, 1.82–3.7; P<0.001), intraoperative blood loss (1.00, 1.00–1.01; P<0.001), abdominal aortic aneurysm surgery (4.54, 1.37–14.91; P=0.013) and major amputation (7.66, 2.19–26.81; P<0.001). Meanwhile, multivariate analysis identified ASARC >3 (2.19, 1.33-3.59; P=0.002), serum albumin level (0.93, 0.90-0.97; P<0.001), intraoperative blood loss (1.00; 1.0001-1.0005; P=0.002) and left ventricular ejection fraction (0.96; 0.94-0.98; P<0.0001).

Conclusions: MACEs were associated with risk factors such as blood albumin level, left ventricular ejection fraction, intraoperative blood loss and American Society of Anesthesiologists risk classification >3. Medical teams should assess such risk factors in patient undergoing major vascular surgery to help reduce the incidence of perioperative MACEs.

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Factors associated with perioperative major adverse cardiovascular events in patients undergoing noncardiac vascular surgery

Pattarapon Chotisun, MD

Assoc.prof. Piyanut Pootracool

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COA. MURA2022/203

Title of Project (English)	Factor associated with perioperative major adverse cardiovascular events (MACE) of patient undergone non-cardiac vascular surgery in department of vascular surgery; Ramathibodi hospital
Title of Project (Thai)	ปัจจัยที่สัมพันธ์กับการเกิดโรคที่เกิดจากเส้นเลือดผิดปกติรุนแรงหลังการผ่าตัดในผู้ป่วยที่ได้รับการผ่าตัดหลอดเลือดของแผนกศัลยกรรมหลอดเลือดของโรงพยาบาลรามาธิบดี
Type of Review	Expedited
Principal Investigator	Pattarapon Chotisun
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator (s)	1. Piyanut Pootracool 2. Surasak Leelaudomlipi 3. Suthas Horsirimanont 4. Nuttaporn Arpornsujaritkun 5. Nutsiri Kittitirapong 6. Bundit Sakulchairungrueng 7. Goragoch Gesprasert 8. Chaowanan Pornwarakorn 9. Gorawee Tepsamrithporn
Approval includes	1. Submission form protocol version 2 date 24/1/2022 2. Information sheet and consent form version 1 date 23/11/2021 3. Curriculum vitae 4. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	March 23, 2022
Date of Expiration	March 22, 2023

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

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COA. MURA2022/203
Ref.2024/666

Title of Project (English)	Factor associated with perioperative major adverse cardiovascular events (MACE) of patient undergone non-cardiac vascular surgery in department of vascular surgery; Ramathibodi hospital
Title of Project (Thai)	ปัจจัยที่สัมพันธ์กับการเกิดโรคที่เกิดจากเส้นเลือดผิดปกติรุนแรงหลังการผ่าตัดในผู้ป่วยที่ได้รับการผ่าตัดหลอดเลือดของแผนกศัลยกรรมหลอดเลือดของโรงพยาบาลรามาธิบดี
Type of Review	Expedited
Principal Investigator	Pattarapon Chotisun
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 21/06/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	March 23, 2022
Renewal Date (2nd)	March 23, 2024
Date of Expiration	March 22, 2025

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Introduction

- Patients undergoing non-cardiac vascular surgery were are known to be at high risk of intraoperative and postoperative complications cause of
  - having multiple comorbidities
  - major vascular procedure was intermediate and high risk for perioperative cardiovascular death and myocardial infarction as well
- These risk resulted in perioperative complication especially in perioperative major adverse cardiovascular events (MACE)
- Incidence of perioperative MACE in global is about 6.5-47%

Introduction

- There are previous studies mainly conducted in Western populations, with while to the best of our knowledge, no such studies have been conducted in the Thai population, which was a population the focus of our primary care.
- This study aims to investigate the factors associated with major adverse cardiovascular events (MACE) perioperatively and within 30 days after major vascular surgery at Ramathibodi Hospital

Material and Methods

- Retrospective cohort study
- Patients who underwent non-cardiac vascular surgery in at the Department of Vascular Surgery, Faculty of Medicine, Ramathibodi Hospital, Bangkok, Thailand. Data from 2014 to 2020
- N = 1,169

Inclusion and exclusion criteria

Inclusion

- Patients who underwent major vascular surgery, including the **following five major procedures.**

Exclusion

- Patients who underwent vascular surgery under local anaesthesia.

Mode of operation
Operation for hemodialysis access
- **Central venous catheter**
- **Arteriovenous access**
- **Continuous ambulatory peritoneal dialysis (CAPD)**
- **Endovascular treatment for Arteriovenous access**
Operation for arterial occlusive disease
- **Open revascularization**
- **Endovascular revascularization**
Operation for arterial aneurysm
- **Open surgery for arterial aneurysm**
- **Endovascular repair for arterial aneurysm**
Operation for carotid artery stenosis
- **Carotid endarterectomy (CEA)**
- **Carotid arterial stenting (CAS)**
Major Amputation
- **Amputation (AKA)**
- **Amputation (BKA)**

Outcome

Primary outcome

- Factors associated with major adverse cardiovascular events (MACE) within 30 days after major vascular surgery

Secondary outcome

- Mortality in 30 days after major vascular surgery or vascular surgery
- Perioperative complications within 30 days after major vascular surgery

Results

- 1,169 patients who underwent vascular surgery were included for analysis
- Incidence of perioperative major adverse cardiovascular events (MACE) within 30 days after surgery was 13 %

Patient characteristics

- Preoperative variables
  - Mean age was 69.59 years.
  - The majority of the patients were male (63.3 %)

Table 1 showing the risk factors and preoperative medical conditions (Preoperative characteristics)

Preoperative characteristics	**Total**
	N= 1,169
Age, Mean(±SD)	69.59(±12.42)
Sex	
Male	740(63.30)
Female	429(36.70)
BMI, Mean(±SD)	23.32(±4.37)
History of smoking	
Never	712(61.01)
Past	360(30.85)
Current	95(8.14)
Previous aortic surgery	68(5.83)
Underlying disease	
Hypertension	971(83.20)
Hyperlipidemia	548(46.96)
Diabetes mellitus	575(49.27)
Stroke	201(17.24)
History of congestive heart failure (CHF)	36(3.08)
Valvular heart disease	82(7.03)
Chronic obstructive pulmonary disease (COPD)	74(6.34)
Coronary arterial disease	326(27.93)
Atrial fibrillation	128(10.97)
Chronic kidney disease	
None	148(12.68)
eGFR ≥ 60	263(22.54)
eGFR 30-59	394(33.76)
eGFR 15-29	145(12.43)
eGFR < 15	217(18.59)
Chronic ulcer wound of leg	517(44.34)

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Patient characteristics

- Intraoperative variables
  - Most surgical procedures (86.23%) were performed under General Anaesthesia

Preoperative characteristics	Total N= 1,169
Current medication	
P2Y12 antagonist use	276(23.65)
Warfarin use	78(6.68)
ASA use	662(56.73)
Sulfonylurea use	145(12.43)
Preoperative laboratory (within 3 months)	
Hb (g/dL), Mean(+SD)	11.16(±2.31)
WBC, Median (p25, p75)	8.5(6.5,11.3)
Serum albumin (g/dL), Mean(+SD)	30.24(±7.18)
Left ventricular ejection fraction, Mean(±SD)	58.66(±12.01)
EKG 12 lead	
Non ischemic pattern	1,044(89.31)
Ischemic pattern	125(10.69)
Time to operation after admission (hour), Median (p25, p75)	28.06(15.15,116.25)
ASA classification	
ASA1	0(0)
ASA2	38(3.25)
ASA3	594(50.86)
ASA4	485(41.52)
ASA5	51(4.37)
ASA6	0(0)

Table 2 showing Intraoperative variables

Intraoperative variables	Total N= 1,169
Intraoperative red blood cell transfusion	516(44.14)
Type of anesthesia	
Regional anesthesia (RA)	96(8.21)
General anesthesia (GA)	1008(86.23)
Monitored anesthesia care (MAC)	65(5.56)
Estimated blood loss (ml), Median (p25, p75)	300(100,600)

Patient characteristics

- Mode of operation
- Arterial occlusive disease was the most common operations, highest accounting for 52.1 % of the total.

Table 3 showing vascular surgical procedures (Mode of operation)

Mode of operation	n (%)
Operation for hemodialysis access	67(5.73)
- Central venous catheter	3(0.26)
- Arteriovenous access	27(2.31)
- Continuous ambulatory peritoneal dialysis (CAPD)	8(0.68)
- Endovascular treatment for Arteriovenous access	29(2.48)
Operation for arterial occlusive disease	609(52.10)
- Open revascularization	289(24.72)
- Endovascular revascularization	320(27.37)
Operation for arterial aneurysm	359(30.71)
- Open surgery for arterial aneurysm	47(4.02)
- Endovascular repair for arterial aneurysm	312(26.69)
Operation for carotid artery stenosis	47(4.02)
- Carotid endarterectomy (CEA)	46(3.93)
- Carotid arterial stenting (CAS)	1(0.09)
Major Amputation	87(7.44)
- Amputation (AKA)	42(3.59)
- Amputation (BKA)	45(3.85)

Perioperative complications

Table 4 showing perioperative and postoperative vascular complications in 30 days after surgery

Perioperative complications	**N (%)**
Perioperative MACE	152 (13)
Perioperative death by any causes	67 (5.73)
Perioperative myocardial infarction	44 (3.76)
Perioperative stroke	21 (1.79)
Perioperative congestive heart failure	64 (5.47)
Wound complication Surgical site infection Hematoma at surgical site	 38(3.25) 39(3.34)
Perioperative pneumonia	75(6.42)
Prolong ventilator	34(2.91)

Results (univariate analysis)

Table 5 showing the univariate analysis of risk factors for Perioperative MACE

Variable	No MACE N =1,017	MACE N =152	Univariate analysis OR (95% CI)	P-value
Age, Mean(±SD)	69.11(±12.51)	72.76(±11.30)	1.02(1.01-1.04)	0.001
Sex				
Male	644(63.32)	96(63.16)	1	-
Female	373(36.68)	56(36.84)	1.01(0.70-1.43)	0.968
BMI, Mean(±SD)	23.39(±4.40)	22.82(±4.07)	0.96(0.93-1.01)	0.130
History of smoking				
Never	613(60.28)	99(66)	1	-
Past	319(31.37)	41(27.33)	0.79(0.53-1.17)	0.249
Current	85(8.36)	10(6.67)	0.72(0.36-1.45)	0.367
Previous aortic surgery	57(5.60)	11(7.33)	1.33(0.68-2.60)	0.400
Hypertension	847(83.28)	12482.67	0.95(0.60-1.50)	0.850
Hyperlipidemia	482(47.39)	66(44)	0.87(0.61-1.23)	0.437
Diabetes mellitus	499(49.07)	76(50.67)	1.06(0.75-1.50)	0.714
Stroke	172(16.93)	29(19.33)	1.17(0.75-1.82)	0.467
History of CHF	23(2.26)	13(8.67)	4.1(2.03-8.28)	<0.001
Valvular heart disease	77(7.57)	5(3.33)	0.42(0.16-1.06)	0.066
COPD	67(6.59)	7(4.67)	0.69(0.31-1.54)	0.370
Coronary arterial disease	277(27.24)	49(32.67)	1.29(0.89-1.87)	0.167
Chronic leg ulcer	460(45.28)	57(38.00)	0.74(0.52-1.05)	0.095
Atrial fibrillation	104(10.23)	24(16.00)	1.67(1.03-2.70)	0.036
CKD stage				
- None	136(13.37)	12(8)	1	-
- eGFR ≥ 60	241(23.70)	22(14.67)	1.03(0.49-2.15)	0.928
- eGFR 30-59	343(33.73)	51(34.00)	1.68(0.87-3.25)	0.121

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Results (univariate analysis)

Variable	No MACE N =1,017	MACE N =152	Univariate analysis OR (95% CI)	P-value
CKD stage				
- eGFR 15-29	111(10.91)	34(51.00)	3.47(1.71-7.02)	0.001
- eGFR < 15	186(18.29)	31(20.67)	1.88(0.93-3.81)	0.076
P2Y12 antagonist use	243(23.89)	33(22.00)	0.89(0.59-1.35)	0.611
Warfarin use	69(6.78)	9(6.00)	0.87(0.42-1.79)	0.720
ASA use	585(57.52)	77(51.33)	0.77(0.55-1.09)	0.154
Sulfonylurea use	129(12.68)	16(10.67)	0.82(0.47-1.42)	0.485
Hb (g/dL), Mean(+SD)	11.26(+2.27)	10.48(+2.46)	0.85(0.79-0.92)	<0.001
WBC, Median (p25, p75)	8.4(6.4,11)	9.55(6.94,14)	1.06(1.03-1.09)	<0.001*
BUN (mg/dL), Median (p25, p75)	17(12,27)	21(15,35)	1.01(1.00-1.02)	0.007*
Cr (mg/dL), Median (p25, p75)	1.09(0.82,2.11)	1.37(0.95,2.58)	1.01(0.94-1.08)	0.766
eGFR, Median (p25, p75)	48.14(23.61,70.70)	33.66(16.99,56.71)	0.99(0.98-0.99)	0.002*
Serum albumin (g/dL), Mean(+SD)	30.76(+6.95)	27.14(+7.72)	0.92(0.90-0.95)	<0.001
Left ventricular ejection fraction, Mean(+SD)	59.57(+11.29)	52.96(+14.58)	0.96(0.94-0.97)	<0.001
EKG 12 lead				
Non ischemic pattern	912(89.68)	132(86.84)	1	-
Ischemic pattern	105(10.32)	20(13.16)	1.31(0.78-2.19)	0.293
ASA classification				
ASA1	0(0)	0(0)	-	-
ASA2	38(3.74)	0(0)	-	-
ASA3	552(54.33)	42(27.63)	1	-
ASA4	405(39.86)	80(52.63)	2.59(1.74-3.85)	<0.001
ASA5	21(2.07)	30(19.74)	18.77(9.90-35.60	-
ASA6	0(0)	0(0)	-	-
Time to operation after admission (hour), Median (p25, p75)	27.13(15.82,107.16)	38.99(3.99,215.9)	1.00(0.99-1.00)	0.922
Intraoperative red blood cell transfusion	418(41.10)	98(64.47)	2.60(1.82-3.70)	<0.001
Type of anesthesia				
RA	87(8.55)	9(5.92)	1	-
GA	869(85.45)	139(91.45)	1.54(0.76-3.14)	0.228
MAC	61(6.00)	4(2.63)	0.63(1.86-2.15)	0.465
Estimated blood loss (ml), Median (p25, p75)	300(100,600)	500(150,1300)	1.00(1.00-1.01)	<0.001

Results (univariate analysis)

Variable	No MACE N =1,017	MACE N =152	Univariate analysis OR (95% CI)	P-value
Mode of operation				
Operation for hemodialysis access	64(6.29)	3(1.97)	1	-
Operation for arterial occlusive disease	550(54.08)	59(38.82)	2.28(0.69-7.51)	0.172
Operation for arterial aneurysm	296(29.11)	63(41.45)	4.54(1.38-14.91)	0.013
Operation for carotid artery stenosis	43(4.23)	4(2.63)	1.98(0.42-9.31)	0.385
Major Amputation	64(6.29)	23(15.13)	7.66(2.19-26.81)	0.001

Results (univariate analysis)

- Preoperative patient status factors:
  - Age, History of CHF, AF
- Preoperative laboratory factors
  - Preoperative Hb, WBC, eGFR, Serum albumin, LVEF, ASA classification-4
- Intraoperative factors
  - Blood transfusion, estimated blood loss
  - Procedure: Operation for arterial aneurysm, Major amputation

Results (Multivariate analysis)

Table 6 showing the multivariate analysis of risk factors for Perioperative MACE

Variable	Multivariate analysis OR (95%CI)	P-value
ASA classification ASA > 3	2.19 (1.33-3.59)	0.002
AF	1.11 (0.58-2.12)	0.743
Albumin	0.93 (0.90-0.97)	0.001
Estimated blood loss	1.00 (1.0001-1.0005)	0.002
Operative group - Operation for arterial occlusive disease - Operation for arterial aneurysm - Operation for carotid artery stenosis - Major Amputation	0.68 (0.18-2.65) 0.95 (0.23-3.85) 1.54 (0.27-8.69) 2.69 (0.62-11.6)	0.588 0.944 0.621 0.182
Left ventricular ejection fraction	0.96 (0.94-0.98)	< 0.0001

Discussion

- This study revealed that incidence perioperative MACE reached in 13% within 30 days after surgery.
- Primary outcome in this study, from multivariate analysis
  - Factor associated with perioperative MACE
    - American Society of Anesthesiologists risk classification >3 (OR 2.19, p<0.0001)
    - Left ventricular ejection fraction (OR 0.96, p<0.0001)
    - Blood albumin level (OR 0.93, p = 0.002)
- Compare with previous studies
  - Risk factors: consistent with previous studies that conducted in western.

Discussion

- **Limitations**
  - Retrospective study
  - Single center
  - Data were collected from 1,169 patients from 2014 to 2020 without calculating the sample size needed to achieve sufficient power for the statistical analyses calculating the sample size
  - Missing data
- Future studies
  - Prospective cohort
  - Preoperative and postoperative biochemical analysis, like troponin level studied that we interested in.

Conclusion

- Incidence of perioperative major adverse cardiovascular events (MACE) within 30 days after surgery at the Department of Vascular Surgery, at Ramathibodi Hospital, was 13 %
- Associated factor : blood albumin level, left ventricular ejection fraction (higher levels of both being of which were protective factor against MACE), and American Society of Anaesthesiologists risk classification 4 or 5, which were risk factors.
- The study was findings also were consistent with those identified in previous studies.
- This work shows that he medical teams should take such these factors into account for preoperative preparation and perioperative patient preparation (Perioperative management) of patients undergoing major vascular surgery to help reduce the incidence of perioperative MACEs.

Thank you

Abstract

Short term outcome of laparoscopic vs open hepatectomy in Ramathibodi hospital

Pattanapak Rakchob, MD

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Background: Laparoscopic liver resection has gained widespread acceptance and is increasingly regarded as a safe and efficacious approach for both benign and malignant hepatic lesions. Prior investigations have reported comparable oncological outcomes between minimally invasive and open hepatectomy. This study aimed to evaluate and compare the short-term surgical outcomes of laparoscopic versus open hepatectomy at Ramathibodi Hospital.

Objectives: To compare the pathological outcome and complications of laparoscopic versus open hepatectomy.

Methods: This retrospective cohort analysis included all patients who underwent either laparoscopic or open liver resection in the Hepatopancreatobiliary (HPB) Department at our institution between January 1, 2022, and May 31, 2024. Collected variables included patient demographics, preoperative indocyanine green retention at 15 minutes, cirrhosis status, surgical approach, operative time, estimated intraoperative blood loss, frequency and volume of intraoperative and postoperative packed red blood cell transfusions, Pringle maneuver duration, postoperative complications (including bile leakage), histopathological findings, morbidity, mortality, and length of hospital and ICU stay. Statistical analyses were performed to compare outcomes between the laparoscopic and open cohorts.

Results: A total of 234 patients met inclusion criteria, 21patients was excluded. comprising 150 undergoing open hepatectomy and 63 undergoing laparoscopic hepatectomy. Baseline characteristics, including age, gender, BMI, and ICG R15, were comparable between groups. Cirrhosis was more common in the laparoscopic group (28.1% vs. 17.1%; p=0.06). The laparoscopic cohort demonstrated a 9.52% conversion rate to open surgery. Operative times did not differ significantly (p=0.67), whereas laparoscopic procedures yielded significantly lower intraoperative blood loss (355.53 mL vs. 665.24 mL; p=0.001) and a decreased requirement for postoperative PRBC transfusions (2.17% vs. 14.81%; p=0.004). However, the laparoscopic approach was associated with a longer median Pringle maneuver time (80.87 min vs. 59.15 min; p=0.008). No statistically significant differences were noted in resection margins, bile leakage rates, morbidity, 90-day mortality, hospital length of stay, or ICU stay.

Conclusion: Laparoscopic hepatectomy represents a safe and effective alternative to open hepatic resection, providing reduced intraoperative blood loss and lower postoperative transfusion without compromising short-term surgical or oncological outcomes.

Short term outcome of laparoscopic vs open hepatectomy in Ramathibodi hospital

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COA. MURA2021/178

Title of Project (English)	An Internal Validation of Ramathibodi Appendicitis Score (RAMA-AS) in diagnosis of acute appendicitis
Title of Project (Thai)	การทวนสอบภายในของคะแนนไส้ติ่งอักเสบรามาธิบดี ในการวินิจฉัยไส้ติ่งอักเสบ
Type of Review	Expedited
Principal Investigator	Thanyaporn Wisitphornanan, M.D.
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator (s)	1. Chumpon Wilasrusmee, M.D. 2. Chairat Supsamutchai, M.D. 3. Jakrapan Jirasiritham, M.D. 4. Napaphat Poprom, Ph.D
Approval includes	1. Submission Form Protocol Version 1 Date 08/01/2021 2. Patient Information Sheet Version 1 Date 08/01/2021 3. Informed Consent Form Version 1 Date 08/01/2021 4. Certificate in Ethics Training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	**February 27, 2021**
Date of Expiration	**February 26, 2022**

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Introduction

- Laparoscopic liver resection has gained widespread acceptance
- Many study show laparoscopic liver resection safe and efficacious approach for both benign and malignant hepatic lesions
- Many previous study show motility 0.3% and morbidity 10.5% (1)

(1) Nguyen KT, Gamblin TC, Geller DA. World review of laparoscopic liver resection-2,804 patients. Ann Surg 2009;250: 831-41.

Introduction

- In some study show advantage of laparoscopic liver resection, in CRLM, laparoscopic surgery has been shown to result in less blood loss, fewer postoperative complications, and shorter hospital stays. While Disease-free survival rates over a 5-year and the surgical margins achieved are equivalent.[1]

(1). Abu Hilal M et. Al The Southampton Consensus Guidelines for Laparoscopic Liver Surgery: From Indication to Implementation. Ann Surg 2018; 268: 11—18.

Introduction

- In other study show, laparoscopic right hepatectomy demonstrates a complication rate of 6.1% compared to 12.2% in open surgery. Additionally, in patients with hilar cholangiocarcinoma, laparoscopic surgery is associated with fewer complications, shorter hospital stays, and comparable survival outcomes to open surgery.[1,2]

1. Wang, J.et al. Laparoscopic vs. open anatomical hepatectomy for intrahepatic cholangiocarcinoma: A retrospective cohort study. *Frontiers in Surgery*, *9*. fsurg.2022.1003948
2. Li, H. et al. Laparoscopic versus open hepatectomy for intrahepatic cholangiocarcinoma: Systematic review and meta-analysis of propensity score-matched studies. *European Journal of Surgical Oncology*, *49*(4), 700–708. j.ejso.2023.02.010

Introduction

- Over the past decade, Ramathibodi Hospital has increased the number of laparoscopic liver resections performed. This study aims to compare the short-term outcomes of laparoscopic versus open liver resection

Material and Methods

Material and Methods

- This retrospective cohort study.
- All patients who underwent either laparoscopic or open liver resection in the Hepatopancreatobiliary (HPB) Department.
- January 1, 2022, and May 31, 2024.
- Data was collected from electrical medical record and operative note record.

Material and Methods

- **Inclusion criteria**
  - Patient who underwent liver resection in ramathibodi hospital, by HPB surgeon

- **Exclusion criteria**
  - Patient who underwent extra HPB operation in same operation
  - Patient who underwent enterohepatic bypass
  - Patient who diagnosed hilar cholangiocarcinoma

Material and Methods

- **Data collection**
- baseline data of the target group
  - Age Gender Body Mass Index (BMI) Cirrhosis status Liver functional assessment using Indocyanine Green (ICG) clearance test Risk stratification based on the American Society of Anesthesiologists (ASA) Physical Status Classification
- Surgical technique
- Pathological report
- Morbidities and mortalities

Outcome

Compare the short-term outcomes and complications of laparoscopic versus open hepatectomy

RESULT

Results

- A total of 234 patients met inclusion criteria
- 170 undergoing open hepatectomy
- 64 undergoing laparoscopic hepatectomy
- Excluded 21case : from open liver resection 20case and laparoscopic resection 1 case

Results

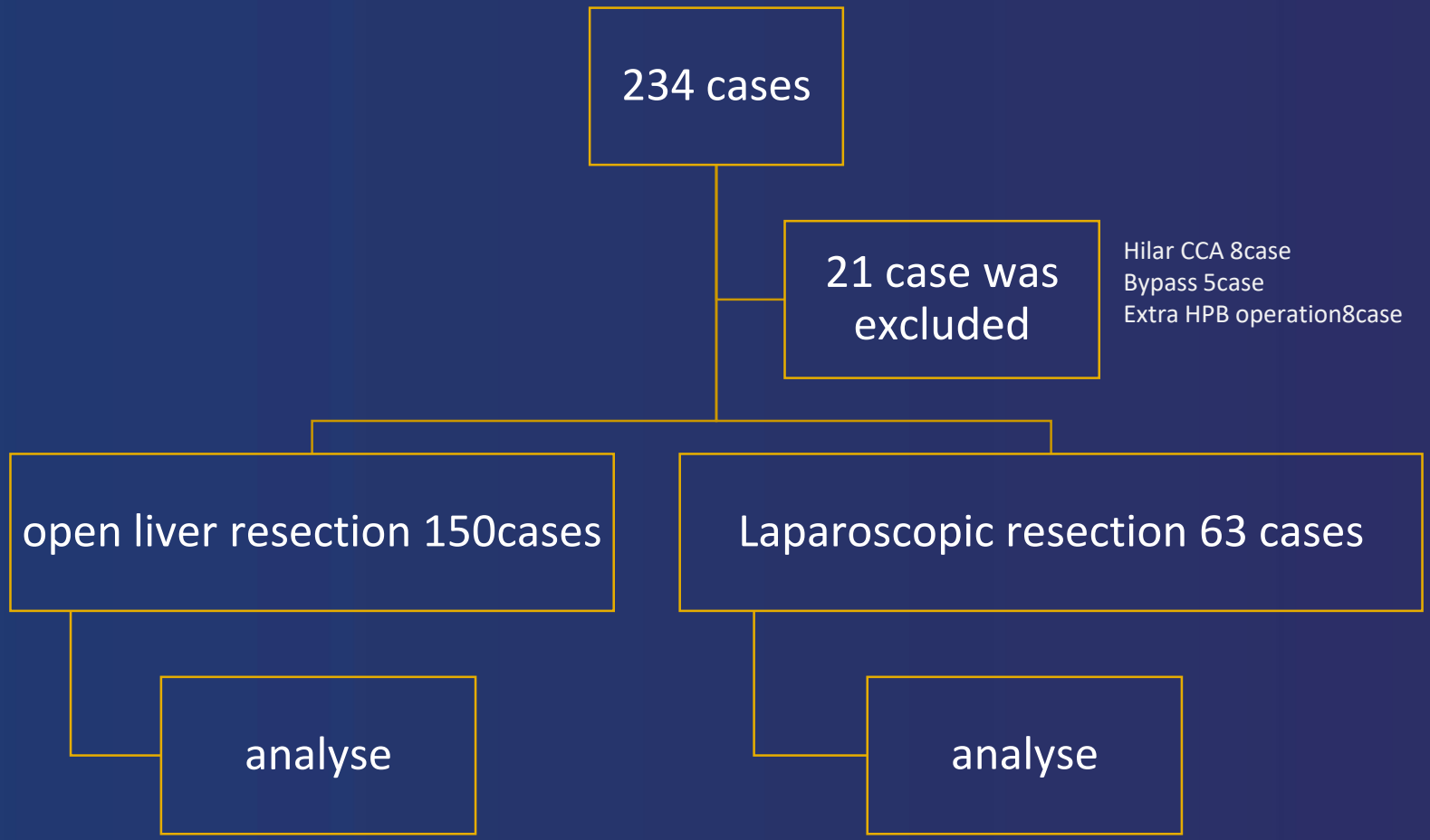

Figure 1. flow chart

Results

variable	Open liver resection(N=150)	Laparoscopic liver resection(N=63)	P-value
Age(mean)	63.62	61.72 years	0.35
BMI(mean±SD)	24.29±3.12	24.28 ±4.84	0.98
ASA ≥3	86(57.3%)	43(68.3%)	0.077
gender			
Male, N(%)	100(66.67)	40(63.35)	0.569
Female, N(%)	50(33.33)	23(36.5)	
ICG-r15	6.69(5.34, 8.04)	7.33(5.71, 8.96)	0.56
cirrhosis	17.06%	28.13%	0.06
Resection type			
Major Resection	34 (22.7%)	11 (17.5%)	0.4
Left Lateral segmentectomy	7 (4.7%)	14 (22.2%)	<0.001
Limited Liver Resection	101 (67.3%)	35 (55.6%)	0.10
Other	8 (5.3%)	3 (4.8%)	0.86

Table 1. Demographic data

Results

variable	Open liver resection(N=150)	Laparoscopic liver resection(N=63)	P-value
HCC	78 (52.0%)	37 (58.7%)	0.37
CRLM	40 (26.7%)	14 (22.2%)	0.50
CCA	10 (6.7%)	4 (6.3%)	0.93
Non-CRLM Mets	9 (6.0%)	4 (6.3%)	0.92
Others	13 (8.7%)	4 (6.3%)	0.57

Table 2. Diagnosis

Results

- In laparoscopic liver resection group conversion to open resection 6 case(9.52%)
- In open liver resection group have history of previous abdominal surgery 8case and laparoscopic group 1 case

Results

variable	Open liver resection	Laparoscopic liver resection	P-value
Operative time(min), mean	289.22	281.64	0.67
Blood loss(ml)	665.24	355.53	0.001
Intra-operative PRC transfusion rate, %	17.07%	4.35%	0.009
Intra-operative PRC transfusion(unit), mean	0.31	0.11	0.109
Pringle maneuver time(min), mean	59.15	80.87	0.008
Bile leakage(%)	6.67	6.35	0.713
Bile leakage need to intervention, n,(%)	2(1.3)	1(1.5)	
Tumor size(cm), mean, (Q1,Q3)	6.59(2.5, 6.4)	3.85(2.7 4.5)	0.041
R1 resection	6(4.0%)	4((6.3%))	0.46
Mortality	0	0	
Morbidities	10.59	10.94	0.94
Clavien–Dindo ≥3	2(1.3%)	3(4.8%)	0.13
Post-op red cell transfusion	14.8	2.17	0.004

Table 3. Result

Results

variable	Open liver resection	Laparoscopic liver resection	P-value
Operative time(min), mean	289.22	281.64	0.67
Blood loss(ml)	665.24	355.53	0.001
Intra-operative PRC transfusion rate, %	17.07%	4.35%	0.009
Intra-operative PRC transfusion(unit), mean	0.31	0.11	0.109
Pringle maneuver time(min), mean	59.15	80.87	0.008
Bile leakage(%)	6.67	6.35	0.713
Bile leakage need to intervention, n,(%)	2(1.3)	1(1.5)	

Table 3. Result

Results

variable	Open liver resection(N=150)	Laparoscopic liver resection(N=150)	P-value
Tumor size(cm), mean, (Q1,Q3)	6.59(2.5, 6.4)	3.85(2.7 4.5)	0.041
R1 resection	6(4.0%)	4((6.3%))	0.46
Mortality	0	0	
Morbidities	10.59	10.94	0.94
Clavien–Dindo ≥3	2(1.3%)	3(4.8%)	0.13
Hospital stay(days)	8.94	8.06	0.25
ICU stay	3.30	2.51	0.15
Post-op red cell transfusion	14.8	2.17	0.004
Re-operation	0	0	
Re-admission	1	0	

Table 3. Result

Results

variable	Open liver resection	Laparoscopic liver resection
VTE	0	0
Pneumonia	2	0
pleural effusion	2	2
atelectesis	2	2
Bile leakage	10	4
Intraabdominal collection	0	2
SSI	1	0
Liver failure	0	0

Table 4. Complication

Discussion

Discussion

- Our study provides an analysis of the short-term outcomes of laparoscopic versus open hepatectomy performed at Ramathibodi Hospital
- Laparoscopic liver resection, particularly for their ability to minimize intraoperative and postoperative complications while maintaining comparable oncological outcomes.

Discussion

- Our study show, in the laparoscopic group was the reduction in intraoperative blood loss, with an average of 355.53 mL compared to 665.24 mL in open surgery p=0.001
- The postoperative packed red blood cell (PRBC) transfusion requirement was significantly lower in the laparoscopic cohort (2.17% vs. 14.81%; p=0.004)
- These findings align with Lin et al.'s review[1], which emphasizes that laparoscopic major hepatectomy reduces intraoperative blood loss

1.Lin NC, Nitta H, Wakabayashi G. Laparoscopic major hepatectomy: A systematic literature review and comparison of 3 techniques. Ann Surg. 2013;257(2):205-13.

Discussion

- the rates of bile leakage, morbidity, and 90-days mortality did not significantly differ between the groups.
- These findings suggest that the laparoscopic approach does not compromise patient safety or surgical effectiveness.
- In our study, the bile leakage rate for laparoscopic hepatectomy was 6.35%, slightly higher than rates reported in other studies[1,2] (3.3% and 4.1% for laparoscopic approaches). Meanwhile, the reported bile leakage rate for open hepatectomy was 6.2%

1. Wang J et al. Laparoscopic vs. open anatomical hepatectomy for intrahepatic cholangiocarcinoma: A retrospective cohort study. Front Surg. 2022;9:1003948.
2. Nam et al. Pure laparoscopic vs open right hepatectomy in patients with hepatocellular carcinoma: A propensity score-matched analysis. J Hepatobiliary Pancreat Sci. 2023;30(3):293-302

Discussion

- The laparoscopic cohort exhibited a longer mean Pringle maneuver time (80.87 minutes vs. 59.15 minutes; p=0.008).

Discussion

- The laparoscopic approach demonstrated a 9.38% conversion rate to open surgery.
- Cases that convert to open procedure for bleeding control.
- One case in the laparoscopic group had a history of prior abdominal surgery but did not require conversion to an open procedure.
- A previous study by Feldbrügge L et al.(1) reported an overall conversion rate of 3%, with a 4% conversion rate in patients with a history of abdominal surgery, without an associated increase in the risk of other complications

(1)Feldbrügge L et al. Safety and feasibility of laparoscopic liver resection in patients with a history of abdominal surgeries. HPB (Oxford). 2020;22(9)

Discussion

- Both groups demonstrated comparable surgical margins and tumor resection outcomes.
- This is consistent with prior studies that suggest laparoscopic techniques achieve oncological results equivalent to open surgery, even for complex resections such as those involving colorectal liver metastases and intrahepatic cholangiocarcinoma.

Limitation

- The retrospective study introduces potential biases, such as selection bias and variations in surgical expertise over the study period
- the relatively small sample size of the laparoscopic group may limit the generalizability of the findings. Prospective randomized studies are needed to confirm these results and explore long-term outcomes.

Conclusion

- In summary, laparoscopic hepatectomy offers a safe and effective alternative to open hepatic resection, particularly in terms of reduced intraoperative blood loss and lower postoperative transfusion rates. As laparoscopic expertise continues to advance, it is likely to play an increasingly prominent role in the management of hepatic lesions.
- Future development
  - Meta analysis of randomized control trial study
  - Evaluated cost effectiveness

Thank you.

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Mahidol University
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Abstract

“A study of quality of life in end-stage renal disease patients undergoing different types of vascular access procedures at the division of vascular surgery, Ramathibodi hospital”

Patompong Chidlerd, MD

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Background: Hemodialysis necessitates the creation of a vascular access, typically established through an arteriovenous fistula (AVF), arteriovenous graft (AVG), or tunnel-cuffed catheter (TCC). Although AVF is generally considered the optimal choice, it is susceptible to failure, which can result in pain and a reduced quality of life.

Objectives: This study seeks to compare the quality of life among patients utilizing these various vascular access methods and to examine the factors influencing it

Materials & Methods: This prospective cohort study aims to compare the quality of life among end-stage renal disease patients aged 18 years and older who underwent their first vascular access procedure (AVF, AVG, or TCC) at the Division of Vascular Surgery, Ramathibodi Hospital. Data will be collected from medical records and the SF-36 quality of life questionnaire before surgery, 2 weeks, and 3 months post-surgery. Collected data from July 2022 to December 2024

Results: A total of 46 participants were included in this study: 15 (32.6%) with AVF, 17 (36.9%) with AVG, and 14 (30.4%) with TCC. Age and BMI differed significantly between groups. [Age, Median(IQR): AVF 57(36) vs TCC 81(21) vs AVG 44(37), p-value 0.010] [BMI, Mean(±SD): AVF 22.3(±3.30) vs TCC 23.24(±4.27) vs AVG 28.16(±6.72), p-value=0.005] In operative details, there is no statistical significant was observed between route of anesthesia, reinterventions and complication. Analysis of complications and reintervention by age showed a higher prevalence among the elderly group (≥ 75 years old). However, no statistically significant differences were found between the three groups. When converted each item in SF-36 into eight quality of life aspect, Preoperatively, patients with AVF demonstrated significantly higher vitality (VT) and physical function (PF) scores compared to those with TCC or AVG. [VT, Median(IQR): AVF 55(15) vs TCC 50(20) vs AVG 48(15), p-value=0.041] [PF, Median(IQR): AVF 55(30) vs TCC 15(20) vs AVG 43(75), p-value=0.008]. However, two weeks postoperatively, patients with TCC exhibited significantly higher vitality scores [VT, Median(IQR): AVF 50(10) vs TCC 60(15) vs AVG 50(30), p-value=0.05]. At three months post-surgery, no significant differences were found among the groups.

Conclusion: The findings of this study indicate that patients with AVF dialysis access exhibited superior preoperative health, particularly in terms of vitality and physical function. However, a temporary reversal was observed two weeks post-surgery, with TCC patients demonstrating improved vitality. The long-term impact of dialysis access type on health outcomes, as assessed at three months post-surgery, did not reveal significant differences among the three groups. These results suggest that while the choice of dialysis access may influence early postoperative recovery, its long-term effects on overall health may be less pronounced. The analysis showed no significant association between complications and reintervention across the three groups. Elderlypatients undergoing fistula surgery had higher rates of complications, particularly infections and occlusions, leading to frequent reoperations

6 ทศวรรษรามาธิบดี
สู่สถาบันการแพทย์ในระดับสากล

“A study of quality of life in end-stage renal disease patients undergoing different types of vascular access procedures at the division of Vascular surgery, Ramathibodi hospital”

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Title of Project (English)	The impaction of vascular access types on quality of life in hemodialysis Patients over 80 years old in department of vascular surgery, Ramathibodi hospital
Title of Project (Thai)	การศึกษาเกี่ยวกับคุณภาพชีวิตของผู้ป่วยไตเรื้อรังระยะสุดท้ายที่มีอายุมากกว่า 80 ปี และเข้ารับการผ่าตัดเพื่อเปิดเส้นฟอกเลือดแต่ละชนิดในแผนกศัลยศาสตร์หลอดเลือด โรงพยาบาลรามาธิบดี
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Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี
FACULTY OF MEDICINE RAMATHIBODI HOSPITAL

Background

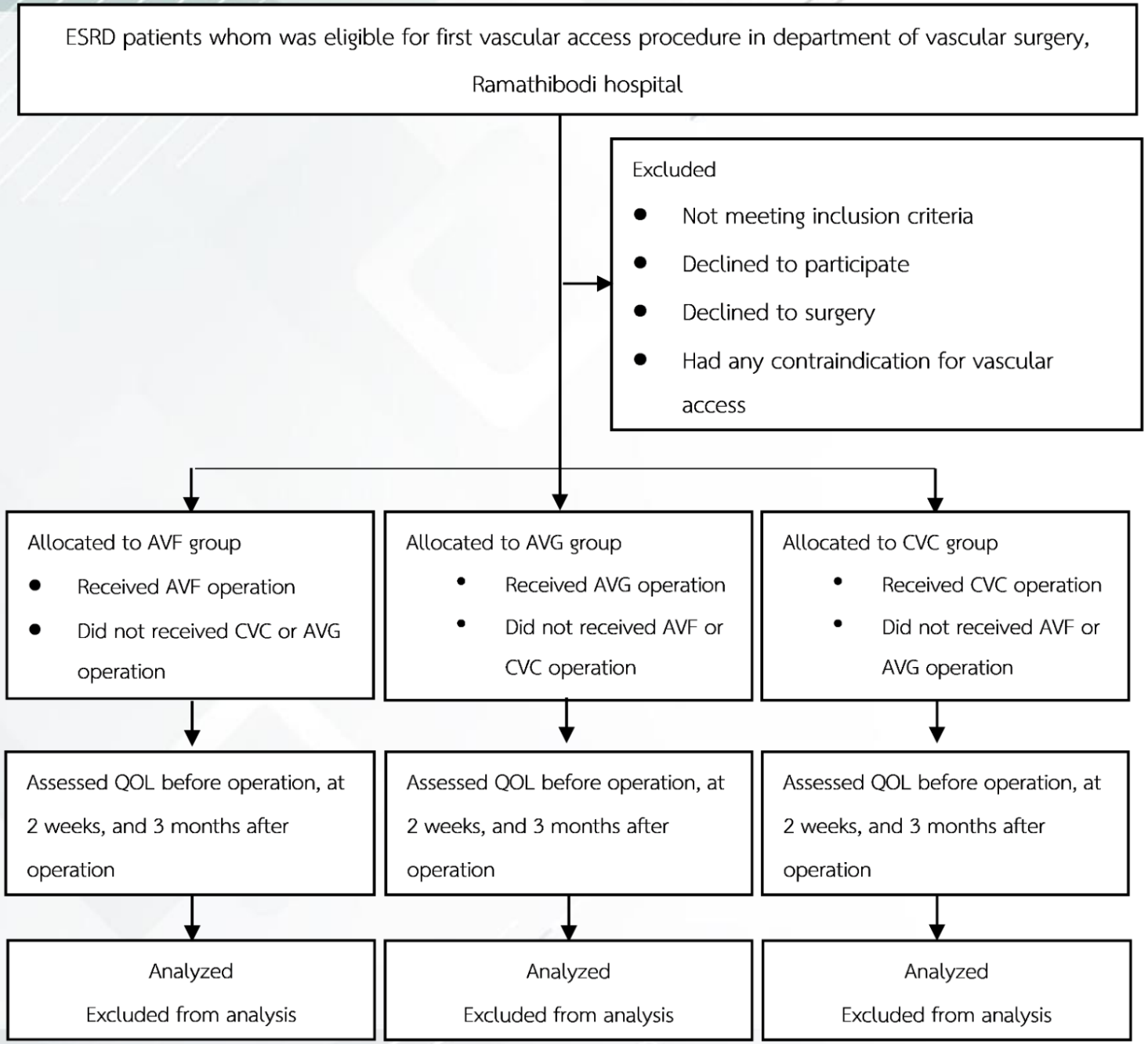
- Hemodialysis necessitates surgical creation of a vascular access, categorized into arteriovenous fistula (AVF), arteriovenous graft (AVG), and tunnel-cuffed catheter (TCC)

- AVF is generally considered the optimal access due to superior outcome
- Nevertheless, evidence indicates that certain patient populations may not derive the same benefits from AVF

- This study seeks to compare the quality of life among patients utilizing these various vascular access methods

Study design

- Prospective cohort study
- Collected data from July 2022 to December 2024


ESRD patients whom was eligible for first vascular access procedure in department of vascular surgery, Ramathibodi hospital
Excluded
Not meeting inclusion criteria
Declined to participate
Declined to surgery
Had any contraindication for vascular access
Allocated to AVF group
Received AVF operation
Did not received CVC or AVG operation
Allocated to AVG group
Received AVG operation
Did not received AVF or CVC operation
Allocated to CVC group
Received CVC operation
Did not received AVF or AVG operation
Assessed QOL before operation, at 2 weeks, and 3 months after operation
Assessed QOL before operation, at 2 weeks, and 3 months after operation
Assessed QOL before operation, at 2 weeks, and 3 months after operation
Analyzed
Excluded from analysis
Analyzed
Excluded from analysis
Analyzed
Excluded from analysis

SF-36 Questionaire

HN.....

แบบสอบถามเกี่ยวกับคุณภาพชีวิตของผู้ป่วยไตเรื้อรังระยะสุดท้าย
ในแผนกศัลยศาสตร์หลอดเลือด โรงพยาบาลรามาธิบดี

ส่วนที่ 1 ข้อมูลพื้นฐาน

วันที่ตอบแบบสอบถาม.....

□ Pre-op	□ Post-op 3 months
□ Post-op 2 week	□ Post-op 1 year

1. เพศ □ ชาย □ หญิง
2. อายุ.....ปี
3. น้ำหนัก.....กิโลกรัม ส่วนสูง.....เซนติเมตร
4. โรคประจำตัวอื่นๆ นอกจากโรคไต □ เบาหวาน □ ความดันโลหิตสูง □ ไขมันในเลือดสูง □ เก๊าท์ □ เส้นเลือดสมองตีบ/แตก
   □ เส้นเลือดหัวใจตีบ □ อื่นๆ โปรดระบุ..... □ ไม่มีโรคประจำตัวอื่น
5. ประวัติการสูบบุหรี่ □ ไม่สูบ □ ยังสูบบุหรี่อยู่
6. ประวัติการดื่มสุรา □ ไม่ดื่ม □ ยังดื่มสุราอยู่

ส่วนที่ 2 ข้อมูลการผ่าตัด (กรอกโดยแพทย์)

1. ชนิดของการผ่าตัดทำเส้นฟอกเลือด □ ผ่าตัดทำเส้นเลือดจริงที่แขน (AVF) □ ผ่าตัดทำเส้นที่หน้าอก (TCC) □ ผ่าตัดทำเส้นเลือดเทียมที่แขน (AVBG)
2. ชนิดของการลดปวดขณะผ่าตัด □ ยาชาเฉพาะที่ (LA) □ ดมยาสลบ (GA) □ ยาชาเฉพาะที่ร่วมกับการติดตามแบบใกล้ชิด (MAC)
3. การผ่าตัดซ่อมแซมเส้นฟอกเลือด □ ไม่มี □ มี ระบุวันที่.....
4. ภาวะแทรกซ้อนหลังการผ่าตัด □ ไม่มี □ มี (ตอบข้อ 5)
5. ชนิดของภาวะแทรกซ้อนหลังการผ่าตัด □ เลือดออก (Bleeding) □ ติดเชื้อ (Infection) □ ใช้การไม่ได้ (Dysfunction) □ ลิ่มเลือดอุดตัน (Thrombosis)

SF-36 Questionnaire

แบบสอบถาม SF -36 ฉบับภาษาไทย ปรับปรุง พ.ศ. 2548 โปรดวาดเครื่องหมายวงกลมเพื่อเลือกคำตอบเพียงหนึ่งตัวเลือกในแต่ละข้อที่ตรงกับตัวท่านมากที่สุด

		1	2	3	4	5	6
1. โดยทั่วไปท่านคิดว่าสุขภาพของท่านเป็นอย่างไร	(1)	ดีเยี่ยม	ดีมาก	ดี	พอใช้ได้	แย่มาก	
2. ท่านคิดว่าสุขภาพของท่านเป็นอย่างไร เมื่อเทียบกับ 1 ปีที่ผ่านมา	(2)	ดีขึ้นมาก	ดี	เหมือนเดิม	แย่ลงบ้าง	แย่ลงมาก	
3. ปัจจุบันท่านสามารถ							
3.1 วิ่ง, ยกของหนัก หรือเล่นกีฬาที่ออกแรงมากได้	(3)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
3.2 เคลื่อนย้ายโต๊ะ, ถูบ้าน, เล่นกอล์ฟ, เล่นโบว์ลิ่งได้	(4)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
3.3 ยกถือของเมื่อไปตลาดหรือซุปเปอร์มาร์เก็ต	(5)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
3.4 ขึ้นบันไดหลายๆชั้น (ตั้งแต่ 2 ชั้นขึ้นไป)	(6)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
3.5 ขึ้นบันได 1 ชั้น	(7)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
3.6 ก้มลงเก็บของ, คุกเข่า	(8)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
3.7 เดินหรือเคลื่อนที่มากกว่า 1 กิโลเมตร	(9)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
3.8 เดินหรือเคลื่อนที่มากกว่า 100 เมตร (หลายช่วงเสาไฟฟ้า)	(10)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
3.9 เดินหรือเคลื่อนที่ประมาณ 100 เมตร (1 ป้านรถเมล์)	(11)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
3.10 อาบน้ำหรือแต่งตัว	(12)	ลดลงมาก	ลดลงเล็กน้อย	ไม่ลดลง			
4. ในช่วง 1 เดือนที่ผ่านมาสุขภาพร่างกายของท่านมีผลต่อการทำงานหรือกิจวัตรประจำวันหรือไม่							
4.1 ต้องลดเวลาการทำงานลง	(13)	ใช่	ไม่ใช่				
4.2 ทำงานได้ปริมาณงานน้อยกว่าที่ควรจะเป็น	(14)	ใช่	ไม่ใช่				
4.3 ทำงานหรือทำกิจวัตรประจำวันบางอย่างไม่ได้	(15)	ใช่	ไม่ใช่				
4.4 ต้องใช้ความพยายามมากกว่าเดิมในการทำงาน	(16)	ใช่	ไม่ใช่				
5. ในช่อง 1 เดือน ที่ผ่านมา ปัญหาทางด้านอารมณ์หรือจิตใจของท่านมีผลต่อการทำงานหรือกิจวัตรประจำวันของท่านหรือไม่							
5.1 ต้องลดเวลาการทำงานลง	(17)	ใช่	ไม่ใช่				
5.2 ทำงานได้ปริมาณงานน้อยกว่าที่ควรจะเป็น	(18)	ใช่	ไม่ใช่				
5.3 ทำงานหรือทำกิจวัตรประจำวันบางอย่างไม่ได้	(19)	ใช่	ไม่ใช่				

		1	2	3	4	5	6
6. ในช่วง 1 เดือนที่ผ่านมา สุขภาพของท่าน มีผลต่อความสัมพันธ์ของท่านกับครอบครัวหรือไม่	(20)	ไม่มีผลเลย	มีผลเล็กน้อย	มีผลปานกลาง	มีผลค่อนข้างมาก	มีผลมากๆ	
7. ในช่วง 1 เดือนที่ผ่านมา ท่านมีอาการเจ็บหรือปวดตามส่วนต่างๆ ของร่างกายมากน้อยเพียงใด	(21)	ไม่มีเลย	มีน้อยมาก	มีน้อย	มีปานกลาง	มีมาก	มีมากที่สุด
8. ในช่วง 1 เดือนที่ผ่านมา อาการเจ็บหรือปวด รบกวนการทำงานตามปกติของท่านหรือไม่	(22)	ไม่รบกวนเลย	รบกวนเล็กน้อย	รบกวนปานกลาง	รบกวนค่อนข้างมาก	รบกวนมากๆ	
9. คำถามต่อไปนี้เกี่ยวข้องกับความรู้สึกและเรื่องราวที่ผ่านมาในช่วง 1 เดือน โปรดเลือกข้อที่ใกล้เคียงกับความรู้สึกของท่านที่สุดในแต่ละข้อ							
11.1 รู้สึกกระปรี้กระเปร่า	(23)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
11.2 วิตกกังวล	(24)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
11.3 รู้สึกซึมเศร้าหรือหดหู่มาก	(25)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
11.4 รู้สึกสงบ	(26)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
11.5 รู้สึกมีพลังใจในการดำรงชีวิต	(27)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
11.6 รู้สึกท้อแท้ หม่นหมอง	(28)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
11.7 รู้สึกเหนื่อยเพลีย หมดกำลัง	(29)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
11.8 รู้สึกมีความสุข	(30)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
11.9 รู้สึกเบื่อหน่าย	(31)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
10. ในช่วง 1 เดือนที่ผ่านมา ปัญหาสุขภาพกายและอารมณ์ มีผลรบกวนต่อการเข้าสังคม การพบปะเพื่อนฝูงและญาติสนิทของท่านอย่างไร	(32)	ตลอดเวลา	เกือบตลอดเวลา	บ่อยๆ	บางเวลา	นานๆครั้ง	ไม่มีเลย
11. เลือกคำตอบที่ตรงกับสุขภาพของท่านมากที่สุด							
14.1 ไม่สบายหรือเจ็บป่วยง่ายกว่าคนอื่น	(33)	ถูกต้องที่สุด	ถูกโดยส่วนใหญ่	ไม่ทราบ	ไม่ค่อยถูก	ไม่ถูกเลย	
14.2 สุขภาพดีเท่าคนอื่น	(34)	ถูกต้องที่สุด	ถูกโดยส่วนใหญ่	ไม่ทราบ	ไม่ค่อยถูก	ไม่ถูกเลย	
14.3 ข้าพเจ้าคาดว่าสุขภาพจะแย่ลง	(35)	ถูกต้องที่สุด	ถูกโดยส่วนใหญ่	ไม่ทราบ	ไม่ค่อยถูก	ไม่ถูกเลย	
14.4 สุขภาพของข้าพเจ้าดีเยี่ยม	(36)	ถูกต้องที่สุด	ถูกโดยส่วนใหญ่	ไม่ทราบ	ไม่ค่อยถูก	ไม่ถูกเลย	

Leurmamkul, Watcharee and Meetam, Paranee (2000) "Development of a Quality of Life Questionnaire: SF-36 (Thai Version)(การพัฒนาแบบสอบถามคุณภาพชีวิต SF-36 ฉบับภาษาไทย) " *The Thai Journal of Pharmaceutical Sciences*: Vol. 24: Iss. 2, Article 4.

