

Is harmonic scalpel during laparoscopic cholecystectomy superior than clips and cautery technique?

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Abstract

The standard laparoscopic cholecystectomy is usually performed using a monopolar electrocautery for dissection and clips for occlusion of the cystic duct and cystic artery. Some pitfalls are associated with the use of the monopolar cautery and clips, therefore other alternative techniques have been described. Ultrasonically activated devices have been used for dissection and cystic duct ligation during laparoscopic cholecystectomy (LC) with encouraging results, however it does not gain widespread acceptance among surgeons. The aim of the present study was to compare the surgical outcome of LC performed by the harmonic scalpel to that performed by the conventional diathermy and clips.

Material and methods: This prospective randomized comparative study included 30 patients (group A) in whom LC was conducted using the conventional method by clipping both the cystic duct and artery with dissection of gallbladder from liver bed by monopolar electrocautery (clips and cautery method = CCM), and 30 patients (group B) who were operated on using laparoscopic harmonic scalpel (LHS) for closure and division of cystic duct and artery and for dissection of gallbladder from liver bed. Our primary end point was the biliary complications; however other intraoperative and postoperative parameters were included: bleeding, duration of operation, postoperative pain, and other complications.

Results: Demographic data was similar in both groups. The operative duration was shorter in LHS than CCM (56.3 min vs. 63.3 respectively, $p < 0.01$), with a significant less incidence of gallbladder perforation (6.66% vs. 20%, $p < 0.001$). No postoperative bile leak was encountered in LHS, but it occurred in 3% of patients in CCM. No patient developed post operative bleeding in both groups however the amount of postoperative drainage was significantly less in LHS (29 vs. 47.7, $p = 0.001$). Most of patients were discharged from hospital on 2nd postoperative day; however the delayed discharge was statistically higher in CCM (16.6% vs. 6.66%, $p < 0.01$).

Conclusion: LHS is a reliable, effective and safe tool in LC. It is a good alternative to standard monopolar electrocautery dissection with clipping of cystic duct and artery. It provides a shorter operative duration, less incidence of gallbladder perforation, and less hospital stay.

Abbreviations: CCM= Clip and cautery method, LC= Laparoscopic cholecystectomy, LHS= laparoscopic harmonic scalpel, HFMC= high frequency monopolar cautery, BDI= bile duct injury, CBC= complete blood picture, INR= international normalized ratio, LFT= liver function test, U/S= ultrasonography.

Introduction:

Laparoscopic cholecystectomy (LC) is the gold standard for the surgical treatment of symptomatic gallstones. The advantages of this surgical approach have included a positive impact on the postoperative quality of the patient's life as well as optimal short- and long-term results.¹

The standard laparoscopic cholecystectomy is commonly performed by means of monopolar electrocautery and titanium clips. The electrosurgical hook, spatula, and/or scissors, using high-frequency monopolar technology, have been used for gallbladder dissection while the clips are the most frequently used technique to achieve both cystic duct and artery closure in most centers.²

However several reports have pointed out special injuries and postoperative complications related to usage of cautery and clips: These include deep thermal damage to distant tissues and bile leakage due to slippage of the clips.³ Alternative techniques for gall bladder dissection and cystic duct closure have been described; however, these alternatives were used infrequently.² The ultrasonically activated (Harmonic) scalpel was designed as a safe alternative to electrocautery for the hemostatic dissection of tissue and was introduced into clinical use nearly a decade ago. Recently some centers are using harmonic scalpel not only for tissue dissection but also for closure of both cystic duct and artery during laparoscopic cholecystectomy,^{4,5} however this application is still not favored in many centers and till now, there is still no consensus about the best way of tissue dissection and cystic duct closure during cholecystectomy.

The objective of this study was to compare outcome of the traditional method of LC using monopolar diathermy and cystic duct clipping versus LC using harmonic scalpel as regards the biliary complication, bleeding, operative time and hospital stay.

