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Original Research Article

# Comparing the outcome of patients in laparoscopic cholecystectomy by using clips vs ligature for cystic duct occlusion

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**Abstract:** During laparoscopic cholecystectomy, it is necessary to occlude cystic permanently in order to prevent leakage of bile into the peritoneal cavity. Traditionally this has been through the application of non- absorbable metal clips. Other alternatives to non absorbable metal clips for cystic duct occlusion are absorbable clips, locking clips and absorbable knots. This study was conducted as prospective randomised study in which we compared outcomes of patients in whom Cystic Duct Occlusion was done by clips with those in whom ligature was used. We share our experience of one hundred cases who were subjected to Laparoscopic Cholecystectomy out of which in fifty cases cystic duct was occluded by clips and in other group of fifty cases the cystic duct was occluded with knot/ ligature. Results of this study demonstrate that cystic duct occlusion with knots/ligatures is a safe, cost effective alternative to clips. Safety of using knots/ligatures is even better than clips as is evident from our study comparing these two methods of cystic duct occlusion.
**Keywords:** cholecystectomy, surgical clips, surgical knots, surgical ligature, cystic duct occlusion, bile leakage

## INTRODUCTION

Cholecystectomy, surgical removal of the gallbladder, is one of the most common elective procedures performed by general surgeons[1]. Since Langenbuch performed the first open cholecystectomy (OC), this technique has remained the "gold standard" for the treatment of symptomatic cholelithiasis and acute cholecystitis for more than 100 years.

The introduction of laparoscopic cholecystectomy induced a significant growth in cholecystectomy rates[2, 3]. In particular, regarding the dimension of the effectiveness of open and laparoscopic cholecystectomy it is possible to distinguish two different kinds of outcome related to admission period i.e. intra-admission and post-admission outcomes. Both procedures are associated with complications like common bile duct injury, bile leak, injury to viscera, haemorrhage, spilled gallstone, retained stones, biliary strictures, slippage of ligatures or clips and others. The spectrum of mishaps has also changed due to involvement of new instruments such as stapling devices, coagulation sheers, and sealing systems. Related complications like migrating clips [4] or stenosis of common bile duct due to wrongly placed clip were completely unknown in open surgery.

During laparoscopic cholecystectomy, it is necessary to occlude cystic permanently in order to prevent leakage of bile into the peritoneal cavity. Traditionally this has been through the application of non- absorbable metal clips.

The incidence of minor post-operative bile leaks in the absence of bile duct injury varies between 0.4 and 0.6 [5]. One reason for the bile leak is laceration of the cystic duct by metal clips resulting in bile leakage from cystic duct [6]. This is because of ability of the metal clips to conduct electricity causing a cut in cystic duct [7] or causing necrosis of clamped tissue [8]. Clips can also cause occlusion & stenosis of the common bile duct without causing any laceration [9]. Rarely the metal clips can erode into the cystic duct & migrate into common bile duct [8]. Such migration of the clip into the common can act as nidus for stone in common bile duct.

In view of these concerns regarding the use of metal clips other alternatives to non absorbable metal

clips for cystic duct occlusion have been suggested. These include:-

- Absorbable Clips [8]
- Locking Clips [10]
- Absorbable Knots [11, 12]

Recently Ultrasonic dissectors have been used to occlude cystic duct [13]**.** Concerns about the use of these alternatives include slipping of knot [12] and efficacy in the prevention of bile leak from the cystic duct stump. The operating time is also longer when knots were used for occlusion of cystic duct [12].

This study was conducted as prospective randomised study in which we compared outcomes of patients in whom Cystic Duct Occlusion was done by clips with those in whom ligature was used. The aim of study was to evaluate the use of ligature as a safe, feasible and cost-effective alternative to use of titanium clips for cystic duct occlusion during laparoscopic cholecystectomy and to compare post operative outcome of patients in whom cystic duct occlusion was done by clips with those in whom ligature was used.

## MATERIAL AND METHODS

It was prospective randomised study of 100 patients undergoing laparoscopic cholecystectomy for any reason (symptomatic gallstones, acalculous cholecystitis, gallbladder polyp, or any other condition). The patients were randomly allocated into two groups of 50 patients each. In one group of patients undergoing laparoscopic cholecystectomy, cystic duct was occluded with clips and in other group knots or ligatures were used to occlude cystic duct.