SF-36 Interpretation

Item numbers	Change original response category *	To recoded value of:
1, 2, 20, 22, 34, 36	1 →	100
	2 →	75
	3 →	50
	4 →	25
	5 →	0
3, 4, 5, 6, 7, 8, 9, 10, 11, 12	1 →	0
	2 →	50
	3 →	100
13, 14, 15, 16, 17, 18, 19	1 →	0
	2 →	100
21, 23, 26, 27, 30	1 →	100
	2 →	80
	3 →	60
	4 →	40
	5 →	20
	6 →	0
24, 25, 28, 29, 31	1 →	0
	2 →	20
	3 →	40
	4 →	60
	5 →	80
	6 →	100
32, 33, 35	1 →	0
	2 →	25
	3 →	50
	4 →	75
	5 →	100

	Scale	Number of items	After recoding per Table 1, average the following items
(PF)	Physical functioning	10	3 4 5 6 7 8 9 10 11 12
(RP)	Role limitations due to physical health	4	13 14 15 16
(RE)	Role limitations due to emotional problems	3	17 18 19
(VT)	Energy/fatigue	4	23 27 29 31
(MH)	Emotional well-being	5	24 25 26 28 30
(SF)	Social functioning	2	20 32
(BP)	Pain	2	21 22
(GH)	General health	5	1 33 34 35 36

https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form/scoring.html

Outcomes

- Primary outcome:
  - The quality of life among patients undergoing different types of vascular access procedures at Ramathibodi Hospital

- Secondary outcome:
  - Complications associated with different types of vascular access procedures
  - Reintervention rate for each type of vascular access procedure

Analysis

- Categorical variables: Chi squared test, Present as count and percentage
- Continuous variables: Anova test, Present as median and interquatile range
- p-value < 0.05 was statistical significant
- STATA program version 14.1

Results

Demographic characteristic

Variable	AVF (n = 15)	TCC (n = 17)	ABG (n = 14)	P-value
Gender				0.154
- Male	12(80)	8(47.06)	8(54.17)	
- Female	3(20)	9(52.94)	6(42.86)	
Age, Median(IQR)	57(36)	81(21)	44(37)	0.010**
BMI, Mean(±SD)	22.30(±3.30)	23.24(±4.27)	28.16(±6.72)	0.005
Other underlying diseases				
- DM	7(46.67)	9(52.94)	7(50)	0.939
- HT	9(60)	13(76.47)	12(85.71)	0.276
- DLP	3(20)	6(35.29)	4(28.57)	0.656*
- Gout	2(13.33)	4(23.53)	3(21.43)	0.808*
- Stroke	1(6.67)	1(5.88)	1(7.14)	0.999*
- IHD	3(20)	2(11.76)	2(14.29)	0.879*
- Other	2(13.33)	8(47.06)	2(14.29)	0.061*
Smoking				
- None or cessation	15(100)	17(100)	13(92.86)	0.304*
- Current	0	0	1(7.14)	
Alcohol drinking				
- None or cessation	15(100)	17(100)	14(100)	-
- Current	0	0	0	

Operative details

Variable	AVF (n = 15)	TCC (n = 17)	AVG (n = 14)	P-value
Anesthesia				0.999*
LA	15(100)	16(94.12)	14(100)	
GA	0	0	0	
MAC	0	1(5.88)	0	
Reintervention	2(13.33)	3(17.65)	2(14.28)	0.861*
Complication	2(13.33)	3(17.65)	1(7.14)	0.526*

Complications and reinterventions

Complication	AVF (n = 2)	TCC (n = 3)	AVG (n = 1)	P-value
Age group				
- Age > 75	2(100)	3(100)	0	0.143
- Age < 75	0	0	1(100)	

Reintervention	AVF (n = 2)	TCC (n = 3)	AVG (n = 2)	P-value
Age group				
- Age > 75	2(100)	3(100)	1(50)	0.167
- Age < 75	0	0	1(50)	

SF-36 Preoperative

Variable	AVF (n = 15)	TCC (n = 17)	ABG (n = 14)	P-value
SF1, Median(IQR)	25(0)	25(25)	25(50)	0.559
SF2, Median(IQR)	25(50)	25(25)	25(25)	0.644
SF3, Median(IQR)	50(50)	0(0)	0(50)	0.011
SF4, Median(IQR)	50(50)	0(0)	25(50)	<0.001
SF5, Median(IQR)	50(100)	0(50)	25(100)	0.05
SF6, Median(IQR)	50(50)	0(50)	50(100)	0.107
SF7, Median(IQR)	100(50)	50(50)	75(100)	0.172
SF8, Median(IQR)	50(100)	0(50)	25(100)	0.142
SF9, Median(IQR)	50(50)	0(0)	50(50)	0.034
SF10, Median(IQR)	50(100)	0(50)	50(100)	0.024
SF11, Median(IQR)	100(50)	0(0)	50(100)	0.003
SF12, Median(IQR)	100(0)	50(50)	75(50)	0.004
SF13, Median(IQR)	0(0)	0(0)	0(100)	0.421
SF14, Median(IQR)	0(0)	0(0)	0(0)	0.739
SF15, Median(IQR)	0(100)	0(0)	50(100)	0.145
SF16, Median(IQR)	0(100)	0(0)	0(0)	0.344
SF17, Median(IQR)	0(100)	0(100)	0(100)	0.733
SF18, Median(IQR)	0(100)	0(100)	0(100)	0.839
SF19, Median(IQR)	0(0)	0(0)	0(100)	0.347
SF20, Median(IQR)	75(25)	75(50)	75(0)	0.714

Variable	AVF (n = 15)	TCC (n = 17)	ABG (n = 14)	P-value
SF21, Median(IQR)	40(40)	40(40)	50(40)	0.274
SF22, Median(IQR)	75(25)	50(50)	63(25)	0.188
SF23, Median(IQR)	40(0)	40(40)	40(40)	0.639
SF24, Median(IQR)	60(20)	40(20)	40(40)	0.328
SF25, Median(IQR)	60(20)	60(40)	60(20)	0.197
SF26, Median(IQR)	60(40)	40(20)	40(40)	0.689
SF27, Median(IQR)	60(60)	40(20)	40(20)	0.054
SF28, Median(IQR)	60(20)	60(40)	40(20)	0.075
SF29, Median(IQR)	60(40)	40(20)	40(20)	0.029
SF30, Median(IQR)	60(40)	40(20)	60(40)	0.447
SF31, Median(IQR)	60(0)	60(20)	40(20)	0.025
SF32, Median(IQR)	75(25)	75(50)	75(50)	0.488
SF33, Median(IQR)	25(25)	25(25)	25(0)	0.343
SF34, Median(IQR)	25(25)	0(25)	25(25)	0.004
SF35, Median(IQR)	25(25)	50(50)	25(0)	0.121
SF36, Median(IQR)	25(25)	25(25)	25(0)	0.09

SF-36 Postoperative 2 weeks

Variable	AVF (n = 15)	TCC (n = 17)	ABG (n = 14)	P-value
SF1, Median(IQR)	25(25)	25(25)	25(0)	0.691
SF2, Median(IQR)	25(50)	50(50)	25(0)	0.115
SF3, Median(IQR)	0(50)	0(50)	50(50)	0.841
SF4, Median(IQR)	50(50)	0(50)	50(50)	0.383
SF5, Median(IQR)	50(50)	25(50)	50(50)	0.977
SF6, Median(IQR)	50(50)	25(50)	50(50)	0.636
SF7, Median(IQR)	50(100)	50(50)	50(100)	0.912
SF8, Median(IQR)	50(100)	50(75)	50(50)	0.938
SF9, Median(IQR)	50(100)	25(50)	50(50)	0.579
SF10, Median(IQR)	50(100)	25(50)	50(50)	0.262
SF11, Median(IQR)	50(50)	25(50)	50(0)	0.292
SF12, Median(IQR)	100(50)	50(50)	50(50)	0.091
SF13, Median(IQR)	0(100)	0(100)	0(0)	0.886
SF14, Median(IQR)	0(100)	0(100)	0(0)	0.269
SF15, Median(IQR)	0(100)	0(100)	0(100)	0.876
SF16, Median(IQR)	0(100)	0(100)	0(100)	0.84
SF17, Median(IQR)	0(0)	100(100)	0(100)	0.122
SF18, Median(IQR)	0(0)	100(100)	0(0)	0.026
SF19, Median(IQR)	0(100)	0(100)	0(0)	0.406
SF20, Median(IQR)	75(50)	75(25)	75(0)	0.513

Variable	AVF (n = 15)	TCC (n = 17)	ABG (n = 14)	P-value
SF21, Median(IQR)	40(20)	40(20)	40(20)	0.854
SF22, Median(IQR)	50(25)	50(50)	50(50)	0.911
SF23, Median(IQR)	40(20)	40(40)	40(40)	0.71
SF24, Median(IQR)	60(20)	60(20)	40(40)	0.136
SF25, Median(IQR)	60(40)	60(50)	40(20)	0.155
SF26, Median(IQR)	60(40)	40(20)	40(20)	0.318
SF27, Median(IQR)	60(40)	60(20)	60(20)	0.547
SF28, Median(IQR)	60(40)	60(30)	40(20)	0.035
SF29, Median(IQR)	60(40)	60(40)	40(0)	0.057
SF30, Median(IQR)	60(60)	60(30)	60(20)	0.394
SF31, Median(IQR)	60(40)	60(30)	40(20)	0.036
SF32, Median(IQR)	75(25)	100(50)	75(50)	0.809
SF33, Median(IQR)	25(50)	25(25)	25(25)	0.258
SF34, Median(IQR)	25(25)	25(25)	25(25)	0.541
SF35, Median(IQR)	50(25)	50(25)	50(25)	0.821
SF36, Median(IQR)	25(50)	50(25)	25(0)	0.122

SF-36 Postoperative 3 months

Variable	AVF (n = 15)	TCC (n = 17)	ABG (n = 14)	P-value
SF1, Median(IQR)	50(25)	50(25)	50(25)	0.892
SF2, Median(IQR)	75(25)	50(25)	50(50)	0.771
SF3, Median(IQR)	50(50)	0(75)	0(50)	0.39
SF4, Median(IQR)	50(50)	0(75)	50(50)	0.605
SF5, Median(IQR)	50(50)	50(75)	50(50)	0.804
SF6, Median(IQR)	50(50)	50(100)	50(50)	0.791
SF7, Median(IQR)	100(100)	50(50)	50(50)	0.979
SF8, Median(IQR)	50(100)	50(100)	50(100)	0.967
SF9, Median(IQR)	50(0)	0(75)	50(100)	0.465
SF10, Median(IQR)	50(50)	50(75)	50(100)	0.568
SF11, Median(IQR)	50(100)	50(75)	50(100)	0.874
SF12, Median(IQR)	100(50)	50(75)	100(50)	0.307
SF13, Median(IQR)	0(100)	0(100)	0(100)	0.925
SF14, Median(IQR)	0(100)	0(100)	0(100)	0.956
SF15, Median(IQR)	100(100)	0(0)	50(100)	0.051
SF16, Median(IQR)	0(100)	0(50)	50(100)	0.392
SF17, Median(IQR)	100(100)	0(100)	50(100)	0.552
SF18, Median(IQR)	100(100)	0(100)	50(100)	0.552
SF19, Median(IQR)	100(0)	0(100)	50(100)	0.161
SF20, Median(IQR)	75(50)	62.5(25)	100(25)	0.059

Variable	AVF (n = 15)	TCC (n = 17)	ABG (n = 14)	P-value
SF21, Median(IQR)	60(40)	60(20)	40(40)	0.561
SF22, Median(IQR)	75(25)	50(38)	75(25)	0.097
SF23, Median(IQR)	60(60)	40(40)	60(40)	0.652
SF24, Median(IQR)	60(20)	50(20)	40(20)	0.609
SF25, Median(IQR)	60(40)	60(50)	50(20)	0.347
SF26, Median(IQR)	60(20)	40(20)	60(20)	0.65
SF27, Median(IQR)	60(0)	40(40)	60(40)	0.689
SF28, Median(IQR)	60(60)	60(40)	40(20)	0.266
SF29, Median(IQR)	60(40)	60(30)	40(20)	0.658
SF30, Median(IQR)	60(0)	60(30)	60(40)	0.713
SF31, Median(IQR)	60(20)	60(30)	40(20)	0.326
SF32, Median(IQR)	100(25)	75(25)	75(25)	0.247
SF33, Median(IQR)	25(0)	25(13)	25(50)	0.343
SF34, Median(IQR)	25(25)	25(38)	25(0)	0.492
SF35, Median(IQR)	50(50)	50(25)	50(25)	0.432
SF36, Median(IQR)	25(50)	38(25)	38(50)	0.452

SF-36 QOL 8 aspect

Variable	AVF (n = 15)	TCC (n = 17)	ABG (n = 14)	P-value
Pre-op				
MH , Median(IQR)	56(12)	48(24)	52(16)	0.491
VT, Median(IQR)	55(15)	50(20)	48(15)	0.041
RP, Median(IQR)	0(50)	0(0)	25(50)	0.119
RE, Median(IQR)	0(33)	0(67)	33(100)	0.591
GH, Median(IQR)	30(20)	30(20)	30(15)	0.551
SF, Median(IQR)	75(25)	75(50)	75(13)	0.974
BP, Median(IQR)	58(33)	45(35)	58(33)	0.223
PF, Median(IQR)	55(30)	15(20)	43(75)	0.008
2 Weeks				
MH, Median(IQR)	52(8)	58(20)	48(24)	0.195
VT, Median(IQR)	50(10)	60(15)	50(30)	0.05
RP, Median(IQR)	25(75)	13(100)	0(50)	0.751
RE, Median(IQR)	0(33)	50(100)	0(33)	0.114
GH, Median(IQR)	35(25)	35(15)	25(20)	0.3
SF, Median(IQR)	75(25)	75(32)	75(25)	0.948
BP, Median(IQR)	55(13)	50(30)	45(40)	0.893
PF, Median(IQR)	55(35)	33(35)	48(58)	0.498

Variable	AVF (n = 15)	TCC (n = 17)	ABG (n = 14)	P-value
3 Months				
MH , Median(IQR)	56(28)	56(24)	50(12)	0.589
VT, Median(IQR)	55(15)	53(20)	50(15)	0.714
RP, Median(IQR)	50(75)	0(50)	25(100)	0.62
RE, Median(IQR)	100(67)	0(100)	50(100)	0.295
GH, Median(IQR)	35(30)	35(15)	43(10)	0.468
SF, Median(IQR)	88(37)	63(25)	88(13)	0.283
BP, Median(IQR)	70(22)	55(29)	64(33)	0.202
PF, Median(IQR)	60(35)	45(63)	50(60)	0.843

Discussion

- LI, M.-T. *et al*. investigated the relationship between vascular access (VA) satisfaction, health-related quality of life (HRQOL), and depression in HD patients

- In this study, no significant difference in satisfaction scores by access type was found in patients with each type of vascular access

- The HRQOL score was higher in patients with AVF than in those with AVG or TCC

LI, M.-T. *et al.* The association between vascular access satisfaction and quality of life and depression in maintained hemodialysis patients. Journal of Vascular Access, *[s. l.]*, v. 25, n. 2, p. 439–447, 2024. DOI 10.1177/11297298221113283. Disponível em: https://research-ebsco-com.ejournal.mahidol.ac.th/linkprocessor/plink?id=5808563b-9743-3a57-80a6-5213201e06f3. Acesso em: 7 jan. 2025.

Discussion

- From baseline characteristics of 46 patients, Age and BMI showed statistically significant differences between groups. AVF was the youngest, TCC the oldest, and ABG had the highest BMI

Discussion

- Preoperatively, patients with AVF demonstrated significantly higher vitality (VT) and physical function (PF) scores compared to those with TCC or AVG.

- This is due to the fact that patients in the AVF group who underwent surgery tended to have better preoperative health, which contributed to a higher success rate of fistula maturation

Discussion

- After two weeks postoperatively, patients with TCC exhibited significantly higher vitality scores (VT)

- This is likely due to the group's unique characteristics: a higher proportion of elderly patients, and elevated pre-fistula creation creatinine levels. Additionally, the immediate usability of TCC for dialysis contributed to faster patient recovery

Discussion

- Analysis of complications and reinterventions by age revealed a higher prevalence among the elderly in the fistula surgery group for both outcomes

- Interestingly, the study found a higher incidence of complications and reoperations among elderly patients. In particular, elderly patients were more prone to infections and fistula occlusions, leading to frequent reinterventions

Discussion

- Limitation
  - Relatively Small Sample Size
  - Focus on a Single Center
  - Limited Exploration of Factors Influencing Quality of Life
  - Short Follow-up Period
  - Some patients had previously undergone other vascular access procedures, such as DLC
  - Preoperative GFR made TCC a more favorable option

Discussion

- For future research
  - Randomized control trial
  - Increased Sample Size
  - Multicenter study
  - Increased exploration of factors Influencing Quality of Life
  - More Follow-up Period

Conclusion

- These results suggest that while the choice of dialysis access may influence early postoperative recovery, its long-term effects on overall health may be less pronounced
- The analysis showed no significant association between complications and reintervention across the three groups
- Elderly patients undergoing fistula surgery had higher rates of complications, particularly infections and occlusions, leading to frequent reoperations

Thank you,
Any question?

Abstract

“Role of indocyanine green assist laparoscopic cholecystectomy compared with conventional laparoscopic cholecystectomy in Ramathibodi hospital: Randomized controlled trial”

Patchaporn Sermsartrat, MD

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Background: Acute cholecystitis is a commonly diagnosed condition, and laparoscopic cholecystectomy (LC) is the gold standard treatment, unless the patient's condition is deemed unsafe for major surgery. One of the most serious complications associated with LC is bile duct injury (BDI), particularly in cases where the critical view of safety (CVS) is difficult to identify or when performed by less experienced surgeons. Various techniques have been proposed to mitigate this risk. Indocyanine green (ICG) has emerged as a potential alternative that may reduce the risks, but its benefits and protocols remain unclear. This study aims to investigate this issue.

Method : Patients who undergo LC were randomly assigned to ICG group or non-ICG group using closed envelopes. Primary outcome is post operative complication. Secondary outcome are time to CVS, conversion rate, length of stay (LOS) and operation time. Data analysis was conducted using the STATA program.

Result: A total of 40 volunteers were enrolled in the study (21 in non-ICG group and 19 in ICG group). The majority of participants were female. General characteristics between the groups did not differ (P = 0.025). There were no complications reported in the non-ICG group, while one case (5.3%) of ICG group was converted to open cholecystectomy, although this was not statistically significant (P = 0.475). Timing to identify the CVS and overall operating time were faster in the non-ICG group, but again, these were not statistically significant (P = 0.322; P = 0.143). The median length of stay was the same for both groups (3 days, P = 0.253).

Conclusion: The use of ICG may aid in identifying the CVS during laparoscopic cholecystectomy, but the clinical benefit remains uncertain, potentially due to the low enrollment number and low complication rates. Some surgeons reported increased confidence when utilizing ICG. Future research focusing on surgeon confidence during training or in complex LC cases is warranted.

Role of indocyanine green assist laparoscopic cholecystectomy compared with conventional laparoscopic cholecystectomy in Ramathibodi hospital

Randomized controlled trial

Patchaporn Sermsartrat, Pongsatorn Tangtawee
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COA. MURA2022/455

Title of Project (English)	Role of Indocyanine Green Assist Laparoscopic Cholecystectomy Compared with Conventional Laparoscopic Cholecystectomy in Ramathibodi Hospital : Randomized Controlled Trial
Title of Project (Thai)	ประโยชน์ของการใช้สารอินโดไซยานินสีเขียว (Indocyanine green) เพื่อช่วยในการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องเปรียบเทียบกับการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องแบบมาตรฐาน
Type of Review	Full Board
Principal Investigator	Patchaporn Sermsartrat
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator(s)	1. Pongsatorn Tangtawee 2. Napaphat Poprom
Approval includes	1. Submission Form Protocol Version 2 Date 22/7/2022 2. Information sheet and consent form Version 2 Date 22/7/2022 3. Case Record Form Version 2 Date 4/7/2022 4. Curriculum Vitae 5. Certificate in Ethics Training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	August 17, 2022
Date of Expiration	August 16, 2023

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

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COA. MURA2022/455
Ref.2024/904

Title of Project (English)	Role of Indocyanine Green Assist Laparoscopic Cholecystectomy Compared with Conventional Laparoscopic Cholecystectomy in Ramathibodi Hospital : Randomized Controlled Trial
Title of Project (Thai)	ประโยชน์ของการใช้สารอินโดไซยานินสีเขียว (Indocyanine green) เพื่อช่วยในการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องเปรียบเทียบกับการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องแบบมาตรฐาน
Type of Review	Full Board
Principal Investigator	Patchaporn Sermsartrat
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 03/09/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	August 17, 2022
Renewal Date (2nd)	August 17, 2024
Date of Expiration	August 16, 2025

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

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4) Written notification is required when the project is complete or terminated

Background

Acute cholecystitis is a commonly diagnosed condition, and laparoscopic cholecystectomy (LC) is the gold standard treatment.

The most serious complications is bile duct injury (BDI). It have a long-term effected, difficult to treatment and impact quality of life.

There are various techniques for identified bile duct anatomy to mitigate this risk. Indocyanine green (ICG) has emerged as a potential alternative that may reduce the risks, but its benefits and protocols remain unclear. This study aims to investigate this issue.

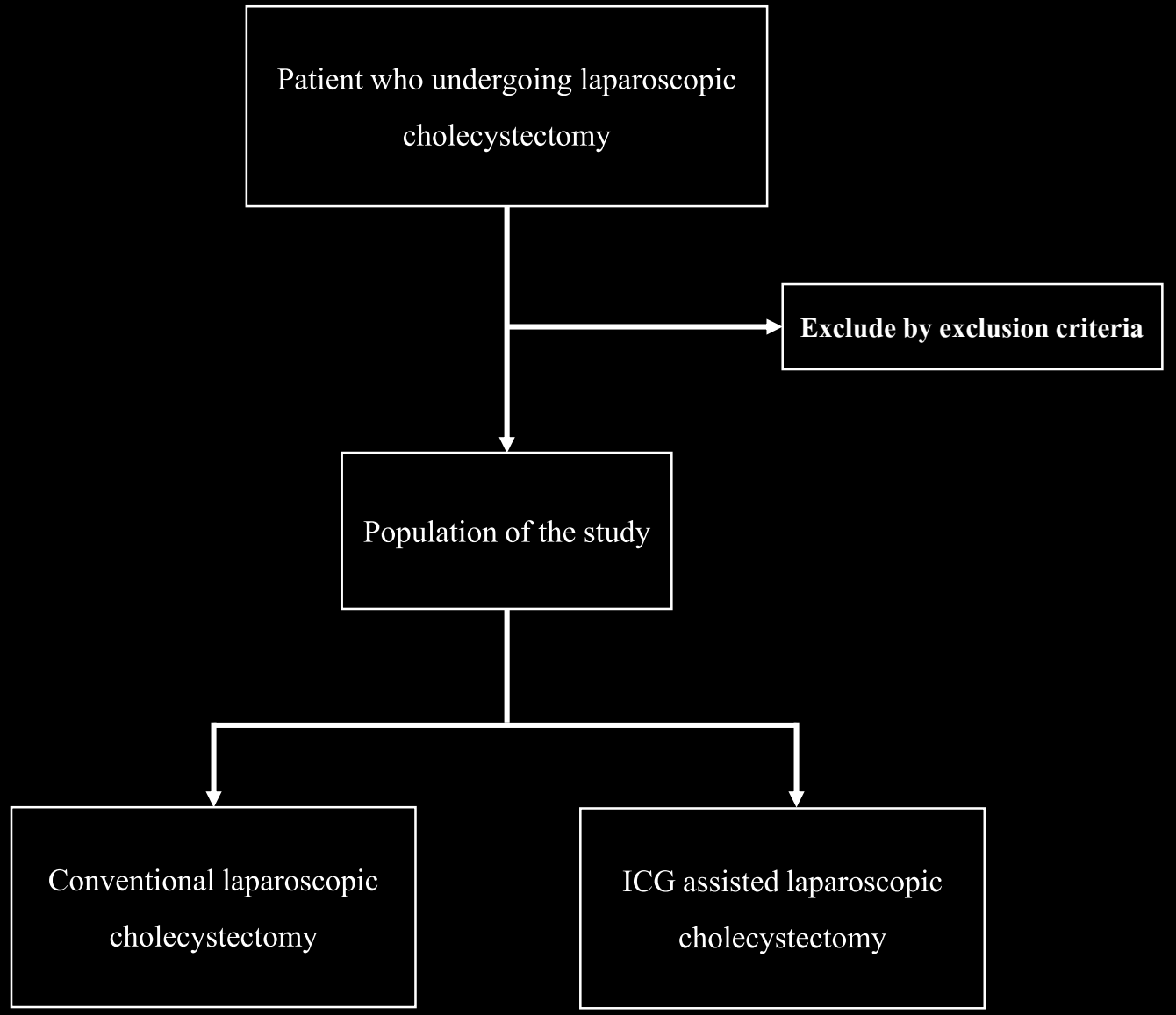
Methods

- Primary outcome : post-operative complication.
- Secondary outcome
  - time to CVS
  - conversion rate
  - length of stay (LOS)
  - operation time
- Data analysis : STATA program

Methods

- closed envelopes, 2 arms
- Inclusion criteria
  - Age ≥18 year-old
  - Volunteer
- Exclusion criteria
  - Concurrent another operation
  - Unstable vital sign or shock
  - History of inotrope or vasopressor during this illness
  - Suspected bile duct injury
  - Iodine or seafood allergy
  - Liver failure
  - Cirrhosis at least Child Pugh B, C

Methods


Patient who undergoing laparoscopic cholecystectomy
Exclude by exclusion criteria
Population of the study
Conventional laparoscopic cholecystectomy
ICG assisted laparoscopic cholecystectomy

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COA. MURA2022/455
Ref.2024/904

Title of Project (English)	Role of Indocyanine Green Assist Laparoscopic Cholecystectomy Compared with Conventional Laparoscopic Cholecystectomy in Ramathibodi Hospital : Randomized Controlled Trial
Title of Project (Thai)	ประโยชน์ของการใช้สารอินโดไซยานินสีเขียว (Indocyanine green) เพื่อช่วยในการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องเปรียบเทียบกับการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องแบบมาตรฐาน
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Principal Investigator	Patchaporn Sermsartrat
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Document reviewed	Annual Progress Report Date 03/09/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	August 17, 2022
Renewal Date (2nd)	August 17, 2024
Date of Expiration	August 16, 2025

Signature of Chair.....
(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

COA NO. MURA2022/455
วันที่รับรอง 1 ธันวาคม 2565
Ref.2721

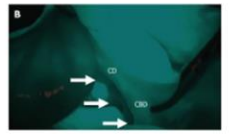
เอกสารข้อมูลและขอความยินยอมสำหรับการวิจัยทางคลินิก

ชื่อโครงการวิจัย : ประโยชน์ของการใช้สารอินโดไซยานินสีเขียวเพื่อช่วยในการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องเปรียบเทียบกับการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องแบบมาตรฐานในโรงพยาบาลรามาธิบดี
ผู้วิจัยหลัก : พญ..พัชภรณ์ เสริมสาสน์วัตน์
สังกัด : ภาควิชาศัลยศาสตร์ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล
ผู้สนับสนุนการวิจัย : ภาควิชาศัลยศาสตร์ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล

ความเป็นมาของโครงการ

การผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้อง เป็นหนึ่งในการรักษามาตรฐานของโรคที่เกี่ยวข้องกับถุงน้ำดีหลายโรค เช่น ถุงน้ำดีอักเสบ นิ่วในถุงน้ำดี ก้อนเนื้อในถุงน้ำดี เป็นต้น โดยเฉพาะอย่างยิ่งโรคถุงน้ำดีอักเสบเป็นโรคที่พบได้บ่อยในประเทศไทย ซึ่งการรักษามาตรฐานในปัจจุบันคือการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้อง แทนที่การผ่าตัดถุงน้ำดีแบบเปิดทางหน้าท้องในอดีต เนื่องจากมีแผลผ่าตัดที่เล็กกว่า และผู้ป่วยสามารถกลับไปใช้ชีวิตประจำวันได้เร็วกว่า

ในการผ่าตัดถุงน้ำดีโดย**วิธีส่องกล้องแบบมาตรฐาน**สามารถทำได้โดยการลงแผลผ่าตัดขนาดเล็ก จำนวน 3-4 แผล บริเวณหน้าท้อง เพื่อใส่กล้องและอุปกรณ์ที่ใช้สำหรับผ่าตัด จากนั้นจะทำการเลาะหาท่อน้ำดีส่วนที่ติดกับถุงน้ำดีและเส้นเลือดที่ไปเลี้ยงถุงน้ำดี แล้วจึงใช้คลิปสำหรับผ่าตัดหนีบตรงบริเวณดังกล่าว เพื่อป้องกันการรั่วไหลของน้ำดีและไม่ให้เกิดการเสียเลือดจากการผ่าตัด จากนั้นทำการตัดท่อน้ำดีและเส้นเลือดที่หนีบไว้และเลาะถุงน้ำดีออก แล้วจึงนำถุงน้ำดีออกมาทางแผลที่หน้าท้อง ซึ่งในผู้ป่วยบางรายการหาท่อน้ำดีหรือเส้นเลือดนั้นอาจจะทำได้ยากขึ้นหากเคยผ่าตัดหรือมีการอักเสบบริเวณนั้นมาก่อน **ซึ่งการฉีดสารอินโดไซยานินสีเขียว**ขณะผ่าตัดถือเป็นทางเลือกหนึ่งที่จะช่วยผ่าตัดที่สามารถช่วยให้เห็นท่อน้ำดีและเส้นเลือดได้ชัดเจนยิ่งขึ้น โดยอาศัยคุณสมบัติของสารอินโดไซยานินสีเขียวที่ถูกขับออกจากร่างกายผ่านทางตับลงสู่ระบบทางเดินน้ำดี และสารนี้สามารถเรืองแสงภายใต้แสงอินฟราเรด ทำให้สามารถมองเห็นลักษณะทางกายภาพของระบบทางเดินน้ำดีขณะผ่าตัดได้ชัดเจนมากขึ้น ซึ่งมีการศึกษาพบว่าสามารถช่วยลดระยะเวลาการผ่าตัดและเพิ่มความถูกต้องในการแยกแยะลักษณะทางกายภาพขณะทำการผ่าตัดได้ดี แต่เนื่องจากยังไม่มีการศึกษาที่มากพอทำให้ยังไม่มีการใช้งานที่แพร่หลาย



รูปประกอบ 1: รูปภาพแสดงลักษณะทางกายภาพของถุงน้ำดีขณะทำการผ่าตัด
หากมีการฉีดสารสีเขียวจะทำให้เห็นลักษณะของระบบทางเดินน้ำดีชัดเจนมากขึ้น (บริเวณที่ลูกศรชี้)

Inform and Consent

Case record form

1

Identical number.....

Case record form

งานวิจัยเรื่อง : ประโยชน์ของการใช้อินโดไซยานินสีเขียวเพื่อช่วยในการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องเปรียบเทียบกับการผ่าตัดถุงน้ำดีโดยวิธีการส่องกล้องแบบมาตรฐานในโรงพยาบาลรามาธิบดี

ส่วนที่1 ข้อมูลทั่วไปของผู้ป่วย

เพศ: ❑ หญิง ❑ ชาย อายุ: ..... ปี
น้ำหนัก: ..... กก. ส่วนสูง: ..... ซม.
โรคประจำตัว: ❑ DM ❑ HT ❑ DLP ❑ CKD ❑ ESRD on HD
❑ Asthma ❑ COPD
❑ Other: 1 .....
2 .....
3 .....

ประวัติการใช้ยาต้านการแข็งตัวของเลือด หรือยาต้านเกร็ดเลือด :
❑ ไม่มี
❑ มี 1 ..... หยุดยาเมื่อ .....
2 ..... หยุดยาเมื่อ .....

ประวัติแพ้ยาแพ้อาหาร: ❑ ไม่มี ❑ มี 1 ..... อาการ .....
2 ..... อาการ .....
3 ..... อาการ .....

เคยได้รับการวินิจฉัยโรคเกี่ยวกับตับ ตับอ่อน และระบบทางเดินน้ำดีมาก่อนหรือไม่
❑ ไม่เคย ❑ เคย ระบุ: .....

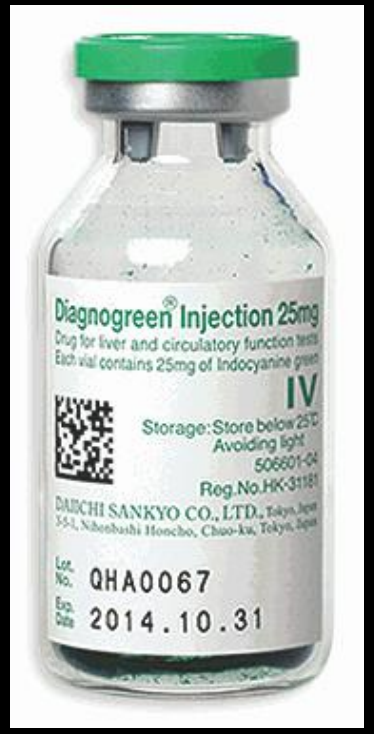
ประวัติการผ่าตัดในช่องท้อง: ❑ ไม่มี ❑ มี (หากมีโปรดกรอกข้อมูลข้างล่างนี้)

ครั้งที่	ปี พ.ศ.	ข้อบ่งชี้หรือคำวินิจฉัย	ผ่าเปิดหน้าท้อง	ผ่าตัดส่องกล้อง
1				
2				
3				
4				

หากมีข้อสงสัยสามารถติดต่อได้ที่ พญ.พัชภรณ์ เสริมสาสน์วัตน์ 064-5861481
version 3 21/6/66

Definition of outcome

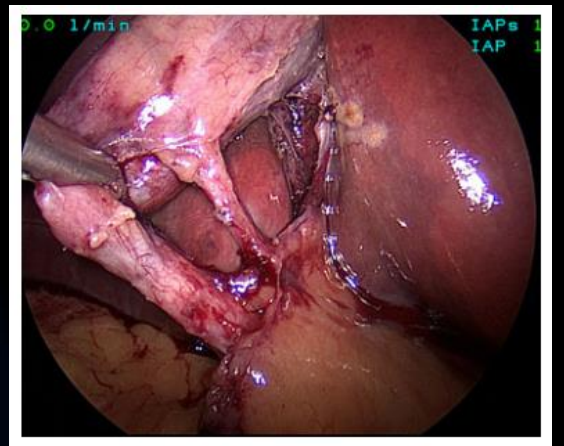
Post opertive compliction (primary outcome)	Bile duct injury, Bile leak, need blood transfusion, intra-abdominal collection, ileus, SSI, wound dehiscence, pneumonia
Critical view of safety	1. The hepatocystic triangle is cleared of fat and fibrous tissue. 2. The lower one third of the gallbladder is separated from the liver to expose the cystic plate. 3. Two and only two structures should be seen entering the gallbladder.
Time to CVS	Time since reach targeted pneumoperitoneum until identify critical view of safety
Conversion	Number of case that convert from LC to OC
Bile duct injury	Confirm with LAB + imaging



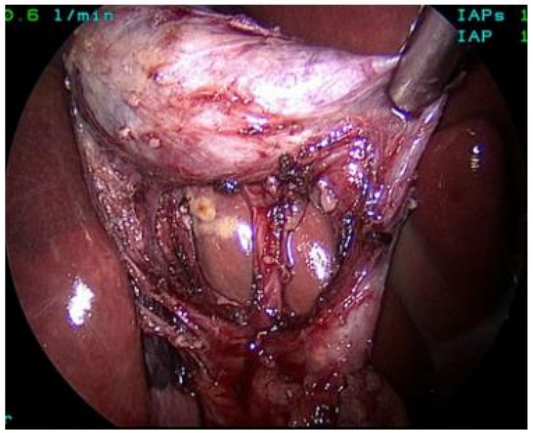
- Diagnogreen[R]
- Indocyanine green (ICG)
- 1 amp = 25 mg/10 ml
- Expired in 6 hr after diluted
- Fix dose = 2.5 mg = 1 ml IV of diluted
- Up to 10 case/amp

Operative protocol (control group)

1. Created pneumoperitoneum 12-14 mmHg >> record time
2. Ports and camera insetion
3. Dissect for CVS
4. Reach CVS >> record time to CVS
5. Use hemoloc for control bile duct stump and cystic artery
6. Dissect GB and put in specimen bag
7. Stop bleeding
8. Remove specimen via camera port (drain can be inserted as surgron preference)
9. Suture woud >> operative time



Visualization of the doublet view (anterior)

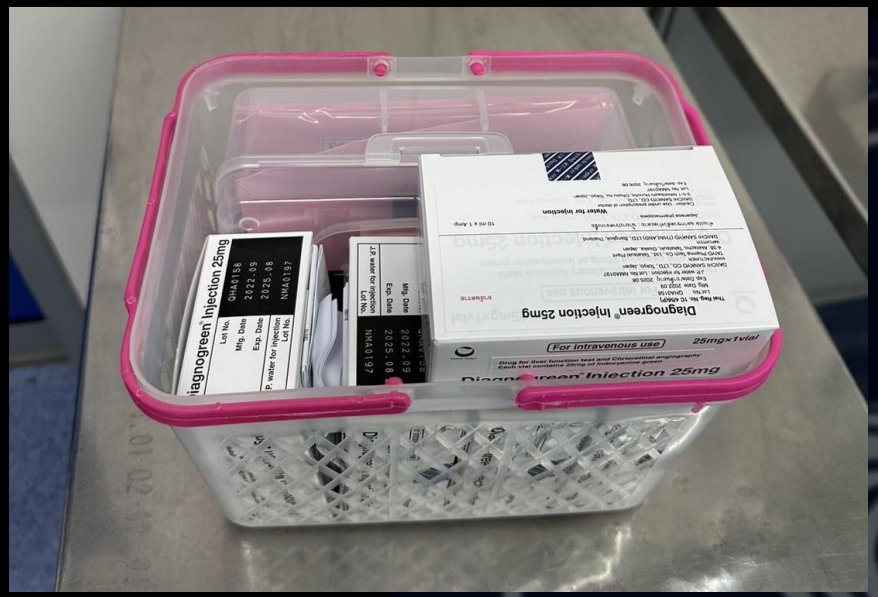


Visualization of the doublet view (posterior)

Operative protocol (ICG group)

The difference!

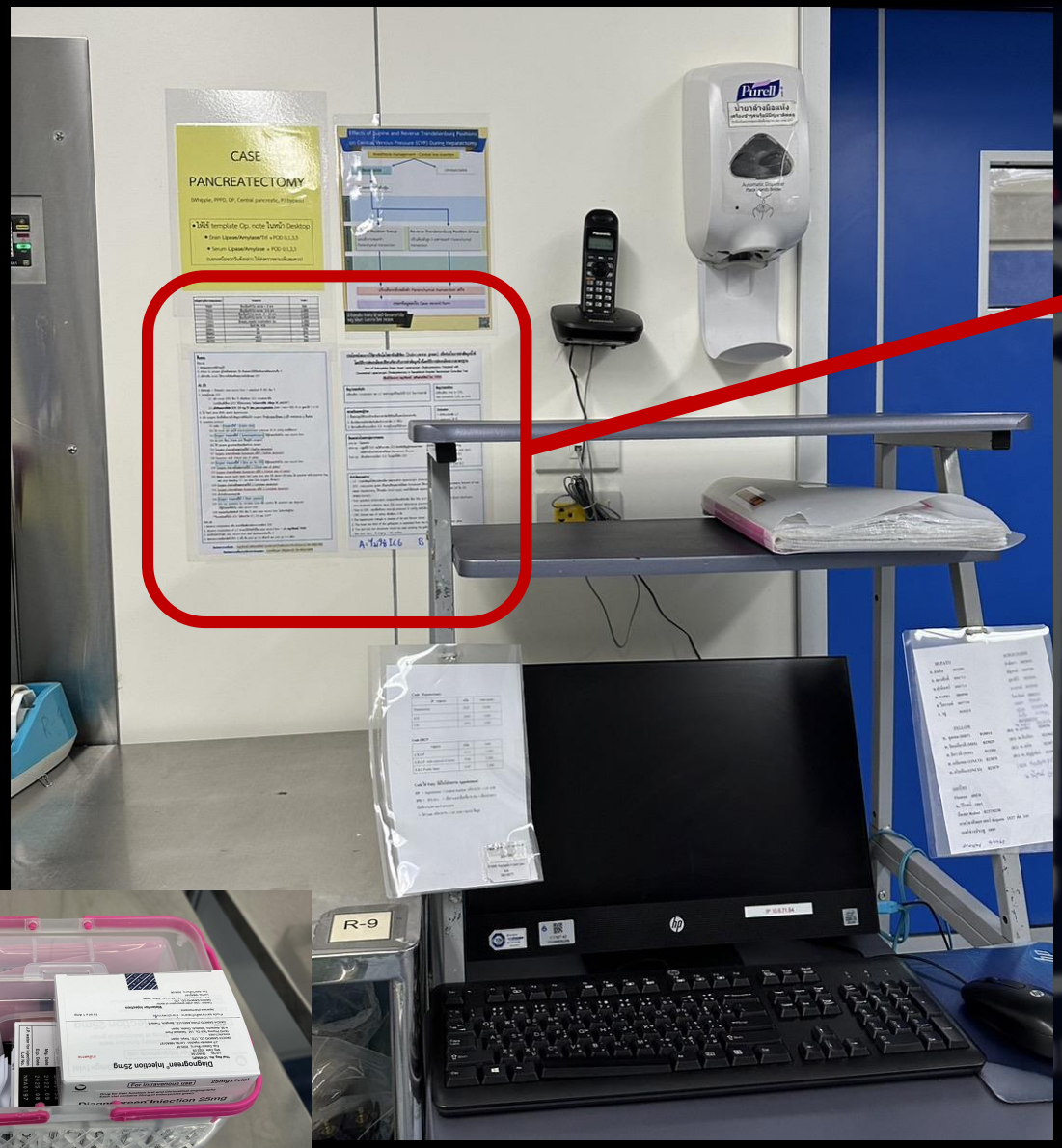
1. 2.5 mg of ICG was injected by Anthologist team before GA
2. Surgeon can switch to the fluorescence light at anytime during dissection.
3. The CVS must be identified under the fluorescence light then record the time to CVS.

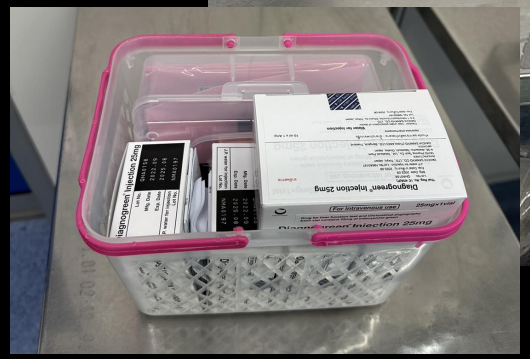

DiagnoGreen® Injection 25mg
For Intravenous use
25mg×1vial
DiagnoGreen Injection 25mg
Lot No. QHA0158
Mfg. Date 2022.09
Exp. Date 2025.08
P. water for Injection Lot No. NMA0197

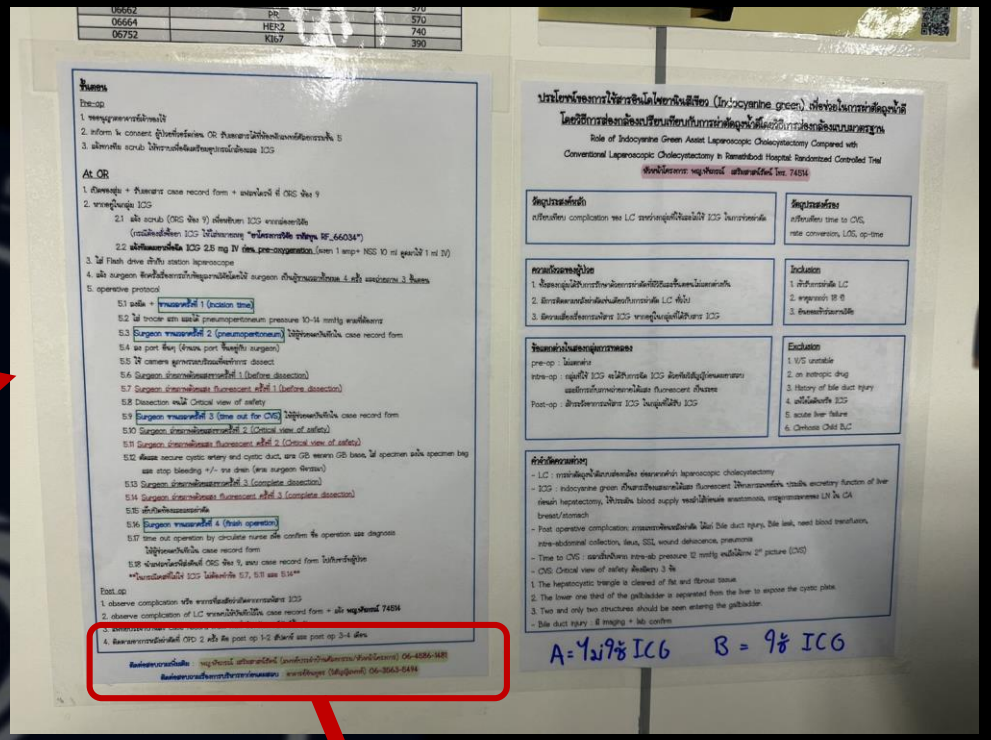
อ.พงศ์ธร
อ.พงศ์ธร
อ.พงศ์ธร
Lexar
Lexar

งานวิจัย
LC+ICG
อ.พงศ์ธร

Staff
เปิดเรียงหมายเลข!!
Laparoscopic Cholecystectomy in Ramathibodi Hospital: Randomized Controlled Trial
ID: 037
Fellow.
เปิดเรียงหมายเลข!!
ID: 003F
Resident
เปิดเรียงหมายเลข!!



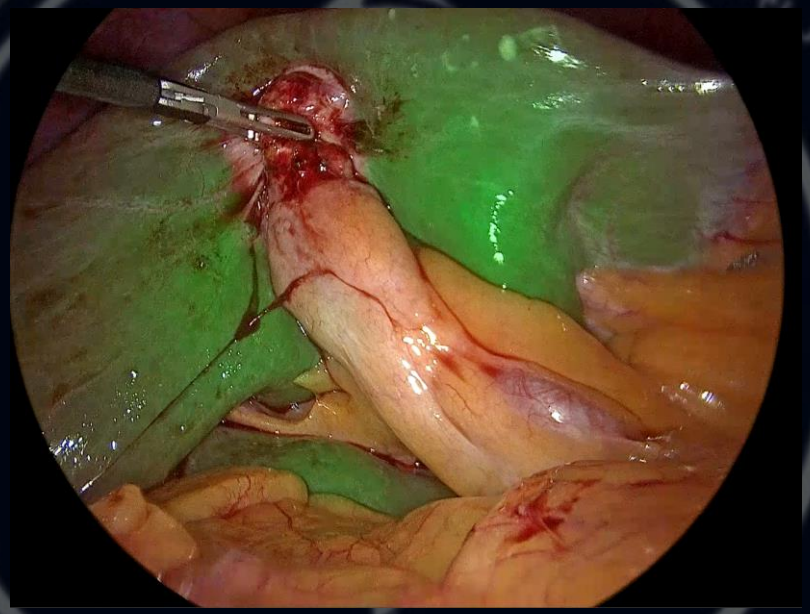


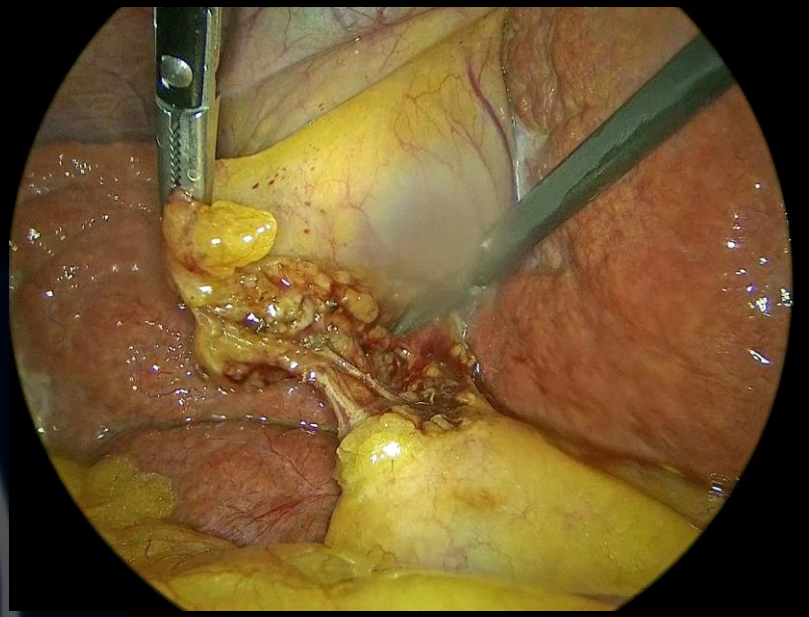


ติดต่อสอบถามเพิ่มเติม : พญ.พัชรกรณ์ เสริมสาสน์รัตน์ (แพทย์ประจำบ้านศัลยกรรม/หัวหน้าโครงการ) 06-4586-1481

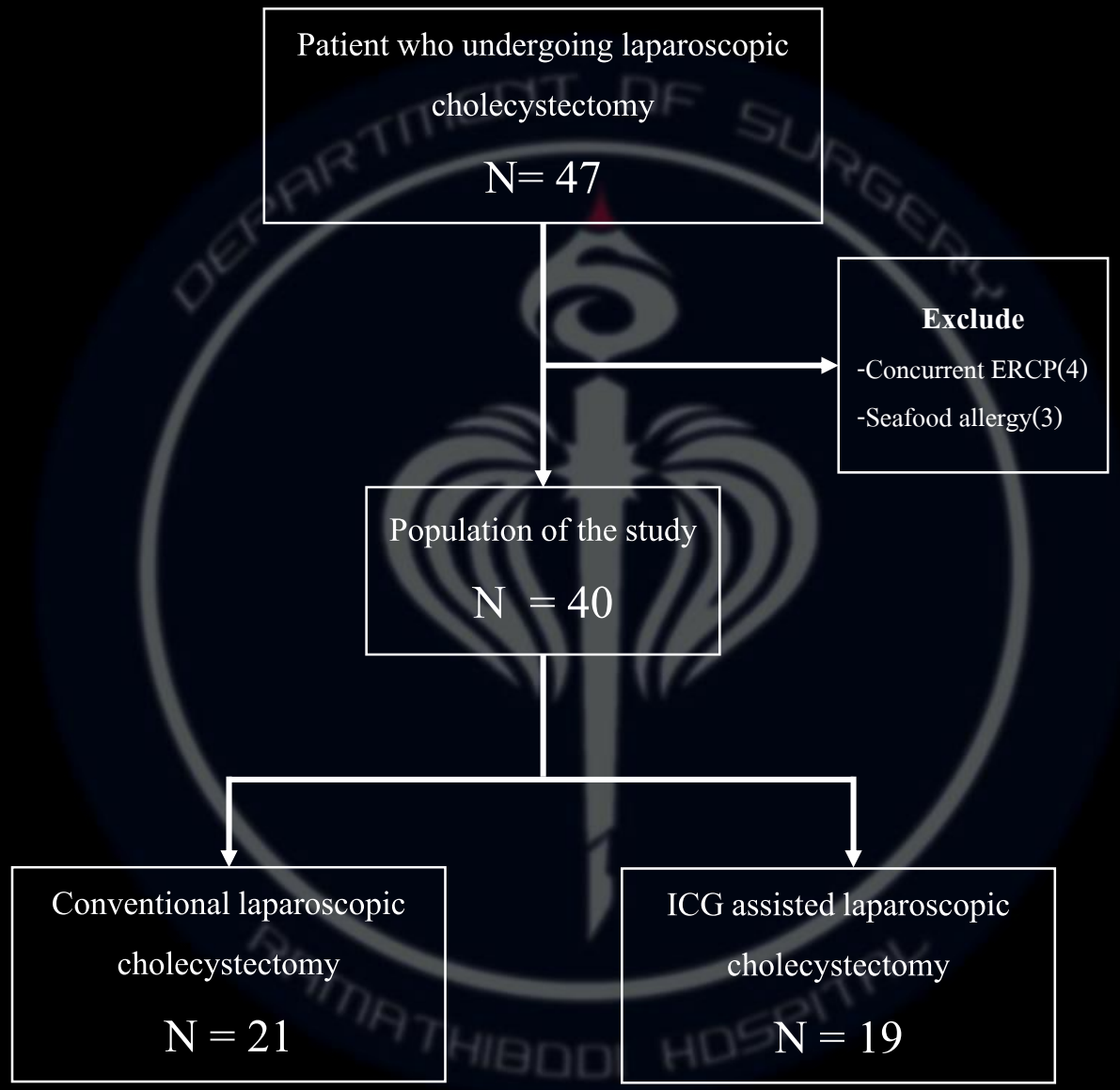
ติดต่อสอบถามเรื่องการบริหารยาก่อนดมสลบ : อาจารย์อินทุอร (วิสัญญีแพทย์) 06-3563-5494

Result





Result


Patient who undergoing laparoscopic cholecystectomy
N= 47
Exclude
-Concurrent ERCP(4)
-Seafood allergy(3)
Population of the study
N = 40
Conventional laparoscopic cholecystectomy
N = 21
ICG assisted laparoscopic cholecystectomy
N = 19

Result

Table 1 Characteristics of the patients

Characteristics	None ICG (n = 21)	ICG (n = 19)	P-value
Gender; n (%)			
Female	16 (76.2)	17 (89.5)	0.270
Male	5 (23.8)	2 (10.5)	
Age (year); mean ± SD	55.2 ± 14.4	58.5 ± 10.8	0.431
Body weight (kg.); median (min, max)	64 (50, 89)	60 (50, 87)	0.524
Height (cm.); mean ± SD	158.9 ± 8.2	157.1 ± 5.3	0.421
Body Mass Index (kg/m^2); mean ± SD	25.5 ± 3.2	25.2 ± 3.8	0.772
Underlying; n (%)	15 (71.4)	17 (89.5)	0.154
Antiplatelet; n (%)	3 (14.3)	4 (21.1)	0.574
Drug allergic history; n (%)	7 (33.3)	5 (26.3)	0.629
History of abdominal surgery; n (%)	7 (33.3)	3 (15.8)	0.201

No significant general characteristic between two groups.

Result

Table 2 Diagnosis and length of stay

Variable	None ICG (n = 21)	ICG (n = 19)	P-value
Pre-op Diagnosis; n (%)			
SGS	15 (71.4)	12 (63.2)	0.769
Cholecystitis	4 (19.1)	5 (26.3)	
Gallbladder polyp(s) / Mass	0 (0.0)	1 (5.3)	
GS pancreatitis	2 (9.5)	1 (5.3)	
Length of stay (day); median (min, max)	3.0 (0.0, 10.0)	3.0 (2.0, 5.0)	0.253

Result

Table 3 Operative data

Variable	None ICG (n = 21)	ICG (n = 19)	P-value
Surgeon; n (%)			
Staff	10 (47.6)	9 (47.4)	0.953
Fellow	4 (19.1)	3 (15.8)	
Resident	7 (33.3)	7 (36.8)	
Time of ICG; mean ± SD	-	44.6 ± 18.9	-
ICG allergy; n (%)	-	0 (0.0)	-
Time to CVS[a] (min); median (min, max)	20 (5, 85)	27 (8, 150)	0.322
Op-time[b] (min); median (min, max)	60 (45, 165)	85 (40, 215)	0.143
ICG identification; n (%)			
Cleary identified	-	4 (21.1)	-
Moderate	-	12 (63.2)	
Cannot identified	-	3 (15.8)	

CVS[a] =critical view of safety, Op-time[b] = operative time, OC[c] = open cholecystectomy

Result

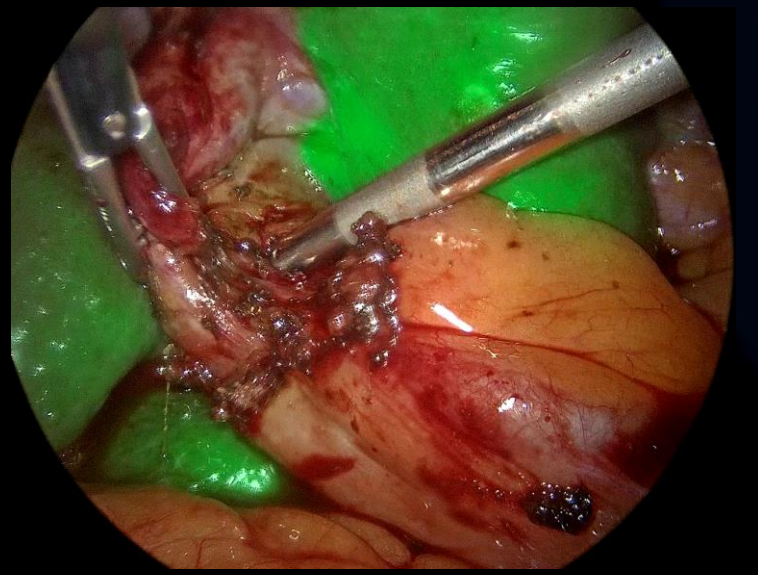


Table 3 Operative data

Variable	None ICG (n = 21)	ICG (n = 19)	P-value
Conversion to OC[c] n (%)	0 (0.0)	1 (5.3)	0.475
Bailout procedure; n (%)			
No	21 (100.0)	19 (100.0)	-
Subtotal cholecystectomy	-	-	
Fundus down	-	-	
Drain insertion; n (%)	1 (4.8)	1 (5.3)	>0.999
Complication; n (%)			
No	21 (100.0)	18 (94.7)	0.475
Bile duct injury	-	-	
Bile leak	-	-	
Significant bleeding	0 (0.0)	1 (5.3)	
Adjacent organ injury	-	-	
Blood loss (ml.); median (min, max)	10 (5, 100)	10 (5, 700)	0.944

CVS[a] =critical view of safety, Op-time[b] = operative time, OC[c] = open cholecystectomy

Result

Table 4 post-operative complication

Post-operative complication	None ICG (n = 21)	ICG (n = 19)	P-value
Post operation 2 weeks; n (%)			
No complication	21 (100.0)	19 (100.0)	-
SSI	-	-	
Intra-abdominal collection	-	-	
Wound dehiscence	-	-	
Pneumonia	-	-	
Prolong bowel dysfunction	-	-	
UTI	-	-	
AFI	-	-	
CBD stone cholangitis	-	-	
Post operation 3 months; n (%)			
No complication	20 (95.2)	19 (100.0)	>0.999
SSI	-	-	
Intra-abdominal collection	-	-	
Wound dehiscence	-	-	
Pneumonia	-	-	
Prolong bowel dysfunction	-	-	
UTI	-	-	
AFI	-	-	
CBD stone cholangitis	1 (4.8)	0 (0.0)	

Discussion

- This study aim to focus on the benefit of ICG in term of post operative complication which is low incidence.
- ICG is not the routine use for LC in Ramathibodi, some cases are the fist ICG assisted operation for the surgeons.
- 1 case have intra operative complication : bleeding
  - Difficult LC
  - Short drug interval before surgery
- The result of this study aligned in the same direction of previous study both time of ICG injection before surgery and duration to reach critical CVS

Discussion

- Limitations
  - Small group of patient
  - Single center
  - Inexperience to used the fluorescence light during laparoscopy
  - Fixed dose regimen

Discussion

- Future Development
  - Record about the impact in qualitative data such as surgeon confidence and patient satisfactory.
  - Easily technique for switch to ICG mode to minimized the difference time during surgery.
  - Compare the best time and dose of ICG identification in biliary system.
  - The cost effectiveness should be kept in mind.

Conclusion

The use of ICG may aid in identifying the CVS during laparoscopic cholecystectomy, but the clinical benefit remains uncertain, potentially due to the low enrollment number and low complication rates.

Some surgeons reported increased confidence when utilizing ICG. The future research focusing on surgeon confidence during training or in complex LC cases is warranted.

Abstract

“Parathyroid surgery in patients with secondary and tertiary hyperparathyroidism”

Panisara Srisuwannives, MD

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Background: Secondary hyperparathyroidism and tertiary hyperparathyroidism are prevalent diseases associated with morbidity and mortality in chronic renal disease patients. There are several alternatives for treatment both medical therapy and surgery. Parathyroid surgery is indicated for those who failed conventional therapy. Total parathyroidectomy with autotransplantation (TPTX +AT group), Total parathyroidectomy without autotransplantation (TPTX group), and subtotal parathyroidectomy (SPTX group) remain controversial for which is the best surgical method.

Objectives: To compare outcome of three different surgical choices for parathyroidectomy in patients with secondary and tertiary hyperparathyroidism. This would be benefit for selecting optimal methods for the future; reduce morbidity and mortality.

Method: A single center retrospective medical record review of total parathyroidectomy, with or without auto-transplantation and subtotal parathyroidectomy from 1 December 2010 to 31 December 2023 performed.

Result: All 344 patients included in study were operated for renal hyperparathyroidism during from 1 December 2010 to 31 December 2023. Two hundreds and thirty-nine patients (69%) were operated with SPTX, 28(8%) for TPTX, and 77(22%) received TPTX+AT. The preoperative parathyroid hormone levels were markedly high in all groups without significant difference.For overall complications, 6(7.79%) patients in the total parathyroidectomy with auto-transplantation (TPTX +AT) were required reoperation for persistent hyperparathyroidism resistant to nonoperative treatment more than subtotal parathyroidectomy group and total parathyroidectomy without auto-transplantation group (SPTX 6.72% and TPTX+AT 3.57%). Nine (3.9%) patients of SPTX group experienced recurrent hyperparathyroism more than other groups.

