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THE OUTCOME OF LAPAROSCOPIC AND OPEN CHOLECYSTECTOMY IN PATIENTS WITH COMPLICATED GALLSTONE DISEASE

Qurat-ul-ain[1], Rehana Yousaf[2], Mehrosh Sarfraz[3], Muneeb Sarfraz[4]

House Officer, Allied Hospital, Faisalabad, **E-mail**: qurat969@gmail.com

[2] House Officer, Allied Hospital, Faisalabad, **E-mail**: rehanayousaf849@gmail.com

[3] House Officer, Allied Hospital, Faisalabad, **E-mail**: mehroshsarfraz@gmail.com

[4] Undergraduate MBBS Student, Combined Military Hospital, Lahore,

E-mail: mnbsarfraz@gmail.com

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Abstract:

Gallstone disease is a major health problem worldwide particularly in the adult population. Previously complicated gallstone disease was considered to be a contraindication for laparoscopic cholecystectomy. This initial reluctance has slowly evaporated as a result of increasing expertise. Laparoscopic cholecystectomy can be a safe and effective treatment option for complicated gallstone disease.

OBJECTIVE: *To compare the outcome of laparoscopic and open cholecystectomy in patients with complicated gallstone disease.*

STUDY DESIGN: *Randomized Controlled Trial*

SETTING: *The study was conducted in Allied Hospital, Faisalabad*

DURATION OF STUDY: *Six month from the date of approval of synopsis from board of study April, 2018 to Oct, 2018*

METHODLOGY: *Total of 372 patients fulfilling the criteria was included for study. A written informed consent was taken from every patient participating in this study. The patient was randomly divided into two equal groups. In group-A laparoscopic cholecystectomy was done. Each patient of both the groups received identical general anesthesia. At introduction, it is 1to 2 ml/kg propofol, 0.05 mg/kg atracurium. During reversal, 2.5-5.0 mg neostigmine and 1.2-2.4 mg atropine was used. In group B open cholecystectomy was done which includes 86 patients. The surgery was performed in North Surgical ward by consultant surgeon. Injection Ceftriaxone 1 gram I.V. was given half hour before surgery and then surgery was performed according to the randomization. The entire patient received injection Ketorolac 30 mg i.v. 8 hourly and postoperative injection Nelbufin 6 mg i.v.12hourly as standard in all patients and Post-operative pain was assessed Visual analog scale after 24 hours. Patients were discharged according to the hospital guidelines for discharge of the patient. All the patients were followed up in OPD on 7th day for post-operative complications observation, monitoring and biopsy report. Data was entered in SPSS-20 version. Quantitative variables like age and hospital stay were presented as mean ± SD. Qualitative variables like gender and postoperative pain was presented as frequency percentage.*

RESULTS: *The mean age of patients in open group was 41.28 ± 13.75 years and in Laparoscopic group was 43.46 ± 13.90 years. In Open group there were 80(43%) male and 106(57%) female cases while in Laparoscopic group there were 65(34.9%) male and 121(65.1%) female cases. The mean hospital stay was statistically shorter in Laparoscopic group (3.80 ± 1.37 days) as compared to Open group (5.12 ± 1.58 days), p-value <0.001. In open group 77(41.4%) cases had post-operative pain and in Laparoscopic group 27(14.5%) cases had post-operative pain. The post-operative pain was statistically higher in open groups, p-value < 0.001.*

CONCLUSION: *Through the findings of this study it is concluded that laproscopic is an ideal treatment option in terms of less pain and shorter duration of hsopital stay as compared to open cholecystectomy for patients with complicated gallstone disease. By opting laparoscopic treatment option, we can decrease the nosocomial infection, work load to the hospital, economic burden and quantity of analgesia needed in post-operative days.*

KEYWORDS: *Laparoscopy, Cholecystectomy, complicated Gallstone, Post-operative pain, infection, hospital stay.*

Corresponding author:

Qurat-ul-ain,

House Officer,

Allied hospital, Faisalabad,

***E-mail**: qurat969@gmail.com*

QR code

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INTRODUCTION:

