ABSTRACT

Introduction: Laparoscopic cholecystectomy today has been rapidly embraced worldwide as the procedure of choice for cholecystectomy. Conventionally, titanium clips are used to ligate the cystic duct. Recently, various methods of suture ligation of the cystic duct both intra corporeal and extracorporeal have been described during laparoscopic cholecystectomy. Only limited number of studies have been carried out prospectively to compare the various methods. The present study was thus designed to compare clip occlusion versus extra corporeal suture ligation (Roeder knot) of the cystic duct in laparoscopic cholecystectomy.

Material and methods: This study was a single blinded randomized controlled trial conducted on 150 adult patients undergoing laparoscopic cholecystectomy. They were randomized into two groups of 75 each to compare the procedures of clip occlusion versus extracorporeal suture ligation (Roeder knot) of the cystic duct with respect to the operative time, complications, associated morbidity, operative cost and hospital stay.

Results: There was no significant (p=0.05) difference in duration of surgery between the groups (Clip ligation=40.44±4.63 minutes, suture ligation=43.32±4.44 minutes). Bile leakage due to slippage of ligature was present in 2 (2.7%) patients with clip ligation as compared to 0% in suture ligation. This difference was found to be statistically significant (p=0.03). Obstructive jaundice due to accidental ligation of CBD was present in 2 (2.7%) patients with clip ligation as compared to 0% in suture ligation. This difference was also found to be statistically significant (p=0.03). The cost of Clip ligation (Rs.369.07±8.08) was higher than suture ligation (Rs.300.00±0.00).

Conclusion: The results of this study indicate that extracorporeal (Roeder’s knot) is a safe, cost effective alternative with a low complication rate as compared to titanium clip ligation of the cystic duct in laparoscopic cholecystectomy.

Keywords: Laparoscopic Cystic Duct Ligation, Clip Occlusion, Roeder Knot

INTRODUCTION

Gallstone disease is defined as the presence of one or more stones in the gallbladder. It is commonly asymptomatic.1 The incidence of gall stone disease is reported to be higher in the female population. Based on the chemical composition 50%, of the stones are cholesterol stones followed by mixed and pigmented stones. Mixed and pigment stones are very common in south India and cholesterol stones are common in North India. The simple mechanism of formation of stones is super saturation of constituents in bile surpassing their maximum solubilities.2 Laparoscopic cholecystectomy was first introduced in the United States by Dr. Eddie Joe Reddick in 1989, and has been rapidly embraced worldwide as the procedure of choice for cholecystectomy.3 It is the gold standard for the treatment of symptomatic gall stone disease and other benign conditions of the gall bladder.4 During cholecystectomy cystic duct can be secured with sutures or clips. Knot tying in open surgery can be easily be learned and performed. However, knot tying becomes challenging and frustrating when performed laparoscopically.5

It is now possible, with increasing experience in advanced laparoscopic techniques, to safely occlude cystic duct with ligature as an alternative to clips.6 The present study was designed to compare clip occlusion versus extra corporeal suture ligation (Roeder knot) of the cystic duct in laparoscopic cholecystectomy.

MATERIAL AND METHODS

The present study was carried out in department of general surgery at Rohilkhand medical college and hospital to compare the advantages and disadvantages of extracorporeal suture ligation versus clip ligation in laparoscopic cholecystectomy.

It was a Single blinded randomized controlled study conducted over a period of one year.

150 adult patients in the age group 16-60 years undergoing laparoscopic cholecystectomy constituted the study population. They were divided into two groups:

Group A: 75 patients in whom extracorporeal suture ligation was done for the cystic duct.

Group B: 75 patients in whom metallic clip occlusion was done for the cystic duct.

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(Roeder knot) was used for suture ligation of the cystic duct. In all the cases metallic clip of size LT 300 were applied for clip occlusion and vicryl no 1, (150 cm). was used for extra corporeal suture ligation of the cystic duct.

**Exclusion criteria**
- Patients with Common Bile Duct stones
- Patients with gall bladder malignancy
- Liver cirrhosis
- Chronic obstructive pulmonary disease
- Cardiac disease
- Pregnancy
- Patients unfit for general anesthesia.

