

Single Working Instrument, Double Trocars, Clip less Cholecystectomy Using Harmonic Scalpel. A Feasible, Safe, and Less Invasive Technique

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Abstract

Aim: to evaluate safety and efficacy of harmonic scalpel in closure/division of the cystic duct and artery, and bladder dissection in laparoscopic cholecystectomy as a single working instrument, with the use of two working trocars technique, compared with regular laparoscopic clip/cautery, three trocars technique.

Method: A prospective study included 160 patients with symptomatic gall stone disease were randomly assigned for laparoscopic cholecystectomy by either harmonic shear as a single working instrument, with two trocars technique (group I = 80 patients), or group II (regular clip/cautery, 3 trocars technique) including 80 patients.

Results: No significant complications were encountered in either group; however 1 case of regular laparoscopy group suffers mild leakage treated conservatively. Intra-operative bile spillage was insignificantly comparable in both groups (10% vs. 13%; $P=0.46$). The median operative time was statistically significantly shorter in harmonic group (20 vs. 45 minutes; $P=0.0001$). Also hospital stay was significantly shorter in harmonic group (1 vs. 1.5 days respectively; $P=0.001$), but no statistically significant difference was found in the incidence of post operative complications. The overall cosmetic results and patient satisfaction was better in harmonic group.

Conclusion: Harmonic shear is as safe and effective as clip/cautery technique in laparoscopic cholecystectomy in achieving hemo-biliary stasis; with shorter operative time especially if used solely as a working instrument. Two trocars technique is safe, feasible, and provides better cosmetic results and patient satisfaction.

Introduction and aim of the work

Laparoscopic cholecystectomy is a commonly performed operation for patients diagnosed with gall stones. Usually the procedure involves electro surgery and sealing of the gall bladder duct and arteries with titanium clips. Dissection with concomitant hemostasis can be performed with the use of ultrasonic instruments as harmonic scalpel can radically simplify the whole operation and offer good hemostasis,¹ so ultrasonically activated devices have been used for dissection with encouraging results.²

The ultrasonically activated (Harmonic) scalpel has proven to be an effective, efficient, and safe instrument for dissection and hemostasis. It works

on the tissue's cutting and coagulating very effectively with the replacement the high frequency current, which can be connected with diverse complications. The primary use of the Harmonic scalpel in laparoscopic cholecystectomy has been for the division of the cystic artery and liver bed dissection.¹ Recently, ultrasonic energy has been used to seal the cystic duct during successful clip-less cholecystectomy.³ So total Harmonic scalpel dissection in the performance of a laparoscopic cholecystectomy was described.⁴

The resulting decrease in temperature, smoke, and lateral tissue damage placed the Harmonic scalpel in contrast to the effects seen with the more traditional electrocautery. 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.¹ It tackles the concerns regarding smoke production, and inadvertent injuries to the abdominal organs and structures,⁵ Moreover, it shortens the operative time and decreased the rate of accidental bile spillage.⁶

A single working instrument means avoidance of repeated instrument changes during the operation, as selecting different instruments breaks the natural flow of the operation and may distract the surgeon.⁵

Moreover, downsizing the port incisions may reduce pain after laparoscopic cholecystectomy,⁷ and Minimizing the number and scope of ports to improve postoperative pain control, rapid return to activity and work, patient satisfaction, and cosmetic result achieved by the laparoscopic method.⁸ So new techniques for laparoscopic cholecystectomy were designed to reduce the number of trocars or the use of very thin instruments with the goal of further minimizing surgical invasiveness,^{9,10,11} some authors use one 1-mm Kirschner wire, introduced at the sub costal line and bent with a special designed device to hook the gallbladder and pull it up,¹² the other used 2-mm grasper forceps inserted directly without a trocar below the costal margin, then the fundus of the gallbladder is ligated and lifted up with a folded 0 silk string and a 16-gauge vessel cannula.⁹ These feasible, safe, minimal invasiveness techniques results in a much smaller wound with less pain than conventional laparoscopic cholecystectomy, and considered as an alternative way to deal with gallstone disease, especially for younger women, who tend to be more concerned about cosmetic outcome.¹³

This study was undertaken to demonstrate the efficiency, and safety of the Harmonic scalpel as the sole instrument to achieve complete hemobiliary stasis in the performance of laparoscopic cholecystectomy, with the use of two trocars technique.

