BASIC STATISTICS FOR CLINICAL RESEARCH

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OUTLINE

- INTRODUCTION TO STATISTICS
- TYPES OF DATA AND MANAGEMENT
- TYPES STATISTICS AND HYPOTHESIS
- SELECTION OF STATISTICS

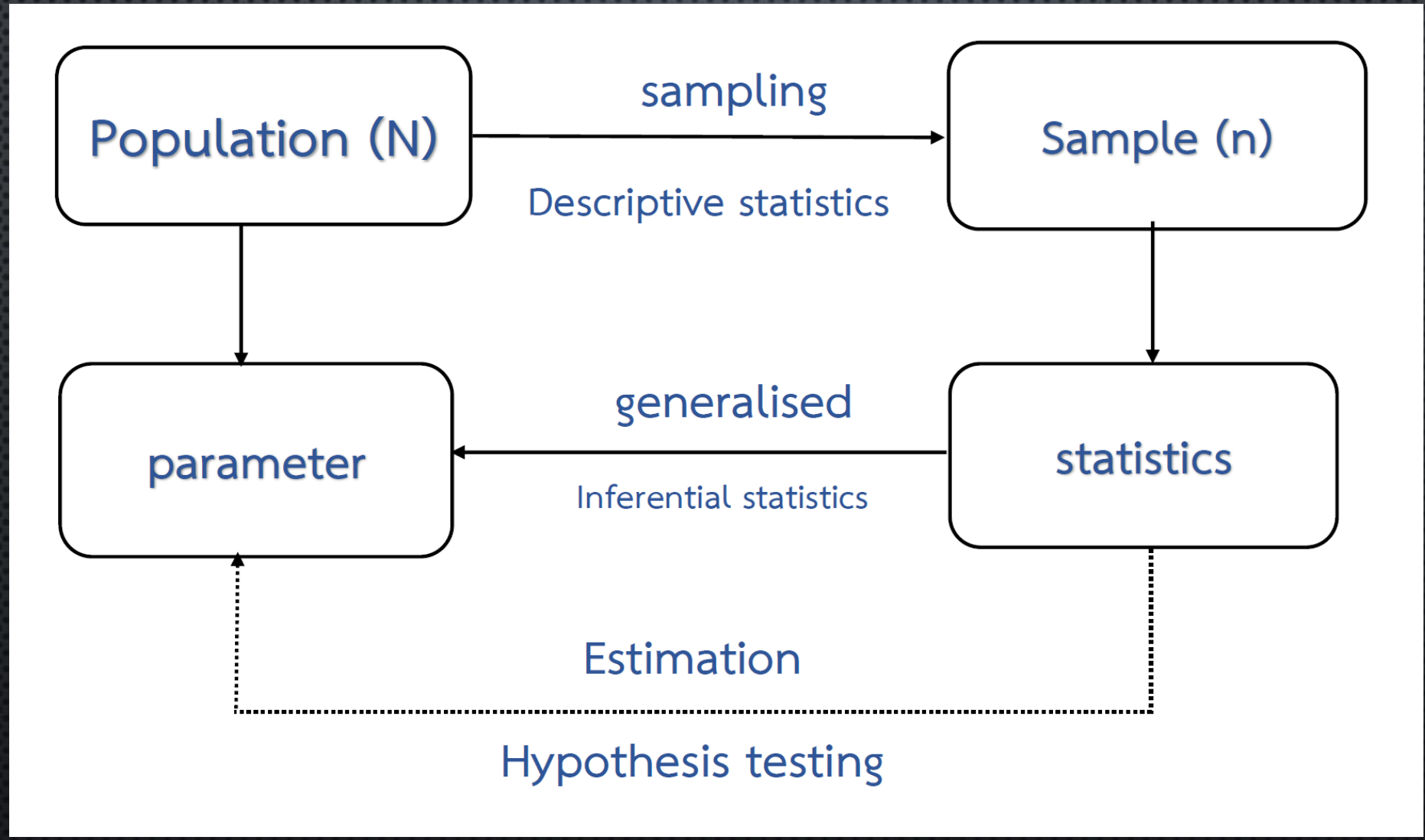
INTRODUCTION TO STATISTICS

Statistical analysis on study sample was consists of the principles and methods for:

- Collecting data and data management
- Analysing data
- Interpreting and explaining results
- Presenting data
- Making decision

DEFINITION: **POPULATION AND SAMPLE**

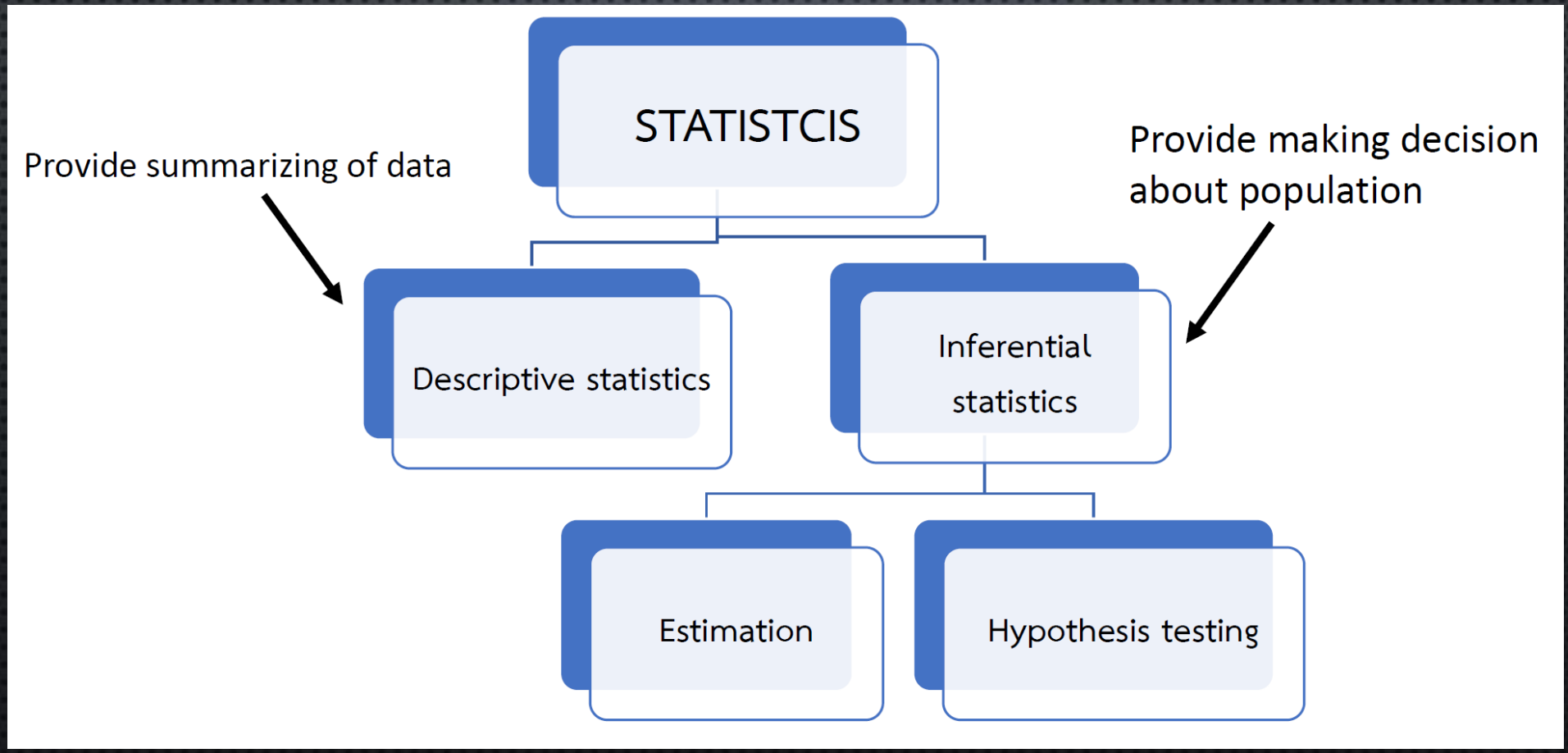
- **POPULATION** THE COLLECTION OF ALL INDIVIDUALS OR ITEMS UNDER CONSIDERATION IN A STATISTICAL STUDY
- **SAMPLE** THE PART OF THE POPULATION FROM WHICH INFORMATION IS COLLECTED


Population (N)
sampling
Sample (n)
Descriptive statistics
parameter
generalised
statistics
Inferential statistics
Estimation
Hypothesis testing

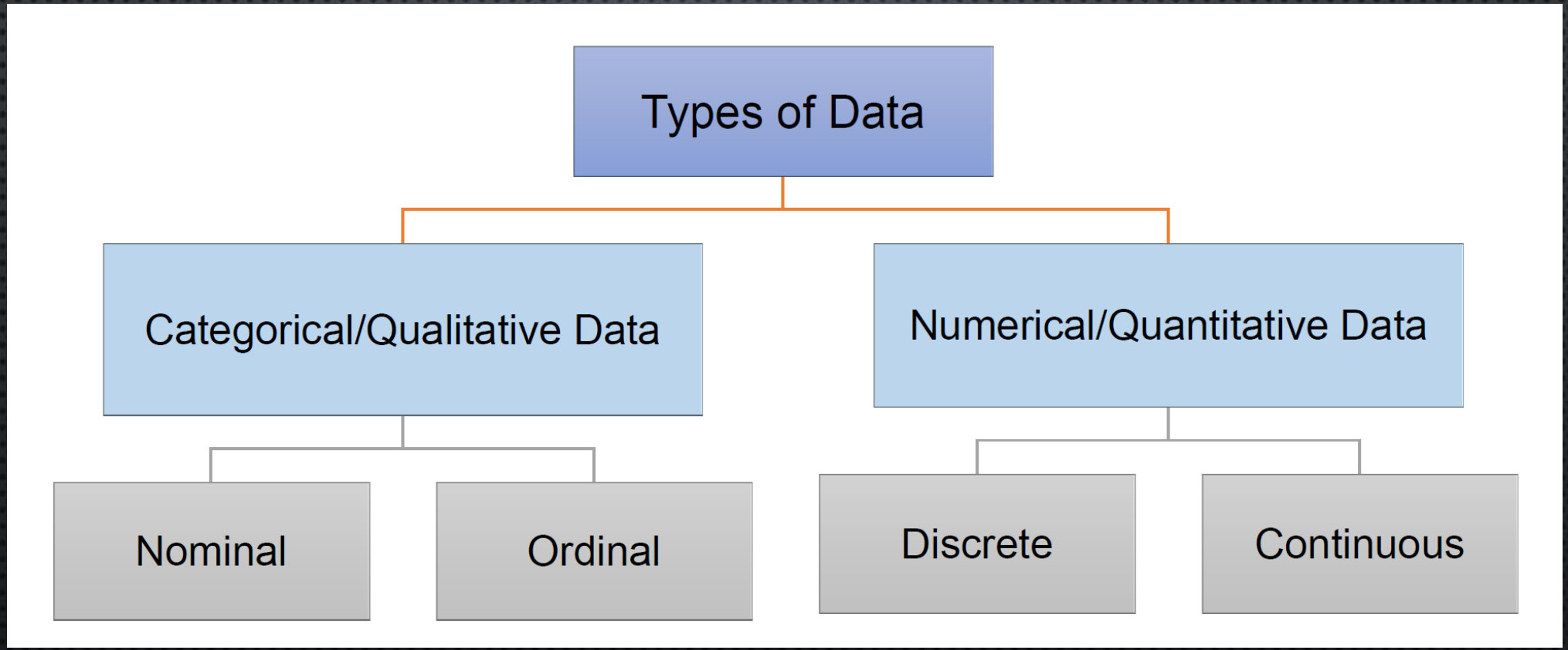
EXAMPLE

	Parameter	statistics
Mean	μ	$\bar{x}$
Standard deviation	σ	s
Variance	σ^2	s^2
Proportion	π	P

DESCRIPTIVE AND INFERENTIAL STATISTICS



TYPE OF DATA


Types of Data
Categorical/Qualitative Data
Numerical/Quantitative Data
Nominal
Ordinal
Discrete
Continuous

Level of measurement

Categorical data

- Nominal data
  - Blood groups: A/B/AB/O
  - Sex: Male/Female -> Binary or Dichotomous
- Ordinal data
  - Staging systems for cancers: Stage I/II/III/IV
  - Degrees of injuries: Mild/Moderate/Severe

	Gender	Age	Clinical	Clinical_o~s	Patho	Patho_others	Staging_T	Staging_N	Size	R	Hos_stay	DOO	Operation
1	male	67	juandice		AmpulCA		3	0	2.5	0	13	6/16/2017	Whipple
2	male	58	ABDdisc		other	CP	0	0	5	0	27	7/27/2017	PPPD
3	female	79	juandice		PAcancer		3	0	3.5	0	11	8/28/2017	PPPD
4	male	52	ABDdisc		PAcancer		3	0	13	1	9	11/3/2017	Whipple
5	female	60	juandice		PAcancer		3	2	4	1	37	11/15/2017	Whipple
6	male	64	incidental		PNET		3	0	6	0	25	11/24/2017	Whipple
7	female	60	weightloss		PAcancer		4	0	1.2	0	11	1/5/2018	PPPD
8	female	53	juandice		PAcancer		2	0	2.5	0	37	8/28/2019	Whipple
9	male	82	juandice		PAcancer		2	2	3	0	12	12/12/2018	Whipple
10	male	58	juandice		AmpulCA		2	0	1.2	0	9	11/23/2018	Whipple
11	male	58	juandice		DuoCA		2	0	4.5	0	16	9/10/2018	Whipple
12	male	52	juandice		PAcancer		4	0	4	0	37	8/29/2018	Whipple
13	female	64	juandice		CHOca		3	0	1	0	19	8/7/2018	PPPD
14	male	54	juandice		PAcancer		4	0	8.6	0	11	7/6/2018	Whipple
15	female	57	other	GI Bleed	PNET		3	0	4.6	0	10	7/3/2018	PPPD
16	male	62	other	Fever	AmpulCA		3	1	3.2	0	13	6/18/2018	PPPD
17	female	60	juandice		PAcancer		3	0	3.5	1	12	5/17/2018	PPPD
18	female	57	ABDdisc		PAcancer		4	1	2.8	1	14	5/3/2018	Whipple
19	male	59	weightloss		PAcancer		2	1	4.5	0	9	4/27/2018	Whipple
20	female	67	other	Steatorlea	PAcancer		2	0	4	0	10	3/13/2018	Whipple
21	female	62	juandice		PAcancer		3	0	5.4	0	12	2/20/2018	Whipple
22	female	59	ABDdisc		PAcancer		4	1	3.4	1	9	1/31/2018	Whipple
23	male	54	juandice		other	chronic pancreatitis	0	0	0	0	8	1/24/2018	Whipple
24	male	46	juandice		other	villous adenoma	0	0	2.1	0	32	6/22/2017	PPPD
25	female	58	ABDdisc		AmpulCA		1b	0	5	0	44	8/3/2017	PPPD
26	male	75	juandice		AmpulCA		2	0	2.6	0	21	7/13/2017	PPPD
27	female	76	weightloss		AmpulCA		2	0	1.9	0	16	7/11/2017	PPPD
28	male	45	juandice		other	Inflamation	0	0	8.5	0	10	9/4/2017	PPPD
29	male	72	juandice		PAcancer		2	1	2.2	1	12	9/20/2017	Whipple
30	female	63	juandice		AmpulCA		4	2	2.5	0	27	3/30/2017	PPPD
31	male	63	juandice		CHOca		2	1	2.5	0	25	3/22/2017	Whipple

Level of measurement

Numerical data

- Discrete data
  - A count data that involves only integer values.
  - No decimal point.
  - Example: number of patients who visit OPD.
- Continuous data
  - All values of numerical data that can measure include decimal point.
  - Not always clean and integer number.
  - Example weight, height, BMI, laboratory results.

	BMI	Panche_duct	Panc_risk	Anastomosis	Stent_place	Omental	Weight	Height	ASA	Blood_loss	Optime	Pan_fistula	Grade
1	22.84	5	low	1	1	2	64	167.4	3	250	420	no	
2	17.36	10	low	2	2	1	45	161	2	100	345	no	
3	17.67	8	low	2	0	2	43	156	3	250	375	no	
4	20.81	10	low	1	0	2	63	174	2	2200	660	no	
5	22.15	6	low	1	1	1	56	159	3	1200	510	yes	
6	26.08	8	low	1	0	2	71	165	3	1700	630	no	
7	18.67	7	low	1	0	1	42	150	2	300	345	no	
8	29.48	5	low	2	0	1	69	153	2	3000	565	no	
9	22.41	5	low	1	1	1							
10	19.60	5	low	1	0	1							
11	18.37	3	low	1	1	1							
12	22.06	5	low	1	1	2	69						
13	22.89	4	low	1	1	2							
14	22.48	15	low	1	0	2							
15	23.44	6	low	1	1	1	63						
16	30.36	8	low	1	0	2	85						
17	18.52	5	low	1	2	2							
18	18.63	5	low	1	2	2	47						
19	21.19	6	low	1	0	2	59						
20	22.94	10	low	1	0	2	53						
21	23.20	5	low	1	1	2	54						
22	24.46	4	low	3	1	2							
23	22.58	5	low	1	1	2							
24	22.21	3	moderate	2	2	1							
25	22.43	5	moderate	2	2	1							
26	20.70	4	moderate	2	2	1							
27	17.98	4	moderate	1	0	1							
28	27.70	3	moderate	2	1	1							
29	19.20	3	moderate	1	1	2							
30	35.09	4	moderate	2	2	1							
31	24.61	4	moderate	4	1	2							
32	19.96	3	moderate	2	2	1	44						

