

Laparoscopic Cholecystectomy for the Dissection of Gall Bladder: A Comparative Study of Harmonic versus Electrocautery

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ABSTRACT

Introduction: Laparoscopic cholecystectomy is the revolutionary new method for the treatment of gallstone disease and has now become the gold standard for the surgical treatment of symptomatic cholelithiasis. The ultrasonically activated (Harmonic) scalpel was designed as a safe alternative to electrocautery for the hemostatic dissection of tissues. This comparative study was undertaken to exhibit the effectiveness and safety of the harmonic scalpel over traditional electrocautery to achieve complete dissection and hemostasis at laparoscopic cholecystectomies.

Materials and Methods: This was a prospective comparative study. Patients were randomly divided into 2 groups. Group I (electrocautery group) included 187 patients while group II (harmonic group) consisted 163 patients. All the patients participated in the study were 25 to 50 years age group.

Results: Incident of minor bleeding were recorded 21 patients of group I while 17 patients of group II. Major bleeding occurred in 15 patients (8.02%) of group I and 5 patients of group II. The range of time needed to control major bleeding was 2 to 9 minutes with a mean of 4.5 minutes. Major bleeding occurred in 5 patients (3.06%) in the group II, 2 of them needed clipping of the site of bleeding; suturing, in one case and several touches by the harmonic instrument in one.

Conclusion: Findings of the present study showed that use of harmonic devices not only improved the results but also decrease the risk of associated disorders of electrocautery trauma. Moreover, findings of current study suggest that use of harmonic devices can make the laparoscopic cholecystectomy more safer procedure.

Key words: Harmonic Scalpel, Electrocautery, Laparoscopic Cholecystectomy.

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INTRODUCTION

Laparoscopic cholecystectomy is the revolutionary new method for the treatment of gallstone disease and has now become the gold standard for the surgical treatment of symptomatic cholelithiasis. For safe effective and careful dissection of the gallbladder in laparoscopic cholecystectomy diverse surgical apparatus have been developed, aiming to decrease intra and postoperative complications to the lowest level.¹ At the present time, in addition to electrocautery, various ultrasonic scalpel, water jet dissectors, laser systems, and specially prepared suction devices have been used. During dissection with various efficacy all these variety of equipment can attain complete hemostasis.²

In most centers the conventional laparoscopic cholecystectomy is usually performed by means of dissector, the electrocautery hook, spatula, and/or scissors, and this method has been used. Simple metal clips are frequently used to achieve cystic duct and artery closure most popular instrument that is used to achieve a bloodless operating field in laparoscopic cholecystectomy is electric hook, on the other hand, the use of electric coagulation

whether monopolar or bipolar may cause injury to nearby organs like the common bile duct, stomach, or small bowel³ or local complication like liver injury, gallbladder perforation and loss of bile or stones into the peritoneal cavity.⁴ The ultrasonically activated (Harmonic) scalpel was designed as a safe alternative to electrocautery for the hemostatic dissection of tissues, it was introduced into clinical use nearly a decade ago.⁵ Its technology relies on the application of ultrasound within the harmonic frequency range to tissues and allows two effects: ultrasonic coagulation and cavitation effects provided by a rapidly vibrating blade contacting various tissues.⁶ The heat generated as a result of stress and friction is below 80 degree Celsius, as a result, tissue charring and desiccation from loss of moisture is minimized. The cavitation or cutting effect is produced by a relatively sharp blade vibrating 55,500 times per second over a distance of 60–100 µm. It cuts the tissue by stretching it beyond its elastic limit and by breaking molecular bonds. Large series studies have demonstrated the effectiveness and safety of the use of the HS for

dissection of the gallbladder.⁷ A Harmonic scalpel is also an effective tool for the closure of biliary ducts and vessels whose diameter is 4mm to 5mm (as certified by the FDA in 2006). This study was undertaken to demonstrate the efficacy and safety of the Harmonic scalpel as the sole instrument to achieve complete hemobiliary stasis in the performance of Laparoscopic cholecystectomy. Moreover, the use of a single instrument during the whole procedure averts or decreases the risk of distant organ injuries.⁸ This comparative study was undertaken to exhibit the effectiveness and safety of the harmonic scalpel over traditional electrocautery to achieve complete dissection and hemostasis at laparoscopic cholecystectomies.

MATERIALS AND METHODS

This was a prospective comparative study. Patients were randomly divided into 2 groups. The randomization was done as follows: the first group was operated upon on odd months; the second group was operated upon on even months. In the first group, electrocautery was used for dissection, in the second group harmonic knife was used for completing the dissection.

