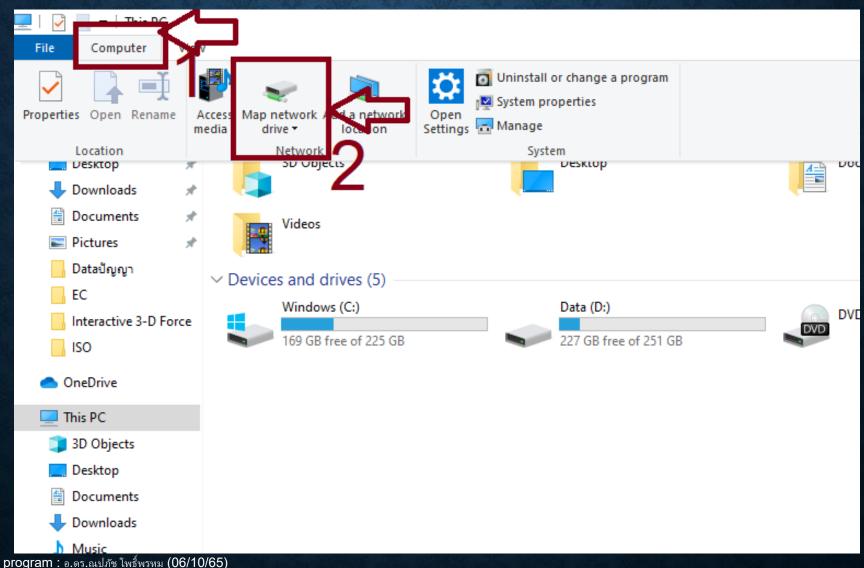
STATISTICAL ANALYSIS ON STATA PROGRAM

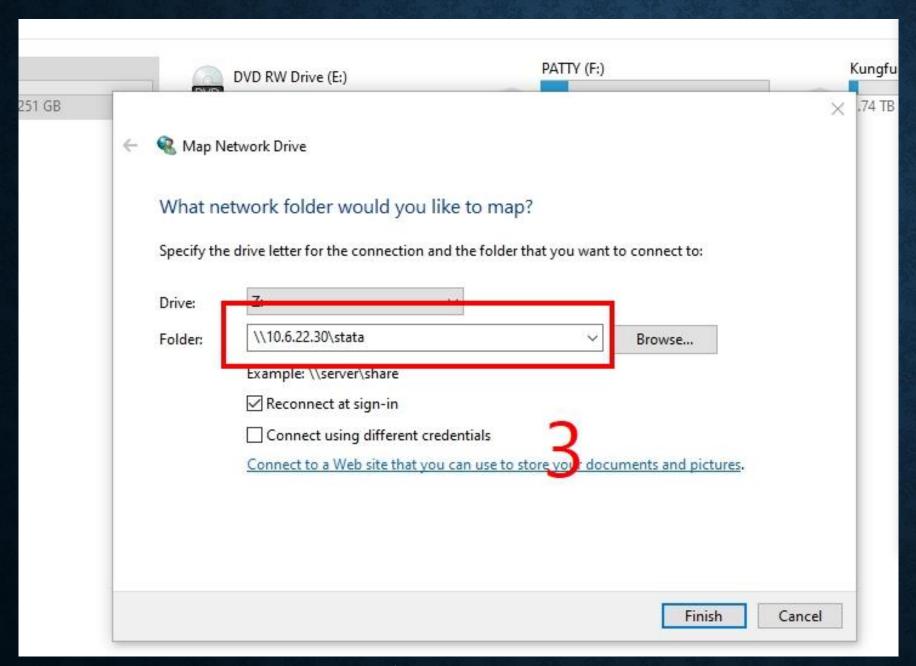
Napaphat Poprom., Ph.D. in Clinical Epidemiology

