Safety and feasibility of cystic duct control with suture ligation during laparoscopic cholecystectomy

Mohie El-Din M. Madany[a], Mansor M. Kabbash[a,b], Hussien A. Mostafa[a], Ahmed M. Maghraby[c], Mahmoud S. Ahmed[a]

Departments of [a]General Surgery, [c]General and Bariatric Surgery, Faculty of Medicine, Aswan University, Aswan, [b]Department of Maxillofacial Surgery, Faculty of Dentistry, Sphinx University, Sphinx, Egypt

Correspondence to Mohie El-Din M. Madany, MD, Faculty of Medicine, New Aswan City, Aswan 81528, Egypt.
Tel: +20 122 449 7380; fax: +20 972 430 767;
e-mail: mohie.madany@med.aswu.edu.eg

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Background
Securing the cystic duct in laparoscopic cholecystectomy (LC) can be achieved through suturing ligation (intracorporeal or extracorporeal), clips, electrocautery, and ultramodern vessel sealing energy devices. Suturing ligation is a safe and a cost-effective measure in low-resource settings such as developing countries.
Patients and methods
The rationale of this current prospective study was to establish the safety and feasibility of intracorporeal suturing ligation for securing the cystic duct during LC in the local setting. Patients who were eligible for LC at the Aswan University Hospital's General Surgery Department were included.
Results
In all, 260 patients were included in our study. Most of the participants were females, representing 92.69% of patients. The mean age of participants was 39.82±9.96 years, and 95.77% were overweight or obese. The mean±SD time for cystic duct ligation and closure was 3.03±0.64, and the median [interquartile range (IQR)] was 2.90 min (1.11 min). The mean±SD operative time was 88.19 ±27.81 min, and the median (IQR) was 84 min (31.75 min). Also, the mean±SD hospital stay was 1.11±0.55 days, and the median (IQR) was 1 day (0 day). There was no intraoperative significant bile duct injury, bile leak, or bleeding. No visceral injury was encountered. The success rate of the operation was 100%. None needed to be redone. No case needed conversion to open surgery. No bile leakage or other complication was seen during the follow-up period.
Conclusion
In resource-constrained settings, suture ligation of the cystic duct is a safe technique with low rates of postoperative complications. Cystic duct control with intracorporeal suture ligation is an essential technique that can be learned, requiring knot-tying skills.

Keywords:
bile leakage, cholecystectomy, cystic duct, extracorporeal knot tying, intracorporeal suturing and knot tying, laparoscopy, ligation by suturing, success rate

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Introduction

Laparoscopic surgery has become the gold standard of care for surgical operations across various disciplines due to its ability to decrease perioperative complications, expedite recovery, and yield superior cosmetic outcomes [1]. Laparoscopic cholecystectomy (LC) is a widely practiced procedure for the removal of the gallbladder for symptomatic cholecystolithiasis and other indications like pyocele, polyps, and adenomyomatosis of the gallbladder [2–4].

Cystic duct leakage (CDL) is an unwanted, potentially life-threatening complication of LC. It is reported in 0.5–3% of patients following LC [3–6]. It has been shown that CDL increases to 4–7% in patients with complicated gallstone disease, such as cholecystitis, pancreatitis, cholangitis, and stones in the common bile duct [3,7–9].

Adequate closure of the cystic duct is essential to prevent CDL, especially in patients with complicated gallstone disease who have a higher risk of bile leakage. Although CDL is classified as a minor injury of the bile ducts, it is associated with a significant re-intervention rate, increased morbidity, and even mortality [3,10–12].

Several techniques have been described to securely close the cystic duct during cholecystectomy. The most common closure technique during LC is simple (nonlocking) metallic clips. Alternatives are locking clips or ligatures [8,9]. Locking clips differ

from metallic clips as they are made of polymers, are usually absorbable, and are designed to lock in place with comparable locking pressure and therefore are thought to provide a more secure closure. With the introduction of vessel sealing devices, such as LigaSure and the harmonic scalpel, their feasibility and outcome in closing the cystic duct during LC are of interest [8,9,13]. However, in a low-resource setting, the cost is an issue.

Therefore, the rationale of this current prospective study was to establish the safety and feasibility of cystic duct ligation by suturing during LC in the local setting.

