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A prospective observational study on cystic stump closure during laparoscopic cholecystectomy: silk sutures (intra-corporeal ligation) or locking clips (Hem-o-Lok®)

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ABSTRACT

Objectives: The present study compares the clinicopathological features and outcomes of two cystic stump closure techniques (locking clips and intra-corporeal ligation with silk sutures) during laparoscopic cholecystectomy.

Methods: This study was conducted in a tertiary health centre as a prospective observational study between October 5, 2021, and February 15, 2022. For randomisation, double rows of silk sutures were used to close the cystic stump in patients on the odd-numbered day of the month (Group 1). In contrast, a single-row locking clip (Hem-o-Lok®) (Group 2) was used to close the cystic stump in patients on the even-numbered day of the month. The study was terminated when at least 50 patients were reached in both groups. The clinicopathological differences and cholecystectomy outcomes were compared between the groups.

Results: This observational study included 114 patients. Of the study cohort, 87 (76.3%) were female, and the mean age was 46.54 ± 14.74 years. There were 64 (56.1%) patients in Group 1 and 50 (43.9%) patients in Group 2. Preoperative ERCP requirement was higher in Group 1 (15.6% vs 4%, $p = 0.045$), while the mean operation room time was longer in Group 2 ($p = 0.015$). Morbidity rates were similar in the two groups (3.1% vs 2%) ($p > 0.05$).

Conclusions: Cystic stump closure is the essential step of laparoscopic cholecystectomy. According to the present study's results, silk sutures (intra-corporeal ligation) and locking clips (Hem-o-lok®) are materials that can be used safely to close a cystic stump.

Keywords: Cholecystectomy, clips, cystic duct, laparoscopy, morbidity, suture

Cholecystectomy due to cholelithiasis is one of the most frequently performed operations in general surgery. This operation can be achieved with open surgery and laparoscopic surgery. Laparoscopic surgery is the standard gold surgery today. The most crucial step is the successful and non-leak closure of the cystic stump orifice. Many techniques have been described in the literature to close the cystic orifice. These methods can be reduced to two main headings: clip closure (locking or non-locking) and clipless closure. The most common clips used during laparoscopic cholecystectomy are metallic clips (non-locking). Alterna-

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tive clips, called locking clips, are Hem-o-Lok® (Teleflex, Wayne, United States), Click'aV® (Grena, Nottingham, United Kingdom) and Lapro-Clip® (Medtronic, Minneapolis, United States) [1, 2]. Locking clips differ from metallic ones as they are made of polymers, are usually absorbable, and are designed to lock in place with comparable locking pressure. Therefore, they are thought to provide a more secure closure.

Clipless closure techniques have become popular due to technological developments. With the introduction of vessel sealing devices such as the Harmonic scalpel® (Ethicon, Somerville, United States) and LigaSureTM (Medtronic, Minneapolis, United States), their feasibility and outcome in closing the cystic duct during laparoscopic cholecystectomy are of interest. On the other hand, simple sutures such as silk and polydioxanone (PDS) and Endoloop® (Ethicon, Somerville, United States) are materials used for clipless closure.

Regardless of the material used, the primary purpose is to close the stump without complications. In cases where the cystic stump is not closed correctly, stump leakage with an incidence of 0.3% to 3% can be seen [3]. In a systematic review with 38 studies that included 47,491 patients, the rate of BL ranged from 0% and 4%, with an odds ratio of 0.17 (95% CI: 0.03-0.93) for overall BL for locking vs non-locking clips [4]. In addition, complications such as surgical site infection, hematoma, abscess, and postoperative bleeding can also be seen during cholecystectomy, as in any surgery [5].

This prospective observational study compared the clinicopathological features and outcomes of two cystic stump closure techniques (locking clips and intracorporeal ligation with silk sutures) during laparoscopic cholecystectomy.