After taking written informed consent, detailed history and examination was done. Baseline investigations like complete blood counts, bleeding time, clotting time, renal function tests, liver function tests, serum electrolytes, Chest X-Ray, Electrocardiography were done. Ultrasonography of abdomen was done.

Primary outcomes like mortality, bile duct injury, biliary peritonitis, bile leak requiring ERCP, bile collection requiring re-operation or image guided drainage, recurrent / residual CBD Stones and obstructive Jaundice were noted.
Secondary outcomes like operating time and hospital stay were also noted.

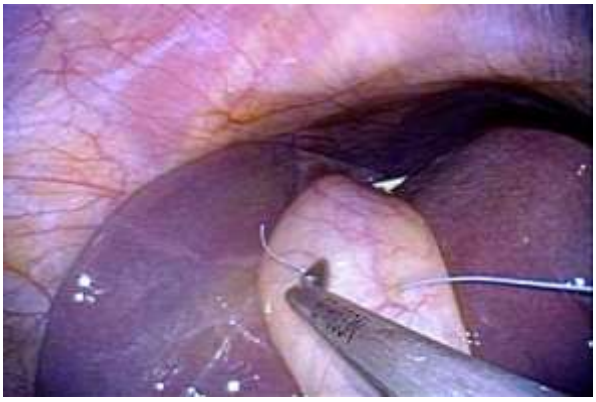

**Fig-1: Ligating the cystic duct with knot**

## EQUIPMENT

The equipment used for laparoscopic cholecystectomy included a high-flow insufflator, light source, high-resolution camera, high-resolution video monitor, irrigation device, and electrocautery unit or ultrasonic scalpel.

### Instruments

The instruments used included cannulas, endoscopes, graspers, dissectors, scissors, clip applicators, cholangiocatheters, and irrigators and aspirators, coagulators, attachments for the ultrasonic scalpel, and gallbladder extraction sacks.

1. **Clip Applicator -** The reusable clip applicator (10 mm diameter) was used. Clips can be loaded into the jaws without removing the instrument, which saves time but is more expensive than the single clip reusable clip applicator.
2. **Knot pusher**

## DISCUSSION

Laparoscopic surgery is a well established alternative to open surgery across all disciplines. Although positive magnitude of impact varies by the procedure, generally the benefits of laparoscopic surgery on post-operative pain, cosmetics, hospital stay and convalescence are recognised widely. Many surgeons have attempted to use alternatives to non absorbable clips such as absorbable clips, locking clips, absorbable knots or more recently ultrasonic dissectors for cystic duct occlusion. So far, many studies are available which favour use of knots over clips in terms of safety, feasibility and cost effectiveness.

The technique of cystic duct occlusion with clips and knots/ligatures are well established. The safety of knots over clips can be gauged from the study of Seenu V [12] who conducted study comparing clips and knots and found knots as safe alternatives to clips. Also cost effectiveness can be shown by study of Ibn Ouf AM [14] who established the intra-corporeal ligatures as cost effective alternatives to clips. M. Tahir Ozer conducted the comparison of different Cystic Duct

Closure Methods in Laparoscopic Cholecystectomy: Silk Suture, Surgical Clip, Harmonic Scalpel and Plasma Kinetic and concluded that Cystic duct closure with the new devices may be an alternative to surgical clips [15].

We took up the study with aim to compare clips and knots for cystic duct occlusion in terms of safety, cost effective and post operative morbidity. In our study, the patients were randomly allocated into two groups of 50 patients each. In one group of patients undergoing laparoscopic cholecystectomy, cystic duct was occluded with clips and in other group knots or ligatures were used to occlude cystic duct. Similar parameters were observed in study conducted by Seenu V [12].

Inclusion criterias in our study were similar to the study conducted by A. Tamij Marane i.e. symptomatic gallstones, acalculous cholecystitis, gall bladder polyp or any other condition warranting laparoscopic cholecystectomy [16].

