International Surgery Journal
Barase AK. Int Surg J. 2018 Sep;5(9):3111-3117
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: http://dx.doi.org/10.18203/2349-2902.isj20183732

Original Research Article

A study of laparoscopic cholecystectomy in rural setup

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Received: 01 July 2018
Accepted: 26 July 2018

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ABSTRACT

Background: Cholelithiasis is one of the major healthcare problems faced by the adult population all over the world. The disease prevalence is ever increasing because of the changing lifestyles and dietary habits. With emergence of laparoscopic cholecystectomy, it has become standard treatment modality for all kind of patients of gall stone disease. But still in India laparoscopic procedures are not routinely carried out in rural setup. So, we have decided to carry out this prospective study of laparoscopic cholecystectomy in rural setup mainly emphasizing on the cost benefit aspect and its impact on economical aspect of the rural government hospital as well as the patient's financial burden.
Methods: In this prospective randomized study, 60 patients of symptomatic cholelithiasis were grouped into open cholecystectomy (OC) and laparoscopic cholecystectomy (LC) groups randomly (30 each). The preoperative, intra operative and postoperative findings were noted and compared with each other and also with previous studies. The results are compared using paired t test and chi square test.
Results: Laparoscopic cholecystectomy was better than open cholecystectomy in terms of less analgesic requirement, postoperative hospital stay, surgical site infection with better cosmetic outcome. The results were comparable regarding intra operative complications. Only duration of surgery was comparatively more in laparoscopic group. Thus, overall laparoscopic cholecystectomy was cost effective alternative as compared to open cholecystectomy.
Conclusions: Laparoscopic cholecystectomy is better alternative to open cholecystectomy in term of less intra and postoperative complications as well as decreased financial burden on public health sector and patient point of view.

Keywords: Cholelithiasis, Cholecystectomy, Cholecystitis, Laparoscopic

INTRODUCTION

Gallstone disease (cholelithiasis) is one of the most common problem affecting digestive tract; in particular the hepatobiliary system encountered by surgeons. Obesity, pregnancy, dietary factors, Crohn's disease, terminal ileal resection, gastric surgery, hereditary spherocytosis, sickle cell disease and thalassemia are all associated with increased risk of gallstones. Women are 3 times more likely to have cholelithiasis than men and first-degree relatives of patients with gall stones have two-fold greater prevalence. About two-third patients of cholelithiasis are presented with chronic cholecystitis, characterised by recurrent episodes of pain in right upper abdomen.[1,2]

Gastro-intestinal surgery has undergone a revolution in the recent years by the introduction of laparoscopic techniques. The concept of "keyhole surgery" created an immediate disparity between the potential of the new technique and training of surgeons to perform it. Now modern surgical methods are aimed at giving cure along with minimal invasive techniques with patient in mind, safety never being compromised. Cholelithiasis is traditionally being dealt by conventional (open) cholecystectomy which was first performed by

Langenbach in 1882.[3] With the introduction of laparoscopic cholecystectomy by, the surgical community witnessed a revolution in basic ideology and the importance of minimal access surgery has suddenly impacted. The introduction of laparoscopic cholecystectomy (LC) has been a major breakthrough in endoscopic microsurgery, and important milestones in the history of surgery, it has rekindled the interest in laparoscopy, marking the beginning of a new era of minimally access surgery (MAS).

Laparoscopic cholecystectomy (LC) has become so safe and easy that it can be performed with much ease and safety because of better magnification. Although LC has shown clear benefits in terms of shortened hospital stay, less morbidity, mortality, a quicker return to work and with cosmetic advantage, some questions regarding this procedure remain unanswered, particularly relative to the cost benefit aspect and use in the rural setup.

Some surgeons have suggested that the rates of serious complications, particularly bile duct injury might be significantly higher in laparoscopic procedures resulting in major morbidity and even mortality. Apart from the high costs of the equipment and the specialized training that is mandatory for mastery of the technique, the procedure inherently carries hazards and risks. Laparoscopic cholecystectomy and open cholecystectomy are comparable procedure for treatment of gallstone diseases in terms of complications, although hospital stay and time taken to return to work are less in laparoscopic surgery; hence laparoscopic cholecystectomy considered as gold standard for treatment of gallstone diseases since 1992.[4]

In a developing country like ours, where the medical costs and loss of working days constitute major issues, could laparoscopic cholecystectomy establish itself as a safe and cost-effective alternative to the open method particularly in public sector hospital in rural setup? is the matter of concern.

