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**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**<http://doi.org/10.5281/zenodo.3597600>Available online at: <http://www.iajps.com>**Research Article****A RANDOMIZED CONTROLLED TRIAL TO KNOW THE
OUTCOME OF OPEN VERSUS MINICHOLECTOMY
FOR CHOLELITHIASIS****Dr. Misbah Mushtaq*, Dr. Kiran Mushtaq*, Dr. Shaista Batool****** Nishtar Medical University, Multan****Article Received:** November 2019 **Accepted:** December 2019 **Published:** January 2020**Abstract:**

Objective: To compare the outcome of mini cholecystectomy with open cholecystectomy in the treatment of cholelithiasis.

Study Design: A randomized controlled trial.

Place and Duration: The study was carried out in Surgical department of Nishtar Hospital Multan for One year duration from July 2018 to June 2019.

Methods: A total of 100 cases; Fifty cases were included in each group. 100 patients who met the inclusion criteria entered the OPD were selected. Demographic data were recorded. All patients were diagnosed based on clinical history, clinical examination and related research. Consent was received in writing. Data were entered and analyzed using SPSS 18.0. Data were analyzed according to the proposed analysis plan.

Results: The mean age of the patients was 39.96 ± 3.84 years. The age range of the patients was 30-48 years. Mean hospital stay in Group A was 5.38 ± 1.15 and mean hospital stay in Group B was 3.02 ± 0.58 days, respectively. At the first visit, 14 patients (28%) in Group B and only 1 patient (2%) in Group A had a wound infection. According to P value, wound infection was significantly associated with the treatment group. Patients in Group A had a lower infection rate than Group B patients. That is, ($p = 0.000$ value) At the second visit, 8 patients (16%) and 3 patients in Group B had a wound infection in Group A. At the second visit, wound infection was statistically identical in both treatment groups. that is, ($p = 0.110$ value). Only 44 patients (88%) had severe pain in Group B, and only 12 patients (24%) had severe pain in Group A. Considering this result, the rate of severe pain at 12 hours was higher in Group B patients than in Group A patients.

Conclusion: Mini cholecystectomy is an effective procedure and associated with less postoperative pain and infection with less discomfort for patients and shorter hospital stay.

Key words: Cholelithiasis, conventional, cholecystectomy, laparoscopic, mini-laparoscopic.

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INTRODUCTION:

Cholelithiasis is the most common problem of hepatobiliary system and cholecystectomy is the most common surgical intervention¹. The first successful cholecystectomy was performed on 15 July 1982 by Carl Langenbuch in a 42-year-old man in Lazaruskrankenhas, Berlin². Historically, cholecystectomy has been performed with a 7-10 cm incision in the shape of a T that intersects most of the rectus muscle. Although exposure is good, but the cosmetic results are relatively poor, with prolonged hospital stay and more pain³. To address these problems, many people attempted to perform a mini-cholecystectomy as described by Dubois and Bertheol in 1990 for the first time⁴. He noted that this incision had less postoperative pain (also comparable to laparoscopic cholecystectomy). The duration of surgery and length of hospital stay are shorter because of the good aesthetic results⁵. However, the disadvantage is relatively poor exposure. Therefore, workers from all over the world have different views on the subject, since Gilliland and Traverso, 1990 and Roslyn JJ et al., 1993, describe the traditional right subcostal kocker incision as the gold standard⁵. Because it provides good access and less complication rate. However, workers such as Moss in 1983, Amir M et al., 2007, Khan N. et al., 2009 and Saeed N et al., In 2010, argue that mini cholecystectomy in the new gold standard refers to an open cholecystectomy⁶. Due to less pain, good cosmetic results, early return to work and lower operating costs. It looks safe and can be used where laparoscopic facilities are not available. Different studies have shown that the risk of complications in mini cholecystectomy, that is, the mean hospital stay is 3.33 ± 1.75 , severe pain is 16% and is evaluated by VAS at zero day's postoperatively⁷. It was a daily care procedure and wound infection was 4%. In the case of conventional open cholecystectomy, hospital stay was 8.66 ± 4 days, severe pain was 56% and wound infection was 24%⁸.

