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Efficacy of harmonic scalpel in total clipless laproscopic cholecystectomy

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ABSTRACT

Laparoscopic cholecystectomy (LC) is a well-known benchmark in the surgical management of gall bladder stones. It has numerous advantages such as its minimal invasiveness and faster recovery for patients. Harmonic scalpel (HS) has been widely used for cystic duct and artery closure. This study aimed to investigate efficacy of HS in the closure of the cystic artery and duct, its beneficial aspects and, if it is a safe instrument. This study included 75 patients had LC performed using HS in closure and division of both the cystic duct and artery with dissection of the gallbladder by it. The perioperative data were recorded. LC was successfully conducted on all included patients; the average duration of the procedures was 35.6±7.1 mins. There is a lower incidence of gallbladder perforation with subsequent avoidance of time loss. No mortality no intraoperative bile duct injury or perioperative bleeding were reported. Nevertheless the major postoperative morbidity rate was in 3 cases 4.0% (one case bile leak from accessory duct, and 2 cases port site infection), The HS is an efficient tool for complete hemo-biliary sealing; it enhances the operative course of elective LC.

Keywords: Harmonic Scalpel, Clipless laparoscopic cholecystectomy.

INTRODUCTION

LC is a well-known benchmark in the surgical management of symptomatic acute cholecystitis as well as gall bladder stones. LC has numerous advantages when compared to conventional surgical laparotomy, yet the most important of these merits are its minimal invasiveness and faster recovery for patients [1].

The majority of surgeons prefer using monopolar electrocautery in laparoscopic dissection [2,3].

Linear staplers and sutures have been suggested to be stander tools during laparoscopic manipulation, in order to avoid common complications encountered while using clips and/or scissors. It is said that linear staplers and endoloops have comparable results to above mentioned conventional equipments [4].

Various complications might occur while dissecting the gall bladder using an instrument bound to electrocautery pole. The heat produced may elicit gallbladder perforation, with a subsequent spillage of bile and stone and may even lead to intra-abdominal abscesses [5].

It was reported that nearby structures (vascular and/or biliary structures) might be seriously injured by using high frequency electrocautery. Furthermore, bile leakage may occur following clips being slipped off, or central ischemic

necrosis causing complication in either ways [6]. HS has been widely approved to be a reasonable substitute for cystic duct closure with minimal complications [7].

Since the introduction of the ultrasonically activated scalpel (Harmonic – Ethicon Endo Surgery INC - Johnson & Johnson Medical) of this relatively new technology a decade ago, its usage has been rocketing by many centers. Its technology relies on the application of ultrasound within the harmonic frequency range to tissues and allows 3 effects that act synergistically: coagulation, cutting, and cavitation [8].

The ultrasonically equipped instruments were genuinely developed in order to minimize the co incidental adverse effects happening with electrocautery [9, 10].This new scalpels have the advantages of reduced lateral energy spread, as well as lesser smoke emission. There a broad range of activities performed by HS, ranging between dissection, grasping, cutting and coagulation at a significant low temperature (100°C) than either electrocautery or laser (150, 200 °C respectively)[11] .

This study investigates efficacy of HS in the closure of the cystic artery and duct, its beneficial aspects and, if it is a safe instrument**.**

MATERIALS AND METHODS

After Ethical committee approval, and sample size calculation. 77 patients with gallbladder lithiasis and/or gallbladder polyp scheduled for elective laparoscopic cholecystectomy were enrolled from December 2013 to June 2015 in the Department of Surgery, Tanta University, Egypt (A University Tertiary referral hospital).

Patients were excluded from the study pole if they had: previous history of open upper abdominal surgery, acute cholecystitis, patients with stones in the common bile duct, cystic duct >5mm, liver dysfunction and/or coagulopathy.

In the study there were 2 patients needed additional clipping of the cystic duct due to large cystic duct more than 5mm and these patients were excluded from the study.

After history taking and clinical examination of the patients assessing the signs and symptom of gallstone and/or chronicity of liver disease if present. Apart of the routine investigations, liver functions, and hepatic virology markers and abdominal ultrasound are carried out to assess the liver condition.

The study was conducted after obtaining an informed written consent from all included patients demonstrating all the details of the procedure and expected course of the perioperative period, and any possible complications**.** The surgical procedure was carried out by two consultant level surgeons with comparable level of training and experience, adopting the same surgical steps.

Surgical technique:
In the morning of the procedure, all patients received their medical treatment, and premedicated prior to arrival to the operating theater (OR). After arrival to OR the patients were monitored by the anesthesia team using the five stander ASA monitor, and IV access was inserted. Prophylactic antibiotic is given within an hour prior to induction.

