

# Clip-Less Extracorporeal Knot Versus Clip Ligation Laparoscopic Cholecystectomy—A Randomized Controlled Trial

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## ABSTRACT

**Introduction:** Laparoscopic cholecystectomy is bread-and-butter not only for hepatobiliary surgeons, but also for general surgeons. To secure cystic duct clips are used routinely. Suture ligation of cystic duct and its various methods have been also described. But there is insufficient studies comparing the various methods prospectively.

**Objectives:** To compare feasibility, operative time (incision to closer), postoperative pain, operative cost, complications of procedure, and cosmetic outcome between patients treated by laparoscopic cholecystectomy with either extracorporeal knotting or clip ligation of cystic duct.

**Methodology:** This was a randomized controlled trial conducted from July 2021 to June 2024. Study patients selected for laparoscopic cholecystectomy were assigned by randomization in to two groups: patients who were treated by extracorporeal knotting through 5 mm epigastric port (study group), and in control group where clips were used.

**Results:** Five hundred and six cases were subjected to laparoscopic cholecystectomy during study period. In study group, operation was significantly prolonged (68.25 Vs. 59.37minutes). Ligation of cystic duct by using suture is cost effective than clips (300 vs. 500 BDT). Both groups had no significant complications. Clip less study group shows cosmetic superiority than clipped control group.

**Conclusion:** Extracorporeal ligation of cystic duct is safe, economic and cosmetically better in comparison to clip ligation for laparoscopic cholecystectomy. The limitation is operative time.

**Keywords:** Clipless laparoscopic cholecystectomy, cystic duct clipping, Extracorporeal knotting.

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## 1. INTRODUCTION

Cholelithiasis is one of the most common diseases encountered by both general physicians and surgeons. Professor Dr. Erich Mühe of Germany performed the first laparoscopic cholecystectomy [1]. Laparoscopic cholecystectomy is performed not only by hepatobiliary surgeons, but also by general surgeons.

Within a very short period of time, laparoscopic cholecystectomy has become popular owing to its safety, easy learning curve, less trauma, early recovery and excellent cosmetic results. Innovation in ergonomics, energy sources, and endo-suturing has tremendously refined laparoscopic

cholecystectomy. Laparoscopic cholecystectomy is considered the gold-standard procedure for gallbladder diseases.

Cystic duct ligation is a crucial step of laparoscopic cholecystectomy. The use of metallic titanium and silicon clips is very popular. However, securing the cystic duct using a harmonic scalpel, plasma kinetic method, and intracorporeal and extracorporeal suturing have also been studied with satisfactory outcome [2]–[8].

Although the intraoperative time is comparatively shorter using clips, slippage of clips from the cystic duct can cause bile leak and bleeding [8]. Clips can also rarely migrate into the common bile duct (CBD) after



cholecystectomy, resulting in choledocholithiasis, biliary obstruction, acute biliary pancreatitis, and cholangitis [9], [10]. The lifelong presence of metallic foreign bodies may impose psychological strain on patients. Low-quality metal clips can interfere with MRI in the future.

Extracorporeal knotting may be the best alternative to clipping in unusual situations, such as a wide cystic duct. The feasibility of cystic duct ligation by knotting with absorbable sutures has been observed in many trials [8]. Extracorporeal knotting is easy to learn and does not require much hand-eye coordination. Furthermore, the clip applicator needs a 10 mm epigastric port, whereas extra corporeal knotting can be done through a 5 mm port which is cosmetically more acceptable.

This randomized study was conducted to assess the feasibility, operative time, postoperative pain, operative cost, postoperative complications, and cosmetic superiority of extracorporeal knotting in comparison to clips for ligating the cystic duct in laparoscopic cholecystectomy in the Bangladeshi population.

## 2. MATERIAL AND METHOD

This prospective randomized study was conducted from July 2021 to June 2024 in the patients who underwent laparoscopic cholecystectomy in the Surgery Department, Shaheed M. Monsur Ali Medical College Hospital and other hospitals in Sirajganj, Bangladesh.

