Evaluation of the efficacy, safety and cost effectiveness of liga clips in laparoscopic cholecystectomy

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Abstract
Objective: Evaluation of liga clips (titanium clips) in laparoscopic cholecystectomy in terms of safety, efficacy and cost effectiveness.

Methods: This study was carried out in Dhiraj Hospital & Sumandeep University, Piparia Vadodara (INDIA) from July 2014 to March 2015. 60 Patients of either sex, more than 20 years of age, who underwent laparoscopic cholecystectomy were included in the study. The patients who had jaundice, empyema, mucocele, mass or dilated CBD (>8 mm in Diameter) and patients having positive hepatitis B or C virus screening test were excluded. All of the patients underwent LC for symptomatic cholelithiasis and closure of the CD and cystic artery were performed, through the application of non-absorbable titanium clips (double clips to the proximal and single clip to the distal).

Results: The mean age of patients was 40.30 years with female to male ratio 5.6:1. Acute cholecystitis was present in 5% cases. The mean operative time was 76 min. The open conversion rate was 5 % (3 cases). 2 cases opened due to adhesion and one cases opened due to acute inflammation. There was no bile duct or colonic injuries. There was also no slippage or migration of liga clip occurred. Two (3.3%) patients had bile leak (minor < 50 cc) which was managed conservatively by putting drain, 1 (1.3%) patient developed port site wound infection,1(1.3%) patient developed intra operative haemorrhage. Drain was placed in Morrison’s pouch in 6 (10%) patients. The post-op hospital stay was 1.63 days. There was no mortality.

Conclusion: We conclude that as far as the haemostasis of the cystic artery & cystic duct ligation is concerned, titanium clips is safe, efficacious and cost effective when applied properly.

Keywords: Laparoscopy, cholecystectomy, Liga clips, cystic duct

1. Introduction
Laparoscopic cholecystectomy (LC) is accepted as the gold standard treatment of symptomatic gallstones. Several methods have been developed[1,2] to close the cystic duct (CD) during a surgical procedure, but titanium clip application is currently the most frequently used technique[3,4]. Several studies have examined the efficacy, safety & cost of various devices in different situations. Each technique has potential drawbacks. Application of endoloops requires dexterity and training. Endoscopic staplers are expensive instruments.

Titanium clips can slip from their primary position[8]. The hem-o-lok clip is costly. Although postoperative bile leakage is rare, it is a serious complication and occurs in 0.2-0.27 % of cases[5-7]. Hemostatic devices used in laparoscopic cholecystectomy are monopolar electrocautery, bipolar electrocautery, ultrasonic coagulator and ligasure vessel sealing system. Although ultrasonic coagulator and ligasure are superior to monopolar electrocautery in terms of safety, they are not universally available in hospitals. So in our study evaluate the role of liga clips in laparoscopic cholecystectomy.
1.1 Objective

To evaluate the efficacy, safety and cost effectiveness of liga clips in laparoscopic cholecystectomy.

2. Material and Methods

This study was carried out in Dhiraj Hospital & Sumandeep University, Piparia Vadodara, India from July 2014 to March 2015. Patients of either sex, more than 20 years of age, who underwent laparoscopic cholecystectomy irrespective of indication were included in the study. The patients who had jaundice, empyema, mucocele, mass or dilated CBD (>8 mm in Diameter) and patients having positive hepatitis B or C virus screening test were excluded. All patients were admitted and necessary preoperative workup including CBC, Urea, Sugar, liver function test and Hepatitis B and C screening were done. Ultrasound abdomen was done in each patient to confirm gallstones and to assess the CBD diameter and was used as a tool for exclusion criteria. Chest X-ray and ECG were done in patient with age above forty year. Fitness for general anaesthesia for all patients was considered. Pre-operative antibiotics in the form of injection ceftriaxone 1 gm IV one dose were given to each patient at the time of surgery. Nasogastric tube was used in all patients. Tube was introduced just after induction. Established operative technique was employed & four-port used. The pneumoperitonium was created by closed method by using Veress needle.

All of the patients underwent LC for symptomatic cholelithiasis and closure of the CD and cystic artery were performed, through the application of non-absorbable metal clips (double clips to the proximal and single clip to the distal). Informed consent were taken from all patients regarding the use of clips. Intra-operative complications like cystic / right hepatic artery injuries and common hepatic duct, common bile duct or cystic duct injuries and postoperative complications like hemorrhage, bile leakage and biliary obstruction were also followed up.

Clip failure was defined as intraoperative or postoperative bleeding due to clip malfunction that necessitated placement of another clip, conversion to an open procedure or postoperative re-exploration. Leakage from the cystic duct after LC was also considered clip failure. All the data about patient were recorded on standardized performa and analysed by SPSS 10.

3. Result

Out of 60 patients, 51 (85%) were female and 9 (15%) were males giving rise to a female to male ratio of 5.6:1. The age ranged from 17 to 65 years, mean age being 40.30 years, majority were in fourth (31.66%) and fifth (25%) decade of life. Six (10%) patient had diabetes mellitus, three (5%) had hypertension. All patients were fit for anaesthesia. Majority of the patients (75%) had multiple stones, 14 (23.3%) had single stone, while 1 (1.7%) had polyp in the gall bladder. Adhesions were present in 10 (16.7%) patients. The status of the gall bladder as observed in this study is given in Table-1. Two (3.3%) patients had bile leak (minor < 50 cc) which was due to GB perforation intraoperatively & managed conservatively by putting drain which removed on 3rd day, 1 (1.3%) patient developed port site wound infection, 1 (1.3%) patient developed collection in pouch of Morrison. There was no bile duct or colonic injuries. The conversion rate was 5%. Two patients were converted due to fibrous adhesions and one was converted due to acute inflammation. The operative time is given in Table-1. Drain was placed in Morrison’s pouch in 6 (10%) patients. The post-op hospital stay was 1–5 days, mean stay being 1.63 days. There was no mortality.