METHODS

This observational study was started as a prospective study in Erzurum Regional Training and Research Hospital General Surgery Clinic after the ethics committee's approval (Decision no: 2021/17-243). Patients who underwent laparoscopic cholecystectomy for cholelithiasis between October 5, 2021, and February 15, 2022, were included in the study. On the other hand, patients in the pediatric age group (0-18 years old) and patients diagnosed and treated in different centres and admitted to our centre were not included in the study. Patients who underwent endoscopic retrograde cholangiopancreatography (ERCP) were operated on in the same hospitalisation after liver

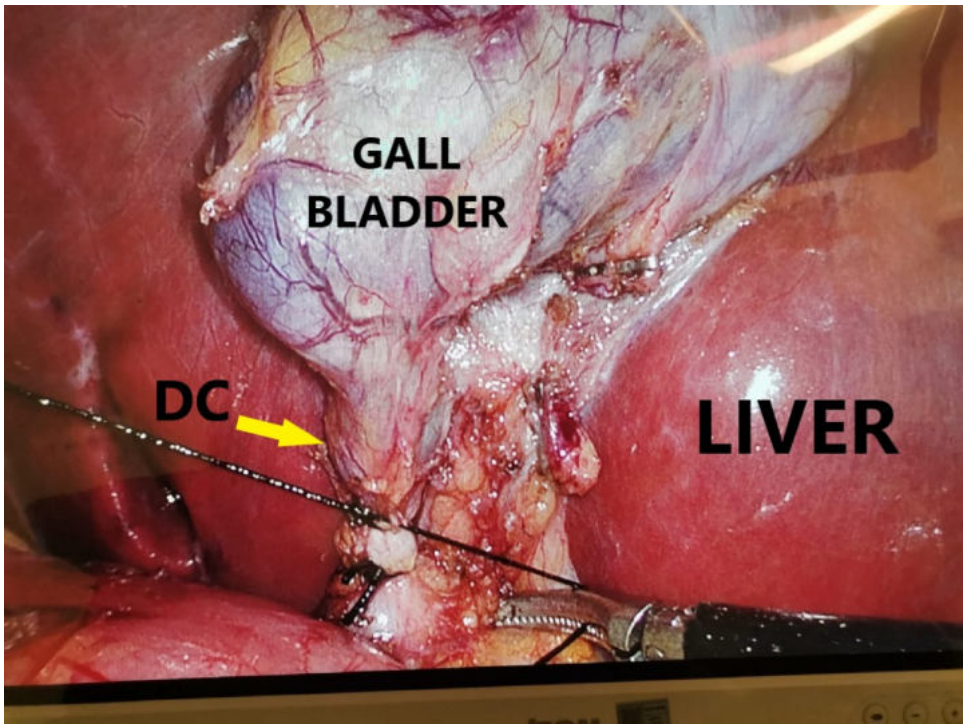

Fig. 1. Intraoperative view of the closure of the cystic duct with silk sutures. DC = ductus cysticus.

function tests returned to normal. None of the patients needed ERCP in the postoperative period.

Checked Parameters

The age and gender of the patients, indication for cholecystectomy (acute or elective), preoperative endoscopic retrograde cholangiopancreatography (ERCP) requirement, materials used to close the cystic duct, surgery time, morbidity and mortality status, length of hospital stay, and pathological evaluation of cholecystectomy specimens were searched. Hospital records, consultation and operation notes, and clinical charts of the patients were evaluated to collect the researched parameters. Patients who developed complications in the postoperative 30 days were assessed as morbidity. Due to the lack of mortality, mortality was not considered a postoperative outcome.

The patients were divided into groups according to the closing material used during cholecystectomy: Group 1= Closure with silk sutures (intra-corporeal ligation) and Group 2= Closure with locking clips (Hem-o-Lok®). The clinicopathological and outcome differences between the groups were evaluated.

Patient Randomization

Silk sutures were used to close the cystic stump in patients operated on the odd-numbered day of the month (Group 1), and locking clips (Hem-o-Lok®) were used to close the cystic stump on the even-numbered day of the month (Group 2). The study was terminated when at least 50 patients were reached in both groups. All patients were given detailed information before the operation, and an informed consent form was obtained from all patients.