In the present study, we have made an attempt to compare the advantages and drawbacks of both the procedures in an Indian set up.

METHODS

We conducted this study in 60 patients admitted in surgical ward of tertiary care rural hospital with cholelithiasis over a period of 2 years.

Inclusion criteria

- Calculous cholecystitis (acute and chronic)
- Asymptomatic gallstones with diabetes mellitus
- Gall bladder polyp >1cm diameter.

Patient selection done with clinical examination and Ultrasonography abdomen.

Exclusion criteria

- Complications like gangrenous gall bladder, empyema gall bladder, Perforation, carcinoma gall bladder
- Associated pathologies like gall stone pancreatitis, Associated cholangitis.

Study design

Random allocation of 60 patients presenting with symptoms s/o gall bladder disease with confirmatory USG study was done in to two groups:

- Group 1: Laparoscopic cholecystectomy
- Group 2: Conventional open cholecystectomy

Standard operative procedure had been followed for both the groups. The intraoperative and postoperative findings are noted and analyzed using the student's t test and Chi square test.

RESULTS

30 patients presenting with symptomatic gallstones disease were operated upon with general intent of performing laparoscopic cholecystectomy. Outcome of these patients compared with outcome of 30 other patients operated by conventional open cholecystectomy procedure for symptomatic cholelithiasis.

Table 1: Sex distribution.

Sex	LC	OC	Total
Male	12	14	26
Female	18	16	34
Total	30	30	60

Sex distribution

In present study we have found that out of 60 patients with symptomatic gallstones, 26(43.33%) were male while females having slightly higher prevalence of 34 (56.67%); but the difference is not statistically significant.

Table 2: Age distribution.

Age in years	LC	OC	Total
<30	4	2	6 (10%)
31-40	6	5	11 (18.33%)
41-50	8	7	15 (25%)
51-60	8	11	19 (31.67%)
61-70	4	5	9 (15%)

Age distribution

In this study out of 60 patients with gallstone disease majority from the age group of 51-60 years i.e. about

31.67%. the mean age for LC group is 46.3 years while that for OC group is 50.03 years. There was no significant difference in the mean age of patients operated by the two techniques.

Table 3: Intraoperative complications.

Operative findings	LC	OC	Z value	P value
Gallbladder perforation with stone spillage	5 (16.67%)	2 (6.67%)	1.22	>0.05
CBD injury	0 (0%)	0 (0%)		>0.05
Liver injury	6 (20%)	4 (13.33%)	0.69	>0.05
Vascular injury	3(10%)	3 (10%)	0	>0.05

Intraoperative complications

In the present study we have compared the intra-operative findings and complications of both groups. Out of the 60 patients, not a single patient having significant anatomical variation in the gallbladder or extra hepatic biliary apparatus.

Table 4: Duration of surgery.

duration	LC	OC
Range (min)	100-140	70-96
average	117.43 min	82.0 min
Standard deviation	9.44	6.70

t value: 16.67; p value <0.001

The commonest intra-operative complication for both the groups is that of liver injury. 6 (20%) cases of the LC group and 4 (13.33%) cases of OC group having liver injury while dissecting the gallbladder fossa from liver bed. The other complications include gallbladder perforation in 16.67% cases of LC and 6.67% cases of OC group; vascular injury in 3 (10%) cases of each group. Here in this study we haven't found a single case among both group having common bile duct injury. There is no statistically significant difference in rate of complication in both the group.

Duration of surgery

The average duration of surgery for LC group is 117.43 min. (range 100-140min.) while that for the OC group is 82 min. (range 70-96min). The duration of surgery for laparoscopic cholecystectomy much more as compared to open cholecystectomy. The difference regarding duration of surgery between these two groups is statistically highly significant.

Conversion to open surgery

Conversion of laparoscopic surgery to open surgery required in 3 (10%) cases out of 30 cases of laparoscopic cholecystectomy. The reasons for conversion include liver injury in 2 cases and vascular injury in one case. The dense intra-operative adhesions is one of the common factor for conversion of surgery in all three cases.

Postoperative complications

Postoperative complications for laparoscopic and open cholecystectomy group are bile leak, wound infection and fever. Among these three-bile leaks is the most significant, which observed in 2 (6.67%) cases of LC group and 3 (10%) cases of OC group. There is no wound infection in LC group as compared with 3 cases of OC group. The difference regarding rate of postoperative complication among laparoscopic and open cholecystectomy group are not statistically significant.

Table 5: Postoperative complications.