Mean age in our study was 43.68 yrs in clip group and 42.64 yrs in knot group. In the Clip Group, maximum patients were in 41-50 yrs age group and in Knot Group; largest group was 31-40 yrs. There is a female predominance in both clip (82%) and knot groups (70%) in our study. Similar female predominance is seen in study by Lim BS [17]**.** The percentage of females and the mean age of participants in the trials conducted by Rohr S1 [18] were 60.7% and 58.1 years respectively.

**Table 1- Comparing preoperatively two groups**

| **Features** | **Clip Group (n=50)** | **Knot Group (n=50)** |
|---|---|---|
| Mean age of patients | 43.68 yrs | 42.64 yrs |
| Male: Female ratio | 1:4.5. | 1:2.3. |
| Past History | | |
| H/O Cholecystitis | 16% | 8% |
| H/O Pancreatitis | 2% | 6% |
| H/O ERCP | 2% | 4% |

Regarding operating time in our study**,** which is time taken from initial incision to closure of wound is 61.18 minutes in clip group and 63.52 minutes in knot group. Longer operating times in knot group is due to learning curve effect for most surgeons as is evident from the fact that first twenty surgeries took longer time as compared to subsequent surgeries. However, this difference was not statistically significant (p-0.493). Similar observations were made in study by A. Tamij Marane and Seenu V where procedure using knots took a longer time. [16, 12] The operating time decreased in the last 15 patients as the experience of the surgeons increased in the latter study. This trial also revealed a statistically significant longer operating time in the absorbable ligature group (P = 0.02) than non-absorbable clip group.

In our study, no bile duct injury was detected intra-operatively in either of the two groups. There was no previous study which has reported such an outcome.

Regarding bile leak requiring ERCP, in our study three (6%) out of fifty patients in clip group required ERCP for persistent bile leakage. In all these three patients, abdominal drains were kept and bile was draining persistently into drains. All these patients were managed by ERCP and Stent placement. In knot group, only one (2%) patient out of fifty developed bile leak which required ERCP. In the study by Hawasli A. which reported similar outcome none of patient in either group had bile leak which required ERCP [8].

**Table 2- Intra-Operative Findings**

| **Intra Operative Findings** | **No. of Patients in Clip Group (n=50)** | **%age** | **No. of Patients in Knot Group (n=50)** | **% age** |
|---|---|---|---|---|
| Multiple adhesions of GB and Omentum | 10 | 20% | 8 | 16% |
| NR Anatomy | 30 | 60% | 30 | 60% |
| Short & Wide Cystic Duct | 1 | 2% | 4 | 8% |
| Mucocele of GB | 1 | 2% | 4 | 8% |
| GB distended Cystic Duct Short | 4 | 8% | 2 | 4% |
| GB thick walled, Calot's difficult to identify | 4 | 8% | 2 | 4% |

Our study had no cases of biliary peritonitis following laparoscopic cholecystectomy in either group. None of previous trials comparing clips and knots for cystic occlusion have reported any cases of biliary peritonitis following laparoscopic cholecystectomy.

Bile collection requiring re-operation - In our study we had no patients in either group which required re-operation for bile collection. The only case of re-operation reported in the trials included in this review was due to slipping of absorbable ligature as reported by Seenu V [12]. This was not statistically significant on Fisher's exact test (P =0.50).

Bile collection requiring image guided aspiration or drainage. Regarding this particular outcome, there was one patient in clip group of our study who required USG guided percutaneous drainage of bile collection after laparoscopic cholecystectomy. In the only trial, which reported this outcome, only one patient belonging to the "non-absorbable clip" group required ultrasound guided aspiration for bile collection [12]. This was not statistically significant on Fisher's exact test (P = 0.50).

Four (8%) patients out of fifty developed port site infections in the clip group. In knot group, three patients (6%) patients out of fifty developed infections at the port site. In the similar study by Hawasli no patients in either group develop port site infections [8].

In our study, one (2%) patient in the clip group had residual CBD calculi for which open CBD exploration with T-tube drainage was done as she had previous failed ERCP for CBD calculi. No patient in the knot group had this outcome. One trial by Rohr S1 *et al.;* that followed patients for one year reported no complications at one year in the 97/100 patients followed for one year (three patients were lost to follow-up) [18].