Operation Technique

The same well-trained surgical team performed all operations. Hasson technique was applied to each patient during the first trocar entrance. All procedures were performed by laparoscopy with four trocars: a 10- or 12-mm trocar inserted supraumbilical (first trocar), a 10- or 12-mm trocar from the xiphoidal region, and two 5 mm trocars inserted from the right para-rectal area. CO_2 insertion was made only through the first trocar in all cases. After creating pneumoperitoneum, all cholecystectomies were performed according to the critical view of the safety principle. Cystic artery and cystic duct were exposed by dissection of Calot's triangle. According to randomisation, the cystic duct stump was closed with a double row of 2/0 silk sutures (intra-corporeal ligation) (Fig. 1) or a single row of locking clips (Hem-o-lok®) (Fig. 2). Cholecystectomy material was taken out of the abdomen from the xiphoidal port.

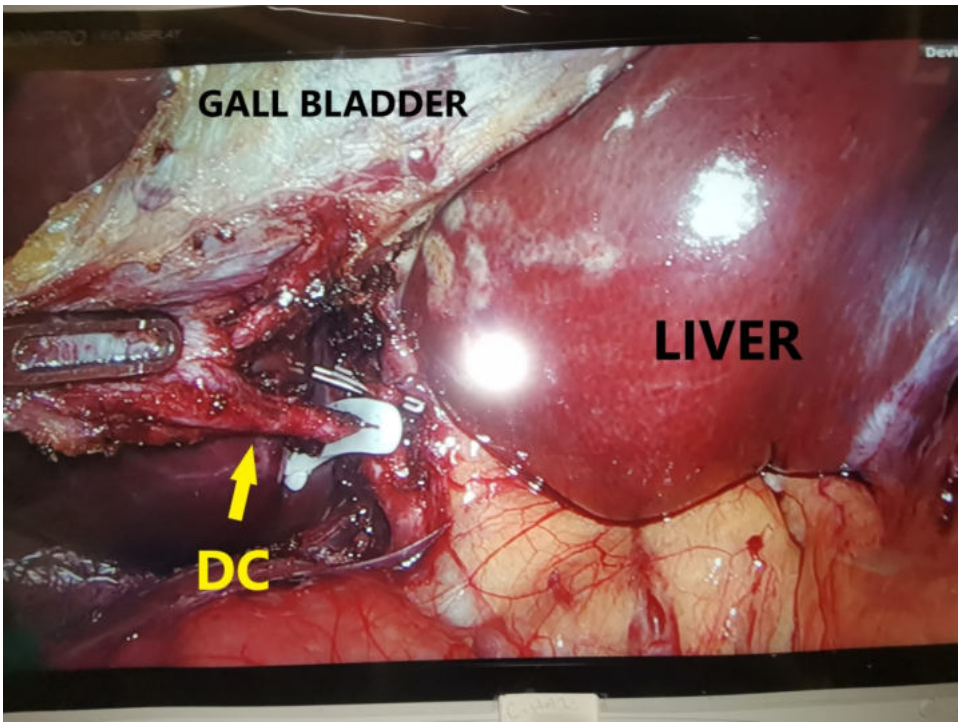

Fig. 2. Intraoperative view of the cystic duct closure with a locking clip. DC = ductus cysticus.

Statistical Analysis

Statistical evaluation was made with SPSS v22.0 (IBM, Armonk, NY, USA). Quantitative variables were expressed as mean ± standard deviation (SD), median, minimum-maximum, interquartile range and interval. Qualitative variables were reported as numbers and percentages. The normality distribution of quantitative variables was checked with the Shapiro-Wilk test. According to Shapiro-Wilk test results, quantitative variables were compared with independent samples t-test or Mann-Whitney U test. Chi-Square tests (Pearson and Fisher's exact) were used to compare qualitative variables. A p-value below 0.05 was considered statistically significant.

RESULTS

This observational study included 114 patients. Of the study cohort, 87 (76.3%) were female, and the mean age was 46.54 ± 14.74 years, with a range of 19-83 years. The clinicopathological features of the patients are shown in Table 1.

There were 64 (56.1%) patients in Group 1 and 50 (43.9%) patients in Group 2. Both groups' demographic features (mean age and gender distribution) were similar. 58 (50.9%) patients underwent laparoscopic cholecystectomy due to cholecystitis. The remaining patients were operated on under elective conditions. The rate of patients operated on for cholecystitis was similar in both groups (46.9% vs 56%, $p = 0.334$).

