COMPARING THE EFFICACY AND SAFETY OF 3 METHODS FOR SECURING THE CYSTIC DUCT IN LAPAROSCOPIC CHOLECYSTECTOMY METALLIC CLIP VERSUS HARMONIC SCALPEL VERSUS SUTURE LIGATION: (PROSPECTIVE STUDY).

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ABSTRACT

Introduction: *Laparoscopic cholecystectomy is the standard of care for treatment of symptomatic gall stones. Securing the cystic duct by the use of metallic clips is the classic method used by most surgeons. There are many other techniques described in the literature to secure the cystic duct. Some surgeons use Harmonic shears to secure the cystic duct and artery.Intra-corporeal suture ligation can be done to secure the cystic duct but it needs high level of laparoscopic skills.* ***Aim of the work:****To compare between metallic clips, Harmonic scalpel and suture ligation in securing the cystic duct regarding the safety and efficacy and to report any complications related to each.* ***Materials and methods:****This is a randomized prospective study conducted in Mansoura university hospital in the period between January 2013 and June 2014.all patients were consented for the study.Cases with frozen calot or dense adhesions were excluded from the study.* ***Results:*** *A total number of 66 patients were included in the study. Three groups were made, the first is the clip group, the second is the Harmonic group and the third is the suture ligation group. Each group includes 22 patients. There was only one case of cystic duct leak in the Harmonic group and it was managed by Ultrasound guided tube drainage. One case of intraoperative bleeding from the cystic artery in the suture ligation group that was managed by clip. No cases of postoperative bleeding.* ***Conclusion:****Securing of the cystic duct in laparoscopic cholecystectomy can be done by different techniques. Metallic clips are safe but it has limitations in case of wide cystic duct and complications like clip migration. Harmonic scalpel is safe method but it must be used with caution in cases with wide cystic duct. Suture ligation is an excellent method to secure the cystic but it needs good skill in doing intra-corporeal knotting.*

INTRODUCTION

It is well knownthat laparoscopic cholecystectomy is the standard treatment for cases of symptomatic gall stones(1,2).

Simple metal clips are used by most surgeons to secure the cystic duct and artery(3,4). Also most of surgeons use mono-polardiathermy for dissection and achievement of critical view of safety(4).The application of clips has some drawbacks like dislodgement with resultant cystic duct leak(5). Another clip related problemwas reported with the long term follow upwhich is clip migrationwhich is reported to result in biliary stoneformation (6).

There are some pitfallsassociated with the use of mono-polar current as the relatively higherrisk of thermal injuries and postoperative biliary complications(7,8).

There are many alternative techniques for securing the cystic duct like ultrasonically activated scalpel (Harmonic scalpel) and intra-corporeal suture ligation(9,10).

Ultra sonically activated scalpel (harmonic)proved to be safe instrument for dissection and hemostasis .This methodof cutting tissueis basedon the coagulatingand cavitational effects given by the vibrating blade(11).

The benefits of such energy source can be summarized in lower temperature,smoke and less lateral tissue damage in contrast to the traditional electro-surgery(12).

The main drawback of such an instrument is the cost and availability. The other major problem facing surgeons with harmonic is lack of confidence in its ability to secure the cystic duct without complications(12,13).

Another good alternative for the classic securing of the cystic duct by metallic clips is intra corporeal suture ligation which needs higher level of laparoscopic skills(1).

MATERIALS AND METHODS

This is randomized prospective study conducted in Mansoura university hospitalfrom January 2013 till July 2014. All patients included were consented for the study.

***Inclusion criteria:.**

All cases of laparoscopic cholecystectomy for chronic or acute cholecystitis.

***Exclusion criteria:.**

-Difficult cases of Mirrizi syndrome, dense adhesions, and frozen Calot.

-Cases converted to open.

-Any general contraindication for laparoscopy like uncorrected coagulopathy.

-Concomitant common bile duct stone

All patients were subjected to

A) Complete history taking including

Personal history (name, age and sex)

Complaint

Present history including analysis of pain (onset, course, duration, site ,radiation ,character ,what increase, what decrease ,, associated GIT symptoms like nausea vomiting) symptoms suggestive of complications like jaundice due to passed stone.

