



KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN KESEHATAN
RSPTN UNIVERSITAS HASANUDDIN
RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR



Sekretariat : Lantai 3 Gedung Laboratorium Terpadu
JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90245.

Contact Person: dr. Agussalim Bukhari, MMed, PhD, SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

REKOMENDASI PERSETUJUAN ETIK

Nomor : 324/UN4.6.4.5.31/PP36/2020

Tanggal: 15 Juni 2020

Dengan Ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

No Protokol	UH20030177	No Sponsor Protokol	
Peneliti Utama	dr Juan Fariz Oktorian	Sponsor	
Judul Peneliti	Perbedaan Rasa Nyeri Pasien Pasca Laparatomi Kolesistektomi Dengan Insisi Kocher dan Insisi Midline		
No Versi Protokol	2	Tanggal Versi	12 Juni 2020
No Versi PSP	2	Tanggal Versi	12 Juni 2020
Tempat Penelitian	RSUP Dr Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard	Masa Berlaku 15 Juni 2020 Sampai 15 Juni 2021	Frekuensi review lanjutan
Ketua Komisi Etik Penelitian Kesehatan FK UH	Nama Prof.Dr.dr.Suryani As'ad.,MSc,Sp.GK (K)	Tanda tangan	Tanggal
Sekretaris Komisi Etik Penelitian Kesehatan FK UH	Nama dr. Agussalim Bukhari,M.Med,PhD,Sp.GK (K)	Tanda tangan	Tanggal

Kewajiban Peneliti Utama:

- Menyerahkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 Jam dan dilengkapi dalam 7 hari dan Laporan SUSAR dalam 72 Jam setelah Peneliti Utama menerima laporan
- Menyerahkan Laporan Kemajuan (progress report) setiap 6 bulan untuk penelitian resiko tinggi dan setiap setahun untuk penelitian resiko rendah
- Menyerahkan laporan akhir setelah Penelitian berakhir
- Melaporkan penyimpangan dari prokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan

DIFFERENCES IN PAIN IN POSTOPERATIVE CHOLECYSTECTOMY LAPAROTOMY PATIENTS WITH THE KOCHER INCISION AND MIDLINE INCISION TECHNIQUES

Juan Fariz Oktorian*, Warsinggih* and Muhammad Asykar Palinrungi*

*Department of Surgery, University of Hasanuddin, Indonesia.

ABSTRACT Purpose: Compare the pain of the Kocher incision and midline incision in postoperative patients with cholecystectomy laparotomy. **Methods:** Observational, randomized controlled double sampling trial study **Results:** Pain that was felt by patients after 24 hours postoperatively with the Kocher incision technique, most showed a score of 3, which was 12 patients (60%), whereas pain felt by patients with a midline incision technique mostly showed a score of 2, i.e. there were 10 patients (50 %). Overall, the midline incision showed lower VAS results when compared to the Kocher incision, where most of the VAS in the midline incision showed a score of 2, whereas the Kocher incision showed a score of 3. The results of the Mann Whitney statistical test showed a value of $p = 0.192$ ($p > 0, 05$), which means that there is no significant difference between the pain level of the Kocher group and the midline group. **Conclusions:** There was no significant difference between the level of pain in the group of patients who received the treatment with the Kocher technique and the group with the midline technique.

KEYWORDS Surgical Pain, Laparotomy Cholecystectomy, Kocher Incision, Midline Incision

Introduction

Cholelithiasis is a formless material or crystals formed in the gallbladder, the composition of cholelithiasis is a mixture of cholesterol, bile pigment, calcium and inorganic matrix.[1]

The specific clinical symptom for diagnosing cholecystitis is biliary colic. Imaging methods that can be used to diagnose cholelithiasis are USG, ERCP, CT-Scan, MRI, and MRCP. It has been agreed that asymptomatic cholelithiasis does not require therapy, even for prophylactic purposes. The main choice of symptomatic cholelithiasis therapy is cholecystectomy. The incision technique in cholecystectomy laparotomy has several techniques, namely the Kocher incision and midline incision. [1,4]