Department of Surgery, Faculty of Medicine,

Ramathibodi Hospital, Mahidol University

วิธีเข้าโปรแกรม STATA ผ่านระบบ RAN

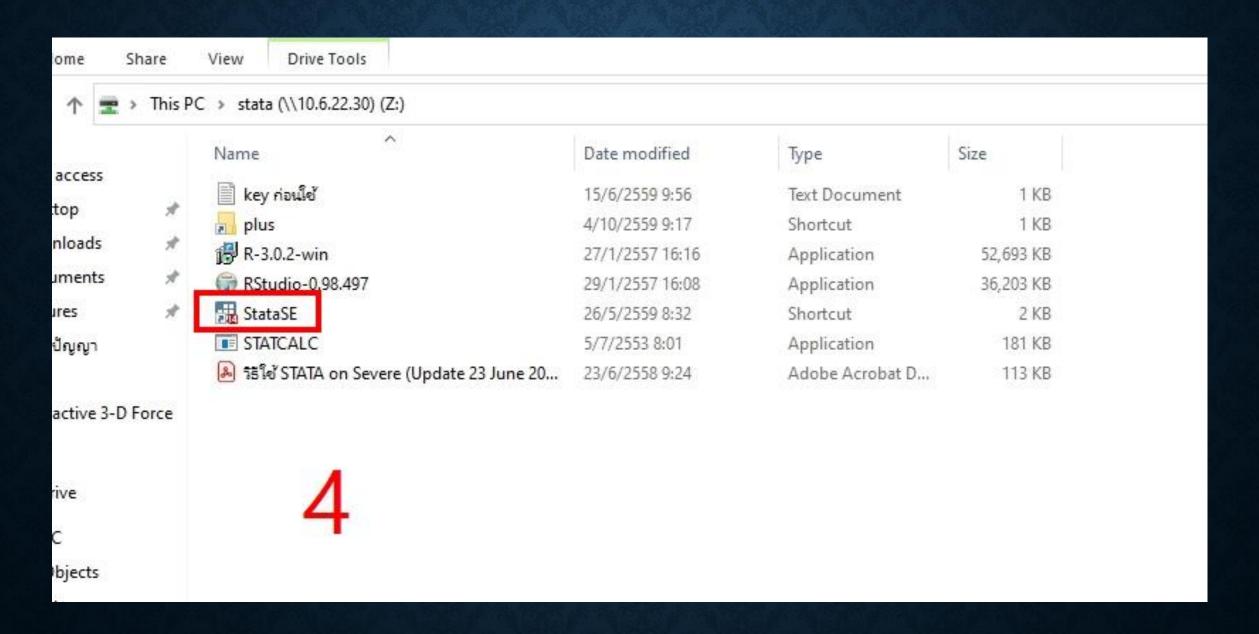




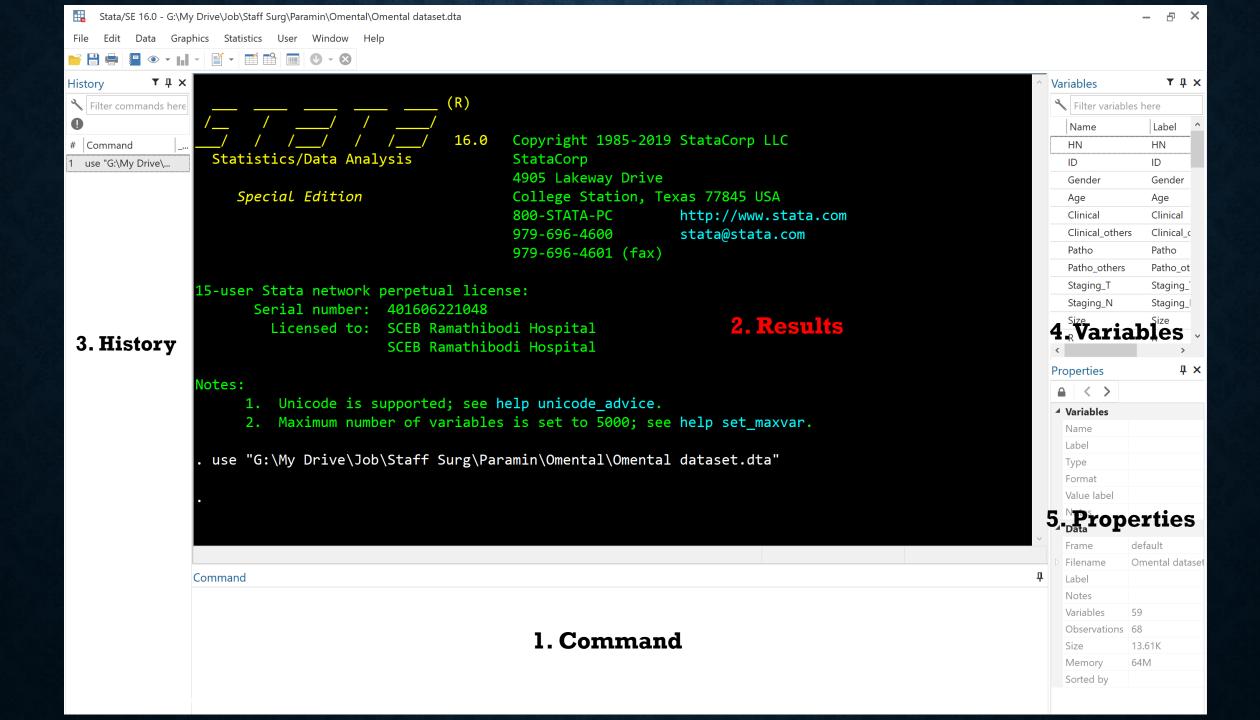
พิมพ์ \\nas002\stata

User: stata

PW: stata

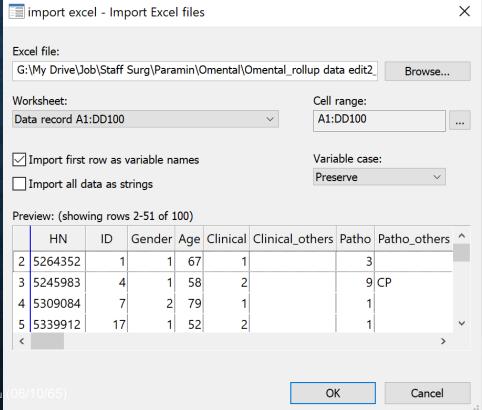


BASIC FUNCTIONS AND COMMANDS IN STATA



IMPORTING DATA FROM EXCEL

- Menu > File > Import
- Select "Import first row as variable names"
- A range of Excel cells to import can also be specified