Conclusion: The subtotal and total parathyroidectomy with or without autotransplantation were practical procedures for patients with rHPT. The best surgical procedure is still unclear. Further prospective, randomized controlled trials with higher statistic power are needed to comparative these three surgeries for the long-term outcome and safety.

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Parathyroid surgery in patients with secondary and tertiary hyperparathyroidism

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COA No. MURA2024/731

Title of Project (English)	Parathyroid surgery in patients with secondary and tertiary hyperparathyroidism
Title of Project (Thai)	การผ่าตัดและปลูกถ่ายต่อมพาราไทรอยด์ในผู้ป่วยที่มีภาวะฮอร์โมนพาราไทรอยด์สูงแบบทุติยภูมิ และตติยภูมิ
Type of Review	Expedited
Principal Investigator	Panisara Srisuwannives
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator (s)	1. Thongchai Sukarayothin 2. Hataikarn Nimitphong
Approval includes	1. Submission form protocol version 2.0 date 10/10/2024 2. Curriculum vitae 3. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	October 17, 2024
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Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

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2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Introduction

- Secondary hyperparathyroidism and tertiary hyperparathyroidism are prevalent diseases associated with morbidity and mortality in chronic renal disease patients.
- There are several alternatives for treatment both medical therapy and surgery.
- Parathyroid surgery is indicated for those who failed conventional therapy.

Introduction

- Total parathyroidectomy with autotransplantation (TPTX +AT group), Total parathyroidectomy without autotransplantation (TPTX group), and subtotal parathyroidectomy(SPTX group) remain controversial for which is the best surgical method.

- The objective of the study was to compare the outcome of three different surgical procedures for renal hyperparathyroidism(rHPTH).

Material and Methods

- A single center retrospective cohort study
- Include patients undergoing parathyroid surgery (total parathyroidectomy, with or without auto-transplantation and subtotal parathyroidectomy) at Ramathibodi Hospital
- from 1 December 2010 to 31 December 2023

Material and Methods

- **Inclusion criteria**
- **Inclusion Criteria:**
  - Patients who have secondary or tertiary hyperparathyroidism.
  - Patients who have undergone parathyroidectomy.
- **Exclusion criteria**
  - Hyperparathyroidism due to genetic abnormalities (MEN I, MEN II, and other hereditary hyperparathyroidism).
  - Malignant diseases related to the parathyroid glands.

Outcome

- **Primary outcome**
  - Persistent and recurrent hyperparathyroidism

- **Secondary outcome**
  - Other complications such as neck hematoma, hypocalcemia, recurrent laryngeal nerve injury

Note : Persistent hyperparathyroidism defined as occurring in 6 months of surgery and recurrent hyperparathyroidism defined as occurring over 6 months of surgery

Results

Results

- All 344 patients included in study were operated for renal hyperparathyroidism during from 1 December 2010 to 31 December 2023.
    - 239(69%) underwent subtotal parathyroidectomy
    - 28(8%) received total parathyroidectomy
    - 77(22%) received total parathyroidectomy with auto transplantation

Patient characteristic

Table 1 Comparing baseline characteristics of the patients undergoing subtotal parathyroidectomy (SPTX), total parathyroidectomy with or without auto transplantation (TPTX+AT, TPTX)

Variable	SPTX (n = 239)	TPTX (n = 28)	TPTX+AT (n = 77)	P-value
Age (year); mean ± SD	45.9 ± 12.6	51.1± 9.9	48.3±13.7	0.066
Gender; n (%)				
Male	109 (45.6)	8 (28.6)	42 (54.6)	0.058
Female	130 (54.4)	20 (71.4)	35 (45.5)	
ESRD; n (%) (n = 118)				
on HD	78 (87.6)	4 (80.0)	23 (95.8)	0.341
on CAPD	4 (4.5)	0 (0.0)	1 (4.2)	
s/p KT	7 (7.9)	1 (20.0)	0 (0.0)	
Diabetes Mellitus; n (%)	41 (17.2)	3 (10.7)	15 (19.5)	0.574
Hypertension; n (%)	67 (28.0)	2 (7.1)	17 (22.1)	**0.043**
Cardiovascular disease; n (%) (n = 118)	10 (11.2)	0 (0.0)	2 (8.3)	>0.999
Respiratory disease; n (%)	3 (1.3)	1 (3.6)	1 (1.3)	0.410
Previous parathyroidectomy; n (%)	-	-	-	-
Diagnosis; n (%)				
2HPTH	124 (51.9)	13 (46.4)	42 (54.6)	0.760
3HPTH	115 (48.1)	15 (53.6)	35 (45.5)	
Pre-PTH (pg/mL); median (IQR)	1992.5 (1382.5, 2791.5)	1747 (843.1, 2726)	1987 (1281, 2854)	0.824
Pre-Calcium (mg/dL); median (IQR)	10.4 (9, 1522)	12 (6.1, 1662.5)	10.1 (7.1, 1242)	0.443

Note: SPTX = subtotal parathyroidectomy, TPTX+AT = Total parathyroidectomy with auto transplantation, TPTX= Total parathyroidectomy without auto transplantation

Results

- No statistically significant difference between diagnosis on 2HPTH and 3HPTH.
- The preoperative parathyroid hormone levels were markedly high in all groups without significant difference.

Results

Table 2 Comparing postoperative laboratory values between patients undergoing subtotal parathyroidectomy (SPTX), total parathyroidectomy with or without auto transplantation (TPTX+AT, TPTX)

Variable	SPTX (n = 239)	TPTX (n = 28)	TPTX+AT (n = 77)	P-value
Length of Hospital stay (days); median (IQR)	5 (3, 6)	5.5 (4, 8)	5 (4, 7)	0.054
Post-PTH (pg/mL); median (IQR)				
24 hrs. (n = 324)	68.4 (21.3, 183.6)	85.2 (18.8, 211)	46.8 (18.3, 153)	0.789
1 month (n = 179)	80.9 (17, 291.2)	20.6 (4.6, 163.9)	54 (14, 260.7)	0.285
3 months (n = 142)	73.2 (18, 263)	15.1 (11.3, 286.4)	60.5 (9.9, 208.6)	0.576
6 months (n = 150)	58.4 (17.2, 256.5)	36.9 (6.2, 375)	64.6 (23.3, 232.7)	0.721
Post-Calcium (mg/dL); median (IQR)				
24 hrs. (n = 335)	7.6 (5.3, 9.1)	7.6 (3.9, 8.6)	7.5 (6.4, 8.3)	0.850
1 month (n = 205)	8.6 (7.3, 10.1)	10.8 (8.6, 65.3)	8.7 (7.4, 27.6)	0.088
3 months (n = 163)	9.3 (7.5, 11)	11.5 (8.8, 148.1)	10 (8.1, 35.2)	0.114
6 months (n = 170)	9.5 (8.6, 11.4)	9.4 (7.3, 94.9)	9.5 (8.4, 25)	0.968

Results

Table 3 Comparing overall complications in patients undergoing subtotal parathyroidectomy (SPTX), total parathyroidectomy with or without auto transplantation (TPTX+AT, TPTX)

Variable	SPTX (n = 239)	TPTX (n = 28)	TPTX+AT (n = 77)	P-value
Hematoma; n (%)	2 (0.8)	0 (0.0)	1 (1.3)	0.666
SSI; n (%)	-	-	-	-
Hypocalcemia; n (%)	45 (18.8)	2 (7.1)	15 (19.5)	0.292
RLN injury; n (%)	-	-	-	-
Persistent HPTH; n (%)	16 (6.7)	1 (3.6)	6 (7.8)	0.746
Recurrent HPTH; n (%)	-	-	-	-
Recurrent HPTH after 2 years; n (%)	9 (3.9)	1 (3.6)	3 (4.1)	>0.999

Note: SSI = Surgical site infection, RLN injury = Recurrent laryngeal nerve injury,

Discussion

- This study aims to find optimal surgical procedures for renal HPTH based on outcomes and complications of three different procedures.

- Previous retrospective cohort studies found the rate of recurrent or persistent HPTH range from 0 to 12% for SPTX and 0-10% for TPTX+AT and TPTX

Discussion

- In this study, 6(7.8%) patients the TPTX +AT group were required reoperation for persistent hyperparathyroidism resistant to non-operative treatment more than subtotal parathyroidectomy group and total parathyroidectomy without auto-transplantation group SPTX (6.7%) and TPTX+AT (3.56%)—>No statistically significant difference.

Discussion

- 9(3.09%) patients of SPTX group experienced recurrent hyperparathyroidism more than other groups —>no significant difference statistically.

- The result of the study showed the disease did not persist in 93% patients and also all three operations —>very low complications

Discussion

- **Limitations**
  - Retrospective study
  - Missing data → lack of long term follow up

- **Future development**
  - Randomized control trial study
  - Evaluation of surgeon experience

Conclusion

- The subtotal and total parathyroidectomy with or without auto transplantation were practical procedures and safe for patients with rHPT. The best surgical procedure is still unclear.

- Further prospective, randomized controlled trials with higher statistic power are needed to comparative these three surgeries for the long-term outcome and safety

Thank you.

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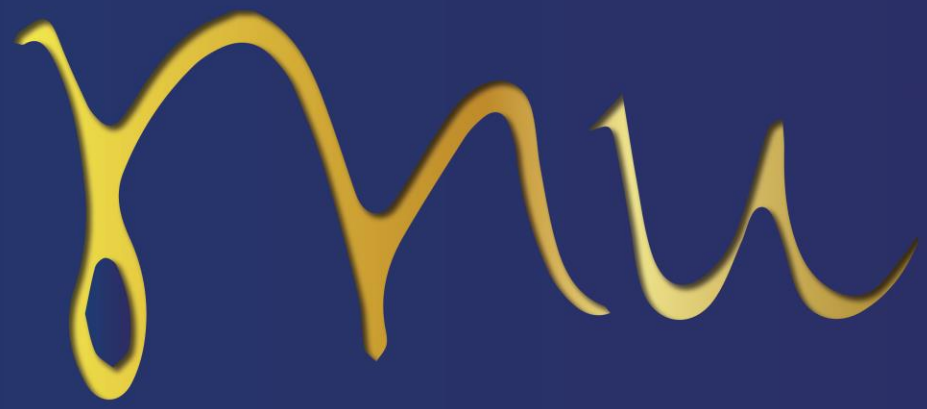

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Abstract

“Prospective Randomized Controlled Trial to evaluate effectiveness of Tranexamic Acid Irrigation on Perioperative Blood Loss During Mini-Percutaneous Nephrolithotomy”

Ornnicha Prohsoontorn, MD

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Introduction: Mini percutaneous nephrolithotomy (Mini-PCNL) has comparable stone clearance rates to standard percutaneous nephrolithotomy (PCNL) which is the gold standard surgical treatment for large renal kidney stones. A smaller sheath size causes less renal trauma but it limits the available working channel in the meanwhile. The visual field is the key to success so it will become more challenging with the bleeding.

Objectives: To evaluate the effectiveness and safety of 0.1% tranexamic acid in irrigation fluid for reducing blood loss during mini-percutaneous nephrolithotomy (mini-PCNL).

Materials and methods: We conducted a study on 40 patients scheduled for mini-PCNL, and they were prospectively randomized into two equal groups. In the experimental group, the irrigation fluid was supplemented with 0.1% tranexamic acid. Conversely, the controlled group received distilled water added to the irrigation fluid during surgery. Operative data were recorded, which included hemoglobin decrease, blood loss, operative duration, irrigation fluid volume, hospital stay length, blood transfusion needs, mini-PCNL complications, and tranexamic acid side effects.

Results: Baseline parameters were comparable between the two groups. The fall in hemoglobin and total blood loss in the tranexamic group was significantly lower than in the placebo group (0.52 vs. 1.52 gm/dL, 91.75 vs. 169.00 mL, respectively, $p < 0.05$). Operative time and hospital stay of the tranexamic group were significantly lower compared to the placebo group ($p < 0.05$). The amount of irrigation fluid used, complete stone clearance rate, and blood transfusion were lower in the tranexamic group, without statistical significance. No adverse events related to the administration of tranexamic acid were noted.

Conclusion: It was found that 0.1% tranexamic acid in irrigant fluid is safe and significantly reduces perioperative blood loss and the requirement for blood transfusion during mini-PCNL.

Prospective Randomized Controlled Trial to evaluate effectiveness of Tranexamic Acid Irrigation on Perioperative Blood Loss During Mini-Percutaneous Nephrolithotomy

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Ethic approval

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COA. MURA2020/579
Ref.1103

Title of Project (English)	Prospective Randomized Controlled Trial to Evaluate Effectiveness of Tranexamic Acid Irrigation on Perioperative Blood Loss During Percutaneous Nephrolithotomy
Title of Project (Thai)	การทดสอบวัดประสิทธิภาพของการใช้ยา Tranexamic Acid ผสมเป็นสารละลายระหว่างผ่าตัดนิ่วในไตโดยการส่องกล้องผ่านผิวหนัง ช่วยลดภาวะเลือดออกระหว่างผ่าตัด
Type of Review	Full Board
Principal Investigator	Chinnakhet Ketsuwan, M.D.
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 02/07/2021

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Date of Initial Approval	March 25, 2020

Project was suspended during March 25, 2021 to July 12, 2021 due to no annual renewal approval in the period

Renewal Date (1st)	July 12, 2021
Date of Expiration	July 11, 2022

Signature of Chair.....
(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

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1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

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Ref.2744

Title of Project (English)	Prospective Randomized Controlled Trial to Evaluate Effectiveness of Tranexamic Acid Irrigation on Perioperative Blood Loss During Percutaneous Nephrolithotomy
Title of Project (Thai)	การทดสอบวัดประสิทธิภาพของการใช้ยา Tranexamic Acid ผสมเป็นสารละลายระหว่างผ่าตัดนิ่วในไตโดยการส่องกล้องผ่านผิวหนัง ช่วยลดภาวะเลือดออกระหว่างผ่าตัด
Type of Review	Full Board
Principal Investigator	Chinnakhet Ketsuwan
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 10/11/2022

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Date of Initial Approval	March 25, 2020

Project was suspended during July 12, 2022 to November 09, 2022 due to no annual renewal approval in the period

Renewal Date (2nd)	November 09, 2022
Date of Expiration	November 08, 2023

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COA. MURA2020/579
Ref. 3993

Title of Project (English)	Prospective Randomized Controlled Trial to Evaluate Effectiveness of Tranexamic Acid Irrigation on Perioperative Blood Loss During Percutaneous Nephrolithotomy
Title of Project (Thai)	การทดสอบวัดประสิทธิภาพของการใช้ยา Tranexamic Acid ผสมเป็นสารละลายระหว่างผ่าตัดนิ่วในไตโดยการส่องกล้องผ่านผิวหนัง ช่วยลดภาวะเลือดออกระหว่างผ่าตัด
Type of Review	Full Board
Principal Investigator	Chinnakhet Ketsuwan
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 08/12/2023

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	March 25, 2020
Renewal Date (3rd)	November 09, 2023
Date of Expiration	November 08, 2024

Signature of Chair.....
(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

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Introduction

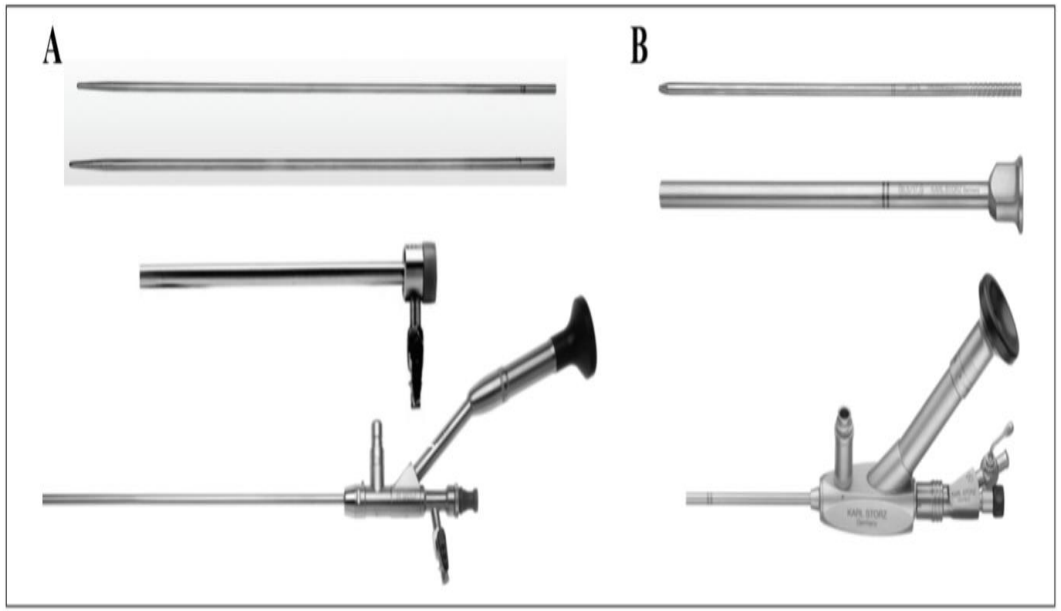
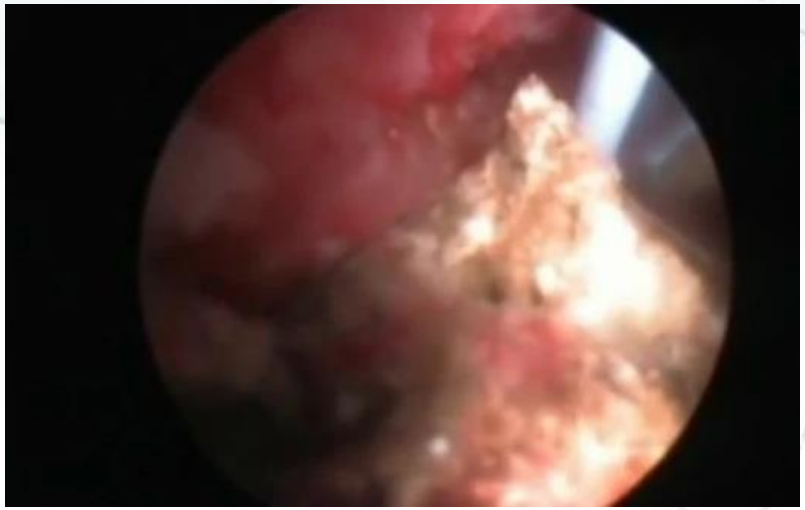


Figure 1. (A) Wolf dilators with sheath and miniature nephroscope. (B) Storz dilator with sheath and miniature nephroscope.

- Mini percutaneous nephrolithotomy **(Mini-PCNL) has comparable stone clearance rates to standard percutaneous nephrolithotomy (PCNL)** which is the gold standard surgical treatment for large renal kidney stones.

Introduction



- A **smaller sheath size(<20-24 Fr)** causes less renal trauma but it limits the available working channel in the meanwhile. The visual field is the key to success so it will become more challenging with the bleeding.

Objectives

To evaluate the effectiveness and safety of 0.1% tranexamic acid in irrigation fluid for reducing blood loss during mini-PCNL.

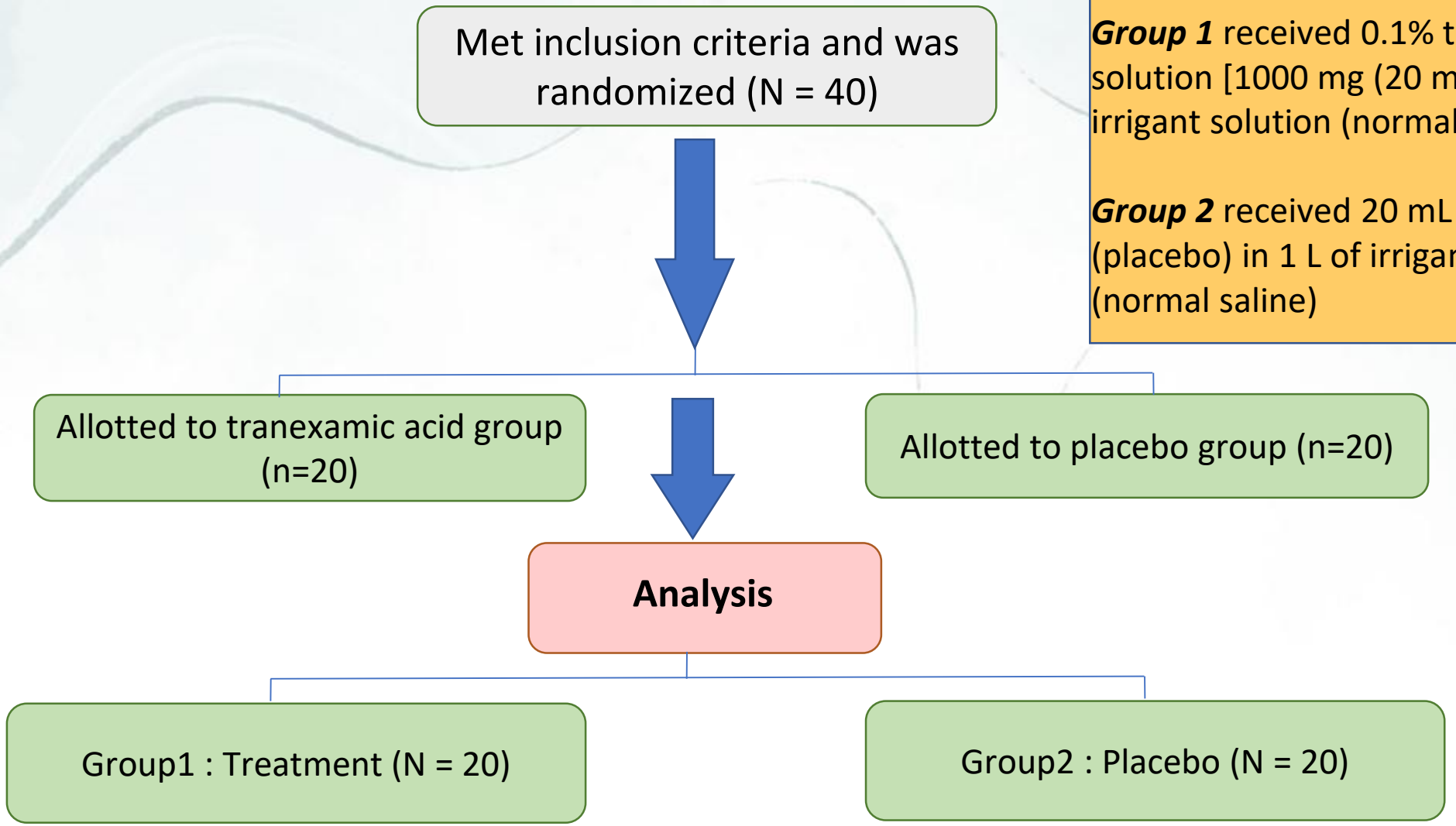
Materials & Methods

- We conducted a study on 40 patients scheduled for mini-PCNL, and they were prospectively randomized into two equal groups.
- In the experimental group, the irrigation fluid was supplemented with 0.1% tranexamic acid. Conversely, the controlled group received distilled water added to the irrigation fluid during surgery.

Materials & Methods

- **Operative data** were recorded, which included hemoglobin decrease, blood loss, operative duration, irrigation fluid volume, hospital stay length, blood transfusion needs, mini-PCNL complications, and tranexamic acid side effects.

Materials & Methods

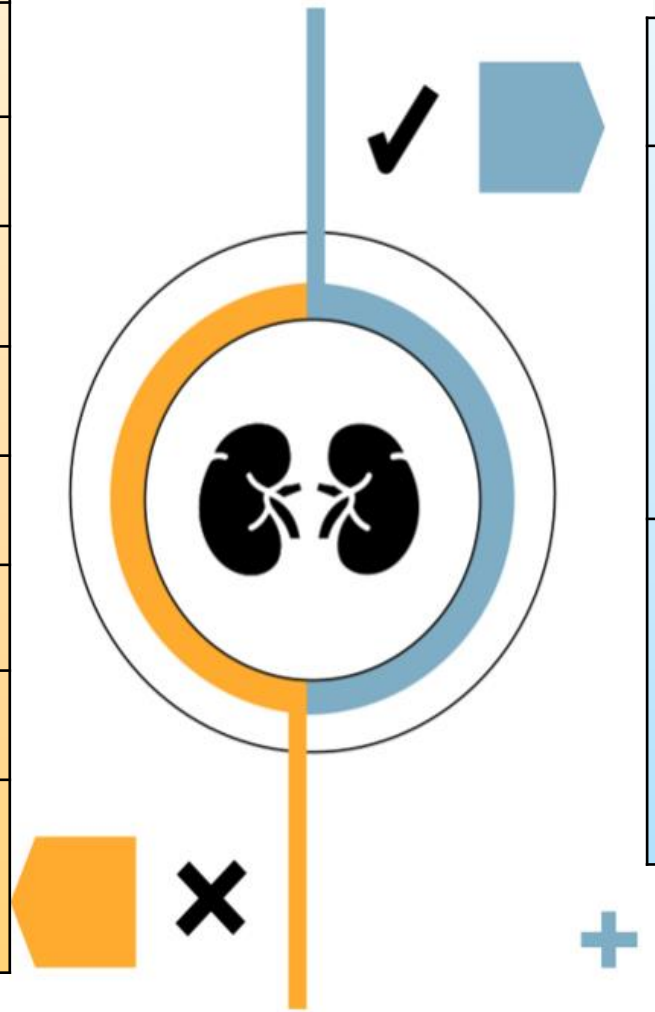


Group 1 received 0.1% tranexamic acid solution [1000 mg (20 mL) in 1 L of irrigant solution (normal saline)]

Group 2 received 20 mL distilled water (placebo) in 1 L of irrigant solution (normal saline)

Inclusion vs Exclusion criteria

Exclusion criteria
1) Hypersensitivity to Tranexamic acid
2) Patient who has SAH
3) Active intravascular clotting
4) Hx of seizure
5) Severe renal impairment
6) Upper renal tract bleeding
7) Acquired defective color vision
8) Hx of vascular occlusive events



Inclusion criteria
1) Age > 18 yo
2) Renal stone size 10-35 mm (AUA guideline)

Materials & Methods

Primary outcome

Perioperative blood loss
- Fall in Hb & Hct
- Total blood loss
- PRC transfusion

Secondary outcome

- Stone free rate
- Length of stay in hospital
- Operative time

STATISTICAL ANALYSIS

- Data analysis was performed using Program **STATA version 14.2** (**STATA Corp., TX, USA**).
- **Quantitative data** was summarized as mean and SD or median and range as appropriate.
- **Categorical data** was summarized as counts and percentage.
- Comparison of quantitative variables between treatment groups was done using the Independent t-test or Wilcoxon rank-sum (Mann-Whitney) test as appropriate.
- Comparison of categorical variables between groups was done using the Chi-square test or Fisher's exact test appropriate.

Results

Variable	Tranexamic acid group (n = 20)	Placebo group (n = 20)	p-value
Age (in years)	59.2 ± 8.5	63.7 ± 9.2	0.12
Gender (n)			
Male	7	7	1.00
Female	13	13	
Laterality			
Right	12	10	0.53
Left	8	10	
BMI (kg/m^2)	25.9 ± 5.5	24.9 ± 5.3	0.59
Stone size (cm^2)	338.7 ± 334.9	395.4 ± 326.1	0.59
No. of tracts (n)			0.43
Single	17	15	
Multiple	3	5	
Site of puncture (n)			
Upper calyx	12	13	0.57
Middle calyx	3	1	
Lower calyx	5	6	
History of previous intervention (n)			0.25
Open pyelolithotomy	1	1	
PCNL	4	4	
RIRS	0	1	
ESWL	4	0	
Skin-to-stone distance (cm)	8.8 ± 1.3	8.0 ± 1.6	0.08
Stone density (Hounsfield unit)	836.8 ± 297.8	1220.9 ± 1646.5	0.31

Table 1 Comparison of patient baseline demographics and clinical parameters between groups

Results

Parameter	Tranexamic acid group (n = 20)	Placebo group (n = 20)	p-value
Fall in hemoglobin (gm/dL)	0.52 ± 0.36	1.52 ± 1.93	0.01
Total blood loss (mL)	91.75 ± 69.42	169.00 ± 145.49	0.02
Operating time (min)	122.25 ± 52.67	168.75 ± 85.53	0.02
Amount of irrigation fluid (L)	8.88 ± 3.99	11.65 ± 8.49	0.09
Requirement of blood transfusion (n, %)	1 (5%)	3 (15%)	0.29
Length of hospital stay (days)	3.15 ± 1.34	5.15 ± 3.91	0.02

Table 2 Comparison of intraoperative and postoperative parameters between groups

Discussion

- **Mini-PCNL** is a modified technique that reduces complications compared to standard PCNL. It was initially used in pediatric patients but is now widely used in adults as well. Although its stone-free rate (SFR) is similar to standard PCNL, mini-PCNL has a longer operative time.

Discussion

- **Bleeding** during mini-PCNL can result from various factors, including age, obesity, comorbidities, stone size, and surgeon expertise.
- Most bleeding is manageable conservatively, though 0.3–1.4% of cases may require angioembolization.

Discussion

- **Tranexamic acid** is an antifibrinolytic agent used in various surgeries to reduce bleeding. This study is the first to use tranexamic acid as an irrigant in mini-PCNL. The results show that 0.1% tranexamic acid significantly **reduces perioperative blood loss, with a notable decrease in hemoglobin drop (0.52 vs. 1.52 gm/dL) and total blood loss (91.75 vs. 169.00 mL)** compared to the placebo group.

Discussion

- These findings align with previous research, such as **Bansal and Arora's study on standard PCNL**, which also showed reduced blood loss with tranexamic acid. Additionally, the tranexamic acid group had a shorter operative time due to better visualization, which may help reduce the time spent controlling bleeding.

Discussion

- Tranexamic acid was safe in both studies, supporting its potential use in mini-PCNL as a standard practice to reduce bleeding. Although the difference in blood transfusion rates was not statistically significant in this study, there was a trend towards fewer transfusions in the tranexamic acid group, especially beneficial for patients with higher risks.

Conclusions

It was found that **0.1% tranexamic acid in irrigant fluid** is **safe and significantly reduces perioperative blood loss** during mini-PCNL.

Limitations

- **Single-institutional study** and relatively **small sample size** may introduce biases
- **Follow up period is limited** to one month but long-term effects such as stone recurrence or renal function were not assessed.

Future Directions

- **Larger, Multicenter Trials** – Conducting trials across multiple institutions with a larger patient pool can strengthen the evidence for using tranexamic acid in mini-PCNL.
- **Long-Term Follow-Up** – Future studies should evaluate the long-term outcomes, including stone recurrence, renal function, and potential thrombotic complications.

Thank you for your attention

Abstract

“An in vitro study of Microencapsulation of Human Parathyroid Cell”

Ornicha Makkasem,MD

Ornicha Makkasem, Ronnarat Suvikapakornkul

Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, 10400, Thailand

Background: The incidence of permanent hypoparathyroidism following surgery for both the parathyroid and thyroid glands is reported to range 0-3% of cases. This leads to an impact on the patient’s quality of life, increased hospitalization rates, and higher healthcare costs.Parathyroid allotransplantation is the definitive treatment for permanent hypoparathyroidism. A significant obstacle of this method is the host’s immune system on the transplanted parathyroid tissue. To overcome this problem microencapsulation of parathyroid cells is a promising method. Cell microencapsulation in hydrogel is a process in which cells or tissues are enclosed in a semi-permeable membrane to prevents the immune system from attacking the cells

Objectives: We describe hydrogel microencapsulation of human parathyroid cells using alginate microfiber. Cell viability, cell growth, and parathyroid hormone production of microencapsulated cells were evaluated

Materials & Methods: Parathyroid cells were cultured and isolated. We produced cells encapsulated in hydrogel microfibers. Alginate lyase-loaded PLGA nanoparticles (NPs) and parathyroid cells were encapsulated into the alginate hydrogel microfibers. The microfluidic laminar flow method was employed to fabricates the cell encapsulated microfibers via an aqueous two-phase system (ATPS)
The structure of alginate microfibers will be then characterized by scanning electron microscope (SEM). Cell viability and PTH secretion of hydrogel microfibers were evaluated in vitro for 21 days compare with monolayer cell culture

Result: Encapsulated parathyroid cells in hydrogel can be cultured and proliferated inside hydrogel microfiber over 21 days. However, the amount of in vitro PTH secretion from encapsulated cells was significantly lower than monolayer culture cell

Conclusion: Cell encapsulated hydrogel microfibers foundational process that can be further developed for the treatment of patients with hypoparathyroidism in the future.

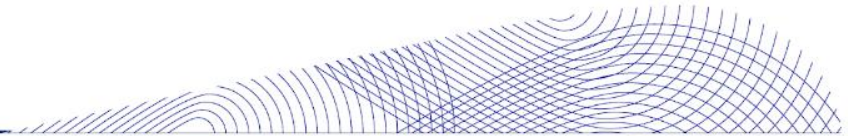
An *in vitro* study of Microencapsulation of Human Parathyroid Cell

Ornicha Makkasem M.D.

Assoc. Prof.Ronnarat Suvikapakornk

Mahidol University
Wisdom of the Land

No disclosures



Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University
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COA. MURA2022/757

Title of Project (English)	*In vitro* study of Human Parathyroid Cell Microencapsulation for parathyroid allotransplantation application
Title of Project (Thai)	การศึกษานอกร่างกายของไมโครเอนแคปซูเลชั่นเซลล์พาราธัยรอยด์ เพื่อใช้ประโยชน์ในด้านการปลูกถ่ายพาราธัยรอยด์จากผู้อื่น
Type of Review	Expedited
Principal Investigator	Ornicha Makkasem
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator (s)	1. Ronnarat Suvikapakornkul 2. Suradej Hongeng 3. Chutintorn Sriphrapradang 4. Somsak Prasongthanakit 5. Mattaka Kongkow 6. Katawut Namdee 7. Panuwat Lertsittichai 8. Yodying Wasutit 9. Prakasit Chirappapha 10. Thongchai Sukarayothin 11. Monchai Leesombatpaiboon
Approval includes	1. Submission form protocol version 1 date 26/10/2022 2. Information sheet and consent form version 2 date 26/11/2022 3. Information sheet and consent for biological samples for future research version 2 date 26/11/2022 4. Information sheet and consent for genetic research version 2 date 26/11/2022 5. Curriculum vitae 6. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval December 27, 2022

Date of Expiration December 26, 2023

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

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Introduction

- Postoperative hypoparathyroidism is a common complication following parathyroid surgery
- Parathyroid allotransplantation is the definitive treatment for permanent hypoparathyroidism

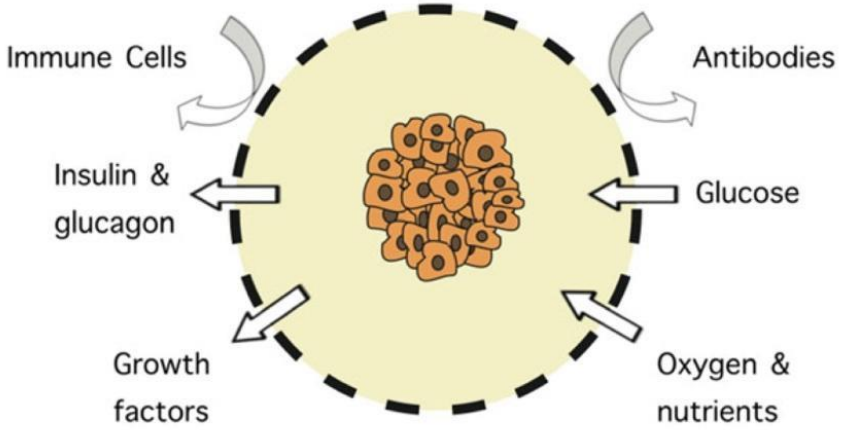
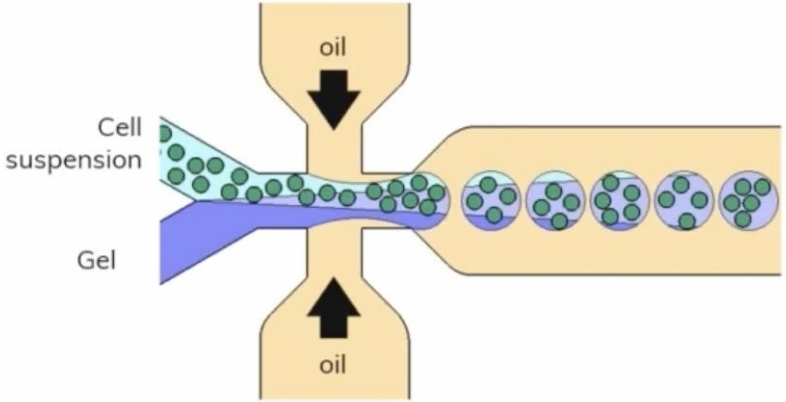


Fig. 2 Illustration of the principle of immunoisolation of islets encapsulated in a semipermeable microcapsule that allows entry and exit of molecules with permissible sizes



Principle of creating hydrogel droplets

Cell microencapsulation is a process in which cells are enclosed in a semi-permeable membrane to prevent the immune system from attacking the cells

The 7th Thailand International Nanotechnology Conference
NANO THAILAND 2021
Nanotechnology in Times of Disruptive Transformation

Microfluidic Aqueous Two-Phase System Forming Cell Encapsulated Degradable Hydrogel Microfibers for Tissue Engineering Applications

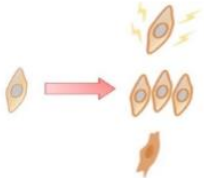
Katawut Namdee, PhD
Mattaka Khongkow, PhD
Wisawat Keaswejjareansuk, PhD

Nanomedicine and Veterinary Research Team
National Nanotechnology Center
National Science and Technology Development Agency

Tissue engineering technology & challenges

To increase

- Cell viability
- Cell proliferation
- Cell differentiation

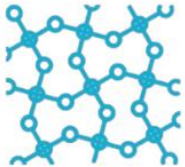


Challenges

Scaffolds those

- Biocompatible and biodegradable
- Degrade with replacement of natural matrices

- **Cell-encapsulated microenvironment : accurate construct 3D tissue with high cell density**



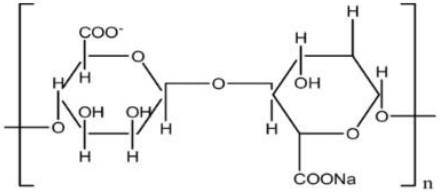
Hydrogels

- water > 20%
- 1,000x dry weight

- Microfluidic aqueous two-phase system
- Cells were immobilized in the microfibers

Sodium alginate

- Biodegradable
- *In vivo* compatibility
- Cell encapsulation
- Tissue engineering

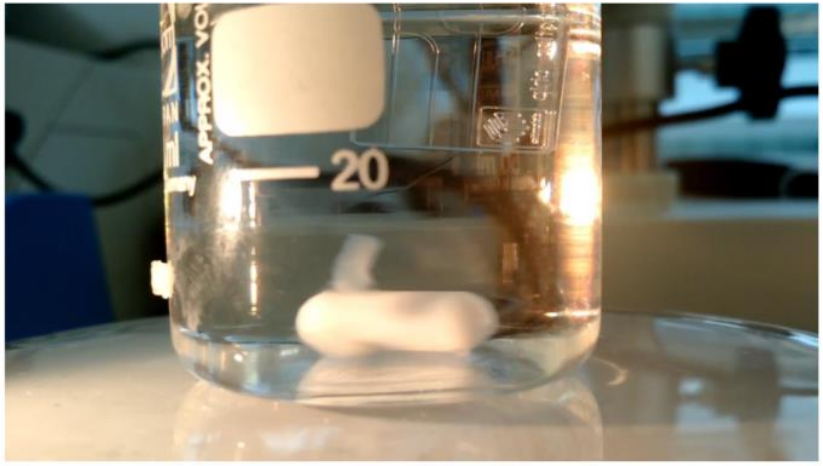


Problem with degradation - alginate remains over a month

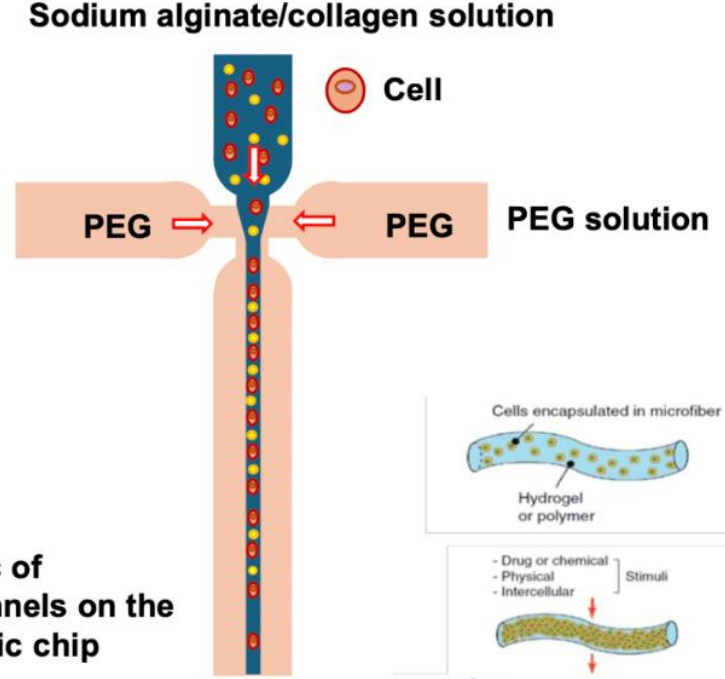
- *Vary* molecular weight, chemical structure, or covalent cross-linking
- **Enzymatic degradation**

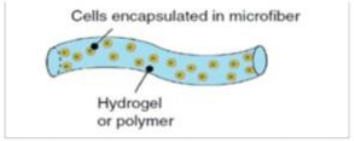
Hydrogel microfibers fabrication

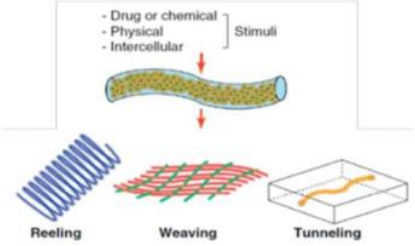
- Laminar flow, aqueous two-phase system
- Alginate and collagen hydrogel
- Parathyroid cells



Schematic of microchannels on the microfluidic chip

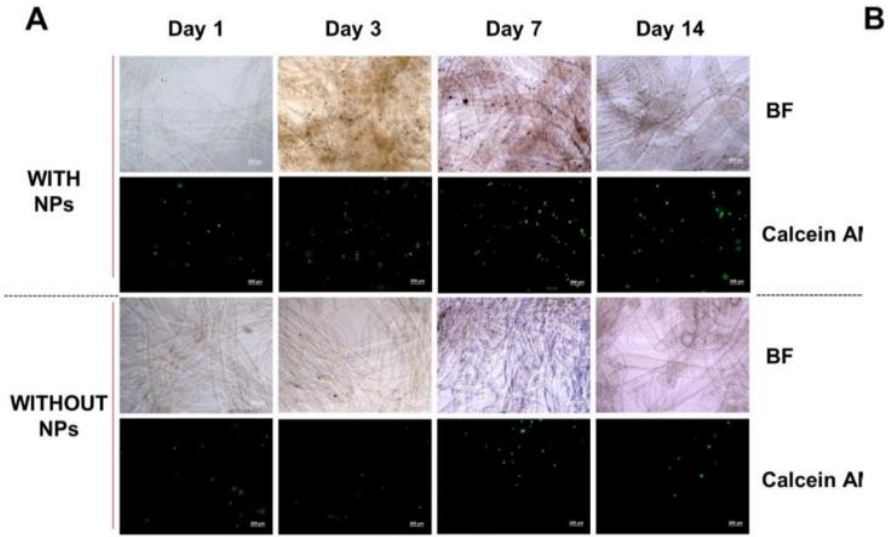


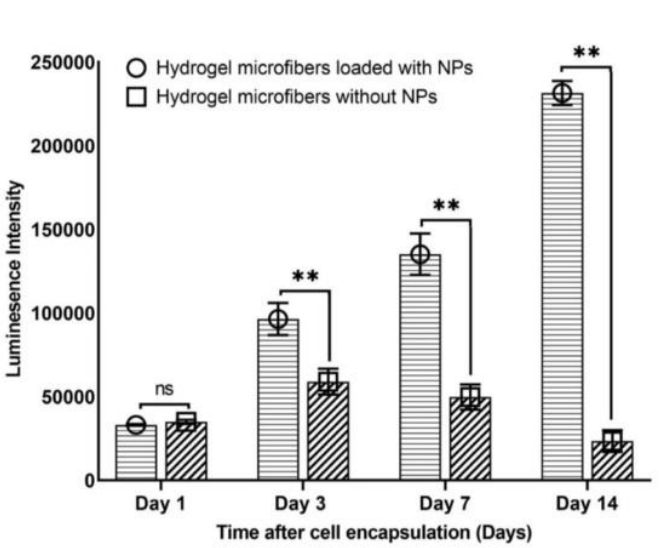




Cell proliferation in microfibers

- Encapsulated fibroblast in the microfibers and cell proliferation over 2 weeks
- **A -** bright field and fluorescence images (green fluorescence - live cells, strained by Calcein-AM)
- **B -** fibroblast proliferation measured by luminescent cell viability assay[2]





2 Markossian S, Grossman A, Brimacombe K, et al., editors. **Assay Guidance Manual**. Bethesda (MD): Eli Lilly & Company and the National Center for Advancing Translational Sciences; 2004-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK53196/

Aim of the study

- We describe hydrogel microencapsulation of human parathyroid cells using alginate microfiber
- Cell viability, cell growth, and parathyroid hormone production of hydrogel microencapsulated cells were evaluated

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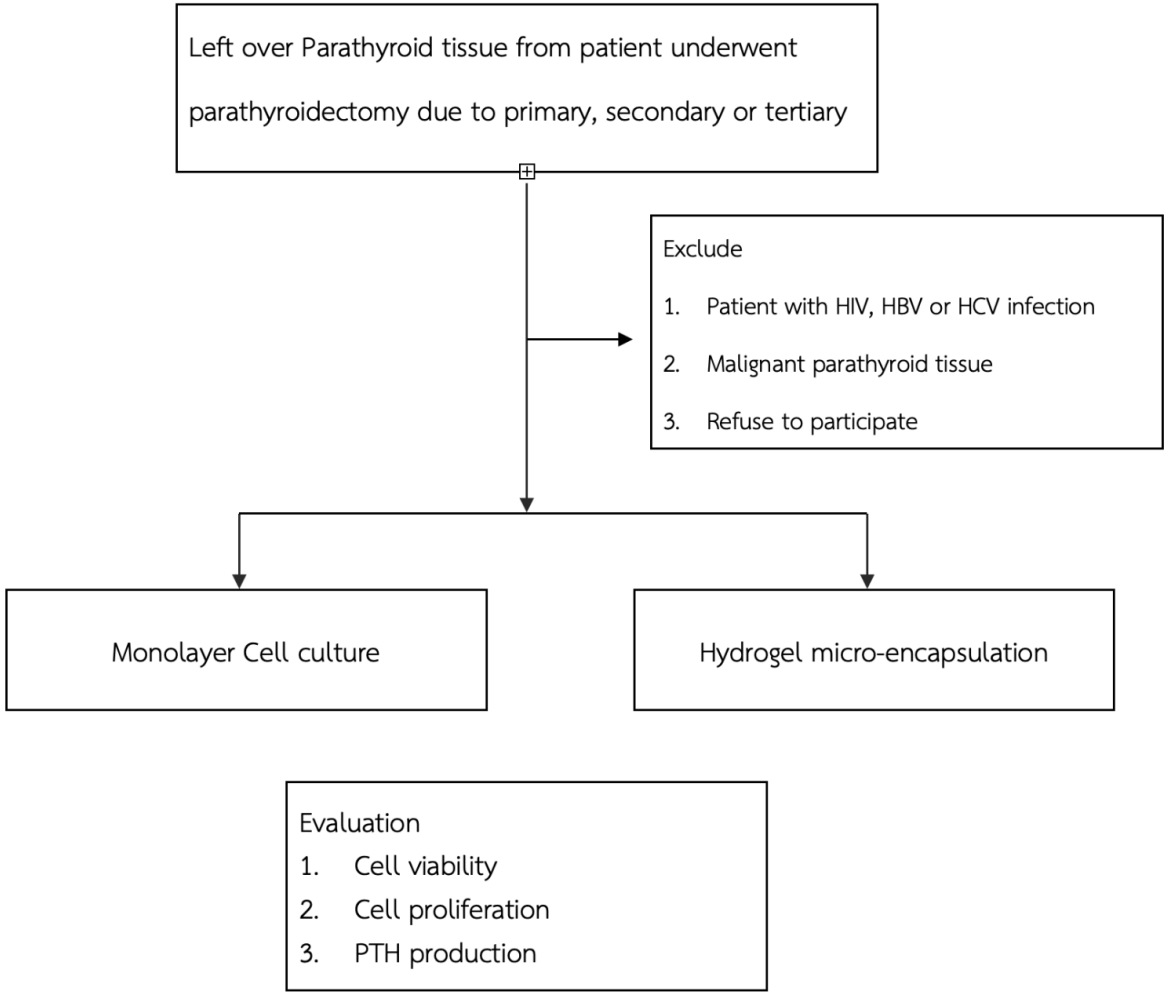
Material and Methods

Material and methods

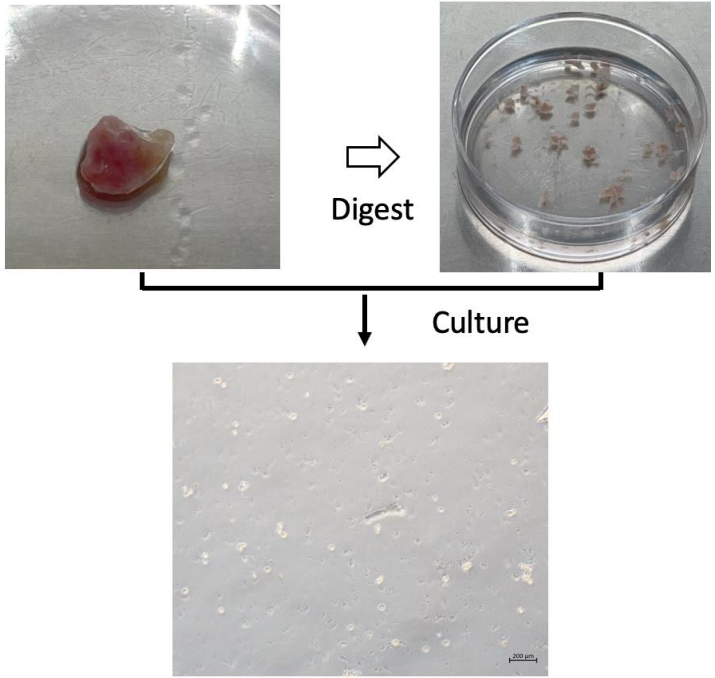
- In vitro study
- Collaborated with Ramathibodi clinical research center and NANOTEC team


Left over Parathyroid tissue from patient underwent parathyroidectomy due to primary, secondary or tertiary
Exclude
1. Patient with HIV, HBV or HCV infection
2. Malignant parathyroid tissue
3. Refuse to participate
Monolayer Cell culture
Hydrogel micro-encapsulation
Evaluation
1. Cell viability
2. Cell proliferation
3. PTH production

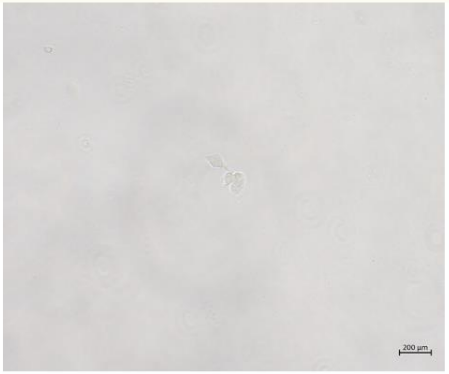
Isolation of parathyroid cell (Monolayer cell culture)

- Trim the parathyroid tissue to a size of 1x1 mm
- Digest the specimen with Collagenase Type II for 40 mins
- Add media +BSA+Dnase+ 1% antibiotic
- Culture parathyroid cell in IMEM medium + 10%FBS + 1%P/S+1% L-Glu + bFGF

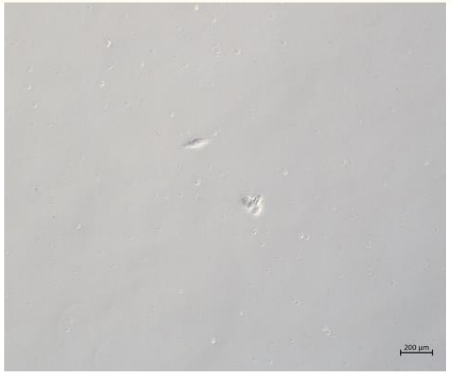
Isolation of parathyroid cell



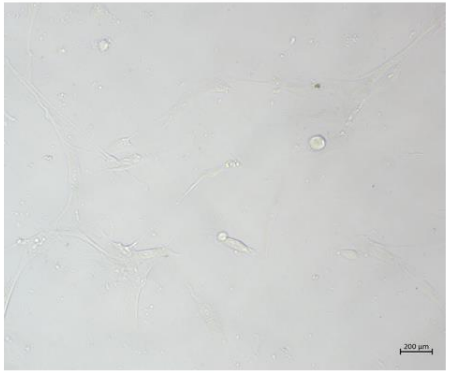
Day 1



Day 3 (10X)



Day 7 (10X)



Day 14 (20x)

Day 28 (10x)

Fabrication of PLGA nanoparticle

- 5 mL of oil phase PLGA solution
- A 500 µL of 2% (w/w) alginate lyase was then added into the solution
- The solution was loaded into a syringe and injected into 90 mL of PVA/PEMA solution under sonication for 1 min.
- The emulsion was stirred for 2 h to evaporate the DCM
- The NPs were frozen at a temperature of − 20 ◦C until use.