Past history of similar condition

B) Examination including

General examination:(Temperature, pulse, jaundice)

Abdominal examination:to elicit signs suggestive of acute attack of cholecystitislike Murphy sign.

C)Investigations

Laboratory:

Complete blood count.

Liver function studies (serum bilirubin total and direct, alkaline phosphatase, SGOT,SGPT, albumin and INR).

Serum creatinine.

Random blood sugar

Radiology:

preoperative ultrasound

MRCP if there is suspicion of passed stone to common bile duct

OPEATIVE TECHNIQUE

The procedure was done under general anesthesia with endotracheal intubation

Position is initially supine the reverse Trendlenburg with tilt to the left

Pneumoperitoneum was achieve with open method

Four ports were inserted (two of them were 11 mm one umbilical for telescope and the other working epigastric).

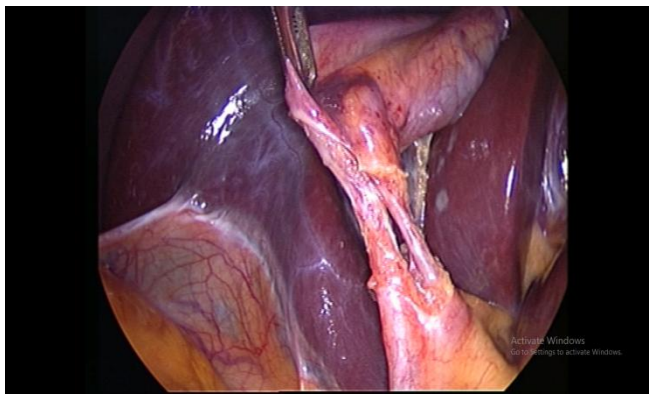
(the other two were 5 mm for traction of Hartman and fundus of the gall bladder)

We had 3 groups

The first (Clip group): Dissection of Calot triangle was done by mono-polar hook till achieving the critical view of safety(Figure1), then clipping of the cystic artery by 2 clips and cutting inbetween then clipping of the cystic duct by 3 clips and cutting between the proximal 2 and distal one(Figure2).

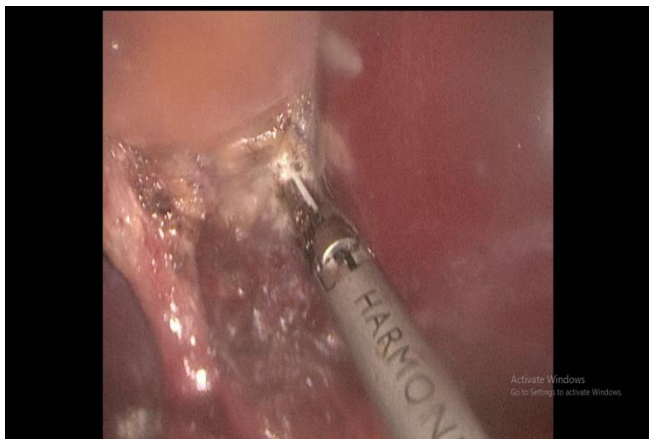
The second group(Harmonic group): Dissection of the calot triangle by the use of Harmonic scalpel till achieving the critical view of safety then application of harmonic blades in the minimum mode on the cystic arteryon 2 different sites then cutting toward the gall bladder then application of the Harmonic shear on the duct on 3 different sites in the minimum mode then cutting between the proximal 2 and distal one(2- 3) minutes duration (Figure3).

Third group (ligature group): The Calot was dissected by the use of monopolar hook till achieving the critical view of safety then cauterization of the the cystic artery well away from the hilum after its adequate dissection (Figure4)then 20 cm vicryl0 suture was passed around the cystic duct and 2 knots were taken proximally and one more distally(on the gall bladder side). (Figure 5,6).