GENERAL STRUCTURE

• bysort Gender: sum Age if Operation==1, detail



Example

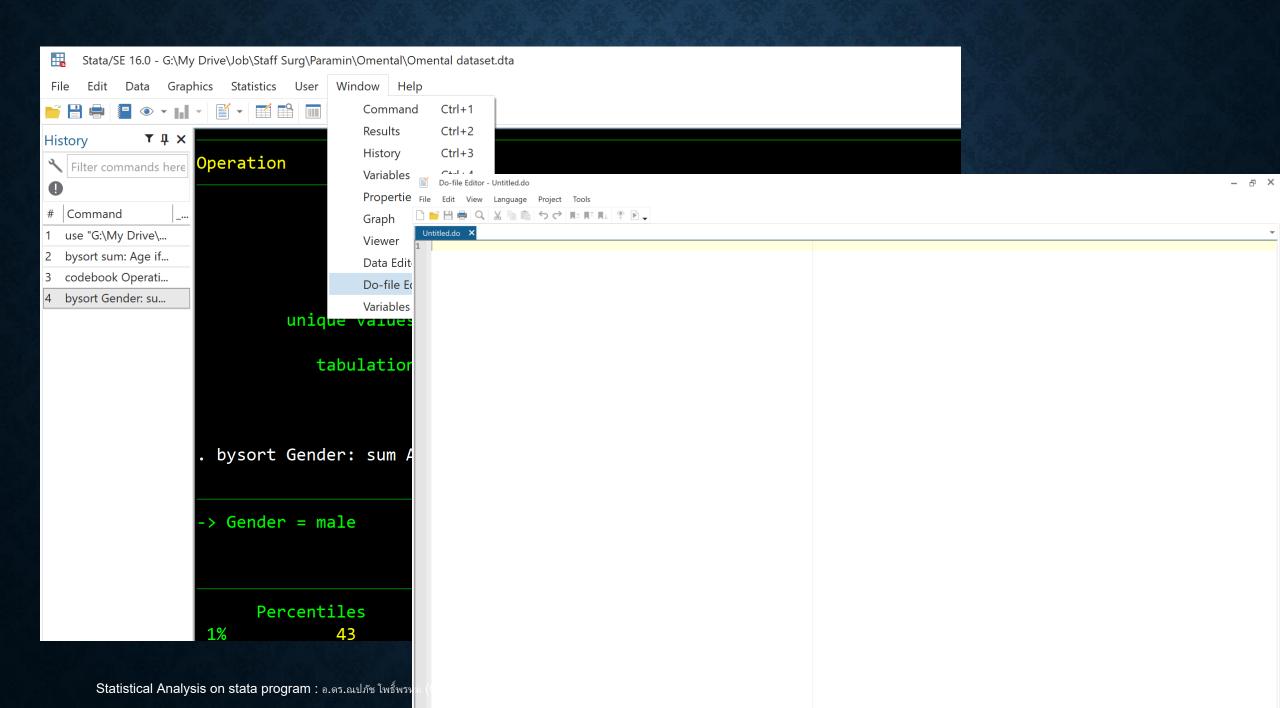
• list id age education if school==1 in 1/5, nolabel