Adult patients with chronic calculus cholecystitis who had undergone surgery were included in this study. The exclusion criteria were patients unfit for general anesthesia, acute cholecystitis, obstructive jaundice, gallbladder malignancy, or coagulation disorders.

All patients were evaluated preoperatively by careful history taking, clinical examination and basic laboratory investigations. Abdominal ultrasonography was performed in all the cases. After evaluation, laparoscopic cholecystectomy was performed by the same surgical team, and the time taken to complete the entire procedure and the time taken to apply the extracorporeal knot were calculated. A follow-up period of six months was scheduled to detect any postoperative complications. To assess postoperative pain (within the first 24 h) at the four respective port

sites a ten point visual analog score was used where a score of zero means no pain and ten means severe pain. Similarly, the cosmetic satisfaction scale was used to assess scar color, stiffness, thickness and irregularity where a score of zero means normal skin and ten means very different from normal skin.

Study subjects were randomized by a simple randomization technique using sealed envelope into 2 groups-patients who were treated by extracorporeal knotting through a 5 mm epigastric port (study group), and a control group where clips were used.

**Group 1 (Study group): 253 patients-** Extracorporeal (Mishra's knot) suture ligation of cystic duct. Four ports are used but only umbilical port is 10 mm, remaining three ports are 5 mm. (Fig. 1)

**Group 2 (Control group): 253 patients-** Metallic clip occlusion done for cystic duct. Four port, two 5 mm and two 10 mm as a standard technique.

Patients were unaware about the procedure group for reason of blinding.

### 2.1. Configuration of Mishra's Knot

In the study group, an extracorporeal Mishra's knot was used to close the cystic duct stump and the cystic artery using polyglactin 910 (Vicryl 1) suture material through the epigastric port (port D). Intra-abdominally, the thread was fed several times to avoid traction while pulling out the tail.

Extra-abdominally, the left hand held the short limb and the right hand held the long limb of the thread, and the short limb was crossed over the longer one. The assistant's index finger was used to make the knot by taking a single hitch, then one wind followed by one half knot, then a second wind followed by a second half knot, the last wind, and to be terminated by a third half knot. (Fig. 2) The left hand was used to hold the intersection point, whereas the right hand made the necessary hitches and loops. Subsequently, the thread was pushed intra-abdominally and secured using help of a knot pusher. (Fig. 3) The traction on Hartmann's pouch was mildly released while the knot was secured. Mishra's knot is a secure and stable knot that can secure structures up to 18 mm in diameter [11].

Data sheets were completed by patients who reported their information through pre-informed appointments and phone calls. Data files were formed on a computer and

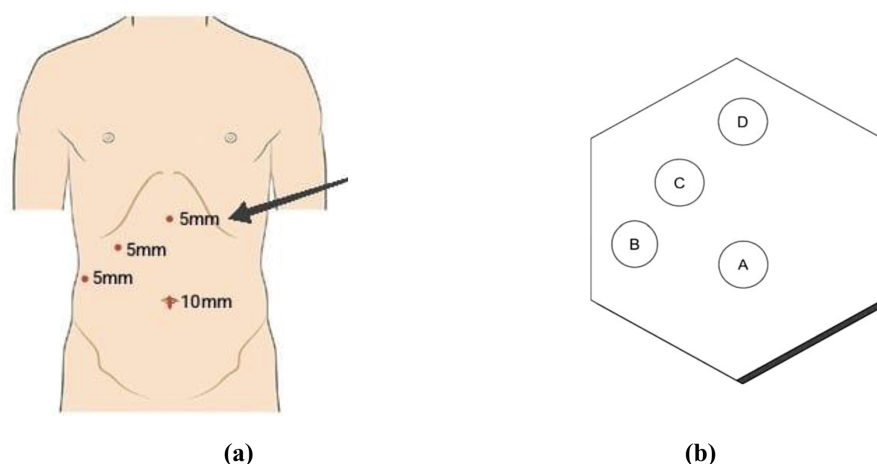


Fig. 1. Port site placement (a) and Extracorporeal knotting through 5 mm epigastric port D (b).



Fig. 2. Shape of extracorporeal Knot.