Patients and methods

Study design

The study complied with the most recent version of the Declaration of Helsinki and adopted the well-recognized GCP criteria. Furthermore, it was authorized by the Local Ethics Committee and complied with all applicable national rules and regulations. Under the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) Statement checklist, this study was planned as a single-group quasi-experimental investigation [14].

The study, approved by the Institutional Review Board (IRB), Faculty of Medicine, Aswan University, was conducted on patients who attended the general surgery outpatient clinic at Aswan University Hospital from May to September 2023. Before being included in the study, every participant who visited the hospital received a thorough explanation in Arabic regarding the procedure and its objective, and each participant signed an informed consent form.

The study covered all cases – male or female, 18 years of age or older – that come to the hospital and are qualified for cholecystectomy either elective or emergency. However, every patient declined to participate, and individuals with mental impairments preventing them from undergoing the routine follow-up were excluded. During the operation, no patient had adhesions in the Calot's triangle or very short cystic arteries to be excluded from the study.

Every patient underwent a thorough history-taking process that covered their medical, surgical, and personal history (age, sex, and unique habits). After being admitted to the hospital, the patients were prepared to undergo the procedure.

Technique description

Following a preoperative workup, a single surgeon with at least 10 years of experience in minimally invasive surgery performed a LC while under general anesthesia.

The standard four-port technique was used to do the surgery. According to the 'American' approach, the surgeon stood to the left of the patient, the first assistant to the right of the patient, and the person operating the laparoscopic video camera to the left of the surgeon. Using a Veress needle and CO_2 gas, pneumoperitoneum was created. A laparoscopic port was then blindly implanted in its place.

The cystic artery, and so Calot's triangle, is situated within the dissected hepatocystic triangle, which is the ventral portion of the region bounded by the gallbladder wall and cystic duct, the liver edge, and the common hepatic duct. The hepatocystic triangle was maximally extended by retracting the gallbladder's infundibulum inferiorly and laterally while maintaining the fundus under traction in a superior and medial position. Following the dissection of Calot's triangle, the cys tic duct was secured and cut. Our technique is different from the classically described one for LC in securing the cystic duct using only intracorporeal suture ligation. A modified Tumble Square knot was used in all cases, at both ends of the cystic duct (no clips were applied). We made this modification to achieve a more secure knot.

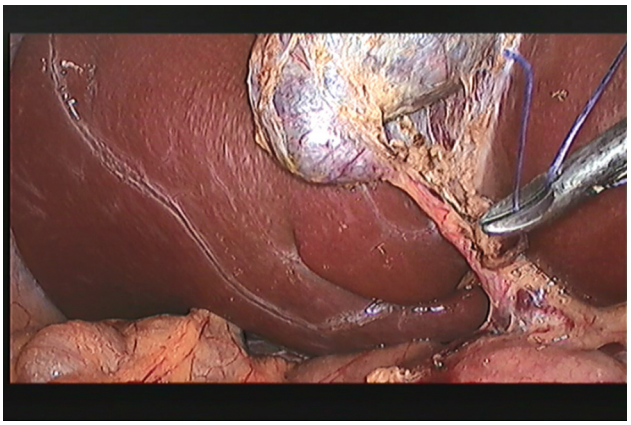
The modified Tumble Square knot technique was done as follows (Video 1):

(1) A 12 cm Vicryl 2/0 suture material was introduced with a needle holder through the epigastric port (Fig. 1).
(2) Another needle holder was introduced through the right hypochondrial port (Fig. 2), while the assistant was doing maximal traction upon the fundus to properly expose the dissected Calot's triangle.

Video 1

xxxx.

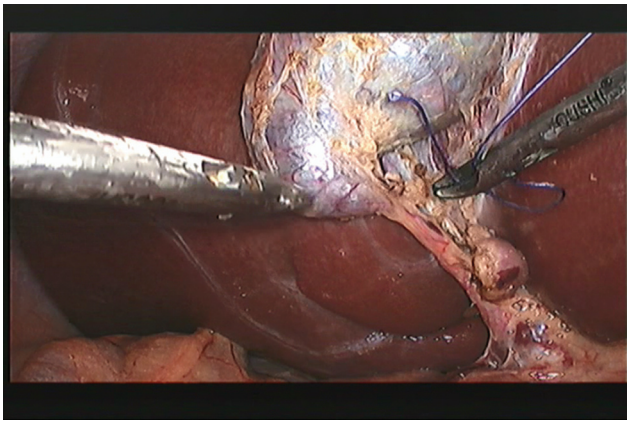
Figure 1



A 12 cm long Vicryl suture is introduced with a needle holder through the epigastric port.