	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V
1	ADMDATE	DISDATE	Diameter of	Cell differentialtion	Number of tumor	number of tumor2	Number of positive	Number of LN can be		Cystic node	Resection margin(	resection margin(	Lympho-vascular	site of recurrence	Recurrence	Time to reccurence(month)	Time to Death(month)
2	10/2/2002	21/2/2002	12	well	Large tumor with sateli			0			R0	20	pos	Liver, pulmonary		2	7
3	21/11/2002	20/12/2002	3.5		1		0	1			R0	<1	neg	No		no	NA
4	20/5/2003	18/7/2003	3.5		1		1	2			R1		pos	Bile duct		14	NA
5	7/7/2003	21/7/2003	5	mucinou	1						R1		pos	Surgical bed,LN		16	21
6	24/8/2003	7/9/2003	5.7		1		0	0		0	R2		neg	Pulmonary recurrence, pleural		4	7
7	13/2/2006	23/2/2006	5	bile duct	1						R1			Surgical bed , liver , LN		87	
8	19/8/2007	30/8/2007	5.5	well diff,	1					1	R0	<1		No recurrence		No	Alive
9	22/8/2007	4/9/2007	7.5		1						R0	2		Intraabdominal LN, Lt adrenal gland		5	
10	16/10/2007	2/11/2007	3.3	well	1		0	9			R1			CBD, LN		23	Alive
11	23/3/2008	1/4/2008	12		Large tumor with		2	18			R0	4		Intraabdominal LN, Liver		5	NI
12	27/7/2008	26/8/2008	3	mod	Large tumor with		1	1			R0	8		Intraabdominal LN		4	NI
13	4/10/2008	25/10/2008	5		1		0	3			R1			NI		No	Alive
14	31/1/2009	4/3/2009	6	well	1		0	3		No	R0	<1		Liver		22	65
15	19/7/2009	28/7/2009	8.5		With intraductal g		0	4		0/3	R1		pos	Liver		24	NI
16	4/10/2009	6/11/2009	15	well	1		1	2		No	R0	6		Liver, peritonium		2.5	NI
17	26/10/2009	7/11/2009	6	combine	Large tumor with		0	19		No	R0	5	Pos	No		no	no
18	16/11/2009	27/11/2009	5.5	well	1		0	1		No	R0	8	neg	Liver, lungs, bone		14	NI
19	22/11/2009	2/12/2009	2.5		1		No	No		No	R1			LN at hepatoduodenal, paraaortic		10	16
20	29/11/2009	13/12/2009	6.8	well	1		No	No		No	R1		pos	Liver, Peritonium, Intrabaominal LN		15	20
21	14/12/2009	28/12/2009	10	well	1		No	No		No	R0	<1	pos	Supraclavicular LN		1	NI
22	25/1/2010	15/3/2010	6	well	1		2	5		No	R0	10	pos	Supraclavicular LN		2	NI
23	19/10/2010	3/11/2010	8	Mod	1		3	5		No	R0	25	pos	Liver, pulmonary		20	NI
24	12/12/2010	13/1/2011	9		1		1	1		No	R0	15	pos	Liver, peritonium, Rt ovary		3	NI
25	9/3/2011	30/3/2011	6	well	1		1	2		No	R0	20	Pos	Liver, peritonium		3	6
26	16/4/2011	16/5/2011	4.5		multilple		No	No		neg	R0	4	pos	No		No	No
27	27/6/2012	5/7/2012	8	mod	1		No	No		No	R0	15		Liver, lungs		7	NI
28	8/7/2012	16/7/2012	4		1		No	No		neg	R0			No		no	Alive
29	18/7/2012	3/8/2012	6	mod	1		0	1		neg	R0	10		Liver at hilar area		40	Alive
30	23/1/2013	3/2/2013	10	mod	Multiple		3	3		neg	R1		pos	Liver, LN, Adrenal gland,peritonium		2	NI
31	13/3/2013	20/3/2013	6	mod	muliple		No	No		No	R0	<1	pos	Liver		5	NI
32	18/5/2013	8/6/2013	14.5		1		1	6		No	R1		pos	Liver, Abdominal LN, Peritonium		11	22
33	14/8/2013	30/8/2013	14	mod	1		No	No		No	R0	12		Liver, diaphragm, abdominal LN		4	NI
34	18/8/2013	31/8/2013	6.5	mod	1		No	No		No	R1		pos	Peritonium		5	NI

Sheet1 | Code_Var | Patho | **Sheet2** | Intraductal growth type | Sheet3 | no.var. | data | treatment | Co-morbid | organ

TYPES OF VARIABLES

- ตัวแปร (VARIABLES) เป็นคุณลักษณะด้านต่างๆ ของสิ่งที่ต้องการศึกษา ซึ่งแบ่งเป็น 2 ประเภท คือ

  - ตัวแปรตามหรือผลลัพธ์ (DEPENDENT VARIABLES OR OUTCOME VARIABLES)

  - ตัวแปรอิสระหรือตัวแปรปัจจัย/ตัวแปรกวน (INDEPENDENT VARIABLES OR FACTOR VARIABLES/CONFOUNDING)

P = Complicated Appendicitis

OPEN

Comparison of Superficial Surgical Site Infe Delayed Primary Versus Primary Wound Complicated Appendicitis

A Randomized Controlled Trial

Boonying Siribumrungwong, MD,† Anuwat Chantip, MD,‡ Pinit Noorit, MD,§ C Winai Ungpinitpong, MD,|| Pradya Chotiya, MD,** Borwornsom Leerc Patarawan Woratanarat, MD, PhD,‡‡ Mark McEvoy, MD, PhD,§§ John and Ammarin Thakkinstian, PhD**

Objective: To compare superficial surgical site infection (SSI) rates between delayed primary wound closure (DPC) and primary wound closure (PC) for complicated appendicitis.

Background: SSI is common in appendectomy for complicated appendicitis. DPC is preferentially used over PC, but its efficacy is still controversial.

Methods: A multicenter randomized controlled trial was conducted in 6 hospitals in Thailand, enrolling patients with gangrenous and ruptured appendicitis. Patients were randomized to PC (ie, immediately wound closure) or DPC (ie, wound closure at postoperative days 3–5). Superficial SSI was defined by the Center for Disease Control criteria. Secondary outcomes included postoperative pain, length of stay, recovery time, quality of life, and cost of treatment.

Results: In all, 303 and 304 patients were randomized to PC and DPC groups, and 5 and 4 patients were lost to follow-up, respectively, leaving 300 and 298 patients in the modified intention-to-treat analysis. The superficial SSI rate was lower in the PC than DPC groups [ie, 7.3% (95% confidence interval 4.4, 10.3) vs 10% (95% CI 6.6, 13.3)] with a risk difference (RD) of −2.7% (−7.1%, 1.9%), but this RD was not significant. Postoperative pain, length of stay, recovery times, and quality of life were nonsignificantly different with corresponding RDs of 0.3 (−2.5, 3 0.02 (−0.01, 0.04), respectively. 2756) Baht cheaper than DPC (~ **Conclusions:** Superficial SSI rate DPC group, but this did not r significantly lower for the PC gr

Keywords: appendicitis, delayed wound closure, wound infection

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Appendicitis is a common pendectomy in a Korean s year, of which 21% was for co and ruptured).[1] Superficial sur complication (ie, 9%–53%[2]) simple appendicitis,[3] and adv healthcare system.[4]

Delayed primary woun World War I,[5] is an interventi SSI,[5] by reducing bacteria and at the surgical site. Instead of

TABLE 1. Baseline Characteristics of the Patient

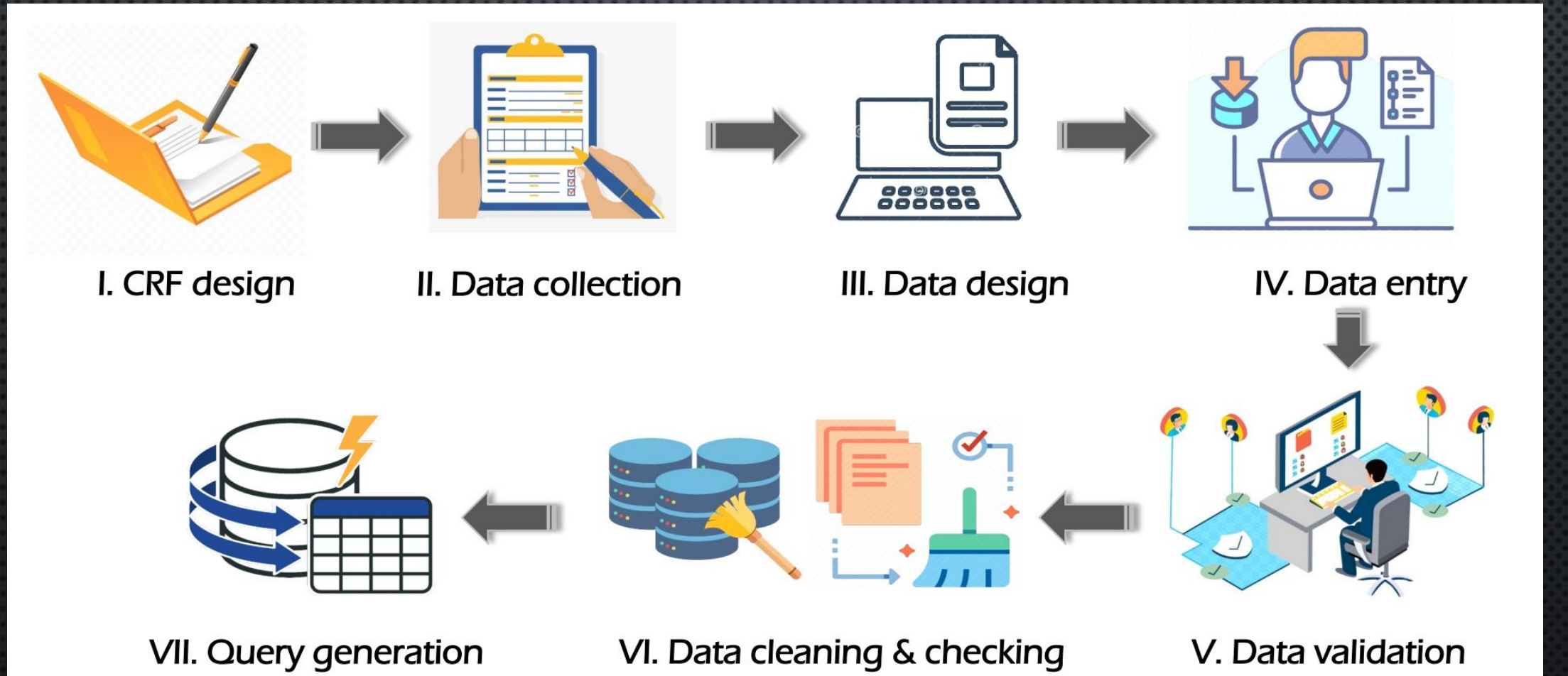
Characteristics	DPC (n = 304)	PC (n = 303)
Age, year, mean (SD)	46 (18.0)	45 (18.1)
Sex, number (%)		
Male	155 (51)	169 (56)
Female	149 (49)	134 (44)
BMI, kg/m^2, mean (SD)	23.4 (4.31)	23.4 (4.34)
Smoking, number (%)	45 (15)	51 (17)
ASA classification, number (%)		
Class I + II	266 (89)	257 (85)
Class III + IV	34 (11)	44 (15)
Diabetes, number (%)	31 (10.3)	20 (6.7)
Hypertension, number (%)	55 (18.2)	60 (20)
Symptom onset, h, mean (SD)	24 (15, 18)	24 (14, 18)
White blood cell count, cell/mm^3, mean (SD)	15561 (4965)	15790 (4979)
Body temperature,°C, mean (SD)	37.7 (1.0)	37.7 (1.1)
Fever, number, %		
≥37.8°C	142 (47)	148 (49)
<37.8°C	159 (53)	154 (51)
Preoperative utility, median (IQR)	0.68 (0.34, 0.80)	0.68 (0.34, 0.80)
Operative time, min, median (IQR)	47 (14, 74)	51 (18, 78)
Operative time classification, number (%)		
≤75 percentile	232 (77)	222 (74)
>75 percentile	68 (23)	80 (26)
Used of drain, number (%)	62 (20.6)	58 (19.2)
Severity, number (%)		
Gangrene	76 (25)	72 (24)
Ruptured	228 (75)	231 (76)
Intraoperative rupture	23 (7.6)	20 (6.6)
Visible wound contamination, number (%)		
Exudative fluid	81 (27)	87 (29)
Plus	118 (39)	108 (36)
Feculent material	38 (13)	38 (13)

ASA indicates American Society of Anesthesiologists; IQR, interquartile range; SD, standard deviation.

postoperative pain, and QoL were not significantly different, total costs were about 2083 Baht (~60 US$) lower in the PC than DPC groups. Although this may appear small ($60 USD and 56 Euros), this represents about 1 week's wages in Thailand.

Four approaches were applied to test the robustness of the results, that is, modified ITT with/without noninferiority test, PP, AT, and a counterfactual method. The ITT analysis is seen as the least biased because it preserves the original random allocation as recommended in the Consolidated Standards of Reporting Trials guideline.[27] However, the ITT estimate may be biased if there is protocol violation and loss to follow-up as in our study. The estimated RD was −2.7%, which may be biased away from the null because protocol violations were higher in the PC than in the DPC groups, that is, 4.6% versus 3.3%. The PP and AT analyses may be more relevant than the ITT analysis in assessing the actual effects of interventions received. The PP analysis considers only patients who were randomly allocated and complied with their allocation, whereas the AT analysis considers actual intervention received, regardless of randomization.[28] The PP analysis is prone to selection bias because the randomization is broken due to nonadherence, whereas the AT approach deals with data as if it was observational. Therefore, both approaches are potentially biased if the pattern of protocol violation and confounders are different between the 2 groups. The IV regression is applied to estimate what the intervention effect would have been (ie, counterfactual effects) if patients who were randomly assigned to PC actually received DPC, or vice versa.[29,30] The IV regression itself can adjust for observed and unobserved confounders. As a result, the RD between PC versus DPC groups was −2.8%, which was about 0.1% higher than the ITT estimate. Surprisingly, the IV regression with adjustment for covariates yielded a higher effect of PC than the IV regression without adjustment, with a RD of −3.6%. Missing data for some covariates used in the adjusted model might have played a role in this discrepancy, given the RDs of the 2 IV models were closer to each other after applying multiple imputations to fill in missing data. Analyses for all approaches using complete/unimputed and imputed data showed similar directions of intervention effect in with favor of PC, although none reached statistical significance for superiority.

DATA COLLECTION AND DATA MANAGEMENT



OBJECTIVES OF DATA MANAGEMENT

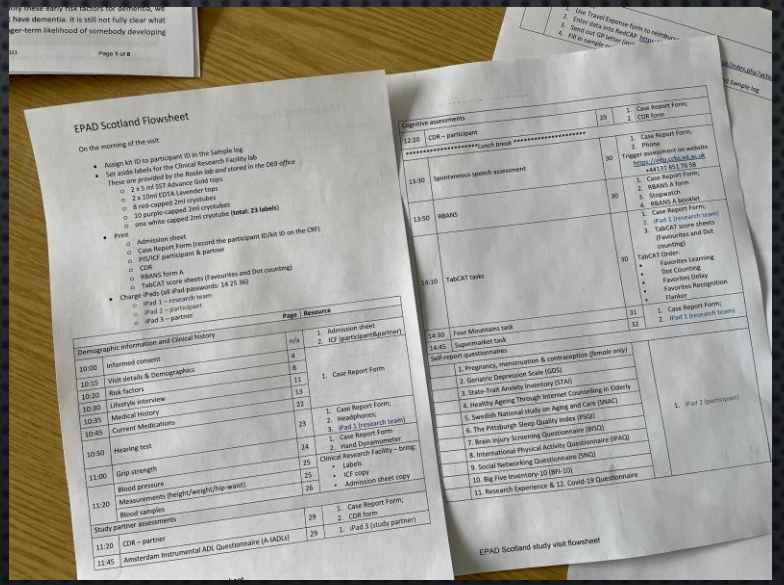
PROVIDE HIGH QUALITY OF DATA:

- ACCURATE
- COMPLETE
- CONSISTENT
- SUITABLE FORMAT FOR DATA ANALYSIS

DESIGN CASE REPORT FORM

CASE RECORD FORM (CRF): A PAPER OR ELECTRONIC FORM WHICH IS DESIGNED TO COLLECT ALL OF DATA BASED ON:

1. UNDERSTAND BASIC QUESTIONS
2. DETERMINE CRF DESIGN LAYOUT
3. DETERMINE ELEMENTS OF CRF
4. RECOMMENDATION FOR WELL-DESIGNED CRF



Form 1: Eligible data

Date of collection ☐☐/☐☐/☐☐☐☐	Name of collector ……………………………………
Site of Study ☐ 1. Ramathibodi ☐ 2. Vajira	

Please check on the box if the participants meet the inclusion criteria follow by:

- Diagnosed as uncomplicated acute appendicitis.	☐ 1. Yes	☐ 2. No
- Age > 18 and < 60 years old at admission date.	☐ 1. Yes	☐ 2. No

Willi

Inter

Form 3: Patient Characteristics

Date of enrollment ☐☐/☐☐/☐☐☐☐	ID ☐-☐☐☐☐	
Collector………………………………………………………………		
Please check × on the box		
1.อายุ	☐☐ ปี	
2. เพศ	☐ 1. ชาย	☐ 2. หญิง
3. น้ำหนัก	☐☐☐.☐ กิโลกรัม	☐ ไม่มีข้อมูล
4. ส่วนสูง	☐☐☐.☐ เซนติเมตร	☐ ไม่มีข้อมูล
5. การศึกษา	☐ 1. มัธยมศึกษาหรือต่ำกว่า	☐ 2. วิชาชีพ (ปวช., ปวส., อนุปริญญา)
	☐ 3. ปริญญาตรี	☐ 4. ปริญญาโท
	☐ 5. ปริญญาเอก	☐ 9. ไม่ทราบ
6. อาชีพหลัก	☐ 1. นักเรียน	
	☐ 2. ผู้จัดการ (เช่น ฝ่ายบริหารระดับสูง, เจ้าหน้าที่อาวุโส, ผู้จัดการด้านบริหาร การค้า และธุรกิ	
	☐ 3. วิชาชีพ (เช่น งานด้านวิทยาศาสตร์และวิศวกร, งานด้านสุขภาพ, ครูและอาจารย์ เป็นต้น)	
	☐ 4. เจ้าหน้าที่เทคนิค (เช่น เจ้าหน้าที่สารสนเทศ, และเจ้าหน้าที่เทคนิคด้านการสื่อสาร)	
	☐ 5. ผู้ที่ทำงานเสมียน (เช่น เสมียน เลขานุการ)	
	☐ 6. ผู้ที่ทำงานบริการและงานขาย (เช่น ผู้ประกอบอาหาร พนักงานเสิร์ฟและบาร์เทนเดอร์ พน	
	☐ 7. ผู้ที่ทำงานด้านเกษตรกรรม ป่าไม้ และประมง (เช่น ชาวนา ชาวประมง ชาวสวน เป็นต้น)	
	☐ 8. ผู้ที่ทำงานเกี่ยวกับฝีมือและการค้า (เช่น ช่างตีเหล็ก ช่างซ่อมเครื่องจักร ช่างซ่อมแซมและ	

Form 4: Acute Appendicitis Information

ID ☐-☐☐☐☐

A) Baseline information Collector………………………………………………………………

Please check × on the box

1. Admission	☐ 1. Yes ☐ 2. No	2. Date of admission ☐☐/☐☐/☐☐☐☐	3. Time ☐☐.☐☐
4. Chief complaint	☐ 1.Abdominal pain ☐ 2. Vomiting ☐ 3. Diarrhea ☐ 4. Other ……………………… ☐☐☐ hours		
5. Abdominal pain characteristics	5.1 Location of pain	☐ 1. Epigastrium ☐ 2. Periumbilibal ☐ 3. Other	
	5.2 Type of pain	☐ 1. Dull aching, constant ☐ 2. Colicky ☐ 3. Other	
	5.3 Migration pain	☐ 1. Yes ☐ 2. No	

☐ *11. Yellow eyes or skin*	☐ *12. Agitation or combativeness*
☐ *13. Anxiety*	☐ *14. Confusion*
☐ *15. Fear of impending death*	☐ *16. Feeling, hearing, or seeing things that are not real*