Majority of cases, 95% presented with a clinical diagnosis of biliary colic. Acute cholecystitis was seen in 5% cases. The cystic artery was single in 94.7%, branched in 5% and absent in 1.3% cases. The post operative was uneventful. Patients, who required conversion to open surgery, remained in the hospital for 5 days post-operatively.

A redivac drain size 16 attached to a drainage bag was placed for a day in cases in which there was bile spillage from the gall bladder There were no clip failures after LC (with bile leakage) also there were no reported case of migration of the clip into the common bile duct (CBD) in our study.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Results</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age + SD</td>
<td>40.30 years</td>
<td></td>
</tr>
<tr>
<td>Sex Distribution</td>
<td>51 (female) 9 (male)</td>
<td>85%,15%</td>
</tr>
<tr>
<td>GB Status</td>
<td>Acute – 3 Chronic – 10 Normal – 47</td>
<td>5% 16.6%</td>
</tr>
<tr>
<td>Conversion rate</td>
<td>3 patients</td>
<td>5%</td>
</tr>
<tr>
<td>Mean operative time</td>
<td>76.2 ± 9.21 min</td>
<td></td>
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<tr>
<td>Hospital stay</td>
<td>1.63 days</td>
<td></td>
</tr>
<tr>
<td>Complication</td>
<td>Intraop haemorrhage – 1 Bile leak (minor) – 2 Port site infection – 1 Bile duct injury -0</td>
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</tbody>
</table>
4. Discussion

During the LC procedure, closure of CD is frequently performed with double titanium clips 1 cm above its junction within a common biliary duct (CBD). Since CD contains rich collagen like arteries, sealing of the duct with instruments such as HS or PK seems to be feasible. Extensive series of CDs sealed with HS have been published in the literature, and no difference in comparison with surgical clip application, in terms of complication, has been reported. There is a lack of human studies about the usage of PK for sealing of CD, but some experimental animal trials are available[9-11]. Although PK is not recommended for CD closure in some studies, some others encourage surgeons to use this instrument in division of CD[12]. But most of the studies have emphasized the need for further research.

As it is reported in the study of Shamiyeh and co-workers, the use of high-tech devices may be contraindicated in the case of a short CD and whenever difficulties in the closure of the CD are expected, such as in the case of acute cholecystitis or porcelain GB [9].

The median age of patients was 40.30 years. The age distribution in this study population is the same as that of western population. The majority of cases, 95% with a clinical diagnosis of biliary colic. Acute cholecystitis was seen in 5% cases. In our study, the cystic artery was absent in 1.3% cases. Suzuki M and colleagues and Hugh TB and colleagues reported a single cystic artery in 76.6% and 72% of their patients respectively.[13,14] This difference may be attributed to a different geographical zone population sample. Ayaz and colleagues noticed a branched cystic artery in 20% of their cases.[15] while it was 5% in our study.

Khan in his study noticed a conversion rate of 6.4%.20 which is comparable to our study 5%. Haemorrhage during the surgery occurred in 1 (1.7%) patient. This haemorrhage did not require conversion. In this study 3 (5%) gall bladders were perforated. This is reported 0.97% by Khan[16] The situation was handled by applying liga clips or holding the perforation site by grasper. Port site wound infection occurred in 1 (1.7%) patient. This is reported 1.63% in arain & Hassan et al study[17]. This infection required no special measures except dressing

Huscher and colleagues[1] compared the ultrasonic coagulation division of the cystic artery and duct with ligature and found no difference in both methods regarding post operative mortality and complications. However with monopolar electrocautery, the depth of burn is less predictable and current can be conducted through non-insulated instruments and trocar. So the laparoscopic surgeon must pay great attention to the anatomical dissection of the Calot’s triangle. Excessive and unnecessary dissection or use of electrocautery near the common bile duct should be avoided. On the other hand haem o lock clip are safe & effective in laparoscopy but their limitations are their cost effectiveness.

The purpose of our study was to identify the safety & efficacy of liga clips in laparoscopic cholecystectomy. As in postoperative period there were no haemorrhage, slippage of liga clip, also no migration of clip noted, so its use in our study was safe & effective, and also it take less time as compare to intracarporeal suturing. As compare to haem o lock clip, it is very cheap, while with intracorporeal suturing its cost comes approximately same. On other hand use of harmonic scalpel for cystic duct closure, most of the studies have emphasized the need for further research.

5. Conclusion

We conclude that as far as the haemostasis of the cystic artery & cystic duct ligation is concerned, titanium clips is safe, efficacious and cost effective. But the most important step is the careful dissection of the Calot’s triangle and the identification of the cystic artery, cystic duct & proper application of liga clip. Surgeons must be educated regarding its proper application.

Complete circumferential dissection of structure
Use appropriate size of clip
Visualization of curved tip of Maryland around &beyond the structure
No cross clipping
Feeling of tactile snap when the clip latched
Placement of clip at 90 degree to the structure
Inspect the ligation site after application to ensure security & proper closure
Minimal 2 clip at CBD end & 1 clip at GB end

References