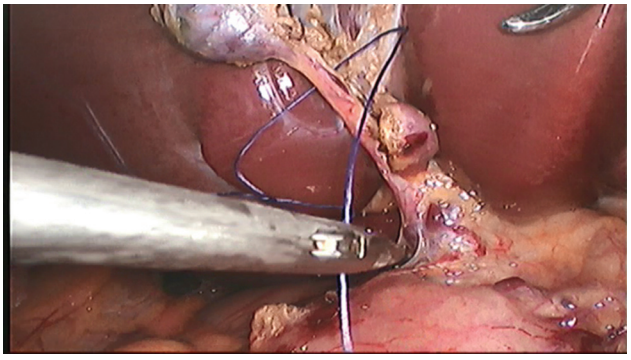
(3) The cystic duct was encircled with the Vicryl 2/0 suture, its long limb on the left side and the short on the right (Fig. 3).
(4) Then, the left-hand needle holder grasped the long limb of the thread (Fig. 4).

Figure 2



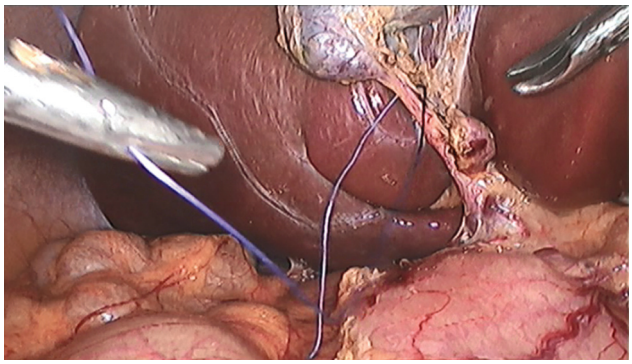
Another needle holder is introduced through the right hypochondrial port.

Figure 3



Cystic duct is encircled with Vicryl suture.

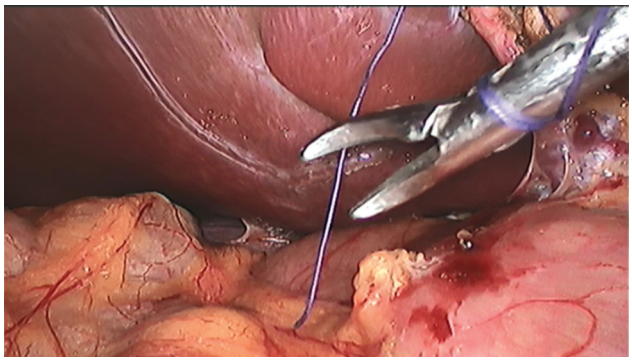
Figure 4



The long limb of the suture is on the left side of the duct and grasped with the left-hand needle holder.

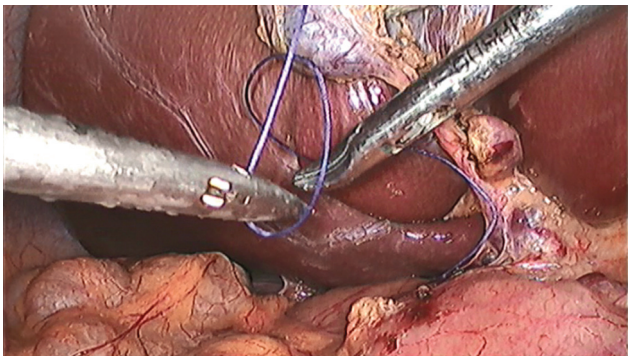
(5) An intracorporeal surgical knot tying technique was carried out while the left-hand needle holder grasped the long limb of the thread on the left side of the cystic duct to perform a double half knot with the right-hand needle holder in one direction (Fig. 5), and the knot tied loosely.
(6) Then, a half knot was carried out in the same manner in the opposite direction (Fig. 6).
(7) The second half knot was tied with some looseness (Fig. 7).
(8) This will allow the positioning of the knot at the proper site (Fig. 8a and b).
(9) This is the modified tumble square knot, which can be changed to a slipping configuration by tightening the thread's same side (Fig. 9), that is, the long limb of the thread and the thread to the left side of the cystic duct. The same side of the thread should be straightened with the help of two needle holders.
(10) It was ready to slide (Fig. 10) after straightening the same side of the thread.
(11) The partially closed jaws of the needle holder (acting as a knot pusher) (Fig. 11) will slide the knot to be secured enough to prevent a bile leak.