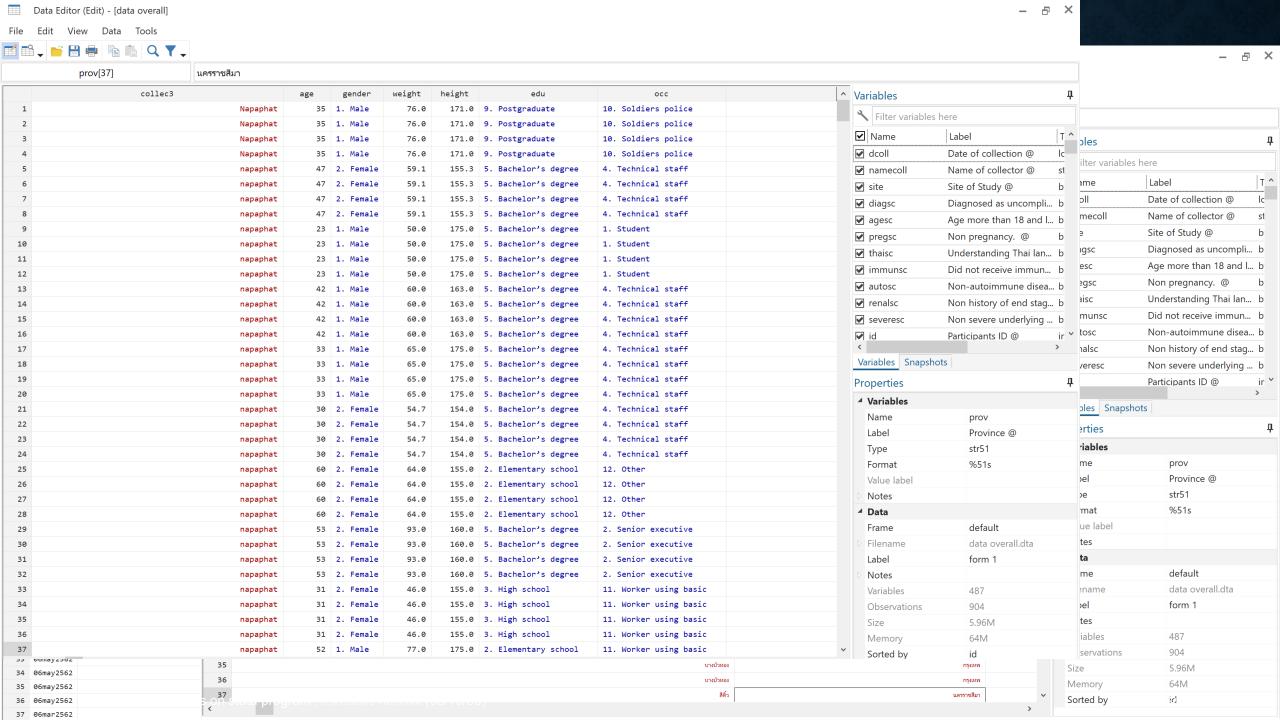
STATA'S .DO FILE

- Do-file: a file containing list of Stata commands
- Useful when you are doing large projects that may require repeated analysis

Starting a new empty do-file:

Window > Do-file Editor > New Do-file Editor (or through the "Do-file" icon)





. tab gender

2. Gender @	Freq.	Percent	Cum.
1. Male	356	39.38	39.38
2. Female	548	60.62	100.00
Total	904	100.00	

. codebook nausea

nausea a

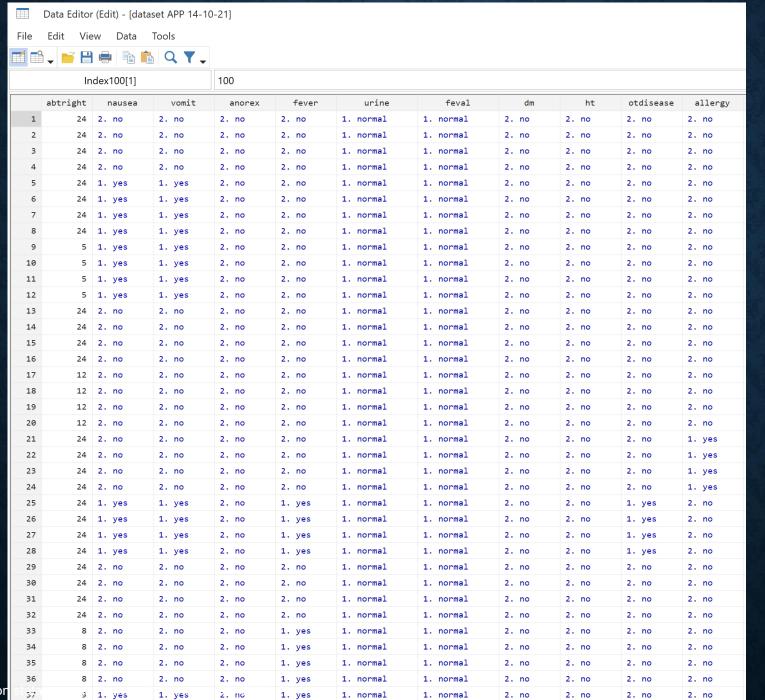
type: numeric (byte)
label: LABEL_ADMIS

range: [1,2] units: 1

unique values: 2 missing .: 0/904

tabulation: Freq. Numeric Label

ANALYSIS OF CATEGORICAL DATA



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****

CHI-SQUARE TEST

In assessing association between types of intervention and recurrence of appendicitis.

H0: Incidence of recurrence of appendicitis between those who received each intervention is not different.

Ha: Incidence of recurrence of appendicitis between those who received each intervention is different.

