

Laparoscopic Cholecystectomy With Harmonic Scalpel

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ABSTRACT

Background: Laparoscopic cholecystectomy is the “gold standard” in the treatment of symptomatic gallbladder lithiasis. Nevertheless, some pitfalls are associated with the use of the monopolar hook, such as the risk of thermal injuries and biliary complications. By contrast, the ultrasonically activated scalpel, ie, Harmonic (Ethicon Endo Surgery INC - Johnson & Johnson Medical SPA, Somerville, NJ) in laparoscopic cholecystectomies has been increasingly used for dissection of the gallbladder and for division of vessels and the cystic duct, because it reduces the risk of thermal injuries.

Methods: During a 2-year period, in a personal series of 95 consecutive patients, the Harmonic scalpel was used as the sole instrument for both division and dissection of the cystic artery and duct. 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 electro-surgery 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 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 hemobiliary 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, Ultrasonic scalpel, Monopolar coagulation.

INTRODUCTION

Laparoscopic cholecystectomy (LC) is considered worldwide the “gold standard” in the surgical treatment of symptomatic gallbladder lithiasis and acute cholecystitis, because it offers well-known and more definite advantages in comparison with the laparotomic procedure.

The standard laparoscopic cholecystectomy is usually performed using a monopolar electro-surgical 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.⁴⁻⁷

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.⁸ 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.⁹⁻¹¹ 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).

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Several studies¹²⁻¹⁴ 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.¹⁵

METHODS

Patients

During a 2-year period, 185 consecutive laparoscopic cholecystectomies were performed in the Department of Surgery, Policlinico of Modena, in patients affected by gallbladder lithiasis, common bile duct stones, and acute cholecystitis. Seventy-four patients were males, and 111 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.

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 1 consisted of 95 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 17 patients (17.89%) with a cystic duct of more than 4mm in diameter). On the other hand, group 2 comprised 90 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, and combined procedures. Patients were randomly treated either with the ultrasonically activated scalpel or with clips.

The indications for cholecystectomy were acute cholecystitis or empyema in 39 patients (19 cases in group 1 and 20 in group 2) and simple gallstones in 146 (76 patients in

group 1 and 70 in group 2) of whom 11 (9 in group 1 and 2 in group 2) also had associated common bile duct stones. The 11 patients with stones in the common bile duct were previously treated with endoscopic retrograde cholangiopancreatography (ERCP) plus sphincterotomy and endoscopic stone extraction. In all cases, the endoscopic procedure was successful.

The preoperative assessment was performed by abdominal ultrasound in all patients along with MR-Cholangiography in 35 cases and ERCP in 11 patients (**Table 1**).

Statistical Analysis

A comparison between qualitative variables was made using the X² test or Fisher's exact test where appropriate, while the Mann-Whitney test and the Student *t* test were chosen for non-normally and normally distributed variables, respectively. P<0.05 was considered statistically significant.

All analyses were conducted using the statistical software package STATA 9.2 for Windows, StataCorp LP, TX, USA.

Surgical Technique

In all cases, the surgical procedure is carried out with patients under general anesthesia. They are supine with their legs extended, in an anti-Trendelenburg position and inclined laterally to the left at an angle of 30 degrees to facilitate exposure of the hepatic region. A gastric tube is placed into the stomach at the beginning of the procedure. Prophylactic intravenous antibiotics are administered before surgery. The first surgeon stands between the patient's legs, and the 2 assistants stand on the patient's left and right side. The laparoscopic equipment is placed on the cranial right side of the operating table. A 12-mm trocar is introduced into the peritoneal cavity and placed in the periumbilical site with an open technique, and pneumoperitoneum to a pressure of 12mm Hg is created.

A 30° laparoscope is introduced through the umbilical trocar (#1), and 3 operative trocars are inserted in the left ipocondrium (12mm) (trocar #2), right ipocondrium (5mm) (trocar #3), and right hip (5mm) (trocar #4) under video guidance.

A grasper forceps (reusable) is inserted through trocar #3 to grasp and draw the gallbladder fundus towards the right axilla, and a second grasper (reusable) is introduced through trocar #4 to apply gentle rightward traction on the infundibulum, thus improving the exposure of Calot's triangle.

Table 1.
Preoperative Data

	Group 1 (Harmonic)	Group 2 (No Harmonic)	P
No of Cases	95	90	-
Males (%) / Females	37(38.95%) / 58 (61.05%)	37 (41.11%) / 53 (58.89%)	0.764
Medium Age (years \pm days)	52.05 \pm 18.13	51.08 \pm 16.41	0.705
Indications [n (%)]			
Acute cholecystitis	13 (13.68%)	15 (16.67%)	0.572
Simple gallstones	76 (80.00%) associated with common bile duct stones	70 (77.78%) associated with common bile duct stones	0.711
Empyema	6 (6.32%)	5 (5.56%)	0.827
Preoperative Ultrasound [n (%)]	94 (98.95%)	90 (100%)	0.329
Preoperative MR-Cholangiography [n (%)]	21 (22,11%)	14 (15,56%)	0.256
Preoperative Endoscopic Retrograde Cholangiopancreatography (ERCP) [n (%)]	9 (9.47%)	2 (2.22%)	0.037
Preoperative CT-scan [n (%)]	9 (9.47%)	10 (11.11%)	0.714
Combined Procedures, n (%)	22 (23.16%)	26 (28.89%)	0.374
Adhesiolysis	13	19	
Hepatic biopsy+Inguinal hernia repair	1	-	
Hepatic biopsy	2	4	
Peritoneal biopsy	1	-	
Hepatic biopsy + Adesiolysis	1	-	
Umbilical hernia repair + Adesiolysis	1	-	
Inguinal hernia repair	-	1	
Breast lumpectomy	-	1	
Appendectomy	1	-	
Hepatic cyst fenestration	1	-	
Nissen Fundoplication	1	-	
Common bile duct exploration	-	1	