Ethical clearance was taken from the institutional Ethics committee. Operative procedures were performed with the patient under general anesthesia. All procedures were performed through three operative ports and a camera port. Dissection of the gallbladder was initiated at the triangle of Calot’s with recognition, dissection, and division of the cystic duct after double clip application, the artery was either clipped or cauterized (in the first group), and was clipped or divided by harmonic scalpel (in the second group). Mobilization of the gallbladder from the liver bed was followed, and subsequent removal of the gallbladder through the umbilicus or epigastric incision was done. The time required for complete dissection and hemostasis started from spreading of Calot’s triangle, controlling the cystic duct and artery till the removal of gallbladder totally from its bed, and complete hemostasis was recorded. The mean, time was calculated, any intra-operative complications in form of bleeding, regarding its site, severity and ways of their control were recorded.

The following criteria were used to classify the severity of bleeding: minor bleeding means bleeding that needed only one

interventional step to stop it without further instrumentation or change of the equipment, major bleeding means bleeding which required more than one pace to control it or further instrumentation or alteration of the equipment, extensive bleeding means bleeding which needed conversion. A biliary complication in form of gallbladder perforation, slipped stones, common bile duct injury and the way of their management and the time needed to control the complication were also documented. The conversion was recorded with its indication.

Inclusion Criteria

Age between 25 and 50 years, normal body weight, ASA 1 or 2, elective cholecystectomy, no, or well-controlled hypertension or diabetes, no previous upper abdominal surgery, the wall thickness of gallbladder less than 6 mm as shown by ultrasound preoperatively and normal biliary passages

Exclusion Criteria

Patients with Multiple co-morbid diseases, coagulation disorders, Suspected/proven malignancy, Contraindication to laparoscopic cholecystectomy e.g. upper major abdominal surgery, common bile duct stone, pregnant patient, emphysema of the gallbladder, unfavorable anatomy (as shown by USG) e.g. sessile gallbladder, very short cystic duct, wide cystic duct more than 6mm.abnormal liver functions were excluded from the study

Statistical Analysis: The Chi-square and Fisher Exact test were used to compare the data of both groups.

RESULTS

The present study included 350 patients. Among them 242 were female whereas, 108 were male patients. These patients were further divided into two groups. Group I (electrocautery group) included 187 patients while group II (harmonic group) consisted 163 patients. All the patients participated in the study were 25 to 50 years age group. The median age for group I was 34 years whereas, for group II was 35 years. Total dissection and hemostasis (dissection of Calot’s triangle, clipping cystic duct, dealing with cystic artery) time range was 8 to 30 minute for both groups. However, The mean time ranges were 17.6 minutes and 15.8 minutes for group I (electrocautery group) and group II (harmonic group) respectively. (Table 1)

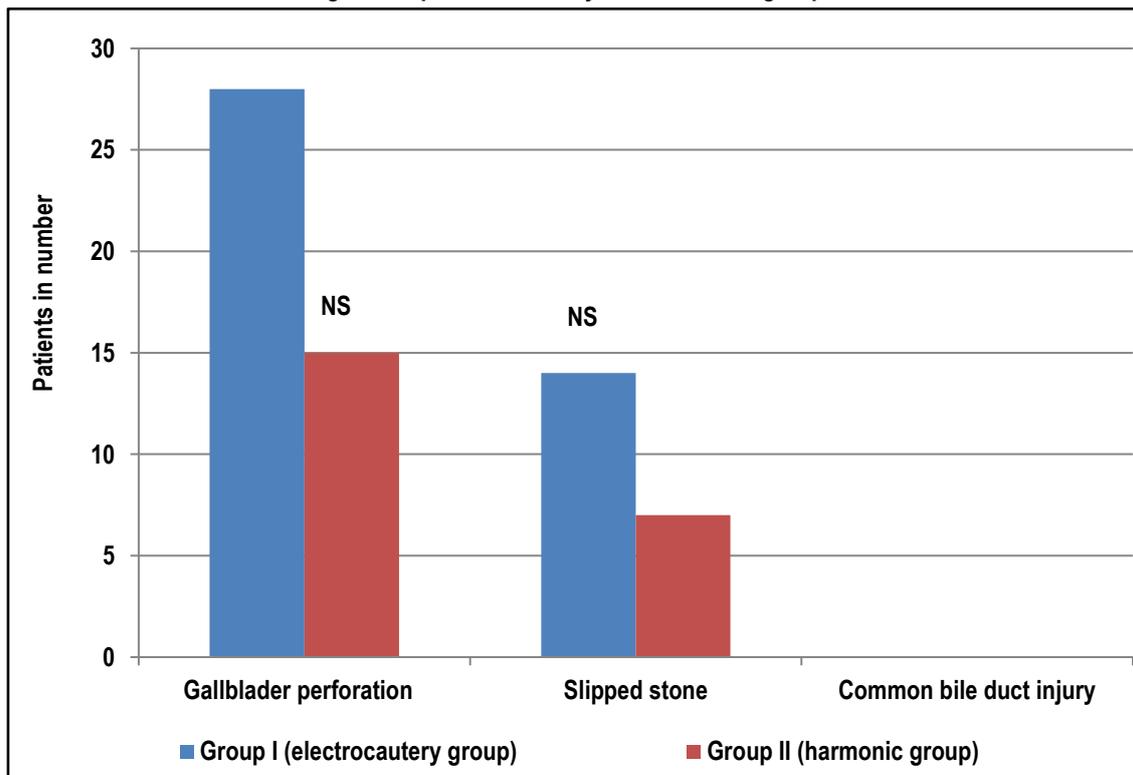
Table 1: Comparison total time for dissection and hemostasis in both groups.