Figure 5



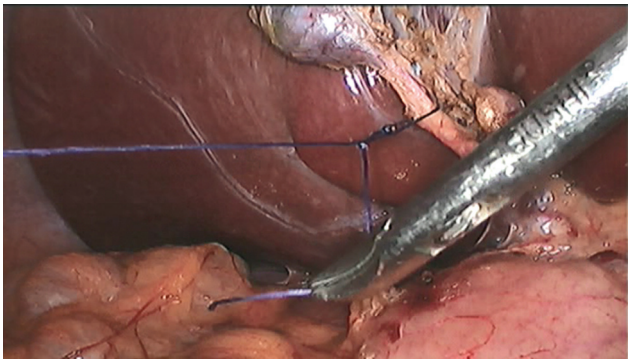
A double half knot with the right-hand needle holder is performed in one direction.

Figure 6



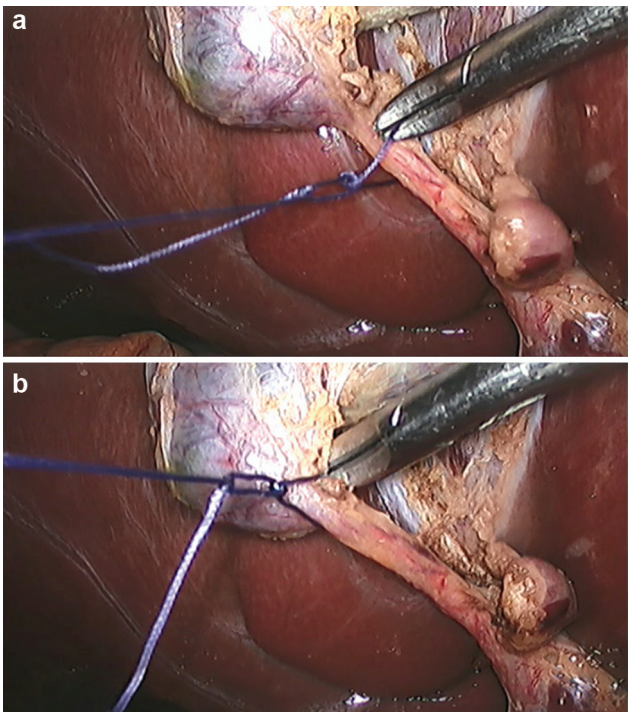
A half knot was carried out in the opposite direction.

Figure 7



The first double half knot and the second half knot was tied with some looseness.

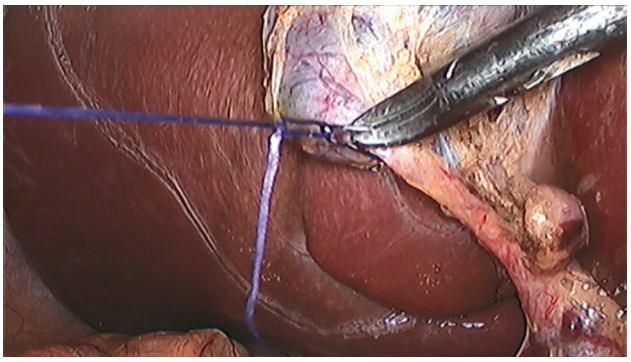
Figure 8



(a) Positioning of the knot at the proper site. (b) Positioning of the knot at the proper site.

