



Surgery

A COMPARATIVE STUDY OF REDUCED PORT SIZE MINI-LAPAROSCOPIC CHOLECYSTECTOMY (MLC) VERSUS STANDARD FOUR PORT CONVENTIONAL LAPAROSCOPIC CHOLECYSTECTOMY (CLC).

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ABSTRACT **Background:** Reduced port size mini-laparoscopic cholecystectomy (MLC) has widened the horizons of modern laparoscopic surgery. Standard four port conventional laparoscopic cholecystectomy (CLC), which has long been established as the “Gold Standard” for gall bladder diseases, is under reconsideration following the advent of further minimally-invasive procedures including MLC. Our study aims to provide a comparison between MLC and CLC and assesses whether MLC has any added benefits. **Materials And Methods:** A prospective randomized controlled study of 46 patients of gall stone disease was conducted at J.L.N. Medical College, Ajmer. The patients assigned in to two groups (23 in each) group A [Reduced port size mini-laparoscopic cholecystectomy {MLC}] or group B [Standard four port conventional laparoscopic cholecystectomy {CLC}] through randomization. Data was collected prospectively and analysed retrospectively using a predesigned Performa.

Results: In our study, both the groups had similar age, body mass index (BMI) and gender distribution. No cases of MLC required insertion of additional ports. The mean operative time for MLC was 63.74 ± 9.50 , which is longer than CLC 44.91 ± 14.73 . The pain was significantly lower in mini laparoscopic group which is analysed on 0th, 2nd 7th and 28th post operatively. Patients who underwent MLC were able to return to normal activity earlier than patients undergoing CLC ($P < 0.01$).

Conclusion: Our experience suggests that MLC can safely be used as an alternative to CLC. Compared to CLC, it has the added benefit of an early return to work along with excellent cosmetic results. Intraoperative blood loss is comparable in both groups, however the operative time in MLC group higher than the CLC group. Further large scale trials are required to prove any additional benefit of MLC.

KEYWORDS : Cholecystectomy, Reduced port size mini-laparoscopic cholecystectomy (MLC), minimally invasive surgery, Standard four port conventional laparoscopic cholecystectomy (CLC).

INTRODUCTION:

The use of laparoscopy has gained widespread popularity in surgical approaches to abdominal wall hernias and intestinal and solid organ resection. However, no other operation has been as profoundly affected by the advent of laparoscopy as cholecystectomy. In fact, laparoscopic cholecystectomy (LC) has clearly become the procedure of choice for routine gallbladder removal. The advantages of this approach include decreased scarring, decreased incisional pain, shorter hospitalization, and faster functional recovery. [1-4] In recent years, many investigators have attempted to further improve on the established technique of LC. Generally, the goal has been to minimize the invasiveness of this procedure by reducing the number and, more commonly, the size of the operating ports and instruments. [5-6] Although several recent trials from Europe and Asia [7-12] provided level I data, the effects of the use of miniaturized instruments for LC are still not well established. In this article, we report the results of a prospective, randomized single blinded study that compared the operating time, postoperative pain, cosmesis and return to normal activity results of laparoscopic cholecystectomy performed Standard four port conventional laparoscopic cholecystectomy (CLC) and using reduced port size (M-LC).

METHOD AND MATERIAL-

A prospective randomized study of 46 patients of gallstone disease was conducted at J.L.N. Medical College and Hospital, Ajmer from January 2019 to December 2019. Approval from hospital ethical committee was obtained beforehand. All the 46 cases of gallstone disease who met the inclusion and exclusion criteria of the study were allocated in to two groups (23 in each) either group A [Reduced port size mini-laparoscopic cholecystectomy {MLC}] or group B [Standard four port conventional laparoscopic cholecystectomy {CLC}]. Randomization done through opaque sealed envelope technique. The detailed history and clinical examinations were taken from all patients. The surgeon was notified of the allocation on the morning of the procedure. The patients remained blinded to the type of instrumentation used until the study was finished.

Inclusion Criteria: All patients who have gall stone disease:

1. Age between 15 years to 55 years.
2. Weight 35kg to 75 kg.
3. ASA grade I and II.

Exclusion Criteria:

1. ASA class III or IV.
2. Age younger than 15 years and older than 55 years.
3. Cirrhosis and portal hypertension.
4. Coagulation disorders,
5. Morbid obesity,
6. Previous major abdominal surgical procedures
7. Acute cholecystitis.

Outcome Variables:

1. Operative time
2. Intra operative blood loss/
3. Intra-operative complications
4. Post-operative pain using VAS (visual analogue scale scored from 0 (no pain) to 5 (severe pain) on 0,2nd,7th and 28th day.
5. Cosmesis (photographic comparative assessment, scored from 1 (worst) to 10 (best) on 0,2nd, 7th and 28th day.
6. Return to normal activity.