Complications	LC	OC	Z value	P value
Bile leak	2 (6.67%)	3 (10%)	0.46	>0.05
Wound infection	0 (0%)	3 (10%)		>0.05
Fever	1 (3.33%)	4 (13.33%)	1.42	>0.05

Postoperative hospital stay

The average postoperative hospital stay for LC group is 4.8 days (range 4-7 days) which is significantly less as compared with the OC having average of 7.93 days (range 7-10 days). This difference is statistically highly significant.

Table 6: Postoperative hospital stay.

Postoperative hospital stay in days	LC (no. of patients)	OC (no. of patients)
4	16	-
5	7	-
6	4	-
7	3	14
8	-	8
9	-	4
10	-	4
Average post-op hospital stay	4.8 days	7.93 days
Standard deviation	1.03	1.08

t value: 11.48; p value<0.001

Postoperative pain (site)

Postoperative pain evaluated with two separate parameters. The site of postoperative pain is epigastric region in 24 cases of LC group and 14 cases of OC group as compared with generalised pain in abdomen in 6 cases

of LC group and 16 cases of OC group. This difference is statistically significant.

Table 7: Postoperative pain (site).

Site	LC	OC
Epigastric	24	14
Generalised	6	16

Chi square: 7.17; P value <0.05

Table 8: Postoperative pain and average duration of analgesic requirement.

	LC	OC	P value
VAS Grade	Grade 2	Grade 3	
Duration of pain (in days)	3	6	0.001
Analgesic used for (in days)	4	7	0.016

Table 9: Cosmetic results.

Cosmetic result	LC	OC
Unacceptable	0	12
Acceptable	6	12
Good	24	6

Postoperative pain and average duration of analgesic requirement

The VAS was median Grade 3 in OC group as compared to median Grade 2 in LC group. The pain was more in the initial 2 days in both groups and it lasted for median duration of 6days in OC group compared to 3 days in LC group, p = 0.001. The NSAID's were used for more days in OC group (median-7days) compared to LC group (median - 4days), p = 0.016.

Cosmetic results

The cosmetic results were analysed using visual analogue score. The results were acceptable in 6(20%) cases and good in 24(80%) cases of LC group. The cosmetic results of scar were unacceptable in 12(40%) cases, acceptable in 12(40%) case, and good in 6(20%) cases of OC group.

Cost analysis

The laparoscopic cholecystectomy group of patients required Rs. 800 per case extra for the titanium clips used for applying it on cystic duct and cystic artey. All other expenses for both the groups are equal as far as the operative procedure is concerned.

Role of laparoscopic cholecystectomy in acute cholecystitis

We had total 14 cases of acute cholecystitis out of which 6 patients undergone laparoscopic surgery while 8 patients undergone open cholecystectomy. As all these patients initially managed by conservative management followed by delayed surgery by 6-8 weeks; there is no obvious difference in intra operative findings and post-operative course as compared with patients with chronic cholecystitis. There is no significant intra peritoneal pathology found in any case from both the groups.

DISCUSSION

The last decade has found laparoscopic cholecystectomy clearly emerging as a safe and cost-effective treatment for symptomatic gallstones disease and its use in elective surgery is well accepted. Many studies have demonstrated that laparoscopic cholecystectomy has all the potential benefits of minimal access procedure having medical and socioeconomic benefits like lower complication rates, shorter total hospital stay and more rapid recovery and return to normal activity. Laparoscopic cholecystectomy has been proven to be a safe and effective technique for treating acute cholecystitis also. Laparoscopic cholecystectomy has become the procedure of choice for managing symptomatic cholelithiasis as well as acute cholecystitis and is considered as gold standard.

Sex distribution

Out of 30 patients who were operated by laparoscopic surgery 12 were males and 18 were females. In the open conventional cholecystectomy group, the distribution was 14 males and 16 females. Though women are 3 times more likely to develop gallstones than men; in the present study the difference is not much significant, and the result is comparable with the other studies.[5]

Age distribution

Most of the patients fall in the age group of 41-60 years of age from both the laparoscopic and the open surgery group. The mean age for laparoscopic surgery group was 46.3 years and that for open surgery was 50.0 years. The difference was not statistically found to be significant. These results are comparable with the results from the studies of Attwood et al (mean LC- 52 years and OC- 51 years), Talpur et al with mean age of 39.85 years and Ghnnam et al having the mean age of patients was 41.9 years.[6-8]

Intra-operative findings and complications

In the present study, out of the 60 patients who had undergone laparoscopic or open cholecystectomy, not a single patient had significant anatomical variation in the gallbladder or extra hepatic biliary apparatus. The results are not comparable with the results of Talpur et al who shown that variation in about 20% cases mainly involving cystic artery followed by cystic duct, right hepatic artery and gallbladder in descending order.[7] The reason for not

getting anatomical in variation in our study might be the less sample size.

