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ORIGINAL ARTICLE

Is LigaSure a safe cystic duct sealer? An *ex vivo* study

Emad Abdallah, Mohamed Abd Ellatif*, Saleh El Awady, Alaa Magdy, Mohamed Youssef, Waleed Thabet, Ahmed Lotfy, Ayman Elshobaky, Mosaad Morshed

Department of General Surgery, Mansoura University Hospital, Mansoura, Egypt

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Summary *Background:* To compare the efficacy and safety of both mechanical methods (clips) and electrosurgical instruments, harmonic scalpel (HS) and LigaSure (LS), for securing the cystic duct during laparoscopic cholecystectomy (LC).
Methods: During the study period from October 2010 to October 2012, 458 patients with gallbladder stones underwent LC. A total of 38 patients were excluded from the study for different reasons. The gallbladder was excised laparoscopically through the traditional method. The gallbladder specimens of the patients were divided into three equal groups randomly, and the distal part of the cystic duct was sealed *ex vivo* using ligaclips (Group A), HS (Group B), and LS (Group C). The gallbladders were then connected to a pneumatic tourniquet device and we very gradually increased the pressure with air. The bursting pressure of the cystic duct (CDBP) was measured and differences between the three groups were calculated.
Results: The mean CDBP was 329.7 ± 38.8 mmHg in the ligaclip group, 358.0 ± 33.1 mmHg in the HS group, and 219.7 ± 41.2 mmHg in the LS group. A comparison of the mean CDBP between the groups indicated the superiority of HS over ligaclip and LS. CDBP was significantly higher in the ligaclips group compared with the LS group ($p < 0.001$). HS and ligaclips were found to be safe sealers as their mean CDBP was found to be higher (>195 mmHg) than the maximum common bile duct pressure, whereas for LS the CDBP range was 150–297 mmHg, indicating that it is not safe for sealing.
Conclusion: HS is a safe alternative to clips. In fact, it was even safer than clips. By contrast, LS is not safe for cystic duct sealing.

Conflicts of interest: None.

* Corresponding author. Department of General Surgery, Mansoura University Hospital, El Gomhoria Street, Mansoura, Egypt.
E-mail address: surg_latif@hotmail.com (M.A. Ellatif).

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1. Introduction

Gallstone disease is common, and cholecystectomy is the treatment of choice for symptomatic disease.[1] Simple metal clips have been used by most surgeons to close the cystic duct since Professor Muhe reported the first successful laparoscopic cholecystectomy (LC) in 1985.[2] However, these clips have been known to migrate into adjacent structures, lead to strictures due to a foreign body response, serve as a nidus for stone formation, and occasionally fall off and result in substantial morbidity.[3]

One problem with LC is the occurrence of postoperative cystic duct leakage (incidence rate, 0.6–2%), which may be related to insufficient closure of the cystic duct after the standard closure with two metal clips.[4] Consequently, different techniques have been proposed for closing the cystic duct including using resorbable clips and performing ultrasonic dissection. In recent years, bipolar energy sources, such as LigaSure (LS), have been used for vascular sealing and investigated for closing the cystic duct.[5]

Contraction of the sphincter of Oddi is the major cause of common bile duct pressure (CBDP). The mean basic CBDP is 15 mmHg (range, 5–35 mmHg) and increases to 135 mmHg (range, 95–195 mmHg) during phasic contractions of the sphincter (4 times/min). Therefore, any sealing method that leads to bursting pressures of the cystic duct (CDBPs) $>$ 195 mmHg could be reasonable.[6]

In the initial years of their use, there were insufficient data about the efficacy and safety of harmonic scalpel (HS) and LS for cystic duct sealing, especially about LS. Therefore, this study was carried out to verify the safety and efficacy of HS and LS for achieving safe closure of the cystic ducts after LC.

2. Materials and methods

Between October 2010 and October 2012, 458 patients with symptomatic gallbladder stones who were admitted to our university hospital were eligible for this prospective, randomized study. LC was performed at our hospital. The exclusion criteria included perforation of the gallbladder during surgery and acute cholecystitis. After obtaining informed consent from all patients to use their gallbladder specimens for the study, the specimens were sent for histopathological analysis. A total of 28 cases were excluded from the study due to perforation of the gallbladder during dissection (n = 17) and acute cholecystitis (n = 11). Ten specimens were excluded during pressure measurement studies. Thus, specimens from 420 patients were eligible. The eligible patients were randomized into three groups (according to the *ex vivo* cystic duct sealing method) using sealed envelopes. The envelopes were drawn and opened by an assistant who was not involved in this study before the operation. The three groups were as follows: (A) ligaclips, (B) HS, and (C) LS.

LC was performed under general anesthesia using the traditional four-port method in the "American" position. A pneumoperitoneum was created using a Veress needle with a maximized pressure of 15 mmHg. A zero-degree optic scope was used.

In all groups, LC was performed using the traditional method, which involved dissection of Calot's triangle using a monopolar hook and then isolation of the cystic duct and cystic artery using curved dissecting forceps. Closure of the cystic duct was performed using (medium/large) 10-mm titanium ligaclips (Ethicon Endo-Surgery, Cincinnati, OH), with two clips on the CBD side and one clip on the gallbladder side and then dividing it in between. The cystic artery was also clipped with two metal clips and divided in between. Mobilization of the gallbladder from the liver bed was completed using a monopolar hook. The gallbladder was retrieved with the ligaclips *in situ* after widening of the 10-mm port. Once the gallbladder is removed, it was prepared *ex vivo* for bursting pressure measurement.

In Group A, the ligaclip was removed and two fresh clips were placed to ensure that the fresh clips are competent.

In Group B, the ligaclip was removed and the HS device was set at level 2 (less cutting and more coagulation). A harmonic ace laparoscopic instrument (Ethicon) was applied to the cystic duct at two levels, starting near the neck of the gallbladder first without complete division of the duct (8 peeps) and then reapplied more distally until the duct is cut completely (Fig. 1A).

In Group C, the ligaclip was removed and the cystic duct was sealed using a 5-mm LS laparoscopic instrument (Valleylab, Boulder, CO, USA) at two levels, with the generator set at level 2 and the instrument knife applied distally (Fig. 1B).

Then a 14-French catheter was inserted from the fundus of the gallbladder and fixed with two rings of purse string 2/0 silk suture. The catheter was connected to a pneumatic tourniquet device (WIKA, Cairo, Egypt). The collected gallbladder was then immersed in a saline-filled kidney dish. The pressure emerging from the tourniquet device was increased very slowly and steadily until air leakage (bubbling) was observed from the sealed cystic duct. At this point, the pressure in the tourniquet device was recorded as the bursting pressure (Fig. 2A–C). We excluded cases in which the bubbling occurred from places other the stump of the cystic duct (n = 10).

Statistical analysis was performed using SPSS version 10.0 software (SPSS Inc., Chicago, IL, USA). Chi-square test was used for categorical variables and independent samples t test was used for continuous variables between the groups. A p value $<$ 0.05 was taken to be significant.

3. Results

During the study period from October 2010 to October 2012, 458 patients with gallbladder stones underwent LC. A total of 38 patients were excluded from the study due to perforation of the gallbladder during dissection (n = 17) and acute cholecystitis (n = 11). Ten specimens were excluded because bubbling occurred from various places other than the stump of the cystic duct. Thus, a total of 420 patients were eligible and randomly divided into three equal groups based on the use of ligaclips, HS, and LS for closure of the cystic duct.

There was no statistically significant difference between groups regarding age, sex distribution, and comorbidities. The mean CDBP was 329.7 $\pm$ 38.8 mmHg in the ligaclip