B) Continuous antibiotics

4. Type of antibiotics; please specify regimen, doses, and frequency	*Regimen*	*Doses*	*Frequency*
	☐ 1.Ceftriaxone 2g	…………………………time	……………………………… day
	☐ 2. Cefoxitin 1g	…………………………time	……………………………… day
	☐ 3. Ciprofloxacin 200 mg	…………………………time	……………………………… day
	☐ 4. Levofloxacin 750 mg	…………………………time	……………………………… day
	☐ 5. Avelox 400 mg	…………………………time	……………………………… day
	☐ 6. Metronidazole 500 mg	…………………………time	……………………………… day
	☐ 7. Meropenem 1 g	…………………………time	……………………………… day
	☐ 8. Invanz 1 g	…………………………time	……………………………… day

5. Route of administration	☐ 1. Intramuscular injection ☐ 2. Intravenous injection

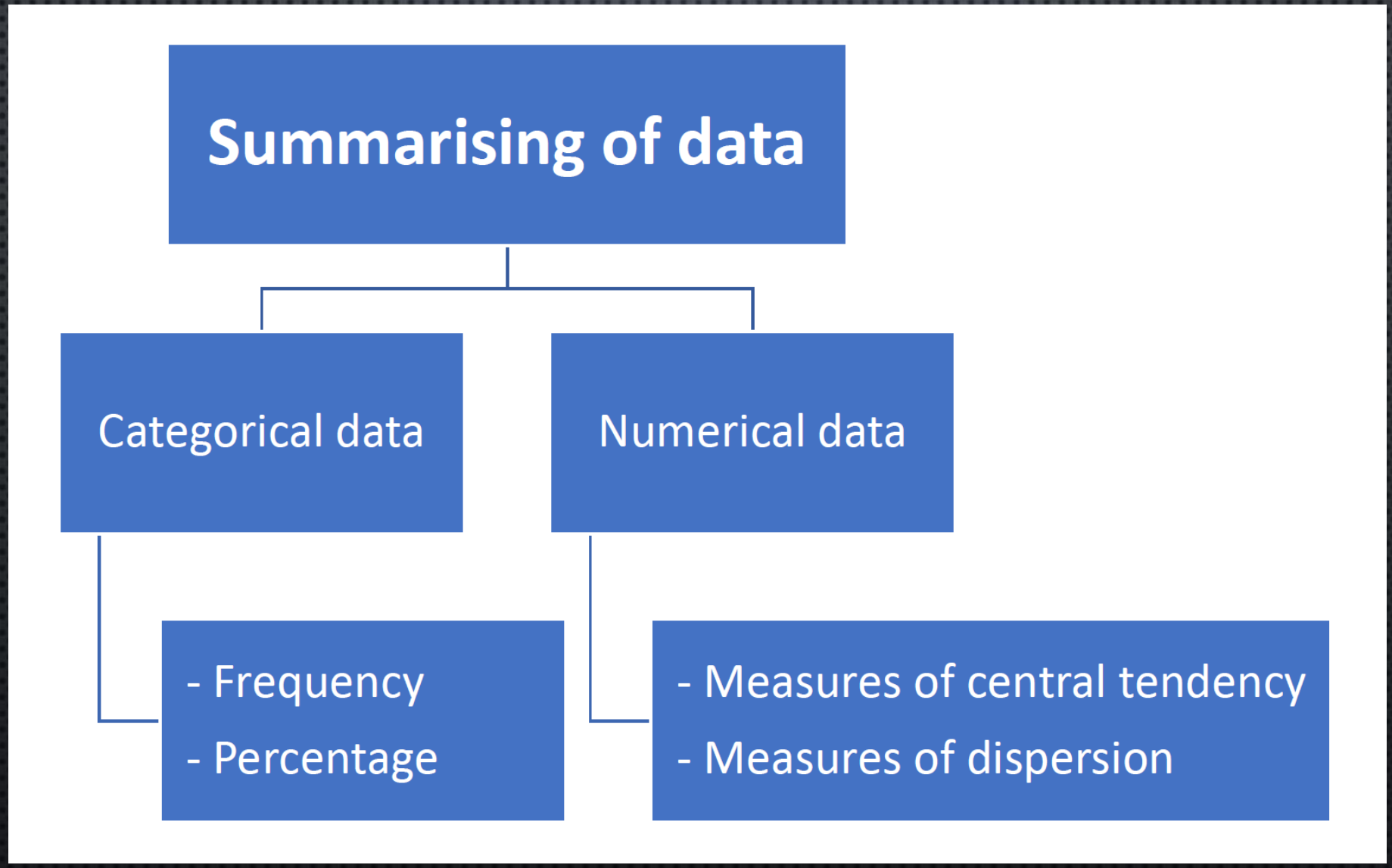
6. Home antibiotic medication; please specify regimen, doses, and frequency	*Regimen*	*Doses*	*Frequency*
	☐ 1. Ciprofloxacin 500 mg	…………………………time	……………………………… day
	☐ 2. Levofloxacin 500 mg	…………………………time	……………………………… day
	☐ 3. Metronidazole 200 mg	…………………………time	……………………………… day
	☐ 4. Avelox 400 mg	…………………………time	……………………………… day

7. Results of initial antibiotic treatment successfully Did subject have successfully after antibiotic treatment?	☐ 1. Success ☐ 2. Failure, please fill details of recurrence in Form 10

TYPES STATISTICS AND HYPOTHESIS

DESCRIPTIVE STATISTICS

- SUMMARISING CATEGORICAL DATA
- SUMMARISING CONTINUOUS DATA


Summarising of data
Categorical data
Numerical data
- Frequency
- Percentage
- Measures of central tendency
- Measures of dispersion

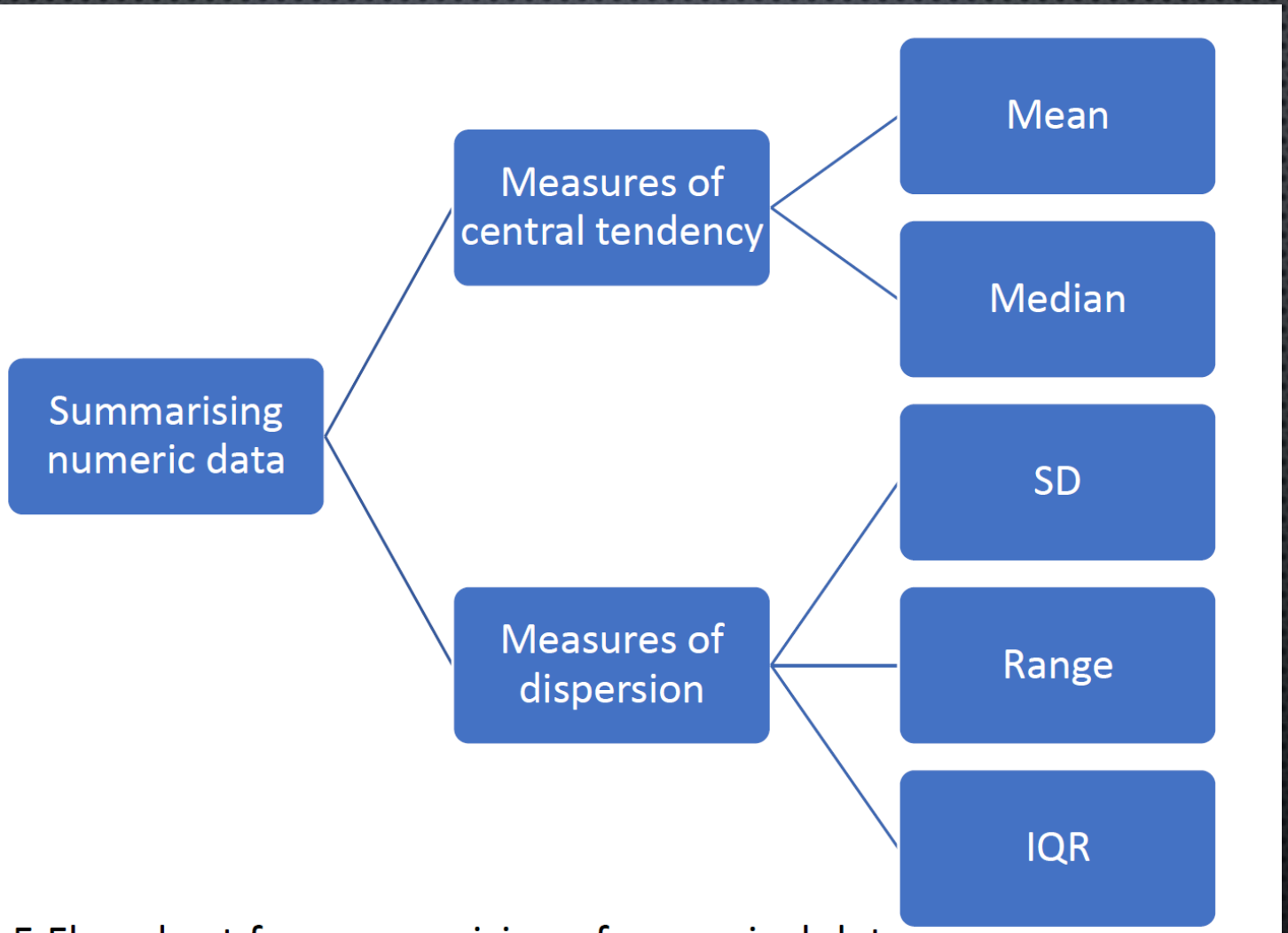


FIGURE 5 Flowchart for summarising of numerical data

MEASURES OF CENTRAL TENDENCY

Measure of central tendency is a number which indicates the middle of the distribution of data

- Mainly used measures are
  - Mean
  - Median
  - Mode

MEASURES OF CENTRAL TENDENCY

Mean is average of all numbers

$$\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n}$$

Example

- Mean of 2, 4, 6, 8, 10 is
- (2+4+6+8+10)/5 = 6

Measures of Central Tendency

Median is the middle value in the list after sorting the list

Example:

- Median of 2, 8, 6, 10, 4 is
- 2, 4, 6, 8, 10 (sorted list)

MEASURES OF DISPERSION

MODE IS NUMBER THAT OCCUR MOST FREQUENTLY.

EXAMPLE:

- MODE OF 2, 8, 6, 10, 4, 6 IS
- 2, 4, 6, 6, 8, 10 (SORTED LIST)

MEASURES OF DISPERSION

- **STANDARD DEVIATION** IS A SQUARE ROOT OF THE VARIANCE.
- THE STANDARD DEVIATION IS DENOTED BY SD.
- THE LARGER VALUE OF THE STANDARD DEVIATION INDICATES A GREATER AMOUNT OF VARIATION.

$$sd = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}}$$

MEASURES OF DISPERSION

Standard deviation:

Example:

- Find SD of 2, 4, 6, 8

$\bar{x}$ =(2+6+4+8)/4 = 5

- $(x-\bar{x})^2$
  - $(2-5)^2 = 9$
  - $(4-5)^2 = 1$
  - $(6-5)^2 = 1$
  - $(8-5)^2 = 9$

- $(x-\bar{x})^2$=9+1+1+9=20
- (n-1)=(4-1)=3
- Sqrt(20/3)=2.58

MEASURES OF DISPERSION

RANGE IS DIFFERENCE BETWEEN THE LOWEST AND HIGHEST OBSERVATIONS.

EXAMPLE:

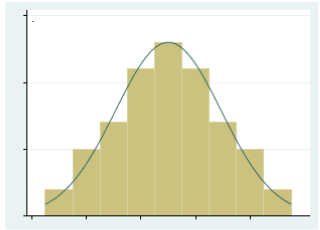
- RANGE OF 2, 8, 5, 6, 6, 4
- HIGHEST (8)-LOWEST(2) = 6

Measures of dispersion

Interquartile range (IQR)

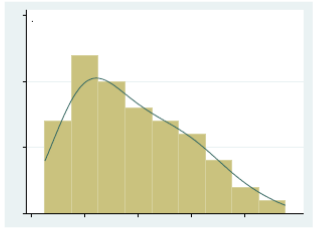
- The difference between Q1 and Q3
  - Q1 is the 25th percentile
  - Q3 is the 75th percentile

Summarizing Numerical Data



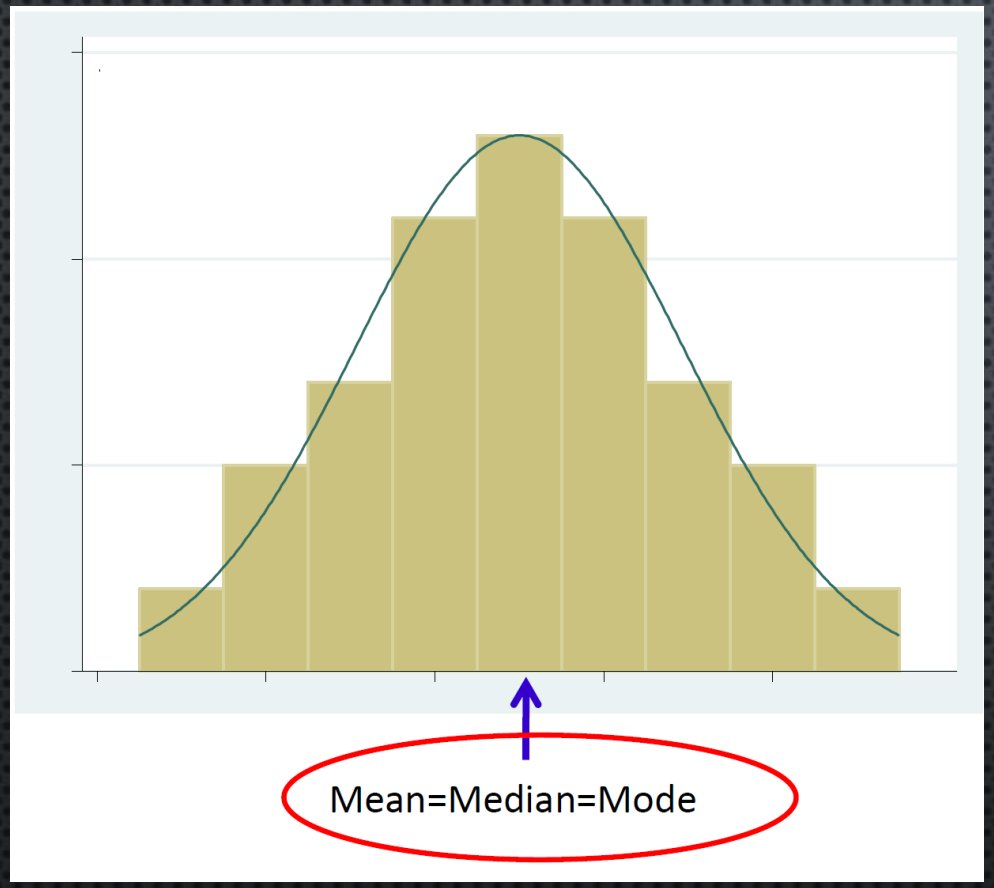
Normal

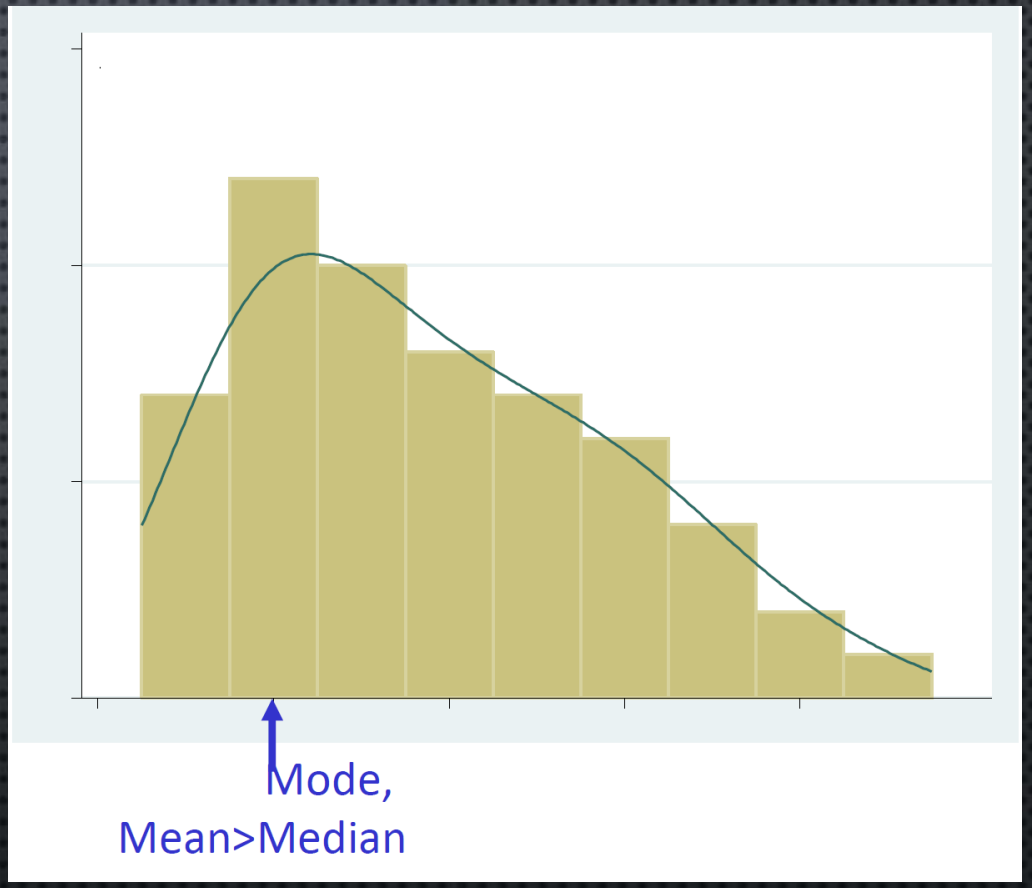
Non-normal



Mean (SD)

Median (Range),
Median (IQR)

