

Mini-Laparoscopic Cholecystectomy Versus Standard Laparoscopic Cholecystectomy: A Comparative study

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Abstract

Background: Laparoscopic cholecystectomy has been accepted as a gold standard for the surgical treatment of gallbladder diseases. In comparison with open surgery, the minimally invasive procedures are considered as a superior method. Using the port smaller than ports in standard laparoscopic cholecystectomy are used by some surgeons.

Objective: The outcome of miniport laparoscopic cholecystectomy and standard laparoscopic cholecystectomy and their intraoperative complications were examined and evaluated in the current study.

Patients and Methods: In this randomized-controlled trial, the same number (65) of patients, matched for gender underwent miniport laparoscopic cholecystectomy and standard laparoscopic cholecystectomy in a private hospital in Iraq from March 2016 to October 2017 following taking ethical clearance from the local department.

Results: The mean age of the patients in miniport and standard arms were 44.82 and 42.85 years, respectively. The study showed that the patients underwent standard laparoscopic cholecystectomy had a significantly shorter operation duration and a substantially higher pain score after 2, 6, and 12 hours of the surgery. The patients in standard group had a lower cosmetic score ($P < 0.001$). The miniport laparoscopic cholecystectomy was completed in more than 80% of the patients. Only one patient converted to open surgery and 11 to standard laparoscopic cholecystectomy. One patient in standard group was converted to open operation only. No significant change was seen in intraoperative complications between two study groups ($P = 0.907$) and the complications were not serious.

Conclusion: The miniport technique was non-inferior to standard laparoscopic cholecystectomy while was superior for cosmesis and pain severity.

Keywords: Miniport laparoscopic cholecystectomy, Standard laparoscopic cholecystectomy, Complication, small ports laparoscopic cholecystectomy.

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Introduction

The surgeons need safer and less-invasive surgical interventions in the management of gallbladder diseases. It is important for a surgeon to select a medical management technique in the management of gallbladder disease according to the overall medical

condition of a patient and the local and systematic complications and consequences of the disease [1]. Since its first introduction of laparoscopic cholecystectomy (LC) in 1985 [2], it has been able to reduce the need for open cholecystectomy and a decrease in

its complications in a dramatic way [3]. The LC has become the standard management technique for symptomatic cholelithiasis and cholecystitis with different severity [4]. The decrease in morbidity, hospital stay, and costs and without increasing the requirement for conversion to open operation have been reported following performing laparoscopic cholecystectomy after 24 hours of cholecystitis onset [5]. Removal of gallbladder or laparoscopic cholecystectomy is a preferred method of cholecystectomy. In standard laparoscopic cholecystectomy, four ports, including two 10-mm diameters, and two 5-mm diameters are used [6, 7]. Using smaller ports called as miniport laparoscopic cholecystectomy has been reported as well [8]. Fewer adverse events have been reported in patients underwent LC, it is claimed that bile duct injury occurs in a frequent way during this procedure than open cholecystectomy may lead to dire consequences [9, 10]. Until now the miniport LC is not recommended as a routine clinical intervention and further clinical trials in terms of complications, operation duration, and cosmesis score were recommended in the systematic review [11].

The main concern of the surgeons in miniport LC is using a smaller port that may lead to more complications, more operation, and conversion to open surgery [11]. The surgeons need further clinical trials to make a decision on the miniport laparoscopic cholecystectomy. In particular that the surgeons are under pressure to use the latest surgical techniques raising the importance of

the current study to have up-to-date findings on the effectiveness and safety of the miniport LC.

The aim of the present study was to assess and evaluate the benefits and intraoperative complications of miniport laparoscopic cholecystectomy versus standard port laparoscopic cholecystectomy in a sample population in Iraq. The author hypothesized that miniport LC is a safer with the lesser pain score and higher cosmetic score compared to standard laparoscopic cholecystectomy.