Statistical Analysis:

Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0; IBM Corporation Chicago. Continuous variables are presented as mean \pm SD, and categorical variables are presented as absolute numbers and percentage. The comparison of normally distributed continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups were compared using Chi-squared test or Fisher's exact test as appropriate. $P < 0.05$ was considered statistically significant.

Surgical Technique- Reduced port size MLC was performed using two 3 mm ports, one 5 mm and one 10 mm port. Following general anesthesia, patients undergoing MLC were placed in reverse Trendelenburg position with the surgeon on the left. A Veress needle

was introduced to create pneumoperitoneum, after which a 10 mm transumbilical port and laparoscope were introduced. The latter three ports were introduced under direct visualization (5 mm epigastric, 3 mm right mid clavicular and 3 mm right anterior axillary) . This technique is also called “10-5-3-3” which needs two 3 mm trocars and two 3 mm graspers. [Figure 1] After dealing with Hepatocystic triangle and achieving critical view of safety, a 5 mm camera was introduced through the epigastric port and a 10 mm camera was retrieved; a 10 mm clip applicator was introduced through the 10 mm umbilical port and clips were placed under direct visualization. After clip application, we switched back to visualization with a 10 mm laparoscope for dividing these structures and after dissection from the liver bed. The gall bladder was retrieved in a specimen bag through the 10-mm umbilical port.

The standard conventional laparoscopic cholecystectomy (CLC) is to use 4 ports. A 10 mm 30 degree telescope is used at the umbilicus. Another 10 mm trocar is used in the epigastrium which is the main right working port for the surgeon. One 5 mm trocar in the right lumbar region is used for gallbladder fundus traction and another 5 mm trocar in the right hypochondrium is used as left hand working port for the surgeon.

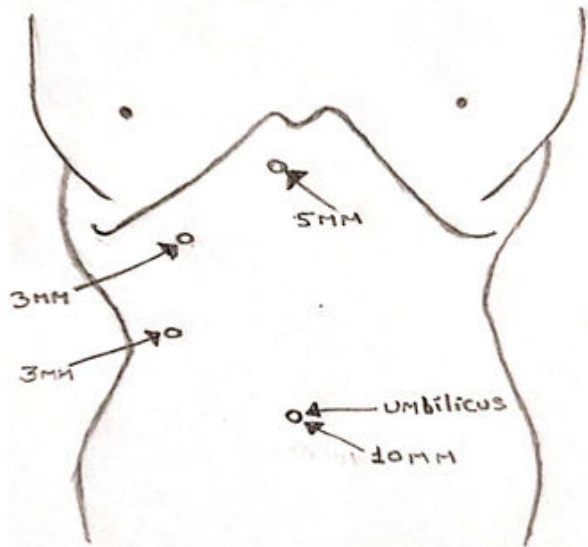


Figure 1: Shows Scheme Of Port Placement In Reduced Port (size) Laparoscopic Cholecystectomy (MLC)

**RESULTS AND DISCUSSION:
Sex Related Demographic:**

In a prospective consecutive study of 90 patients with symptomatic gall stone disease conducted by Sarli L et al, 76% cases were females and 24% cases were males. [13] In a study conducted by Huang MT et al 61% cases were females and 39% cases were males. [14] While in a study conducted by Sen Chang yu et al, 65% cases were females and 35% cases were males. [18] In our study, 89.13% patient were females and only 10.86% were males. The female to male ratio in our study is 9:1 which is considerably higher than other studies. [Table 1] This may be due to geographical variation of the gender distribution of the disease.

Table 1: Sex Distribution Of Patients In Various Studies Study

Study	Female	Male
Sarli L et al ¹³	76%	24%
Hung MT et al ¹⁴	61%	39%
Sen-Chang Yu et al ¹⁸	65%	35%
Our Study	89.13%	10.86%

Age Related Demographics:

In a prospective consecutive study of 90 patients with symptomatic gall stone disease conducted by Sarli L et al, the age of patient included varied from 40.2 ± 11.7 years in MLC group while the mean age of the patient included varied from 41.2 ± 12.1 years in CLC group. [13] In the study by Huang MT et al, the mean age of the patient in the MLC group was 49.6 ± 15.2 years while the mean age in the CLC group was 48.2 ± 14.7 years. [14] While in the study conducted by Sen-Chang yu

et al, the mean age of patient included varied from 51.2 ± 12.3 years in the MLC group and 49.0 ± 14.1 years in CLC group. [18] In our study, Male Female 41.28 ± 9.30 years in MLC group and 34.24 ± 12.37 years in CLC group. [Table 2]

Table 2: Age Distribution Of Patients In Various Studies.

