

“Laparoscopic Versus Minilaparotomy Cholecystectomy - A Comparative Study”

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Abstract:

Background And Objectives: Laparoscopic cholecystectomy has rapidly gained popularity due to its many advantages over the conventional cholecystectomy. Its superiority over mini-cholecystectomy however remains to be proved. M.C. is also reported to have produced results similar to L.C. Aim of this study was to determine the better of the two by comparing them with respect to various parameters.

Method: 40 Patients, below 70 years of age, presenting with calculus cholecystitis, with no evidence of C.B.D. stones or other major medical illness were randomized to undergo either L.C. or M.C. Data was collected and analyzed.

Results: The two groups were similar with respect to demographic and clinical variables. The laparoscopic procedure took longer to perform than the minicholecystectomy procedure (median 102.5 versus 80 minutes). Though less pain and lesser analgesic use was noted in the L.C. group, it was statistically insignificant. Intra operatively, bile leak was more common the L.C. group whereas all other complications were comparable between the two groups. Median hospital stay and costs were also similar with only minor differences. The patients in the L.C. group paid an average of Rs 432 more than those in the M.C. group, (cost of instruments being excluded).

Conclusion: Though laparoscopy offers a good cosmesis, less postoperative pain and short hospital stay, it takes longer to perform, requires special training and is found to offer no significant advantage over minicholecystectomy. However it is recommended that a further randomized study involving larger number of patients be undertaken to reach a definite conclusion.

Keywords: cholelithiasis; laparoscopic cholecystectomy; minilaparotomy cholecystectomy.

I. Introduction

Surgical removal of gall bladder has been the gold standard for treatment of gall stones since it was described in 1882 by Carl Langenbuch. Oral dissolution agents, lithotripsy and contact dissolution have been suggested as alternatives to the surgical removal of gall bladder. Because all of these methods leave a diseased gall bladder in place, cholecystectomy has remained the treatment of choice for symptomatic gallstone disease. The alternative treatments are generally reserved for the patients who are not fit surgery. As Carl Langenbuch so aptly stated “The gallbladder should be removed not because it contains stones, but because it forms them.”

“To cut is to cure”, “the greater the surgeon, the bigger the incision”, are a few aphorisms, not accepted in today's era of minimal access surgery. B.A.Pruitt has rightly stated, “...surgery...is a controlled injury of variable magnitude...” So it becomes quite obvious that this ‘controlled injury’ causes morbidity and mortality which can be decreased or increased. One way by which the morbidity and mortality can be decreased is by limiting the procedure to its minimum.

Each surgical advance is based on thoughtful observation, laboratory experimentation and carefully planned clinical trials. These principles have formed the foundation of surgery and led to the establishment of the highest standards of surgical practice. The evolution of minimal access procedures represents part of the traditional surgical development. Laparoscopic cholecystectomy and minilaparotomy cholecystectomy are the minimum access procedures which came into existence to reduce the surgical trauma. With the introduction of minimal access procedures, cholecystectomy is evolving into an outpatient procedure. Patients are able to return to preoperative functional status rapidly with minimal postoperative morbidity and pain. Additionally these procedures have gained more acceptance because of cosmetic desirability of the small size of the scar.

Despite the increasing interest in the minimally invasive technique of laparoscopic surgery, the role of this new technique has been questioned in the management of gall bladder diseases because of its association with higher rate of complications, especially in the early phases of learning curve of the surgeons.

Minilaparotomy cholecystectomy has been suggested as an alternative to conventional as well as to the laparoscopic cholecystectomy as it incorporates the benefits of both these procedures. Like

conventional cholecystectomy it does not require any special instruments or any specialized training and the procedure is done under direct vision. Unlike L.C. where image of the operative field is obtained on the screen, and lacks three dimensions, M.C. is done under direct vision. Because of its minimal invasive nature like L.C., there is shorter hospital stay and early return to work.

Exactly what is M.C.? The answer to this is variable. In simple terms, M.C. is a procedure of removal of gall bladder through a small incision. How small should the incision be, and what is the maximum permissible limit of the incision to be termed as minilaparotomy? Most of the authors have limited their M.C. incision to 5 cms, though incisions up to 10 cms have been described as minilaparotomy.

The minimum incision limit is variable and cholecystectomy with 2 cms incision is reported by some authors.

In this study, the maximum limit of the incision was kept at 10 cms. The minimum incision used was 5 cms.