Gallbladder stone is the major cause of morbidity all over the world. In well developed countries the prevalence of Cholelithiasis is about 24%.[1] The complicated gall bladder pathologies like chronically inflamed GB, Gangrenous GB, Empyema GB can make dissections around the Calot's triangle difficult with high risk of injury to CBD and hepatic artery or its branches.[2] Cholecystectomy is the treatment of choice for gall stone disease. [3] Surgery for Acute Cholecystitis (AC), either open or laparoscopic, has always been a challenge and surgeons have therefore, a divided opinion to operate early or treat conservatively. [4,5] After the introduction of laparoscopic cholecystectomy (LC), it is considered as the gold standard for the management of the symptomatic gall stone disease. [6] Laparoscopic surgery has induced a tremendous revolution in the treatment of gallbladder disease.[7] Surgery has been traditionally considered the last therapeutic resort for symptomatic cholelithiasis before the advent of laparoscopy, whereas lithotripsy and cholecystostomy have been commonly favored as less invasive alternatives. [8] Thus, subtotal cholecystectomy can be considered as a safe alternative in the management of patients with complicated GB where the degree of inflammation precludes safe visualization of the biliary structures. [2]

In one of the studies done in Pakistan, post-operative pain was 38% in open cholecystectomy patients and 24% in laparoscopic cholecystectomy patients (p- 0.005), wound sepsis was seen in 30% patients in OC Vs. 16% patients in LC group as port site sepsis. The mean hospital stay in OC group was 5.96±3.20 days and LC group were 3.5±2.50 (p=0.001) days.[9]

The rational of the study is to compare outcome of open versus laparoscopic cholecystectomy in patients with complicated gallstone disease. Data on complicated cholecystitis is not widely available and previously complicated gallstone disease was considered to be a contraindication for laparoscopic cholecystectomy. [9] If we find favorable outcome of LC then in future it can be utilized to gain less pain and wound related complications as well as lesser hospital stay. Furthermore, it can help in early discharge of the patient from the hospital, decreasing the nosocomial infection, work load to the hospital, economic burden and quantity of analgesia needed in post-operative days.

MATERIAL AND METHODS:

This research was conducted in Allied Hospital, Faisalabad, six months after approval from the hospital ethical review committee. Patient of either gender age group 18 – 65 years and patients with complicated gallstone disease as defined in operational definition. COMLICATED GALL BLADDER: Complicated Gallbladder disease: It includes: A) acute cholecystitis, B) empyema gall bladder, C) mucocele. Diagnostic criteria for acute cholecystitis: Diagnosed if there is right upper quadrant pain (>3 on VAS) and Murpy's sign, sometimes accompanied by fever (> 98.6 F), chills, nausea, and vomiting (>2 per day) along with presence of cholelithiasis on Ultrasonography in combination with sonographic murphy's sign and gall bladder wall thickness more than 3 mm and pericholecystic fluid. Mucocele Gallbladder: A grossly distended, thin-walled gallbladder measuring more than 5 cm across anteroposterior, an impacted stone in the infundibulum or neck of the gallbladder or in the cystic duct, and clear fluid content indicate a possible mucocele. The ultra-sonographic Murphy sign may be positive. Empyema Gallbladder: Clinical features of cholecystitis as mentioned above and ultra-sonographic features of impacted stone at the neck of gallbladder with increased echogenicity of fluid inside the gallbladder with peri cholecystitic fluid collection. Outcome determined in terms of post-operative pain and mean hospital stay. Post-operative Pain: It was measured on visual analogue score (VAS) varying from 0-10 (0 shows no pain and 10 shows worts pain) and was assessed on 24 hours, pain was considered if > 3. Hospital stay: That was measured once patient was shifted in ward after surgery till his discharge, in days. All patients were discharged once they were oral and tolerating oral diet. Hypothesis: There is a difference in the outcome of laproscopic verus open cholecystectomy in patients with complicated gallstone disease. Patient with comorbid features (previous history of diabetes, hypertension, cardiac or CVA), carcinoma gallbladder, obstructive jaundice acalculous cholecystitis and pancreatitis and not giving informed consent. After approval from hospital ethical committee, patients fulfilling inclusion criteria was admitted from out-patient department and emergency department. The diagnosis of complicated gallstone disease was made on the basis of history, clinical examination and ultrasonography. Total of 372 patients fulfilling the criteria was included for study. A written informed consent was taken from every patient participating in this study. The patient was randomly divided into two equal groups. In group-A laparoscopic cholecystectomy was done. Each patient of both the groups received identical general anesthesia. At introduction, it is 1to 2 ml/kg propofol, 0.05 mg/kg atracurium. During reversal, 2.5-5.0 mg neostigmine and 1.2-2.4 mg atropine was used. In group B open cholecystectomy was done which includes 86 patients. The surgery was performed in North Surgical ward by consultant surgeon. Injection