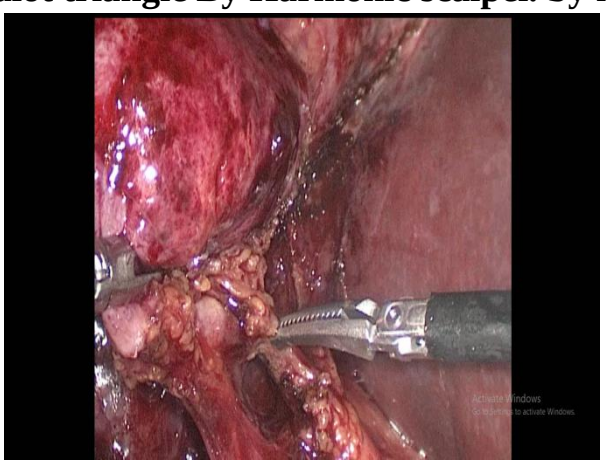


Figure(1).Critical view of safety with exposure of cystic duct and artery .

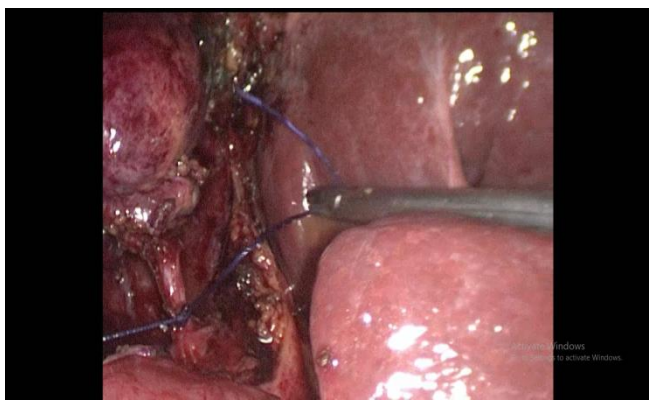
Figure (2).Clipping of the cystic duct and artery.



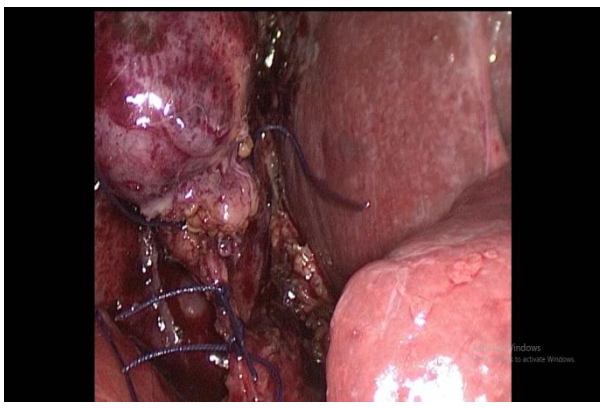
Figure(3). Dissection of the Calot triangle By Harmonic scalpel. by monopolar diathermy.



Figure(4). Cauterization of the cystic artery



Figure(5).Ligation of the proximal knot on the Cystic duct.



Figure(6). The final view after the three ligatures.

Method of randomization

Case 1: Clip
Case 2: Harmonic
Case 3: Intracorporeal ligature and so by that order
Alloperations were done by consultant surgeons (lectures, assistant professor and professors)
All patients were subjected to ultrasound on the seventh postoperative day
Follow up period was up to3- 6 months postoperatively.

RESULTS

66 patients (48 females and 18 males)were included in the study,22 patients in each group.

There was neitherdeath nor major bile duct injuries in any of the 3 groups

Intraoperative bleeding from cauterizedartery was detected in 1 patient in **ligature group**andthis was managed by application of metallic clip. No post-operative bleeding was detected in any patient in the 3 groups. Mean operative time in the first group(**Clip group**) was 49 min. Mean operative time in the second group(**Haromonic group**)was 38 min. Mean operative time of the third groupwas 54 min. There was only 1 case of cystic duct leak that was in the second group(**Harmonicgroup**) that was discovered on routine postoperative ultrasound done on the seventh postoperative day. It was manages by percutaneous ultrasound guided tube drainage. Leak stopped after 12 day, the tube was removed with no further complications.

Preoperative data.

	Group 1 (clip)	Group 2 (Harmonic)	Group 3 (suture ligation)
Number of cases	22	22	22
Male to female ratio	8-14	6-16	4-18
Mean age	38 years	45 years	49 years
Indication of surgery			
Chronic cholecystitis	19	20	21
Acute cholecystitis	3	2	1

Operative and postoperative data.