Total time for dissection and hemostasis in minutes	Group I (electrocautery group) n = 187	Group II (harmonic group) n = 163	p value
≤10	29 (15.5%)	36 (22.08%)	>0.05
11-15	53 (28.34%)	59 (36.19%)	>0.05
16-20	42 (22.45%)	25 (15.37%)	>0.05
21-25	40 (21.39%)	21 (12.88%)	<0.05
26-30	23 (12.29%)	22 (13.49%)	>0.05
Total	187 (100%)	163 (100%)	<0.05
Mean±SD	17.6 ± 7.3	15.8 ± 6.8	

Table 2: Comparison types of bleeding in both groups.

Types of bleeding	Group I (electrocautery group) n = 187	Group II (harmonic group) n = 163	p value
Minor	21 (11.22%)	17 (10.42%)	>0.05
Major	15 (8.02%)	5 (3.06%)	<0.05
Extensive	1 (0.53%)	0 (0.0%)	>0.05
No bleeding	150 (80.21%)	141 (86.5%)	>0.05
Total	187 (100%)	163 (100%)	>0.05

Fig 1: Comparison of biliary trauma in both groups.



The cystic duct, in both groups was doubly clipped and divided. The cystic artery was cauterized in 121 (64.7%) patients in the first group and clipped in 66 (35.3%) patients according to the preference of surgeon. Whereas, cystic artery was cut by the harmonic knife in 98 (60.12%) and clipped in 65 (39.87%) patients. Intraoperative bleeding was recorded in 37 patients (19.78%) in group I and in 22 patients (13.49%) in group II. Incident of minor bleeding were recorded 21 patients of group I while 17 patients of group II. Major bleeding occurred in 15 patients (8.02%) of group I and 5 patients of group II. The range of time needed to control major bleeding was 2 to 9 minutes with a mean of 4.5 minutes. Major bleeding occurred in 5 patients (3.06%) in the group II, 2 of them needed clipping of the site of bleeding; suturing, in one case and several touches by the harmonic instrument in one. The range of time needed to control major bleeding was 1 to 7 minutes with a mean of 3.5 minutes. The cystic artery was the site of major bleeding in 10 (5.34%) patients and gallbladder bed in 5 (2.67%) patients in group I. Extensive bleeding was observed in 1 patient (0.53%) of group I while no patient of group II showed extensive bleeding. (Table 2) It is evident from figure 1 that incidence of biliary trauma in the form of gallbladder perforation (14.97%) slipped stone (7.48%) were present in group I (electrocautery group). Whereas, incidences of gallbladder perforation and slipped stone were recorded in 9.2% and 4.29% of patients respectively for group II (harmonic group). However, no incidence of gallbladder injury was observed in any group.

DISCUSSION

The main aim in gallbladder surgery is a reduction in operative blood loss, less local thermal damage to tissue, less gallbladder perforation and common bile duct injury, less intraoperative time and more cost effectiveness, which can be attained when the