**Procedure**

**Laparoscopic cholecystectomy (Standard Four Port)**

Statistical analysis

The results are presented in frequencies, percentage and mean±SD. The Chi-square test was used to compare categorical variables. The Unpaired t-test was used to compare continuous variables between the groups. The p-value<0.05 was considered significant. All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA).

**RESULTS**

Majority of patients of both Clip ligation (92%) and suture ligation (94.7%) had abdominal pain. There was no significant (p>0.05) difference in presenting symptoms between the groups (figure-2).

There was no significant (p>0.05) difference in duration of surgery between the groups (Clip ligation=40.44±4.63 minutes, suture ligation=43.32±4.44 minutes) (table-1).

Bile leakage due to slippage of ligature was present in 2 (2.7%) patients with clip ligation as compared to 0% in suture ligation. This difference was found to be statistically significant. (p=0.03) (table-2).

Obstructive jaundice due to accidental ligation of CBD was

**Table-1:** Comparison of duration of surgery between the groups

<table>
<thead>
<tr>
<th>Groups</th>
<th>No. of patients (n=150)</th>
<th>Duration of surgery in minutes (Mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clip ligation</td>
<td>n=75</td>
<td>40.44±4.63</td>
</tr>
<tr>
<td>Suture ligation</td>
<td>n=75</td>
<td>43.32±4.44</td>
</tr>
</tbody>
</table>

1Unpaired t-test

**Table-2:** Comparison of Bile leakage due to ligation slippage

<table>
<thead>
<tr>
<th>Bile leakage due to ligation slippage</th>
<th>Clip ligation (n=75)</th>
<th>Suture ligation (n=75)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Yes</td>
<td>2</td>
<td>2.7</td>
<td>0</td>
</tr>
<tr>
<td>No</td>
<td>73</td>
<td>97.3</td>
<td>75</td>
</tr>
</tbody>
</table>

*Chi-square test, *Significant

**Table-3:** Comparison of cost of suture / Clip ligation between the groups

<table>
<thead>
<tr>
<th>Groups</th>
<th>No. of patients</th>
<th>Cost of suture / Clip ligation in Rupees (Mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clip ligation</td>
<td>75</td>
<td>369.07±8.08</td>
</tr>
<tr>
<td>Suture ligation</td>
<td>75</td>
<td>300.00±0.00</td>
</tr>
</tbody>
</table>

1Unpaired t-test

**Figure-2:** Comparison of presenting symptoms between the groups
present in 2 (2.7%) patients with clip ligation as compared to 0% in suture ligation. This difference was also found to be statistically significant. (p=0.03) (fig-3).

The cost of Clip ligation(369.07±8.08) was higher than suture ligation (300.00±0.00) (table-3).

**DISCUSSION**

Laparoscopic surgery is a well-established alternative to open surgery across all disciplines and is considered the gold standard in cholecystectomy. Although positive magnitude of impact varies by the procedure, generally the benefits of laparoscopic cholecystectomy on post-operative pain, cosmesis, 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.

Few studies comparing sutures over clips in terms of safety, feasibility and cost effectiveness are available thus necessitating this study.

In the present study, the mean age of patients of Group A and Group B was 41.49±11.85 and 41.03±10.78 years respectively. There was no significant (p>0.05) difference in age between the groups showing comparability of the groups in terms of age. This is similar to a study by Riaz et al (2017) in which the mean age of patients undergoing laparoscopic cholecystectomy was 40.3±11.9 years and 38.3±10.8 years in two similar groups.

In this study, majority of patients of both Group A (70.7%) and Group B (73.3%) were females. There was no significant (p>0.05) difference in gender between the groups showing comparability of the groups in terms of gender. Similar finding were reported by Singh et al (2017) in which majority of the patients in his study were females in both the groups i.e. 93.33% in group A (Patients in whom extra corporeal knotting was done for ligation of cystic duct) and 83.33% in group B (Patients in whom liga clips were used for occluding the cystic duct).

In our study majority of patients of both Clip ligation (74.7%) and suture ligation (69.3%) belonged to rural areas. Zamani et al (2014) also showed a higher incidence of gallstone disease in rural areas.