Study	Mean age MLC	Mean age CLC
Sarli L et al ¹³	40.2 ± 11.7 years	41.2 ± 12.1 years
Hung MT et al ¹⁴	49.6 ± 15.2 years	48.2 ± 14.7 years
Sen-Chang Yu et al ¹⁸	51.2 ± 12.3 years	49.0 ± 14.1 years
Our Study	41.28 ± 9.30 years	34.24 ± 12.37 years

Operative Time: In the study conducted by Reardon et al, the mean operative time in MLC group was 88.7 ± 5.9 minutes whereas the mean operative time was 78 ± 5.5 minutes in the CLC group. [7] In contrast to study conducted by Sarli L et al, the mean operative time in MLC group was 50.6 ± 12.3 minutes while the mean operative time was 45.8 ± 10.7 minutes in the CLC group. [13] Similarly, in the study by Schwenk et al, the mean operative time in the MLC group was 70 minutes (60-80) and in C-LC group the mean operative time was 70 minutes (60- 87) minutes. [15] In the study by Sen-Chang yu et al, the mean operative time in MLC group was 72.8 ± 26.5 minutes and 57.9 ± 17.3 minutes in the CLC group. [18] In our study, the mean operative time in the MLC group was 63.74 ± 9.50 minutes versus the mean operative time was 44.91 ± 14.73 minutes in the CLC. [Table 3] The operative time in our study is comparable to the literature available with few studies reporting higher operative time than our study. Also the operative time in MLC group higher than the CLC group implying that the reduced port size mini laparoscopic cholecystectomy has higher operating time than the conventional laparoscopic cholecystectomy.

Table 3: Mean Operative Time In CLC And MLC In Various Studies.

Study	Operative time in MLC (min)	Operative time in CLC (min)
Reardon et al ⁷	88.7 ± 5.9	78 ± 5.5
Sarli L et al ¹³	50.6 ± 12.3	45.8 ± 10.8
Schwenk et al ¹⁵	70(60-87)	70(60-80)
Sen-Chang Yu et al ¹⁸	72.8 ± 26.5	57.9 ± 17.3
Our Study	63.74 ± 9.50	44.91 ± 14.73

Pain score: Bisgaard et al, found MLC group suffered less pain in first 3 hours by the dose of prophylactic multimodal analgesic regimen. In contrast, the CLC group experienced a significant increase in pain intensity compared with preoperative value. Comparison between groups showed that the MLC group experienced pain score 37(5-130) is significantly less than the CLC group experienced pain score 52(0-197) pain during mobilization and significantly less incisional pain at rest and during mobilization (as measured by VRS). [11] Alponat et al, also find less pain score 0.71+ 0.82 in MLC group than pain score 1.93+ 1.2 in CLC group with significance (p-value=0.0045). [12] In the study conducted by Huang et al, the pain score for the right upper quadrant and flank ports at 24 hours and 48 hours after surgery did not reveal any notable difference between the CLC and MLC. [14] In the study conducted by Schwenk et al, they found that at 8:00 PM on the day of surgery, the VAS score for pain did not differ between CLC and MLC groups during rest and sitting but reported lower VAS pain score while coughing in the MLC group. [15] In the study conducted by Cheah et al, they found decreased pain in mini-laparoscopic cholecystectomy in comparison to conventional laparoscopic cholecystectomy. [16]. Look M et. al. observed that there is no advantage of Needleoscopic cholecystectomy over CLC in terms of post-operative pain or recovery. [17] In our study the pain was significantly lower in MLC group than the CLC group which is analyzed on 0th, 2nd 7th and 28th post operatively. [Table 4]

Table 4: Pain Comparison In Laparoscopic Cholecystectomy In Various Studies.

Study	Pain score (MLC)	Pain score (CLC)	p-value
Bisgaard et al ¹¹	37(5-130)	52(0-197)	0.31
Alponat et al ¹²	0.71 ± 0.82	1.93 ± 1.2	0.0045
Schwenk et al ¹⁵	100(82-192)	158(96-228)	0.5
Our Study at day-0	3.48 ± .67	4.30 ± .70	0.002
Our Study at day-2	1.30 ± .56	2.52 ± .90	0.001
Our Study at day-7	0.04 ± 0.21	0.49± 0.70	0.001
Our Study at day-28	0.0 ± 0.0	0.0 ± 0.0	0.00

Type of analgesia required: In our study we found that in patients who underwent MLC oral analgesia was required in 96% and injectable in 4% of patients on day-0, while in CLC injectable analgesia was required in 8% of patients. But this variation in type of analgesia required is not significant statistically. Similarly on day-2nd, in patients who underwent MLC, 8% patients did not require any analgesia and rest of all (92% patients) managed by oral analgesia whereas in patients who underwent CLC oral analgesia was required in 96% patients. Type of analgesia required can be used as a marker for intensity of pain in postoperative period. More number of patients would be required to establish any definitive link between the postoperative analgesia required and type of surgery. The research in this connection regarding analgesic requirement and port size and port numbers are still to be done so a comparison between other studies is not possible.

