ORIGINAL ARTICLE

Single-incision laparoscopic cholecystectomy versus mini-laparoscopic cholecystectomy: A randomized clinical trial study

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Background: Surgical technique using small-diameter instruments and single-incision laparoscopy are two new options for less invasive laparoscopic cholecystectomy (LC). In this study, we have compared mini-LC (MLC) with single-incision LC (SILC). **Materials and Methods:** This study is a randomized clinical trial conducted on the patients diagnosed with symptomatic cholelithiasis who underwent LC. Forty patients were randomized to two equal groups of MLC and SILC. They were compared in terms of demographic data, operation time, and surgical complications. **Results:** Baseline characteristics were similar in two groups. Operation time in MLC was significantly shorter than that in SILC (45.1 ± 69 min vs 63.75 ± 7.57 min, *P*-value < 0.001). Also, the total length of the wound in SILC group was shorter than that in MLC group (*P*-value < 0.003). Postoperative pain scores were similar in two groups. Hospital stay was shorter in MLC (1.2 ± 0.6 days vs 1.6 ± 0.8 days, *P* < 0.021). There was no difference in postoperative complications in two groups. **Conclusion:** MLC because of less operation time is preferred than SILC. Also, by subjective measures, it was a more comfortable method compared to SILC.

Key words: Cholecystectomy, incision laparoscopic cholecystectomy, laparoscopic, mini-laparoscopic cholecystectomy (MLC), operation time, single-incision laparoscopic cholecystectomy (SILC)

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INTRODUCTION

Surgical procedures have developed in all the fields nowadays. In addition to the progresses made in the areas of surgical techniques and surgical tools, efforts are being made to take surgical measures for the patient in such a manner so that they are economical and with less side effects and least hospitalization period in addition to maximum benefits for the patient regarding the elimination of the disease. Cholecystectomy is not an exception and since the time Philippe Moure invented laparoscopic cholecystectomy (LC) technique in 1987, in France, and noticeable advancements have occurred in the relevant techniques and instruments.[1] The common LC method is an American method with four ports that leads to lesser scars and pain, shorter hospitalization duration, and quicker recovery in comparison with the open surgery. Of course, the LC method has a 1.3-9% chances of wound infection and 0.77-3% chances of port-site hernia. They have therefore tried to obtain better results in comparison with the LC method in the recent year regarding the matters of beauty, pain after the surgery, and being economical through using fewer ports or decreasing the port sizes. The belief is that these methods are more economical considering the number of hospitalization days, the duration of the surgical procedure, and the surgery expenses.

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The efforts made in the field of improving LC results led to the invention of single-incision LC (SILC) method in 1990. The benefits of the SILC method include reduced risk of wound infection, quicker recovery period, lesser postsurgical pain, and better aesthetic results compared to the results of the four-port LC method. This method also suffers disadvantages in comparison to the common methods, which are as follows: Increased surgical-procedure period, difficult to learn for the surgeons, and more compromised vision during the surgery that increased risk of damage to the bile duct and the common bile duct (CBD) and increased chances of port-site hernia.

Therefore, some surgeons held the belief that this surgery with four ports had lesser chances of unexpected occurrences during surgery, and as a result this technique was easier and quicker. The MLC method was invented with four smaller ports. It seemed like the surgery was done in a shorter time since the surgeon saw better while operating using this method and it seemed like this method had lesser side effects compared to the SILC method. Also, since the cut on the skin is smaller, the postsurgical pain is expected to be lesser and the skin is expected to look better.

Many studies have been dedicated to comparing the SILC method and the common method so far but the SILC method has not been considered a good replacement for the four-port method in these research works with regard to the fact that the surgery duration was longer in most of these studies when using the SILC method and there were more side effects in some cases. Very few research works have been conducted on comparing the SILC method and the MLC method while it seems like the MLC method takes lesser time since the surgeon has a clearer vision during the surgery that leads to lesser side effects in comparison with the SILC method. Also, since the cut on the skin is smaller, the postsurgical pain is expected to be lesser and the skin is expected to look better. Therefore, this study aims at comparing these two methods (MLC and SILC methods) logically in order to examine whether the surgery could be performed in a shorter time period and result in lesser side effects since the vision is better during the surgery when smaller ports are used in comparison with when fewer ports are used. The study also tries to find answer to the following questions: Do the postsurgical pain and the beauty results make this a more confident and less dangerous surgery? Is this surgery beneficial to the patient and the health system in general?