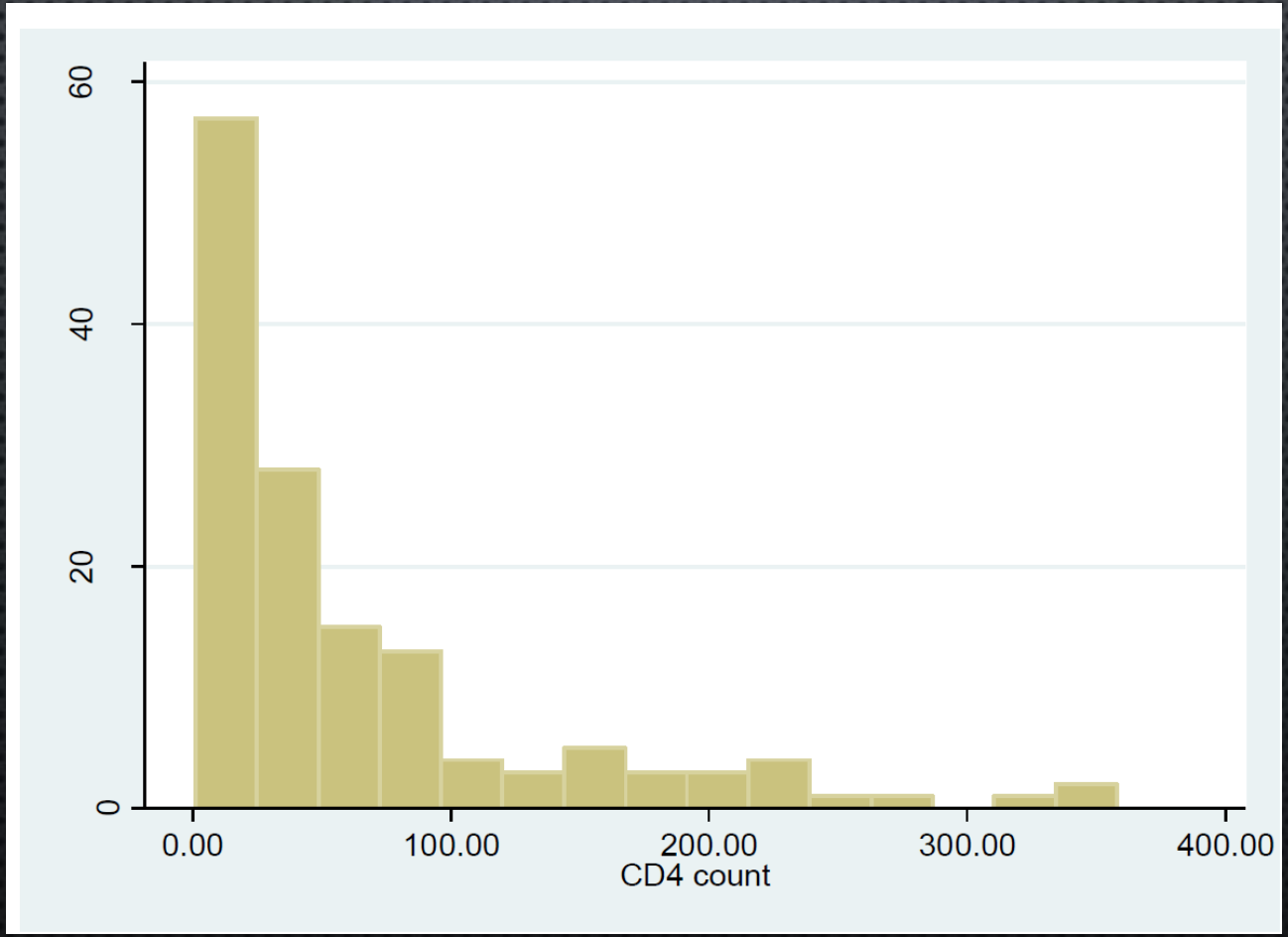

Mean=Median=Mode


Mode,
Mean>Median

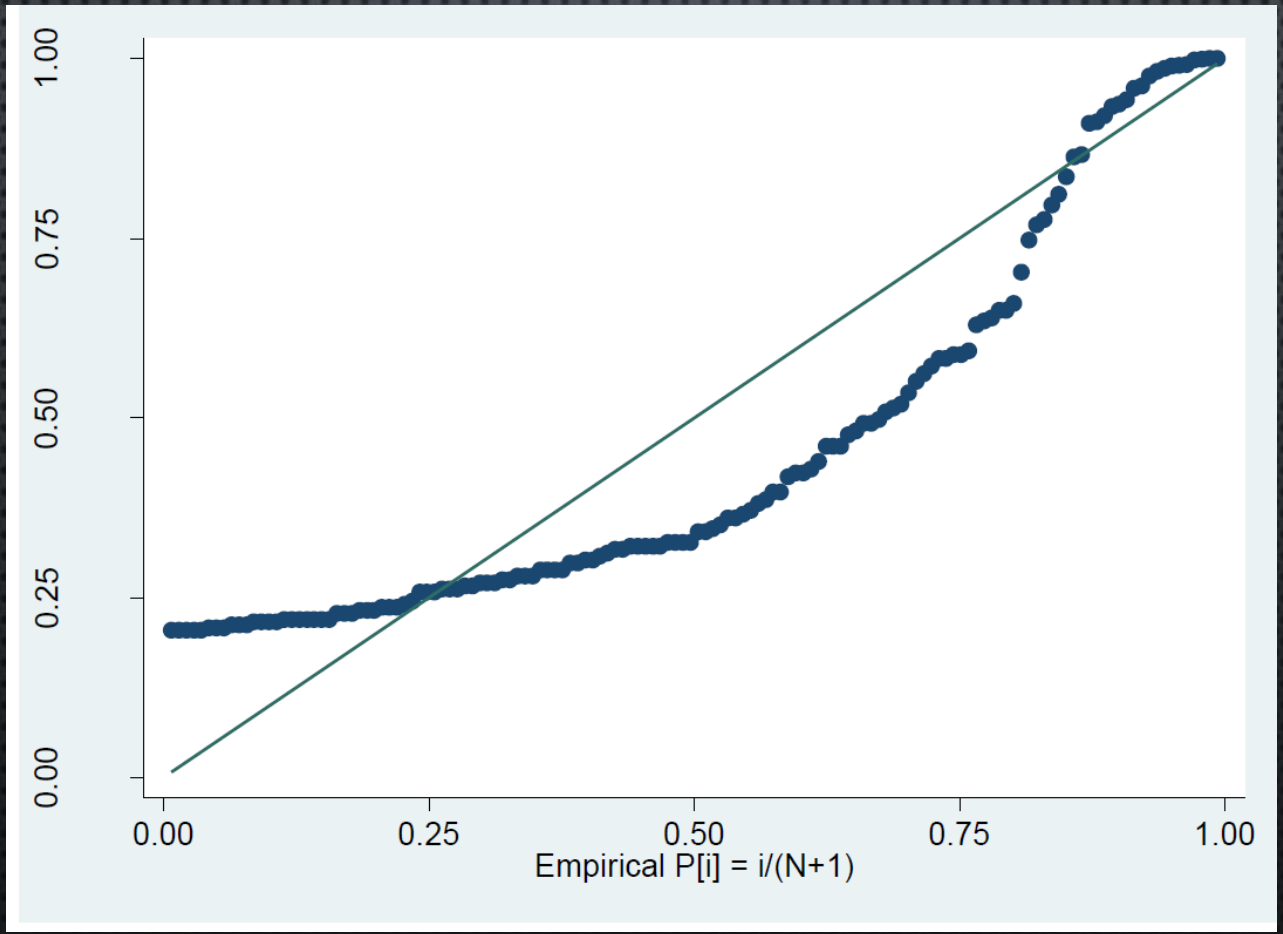
CHECKING FOR NORMAL DISTRIBUTION

- CONSTRUCT THE HISTOGRAM
- CONSTRUCT THE NORMAL PROBABILITY PLOT
- COMPARE MEAN AND MEDIAN
- COMPARE MEAN AND STANDARD DEVIATION

HISTOGRAM



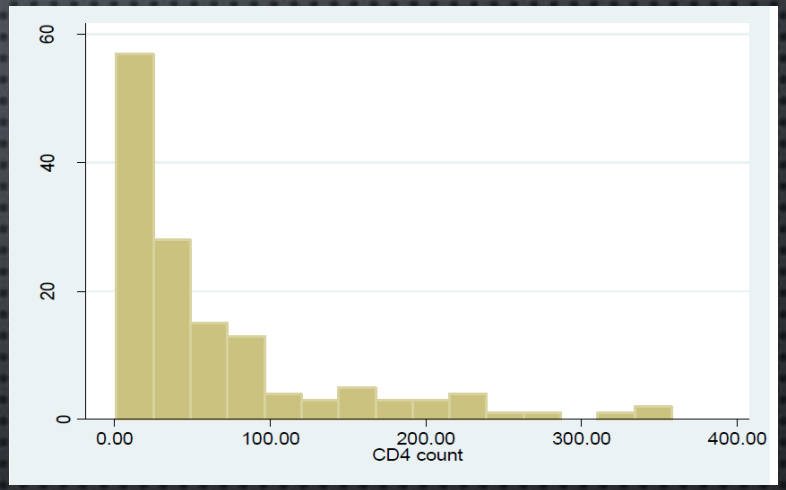
NORMAL PROBABILITY PLOT



COMPARE MEAN AND MEDIAN

FOR CD4 COUNT DATA:

- THE MEAN IS 62.4
- THE MEDIAN IS 30.5



THEREFORE, THE DISTRIBUTION OF THE CD4 COUNT DATA IS SKEWED TO THE RIGHT BECAUSE THE MEAN IS GREATER THAN THE MEDIAN.

SUMMARIZING OF NUMERICAL DATA

Characteristics	Mean (SD)
Age (year)	49.6 (14.3)
Weight (kg)	95.6 (21.7)
Height (cm)	171.5 (9.2)
BMI	32.5 (7.1)
CD4 count	62.4 (74.4)

→ 30.5 (1, 358)

```
. sum age, det

                          age
-------------------------------------------------------------
      Percentiles      Smalles+
 1%           37
 5%           42
10%           44
25%           51

50%           57

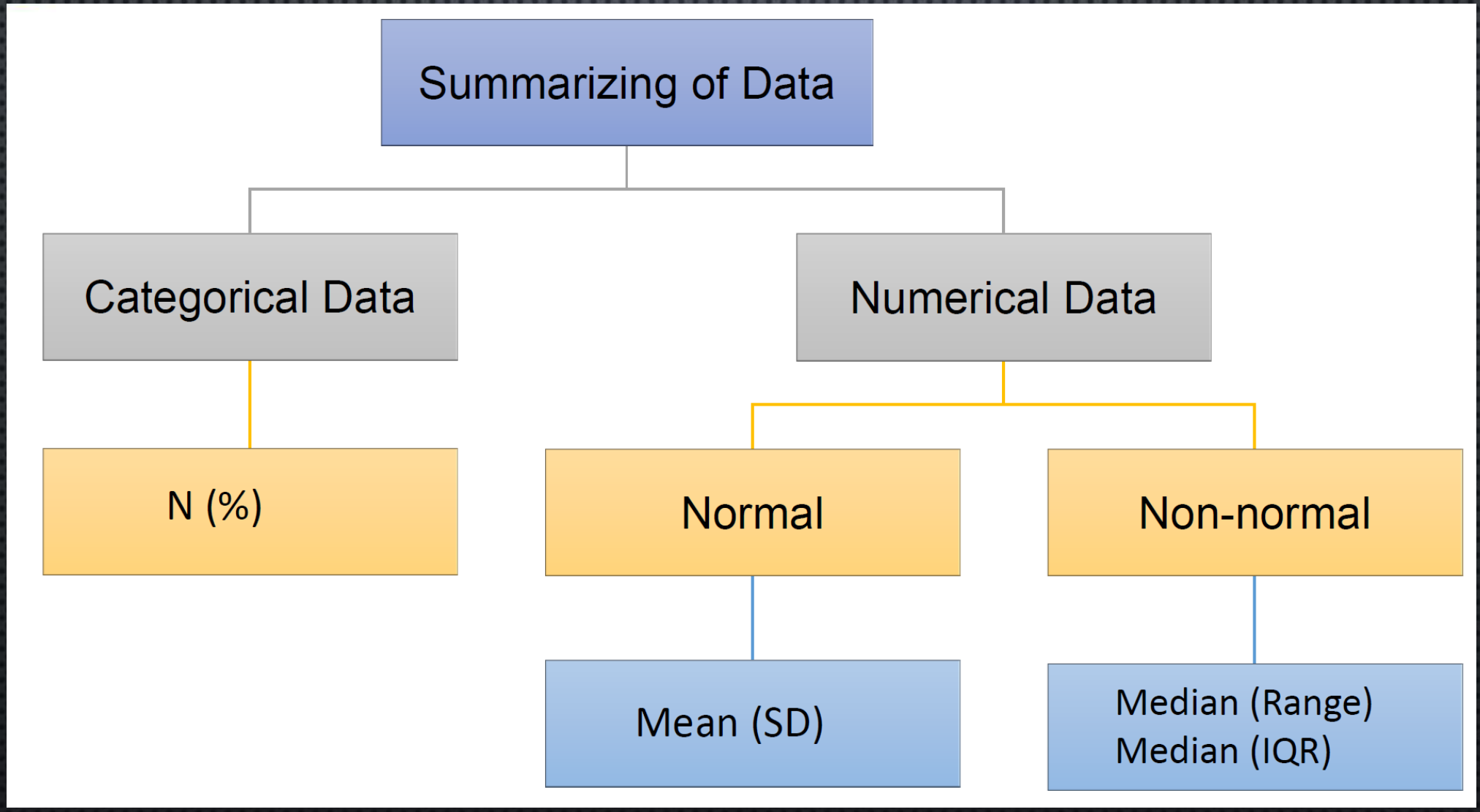
                      Larges
75%           66
90%           75
95%           76
99%           82
```

```
. sum CA_19_9 , det

                         CA_19_9
-------------------------------------------------------------
      Percentiles      Smallest
 1%            0              0
 5%            0              0
10%            0              0       Obs                  47
25%         3.33              0       Sum of wgt.          47

50%         37.2                      Mean            4653.107
                      Largest         Std. dev.       15599.02
75%        564.5          18797
90%      15529.7          25130       Variance        2.43e+08
95%        25130          27960       Skewness        5.145447
99%       100000         100000       Kurtosis        31.20741

.
```


Summarizing of Data
Categorical Data
Numerical Data
N (%)
Normal
Non-normal
Mean (SD)
Median (Range)
Median (IQR)

INFERENTIAL STATISTICS

- Parameter estimation
- Hypothesis testing

Parameter estimation

Point estimate

- Single value which is calculate from a sample

Interval estimate

- Confidence interval is calculated around a point estimate, which contains the true population parameter
- The confidence level is defined as 100(1-a)%, where a is the level of significance

HYPOTHESIS TESTING

- TYPE OF HYPOTHESIS TESTING
- TYPE OF ERROR
- TEST STATISTICS
- THE P VALUE
- STEPS OF HYPOTHESIS TESTING

HYPOTHESIS TESTING

การทดสอบสมมติฐาน คือ การทดสอบข้อสมมติ (Assumption) ซึ่งอาจจะเป็นจริงหรือไม่เป็นจริงก็ได้ (type I and II error)

		In the population	
		H_0 is true	H_0 is false
Statistical decision based on sample	Reject H_0	$\boldsymbol{\alpha}$ **(Type I error)**	$1-\beta$ (power of test)
	Do not Reject H_0	$1-\alpha$ (Confidense)	$\boldsymbol{\beta}$ **(Type II error)**

แนวความคิดในการทดสอบสมมติฐาน

- เพื่อนำไปสู่การตัดสินและการสรุปผลโดยตั้งอยู่บนพื้นฐานของหลักฐานที่ได้จากการสุ่มตัวอย่าง
- การตัดสินบนกลุ่มตัวอย่างอาจจะมีความผิดพลาด (ERROR) เกิดขึ้นได้
  - TYPE I ERROR OR α ERROR คือ โอกาสที่ผลการศึกษาจะปฏิเสธความจริง
  - TYPE II ERROR OR β ERROR คือ โอกาสที่ผลการศึกษาจะยอมรับสิ่งที่ไม่ใช่ความจริง

		Actual condition in the population	
		without disease	with diseaase
Statistical decision based on sample	Positive	α (false positive)	$1-\beta$ (true positive/ sensitivity)
	Negative	$1-\alpha$ (true negative/specificity)	β (false negative)

TYPE OF HYPOTHESES

A NULL HYPOTHESIS

- $H0$
  - A POPULATION PARAMETER IS ASSUMED TO BE TRUE OR THERE IS NO DIFFERENCE BETWEEN GROUPS

AN ALTERNATIVE HYPOTHESIS

- HA
  - IT IS OPPOSED TO A NULL HYPOTHESIS

TYPE OF HYPOTHESES

- A one-tailed test
- Test for one direction of real difference
- Less than (<) or greater than (>)

- A two-tailed test
- Test for two directions of real difference
- Not equal to (≠)

EXAMPLE

- H_0: the mean birth weight of live born infants who were delivered by mothers with low socioeconomics status **is equal to 3,000 grams** (μ=3,000 GRAMS)

- H_A: the mean birth weight of live born infants who were delivered by mothers with low socioeconomics status **is different from 3,000 grams** (μ≠3,000 GRAMS)

THE P VALUE

- THE P VALUE OBTAINING A SAMPLE OUTCOME IS COMPARED TO THE LEVEL OF SIGNIFICANCE.
  - IF THE *P* VALUE IS LESS THAN OR EQUAL TO A THEN THE NULL HYPOTHESIS IS REJECTED
  - IF THE *P* VALUE IS GREATER THAN A THEN THE NULL HYPOTHESIS IS FAILED TO REJECT.