Group 1 (Harmonic): the Harmonic scissors are inserted through trocar #2 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.³ It is important to close the blades carefully and slowly and to avoid lateral traction on the structure.⁸ 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. Intraoper-

ative cholangiography is performed only in some specific cases. When necessary, a small opening is made to introduce the catheter into the duct wall by using the ultrasonic scissors.⁸ Duct division is then carried out in the proximity of the opening made to perform cholangiography.

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.¹⁶

The instrument inserted through trocar #2 is not simply the same Harmonic scalpel but also the sole device used during the whole procedure.

Group 2 (monopolar coagulation plus clips): different instruments are used and introduced through trocar #2: first, a dissector and a monopolar hook, which are used to isolate and visualize the artery and the duct, and, second, clips (disposable) and scissors (disposable), which are used to close and to cut them. The indications for intraoperative cholangiography are the same and a similar technique using nonelectrified scissors is applied to perform it. The dissection from the liver bed is carried out using a monopolar hook.

In both groups, the gallbladder is extracted in a bag through the umbilical port, and the drainage is systematically performed in the first 30 patients of the 2 groups and afterwards only in some selected cases, such as severe acute cholecystitis, intraoperative bleeding, or accidental opening of the gallbladder during dissection.

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 184 patients (99.4%). Conversion was necessary in 1 patient (0.54%) in group 1 due to diffuse peritoneal adhesions. Additional cystic duct clipping was necessary in 17 patients (17.9%) in group 1 because of a large duct (8 cases of common bile duct stones, 4 cases of acute cholecystitis, and 5 cases of gallbladder empyema). Intraoperative cholangiography was performed in 18 cases (10 in group 1 and 8 in group 2). The median operating time (from the first skin incision to the last skin stitch) of the series was 72 minutes (range, 20 to 205) and was calculated by considering also the 35 procedures in which different laparoscopic operations were combined together. A drainage tube was positioned in 101 cases (54.5%), 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 (range, 1 to 16). Absence of mortality was observed in the postoperative period together with a major complication rate of 2.1% (4 cases): a case of hemoperitoneum due to bleeding of the hepatic bed laparotomically treated (group 2), a pleural suffusion medically treated (group 2), 2 cases of peritoneal fluid collection treated with percutaneous drainage (group 1) in patients with severe acute cholecystitis. In these 2 patients, an MR-cholangiography demonstrated the integrity of the biliary tract. No bile leakage and common bile duct lesions were observed (Table 3).

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 1 vs. group 2 = 1(1.05%) vs. 0 (0%) P=1, Fisher test), morbidity rate (2.11% vs. 2.22%, P=1), and median hospital stay (2 vs. 2 days, P=0.799) are concerned, no statistically significant difference has been recognized between the 2 groups. Nevertheless, median operative time was 60 minutes in group 1 versus 85 minutes in group 2 (P<0.001) when considering the whole series, whereas it was 60 minutes vs. 80 minutes (P<0.001) when considering those patients who did not undergo additional procedures. Overall, a statistically significant difference has resulted from the use of the Harmonic scalpel (Group 1) and monopolar coagulation plus clips (Group 2), 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^{3,8,15} 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

Table 2.
Intraoperative Data

	Group 1	Group 2	P
Median Operative Time [min (range)]	60 (20 - 205)	85 (45-150)	< 0.001
Median Operative Time Without Combined Procedures [min (range)]	60 (20 - 140)	80 (45-130)	< 0.001
Endobag [n (%)]	95 (100%)	90 (100%)	-
Drainage [n (%)]	32 (33.68%)	69 (76.67%)	< 0.001
Intraoperative Cholangiography [n (%)]	10 (10.53%)	8 (8.89)	0.707
Conversion Rate	1 for diffuse peritoneal adhesions (1%)	-	1

Table 3.
Postoperative Data

	Group 1	Group 2	P
Median postop hosp stay [days (range)]	2 (1 - 16)	2 (1 - 12)	0.799
Complications	2 (2.1)%	2 (2.22%)	1
Peritoneal fluid collection	2*	-	
Hemoperitoneum	-	1†	
Pleural effusion	-	1‡	

*Percutaneous drainage.

†Surgically treated.

‡Medically treated.

duct. In 1999, the use of ultrasonically activated shears for both dissection and closure-division of the cystic duct and artery was first reported.¹⁷

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,¹⁵ and Tebala,¹⁸ 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.

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 smoke⁵ (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.

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