PATIENTS AND METHODS

This study is a randomized clinical trial conducted on the patients admitted to Shariati Hospital, Tehran who were diagnosed with cholecystitis, and those with symptomatic cholelithiasis had indications for LC. The study protocol was approved in the Institutional Review Board and informed consent was obtained from the patients. The patients were randomized to receive SILC or MLC using a blinded envelope system. All the operations were performed by the same surgeon, who had experience of performing MLC and SILC procedures. The duration of the surgery and the events occurring during the surgery were registered. Postoperatively, the levels of pain was recorded using the visual analog scale (VAS) scores (ranged from 0 to 10) as well as the parameters such as dosage of intravenous analgesics, wound length, hospitalization period, and postsurgical side effects (including wound infection, nausea and vomiting, and reoperation and readmissions).

The study population included the patients (aged 18 years and above) who were admitted to Shariati Hospital, Tehran, between 2013 and 2014 and were candidates of LC. The exclusion criteria included: Age >50 years, signs of concurrent CBD stone, morbid obesity (BMI ≥40), severe acute cholecystitis, the American Society of Anesthesiologists (ASA) score of 3 or 4, and previous surgeries in the upper abdominal areas.

Surgical procedure

General anesthesia was induced and maintained using a standardized protocol. Under sterile conditions, the umbilicus was cautiously cleaned and the abdominal surface was prepared and draped for surgery. The patient was positioned supine, an in approximately 30° reverse Trendelenburg position.

MLC

A 10-mm port was placed in the lower part of the umbilicus, a 2.7-mm port was placed in the epigastric region, a 2.7-mm port was placed 2 cm below the right costal margin in the midclavicular line, and another 2.7-mm port was placed in the lower right side of the anterior axillary line. A 10 mm 30° camera was sent in from the 10-mm port, and the grasper holding the fundus of the gallbladder (GB) was sent in through the right lower port. A standard dissection with achieving critical view of safety was performed. The GB was then taken out using the 10-mm port.

SILC

Using conventional instruments and equipment, a 2.5-cm vertical incision was made inside the umbilicus. After the insertion of a Veress needle, CO_2 pneumoperitoneum was created and preserved at a pressure of 14 mmHg. A 10-mm port was used in the most inferior portion of the incision and two 5-mm ports were used in the upper left and right corners through the medial portion of the rectus sheets.

We started the procedure with the insertion of a 0° 10-mm camera through the 10-mm port and changed it to a 30°

camera when required. Conventional rigid instruments were used throughout the operation. The cholecystectomy procedure was performed using the same rules of classic LC. When the GB was completely separated, we temporarily removed the camera and entered the bag using the 10-mm port with the distal part of the connected thread (tail of purse string in the opening of the bag) still outside. Using the connected thread, we took out the bag containing GB by pulling the bag to the 10-mm opening. At the end of the procedure, the 10-mm port site was closed using 1.0 Vicryl for the fascia.

Postoperative care

After the LC, the patients underwent the recovery period of the operating room and were transferred to the ward. Acetaminophen was used for the baseline pain relief (1 gm every 6 h pro re nata (PRN)) and in case of severe pain, 25 mg of pethidine was used.

The information of each patient was collected in the information form by the concerned nurse who was blinded to the surgery. The patients' pain was registered within the ward based on VAS score (0, completely painless, to 10, unbearable pain) in specific time intervals after the surgery (every 8 h before receiving the baseline pain reliever and then 1 week after the surgery in the first visit).

During a 1- and a 3-month telephone survey, they were asked to evaluate their overall satisfaction with the procedure and cosmetic results using a 10-point Likert scale and report it themselves (1: The least degree of satisfaction and 10: The maximum satisfaction degree).