The commonest intra operative complication among both groups was liver injury (in 20%cases of LC group and 13.33% cases of OC group). The difference was not statistically significant. The next common complication found in this study was that of gallbladder perforation with stone spillage which occurred in 16.67% cases of LC group and 6.67% cases of OC group. There was no common bile duct injury in a single case from both the groups. The vascular injury observed in 10% cases from both the groups. These values are comparable with the studies of Lujan et al having complication rate of 14% in LC group and 23% in OC group.[9] Similar results also found in the study of Rooh-ul-Muqim et al which showed that vascular injury in about 16% cases, liver injury in 11% cases, spilled gallstones in about 10% cases and biliary leak in about 4% cases.[10] While the study of Duca et al shown that the commonest intraoperative complication was that of iatrogenic perforation of gallbladder in 15.9% cases.[11] The results of the present study were not comparable with the study of Buanes and Mjaland which shown significantly less complications in the laparoscopic group as compared to open surgery group (3.6 versus 10.4%).[12]

The reason behind increased rate of liver bed injury in our study was mainly due to excessive use of monopolar electro-cautery for the dissection purpose and secondly due the dense adhesions between fundus of gallbladder and liver bed in most of the cases.

Duration of surgery

In the present study we have found that the average duration of surgery in laparoscopic group was significantly more as compared with the mean time duration of open surgery group (117.43 minutes versus 82 minutes). The results were statistically highly significant. The range of duration of surgery for LC group was from 90 to 140 minutes and that for OC group was 70-105 minutes. These results were comparable with study of Lujan et al with mean operating time for LC was 88 minutes and for OC was 77 minutes.[9]

Bosch et al also had similar results with 66 minutes for open surgery and 92 minutes for laparoscopic group.[13] Johansson et al in their study of randomised clinical trial of open versus laparoscopic cholecystectomy in the treatment of acute cholecystitis shown the median operating time for OC group was 80 minutes and for LC group was 90 minutes.[14]

While Hardy et al had shown much higher operating time for both the groups (mean 131 minutes for OC and 164 minutes for LC).[15] The reason behind much higher operating time for laparoscopic surgery in our study was probably due to lack of experience and the operating surgeon was in learning phase.

Conversion to open surgery

As far as any type of laparoscopic surgery; the conversion is not considered as complication. Conversion in other sense considered as a step to avoid complications.

In the present study out of 30 patients who undergone laparoscopic cholecystectomy 3 (10%) patients required conversion to open surgery. The reasons for conversion were liver injury in 2 cases and vascular injury in one case. The dense intra-operative adhesions was one of the common factor for conversion of surgery in all three cases. The results from the present study were favourable in comparison with various studies carried out by Eldar et al (27%), Lujan et al (15%), Koperna et al (44.9%) and Johansson et al (about 15%).[16,9,17,14] While there was less conversion rate found in various studies like Hardy et al (4.5%), al Hadi et al (2.7%), and Ghnnam et al (5%).[15,18,8] In most of the studies the cause for conversion were found to be dense adhesions and fused Calot's triangle. The various factors associated for the same were male sex, old age patient having acute cholecystitis.

Postoperative complications

In present study we had 3 patients having postoperative complications out of the 30 cases of laparoscopic surgery group and 7 patients from the open surgery group. Bile leak, which is considered as one of the most significant complication after cholecystectomy, observed in 2 (6.67%) patients of LC group and 3 (10%) patients of OC group. The difference was not statistically significant. There was not a single case of wound infection in LC group as compared with 3 patients (10%) with wound infection in OC group. Fever observed in 3.33% cases of LC and 13.33% of OC group. This difference was also statistically not significant. No mortality in any group noted. The results from the present study were comparable with the studies of Trondsen et al, Ahmed et al and Rooh-ul-Muqim et al.[19,20,10] Al Haidi et al, Koperna et al, and Capizzi et al suggested that the postoperative complications were less in LC compared to OC.[18,17,21] The reason for higher percentage of complication rate in our study was mainly due to the small sample size. The decreased wound infection after laparoscopic surgery was one of the main benefits of minimally invasive surgery. The wound infections occurred in open surgery were tackled with adequate antibiotic coverage and daily dressings which in turn resulted into increased hospital cost and postoperative hospital stay.