Until now, cholelithiasis is still one of the most common gastrointestinal diseases, in some Western countries it is reported

that complaints related to gallstone disease and its complications are the most common cause of treatment for groups of gastrointestinal disorders. Although most have stones without symptoms when symptoms appear it is not uncommon to continue with problems and complications whose management requires high costs.[5]

Cholecystectomy is a definitive therapy for patients with symptomatic cholelithiasis, various incision techniques used in cholecystectomy laparotomy in which many different effects of Kocher incision and midline incision on pain in symptomatic cholelithiasis patients are performed after cholecystectomy laparotomy in which many Kocher incision techniques are performed. Tissue structure is incised, causing a higher pain perception when compared to the midline incision technique. [4]

Research purposes

Our Purpose in this study is to Comparing the pain of the Kocher incision and midline incision in postoperative cholecystectomy laparotomy patients.

Methods

This study was an observational, randomized controlled double sampling trial study, with a population of all patients coming to

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DOI:10.5455/IJMRCR.2020-05-171-pain

First Received: May 08, 2020

Accepted: July 02, 2020

Associate Editor: Ivan Inkov (BG);

¹Department of Surgery, University of Hasanuddin, Indonesia; Email Address: surgeon.jo@gmail.com

the General Surgery or Digestive Surgery section who entered through the IGD or Digestive Surgery at the Hospital Network of the Department of Surgery, Faculty of Medicine, Hasanuddin University, Makassar, starting in August 2019 - completed that was diagnosed with symptomatic cholelithiasis. Data were analyzed on the VAS using the Mann-Whitney U-test, where if the P-value <0.05.

Results

From this randomized controlled trial double sampling observational study, we obtained data on pain felt by patients after 24 hours postoperatively with the Kocher incision technique, most of which showed a score of 3, which was 12 patients (60%). In contrast, pain felt by patients with Midline incision techniques mostly show a score of 2 in which there are 10 patients (50%). Overall, the midline incision showed lower VAS results when compared to the Kocher incision, where most of the VAS in the midline incision showed a score of 2, whereas the Kocher incision showed a score of 3. The results of the Mann Whitney statistical test showed a value of $p = 0.192$ ($p > 0, 05$), which means that there is no significant difference between the pain level of the Kocher group and the midline group.

Based on table 1. it is known that patients with the Kocher incision technique are mostly performed in the group of patients classified as adults (18 to <60 years), that is 18 patients (90%), and patients with midline incision techniques are mostly also performed in the patient group the adult category is 15 patients (75%). The results of the fisher's exact test statistic showed that the value of $p = 0.4075$, which means that there were no significant differences in patient characteristics based on age between the groups that received surgery with the Kocher incision technique and the midline incision technique.

Based on the gender category, patients with Kocher incision were mostly performed in a group of patients with female gender, and there were 12 patients (60%). In contrast, patients with midline incision techniques were mostly carried out on male gender, i.e. there were 12 patients (60%). The statistical results of the fisher's exact test showed that the value of $p = 0.3431$, which means that there were no significant differences in patient characteristics by gender between the groups that received surgery with the Kocher incision technique and the midline incision technique.

Based on the category of history of hypertension, most patients with Kocher incision did not suffer from hypertension, there were 14 patients (70%), whereas patients with midline incision techniques were also mostly not suffering from hypertension, there were 16 patients (80%). The statistical results of the fisher's exact test showed that the value of $p = 0.7164$, which means that there were no significant differences in patient characteristics based on the presence or absence of a history of hypertension between the groups that received surgery with the Kocher incision technique and midline incision technique.

Based on the BMI category, most of the patients with Kocher incision suffer from obesity, and there is one patient (55%). In contrast, the patients with midline incision technique mostly do not suffer from hypertension, and there are 14 patients (70%). The statistical results of the fisher's exact test showed that the value of $p = 0.5896$, which means that there were no significant differences in patient characteristics based on the BMI category between the groups that received surgery with the Kocher incision technique and the midline incision technique.

