ORIGINAL ARTICLE

Open versus Minicholecystectomy: Comparative Prospective Randomized Controlled Trial in the Management of Cholelithiasis

TANVEER ANWER, AFSAR A BHATTI, SIKANDER H GONDAL

ABSTRACT

Aim: To compare the outcome of mini cholecystectomy with open conventional cholecystectomy in the management of cholelithiasis.

Methods: This was a randomized controlled trial, conducted in the Department Of Surgery, Lahore General Hospital/Post Graduate Medical institute, Lahore. A total of 100 cases; 50 cases in each group was included in the study. 100 patients were admitted from OPD of Lahore General Hospital Lahore fulfilling inclusion criteria. Demographic information was recorded. All admitted patients were diagnosed on the basis of history, clinical examination and relevant investigations. Written consent was obtained. Data entry and analysis was done by using SPSS 11. Data was analyzed according to the proposed analysis plan.

Results: Mean age of all patients was 39.96±3.84 years. Age range of patients was 30-48 years. In Group-A mean hospital stay was 5.38±1.15 and in Group-B mean hospital stay was 3.02±0.58 days respectively. At 1st visit 14(28%) patients in Group-B and only 1(2%) patient in Group-A had wound infection. According to p-value wound infection was significantly associated with treatment group. Patients in Group-A had less infection rate as compared to Group-B patients. i.e., (p-value=0.000) Whereas at 2nd visit 8(16%) patients in Group-B and 3 patients in Group-A suffered from wound infection. At 2nd visit wound infection was statistically same in both treatment groups. i.e., (p-value=0.110). It was observed that in Group-B only 44(88%) of the patients had severe pain whereas only 12(24%) of the patients in Group-A had severe pain. Keeping in mind this results rate of severe pain at 12th hour was high in Group-B patients as compared to Group-A patients.

Conclusion: Mini cholecystectomy is effective and associated with less patients discomfort in terms of post operative pain and infection as well as with less hospital stay.

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

INTRODUCTION

Cholelithiasis is the most common problem of the hepatobiliary system and cholecystectomy the commonest surgical intervention[1]. The first ever successful cholecystectomy was performed by Carl Langenbuch, on 15 July 1982 at the Lazaruskrankenhas in Berlin on a 42 yrs old man[2].

Historically cholecystectomy has been done through T-shaped 7-10cm incision that cuts the majority of the rectus muscle. Although exposure is good but its cosmetic results are relatively poor, along with more pain and prolong hospital stay[3].

To address these problems many people tried Mini cholecystectomy as describe by dubois and Bertheol in 1990 for the first time[4]. They claimed that this incision has lesser post operative pain (which is also comparable with laparoscopic cholecystectomy)[5,6]. Operative time and hospital stay are less with good cosmetic results. But disadvantage is relative poor exposure[7]. Therefore on the subject, workers all over the world are of the different opinion as Gilliland & Traverso, 1990 and Roslyn JJ et al., 1993 described that traditional right subcostal kocher incision is gold standard as it give good access and less complication rates. But the workers like Moss in 1983, Amir M et al., 2007, Khan N. et al 2009, and Saeed N, et al., in 2010 are of argument that mini cholecystectomy in new gold standard as for an open cholecystectomy is concerned because of less pain good cosmetic results, early return to work and less operation cost. It appears to be safe and can be used where laparoscopic facilities are not available[8,9]. Different studies have shown that risk of complications in mini cholecystectomy i.e., mean hospital stay was 3.33±1.75, sever pain was 16% and was assessed in zero post operative day through VAS as it is a day care procedure and wound infection was 4%. Whereas in case on conventional open cholecystectomy hospital stay was 8.66±4 days, sever pain 56% and wound infection was 24%[10].

Department of Surgery, Lahore General Hospital, Lahore
Correspondence to Dr. Afsar Ali Bhatti, Associate Professor Email: afsarbhatti@hotmail.com

The rationale of this study is to compare mini cholecystectomy with that of conventional open cholecystectomy and there is only one study available conducted by Abdul Manan with sample size of 25 in each group, which is less that of this study. There are lots of comparative studies available between laparoscopic versus mini cholecystectomy[3,5,7,8] which shows mini cholecystectomy is as effective as laparoscopic cholecystectomy, which is gold standard. But I want to compare mini cholecystectomy with conventional open cholecystectomy which will add to the literature and help surgeons to opt this technique.