Ceftriaxone 1-gram I.V. was given half hour before surgery and then surgery was performed according to the randomization. The entire patient received injection Ketorolac 30 mg i.v. 8 hourly and postoperative injection Nelbufin 6 mg i.v.12hourly as standard in all patients and Post-operative pain was assessed Visual analog scale after 24 hours. Patients were discharged according to the hospital guidelines for discharge of the patient. All the patients were followed up in OPD on 7th day for post-operative complications observation, monitoring and biopsy report.

Data was entered in SPSS-20 version. Quantitative variables like age and hospital stay were presented as mean ± SD. Qualitative variables like gender and postoperative pain was presented as frequency percentage. Independent sample t-test was applied to compare mean hospital stay in both groups and Chi-square test was applied to compare post-operative pain in both study groups. The p-value <0.05 was taken as significant. Data was stratified for age, gender, duration of symptoms, type of complicated gall bladder disease and obesity. Post stratified independent sample t-test and Chi-square test was applied taking p-value ≤ 0.05 as significant respectively.

RESULTS:

The mean age of patients in open group was 41.28 ± 13.75 years and in Laparoscopic group was 43.46 ± 13.90 years. Table -1

Table-1: Descriptive statistics of Age (years) in both study groups

Study groups	Age (years)			
	Mean	S.D	Minimum	Maximum
Open	41.28	13.75	18.00	65.00
Laparoscopy	43.46	13.90	18.00	65.00
Total	42.37	13.85	18.00	65.00

In Open group there were 80(43%) male and 106(57%) female cases while in Laparoscopic group there were 65(34.9%) male and 121(65.1%) female cases. Table -2

Table-2: Gender distribution in both study groups

		Study groups		Total
		Open	Laparoscopy	
Gender	***Male***	80(43.0%)	65(34.9%)	145(39.0%)
	Female	106(57.0%)	121(65.1%)	227(61.0%)
Total		186(100.0%)	186(100.0%)	372(100.0%)

The mean hospital stay was statistically shorter in Laparoscopic group (3.80 ± 1.37 days) as compared to Open group (5.12 ± 1.58 days), p-value <0.001. Table -3

Table-3: Comparison of mean Hospital Stay in both study groups

Study groups	Hospital stay (days)			
	Mean	S.D	Minimum	Maximum
Open	5.12	1.58	3.00	8.00
Laparoscopy	3.80	1.37	2.00	7.00
Total	4.46	1.62	2.00	8.00

t- test = 8.60
p-value < 0.001

In open group 77(41.4%) cases had post-operative pain and in Laparoscopic group 27(14.5%) cases had post-operative pain. The post-operative pain was statistically higher in open groups, p-value < 0.001. Table -4

Table-4: Comparison of pain in both study groups

		Study groups		Total
		Open	Laparoscopy	
Pain	***Yes***	77(41.4%)	27(14.5%)	104(28.0%)
	No	109(58.6%)	159(85.5%)	268(72.0%)
Total		186(100.0%)	186(100.0%)	372(100.0%)

Chi-square = 33.367

P-value ≤ 0.001q

When data was stratified for age, gender, types of complicated disease, duration of disease and BMI, the mean duration of hospital stay and post-operative pain was statistically lower in Laparoscopic group as compared to open group, p-value < 0.05. Table -5 till 14

Table-5: Comparison of mean Hospital Stay in both study groups with respect to age groups

Age groups	**Study groups**	**Hospital stay**			
		Mean	**S.D**	**t-test**	**p-value**
18-40	Open	5.07	1.59	5.679	≤ 0.001
	Laparoscopy	3.73	1.43		
41-65	Open	5.16	1.58	6.474	≤ 0.001
	Laparoscopy	3.85	1.32		

Table-6: Comparison of mean Hospital Stay in both study groups with respect to gender

Gender	**Study groups**	**Hospital stay**			
		Mean	**S.D**	**t-test**	**p-value**
Male	Open	4.79	1.38	3.890	≤ 0.001
	Laparoscopy	3.89	1.37		
Female	Open	5.37	1.68	7.996	≤ 0.001
	Laparoscopy	3.75	1.37		