STATA COMMAND

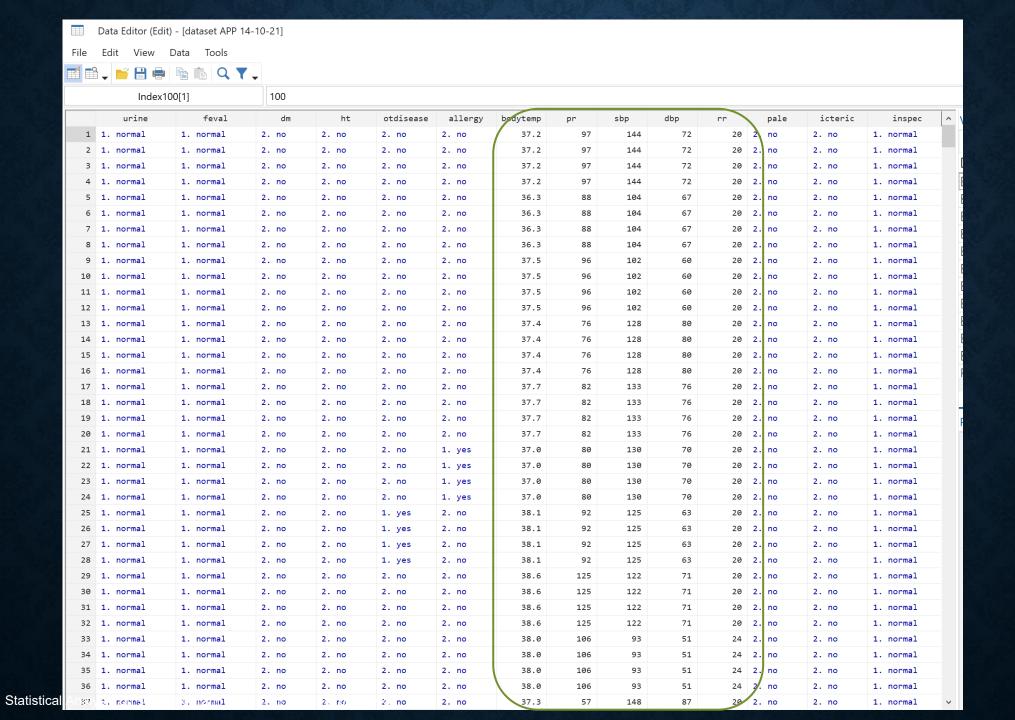
• tab intervention recurrence, col chi2 exact expect

The second second				
		rence		
intervention	0. no	1. yes	Total	
Open	552	0	552	
	536.7	15.3	552.0	
	62.80	0.00	61.06	
Laparoscopic	32	0	32	
	31.1	0.9	32.0	
	3.64	0.00	3.54	
Betalactamase	67	5	72	
	70.0	2.0	72.0	
	7.62	20.00	7.96	
Quinolone	46	6	52	
	50.6	1.4	52.0	
	5.23	24.00	5.75	
Cef_Metro	182	14	196	
	190.6	5.4	196.0	
	20.71	56.00	21.68	
Total	879	25	904	
	879.0	25.0	904.0	

CONCLUSIONS

- The p value is <0.001 which is less than the level of significance (0.05).
- We can reject the null hypothesis and conclude that types of intervention is associated with recurrence of appendicitis.
- In other words, the incidence of recurrence of appendicitis among those interventions are different.

ANALYSIS OF CONTINUOUS DATA

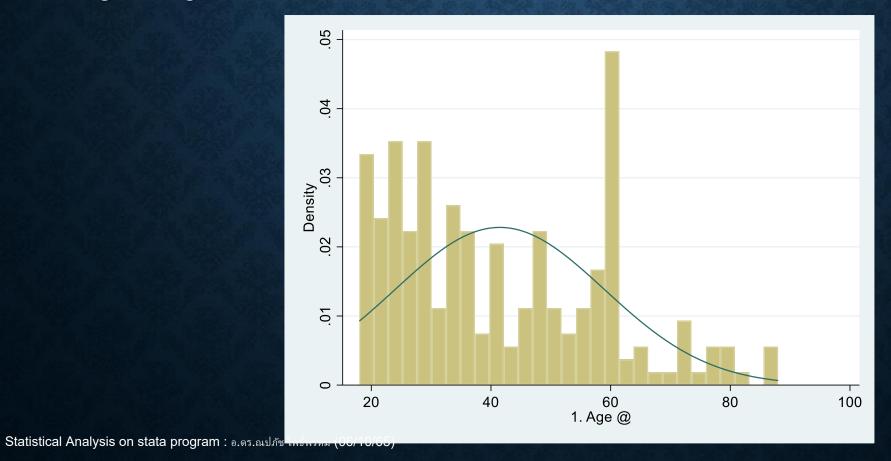


CHECKING FOR NORMAL DISTRIBUTION

- Construct the histogram
- Construct the normal probability plot
- Compare mean and median
- Compare mean and standard deviation