MATERIAL & METHODS

This was a randomized controlled trial conducted in the Department Of Surgery, Lahore General Hospital/Post Graduate Medical institute, Lahore during six month. A total of 100 cases; 50 cases in each group is calculated with 80% power of test, 5% level of significance and taking expected percentage of wound infection i.e., 4% with minim cholecystectomy and 24% with conventional cholecystectomy. Sampling technique used was non probability purposive sampling. Patients of both sexes, age between 30 to 70 with diagnosis of cholelithiasis (diagnosed on the basis of history with complain of pain in right hypochondrium, and gall stones on ultrasound abdomen) and fit for general anesthesia (ASA I and II) were included in the study. Patients having peritonitis, ascites, assessed by history, clinical examination and ultrasound abdomen, having diabetes diagnosed as blood fasting sugar level >110mg/dl or patients already taking medications for this, pregnant female and choledocholithiasis and acute cholecysititis were excluded from the study. 100 patients were admitted from OPD of Lahore General Hospital Lahore fulfilling inclusion criteria. Demographic information was recorded. All admitted patients were diagnosed on the basis of history, clinical examination and relevant investigations. Written consent was obtained. Proven cases fulfilling with inclusion criteria were divided into two groups, Group A and Group-B with random lottery method **1.** Group-A: Minim cholecystectomy was done through a right sub costal incision transverse 5cm in length or less rectus muscle sparing.

Group-B: Conventional open cholecystectomy was done through right subcostal Conventional Kocher's incision with rectus muscle transaction. Follow up was done on the 7th post op day after the discharge of the patient for the removal of stitches and to note the wound infection, 2nd visit was done ten day after the first visit to note the wound infection. All the data regarding stay in hospital and compilations like sever pain, wound infection, was collected in a specially designed proforma.

Data was analyzed by SPSS version 11. Variables to be analyzed include hospital stay and complications like pain, wound infection. The variable analyzed by using simple descriptive statistics, mean and standard deviation for quantitative variables, like stay in hospital and age. Frequency and percentage for qualitative data like wound infection and gender. Independent sample t-test for quantitative data like mean hospital stay and Chi-square for qualitative variables like wound infection and sever pain. p-value <0.05 was taken as significant.

RESULTS

Total 100 patients were admitted from OPD of Lahore General Hospital Lahore fulfilling inclusion criteria. Demographic information was recorded. All admitted patients were diagnosed on the basis of history, clinical examination and relevant investigations. Mean age of all patients was 39.96±3.84 years. Age range of patients was 30-48 years. Mean age of patients in Group-B and in Group-A was 41.26±2.76 and 38.66±4.33 years respectively (Table-1). Gender distribution of patients shows that in Group-B there were 7 male and 43 female patients. In Group-A there were 10 male and 40 female patients respectively (Table-2) Mean hospital stay for all patients was 4.20±1.49 days. Hospital stay ranges between 2-8 days. In Group-A mean hospital stay was 5.38±1.15 and in Group-B mean hospital stay was 3.02±0.58 days respectively (Table 3). At 1st visit 14(28%) patients in Group-B and only 1(2%) patient in Group-A had wound infection. According to p-value wound infection was significantly associated with treatment group. Patients in Group-A had less infection rate as compared to Group-B patients. i.e., (p-value=0.000) Whereas at 2nd visit 8(16%) patients in Group-B and 3 patients in Group-A suffered from wound infection. At 2nd visit wound infection was statistically same in both treatment groups. i.e., (p-value=0.110) (Table 4).

Pain status was assessed in both treatment groups at 12 hours. It was observed that in Group-B only 44(88%) of the patients had severe pain whereas only 12(24%) of the patients in Group-A had severe pain. Keeping in mind this results rate of severe pain at 12th hour was high in Group-B patients as compared to Group-A patients. i.e. (p-value=0.000) (Table-5). So it can be said that Mini Cholecystectomy is effective in the management of cholelithiasis in terms of wound infection and severity of pain experienced by patients.