Cosmesis: Bisgaard et al, in their study found MLC group has better cosmesis score than CLC group. [11] In the study conducted by Alponat et al, they found cosmesis in MLC is superior to CLC. [12] In the study conducted by Sarli L et al, they found in 25 out of the 30 patients undergoing MLC (83%), the three 3-mm wounds were almost scarless on examination 1 week after surgery. More patients in the MLC group than in the CLC group was very satisfied with the cosmetic result. Ten patients who underwent MLC (33%) thought that their operation had been performed with a single incision. [13] In the study conducted by Schwenk et al, they found cosmesis in MLC is superior to cosmesis in CLC. [15] In our study the cosmesis is on day-0 was 3.22 ± 0.67 in MLC and 1.91 ± 0.99 in CLC. And at day-28th day the 8.26 ± 0.68 in MLC group and 7.04 ± 0.82 in CLC group with significant P-value 0.001. [Table 5]

Table 5: Cosmetic Comparison In Laparoscopic Cholecystectomy In Various Studies.

Study	Cosmesis score (MLC)	Cosmesis score (CLC)	p-value
Bisgaard et al ¹¹	*	*	<0.01
Alponat et al ¹²	0.71 ± 0.82	1.93 ± 1.2	0.0045
Sarli et al ¹³	19(63%) Very Satisfied	26(87%) Very Satisfied	<0.05
Schwenk et al ¹⁵	9(8-10)	10(9-10)	0.04
Our Study day-0	3.22 ± 0.67	1.91 ± 0.99	0.001
Our Study day-2	4.39 ± 0.84	2.52 ± 0.99	0.001
Our Study day-7	6.78 ± 0.74	5.13 ± 1.09	0.001
Our Study day-28	8.26 ± 0.68	7.04 ± 0.82	0.001

Return to normal activity: A secondary variable evaluated was the immediate time taken for the patient to mobilize following surgery. With studies suggesting that due to decreased postoperative pain with MLC techniques patients were able to mobilize in a lesser amount of time than those who underwent CLC. One of the most important benefits to the patient in terms of overall health of laparoscopic cholecystectomy has been a reduced length of hospital stay and an earlier resumption of the day-to-day activities for the patient. [19] In our study there is significant data observed on return to normal activity. In MLC group all selected patients resume their activity on same day and in CLC group 7 out of 23 patients resume their activity on same day but remaining 16 out of 23 patients resume their activity on 2nd day post operatively with statistical significance (P-value = 0.001). [Figure 2]

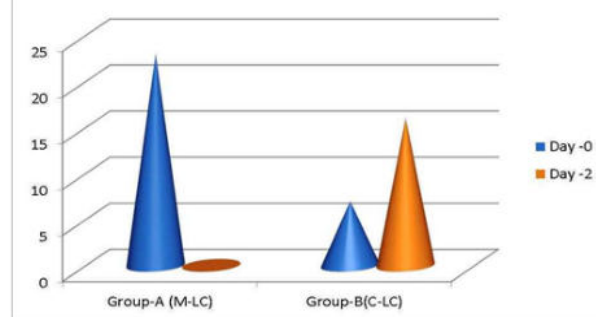


Figure 2: Graph Shows Return To Normal Activity In MLC And CLC.

Operative blood loss: Out of the earlier reported studies that difference in Intraoperative blood loss between CLC and MLC is

negligible with Huang et al [14]. Shaikh HR et al, evaluated for the same parameter, reflected a similar finding and did not find a statistically significant difference between the two groups with MLC 18 mL versus CLC: 21.4 mL (P = 0.258) of Intraoperative blood loss. [19] Our study also supports findings of previous studies.

Intra operative complications: In the context of intra operative complication, the bile duct injury, slippage of clip, port site bleeding are noted in various studies. Study by Mohil et al noted a single case of bile duct injury, except this no any other intraoperative complications are noted. [20] In our study there is no any intra operative complication noted in both groups.

Limitations Of Study: The primary limitations of this study are sample size and it was performed at a single centre, a multicentre trial with large number of patients would lay rest to all questions

CONCLUSION:

Our experience suggests that MLC can safely be used as an alternative to CLC. Compared to CLC, it has the added benefit of an early return to work along with excellent cosmetic results. Intraoperative blood loss are comparable in both groups. However the operative time in MLC group higher than the CLC group implying that the reduced port size mini laparoscopic cholecystectomy has higher operating time than the conventional laparoscopic cholecystectomy, this may be due to learning curve. Further large scale trials are required to prove any additional benefit of MLC.

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