Statistical analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 19 (Chicago, Inc). Based on the Smirnov-Kolmogorov test, operative time, VAS scores, total pethidine dosage, and postoperative hospital stay were all compared among the 2 groups by using the nonparametric Kruskal-Wallis test. Intraoperative and postoperative adverse events were compared among groups by using the Chi-square test. Although the data for nonparametric continuous/quantitative variables are usually presented in terms of median and interquartile percentage, we thought that the mean ± standard deviation (SD) representation would aid in the comparison with the results of other studies. Hence, quantitative variables have been presented in terms of mean ± SD values, and the values have been considered statistically significant at P-value < 0.05.

RESULTS

The total number of the patients who were eligible to enter this study was 53, out of whom 13 were excluded for a variety of reasons such as acute cholecystitis (based on clinical and ultrasonographic findings), clinical evidence of CBD stones, severe obesity, and previous upper abdominal surgery. Four patients refused to participate in the study. Forty patients with symptomatic cholelithiasis who met the criteria of the American Society of Anesthesiologists classification I or II were randomly assigned to the SILC and MLC groups (20 participants in each group) [Figure 1]. As it could be seen in Table 1, the mean and SD of the age of the patients was 38.2 ± 6.46 years, the mean age in the MLC group and in the SILC group were 39.4 ± 7.04 years and 36.65 ± 5.66 years, respectively, the age had a normal distribution in both groups and comparing the two groups indicated that there is no significant difference regarding this matter (P-value = 0.19). In total 29 patients were female in the MLC (75%) (N = 15) and the SILC groups (70%) (N = 14), this difference was not significant (P-value = 0.7).

Operation time and intraoperative adverse events

The surgery duration had a normal distribution in both groups and the comparison between them showed that the average surgery time was 45.1± 6.88 min in the MLC group and it was equal to 63.75 ± 7.57 min in the SILC group, this difference was significant (P-value < 0.001). The findings-were divided into three groups of uninflamed GB, acute cholelithiasis, and severe cholelithiasis with adhesion. The results from the comparison of these findings in the two under-study groups have been summarized in Table 2.

Table 1: Demographics characteristics of the patient in two groups (MLC and SILC)

Age (year)*	Level	MLC (N = 20)	SILC (N = 20)	P-value
		39.4±7.04	36.6±5.6	0.19
Sex (Number %)	Female	15 (75%)	14 (70%)	0.72
	Male	5 (25%)	6 (30%)	

*Mean ± standard deviation

Table 2: Intraoperative and postoperative complications in the patients who underwent surgery#

Variables	MLC (N = 20)	SILC (N = 20)	P-value
Operative time (min)	45.1±6.9	63.7±7.5	<0.001*
Intraoperative findings: Gallbladders without inflammation	8 (40%)	9 (45%)	0.9
Acute cholecystitis	7 (35%)	7 (35%)	
Severe cholecystitis with adhesion	5 (25%)	4 (20%)	
Conversion to open surgery	0 (0%)	0 (0%)	N/A
Intraoperative complications Gallbladder perforation	4 (20%)	3 (15%)	0.51
Damage to the diaphragm	0 (0%)	0 (0%)	N/A
Bleeding in GB bed	0 (0%)	0 (0%)	N/A
Stone spillage	0 (0%)	0 (0%)	N/A
Embedding of drain	4 (20%)	3 (15%)	0.75
Total wound length	2.7 ± 0/2	2/5 ± 0/2	0/003*

#Based on using the Chi-square test, cross tabs, and Kruskal-Wallis test; *Statistically significant

The Chi-square test could not show a significant difference between the two groups (*P*-value = 0.9).

Comparing the complications occurring during the operation in the two groups showed that the GB burst during the operation in four individuals (20%) from the MLC group and three individuals (15%) from the SILC group. This difference was not statistically significant (*P*-value = 0.51). In these cases, the drain was inserted that the day after surgery, without any problem, it was exerted. Other complications during the surgery included damage to the diaphragm, significant bleeding at the surgical site (blood loss >100 cc), and stone spillage; damage to the bile duct did not occur in any of the groups. There is no conversion to open surgery in two groups [Table 2].