This study was undertaken to compare the two minimal access techniques of cholecystectomy, the L.C. and the M.C. with regard to various parameters, in order to determine the better of the two. Various series available, give conflicting results, some claim L.C. to be superior while others claim M.C. to be better. Some even equate them as interchangeable with no edge of one over the other.

II. Materials and Methods and Patients

The study subjects were patients, admitted with diagnosis of cholelithiasis, who subsequently underwent cholecystectomy at Santhiram Medical College & General Hospital between October 2011 to September 2013.

All the patients were interviewed for detailed clinical history and examined. They were then subjected to routine blood, urine and other investigations as per protocol and an abdominal ultrasound was performed in all cases.

Inclusion Criteria:

Patients presenting with at least one episode of right upper quadrant pain or epigastric pain (typical biliary colic) with ultrasonographically proven cholelithiasis.

Patients considered otherwise fit for elective cholecystectomy under general anaesthesia.

Exclusion Criteria:

History or laboratory tests suggesting presence of common bile duct stones,

History of prior abdominal surgery,

Patients above 70 years of age,

Patients having diabetes mellitus or any other co-morbid condition,

Patients having acalculus cholecystitis. A written informed consent was taken from all patients before their inclusion in the study. The study was approved by the ethical committee of the hospital. Patients were randomly allocated to the two study groups using simple lots (20 in each group). Patients in one group underwent laparoscopic cholecystectomy while

those in the other group underwent cholecystectomy through a small subcostal incision varying between 5 - 10 centimeters in length. All the patients were kept nil by mouth overnight, prior to surgery and were given a dose of prophylactic antibiotic. All the patients were asked to evacuate bladder prior to surgery and a nasogastric tube was passed if thought to be necessary. All the surgeries were performed under general anesthesia, by the same surgical team, consisting of a consultant and two residents.

Intra operative findings and post operative data were all recorded and analyzed, using simple statistical tests like Chi square test and Z-test, to compare the results.

Surgical Procedure

Laparoscopic cholecystectomy: L.C. was performed with patient in classical supine position and the surgeon standing on left side of the table. Pneumoperitoneum was created using Veress needle, in most cases, with Hassan's technique used in a few cases. Two 10 mm and two 5 mm trocars were used. Peritoneal cavity was examined and dissection carried out using electrocautery. Titanium clips were used to secure the cystic duct and artery.

Minilaparotomy cholecystectomy: An oblique right subcostal incision was taken varying between 5 - 10 cms. in length, depending on the patient's body stature. The incision was extended if adequate exposure was not achieved through the small incision. Fundus first method was used in most cases. If the Calot's triangle was clearly visible, dissection was first started there and then proceeded antegradely towards the fundus.

In both the groups, a subhepatic drain was inserted if thought to be necessary, as in cases of excessive adhesions or acute cholecystitis. All wounds were infiltrated with local anesthesia. Patients were observed in the

recovery room for about one hour before shifting to post operative ward. Analgesics and anti-emetics were used according to patient requirements. Oral intake was instituted after return of bowel sounds.

Patients were encouraged to mobilize early and were discharged once they were tolerating orally and achieved adequate pain relief. Post operative pain was measured using Visual Analogue Scale as rated by the patient from 0 - 5. Early resumption of day to day activities and return to normal work was encouraged

Patients were asked to follow up in O.P.D., 1 week, 4 weeks, and 6 months after surgery, or in between if they had any problem. Data of patients' demographics, history, investigation reports, operative findings, duration of surgery, operation time (from incision to closure), complications (intra operative and post operative), duration of post operative pain, analgesic requirement and length of hospital stay were all recorded prospectively. The total cost incurred by each patient was also noted. This included costs of investigations, operation (including anesthesia) costs and medication costs. The histopathology report of the specimen was also recorded.

III. Observations And Results

IV.

There were 20 patients in each of the study groups. The results were

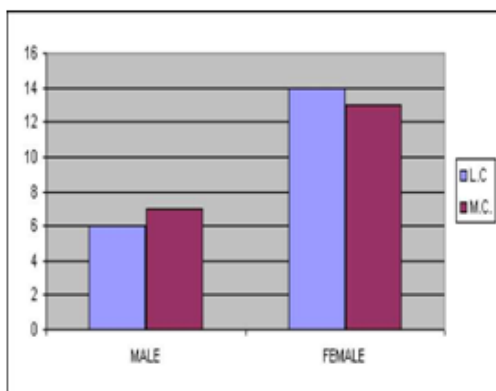
Patient Demographics:

1) Sex Distribution

SEX	L.C.	M.C.
MALE	6	7
FEMALE	14	13

Table -1

In the laparoscopic cholecystectomy group there were 6 males and 14 females whereas the minilaparotomy cholecystectomy group consisted of 7 male and 13 female patients.