Steps of hypothesis testing

- Step 1 Generate the null and alternative hypothesis
- Step 2 Determine the significance level
- Step 3 Select an appropriate test statistics
- Step 4 Calculate the test statistic and corresponding p value
- Step 5 Draw a conclusion

SELECT AN APPROPRIATE TEST STATISTICS

- วัตถุประสงค์การวิจัย
- ชนิดของข้อมูล
- จำนวนกลุ่มข้อมูล
- ความสัมพันธ์ของข้อมูลแต่ละกลุ่ม

การเลือกใช้สถิติสำหรับหาความสัมพันธ์ของงานวิจัยเชิงวิเคราะห์

ประเภทข้อมูลตัวแปรปัจจัย (Independent)	ประเภทข้อมูลตัวแปรผล (outcome)		
	Categorical	Continuous	Time to event
Categorical 2 group	**Chi square** or Fisher's exact	**Independent t test** or **Pairs t test**	Cox proportional hazards regression
Categorical >2 group	Chi square or Fisher's exact	**ANOVA** or Kruskal Wallis	Cox proportional hazards regression
Continuous	**Logistic regression**	Pearson's correlation coefficient(r) or linear regression	Cox proportional hazards regression

การเลือกใช้สถิติสำหรับหาปัจจัยเสี่ยงของการวิจัยเชิงวิเคราะห์

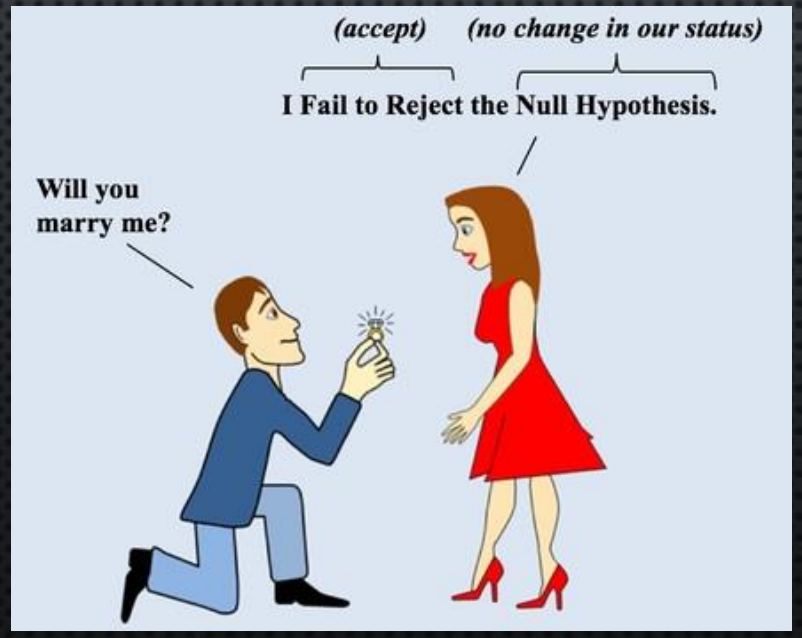
ประเภทข้อมูลตัวแปรปัจจัย	ประเภทข้อมูลตัวแปรผล (**outcome**)	
	Categorical	Time to event
Categorical 2 group or more group	OR, RR, logistic regression	HR, Cox proportional hazards regression
Ordinal	OR, RR, logistic regression	HR, Cox proportional hazards regression
Continuous	OR, RR, logistic regression	HR, Cox proportional hazards regression

CATEGORICAL DATA

CHI-SQUARE TEST

ตัวอย่างคำถามการวิจัย

- ผู้ป่วยเพศหญิงและชาย มี***สัดส่วน***ของชนิดของการผ่าตัดแตกต่างกันหรือไม่



ข้อตกลงเบื้องต้นในการใช้ CHI-SQUARE TEST

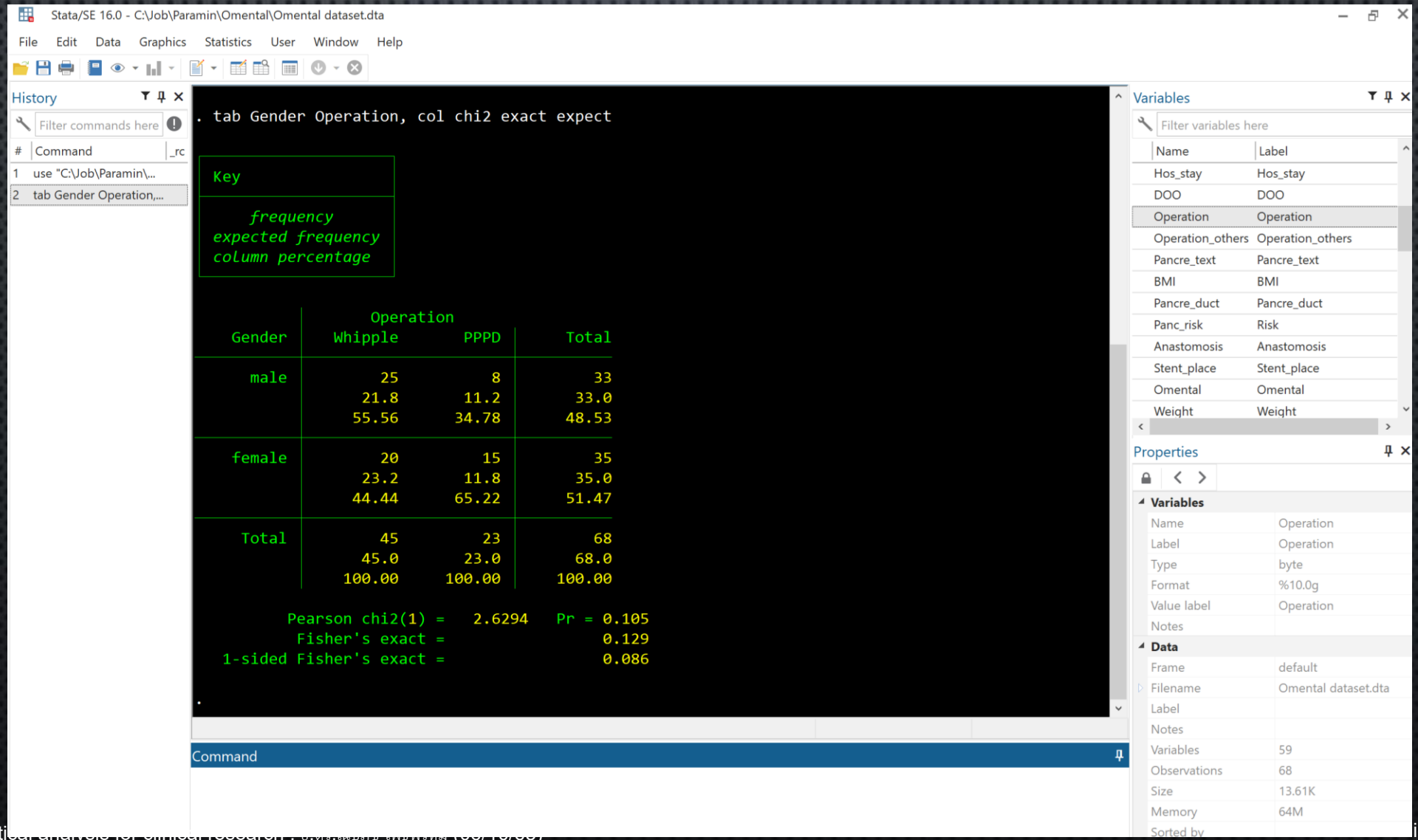
- ประชากร 2 กลุ่มหรือมากกว่า และเป็นอิสระต่อกัน
- ข้อมูลเป็น CATEGORICAL DATA
- ค่าคาดหวัง (EXPECTED FREQUENCY) น้อยกว่า 5 ไม่เกิน 20% ของจำนวน CELL ทั้งหมด

*******ถ้าไม่เป็นไปตามข้อตกลงนี้ให้ใช้ FISHER'S EXACT TEST*******

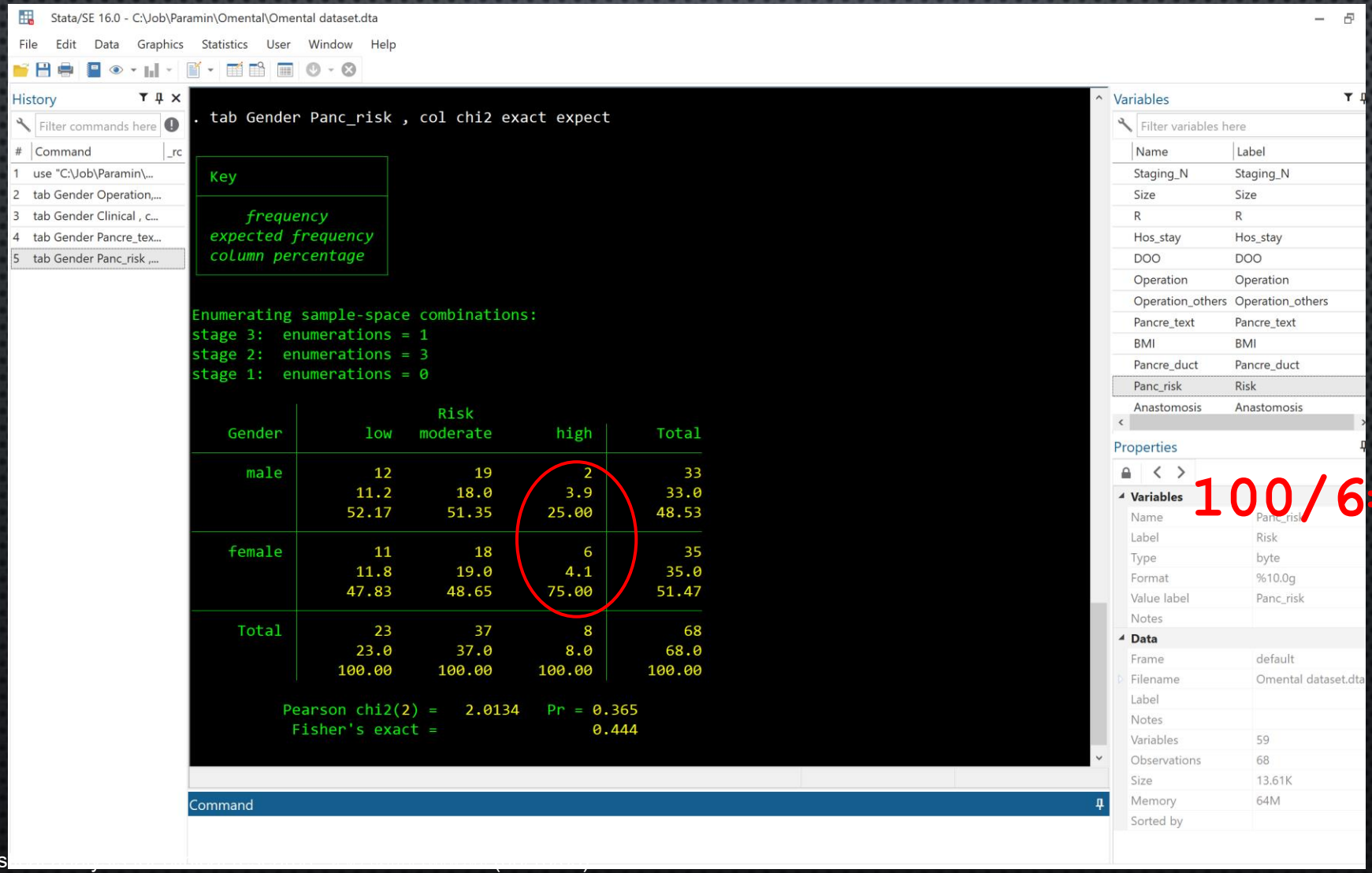
EXAMPLE

	Gender	Age	Clinical	Clinical_o~s	Patho	Patho_others	Staging_T	Staging_N	Size	R	Hos_stay	DOO	Operation	Op
1	male	67	juandice		AmpulCA		3	0	2.5	0	13	6/16/2017	Whipple	
2	male	58	ABDdisc		other	CP	0	0	5	0	27	7/27/2017	PPPD	
3	female	79	juandice		PAcancer		3	0	3.5	0	11	8/28/2017	PPPD	
4	male	52	ABDdisc		PAcancer		3	0	13	1	9	11/3/2017	Whipple	
5	female	60	juandice		PAcancer		3	2	4	1	37	11/15/2017	Whipple	
6	male	64	incidental		PNET		3	0	6	0	25	11/24/2017	Whipple	RP
7	female	60	weightloss		PAcancer		4	0	1.2	0	11	1/5/2018	PPPD	
8	female	53	juandice		PAcancer		2	0	2.5	0	37	8/28/2019	Whipple	
9	male	82	juandice		PAcancer		2	2	3	0	12	12/12/2018	Whipple	
10	male	58	juandice		AmpulCA		2	0	1.2	0	9	11/23/2018	Whipple	
11	male	58	juandice		DuoCA		2	0	4.5	0	16	9/10/2018	Whipple	
12	male	52	juandice		PAcancer		4	0	4	0	37	8/29/2018	Whipple	
13	female	64	juandice		CHOca		3	0	1	0	19	8/7/2018	PPPD	
14	male	54	juandice		PAcancer		4	0	8.6	0	11	7/6/2018	Whipple	
15	female	57	other	GI Bleed	PNET		3	0	4.6	0	10	7/3/2018	PPPD	
16	male	62	other	Fever	AmpulCA		3	1	3.2	0	13	6/18/2018	PPPD	
17	female	60	juandice		PAcancer		3	0	3.5	1	12	5/17/2018	PPPD	
18	female	57	ABDdisc		PAcancer		4	1	2.8	1	14	5/3/2018	Whipple	
19	male	59	weightloss		PAcancer		2	1	4.5	0	9	4/27/2018	Whipple	
20	female	67	other	Steatorlea	PAcancer		2	0	4	0	10	3/13/2018	Whipple	
21	female	62	juandice		PAcancer		3	0	5.4	0	12	2/20/2018	Whipple	
22	female	59	ABDdisc		PAcancer		4	1	3.4	1	9	1/31/2018	Whipple	
23	male	54	juandice		other	chronic pancreatitis	0	0	0	0	8	1/24/2018	Whipple	
24	male	46	juandice		other	villous adenoma	0	0	2.1	0	32	6/22/2017	PPPD	
25	female	58	ABDdisc		AmpulCA		1b	0	5	0	44	8/3/2017	PPPD	
26	male	75	juandice		AmpulCA		2	0	2.6	0	21	7/13/2017	PPPD	

CHI-SQUARE TEST BY STATA



ASSUMPTION FAILURE



100/6=16.67**

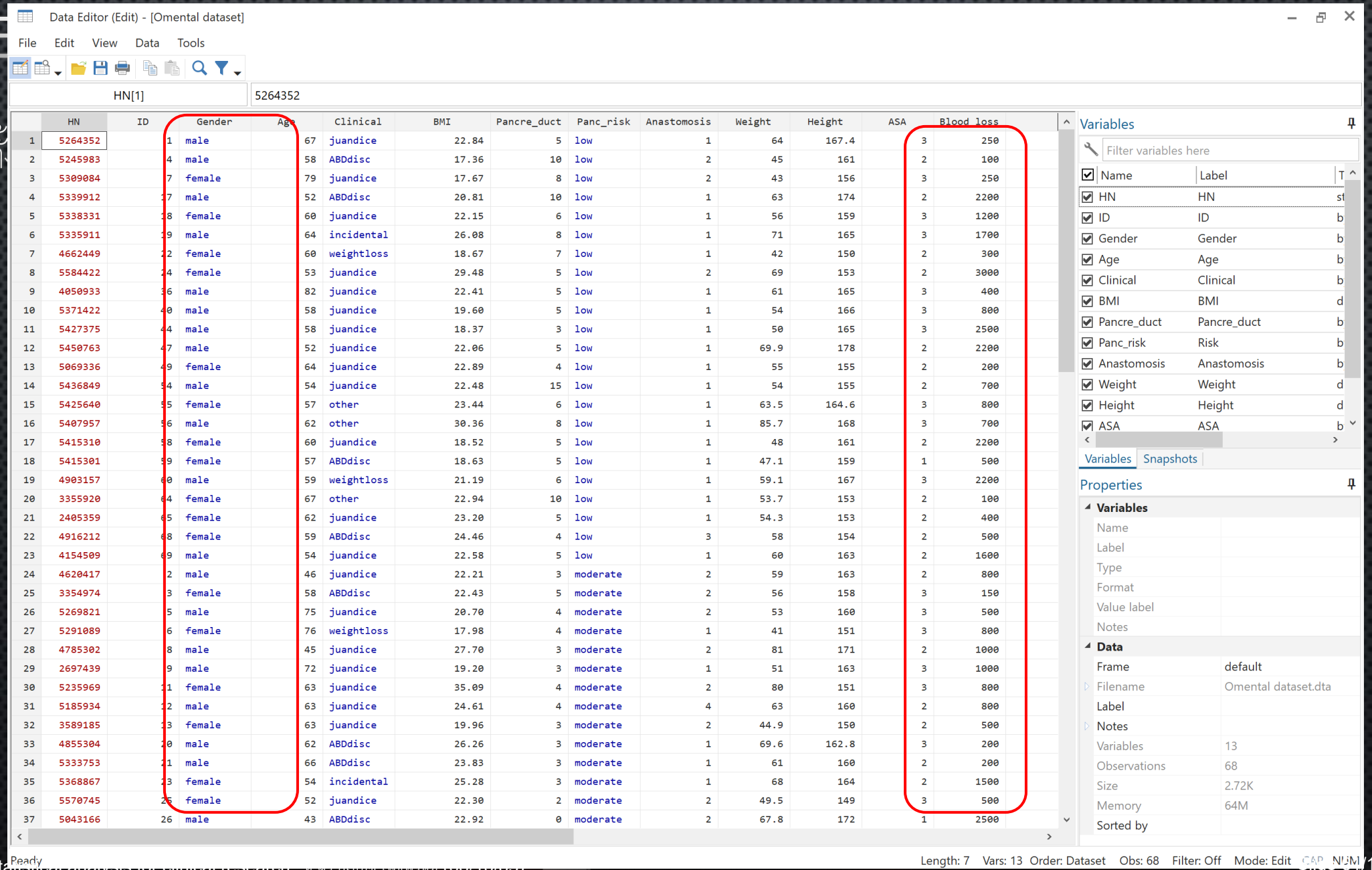
CONTINUOUS DATA

INDEPENDENT OR STUDENT T-TEST

ข้อตกลงเบื้องต้น

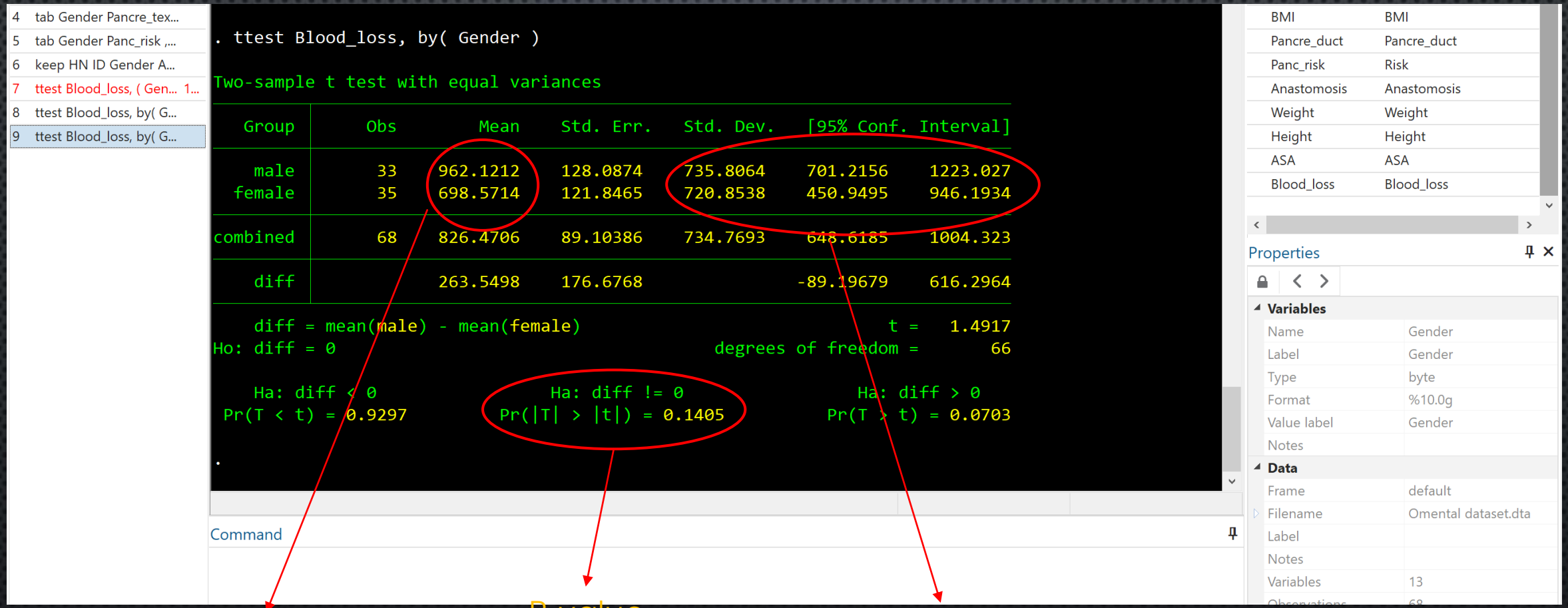
- ประชากร 2 กลุ่ม ที่เป็นอิสระต่อกัน
- ข้อมูลเป็นแบบ CONTINUOUS DATA
- การกระจายเป็นแบบ NORMAL DISTRIBUTION