Fabrication of PLGA alginate microfiber

- The microfluidic system was employed to produces microfibers via an **aqueous two-phase system (ATPS) set up by Dolomite** (Royston, United Kingdom)

Cell viability

- Bright field and fluorescence images
- SEM micrographs show the morphology of the hydrogels

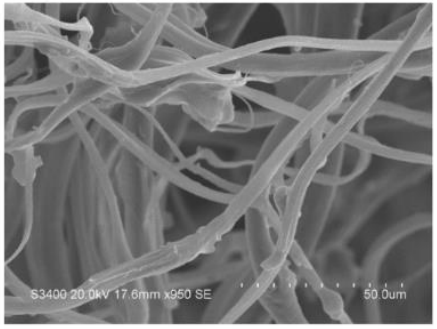
Cell proliferation

- Hydrogel encapsulated parathyroid cell proliferation, at 1, 7 and 14 day were stained by Calcein-AM (green).
- The proliferation was measured by luminescent cell viability assay

PTH production

- Supernatant of the specimen was sent for parathyroid hormone measurement at day 1, 7 and 14 day using ELISA kit

Result

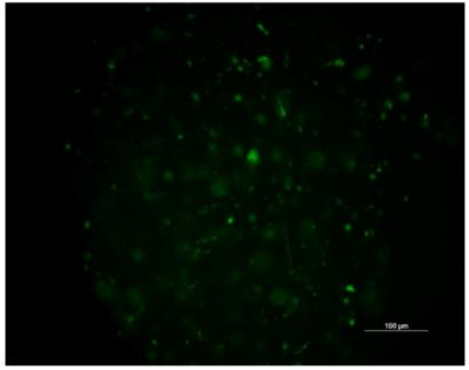


SEM of microfiber

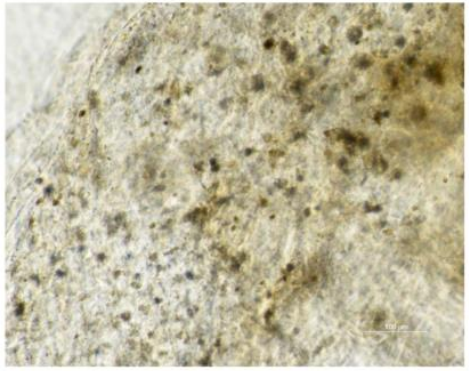
BF

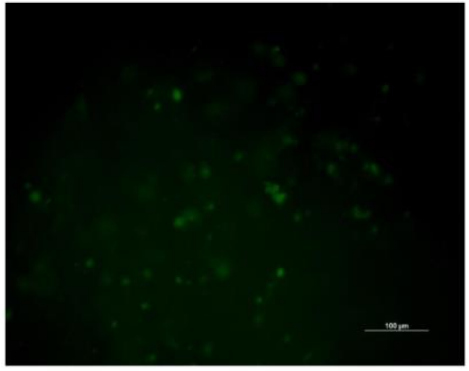
Calcein

Day 1

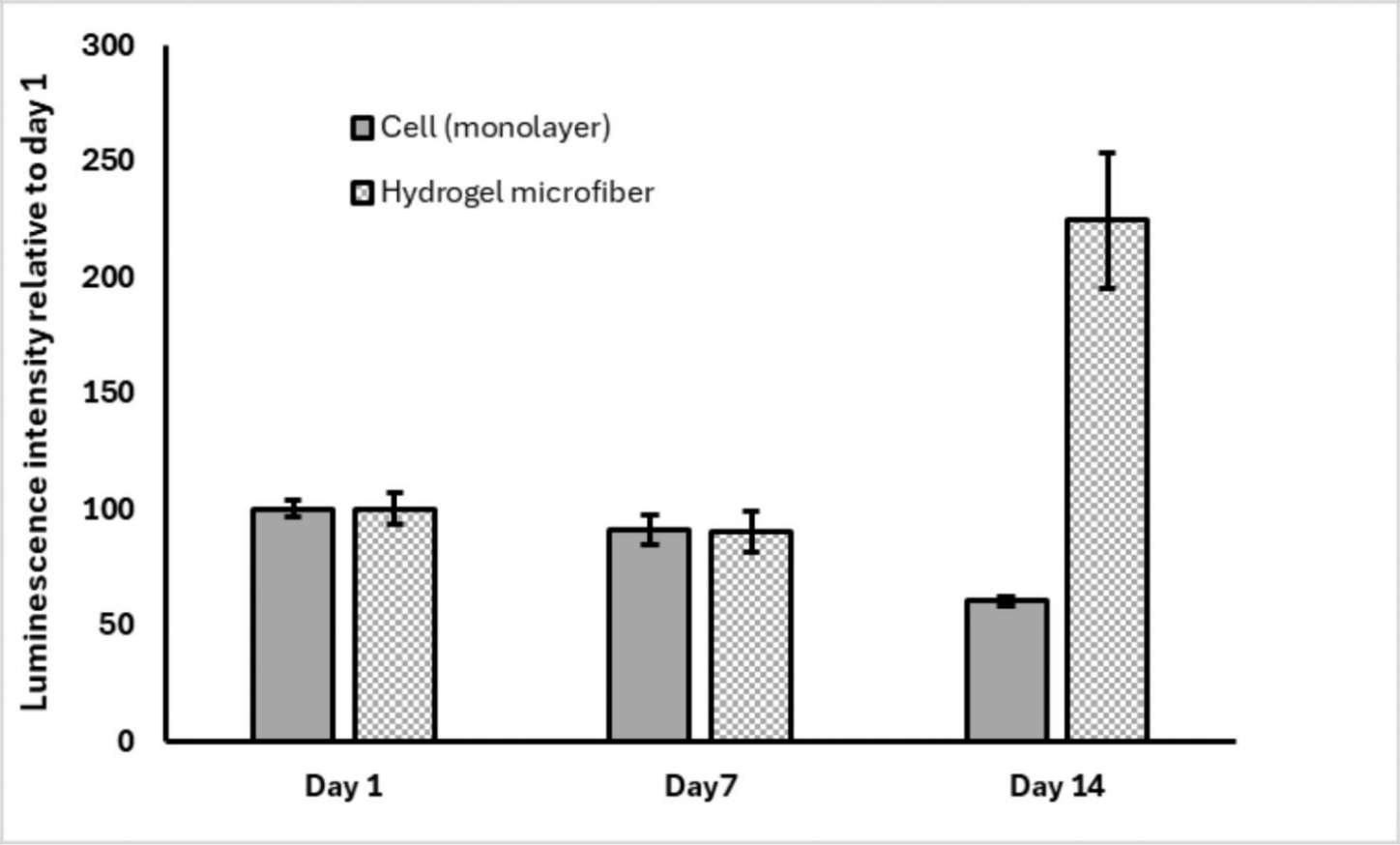


Day 21





Cell proliferation



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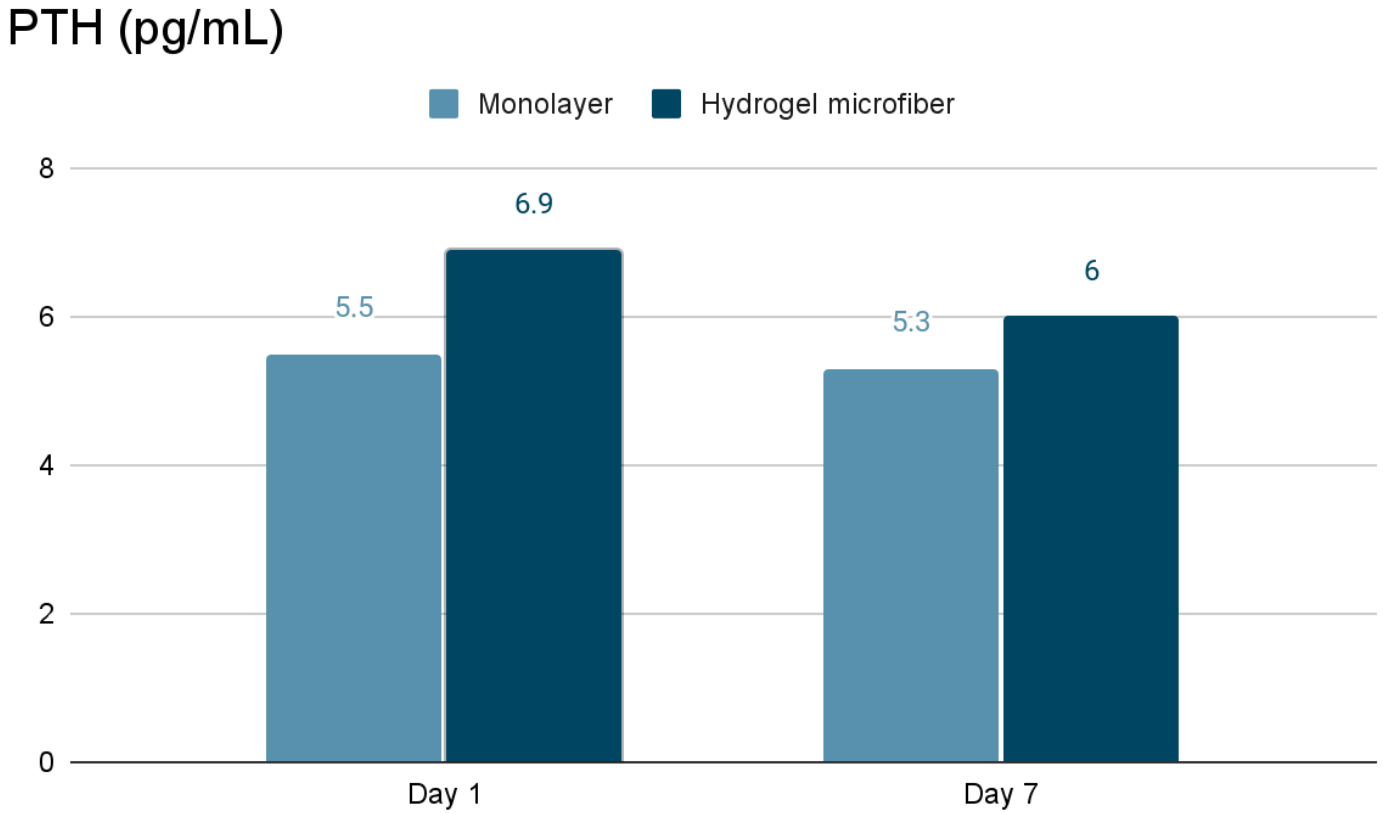
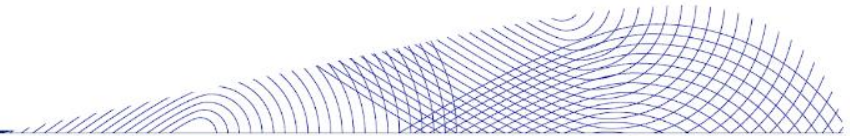
PTH production



Discussion



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Discussion

- Hydrogel microencapsulation forming by microfluidic ATPS is a new engineering technique that can be applied in many medical field
- In this study we describe for the first time hydrogel microencapsulation of human parathyroid cells
- The results show that hydrogel microencapsulation parathyroid cell can be survive and increase proliferation after 14 day as well as prior study with fibroblast cell
- Moreover it can maintain functional feature of differentiated cell by release PTH

Future work

- Material toxicity: Inflammatory cytokines
- Long-term culture with PTH release
- In vivo study
- Storage and Reproducible Production

Thank you.

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999 มหาวิทยาลัยมหิดล ถนน พุทธมณฑลสาย 4
ตำบล ศาลายา อำเภอพุทธมณฑล นครปฐม 73170
โทร : 02 849 6000

Mahidol University

Wisdom of the Land

Abstract

“Patient characteristic and outcome after second kidney transplantation, single center experience”

Nuttakhom Kaewpaetra,MD

Bundit Sakulchairungrueng, Goragoch Gesprasert, Nuttakhom Kaewpaetra

Division of Vascular Surgery, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, 10400, Thailand

Background: Second kidney transplantation offers a renewed chance of survival and improved quality of life for individuals with end-stage renal disease whose first transplant has failed. However, this complex procedure presents unique challenges, and understanding the factors associated with successful outcomes is crucial for optimizing patient care and graft survival.

Objectives:

1. To study the survival rate of transplanted kidneys and patients after receiving a second kidney transplant.
2. To study the factors affecting the survival of transplanted kidneys and patients after receiving a second kidney transplant.
3. To study the characteristics of patients undergoing second kidney transplantation.
4. To study the waiting time for a second kidney transplant.

Materials and Methods: This retrospective study investigated the factors influencing graft and patient survival rates following a second kidney transplant. Data were collected on all patients receiving a second kidney transplant at our center between January 1, 1997, and December 31, 2022. Factors analyzed included patient demographics, cause of end-stage renal disease (ESRD), donor type, ischemic time, early graft function, rejection episodes, immunosuppressive regimen, and post-operative complications.

Results: Fifty-nine patients were included in the study, with 49 (83%) experiencing successful graft function and 10 (17%) experiencing graft loss. A history of a first-living donor kidney transplant was associated with improved second-graft survival in both living and deceased donor groups (p=0.044). The absence of delayed graft function was significantly associated with improved second graft survival (OR 6.5, 95% CI 1.27-33.20, p=0.024). The median dialysis vintage was approximately three years.

Conclusions: The results of this study suggest that a history of a living donor in the first kidney transplant and the occurrence of delayed graft function in the second kidney transplant significantly affect both graft and patient survival.

มหาวิทยาลัยมหิดล
ปัญญาของแผ่นดิน

Patient Characteristic and Outcome after Second Kidney Transplantation, Single Center Experience

Researcher: Nuttakhom Kaewpaetra, MD.
Advisor: Bundit Sakulchairungrueng, MD.
Co-Advisors: Goragoch Gesprasert, MD.
Department of surgery, Ramathibodi Hospital, Mahidol university

มหาวิทยาลัยมหิดล
ปัญญาของแผ่นดิน

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COA. MURA2022/74
Ref. 2024/99

Title of Project (English)	Patient characteristic and outcome after second kidney transplantation, single center experience
Title of Project (Thai)	การศึกษาคุณลักษณะ และอัตราการอยู่รอดของการปลูกถ่ายไตครั้งที่สอง ในผู้ป่วยไตปลูกถ่ายครั้งแรกสัมเหลว
Type of Review	Expedited
Principal Investigator	Nuttakhom Kaewpaetra
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 28/01/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	February 02, 2022
Renewal Date (2nd)	February 02, 2024
Date of Expiration	February 01, 2025

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Introduction

- Second kidney transplantation offers a renewed chance of survival and improved quality of life for individuals with end-stage renal disease whose first transplant has failed.
- However, this complex procedure presents unique challenges, and understanding the factors associated with successful outcomes is crucial for optimizing patient care and graft survival.

Literature Review

Research	Population and study design	N	Result
Korea: Long-term Clinical Outcomes of Kidney Re-transplantation(S.M. Yeo, et al., 2017)	- Retrospective study - November 1982 and August 2016	105	Delayed graft function and acute rejection associated with graft failure in kidney re-transplantation recipients in multivariate analysis
Germany: Risk Factors Infuencing the Outcomes of KidneyRe-Transplantation (Schwarz A, et al., 2021)	- Retrospective study - January 2000 and December 2009 - follow-up of 10 years	162	- Graft and patient survival in 2nd KT with 3-5 were inferior to 0-2 comorbidities - Severe infection effect graft survival HR 1.544, (1.010, 2.355), 0.0437 - humoral rejection effect graft survival 1.962, (1.075, 3.391), 0.0207
Thailand: Long-term Outcome of Kidney Retransplantation in Comparison With First Kidney Transplantation (A. Ingsathi, et al., 2013)	- January 1993 to December 2011 - divided into two groups; first or a retransplantation	113	- PRA, HLA mismatch and induction therapy were higher in 2nd KT - After adjust potential confounding factors, show did not influence graft outcomes.

Gap of Knowledge

- Still limited data related to factors associated with kidney graft and patient survival in 2nd kidney transplantation

Objective

- To study the survival rate of transplanted kidneys and patients after receiving a second kidney transplant.
- To study the factors affecting the survival of transplanted kidneys and patients after receiving a second kidney transplant.
- To study the characteristics of patients undergoing second kidney transplantation.
- To study the waiting time for a second kidney transplant.

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Study Design

Retrospective study

2nd kidney transplant
at Ramathibodi hospital
2000-2021

power 80%,P <0.05
By Stata V14.1

Method

Proposal submission

Ethic approval

Request data from transplant center Ramathibodi hospital

Request for redcap program access

Data collection by redcap program

REDCap
Research Electronic Data Capture

Export in excel program

Data analysis

Statistical Analysis

- Demographic data: **Descriptive statistics**
- Categorical data: using number and percentage
  compare by **Chi-Square test** or **Fisher's exact test**
- Continuous data: compare by
  Normal distribution : **Student's t test**
  Non-normal distribution : **Mann-Whitney U test**
- Evaluation correlation: **Univariate and multivariable logistic regression**
- Survival analysis: **Kaplan-Meier Analysis**

Populations

Inclusion Criteria

- Age > 18 years
- Patients with first kidney transplant failure
- Received a second kidney transplant at Ramathibodi Hospital.

Populations

Exclusion Criteria

- Received simultaneous other organs transplant
- Having received more than two kidney transplants
- Did not come to follow up on treatment

Definition

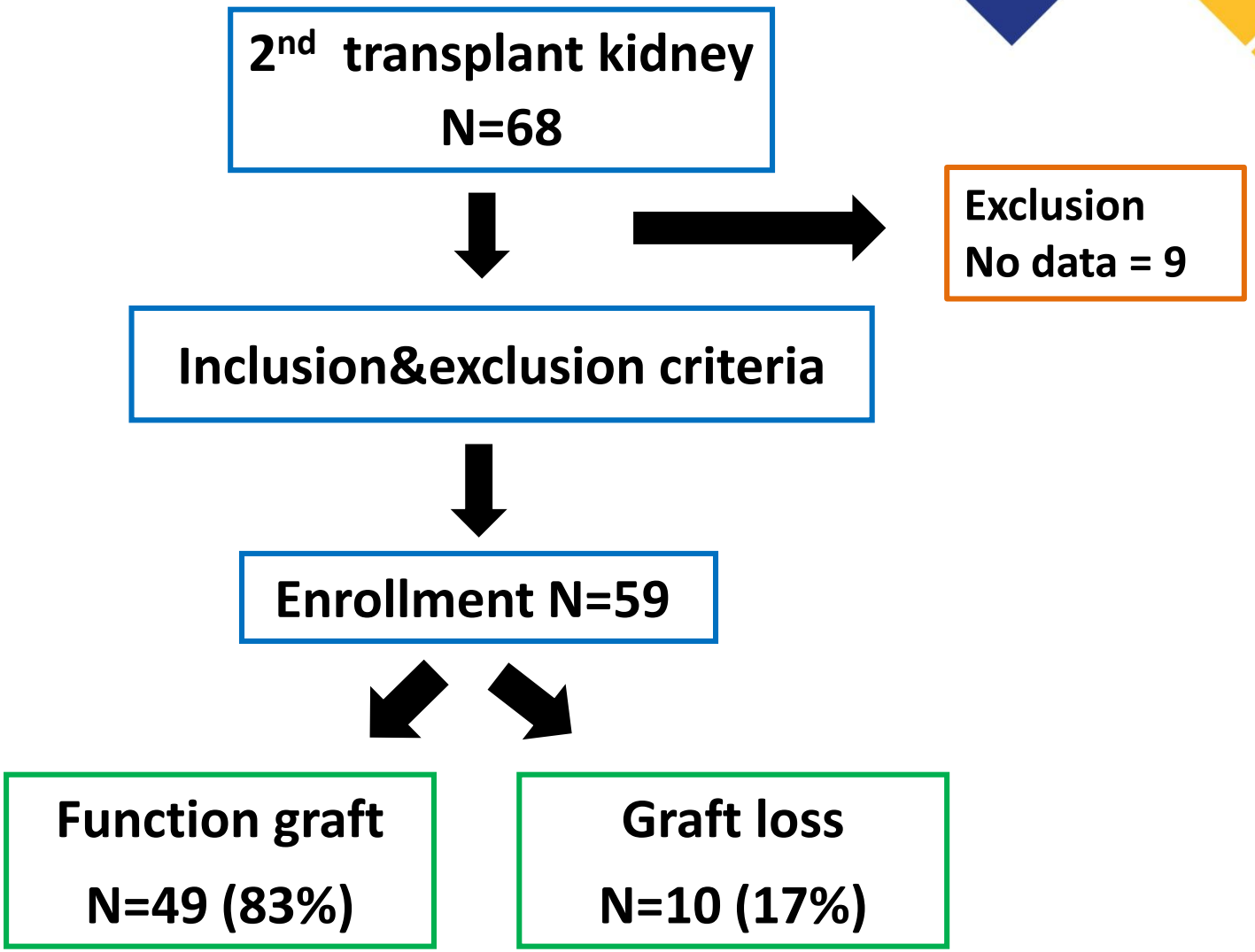
Graft loss

- Initiate hemodialysis or graft nephrectomy

Delayed graft function

- Hemodialysis in first week after transplantation

Results


2nd transplant kidney
N=68
Exclusion
No data = 9
Inclusion&exclusion criteria
Enrollment N=59
Function graft
N=49 (83%)
Graft loss
N=10 (17%)

Demographic Data

Recipient	Total N=59	Graft function N=49	Graft loss N=10	*P-value*
Age (year); mean (±SD)	46(±10.89)	47(±10.84)	42(±10.47)	0.150
Gender; n(%) • Male • Female	 48(81.36) 11(18.64)	 42(85.71) 7(14.29)	 6(60) 4(40)	0.079
BMI, Mean(±SD)	21.75(±3.65)	21.65(±3.87)	22.22(±2.44)	0.653
Blood group; n(%) A B AB O	 13(22.03) 26(44.07) 4(6.78) 16(27.12)	 9(18.37) 21(42.86) 4(8.16) 15(30.61)	 4(40) 5(50) 0 1(10)	0.324
Rh; n(%) Positive negative	 2(4.88) 39(95.12)	 1(3.13) 31(96.88)	 1(11.11) 8(88.89)	0.395

Demographic Data

Recipient	Total N=59	Graft function N=49	Graft loss N=10	*P-value*
Cause of ESRD; n(%)				
Unknown	27(45.76)	23(46.94)	4(40)	0.266
IgA Nephropathy	8(13.56)	6(12.24)	2(20)	
FSGS	1(1.69)	0	1(10)	
Chronic glomerulonephritis	2(3.39)	2(4.08)	0	
Lupus nephritis	3(5.08)	2(4.08)	1(10)	
Other	18(30.51)	16(32.65)	2(20)	
Dialysis vintage (year), Median(IQR)	3 (2,5)	3 (2,5)	2 (1,5)	0.775
Pre-transplant RRT; n(%)				
Pre-emptive	3(5.36)	3(6.52)	0	0.999
Hemodialysis	51(91.07)	41(89.13)	10(100)	
Peritoneal dialysis	2(3.57)	2(4.35)	0	
First graft nephrectomy; n(%)				
No	48(82.76)	41(85.42)	7(70)	0.353
Yes	10(1724)	7(14.58)	3(30)	

Demographic Data

Donor in 2nd transplant	Total N=59	Graft function N=49	Graft loss N=10	*P-value*
Age (year); mean (±SD)	38(±11.88)	37(±11.93)	42(±11.11)	0.207
Gender; n(%) • Male • Female	 38(69.09) 17(30.91)	 31(68.89) 14(31.11)	 7(70) 3(30)	0.999
BMI; Mean(±SD)	23.28(±3.06)	23.17(±3.72)	23.94(±2.77)	0.667
Donor type; n(%) Living Deceased	 19(32.20) 40(67.80)	 17(34.69) 32(65.31)	 2(20) 8(80)	0.476
Graft abnormality; n(%) No Yes	 47(92.16) 4(7.84)	 39(95.12) 2(4.88)	 8(80) 2(20)	0.140

Demographic Data

2nd Transplantation	Total N=59	Graft function N=49	Graft loss N=10	*P-value*
Total Ischemic time(min);				
≤1080; n(%)	36(61.02)	32(65.31)	4(40)	0.232
>1080; n(%)	23(38.98)	17(34.69)	6(60)	0.166
Delayed graft function; n(%)				
No	45(84.91)	39(90.70)	6(60)	**0.033**
yes	8(15.09)	4(9.30)	4(40)	
Graft rejection; n(%)	10(16.95)	6(12.24)	4(40)	0.055
PRA; n(%)				
≤50%	21(42.86)	16(40)	5(55.56)	0.470
>50%	28(57.14)	24(60)	4(44.44)	
HLA mismatch; Median(IQR)	2 (1,2)	2 (1,2)	3 (0,1)	0.785

Demographic Data

2nd Transplantation	Total N=59	Graft function N=49	Graft loss N=10	*P-value*
CMV infection; n(%) No yes	54(96.43) 2(3.57)	44(95.65) 2(4.35)	10(100) 0	0.999
BK virus infection; n(%) No yes	53(94.64) 3(5.36)	44(95.65) 2(4.35)	9(90) 1(10)	0.452
Adeno virus infection; n(%) No yes	53(94.64) 3(5.36)	49(9348) 3(6.52)	10(100) 0	0.999

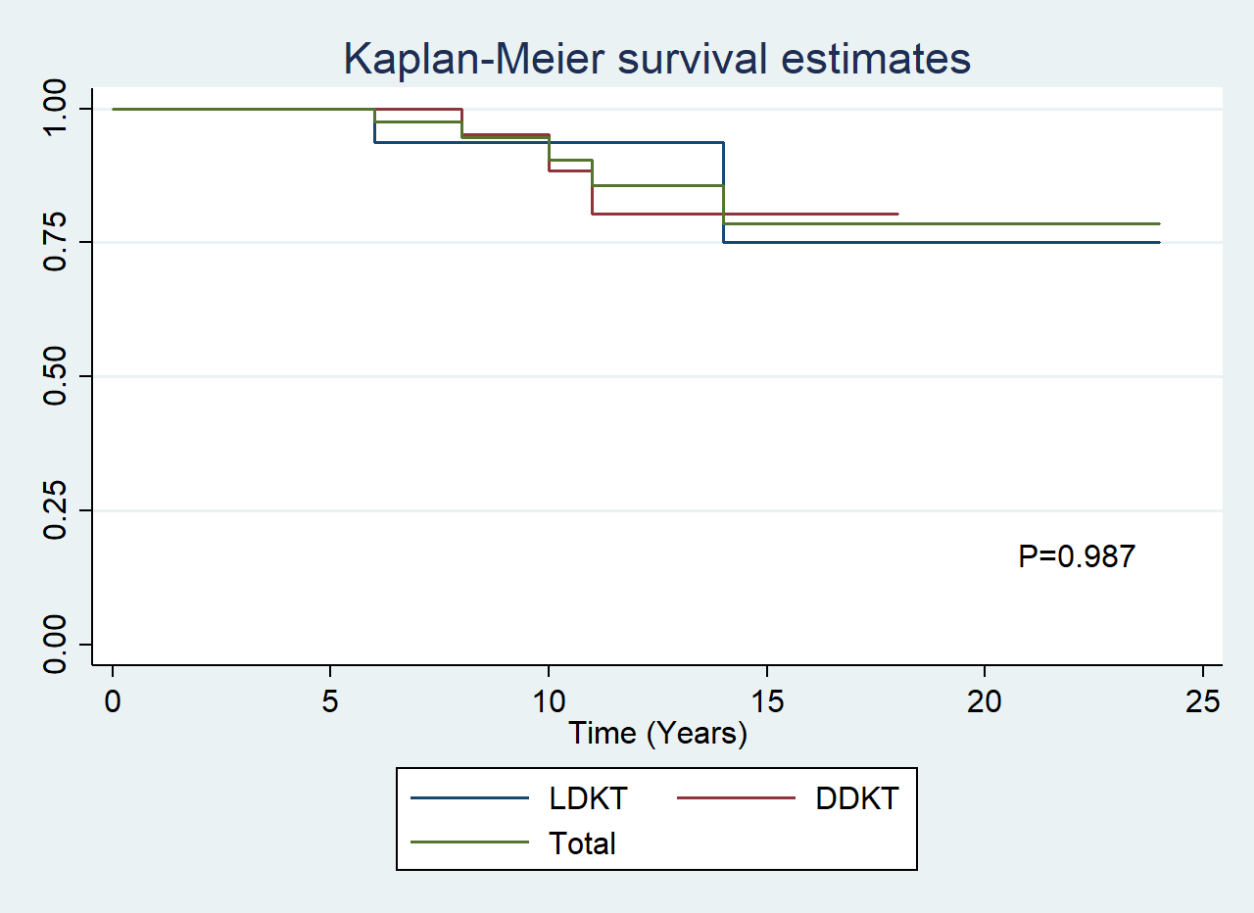
Univariate Logistic Regression

Variable	Odd ratio	95%CI	*P*
Recipient's age	0.95	(0.89-1.02)	0.154
Donor's age	1.04	(0.97-1.11)	0.210
Donor type	2.21	(0.40-11.14)	0.373
PRA	0.53	(0.12-2.29)	0.398
HLA mismatch	1.06	(0.63-1.79)	0.800
Total Ischemic time	2.82	(0.69-11.39)	0.145
Graft abnormality	4.87	(0.59-39.90)	0.140
Delayed graft function	6.5	(1.27-33.20)	0.024
Graft rejection	4.77	(1.03-21.98)	0.055

Multivariable Logistic Regression

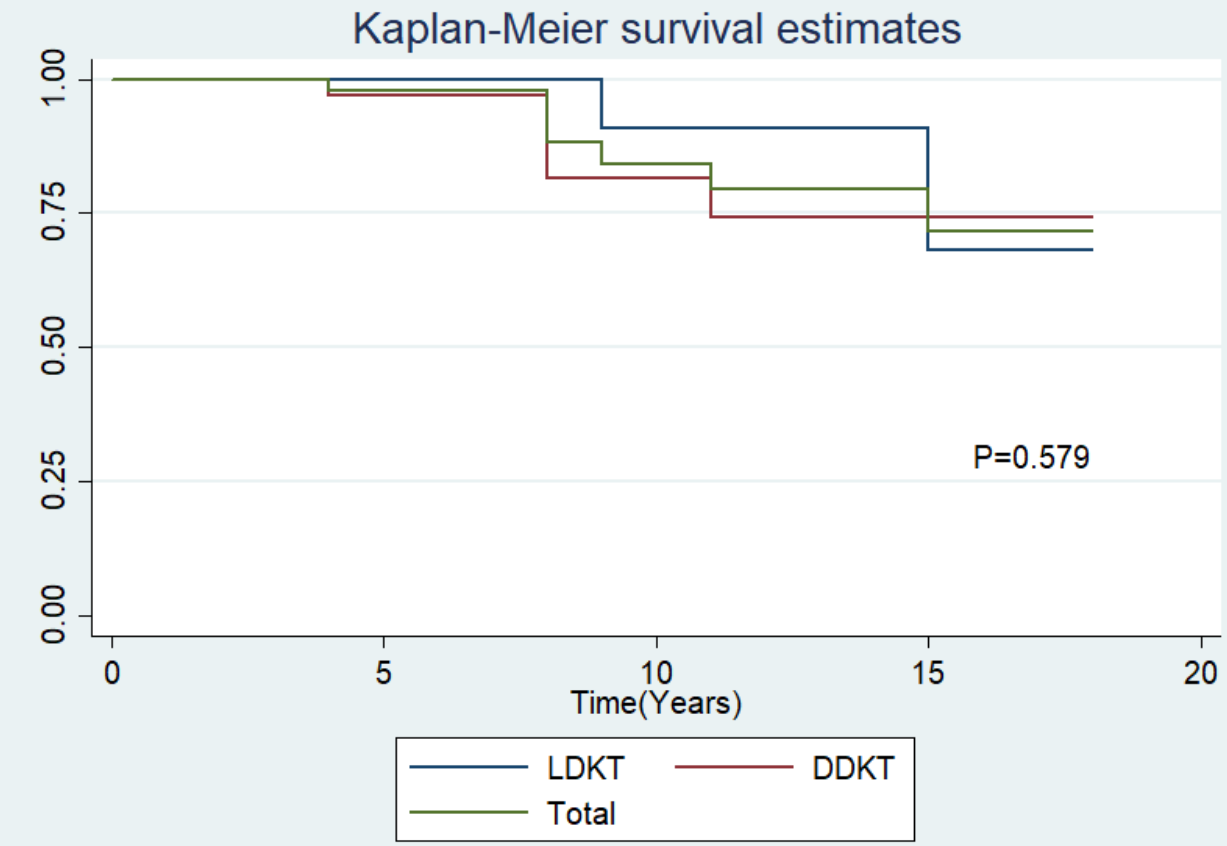
Variable	Adjusted Odd ratio	95%CI	*P*
Donor type	0.26	0.01-9.17	0.46
PRA	0.34	0.05-2.38	0.28
HLA mismatch	0.49	0.19-1.27	0.14
Total ischemic time	10.05	0.25-397.39	0.22
Delayed graft function	7.92	0.85-74.04	0.07
Graft rejection	16.11	1.52-170.53	0.021

Kidney graft survival



Outcome	LDKT	DDKT	Total
Graft survival rate; % (95%CI) 10 year	0.94(0.632-0.991)	0.88(0.603-0.971)	0.90(0.726-0.963)

Patient survival



Outcome	LDKT	DDKT	Total
Patient survival rate; % (95%CI) 10 year	0.90(0.508-0.987)	0.82(0.574-0.928)	0.84(0.658-0.933)

Discussion

- In our study, we found that delayed graft function and acute rejection were significantly associated with kidney graft survival, in accordance with previous studies conducted in Korea (S.M. Yeo et al., 2017).
- Higher PRA levels and HLA mismatch did not affect graft function, as shown in a previous study (A. Ingsathi et al., 2013), possibly due to the use of modern immunosuppressive drugs or less sample size.

Discussion

- Post-kidney transplant infections showed no significant effect, which may be due to the small sample size, as seen in a study conducted in Germany (Schwarz A et al., 2021).

Limitation

- Retrospective study
- Small sample size
- Absence of randomization
- Some missing data

Conclusion

- Factors associated with graft function include the delayed graft function and acute rejection.
- There were no significant differences in patient and graft survival between living and deceased donors.
- Improving these factors may lead to better graft outcomes.

Thank you

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Appendix

Cause of 1st graft loss	N	%
1 Rejection	9	15.25
2 IgA Nephropathy	7	11.86
3 Chronic nephropathy	7	11.86
4 Interstitial Fibrosis and Tubular Atrophy (IFTA)	2	3.39
5 BKVAN	2	3.39
6 poor compliance	2	3.39
7 FSGS	1	1.69
8 Chronic Glomerulonephritis	1	1.69
9 transplant renal artery thrombosis	1	1.69
10 Renal artery avulsion	1	1.69
11 renal vein thrombosis	1	1.69
12 pyelonephritis	1	1.69
13 trauma	1	1.69
14 CNI intoxication	1	1.69
15 unknown	22	37.29

Cause of 2nd graft loss	N = 10
bleeding graft	2
nephropathy	2
Acute rejection	1
Chronic rejection	1
TRAS	1
Recurrent UTI	1
Other	2

Demographic Data

	Total N=59	Graft function N=49	Graft loss N=10	*P*
TX1 donor type; n(%)				0.044
Living	32(69.57)	29(76.32)	3(37.50)	
Deceased	14(30.43)	9(23.68)	5(62.5)	

Abstract

> Prevalence of and factors associated with intraductal papillary lesion, both of benign and malignant, in patients with nipple discharge undergoing mammary duct excision

Ninnat Fongsupa,MD

Ninnat Fongsupa, Panuwat Lertsithichai

Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, 10400

Background : Nipple discharge is a common symptom in women, with a prevalence of 5–12%. It is the third most frequently reported breast-related complaint. Nipple discharge is classified as either physiologic or pathologic, with intraductal papillary papilloma being a common cause of pathologic discharge. These lesions can be benign or malignant. Diagnostic approaches, including mammary duct excision, are crucial in cases where imaging or biopsy is inconclusive. While international studies show the prevalence of intraductal papilloma, duct ectasia, and breast cancer as common causes, data specific to Thailand remain limited. Understanding the prevalence and factors associated with these lesions can improve diagnostic and treatment strategies.

Objective : To determine the prevalence of intraductal papilloma in patients with nipple discharge undergoing mammary duct excision.
To identify factors associated with the occurrence of intraductal papilloma.

Materials and methods : This retrospective study analyzed medical records and surgical logs of female patients aged 18 years or older who underwent mammary duct excision at Ramathibodi Hospital from January 2009 to August 2024. Data included demographic characteristics, clinical findings, imaging results (mammography and ultrasound), and pathological diagnoses. Descriptive statistics were used to calculate prevalence. Chi-square tests and logistic regression were employed to identify factors associated with intraductal papilloma.

Results : Among 208 female patients who underwent mammary duct excision, intraductal papilloma were identified in 55.77% (116/208). Cancer was diagnosed in 11.54% (24/208), including invasive cancer in 3.37% (7/208). Age, hypertension, dyslipidemia, and taking oral contraceptive pills is not risk factors for intraductal papilloma. But diabetes is protective factor for intraductal papilloma (OR = 0.24, p = 0.016). In ultrasound and mammogram, finding mammary duct dilatation is associated with intraductal papilloma (OR = 1.88, p = 0.045).

Conclusion : This study demonstrates a prevalence of intraductal papilloma in patients undergoing mammary duct excision for nipple discharge. Mammary duct dilatation is associated with intraductal papilloma. These findings provide critical insights into diagnostic and management strategies, with potential to improve patient outcomes.

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PREVALENCE OF AND FACTORS ASSOCIATED WITH INTRADUCTAL PAPILLARY LESION, BOTH OF BENIGN AND MALIGNANT, IN PATIENTS WITH NIPPLE DISCHARGE UNDERGOING MAMMARY DUCT EXCISION

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4th year general surgery resident
Department of surgery, Ramathibodi hospital

Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University
270 Rama 6 Rd. Phayatai Ratchathewi Bangkok 10400 Tel.(660)2012175, 2011544, 2010388
Website: https://med.mahidol.ac.th/research/ethics
E-mail: raec.mahidol@gmail.com

COA No. MURA2024/694

Title of Project (English)	Prevalence of and Factors associated with Intraductal Papillary lesion, both of Benign and Malignant, in Patients with Nipple Discharge Undergoing Mammary Duct Excision
Title of Project (Thai)	การศึกษาความชุกและปัจจัยที่เกี่ยวข้องกับภาวะเนื้องอกภายในท่อน้ำนม ในผู้ป่วยที่มีสารคัดหลั่งออกทางหัวนมและเข้ารับการผ่าตัดท่อน้ำนม
Type of Review	Expedited
Principal Investigator	Ninnat Fongsupa
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator	Panuwat Lertsithichai
Approval includes	1. Submission form protocol version 1 date 29/08/2024 2. Curriculum vitae 3. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	October 01, 2024
Date of Expiration	September 30, 2025

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Background

- Nipple discharge is a common symptom in women
- Intraductal papillary papilloma being a common cause of pathologic discharge

Background

- International studies show intraductal papilloma, duct ectasia, and breast cancer as common causes.
- But data specific to Thailand remain limited.
- Understanding the prevalence and factors associated with these lesions can improve diagnostic and treatment strategies.

Objective

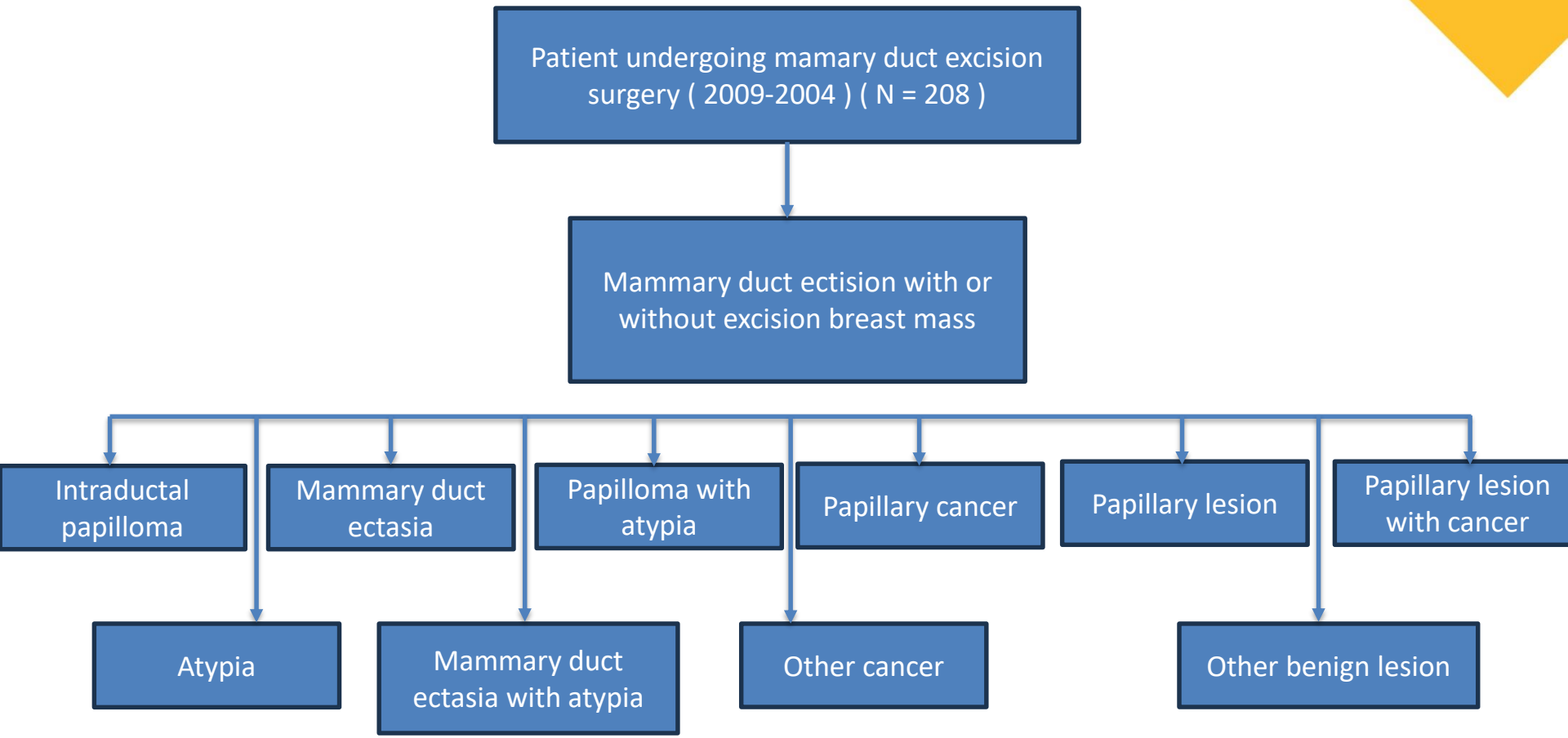
1. To determine the prevalence of intraductal papilloma in patients with nipple discharge undergoing mammary duct excision.

2. To identify factors associated with the occurrence of intraductal papilloma.

Material and Method

- Retrospective study of patient underwent mammary duct excision.

- Data was collected from medical records and surgical logs of female patients aged ≥ 18 years who underwent mammary duct excision at Ramathibodi Hospital from January 2009 - August 2024.


Patient undergoing mamary duct excision surgery (2009-2004) (N = 208)
Mammary duct ectision with or without excision breast mass
Intraductal papilloma
Mammary duct ectasia
Papilloma with atypia
Papillary cancer
Papillary lesion
Papillary lesion with cancer
Atypia
Mammary duct ectasia with atypia
Other cancer
Other benign lesion

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Results

Table – Demographic data

	Intraductal papilloma	Mammary duct ectasia	Papilloma with atypia	Papillary cancer	Papillary lesion	Papillary lesion with cancer	Atypia	Mammary duct ectasia with atypia	Other cancer	Other benign lesion	All (n = 208)
N(% of all)	116(55.77%)	22(10.58%)	8(3.85%)	7(3.36%)	0(0%)	4(1.92%)	4(1.92%)	1(0.48%)	24(11.54%)	22(10.58%)	208(100%)
Mean age(year)	46.974±14.658	48.363±16.043	51.625±20.120	62.857±17.062		44.75±14.997	51±19.304	48	50.541±14.304	45.181±17.192	48.096±15.476
Age • <65 • ≥65	 98(84.48%) 18(15.52%)	 19(86.36%) 3(13.64%)	 5(62.5%) 3(37.5%)	 2(28.57%) 5(71.43%)	 0(0%) 0(0%)	 3(75%) 1(25%)	 3(75%) 1(25%)	 1(100%) 0(0%)	 20(83.33%) 4(16.67)	 19(86.36%) 3(13.64%)	 170(81.73%) 38(18.27%)
Underlying disease • Diabetes • Hypertension • Dyslipidemia	 4(3.45%) 26(22.41%) 20(27.24%)	 5(22.73%) 5(22.73%) 1(4.54%)	 1(12.5%) 3(37.5%) 1(12.5%)	 1(14.28%) 3(42.86%) 3(42.86%)	 0(0%) 0(0%) 0(0%)	 0(0%) 2(50%) 1(25%)	 0(0%) 1(25%) 1(25%)	 0(0%) 0(0%) 0(0%)	 2(8.33%) 5(20.83%) 7(29.17%)	 2(9.09%) 3(13.64%) 2(9.09%)	 15(7.21%) 48(23.08%) 36(17.31%)
Menstruation status • Premenopause • Post menopause	 87(75%) 29(25%)	 18(81.82%) 4(18.18%)	 5(62.5%) 3(37.5%)	 2(28.57%) 5(71.43%)	 0(0%) 0(0%)	 3(75%) 1(25%)	 3(75%) 1(25%)	 1(100%) 0(0%)	 16(66.67%) 8(33.33%)	 18(81.82%) 4(18.18%)	 153(73.56%) 55(26.44%)
OCP History • OCP taking • Non OCP taking	 3(2.59%) 113(97.41%)	 0(0%) 22(100%)	 0(0%) 8(100%)	 0(0%) 7(100%)	 0(0%) 0(0%)	 0(0%) 4(100%)	 1(25%) 3(75%)	 0(0%) 1(100%)	 2(8.33%) 22(91.66%)	 0(0%) 22(100%)	 6(2.88%) 202(97.11%)
Clinical presentation • Nipple discharge • Breast mass • Mastitis	 110(94.83%) 6(5.17%) 0(0%)	 20(90.91%) 1(4.45%) 1(4.45%)	 8(100%) 0(0%) 0(0%)	 6(85.71%) 1(14.28%) 0(0%)	 0(0%) 0(0%) 0(0%)	 3(75%) 1(25%) 0(0%)	 4(100%) 0(0%) 0(0%)	 0(0%) 1(100%) 0(0%)	 22(91.67%) 2(8.33%) 0(0%)	 16(72.73%) 0(0%) 6(27.27%)	 189(90.86%) 12(5.77%) 7(3.36%)

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Results

Table – Demographic data

	Intraductal papilloma	Mammary duct ectasia	Papilloma with atypia	Papillary cancer	Papillary lesion	Papillary lesion with cancer	Atypia	Mammary duct ectasia with atypia	Other cancer	Other benign lesion	All (n = 208)
Physical examination											
• Palpable mass	28(24.14 %)	3(13.6%)	2(25%)	4(57.14 %)	0(0%)	1(25%)	1(25%)	1(100%)	9(37.5)	3(13. 64%)	52(25%)
Mamogram and ultrasound finding											
• Mass finding	55(47.41 %)	5(22.73%)	1(12.5%)	4(57.14 %)	0(0%)	2(50%)	3(75%)	1(100%)	15(62.5 %)	7(31. 82%)	93(44.71 %)
• Mammary duct dilatation	73(62.93 %)	9(40.91%)	4(50%)	3(42.86 %)	0(0%)	2(50%)	2(50%)	0(0%)	14(58.3 3%)	9(40. 91%)	117(56.2 5%)
Operation											
• Mammary duct excision	80(68.96 %)	21(95.45%)	6(75%)	2(28.57 %)	0(0%)	4(100%)	0(0%)	1(100%)	9(37.5 %)	17(77 .27%)	140(67.3 1%)
• Mammary duct excision with breast mass excision	36(31.03)	1(4.55%)	2(25%)	5(71.43 %)	0(0%)	0(0%)	4(100 %)	0(0%)	15(62.5 %)	5(22. 73%)	68(32.69 %)

Results

- Prevalence of intradutal papilloma
  - Prevalence = 0.557 (95%CI : 0.489-0.624)

- Prevalence of Cancer
  - Prevalence = 0.115 (95%CI : 0.078-0.166)

Results

- Rate of Pure papilloma
  - Rate = 55.77%
- Rate of Cancer
  - Rate = 11.54%

Results

- Factor associated with intraductal papilloma
- Logistic regression

	Odd ratio	P-value ; 95%CI
Age <65	0.661	0.251
Underlying disease		
• Diabetes	0.238	0.016
• Hypertension	0.866	0.663
• Dyslipidemia	0.989	0.977
Menstruation status		
• Menopause	0.846	0.455
OCP taking	0.787	0.773
Palpable mass	0.901	0.747
Mamogram and ultrasound finding		
• Mass finding	1.206	0.533
• Mammary duct dilatation	1.880	0.045

Discussion

- The study shows the prevalence and associated factors of intraductal papilloma in patients undergoing mammary duct excision.
- **The prevalence of intraductal papilloma in our cohort was 55.77%.**
- **Mammary duct dilatation finding ultrasound and mammography is associated with intraductal papilloma** (OR = 1.88, p = 0.045).
- **However, diabetes appeared to be a protective factor** (OR = 0.24, p = 0.016), it should be have further investigation to clarify its biological mechanism.
- The absence of significant associations between age, hypertension, dyslipidemia, and oral contraceptive use, and intraductal papilloma shows the multifactorial nature of this pathology.

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Limitation

- Sample Size
- Retrospective Design
- Single-Center Study

Conclusion

- This study demonstrates a prevalence of intraductal papilloma in patients undergoing mammary duct excision
- **The prevalence of intraductal papilloma is 0.557 (95%CI : 0.489-0.624)**
- Age, hypertension, dyslipidemia, and taking oral contraceptive pills is not risk factors for intraductal papilloma
- **Diabetes is protective factor for intraductal papilloma (OR = 0.24, p = 0.016)** , but it should be have further investigation to clarify its biological mechanism.
- Finding mammary duct dilatation is associated with intraductal papilloma (OR = 1.88, p = 0.045) but not associated with cancer

Thank you for attention

Abstract

> Overall 5-year survival rate and disease-free survival after segmentectomy versus lobectomy in patients with non-small cell lung cancer

Khunthorn Kadeetham, MD

Khunthorn Kadeetham, Montien Ngodngamthaweesuk, Narongrit Kantathut, Piya Samankatiwat, Piya Cherntanomwong, Parinya Leelayana, Siam Khajarern

Division of Cardiothoracic Surgery, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, 10400

Objectives: Anatomical lobectomy has always been the standard operative treatment of early-stage non-small cell lung cancer. However, there have been emerging evidences suggesting that a sub-anatomical resection, such as segmentectomy, may yield the same treatment results, even in patients with higher-stage non-small cell lung cancer. This study aimed to compare overall 5-year survival rate and disease-free survival between lobectomy and segmentectomy in patients with non-small cell lung cancer.

Methods: The retrospective study included 380 patients who underwent surgery for non-small cell lung cancer at Ramathibodi Hospital between 1st January 2016 and 31st December 2020. Of 380 patients, 307 patients underwent lobectomy, while the other 73 patients underwent segmentectomy. Operative, admission, and follow-up data were collected from electronic medical records. Missing data were collected by telephone calls to patients or their relatives in deceased cases. Overall and disease-free survival were analyzed.

Results: Median overall 5-year survival time after lobectomy and segmentectomy seemed to be different but not statistically significant (18.5 months versus 5.8 months, p = 0.127). Median disease-free survival time after lobectomy and segmentectomy was also similar (8.6 months versus 4.5 months, p = 0.511). Two deaths occurred during perioperative period, one from lobectomy group due to acute massive pulmonary embolism (0.3%) and the other from segmentectomy group due to acute exacerbation of chronic obstructive pulmonary disease with respiratory failure (1.4%).

Conclusion: Lobectomy and segmentectomy result in similar overall 5-year survival rate and disease-free survival between these two comparison groups. Therefore, segmentectomy may be a potential alternative for operative treatment of non-small cell lung cancer. However, a larger and randomized-controlled trial may be needed to further validate these results.

Overall 5-year survival rate and disease-free survival after segmentectomy versus lobectomy in patients with non-small cell lung cancer

Presenter: Khunthorn Kadeetham, M.D.

Advisor: Associate Professor Montien Ngodngamthaweesuk, M.D.

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Ref.2478

Title of Project (English)	Overall Survival, Disease-free Survival and Pulmonary Function Test after Segmentectomy versus Lobectomy in Patients with Stage I Non-small Cell Lung Cancer
Title of Project (Thai)	อัตราการรอดชีวิต ภาวะปลอดโรค และผลการตรวจสมรรถภาพปอดหลังการผ่าตัดปอดเพียงบางส่วนเปรียบเทียบกับการผ่าตัดปอดทั้งกลีบในผู้ป่วยมะเร็งปอดระยะที่ 1
Type of Review	Expedited
Principal Investigator	Khunthorn Kadeetham, M.D.
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 03/09/2022

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	September 18, 2020
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Date of Expiration	September 17, 2023

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

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1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

หนังสือรับทราบการขอเปลี่ยนชื่อโครงการวิจัย
Acknowledgment of Change in Research Title

Main Title (English)	Overall survival, disease-free survival and pulmonary function test after segmentectomy versus lobectomy in patients with stage I non-small cell lung cancer
Main Title (Thai)	อัตราการรอดชีวิต ภาวะปลอดโรค และผลการตรวจสมรรถภาพปอดหลังการผ่าตัดปอดเพียงบางส่วนเปรียบเทียบกับการผ่าตัดปอดทั้งกลีบในผู้ป่วยมะเร็งปอดระยะที่ 1
Principal Investigator	Khunthorn Kadeetham
Date of 1st Approval	September 18, 2020
Certificate of Approval	COA. MURA2020/1524

คณะกรรมการจริยธรรมการวิจัยในคน คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล พิจารณาแล้วรับทราบการขอเปลี่ยนชื่อโครงการวิจัยเป็น

New Title of Project (English)	Overall 5-year survival rate and disease-free survival after segmentectomy versus lobectomy in patients with non-small cell lung cancer
New Title of Project (Thai)	อัตราการรอดชีวิตที่ 5 ปี และ ภาวะปลอดโรค หลังการผ่าตัดปอดบางส่วนเปรียบเทียบกับการผ่าตัดปอดทั้งกลีบในผู้ป่วยมะเร็งปอด
Date of Acknowledgement	January 19, 2022

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

มุ่งเรียนรู้ คู่คุณธรรม ใฝ่คุณภาพ ร่วมสานภารกิจ คิดนอกกรอบ รับผิดชอบสังคม

Introduction

- Contemporary treatment for early-stage non-small cell lung cancer (NSCLC) has always been an anatomical lobectomy with mediastinal lymph node staging.
- However, there were emerging reports regarding sublobar resection which yielded similar results.
- Even that said, some authors still supported lobectomy as the standard treatment according to their results.

Introduction

- The reasons behind these conflicting results lied behind the fact that there was a heterogeneity in study population and the general patient characteristics between the two cohorts were significantly different.
- According to different studies, markers affecting worse outcomes for segmentectomy included low number of mediastinal lymph nodes sampling and positive surgical margin whether from final pathological reports or frozen section.

Introduction

- We performed a retrospective cohort study to compare lobectomy versus segmentectomy in patients with NSCLC.
- Primary outcomes:
  - **Disease-free survival**
  - **Overall survival**

Materials and methods

- Ethical approval by Human Research Ethics Committee, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand
- **380 patients** who underwent surgery for NSCLC at Ramathibodi Hospital between 1st January, 2016 and 31st December, 2020
  - **Lobectomy: 307 patients**
  - **Segmentectomy: 73 patients**
- Operative, admission, and follow-up data were collected from electronic medical records.
- Missing data were collected through telephone calls to patients or their relatives in deceased cases.

Materials and methods

- **Pleural lavage cytology (PLC)**
- Three lavages:
  - First lavage (PLC 1) upon entering the thoracic cavity by irrigating and collecting it with 500 milliliters (ml) of normal saline
  - Second lavage (PLC 2) after complete lung resection and lymph node dissection, also by irrigating and collecting the thoracic cavity with 500 ml of normal saline
  - Third lavage (PLC 3) after performing pleural washing with 5000 ml of normal saline to wash out any possible residual malignant cells from lung manipulation and then irrigating and collecting the thoracic cavity with 500 ml of normal saline

Materials and methods

- Reports were divided into three groups:
  - **Positive ->** malignant cells in pleural lavage fluid
  - **Negative ->** no malignant cells in pleural lavage fluid
  - **Equivocal ->** atypical cells in pleural lavage fluid

Statistical analysis

- Variables
  - Continuous variables -> Student's *t*-test
  - Categorical variables -> chi-square or Fisher's exact tests
- A *p*-value < 0.05 was considered statistically significant.
- Survival analyses were performed using the Kaplan–Meier method and evaluated with the log-rank test.

Results

Demographic data and clinical characteristics

Table 1. Demographic data and clinical characteristics.

Variables	Lobectomy ($n=307$)	Segmentectomy ($n=73$)	p-Value
Age (year), mean ± SD	65.3 + 9.3	68.5 + 10.5	0.009
Gender, *n* (%)			
Male	111 (36.2)	33 (45.2)	0.152
Female	196 (63.8)	40 (54.8)	
BMI (kg/m^2), mean ± SD, $n=376$	25.2 + 11.6	23.7 + 4.0	0.078
Weight (kg), mean ± SD	60.6 + 11.2	59.5 + 10.9	0.439
Height (cm), mean ± SD, $n=376$	157.7 + 12.6	158.2 + 9.2	0.712
COPD, *n* (%)	37 (12.1)	17 (23.3)	0.013
Asthma, *n* (%)	8 (2.6)	4 (5.5)	0.207
OSA, *n* (%)	3 (1.0)	0	0.999
ILD, *n* (%)	0	1 (1.4)	0.192
HT, *n* (%)	145 (47.2)	32 (43.8)	0.696
DM, *n* (%)	85 (27.7)	18 (24.7)	0.601
DLP, *n* (%)	133 (43.3)	23 (31.5)	0.065
CKD, *n* (%)	14 (4.6)	4 (5.5)	0.740
CVA, *n* (%)	15 (4.9)	3 (4.1)	0.779
AF, *n* (%)	7 (2.3)	1 (1.4)	0.999
CAD, *n* (%)	26 (8.5)	9 (12.3)	0.305
PAD, *n* (%)	0	1 (1.4)	0.192
Smoking, *n* (%)			
No	228 (74.3)	50 (68.5)	0.317
Yes	79 (25.7)	23 (31.5)	
Smoking (pack–years), median (IQR) $n=101$	20 (10, 40)	20 (10, 40)	0.829
Quit smoking (years), median (IQR) $n=81$	10 (2, 24)	10 (1, 30)	0.833
FEV1(liters), median (IQR)	1.9 (1.6, 2.3)	1.9 (1.6, 2.2)	0.502

BMI: body mass index; COPD: chronic obstructive pulmonary disease; OSA: obstructive sleep apnea; ILD: interstitial lung disease; HT: hypertension; DM: diabetes mellitus; DLP: dyslipidemia; CKD: chronic kidney disease; CVA: cerebrovascular accident; AF: atrial fibrillation; CAD: coronary artery disease; PAD: peripheral arterial disease; FEV1: forced expiratory volume in 1 second; IQR: interquartile range.

Results

Staging and 5-year follow-up

Table 2. Staging and 5-year follow-up: Pathological NSCLC in both groups.

Stages	Lobectomy	Segmentectomy	5-year follow-up			
			Death		Recurrence	
			Lobectomy	Segmentectomy	Lobectomy	Segmentectomy
TmiN0M0	5	2	1	0	0	0
T1AN0M0	9	4	0	0	1	0
T1BN0M0	79	31	3	1	6	1
T1CN0M0	60	17	4	0	8	4
T2AN0M0	78	6	3	0	16	2
T2BN0M0	27	2	3	0	7	0
T3N0M0	26	3	3	1	9	1
T1BN1M0	3	2	0	0	0	1
T1BN2M0	6	1	1	0	5	0
T1CN2M0	5	4	0	0	3	3
T3N2M0	9	1	3	0	7	0
Total	307	73	21	2	62	12

Results

Pathological findings (LVI, VPI, and margin status)

Table 3. Pathological finding of NSCLC in both groups (LVI, VPI, and margin status).

Variables	Lobectomy ($n=307$)	Segmentectomy ($n=73$)	p-Value
LVI, *n* (%) $n=362$			
No	206 (70.1)	54 (79.4)	0.123
Yes	88 (29.9)	14 (20.6)	
VPI, *n* (%) $n=335$			
No	205 (75.6)	51 (79.7)	0.493
Yes	66 (24.4)	13 (20.3)	
Margin status, *n* (%)			
Free margin	303 (98.7)	73 (100)	0.999
Cancer involvement	4 (1.3)	0	

NSCLC: non-small cell lung cancer; LVI: lymphovascular invasion; VPI: visceral pleural invasion.

Results

Operative details

Table 4. Operative details.