Based on smoking habits, most of the patients with incisors

Table 1 Characteristics of Research Subjects

Characteristics	Incision		Total
	Kocher (n=20)	Midline (n=20)	
Age			
Adult	18 (90%)	15 (75%)	33 (82.5%)
Elderly	2 (10%)	5 (25%)	7 (17.5%)
Gender			
Male	8 (40%)	12 (60%)	20 (50.0%)
Female	12 (60%)	8 (40%)	20 (50.0%)
Histoty Of Hipertention			
Yes	6 (30%)	4 (20%)	10 (25%)
No	14 (70%)	16 (80%)	30 (75%)
Body Mass Index			
Underweight (<18,5)	1 (5%)	1 (5%)	2 (5%)
Normoweight (18,5 – 22,9)	8 (40%)	5 (25%)	13 (32,5%)
Overweight dan obesitas (≥ 23)	11 (55%)	14 (70%)	25 (62,5%)
Smoking			
Yes	5 (25%)	4 (20%)	9 (22,5%)
No	15 (75%)	16 (80%)	31 (77,5%)

Table 2 Differences in Pain Levels in Patients Post Cholecystectomy Laparotomy with Kocher Incision and Midline Incision Techniques

	Incision		Total	P
	Kocher (n=20)	Midline (n=20)		
Score 2	7 (35%)	10 (50%)	17 (42.5%)	0,192
Score 3	12 (60%)	8 (40%)	20 (50%)	
Score 4	1 (5%)	2 (10%)	3 (7.5%)	

are not a smoker, there are 15 patients (75%), while the patients with midline incision techniques are mostly non-smokers, there are 16 patients (80%). The statistical results of the Fisher's exact test showed that the value of $p = 1$, which means that there were no significant differences in patient characteristics based on smoking habits between the groups that received surgery with the Kocher incision technique and the midline incision technique. Based on the above results, it can be seen that the patient's characteristics based on age, gender, presence of a history of hypertension, BMI, and smoking habits, do not show significant or homogeneous differences.

Based on the data above, the pain felt by patients after 24 hours postoperatively with the Kocher incision technique, most showed a score of 3, i.e. 12 patients (60%). In contrast, the pain felt by patients with midline incision techniques mostly showed a score of 2 namely there were 10 patients (50%). Overall, the midline incision showed lower VAS results when compared to the Kocher incision, where most of the VAS in the midline incision showed a score of 2, while the Kocher incision showed a score of 3. But the results of the Mann Whitney statistical test showed a value of $p = 0.192$ ($p > 0.05$), which means that there was no significant difference between the pain levels of the Kocher group and the midline group. Thus, the difference in the level of pain in patients undergoing surgery with the Kocher incision technique is not significantly different from that undergoing surgery with a midline incision technique.

Discussion

Based on the results of research that has been conducted on 40 patients diagnosed with symptomatic cholelithiasis it can be concluded that there is no significant difference between the level of pain in the group of patients who received the Kocher technique and the group with the midline technique. Cholecystectomy is the definitive therapy for patients with symptomatic cholelithiasis, where there are various incision techniques used in these cholecystectomy operations. There are two types of incisions that are often used namely midline and subcostal oblique (Kocher Incision).[7] Midline incisions are used if there are pathological conditions such as hiatal hernias or duodenal ulcers that require surgical consideration, by making vertical incisions through the skin, subcutaneous fat, linea alba, and peritoneum.[7] Most fibers, crossing the alba line in the medial-caudal and medio-proximal directions, are cut transversely. Incision in this technique is easy and the risk of blood loss is minimal due to the avascular nature of the linea alba. Incisions can also be made quickly, averaging 7-9 minutes.[7] In addition, the area of view of surgery is very good for some cases. If an incision extension is needed, it can easily be made superior or inferior, and reach access to the entire abdominal cavity, including the retroperitoneum, making it very suitable for emergency exploration operations.[7]

The intensity of pain 24 hours postoperatively using VAS in patients with Kocher incisions mostly with a score of 3, there are 12 patients (60%), while patients with midline incision treatment mostly with a score of 2, there are 10 patients (50%), the test results statistically known that there is no significant difference in pain level between the Kocher group and the midline group.