หากไม่เป็นไปตามข้อตกลงเบื้องต้นให้ใช้ MANN WHITNEY U TEST, WILCOXON RANK SUM TEST



	HN	ID	Gender	Age	Clinical	BMI	Pancre_duct	Panc_risk	Anastomosis	Weight	Height	ASA	Blood_loss
1	5264352	1	male	67	juandice	22.84	5	low	1	64	167.4	3	250
2	5245983	4	male	58	ABDdisc	17.36	10	low	2	45	161	2	100
3	5309084	7	female	79	juandice	17.67	8	low	2	43	156	3	250
4	5339912	17	male	52	ABDdisc	20.81	10	low	1	63	174	2	2200
5	5338331	18	female	60	juandice	22.15	6	low	1	56	159	3	1200
6	5335911	19	male	64	incidental	26.08	8	low	1	71	165	3	1700
7	4662449	22	female	60	weightloss	18.67	7	low	1	42	150	2	300
8	5584422	24	female	53	juandice	29.48	5	low	2	69	153	2	3000
9	4050933	36	male	82	juandice	22.41	5	low	1	61	165	3	400
10	5371422	40	male	58	juandice	19.60	5	low	1	54	166	3	800
11	5427375	44	male	58	juandice	18.37	3	low	1	50	165	3	2500
12	5450763	47	male	52	juandice	22.06	5	low	1	69.9	178	2	2200
13	5069336	49	female	64	juandice	22.89	4	low	1	55	155	2	200
14	5436849	54	male	54	juandice	22.48	15	low	1	54	155	2	700
15	5425640	55	female	57	other	23.44	6	low	1	63.5	164.6	3	800
16	5407957	56	male	62	other	30.36	8	low	1	85.7	168	3	700
17	5415310	58	female	60	juandice	18.52	5	low	1	48	161	2	2200
18	5415301	59	female	57	ABDdisc	18.63	5	low	1	47.1	159	1	500
19	4903157	60	male	59	weightloss	21.19	6	low	1	59.1	167	3	2200
20	3355920	64	female	67	other	22.94	10	low	1	53.7	153	2	100
21	2405359	65	female	62	juandice	23.20	5	low	1	54.3	153	2	400
22	4916212	68	female	59	ABDdisc	24.46	4	low	3	58	154	2	500
23	4154509	69	male	54	juandice	22.58	5	low	1	60	163	2	1600
24	4620417	2	male	46	juandice	22.21	3	moderate	2	59	163	2	800
25	3354974	3	female	58	ABDdisc	22.43	5	moderate	2	56	158	3	150
26	5269821	5	male	75	juandice	20.70	4	moderate	2	53	160	3	500
27	5291089	6	female	76	weightloss	17.98	4	moderate	1	41	151	3	800
28	4785302	8	male	45	juandice	27.70	3	moderate	2	81	171	2	1000
29	2697439	9	male	72	juandice	19.20	3	moderate	1	51	163	3	1000
30	5235969	11	female	63	juandice	35.09	4	moderate	2	80	151	3	800
31	5185934	12	male	63	juandice	24.61	4	moderate	4	63	160	2	800
32	3589185	13	female	63	juandice	19.96	3	moderate	2	44.9	150	2	500
33	4855304	10	male	62	ABDdisc	26.26	3	moderate	1	69.6	162.8	3	200
34	5333753	11	male	66	ABDdisc	23.83	3	moderate	1	61	160	2	200
35	5368867	13	female	54	incidental	25.28	3	moderate	1	68	164	2	1500
36	5570745	25	female	52	juandice	22.30	2	moderate	2	49.5	149	3	500
37	5043166	26	male	43	ABDdisc	22.92	0	moderate	2	67.8	172	1	2500

ANALYSIS STUDENT T-TEST OUTPUT



Mean

P-value

SD and 95%CI

PAIRED T-TEST

ข้อตกลงเบื้องต้น

- ประชากร 2 กลุ่ม ที่เป็นไม่อิสระต่อกัน
- ข้อมูลเป็นแบบ CONTINUOUS DATA
- การกระจายเป็นแบบ NORMAL DISTRIBUTION

****หากไม่เป็นไปตามข้อตกลงเบื้องต้นให้ใช้ WILCOXON MATCHED SIGNED RANKS TEST***

Data Editor (Edit) - [dataset isara]

File Edit View Data Tools

ลำดับ[1] 1

	ลำดับ	HN	อายุ	adjuvant	วันที่ผ่าตัด	preopVanco~o	postop1mo	postop2mo	postop3mo	postop1yr
1	1	5064516	35	imiquimod	15/12/2558	4	3	4	3	3
2	2	4992436	48	kenacort	25/12/2558	5	6	4	3	3
3	3	4031064	30	imiquimod	11/12/2558	6	6	7	7	11
4	4	4412062	28	kenacort	8/1/2559	6	6	5	3	3
5	5	2364906	25	kenacort	11/1/2559	8	8	4	4	4
6	6	5095051	19	kenacort	2/2/2559	6	6	6	4	4
7	7	5074955	22	imiquimod	5/2/2559	8	8	9	9	10
8	8	5086213	23	kenacort	16/02/2559	3	3	6	5	5
9	9	3770830	60	kenacort	4/2/2559	9	11	8	7	8
10	10	5084588	26	imiquimod	23/01/2559	1	1	3	3	8
11	11	5001013	33	imiquimod	26/02/2559	7	7	9	8	11
12	12	5097555	22	kenacort	1/3/2559	6	6	5	5	6
13	13	5035035	24	kenacort	26/02/2559	9	9	8	6	4
14	14	5115409	23	kenacort	25/03/2559	4	4	3	3	3
15	15	5109335	23	imiquimod	29/03/2559	4	4	4	4	4
16	16	5095065	29	kenacort	5/4/2559	6	6	4	3	3
17	17	5118461	30	imiquimod	20/4/2559	5	6	6	6	8
18	18	5086328	21	kenacort	29/04/2559	7	7	5	5	5
19	19	5113389	20	imiquimod	17/05/2559	7	7	6	8	8
20	20	5113416	21	imiquimod	24/05/2559	4	3	3	3	3
21	21	4485708	28	imiquimod	4/3/2559	6	6	5	4	5
22	22	5107823	20	imiquimod	31/05/2559	5	3	4	4	5
23	23	4641927	20	imiquimod	5/7/2559	3	3	3	2	2
24	24	2561229	24	kenacort	15/07/2559	5	4	3	3	3
25	25	5155235	41	imiquimod	16/08/2559	5	5	5	4	4
26	26	5139724	27	imiquimod	30/08/2559	3	3	3	3	9
27	27	4950133	31	kenacort	9/9/2559	4	4	4	4	7
28	28	5131767	26	kenacort	9/9/2559	3	3	3	3	3
29	29	5150536	24	kenacort	26/08/2559	5	5	4	5	4
30	30	5048300	22	kenacort	19/08/2559	5	4	4	3	3

Variables

Filter variables here

Name	Label	T
ลำดับ	ลำดับ	b
HN	HN	lo
อายุ	อายุ	b
adjuvant	adjuvant	st
วันที่ผ่าตัด	วันที่ผ่าตัด	st
preopVancouver...	pre op (Vancouver scar ...	b
postop1mo	post op 1 mo	b
postop2mo	post op 2 mo	b
postop3mo	post op 3 mo	b
postop1yr	post op 1yr	b
complication	complication	st
ความพึงพอใจ	ความพึงพอใจ	b

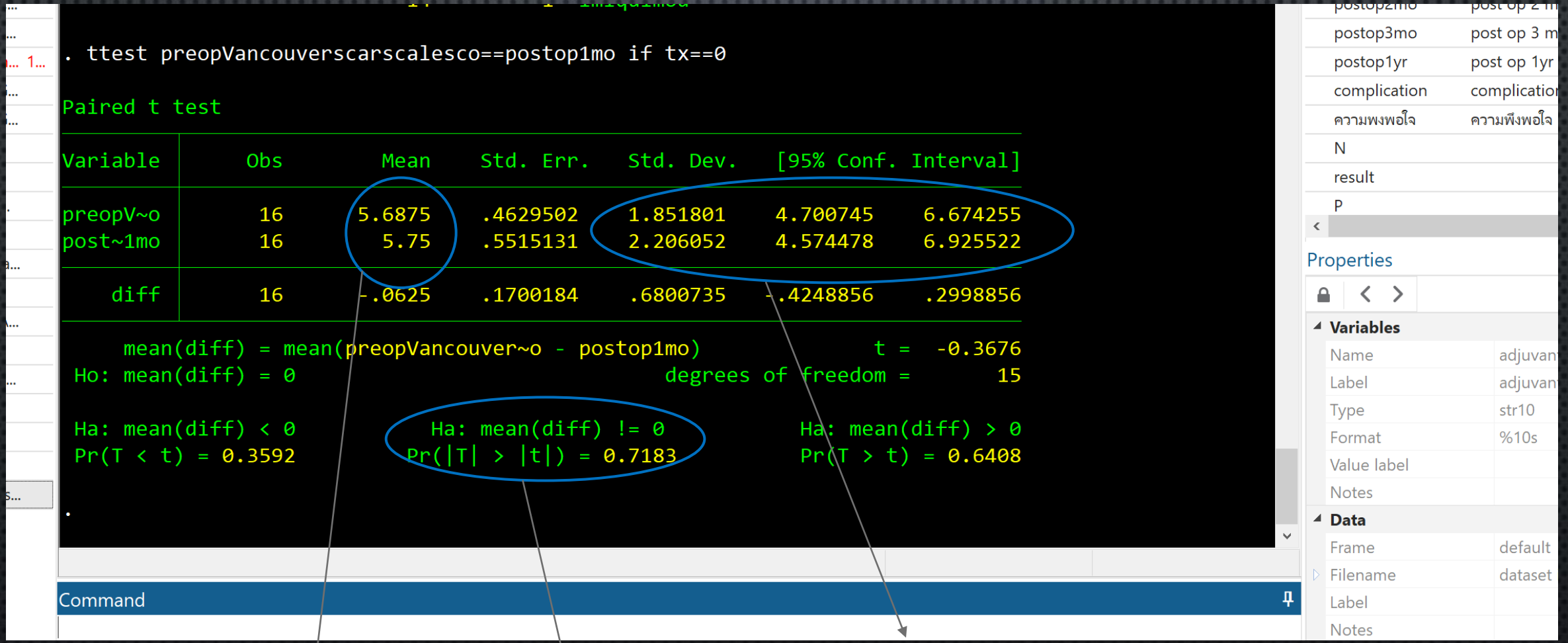
Variables Snapshots

Properties

Variables
- Name
- Label
- Type
- Format
- Value label
- Notes

Data
- Frame: default
- Filename: dataset isara.dta
- Label
- Notes

ANALYSIS OF PAIRED T-TEST OUTPUT



Mean

P-value

SD and 95%CI

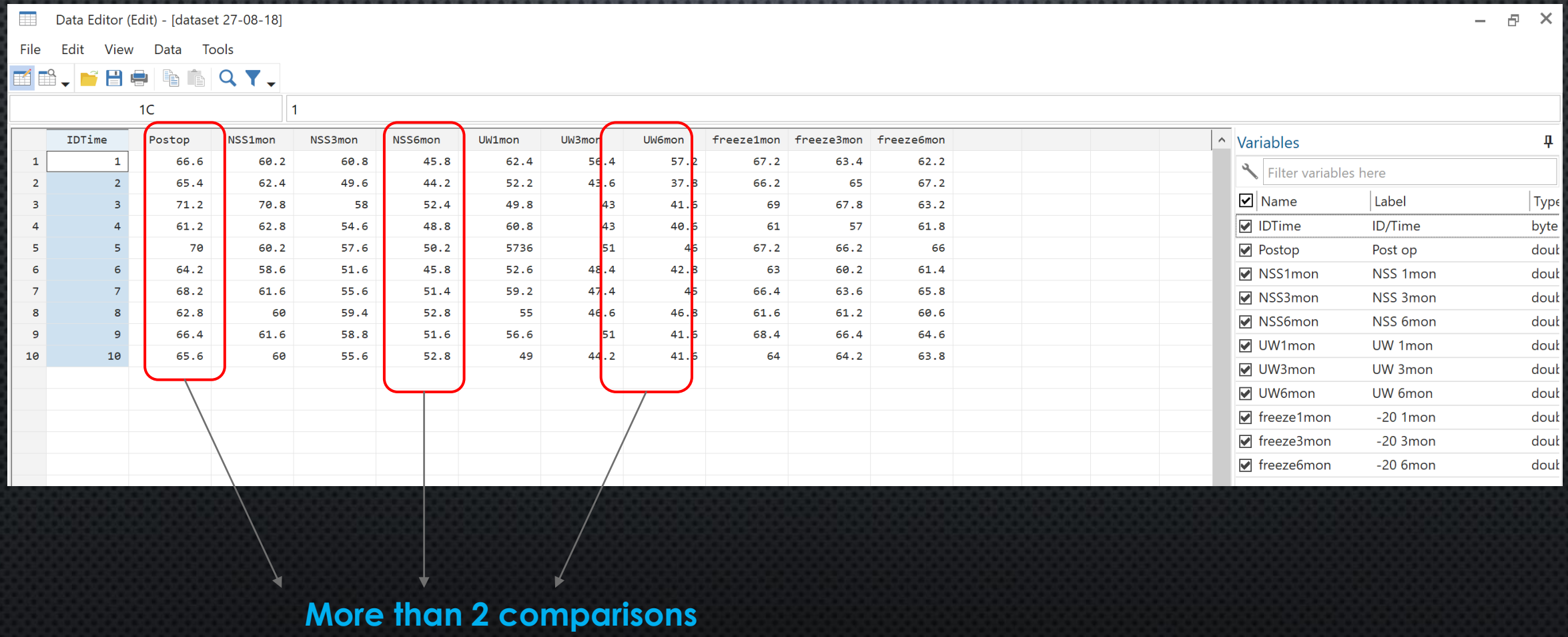
ANALYSIS OF VARIANCE (ANOVA)

ข้อตกลงเบื้องต้น

- ประชากรมากกว่า 2 กลุ่ม ที่เป็นอิสระต่อกัน
- ข้อมูลเป็นแบบ CONTINUOUS DATA
- การกระจายเป็นแบบ NORMAL DISTRIBUTION

หากไม่เป็นไปตามข้อตกลงเบื้องต้นให้ใช้ KRUSKAL WALLIS TEST

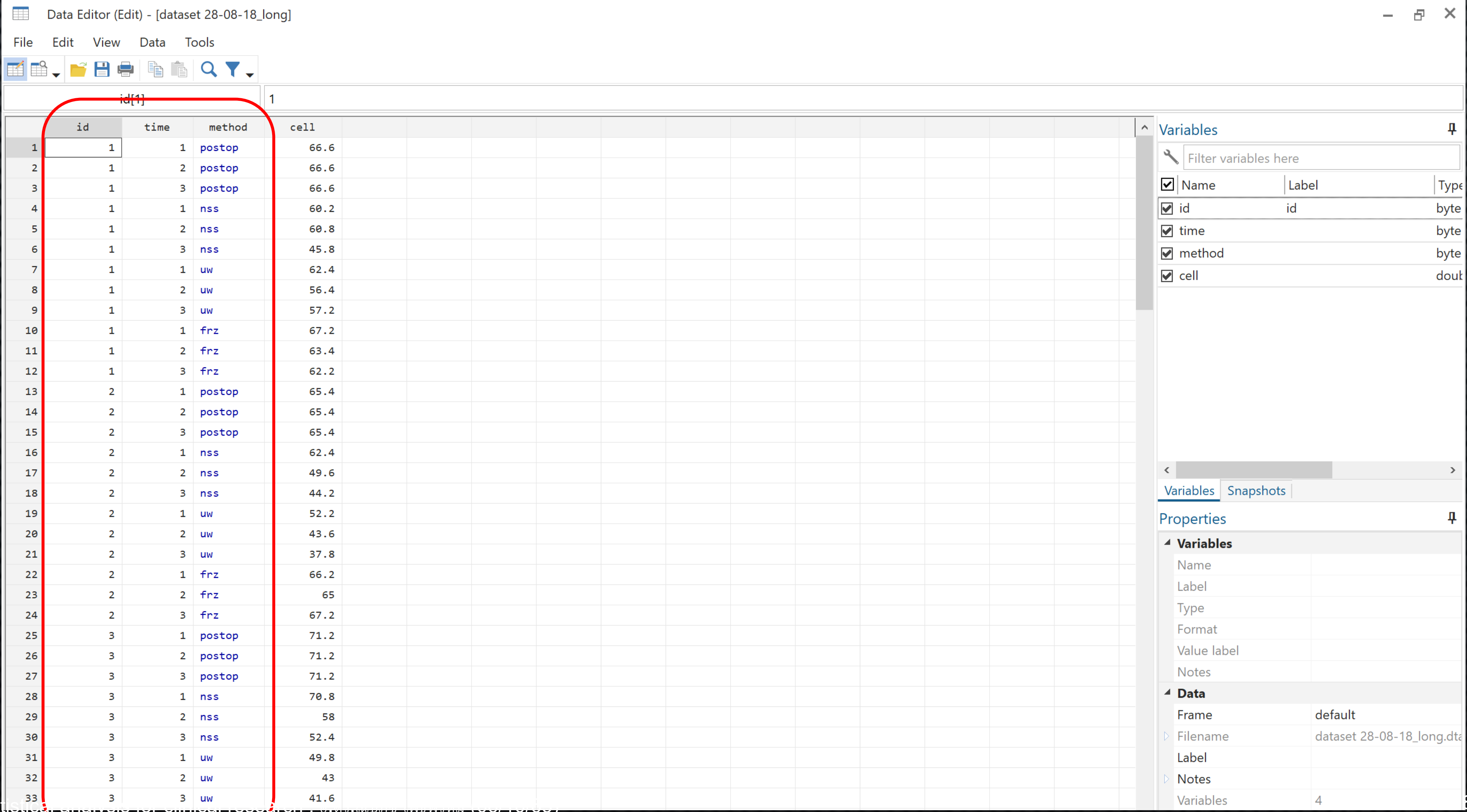
EXAMPLE



	IDTime	Postop	NSS1mon	NSS3mon	NSS6mon	UW1mon	UW3mon	UW6mon	freeze1mon	freeze3mon	freeze6mon
1	1	66.6	60.2	60.8	45.8	62.4	56.4	57.2	67.2	63.4	62.2
2	2	65.4	62.4	49.6	44.2	52.2	43.6	37.8	66.2	65	67.2
3	3	71.2	70.8	58	52.4	49.8	43	41.6	69	67.8	63.2
4	4	61.2	62.8	54.6	48.8	60.8	43	40.6	61	57	61.8
5	5	70	60.2	57.6	50.2	5736	51	45	67.2	66.2	66
6	6	64.2	58.6	51.6	45.8	52.6	48.4	42.8	63	60.2	61.4
7	7	68.2	61.6	55.6	51.4	59.2	47.4	45	66.4	63.6	65.8
8	8	62.8	60	59.4	52.8	55	46.6	46.8	61.6	61.2	60.6
9	9	66.4	61.6	58.8	51.6	56.6	51	41.6	68.4	66.4	64.6
10	10	65.6	60	55.6	52.8	49	44.2	41.6	64	64.2	63.8