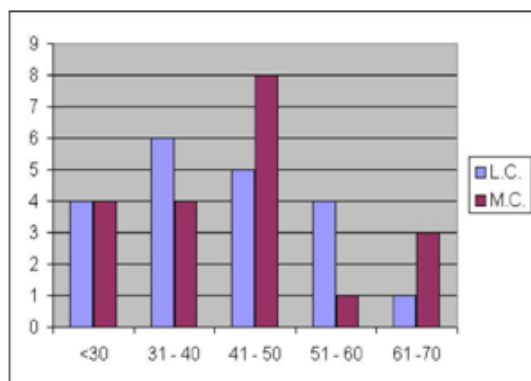
2) Age Distribution

Table 2

AGE (IN YEARS)	L.C.	M.C.
<30	4	4
31 - 40	6	4
41 - 50	5	8
51 - 60	4	1
61 -70	1	3

p value >0.05 (Chi Square test)

The median age (range) of the patients was 41 (22 - 65) and 45.5 (20 -70) years in the laparoscopic and the minilaparotomy groups respectively. Most of the patients were between 31 - 50 years of age. The difference between the two groups was not found to be statistically significant.



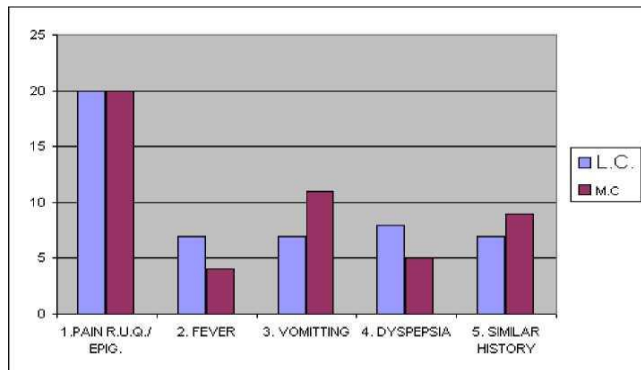
3) Presenting Complaints

Table -3

COMPLAINTS	L.C.	M.C
1. PAIN R.U.Q. / EPIG.	20	20
2. FEVER	7	4
3. VOMITTING	7	11
4. DYSPEPSIA	8	5
5. SIMILAR HISTORY	7	9

p value >0.05 (Chi Square test)

Pain in the right upper quadrant was one of the presenting complaints in all the patients. Among other complaints were fever (7 in L.C. and 4 in M.C.), vomiting (7 in L.C. and 11 in M.C.) and dyspepsia (8 in L.C. and 5 in M.C.). 7 patients in L.C. group and 9 in the M.C. group complained of having similar complaints in the past. No patient had a history of jaundice or icterus at the time of admission. Regarding presenting complaints the difference between the two groups was not found to be statistically significant.



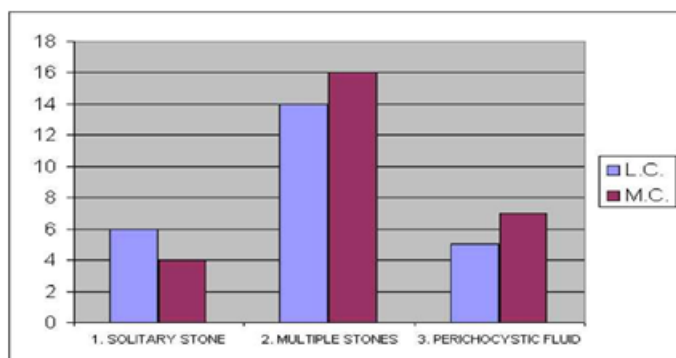
4) Sonographic Findings

Table - 4

U.S.G. FINDINGS	L.C.	M.C.
1. SOLITARY STONE	6	4
2. MULTIPLE STONES	14	16
3. PERICHOLECYSTIC FLUID	5	7

p value >0.05(Chi Square test)

All the patients in this study were subjected to abdominal ultrasonography. Solitary stones were reported in 6 patients of L.C. group and 4 of the M.C. group. Multiple stones were noted in 14 and 16 patients in the L.C. and the M.C. groups respectively. 5 patients in the L.C. and 7 patients in the M.C. group were found to have pericholecystic fluid collections suggestive of acute cholecystitis. No statistically significant difference was however noted between the two groups.

