Journal of Cardiovascular Disease Research

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 10, 2023

Original Research

Cystic Duct Ligation in Laparoscopic Cholecystectomy: A Comparison Study of Metallic Clips and Ligatures

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Article History: **Received:** 19.07.2023 **Revised:**20.09.2023 **Accepted:1**6.10.2023

ABSTRACT

Background: The present study was conducted to compare the efficacy and safety of ligature application with metallic clip application for cystic duct ligation in laparoscopic cholecystectomy.

Methods: This was a cross-sectional study conducted between May 2021 and May 2022 for a duration of 12 months among patients undergoing laparoscopic cholecystectomy (elective or emergency) for any reason (symptomatic gallstones, acalculous cholecystitis, gallbladder polyp, or any other condition) in the Department of General Surgery, PSG Hospitals, Coimbatore. Patients were assigned to either Group A (cystic duct occlusion with ligatures) or Group B (cystic duct occlusion with metallic clips).

Results: The study found significantly less operating time in the clip group compared to the ligature group. The mean clip/ligature time of the ligature group was 12.30 ± 4.36, and that of the clip group was 8.67 ± 2.87. The mean difference in the clip/ligature time between the study groups was statistically significant, with a p-value of <0.001. We found a significantly shorter time to clip the ligation of the cystic duct as compared to the ligature technique. Both groups found all subjects to have no post-op complications or interventions. In both groups, the median hospital stay was 3 days (IQR 2.0 to 3.0), p-value 0.3589. The surgery and post-surgery follow-up of 1 month were uneventful in both groups.

Conclusions: Metal clips are frequently used to tie up the cystic duct, but they have their own limitations and complications. There are equally effective alternative methods available. One such method is the simple, safe, and economical suture ligation of the cystic duct. Although the use of ligatures is associated with a longer duct occlusion time and thereby total surgical duration and also needs greater surgical expertise, they can be used as an equivalent alternative to clips, especially in patients with wide and short cystic ducts.

Keywords: Laparoscopic Cholecystectomy, Cystic Duct Ligation, Suture Ligation, Metal Clip Ligation

DOI: 10.48047/ecb/2023.12.1.623

INTRODUCTION

Cholecystectomy is fast becoming one of the most common elective surgical procedures performed. The "gold standard" for treating symptomatic gallstone disease is laparoscopic cholecystectomy. Gallstone disease is typically treated with LC, which has a low mortality and morbidity rate. A common operative problem during laparoscopic cholecystectomy is gallbladder perforation during dissection from the liver bed, resulting in bile spillage and stone loss in the peritoneal cavity.[1] Following LC, 0.5%–3% of patients have been reported to have CDL (Cystic Duct Leakage).[2] In patients with complicated gallstone disease, such as cholecystitis, pancreatitis, cholangitis, and stones in the common bile duct, CDL rises to 4%–7%, according to recent studies.[2,3] In particular, in patients with complicated gallstone disease who have a higher risk of bile leakage, adequate closure of the cystic duct is crucial to prevent CDL. Despite being a minor injury to the bile ducts, CDL is linked to a high rate of re-intervention, increased morbidity, and even mortality.[4] A postoperative complication with significant morbidity is bile duct injury.[4] Bile duct injury has been reported to occur at a rate of 0.5% to 1% in reports on LC complications.[5] Cystic stump leakage rates (type A bile duct injury) have recently been found to be underreported, particularly in a subpopulation of patients with complex biliary

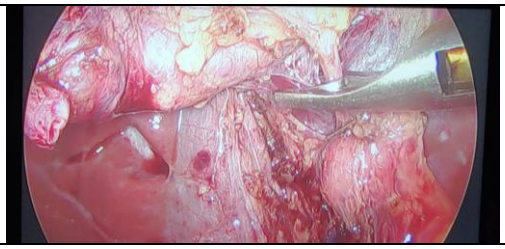
ISSN: 0975-3583,0976-2833 VOL14, ISSUE 10, 2023