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
Minimu7m	30	36	30
Maximum	48	48	48

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

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

Table 4: Wound infection in treatment group

Wound infection	1st Visit		2nd 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	

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 12th 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)

DISCUSSION

Biliary diseases constitute a major portion of digestive tract disorders world over, with cholelithiasis being the fore-runner and causing general ill-health requiring surgical intervention for total cure. For last more than 100 years cholecystectomy has enjoyed supremacy as treatment of choice for Gallstones. The credit of performing first ever cholecystectomy goes to Carl Langenbuch, who performed it on 15 July 1882 at the Lazaruskrankenhas in Berlin on a 42 years old man[11,12]. Historically cholecystectomy has been done through an T-shaped 7-10cm incision that cuts the majority of rectus muscle. Since then seven further incisions for cholecystectomy have been described, of these most commonly used are the right paramedian and Kocher sub-costal incision. Mini-cholecystectomy was first described more than two decades ago by dubois and Berthelot and their favourable results were reported at the same time Laparoscopic cholecystectomy was introduced in 1990[13,14,15],..

Since then laparoscopic cholecystectomy has become a gold standard treatment for cholelithiasis, but overall benefits of less postoperative pain, early ambulation, less conspicuous scar and early return to work, this technique is tedious and team work is required, moreover expenditure is high as it involves sophisticated expensive instruments which may not be available in most hospitals. A period of specialist hand on training is mandatory as short courses are generally unhelpful. Besides, it should only be practiced by those proficient in open biliary surgery Familiarisation with special instruments is crucial. The surgeon has to learn to operate from a two-dimensional television image with lack of depth or tactile stimulus. Significant number of complications is also associated with laparoscopic cholecystectomy, Deziel *et al* reported 1.2% of complications requiring laparotomy (0.6% rate of common bile duct injury). Mini-cholecystectomy implies performing a cholecystectomy through 4–6cm incision subcostal rectus sparing incision[16]. For the past few years there were studies comparing laparoscopic cholecystectomy with minicholecystectomy and found mini-cholecystectomy comparable with laparoscopic cholecystectomy[17,18,19]. Mean age of patients in this study was 39.96±3.84 years. Age range of patients was 30-48 years. Gender distribution shows greater female presentation as compared to male patients. i.e., (male:17% & female:87%). A local study from Karachi reported age range of patients 25-70 years with female dominancy (90%) who presented with cholelithiasis[3]. Another local study from Multan reported age range of patients who presented with cholelithiasis was <40(28%) >50(40%) years. Female presentation (84%) was high as compared to male patients with cholelithiasis[10]. A local study from Lahore reported mean age of patients who presented with cholelithiasis was 43 years with age range 18-77 years. Female presentation with cholelithiasis was higher as coampred to male patients[4].

According to the results of an Indian study the age range of patients who presented with cholelithiasis was 9 to 70 years. The mean age incidence was 41.55 yrs. Male: female ratio was 1:2.75[20]. The age incidence of present study is comparable with the other local & international studies. In contrast to Western countries, the Pakistani patients are younger in age. Various factors like shorter life span, racial, socioeconomic and dietary factors have been implicated. The gender distribution of current study i.e. female: 83% & male:17% compares well with the other studies.

There is consistent evidence that the gall bladder diseases are more common in females in all age groups. Down et al in 1983 reported that it is the progesterone rather than oestrogen which is responsible for cholelithiasis[20,21].

Mean hospital stay in Mini Cholecystectomy was 3.02±0.58 with range for hospital stay was (2-5) days and in conventional cholecystectomy was 5.38±1.15 days with age range was (4-8) days respectively. Study from Karachi reported mean hospital stay of 2 days with mini cholecystectomy[3]. Patients who were treated conventional open cholecystectomy; the average hospital stay was 8.66 days with shortest stay of 6 days and longest stay of 10 days. While patients who were treated with mini cholecystectomy, the mean hospital stay was 3.33 days with shortest of 2 days and longest of 5 days[10].

Study from Lahore reported that average post-operative hospital stay after mini cholecystectomy was 2 days (1-5 days). All patients returned back to work within 2 weeks of surgery[4]. Study from Thailand reported the postoperative hospital stay after Mini-cholecystectomy was shorter in patients with chronic cholecystitis: 2 days (range 2-5) vs 4 days (range 2-14), p=0.0009[22]. O'Kelly TJ et al confirmed cholecystectomy performed through a small incision is feasible and followed by shorter recovery time than conventional cholecystectomy[26]. Olsen DO3 in 1993 reviewed the literature and concluded that minilaparotomy cholecystectomy is a suitable alternative to laparoscopic cholecystectomy, a technique which has the same benefits without problems inherent in laparoscopic surgery[27].