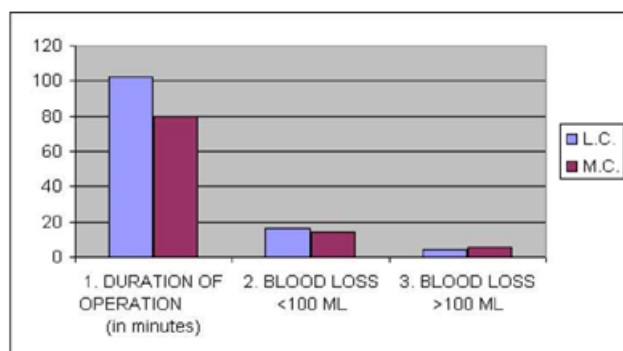


5. Intra Operative Findings

Table - 5

OPERATIVE FINDINGS	L.C.	M.C.	p VALUE
1. DURATION OF OPERATION (in minutes)	102.5	80	<.05 (S)
2. BLOOD LOSS <100 ML	16	14	>.05 (NS)
3. BLOOD LOSS >100 ML	4	6	>.05 (NS)
4. DRAINS USED	17	16	>.05 (NS)
5. CONVERSIONS	2	1	>.05 (NS)

All the patients were operated under general anaesthesia. The median duration of operation was 102.5 minutes (60 - 150) in the L.C. group and 80 minutes (60 - 135) in the M.C. group and this difference was found to be statistically significant. L.C. took longer due to gas leak, difficult adhesions and slippage of clips. Among the patients who underwent L.C., 16 had less than 100 ml. blood loss and only 4 had more than 100 ml. blood loss. Among the M.C. group, 14 had less than 100 ml. blood loss and 6 had more than 100 ml. blood loss. This was however statistically insignificant.



6) Pain Score And Analgesics

Table - 6

PAIN AND ANALGESICS	L.C.	M.C.	p VALUE
1. VAS GRADE 0 - 5 (RANGE)	2 (1 - 3)	3 (1 - 4)	>.05 (NS)
2. DURATION OF PAIN (RANGE)	2 DAYS (1 - 3)	3 DAYS (2 - 6)	>.05 (NS)
3. ANALGESICS USED (RANGE)	2 DAYS (2 - 5)	2 DAYS (2 - 6)	>.05 (NS)

(chi square test)

The Visual Analogue Score for pain was a median of grade 2 in L.C group against a median of grade 3 in the M.C. group. Most of the patients in both the groups had more pain on first two postoperative days. Those in the L.C. group had pain for a median duration of 2 days (1 - 3) as compared to 3 days (2 - 6) in the M.C. group. Analgesics were required for a median duration of 2 days (2 - 5) in L.C group as against 2 days (2 - 6) in the M.C. group. All these were also statistically not significant, through there was more pain and more

analgesics were required in patients in the M.C. group, especially if the patient developed infection of the wound site.

