Laparoscopic Cholecystectomy with the Use of Harmonic Scalpel

SALAH FATHI, M.D.* and MOAWAD S. ABD EL-HAFEZ, M.D.**
The Department of General Surgery, Matarya Teaching Hospital* and Damanhour National Medical Institute**

Abstract

Introduction: The ultrasonically activated (Harmonic) scalpel has proven to be an effective, efficient, and safe instrument for dissection and hemostasis in both open and laparoscopic surgical procedures. This Harmonic scalpel work on the tissue’s cutting and coagulating very effectively with the replacement of the high frequency current, which can be connected with diverse complications. The principle is transforming of the electric power into mechanical longitudinal movement of the working part of the instrument, by piezo-electrical transducer situated in the hand piece. The primary use of the Harmonic scalpel in laparoscopic cholecystectomies has been for the division of the cystic artery and liver bed dissection. Advancements in the Harmonic scalpel blade tip now provide for the reliable ultrasonic division and closure of the cystic duct.

Methods: This was a prospective study of 40 patients undergoing laparoscopic cholecystectomy in Matarya Teaching Hospital using the harmonic scalpel. These were elective patients for gallstones disease diagnosed with Ultrasound. Harmonic scalpel was used as the sole instrument for division of the cystic duct and artery as well as dissection of the liver bed. The average age of patients was 42.5 years (range 22-61 years) with 8 male and 32 female patients. The average length of inpatient stay, procedure duration, and complications were compared with the data of a homogenous control group of patients who were treated using monopolar electrosurgery and clips.

Results: Neither major complications nor bile duct injuries were detected in either group, and no statistically significant difference was found between the 2 groups in terms of the incidence of postoperative complications. However, the mean operative time was significantly shorter in patients treated with the Harmonic scalpel.

Conclusion: The Harmonic scalpel is not only a safe and effective instrument but also a reliable substitute for clips because it provides complete hemo-biliary stasis. Even if the study revealed no differences with regard to postoperative complications, the Harmonic scalpel represents a viable alternative because of the shorter operation time and cost savings that are inherent in a procedure using it as a single instrument.

Key Words: Laparoscopic cholecystectomy – Harmonic scalpel.

Introduction

LAPAROSCOPIC cholecystectomy is the "gold standard" in the treatment of symptomatic gallbladder lithiasis. The technique of laparoscopic cholecystectomy still has areas of refinements, including complications of clips being dislodged. The use of ultrasonically activated scalpel for tissue cutting and coagulation is a potential replacement for electrosurgery, which can be related to different complications. The harmonic scalpel has been used safely in other general surgical operations. The primary use of the Harmonic scalpel in laparoscopic cholecystectomies has been for the division of the cystic artery and liver bed dissection. Advancements in the Harmonic scalpel blade tip now provide for the reliable ultrasonic division and closure of the cystic duct.

The standard laparoscopic cholecystectomy is usually performed using a monopolar electrosurgical hook for dissection and clips for occlusion of the cystic duct and cystic artery. Alternative techniques for duct ligation have included linear stapler, endoloops, or sutures, which are however, seldom used [1,2].

Even if laparoscopic cholecystectomy is considered a safe procedure, some pitfalls are associated with the use of the monopolar electric scalpel, such as the high risk of thermal injuries and significantly more common postoperative biliary complications. Furthermore, not to be underestimated are visceral and solid organ injuries caused by the frequent instrument exchange [3] such as bile leakage due to slippage of the clips [4-8].

Designed as a safe alternative to electrocautery for the hemostatic dissection of tissue, the ultrasonically activated (Harmonic) scalpel was introduced into clinical use nearly a decade ago.

This innovative method of cutting tissue was based upon the coagulating and cavitation effects
provided by a rapidly vibrating blade contacting various tissues [9,10]. The resulting decrease in temperatures, smoke, and lateral tissue damage placed the Harmonic scalpel in contrast to the effects seen with the more traditional electrosurgery/cautery. In addition, the elimination of inadvertent, sometimes unrecognized, electrical arcing injuries with their potentially hazardous sequelae supported the role of the Harmonic scalpel as a potentially safer instrument for tissue dissection. Since its inception, the Harmonic scalpel has gained significant clinician acceptance and applications.