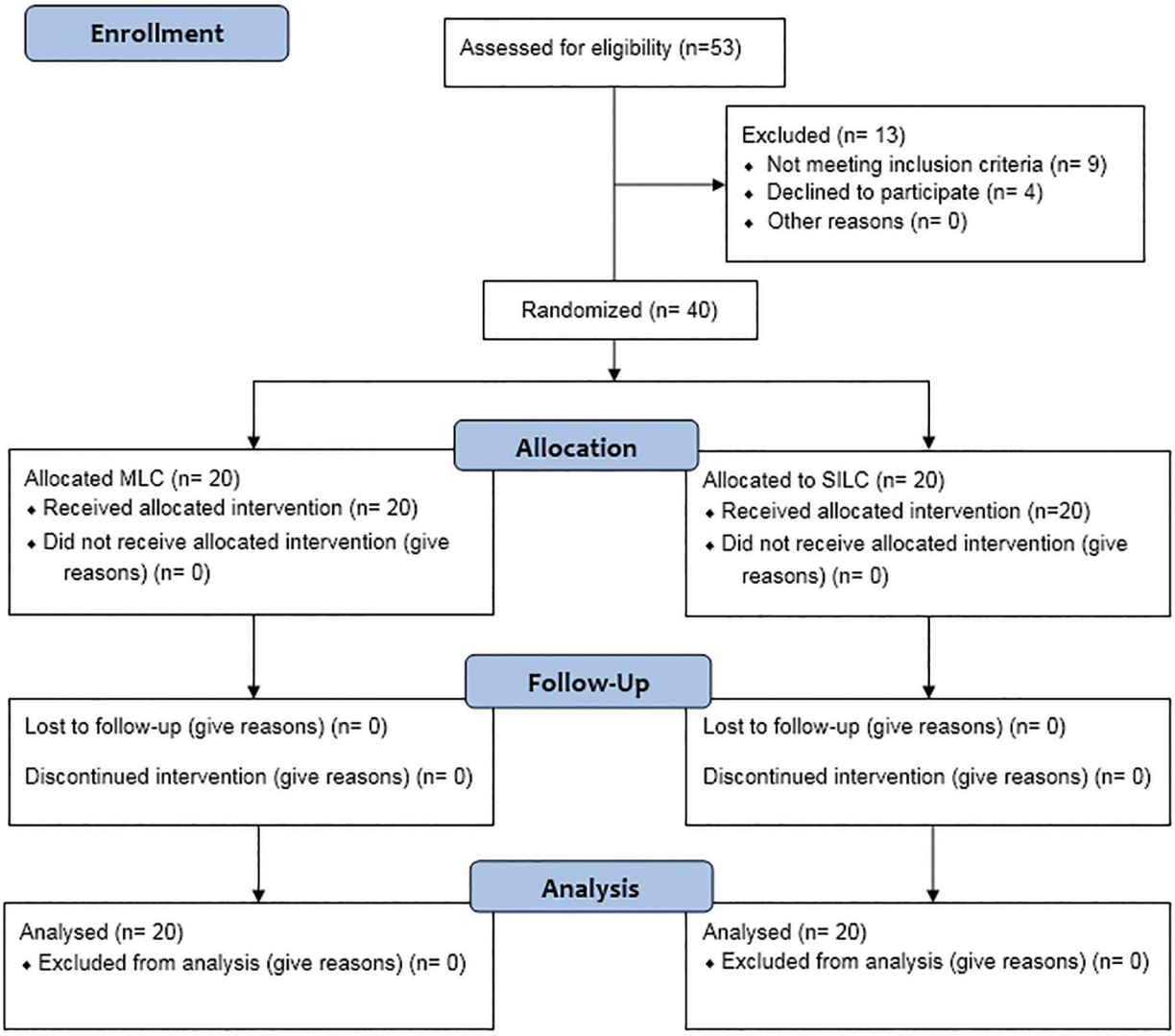
Postoperative pain and follow-up

Postoperative complications such as chest pain, heart and lung effects, hernia or port-site seroma, and wound infection did not occur in any of the groups. Also in terms of postoperative nausea and vomiting, pain (at 8 h, 16 h, 24 h, and 1 week after the operation), pethidine intake, and hospitalization period there was no difference between two groups.