Patients and methods

Patient population: From Jan. 2007 to July 2009, a sample of 160 cases of symptomatic gall stones were included in this study from unit C, general surgery department, Assuit university hospitals.

Clinical and diagnostic work-up: all patients were subjected to:



Fig. (1). Harmonic scalpel and two working trocars.

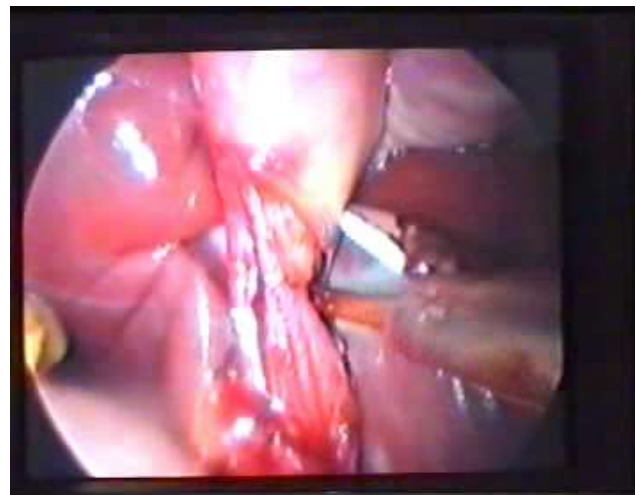


Fig. (2). Lap. Anterior Dissection of cystic artery

-Full history taking. -Clinical examination.

Investigations which included:

- * Routine laboratory tests (blood count, random sugar, serum creatinine)
- * Routine chest X-ray, ECG, ...etc.
- * Liver function tests.
- * Prothrombine time.
- * Abdominal ultrasonography.
- * Additional investigations were needed in some doubtful cases as CT, and MRCP.

Management: All patients were randomly assigned for laparoscopic cholecystectomy as:

Group I (clip less harmonic group):

Included 80 cases; the harmonic scalpel was used as a single working instrument with only two working trocars.

The patient is positioned in an anti-Trendelenburge position with some rotation to the left side to help in good visualization and manipulation of the gall bladder, if difficulty is still encountered, thereafter

Harmonic Clipless Cholecystectomy

a curved Kirschner wire 1 mm is introduced in the sub costal area and hooks the gall bladder fundus with gentle retraction upwards, or by direct introduction of the laparoscopic trocars wound closure forceps through the sub costal region with gentle retraction of the gall bladder upwards, however these maneuvers was rarely resoled to during the work.

Ultrasonic shear (Olympus Keymed Sono surg version G2 220-240 V 3A. 50/60 Hz.) was used as the only working instrument during the procedure through 10 mm epigastric port, for dissection/cutting of cystic artery and duct, then gall bladder dissection from liver bed helped by grasper through right mid clavicular 5 mm port to attain complete hemo-biliary stasis, lastly the gall bladder is retrieved from the epigastric 10 mm trocars site.

Group II (clip/cautery group):

Included 80 cases; the conventional instruments were used with the application of clips and the use of the cautery in a three working trocars laparoscopic cholecystectomy technique.

* One small catheter drain was put in all cases that was removed a few hours later, All patients were followed up in general surgery department, Assuit university hospitals with the appropriate post operative treatment in the form of broad spectrum antibiotic prophylaxis, and analgesics according to the amplitude of pain using "pain scoring system" where single shot of narcotics was sufficient to kill pain in moderate type, but more doses was needed (double) with severe type of pain¹⁴ till discharged from the hospital.