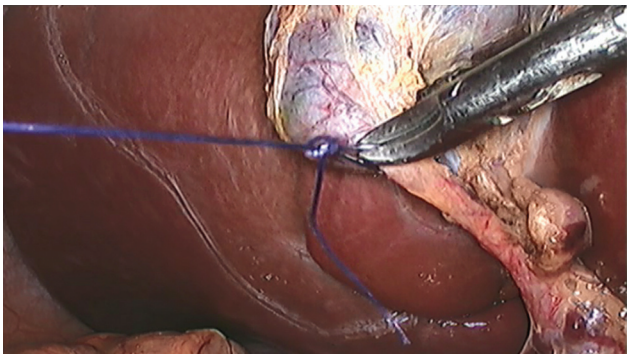
(12) After securing the cystic duct by tightening the knot, the knot is locked again by pulling both limbs of the thread (Fig. 12).
(13) One more knot is tied (Fig. 13) to prevent the slipping of the modified tumble square knot.
(14) Any indication of bile leakage was observed over the split cystic duct stumps (Fig. 14).

Figure 9



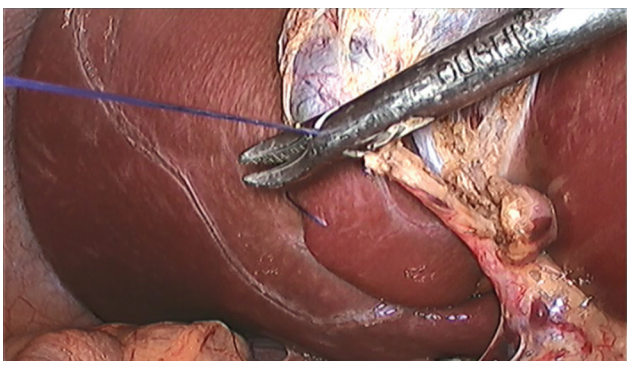
Tightening the thread's same side to tumble the knot.

Figure 10



The modified tumble square knot is changed to a slipping configuration.

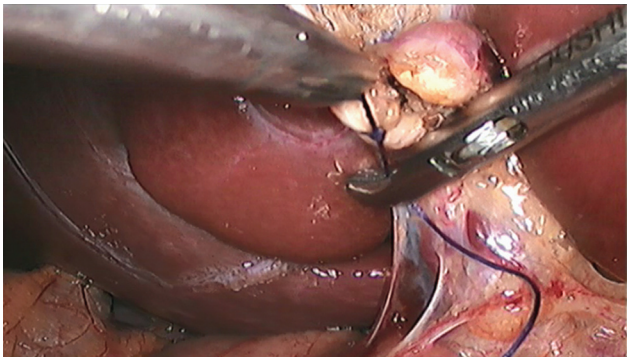
Figure 11



The partially closed jaws of the needle holder act as a knot pusher.

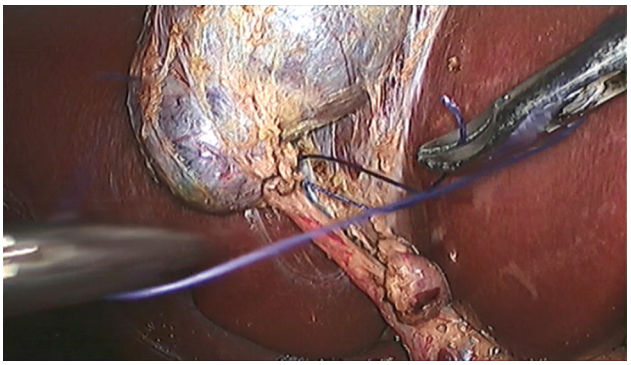
After the cholecystectomy was carried out using the standard procedure, the gallbladder was removed. Hemostasis was kept stable throughout the process. Using suction, the blood clots and debris were extracted. The cystic duct stump bile leakage and cystic artery stump hemorrhages were reexamined. For postoperative analgesia, bupivacaine was administered into each port incision. The incisions on the skin were closed with Xylon 3-0. There were no instances of biliary leakage or postoperative hemorrhage among the patients. A measure of more than 100 ml of fresh blood was considered a significant bleed. The patients were all discharged from the hospital after being judged well. The duration of hospitalization and any problems following surgery were noted and tracked.