equipments, techniques, and experience get to the optimum level of requirement.⁸ The ultrasonic generator cuts and coagulates by using low temperatures, lower than those used by electro surgery or lasers. Ultrasonic technology controls bleeding by coaptive coagulation at low temperatures which ranges from 50 to 100 degrees celsius. By a protein coagulum vessels are tamponaded and sealed. Coagulation occurs by means of protein denaturation as the blade couples with protein, denaturing it to form a coagulum which finally contracts to seal small coapted vessels. Secondary heat is produced, when the effect is prolonged that seals larger vessels. By contrast, electrosurgery and lasers provide the technique of obliterative coagulation that is coagulation by burning at higher temperatures. Blood and tissue are dried out and oxidized, forming Escher that covers and stick the bleeding area.⁸⁻¹⁰ When blades are removed during electrosurgery and they stick to tissue disrupting the Escher re-bleeding can be dangerous.¹¹ In addition, the ultrasonic scalpel shows an roughly 1mm zone of denatured tissue around the ultrasonic incision similar to the lateral energy dispersion demonstrated with ultrasonic instrumentation in porcine models. This finding compares favorably with the 0.24 to 15.0 mm range of thermal energy damage associated with electrocautery.¹² In our series there was a decrease in number of gall bladder perforation from 15% to 8% (P value >0.05), as well as slipped stones from 6.7% to 3.4% (P value >0.05), this is attributed to a very small perforation induced by harmonic knife in comparison with perforation caused by lectrocautery. Janssen I et al¹³ on 200 patients conducted a randomized clinical trial of ultrasonic versus electrocautery dissection of the gallbladder in laparoscopic cholecystectomy. They reported that the incidence of gallbladder perforation dropped down drastically and the operation progressed more smoothly with the use of ultrasonic generators in laparoscopic cholecystectomy.

At the Calot's triangle fat was quickly cleared up which was dissolved by ultrasonic dissector allowing the cystic duct and artery to be bared with less risk of injury.¹⁴ Additionally, because of the minimal thermal dispersion, the use of the harmonic reduces the risk of injuries.¹⁵ A small but statistically significant difference in blood loss was detected in a single randomized clinical trial that involved two hundred patients going through a laparoscopic cholecystectomy procedure.¹⁶

In our study definitely due to less trauma produced by harmonic scalpel there was a decline in the percentage of minor as well as major bleeding. Bessa S et al¹⁷ in their study found a significant difference in surgery time in favor of ultrasonic instrumentation. Which may be accredited to less number of extraction and insertion of different instruments. In addition, 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, or to repeatedly clean the lens the electronically activated harmonic scalpel produces almost no smoke. In our study there was no significant difference in time between the two groups in relation to the mean time of dissection of gall bladder from its bed including the control of cystic duct and artery, which are the main procedures during laparoscopic cholecystectomy. This may be due to that the authors had less experience with harmonic scalpel and that others showed decrease in the operating time by using clipless technique. However, especially when operating time is mainly dependent on the training and expertise of individual surgeons, the statistical significance of short time does not necessarily mean a clinical advantage. Ultrasonic dissection by the inexperienced hands may well be a long, unsafe dissection procedure while most surgeons can improve their use of monopolar electro-surgery, which will shorten their operating time.¹⁸

Results of the present study revealed that use of harmonic device for the control of cystic artery in majority of cases only because of less personal experience, especially at the beginning of the present study. Nevertheless, excellent vascular control as observed in the present study group II (harmonic group) was significantly better in comparison of group I (electrocautery group). These findings were similar to the observations of Power C et al¹⁹ as they recorded that blood loss was minimal in laparoscopic cholecystectomy performed with the harmonic scalpel. Moreover, use of harmonic device was feasible, effective and operating time was shorter. Further, no bile duct injury was recorded in group II (harmonic group). Which resulted in easy dissection, thereby it helped to reduce operative time and lower the need for conversion to open surgery.

Similarly Abrar H et al²⁰ observed gallbladder perforation in 2.7% and slipped stone in 1.8% patients. Further, they recorded no bleeding, and injury to common bile duct or post-operative biliary discharge. Average dissection time was 40 minute ranging from 17 to 70 minutes and there was no mortality in his study.

Conversion needed in current study in 5 patients (2.67%), 3 (1.6%) patients belonged to group I and 1 patient (0.61%) of group II. These findings are very similar to the earlier studies.^{21,22} This very low percentage may be due to exclusion of acute cholecystitis from the study.²³

Harmonic device was not used for the cystic duct control in all cases in the present study. Instead of that conventional clipping method had been used in this study.

By knowing that both ultrasonic and monopolar electro surgery are now reusable instruments, making cost comparisons more difficult. It is therefore advocated that further comparative studies should be carried out preferably within a single health system or even within a single health institution.

CONCLUSION

Findings of the present study showed that use of harmonic devices not only improved the results but also decrease the risk of associated disorders of electrocautery trauma. Moreover, findings of current study suggest that use of harmonic devices can make the laparoscopic cholecystectomy more safer procedure.

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