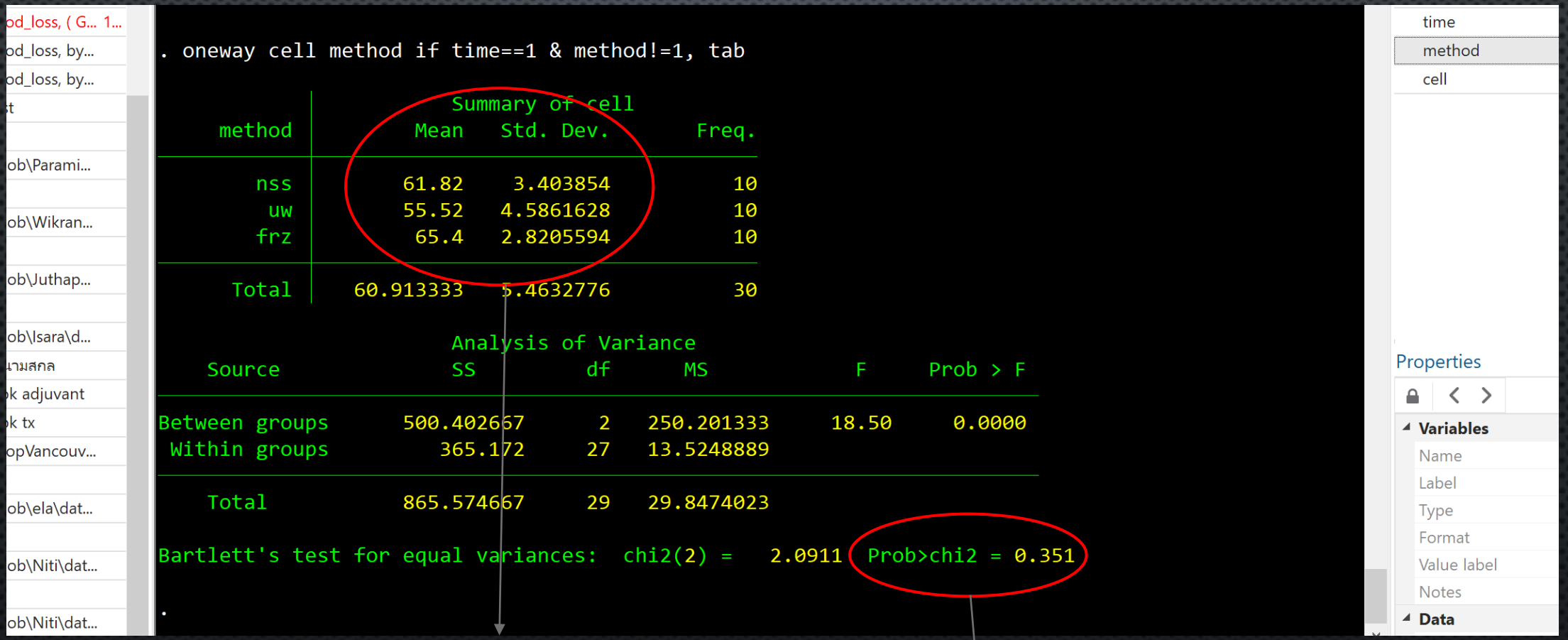
More than 2 comparisons

RESHAPE TO LONG FORMAT



	id	time	method	cell
1	1	1	postop	66.6
2	1	2	postop	66.6
3	1	3	postop	66.6
4	1	1	nss	60.2
5	1	2	nss	60.8
6	1	3	nss	45.8
7	1	1	uw	62.4
8	1	2	uw	56.4
9	1	3	uw	57.2
10	1	1	frz	67.2
11	1	2	frz	63.4
12	1	3	frz	62.2
13	2	1	postop	65.4
14	2	2	postop	65.4
15	2	3	postop	65.4
16	2	1	nss	62.4
17	2	2	nss	49.6
18	2	3	nss	44.2
19	2	1	uw	52.2
20	2	2	uw	43.6
21	2	3	uw	37.8
22	2	1	frz	66.2
23	2	2	frz	65
24	2	3	frz	67.2
25	3	1	postop	71.2
26	3	2	postop	71.2
27	3	3	postop	71.2
28	3	1	nss	70.8
29	3	2	nss	58
30	3	3	nss	52.4
31	3	1	uw	49.8
32	3	2	uw	43
33	3	3	uw	41.6

ANALYSIS ANOVA OUTPUT



```
. oneway cell method if time==1 & method!=1, tab

                Summary of cell
    method |      Mean   Std. Dev.       Freq.
-----------+------------------------------------
       nss |       61.82   3.403854          10
        uw |       55.52   4.5861628         10
       frz |        65.4   2.8205594         10
-----------+------------------------------------
     Total |  60.913333   5.4632776          30

                        Analysis of Variance
    Source              SS         df      MS            F     Prob > F
------------------------------------------------------------------------
Between groups      500.402667      2   250.201333     18.50     0.0000
 Within groups         365.172     27   13.5248889
------------------------------------------------------------------------
    Total           865.574667     29   29.8474023

Bartlett's test for equal variances:  chi2(2) =   2.0911  Prob>chi2 = 0.351

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Mean and SD

P-value

ปัจจัยเสี่ยงของการวิจัยเชิงวิเคราะห์ (RISK FACTORS ANALYSIS)

LOGISTIC REGRESSION

Asian Journal of Surgery 43 (2020) 913–918

Contents lists available at ScienceDirect

Asian Journal of Surgery

journal homepage: www.e-asianjournalsurgery.com

ORIGINAL ARTICLE

Outcomes of delayed endoscopic retrograde cholangiopancreatography in patients with acute biliary pancreatitis with cholangitis

Paramin Muangkaew [a], Patarapong Kamalaporn [b], Somkit Mingphruedhi [a], Narongsak Rungsakulkij [a], Wikran Suragul [a], Watoo Vassanasiri [a], Pongsatorn Tangtawee [a, *]

[a] Department of Surgery, Hepato-Pancreato-Biliary Division, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand
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Outcome: Explored pre-operative factors associated with delayed ERCP.

ARTICLE INFO

Article history:
Received 15 October 2019
Accepted 21 November 2019
Available online 6 January 2020

Keywords:
Biliary pancreatitis
Cholangitis
Endoscopic retrograde cholangiopancreatography
Gallstone pancreatitis

ABSTRACT

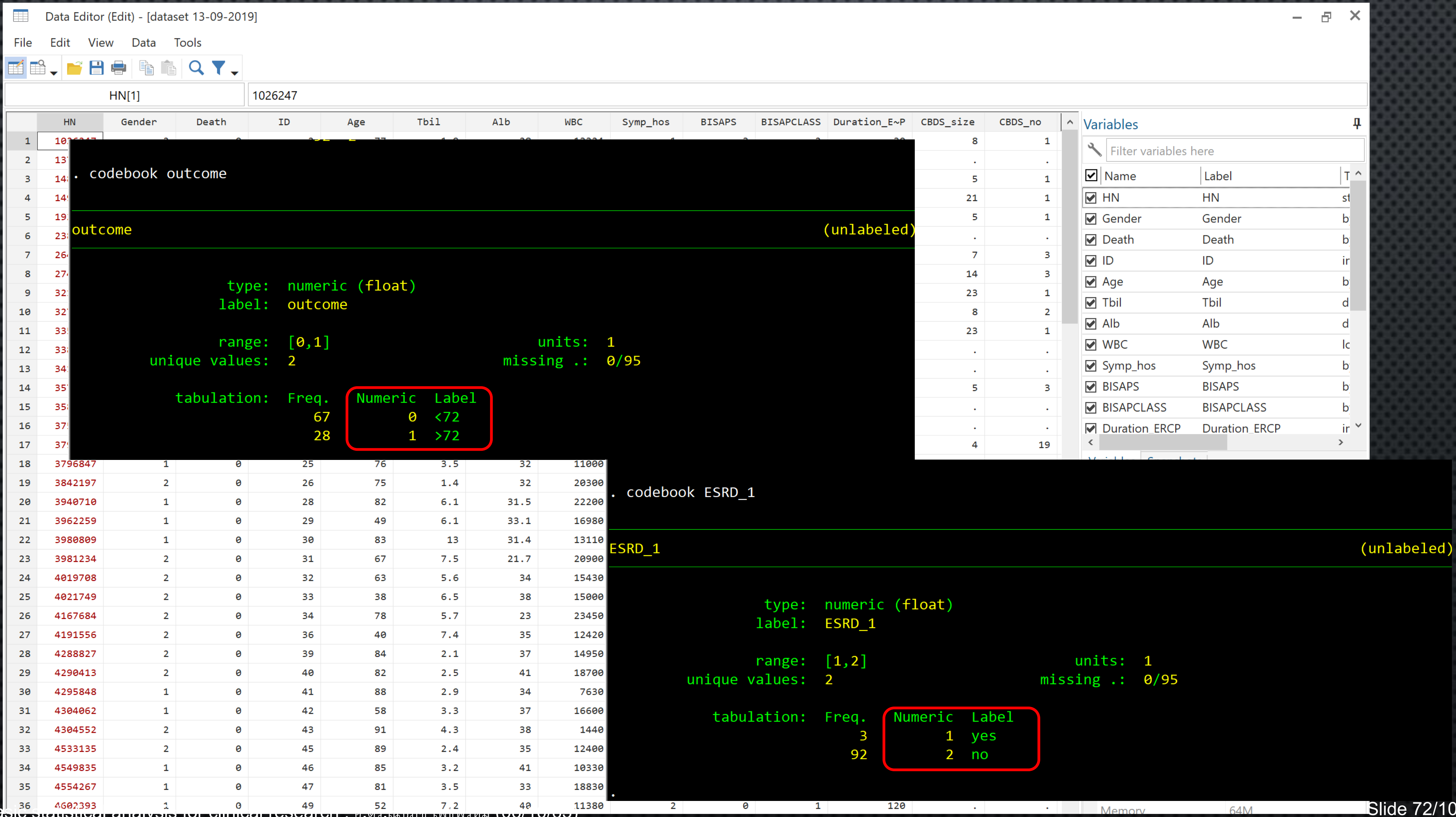
Objective: The recommended treatment for acute biliary pancreatitis(ABP) with cholangitis is urgent endoscopic retrograde cholangiopancreatography(ERCP). However, tight schedules in the endoscopy room mean that urgent ERCP may not always be performed. This study aimed to compare the outcomes of early (≤72 h) and delayed(>72 h) ERCP in patients with ABP with cholangitis.

Methods: Ninety-five patients diagnosed with ABP with cholangitis who underwent ERCP between May 2012 and April 2018 were retrospectively reviewed.

Results: Sixty-seven patients(70.5%) were classified in the early ERCP and 28(29.5%) in the delayed ERCP groups. There was no significant difference in pancreatitis severity between the groups. Total bilirubin was higher in the early compared with the late ERCP group (5.7 ± 5.2 versus 3.5 ± 2.3 mg/dL, p = 0.03). Fewer patients in the early group had end-stage renal disease (0 versus 3, p = 0.006) and relatively fewer patients in the early group took aspirin (15(22.4%) versus 12(42.9%), p = 0.04). There were no significant differences between the early and delayed ERCP groups in terms of mortality (2(3.0%) versus 0), disease-related complications(11 (16.4%) versus 5(17.9%), p = 0.86), or ERCP-related complications(5(7.5%) versus 3(10.7%), p = 0.60). The total length of stay(LoS) was shorter in the early group(6.3 ± 4.4 versus 9.8 ± 6.1 days, p = 0.002). The rate of complete stone removal was lower in the early compared with the delayed ERCP group(32/42(76.2%) versus 18/18(100%), p = 0.02).

Conclusion: Delayed ERCP can be performed in selected patients with ABP with cholangitis, with similar complication rates but longer LoS compared with early ERCP.

EXAMPLE


Data Editor (Edit) - [dataset 13-09-2019]
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HN[1]
1026247
HN Gender Death ID Age Tbil Alb WBC Symp_hos BISAPS BISAPCLASS Duration_E~P CBDS_size CBDS_no
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label: outcome
range: [0,1] units: 1
unique values: 2 missing .: 0/95
tabulation: Freq. Numeric Label
67 0 <72
28 1 >72
Variables
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Name Label
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Gender Gender
Death Death
ID ID
Age Age
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Alb Alb
WBC WBC
Symp_hos Symp_hos
BISAPS BISAPS
BISAPCLASS BISAPCLASS
Duration_ERCP Duration_ERCP
. codebook ESRD_1
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label: ESRD_1
range: [1,2] units: 1
unique values: 2 missing .: 0/95
tabulation: Freq. Numeric Label
3 1 yes
92 2 no

ANALYSIS LOGISTIC REGRESSION OUTPUT

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P. Muangkaew et al. / Asian Journal of Surgery 43 (2020) 913–918 915

Table 1
Patient characteristics.

	Early ERCP ≤72 h (N = 67)	Delayed ERCP >72 h (N = 28)	p-value
Sex, N(%)			0.44
Male	32(47.8%)	11(39.3%)	
Female	35(52.2%)	17(60.7%)	
Age (years), mean ± SD	67.7 ± 16.3	66.3 ± 16.2	0.70
Body mass index (kg/m^2), mean ± SD	25.9 ± 5.1	23.9 ± 3.4	0.05
Total bilirubin (mg/dL), mean ± SD	5.7 ± 5.2	3.5 ± 2.3	0.03
Albumin (g/L), mean ± SD	33.1 ± 5.8	33.7 ± 4.6	0.67
Lipase (U/L), mean ± SD	11709.7 ± 8275.8	11618.6 ± 9125.4	0.98
Amylase (U/L), mean ± SD	1291.6 ± 1282.6	1560.6 ± 1883.3	0.59
WBC, mean ± SD	15630.6 ± 11997	14465.5 ± 5612	0.62
ASA, N(%)			0.23
Class I	1(1.5%)	0	
Class II	18(26.9%)	10(35.7%)	
Class III	33(49.3%)	8(28.6%)	
Class IV	15(22.4%)	10(35.7%)	
Underlying disease, N(%)			
Myocardial infarction/atrial fibrillation	*10(14.9%)*	*6(21.4%)*	*0.44*
End-stage renal disease	*0*	*3(10.7%)*	*0.006*
Diabetes mellitus	*21(31.3%)*	*8(28.6%)*	*0.78*
Other	*15(22.4%)*	*5(17.9%)*	*0.62*
Anti-platelet or anti-coagulant, N(%)			
Aspirin	15(22.4%)	12(42.9%)	0.04
Warfarin	2(3.0%)	2(7.1%)	0.35
Other	3(4.5%)	1(3.6%)	0.84
Pancreatitis severity, N(%)			0.80
Mild	51(76.1%)	23(82.1%)	
Moderately severe	9(13.4%)	3(10.7%)	
Severe	7(10.4%)	2(7.1%)	
BISAP score, N(%)			0.24
<3	55(82.1%)	20(71.4%)	
≥3	12(17.9%)	8(28.6%)	
Duration from presenting symptom to hospital (day), mean ± SD	2.0 ± 2.0	2.5 ± 3.8	0.42
Duration from admission to ERCP (h), mean ± SD	42.1 ± 18.4	152.9 ± 92.4	<0.001
Cholangitis criteria, N(%)			0.23
Definite cholangitis	53(79.1%)	25(89.3%)	
Suspected cholangitis	14(20.9%)	3(10.7%)	
Pre-ERCP imaging, N(%)			0.36
Ultrasound	35(53.8%)	9(34.6%)	
Computed tomography	25(38.5%)	13(50.0%)	
MRCP	4(6.2%)	3(11.5%)	
Endoscopic ultrasound	1(1.5%)	1(3.8%)	
Presence of choledocholithiasis by imaging, N(%)	30(44.8%)	18(64.3%)	0.08

ERCP, endoscopic retrograde cholangiopancreatography; *ASA*, American Society of Anesthesiologists; *BISAP*, bedside index of severity in acute pancreatitis; *MRCP*, magnetic resonance cholangiopancreatography; *SD*, standard deviation; *WBC*, white cell count.

STATISTICAL SOFTWARE

Name	Website	Price	Features	Ease of use	Note
SPSS	http://www.ibm.com/software/analytics/spss/	$$$$$	++++	++++	Need to purchase separate modules for complicated analyses (such as Survival Analysis) Available from MU (http://softwaredownload.mahidol/)
Stata	http://www.stata.com/	$$$$	++++	+++	Ramathibodi access (CEB server)
R	http://www.r-project.org/	(Free)	+++	+	R-commander is nice add on
SAS	http://www.sas.com/	$$$$$	++++	0	Need programming skill

SAMPLE SIZE ESTIMATION

Outline

Categorical data

- Two independent proportions
- More than two groups of proportions

Continuous data

- Two independent means
- Two dependent means
- More than two groups of means

Why we need a sample from the population

Cannot study in the whole population

- Time, financial, resources

Study plan

- Manpower, budget, time

Ethical consideration

- Studies that are too small or to large may be judged as unethical studies

RECOMMENDATION

- A RESEARCHER WOULD LIKE TO A STATISTICAL SIGNIFICANT DIFFERENCE.
- THE DIFFERENCE SHOULD ALSO BE MEANINGFUL.

******THEREFORE, THE RESEARCHER MUST DEFINE WHAT A MEANINGFUL DIFFERENCE IS.******

TWO INDEPENDENT PROPORTIONS

EXAMPLE

- Compare incidence of SSI event in colectomy between patients who received Beta-lactam and non-Beta-lactam.
- Compare incidence of micro or macro-albuminuria between patients who received ACEI and other hypertensive drugs.
- Compare rates of breast cancer between HRT vs Non-HRT.

FORMULA OF TWO INDEPENDENT PROPORTIONS

$$n = \frac{\left[Z_{\alpha/2}\sqrt{2\overline{P}(1-\overline{P})} + Z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)} \right]^2}{(P_1-P_2)^2}$$

$$\overline{P} = \frac{P_1+P_2}{2}$$

β-Lactam vs Non-β-Lactam Antibiotics and Surgical Site Infection in Colectomy Patients

Jonathan P Kuriakose, MS, Joceline Vu, MD, Monita Karmakar, MS, Jerod Nagel, PharmD, Shitanshu Uppal, MBBS, Samantha Hendren, MD, MPH, FACS, Michael J Englesbe, MD, FACS, Raj Ravikumar, MD, Darrell A Campbell, MD, FACS, Greta L Krapohl, PhD, RN

BACKGROUND: Surgical site infections (SSIs) represent a significant preventable source of morbidity, mortality, and cost. Prophylactic antibiotics have been shown to decrease SSI rates, and β-lactam antibiotics are recommended by national guidelines. It is currently unclear whether recommended β-lactam and recommended non-β-lactam antibiotic regimens are equivalent with respect to SSI risk reduction in colectomy patients.

STUDY DESIGN: We conducted a retrospective cohort study of SSI rates between prophylactic intravenously administered recommended β-lactam and non-β-lactam in colectomy patients (25 CPT codes) collected by the Michigan Surgical Quality Collaborative from January 2013 to February 2018. Surgical site infection rates were compared as a dichotomous variable (no SSI vs SSI). Mixed-effects regression was used to compare the association between receiving a β-lactam or non-β-lactam antibiotic and likelihood of having an SSI.

RESULTS: Of 9,949 patients, 9,411 (94.6%) received β-lactam antibiotics and 538 (5.4%) received non-β-lactam antibiotics. Overall, there were 622 (6.3%) patients with SSIs. Of the patients receiving β-lactam antibiotics, SSIs developed in 571 (6.1%) compared with 51 (9.5%) patients in the non-β-lactam group. After applying mixed-effects logistic regression, prophylactic treatment with a non-β-lactam regimen was associated with significantly higher odds of surgical site infection (odds ratio 1.65; 95% CI 1.20 to 2.26; $p < 0.01$).

CONCLUSIONS: Colectomy patients receiving β-lactam antibiotics had a lower likelihood of SSI compared with those receiving non-β-lactam antibiotics, even when antibiotics were compliant with national recommendations. Our findings suggest that surgeons should prescribe β-lactam antibiotics for prophylaxis whenever possible, reserving alternatives for those rare patients with true allergies or clinical indications for non-β-lactam antibiotic prophylaxis. (J Am Coll Surg 2019;229: 487–496. © 2019 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

P1= 6.1%
P2= 9.5%

Surgical site infection (SSI) represents a significant preventable source of morbidity, mortality, and cost.[1-3] With estimates of 1 million additional hospital days and $1.5 billion in added costs,[3] reducing SSIs is an imperative patient safety and quality improvement opportunity. For patients undergoing operations, the rate of SSI is approximately

CME questions for this article available at http://jacscme.facs.org

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ISSN 1072-7515/19

ESTIMATION FOR 2 INDEPENDENT PROPORTION

```
. power twoproportions 0.61 0.95, test(chi2)

Performing iteration ...