Majeed et al in 1996 concluded that laparoscopic cholecystectomy takes longer to do than minilaparotomy cholecystectomy and does not have any significant disadvantages in terms of hospital stay or postoperative recovery[28]. Supe AN et al observed that both are comparable procedures for the treatment of gall stones disease in India[29]. In the present study also the postoperative hospital stay was less in mini cholecystectomy group as compared to standard open method. There were 3 local studies in which reported infection rate was 2% on with mini cholecystectomy in the management of cholelithiasis[3,4,9]. Whereas in a local comparative study infection rate was 24% in conventional cholecystectomy and 4% in mini cholecystectomy[10].

Study done by Manan reported a significant difference in occurrence of pain post operatively with the use of mini and open Cholecystectomy technique. In open Cholecystectomy 56% of the patients experienced severe pain wile in mini cholecystectomy only 16% of the patients reported that they had severe pain[10].

A study was conducted in K.V.S.S. Site Hospital, Karachi, which discussed 10 years, experience on minicholecystectomy versus 10 years experience of conventional cholecystectomy. In this study minicholecystectomy was performed through a small (about 3.5 cm) subcostal incision and cases were studied for operative time, postoperative pain, postoperative hospital stay, resumption of daily life and work. It states that as a result of comparison of 2 procedures it is concluded that mini-cholecystectomy is superior to conventional cholecystectomy[30].

In an international study conducted at Dahr-e Bacheq Hospital, Beyrouth, Liban in 1998 showed that in minicholecystectomy no biliary complications, little pain with low analgesia, average hospital stay of 2 days and return to normal working is between 8 days and 14 days[31].

CONCLUSION

Mini cholecystectomy is an excellent alternative of conventional cholecystectomy as far as postoperative hospital stay, postoperative infection and pain as well as with good cosmetics concerned with scar mark. Mini- cholecystectomy is associated with less patient's discomfort, and less incidence of postoperative complications.

REFERENCES

1. Saeed A, Nawaz M, Noreen A, Ahmad S. Early cholecystectomy in acute cholecystitis: experience at dhq hospital Abbottabad. J Ayub Med Coll Abbottabad. 2010;22(3).
2. Chalkoo M AS. The Historical Perspective, Current Advancements and Innovations in Laparoscopic Cholecystectomy. J Pak Med Stud. 2012;2(3):5-6.
3. Saeed N, Nasir T, Burki B, Channa GA. Mini-cholecystectomy: a feasible option. J Ayub Med Coll Abbottabad. 2010;22(3):3.
4. Hammad Naeem Rana FHT, Mohd. Mini Cholecystectomy through a 5cm Subcostal Incision Experience at NSSSH Lahore. Pak. J Med Health Sci.2010;5(4):120-5.
5. Purkayastha S, Tilney HS, Georgiou P, Athanasiou T, Tekkis PP, Darzi AW. Laparoscopic cholecystectomy versus mini-laparotomy cholecystectomy: a meta-analysis of randomised control trials. Surgical endoscopy. 2007;21(8):1294-300.
6. Kesus F AU, Noordergraaf GJ, Roukema JA, Gooszen HG. Laparoscopic vs. small incision cholecystectomy implications for pulmonary function and pain by Jesus. Acta Anaesthesiol Scand. 2008;52:363-73.
7. Chalkoo M, Ahangar S, Durrani AM, Chalkoo S, Shah MJ, Bashir MI. Mini-lap cholecystectomy: Modifications and innovations in technique. International Journal of Surgery. 2010;8(2):112-7.
8. Khan N, Haleem A, Ahmad I, Jan A.