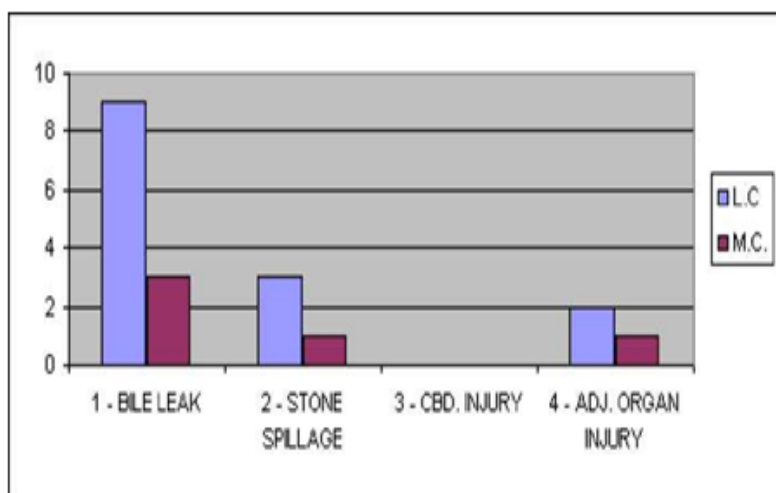
7) Incidence Of Complications

Table - 7

INTRA OPERATIVE	L.C	M.C.	p VALUE
1 - BILE LEAK	9	3	<.05 (S)
2 - STONE SPILLAGE	3	1	>.05 (NS)
3 - C.B.D. INJURY	0	0	>.05 (NS)
4 - ADJ. ORGAN INJURY	2	1	>.05 (NS)
POST OPERATIVE			
I. WOUND INFECTION			
A. NIL	19	17	>.05 (NS)
B. MODERATE	1	2	>.05 (NS)
C. SEVERE	0	1	>.05 (NS)
2. BILE LEAK	1	1	>.05 (NS)
3. INCISIONAL HERNIA	0	1	>.05 (NS)

(Z - test)

Intra operatively bile leak was the most common complication (9 in L.C. and 3 in M.C. group). Other complications noted were, stone spillage (3 in L.C., 1 in M.C.) and adjacent organ injury (2 in L.C. and 1 in M.C.). In the L.C. group, injuries to liver occurred while dissection and in M.C. group it was during retraction. Postoperatively there was moderate wound infection in 1 patient in L.C. group and in 2 patients of M.C. group. One patient in M.C. group had severe infection leading to dehiscence. It was later sutured secondarily. Post operatively there was some amount of bile leak in one patient from each group but both resolved spontaneously. One patient from M.C. group developed incisional hernia, after four months of surgery. She later underwent mesh plasty.



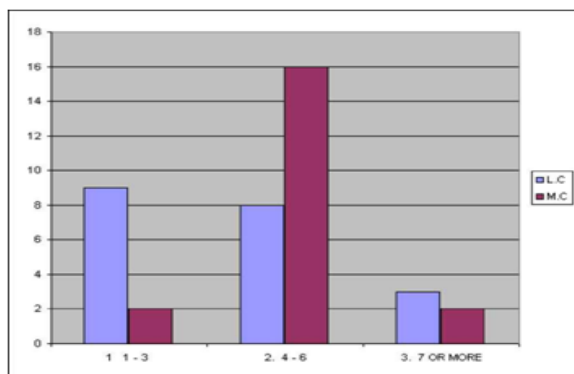
8) Duration Of Hospital Stay

Table - 8

DAYS OF STAY	L.C	M.C
1 1 - 3	9	2
2. 4 - 6	8	16
3. 7 OR MORE	3	2

p value >0.05 (Chi Square test)

The duration of hospital stay after surgery was for a median period of 4 days (2 - 7) in the L.C. group and 5 days (2 - 10) in the M.C. group. The difference was however not found to be statistically significant.



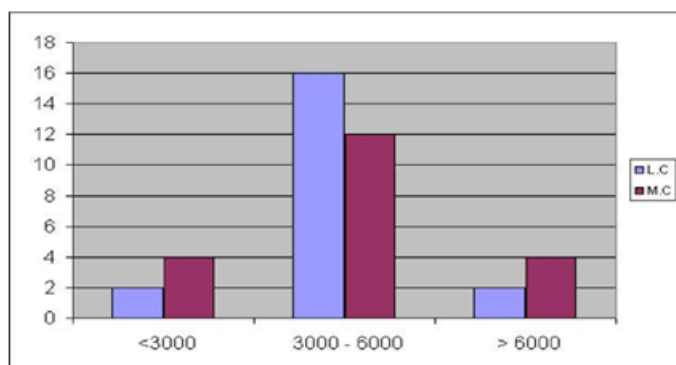
9) COST ANALYSIS

Table 9

COST IN RUPEES	L.C	M.C
<3000	2	4
3000 - 6000	16	12
> 6000	2	4

p value >0.05 (Chi Square test)

On analysis of expenditure, L.C. was found to be a little costlier as compared to M.C. The difference was mainly in the cost of surgery. The cost of medications, including anesthesia and that of investigations was almost same in both the groups. The analgesics and medications used were also similar. The average cost of L.C. was Rupees 4848.85 while that of M.C. was Rupees 4416.95 The instruments used were all reusable ones and the cost of instruments was not taken into account. The difference was however statistically insignificant.



V. DISCUSSION

Cholecystectomy is a commonly performed surgery. Though it is inherently dangerous due to the crowded anatomical details, common and inimical anomalies, and exposure difficulties, it is conceptually simple, requiring disconnection of the gallbladder by division of a small end artery, a narrow caliber cystic duct, an avascular peritoneal envelop, and variable adhesions and venules.