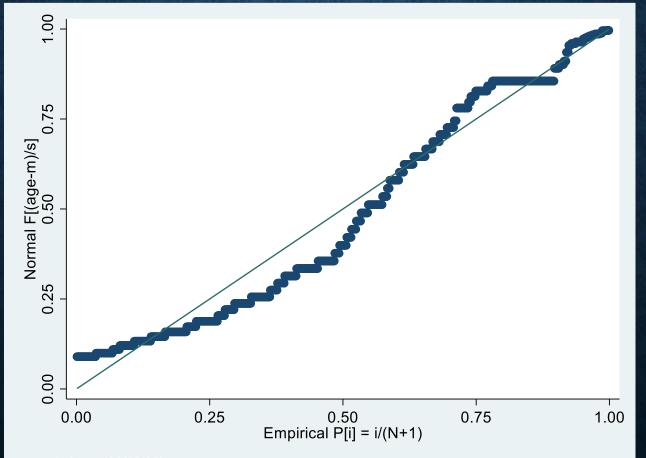
CONSTRUCT THE HISTOGRAM

• histogram age, norm



CONSTRUCT THE NORMAL PROBABILITY PLOT

pnorm age

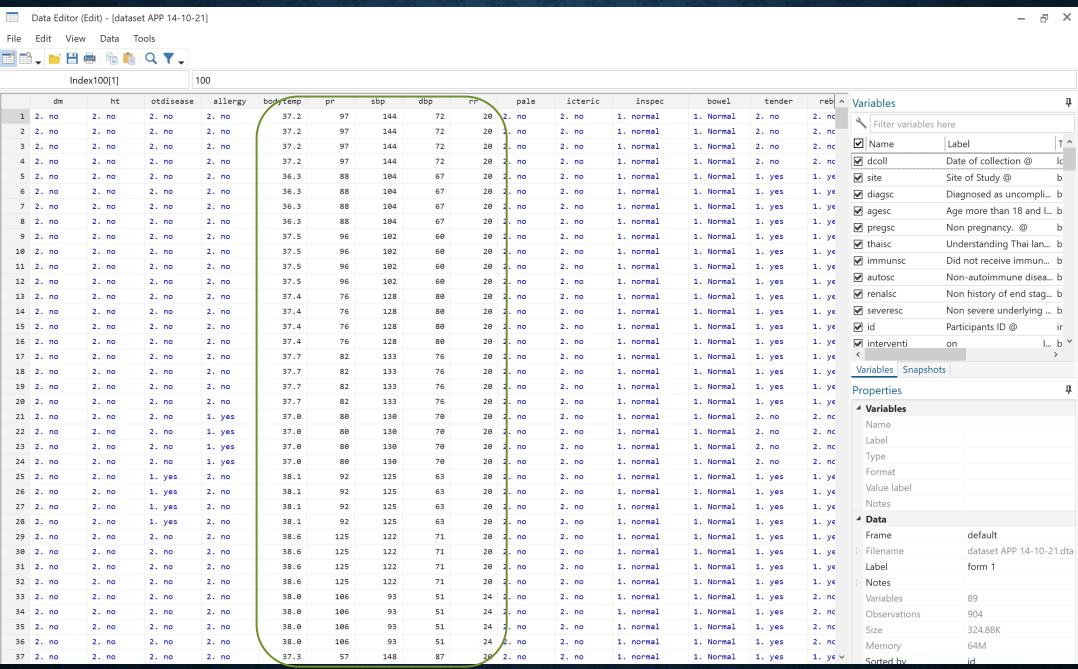


COMPARE MEAN WITH MEDIAN & COMPARE MEAN WITH STANDARD DEVIATION

• sum age, details

. sum a	ge, det			
		1. Age @		
Р	ercentiles	Smallest		
1%	18	18		
5%	19	18		
10%	21	18	Obs	892
25%	26	18	Sum of Wgt.	892
50%	37		Mean	41.47534
		Largest	Std. Dev.	17.48466
75%	58	88		
90%	63	88	Variance	305.7132
95%	73	88	Skewness	.5576089
99%	87	88	Kurtosis	2.375658

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**

EXAMPLE

• Researchers wanted to test if the mean/median age of these patients is different among recurrence appendicitis patients

H0: The mean/median age between the patients who have recurrence of appendicitis and who did not is not different.

Ha: The mean/median age between the patients who have recurrence of appendicitis and who did not is different.

STATA COMMAND

- i) Variance ratio test
- sdtest age, by(recurrence)

Interval]	[95% Conf.	Std. Dev.	Std. Err.	Mean	Obs	Group
42.67225	40.3266	17.59497	.5975564	41.49942	867	0. no
46.1483	35.1317	13.34441	2.668882	40.64	25	1. yes
42.62432	40.32635	17.48466	.5854296	41.47534	892	combined
= 1.7385	f =		s)	/ sd(1. ye	sd(0. no)	ratio =
= 866, 24	of freedom =	degrees			1	Ho: ratio =
atio > 1	Ha: ra	1	Ha: ratio !=		io < 1	Ha: rat:
) = 0.0505	Pr(F > f)	.1009	r(F > f) = 0	2*P	= 0.9495	Pr(F < f)

STATA COMMAND

- ii) Student t-test
- ttest age, by(recurrence)

Group	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf.	Interval]
0. no	867	41.49942	.5975564	17.59497	40.3266	42.67225
1. yes	25	40.64	2.668882	13.34441	35.1317	46.1483
combined	892	41.47534	.5854296	17.48466	40.32635	42.62432
diff		.8594233	3.548865		-6.105697	7.824543
diff = r	mean(0. n	o) - mean(1.	yes)		t	0.2422
lo: diff = 0	9			degrees	of freedom	890
Ha: dif	f < 0		Ha: diff !=	0	Ha: d	iff > 0
Pr(T < t) =	0.5956	Pr(T > t = 0	0.8087	Pr(T > t	= 0.4044

CONCLUSION

- The p value is 0.8087 which is greater than the level of significance.
- Therefore, we cannot reject the null hypothesis and conclude that the mean age of among recurrence of appendicitis is not different.