Figure 12



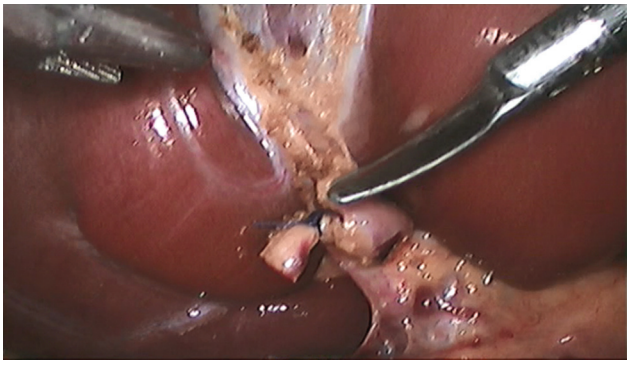
The knot is locked again by pulling both limbs of the thread.

Figure 13



One more knot is tied.

Figure 14



Check for any bile leakage over the split cystic duct stumps.

Follow-up

All patients were followed up postoperatively for any emergent events related to the operation. Follow-up was made by seeing all the cases 1 day, 1 week, and 1 month after the surgery: in addition, a telephone call was made for all cases 2 months after the procedure.

The outcome variables

The primary outcome variable was the postoperative bile duct leakage. Secondary outcome variables were surgical success, the conversion rate, length of the procedure, time needed for suture ligation of the cystic duct, complications (intraoperative major bile duct injury, bleeding), postoperative discomfort [measured by visual analog scale (VAS) score], hospital stay, and postoperative complications (such as infection, seroma, hematoma, bile leakage).

Statistical analysis

According to the study of van Dijk *et al.* [3], the incidence of CDL following LC was 3%. In the current study, with the use of suture ligation, we expect the incidence to decrease 0.5%. Thus, with a significance level of 95% and a power of 80%, the calculated sample size was 248 participants. To allow for a dropout rate of 5%, the sample size will be 260 participants.

Continuous data were presented as mean±SD or median+interquartile range (IQR), depending on the normality test results of the variable distribution. For qualitative data, we used numbers and percentages. SPSS software (Statistical Package for the Social Sciences, version 25.0; SSPS Inc., Chicago, Illinois, USA) was used for the statistical analyses.

Results

Baseline characteristics

In this study, 260 patients were enrolled and were followed up postoperatively, with an average age of 39.82±9.96 years. The majority of cases were female (241, 92.69%). Only 11 (4.23%) cases had normal weight, 85 (32.69%) were 'overweight,' and 164 (63.08%) were 'obese.' The average BMI was 32.08 ±4.22 kg/m^2 as shown in Table 1.

Only 25 (9.62%) had hypertension, 26 (10.00%) had diabetes mellitus, and 11 (4.23%) had ischemic heart disease. More than half of the cases, 133 (51.15%), were American Society of Anesthesiologists (ASA) II, and the remaining 119 (45.77%) were ASA I and only eight (3.08%) cases were ASA III.

Operative details

All cases underwent LC.

Most of the cases (191, 73.46%) had chronic calcular cholecystitis. However, only two cases had gallstone pancreatitis, one case had gangrenous gallbladder, and only one case had perforated gallbladder. All other findings are shown in Table 1.

As depicted in Table 2, the mean±SD cystic duct length was 2.21±0.24 cm, and the mean±SD cystic duct width was 0.73±0.04 cm. The mean±SD time for cystic duct ligation and closure was 3.03±0.64, and the median (IQR) was 2.90 min (1.11 min).

The mean±SD operative time was 88.19±27.81 min, and the median (IQR) was 84 min (31.75 min). Also, the mean±SD hospital stay was 1.11±0.55 days, and the median (IQR) was 1 day (0 day).

There was no intraoperative major bile duct injury, bile leak, or bleeding. No visceral injury was encountered. The success rate of the operation was 100%. None needed to be redone. No case needed conversion to open surgery.

Table 1 Baseline characteristics

Categorical variables		
Indication		
Chronic calculator cholecystitis	202	77.69%
Acute calculator cholecystitis	16	6.15%
Pyocele of the GB	11	4.23%
Symptomatic gallbladder polyps	10	3.85%
Mucocele of the GB	9	3.46%
Adenomyomatosis of the GB	8	3.08%
Gangrenous GB	1	0.38%
Gallstone pancreatitis	2	0.77%
Perforated GB	1	0.38%
Continuous variables		
	Age	BMI
Valid number	256	260
Mean	39.82	32.08
SD	9.96	4.22
Minimum	25.00	24.50
Lower quartile	31.00	28.98
Median	39.00	32.30
Upper quartile	48.00	35.73
Maximum	65.00	39.00
Interquartile range	17.00	6.75

GB, gallbladder.