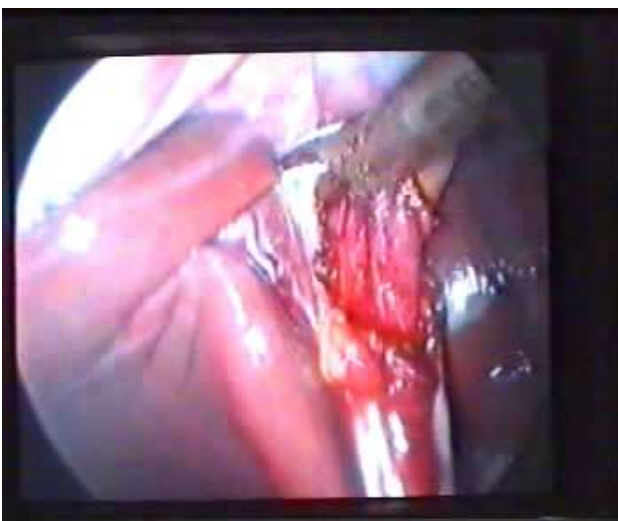


Fig. (3). Harmonic Posterior dissection

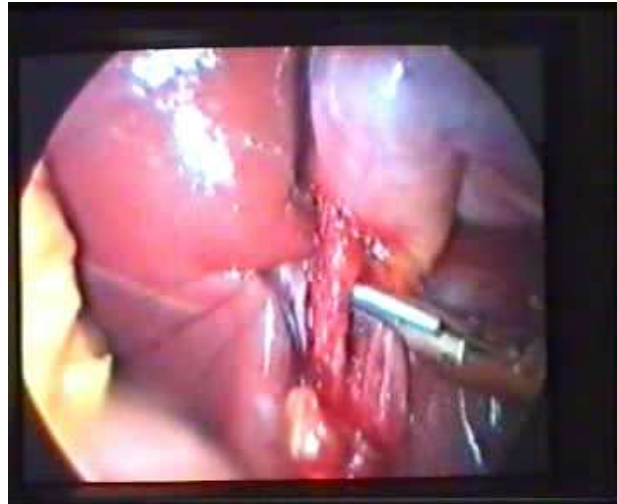


Fig. (4). Harmonic coagulation/cutting of the cystic artery.

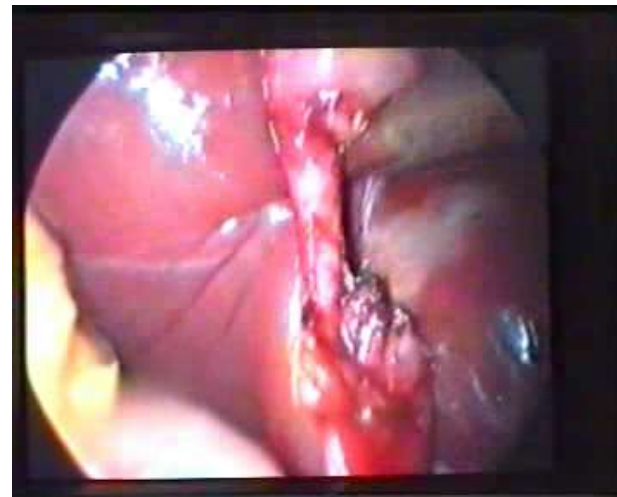


Fig. (5). Harmonic skeletonization of cystic duct.

* Recording of all patients data were done, and categorized as: intra-operative difficulty, intra-operative perforation of the bladder and biliary spillage, intra-operative injuries, or complications, operative time, as well as post operative complications, post-operative pain and the need for analgesics, and hospital stay.

Follow up: patients were followed up in outpatient clinic for detection of any complications, with assessment of the cosmetic results and also patient satisfaction of the surgery.

Ethical considerations and informed consent: The study protocol was approved by the local ethical committee, and it was explained to each patient and his/her informed consent obtained prior to entry into the study.

Statistical analysis: The results are expressed as the mean \pm SD & number (%). Statistical analysis was performed with the software SPSS version 12, using student T. test to determine significant for numeric data, using Chi. square to determine sign for non parametric data. P value was determined as significant ($P < 0.05$).

Results

Age and sex incidence in both groups:

This study included 160 cases, most of them were females (100 = 62.5%) compared to males (60 = 37.5%), with male to female ratio about 1: 1.6. All data about age groups are shown in *table 1*.