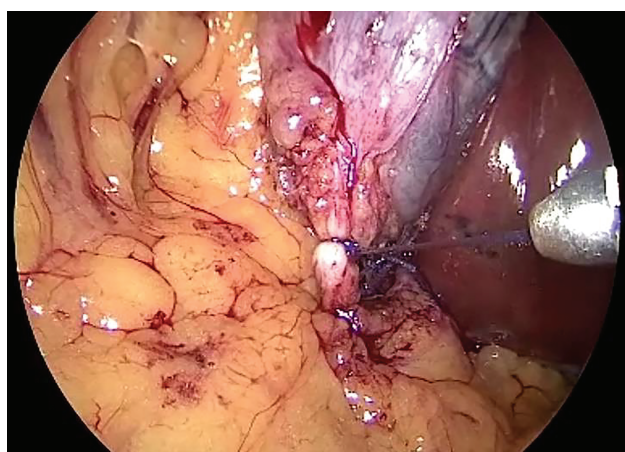


Fig. 3. Secured extracorporeal knotting of cystic duct.

analyzed using SPSS version 16.0. Independent Student's t-test and Chi-square test were used for analyzing variables with  $p < 0.05$  as statistically significant.

### 3. RESULTS

This randomized controlled trial included 506 patients who underwent laparoscopic cholecystectomy. Each group was comprised of 253 patients, and there were no drop outs.

There was no significant difference in the demographic data (Table I). The mean operative time was significantly longer in the extracorporeal knotting group (68.25 min) than in the control group (59.37 min) (Table II).

Ligation of the cystic duct using sutures is less expensive than that using titanium clips (average cost 2.5 vs. 4.2 USD) (Table III).

Post-operative complications were minor bile leak and superficial surgical site infection ranging from 1.1% to 7.1% in both groups, but the difference was not significant (Table IV).

Comparison of median cosmetic scores between the groups showed that the control group had a relatively poor cosmetic outcome. Because the epigastric port was 5 mm, it was cosmetically more acceptable in the study group. Ligation of the cystic duct using sutures is less expensive than that using titanium clips (average cost 300 vs. 500 BDT) (Table V).

### 4. DISCUSSION

Cholecystectomy is the treatment of choice for symptomatic gall stone disease [8]. Laparoscopic cholecystectomy is the procedure of choice for elective cholecystectomy. The advantage of minimal-access surgery makes laparoscopic cholecystectomy popular choice over open cholecystectomy [8].

Titanium clips are commonly used to secure the cystic duct during laparoscopic cholecystectomy. Alternatively, sutures can be used to occlude the cystic duct, either by intracorporeal or extracorporeal knotting. However, the available literature comparing cystic duct occlusion with suture knotting and using clips in laparoscopic cholecystectomy is not sufficient to decide superiority [8].

In current study, the maximum patients who underwent laparoscopic cholecystectomy were 30–50 years of age which was identical to a similar study [12]. Another study with a similar comparison also stated that 30–49 years was the most common age -group to undergo laparoscopic cholecystectomy [8].

In the present study, operation was significantly prolonged (68.25 vs 59.37 minutes) in the study group, which was comparable to the observations of similar studies conducted by Teja *et al.* (2022) and Gurusamy *et al.* (2010) [8], [9], [13]. The operative duration decreases with the repetitive practice of suture ligation [9]. Jain *et al.* (2011) and Kandil *et al.* (2010) reported that the mean operative time using the harmonic scalpel was  $50 \pm 9.36$  and  $52.14 \pm 9.8$  respectively which is shorter than our time [14], [15]. The continuous practice of extracorporeal knotting has led to improved performance, resulting in a less time-consuming procedure [11].

In the current study, ligation of the cystic duct using sutures was less expensive than titanium clips (average cost 2.5 vs 4.2 USD). A similar comparison was reported by Teja *et al.* (2022) [8]. In a study by Seifalyazal *et al.*, the cost of using suture material was (10–14 \$) which is cheaper than the cost of using clips and incomparable to the cost of using Harmonic scalpel [11]. Singal *et al.*, (2018) concluded that the cost of silk suture is much cheaper (0.62–0.92 \$) than that of titanium clips (12.28–15.55 \$). Also, he found that the total cost is 900\$ for clips, 2900 \$ for Harmonic and 1800\$ for bipolar devices, respectively [16].