Variables	Lobectomy ($n=307$)	Segmentectomy ($n=73$)	p-Value
Muscle-sparing thoracotomy/VATS, n (%)			
Muscle-sparing thoracotomy	79 (25.7)	9 (12.3)	0.015
VATS	228 (74.3)	64 (87.7)	
PLC 1, n (%) $n=211$			
Negative	164 (91.6)	29 (90.6)	0.864
Positive	7 (3.9)	1 (3.1)	
Equivocal	8 (4.5)	2 (6.3)	
Not done	41	128	
PLC 2, n (%) $n=211$			
Negative	160 (89.4)	27 (84.4)	0.658
Positive	6 (3.4)	2 (6.3)	
Equivocal	13 (7.3)	3 (9.4)	
Not done	128	41	
PLC 3, n (%) $n=211$			
Negative	158 (88.3)	28 (87.4)	0.546
Positive	5 (2.8)	2 (6.3)	
Equivocal	16 (8.9)	2 (6.3)	
Not done	128	41	
Tumor size (cm), median (IQR)	2.5 (1.8, 3.5)	2.0 (1.5, 2.5)	0.000
Number of lymph nodes examined, median (IQR)	8 (4, 12)	3 (2, 7)	0.000
Blood loss (ml), median (IQR) $n=378$	150 (100, 200)	100 (50, 200)	0.001
Muscle-sparing thoracotomy, median (IQR) $n=87$	200 (100, 300)	200 (100, 400)	0.591
VATS, median (IQR) $n=291$	120 (80, 200)	100 (50, 150)	0.001
Operative time (min), mean ± SD	191 ± 53	184 ± 55	0.291
Muscle-sparing, mean ± SD $n=88$	201 ± 53	244 ± 54	0.024
VATS, mean ± SD $n=292$	187 ± 53	175 ± 50	0.096

VATS: video-assisted thoracoscopy surgery; PLC: pleural lavage cytology; IQR: interquartile range.

Results

Perioperative complications

Table 5. Perioperative complications.

Variables	Lobectomy ($n = 307$)	Segmentectomy ($n = 73$)	p-Value
Complications, *n* (%)			
No	261 (85.0)	62 (84.9)	0.985
Yes	46 (15.0)	11 (15.1)	
Complications, *n* (%)			
Postoperative AF	6 (1.9)	3 (4.1)	
Air leak > 5 days	30 (9.8)	7 (9.6)	
Postoperative bleeding	0	1 (1.4)	
RML torsion	1 (0.3)	0	
Prolonged ventilation > 48 h	3 (1.0)	1 (1.4)	
Postoperative pneumonia	3 (1.0)	1 (1.4)	
Postoperative MI	0	0	
Chylothorax	4 (1.3)	1 (1.4)	
Acute renal failure	2 (0.7)	1 (1.4)	
PE	1 (0.3)	0	
Stroke	3 (1.0)	0	
Operative mortality	1 (0.3)	1 (1.4)	
Hospital stay (days), median (IQR)	6 (5, 8)	6 (5, 8)	0.802
Chest tube duration (days), median (IQR)	4 (3, 6)	4 (3, 6)	0.775
Number of repeated surgeries, *n* (%)	1 (0.3)	1 (1.4)	0.348

AF: atrial fibrillation; RML: right middle lobe; MI: myocardial infarction; IQR: interquartile range; PE: Pulmonary embolism.

Results

Survival analysis

Table 6. Survival analysis.

Variables	Lobectomy ($n = 307$)	Segmentectomy ($n = 73$)	p-Value
Recurrence, *n* (%)			
No	245 (79.8)	61 (83.6)	0.466
Yes	62 (20.2)	12 (16.4)	
Death, *n* (%)			
No	286 (93.2)	71 (97.3)	0.187
Yes	21 (6.8)	2 (2.7)	
Time to death (months), median (IQR)	18.5 (10.1, 25.1)	5.8 (1.4, 10.2)	0.127
Time to recurrence (months), median (IQR)	8.6 (0.9, 20.6)	4.5 (1.2, 16.3)	0.511
Time to follow-up (months), median (IQR)	26.5 (13.2, 39.2)	29.7 (17.1, 40.8)	0.355

IQR: interquartile range.

Results

Survival analysis

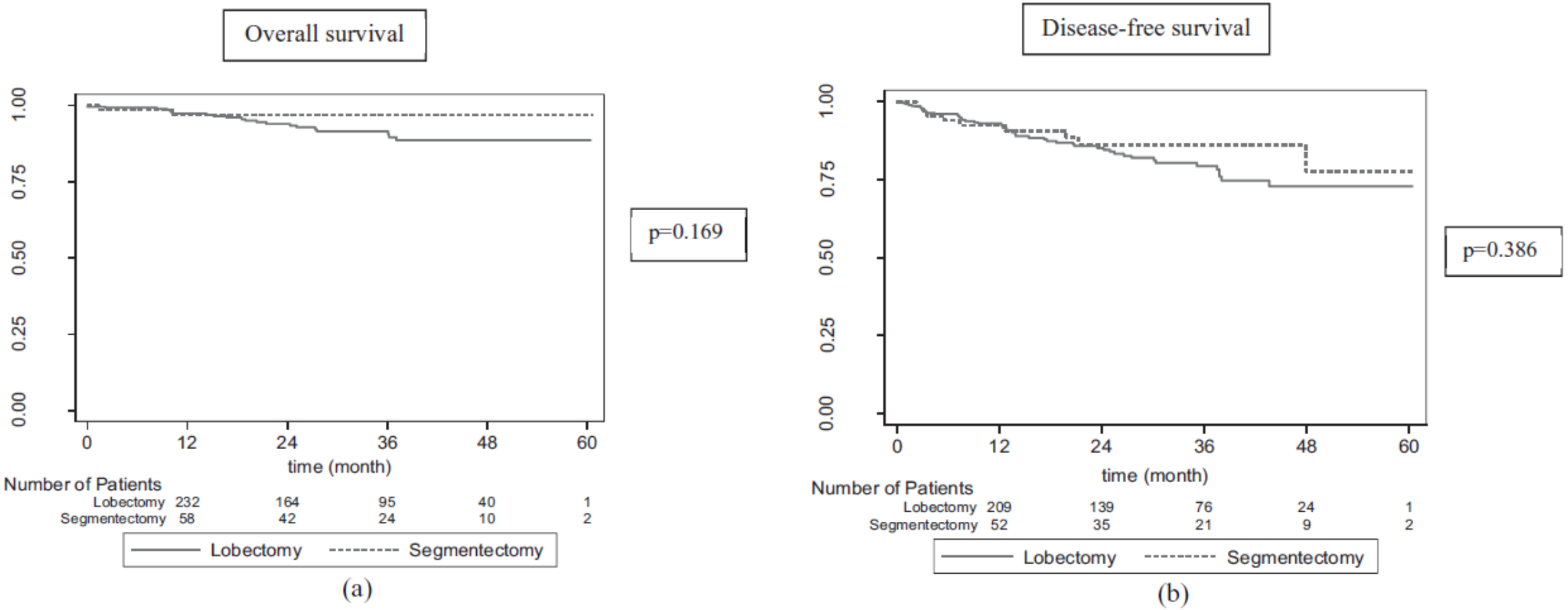

Figure 1. Kaplan–Meier curves comparing (a) overall and (b) disease-free survival between lobectomy and segmentectomy group are shown.[12]

Discussion

- Surgical margin matters.
- Number of mediastinal lymph nodes acquired during surgery might or might not affect results.
- Tumor spillage is not of a concern when performing segmentectomy.
- VATS is more advantageous in terms of operative time and blood loss.

Limitations

- Single-center, retrospective trial
- Limited and unbalanced cohorts
- Longer-term follow-up data required

Conclusion

- Lobectomy and segmentectomy result in **similar overall 5-year survival rate and disease-free survival** between lobectomy and segmentectomy in patients with NSCLC.
- Segmentectomy may be a potential alternative surgical treatment.
- However, a larger and randomized-controlled trial may be needed to further validate these results.

Abstract

“Comparison of Robotic vs Laparoscopic Radical Nephroureterectomy with bladder cuff excision in Upper Urinary Tract Urothelial Carcinoma: A Retrospective Cohort Study”

Kan Panyapinitnugoon, MD

Kan Panyapinitnugoon, Kittinut Kitvikai

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Introduction: The best bladder cuff management technique for upper tract urothelial carcinoma (UTUC) is still controversial. There were few data published regarding to outcome and technique for robotic assisted nephroureterectomy (RANU). Our institute offered RANU for UTUC and considered to be an alternative standard treatment for our patients.

Objective: The main purpose of the study was to compare the perioperative outcomes between single-docking RANU, Laparoscopic nephroureterectomy with laparoscopic bladder cuff excision (LNULBCE), and Laparoscopic nephroureterectomy with open bladder cuff excision (LNUOBCE) for UTUC. The secondary purpose was to compare the oncological outcomes between the three different operative techniques.

Patients and Methods: The study was conducted at Ramathibodi hospital during Jan 2013 to July 2024. UTUC patients were categorized into three groups based on operative technique including RANU, LNULBCE, and LNUOBCE. The data were collected retrospectively for perioperative and oncological outcomes, and analyzed using STATA software.

Results: For overall 125 patients, 36 patients were in RANU group, 43 patients were in LNULBCE group, and 46 patients were in LNUOBCE group.Perioperative outcomes were favored to RANU group over LNULBCE and LNUOBCE groups including blood loss (100ml vs 150ml vs 250ml, p-value 0.00), Length of stay (7days vs 8days vs 8days, p-value 0.102), and pain score (3.1 vs 4.9 vs 5.7, p-value 0.00). Margin status was 8.3% vs 7% vs 17.4%, P-value 0.28 on RANU, LNULBCE, and LNUOBCE groups. 5-years bladder recurrence free probability were 71.87% vs 64.90% vs 35.29%, p-value 0.013 and 5-years local recurrence free probability were 100% vs 87.95% vs 97.50%, p-value 0.183 on RANU, LNULBCE, and LNUOBCE groups respectively.

Conclusion: The RANU is an alternative effective technique for distal ureterectomy with bladder cuff excision in UTUC. It provides superior perioperative outcomes and equivalent oncological outcomes compared with LNULBCE and LNUOBCE technique. However, further randomized controlled study and larger sample size may be needed to confirm the operative outcomes.

COMPARISON OF ROBOTIC VS LAPAROSCOPIC RADICAL NEPHROURETERECTOMY WITH BLADDER CUFF EXCISION IN UPPER URINARY TRACT UROTHELIAL CARCINOMA: A RETROSPECTIVE COHORT STUDY

KAN PANYAPINITNUGOON, MD. , KITTINUT KITVIKAI, PROF MD.

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ETHICAL APPROVAL

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COA. MURA2023/433

Title of Project (English)	Comparison of Robotic Radical Nephroureterectomy with bladder cuff excision vs Laparoscopic Radical Nephroureterectomy with Laparoscopic or Open bladder cuff excision in Upper Urinary Tract Urothelial Carcinoma: A Retrospective Cohort Study
Title of Project (Thai)	การศึกษาผลลัพธ์การผ่าตัดไตและท่อไตด้วยหุ่นยนต์เปรียบเทียบกับการผ่าตัดไตและท่อไตโดยการส่องกล้องร่วมกับการผ่าตัดท่อไตส่วนล่างแบบส่องกล้องหรือแบบเปิด ในผู้ป่วยมะเร็งท่อไต
Type of Review	Expedited
Principal Investigator	Kan Panyapinitnugoon
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator	Kittinut Kijvikai
Approval includes	1. Submission form protocol version 2 date 16/5/2023 2. Case record form version 2 date 16/5/2023 3. Curriculum vitae 4. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	May 22, 2023
Date of Expiration	May 21, 2024

Signature of Chair.....
(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:
1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University
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COA. MURA2023/433
Ref.2024/468

Title of Project (English)	Comparison of Robotic Radical Nephroureterectomy with bladder cuff excision vs Laparoscopic Radical Nephroureterectomy with Laparoscopic or Open bladder cuff excision in Upper Urinary Tract Urothelial Carcinoma: A Retrospective Cohort Study
Title of Project (Thai)	การศึกษาผลลัพธ์การผ่าตัดไตและท่อไตด้วยหุ่นยนต์เปรียบเทียบกับการผ่าตัดไตและท่อไตโดยการส่องกล้องร่วมกับการผ่าตัดท่อไตส่วนล่างแบบส่องกล้องหรือแบบเปิด ในผู้ป่วยมะเร็งท่อไต
Type of Review	Expedited
Principal Investigator	Kan Panyapinitnugoon
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 25/04/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	May 22, 2023
Renewal Date (1st)	May 22, 2024
Date of Expiration	May 21, 2025

Signature of Chair.....
(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

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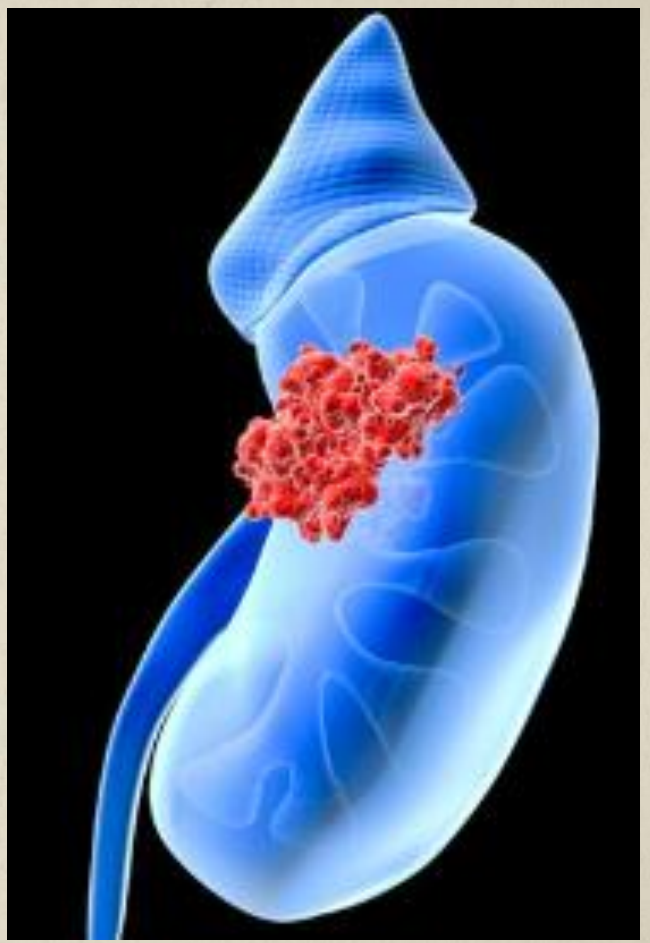
INTRODUCTIONS

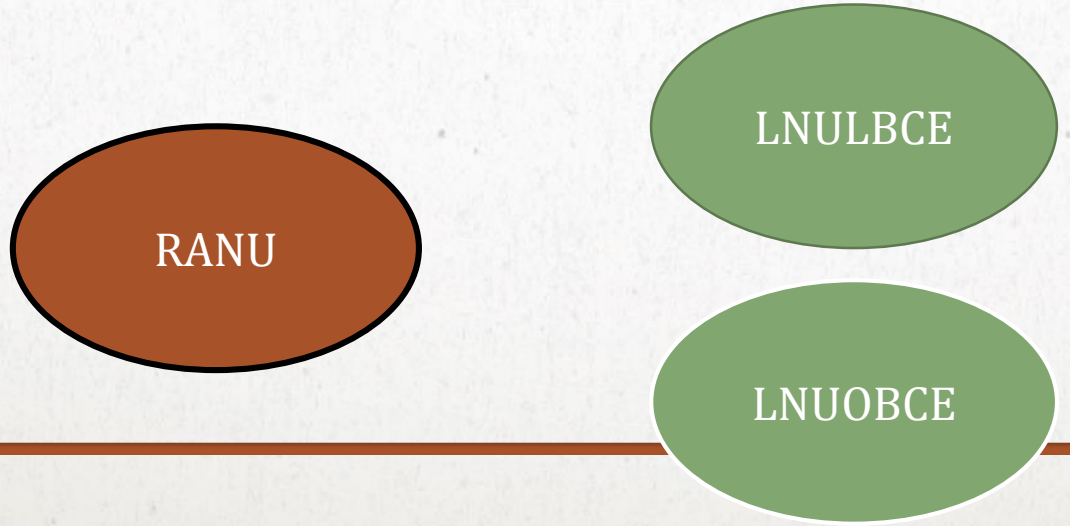


INTRODUCTIONS

- Upper tract urothelial carcinoma (UTUC) accounts for 5-10% of all urothelial carcinomas.
- Radical nephroureterectomy (RNU) with complete bladder cuff excision (BCE) is the gold standard treatment for localized disease
- Bladder Cuff Excision part is still Controversy
  - Various techniques have been described without conclusive data on superiority.
  - Inadequate bladder cuff excision may lead to worse oncological outcomes.
- Robotic-assisted radical nephroureterectomy (RANU) initiated with limited published data on outcomes and techniques.
- Our Center's Technique utilizes robotic surgery advantages to manage the distal ureter with simplicity and without redocking.
- Study aims to introduce feasibility and outcomes of single-docking RANU based on our center's technique.

OBJECTIVES

- To compare the **perioperative outcomes** for UTUC between
  - 1. Single docking robotic-assisted radical nephroureterectomy (RANU)
  - 2. Laparoscopic nephroureterectomy with laparoscopic bladder cuff excision (LNULBCE)
  - 3. Laparoscopic nephroureterectomy with open bladder cuff excision (LNUOBCE)
- To compare the **oncological outcomes** between the three different operative techniques.



MATERIALS AND METHODS

MATERIALS AND METHODS

- Retrospective data collection
- From Jan 2013 to July 2024
- Single-center data ; Ramathibodi Hospital
- Included ;
  - Localized UTUC patients
  - Patho ; Urothelial carcinoma
  - Underwent Robotic or Laparoscopic surgery

MATERIALS AND METHODS

- 3 groups
  - 1. RANU (Single-docking Robotic assisted nephroureterectomy)
  - 2. LNULBCE (Laparoscopic nephroureterectomy with Laparoscopic bladder cuff excision)
  - 3. LNUOBCE (Laparoscopic nephroureterectomy with Open bladder cuff excision)

} Control

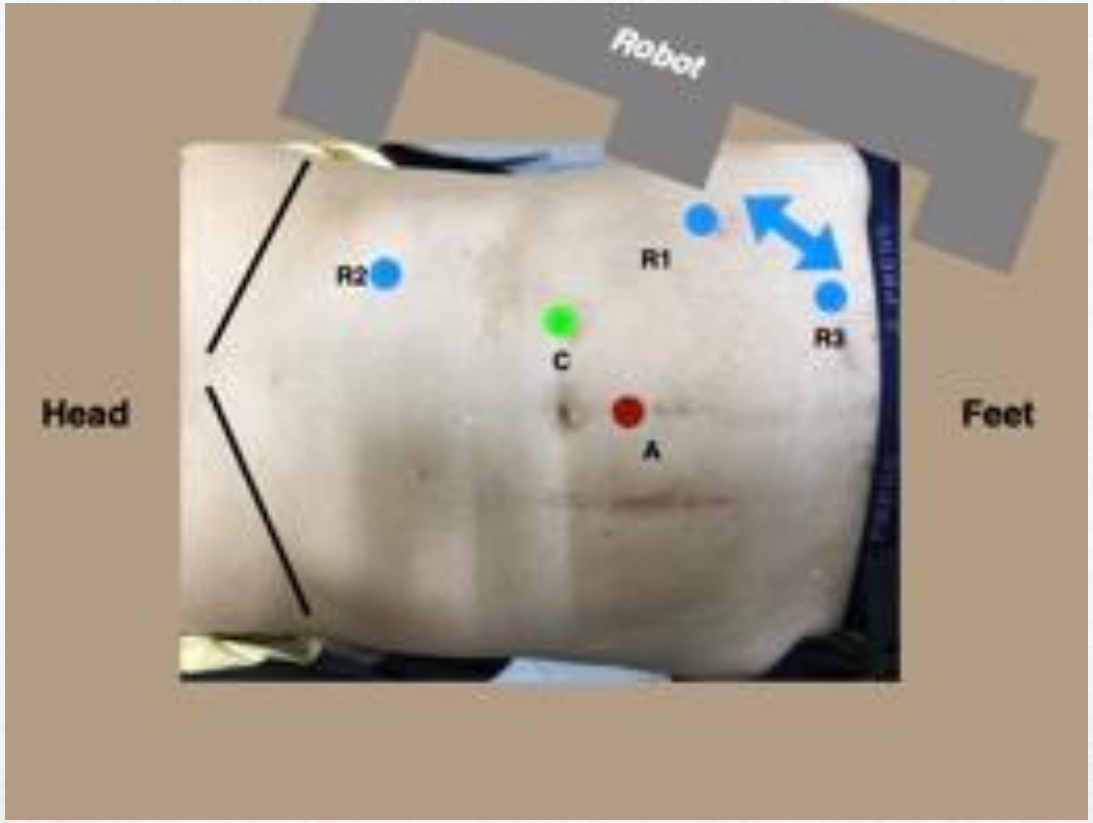
MATERIALS AND METHODS

- Perioperative outcomes (Primary objective)
  - Operative time
  - Blood loss
  - Length of hospital stay
  - Conversion
  - Perioperative complication
  - Pain score
- Oncologic outcomes (Secondary objective)
  - Local recurrence
  - Bladder recurrence
  - Distant recurrence
  - Nodal recurrence
  - Contralateral recurrence

SURGICAL TECHNIQUE

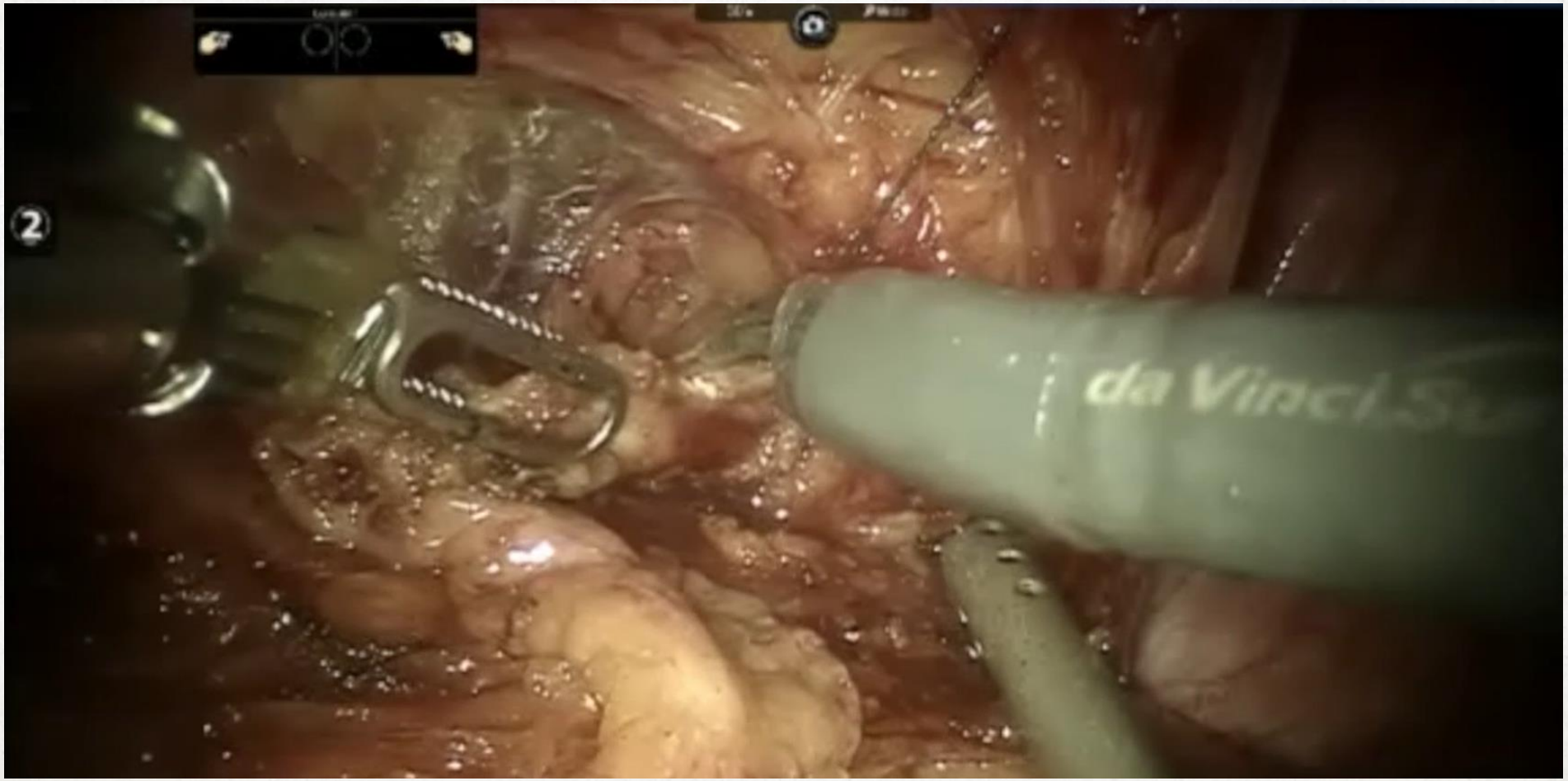
RANU

- Robotic da Vinci surgical system (SI)

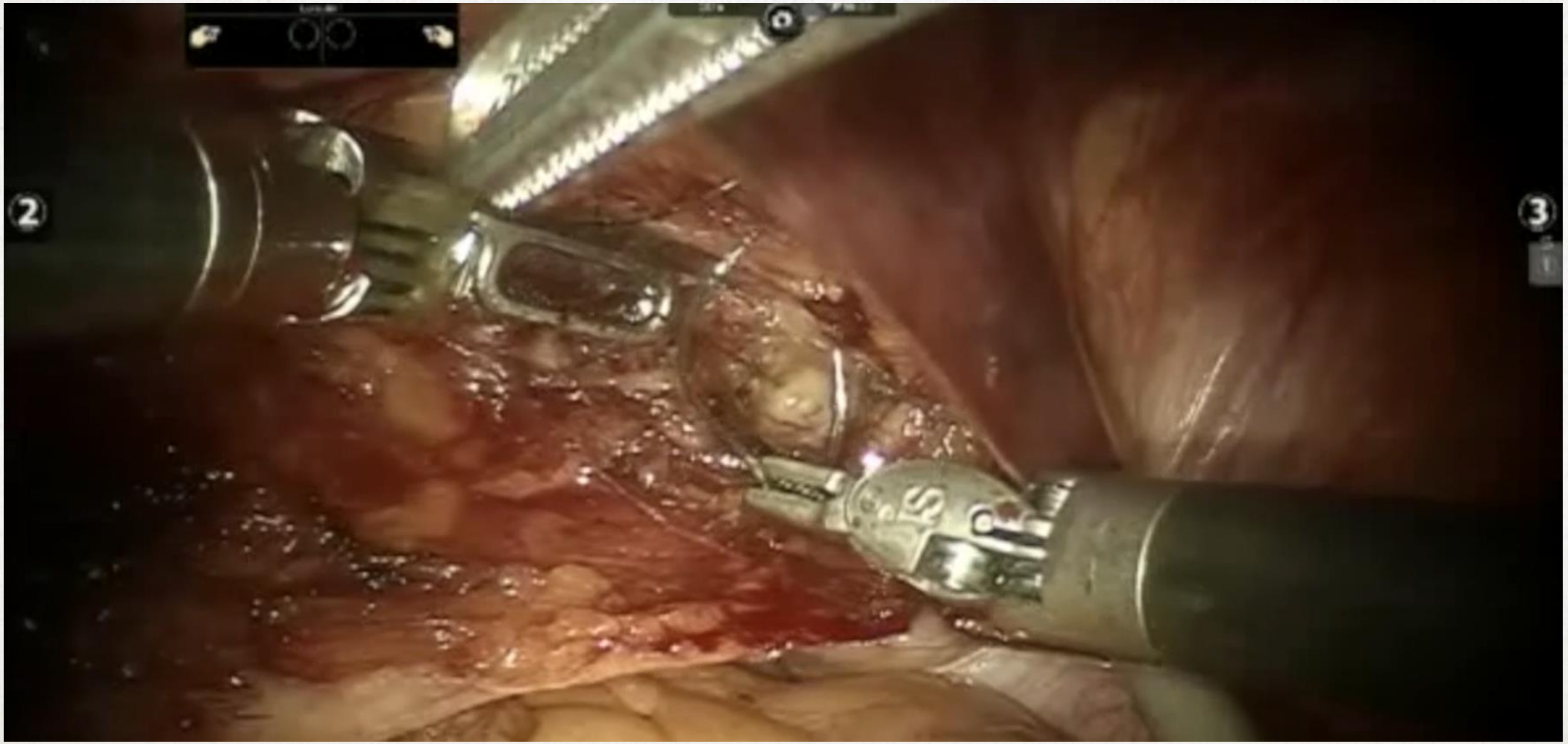


RANU

RANU



RANU



STATISTICAL ANALYSIS

- Patient characteristics with continuous variables were compared by Student's t-test or Wilcoxon rank-sum test
- Categorical variables were compared with Chi-square test or Fisher's exact test
- A P-value of < 0.05 was considered statistically significant
- Recurrence free probability and overall survival was performed using the Kaplan-Meier method and evaluated by the log-rank test
- All statistical calculations are performed using STATA software

RESULTS

PATIENTS AND TUMOR CHARACTERISTICS

Table 1: Patients and tumor characteristics

Variable	Total (n=125)	RANU (n=36)	LNULBCE (n=43)	LNUOBCE (n=46)	p -value
Gender, n (%)					
Male	71(56.8)	16(44.4)	24(55.8)	31(67.4)	0.113
Female	54(43.2)	20(55.6)	19(44.2)	15(32.6)	
Age(year), mean±SD	69.5±10.1	70.6±8.9	69.4±9.5	68.6±11.6	0.204
Weight (kg), mean±SD	62.9±15.4	58.5±10.9	62.9±15.0	66.5±17.9	0.012
Height (cm), mean±SD	161.1±8.5	159.4±8.5	160.9±8.6	162.7±8.4	0..983
BMI(kg/m^2), mean±SD	24.1±4.9	22.9±3.5	24.2±5.0	24.9±5.6	0.022
Comorbidity, n(%)					
DM	32(25.6)	4(11.1)	13(30.2)	15(32.6)	0.060
HT	85(68.0)	25(69.4)	28(65.1)	32(69.6)	0.882
DLP	27(21.6)	13(36.1)	7(16.3)	7(15.2)	0.043
CKD	20(16.0)	8(22.2)	5(11.6)	7(15.2)	0.434
CAD	3(2.4)	3(8.3)	0	0	0.022
ASA, n(%)					
I	3(2.4)	0	1(2.3)	2(4.3)	0.469
II	32(25.6)	11(30.6)	8(18.6)	13(28.3)	
III	86(68.8)	25(69.4)	31(72.1)	30(65.2)	
IV	4(3.2)	0	3(7.0)	1(2.2)	
Pathologic stage					
Ta	24(19.2)	7(19.4)	7(16.3)	10(21.7)	0.989
Tis	-	-	-	-	
T1	34(27.2)	10(27.8)	11(25.6)	13(28.3)	
T2	26(20.8)	6(16.7)	10(23.3)	10(21.7)	
T3	36(28.8)	11(30.6)	13(30.2)	12(26.1)	
T4	5(4.0)	2(5.5)	2(4.6)	1(2.2)	

PATIENTS AND TUMOR CHARACTERISTICS

Table 1: Patients and tumor characteristics

Variable	Total (n=125)	RANU (n=36)	LNULBCE (n=43)	LNUOBCE (n=46)	p -value
Grade, n (%)					
Low	19(15.2)	3(8.3)	7(16.3)	9(19.6)	0.361
high	106(84.8)	33(91.7)	36(83.7)	37(80.4)	
Tumor location					
Renal pelvis, n (%)	72(57.6)	21(58.3)	32(74.4)	19(41.3)	0.007
Proximal ureter, n (%)	22(17.6)	8(22.2)	6(13.9)	8(17.4)	0.629
Mid ureter, n (%)	15(12.0)	2(5.6)	7(16.3)	6(13.0)	0.331
Distal ureter, n (%)	33(26.4)	7(19.4)	3(7.0)	23(50.0)	0.000
Side, n (%)					
Left	71(56.8)	19(52.8)	24(55.8)	28(60.9)	0.754
Right	54(43.2)	17(47.2)	19(44.2)	18(39.1)	
Multifocality, n (%)	14(11.2)	3(8.3)	5(11.6)	6(13.0)	0.881
Synchronous Bladder tumor, n (%)	8(6.4)	5(13.9)	0	3(6.5)	0.025
Concomitant Operation, n (%)	14(11.2)	5(13.9)	3(7.0)	6(13.0)	0.593
Perioperative intravesical chemotherapy, n (%)	11(8.8)	8(22.2)	3(7.0)	0	0.001
Follow up time(month), median(IQR)	23(8, 51)	27(7, 46)	23(7, 60)	21(10, 43)	0.876

PERIOPERATIVE OUTCOMES

Table 2: Perioperative outcomes

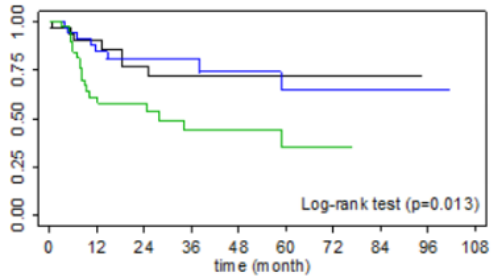
Variable	Total (n=125)	RANU (n=36)	LNULBCE) (n=43)	LNUOBCE (n=46)	p -value
Operative time(min), mean±SD	230±81	223±62	222±88	244±88	0.073
Estimated Blood Loss(ml), median(IQR)	150(100, 300)	100(50, 175)	150(100, 250)	250(150, 300)	0.000
Length of Stay(day), median(IQR)	8(6, 9)	7(6, 8)	8(6, 9)	8(7, 10)	0.102
Positive Margin, n(%)	14(11.2)	3(8.3)	3(7.0)	8(17.4)	0.282
Pain score, mean±SD	4.7±2.5	3.1±2.2	4.9±2.5	5.7±2.2	0.000
Complications, n(%)	17(13.6)	5(13.9)	2(4.6)	10(21.7)	0.064
Bowel ileus	3(2.4)	0	0	3(6.5)	
Fever	4(3.2)	2(5.5)	1(2.3)	1(2.2)	
Intraabdominal collection	1(0.8)	0	0	1(2.2)	
LGIB	1(0.8)	1(2.8)	0	0	
lymphatic leakage	1(0.8)	0	0	1(2.2)	
Urine leakage	2(1.6)	0	0	2(4.3)	
Volume overload	4(3.2)	1(2.8)	1(2.3)	2(4.3)	
wound dehiscence	1(0.8)	1(2.8)	0	0	

ONCOLOGICAL OUTCOMES

Table 3: Oncological outcomes

Variable	Total (n=125)	RANU (n=36)	LNULBCE (n=43)	LNUOBCE (n=46)	p - value
Bladder recurrence, n (%)	34(27.2)	7(19.4)	8(18.6)	19(41.3)	0.026
Local recurrence, n (%)	4(3.2)	0	3(7.0)	1(2.2)	0.262
Distant recurrence, n (%)	10(8.0)	2(5.6)	5(11.6)	3(6.5)	0.650
Nodal recurrence, n (%)	6(4.8)	4(11.1)	0	2(4.4)	0.075
Contralateral upper tract recurrence, n (%)	3(2.4)	2(5.6)	0	1(2.2)	0.286
Overall recurrence, n (%)	55(44.0)	15(41.7)	14(32.6)	26(56.5)	0.071
Time to recurrence (month), median(IQR)	-	18(5, 27)	9(4, 18)	8(5, 11)	0.470

Fig.1 BladderRecurrence by Operative Technique

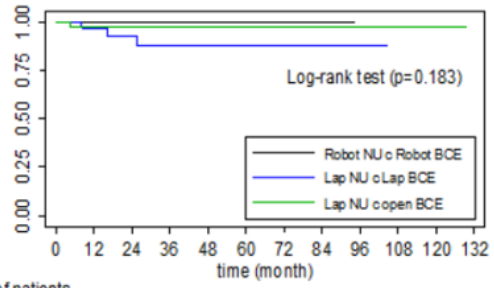


OpTech_3gr		Op1	Op2	Op3
time	12	0.9037	0.8459	0.6114
	24	0.7700	0.8092	0.5792
	36	0.7187	0.8092	0.4411
	48	0.7187	0.7417	0.4411
	60	0.7187	0.6490	0.3529
	72	0.7187	0.6490	0.3529
	84	0.7187	0.6490	.
	96	.	0.6490	.
	108	.	.	.

Number of patients

Robot NU c Robot BCE	21	15	11	8	5	3	3	0	0
Lap NU c Lap BCE	24	16	13	11	7	6	4	3	0
Lap NU c open BCE	19	13	9	7	3	2	0	0	0

Fig.2 Local recurrence by Operative Technique

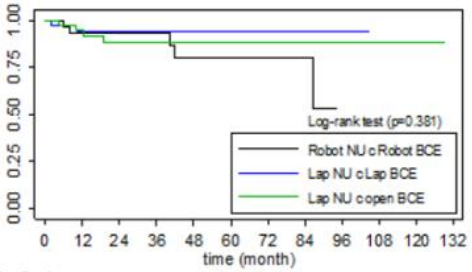


OpTech_3gr		Op1	Op2	Op3
time	12	1.0000	0.9688	0.9750
	24	1.0000	0.9284	0.9750
	36	1.0000	0.8795	0.9750
	48	1.0000	0.8795	0.9750
	60	1.0000	0.8795	0.9750
	72	1.0000	0.8795	0.9750
	84	1.0000	0.8795	0.9750
	96	.	0.8795	0.9750
	108	.	.	0.9750
	120	.	.	0.9750
	132	.	.	.

Number of patients

Robot NU c Robot BCE	24	20	16	9	5	3	3	0	0	0	0
Lap NU c Lap BCE	28	20	17	15	12	9	5	4	0	0	0
Lap NU c open BCE	32	22	15	10	7	6	3	2	2	2	0

Fig.4 Overall survival by Operative Technique



OpTech_3gr		Op1	Op2	Op3
time	12	0.9295	0.9437	0.9471
	24	0.9295	0.9437	0.8802
	36	0.9295	0.9437	0.8802
	48	0.7967	0.9437	0.8802
	60	0.7967	0.9437	0.8802
	72	0.7967	0.9437	0.8802
	84	0.7967	0.9437	0.8802
	96	.	0.9437	0.8802
	108	.	.	0.8802
	120	.	.	0.8802
	132	.	.	.

Number of patients

Robot NU c Robot BCE	24	20	16	9	5	3	3	0	0	0	0
Lap NU c Lap BCE	29	20	17	15	12	9	5	4	0	0	0
Lap NU c open BCE	33	22	15	10	7	6	3	2	2	2	0

	RANU	LNULBCE	LNUOBCE	
5-years bladder recurrence free probability	71.87%	vs 64.90%	vs 35.29%,	p-value 0.013
5-years local recurrence free probability	100%	vs 87.95%	vs 97.50%,	p-value 0.183
5-years overall survival	79.67%	vs 94.37%	vs 88.02%,	p-value 0.38

DISCUSSION

PERIOPERATIVE OUTCOMES

Robotic surgery provides excellent dexterity, surgeon ergonomic and visualization especially in small working space

<u>For patients</u>
less morbidities, shorter length of stay, reduced blood loss compared to laparoscopic approach

<u>For surgeon</u>
distal ureterectomy and bladder cuff excision can be performed by pure single dock robotic approach

Shorter operative time compared to LNUOBCE group

Reduce the complication from patient re-position setting up

ONCOLOGICAL OUTCOMES

Not statistically difference including margin status

However, the bladder recurrence and local recurrence were higher in laparoscopic group

In transvesical open technique, there might be some chances of tumor contamination during the bladder cuff excision removal

In robotic approach, the ureter has been clipped below the mass and the bladder cuff can be removed by pure extravesicle technique without any spillage of tumor cell

Less tumor contamination than laparoscopic or open bladder cuff technique and may reduced recurrence

DISCUSSION

Most of current studies outcome go in the same direction as our study.

Huang et al.

- benefit of robotic over laparoscopic surgery in term of less blood loss and shorter length of stay in their retrospective larger series of 231 UTUC patients
- The oncology and perioperative outcomes were comparable
- Intraoperative blood loss was 30 ml in robotic group whereas it was 150 ml in laparoscopic group
- The 5-years overall survival, cancer-specific survival and bladder recurrence free survival were comparable between the groups

Huang YP, Huang EY, Chung HJ, Tai MC, Huang TH, Wei TC, et al. Is Robotic Superior to Laparoscopic Approach for Radical Nephroureterectomy with Bladder Cuff Excision in Treating Upper Urinary Tract Urothelial Carcinoma? J Endourol. 2023;37(2):139-46

Bae and colleagues

- comparable oncology outcomes including progression free survival, cancer specific survival and overall survival in their study of 119 patients who underwent open, laparoscopic and robotic surgery for UTUC

Bae H, Chung JH, Song W, Kang M, Jeon HG, Jeong BC, et al. Robotic Radical Nephroureterectomy with Bladder Cuff Excision for Upper Tract Urothelial Carcinoma: A Trend Analysis of Utilization and a Comparative Study. Cancers. 2022;14(10):2497

LIMITATIONS

- Small , nonrandomized retrospective study
  - may contain bias
- Moderate follow up durations
  - difficult to provide the definite conclusion in oncology outcomes
- Did not perform template lymphadenectomy
  - which should be offered in high-risk (T3) diseases
- Cost of robotic treatment not analyzed

FUTURE DIRECTIONS

- Newer robotic platform (Davinci Xi) will provide better perioperative outcomes for our upcoming patients
  - port placement was placed linearly along the rectus muscle which
    - much more convenience
    - Less port clashing

- Explore cost-effectiveness of robotic surgery

CONCLUSION

- RANU provides comparable oncology outcomes to laparoscopic approach in UTUC management.
- RANU has less morbidities in term of perioperative outcomes.
- Further randomized prospective study are required to confirm these outcomes.

THANK YOU

Abstract

“In Search of Aesthetic Nasal Profile in East Asians”

Chawisa Maleewan, MD

Chawisa Maleewan, Ajchariya Sarovath, Thiti Tantitham

Division of Plastic and Maxillofacial, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University

Objective: While the aesthetics of the Caucasian nose have been extensively described in textbooks, the ideal aesthetic characteristics of the Asian nose remain undescribed. Therefore, the purpose of this study was to determine the aesthetic nasal profile in the East Asian population.

Methods: A prospective survey was carried out to evaluate preferences for the optimal nasal profile, including radix location, nasal projection, and tip rotation. Eight volunteers (4 women and 4 men) served as models and were photographed. Raters (n=138), including professionals (n=65) and laypersons (n=73), evaluated a series of computer-manipulated photographs and rated their preferences. The primary outcome was the preferred aesthetic nasal parameters. Differences between professionals and laypersons were subsequently compared.

Results: With the eyes in a horizontal gaze, both groups preferred the radix location to be positioned between the pupil and upper lash line. Preferred tip projection was 0.85-0.9 of the ideal Caucasian projection in females and 0.9-0.95 in males. The preferred nasolabial angle was 100°-105° in females and 95°-100° in males.

Conclusions: Aesthetic nasal preferences in East Asians, when compared to Caucasians, favor a lower radix location, a more obtuse nasolabial angle, and a less projected nasal tip.

Plastic & Maxillofacial Surgery

In Search of Aesthetic Nasal Profile in East Asians

การศึกษาโครงสร้างรูปทรงจมูกตามมาตรฐานความงามของชาวเอเชียตะวันออก

Principal Investigator : Chawisa Maleewan, M.D.

Co-investigators : Ajchariya Sarovath, Assist.Prof., M.D.

Thiti Tantitham, M.D.

Mahidol University

Faculty of Medicine Ramathibodi Hospital

Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University
270 Rama 6 Rd. Phayatai Ratchathewi Bangkok 10400 Tel.(660)2012175, 2011544, 2010388
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E-mail: raec.mahidol@gmail.com

COA. MURA2023/184

Ref.2024/303

Title of Project (English)	In Search of Aesthetic Nasal Profile in East Asians
Title of Project (Thai)	การศึกษาโครงสร้างรูปทรงจมูกตามมาตรฐานความงามของชาวเอเชียตะวันออก
Type of Review	Expedited
Principal Investigator	Chawisa Maleewan
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Document reviewed	Annual Progress Report Date 19/03/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Initial Approval	**February 16, 2023**
Renewal Date (1st)	**February 16, 2024**
Date of Expiration	**February 15, 2025**

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

Background & Rationale

Rhinoplasty

is one of popular aesthetic operations performed in East Asia.

Ideal aesthetics

of the Caucasian nose have been described extensively.

Textbook anatomy

does not exactly mirror clinical experience in Asians.

There is no standard nasal parameter in Asians yet.

The ideal aesthetics

as described in standard textbooks

not suitable for Asians

Radix location
upper lash line – supratarsal crease
15mm depth

Nasolabial angle
♀ 95°-100°
♂ 90°-95°

Tip projection
2/3 of nasal length

Rubin JP, Neligan P. Plastic surgery: Volume 2: Aesthetic surgery. 4th ed.

Research Question

What is the ideal nasal profile in East Asians?

Outcome

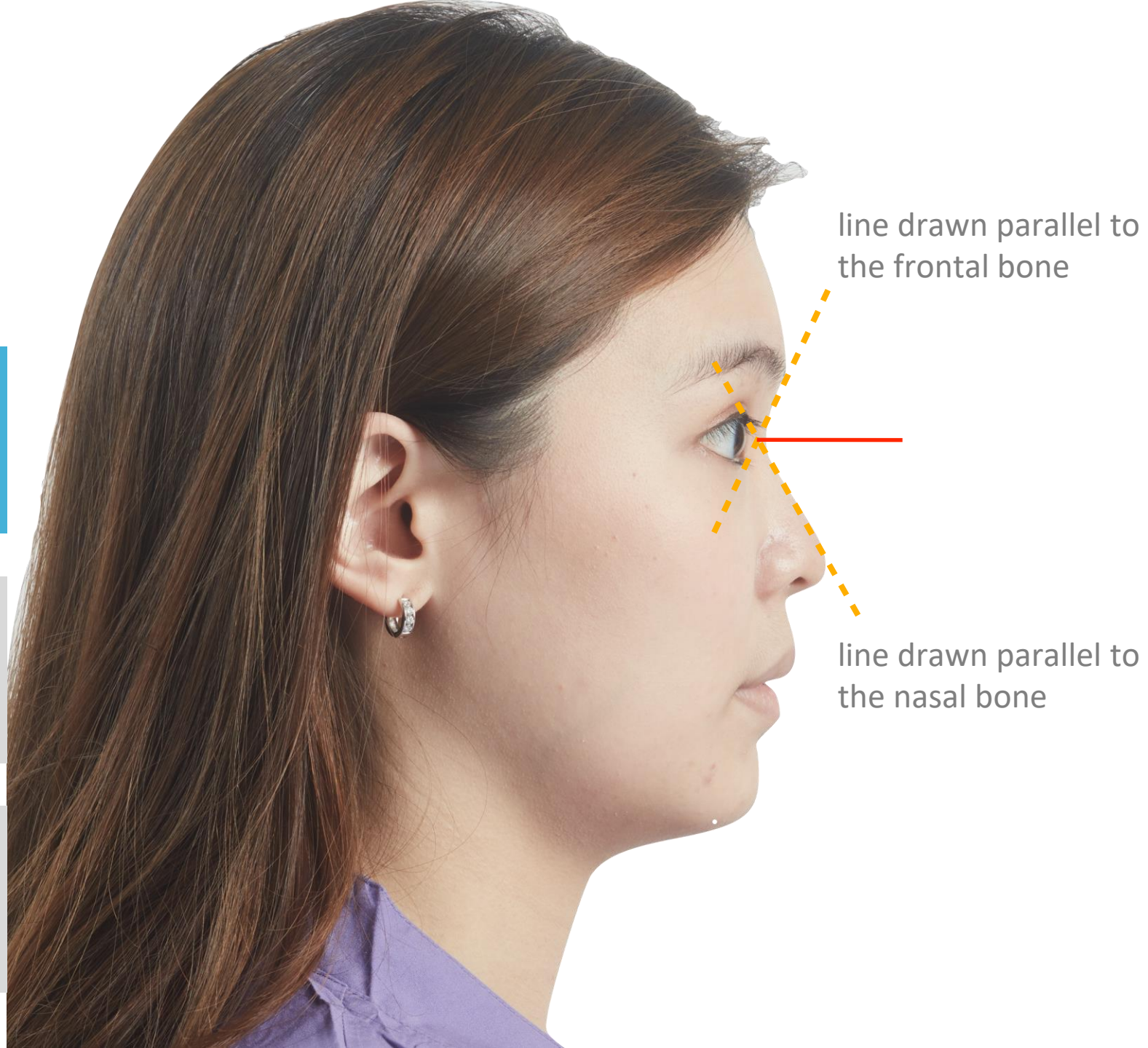
Aesthetic nasal profile

- Radix location
- Tip projection
- Nasolabial angle

Outcome

Aesthetic nasal profile

- Radix location
- Tip projection
- Nasolabial angle



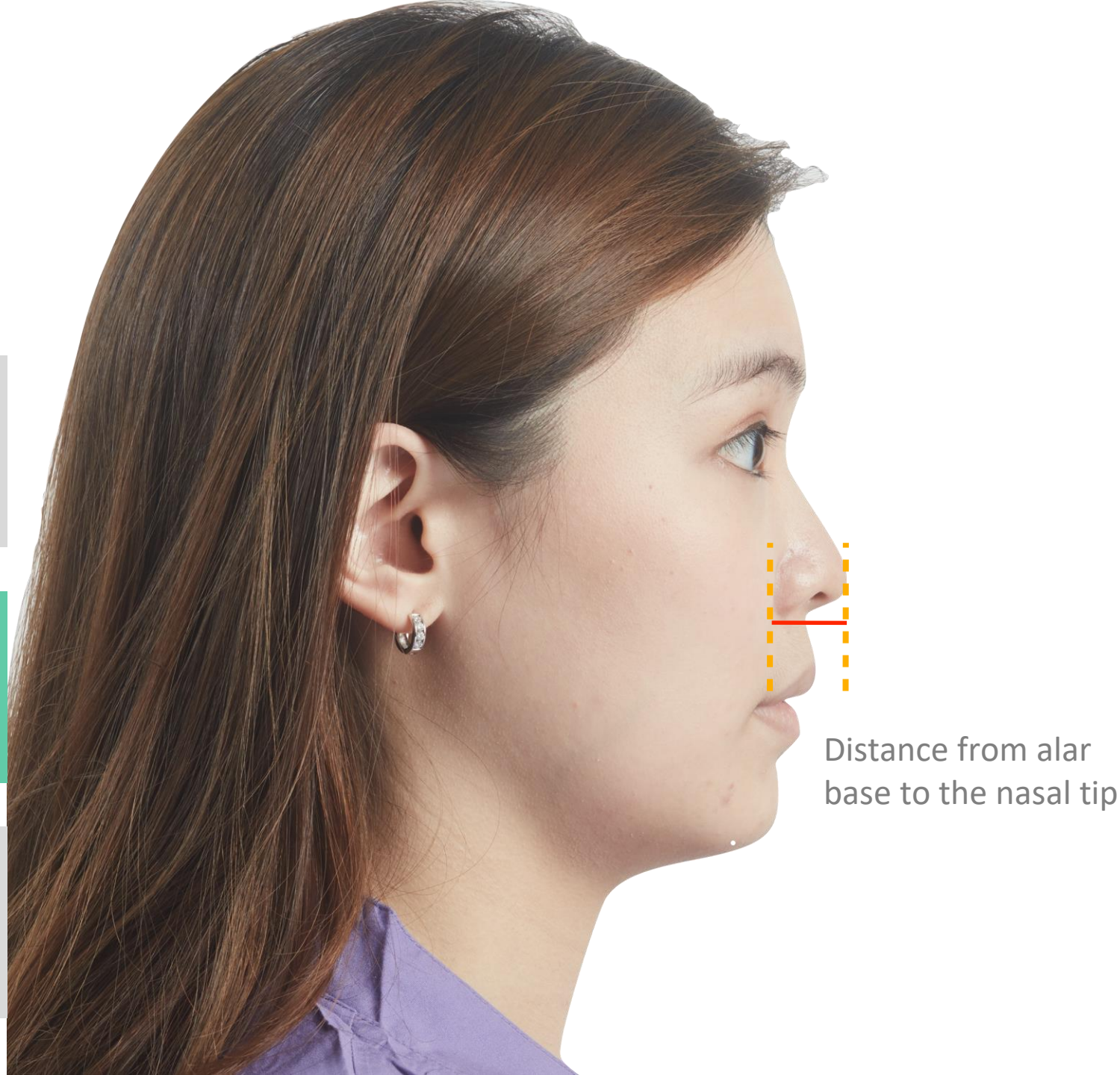
Outcome

Aesthetic nasal profile

Radix location

Tip projection

Nasolabial angle



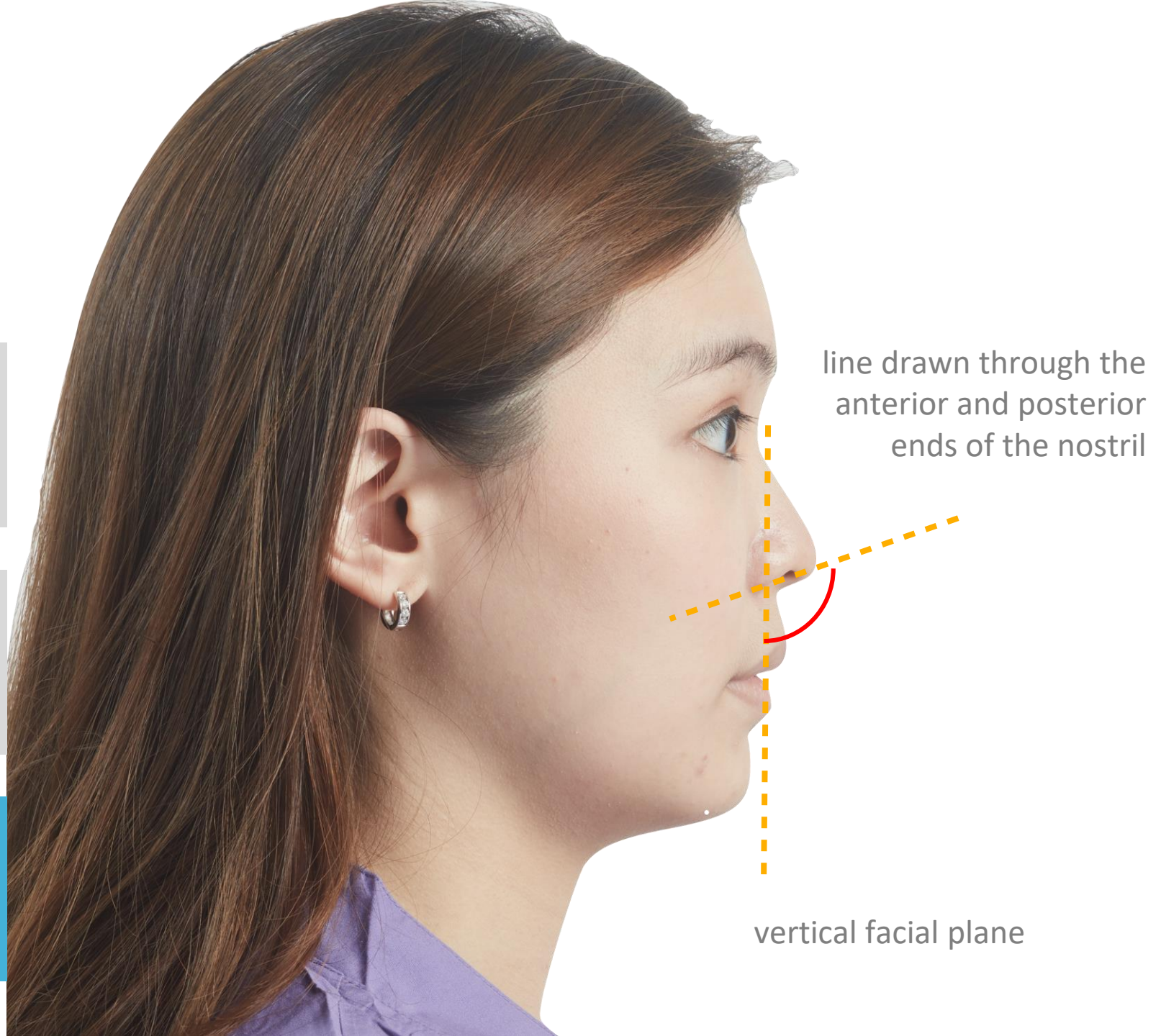
Outcome

Aesthetic nasal profile

Radix location

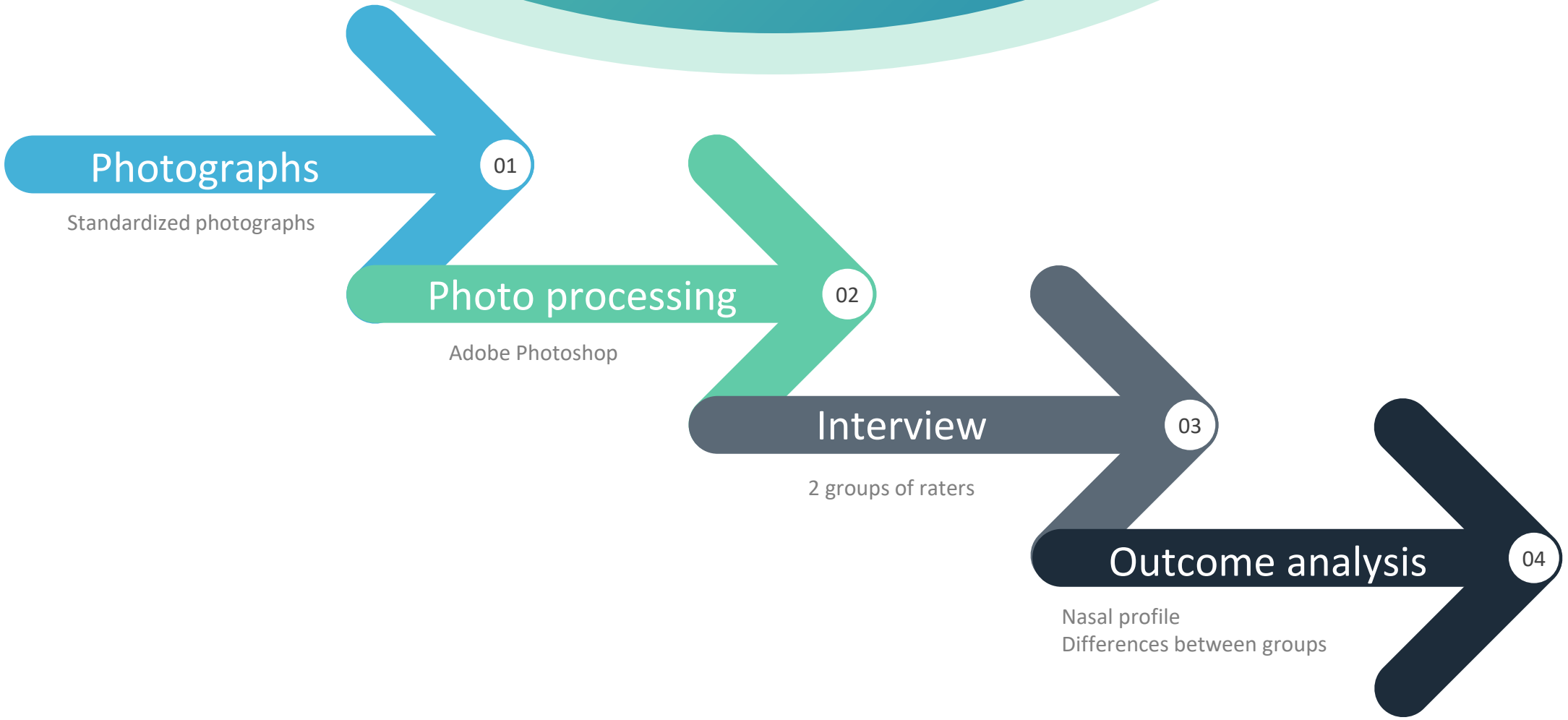
Tip projection

Nasolabial angle



Protocol Flow Chart

In Search of Aesthetic Nasal Profile in East Asians



Photographs

01

Standardized photographs

Total 8 models

Inclusion criteria

- Age 20 - 45 years old
- No prior facial trauma
- No prior cosmetic facial surgery or filling agents
- No congenital craniofacial deformities
- Native East Asian ethnicity