Furthermore, total Harmonic scalpel dissection in the performance of a laparoscopic cholecystectomy is a technique described only in the European literature [11] and, at best, is only anecdotal in the United States. This study was undertaken to demonstrate the efficiency, safety, and cost effectiveness of the Harmonic scalpel as the sole instrument to achieve complete hemobiliary stasis in the performance of laparoscopic cholecystectomies.

A Harmonic scalpel is a piece of medical equipment used in surgical procedures as an option to a steel scalpel. It uses ultrasound technology to cut tissues while simultaneously sealing them the edges of the cut. The system typically is composed of a hand-held ultrasonic transducer, generator, hand switch, foot pedal, and scalpel that serves as the cutting instrument.

During the procedure, the scalpel vibrates in the 55,500 hertz range while cutting through a tissue and at the same time sealing them by employing protein denaturation to stop bleeding.

The ultrasonically activated scalpel (Harmonic-Ethicon Endo Surgery INC - Johnson & Johnson Medical SPA Somerville, NJ) was introduced into clinical use more than a decade ago. 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 [12]. The temperature obtained and the lateral energy spread are lower than those detected when the monopolar hook is used, thus reducing the risk of tissue damage [13,14,15]. The Harmonic scalpel is also an effective tool for closure of biliary ducts and vessels whose diameter is 4mm to 5mm (as certified by the FDA in 2006).

Several studies [16,17,18] have demonstrated the effectiveness and safety of the use of the Harmonic scalpel for dissection of the gallbladder, but only a few researchers have examined its efficacy in the closure of the cystic artery and duct.

Thus, in an attempt to fill this gap, this study, albeit at a preliminary stage, aims to demonstrate that the ultrasonically activated scalpel is a safe instrument that, similarly to the standard clips, is effective for a correct and complete closure and division of the cystic duct and artery in laparoscopic cholecystectomy.

Moreover, the use of a single instrument during the whole procedure averts or decreases the risk of distant organ injuries [19].

Patients and Methods

During a 2-year period, 80 consecutive laparoscopic cholecystectomies were performed in the Department of Surgery, in patients affected by gallbladder lithiasis, and acute cholecystitis. Thirty-two patients were males, and forty-eight patients were females with an average age of 51.5 years (range, 17 to 84). All the patients were classified according to the American Society of Anesthesiology (ASA) physical status classification system, and their average BMI (Body Mass Index) was 22.6 (range, 12.7 to 39). All the patients underwent laparoscopic cholecystectomy performed by 2 surgeons with similar experience and skill levels, who adopted the same approach and techniques.

<table>
<thead>
<tr>
<th>Table (1): Preoperative data.</th>
<th>Group A (Harmonic)</th>
<th>Group B (Non Harmonic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of cases</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>Males (%)/Females</td>
<td>16 (40%)/24 (60%)</td>
<td>16 (40%)/24 (60%)</td>
</tr>
<tr>
<td>Medium Age (years ± days)</td>
<td>52.05±18.13</td>
<td>51.08±16.41</td>
</tr>
<tr>
<td>Indications [n (%)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute cholecystitis</td>
<td>5 (12.5%)</td>
<td>6 (15%)</td>
</tr>
<tr>
<td>Simple gallstones</td>
<td>32 (80)</td>
<td>31 (77.5%)</td>
</tr>
<tr>
<td>Empyema</td>
<td>3 (7.5%)</td>
<td>3 (7.5%)</td>
</tr>
<tr>
<td>Preoperative Ultrasound [n (%)]</td>
<td>39 (97.5%)</td>
<td>40 (100%)</td>
</tr>
<tr>
<td>Preoperative MR-Cholangiography [n (%)]</td>
<td>9 (22.5%)</td>
<td>6 (15%)</td>
</tr>
<tr>
<td>Preoperative Endoscopic Retrograde</td>
<td>4 (10%)</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>Cholangiopancreatography (ERCP) [n (%)]</td>
<td>4 (10%)</td>
<td>4 (10%)</td>
</tr>
<tr>
<td>Preoperative CT-scan [n (%)]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Patients were retrospectively divided into 2 groups according to the instruments used for division of the cystic artery and duct as well as for dissection of the liver bed. On the one hand, group (A) consisted of 40 patients who were all treated with the ultrasonically activated scalpel as the sole instrument used in the whole procedure (an additional ligature with clips was performed in 7 patients (17.5%) with a cystic duct of more than 4mm in diameter. On the other hand, group (B) comprised 40 patients in whom dissection and coagulation were performed using monopolar coagulation, and section of the artery and duct with clips. The 2 groups were comparable for age, sex, indication for cholecystectomy, average length of hospital stay, procedure duration, complications and combined procedures. Patients were randomly treated either with the ultrasonically activated scalpel or with clips.