In our study majority of patients of both Clip ligation (92%) and suture ligation (94.7%) presented with abdominal pain. There was no significant (p>0.05) difference in presenting symptoms between the groups. Singal et al (2018) conducted a similar study comprising of 160 patients, all of them (100%) having abdominal pain as the chief complaint prior to admission. Vomiting (35%) was the second most common complaint.

In this study, there was no significant difference in preoperative biochemical parameters liver function tests and preoperative ultrasonography findings (p>0.05) between the two groups. Serum bilirubin (mg%) was 1.30±0.12 in clip ligation and 1.34±0.10 in suture ligation, serum alkaline phosphatase (IU/l) was 90.11±20.36 in clip ligation and 88.69±20.87 in suture ligation. Serum SGPT (IU/l) was 34.35±16.79 in clip ligation and 34.56±16.23 in suture ligation.

Aslam et al in 2013 found that in liver function tests, total bilirubin was elevated in 62(13.6%) patients while 392 (86.3%) had normal values. Alkaline phosphatase was elevated in 186(41%) patients while SGPT was found to be raised in 160(35.2%) patients of gallstone disease.

Chronic cholecystitis with cholelithiasis was seen in 77.3% patients of Clip ligation group and in 74.7% of suture ligation group on USG abdomen. Acute cholecystitis with cholelithiasis was in 22.7% patients of Clip ligation group and in 25.3% of suture ligation group on USG abdomen. Both the groups were thus equally matched.

There was no significant (p>0.05) difference in the duration of surgery between the two groups (Group A=40.44±4.63 minutes, Group B=43.32±4.44 minutes) in the present study. Gurusamy et al (2010) showed that the operating time was 12 minutes longer in the absorbable suture ligation group than in the group randomised to clip ligation. Duration of suture ligation is dependant on the surgeon’s experience and tends to get shorter with practice as was in our case.

In the present study, the post-operative pain according visual analogue scale in <12 hours was insignificantly (p>0.05) lower among patients of Group A (6.29±0.81) than Group B (6.45±0.90). The post-operative pain in 12-24 hours was less in both Group A (3.65±0.64) and Group B (3.69±0.77) with insignificant (p>0.05) difference. Singal et al (2018) evaluated postoperative pain in 70 patients who underwent laparoscopic cholecystectomy using cystic duct and artery ligation with silk 2-0 and 70 patients in whom cystic duct and cystic artery were ligated with Liga clips. They also found no significant difference in the post-operative pain on a visual analogue pain score.

In the present study, bile leakage due to slippage of ligature occurred in two patients (2.7%) with clip ligation as compared to 0% with suture ligation (p=0.03).

Bile leakage due to slippage of clip ligature in both patients was managed with re exploration followed by ligation of the cystic duct stumps. Riaz et al (2017) found that there was 3.3% bile leakage in the group with clip ligation while no case occurred with suture ligation.

In our study, obstructive jaundice due to accidental ligation of Common bile duct was present in 2 (2.7%) patients with clip ligation as compared to 0% with suture ligation. This
difference was also found to be statistically significant (p=0.03). Obstructive jaundice due to accidental ligation of Common bile duct was managed in both the patients with ERCP and stenting. This result is further supported by a study by Bali and Singal (2018) who concluded that silk suture can be tied near the CBD, as risk of involving the CBD wall is very little as compared to clips.

Return to routine activities is another outcome calculated in this study. The duration of returned to work was significantly (p<0.05) higher in Group A (8.35±1.38 days) than Group B (6.76±1.12 days) in the present study. Rajra et al (2016) also found that mean time taken for patients to get back to routine in the clip group was 8.18 days in comparison to 6.79 days in knot occlusion, group patients.

The operative cost of Group A (369.07±8.08) was higher than Group B (300.00±0.00) in the present study. Rajra et al (2016) reported that cystic duct occlusion with knots/ligatures was a safe, cost effective alternative to clip ligation.

CONCLUSION

The present study was conducted to compare the procedures of clip occlusion versus extracorporeal suture ligation (Roeder knot) of the cystic duct in laparoscopic cholecystectomy. Results of this study demonstrate that cystic duct occlusion with knots/ligatures is a safe, cost effective alternative to clip ligation with a lesser incidence of complications viz; bile leakage, accidental ligature of the common bile duct at a much lesser cost to the patient.

REFERENCES