Patients and methods:

60 consecutive patients with gallbladder stones planned to do laparoscopic cholecystectomy (LC) were included in a prospective comparative manner and were randomly assigned by using the sealed-envelope technique to 2 groups:

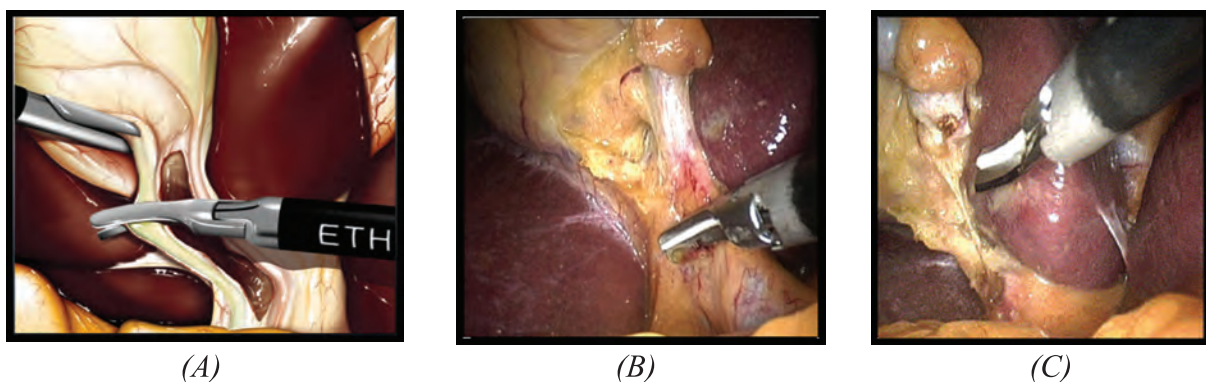
- 1- Group(A) that included 30 patients who were subjected to traditional laparoscopic cholecystectomy using monopolar cautery and clip applicator.
- 2- Group(B) that included 30 patients who were operated on using LHS that replaced both cautery and clips (Ethicon Endosurgery Ultracision harmonic scalpel, Generator 300).

Patients were recruited from authors' hospital at Ain Shams University Hospitals, Cairo, Egypt and Doctor Soliman Fakeeh Hospital, Jeddah, Saudi Arabia. Patients' age, sex, body mass index (BMI), and associated comorbidities were recorded. Preoperative investigations included: Pelvi-abdominal ultrasound, CBC, LFT, renal function, prothrombin time, INR, OR screening, ECG, and plain X-ray chest.

Patients who were excluded: Cases associated with common bile duct stone(s), empyema of the gallbladder, unfavourable intraoperative anatomy e.g, sessile gallbladder, very short cystic duct, wide cystic duct $5 \geq$ mm and abnormal laboratory investigation e.g abnormal serum bilirubin, alkaline phosphatase, gamma glutamil transferase (GGT).

Operative technique:

Laparoscopic cholecystectomy was performed as previously described.⁶ After the dissection of Calot's triangle, the cystic artery and proximal cystic duct were sealed with titanium surgical clips in group(A); this was followed by gall bladder dissection from its hepatic bed by electrocautery. In the second group(B) the artery and duct were sealed with harmonic scalpel and the gallbladder was removed using the same instrument. Harmonic scalpel was set at the power level "2" to give less cutting and more coagulation effect with powerful sealing. At the start, it was ascertained that there were no micro-calculi in the lumen of the cystic duct by moving the jaws of the harmonic scalpel up and down. The cystic duct was inserted between the jaws at a safe distance from common bile duct to avoid its damage then the jaws were closed until a click was heard. The harmonic was activated with great care to avoid stretching or rotating cystic duct but rather to keep it still until the gallbladder was detached from the cystic duct. The cutting points of the cystic duct were checked for any bile leakage. Finally, a closed intra abdominal drain in hepatorenal space was left in all patients **Figure(1)**.



Figure(1)(A): It was ascertained that there were no micro-calculi in the lumen of the cystic duct by moving the jaws of the harmonic ACE up and down.
 (B): The cystic duct was inserted between the jaws at a safe distance from common bile duct to avoid damage to this structure then the jaws were closed until a click was heard.
 (C): The cutting points of the cystic duct were checked for any bile leakage.

Patients were postoperatively reviewed and analyzed regarding: Clinical general and abdominal examination with daily chart for abdominal drain till discharge; U/S on 3rd and 10th postoperative days with special attention to the presence or absence of any sub-hepatic collection and laboratory investigation namely CBC and LFT. The operative time, intra-operative difficulties, and postoperative complications were recorded.