Post-operative complications were minor in this study. Bile leak and superficial surgical site infection found ranging from 1.1% to 7.1% in both groups, but the difference was not significant. In contrast, the clip group had adversities such as bile leak, clip migration, clip slippage, and stone spillage in a study by Teja *et al.* (2022) [8].

In the current study, the post-operative pain was comparable between the groups. Similar to our observation, an identical prospective study conducted by Singal *et al.* (2018) evaluated postoperative pain and found no significant difference in a visual analogue pain score [16]. In current study, comparison of median cosmetic score between groups showed control group with 10 mm epigastric port had the poorest result than study group with 5 mm epigastric port. This observation is identical to a retrospective study [17]. However, they did not compare the cosmetic outcomes between the groups. It is unknown whether any study has addressed this issue.

TABLE I: DEMOGRAPHIC DATA

Age (Years)	Number of patients (N = 506)	Percentage
21–30	69	13.6
31–40	135	26.7
41–50	270	53.4
51–61	32	6.3
Sex	Number of patients (N)	Percentage
Male	150	29.64
Female	356	70.36

TABLE II: DIFFERENCE IN OPERATION TIME (MINUTES)

Operation-time (minutes)	Mean	±SD	Difference in mean (%)	p value
Study group	68.25	15.230	8.91 (13.94%)	p = 0.01
Control group	59.37	10.55		

TABLE III: DIFFERENCE IN EXPENSE OF SUTURE/CLIPS (IN USD)

Expense of suture/clips (USD)	Mean	± SD	Difference in mean (%)
Study group	2.5	0.000	1.7 (51%)
Control group	4.2	0.000	

TABLE IV: COMPARISON OF POSTOPERATIVE COMPLICATIONS

Post op. complications	Group-1	Group-2	p-value
Bile leak	3 (1.18%)	5 (1.97%)	p = 0.379
Surgical site infection	18 (7.11%)	15 (5.93%)	
No complication	232 (91.70%)	233 (92.09%)	
Total	253 (100%)	253 (100%)	

TABLE V: COMPARISON OF COSMETIC OUTCOME ACCORDING TO PORT SITES

Cosmetic feature	Study group Port sites				Control group Port sites			
	A	B	C	D	A	B	C	D
Color	1	1	1	2	3	2	2	4
Stiffness	1	1	1	1	1	1	1	3
Thickness	1	1	1	1	2	1	1	2
Irregularity	1	1	1	1	1	1	1	1

Accidental ligation of the common bile duct resulting in obstructive jaundice was observed by Kumar *et al.*, (2020) [8], [13]. Despite relatively prolonged intraoperative time, extracorporeal knotting eliminates the drawbacks of clipping, such as: clip migration, slippage, internalization, and cat-eye stones. Ghavidel (2015) stated that cat-eye stones due to clip migration can occur mostly after a median period of two years post cholecystectomy [18].

Stone formation and cholangitis have been reported in some studies secondary to the migration of clips [19], [20]. Other complications, such as postoperative Mirizzi syndrome and recurrent abdominal abscesses related to clip migration and fall from the applicator, have also been reported in some studies [21], [22]. Contrary to these findings, the current study did not observe any complications related to the metallic clips. A short follow-up period may be the reason for this finding. Bile leak and biliary stricture due to electrothermal injuries caused by transferred energy have also been reported by Humes *et al.* (2010) [23]. However, complications related to the use of energy sources to secure the cystic duct were not considered in this study.

## 5. LIMITATIONS

Due to the short follow-up period, it was difficult to highlight any remote complications.

## 6. CONCLUSION

Extracorporeal suture ligation of the cystic duct during laparoscopic cholecystectomy is feasible, economical, easy to learn, cosmetically better, and safe. Only drawback is operative time.

## CONFLICT OF INTEREST

The authors declare that they do not have any conflict of interest.

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