Patients and Methods

In the current randomized controlled trial, a total of 130 patients consecutively visited the surgery clinic of a private hospital in Duhok-Iraq and diagnosed with symptomatic gallbladder stones by the surgeon were assigned randomly into two arms of the study. The miniport arm was undergone four-port mini laparoscopic cholecystectomy and the standard arm were undergone under four-port standard laparoscopic cholecystectomy.

The patients met eligibility criteria if they are male or female aged 18 years and older and irrespective of their socio-demographic perspectives. The patients with ASA grade III/IV had previous major abdominal surgeries, those with features of choledocholithiasis or acute cholecystitis, malignancy, pancreatitis on ultrasonography evaluations, and those with BMI>30 were not included in the study. Of the total 313 patients assessed for the eligibility criteria of the study, 130 of them met all inclusion criteria, and remaining 183 patients were

excluded due to not met eligibility criteria [124], decline to participate [32], and having other diseases [27], and finally 65 patients were assigned to each arm, as shown in Figure (1).

The patients were randomly assigned into two arms of the study through the selecting the separate closed opaque envelope randomization method by the patient

following taking their ethical and written consent forms with giving required information on the study objectives. The study was conducted over 18 months between March 2016 and October 2017. The patients visited the clinic for the suspected gallbladder diseases were carefully and clinically evaluated by the study surgeon.

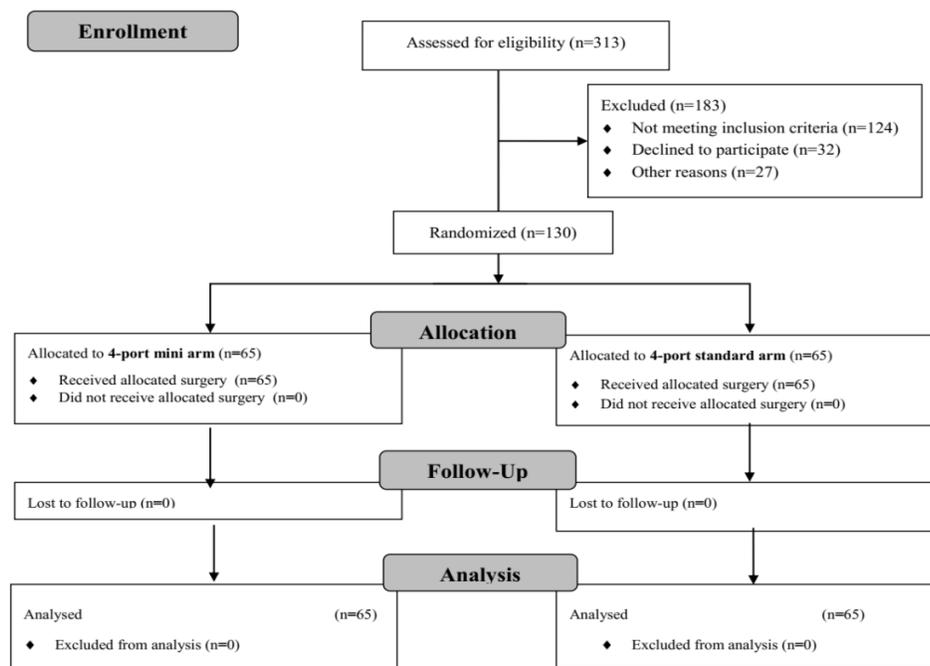


Figure (1): Research flowchart.

Clinical procedures

The detailed history and clinical examinations were taken from all patients ,many investigations including complete hemogram, Renal function test and liver function test . The surgery was performed by the study surgeon by the assistance of a senior house officer and 2 nurses. The patients of two study groups stayed at the

hospital for less than 24 hours and those two patients converted to open surgery stayed for two days. Veress needle placement and CO2 gas were used to create Pneumoperitoneum followed by insertion of a transumbilical / subumbilical/ supraumbilical 10-mm port with pressure at abdominal cavity maintained at 12 mm Hg and the 10-mm laparoscope was passed. The patients had difficulties to

proceed in miniport LC was converted to standard LC or to open cholecystectomy as the first criterion of the study.