Operative procedures were performed with the patient under general anesthesia and placed in the standard supine, crucifix, reverse-Trendelenburg position. Pneumoperitoneum was achieved by either Veress needle or visually guided cannula CO2 insufflation. All procedures were performed through 2 operative ports and a camera port. A gastric tube is placed into the stomach at the beginning of the procedure. Prophylactic intravenous antibiotics are administered before surgery.

A grasper forceps (reusable) is inserted to grasp and draw the gallbladder fundus towards the right axilla, and a second grasper (reusable) is introduced to apply gentle rightward traction on the infundibulum, thus improving the exposure of Calot’s triangle.

Dissection of the gallbladder was initiated at the Triangle of Calot with identification, skeletonization, and division of the cystic duct and artery.

Two patients with visibly large cystic ducts (greater than 5mm) underwent additional Endoloop closure of the duct remnant.

No intraoperative cholangiograms were performed. Any patient presenting with clinical evidence of cholecodolithiasis or biliary pancreatitis underwent preoperative endoscopic retrograde cholangiopancreatography (ERCP) evaluation and treatment. All patients were evaluated up to 4 weeks postoperatively in the office. A cost comparison was carried out to determine any potential cost benefit in using the Harmonic scalpel as a single disposable instrument.

Group (A) (Harmonic): The Harmonic scissors are inserted and used as a dissector 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 ultrasonically activated scissors on minimum position. It is important to close the blades carefully and slowly and to avoid lateral traction on the structure. In case of large cystic ducts (with an external diameter exceeding 4mm), an additional ligature with clips is performed. 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 additional clips are placed on the cystic duct that is then sectioned distally using the Harmonic scalpel. The gallbladder dissection from the liver bed is carried out using the ultrasonically activated scalpel in the maximum position from the infundibulum to the fundus, taking advantage of the positive effects of ultrasound, cavitation, and coagulation.

Results

The mean operative time, conversion rates, postoperative hospital stay, and morbidity for each group were analyzed and compared with each other. Laparoscopic cholecystectomy was successfully completed in 79 patients (98.75%). Conversion was necessary in 1 patient (1.25%) in group A due to diffuse peritoneal adhesions. Additional cystic duct clipping was necessary in 7 patients (7.15%) in group A because of a large duct (3 cases of common bile duct stones, 1 case of acute cholecystitis, and 3 cases of gallbladder empyema). The median operative time varied depending on the degree of pericholecystic and cholecystic and/or associated intraperitoneal adhesions with an average incision to closure time of 42 minutes. Division of the cystic duct by the Harmonic scalpel required approximately 2 to 3 minutes, depending on the ductal thickness and associated inflammation. A drainage tube was positioned in 44 cases (55%), and it was maintained for at least 24 hours (Table 2). Median postoperative hospital stay of all patients in the 2 groups was 2 days. Absence of mortality was observed in the postoperative period together with a major complication rate of 2.5% (2 cases); a case of hemoperitoneum due to bleeding of the hepatic bed laparotomically treated (Group B), one case of peritoneal fluid collection treated with percutaneous drainage Group (A) in patients.