Pain is a subjective sensation, discomfort usually associated with actual or potential tissue damage.[8] Pain can also be caused by mechanical stimuli such as tissue swelling that suppresses pain receptors.[8] Postoperative pain is pain that results from actual tissue damage (damage) which is followed by an inflam-

matory process.[8] Pain that occurs after cholecystectomy is associated with an area sensitive to incision wounds, the Kocher incision technique has many muscular tissue structures incised so that it is possible to cause a higher pain perception when compared to the midline incision technique, however the results of this study does not show any significant results based on statistical test results.[8]

The subcostal oblique incision technique (Kocher incision) used has the advantage of being believed to provide a good viewing area, more comfortable postoperative injuries and the incidence of incisional hernias less frequently than vertical incisions in the linea mediana.[9] A subcostal oblique or Kocher incision is an oblique incision that follows the costal margin approximately 2 cm below the right costus arcus and is directed toward the medio-cranial to below the xipoid, by making an incision in the transversus abdominis, rectus abdominis and internal oblique abdominis muscles.[10] This technique provides good exposure for biliary and bariatric surgery and can be extended bilaterally if needed. Many blood vessels and nerves are cut off, and the time to make an incision and the amount of blood loss is proportional to the transverse incision. [10]

Thus the hypothesis stating "there are differences in post-operative laparotomy pain with Kocher incision techniques and midline incision techniques in symptomatic cholelithiasis patients" is not proven. Patient characteristics based on age, sex, history of hypertension, BMI, and smoking habits, did not show significant or homogeneous differences. The prevalence of cholelithiasis is influenced by many factors, including ethnicity, gender, comorbidity, and genetics. In the United States, about 20 million people (10-20% of adults) have cholelithiasis. The risk of developing cholelithiasis increases with age. Cholelithiasis is uncommon in children without congenital abnormalities or haemolytic disorders.[11] Starting puberty, cholesterol concentrations in bile increase. After the age of 15 years, the prevalence of cholelithiasis in US women increases by about 1% per year; in men, the amount is less, about 0.5% per year. [11]

Cholelithiasis continues to form throughout adult life and the greatest prevalence in the elderly. The incidence in women falls with menopause, but the formation of new stones in men and women continues at a rate of around 0.4% per year until the end of the age.[11] The prevalence of cholelithiasis is lower in Asians and African Americans. Women are more likely to suffer from cholesterol cholelithiasis than men, especially during their reproductive period, when the incidence of cholelithiasis in women is 2-3 times in men. The difference seems to be due primarily to estrogen, which increases biliary cholesterol secretion.[11]

Cholelithiasis or gallstones is essentially a precipitate of one or more bile components (cholesterol, bilirubin, bile salts, calcium and protein). Risk factors for gallstones include cirrhosis, hemolysis, and bile duct infection. Risk factors for cholesterol include oral contraceptives, estrogens, and clofibrates; women experience cholesterol stones and gallbladder disease four times more often than men: usually over 40 years, multipara, and obesity.[2,11]

Conclusion

Based on the results of research that has been conducted on 40 patients diagnosed with symptomatic cholelithiasis it can be concluded that there is no significant difference between the level of pain in the group of patients who received the Kocher technique and the group with the midline technique. Thus, if seen from the level of pain, both the Kocher incision and the

midline incision can be used in operation, wherein it is known that the level of pain 24 hours postoperatively with patients with a Kocher incision is VAS 3 and the midline incision is VAS 2.

The Kocher incision provides an angle of view and surgery technique that makes it easier for the operator to perform the surgical technique because the incision is made right above the target organ so that it can still be an option when performing a cholecystectomy.

Conflict of interest

There are no conflicts of interest to declare by any of the authors of this study.

Funding

No funds were obtained to perform this case report.

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