Laparoscopic cholecystectomy has many advantages such as better cosmesis, minimal wound pain, short hospital stay and early return to work, but it is questionable whether it has a major advantage over the minicholecystectomy. In this study, the laparoscopic procedure was found to be associated with a longer operating time than M.C. (Median of 102.5 minutes against 80 minutes for M.C.). This finding is comparable with that of Ros et al³⁶, who reported 100 & 85 20 minutes for L.C. and M.C. respectively. Mc Mohan²⁰ also reported that mean operating time was 14 minutes longer for L.C. in their study. Likewise Majeed³⁰ reported that L.C. took longer to perform than M.C. (median 65 versus 40 minutes). Similarly others^{11,23,27,31,35} too found L.C. to take longer to perform. As experience is gained, the operating time is decreased. The surgeon gets trained in dealing with challenging cases in the course of his / her learning curve.

The patients in L.C group experienced less pain as compared to their counterparts in the M.C. group (median 2 versus 3 days), although the difference was not found to be statistically significant. The analgesic requirement was also seen to be less in patients of L.C. group (2 – 5 days versus 2 – 6 days). Mc Mohan²⁰ too reported less pain in the L.C. group as compared to M.C. group,

but only till one week post operatively. At follow up, four weeks and three months after surgery, no difference in pain was noted between the two groups. Mc Mohan²¹ also reported less pain and less analgesic requirement in the L.C. group, especially till 48 hours post operatively. Similarly McGinn²⁷ reported reduced analgesic requirement in the L.C. group.

In this study, we were lucky to have no major complications, though we did encounter some minor ones. We had no deaths, and there was no case of injury to the Common Bile Duct. Two cases of injury to the liver in L.C. group and one in M.C. group were seen. In the L.C. group, we had 9 cases of bile leak, intra operatively and 3 in the M.C. group. Other complications, like wound infection, Postoperative bile leak, and incisional hernia were comparable in the two groups and the difference was not statistically significant. Ross³⁶ too reported more intra operative complications, like bile leak in the L.C. group and comparable post operative complications in the two groups. Mc Mohan²⁰ has also reported that post operative complication rates were same between the two groups.

This study showed a shorter period of hospital stay for patients undergoing L.C. as compared to those undergoing M.C. (median 4 versus 5 days). The difference was however statistically insignificant. Mc Mohan²⁰ reported that median post operative hospital stay was two days shorter for L.C. as compared to M.C. Several other authors^{13,15,27,29,36,38} have reported shorter hospital stay, after L.C. but some others^{23,30,31,35} have reported no difference between the two groups. In this study we did not find any significant difference in the costs, incurred by the patients in the two groups. L.C. was however found to be a little costlier than M.C. (median of Rupees 4722.5 versus 4146). On an average a patient in the L.C. group spent rupees 4848.85 whereas one in M.C. spent Rupees 4416.95 only. We had used reusable instruments and the costs of instruments were not taken into account. The charges for laparoscopic surgery were higher but more of analgesics and antibiotics were required in the patients belonging to the M.C. group. Mc Dermott¹¹ and Majeed³⁰ have also reported L.C. to be costlier in comparison to M.C. Mc Mohan and Calvert have reported significant difference between the costs of the two procedures, claiming laparoscopic technique to be costlier. Mc Mohan²⁰ found L.C. to be costlier by about 400 pounds and Calvert³⁵ reported L.C. to be about 29% costlier as compared to M.C. The difference was mainly in the costs of surgery and the equipments. Using disposable instruments like trocars was obviously costlier as reported by Mc Mohan²⁰. Nilsson³⁷ reported a reduction in the cost of the laparoscopic procedure if the number of surgeries performed per year was more and reusable instruments were used. Under such circumstances, the costs of the two procedures were found to be comparable.

V. CONCLUSION

Surgical removal of gall bladder has been the gold standard for treatment of gall stones, ever since it was described by Carl Langenbuch in 1882, and continues to be so till today. The only difference in management has been the limitation of morbidity, by using minimal access procedures like laparoscopic cholecystectomy and the minilaparotomy cholecystectomy. Both these techniques have resulted in early return to preoperative functional status, due to rapid recovery and minimal post operative morbidity and pain. They have also gained popularity because of the cosmetic desirability of the small size of the scar.