Exclusion criteria

- Refusal to consent

Standardized photographs of 8 models

- Color digital photographs
- Right lateral profile
- Frankfort horizontal plane parallel to the ground
- Wall marking for eye focus
- Camera : Canon EOS 5D SR with tripods
- Lens : Canon 70-200 mm f/2.8-f/32 (100 mm f/11)
- 2 flash units
- Blue background

Photo processing

02

Computer-generated distortions Adobe Photoshop

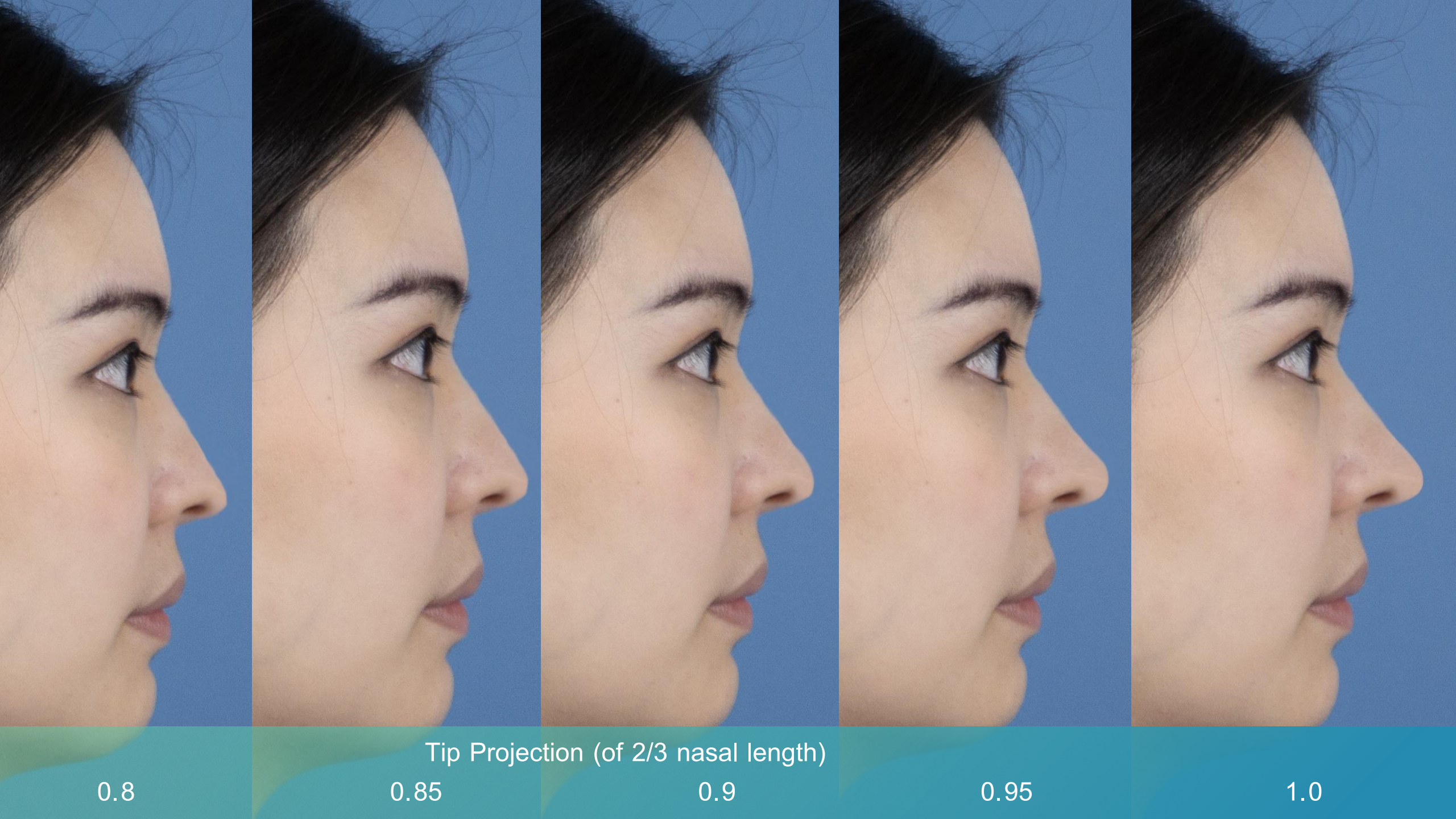
Keyframe photos

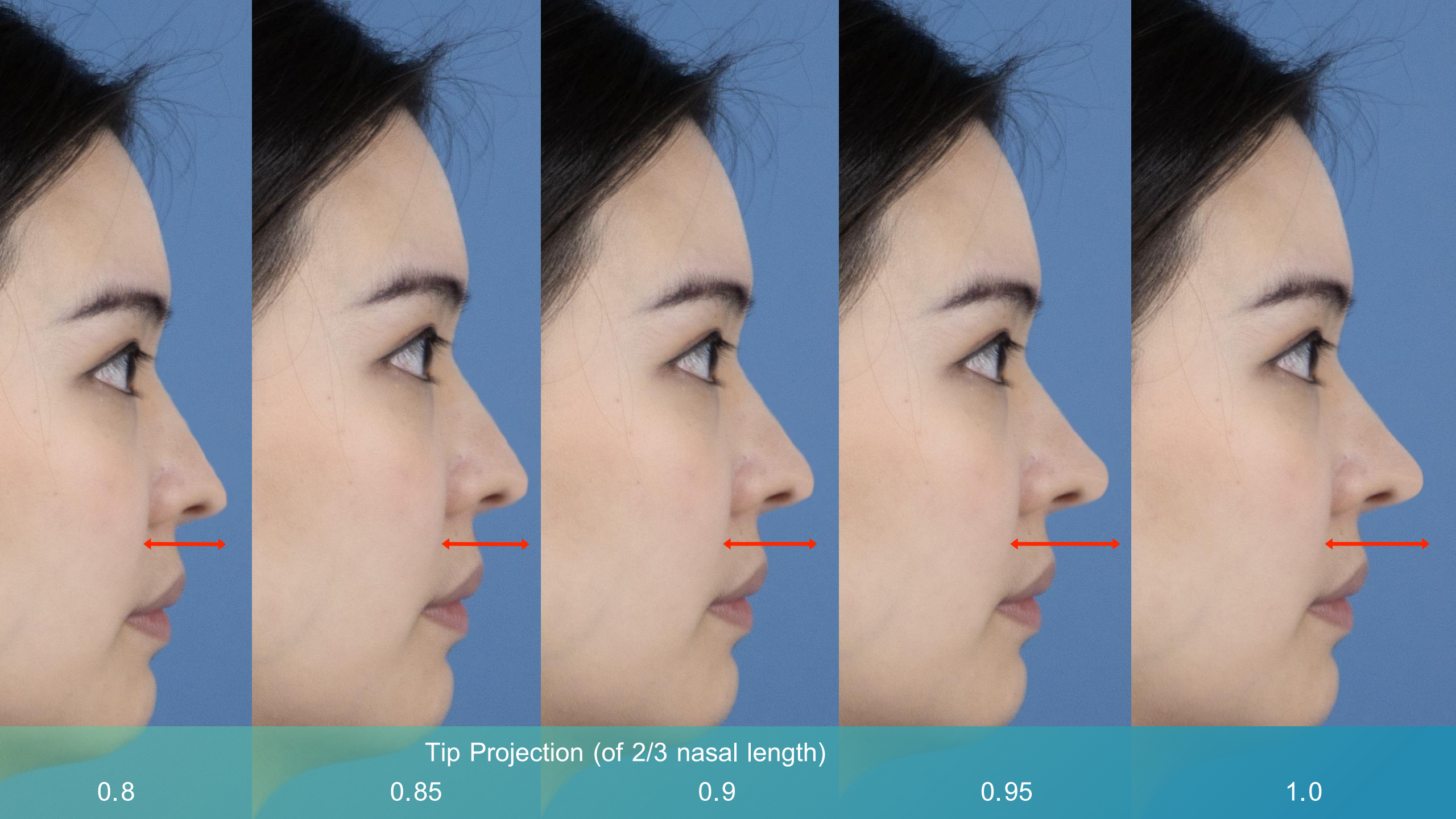
- Radix location — Pupil / Upper lash line / Supratarsal crease
- Nasolabial angle (°) — 85 / 90 / 95 / 100 / 105 / 110
- Tip projection — 0.8 / 0.85 / 0.9 / 0.95 / 1.0

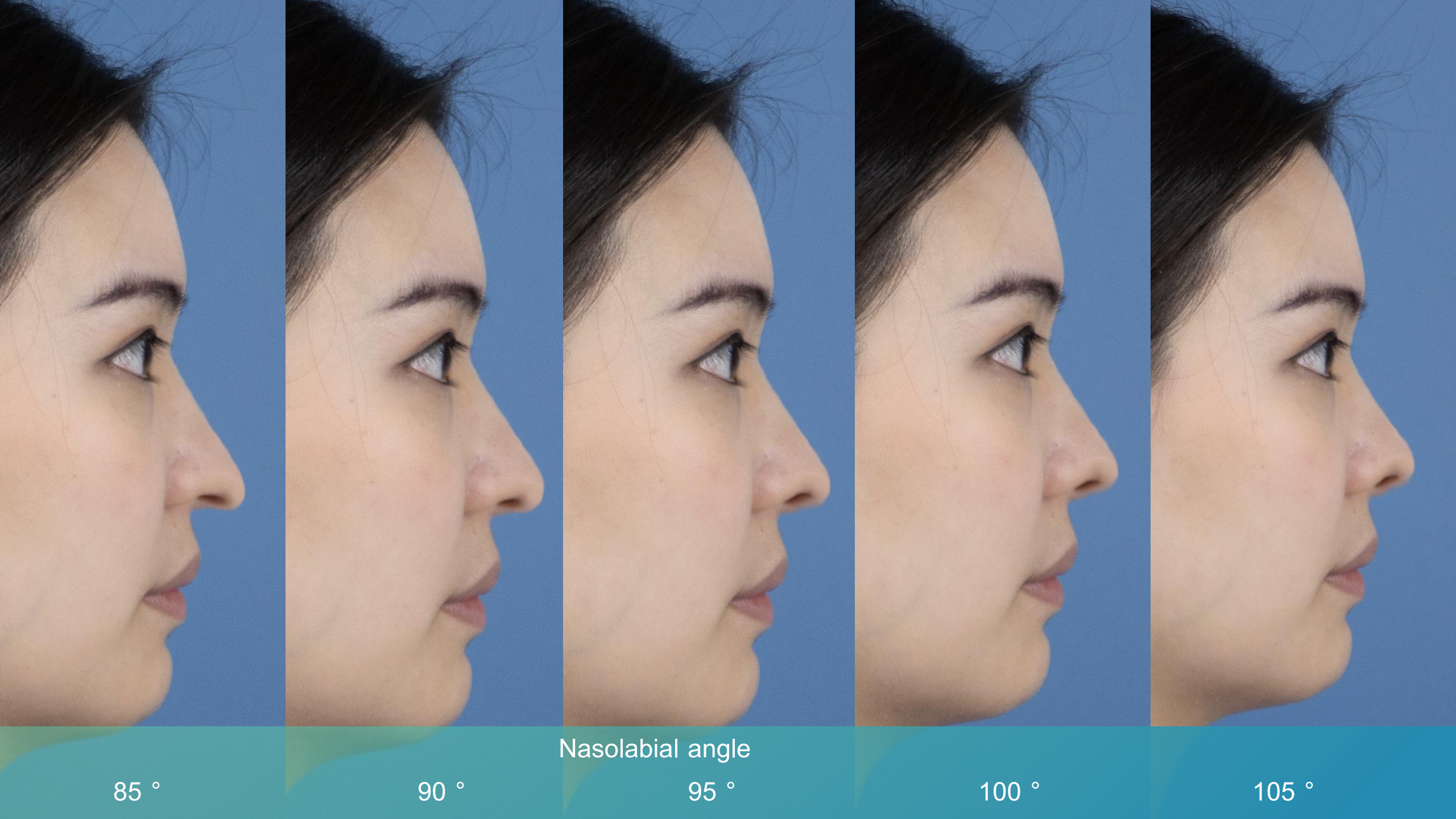
(of 2/3 nasal length)

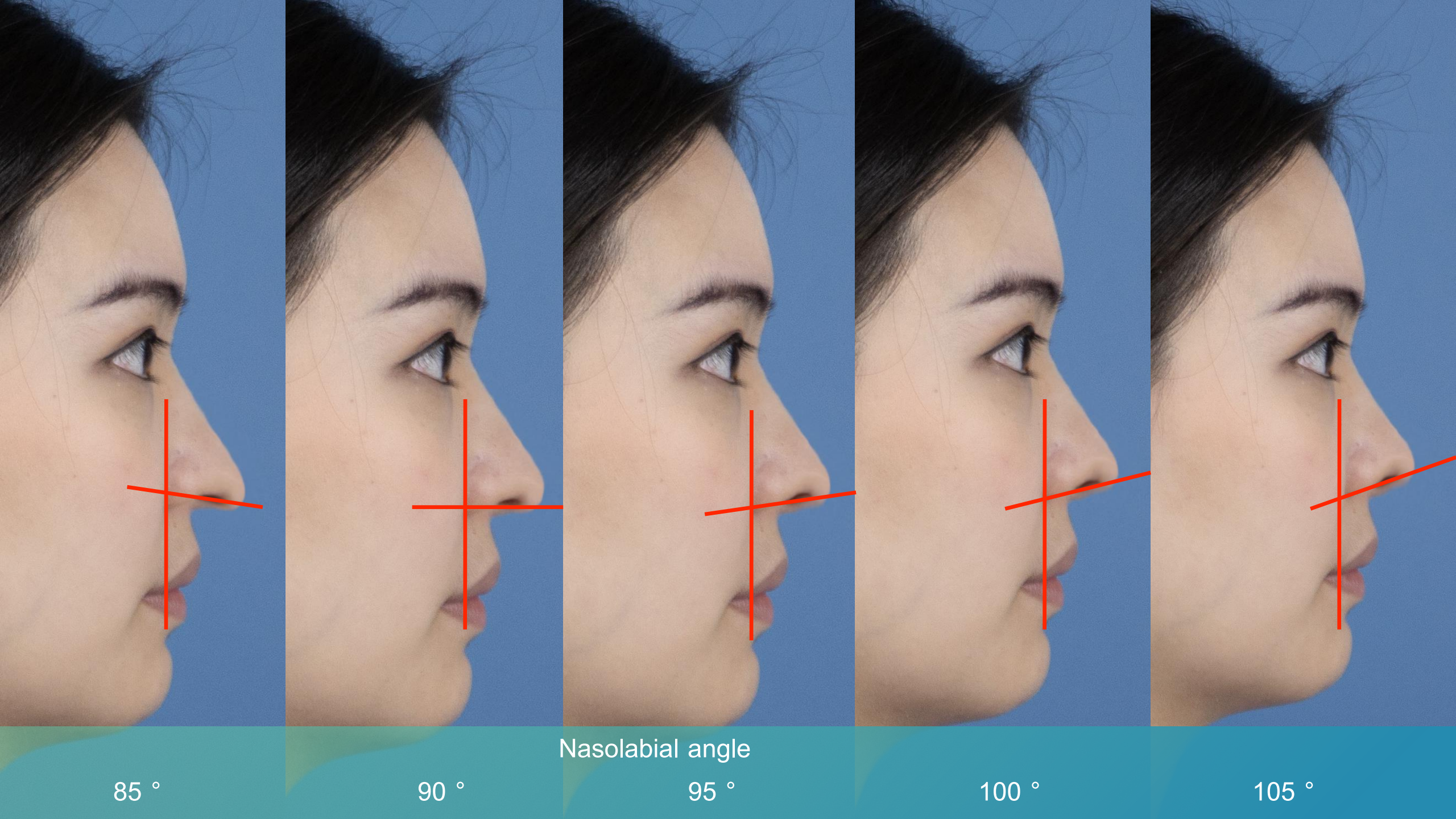
Radix location
Pupil
Upper lash line
Supratarsal crease

Radix location
Pupil
Upper lash line
Supratarsal crease


Tip Projection (of 2/3 nasal length)
0.8
0.85
0.9
0.95
1.0


Tip Projection (of 2/3 nasal length)
0.8
0.85
0.9
0.95
1.0


Nasolabial angle
85 °
90 °
95 °
100 °
105 °


Nasolabial angle
85 °
90 °
95 °
100 °
105 °

Professionals

in aesthetic fields or fields involving nose

- Plastic surgery
- Otolaryngology (ENT)
- Dermatology
- Nurses working in aesthetic fields

63

Interview

03

2 groups of raters

Laypersons

75

Demographic Data

- Age
- Sex
- Occupation

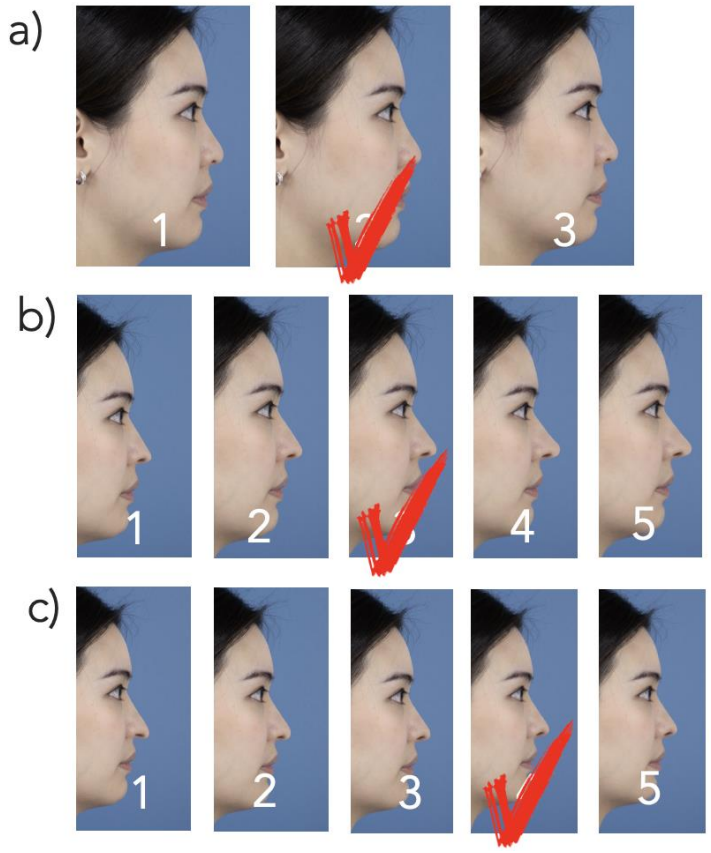
Interview 03

2 groups of raters

Photograph preference (performed twice)

Model 1

(example)



Model 2

Model 3

Model 4

Model 5

Model 6

Model 7

Model 8

Results

Demographic Data (n =138)

Professionals (n =65)

Mean age 32.94 years

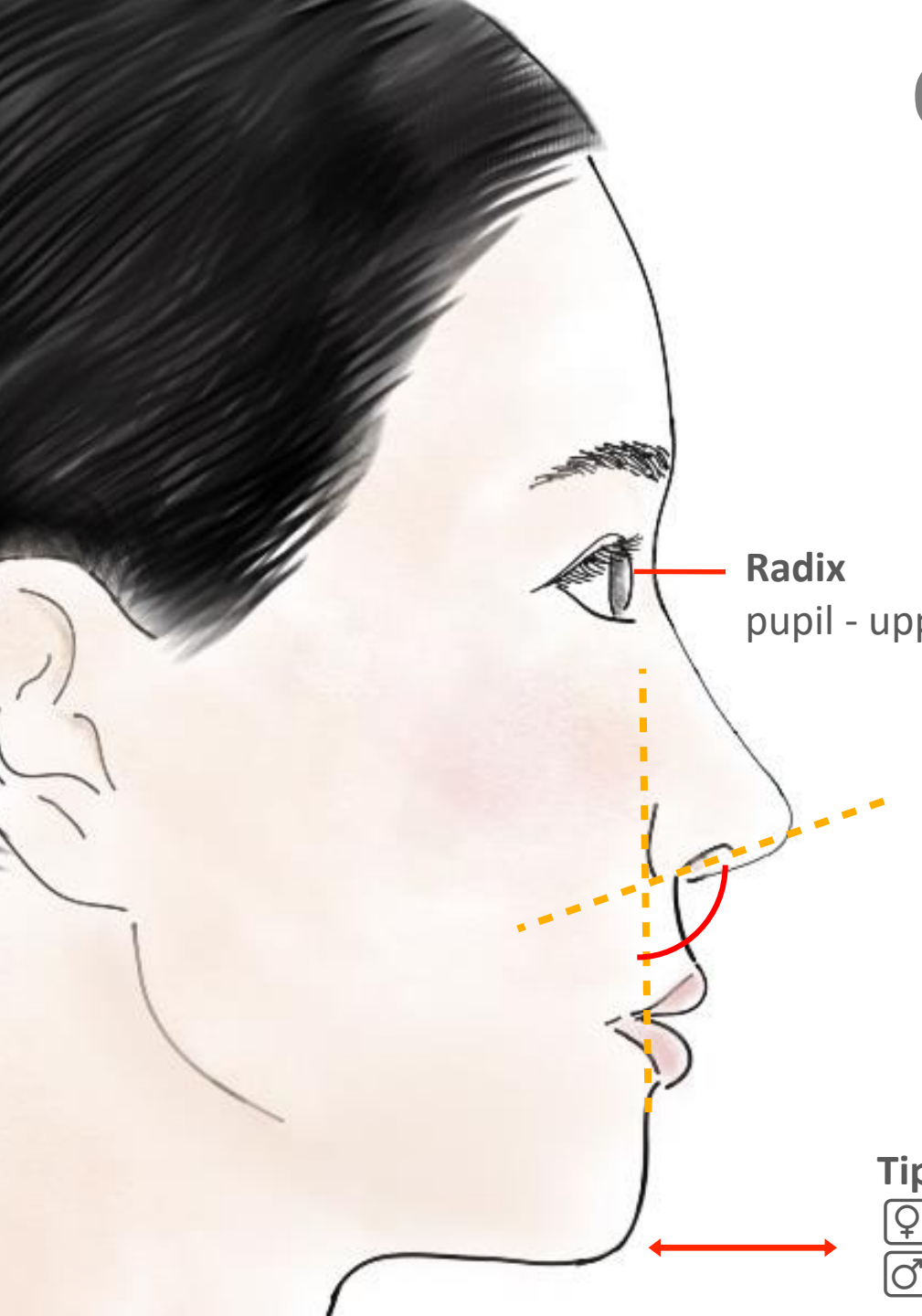
	No. (%)
Sex	
Male	33 (50.8)
Female	32 (49.2)
Specialties	
Dermatology	8 (12.3)
ENT	11 (16.9)
Nurse	2 (3.1)
Plastic surgery	44 (67.7)

Laypersons (n =73)

Mean age 33.58 years

	No. (%)
Sex	
Male	21 (28.8)
Female	52 (71.2)
Specialties	
Business	8 (11)
Employee	7 (9.6)
Healthcare	46 (63)
Professional occupation	3 (4.1)
Public sector	4 (5.5)
Student	3 (4.1)
Other	2 (2.7)

Overall Preference (n =138)



Radix
pupil - upper lash line

Nasolabial angle
♀ 100°-105°
♂ 95°-100°

Tip projection (of 2/3 of nasal length)
♀ 0.85 - 0.9
♂ 0.9 - 0.95

	Female	Male
Radix	%	%
Pupil	**36.3**	**30.4**
Lash	**51.3**	**47.0**
Crease	12.4	22.6
Projection		
0.8	19.6	10.1
0.85	**41.7**	19.33
0.9	**27.0**	**32.5**
0.95	9.9	**24.81**
1.0	1.7	13.27
NLA		
85	0.1	0.481
90	5	3.654
95	19.9	**26.73**
100	**45.2**	**50.1**
105	**29.8**	19.04

Results

Difference of preference between groups

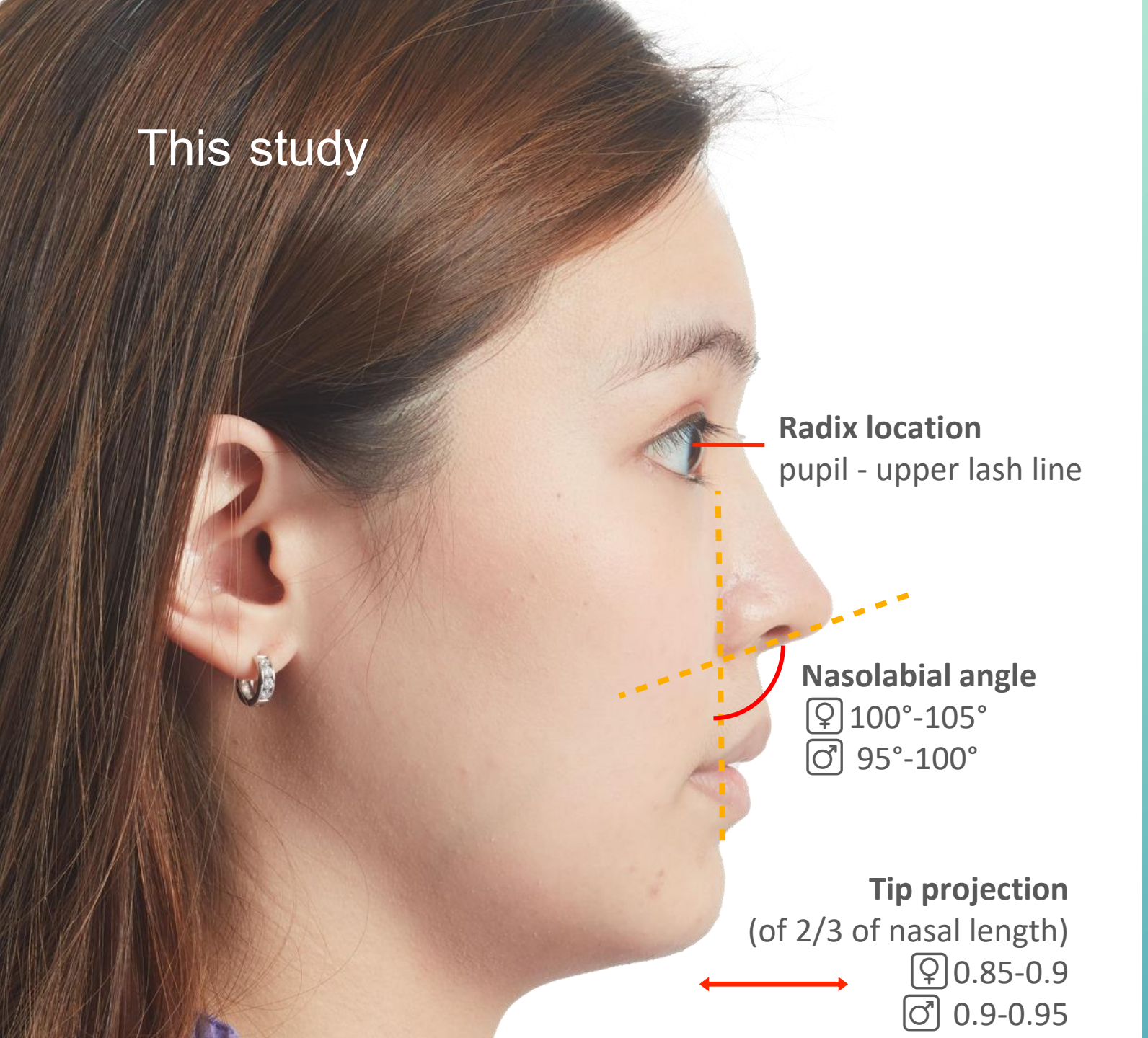
	Female		Male	
	Professionals	Lay	Prof	Lay
	No.(%)	No.(%)	No.(%)	No.(%)
Radix				
Pupil	185 (35.6)	195 (37.5)	128 (24.6)	191 (36.7)
lash	**278 (53.5)**	**253 (48.7)**	**270 (51.9)**	**216 (41.5)**
crease	57 (10.9)	72 (13.8)	122 (23.5)	113 (21.7)
Projection				
0.8	91 (17.5)	91 (17.5)	54 (10.4)	45 (8.7)
0.85	**208 (0.4)**	**235 (45.2)**	93 (17.9)	102 (19.6)
0.9	145 (27.9)	147 (28.3)	**172 (33.1)**	**170 (32.7)**
0.95	63 (12.1)	42 (8.1)	143 (27.5)	120 (23.1)
1	13 (2.5)	5 (1.0)	58 (11.2)	83 (16.0)
NLA				
85	0 (0)	1 (0.2)	1 (0.2)	4 (0.8)
90	24 (4.6)	30 (5.8)	17 (3.3)	27 (5.2)
95	96 (18.5)	125 (24.0)	143 (27.5)	147 (28.3)
100	**257 (49.4)**	**203 (39.0)**	**276 (53.1)**	**237 (45.6)**
105	143 (27.5)	161 (31.0)	83 (16.0)	105 (20.2)

Difference of preference between groups

	Occasion 1		Occasion 2	
	OR (95%CI)	P-value	OR (95%CI)	P-value
Radix				
	1.20 (0.86 to 1.66)	0.285	1.31 (0.91 to 1.89)	0.141
Tip Projection				
	1.08 (0.66 to 1.76)	0.763	1.27 (0.79 to 2.02)	0.322
Nasolabial angle				
	1.08 (0.69 to 1.69)	0.725	0.93 (0.57 to 1.51)	0.760

Ordinal logistic regression of parameters between rater groups in occasion 1 and occasion 2

Discussion



Caucasians

Radix location
upper lash line – supratarsal crease

Nasolabial angle
♀ 95°-100°
♂ 90°-95°

Tip projection
2/3 of nasal length

Primary

- The aesthetic nasal profile
  - Radix location — pupil – upper lash line
  - NLA (degree) — Female 100°-105°, Male 95°-100°
  - Tip projection — Female 0.85-0.9, Male 0.9-0.95

    (of 2/3 of nasal length)

Secondary

- Preference between professionals and laypersons is not statistically different.

thank
you

Abstract

“Association between image-defined risk factor and surgical outcome and complication in abdominal neuroblastoma in Ramathibodi hospital”

Bhavita Thamsopitt, MD

Bhavita Thamsopitt, Thitiporn Junhasavasdikul, Suwadee Eng-Chuan, Pornsri Thanachatchairattana

Division of Pediatric Surgery, Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Bangkok,

Background: Image-Defined Risk Factors (IDRFs), part of the International Neuroblastoma Risk Group Staging System, are crucial for assessing surgical complexity and guiding management in neuroblastoma patients. Patients with positive IDRFs often received neoadjuvant therapy. However, it remains unclear which specific IDRFs impact surgical outcomes and complications. Moreover, as IDRFs change following chemotherapy, it is still inconclusive whether at diagnosis or post-chemotherapy IDRFs are associated with surgical completeness and complications.

Objectives: This study aimed to evaluate the relationship between IDRFs and completeness of resection and complications and to identify specific IDRFs influencing surgical outcomes and complications in pediatric abdominal neuroblastoma patients treated at Ramathibodi Hospital.

Materials & Methods: This retrospective study included pediatric neuroblastoma patients treated at Ramathibodi Hospital from January, 2003 to August, 2023. Two pediatric radiologists assessed IDRFs for both diagnostic and preoperative CT imagings and made agreement IDRFs. The mean IDRFs and each IDRF were compared in patients with complete and incomplete tumor resection, and those with complications and without complications.

Result: 50 patients who received neoadjuvant therapy were included. Patients with incomplete resections or with complications had significant higher IDRF scores at the time of diagnosis than those with complete resection or without complications. Infiltrating the porta hepatis and/or the hepatoduodenal ligament detected at the time of diagnosis was the risk factor for incomplete excision (p-value 0.006; OR 7.7). After receiving neoadjuvant therapy, overall IDRFs decreased from 4.1+2.67 to 1.62+ 1.74. Patient with complications had significantly higher post-chemotherapy IDRF than those without complication (p-value 0.0197). Overall survival rate in this cohort was 60%. Patient with progression of disease had more incomplete resection than complete resection significantly (p = 0.04). Patient who received complete surgery did not correlated with complications.

Conclusion: IDRFs at the time of diagnosis strongly predicted surgical completeness and complications. Neoadjuvant chemotherapy effectively reduced IDRF scores; post-chemotherapy IDRFs correlated with complications only. Infiltrating the porta hepatis and/or the hepatoduodenal ligament detected at the time of diagnosis was only risk factor for incomplete resection. Complete tumor removal in neuroblastoma should be considered to avoid disease progression.

Mahidol University
Faculty of Medicine Ramathibodi Hospital

Association between image-defined risk factor and surgical outcomes and complications in abdominal neuroblastoma in Ramathibodi hospital

Bhavita THAMSOPITT(presenting author), Thitiporn JUNHASAVASDIKUL, Suwadee ENG-CHUAN, Pornsri THANACHATCHAIRATTANA

Ecthic Approval

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COA. MURA2022/587
Ref.2024/999

Title of Project (English)	The Prognostic factors and Surgical outcome after using International Neuroblastoma Risk Group Staging System for treating neuroblastoma in Ramathibodi Hospital
Title of Project (Thai)	ปัจจัยที่มีผลต่อการพยากรณ์โรคและผลการผ่าตัดโดยใช้ระบบไทเหนหยีเทส ของผู้ป่วยมะเร็งนิวโรบลาสโตมาในโรงพยาบาลรามาธิบดี
Type of Review	Expedited
Principal Investigator	Bhavita Thamsopitt
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator (s)	1. Pomsri Thnachatchairattana 2. Thitiporn Junhasavasdikul Added date: 10/09/2024 3. Suwadee Eng Chuan Added date: 10/09/2024
Approval includes	1. Amendment letter date 05/09/2024 2. Protocol version 5 date 04/09/2024

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH GCP)

Date of Approval of Amendment September 10, 2024

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Disclosure

- No conflict of interest

Introduction

- Neuroblastoma[1]
  - Most common solid tumor of infancy
- International Neuroblastoma Risk Group Staging System (INRGSS)
  - Image-defined risk factors (IDRFs)
    - Correlates with more challenging surgeries and poorer surgical outcomes
    - Adopted in ThaiPOG protocol

1 : Park JR, Eggert A, Caron H. Neuroblastoma: Biology, Prognosis, and Treatment. Hematology/Oncology Clinics of North America. 2010;24(1):65-86.

Objective

- To evaluate the relationship between IDRFs and completeness of resection and complications
- To identify specific IDRFs influencing surgical outcomes and complications

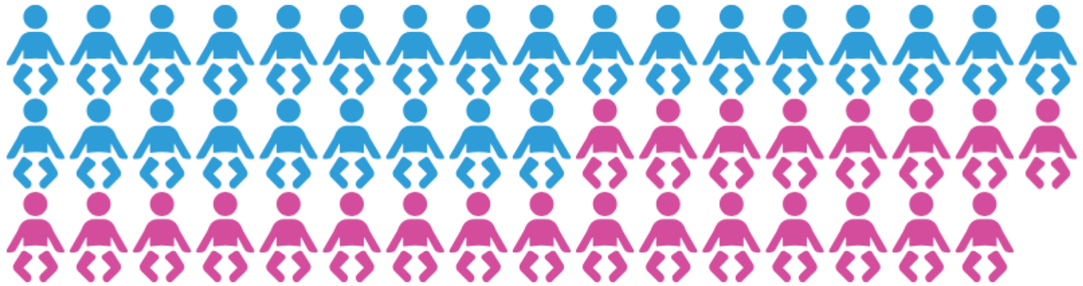
Methods

- Retrospective study
- January, 2003 to August, 2023
- Inclusion criteria :
  - Age < 15 years at the time of diagnosis of abdominal neuroblastoma
  - Receiving neoadjuvant therapy
- Exclusion criteria :
  - Missing or incomplete data and image studies

Methods

- Age at diagnosis, Sex, Presenting signs and symptoms, Tumor staging by INRG system, ThaiPOG risk stratification, Post-operative outcomes
- Image-defined risk factors
  - First diagnosed CT scan
  - Latest CT scan before surgery
  - Independently blinded-review by 2 experienced pediatric radiologists
  - Co-reviewed IDRFs -> agreement-IDRFs

Results : Patient Characteristics

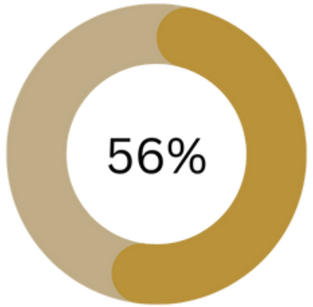


24

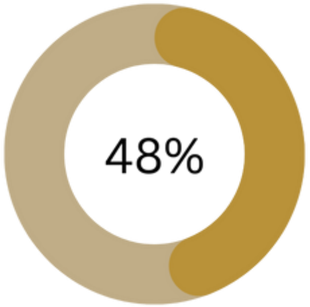
26

Total 50 patients

Median age at diagnosis
33.5 months old



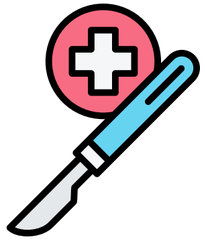
Fever



Abdominal mass

- 88% of Stage M Neuroblastoma
- 94% of High-risk (ThaiPOG)

Results : Patient Characteristics



Complete surgery

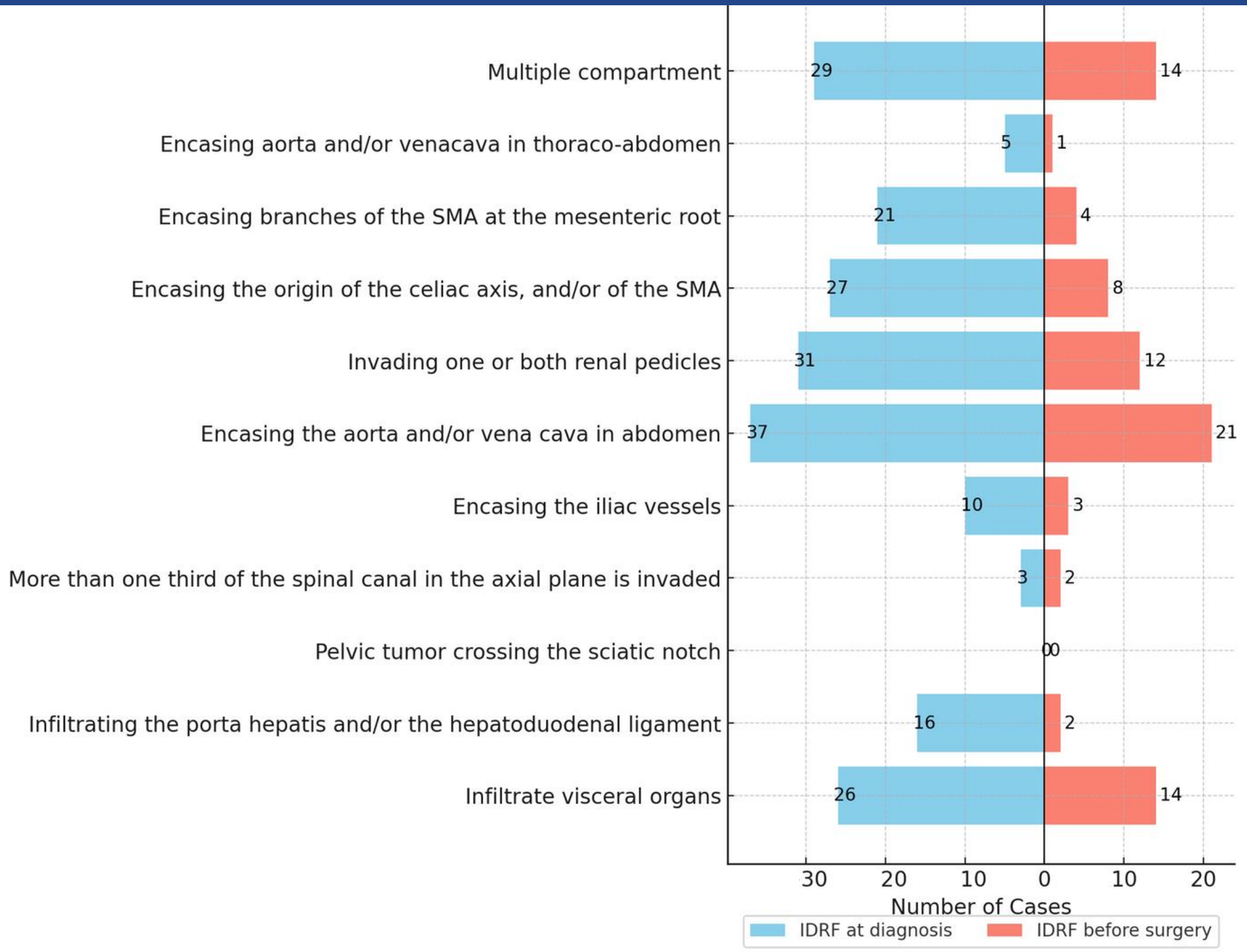
70% (35/50)

Complications

48% (24/50)

- Vascular injury 30% (15/50)
- Visceral organ injury 28% (14/50)
- Chyle leakage 6% (3/50)
- SSI 2% (1/50)
- Pancreatitis 2% (1/50)
- Other infections 4% (8/50)

Results : IDRF



Mean IDRF at diagnosis = 4.1

6 cycles

Mean IDRF at pre-operation = 1.6

Results : IDRF at the time of diagnosis vs surgical completeness and complications

	IDRF n=50	Complete Surgery n=35 (%)	Incomplete Surgery n=15 (%)	p-value	No complication n=26 (%)	Complication n=24(%)	p-value
Total IDRF (mean ± SD)	**4.1±2.67**	**3.6±2.83**	**5.27±1.87**	**0.042**	**2.96 ± 2.58**	**5.33 ± 2.22**	**0.0011**
Extensive IDRF							
Multiple Compartment	29/50	18/35 (51.43)	11/15 (73.33)	0.150	18/26 (46.15)	11/24 (70.83)	0.077
Vascular							
Encasing aorta and/or IVC in thoraco-abdomen	5/50	3/35 (8.57)	2/15 (13.33)	0.607	2/26 (7.69)	3/24 (12.5)	0.571
Encasing branches of SMA at the mesenteric root	21/50	12/35 (34.29)	9/15 (60)	0.091	7/26 (26.92)	14/24 (58.33)	0.025
Encasing the origin of the celiac axis, and/or of the SMA	27/50	17/35 (48.57)	10/15 (66.67)	0.239	10/26 (38.26)	17/24 (70.83)	0.022
Invading one or both renal pedicles	31/50	22/35 (62.86)	9/15 (60)	0.849	12/26 (46.15)	19/24 (79.17)	0.016
Encasing abdominal aorta and/or IVC	37/50	23/35 (65.71)	14/15 (93.33)	0.041	14/26 (53.85)	23/24 (95.83)	0.001
Encasing the iliac vessels	10/50	5/35 (14.29)	5/15 (33.33)	0.123	3/26 (11.54)	7/24 (29.17)	0.119
Neurological							
More than 1/3 of the spinal canal in the axial plane is invaded and/or the perimedullary leptomeningeal spaces are not visible and/or the spinal cord signal is abnormal	3/50	2/35 (5.71)	1/15 (6.67)	0.897	3/26 (11.54)	0/24 (0)	0.086
Pelvic tumor crossing the sciatic notch	0/50	-	-	-	-	-	-
Infiltrative							
Infiltrating the porta hepatis and/or the hepatoduodenal ligament	16/50	6/35 (17.14)	10/15 (66.67)	0.001	5/26 (19.23)	11/24 (45.83)	0.044
Invading visceral organs	26/50	18/35 (51.43)	8/15 (53.33)	0.902	9/26 (34.62)	17/24 (70.83)	0.01

Results : IDRF before surgery vs surgical completeness and complications

	IDRF n= 50	Complete Surgery n =35 (%)	Incomplete Surgery n=15 (%)	p-value	No complication n=26 (%)	Complication n=24(%)	p-value
Total IDRF (mean ± SD)	**1.62±1.74**	**1.34±1.55**	**2.27±2.02**	**0.085**	**1.08±1.38**	**2.21±1.91**	**0.0197**
Extensive IDRF							
Multiple Compartment	14/50	9/35 (25.71)	5/15 (33.33)	0.582	5/26 (19.23)	9/24 (37.5)	0.151
Vascular							
Encasing aorta and/or IVC in thoraco-abdomen	1/50	1/35 (2.86)	0/15 (0)	0.508	0/26 (0)	1/24 (4.17)	0.293
Encasing branches of SMA at the mesenteric root	4/50	1/35 (2.86)	3/15 (20)	0.041	1/26 (3.85)	3/24 (12.5)	0.260
Encasing the origin of the celiac axis, and/or of the SMA	8/50	3/35 (8.57)	5/15 (33.33)	0.029	4/26 (15.38)	4/24 (16.67)	0.902
Invading one or both renal pedicles	12/50	7/35 (20)	5/15 (33.33)	0.312	4/26 (15.38)	8/24 (33.33)	0.138
Encasing abdominal aorta and/or IVC	21/50	13/35 (37.14)	8/15 (53.33)	0.288	7/26 (26.92)	14/24 (58.33)	0.025
Encasing the iliac vessels	3/50	1/35 (2.86)	2/15 (13.33)	0.153	1/26 (3.85)	2/24 (8.33)	0.504
Neurological							
More than 1/3 of the spinal canal in the axial plane is invaded and/or the perimedullary leptomeningeal spaces are not visible and/or the spinal cord signal is abnormal	2/50	1/35 (2.86)	1/15 (6.67)	0.529	2/26 (7.69)	0/24 (0)	0.166
Pelvic tumor crossing the sciatic notch	0/50	-	-	-	-	-	-
Infiltrative							
Infiltrating the porta hepatis and/or the hepatoduodenal ligament	2/50	1/35 (2.86)	1/15 (6.67)	0.529	0/26 (0)	2/24 (8.33)	0.133
Invading visceral organs	14/50	10/35 (28.57)	4/15 (26.67)	0.891	4/26 (15.38)	10/24 (41.67)	0.039

Results : Risk factor for Incomplete surgery

Variables	Univariate		Multivariate	
	OR (95%CI)	p-value	OR (95%CI)	p-value
IDRF at diagnosis				
Extensive IDRF				
Multiple compartment	2.60(0.69-9.75)	0.157		
Vascular				
Encasing aorta and/or IVC in thoraco-abdomen	1.64(0.24-10.99)	0.610		
Encasing branches of SMA at the mesenteric root	2.88(0.83-10.00)	0.097		
Encasing the origin of the celiac axis, and/or of the SMA	2.11(0.60-7.48)	0.244		
Invading one or both renal pedicles	0.89(0.26-3.06)	0.849		
Encasing abdominal aorta and/or IVC	7.30(0.85-62.42)	0.069		
Encasing the iliac vessels	3(0.72-12.55)	0.132		
Neurological				
More than 1/3 of the spinal canal in the axial plane is invaded and/or the perimedullary leptomeningeal spaces are not visible and/or the spinal cord signal is abnormal	1.18(0.1-14.08)	0.897		
Pelvic tumor crossing the sciatic notch	-	-		
Infiltrative				
Infiltrating the porta hepatis and/or the hepatoduodenal ligament	9.67 (2.41-38.71)	0.001	7.7 (1.78-33.20)	0.006
Invading visceral organs	1.08 (0.32-3.63)	0.902		

Results : Risk factor for Incomplete surgery

Variables	Univariate		Multivariate	
	OR (95%CI)	p-value	OR (95%CI)	p-value
IDRF before operation				
Extensive IDRF				
Multiple compartment	1.44 (0.39-5.37)	0.583		
Vascular				
Encasing aorta and/or IVC in thoraco-abdomen	-	-		
Encasing branches of SMA at the mesenteric root	8.5 (0.80-89.75)	0.075		
Encasing the origin of the celiac axis, and/or of the SMA	5.33 (1.08-26.36)	0.04	2.09(0.34-12.83)	0.423
Invading one or both renal pedicles	2 (0.52-7.76)	0.145		
Encasing abdominal aorta and/or IVC	1.93 (0.57-6.58)	0.291		
Encasing the iliac vessels	5.23 (0.44-62.72)	0.192		
Neurological				
More than 1/3 of the spinal canal in the axial plane is invaded and/or the perimedullary leptomeningeal spaces are not visible and/or the spinal cord signal is abnormal	2.43 (0.14-41.60)	0.54		
Pelvic tumor crossing the sciatic notch	-	-		
Infiltrative				
Infiltrating the porta hepatis and/or the hepatoduodenal ligament	2.43(0.14-41.60)	0.54		
Invading visceral organs	0.90 (0.23-3.54)	0.891		

Results : Risk factor for Complications

Variables	Univariate		Multivariate	
	OR (95%CI)	p-value	OR (95%CI)	p-value
IDRF At diagnosis				
Extensive IDRF				
Multiple compartment	2.83(0.87-9.13)	0.081		
Vascular				
encasing aorta and/or IVC in thoraco-abdomen	1.71(0.26-11.26)	0.575		
encasing branches of SMA at the mesenteric root	3.89(1.19-12.68)	0.025	1.24(0.14-11.17)	0.846
encasing the origin of the celiac axis, and/or of the SMA	3.80(1.16-12.45)	0.028	0.89(0.08-8.85)	0.922
invading one or both renal pedicles	4.43(1.27-15.49)	0.020	2.45(0.49-12.23)	0.276
encasing abdominal aorta and/or IVC	19.71(2.31-168.48)	0.006		
encasing the iliac vessels	3.15(0.71-14.02)	0.131		
Neurological				
More than 1/3 of the spinal canal in the axial plane is invaded and/or the perimedullary leptomeningeal spaces are not visible and/or the spinal cord signal is abnormal	-	-		
Pelvic tumor crossing the sciatic notch	-	-		
Infiltrative				
infiltrating the porta hepatis and/or the hepatoduodenal ligament	3.55(1.00-12.57)	0.049	1.73(0.32-9.22)	0.521
Invading visceral organs	4.59(1.39-15.15)	0.012		

Results : Risk factor for Complications

Variables	Univariate		Multivariate	
	OR (95%CI)	p-value	OR (95%CI)	p-value
IDRF before Op tumor				
Extensive IDRF				
Multiple compartment	2.52(0.70-9.05)	0.156		
Vascular				
Encasing aorta and/or IVC in thoraco-abdomen	-	-		
Encasing branches of SMA at the mesenteric root	3.57(0.34-36.94)	0.286		
Encasing the origin of the celiac axis, and/or of the SMA	1.10(0.24-4.99)	0.902		
Invading one or both renal pedicles	2.75(0.70-10.73)	0.145		
Encasing abdominal aorta and/or IVC	3.80(1.16-12.45)	0.028	2.31(0.41-12.98)	0.344
Encasing the iliac vessels	2.27(0.19-26.81)	0.514		
Neurological				
More than 1/3 of the spinal canal in the axial plane is invaded and/or the perimedullary leptomeningeal spaces are not visible and/or the spinal cord signal is abnormal	-	-		
Pelvic tumor crossing the sciatic notch	-	-		
Infiltrative				
Infiltrating the porta hepatis and/or the hepatoduodenal ligament	-	-		
Invading visceral organs	3.92(1.03-14.99)	0.045	3.73(0.86-16.31)	0.080

Results : Longterm outcome

Follow-up time

25 months
(IQR 15–47 months)

Progression of disease	**Recurrence of disease**	**Death**
30% (15/50)	22% (11/50)	32% (16/50)

Results : Longterm outcome

variables	Complete surgery N = 35 (%)	Incomplete surgery N = 15 (%)	p-value	No complications N = 26 (%)	Complication N = 24 (%)	p-value
Progression of disease (N=15)	7 (20)	8 (53.33)	0.018	9 (34.62)	6 (25)	0.459
Recurrence of disease (N=11)	7 (20)	4 (26.67)	0.602	5 (19.23)	6 (25)	0.623
Death (N=16)	10 (37.04)	6 (46.15)	0.581	8 (38.1)	8 (42.11)	0.796

Discussion

- Significant decreased in mean IDRF after chemotherapy
  - Patient in each IDRFs were reduced more than half, except encasing abdominal aorta and invading of visceral organs
  - Avanzini et. al. : IDRFs remained unchanged for 50%, and new IDRFs developed nearly 20% (N=143)
  - Irtan et. al.: patients with metastasis disease significantly had more reductions in IDRFs (N=39)

Discussion

- Only mean IDRF at diagnosis was significant difference in <u>resectability</u>
  - Parallels with Simon et al. : IDRFs at diagnosis correlated with lower rates of complete resection (N = 366)
  - Contrasts with Irsan et. al. : preoperative IDRFs alone linked to resectability (N = 39)
  - Parhar et. al. : IDRFs at diagnosis as equally predictive of resectability as preoperative IDRFs (N = 971)

Discussion

At diagnosis

- **infiltrating the porta hepatis**
- encasing abdominal aorta or IVC

At pre-operation

- encasing the origin of the celiac axis or SMA
- encasing braches of SMA at mesenteric roots

Incomplete resection

- Mansfield et. al. : infiltration of the porta hepatis (N=88)
- Avanzini et al. : encasing the branches of the SMA at the mesenteric root and at origin of the celiac axis or SMA (N=143)
- Zhang et. al. : encasement of the aorta and its midline branches (N=67)

Discussion

- Higher IDRFs both at the time of diagnosis and preoperatively significantly associated with complications

Discussion

At diagnosis

- encasing branches of the SMA at the mesenteric root
- encasing the origin of the celiac axis or SMA
- encasing of abdominal aorta or IVC
- invading one or both renal pedicles
- infiltrating the porta hepatis
- invading of visceral organs

At pre-operation

- encasement of the abdominal aorta or IVC
- invasion of visceral organs

Complications

- Temple et. al. : aggressive histopathology associated with vascular and infiltrative IDRFs and higher complications rate (N=76)
- Günther et. al. : encasement of the IVC or aorta (N=60)
- Chidiac et. al. : vascular IDRFs are associated with more surgical complications than non-vascular IDRFs (N=28)

Discussion

- Patients with incomplete resections had higher rate of disease progression not the mortality rate
  - Mullassery et. al. : gross total resection indicated to improve disease-free survival rate

Conclusion

- IDRFs are critical predictors of surgical completeness and complications.
- Specific IDRFs were associated with incomplete resection and complications
- IDRFs are essential in operative planning, allowing surgeons to anticipate challenges and refine strategies. Their application is crucial for achieving complete resection, which is vital for preventing disease progression.

Limitation & Further improvement

- Retrospective review
- Small cohort cases
- Further improvement
  - Adopt International Neuroblastoma Surgical Report Form (INSRF)[2]
  - More sample size : improve data robustness
  - Further investigations into IDRF clusters of pre-operation CT and surgical complexity

2: Matthyssens LE, Nuchtern JG, Van De Ven CP, Gabra HOS, Bjornland K, Irtan S, et al. A Novel Standard for Systematic Reporting of Neuroblastoma Surgery: The International Neuroblastoma Surgical Report Form (INSRF): A Joint Initiative by the Pediatric Oncological Cooperative Groups SIOPEN*, COG**, and GPOH***. Ann Surg. 2022;275(3):e575-e85.