Standard Laparoscopic cholecystectomy

In this method, the patient was placed in reverse Trendelenburg position and tilted to the left and surgery proceeded as standard procedure. In the epigastrium located in the right side of the falciform ligament, a 10-mm trocar was placed and two additional 5-mm ports in the right upper side of abdomen just with two fingers width under the costal margin in midclavicular line and anterior/midaxillary line through or slightly under the umbilicus. The technique was performed by dissection of the gallbladder by the first grasping and lifting fundus, then the neck of the gallbladder subsequently, the cystic duct and artery were dissected using Maryland dissector. Once the 'critical view' of these structures was obtained, these were clipped and divided. Using electrocautery, the gallbladder was removed from its bed and it was retrieved through the epigastric port [12].

Miniport-laparoscopy cholecystectomy

In this technique, a 5-mm epigastric port was placed. Two special 2.8 mm alligator graspers (2 Trocar with Grasping forceps, automatic, tk783-741 Tekno, Germany) were used transabdominally in order to grasp the fundus and Hartmann's pouch of the gallbladder to retract and manipulate. The cystic duct and artery were dissected using the standard Maryland laparoscopic instrument, as described in the standard technique. The surgeon changes the position and size of the scope to 5-mm 300 through the epigastric port. Subsequently, the medium to large clips were applied through the 10-mm umbilical port using clip applicator to clip the cystic duct and artery.

The laparoscope was reversed to umbilical port in order to divide and dissect the structures, again using 5-mm 300 scope through the epigastric port together with 10-mm jaw forceps from the umbilical port, the gallbladder specimen was retrieved Figure (2).

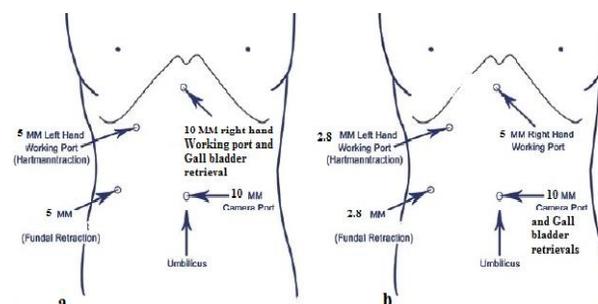


Figure (2): Comparison locations and diameters for miniport-laparoscopic cholecystectomy (b) and standard laparoscopic cholecystectomy (a).

The sheath at site of umbilical ports were closed with 0 vicryl and skin with 3/0 nylon in both procedures.

Diagnostics and Measurement criteria

If in any patient, for any reason, there was difficulty in proceeding with Mini LC, the

procedure was converted to Standard LC or to open cholecystectomy . The patients were followed up for 7 days after discharge.

To compare the two methods, following data were noted:

- a) Time of operation: Counted from “skin to skin”, i.e., from first incision to the end of closure of the final wound.
- b) Conversion from Mini - LC to Standard - LC/open cholecystectomy.
- c) Complications: CBD injury, hepatic injury/bleed, biliary/ stone spillage, bowel injury, vascular injury or any other complication up to 30 days post-operatively.
- d) Post-operative pain: The pain severity of surgery of both groups was measured through the Wong-Baker Face Scale at 2, 6 and 12 hours . The scale has six faces with different appears indicating each face for one pain severity ranging from no pain (hurt) to a lot of pain. In this scale, the faces were given a number indicating 0 for doesn't hurt at all; face 2 as hurts just a little bit; face 4 hurts as a little bit more; face 6 as hurts even more; face 8 hurts a whole lot; face 10 hurts as much as the patient can imagine [13].
- e) Analgesia requirement of the patient apart of paracetamol any additional Analgesia recorded .
- f) Cosmesis: assessed after 7 days by the patient and the nurse in the ward/clinic . Each was asked to rate cosmesis on a scale of 1 to 5 . (ie,1 indicating all

wounds were prominent ; 2 , three wounds were prominent ; 3, two wounds were prominent; 4, one wound was prominent and 5 that no wounds were prominent), The mean of both the patients' score and nurse's score was taken as the final score.