With severe acute cholecystitis in whom, an MR-cholangiography demonstrated the integrity of the biliary tract. No bile leakage and common bile duct lesions were observed.
Table (2): Postoperative data.

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median postoperative hospital stay</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Complications</td>
<td>1 (2.5%)</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>Peritoneal fluid collection</td>
<td>1</td>
<td>–</td>
</tr>
<tr>
<td>Hemoperitoneum</td>
<td>–</td>
<td>1</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Percutaneous drainage</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Surgically treated</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Medically treated</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

On the basis of the subdivision of the cases into the 2 groups under study, we compared all clinical results. As far as conversion rate (Group A vs. Group B) 1 (2.5%) vs. 0 (0%), morbidity rate (2.5% vs. 2.5%), and median hospital stay (2 vs. 2 days) are concerned, no statistically significant difference has been recognized between the 2 groups. Overall, a statistically significant difference has resulted from the use of the Harmonic scalpel (Group A) and monopolar coagulation plus clips (Group B), which makes the former more advantageous than the latter. Six months after the procedure, all patients were in good health and the follow-up was uneventful.

Discussion

Several studies [3,12,19] have confirmed the effectiveness and safety of the use of the ultrasonically activated scalpel for dissection of the gallbladder, but only a few authors have examined its efficacy in the closure of the cystic artery and duct. In 1999, the use of ultrasonically activated shears for both dissection and closure/division of the cystic duct and artery was first reported [21].

The most significant result to emerge from this study is the absence of bile leaks and postoperative hemorrhage in patients who underwent LS with the Harmonic scalpel as the sole instrument. In line with Bessa [3], Westervalt [19] and Tebala [20], this study clearly demonstrates that the Harmonic scalpel is an effective and safe tool for the closure of both the cystic duct and artery in patients who undergo laparoscopic cholecystectomy.

Except for the 2- to 3-minute interval required for cystic duct division, use of the Harmonic scalpel did not adversely affect the length of procedures. In fact, properties intrinsic to the Harmonic scalpel (cavitation and smokeless coagulation) seem to provide an advantage over electrocautery in the dissection of the gallbladder and may enhance surgeon performance. Certainly, Harmonic scalpel division of the cystic duct could be utilized independently of the direction of gallbladder dissection.

One additional benefit of Harmonic scalpel dissection of the liver bed is the more effective closure of the ducts of Luschka. While rarely of clinical significance, bile leakage from the liver bed may contribute to postoperative pain, small bilomas, and the occasional return to the operative room.

Objective data documenting length of hospitalization and resumption of normal activities were not studied. In a previous investigation, Tsimoyiannis et al. [20] demonstrated comparable recovery times in patients undergoing laparoscopic cholecystectomies using ultrasonically activated shears for dissection when compared with patients undergoing the more traditional clip and cautery technique. Subjective observations throughout this study would substantiate this finding.

The data collected and analyzed show a statistically significant difference in the average operative time in the 2 groups, which makes the procedure performed with the Harmonic scalpel preferable. This is motivated by the use of the Harmonic scalpel as the sole instrument, which prevents the extraction and insertion of different instruments and subsequent waste of time. In addition, the electronically activated Harmonic scalpel produces almost no smoke [3] (in fact it does not work at high temperatures). Thus, the visibility of the operative field is preserved during the whole procedure, and there is no need to remove the smoke and to recreate the pneumoperitoneum.

Laparoscopic cholecystectomy performed with an ultrasonically activated scalpel is feasible and effective. The method offers several considerable advantages, such as the utilization of a single instrument both for dissection of the gallbladder from the hepatic bed and division of the artery and duct. Furthermore, because of the minimal thermal dispersion, the use of the Harmonic reduces the risk of injuries. Nevertheless, the main obstacle hindering the applicability of the procedure is the cystic duct size: If it exceeds 4mm to 5mm in diameter, an additional ligature is necessary.

Conclusion:

The Harmonic scalpel is a safe, efficient, and practical instrument to use during laparoscopic cholecystectomies, and its role can be expanded to include complete hemobiliary stasis.
References