Laparoscopic Cholecystectomy has emerged as the gold standard in the treatment of gall stones because of the many advantages like better cosmesis, minimal wound pain, with early resolution, shorter hospital stay and early return to work. In our study, we found it to be true, that the laparoscopic procedure does have all these advantages but minilaparotomy cholecystectomy too produced similar results, additional advantage in shorter duration. M.C. also produces a small scar, though not as insignificant as L.C. Similarly M.C. also resulted in decreased post operative pain and discomfort, though it was slightly more than L.C. and on an average more analgesic use per day was seen in patients undergoing M.C. Hospital stay was also seen to be less in the L.C. group. On statistical analysis, all these differences were found to be insignificant.

Among intra operative complications, bile leak was significantly more commonly seen in the laparoscopic group. Other complications were also more in the laparoscopic group though only insignificantly. Wound infections were more commonly seen in the minilaparotomy group but overall no significant difference was noted between the two groups.

Laparoscopic procedure was also found to be a little costlier than the minilaparotomy procedure (each patient spending about 432 rupees more than their counterparts in the minilaparotomy group. Though this was statistically not significant, it is noteworthy that the calculated costs did not include the costs of the instruments and all the instruments used were reusable ones. Adding the costs of instruments would certainly make significant difference in the costs of the two procedures and in a country like India, financial aspect is a major factor to be considered.

Though it is easier to teach and learn the laparoscopic procedure with the help of magnified visual display, specialized training is a must in case of the laparoscopic technique. On the other hand, minilaparotomy

cholecystectomy does not require any special training (nor any additional / special instruments). Any surgeon, conversant with the standard open technique of cholecystectomy can gradually decrease the size of the incision in subsequent patients to master the technique of minilaparotomy cholecystectomy.

We found laparoscopic procedure to take longer to perform, as compared to the minilaparotomy procedure. This finding has been constant in almost all the reported series. As with all the new techniques, there is a learning curve and though initially it may take 3 - 4 hours, for a surgeon to perform the laparoscopic procedure, the time taken gradually reduces. Laparoscopic cholecystectomy is better suited for the more straight forward, easy cases. Only with greater experience and instrumentation the operation can be performed in the presence of adhesions and acute inflammation. Minilaparotomy cholecystectomy therefore appears to be a better alternative in busy surgical units and also in cases of acute cholecystitis where adhesions are expected to be present. Laparoscopic cholecystectomy therefore, does not appear to offer any major advantage over the minilaparotomy technique, which incorporates the benefits of both, the standard open technique as well as the minimally invasive laparoscopic technique. Minilaparotomy cholecystectomy can be done using simple instruments, with no special training. Furthermore minilaparotomy is done under direct vision, unlike laparoscopy where the image of the operating field is obtained on the screen and lacks three dimensions. However, since the number of cases taken in our study is small, further randomized studies involving larger number of cases are required to come to a definite conclusion.

VI. SUMMARY

The study group comprised of 40 patients admitted at Santhiram Medical College & General Hospital, with a diagnosis of cholelithiasis. They were randomized into two groups of 20 each, one underwent laparoscopic cholecystectomy and the other, mini-cholecystectomy. The results of the study were:

About two thirds of the patients were females,

Most of the patients were between 31-50 years of age, All the patients presented with pain in the right upper quadrant (or epigastrium) with either vomiting, fever, dyspepsia or previous history of similar episodes. 75% of the patients were found to have multiple gallbladder stones and 30 % had pericholecystic fluid on ultrasonography, suggesting acute cholecystitis.

Laparoscopic procedure took longer to perform than the minilaparotomy procedure (median of 102.5 minutes versus 80 minutes).

The Visual Analogue Score for pain was less for patients in the L.C. group as compared to the M.C. group (median of grade 2 versus grade 3).

The duration of postoperative pain was also less in the L.C. group as compared to M.C. group (median of 2 days versus 3 days), The analgesic requirement was therefore found to be less in the L.C. group.

The incidence of complications intra operatively was a little more in the L.C. group but post operative complication rates were found to be similar in both the groups.

Duration of hospital stay after surgery was found to be a little less in the laparoscopic group as compared to the minilaparotomy group (median of 4 days versus 5 days).

The laparoscopic procedure was found to be a little costlier as compared to the minilaparotomy procedure, but the difference was not found to be statistically significant. Patients in the L.C. group paid on an average Rs. 432 more than their counterparts in the M.C. group. The difference was mainly in the cost of operation and that of the instruments.

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