Statistical analysis

The descriptive purposes of the study were examined through the frequency distribution. The difference between operation duration, pain severity, and cosmetic score and conversion and complications were examined through the independent t-test and Fishers' exact test with taking into account the p-value less than 0.05 as the statistically significant difference. The SPSS version 24:00 was used for statistical calculations.

Ethical aspects: The ethical clearance of the study was obtained from the corresponded local department in Duhok registered as reference number: 16032016-3 in 16th March 2016. The patients' characteristics were used for the study purposes following taking their written consent forms from all patients in two arms of the study. The confidentiality of their personality was protected throughout the study process.

Results

The comparison of baseline characteristics of the patients in standard and mini arms of the study showed that they are comparable in age (P=0.0443) and gender (P=1.000), Table (1).

Table (1): Baseline characteristics between patients in standard and mini arms of the study.

Patients' characteristics	Standard Laparoscopy Cholecystectomy (n=65)	Mini-Laparoscopy Cholecystectomy (n=65)	P-value (two-sided)
Age	44.82 (14.19)	42.85 (14.98)	0.443*
Gender, male	15 (23.1%)	15 (23.1%)	1.000**
*Independent t-test and ** Chi-square test were performed for statistical analyses.			

The patients underwent mini-laparoscopic cholecystectomy had a longer surgery duration (40.14 minutes) compared to those patients underwent standard laparoscopic cholecystectomy (31.49 minutes), $p < 0.001$.

In addition, the patients in mini-group of the study had a lower pain after 2, 6, and 12 hours of the surgery and a higher cosmetic score compared to the standard group table (2).

Table (2): Operation duration, pain and cosmetic scores between patients in standard and mini arms of the study.

Patients' characteristics	Standard Laparoscopy Cholecystectomy	Mini-Laparoscopy Cholecystectomy	P-value (two-sided)
Operation duration, min	31.49 (8.28)	40.14 (5.50)	$P < 0.0001$ *
Pain after 2 hours	5.28 (1.62)	3.75 (1.40)	$P < 0.0001$ *
Pain after 6 hours	4.98 (1.37)	3.52 (1.55)	$P < 0.0001$ *
Pain after 12 hours	4.83 (1.43)	3.25 (1.51)	$P < 0.0001$ *
Cosmetic score	2.75 (.59)	3.45 (.83)	$P < 0.0001$ *
*Independent t-test was performed for statistical analysis			

The study showed that mini-LC was completed in more than 80% of the patients assigned to mini port compared to 98.5% of patients underwent standard port LC with a significant difference ($P = 0.001$), however, their observed complications were not different statistically between two groups of the study ($P = 0.907$). Of the total 130 patients recruited in the study, two patients were converted to open surgery, one in standard LC due to bleeding and dense adhesion and one in miniport LC owing to bile duct injury. Also, 11 patients were converted to the standard of the patients underwent miniport

LC owing to different reasons; 6 patients due to thick wall gallbladder and 5 conversion due to dense adhesion. The most prevalent immediate complication (during surgery) was bile spillage in both groups, followed bleeding from gallbladder bed, and wound infection. Only one patient was observed by bile duct injury, subsequently was converted to open operation Table (3). The patients underwent miniport LC received the less post-operative analgesics compared the patients in standard arm ($P = 0.012$).

Table (3): Conversion and complications between patients in standard and mini arms of the study.