Regarding obstructive jaundice, one (2%) patient in clip group of our study developed obstructive jaundice on third post operative day of laparoscopic cholecystectomy. No intervention was required for this patient. No cases of obstructive jaundice were reported by Rohr S1 in their study [18].

Another secondary outcome in our study was hospital stay after surgery. Mean hospital stay in clip group was 2.66 days while it was 2.08 days in knot group. This was statistically not significant (p-0.79). The only trial by Rohr S1 et al that reported the mean hospital stay, did not report a significant difference between the groups (MD0.10 days; 95% CI 0.00 to 0.20; P = 0.05). [18] There was no statistically significant difference in the number of patients who were discharged on the same day in the only trial (Hawasli) that reported this outcome (Fisher's exact test: P = 0.78) [8].

Return to work/routine is another outcome calculated in our study. Mean time taken for patients to get back to routine in clip group is 8.18 days in comparison to 6.79 days in knot group patients. This was statistically significant (p-0.046). There are previous trials reporting this outcome.

The surgical management of gallstones have been revolutionised after the advent of laparoscopic cholecystectomy. This minimally invasive technique has virtually become the gold standard in the management of cholelithiasis. As the number of surgeons performing Laparoscopic Cholecystectomy is increasing, therefore a rigorous evaluation of safety of Laparoscopic Cholecystectomy is warranted. In Laparoscopic Cholecystectomy cystic duct occlusion has been tried with different materials including metallic clips, absorbable clips, absorbable ligatures and more recently harmonic scalpel. It is essential to determine the extent of difference in morbidity and mortality when comparison is made between different methods of cystic duct occlusion. This study was undertaken to compare the safety, cost effectiveness, post operative morbidity and mortality of cystic duct occlusion with clips versus knot/ ligature.

**Table 3- Post Opertative Findings**

| | **Clip Group (n=50)** | **Knot Group (n=50)** |
|---|---|---|
| Mean Operating Time | 61.18 min | 63.52 min |
| Drain kept | 36% | 36% |
| Bile Duct Injury | 0 | 0 |
| Bile leak requiring ERCP | 6% | 2% |
| Bile collection requiring re-operation | 2% | 0% |
| Portsite infections | 8% | 6% |
| Retained/ Recurrent CBD Stones | 2% | 0% |
| Obstructive Jaundice | 2% | 0% |
| Mean Hospital stay | 2.66 Days | 2.08 days |
| Mean no of days | 8.18 days | 6.79 days |

## CONCLUSIONS

We share our experience of one hundred cases who were subjected to Laparoscopic Cholecystectomy out of which in fifty cases cystic duct was occluded by clips and in other group of fifty cases the cystic duct was occluded with knot/ ligature. No cases of bile duct injury were detected intra-operatively in either of two groups of our study.

6% of the patients in clip group required ERCP for persistent bile leak while only 2% of the patients in the knot group required ERCP for the similar complaints. No patient in either group developed biliary peritonitis after laparoscopic cholecystectomy during the period of follow-up.

Only 2% of the patients in the clip group had bile collection which required USG guided per cutaneous pig tail drainage. While no patient in the other group in which cystic duct was occluded with knots/ligatures developed such complications during period of follow up after surgery.

8% of the patients of the clip group and 6% of the patients belonging to the knot group developed port site infections. 2% of the patients in the clip group had residual/recurrent CBD calculi while no patient in the knot group developed this outcome.

2% of the patients in the clip group of our study developed obstructive jaundice while no patient in the knot group had obstructive jaundice during the period of follow up. Regarding the operating time, time taken during cystic duct occlusion with knot was more as compared to time taken in surgery of the patients in clip group. Mean operating time in clip group was 61.18 minutes while it was 63.52 minutes in knot group.

Hospital stay in clip group of our study was 2.66 days while it was 2.08 days in the knot group. Clip group had more post operative complications contributing to increased hospital stay in this group. Patients in the clip group took more time return to routine/work as compared to the patients in the knot group. Patient in clip group took 8.18 days as compared to knot group patients who took 6.79 days to get back to routine. This was statistically significant.

Results of this study demonstrate that cystic duct occlusion with knots/ligatures is a safe, cost effective alternative to clips. Safety of using knots/ligatures is even better than clips as is evident from our study comparing these two methods of cystic duct occlusion.

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