disease. Patients who have had acute cholecystitis or prior biliary events, such as cholecystitis, cholangitis, or pre-operative ERCP (Endoscopic Retrograde Cholangiopancreatography) for suspected choledocholithiasis, are more likely (4%–7%) to experience cystic stump leakage. These patients frequently need stent placement, re-laparoscopy or re-laparotomy, endoscopic sphincterotomy, percutaneous drainage of the biloma, and so on.[6]
Simple (non-locking) metallic clips are the most typical closure method used during LC.[7] Alternatives include ligatures (such as ENDOLOOP®, Ethicon, Somerville, United States) or locking clips (such as Hem-o-Lok®, Teleflex, Wayne, United States; Lapro-Clip®, Medtronic, Minneapolis, United States; and Click'aV®, Grena, Nottingham, United Kingdom).[8] Locking clips are thought to offer a more secure closure than metallic clips because they are made of polymers, are typically absorbable, and are designed to lock in place with comparable locking pressure. The present study was conducted to compare the efficacy and safety of ligature application with metallic clip application for cystic duct ligation in laparoscopic cholecystectomy and to compare the operating time and cost of ligature with metallic clip application for cystic duct ligation in subjects undergoing laparoscopic cholecystectomy.

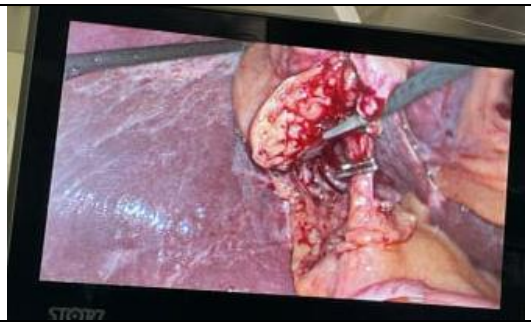
MATERIALS AND METHODS

Study Site: This was a cross-sectional study carried out in the Department of Surgery at PSG Hospitals, Coimbatore. The data collection for the study was conducted between May 2021 and May 2022 for a duration of 12 months, involving 28 subjects in each group. Patients undergoing laparoscopic cholecystectomy (elective or emergency) for any reason (symptomatic gallstones, acalculous cholecystitis, gallbladder polyp, or any other condition) were included in the group. Patients with proven common bile duct (CBD) calculi and those undergoing subtotal cholecystectomy were excluded. Data collection and statistical analysis were done. Descriptive analysis was carried out for frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like pie diagrams, bar charts, and cluster bar charts. For normally distributed quantitative parameters, the mean values were compared between study groups using an independent sample t-test (2 groups). For non-normally distributed quantitative parameters, medians and IQR (Interquartile Range) were compared between study groups using the Mann-Whitney U test (2 groups). Categorical outcomes were compared between study groups using the chi-square test. P-value < 0.05 was considered statistically significant. The data were analyzed using Co-Guide software.

Clinical Image 1: Metallic Clips That Were Used

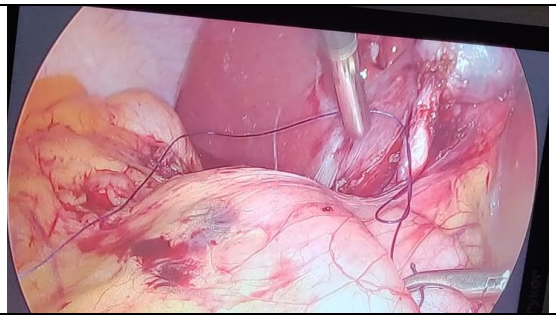


Clinical Image 2: Cystic Duct Being Ligated with Metallic Clips Using Clip Applicator

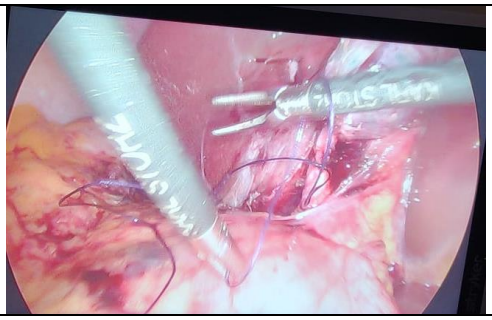


Clinical Image 3: Cystic Duct after Application of Clips

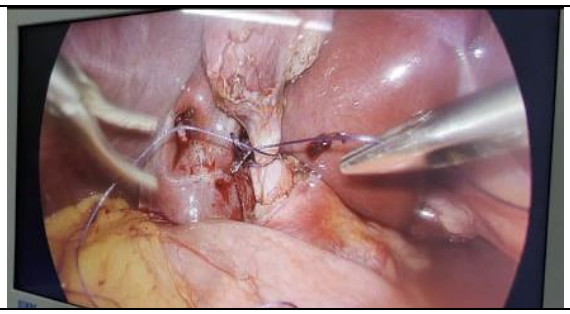
ISSN: 0975-3583,0976-2833 VOL14, ISSUE 10, 2023