PAIRED T-TEST

ข้อตกลงเบื้องต้น

- ประชากร 2 กลุ่ม ที่เป็นไม่อิสระต่อกัน
- ข้อมูลเป็นแบบ continuous data
- การกระจายเป็นแบบ normal distribution

****หากไม่เป็นไปตามข้อตกลงเบื้องต้นให้ใช้ Wilcoxon matched signed ranks

test***

EXAMPLE

• Researchers wanted to test if the mean utility score of appendicitis patients before and after 7 days of received treatment are different.

H0: The mean of utility score before and after 7 days of reived treatment in the appendicitis patients are not different.

Ha: The mean of utility score before and after 7 days of reived treatment in the appendicitis patients are different.

STATA COMMAND

ttest base_Utility== after_Utility

```
Paired t test
                                                        [95% Conf. Interval]
Variable
              0bs
                         Mean
                                Std. Err.
                                            Std. Dev.
base U~y
              904
                     .4218142
                                 .0062965
                                            .1893128
                                                        .4094568
                                                                    .4341715
after ~y
              904
                     .6341018
                                 .0125648
                                             .377781
                                                        .6094421
                                                                    .6587614
   diff
              904
                    -.2122876
                                 .0132227
                                            .3975608
                                                       -.2382384
                                                                   -.1863369
    mean(diff) = mean(base_Utility - after_Utility)
                                                                t = -16.0548
                                               degrees of freedom =
Ho: mean(diff) = 0
                                                                        903
Ha: mean(diff) < 0 Ha: mean(diff) != 0 Ha: mean(diff) > 0
Pr(T < t) = 0.0000
                           Pr(|T| > |t|) = 0.0000
                                                          Pr(T > t) = 1.0000
```

CONCLUSION

- The p value is less than 0.001 which is less than the level of significance.
- So, we reject the null hypothesis and conclude that the mean difference of utility score is not equal to zero.
- Alternatively, the mean utility score of appendicitis patients before and after receiving treatment are different.

ANALYSIS OF VARIANCE (ANOVA)

ข้อตกลงเบื้องต้น

- ประชากรมากกว่า 2 กลุ่ม ที่เป็นอิสระต่อกัน
- ข้อมูลเป็นแบบ continuous data
- การกระจายเป็นแบบ normal distribution

หากไม่เป็นไปตามข้อตกลงเบื้องต้นให้ใช้ Kruskal Wallis test

EXAMPLE

• Researchers wanted to test if the mean weights of appendicitis patients among the treatment (i.e., open, LAP, beta-lactamase, quinolone and cephalosporin) are different.

H0:
$$\mu_{\text{open}} = \mu_{\text{LAP}} = \mu_{\text{beta}} = \mu_{\text{qui}} = \mu_{\text{cep}}$$

HA: Not all µ's are identical

STATA COMMAND

• oneway weight intervention, tabulate

interventio	Summary of 1				
n	Mean Std	. Dev.	Freq.		
0pen	61.1	12.2	552		
Laparosco	66.6	13.7	32		
Betalacta	61.1	11.8	72		
Quinolone	61.0	11.4	52		
Cef_Metro	62.6	12.9	196		
Total	61.6	12.4	904		
	Analysi	s of Va	riance		
Source	SS	df	MS	F	Prob > F
etween groups	1153.23427	4	288.308566	1.89	0.1107
Within groups	137396.545	899	152.832642		
Total	138549.779	903	153.432757		

Slide 40/50

CONCLUSION

- The p value from Bartlett's test is 0.666, which is greater than significance level, so we fail to reject the null hypothesis.
- We conclude that the variances of the patients weights among five different treatment groups are not different.
- The p value from ANOVA is 0.1107 which is less than the level of significance.
- Conclusion, we can not reject the null hypothesis and conclude that the mean weight of appendicitis patients is no different.

LOGISTIC REGRESSION

LOGISTIC REGRESSION ANALYSIS VS CORRELATION

Correlation

- Strength of Association
- NOT for cause-effect analysis
- NOT for Predictive purpose

Regression

- Strength of Association
- Cause-effect analysis
- Predictive model

EXAMPLE

• Determine the risk factors which associated with overall morbidity!!