Patients' characteristics	Standard Laparoscopy Cholecystectomy	Mini-Laparoscopy Cholecystectomy	P-value (two-sided)
Conversion			0.001*
No conversion	64 (98.5%)	53 (81.5%)	
Open surgery standard	1 (1.5%)	11 (16.9%)	
Complications			0.907*
No complication	57 (87.7%)	55 (84.6%)	
Bile spillage	4 (6.2%)	5 (7.7%)	
Bleeding from gallbladder bed	3 (4.6%)	2 (3.1%)	
Wound infection	1 (1.5%)	2 (3.1%)	
Bile duct injury	0 (0.0%)	1 (1.5%)	
Added analgesia post-operatively			0.012
One dose	16 (24.6%)	8 (12.3%)	
Two doses	7 (19.8%)	1 (1.5%)	

* Fishers' exact test was performed for statistical analyses.

Discussion

The current study showed that the four-port mini-LC has a substantially longer operation duration compared to standard LC. However, the patients underwent miniport LC had a lower pain score and a better cosmetic score. More than 80% and 98% of the patients completed the procedure in mini and standard arms, respectively. The study did not find any serious intra-operative complications.

The current study showed that the miniport LC requires a longer operation duration (40.14 minutes) in contrast with 31.49 minutes in standard LC. Although the difference in operation duration is statistically substantial, the author does not see that 10 minutes longer will put the patient at a more substantial risk of morbidity and post-operative complications (excluding patients with a severe

inflammation). The 10 minutes longer in the mini LC backs to change in the trocars and camera in the incisions only. The mini LC is a more challenging technique to learn and is a cost increasing method led to a failure to wide acceptance among surgeons [14]. The longer operation duration has been confirmed in a systematic review as well. Gurusamy *et al* [11] found out that the miniport LC has a five minutes longer operation duration compared to the standard LC extracted from 12 trials with 695 patients.

A review study of comparisons of miniports versus standard port for laparoscopic cholecystectomy included 12 clinical trials with 734 patients confirmed that the miniport LC can be completed successfully in more than 80% of the patients [11]. The review did not find any case of mortality in seven trials reported mortality (0/194 in miniport LC

compared to 0/203 patients in standard port LC. The current study as previously mentioned did not follow the patients for longer than one week, hence honestly the investigator unable to report any finding on this point. But, other studies did report the comparable duration of hospital stay [15].

The surgeon must select the appropriate medical technique in the management of gallbladder diseases following by careful and thorough medical and clinical examinations as dissecting the marked inflammation in a patient could distort local anatomy and raise the risk of bile duct injury. Therefore, the surgeon should locate the prevention of bile duct injury at the first step [16] meaning a patient still has a low threshold for conversion to open cholecystectomy. The surgeon must avoid progress in dissection when the anatomy is poorly defined in favor of subtotal cholecystectomy [17]. The risk of bile duct injury is increased owing to more challenge of visualization, intraoperative cholangiography, and dissection in laparoscopic cholecystectomy [18], Standard laparoscopic cholecystectomy will remain as an alternative technique to miniport laparoscopic cholecystectomy in case of failure.

The conversion to standard port LC was seen in 11 patients in the miniport LC (16.5%). It is lower than 24% reported by Novitsky et al [19] in a randomized controlled trial with 34 patients. One patient was converted to open surgery in conventional LC group owing to bleeding and dense adhesion. It was not possible for

the surgeon to control its severe bleeding, therefore, I decided to perform open surgery. The risk factors of conversion from laparoscopy to open cholecystectomy were mentioned in the literature are: high body mass index, thickness gallbladder, history of abdominal surgery, choledocholithiasis, older age, emergency cases, elevated total bilirubin, elevated white cell count, and raised alkaline phosphatase [20].

In addition, one patient in miniport laparoscopic cholecystectomy was converted to open operation owing to bile duct injury and Roux en Y Hepaticojejunostomy was done. Bile duct injury is most frequently reported complication in comparison with open cholecystectomy [21-23]. It is important to mention that between 29% and 50% of bile injuries are diagnosed intra-operatively [24-26], therefore, the surgeons require to diagnose these injuries earlier [27] as the conversion raises the postoperative time, complications rate, hospital stay, and postoperative costs [28, 29].