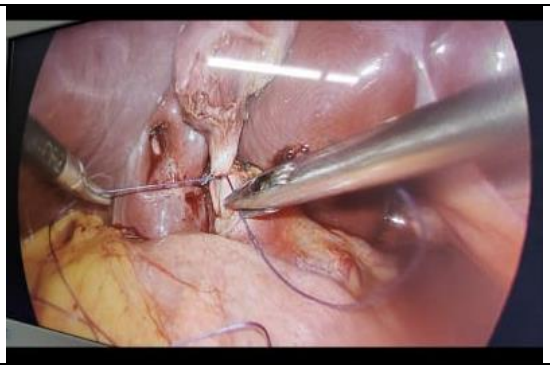
Clinical Image 4



Clinical Image 5



Clinical Image 6



Clinical Image 7

Clinical Images 4-7: Ligature being tied around the cystic duct

RESULTS

A total of 60 subjects were included in the final analysis.

Study Group	Frequency	Percentage
Ligature Group	30	50.00%
Clip Group	30	50.00%

Table 1: Descriptive Analysis of Study Group in the Study Population (N=60)

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 10, 2023

Among the study population, 30 (50.00%) participants were in the ligature group and 30 (50.00%) were in the clip group. (Table 1)

Parameter	Study Group (Mean ± SD)		P-Value (IST)
	Ligature Group (N=30)	Clip Group (N=30)	
Age (in years)	50.70 ± 16.34	49.20 ± 14.30	0.7065
Table 2: Comparison of Age with Study Group in the Study Population (N=60)			

The mean age (in years) of the ligature group was 50.70 ± 16.34 and that of the clip group was 49.20 ± 14.30. The mean difference between the study groups was statistically not significant, with a p-value of 0.7065. (Table 2)

Gender	Study Group		Chi-Square Value	P-Value
	Ligature Group (N=30)	Clip Group(N=30)		
Male	12 (40.00%)	10 (33.33%)	0.29	0.5921
Female	18 (60.00%)	20 (66.67%)		
Table 3: Comparison of Gender with Study Group in the Study Population (N=60)				

In the ligature group, 12 (40.00%) participants were male and 18 (60.00%) were female. In the clip group, 10 (33.33%) participants were male and 20 (66.67%) were female. The difference in the proportion of gender between the study groups was statistically not significant, with a p-value of 0.5921. (Table 3)

Diagnosis	Study Group		Chi Square Value	P-Value
	Ligature Group (N=30)	Clip Group (N=30)		
Gall Bladder Polyp	2 (6.67%)	1 (3.33%)	1.90	0.7541
Symptomatic Cholelithiasis	14 (46.67%)	18 (60.00%)		
Acute Cholecystitis	8 (26.67%)	7 (23.33%)		
Choledocholithiasis	3 (10.00%)	1 (3.33%)		
Chronic Cholecystitis	3 (10.00%)	3 (10.00%)		
Table 4: Comparison of Diagnosis with Study Group in the Study Population (N=60)				

In the ligature group, the majority of 14 (46.67%) participants reported with cholelithiasis as a diagnosis, followed by acute cholecystitis and choledocholithiasis which were 8 (26.67%) and 3 (10.00%) respectively. In the clip group, the majority of 18 (60.00%) participants reported with cholelithiasis as a diagnosis, followed by acute cholecystitis and chronic cholecystitis which were 7 (23.33%), 3 (10.00%) respectively. The difference in the proportion of diagnosis between study groups was statistically not significant with a p-value of 0.7541. (Table 4)

Parameter	Study Group (Mean ± SD)		P-Value (IST)
	Ligature Group (N=30)	Clip Group (N=30)	
Total Operating Time (in minutes)	133.67 ± 32.72	112.67 ± 19.33	0.0037
Table 5: Comparison of Total Operating Time (in minutes) with Study Group in the Study Population (N=60)			