Estimated sample sizes for a two-sample proportions test
Pearson's chi-squared test
Ho: p2 = p1  versus  Ha: p2 != p1

Study parameters:

        alpha =    0.0500
        power =    0.8000
        delta =    0.3400  (difference)
           p1 =    0.6100
           p2 =    0.9500

Estimated sample sizes:

            N =        46
  N per group =        23
```

MORE THAN TWO GROUPS OF PROPORTIONS

EXAMPLE

- Compare SSI rates among the methods of irrigation after open appendectomy for acute appendicitis.
- Compare incidence of GI ulcer between Celecoxib, Valecoxib, and Naproxen in Arthritis patients.
- Compare recovery rates among Acyclovir plus Prednisolone, Acyclovir alone, and Prednisolone alone in Bell's palsy patients.

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Randomised Controlled Trial

A randomized controlled trial on irrigation of open appendectomy wound with gentamicin- saline solution versus saline solution for prevention of surgical site infection

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ARTICLE INFO

Keywords:
Mesh terms): therapeutic irrigation
Surgical wound infection
Appendectomy
Gentamicins
Saline solution
Randomized controlled trial

ABSTRACT

Background: Surgical site infection (SSI) is one of the most common complications after abdominal surgery. The present trial examined the efficacy of saline irrigation of open appendectomy wound with or without topical antibiotics in prevention of SSI.

Methods: This was a double-blind randomized trial on patients with acute appendicitis who underwent open appendectomy. Patients were randomly allocated to one of three equal groups; group I had layer-by-layer wound irrigation with gentamicin-saline solution, group II had wound irrigation with saline solution, and group III received no irrigation (Control group). The main outcome measures were the incidence of incisional SSI, surgical site occurrence (SSO), other complications, operation time, postoperative pain, and patients' satisfaction.

Results: 205 patients (113 female) of a mean age of 27.9 years were included. The average hospital stay and pain scores were similar in the three groups. Groups I and II had significantly lower rates of incisional SSI (4.3% Vs 2.9%; Vs 17.4%, p = 0.005) and SSO (24.6% Vs 13.4% Vs 43.5%; p = 0.0003) as compared to group III. Groups I and II had comparable rates of SSI and SSO. The three groups had similar rates of wound seroma, hematoma, and dehiscence. Groups I and II had significantly higher satisfaction with the procedure than group III.

Conclusions: Layer-by-layer irrigation of open appendectomy wound decreased the rates of incisional SSI and SSO significantly compared to the no-irrigation group. Adding gentamicin to saline solution was useless to improve the outcome and did not decrease rates of SSI or other complications.

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- Group I had layer by layer irrigation of the surgical wound with gentamicin-saline solution.
- Group II had layer by layer wound irrigation with normal saline 0.9% solution.
- Group III (Control group) did not receive wound irrigation.

Gr1 =4.3%
Gr2 =2.9%
Gr3 =17.4%

ESTIMATION FOR MORE THAN 2 INDEPENDENT PROPORTION

```
. artbin, pr(.043 .029 .174) ngroups(3) aratios(1 1 1 ) distant(0) alpha(0.05) power(0.8)

ART - ANALYSIS OF RESOURCES FOR TRIALS (version 1.0.0, 3 March 2004)
-------------------------------------------------------------------------------

A sample size program by Abdel Babiker, Patrick Royston & Friederike Barthel,
MRC Clinical Trials Unit, London NW1 2DA, UK.
-------------------------------------------------------------------------------

Type of trial                          Superiority - binary outcome
Statistical test assumed               Unconditional comparison of 3
                                        binomial proportions
Number of groups                       3
Allocation ratio

Anticipated event probabilities

Alpha                                  0.050 (two-sided)
Power (designed)                       0.800

Total sample size (calculated)         171
Expected total number of events        14
-------------------------------------------------------------------------------
```

This study needs to enroll 171 subjects and then randomly allocate 57 subjects for each group

TWO INDEPENDENT MEANS

EXAMPLE

- Compare duration time of surgery between open and laparoscopic appendectomy.
- Compare BMD between patients who received calcium supplement vs placebo.
- Compare pain score of patient who received robotic hepatectomy and open hepatectomy.
- Compare blood pressure between angiotensin-receptor blocker and angiotensin-converting enzyme inhibitor (ACEI) in DM patents.

FORMULA

- Ho: $\mu_1 - \mu_2 = 0$
- Ha: $\mu_1 - \mu_2 \neq 0$

$$n = \left[\frac{(r+1)x(Z_{\alpha/2} + Z_{\beta})\sigma}{r(\mu_1 - \mu_2)} \right]^2$$

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https://doi.org/10.1007/s00464-019-06746-6

REVIEW ARTICLE

Laparoscopic appendicectomy is superior to open sur for complicated appendicitis

Gaik S. Quah[1] · Guy D. Eslick[1] · Michael R. Cox[1,2]

Received: 19 July 2018 / Accepted: 6 March 2019 / Published online: 13 March 2019

Abstract

Background Over the last three decades, laparoscopic appendicectomy (LA) has bec plicated acute appendicitis. The role of laparoscopic surgery for complicated appen remains controversial due to concerns of an increased incidence of post-operative in compared to open appendicectomy (OA). The aim of this study was to compare the o cated appendicitis.

Methods A systematic literature search following PRISMA guidelines was conducted and Cochrane Database for randomised controlled trials (RCT) and case–control stud for complicated appendicitis.

Results Data from three RCT and 30 CCS on 6428 patients (OA 3,254, LA 3,174) w difference in the rate of IAA (LA = 6.1% vs. OA = 4.6%; OR = 1.02, 95% CI = 0.71 appendicitis has decreased overall post-operative morbidity (LA = 15.5% vs. OA = 2 $p < 0.0001$), wound infection, (LA = 4.7% vs. OA = 12.8%; OR = 0.26, 95% CI: 0.19–(tions (LA = 1.8% vs. OA = 6.4%; OR = 0.25, 95% CI: 0.13–0.49, $p < 0.001$), post-op (LA = 3.1% vs. OA = 3.6%; OR = 0.65, 95% CI: 0.42–1.0, $p = 0.048$) and mortality rat 95% CI: 0.04–0.61, $p = 0.008$). LA has a significantly shorter hospital stay (6.4 days vs. tion of solid food (2.7 days vs. 3.7 days, $p = 0.03$).

Conclusion These results clearly demonstrate that LA for complicated appendicitis significantly reduced morbidity, mortality and length of hospital stay compared with C dicitis at laparoscopy is not an indication for conversion to open surgery. LA should with complicated appendicitis.

Keywords Laparoscopic appendicectomy · Open appendicectomy · Complicated appendicitis · Gangrenous appendicitis · Perforated appendicitis · Appendiceal abscess

Secondary outcomes

Twenty-five studies reported the operative duration (OT) [26–30, 32, 34, 36–39, 42–46, 48–50, 52–57] which was similar (LA group 74.6 min ± 19.6 and OA group 82.2 min ± 24.7, $p = 0.19$) (Table 4). Thirty studies reported the average LOS [26–30, 32–34, 36–39, 42–57] which was significantly shorter for the LA group (6.4 ± 2.8 days) compared to the OA group (8.9 ± 4.8 days) ($p = 0.02$) (Table 4). Twelve studies reported the average time to resume normal diet [26–30, 32–34, 36–39, 42–57] which was significantly shorter for the LA group (2.7 ± 0.9 days) compared with the OA group (3.7 ± 1.1 days) ($p = 0.03$) (Table 4). Eight studies reported the duration of IV antibiotics and there was no significant difference between LA and OA ($p = 0.49$) (Table 4).

acute cholecystitis [60].

As the majority of the studies used in the present study were CCS, there may be some risks of bias of some form that may favours better outcomes in the LA group. One potential selection bias is the patient co-morbidities resulting in bias that may favour either LA or OA. As the patient characteristics in both groups including sex, gender, BMI and ASA scores were similar, a selection bias based on co-morbidities is most unlikely. Another potential bias is the nature or extent of disease may be different due to a selection bias that may favour one approach. Although there was a range of definitions for complicated appendicitis across the various studies, there was no significant difference in the distribution of disease between the LA and OA groups. Similarly, there was no significant difference in the duration of symptoms between LA and OA. The

Table 4 Secondary outcomes for combined RCT and CSS data

	# of studies	LA	OA	*p* value
Mean length of hospital stay (days)	30	6.4 ± 2.8	8.9 ± 4.8	0.02
Mean OT (min)	25	82.2 ± 24.7	74.6 ± 19.6	0.19
Solid food resumption (days)	12	2.7 ± 0.9	3.7 ± 1.1	0.03
IV Abx (day)	8	5.5 ± 1.8	6.3 ± 3.2	0.49

ESTIMATION FOR 2 INDEPENDENT MEANS

```
. power twomeans 74.6 82.2, sd1(19.6) sd2(24.7)

Performing iteration ...

Estimated sample sizes for a two-sample means test
Satterthwaite's t test assuming unequal variances
Ho: m2 = m1  versus  Ha: m2 != m1

Study parameters:

        alpha =    0.0500
        power =    0.8000
        delta =    7.6000
           m1 =   74.6000
           m2 =   82.2000
          sd1 =   19.6000
          sd2 =   24.7000

Estimated sample sizes:

            N =       274
  N per group =       137

.
```

This study needs to enroll 274 subjects and then randomly allocate 137 subjects for each group

TWO DEPENDENT MEANS

EXAMPLE

Before and after study

- Compare mean of VAS score before and after minimal invasive endoscopic technique in patients with benign bone Lesion.
- Compare mean BP before and after receiving analgesic Treatment.

FORMULA

- Ho: $\mu_{before} = \mu_{after}$
- Ha: $\mu_{before} \neq \mu_{after}$

$$n = \left[\frac{(Z_{\alpha/2} + Z_{\beta})\sigma}{\Delta} \right]^2$$

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Journal of Bone Oncology

journal homepage: www.elsevier.com/locate/jbo

The minimally invasive endoscopic technique for the treatment of symptomatic benign bone lesions: Preliminary results from a retrospective study

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ARTICLE INFO

Keywords:
Minimally invasive
Endoscopy
Benign bone lesion
Clinical efficacy
Surgical intervention

ABSTRACT

Objective: The present study aimed to evaluate the short-term clinical feasibility and effic invasive endoscopic technique (MIET) for the treatment of symptomatic benign bone lesic

Materials and methods: This single-institution retrospective study investigated 34 patient benign bone lesions from December 2015 to June 2017. Patients involved in this study pr indications for surgical intervention. All procedures were performed under endoscopic gu sualization followed by complete curettage of tumor tissue. There were 19 males and 15 f age of 33.3 ± 12.7 years (range, 17–68 years). The lesions were located in the upper extr lower extremities (9, 26.5%) and pelvis (5, 14.7%). Primary outcomes were measured before and after intervention using the visual analog scale (VAS), the Musculoskeletal Tumor Society (MSTS) stage and the 36-item Short-Form Health Survey (SF-36) scoring system.

Results: Of the 34 patients included in this study, all completed follow-up examinations, with a mean follow-up duration of 22.4 ± 7.6 months (range, 13–35 months). Significantly improved VAS, MSTS and SF-36 scores were observed at 3 months after the initial treatment ($P < 0.001$), suggesting enhanced pain relief and improved functional recovery and quality of life following surgery. All procedures were technically successful, with the exception of 3 cases (8.8%) manifesting access site numbness; these patients recovered within the follow-up period through symptomatic treatment alone. Only 2 patients (5.9%; one osteoblastoma and one enchondroma) experienced local recurrence and underwent standard open curettage within the follow-up period. All patients showed functional stability without any major complications.

Conclusion: The MIET is an effective and safe alternative treatment for symptomatic benign bone lesions. The short-term efficacy of MIET was favorable and associated with improved pain palliation, quality of life and functional recovery.

Table 2
Preoperative and postoperative data regarding surgical efficacy according to the VAS, MSTS and SF-36 scores.

	Pre	Pos	t value	P value
VAS score	4.9 ± 1.4	0.3 ± 0.5	18.6053	< 0.001
MSTS score	17.8 ± 2.8	25.5 ± 1.9	−20.0909	< 0.001
SF-36 score	61.1 ± 6.2	79.7 ± 5.5	−26.6391	< 0.001

Pre: Preoperatively, Pos: Postoperatively, VAS: Visual analog scale, MSTS: Musculoskeletal Tumor Society, SF-36: 36-item Short-Form Health Survey.

ESTIMATION FOR 2 DEPENDENT MEANS

```
. power pairedmeans 4.9 0.3, sddiff(1.4)

Performing iteration ...

Estimated sample size for a two-sample paired-means test
Paired t test
Ho: d = d0  versus  Ha: d != d0

Study parameters:

        alpha =    0.0500
        power =    0.8000
        delta =   -3.2857
           d0 =    0.0000
           da =   -4.6000
         sd_d =    1.4000
         ma1 =    4.9000
         ma2 =    0.3000

Estimated sample size:

            N =         3
```

Three subjects needed to enroll in order to detect a difference of VAS score of 4.6 between before and after receiving treatment

MORE THAN TWO GROUPS OF MEANS

EXAMPLE

- Compare VAS score among the methods of irrigation after open appendectomy for acute appendicitis.
- Compare mean VAS score between treatment of Celecoxib, Valdecoxib, and Naproxen after receiving treatments for 7 days.

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Randomised Controlled Trial

A randomized controlled trial on irrigation of open appe with gentamicin- saline solution versus saline solution fo surgical site infection

Sameh Hany Emile *, Ahmed Hossam Elfallal, Mohamed Anwar Abdel-Raz Ayman Elshobaky

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ARTICLE INFO

Keywords:
Mesh terms): therapeutic irrigation
Surgical wound infection
Appendectomy
Gentamicins
Saline solution
Randomized controlled trial

ABSTRACT

Background: Surgical site infection (SSI) is one of the m present trial examined the efficacy of saline irrigation antibiotics in prevention of SSI.

Methods: This was a double-blind randomized trial on patients with acute appendicitis who underwent open appendectomy. Patients were randomly allocated to one of three equal groups; group I had layer-by-layer wound irrigation with gentamicin-saline solution, group II had wound irrigation with saline solution, and group III received no irrigation (Control group). The main outcome measures were the incidence of incisional SSI, surgical site occurrence (SSO), other complications, operation time, postoperative pain, and patients' satisfaction.

Results: 205 patients (113 female) of a mean age of 27.9 years were included. The average hospital stay and pain scores were similar in the three groups. Groups I and II had significantly lower rates of incisional SSI (4.3% Vs 2.9%; Vs 17.4%, p = 0.005) and SSO (24.6% Vs 13.4% Vs 43.5%; p = 0.0003) as compared to group III. Groups I and II had comparable rates of SSI and SSO. The three groups had similar rates of wound seroma, hematoma, and dehiscence. Groups I and II had significantly higher satisfaction with the procedure than group III.

Conclusions: Layer-by-layer irrigation of open appendectomy wound decreased the rates of incisional SSI and SSO significantly compared to the no-irrigation group. Adding gentamicin to saline solution was useless to improve the outcome and did not decrease rates of SSI or other complications.

Table 2
Outcome of the three groups.

Variable	Gentamicin-saline (N = 69)	Saline (N = 67)	No irrigation (N = 69)	P value
Mean operation time in minutes	55.1 (SD 8.7)	55.6 (SD 8.2)	50.2 (SD 8.4)	**<0.001**
Surgical site infection (%)	3 (4.3)	2 (2.9)	12 (17.4)	**0.005**
Seroma (%)	12 (17.4)	6 (8.9)	15 (21.7)	0.11
Hematoma (%)	2 (2.8)	1 (1.5)	1 (1.4)	0.84
Wound dehiscence (%)	0	0	2 (2.8)	0.22
Total surgical site occurrence (%)	17 (24.6)	9 (13.4)	30 (43.5)	**<0.001**
Other complications (%)	2 (2.8)	3 (4.4)	1 (1.4)	0.45
Mean hospital stay in days	1.1 (SD 0.26)	1.05 (SD 0.24)	1.14 (SD 0.3)	0.18

Table 3
Patient-reported outcomes of the three groups.

Variable		Gentamicin-saline (N = 69)	Saline (N = 67)	No irrigation (N = 69)	P value
Pain visual analogue score		4.04 (SD 1.4)	3.68 (SD 1.2)	4.13 (SD 1.6)	0.83
Satisfaction	**Satisfied (%)**	52 (75.3)	59 (88)	41 (59.4)	**<0.001**
	Partly satisfied (%)	12 (17.4)	6 (9)	13 (18.8)	
	Unsatisfied (%)	5 (7.2)	2 (3)	15 (21.7)	

4. Discussion

ESTIMATION FOR MORE THAN 2 INDEPENDENT MEANS

```
. power oneway 4.13 4.04 3.68, varerror(2.56)

Performing iteration ...

Estimated sample size for one-way ANOVA
F test for group effect
Ho: delta = 0  versus  Ha: delta != 0

Study parameters:

        alpha =    0.0500
        power =    0.8000
        delta =    0.1215
          N_g =         3
           m1 =    4.1300
           m2 =    4.0400
           m3 =    3.6800
        Var_m =    0.0378
        Var_e =    2.5600

Estimated sample sizes:

            N =       657
  N per group =       219
```

This study needs to enroll 657 subjects and then randomly allocate 219 subjects for each group

TO BE CONTINUE ON WORK SHOP

QUESTION?

THANK YOU