Outcome: having morbidity and non-having morbidity

Predictors:

- Gender
- Age
- WBC
- Intervention

SAMPLE SIZE ESTIMATION

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

Check for updates



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

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 \(\beta\)-lactam and recommended non-\(\beta\)-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 \(\beta\)-lactam and non-\(\beta\)-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 nonβ-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

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.)

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

Disclosure Information: Authors have nothing to disclose. Timothy I Eberlein. Editor-in-Chief, has nothing to disclose.

Disclosures outside the scope of this work: Drs Campbell, Englesbe, and Krapohl's institution receives a partial salary paid for by the Blue Cross Blue Shield of Michigan value partnerships for the Michigan Surgical Quality Collaborative.

Support: Dr Vu's institution is supported by the Ruth L Kirstein National Service Research Service Award/National Institute of Diabetes, Digestive, and Kidney Diseases grant #1F32DK115340-01A1. Mr Kuriakose

institution was supported by the University of Michigan Institute for Healthcare Policy & Innovation Summer Fellowship Program.

Received June 2, 2019; Revised July 17, 2019; Accepted July 23, 2019. From the Michigan Surgical Quality Collaborative (Kuriakose, Vu, Englesbe, Campbell, Krapohl), Departments of Chemistry (Kuriakose), Surgery

(Vu, Karmakar, Hendren, Englesbe, Campbell, Krapohl), Pharmacy (Nagel), Obstetrics and Gynecology (Uppal), and Allergy and Immunology (Ravikumar), University of Michigan, Ann Arbor, MI.

Correspondence address: Greta L Krapohl, PhD, RN, Michigan Surgical Quality Collaborative, 2800 Plymouth Rd, Bldg 16 124W, Ann Arbor, MI 48109. email: krapohlg@med.umich.edu

RTIONS

P1 = 6.1%P2 = 9.5%



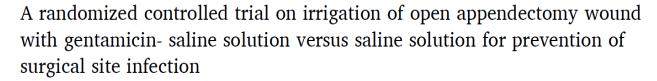
Contents lists available at ScienceDirect

International Journal of Surgery

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



Randomised Controlled Trial





Sameh Hany Emile *, Ahmed Hossam Elfallal , Mohamed Anwar Abdel-Razik , Mohamed El-Said , Ayman Elshobaky

General Surgery Department, Mansoura University Hospitals, Mansoura University, Mansoura City, Egypt

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

she 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.

ROPORTIONS

International Journal of Surgery 81 (2020) 140-146

- 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% Slide 47/50

REVIEW ARTICLE







Laparoscopic appendicectomy is superior to open surfor complicated appendicitis

Gaik S. Quah¹ · Guy D. Eslick¹ · Michael R. Cox^{1,2}

Received: 19 July 2018 / Accepted: 6 March 2019 / Published online: 13 March 2019 © Springer Science+Business Media, LLC, part of Springer Nature 2019

Abstract

Background Over the last three decades, laparoscopic appendicectomy (LA) has bee plicated acute appendicitis. The role of laparoscopic surgery for complicated appendicement 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: 0.19–4 tions (LA=1.8% vs. OA=6.4%; OR=0.25, 95% CI: 0.13–0.49, p < 0.001), post-or (LA=3.1% vs. OA=3.6%; OR=0.65, 95% CI: 0.42–1.0, p = 0.048) and mortality rate 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.

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 \pm 19.6 and OA group 82.2 min \pm 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 \pm 2.8 days) compared to the OA group (8.9 \pm 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 \pm 0.9 days) compared with the OA group (3.7 \pm 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).

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 <u>±</u> 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



 $\textbf{Keywords} \ \ Laparoscopic \ appendicectomy \cdot Open \ appendicectomy \cdot Complicated \ appendicitis \cdot Gangrenous \ appendicitis \cdot Perforated \ appendicitis \cdot Appendiceal \ abscess$



Contents lists available at ScienceDirect

Journal of Bone Oncology

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



EANS

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

Min-hao Wu¹, Ling-fei Xiao¹, Chong Zhang, Jun Lei, Zhou-ming Deng*

Department of Spine Surgery and Musculoskeletal Tumor, Zhongnan Hospital of Wuhan University, 168 Donghu Street, Wuchang District, Wuhan 430071, Hubei, People's Republic of China

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 prindications for surgical intervention. All procedures were performed under endoscopic graphication followed by complete curettage of tumor tissue. There were 19 males and 15 frage of 33.3 \pm 12.7 years (range, 17–68 years). The lesions were located in the upper extraphication (9, 26.5%) and pelvis (5, 14.7%). Primary outcomes were measured by

vention 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 \pm 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.

M.-h. Wu, et al.

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
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.





Contents lists available at ScienceDirect

International Journal of Surgery

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



OF MEANS

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 $\dot{}$, Ahmed Hossam Elfallal , Mohamed Anwar Abdel-Raz Ayman Elshobaky

General Surgery Department, Mansoura University Hospitals, Mansoura University, Mansoura City, Egypt

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 mepresent 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.



S.H. Emile et al.

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

International Journal of Surgery 81 (2020) 140–146

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
	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