The mean total operating time (in minutes) of the ligature group was 133.67 ± 32.72 and that of the clip group was 112.67 ± 19.33. The mean difference in total operating time between the study group was statistically significant with a p-value of 0.0037. (Table 5)

Parameter	Study Group (Mean ± SD)		P-Value
	Ligature Group (N=30)	Clip Group (N=30)	
Clip/Ligature Time	12.30 ± 4.36	8.67 ± 2.87	<0.001
Table 6: Comparison of Clip/Ligature Time with Study Group in the Study Population (N=60)			

The mean clip/ligature time of the ligature group was 12.30 ± 4.36 and that of the clip group was 8.67 ± 2.87. The mean difference in clip/ligature time between the study groups was statistically significant with a p-value of <0.001. (Table 6)

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 10, 2023

Post-Op Complications/Interventions	Study Group		P-Value
	Ligature Group (N=30)	Clip Group (N=30)	
Nil	30 (100.00%)	30 (100.00%)	*

Table 7: Comparison of Post-Op Complications/Interventions with Study Group in the Study Population (N=60)

****No test is applicable due to the nature of the data***

In the ligature group, none of the 30 patients (100.00%) had post-op complications or interventions and it was the same in the clip group (Table 7)

Parameter	Study Group (Median (IQR))		Mann Whitney U Test (P-Value)
	Ligature Group (N=30)	Clip Group (N=30)	
Duration of Hospital Stay (day's)	3.00 (2.0 to 3.0)	3.00 (2.0 to 3.0)	0.3589

Table 8: Comparison of Duration of Hospital Stay (day's) with Study Group in the Study Population (N=60)

Among the people in the ligature group, the median hospital stay was 3 days (IQR 2.0 to 3.0) and 3 days (IQR 2.0 to 3.0) in the clip group. The difference in the duration of hospital stay between the study groups was statistically not significant with a p-value of 0.3589. (Table 8)In the ligature group, 30 (100.00%) people were uneventful and it was 30 (100.00%) even in the clip group.

DISCUSSION

Laparoscopic cholecystectomy has undergone significant advancements over time, including improved ergonomics, the introduction of new energy sources, and endo-suturing.[1] With encouraging results, additional cystic duct closure techniques like clipping, harmonic scalpel, and intracorporeal ligation have been tried. The most popular method for closing cystic arteries and ducts is the metallic clip, possibly because it is simple to use, requires little training, and has a long history of safety. Although it is not insignificant for a beginning surgeon, complications can still arise. There have been reports of bile leaks, clip migration, and unintentional chopping of the right hepatic artery and common bile duct in the literature. Hence, the present study compared the efficacy of ligature and clipping methods for cystic duct ligation in laparoscopic cholecystectomy. The present study was a prospective study involving 60 subjects. The study population was grouped into two groups, with 50% in the ligature group and 50% in the clip group. Between both groups, there was no significant difference in the distribution of age (50.70 ± 16.34 vs. 49.20 ± 14.30, p-value of 0.7065). Similarly, the difference in the proportion of males and females among the two groups was insignificant (M:F = 40%:60% vs. 33.33%/66.67%, p-value 0.5921). In Harvesh Kumar et al.[9] studies, women made up the majority of patients in Groups A (70.7%) and B (73.3%). In terms of gender, there was no statistically significant ($p > 0.05$) difference between the groups, demonstrating the equality of the groups. Singh et al. [10] found similar results. Most of the patients in his study were women, with 83.33% in group B and 93.33% in group A (patients who had extracorporeal knotting for the ligation of the cystic duct) (patients in whom liga clips were used to close off the cystic duct). These results were in accordance with our study, where we also found female predominance in both groups. A study by Sinsinwar LC et al.[11] found involved 100 subjects with 50% of each group ligature and clip group, with no significant difference in the age and gender distribution across the groups. In addition, the Harvesh Kumar et al.[9] study involved 150 subjects, with 75 subjects in each group, and found an insignificant difference in the mean age between the groups. In another prospective study by Prabu, K. et al.[12] studied the efficacy and safety of ligatures of the cystic duct (CD) with sutures with 70 subjects involved. Another study by Saha, P. et al.[13] also studied the clipless method of ligature in 50 subjects undergoing laparoscopic cholecystectomy. The difference in the proportion of diagnosis between study groups was statistically not significant with a p-value of 0.7541. In both groups, the majority of the study population reported cholelithiasis as the diagnosis. Similarly, in Harvesh Kumar et al.[9] studies on USG abdomen, patients in the clip ligation group and those in the suture ligation group both had chronic cholecystitis with cholelithiasis. On the USG abdomen, patients in the clip ligation group had acute cholecystitis with cholelithiasis at a rate of 22.7%, compared to 25.3% in the suture ligation group. Thus, the two groups were matched equally. In the present study, the mean of the total operating time (in minutes) of the ligature group was 133.67 ± 32.72, and the clip group was 112.67 ± 19.33. The mean difference in total operating time between study groups was statistically significant with a p-value of 0.0037. Hence, the study found significantly less operating time in the clip group compared to the ligature group. In contrast, Harvesh Kumar et al.[9] found no difference in the length of the surgery between the two groups (Group A = 40.444.63 minutes, Group B = 43.324.44 minutes) that could be considered statistically significant ($p > 0.05$). A systematic review by Gurusamy et al.[10] demonstrated that the