Statistical analysis:

All data analyses were performed with the Statistical Package for the Social Sciences

version 11.5 software (SPSS, Inc. Chicago, IL). The Student's t test was used for continuous variables. A value of $P < 0.05$ was considered statistically significant.

Results:

Patients' demographics data: in this work 60 patients were included, 51 females (85%) and 9 males (15%) with symptomatic gallstone disease, with a mean age 45 years (range 22-74 years). No statistically significant difference was found in age, sex, BMI and associated co-morbidities between both groups **Table(1)**.

Table (1): Demographic data, clinical characteristics and associated co-morbidities.

	Total (N=60)	Group (A) (n=30)	Group (B) (n=30)	P Value
Mean age years		42.1(23-60)	47.76 (22-74)	0.1
Female (%)	51	26(86.60%)	25 (83.33%)	0.3
Male %	9	4 (13.33%)	5 (16.66%)	0.1
Mean BMI*		26.22 (21-31)	26.1(20.1-34.2)	0.2
Obese >30	5	2(6.66%)	3(10%)	0.1
D.M."	18	8 (26.66%)	10 (30%)	0.2
Hypertension	12	6(20%)	6(20%)	0.1
Cirrhosis	3	1(3.33%)	2(6.66%)	0.3
Bronchial asthma	3	2(6.66%)	1(3.33%)	0.2
Ischemic heart	3	1(3.33%)	2(6.66%)	0.2
Atherosclerosis	2	1(3.33%)	1(3.33%)	0.9

*BMI: Body Mass Index, "D.M: Diabetes Mellitus.

The procedure was completed laparoscopically in both groups. The mean operative time was significantly longer in group (A) than group(B) (mean = 63.3min vs. 56.3min, $p<0.01$) with a higher incidence of

gallbladder perforation in Group(A) (20% vs. 6.66%, $p<0.001$). Gallbladder perforation has been found to lengthen the operative time in both studied groups **Figure(2), Table(2).**

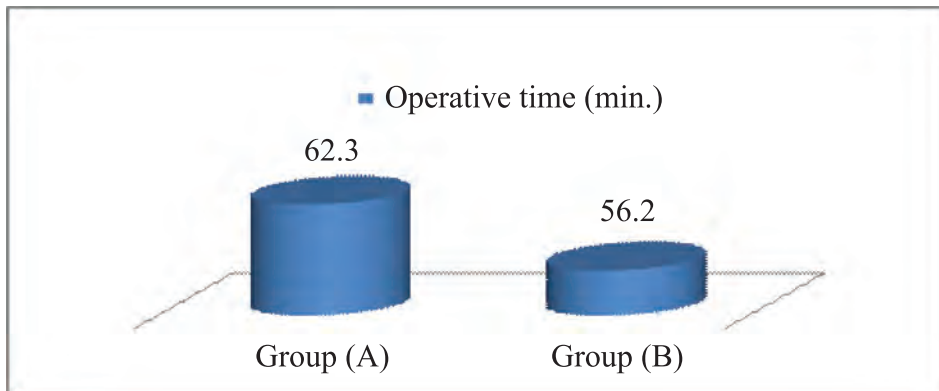


Figure (2): Graph showing operative time.

Table (2): Operative data.

	Group A	Group B	P value
Mean over whole operative time	62.3 (37-123)	56.2 (30-100)	<0.01
Mean operative time without G.B* perforation	59.3 (37-98)	53.5 (30-78)	<0.01
Mean operative time with G.B* perforation	65.3 (42-123)	58.9 (38-100)	<0.01
G.B* perforation	2 (6.66%)	6 (20%)	<0.001
Biliary leak	1 (3%)	0	NS"

*G.B= Gall bladder "NS= Non-significant.

Postoperative biliary leak was encountered in one patient in Group A, who was discovered by biliary staining of the drain's discharge and was managed conservatively till cessation of discharge at 5th day. Chest infection was higher in Group A than Group B (6.66% vs. 3%, $P= 0.3$).