Postoperative hospital stay

The mean postoperative hospital stay after laparoscopic cholecystectomy was 4.8 days (median - 4 days). It was significantly less compared with postoperative hospital stay after open surgery (mean - 7.93 days and median - 8 days). This is one of the most important advantage of

laparoscopic surgery. The less postoperative hospital stay in turn results in early return to normal daily activity, decreased sick leave. It also helpful in decreasing the burden of patients in government hospitals and decreasing the total hospital cost per patient. These results were comparable with the following studies.[22,15,23,12,24,9,25]

Table 10: Comparison of postoperative hospital stay.

Study	LC	OC
Grace et al[22]	3.5 days	8.8 days
Hardy et al[15]	2 days	6.5 days
Chan et al[23]	3.5 days	5.9 days
Buanes et al[12]	2 days	6 days
Porte and DeVries[24]	3 days	7 days
Lujan et al[9]	3.3 days	8.1 days
Schietroma et al[25]	2-3 days	7-9 days

The postoperative pain also evaluated in terms of severity, duration of pain and analgesic requirement. The severity of pain evaluated with visual analogue score. The score 0 considered as no pain while grade V considered as intolerable pain. The average grade of pain in LC group was grade II while that for OC group was grade IV. The pain duration for LC group was for 3 days on an average with comparison to 6 days of OC group. The analgesic used was inj. Diclofenac 50mg.i.m. as and when required. The average duration of analgesic requirement were 4 days for laparoscopic surgery group and 7 days for open surgery group. These results were comparable with the results of Kum et al, who shown that patients with LC had significantly less pain compared to patients with OC (mean VAS score 3.8 versus 7.7 out of 10).[26] The analgesic requirement was comparable with the study of Berggren et al, Chan et al, Buanes et al, Al Haidi et al and Hendolin et al.[27,23,12,18,28] All these studies shown that the analgesic requirement after LC is significantly less compared to OC.

Cosmetic results

Though the study carried out in rural area, the cosmetic result was compared in both the study group using ordinal data. Most of the patients from LC group were fully satisfied with the post-operative outcome. (80% fully satisfied and 20% accepted). While in OC group 40% patients not satisfied, 40% having acceptable results and only 20% fully satisfied. The cosmetic results were added advantages of laparoscopic surgery.

Treatment cost

The average operative treatment cost for both group of surgery was similar except the additional cost of titanium clips of Rs. 800 extras for each patient of laparoscopic cholecystectomy. The average cost of CO_2 used for creating pneumoperitoneum was negligible while the post-operative hospital stays after open cholecystectomy taken into consideration. The hospital burden in government setup also decreased by using laparoscopic surgery which are having heavy patient load.

While dealing with the patients with cholelithiasis by open or laparoscopic approach we had not found any other significant intra peritoneal pathology. The role of laparoscopic cholecystectomy in acute cholecystitis though now well established not separately dealt in this study because most of the patients of acute cholecystitis presented after 72 hours of initial symptom. Therefore, these patients first managed with conservative management to reduce the acute inflammatory process and then elective surgery after 6-8 weeks later.

This study showed that morbidity rate is more with open cholecystectomy than laparoscopic cholecystectomy. The "learning curve" represents adapting to operating in the 2-D screen, becoming familiar with the instrumentation and becoming accustomed to the technique. In this study, there were no major complications and several minor ones. There was no peri-operative mortality and no CBD injury. The wound infection rate in this study was found to be less in laparoscopic group. This also reduced the need for postoperative antibiotics in the laparoscopy group.

Use of minimally invasive techniques in elective surgeries was associated with a reduced inflammatory stress response. The two most beneficial aspects of LC were the short hospital stay and the rapid recovery. The cost of laparoscopy operation was overcome by other costs of open procedure namely increased expenditure on the analgesics, antibiotics, number of dressing changes and the loss of working hours.

CONCLUSION

Laparoscopic cholecystectomy is a considerable advancement in the treatment of gallbladder disease. The advantages of laparoscopic cholecystectomy are several like precise surgical dissection, less chances of wound infection, less antibiotic and analgesic usage. The lesser duration of hospital stay and earlier return to daily activity or work after laparoscopic cholecystectomy is associated with significant financial saving for the patient; it also help in reducing the effective cost per surgery to the heavily burdened public hospital by increasing the turnover of patients.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Barase AK. A study of laparoscopic cholecystectomy in rural setup. Int Surg J 2018;5:3111-7.