Cholecystectomy was performed in 12 (10.5%) patients after endoscopic retrograde cholangiopancreatography (ERCP). The rate of preoperative ERCP requirement was higher in Group 1 (15.6% vs 4%, $p = 0.045$). Intraoperative complications were seen in 5 (4.4%) patients: 3 of 5 had liver bed bleeding, and 2 of 5 had trocar site haemorrhage. All liver bed haemorrhages were controlled during laparoscopy. While 2 of these haemorrhages were controlled by energy devices, the bleeding was stopped with liver bed suturing in the remaining case. Trocar site haemorrhages were controlled with simple sutures and energy devices. Intraoperative complication rates were similar in the two groups (4.7% vs 4%). However, operation room time was lower in Group 1 ($p = 0.015$).

The morbidity rate of the study was 2.6% (n = 3), and 2 of the three patients were in Group 1. All postoperative complications were port site infections and treated with daily cleaning and drainage. Morbidity rates were similar in the two groups (3.1% vs 2%) ($p = 1.000$). A comparison of clinicopathological variables is shown in Table 2.

DISCUSSION

Laparoscopic cholecystectomy is a minimally invasive surgical procedure that removes a diseased gallblad-

Table 1. Clinicopathological data of all patients

Parameters	n (%) or mean ± SD (range)
Age (years)	46.54 ± 14.74 (19-83)
Gender	
Female	87 (76.3)
Male	27 (23.7)
Preoperative diagnoses	
Acute Cholecystitis	58 (50.9)
Cholelithiasis	56 (49.1)
Preoperative ERCP	
Yes	12 (10.5)
No	102 (89.5)
Intraoperative complication	
Yes	5 (4.4%
No	109 (95.6)
Cystic stump closure	
Silk suture (Group 1)	64 (56.1)
Locking clips (Group 2)	50 (43.9)
Operation room time (min)	42.75 ± 15.05 (20-115)
Morbidity	
Yes	3 (2.6)
No	111 (97.4)
Hospital stay (days)	1.91 ± 1.2 (1-10)
Pathology	
Acute cholecystitis	34 (29.8)
Chronic cholecystitis	80 (70.2)

ERCP = endoscopic retrograde cholangiopancreatography, SD = standard deviation

Table 2. Comparison of the cystic duct closure techniques

Parameters	Group 1 (n = 64)	Group 2 (n = 50)	*p* value
Age (years)	45.48 ± 15.56	47.90 ± 13.65	0.388*
Gender, n (%)			0.709**
Female	48 (55.2)	39 (44.8)	
Male	16 (59.3)	11 (40.7)	
Preoperative diagnosis, n (%)			0.334**
Cholelithiasis	34 (60.7)	28 (48.3)	
Acute cholecystitis	30 (51.7)	22 (39.3)	
Preoperative ERCP, n (%)			**0.045****
Yes	10 (15.6)	2 (4)	
No	54 (84.4)	48 (96)	
Intraoperative complication, n (%)			1.000***
Yes	3 (4.7)	2 (4)	
No	61 (95.3)	48 (96)	
Operation room time (min), (median/IQR)	39 (IQR=12)	43.50 (IQR=20)	**0.015****
Morbidity, n (%)			1.000**
Yes	2 (3.1)	1 (2)	
No	62 (96.9)	49 (98)	
Hospital stay (days), (median/IQR)	2 (IQR=1)	2 (IQR=1)	0.641****
Pathology, n (%)			0.707**
Acute cholecystitis	20 (31.3)	14 (28)	
Chronic cholecystitis	44 (68.8)	36 (72)	

Data are shown as mean±standard deviation or n (%) or median/IQR. ERCP = endoscopic retrograde cholangiopancreatography, IQR = Interquartile range

*Independent samples t-test, **Pearson chi-square test, ***Fisher's exact test, ****Mann Whitney U test

der. Since the early 1990s, laparoscopy has primarily replaced the open technique for cholecystectomy. Laparoscopic cholecystectomy is currently indicated for treating acute or chronic cholecystitis, symptomatic cholelithiasis, calculous cholecystitis, gallstone pancreatitis, biliary dyskinesia, and gallbladder masses or polyps [6-8].