Thank you

Abstract

“5-year survival rate of Pediatric pulmonary metastatic sarcoma , Post-pulmonary metastasectomy in Ramathibodi Hospital, A retrospective study”

Apipat Dhirakul, MD

Apipat Dhirakul, Montien Ngodngamthaweesuk, Pongpak Pongpitcha, Suradej Hongeng

Division of Cardiothoracic Surgery, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, 10400

Introduction: To report Post pulmonary metastasis survival of sarcoma after metastasectomy, which is a standard operative treatment for lung metastatic sarcoma, in pediatric patients treated at Ramathibodi hospital. This study aimed depict 5 years survival rate compare between anatomical resection group and non-anatomical resection group. Others relevant prognostic factors were also analyzed in this study

Method: This report is a retrospective study,which includes twenty-seven sarcoma with pulmonary metastasis pediatric patients, age under 20 years-old, who underwent surgical pulmonary metastasectomy in Ramathibodi hospital from 1 Jan 2007 to 31 Dec 2019. Endpoint of this study was overall survival using the Kaplan and Meier method and evaluated with log-rank test. Others potential associated factors were analyzed by univariate using the Cox regression model and independent risk factors were expressed.

Results: 27 patients diagnosed pulmonary metastatic sarcoma and underwent pulmonary metastasectomy in Ramathibodi hospital. The overall survival were 34 % at 3 year and 12.6 % at 5 year with overall disease free interval of 8.6 month. The data shows no significant difference between any approach or type of resection. Older age patient demonstrated a statistically significant association with an elevated risk of recurrence (P=0.046), with a hazard ratio of 1.12.

Conclusion: Any type of resection and approach for pulmonary metastasectomy for pulmonary metastatic sarcoma result in similar survival rate and disease-free interval outcome. Moreover we found that age of patients effect the survival rate

5-Year Survival Rate of Pediatric Pulmonary Metastatic Sarcoma , Post-Pulmonary Metastasectomy in Ramathibodi Hospital, a Retrospective Study

R5 Apipat Dhirakul

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COA. MURA2020/1561

Title of Project (English)	Prognostic factor in Pediatric Patient with Primary chest wall Soft Tissue Sarcoma and Lung Metastatic Sarcoma. Post-resection Survival Rate, Retrospective Design study
Title of Project (Thai)	ปัจจัยในการพยากรณ์โรคซาร์โคมาบริเวณปอดหรือมีการลุกลามของเนื้องอกมาที่ปอด ในผู้ป่วยเด็ก ที่ได้รับการผ่าตัดทรวงอกในโรงพยาบาลรามาธิบดี
Type of Review	Expedited
Principal Investigator	Apipat Dhirakul, M.D.
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator (s)	1. Montien Ngodngamthaweesuk, M.D. 2. Pongpak Pongphitcha, M.D. 3. Suradej Hongeng, M.D
Approval includes	1. Submission Form Protocol Version 1 Date 04/09/2020 2. Certificate in Ethics Training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Abstract

5 - year survival rate of Pediatric pulmonary metastatic sarcoma , Post-pulmonary metastasectomy in Ramathibodi Hospital, A retrospective study

Authors: Apipat Dhirakul, M.D., Montien Ngodngamthaweesuk, M.D., Pongpak Pongpitcha, M.D., Suradej Hongeng, M.D.
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Division of Cardiothoracic Surgery, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, 10400

Abstract

Objectives: To report Post pulmonary metastasis survival of sarcoma after metastasectomy ,which is a standard operative treatment for lung metastatic sarcoma ,in pediatric patients treated at Ramathibodi hospital. This study aimed to depict 5 years survival rate compare between anatomical resection group and non – anatomical resection group. Others relevant prognostic factors were also analyzed in this study

Methods: This report is a retrospective study ,which includes twenty-seven sarcoma with pulmonary metastasis pediatric patients, age under 20 years - old, who underwent surgical pulmonary metastasectomy in Ramathibodi hospital from 1 Jan 2007 to 31 Dec 2019. Endpoint of this study was overall survival using the Kaplan and Meier method and evaluated with log - rank test. Others potential associated factors were analyzed by univariate using the Cox regression model and independent risk factors were expressed.

Result : 27 patients diagnosed pulmonary metastatic sarcoma and underwent pulmonary metastasectomy in Ramathibodi hospital. The overall survival were 34 % at 3 year and 12.6 % at 5 year with overall disease free interval of 8.6 month. The data shows no significant difference between any approach or type of resection .

Conclusion : Any type of resection and approach for pulmonary metastasectomy for pulmonary metastatic sarcoma result in similar survival rate and disease – free interval outcome. Moreover we found that age of patients effect the survival rate

Introduction

- Pediatric sarcoma with pulmonary metastases presents a complex treatment challenge.
- Nowadays, the best treatment modality for potentially curative outcome of pulmonary metastasis lesion is pulmonary metastasectomy.
- No study focus on pediatric patients.

Materials and methods

- Ethical approval by Human Research Ethics Committee, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

- This report is a retrospective study included twenty-seven pediatric patients with pulmonary metastasis sarcoma, age under 20 years old, who underwent surgical pulmonary metastasectomy in Ramathibodi hospital from 1 Jan 2007 to 31 Dec 2019.

Materials and methods

- Primary outcome : Death and recurrent
- The Data used in this study including Treatment, Operative detail and follow- up were collected from Electronic medical records (EMR). Our study review the patient’s demographic data

Statistical Analysis

- This study analyzed disease-specific survival as the primary endpoint using the Kaplan-Meier method, the differences between the survival curves were assessed using log-rank test.
- Variables
  - Continuous variables →Student's *t*-test
  - *Categorical variable* → *Fisher/s exact test*
- P-value of < 0.05 were considered to be statistically significant.
- Univariate analysis was performed using the Cox regression model to examine other potential associated factors

Result

Table 1 Patient Characteristics by Survival

Variable	Total (n=27)	Alive (n=5)	Death (n=22)	p-value
Age(year), mean±SD	12.2+4.4	12.7+5.6	12.1+4.2	0.791
Gender				
Male	19(70.4)	4(80.0)	15(68.2)	0.999
Female	8(29.6)	1(20.0)	7(31.8)	
Diagnosis n(%)				
Synovial sarcoma	3(11.1)	0	3(13.5)	0.423
Osteosarcoma	18(66.7)	5(100)	13(59.0)	
Rhabdomyosarcoma	2(7.4)	0	2(9.1)	
Epithelial cell sarcoma	1(3.7)	0	1(4.6)	
Embryonal cell sarcoma	1(3.7)	0	1(4.6)	
Ewing sarcoma	1(3.7)	0	1(4.6)	
Fibrosarcoma	1(3.7)	0	1(4.6)	
Primary lesion location, n(%)				
Non-extrimites	5(18.5)	0	5(22.7)	0.547
Extrimitites	22(81.5)	5(100)	17(77.3)	
Size tumor, n(%)				
Small (≤3 cm)	22(81.5)	5(100)	17(77.3)	0.547
Large (>3 cm)	5(18.5)	0	5(22.7)	
Number of lesion, n(%)				
Single lesion	21(77.8)	5(100)	16(72.7)	0.555
Multiple lesion	6(22.2)	0	6(27.3)	
Lung metastasis location, n(%)				
Right lung	10(37.0)	2(40.0)	8(36.4)	0.493
Left Lung	11(40.7)	3(60.0)	8(36.4)	
Bilateral	6(22.3)	0	6(27.2)	
Pleural Effusion, n(%)				
No	20(74.1)	5(100)	15(68.2)	0.283
Yes	7(25.9)	0	7(31.8)	
Approach, n(%)				
Posterolateral thoracotomy	21(77.8)	4(80.0)	17(77.3)	0.999
VATS	6(22.2)	1(20.0)	5(22.7)	
Type of Resection, n(%)				
Wedge resection	19(70.4)	5(100)	14(63.6)	0.580
Segmentectomy	3(11.1)	0	3(13.7)	
Lobectomy	5(18.5)	0	5(22.7)	
Complete, n(%)				
Complete resection	18(66.7)	4(80.0)	14(63.6)	0.636
Incomplete resection	9(33.3)	1(20.0)	8(36.4)	
Number of Surgery,, n(%)				
1	15(55.6)	4(80.0)	11(50.0)	0.195
2	7(25.9)	0	7(31.8)	
3	1(3.7)	1(20.0)	0	
4	3(11.1)	0	3(13.6)	
5	1(3.7)	0	1(4.6)	
Number of surgery1, n(%)				
1	15(55.6)	4(80.0)	11(50.0)	0.342
>1	12(44.4)	1(20.0)	11(50.0)	
Number of surgery2, n(%)				
≤2	22(81.5)	4(80.0)	18(81.8)	0.999
>2	5(18.5)	1(20.0)	4(18.2)	
Number of surgery3, n(%)				
≤3	23(85.2)	5(100)	18(81.8)	0.561
>3	4(14.8)	0	4(18.2)	
Recurrence, n(%)				
No	10(37.0)	4(80.0)	6(27.3)	0.047*
Yes	17(63.0)	1(20.0)	16(72.7)	

Table 2 Patient Characteristics by Recurrent

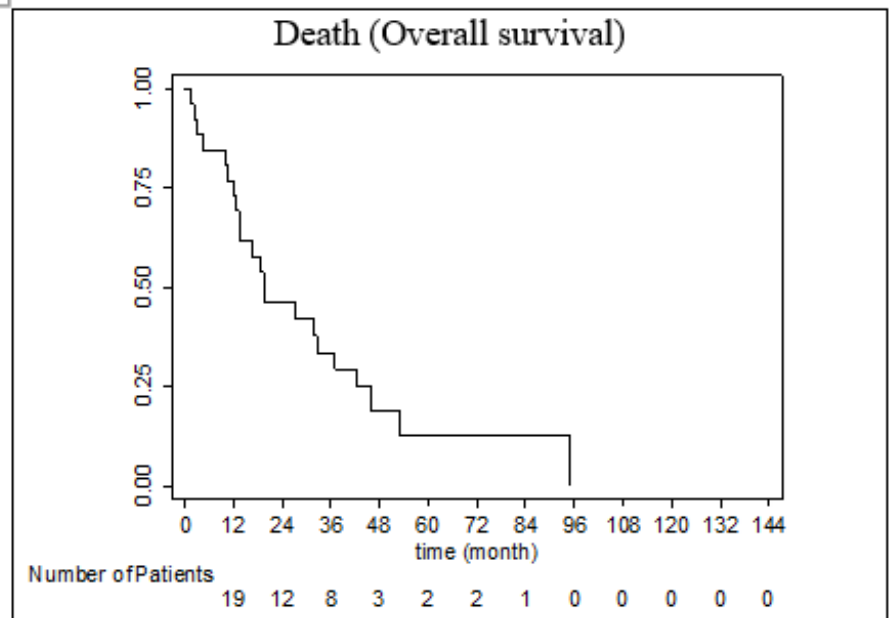
Variable	Total (n=27)	Non-Recurrent (n=10)	Recurrent (n=17)	p-value
Age(year), mean±SD	12.2+4.4	9.9+4.6	13.6+3.8	0.037
Gender				
Male	19(70.4)	7(70.0)	12(70.6)	0.999
Female	8(29.6)	3(30.0)	5(29.4)	
Size tumor, n(%)				
Small (≤3 cm)	22(81.5)	9(90)	13(76.5)	0.621
Large (>3 cm)	5(18.5)	1(10)	4(23.5)	
Number of lesion, n(%)				
Single lesion	21(77.8)	9(90)	12(70.6)	0.363
Multiple lesion	6(22.2)	1(10)	5(29.4)	
Lung metastasis location, n(%)				
Right lung	10(37.0)	3(30)	7(41.2)	0.351
Left Lung	11(40.7)	6(60)	5(29.4)	
Bilat	6(22.3)	1(10)	5(29.4)	
Pleural Effusion, n(%)				
No	20(74.1)	6(60)	14(82.4)	0.365
Yes	7(25.9)	4(40)	3(17.6)	
Approach, n(%)				
Posterolateral thoracotomy	21(77.8)	9(90)	12(70.6)	0.363
VATS	6(22.2)	1(10)	5(29.4)	
Type of Resection, n(%)				
Wedge resection	19(70.4)	7(70)	12(70.6)	0.999
Segmentectomy	3(11.1)	1(10)	2(11.8)	
Lobectomy	5(18.5)	2(20)	3(17.6)	
Number of Surgery,, n(%)				
1	15(55.6)	8(80)	7(41.2)	0.370
2	7(25.9)	1(10)	6(35.3)	
3	1(3.7)	0	1(5.9)	
4	3(11.1)	1(10)	2(11.7)	
5	1(3.7)	0	1(5.9)	
Number of surgery1, n(%)				
1	15(55.6)	8(80)	7(41.2)	0.107
>1	12(44.4)	2(20)	10(58.8)	
Number of surgery2, n(%)				
≤2	22(81.5)	9(90)	13(76.5)	0.621
>2	5(18.5)	1(10)	4(23.5)	
Number of surgery3, n(%)				
≤3	23(85.2)	9(90)	14(82.4)	0.999
>3	4(14.8)	1(10)	3(17.6)	
Re-operative (complication), n(%)				
No	25(92.6)	10(100)	15(88.2)	0.516
Yes	2(7.4)	0	2(11.8)	

Table 3 Univariate Cox Regressing analyses of Recurrence (hazard ratio/ HR)

Variable	Univariate HR(95%CI)	p-value
Age(year)	1.12(1.0-1.3)	0.046
Gender		
Male	1	
Female	0.75(0.3-2.2)	0.602
Size tumor		
Small (≤3 cm)	1	
Large (>3 cm)	1.49(0.5-4.6)	0.490
Number of lesion		
Single lesion	1	
Multiple lesion	1.34(0.5-3.9)	0.563
Lung metastasis location		
Right lung	1	
Left Lung	0.61(0.2-1.9)	0.402
Bilateral lung	1.07(0.3-3.5)	0.909
Pleural Effusion		
No	1	
Yes	0.57(0.2-2.0)	0.387
Approach		
Posterolateral thoracotomy	1	
VATS	1.36(0.5-3.9)	0.568
Type of Resection		
Wedge resection	1	
Segmentectomy	0.86(0.2-3.9)	0.846
Lobectomy	0.99(0.3-3.6)	0.990
Number of Surgery		
I	1	
II	2.21(0.7-6.7)	0.160
III	-	
IV	1.7(0.3-8.5)	0.509
V	-	
Number of surgery1		
1	1	
>1	1.91(0.7-5.0)	0.190
Number of surgery2		
≤2	1	
>2	1.24(0.4-3.9)	0.718

Survival analysis

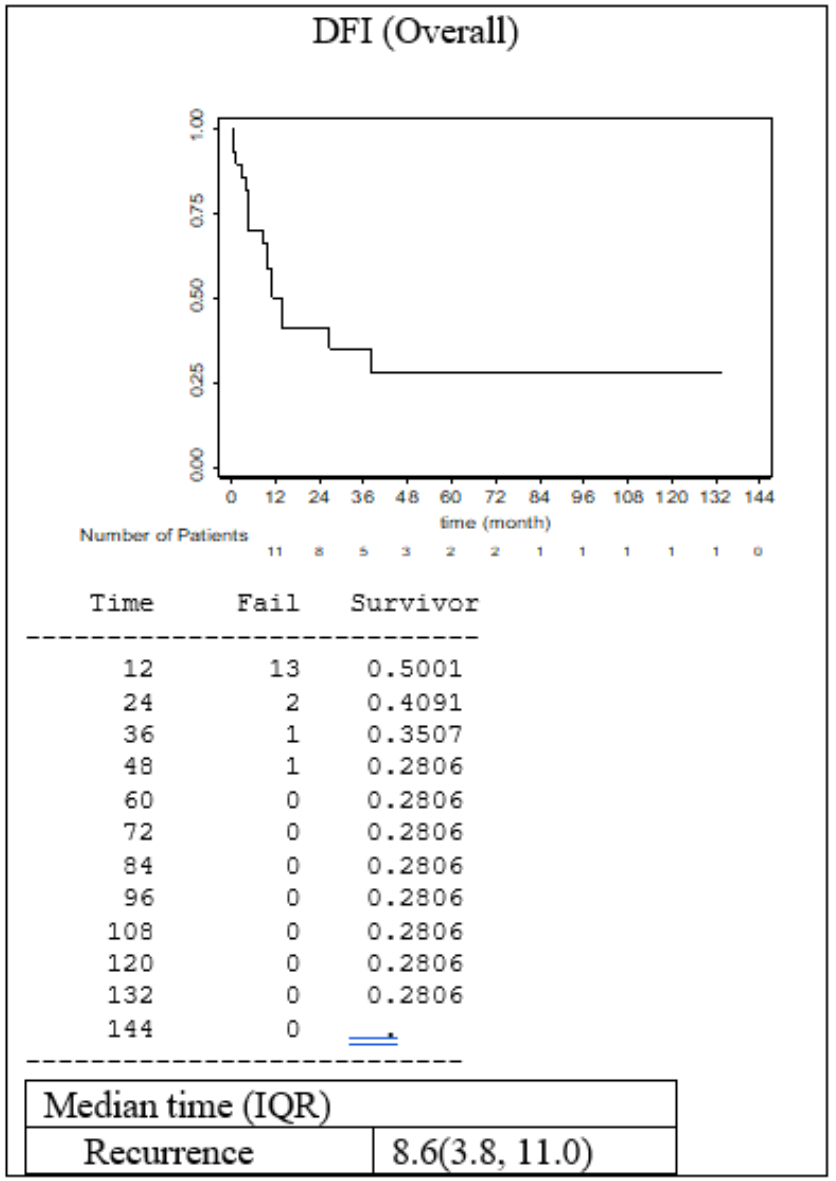
Graph 1 : Represents the overall survival of patients over time.



Median time (IQR) month	
Survival	13(12, 37)

the overall survival rates were 33.6 % at 3 years and 12.6 % at 5 years

Graph 2 : Represents the Disease – Free Interval (DFI)over the time.



Time	Fail	Survivor
12	13	0.5001
24	2	0.4091
36	1	0.3507
48	1	0.2806
60	0	0.2806
72	0	0.2806
84	0	0.2806
96	0	0.2806
108	0	0.2806
120	0	0.2806
132	0	0.2806
144	0	.

Median time (IQR)	
Recurrence	8.6(3.8, 11.0)

Conclusion

- Pulmonary metastasectomy for pulmonary metastasis sarcoma in pediatric patients resulted in overall survival rates 33.6 % at 3 years and 12.6 % at 5 years, with disease-free interval 8.6 month.
- The recurrence of the disease significantly impacts survival outcomes.
- Advance age patient Show a higher tendency for disease recurrence.
- The study is limited by a small participant size and a retrospective study design. To validate these findings, larger-scale studies with higher levels of evidence may be necessary

Special thanks

Corresponding author: Montien Ngodngamthaweesuk, M.D.

Pongpak Pongpitcha, M.D.

Suradej Hongeng, M.D.

Abstract

“The anatomical relation between Transverse-Sigmoid sinus and skull landmarks in 3D imaging study”

Arnupap Puchaisang , MD

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Objective: This study aimed to investigate the anatomical relationship between the transverse-sigmoid sinus complex and external skull landmarks, particularly focusing on the digastric point (DP) and the asterion line. The study validated the DP–asterion line as a reliable reference for identifying the vertical segment of the sigmoid sinus and examined variations between both sides.

Method: An experimental radiologic study was conducted using 51 three-dimensional (3D) computed tomography (CT) scans with contrast, obtained from patients older than 15 years at Ramathibodi Hospital. Volume-rendering techniques were applied to identify the asterion, the digastric point, the transverse-sigmoid sinus junction, and the vertical segment of the sigmoid sinus. Measurements were taken at the proximal, mid, and distal portions relative to the DP–asterion line. An independent t-test was used to evaluate the distance from the DP–asterion line to the sigmoid sinus.

Results: The line connecting the asterion and the digastric point serves as a reliable landmark for locating the vertical segment of the sigmoid sinus on both sides. Measurements were 12.9 mm proximally, 15.2 mm at the midpoint, and 18 mm distally, with the right sigmoid sinus being significantly larger than the left in most cases.

Conclusion: The DP–asterion line is a key surface landmark for planning a retrosigmoid approach, helping to avoid inadvertent injury to the transverse-sigmoid venous sinus.

Keywords: Transverse-sigmoid sinus, Asterion, Digastric point, 3D imaging, Retrosigmoid craniotomy, Skull landmarks

The anatomical relation between Transverse-Sigmoid sinus and skull landmarks in 3D imaging study

Presented by Arnupap Puchaisang , MD

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COA. MURA2021/848

Title of Project (English)	The anatomical relation between transverse-sigmoid sinus and skull landmarks on computed tomography venography images
Title of Project (Thai)	การศึกษาความสัมพันธ์ระหว่างร่องหลอดเลือดโหญ่บนผิวกะโหลกด้านในและจุดอ้างอิงบนผิวกะโหลกด้านนอกส่วนหลัง ด้วยเอ็กซเรย์คอมพิวเตอร์หลอดเลือด
Type of Review	Expedited
Principal Investigator	Anupap Puchaisang, M.D.
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator	Siriwut Pokanan, M.D.
Approval includes	1. Submission form protocol version 2 date 22/09/2021 2. Curriculum vitae 3. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Date of Approval	**September 27, 2021**
Date of Expiration	**September 26, 2022**

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated

Abstract

Objective : This study aimed to investigate the anatomical relationship between the transverse-sigmoid sinus complex and external skull landmarks, particularly focusing on the digastric point (DP) and the asterion line, by validating the DP–asterion line as a reliable reference for identifying the vertical segment of the sigmoid sinus and examining side-to-side differences in these measurements.

Method : An experimental radiologic study was conducted using 50 three-dimensional (3D) computed tomography (CT) scans obtained from patients older than 15 years at Ramathibodi Hospital. Volume-rendering techniques were applied to identify the asterion, the digastric point, and the transverse-sigmoid sinus junction, and the vertical segment of the sigmoid sinus was measured at proximal, mid, and distal portions, relative to the DP–asterion line. An independent t-test was performed to assess sex-based differences, while a paired t-test was used to evaluate differences between the right and left sides.

Result : Findings revealed that the DP–asterion line provided a consistent and practical landmark for localizing the vertical segment of the sigmoid sinus on both sides, with the right sigmoid sinus significantly larger than the left in most cases. Additionally, there were no significant sex-based differences in the measured distances, underscoring the potential utility of the DP–asterion line in minimizing risks associated with retrosigmoid craniotomy.

Conclusion : Surgeons may incorporate the DP–asterion line as a key surface landmark when planning a retrosigmoid approach to reduce inadvertent injury to the transverse-sigmoid venous sinus

Keywords: Transverse-sigmoid sinus, Asterion, Digastric point, 3D imaging, Retrosigmoid craniotomy, Skull landmarks

การศึกษาความสัมพันธ์ระหว่างร่องหลอดเลือดใหญ่บนผิวกะโหลกด้านในและจุดอ้างอิงบนผิวกะโหลกด้านนอกส่วนหลัง ด้วยเอ็กซเรย์คอมพิวเตอร์หลอดเลือด

ภูมิหลัง : เนื่องจากการผ่าตัดบริเวณ posterior fossa เป็นหัตถการที่ท าบ่อยในทางประสาทศัลยศาสตร์ ความผันผวนเส้นโพรงเส้นเลือดด าบริเวณ posterior fossa เช่น transverse sinus , sigmoid sinus มีมาก ซึ่งต าแหน่งของโพรงเส้นเลือดด าบริเวณposterior fossa จะขึ้นอยู่กับจุดอ้างอิงที่กะโหลกศีรษะซึ่งจะต้องทราบจุดส าคัญ เพื่อที่จะหลีกเลี่ยงการบาดเจ็บต่อเส้นโพรงเส้นเลือดด า ป้องกันไม่ให้เกิดการสูญเสียเลือดปริมาณมากขณะผ่าตัดหรือเกิดเส้นโพรงเส้นเลือดด าอุดตัน

วัตถุประสงค์ : เพื่อที่จะศึกษาจุดอ้างอิงบนกะโหลกศีรษะจุดใหม่ที่สัมพันธ์กับเส้นโพรงเส้นเลือดด าที่กะโหลกศีรษะส่วนหลัง

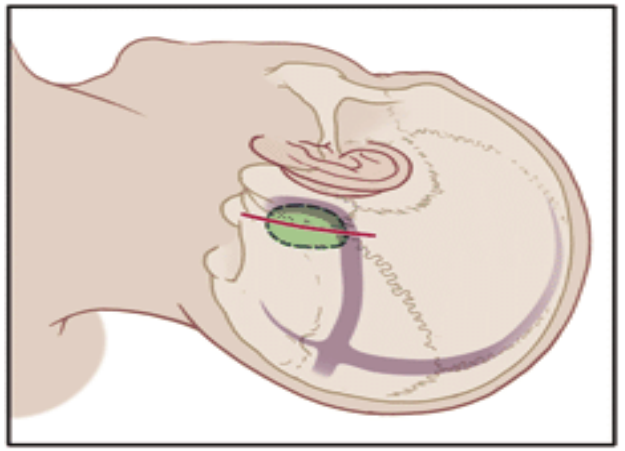
วัสดุและวิธีการ : An experimental radiologic study, โดยการนำ CT brain คนไข้ 50 รายของโรงพยาบาลรามาธิบดี จากนั้นนำมาสร้างภาพให้เป็น 3D ด้วย Volume-rendering techniques และจะหาจุดอ้างอิงบนกะโหลกศีรษะ ได้แก่ asterion และ Digastric point แล้วลากเส้นเชื่อมจุดทั้งสอง ซึ่งจะเป็นเส้นตรง ซึ่งจะวัดระยะห่างจาก vertical part of sigmoid sinus และวัดขนาดของ sigmoid sinus ทั้งสองข้าง

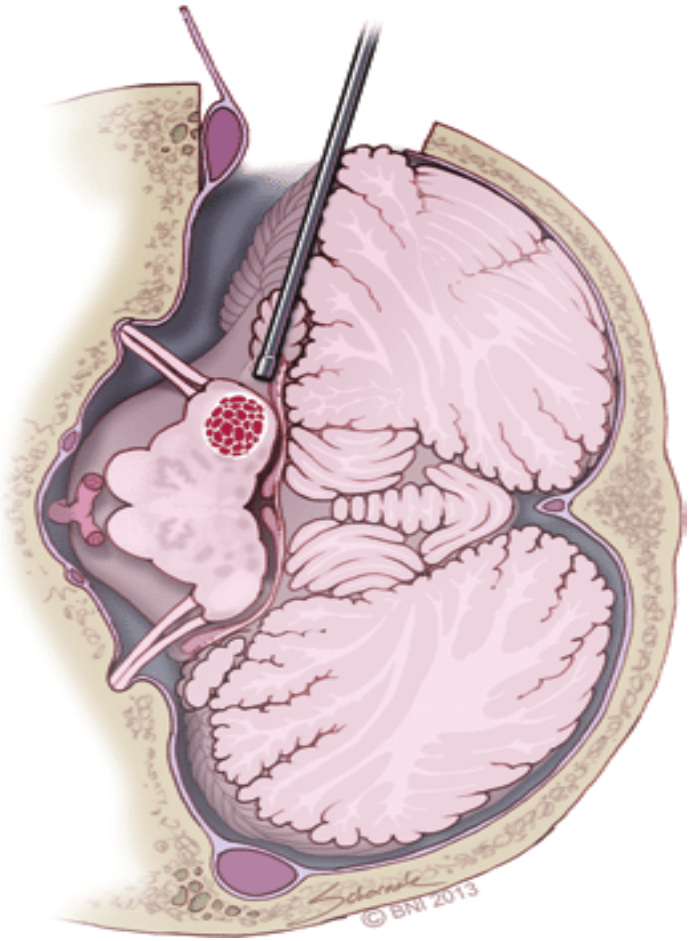
ผลการศึกษา : ผลการศึกษาพบว่า เส้นที่ลากเชื่อมระหว่าง asterion กับ digastric point สามารถอ้างอิงถึงต าแหน่งของ sigmoid sinus ส่วนที่เป็น vertical segment ได้ในทั้งสองข้าง โดยส่วนใหญ่จะพบว่า sigmoid sinus ด้านขวา มักจะมีขนาดใหญ่กว่า sigmoid sinus ด้านซ้าย

สรุป : neurosurgeon สามารถใช้เส้นที่ลากเชื่อมระหว่าง asterion กับ digastric point เป็นส่วนหนึ่งของจุดอ้างอิงบนผิวกะโหลกในการวางแผนการผ่าตัดเปิดกะโหลกแบบ retrosigmoid เพื่อลดความเสี่ยงที่จะเกิดการบาดเจ็บของ transverse-sigmoid venous sinus

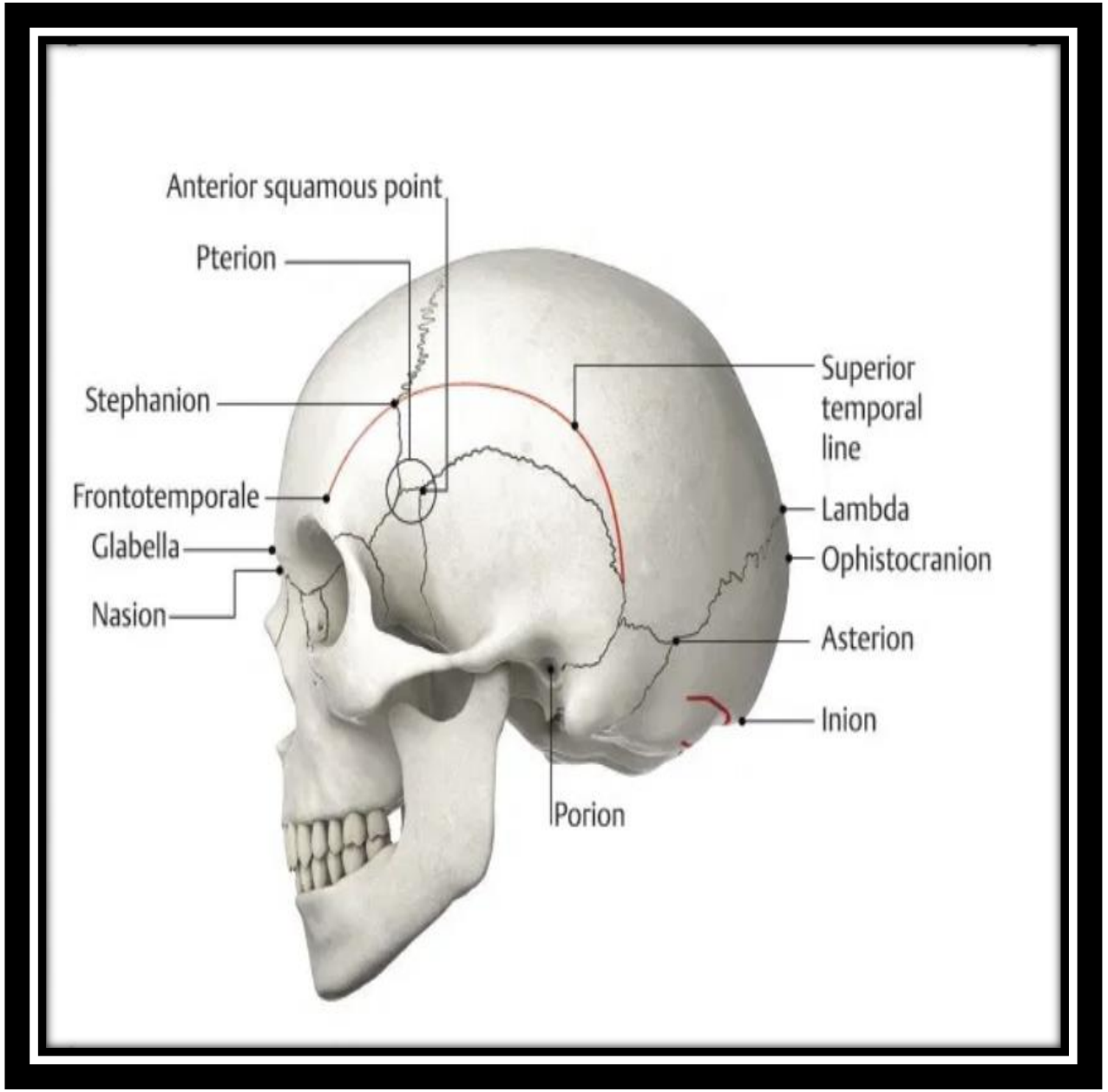
introduction

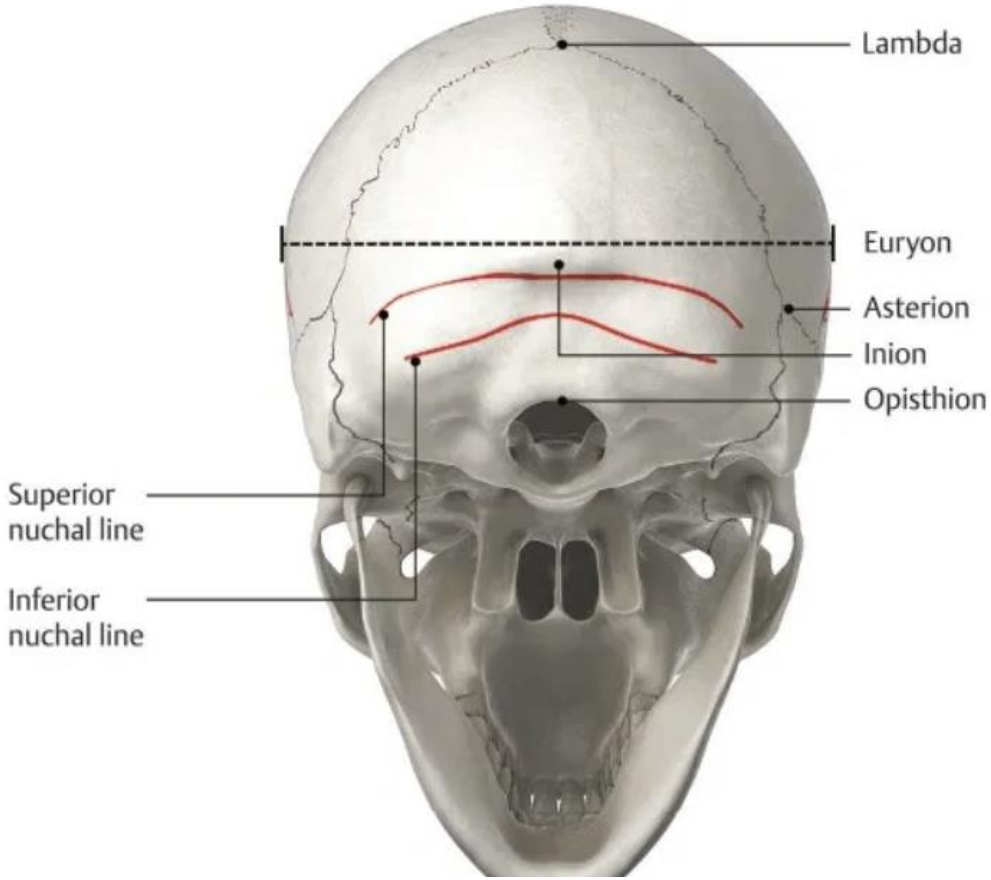
The retrosigmoid craniotomy is one of the most common approaches in neurosurgery to deal with lesions in cerebellopontine angle.

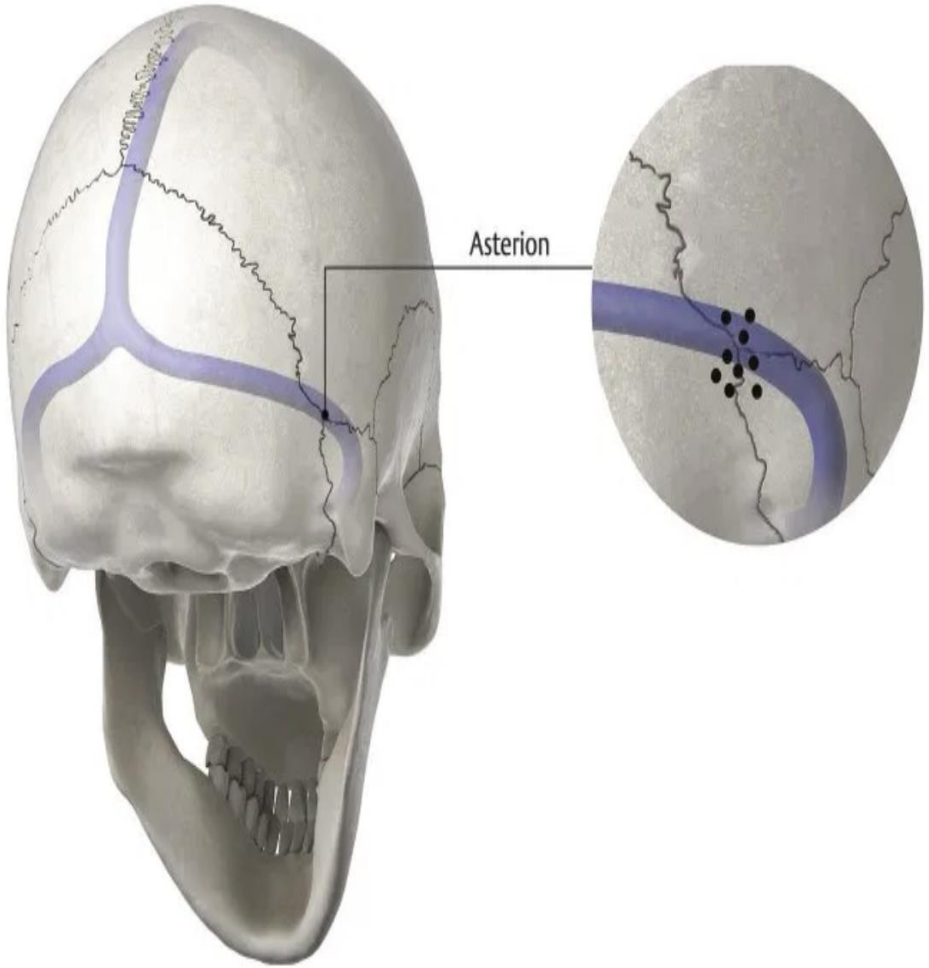




Localization of internal cranial anatomy based on external landmarks is paramount in identifying and avoiding important structures during retrosigmoid surgery of the posterior cranial fossa in order to reduce surgical morbidities




Lambda
Euryon
Asterion
Inion
Opisthion
Superior nuchal line
Inferior nuchal line


Asterion

Review literature

A New Landmark for Finding the Sigmoid Sinus in Suboccipital Craniotomies

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BACKGROUND: The suboccipital craniotomy is one of the most commonly performed neurosurgical approaches.

OBJECTIVE: To define a new cranial landmark, the digastric point, located at the top of the mastoid notch in the mastoid portion of the temporal bone that may assist surgeons performing this craniotomy and to study the relationships between this point and other surface landmarks.

METHODS: Craniometric measures were taken from 127 dry human adult skulls (90 male and 37 female). The measures were taken in millimeters by a digital caliper. Transillumination of the skull with laser or light-emitting diode was used to assess the correspondence of the digastric point in the inner surface of the skull.

RESULTS: The mean distance between the digastric point and the sigmoid sulcus in 254 measures was 3.10 mm (SD, 3.11 mm). The digastric point was over the sulcus of the sigmoid sinus in 49.6% of the cases on the right side and in 29.9% of the cases on the left side. The distance between the jugular point and the stylomastoid foramen was smaller on the right side (mean, 8.89 mm; SD, 2.61 mm; $P = .041$). Comparing genders regardless of side, the distances between the digastric and jugular points and from the jugular point to the stylomastoid foramen were smaller in female skulls ($P = .000$ and .006, respectively).

CONCLUSION: The digastric point may be a useful landmark to expose the sigmoid sinus during suboccipital approaches.

KEY WORDS: Anatomy, Cephalometry, Sigmoid sinus, Skull base, Suboccipital craniotomy, Surgical procedures

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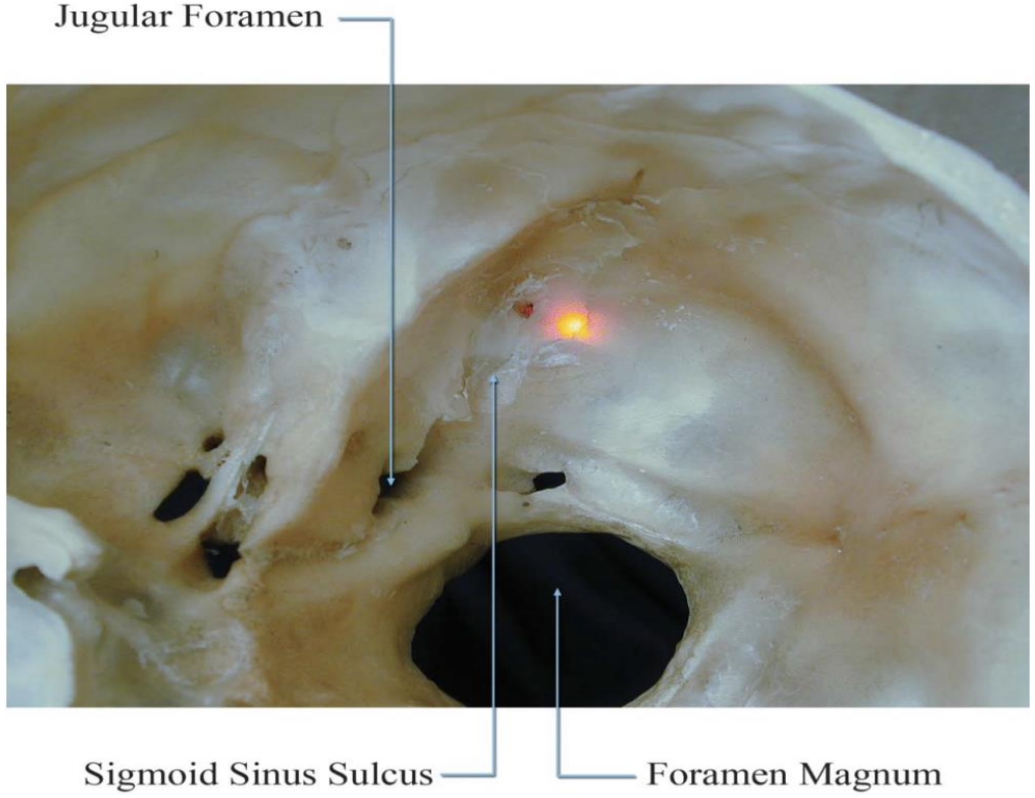

FIGURE 1. *Transillumination of the skull with a laser pointer to find the correspondence of the digastric point in the inner surface of the skull.*

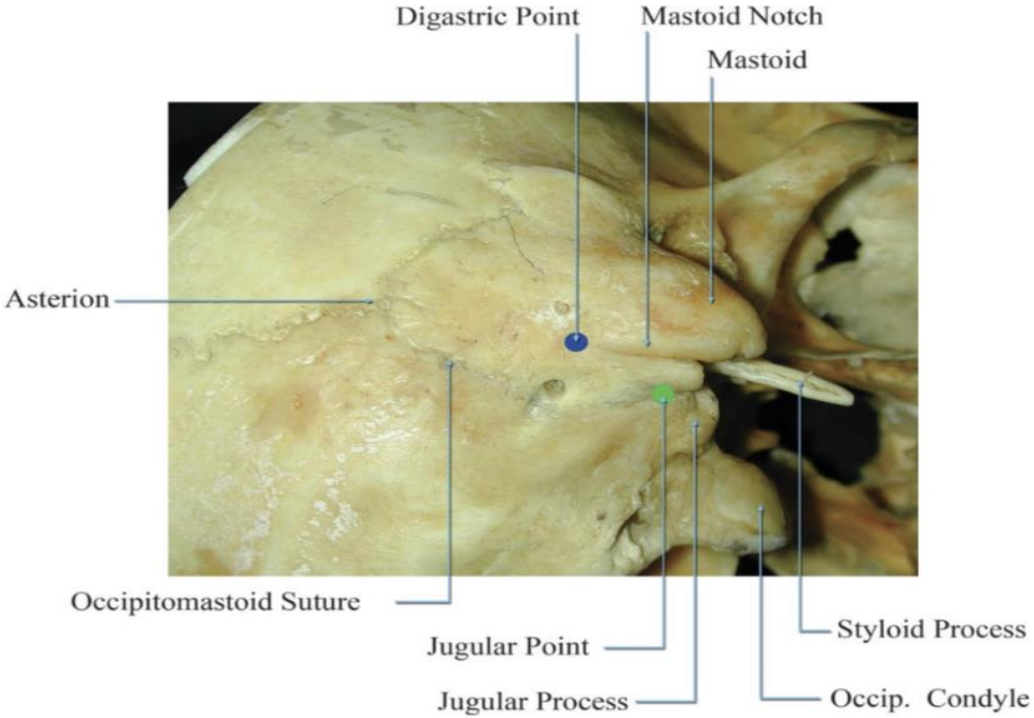

FIGURE 2. *Posterolateral surface of the skull on the right side. The digastric point is located at the top of the digastric groove. The asterion is the point of junction of the parietomastoid, lambdoid, and occipitomastoid sutures. The digastric point is defined as the point at the top of the digastric groove (blue circle). This point is easily identifiable in dry skulls and during surgical procedures because the digastric groove is covered by the posterior belly of the digastric muscle. The jugular point is a point over the occipitomastoid suture at the level of the posterior border of the jugular process of the occipital bone (green circle). The jugular process of the occipital bone is a bulged bone at each side of the occipital bone, located between the occipital (Occip.) condyle medially and the mastoid process laterally. The occipitomastoid suture is the junction of the occipital bone with the mastoid portion of the temporal bone. It begins at the asterion and descends, surrounding the jugular process of the occipital bone and ending at the jugular foramen.*

TABLE. **Mean Values of the Digastric Point on the Inner Surface of the Skull–Sigmoid Sulcus Distance in Both Sexes Regardless of Skull Side**

	n	Mean, mm	SD, mm
Mean	254	3.10	3.11
Male	180	3.45	3.01
Female	74	2.23	3.20

The Relationships between Asterion, the Transverse-Sigmoid Junction, the Superior Nuchal Line and the Transverse Sinus in Thai Cadavers: Surgical Relevance

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Background: *Anatomical localization of the venous sinuses in the posterior cranial fossa is important to preventing inadvertent venous sinus injury during surgical approaches to the area. Identification of surface landmarks related to these structures is useful in planning such approaches.*
Objective: *To identify the positions of the asterion and the superior nuchal line for localization of the venous sinus in the posterior fossa.*
Material and Method: *Twenty fresh cadaveric heads, yielding 40 sides, were used. The vessels were injected with colored silicone. The soft tissues were removed to expose the posterior cranium, from inion to the foramen magnum and laterally to the mastoid process. Using digital calipers, the relationship of asterion to the transverse-sigmoid sinus junction was determined and the distance from the highest superior nuchal line to the nearest transverse sinus was measured.*
Results: *Asterion was located in 82.5% of the cadavers on the right side and 85.0% on the left side. The most common asterion position was at the junction of the transverse and sigmoid sinuses (67.5%), of which 5.0% were superior to the transverse-sigmoid junction, 2.5% inferior to the transverse-sigmoid junction and 7.5% medial to the transverse-sigmoid junction, at the transverse sinus. The superior nuchal line was identified in all cadavers. The most common position was inferior to the transverse sinus (60.0%) at an average distance of 8.55 mm 35.0% were at the same level as the transverse sinus and 5.0% were superior to the transverse sinus at an average distance of 2.14 mm.*
Conclusion: *A burr hole inferior-medial to asterion can expose the posterior fossa dura with the least risk. The superior nuchal line is always identifiable and relatively close to the transverse sinus. A burr hole more than 3 mm inferior to the superior nuchal line can expose the posterior fossa dura with the least risk.*

Keywords: *Posterior cranial fossa, Retrosigmoid approach, Venous injury, Surgical safety*

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Full text. e-Journal: *http://www.jmatonline.com*

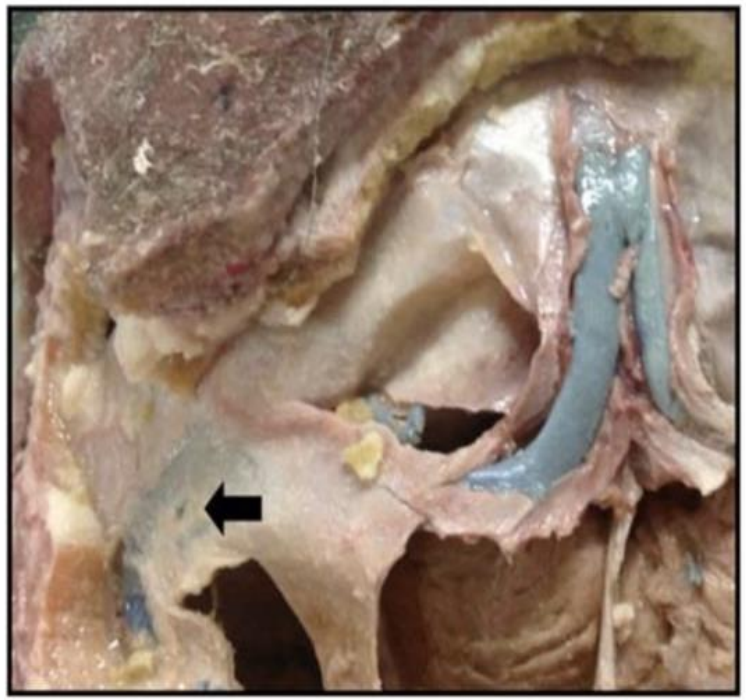


Fig. 1 The burr hole at asterion (arrow) and the opened skull with exposed transverse-sigmoid junction (veins injected with colored silicone).

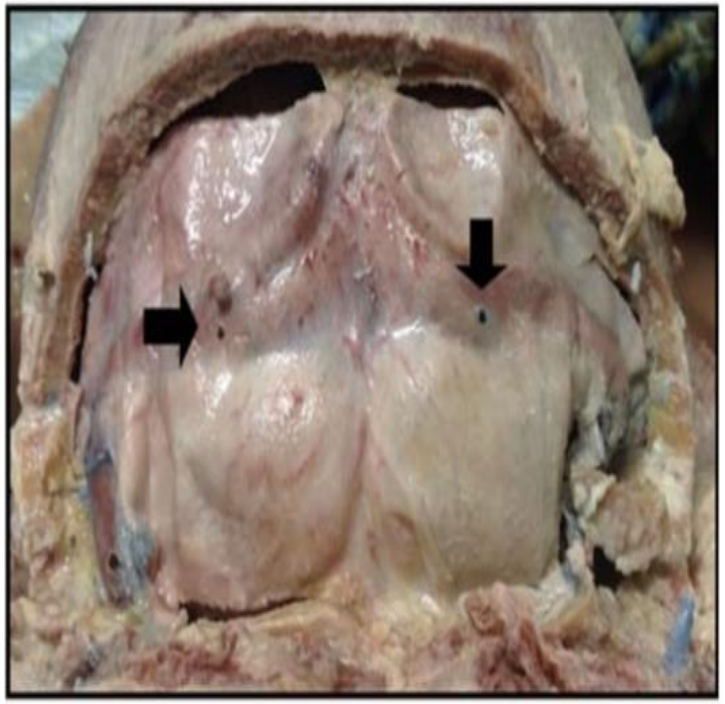


Fig. 2 The highest point of superior nuchal line (arrows) with burr holes.

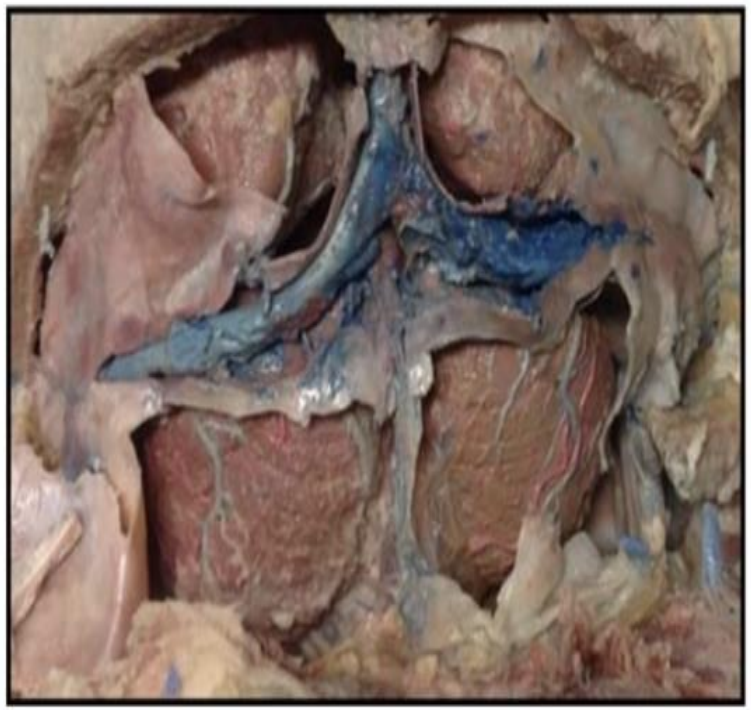


Fig. 3 The opened durawhich allows measurements of the distance from the superior nuchal line to the lower border of the transverse sinus.

Table 1. Position and distance between asterion and the transverse-sigmoid junction

Asterion position	Number (total = 33)	Mean distance from transverse-sigmoid junction (mm)
Superior to transverse-sigmoid junction	2 (5.0%)	12.62
At transverse-sigmoid junction	27 (67.5%)	0.00
Inferior to transverse-sigmoid junction	1 (2.5%)	2.90
Medial to transverse-sigmoid junction (at transverse sinus)	3 (7.5%)	12.06

Table 2. Position and distance between superior nuchal line and transverse sinus

Superior nuchal line position	Number (total = 40)	Mean distance from superior nuchal line to transverse sinus (mm)	Right side	Left side
Superiorto transverse sinus	2 (5.0%)	2.14 (range 2.50-1.79)	0	2
At the same level as transverse sinus	14 (35.0%)	0	9	5
Inferior to transverse sinus	24 (60.0%)	8.55 (range 1.68-19.00)	10	14

Objective

The objectives of this study were

1. To validate the DP-asterion line as a reference for the vertical part of sigmoid sinus and skull landmark for other part of transverse-sigmoid sinus.
2. To evaluate the difference in these measures as far as skull side.

statistical analysis

- Study design : experimental radiologic study
- Statistical analysis :

Data analysis was performed using Program STATA. Quantitative data was summarized as mean and SD or median and range as appropriate. Categorical data was summarized as counts and percentage. Comparison of quantitative variables between groups was done using the Two-sample t test or Wilcoxon rank-sum (Mann-Whitney) test as appropriate. Comparison of categorical variables between groups was done using the Chi-square test or Fisher's exact test appropriate.