The systematic review did not find a substantial difference in the serious adverse events between two surgical techniques, including conversion to open operation. The overall conversion to open surgery in patents underwent miniport laparoscopic cholecystectomy was 8/351 with adjusted proportion 2.3% versus 6/319 with the adjusted proportion of 1.9% among patients treated with standard LC [11].

In the mini-port technique was performed in this study, one 10-mm, one 5-mm, a two 2.8 mm were used to the patients. One of the

reasons for the acceptance of mini-LC for gallbladder diseases is better cosmetic after the surgical procedure. The smaller and lesser incisions are made in mini-LC resulting in minimal scar and improved cosmesis [19]. As using fine-caliber instruments produce smaller surgical wounds and result in a reduction to minimum damage with overall improvement in the postoperative course and the cosmetic outcome. There is no standard and united scale to measure the cosmesis precluding the study to make the comparison between various investigations. The study showed a better cosmetic score in patients underwent mini-LC. The surgeons need to collect their efforts to minimize surgical trauma through using smaller and fewer laparoscopic ports.

The surgeons even used one single large incision laparoscopic cholecystectomy is performed in transumbilical by multi-instrument instead of four ports leading to a periumbilical scar only [1] with unproven improvement in cosmesis, a reduction in postoperative pain, recovery pain, and a decrease in adverse events associated with the wound [30, 31]. The cosmetic score was measured following one week of the surgery and the author unable to justify for longer than this time. However, the Cochrane review concluded that there is no a significant difference in the cosmesis score following six months between two groups [11].

The study was measured the pain score following 2, 6, and 12 hours of surgery and found a substantial lower pain score in the

patients underwent miniport LC. The investigators reported the controversial findings on the pain score following miniport LC, for instance [8, 11], Novitsky et al [19] did not find a substantial reduction in pain score contrast with Sarli et al [15], [32, 33]. Reduction in pain score in the present study is logic as these patients received less added analgesics postoperatively in this study. The reason for this discrepancy could back to the experience of the surgeon.

The study did not find a hernia as a complication as the author did not follow the patients following hospital discharge and hernia occur after this time as a post-operative complication, therefore, the surgeon unable to make justification in this regard. It is necessary to mention that post-operative hernias occur more significantly following laparoscopic cholecystectomy compared to open cholecystectomy [34].

The patients underwent both techniques for gallbladder diseases were discharged within one day of hospital stay, only two patients converted to open surgery from both arms of the study were discharged within two days, therefore the author can say that there is no statistically significant difference in hospital stay and confirmed by a Cochrane review performed by Gurusamy *et al* [11].

It is necessary to pay attention in the interpretation of the findings reported in the current study. The strong point of the current investigation was the random allocation of the patients into two arms of the study. However, it was not exempt from the weaknesses. In addition, the intra-operative

were only reported complications in the present study and the author could not record long post-operative complications owing to high load of work at the department. It is important to mention that miniport LC has not been standardized yet and currently the ports with different diameters are used by surgeons, for instance Sarli *et al* [15] used one 12-mm and three 3-mm ports and Bisgaard *et al* [7] used one 10-mm and three 3.5-mm trocars for the patients, however two 2.8 mm, one 10-mm, and one 5-mm ports were used in the present study.

Conclusion

The present study showed that four-port LC of one 10-mm, one 5-mm, and two 2.8 mm can be performed for the patients with gallbladder diseases with 81.5% success rate, 1.5% conversion rate to open operation and 16.5% conversion rate to standard LC. With taking into account the comparison of findings of two surgical techniques, it could conclude that the miniport laparoscopic cholecystectomy can be performed for the patients with gallbladder diseases by the experienced surgeons as it prohibits the surgeon to visualize the operation place in a better way. However, the safety of this is a need to be more established in trials with a longer follow-up time period. Finally, the only reasons to select this method are having a lower pain score and a better cosmetic score. Therefore, it is better to be done in selected cases and leave the decision for the patient.

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