All patients received general anesthesia using a titrated dose of propofol, rocuronium, midazolam, and fentanyl. Control of the airway was carried out using an endotracheal tube, and controlled mechanical ventilation. After induction an oro-gastric tube is inserted to deflate the stomach. Patients were positioned supine in an anti-trendelenburg position and inclined laterally to the left at an angle of 30 degrees to facilitate exposure of the hepatic region.

The set of laparoscopic appliances is placed cranially and to the right of the operating table. The abdomen was insufflated to a pressure of 12 mmHg, then a large bore trocar (11-mm) is introduced in the periumbilical region, through which 30° a laparoscope was introduced. Under video assistance another three trocars were inserted in the right hypochondrium, subxiphoid area, and right hip.

The HS is used for dissection of the cystic artery and duct. When both artery and duct are well visualized and isolated, their section is performed with a single application of HS at the power level ‘‘1’’ (less cutting, more coagulation) due to avoidance of bile leakage.

It is important to close the blades carefully and slowly and to avoid lateral traction on the structure. In case of mega cystic ducts sizing more than 5mm an extra ligature with clips is needed. To assess its diameter, the duct is positioned between the blades of the ultrasonically activated scalpel: if the cystic duct cannot be entirely included between them, an extra ligature is necessary.

The HS was used for dissection in the Calot’s triangle, and liver bed with the power level set at ‘‘5’’ (more cutting, less coagulation).

Finally, insertion of a subhepatic tube drain is performed before ending the procedure.

RESULTS

In this study 75 patients aged between 18 and 70 years with a median 38.5 ± 13.3years were included. Their gender distribution was 42 females and 33 males. The BMI of the included patients ranged between 21.8 and 38 with a median 28.9 ± 4.4. Regarding the co-morbidity 5 patients had hypertension, and 6 patients were diabetic. The indication for LC was gallstones in 72 cases and there were 3 cases of gallbladder polyps.

LC was successful in all included patients, with no need to conversion into open technique. Gall bladder perforation occurred in 7 cases (9.3%).

The average duration of the procedures of the study was 35.6 ± 7.1 min ranging between 25 and 68 min. No mortality was observed in the postoperative period, and no intraoperative bile duct injury or perioperative bleeding were reported. Nevertheless the major postoperative morbidity rate was 4.0% (only 3 cases): two patients had port site infection (2.6%), and one patient suffered from bile leak (1.3%) from accessory duct of Luschka, and the integrity of the biliary tract was assessed using magnetic resonance cholangiopancreaticogram, and the patient was treated conservatively.

The average postoperative hospitalization period was 1.62 days ranging from 1 to 7 days. The six month follow up for all patients was uneventful.

DISCUSSION

After 5 years of the introduction of LC, there was a general acceptance to consider it as the gold stander [12,13]. Titanium made surgical clips (SC) was frequently used for cystic duct closure in the earlier period [14, 15]. It is evident that leakage from common bile duct is intolerable complication, and hence the cystic duct should be totally sealed. Despite the popularity and relative safety of SC, a hazardous complication of bile leakage can take place due to SC slippage from previously clipped cystic bile duct stump [16]. Moreover, the Titanium SC could fell from the holder during SC application [17] causing various complications [18].

Nowadays, the efficacy and safety of HS for gallbladder dissection are concurred by numerous randomized studies. Since its early introduction in 1999, reports have demonstrated the positives of the surgical manipulation (dissection, coagulation, division, and closure of the cystic duct) using HS [6]. HS denatures protein by means of ultrasonic vibrations at a frequency of 55500 Hz with a vibratory excursion of 50–100 μm. The vibration transfers mechanical energy to the tissue, resulting in simultaneous cutting and coagulation. The vibrating ultrasonic dissector produces a coagulum of denatured protein and blood clot that occludes adjacent blood vessels and reduces bleeding. Vibration of the dissector scalpel blade does not generate as much heat as monopolar cautery or laser cautery, and the vibration in potential spaces results in cavitations, which may facilitate tissue dissection [19]. HS provides an excellent alternative to electrocautry in patients with implantable pace maker, as there is no detectable electrical current in the field [20].

Because data are conflicting regarding the potential benefits and risks of HS in laparoscopic cholecystectomy, this paper attempts to further explore such outcomes that could be related to tissue handling and any resulting tissue injury.

The intra-operative complication with high frequency during laparoscopic cholecystectomy is gallbladder perforation, and this may be caused by either traction by a grasper or dissection by an electro-cautery [21].The overall incidence of gallbladder perforation in the study using HS was 9.3% (7 cases).