There were no readmission, reoperation, and mortality in this cohort of patients. In terms of patients' self-evaluated outcomes either in 1-month or 3-month follow-ups, no statistically significant difference was observed in cosmesis [Table 3].

DISCUSSION

There were 20 patients in the MLC group and 20 patients in the SILC group and since the *P*-value was not significant in the two groups regarding the age and gender, we could conclude that both the groups were homogeneous regarding the age and gender factors. As previously mentioned, the



1: CONSORT Flow diagram for this trial

Table 3: Early outcomes of the patients in two groups after operation (cholecystectomy)

Variables	MLC (*N* = 20)	SILC (*N* = 20)	*P*-value
Postoperative pain[a]			
VAS 8 (median)	6.7±1.03 (7)	6.7±1.1 (6)	0.91
VAS 16 (median)	5.2±0.9 (5)	5±1.2 (5)	0.46
VAS 24 (median)	3.9±1.1 (3)	3.9±1.1 (4)	0.92
VAS 1 week (median)	0.9±0.9 (1)	1.3±0.9 (1)	0.2
Total pethidine (mg)	32.5±28.2	48.7±30.8	0.086
Postoperative complications Nausea and vomiting	7 (35%)	9 (45%)	0.74
Chest pain, lung and heart complications	0 (0%)	0 (0%)	N/A
Wound infection	0 (0%)	0 (0%)	N/A
Port-site hernia	0 (0%)	0 (0%)	N/A
Postoperative hospital stay (day)	1.2 ± 0.6	1.5 ± 0.8	0.021*
Satisfaction score[b]			
1 months	8.9 ± 1.1	8.5 ± 0.9	0.18
3 months	9.3 ± 0.7	9 ± 0.8	0.15

[a]Visual Analog Scale (VAS) for pain in 8 h, 16 h, 24 h, and 1 week after the operations; [b]Reported as mean ± SD score based on a 10-point Likert scale (NRS); *Statistically significant; #Based on using the Chi-square test, cross tabs, Mann-Whitney U-test, and Kruskal-Wallis test; N/A = Not applicable

duration of the surgery was significantly and noticeably shorter in the MLC group in comparison with single incision group (approximately 18.65 min). It is worth mentioning that only one comparison has been made between the surgery duration of the MLC and SILC procedures.[2] The duration was also shorter in the MLC group in the mentioned study.

Many other research works compared the surgery duration of SILC with that of the common four-port LC. The surgery duration of SILC was clearly longer in most of these research works.[3-8] MLC was compared with the common method in a few studies, which indicated that the MLC method did not take a longer time period than the common method.

Also, the MLC and SILC methods have been separately compared with the common method in two studies. The SILC method was longer than the common method only in Hosogi's study,[9] and both the SILC and MLC methods took longer time than the common four-port method in Saad's research.[10] The significant difference between the two methods in terms of operation time could be because the SILC method is more difficult to perform and that most of the surgeons are not familiar with this method. The surgeon can work more freely when there are a number of ports.

Our study made it clear that the postsurgical pain was almost the same in the two groups at 8 h, 16 h, 24 h, and also 1 week after the operation. Of course, the SILC group received more pain relievers (a mean of 48 mg in the-SILC group against 32 mg pethidine in the MLC group); however, this amount was not significantly different. The postsurgical pain was similar in both the groups in the only study that compared the MLC and SILC methods.[2] Another study compared the severe postsurgical pain in the MLC and common LC methods, and it was found that the pain was less in the MLC method,[11,12] and the SILC method was more painful than the common LC in some of the research works.[13,14] And, of course, some articles have stated that both groups experienced the same amount of pain.[3,4,7,9] These differences between the results could stem from the surgeon's technique in cutting the skin and the elasticity of the tissue. The results could also be more valid if the comparison was made among a larger sample.