	Group 1	Group 2	Group 3
Mean operative time	49 min	38 min	54 min
Mean postoperative hospital stay	1.3 day	1.1 day	1.4 day
Cystic duct leak	0	1	0
Porte site infection	2	0	0

DISCUSSION

Laparoscopic cholecystectomy is the gold standard technique for treatment of symptomatic gall stones.

Simple metallic clips are used by most surgeons to secure the cystic duct and artery since Muhe repoted the first laparoscopic cholecystectomy in 1985. Although this standard technique is easy and can be done by most of surgeons but it has some pitfalls .postoperative cystic duct leak is a potentially serious complication causing bilioma or biliary peritonitis(3) .In our study we had no case of cystic duct leak in group 1 (**clip group**). This may be due to the smaller size of the group study in comparison to other studies. Cystic duct leakage has many reasons like mismatch between the cystic duct diameter and clip size or slippage of the clip off the end of the duct(13). In our study, we used 2 clip sizes,medium large and large. Medium large was used in 18 cases. In other 2 cases we used the large clip to safely secure the cystic duct. In the remaining 2 cases we used 3 clips in stepladder fashion to safely secure the cystic duct.

Cettal et al reported that clip migration occurred in 18 of 71 patients over the course of one year. Clips migrated from initial site to either the peritoneal cavity or the common bile duct serving as a potential nidus for common bile duct stones (14).

In our study we did not have this complication may be due to the smaller size of the study group or the the shorter period of follow up.

Locking absorbable clips were used instead of simple metallic clips to secure the cystic duct but they are more expensive than metallic ones(16,17).

Several studies had confirmed the effectiveness and safety of the use of ultrasonically activated scalpel (Harmonic scalpel) for dissection of the gall bladder,but only few surgeons had examined its efficacy and safety in securing the cystic duct .In studies by Bessa, westervolt and Tebala confirmed that harmonic is safe tool for closure of cystic duct and artery(18,19,20).

In 1999, the use of ultrasonically activated scalpel (Harmonic scalpel) for both dissection and closure division of the cystic was first reported(21) .In our study, we had one case of leak from 22 patients of the second group (Harmonic), this leak was detected on the seventh post day and was managed by Ultrasound guided tube drainage. Our explanationfor this leak is that Harmonic was used on wide cystic duct.

The mean operative time of the Harmonic group was less than the other 2 groups inspite of 2-3 minutes interval required for cystic duct division. This could be explained by better tissue planes done by Harmonic and better visualization due to smokeless coagulation of the Harmonic.

One additional benefit of Harmonic scalpel is its more efficacy in securing the duct of Luschka, preventing the bile leak from the liver bed that may lead to small bilioma.

The main obstacle facing surgeons in using Harmonic is its cost and availability,

Technically it must be used with caution especially in cases with wide cystic duct.

We did not notice complication related to the suture ligation group.

The only limitation of the intracorporeal ligature is that it needs skill that develops with time. This is in line with a study done by ElGeidie (22).

We did not find complications related to the use of mono polar diathermy for securing the cystic artery after its adequate dissection and cautery as far as possible from its origin.

In another study by Golash, he used bipolar diathermy for more safety(23)

The suture ligation technique needs some prerequisites to improve its results:

1- Control the artery first before attacking the duct.
2- Use of needle holder and Marryland forceps for better holding of the sutures.
3- G.B dissectionas far as possible off its bed to decrease manipulation of the G.B after ligation to prevent leak of the bile from it.

CONCLUSION

Clipping of the cystic duct and artery is a safe and efficient method for laparoscopic cholecystectomy but it has some challenges like cystic duct diameter and complications like spillage and migration.

Harmonic scalpel is safe, efficient and practical method for securing cystic duct but it must be used with caution in cases with wide cystic duct(more than 5 mm).

Suture ligation is safe, cost effective method for securing cystic duct but it needs good level of skill in doing intra-corporeal knotting which is very important skill in advanced laparoscopic procedures.

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