Postoperative follow-up

The postoperative pain (VAS score) was mean±SD 1.88±0.72 and the median (IQR) was 2 (1), with a minimum VAS of 1 and a maximum of 3. Only four (1.54%) cases experienced seroma, four (1.54%) cases hematoma, and four (1.54%) cases port-site infection during 1 month of the postoperative period. No bile leakage or other complication was seen during the follow-up period.

Discussion

These days, LC is one of the most frequently performed operations. LC initially caused a marked increase in morbidity, particularly iatrogenic biliary injury and arterial bleeding. To avoid harming the extrahepatic biliary tree, the surgeon must therefore perform cautious dissection and rely on his thorough understanding of the anatomy of Calot's triangle [15,16].

Many advancements have been made in cystic duct closure; yet, there is still mystery around the procedure's effectiveness, safety, and potential difficulties for the operating surgeon during LC [15]. Thus, various techniques have been used to

Table 2 Operative and postoperative details

Continuous variables						
	Operative time (min)	CD length	CD width	CD time for closure	Hospital stay, days	VAS
Valid number	260	260	260	260	260	260
Mean	88.19	2.21	0.73	3.03	1.11	1.88
SD	27.81	0.24	0.04	0.64	0.55	0.72
Minimum	48.00	1.81	0.66	2.21	1.00	1.00
Lower quartile	67.75	2.01	0.70	2.43	1.00	1.00
Median	84.00	2.20	0.73	2.90	1.00	2.00
Upper quartile	99.50	2.42	0.76	3.54	1.00	2.00
Maximum	165.00	2.60	0.79	4.27	5.00	3.00
Interquartile range	31.75	0.42	0.07	1.11	0.00	1.00

VAS, visual analog scale.

achieve secure cystic duct control. These techniques described in the literature to deal with ligation of the cystic duct include intracorporeal suture ligation of the duct and extracorporeal ones. Despite that this technique is complex, time-consuming, and necessitates learning intracorporeal suturing is very effective in securing the cystic duct. Some studies compared the harmonic scalpel and clip to close the cystic duct and cystic artery in a single incision LC. A harmonic scalpel has been recently used for securing cystic ducts, which is feasible, safe, and effective although the cost is a constraint [2,3,13].

In the current study, most cases are females (92.69%). Also, female preponderance was observed in other studies by Emmi and Suhas [17] and Hugh *et al.* [18]. Also, the length of stay in the hospital in our study was 1.11±0.55 days, and the duration of surgery was 88.19±27.81 min, all are comparable to the results of other studies [17,18]. Also, in the current study, there was no incidence of bile leak documented, which was mentioned in other studies [17].

The success of cystic duct intracorporeal suture ligation in the current study without any incidence of complications like bile leakage, cystic artery injury, or right hepatic artery injury is consistent with the results mentioned in other studies [17].

In their study, Seenu and colleagues aimed to compare the postoperative outcomes of cystic duct occlusion using titanium clips versus ligation during LC. The study included 105 patients who were randomly assigned to two groups: Group I underwent cystic duct occlusion with clips, while group II underwent cystic duct occlusion with ligation. The incidence of overall bile leak following LC was found to be 3.8%, with no significant difference between the two groups. Specifically, the leak rate following cystic duct occlusion with clips was 3.9%, and that following ligature was 3.8%. The ligature technique took slightly longer than the clip technique, but there were no significant differences in postoperative outcomes between the two groups. The study suggests that the use of ligature is a feasible, safe, and cost-effective alternative to titanium clips for cystic duct occlusion during LC. However, it is important to note that this study was the first to compare these methods [19].

According to the results of the current work, the mean ±SD time for cystic duct ligation and closure was 3.03 ±0.64 and the median (IQR) was 2.90 min (1.11 min). There was no intraoperative major bile duct injury, bile leak, or bleeding. No visceral injury was encountered. The success rate of the operation was 100%. None needed to be redone. No case needed conversion to open surgery. Only 1.54% experienced seroma, 1.54% hematoma, and four cases of 1.54% port-site infection during 1 month of the postoperative period. No bile leakage or other complication was seen during the follow-up period.