Cystic stump closure is the essential step of laparoscopic cholecystectomy. Closing can be done with many techniques. The most common technique is to close the stump with simple (non-locking) metallic clips. Alternatives are locking clips or ligatures [1, 2]. Locking clips differ from metallic ones as they are made of polymers, are usually absorbable, and are designed to lock in place with comparable locking pressure. Therefore, they are thought to provide a more secure closure.

Regardless of the material used, the primary purpose is to close the stump without complications. In cases where the cystic stump is not closed correctly, stump leakage with an incidence of 0.3% to 3% can be seen [3]. In addition, complications such as surgical site infection, hematoma, abscess, and postoperative bleeding can also be seen during cholecystectomy, as in any surgery [5]. In one meta-analysis, the 30-day complication rate of cholecystectomy ranged from 4-31% [9]. The morbidity rate of the present study was found to be 2.6%, which is lower than the literature.

The problem of biliary leakage has been evaluated in both retrospective and prospective studies. However, very few studies compare intracorporeal ligation with silk suture and Hem-o-Lok® clip closure, and our

study stands out in terms of the number of cases. In a systematic review of 38 studies, the overall incidence of biliary leakage ranged from 0% to 4% [4]. According to the study by Singal *et al*. [10], when silk suture ligation (80 patients) and ligaclips closure (80 patients) of the cystic stump were compared, no postoperative complications, including bile leakage, were observed in the silk suture group. However, in a randomised controlled study with 105 patients comparing tied knots with Hem-o-Lok® clips, the incidence of bile leakage was 3.8% in the tied knots group, with no difference in postoperative complications [11]. In a comparative randomised controlled trial comparing intracorporeal ligation and ligaclips with 120 patients, the mean operative time was longer in the intracorporeal ligation group, with no difference in postoperative complications [12].In a comparative study using different materials (intracorporeal knotting using 2/0 vicryl suture and titanium clips), there was no difference between the groups in terms of preoperative clinical presentation, preoperative ERCP requirement, mean operation room time, and postoperative complications [13]. In a non-comparative pilot study of 80 patients, silk sutures were used to close the cystic duct, and no postoperative complications and bile leakage were observed [14]. Talebpour *et al*. [15] showed that ligation by suturing is safer with 0% bleeding and biliary leakage rates. The present study's overall morbidity rate was 2.6% without bile leakage. However, unlike the literature, the preoperative ERCP requirement rate was higher, and the mean operation time was shorter in the intracorporeal ligation group. In contrast, the preoperative clinical presentation rate (cholelithiasis/cholecystitis) was similar to the literature. While it is expected that the cholecystectomy time will be shorter in patients using locking clips, silk suture ligation time has reached similar times when the learning curve is gone. In addition, new studies with more cases are needed, as the severity of the acute cholecystitis attack, the difficulty of dissection, and the duration of removal of the cholecystectomy specimen from the abdominal cavity may affect the operation time.

Limitations

A significant shortcoming of our study is that the cystic closure times were not evaluated. In addition, new studies excluding patients who underwent ERCP and patients who underwent surgery for acute cholecystitis to make the study more homogeneous will fill the lack of literature and provide more robust data. In addition, longer period outcomes should be evaluated to compare the two closure techniques.

CONCLUSION

Silk sutures (intra-corporeal ligation) and locking clips (Hem-o-Lok®) are materials that can be used to close a cystic stump. Closing the cystic stump with a silk suture, more commonly used in patients who underwent ERCP in the preoperative period, is advantageous and reliable since it shortens the operation time without increasing morbidity.

Authors' Contribution

Study Conception: MY, TK; Study Design: MY, TK; Supervision: MY, TK; Funding: MY, TK; Materials: MY, TK; Data Collection and/or Processing: MY, TK; Statistical Analysis and/or Data Interpretation: MY, TK; Literature Review: MY, TK; Manuscript Preparation: MY, TK and Critical Review: MY, TK.

Conflict of interest

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

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