Discharge from hospital on 1st and 2nd postoperative day was higher in Group B (6.66% vs. 0, P value <0.01) (86.6% vs. 83.3%, p value 0.3) respectively. Delayed discharge (more than 2 days) was statistically higher in Group A than Group B (16.6% vs. 6.66%, p value <0.01) **Figure(3), Table(3).**

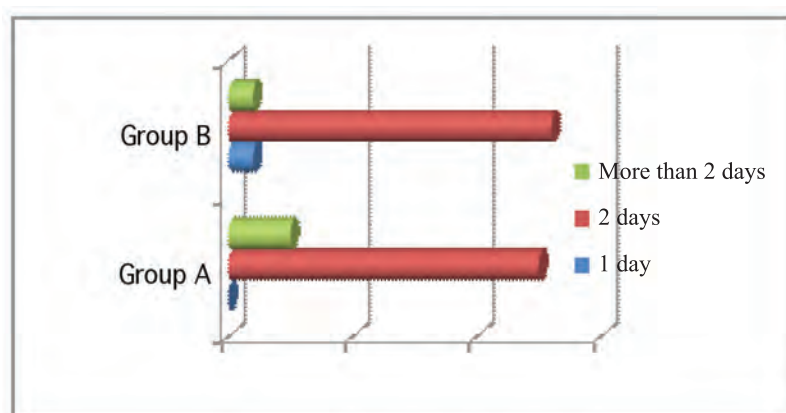


Figure (3): Graph of hospital discharge.

Table (3): Hospital stay.

	Group A (n=30)	Group B (n=30)	P Value
1 day	0	2 (6.66%)	<0.01
2 days	25 (83.3%)	26 (86.6%)	0.3
More than 2 days	5 (16.6%)	2 (6.66%)	<0.01

Discussion:

Laparoscopic cholecystectomy was first reported in the 1980s; thereafter it led to broad dissemination of minimally invasive surgery. 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.^{4,7} Alternative techniques for duct ligation have included linear stapler, endoloops, or sutures. The clips are known to slip, dislodge, ulcerate, migrate, embolize, and give rise to necrosis of the cystic duct with resultant bile leak and other complications and the monopolar electrocautery is associated with high risk of thermal injuries and significantly more common postoperative biliary complications.^{8,9,10}

The ultrasonically activated scalpel was introduced into clinical use for tissue dissection 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.¹⁻³ 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.⁵ Some investigators have used Harmonic Scalpel (HS) in the closure of the cystic duct and artery instead of clips, this technique was called "clipless cholecystectomy".^{5,7,8} The use of HS as a single instrument during the whole procedure avoids the frequent instrument exchange and replacement through the trocars which is sometimes performed without optic guidance and consequently, reducing the possibility of causing injuries to the intra-abdominal organs.^{3,5,9} Several studies¹⁻³ have demonstrated the effectiveness and safety of the use of the HS for dissection of the gallbladder, but until now and for unknown reasons "clipless cholecystectomy" did not

gain popularity in Egypt and other countries.

In our study, the use of the HS was associated with lower incidence of gallbladder perforation, compared to traditional method. This could be explained by the fact that cavitation effect aids in tissue plane dissection that enhances visibility in the operative field, minimal local thermal injury and the lack of electrical current with risk of distant tissue damage.¹¹ Operative time was prolonged in operations complicated by gallbladder perforation in both groups as stone spillage and bile loss which led to obstruction of laparoscopic visual field with frequent exchange in instruments and led to time loss in abdominal lavage and spilled stones retrieval.

Similar to others,¹¹ in this study, operative time was shorter in Group(B) than Group(A). This has many potential advantages, including reducing the overall anesthetic time and increasing the number of cases that can be done on an average operative list. Shorter operative time in Group(B) can be attributed to lower incidence of gallbladder perforation and cavitation effect of HS on the surrounding pericholecystic tissues that allowed easier mobilization of the gallbladder. HS is a multifunctional instrument: It replaces four instruments used in the CCM laparoscopic cholecystectomy, namely, the dissector, clip applier, scissors, and electro-surgical hook or spatula. Its use, therefore, prevents the frequent blind extraction and reinsertion of these different instruments with the subsequent avoidance of time loss.¹²