Table-7: Comparison of mean Hospital Stay in both study groups with respect to types of complicated disease

Types of complicated disease	**Study groups**	**Hospital stay**			
		Mean	**S.D**	**t-test**	**p-value**
Acute cholecystitis	Open	5.24	1.71	4.385	≤ 0.001
	Laparoscopy	3.98	1.39		
Empyema gall bladder	Open	5.06	1.58	4.993	≤ 0.001
	Laparoscopy	3.68	1.43		
Mucocele	Open	5.05	1.45	5.332	≤ 0.001
	Laparoscopy	3.77	1.29		

Table-8: Comparison of mean Hospital Stay in both study groups with respect to duration of disease

Duration (months)	Study groups	Hospital stay			
		Mean	S.D	t-test	p-value
< 4 weeks	Open	5.14	1.58	6.880	≤ 0.001
	Laparoscopy	3.72	1.29		
≥4 weeks	Open	5.09	1.58	5.266	≤ 0.001
	Laparoscopy	3.89	1.45		

Table-9: Comparison of mean Hospital Stay in both study groups with respect to BMI

BMI		Hospital stay			
	Study groups	Mean	S.D	t-test	p-value
Obese	Open	4.58	1.39	2.973	0.004
	Laparoscopy	3.69	1.16		
Non-obese	Open	5.26	1.60	8.190	≤ 0.001
	Laparoscopy	3.83	1.41		

Table-10: Comparison of pain in both study groups with respect to age groups

Age groups(years)			Study groups		Chi-square	p-value
			Open	Laparoscopy		
18-40	*Pain*	Yes	32(36.4%)	11(13.9%)	10.964	0.001
		No	56(63.6%)	68(86.1%)		
41-65	*Pain*	Yes	45(45.9%)	16(15.0%)	23.465	≤ 0.001
		No	53(54.1%)	91(85.0%)		

Table-11: Comparison of pain in both study groups with respect to gender

Gender			Study groups		Chi-square	p-value
			Open	Laparoscopy		
Male	*Pain*	Yes	27(33.8%)	8(12.3%)	9.004	0.003
		No	53(66.2%)	57(87.7%)		
Female	*Pain*	Yes	50(47.2%)	19(15.7%)	26.444	≤ 0.001
		No	56(52.8%)	102(84.3%)		

Table-12: Comparison of pain in both study groups with respect to types of complicated disease

Types of complicated disease			Study groups		Chi-square	p-value
			Open	Laparoscopy		
Acute cholecystitis	Pain	Yes	29(43.9%)	11(20.0%)	7.769	0.005
		No	37(56.1%)	44(80.0%)		
Empyema gall Bladder	Pain	Yes	24(44.4%)	8(12.3%)	15.495	≤ 0.001
		No	30(55.6%)	57(87.7%)		
Mucocele	Pain	Yes	24(36.4%)	8(12.1%)	10.560	0.001
		No	42(63.6%)	58(87.9%)		

Table-13: Comparison of pain in both study groups with respect to duration of disease

Duration (months)			Study groups		Chi-square	p-value
			Open	Laparoscopy		
< 4 weeks	*Pain*	*Yes*	39(39.0%)	13(13.5%)	16.286	≤ 0.001
		No	61(61.0%)	83(86.5%)		
≥4 weeks	*Pain*	*Yes*	38(44.2%)	14(15.6%)	17.318	≤ 0.001
		No	48(55.8%)	76(84.4%)		

Table-14: Comparison of pain in both study groups with respect to obesity

BMI			Study groups		Chi-square	p-value
			Open	Laparoscopy		
Obese	*Pain*	*Yes*	13(34.2%)	3(8.6%)	6.998	0.008
		No	25(65.8%)	32(91.4%)		
Non-obese	*Pain*	*Yes*	64(43.2%)	24(15.9%)	26.917	≤ 0.001
		No	84(56.8%)	127(84.1%)		

DISCUSSION:

Gall stones are a leading cause of morbidity with prevalence ranging from 10-20% 94.It affects nearly 4.3% of the population. [10] Open cholecystectomy (OC) has been the mainstay of treatment for cholelithiasis and was first performed in 1882 by a German surgeon Carl August Langenbuch.[11] Various alternative methods like oral dissolution agents and lithotripsy exists but lack the desired impact on treatment of cholelithiasis and are therefore rarely used in clinical practice. [12]