In their work, Singal *et al.* [15] reported a mean time for ligation of the cystic duct by intracorporeal suture as 2.50 min (SD±0.25 min) with no postoperative complications, such as wound infection or bile leakage.

Another study performed the 'C' technique for closure of the cystic duct in 1000 consecutive patients subjected to LC using intracorporeal knotting. Neither bile leakage nor any other procedure-related complication was seen. The mean time taken for cystic duct ligation was 3.5 min. The method of total intracorporeal cystic duct and artery ligation in LC is simple, technically easy, secure, and economical. If you start using intracorporeal knotting routinely, the procedure becomes less time-consuming with an increasing number of cases [20].

In their systematic review, van Dijk and colleagues included 38 studies out of 1491. A total of 47 491 patients were included. The studies were about cystic duct closure techniques concerning the prevention of bile duct leakage after LC. They concluded that based on available evidence, it is not possible to either recommend or discourage any of the techniques for cystic duct closure during LC concerning CDL, although data point out a slight preference for locking clips and ligatures vs other techniques. No separate recommendation can be made for complicated gallbladder disease [3].

Other authors have reported additional benefits of simple ligation of the cystic duct, highlighting its ease and practicality compared with intracorporeal knotting, which requires specialized expertise [21]. This simple technique can be performed without difficulty, and the use of simple ties is readily available and cost-effective. However, it is not always a matter of simplicity. Efficacy in securing the cystic duct is more important than simplicity and time.

Another study focused on appendicectomy found that ligation by intracorporeal knotting is a safe, successful, and feasible method. The authors also observed that silk was a suitable alternative, particularly in resource-

limited or financially constrained settings where expensive instruments may not be affordable [22].

Mehmedovic and colleagues emphasized that LC carries a higher risk of intraoperative lesions, particularly involving biliary ducts. Biliary fistulas may occur in a small percentage of cases, often due to leakage from the cystic duct stump or accessory bile ducts [23]. However, in our study, we observed that with tight and secure suturing of the cystic duct, the color of the duct changed to white, and no injuries were encountered.

We think that if LC is carried out carefully and under safety supervision, complications could be avoided. Our study also revealed that to prevent the formation or migration of common bile duct strictures, suture ligation was a safer approach than clip application. There were no significant variations in timing; however, a piece of thread could be used to ligate the cystic duct or artery independently. One very affordable and cost-effective method of ligation is the use of sutures. Because different surgeons would have different operating times, difficulties were avoided in the current trial by having a single surgeon do the procedure.

Consequently, the following are some benefits of the current study: (a) suture ligation requires expertise and experience, both of which can be gained through training. (b) The skills of intracorporeal knot tying are essential for laparoscopic surgeons in most laparoscopic procedures, LC is the most frequent operation done all over the world, so it is a good chance to enhance our skills in intracorporeal knot tying. (c) Cystic duct color turning white indicates that the tie is sufficiently secure. (d) The cost of clips is significantly more than that of the suture. (e) Suture is widely available, but clips' availability – even in terms of proper size – can occasionally be questioned. (f) Ligature is simple to apply in dilated or short cystic ducts.

During LC, sutures can be used to ligate the cystic duct or artery efficiently and securely. If a clip applier is unavailable, sutures might be used as a substitute. Both approaches should be well-versed by the laparoscopic surgeon. The experience and expertise of surgeons or residents also affect total timing and complications, which can be reduced with training, the right instructions, and supervision.

This study has a number of limitations. First, it did not compare the intracorporeal suture to another technique. However, this pilot study's goal was to assess the effectiveness and safety of suturing. To further bolster the evidence supporting its efficacy and safety, this method will be tested in a randomized, controlled trial against alternative approaches. Also, the study did not elicit the learning curve. This is because the aim of this current work was only to highlight the safety and efficacy of the procedure. Also, the maximum time for cystic duct ligation in the current study was 4.27 min.

Conclusion

In conclusion, intracorporeal suture ligation of the cystic duct is a safe technique with low rates of postoperative complications. Also, it was a feasible and effective method. Cystic duct control with suture ligation is not a simple technique. It necessitates a long time to be learned and properly performed by surgeons.

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Nil.

Conflicts of interest

Mohie El-Din M. Madany, Mansor M. Kabbash, Hussien A. Mostafa, Ahmed M. Maghraby, Mahmoud S. Ahmed have nothing to disclose.

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