MATERIALS AND METHODS:

This randomized controlled trial was held in the Surgical department of Nishtar Hospital Multan for One year duration from July 2018 to June 2019. Total 100 cases; Fifty cases in each group were calculated by taking 80% strength of the test, 5% significance level and the expected percentage of wound infection, ie 4% with minimal cholecystectomy and 24% with conventional cholecystectomy. The

sampling technique used was non probability. Patients with a diagnosis of cholelithiasis (diagnosed by ultrasonography on the basis of gallstones in the abdomen and pain in the right hypochondrium) and for general anesthesia (AAS I and II) were included in both sexes. Patients with diabetes mellitus, pregnant women, and women diagnosed with peritonitis, ascites, clinical history, clinical examination and ultrasound of the abdomen, fasting blood glucose level > 110 mg / dl were excluded from the study. 100 patients were recruited from the OPD, which met the inclusion criteria. Demographic data were recorded. All patients were diagnosed based on clinical history, clinical examination and related research. Consent was received in writing. The confirmed cases that met the inclusion criteria were randomly divided into two groups as Group A and Group B by lotto 1. Group A: Minimum cholecystectomy was performed with a 5 cm transverse right lower cortical incision, preserving the length or less of the rectus muscle. Group B: conventional open cholecystectomy was performed by conventional right subcostal Kocher incision with rectus muscle procedure. Follow-up was performed on the seventh day after patient removal to remove the suture and observe infection of the wound; the second visit was made ten days after the first visit to observe wound infection.

All data related to hospitalization and reviews such as severe pain and wound infection were compiled in a specially designed manner. Data were analyzed with SPSS 18.0 version. The variables to be analyzed included hospital stay and complications such as pain and wound infection. Variable simple descriptive statistics were analyzed using mean and standard deviation for quantitative variables such as hospitalization and age. Frequency and percentage of qualitative data such as wound infection and gender. Independent sample t test for quantitative data such as Chi-square and mean hospital stay for qualitative variables such as injury infection and severe pain. $P < 0.05$ was accepted as significant.

RESULTS:

All patients were diagnosed based on clinical history, clinical examination and related research. The mean age of all patients was 39.96 ± 3.84 years. The age range of the patients was 30-48 years. The mean age of the patients in Group B and Group A was 41.26 ± 2.76 and 38.66 ± 4.33 , respectively (Table-1).

Table 1: Descriptive statistics for age (years) in treatment

	Group A	Group B	Total
Mean	38.66	41.26	39.96
Std. deviation	4.33	2.76	3.84
Minimum	30	36	30
Maximum	48	48	48

The distribution of patients by gender indicates that there were 7 male and 43 female patients in Group B. In Group A, there were 10 male patients and 40 female patients, respectively (Table 2).

Table 2: Gender distribution of patients in treatment groups

Gender	Group A	Group B	Total
Male	10(20%)	7(14%)	17
Female	40(80%)	43(84%)	83

The mean length of hospital stay for all patients was 4.20 ± 1.49 days. The length of hospital stay varies between 2-8 days. Mean hospital stay in Group A was 5.38 ± 1.15 and mean hospital stay in Group B was 3.02 ± 0.58 days, respectively (Table 3).

Table 3: Descriptive statistics for hospital stay (days) in treatment group

	Group A	Group B	Total
Mean	3.02	5.38	4.20
Std. deviation	0.58	1.15	1.49
Minimum	2	4	2
Maximum	5	8	8

At the first visit, 14 patients (28%) in Group B and only 1 patient (2%) in Group A had a wound infection. According to P value, wound infection was significantly associated with the treatment group. Patients in Group A had a lower infection rate than Group B patients. That is, ($p = 0.000$ value) at the second visit, 8 patients (16%) and 3 patients in Group B had a wound infection in Group A. At the second visit, wound infection was statistically identical in both treatment groups. That is, ($p = 0.110$ value) (Table 4).

Table 4: Wound infection in treatment group

Wound infection	1 st Visit		2 nd Visit	
	Group A	Group B	Group A	Group B
Yes	1(2%)	14(28%)	3(6%)	8(16%)
No	49(98%)	36(72%)	47(94%)	42(84%)
Pvalue	0.000		0.110	

Pain was assessed at 12 hours in both treatment groups. Only 44 patients (88%) had severe pain in Group B, and only 12 patients (24%) had severe pain in Group A. Considering this result, the rate of severe pain at 12 hours was higher in Group B patients than in Group A patients. That is, (p value = 0.000) (Table-5).