But with the advent of laparoscopic cholecystectomy (LC) there has been a gradual shift in the treatment with most surgeons preferring LC over OC. The first laparoscopic cholecystectomy was performed by PhilleppeMouret in Lyon, France and has now become the most common laparoscopic surgery performed worldwide. [13] Earlier open cholecystectomy was the gold standard for treatment of stones in the gall bladder. Most studies now suggest that laparoscopic cholecystectomy is the standard surgery for symptomatic gall stone disease. It has improved patient satisfaction in terms of early post-operative pain relief, need for post-operative analgesia, hospital stay, total cost and return to normal activity when compared to open cholecystectomy. [14]

However, there are certain pitfalls of laparoscopic cholecystectomy. Three-dimensional depth perception is limited by the two-dimensional monocular image. It is more difficult to control significant hemorrhage in the surgical field.[15] There is less discrimination of structures using laparoscopic instruments as compared to direct digital palpation during open cholecystectomy. [16] The most troublesome complication in laparoscopic cholecystectomy continues to be bile leak and bile duct injuries. The success rate of laparoscopic procedures is directly proportional to the learning curve of the operating surgeon. Laparoscopic procedures also require a higher cost setup as compared to open procedures and warrant precise knowledge and expertise. [17] Thus in many low resource settings and at grass route levels open cholecystectomy is still the preferred approach. With this knowledge of advantages and disadvantages of laparoscopic cholecystectomy and open cholecystectomy in symptomatic cholelithiasis, further studies are necessary to provide conclusion as to which method is safer, cost effective and provides better patient satisfaction. [18]

A study reported that the mean age was 41.28±12.30 years for group A and 38.44±13.50 for group B. [19] In current study the mean age of patients in open group was 41.28 ± 13.75 years and in Laparoscopic group was 43.46 ± 13.90 years. The mean age in both groups is almost same. A study reported that out of 100 patients there was female preponderance with male to female ratio of 1:1.5 in group A and 1:3.5 group B. [19] We also found that in Open group there were 80(43%) male and 106(57%) female cases while in Laparoscopic group there were 65(34.9%) male and 121(65.1%) female cases. The findings regarding higher female ratio is similar in both studies.

A study done on complicated gallstone disease reported that the mean time in OC group was 54.90±15.90 minutes and LC group was 48.30±12.96 minutes (p 0.026). No mortality was reported in this series. Thus, it can be concluded that Laparoscopic cholecystectomy is a safe and effective treatment of complicated gallstone disease. [104] The mean operation was not our core variable so, in current study the mean hospital stay was statistically shorter in Laparoscopic group (3.80 ± 1.37 days) as compared to Open group (5.12 ± 1.58 days), p-value <0.001. We in current study in open group 77(41.4%) cases had post operative pain and in Laparoscopic group 27(14.5%) cases had post operative pain. The post operative pain was statistically higher in open groups, p-value < 0.001. Another study reported almost similar findings, i.e. post-operative pain was 38% in open cholecystectomy patients and 24% in laparoscopic cholecystectomy patients (p- 0.005), wound sepsis was seen in 30% patients in OC Vs. 16% patients in LC group as port site sepsis. The mean hospital stay in OC group was 5.96±3.20 days and LC group was 3.5±2.50 (p=0.001) days. [9] One more study reported that the mean period of postoperative hospital stay was 1.8 days in group A and 4.8 days in group B. Post-operative resumption of normal diet was possible in 2.1 days in OC while it took lesser time (1.2 days) in LC. The rate of surgical site infection was higher in OC as compared to LC. Thus, Laparoscopic cholecystectomy can be recommended as first choice operative treatment for patients with cholelithiasis as it provides better cosmetic results, lesser pain, lesser post-operative hospital stay and fewer incidence of surgical site infection. [20]

CONCLUSION:

Through the findings of this study it is concluded that laproscopic is an ideal treatment option in terms of less pain and shorter duration of hsopital stay as compared to open cholecystectomy for patients with complicated gallstone disease. By opting laparoscopic treatment option we can decrease the nosocomial infection, work load to the hospital, economic burden and quantity of analgesia needed in post-operative days.

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