Cholecystectomy through mini laparotomy incision. Gomal Journal of Medical Sciences. 2009;7(2).
9. Amir M, Haider M. Mini-open cholecystectomy in the management of cholelithiasis. Journal of the College of Physicians and Surgeons-- Pakistan: JCPSP. 2007;17(5):269.
10. Manan A AI, Aftab F. Conventional open and mini cholecystectomy; A comparison in the treatment of gall stone Disease regarding postoperative pain, and Hospital stay. Professional Med J 2007;14(2):212-7.
11. Gilliland TM, Traverso L. Modern standards for comparison of cholecystectomy with alternative treatments for symptomatic cholelithiasis with emphasis on long-term relief of symptoms. Surgery, gynecology & obstetrics. 1990;170(1):39-44.
12. William L. Clinical manifestations and impact of gallstone disease. The American journal of surgery. 1993;165(4):405-9.
13. Garcia-Valdecasas J, Almenara R, Cabrer C, De Lacy A, Sust M, Taura P, et al. Subcostal incision versus midline laparotomy in gallstone surgery: a prospective and randomized trial. The British journal of surgery. 1988;75(5):473.
14. O'Dwyer P, Murphy J, O'higgins N. Cholecystectomy through a 5 cm subcostal incision. British Journal of Surgery. 1990;77(10):1189-90.
15. Ledet Jr WP. Ambulatory cholecystectomy without disability. Archives of Surgery. 1990;125(11):1434.
16. Deziel DJ, Millikan KW, Economou SG, Doolas A, Ko S-T, Airan MC. Complications of laparoscopic cholecystectomy: a national survey of 4,292 hospitals and an analysis of 77,604 cases. The American journal of surgery. 1993;165(1):9-14.
17. Ros A, Gustafsson L, Krook H, Nordgren C-E, Thorell A, Wallin G, et al. Laparoscopic cholecystectomy versus mini-laparotomy cholecystectomy: a prospective, randomized, single-blind study. Annals of surgery. 2001;234(6):741.
18. Sharma AK, Rangan HK, Choubey RP. Minilapcholecystectomy: a viable alternative to laparoscopic cholecystectomy for the third world? Australian and New Zealand journal of surgery. 1998;68(11):774-7.
19. Tate J, Lau W, Leung K, Li A. Laparoscopic versus mini-incision cholecystectomy. The Lancet. 1993; 341(8854):1214-5.
20. Hedawoo J, Rathod V, Kamath B. Minilaparotomy Cholecystectomy- A Feasible Option.
21. Down R, Whiting M, Watts J, Jones W. Effect of synthetic oestrogens and progestagens in oral contraceptives on bile lipid composition. Gut. 1983;24(3):253-9.
22. Watanapa P. Mini Cholecystectomy: a personal series. in acute and chronic cholecystitis. Hpb. 2003;5(4):231-4.
23. Supe A, Bapat V, Pandya S, Dalvi A, Bapat R. Laparoscopic versus mini-lap cholecystectomy for gallstone disease. Indian journal of gastroenterology: official journal of the Indian Society of Gastroenterology. 1996;15(3):94-6.
24. Faggioni A, Moretti G, Mandrini A, Viazzi P, Noceti A, Faggioni M. Mini-laparoscopic cholecystectomy. Hepato-gastroenterology. 1998;45(22):1014-5.
25. Sennu-V MM. Mini-cholcystectomy. An alternative to conventional cholecystectomy. All India Institute of Med Sciences, New Dehli Trop Gestroenterol. 1994; 15(1):29-31.
26. O'Kelly T, Barr H, Malley W, Kettlewell M. Cholecystectomy through a 5 cm subcostal incision. British Journal of Surgery. 1991;78(6):762-. 144. Olsen DO. Mini-lap cholecystectomy. The American journal of surgery. 1993;165(4):440-3.
27. Majeed A, Troy G, Smythe A, Reed M, Stoddard C, Peacock J, et al. Randomised, prospective, single-blind comparison of laparoscopic versus small-incision cholecystectomy. The Lancet. 1996;347(9007):989-94.
28. Srivastava A, Srinivas G, Misra MC, Pandav CS, Seenu V, Goyal A. Cost-effectiveness analysis of laparoscopic versus minilaparotomy cholecystectomy for gallstone disease. International journal of technology assessment in health care. 2001;17(4): 497.
29. Ahmad Q, Dulfam M, Noorani S, Khan N. Ten years experience on mini-cholecystectomy versus ten years experience of conventional Cholecystectomy at KVSS Site hospital, Karachi. Pak J Surg. 2004;20:8.
30. Daou R, editor. Minilaparotomy cholecystectomy. Annales de Chirurgie; 1998: Expansion SCI francaise 31 BLVD latour maubourg, 75007 Paris.
31. Chand S QH, Ali AA, Khan AFA, Chaudhry AM. Randomized trial of standard cholecystectomy versus mini-cholecystectomy. Ann King Edward Med Coll. 1997; (3):106-8.