Moreover, activation of the HS does not form smoke - although mist may be generated by vibration- therefore allowing the surgeon to work in a clear operative field throughout the operation. The use of electrocautery causes smoke formation in the abdominal cavity and decreases visibility. Moreover, smoke must be

evacuated by opening the valves of the trocars, thus causing repeated loss of the pneumoperitoneum and a subsequent loss of time.¹³

The incidence of bile duct injury is (0-2%) when the harmonic scalpel has been used.¹²⁻¹⁶ In our study no patients developed bile duct injury in LHS vs 3% in CCM. Factors known to predispose to bile-duct damage have included the use of diathermy, producing what became known as “the diathermy-induced bile duct injury.”¹² Ultrasonic instruments were developed to eliminate the collateral damage associated with electrosurgery.¹³ With HS, the lateral energy spread is minimal, and the risk of distant tissue damage is lower than that of high-frequency electrosurgery.¹⁴ Further, ultrasonic devices can coagulate and cut at a lower temperature (100°C) than that during electrosurgery (150°C) or laser surgery (200°C). The absence of bile-duct injuries in the present study adds further evidence to the safety of ultrasonic devices in the dissection of biliary structures in the laparoscopic cholecystectomy, the same findings were reported by others.^{15,16}

Effective sealing of the cystic-duct stump by the harmonic shears has been confirmed histologically.^{3,15} All morphologic changes were found within 1.5 mm of the cutting edge, and the airtight pressure of the sealed cystic duct was calculated to be higher than 320 mm Hg. Wise and coworkers¹⁷ demonstrated that simple titanium clips applied to the cystic duct could not be displaced by a pressure of 300 mm Hg. However, the literature provides various examples of cystic-duct leakage due to inadequate closure of the duct due to mismatch of the clip arms, necrosis of the duct at the site of clipping, or slippage of the clips off the end of the duct and migration into the biliary tract.¹⁸

In our study neither minor nor major bile leaks were encountered throughout the study period in Group(B), this could be explained partially by small number of patients, although similar findings were reported by Tebala.⁵ Huscher and associates¹⁵ reported bile leaks in 7 of the 331 patients (2.1%), in whom closure and division of the cystic duct was achieved by the harmonic shears alone, compared to 3

of the 130 patients (2.3%) in whom the closure was achieved by the harmonic shears and end-loop of absorbable suture material.¹⁵ This 2.1% cystic-duct leakage rate is comparable to the 2% rate reported in the literature when using other cystic-duct closure techniques.¹⁷ Huscher and associates¹⁵ applied the blades first more proximally for a few seconds to achieve a simple sealing of the lumen, then they were applied a few millimeters distal to the previous application site, holding the grasper until the division of the duct was accomplished.¹⁵

In view of the facts that the instrument has no feedback sensors capable of differentiating between simple sealing and the sealing and division of the cystic duct, and that such differentiation can only be made on a visual basis, we presumed that it would be rather difficult to determine the amount and type of damage done to the cystic duct by applying the harmonic shears for a few seconds to the site of proximal application. Whether the sites of proximal application were the source of some bile leaks in their study remains uncertain, although the possibility theoretically exists.¹⁵

In the present study, as well as in the Tebala⁵ and Westervelt⁷ studies, the harmonic shears were applied to only one site on the cystic duct where sealing and division were achieved with no bile leaks from the cystic-duct stump encountered in any of the three studies. Like others,⁵ it is our belief that a double application of the harmonic shears to the cystic duct is unnecessary and may be an unsafe practice.

Jannsen and coworkers¹⁹ reported that harmonic scalpel was associated with shorter operative times, fewer overnight hospital stay and lower pain scores. In our study the overall hospital stay in Group(B) was less than Group(A). The greater cost of the harmonic scalpel, when compared with the cost of an electro-cautery probe, has been regarded as a potential disadvantage. However, we feel that LC, using the harmonic scalpel, is cost-effective when considering the shorter stay, using fewer overall instruments and shorter operative time.

Conclusion:

The use of HS during laparoscopic cholecystectomy is safe and effective. It provides a superior alternative to the currently

used clips and cautery technique, as it is associated with a shorter operative time, lower incidence of gallbladder perforation, lower incidence of biliary leak, better control of oozing from dissected tissue, and shorter hospital stay.

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