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 10, 2023

absorbable suture ligature group's operating time was 12 minutes longer than the group randomly assigned to clip ligation. The length of the suture ligation depends on the surgeon's experience and typically decreases with repetition, as it did in the Harvesh Kumar et al.[9] and Singal, R. et al.[14] study populations. Hence, this could be a reason for the shorter duration of surgery compared to the present study.In the present study, the mean ligature time of the suture ligature group was 12.30 ± 4.36, and the clip group was 8.67 ± 2.87. The mean difference in clip/ligature time between study groups was statistically significant with a p-value of <0.001. We found a significantly shorter clip compared to the ligature technique. Sinsinwar LC et al.[11] found a significantly lesser time in the ligation used by the clip method compared to suture ligation (ligature 2.60 min vs. clip 1.73 min). In the Prabu, K et al.[12] study the mean time required for suture ligation was 5 minutes and furthermore, they used suture plus clips when the cystic duct was greater than 5 mm in diameter. Hence, they found that ligatures with sutures and clips are an extremely safe and secure replacement for dilated cystic ducts. In addition, ligature with the suture is easily accessible, very affordable, and avoids the difficulties of clips. The only drawback is that it requires expertise to perform, which extends the operating time. In all laparoscopic cholecystectomies, particularly in challenging cases, this technique is advised. Further, Saha, P et al.[13] recommend separate suture ligation of the duct and artery to avoid timing of the surgery.

Complications

In our study, both groups found all subjects to have no postoperative complications or interventions. Bile leaks following ligatures may happen in up to 3.8% of cases, just like in clips.[15] When using clips, a cystic duct leak may occur for a number of reasons, including insufficient closure of the duct due to mismatched clip arms, necrosis of the duct at the site of clipping, or clip slippage and migration into the biliary tract. With separate ligation of the artery and duct, these clip-related complications are avoided, and there is also less chance of pain, discomfort, and port-site infection.[13]In both groups, the median hospital stay was 3 days (IQR 2.0 to 3.0), p = 0.3589. The surgery was uneventful for both groups. The number of days of hospital stay in both groups in the Sinsinwar LC et al.[11] study was one day. Although post-cholecystectomy clip migration is uncommon, Ghavidel A et al.[16] found that it could result in complications like clip-related biliary stones. The majority of these incidents have been documented in the literature as case studies. It can happen at any time, but it usually happens two years after the cholecystectomy. In our group, neither a bile duct leak nor a similar complication was noticed during the postoperative period. Other authors pointed out additional benefits of simple cystic duct ligation. It is simple and useful. Some of the limitations are that the study results cannot be generalized as the sample size was small, and long-term follow-up after 1 month with further clinical, radiological, and laboratory investigation was not evaluated.

CONCLUSION

Although the use of ligatures is associated with a longer duct occlusion time and total surgical duration and also requires greater surgical expertise, they can be used as an equivalent alternative to clips, especially in patients with wide and short cystic ducts. Although there is no significant difference in cost, ligatures can alleviate the need for clip applicators, especially when performed in rural and peripheral settings.

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ISSN: 0975-3583,0976-2833 VOL14, ISSUE 10, 2023

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