Duration of surgery: (Fig. 1-10).

The surgical maneuver time was statistically significant shorter in harmonic group compared to the regular laparoscopy group as shown in *table 2*.

Division of the cystic duct by harmonic scalpel required approximately 2-3 minutes depending on the ductal thickness and associated inflammation. In general the cavitational effect on the surrounding peri-cholecystic tissues especially in the region of the liver bed allowed for easier mobilization of the gall bladder thus avoiding inadvertent compromise of the gall bladder wall and bile spillage. No liver bed charring or bilious leakage from any ducts of Luschka was observed.

Intra-operative complications:

There was no statistically significant difference between the two groups as regard the incidence of intra operative complications, however there was a comparable incidence of intra operative bile spillage (10% vs. 13% for harmonic and regular laparoscopy groups respectively) due to gall bladder perforation or leakage from its duct with manipulation in acute cholecystitis and obstructed distended bladder.

Also difficult maneuver was seen in both groups in comparable incidence, due to distended obstructed bladder in harmonic group (managed by repeated change in patient position), or acute cholecystitis in regular laparoscopy group managed by meticulous maneuvers. Fortunately no conversion to open cholecystectomy encountered as shown in *table 3*.

Post operative complications:

There was only one case of post operative bile soaking that was treated conservatively in the regular laparoscopy group.

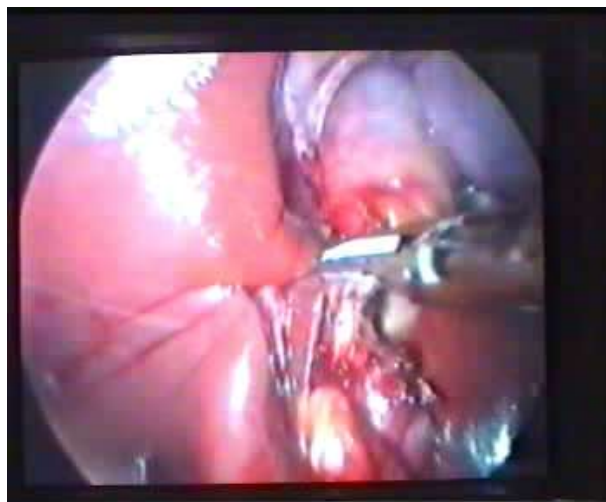


Fig. (6). Harmonic coagulation/cutting of cystic duct.

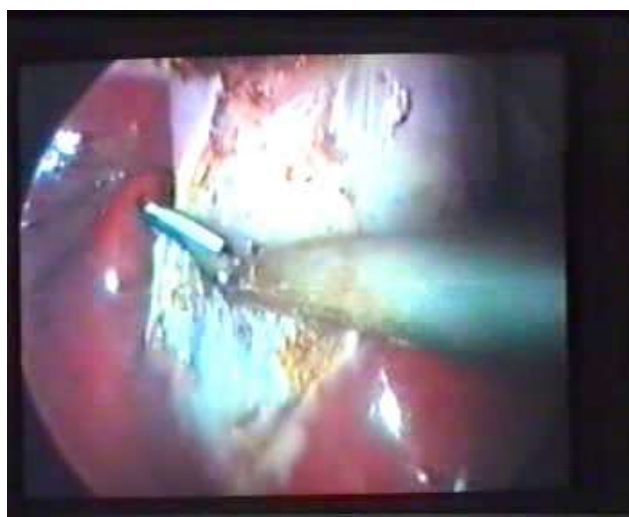


Fig. (7). Harmonic dissection of gall bladder bed.

The post operative pain was somewhat more in regular laparoscopy group and consequently more dose of analgesic was needed than harmonic group as shown in *table 4*.

Hospital stay:

The hospital stay was statistically significant shorter in the harmonic group than regular laparoscopy group as shown in *table 5*.

Follow up:

All patients were followed up in the general surgery department till discharge for outpatient clinic follow up with meticulous monitoring of their satisfaction about the surgical maneuver and the cosmetic results that was in favor of the harmonic group more than the regular laparoscopy group.