Matching findings were published by Tharwat [3], Zanghi[4], and varuan[22] at a rate of 7.1%, 6.98%, and 16.7% respectively.

The manufacturer of HS stresses on its potential safety when applied to vessels less than 5 mm like the cystic artery, and that perioperative bleeding is not considered an anticipated complication. It is noted that there was no record of postoperative bleeding in any patient included in this study.

Narrow area of thermal lesioning is considered one of the major merits of the HS. This advantage makes the heat generated lesion from dissection in the liver bed much more lower when compared to monopoler diathermy[23] allowing the operator to use the harmonic dissector safely even near to important viscus as the common bile duct with no fear of thermal injury. On the other hand, monopolar electrocautery may cause thermal injury to the biliary tract leading to a broad range of complications such as bile leak, biliary stricture, or biliary fistula, and it also cannot be used for cystic duct closure [24, 25].

There is an ongoing debate regarding the use of HS for dissecting and securing the cystic duct and the fear of postoperative bile leak could be a limiting factor for its widespread use, particularly in mega cystic more than 5mm which requires an extra knot to securing the duct stump. The main finding of the present study is the absence of either minor or major bile leaks from the cystic-duct stump, except one case suffered from postoperative bile leak (1.3%) from accessory duct of Luschka, and the integrity of the biliary tract was assessed using magnetic resonance cholangiopancreaticogram MRCP, and the patient was treated conservatively, which is according with others reports (Table 1).

Table: 1.Incidence of bile leakage in HS experience in sealing and division of the cystic duct

Author	Year	No. of cases	bile leak
Huscher et al.[6]	1999	50	1
Huscher et al.[8]	2003	331	7
Godina et al.[26]	2004	115	0
Westervelt et al.[27]	2004	98	0
Tebala et al.[28]	2006	100	0
Bessa et al.[29]	2008	60	0
Vu et al .[30]	2008	22	0
Gelmini et al.[2]	2010	78	0
Redwan et al.[31]	2010	80	0
El nakeeb et al.[32]	2010	60	1
Kandill et al.[3]	2010	70	0
Jain et al.[33]	2011	100	0
Varun et al.[22]	2012	30	0
Wills et al.[34]	2013	57	1
Zanghi et al.[4]	2014	38	0
Ramos et al.[35]	2015	125	0
Total		1414	10

A comparative study had the highest frequency of bile leakage, the results were postulated to compromising of one group by a trainee operator responsible for the high rate complications[6,8].The frequency of bile leakage by HS were 0.7 % (10/1414), which is according to bile leaks from cystic duct occluding by clips [36, 37].

Although the reported bile leaks in clipless cholecystectomy occurred probably by temporary sealing of the cystic duct by harmonic shears, it is worth remind that post-cholecystectomy bile leaks most commonly occur due to injury of the common bile duct [38], and could also come from accessory duct of Luschka [39,40] .

In the current research, the mean operative time was 35.6 ± 7.1 min ranging between 25 and 68 min. The shorter mean operative time using HS can be postulated to array of factors such as, lower incidence of gallbladder perforation leading to omitting the time used for retrieval of spilled stones or in abdominal lavage. HS is a multifunctional device used to replace several instrument used in the LC namely, the dissector, clip applier, scissors, and electrosurgical hook or spatula. Finally, using harmonic scalpel does not elicit smoke with only slight mist generated from its action, this fact led to decreasing evacuation the abdomen to clean smoke [41.

The use of this procedure is only hindered by size of the cystic duct particularly if it exceeds 5 mm in diameter; an extra knot will be required.

Turning to the other point, the main negatives of harmonic dissection is the price of the device, even if compared with combined cost of using multiple disposable instruments (scissors, a clipper, an electrocautery hook, and a grasper): this is particularly true if the surgical unit is equipped with reusable instruments [42, 43, 44]. However, the major goal of this study was to investigate and demonstrate the effectiveness and reliability of the HS on the closure of the cystic duct. Therefore, we did not observe and calculate the total cost of the operation.

The HS may have a cost –benefit in centers having high rate of procedures, where the reduced time of operation may outweigh the frequency of procedures done daily [45, 46].

CONCLUSION

HS is an efficient tool for complete hemo-biliary sealing with high safety profile. HS enhances the operative course of elective laparoscopic cholecystectomy as its use is associated with a shorter operative time, and lower incidence of gallbladder perforation. The major demerit is its relatively high cost, and limited use in mega cystic duct sizing more than 5 mm.

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