Table 5: Sever pain at 12th hours in treatment groups

Gender	Group A	Group B	Total
Male	10(20%)	7(14%)	17
Female	40(80%)	43(84%)	83

Table 5: Sever pain at 12th hours in treatment groups

Severe pain at 12 th hour	Group A	Group B	Total
Yes	12(24%)	44(88%)	56
No	38(76%)	6(12%)	44

P value= 0.000 (Significant: p -value<0.05)

Therefore, it can be said that mini cholecystectomy is effective in the treatment of cholelithiasis in terms of wound infection and pain severity experienced by patients.

DISCUSSION:

Biliary diseases are an important part of the digestive system diseases in the world; cholelithiasis

is the precursor corridor and causes general disease requiring surgical intervention for a general treatment⁹. Over the past 100 years,

cholecystectomy has prevailed as the preferred treatment for gallbladder stones. The basis for performing the first cholecystectomy in history was Carl Langenbuch, who performed it on July 15, 1882 in a 42-year-old man in Lazaruskrankenhaus in Berlin. Historically, cholecystectomy has been performed with a 7-10 cm incision in the shape of a T that intersects most of the rectus muscle¹⁰. Since then, seven additional incisions have been described, the most commonly used paramedian and Kocher subcostal incisions for cholecystectomy. Mini cholecystectomy was first performed by Dubois and Berthelot more than twenty years ago¹¹.

In 1990, laparoscopic cholecystectomy was presented and positive results were published. Since then, laparoscopic cholecystectomy has become a gold treatment for cholelithiasis, but the general benefits are less postoperative pain, early ambulation, scarring, early return to work, this technique is annoying and expensive for teamwork, high costs, and not available in most hospitals and because it contains sophisticated instruments¹². Since short courses are often useless, the training period of experts is compulsory. In addition, it should only be performed by specialists in open bile surgery. Meeting special tools is very important. The surgeon should learn to work from a two-dimensional television image with a lack of depth or tactile stimulation. Numerous complications are also associated with laparoscopic cholecystectomy. Deziel et al. Reported 1.2% (0.6% common bile duct injury rate) of complications requiring laparotomy. Mini-cholecystectomy involves performing a cholecystectomy through a rectal subcostal incision of 4-6 cm. In recent years, there have been studies comparing laparoscopic cholecystectomy with minicolectomy and found a mini cholecystectomy similar to laparoscopic cholecystectomy¹³. In this study, the mean age of the patients was 39.96 ± 3.84 . The age range of the patients was 30-48 years. The distribution by sex shows more female presentations than male patients. That is, (male: 17% and female: 87%). In a local study from Karachi, the age range of patients aged 25 to 70 years, female predominance with cholelithiasis (90%) was reported¹⁴. Another local study by Multan reported that the age range of patients presenting with cholelithiasis was <40 (28%) > 50 (40%) years. The rate of female patients (84%) was higher than male patients with cholelithiasis. A local study in Multan reported that the average age of patients diagnosed with cholelithiasis ranged from 18 to 77 years. Female case presentation with cholelithiasis was higher than male patients.

The mean hospital stay was 3.02 ± 0.58 , minicolectomy was 2 to 5 days, and conventional cholecystectomy was 5.38 ± 1.15 days,

respectively. The Karachi study reported that he was hospitalized on average for 2 days with mini cholecystectomy. Patients treated with conventional open cholecystectomy; mean hospital stay was 8.66 days, the shortest 6 days and the longest 10 days. The patients were treated with mini cholecystectomy, mean hospital stay was 3.33 days, less than 2 days and longer than 5 days¹⁵.

In an international study conducted at Beyrouth, Beyrouth Dahr-e Bacheq Hospital in 1998, it was shown that there was no biliary complication in minicolectomy, low analgesia, low pain, and hospitalization for an average of 2 days. Normal back to work is after 8 days and 14 days.

CONCLUSION:

Mini cholecystectomy is an excellent alternative to conventional cholecystectomy in terms of good cosmetics related to postoperative hospital stay, infection and postoperative pain and scar scarring. Mini-cholecystectomy is associated with less inconvenience for the patient and the incidence of postoperative complications.

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