Inclusion criteria

1. CTV brain of patient older than 15 years

Exclusion criteria

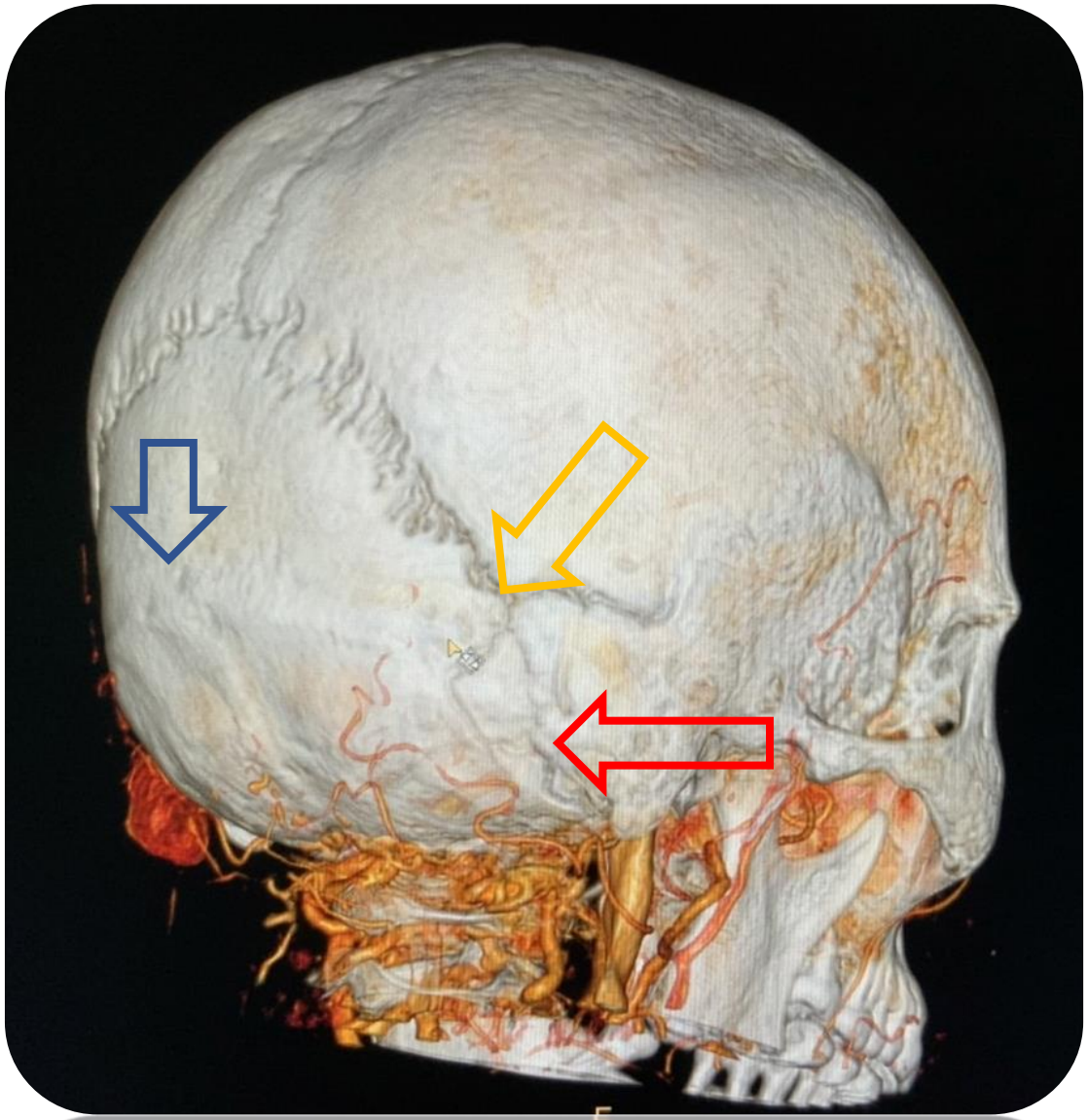
1. CTV brain underwent surgery at posterior cranial fossa
2. CTV brain of patients with disease of vascular and intracranial lesion that invade transverse-sigmoid sinus , for example cerebral venous sinus thrombosis

Methods

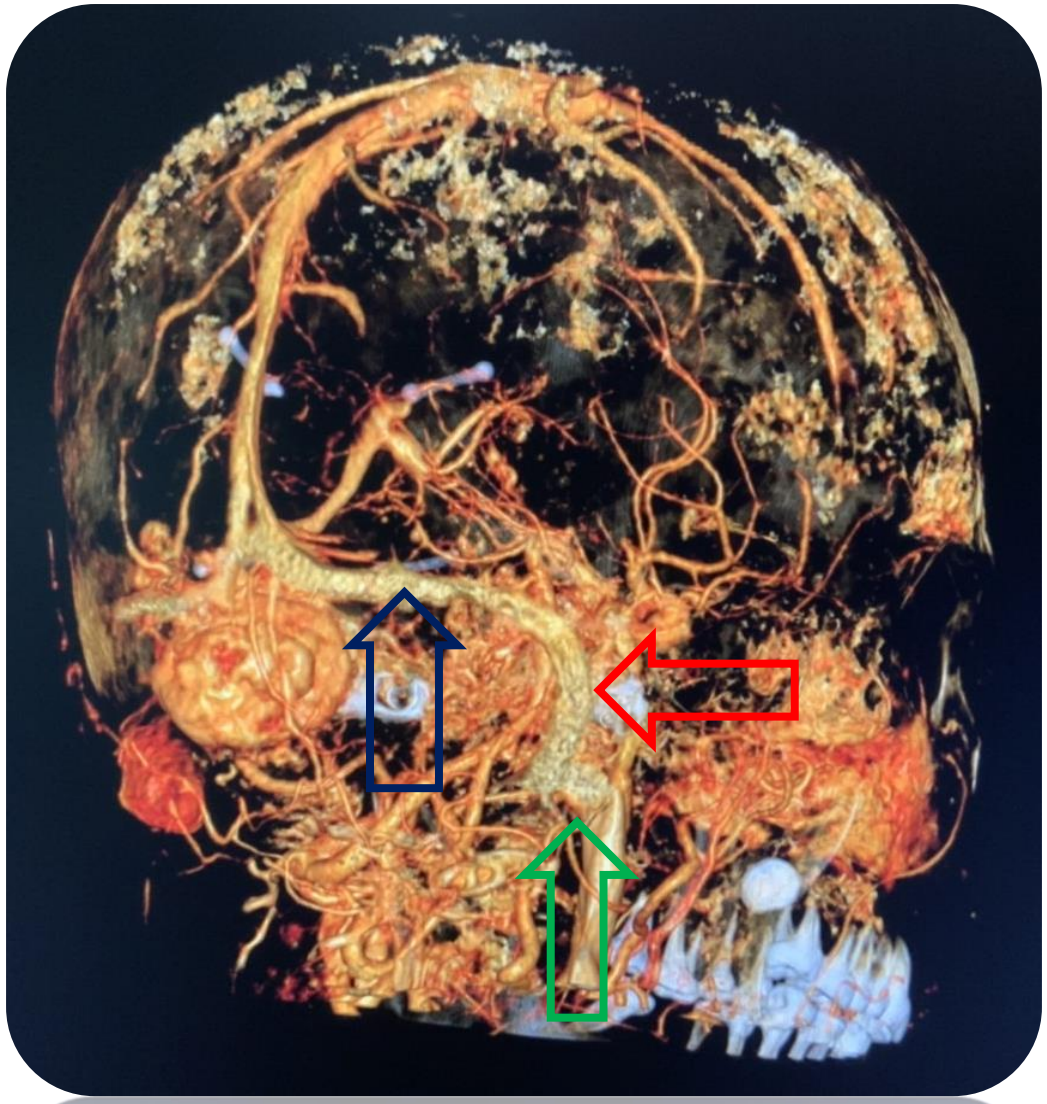
1. We will use fifty hospital number of computed tomography brain images from Ramathibodi Hospital to Volume-rendering technique(Phillips program)

2. Identify location of asterion , digastric point, transverse-sigmoid sinus junction and size of sigmoid sinus

3. Measure the median distance between asterion and DP line to posterior edge of vertical part of sigmoid sinus in proximal, mid and distal portion



Bule arrow : inion
Orange arrow : asterion
Red arrow : diagastric point



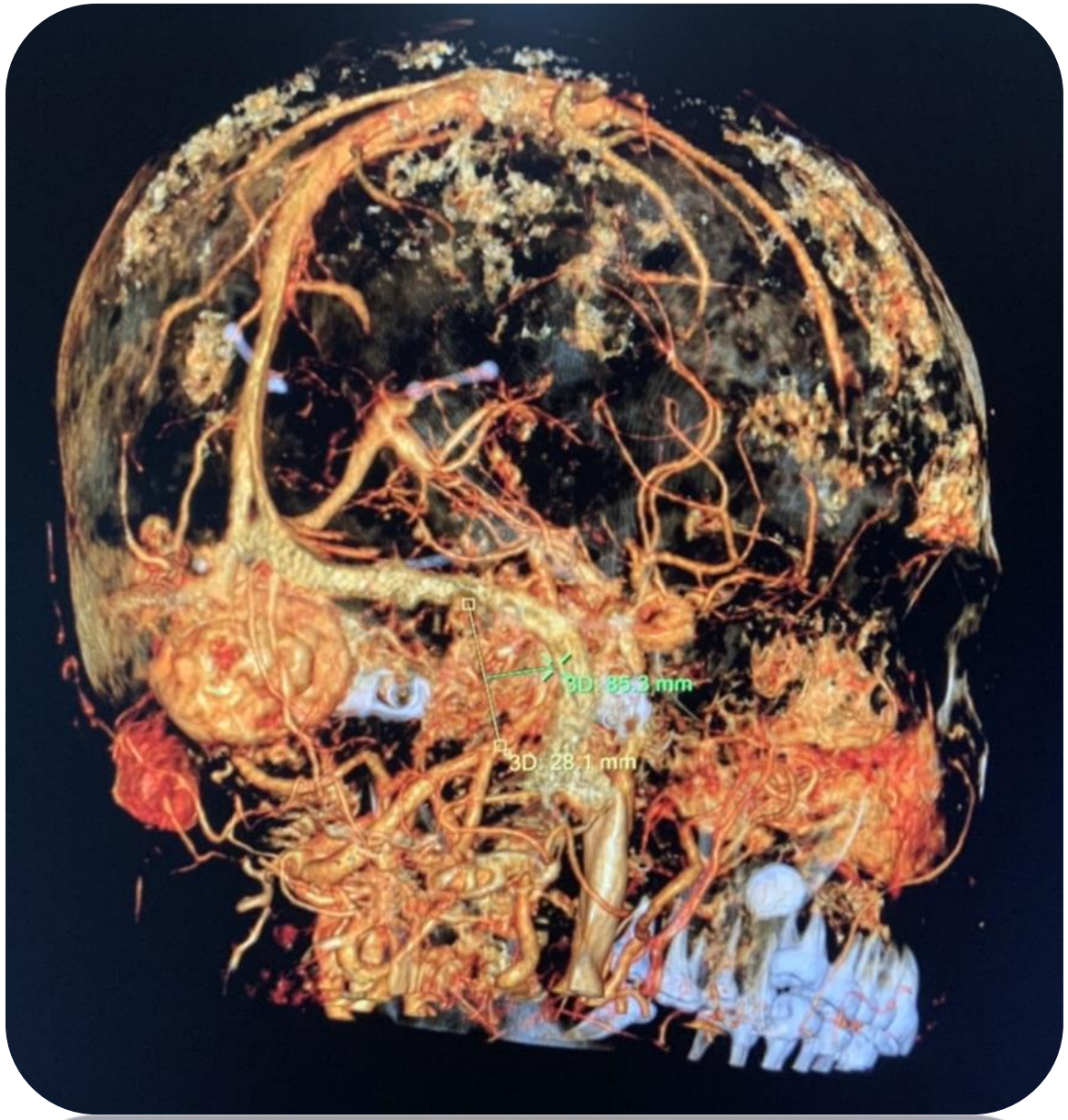
Bule arrow : transverse sinus

Red arrow : vertical part of sigmoid sinus

Green arrow : horizontal part of sigmoid sinus

3D: 28.1 mm

3D: 28.1 mm


3D: 85.3 mm
3D: 28.1 mm

Collect data

- We will use descriptive measure : mean , SD , median , minimal and maximum for

1. The DP-asterion line to the vertical part of sigmoid sinus

2. To identify the asterion point for localization of transverse-sigmoid junction

Collect data

Right						Left					
asterion line	SS	proximal	mid	distal	CD	asterion line	SS	proximal	mid	distal	CD
23	0.5	6.8	7.5	7.8	medial	21	0.4	5	7	7.1	medial
27	2.4	7	7.7	7.2	medial	25	0.27	7.7	7.8	8.3	medial
18	2.2	16	17	19	medial	24	1.8	23	24	21.8	medial
20.7	1.8	12.6	12.4	1.19	medial	22	2	15	20	21.5	medial
22	2.4	18	20	22	medial	20	2	17	19	20	medial
23.8	2.2	9.8	7.9	6.6	medial	22	1.6	1	3	2	midpoint
23	2	16	17.4	18	medial	22	1.4	15.2	17	18.2	medial
23.6	2.8	6.2	11.4	12	mid poin	4	2.8	4	10	12	medial
20	1.6	18	20	20.4	medial	20	1.4	19	21	21.8	medial
21	2.4	18	19	22	medial	22	2	15.6	17	19	medial
22.5	3.7	24.3	26.3	21.8	medial	25.5	2.5	3.6	7.1	7.7	lateral
18	2	12	14	17	medial	19	1.4	17	18	20	medial
20	2.4	14.2	16	18	medial	21	2	15	16.4	18	medial
18	1.8	15	16.4	17	medial	20	1.7	17	18	20.3	medial
24	2.2	2	4	6.5	mid poin	22	1.4	15	16.2	17	medial
22	1.8	13.7	16	18	medial	24	2	16	18.2	19	medial
24	2	14	16.8	17	medial	23	1.2	18	19.7	21	medial
22.6	1.9	13	15.8	18	medial	23	21	14	15.3	15.8	medial

Activate Windows

Table 1 Characteristics of patients (n = 51)

Characteristics	Statistics
Age (years); median (min, max)	67.0 (16.0, 87.0)
Gender; n (%)	
Male	18 (35.3)
Female	33 (64.7)

Table 2 Comparison outcomes between right and left of skull of each parameter (n = 51)

Outcomes	Right	Left	p-value
Asterion line; median (min, max)	21.8 (16.0, 27.0)	21.0 (4.0, 26.0)	0.973
SS; median (min, max)	2.0 (0.5, 3.7)	1.8 (0.3, 2.8)	**0.003**
Proximal; median (min, max)	12.2 (2.0, 24.3)	14.0 (1.0, 23.0)	0.234
Mid; median (min, max)	15.0 (4.0, 26.3)	15.5 (3.0, 24.0)	0.246
Distal; median (min, max)	18.0 (1.2, 22.5)	18.0 (2.0, 22.5)	0.233
CD; n (%)			
lateral	0 (0.0)	1 (2.0)	0.487
medial	48 (94.1)	45 (88.2)	
midpoint	3 (5.9)	5 (9.8)	

Discussion

1. **Reliability of the DP–asterion line for localizing the sigmoid sinus**
   The present study demonstrated that the digastric point (DP)–asterion line maintained comparable distances to the vertical part of the sigmoid sinus on both the left and right sides. This consistency indicates that the DP–asterion line may serve as a reliable external landmark during retrosigmoid craniotomy, potentially reducing the risk of inadvertent venous sinus injury. Furthermore, subdividing the distance along this line into three discrete portions could facilitate a more precise estimation of the extent of drilling required for adequate exposure of the sigmoid sinus.
2. **Significant asymmetry in sigmoid sinus size**
   Analysis of the measured dimensions revealed that the right sigmoid sinus was significantly larger than its left counterpart. This observation underscores the importance of recognizing anatomical variations between sides when planning surgical approaches in the posterior fossa, as such differences may influence intraoperative strategy and potential complications.
3. **Limitations in identifying the mastoid emissary foramen**
   Due to suboptimal visualization on the CT volume-rendering images, the mastoid emissary foramen could not be consistently identified or measured. Consequently, the relationship between the size of the foramen and the adjacent sigmoid sinus remains unexamined in this study. Future investigations employing higher-resolution imaging or alternative modalities may be warranted to elucidate this anatomical correlation.

Conclusion

The findings of this study indicate that the **DP–asterion line** serves as a practical and consistent external landmark for estimating the position of the vertical segment of the sigmoid sinus, showing comparable distances on both the left and right sides. Moreover, the measurements along the proximal-to-distal regions of this line progressively widened relative to the sinus, suggesting that these distances could assist surgeons in planning the extent of bone drilling required to achieve a clear exposure of the sigmoid sinus.

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Thank you

Abstract

“Risk Factors of Bottoming-out Deformity in Primary Breast Augmentation Patients in Ramathibodi Hospital: A Retrospective Study”

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Background: Breast augmentation is one of the most commonly performed cosmetic procedures, but it’s not without complications. One of the more frequent issues is implant malposition, particularly bottoming-out deformity, where the implant descends below its intended position over time. This study looks at potential risk factors for early implant displacement, focusing on patient characteristics, implant selection, and the progression of bottoming-out deformity postoperatively.

Methods: We conducted a retrospective review of 124 patients who underwent primary breast augmentation at Ramathibodi Hospital from 2016 to 2020, categorizing them into two groups: No detection (n=83) and Detection (n=41), based on whether implant displacement was noted. We analyzed factors such as age, BMI, implant volume, incision type, breastfeeding history, and lowering IMF. Statistical analyses, including logistic regression, were performed to identify risk factors contributing to implant malposition.

Results: Breastfeeding was significantly associated with early implant displacement (p=0.003), while other factors such as age, BMI, implant volume, implant profile, and lowering IMF showed no significant correlation. The median time to detection was 4.3 months, with IMF scar migration increasing the most in the first 12 months. Logistic regression suggested that breastfeeding might contribute to early implant detection (OR=2.59, 95% CI: 0.97-6.86, p=0.056)

Conclusion: Bottoming-out deformity remains a common concern in breast augmentation surgery, with prior breastfeeding could be a potential risk factor. This highlights the importance of careful patient selection, implant choice, and surgical technique to minimize complications. Future research should focus on refining predictive models and optimizing surgical strategies to enhance long-term outcomes and patient satisfaction.

Risk Factors of Bottoming-out Deformity in Primary Breast Augmentation Patients in Ramathibodi Hospital : A Retrospective Study

การศึกษาเกี่ยวกับความเสี่ยงที่ทำให้เกิดภาวะซิลิโคนเต้านมอยู่ต่ำกว่าปกติ
ของผู้ป่วยผ่าตัดเสริมเต้านมในโรงพยาบาลรามาธิบดี

Amalin Pamarapa, 5th year resident
Advisor : Surawej Numhom, M.D.
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COA No. MURA2024/844

Title of Project (English)	Risk factors of bottoming-out deformity in primary breast augmentation patients in Ramathibodi Hospital: A retrospective study
Title of Project (Thai)	การศึกษาความเสี่ยงที่ทำให้เกิดภาวะซิลิโคนเต้านมอยู่ต่ำกว่าปกติของผู้ป่วยผ่าตัดเสริมเต้านมในโรงพยาบาลรามาธิบดี
Type of Review	Expedited
Principal Investigator	Amalin Pamarapa
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
Co-investigator	Surawej Numhom
Approval includes	1. Submission form protocol version 1.0 date 10/10/2024 2. Curriculum vitae 3. Certificate in ethics training

Institutional Review Boards in Mahidol University are in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

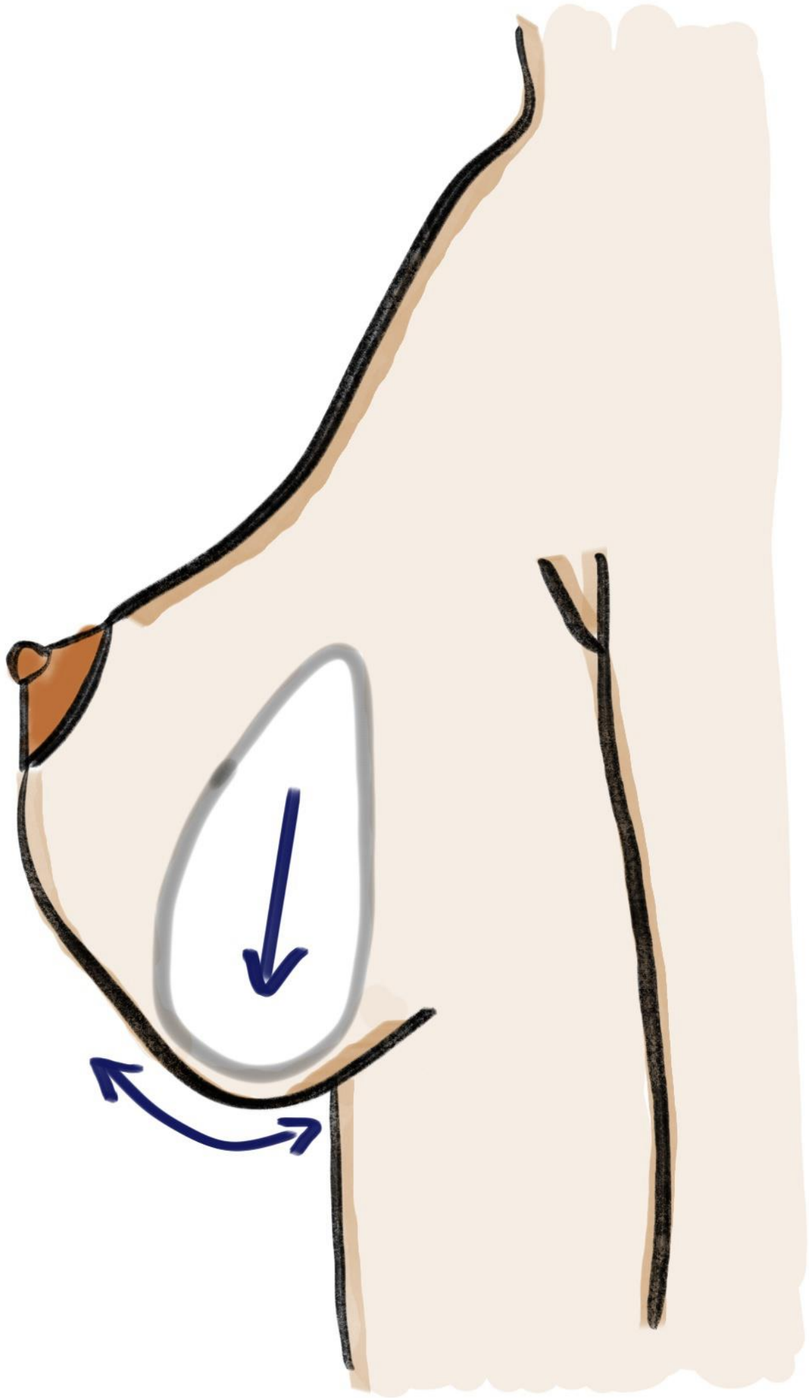
Date of Approval	**November 21, 2024**
Date of Expiration	**November 20, 2025**

Signature of Chair.....

(Asst. Prof. Chusak Okascharoen, M.D., Ph.D.)

This certificate is subject to the following conditions:

1) Approval is granted only for the project with details described in submitted proposal
2) Submission of modification to the approved project is needed before implementation
3) A yearly progress report is required for renewing of approval
4) Written notification is required when the project is complete or terminated



BACKGROUND OF THE STUDY

- Implant malposition is the second most common complication in most studies. It has been reported as high as 12% after primary breast augmentation
- **“Bottoming-out”** deformity is usually a grouped within the category of implant malposition complications after breast augmentation
- It is an inferior implant displacement with a high-riding nipple, resulting in the lower pole being longer than it should be

Aim of this study

Potential risk factors for implant displacement, focusing on patient characteristics, implant selection, lowering IMF

Progression of bottoming-out deformity postoperatively.

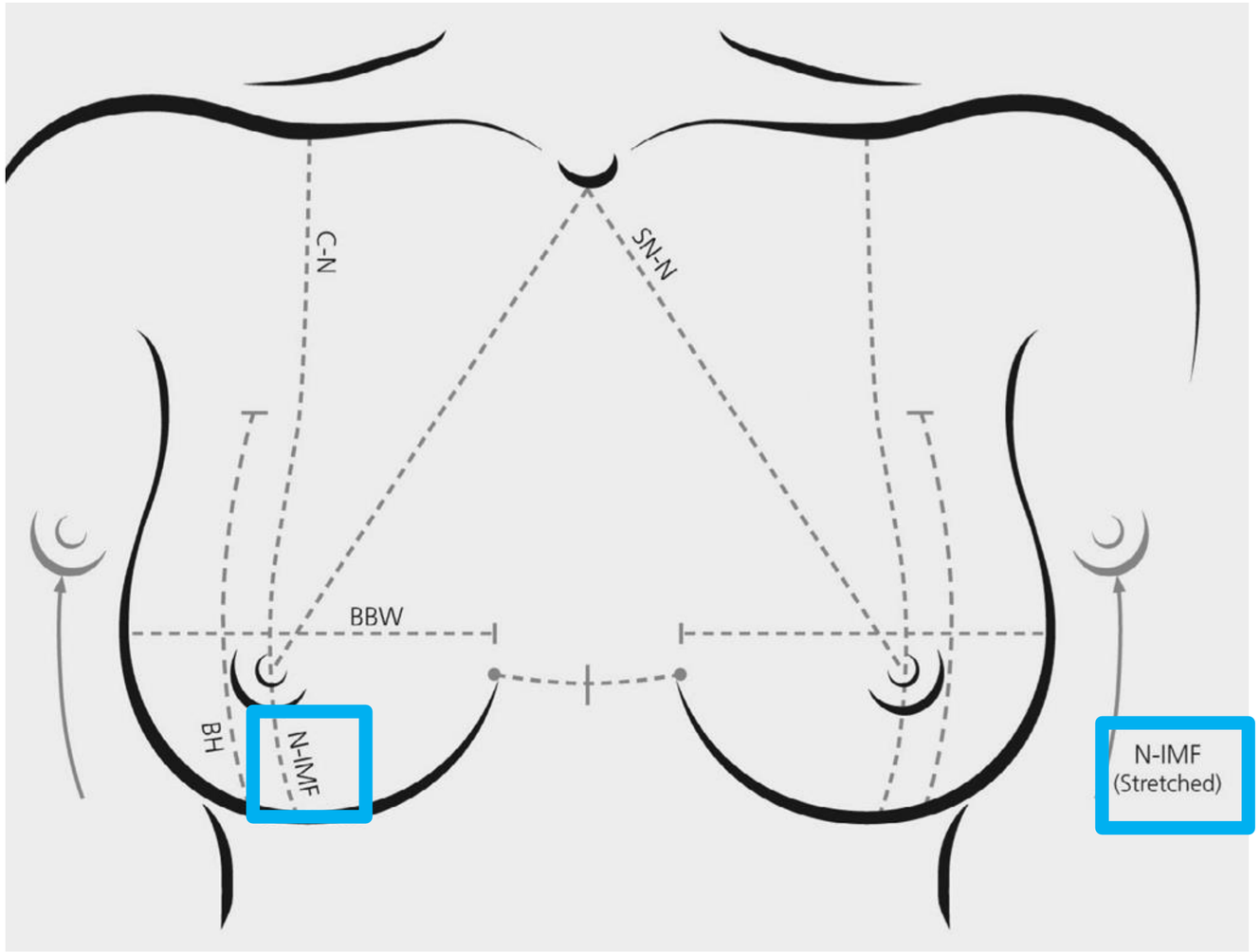
METHODS

- Retrospective review
- Patients who underwent primary breast augmentation at Ramathibodi Hospital from January 2016 to December 2020, and followed up for at least 6 months
- **Exclusion criteria** : incomplete data

FACTORS

- BMI
- Incision
- History of breastfeeding
- % Stretch in distance

$$= \frac{(NIMF_{stretched} - NIMF)}{NIMF\ distance} \times 100$$



Ref : Neligan Plastic Surgery, 4th edition

FACTORS

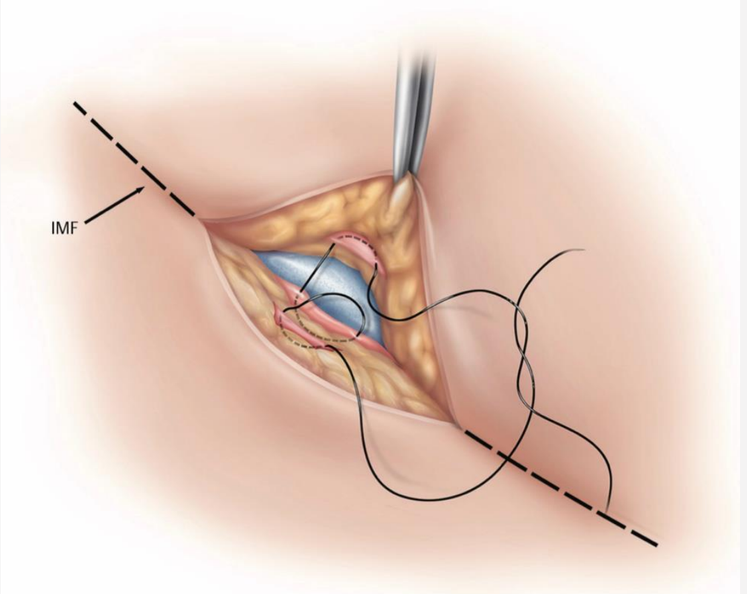
- BMI
- Incision
- History of breastfeeding
- % Stretch in distance

$$= \frac{(NIMF_{stretched}\text{-}NIMF)}{NIMF\ distance} \times 100$$

- Implant profile
- Implant volume
- Implant volume to BMI ratio
- Lowering IMF

METHODS

- Surgical Techniques
  - Subpectoral, Dual plane
  - IMF fixation : three-point fixation
  - No muscle / fascial sling

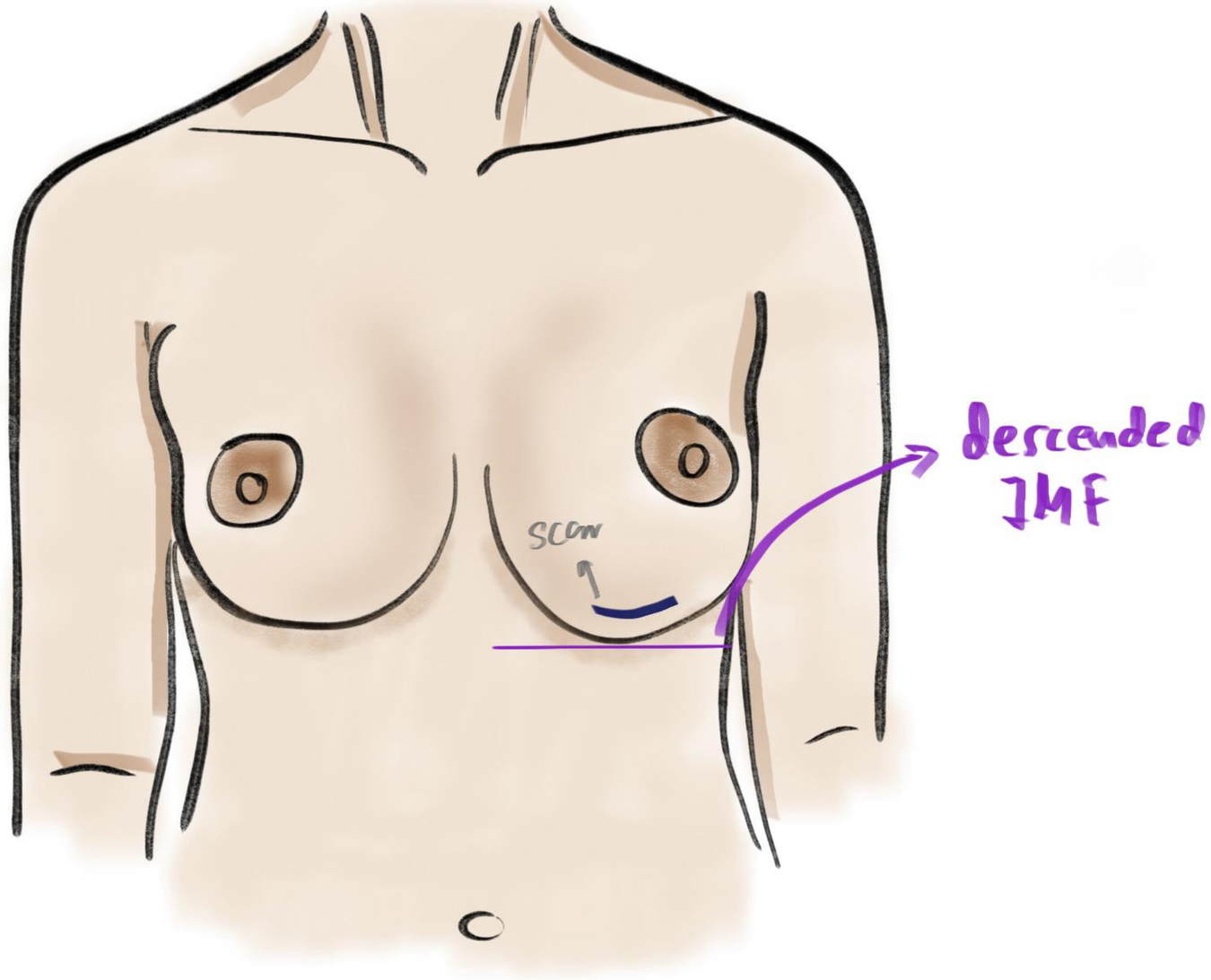


- Post-op care
  - Wearing support bra for at least 6 months
  - Avoid strenuous exercise 2 months

OUTCOME MEASUREMENT

- **Bottoming-out** = distance between the IMF — scar ≥ 5mm

- Categorized into 2 groups : Detection / No detection
- Review EMR at each follow-up
- If there was any inconsistency in the document data, it was confirmed through the photograph



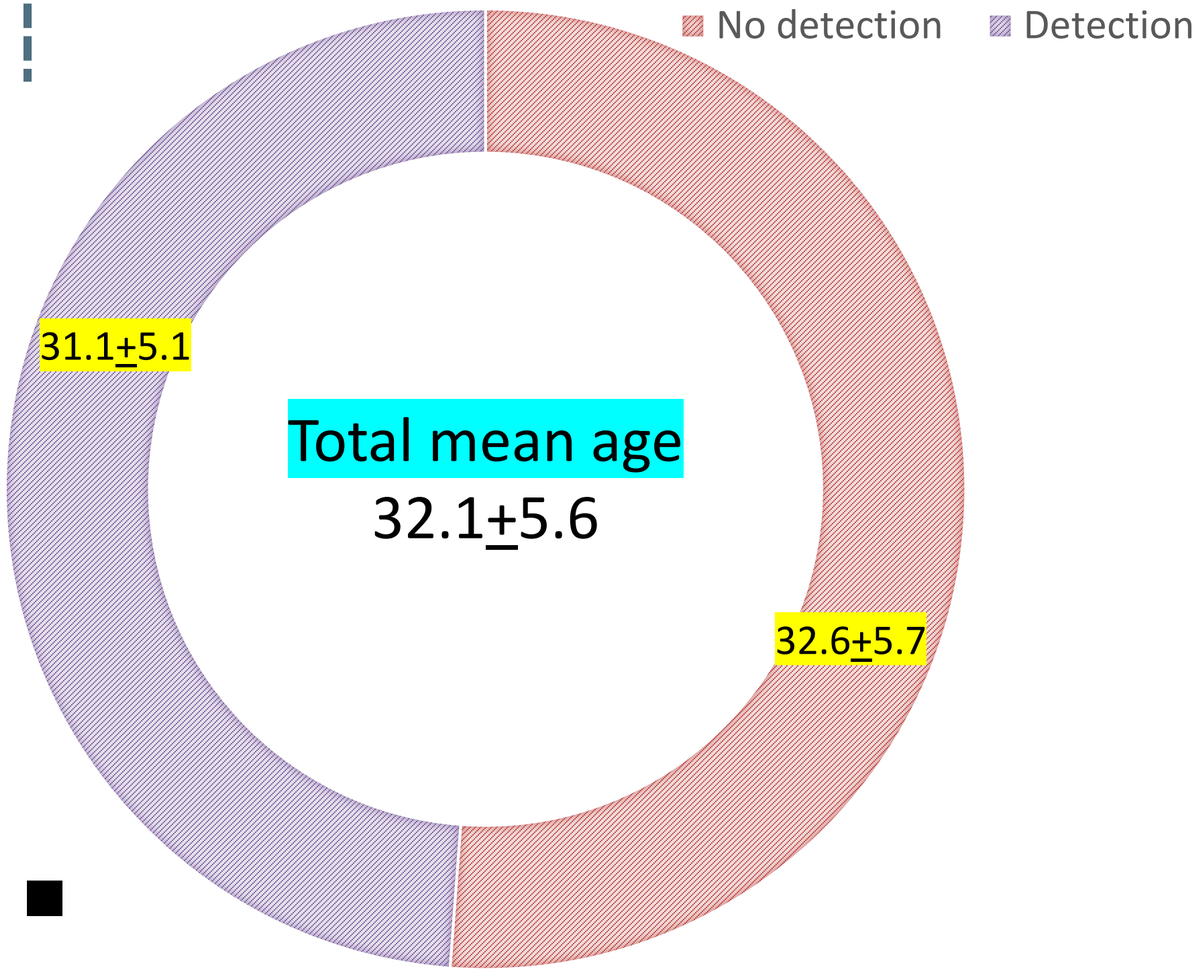
STATISTICAL ANALYSIS

- Comparison between 2 groups ;
  - Categorical variables : Fisher’s exact test / Chi-square test
  - Continuous variables(normal distribution) : t-test
  - Continuous variables(abnormal distribution) : Mann-Whitney test
- Risk factors : Binary logistic regression
- Significance difference : p-value<0.05

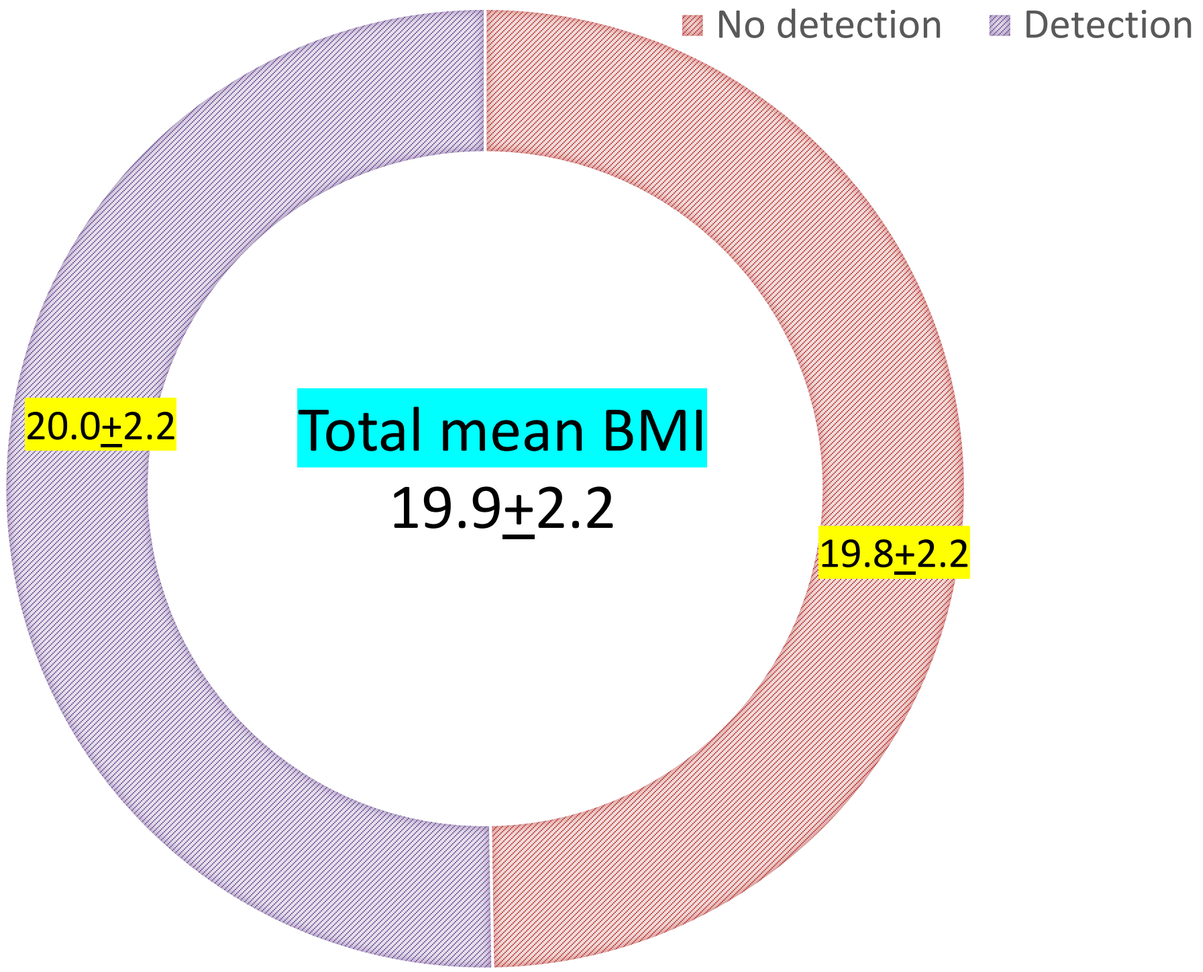
RESULTS

Total = 124 patients

AGE



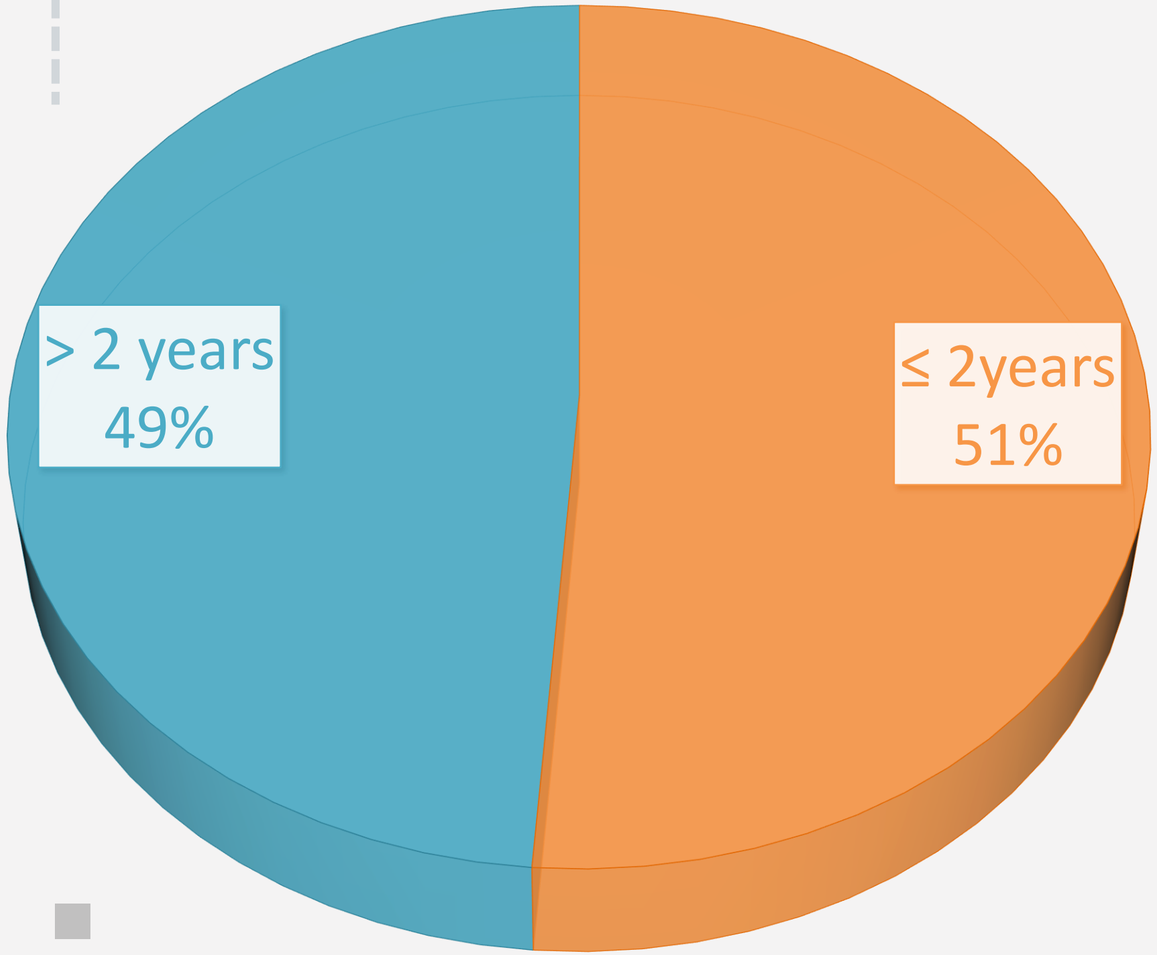
BMI



RESULTS

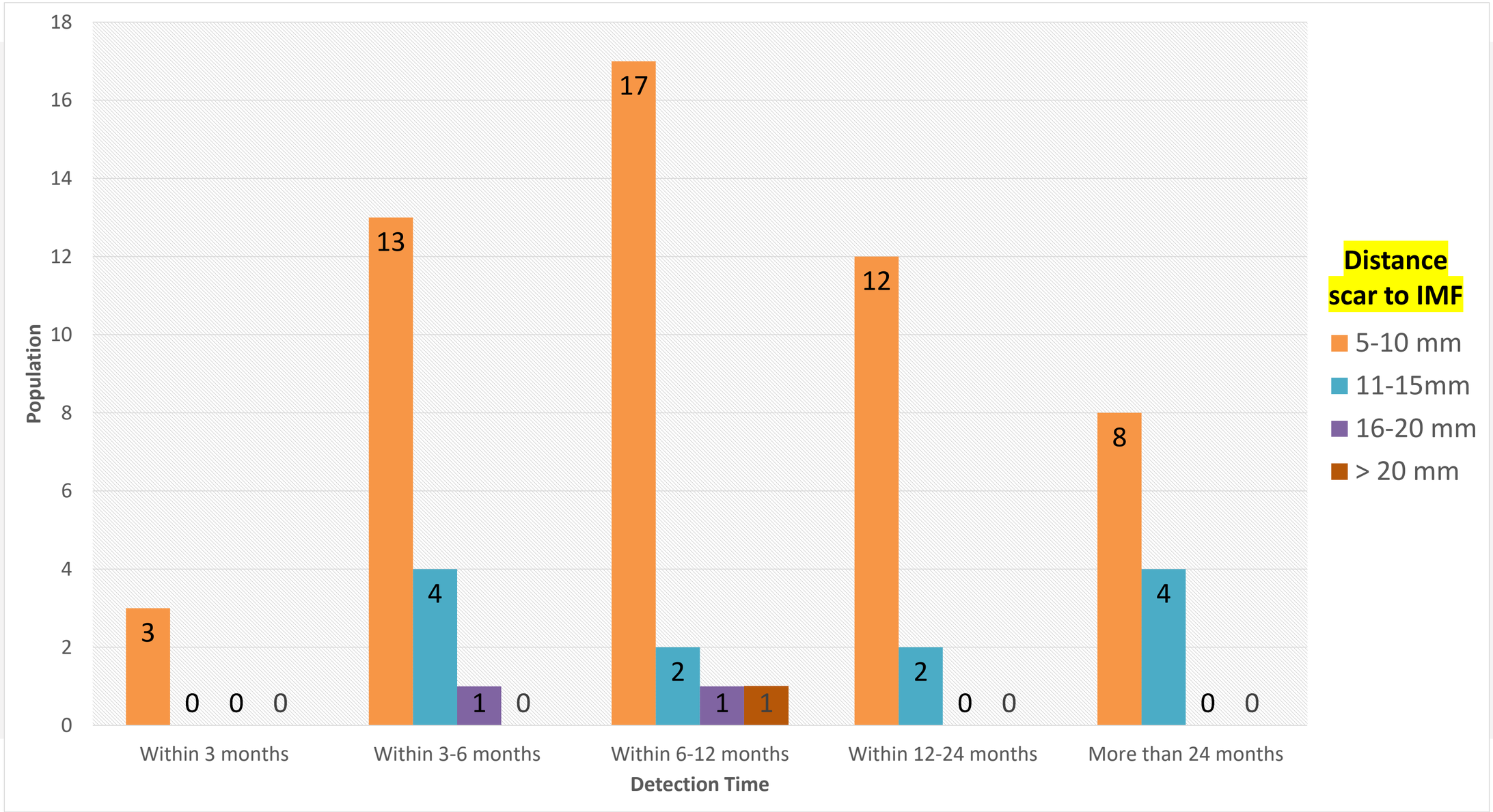
- Median follow-up time : 18.8 months (IQR : 11.1-37.5)
  - No detection group : 19.7 months
  - Detection group : 13.6 months
- Median detection time : 4.3 months (IQR : 1.3-11.8)

DETECTION

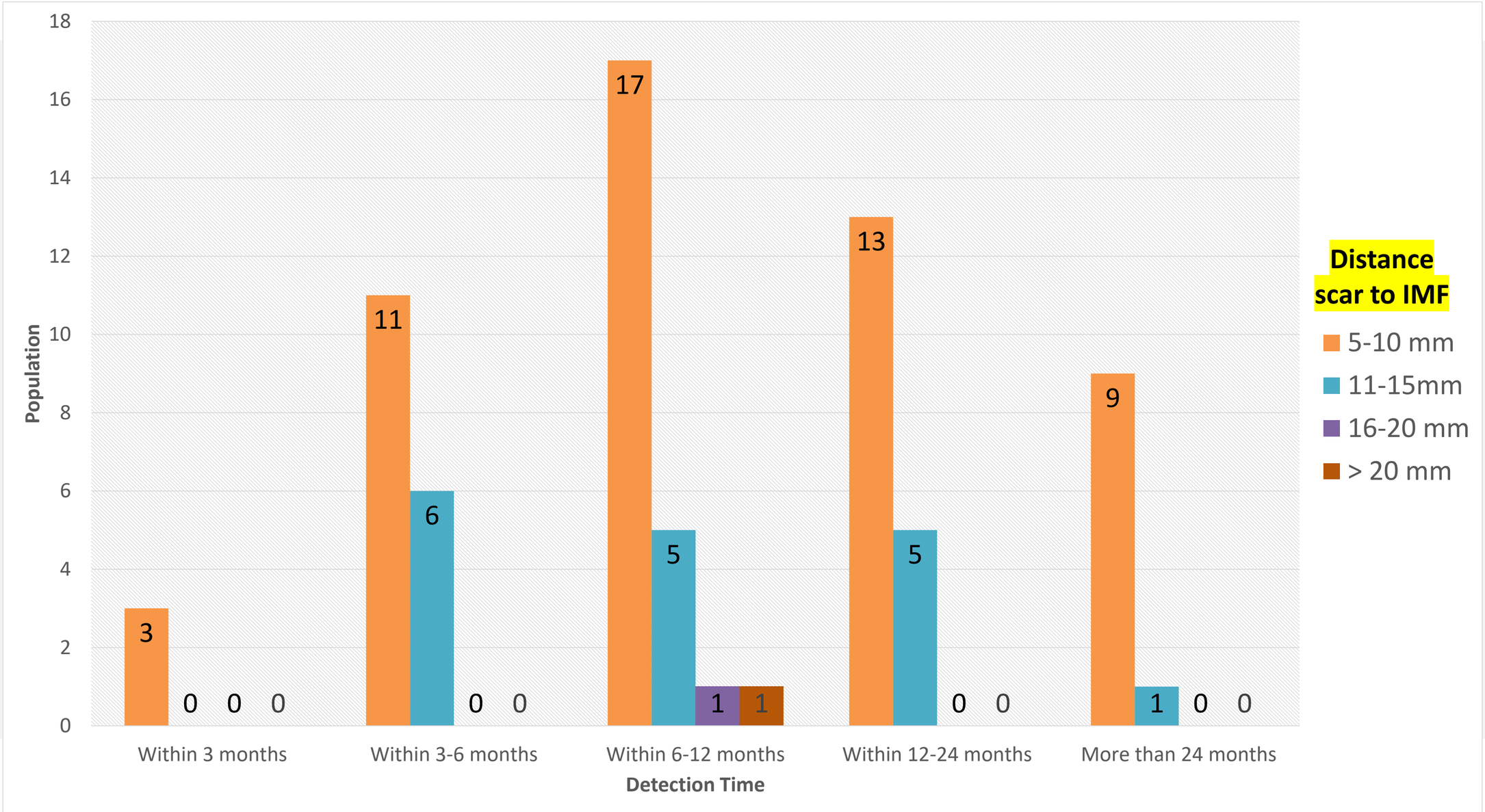


Detection	
Detection Right, n(%)	29(23.4)
Detection Left, n(%)	34(27.4)
Detection Right or Left, n(%)	41(33.1)
Detection both, n(%)	22(17.7)

DETECTION (Right)



DETECTION (Left)



RESULTS

Variable	Total (n=124)	Detection		
		No (n=83)	Yes (n=41)	p-value
Incision, n(%)				
IMF	118(95.2)	78(94.0)	40(97.6)	0.663
Transaxilla	6(4.8)	5(6.0)	1(2.4)	
Breastfeeding, n(%)				
No	85(68.5)	64(77.1)	21(51.2)	0.003
Yes	39(31.5)	19(22.9)	20(48.8)	

RESULTS

Variable	Total (n=124)	Detection		
		No (n=83)	Yes (n=41)	p-value
% Stretch in distance, mean±SD				
Right	49.5±19.3	47.6±20.4	53.4±16.3	0.114
Left	51.6±17.5	50.7±19.2	53.4±13.7	0.368
Implant profile (Rt.), n(%)				
Medium profile	31(25.0)	21(25.3)	10(24.4)	0.912
High profile	93(75.0)	62(74.7)	31(75.6)	
Implant profile (Lt.), n(%)				
Medium profile	33(26.6)	22(26.5)	11(26.8)	0.969
High profile	91(73.4)	61(73.5)	30(73.2)	

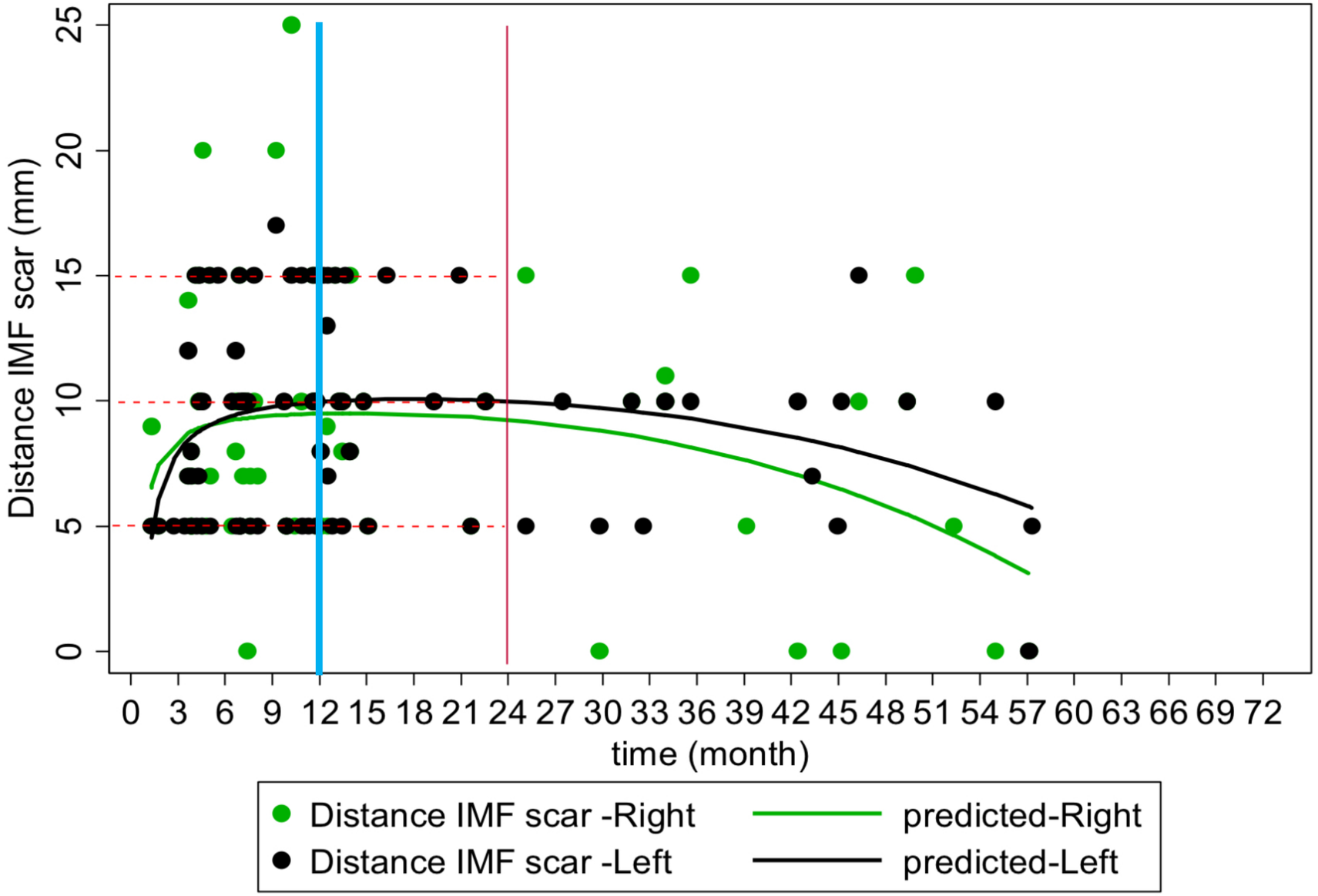
RESULTS

Variable	Total (n=124)	Detection		
		No (n=83)	Yes (n=41)	p-value
Implant volume (ml), mean±SD				
Right	314±45	313±45	316±44	0.724
Left	311±44	311±43	313±45	0.804
Implant volume : BMI (%), mean±SD				
Right	15.8±2.1	15.8±2.1	15.9±2.1	0.886
Left	15.7±2.1	15.7±2.0	15.7±2.1	0.967

RESULTS

Variable		Total (n=124)	Detection		
			No (n=83)	Yes (n=41)	p-value
Lowering IMF (mm), mean±SD					
	Right	7.3±5.9	7.8±6.0	6.2±5.5	0.157
	Left	7.5±6.2	7.9±6.4	6.6±5.6	0.314
Right , n (%)					
No lowering IMF			18 (22.78)	13 (33.33)	0.456
≤ 10 mm			44 (55.7)	18 (46.15)	
>10 mm			17 (21.52)	8 (20.51)	
Left, n (%)					
No lowering			20 (25.32)	13 (33.33)	0.497
≤ 10 mm			37 (46.84)	14 (35.9)	
>10mm			22 (27.85)	12 (30.77)	

PROGRESSION



Distance IMF scar (mm)	
within 3 months	5.7±1.6
within 6 months	9.5±4.3
within 12 months	10.5±5.5
within 24 months	7.5±2.9

DISCUSSION

- These findings shows the importance of preoperative risk assessment and intraoperative precision in reducing implant malposition.
- Breastfeeding history was identified as a significant risk factor for bottoming-out, likely due to alterations in tissue integrity and elasticity
- There is **no significant difference** in lowering IMF in bottoming-out patients

DISCUSSION

- Compare with a previous study by Fracol et al., which stated that risk factors for inferior implant malposition were older age, BMI<25 and bilateral reconstruction
  - Our study did not find age and implant volume to BMI as significant factors

DISCUSSION

- We observed one patient who developed a stitch abscess and subsequently experienced bottoming-out deformity.
- There was also a change in bottoming-out degree if the patient was pregnant, gained or lose weight
- There was no revision surgery in bottoming-out patients in our study

LIMITATIONS

- Retrospective nature
- Differences in surgical techniques among different surgeons
- The study does not compare with prepectoral augmentation.
- Emerging techniques such as muscle sling have been proposed to provide additional implant support and decrease the risk of bottoming-out.
  - ✓ Further prospective, controlled studies are needed to assess their long-term effectiveness
- Long-term follow-up beyond two years is necessary to assess the durability of outcomes

CONCLUSION

- Bottoming-out deformity remains a common concern in breast augmentation surgery, with **prior breastfeeding** could be a potential risk factor.
- This highlights the importance of **careful patient selection** to minimize complications. Future research should focus on refining predictive models and optimizing surgical strategies to enhance long-term outcomes and patient satisfaction

THANK YOU

MORE **ABOUT US**

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