Nausea and vomiting are common after the LC surgery, which was not different in two groups in the present study. No study was conducted on this matter. We divided the surgery effects into two groups—intraoperative events and postoperative complications. With regard to the previous studies, it seems like GB bursting during the operation occurs in the MLC group since the ports are small and the damage to the bile duct occurs in the SILC group since the surgeon cannot easily see while operating. However, no significant difference was found between the two groups in the case of the surgery complications during the operation such as the GB bursting. Significant bleeding in GB bed, damage to bile duct, and damage to diaphragm did not occur in any of the patients in the two groups.

The complications during and after the surgery (cholelitiasis, damage to diaphragm, wound infection, and hernia in the port site) were more in the SILC group.[10] In Saad's study, the effects were also more in SILC method in comparison with the common method in Kasara's study. However, the effects of the bile duct were the same in the common LC and the SILC method[13] in the study of Philip *et al*., although the effects related to the wound and the postsurgical pain were more in the SILC method. The bile duct may be more damaged in the SILC group since the surgeon's vision is more compromised in this method in comparison with the port surgery.

The postsurgical complications (such as chest pain, heart and lung problems, hernia, and wound infections) had no significant difference between two groups. In some researches, the postsurgical effects such as port-site hernia and wound infection were more in the SILC group.[10] In other studies, this different was not significant.[4,5] This difference between the research works may be due to the fact that there might be other reasons other than the port size affecting this matter. The postsurgical effects were not compared between the MLC and the common method. Although we did not have sufficient time to follow up the patients' conditions for long in this study, yet at the short-term follow-up that continued for 1 and 3 months after the

surgery, both groups were similarly satisfied with their surgery scar and there was no significant difference between the groups regarding this matter (based on the VAS system). The MLC method was superior to the common LC method in different studies regarding the surgery scar.[11,12] On the other hand, the scars of the SILC group looked better in MLC in Lee's study,[2] SILC method was preferred in most of the studies such as the works of Hosogi, Sasaki, and Sharma in comparison to the common LC regarding the matter of the surgery scar.[5,7,9,15-18] The reason behind these statistical differences could be the manner in which the surgeon stiches the skin and not so much the cut length or the port size. Examining this topic would require another research.

There is no conversion to open surgery in both the groups. Three groups were defined regarding the findings, the first group included uninflamed GB, the second group included acute cholelithiasis, and the third group included severe cholelithiasis with adhesion and no significant difference was observed between the two groups. This is another evidence which proved that the patients were homogeneous.

The hospitalization period was the same for both MLC and SILC groups and there was no significant difference between them. However, the SILC group had a shorter hospitalization period in Lee's study.[2]

CONCLUSION

In conclusion, the findings show that except the operating time that was shorter in MLC group, in other aspects MLC compared to SILC had no superiority. Complications, such as postoperative pain, length of hospital stay, and short-term cosmetic outcomes, were similar in the two groups.

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Conflicts of interest
There are no conflicts of interest.

AUTHOR'S CONTRIBUTION

ND contributed in the conception and design of the work, conducting the study, acquisition, analysis, and interpretation of data for the work, drafting and revising the draft, approval of the final version of the manuscript, and agreed for all aspects of the work. AS contributed in the conception and design of the work, revising the draft, approval of the final version of the manuscript, and agreed for all aspects of the work. ZK contributed in the design of the work, revising the draft, approval of the final version of the manuscript, and agreed for all aspects of the work. AS:contributed in the design of the work, revising the draft, approval of the final version of the manuscript, and agreed for all aspects of the work. MJ: contributed in the design of the work, revising the draft, approval of the final version of the manuscript, and agreed for all aspects of the work. AG: contributed in the design of the work, revising the draft, approval of the final version of the manuscript, and agreed for all aspects of the work. HM: contributed in the design of the work, revising the draft, approval of the final version of the manuscript, and agreed for all aspects of the work.

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