

# Effectiveness of Ultrasound Shear for Clipless Laparoscopic Cholecystectomy Versus Conventional Unipolar Electrocautery in Patients with Cholelithiasis

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## ABSTRACT

**Objective:** To determine the efficacy of ultrasound shear in laparoscopic cholecystectomy in terms of total operative time, postoperative bile leaks, gall bladder perforation rate, and postoperative bleeding from cystic artery and collateral injury to bowel and duodenum.

**Study Design:** Comparative study.

**Place and Duration of Study:** Mayo Hospital, Lahore, from June 2013 to May 2014.

**Methodology:** 150 cases (75 in each group) were randomized into two groups, i.e. harmonic scalpel clipless group (HSG) versus conventional laparoscopic cholecystectomy (CLC) with electrocautery group. The above stated variables were documented. The data for age, blood loss, and drain output were positively skewed as calculated using the Shapiro-Wilk test. The histograms, Q-Q plots and box plots were analyzed for all the dependent variables. Skewed qualitative continuous data was analyzed using the Mann-Whitney U-Test.

**Results:** Operative time was significantly lower in HSG as compared to CLC. Median operative times were 30 minutes (IQR 10) versus 35 minutes (IQR 10) ( $p < 0.001$ ). HSG group had perforation rate of 5/75 (6.67%) as compared to 16/75 (21.33%) in CLC ( $p = 0.010$ ). Intraoperative blood loss in group A was significantly lower than in group B ( $p = 0.001$ ). Post-operative median pain score was 3 (IQR 2) versus 3 (IQR 3) in HSG versus CLC, respectively.

**Conclusion:** All the primary outcomes showed improved results in the ultrasound shear group as compared to the group for conventional electrocautery.

**Key Words:** *Clipless cholecystectomy. Ultrasonic sealing device. Cystic duct sealing.*

## INTRODUCTION

Laparoscopic cholecystectomy is the gold standard procedure for gall stone disease. The procedure was first performed in France and United States in 1980's.<sup>1,2</sup> There have been various technical modifications since then; improving the outcome of surgery by scientific innovations. Modern energy devices used to dissect and coagulate tissue in laparoscopic surgery has made surgery safer and less invasive.<sup>3</sup> Harmonic scalpel is being used in a number of complex operations other than cholecystectomy, owing to its effective sealing capabilities.<sup>4-7</sup>

Laparoscopic cholecystectomy using the conventional tools like monopolar diathermy and liga-clips are

associated two to three times more frequently with injuries to common bile duct and/or collateral organ injuries as compared to open cholecystectomy.<sup>2</sup> Monopolar cautery is still the most commonly used energy device to dissect and coagulate tissue while performing laparoscopic procedures till early 2000. Use of monopolar L-hook device is associated with known risks of collateral thermal injuries to surrounding viscera, arcing with the metallic sleeve and/or metallic ports as well as thick smoke due to charring of tissues.<sup>3</sup> Scientists have developed an ultrasonically activated scalpel. Harmonic - (Ethicon Endosurgery Inc. J&J Medical SPA, Somerville, NJ) relies on mechanical effect of vibration at high ultrasonic frequency constructed.

It allows three effects which act synergistically, i.e. coagulation, clotting and cavitation. The device can be used to cut the tissue once coagulated as well.<sup>8</sup> All these effects are achieved by producing at a considerably less temperature as compared to conventional monopolar L-hook cautery. This in turn is associated with lower collateral thermal injuries and is FDA approved to seal vessels up to diameter of less than 5 mm. Use of harmonic scalpel further reduces the operative time by reduction in number of times instruments are changed, number of times camera port needs to be cleaned and amount of gas used due to lower smoke formation.<sup>9</sup>

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Few researchers have studied the use of ultrasound shear only to dissect the gall bladder off its bed.<sup>8,10,11</sup> Whereas, others have used ultrasound technology to ligate the cystic artery or cystic duct as well.<sup>9,12,13</sup> However, these studies have been done in acute setting where chances of bleeding are more due to difficult adhesions and surgery is associated with more complications and higher conversion rates.<sup>14</sup>

This randomized controlled trial was designed to determine any statistically significant difference in the treatment outcome of use of harmonic scalpel when all steps of procedure are done using this device only as compared to use of conventional monopolar diathermy L-hook and ligaclips in laparoscopic cholecystectomy.

### METHODOLOGY

A comparative study was conducted in Mayo Hospital, Lahore, from June 2013 to May 2014. Approval was obtained from Institutional Ethical Review Committee.

All adult patients diagnosed with gall stones based on history and examination and confirmed by an upper abdominal ultrasound for presence of stone with normal liver function tests were included in the study. All patients signed an informed consent form and were free to leave the study at any point, if they feel uncomfortable prior to induction.

Any case with common bile duct stones, intrahepatic biliary channel dilatations, raised gamma GT or alkaline phosphatase (evidence of obstructive jaundice), fever with rigors and chills, previous hepatobiliary surgery, and previous midline abdominal surgeries were excluded in the screening phase. Peroperatively any case with cystic duct size more than 5 mm were excluded from the study based on safety recommendation of use of vessel sealing device's recommendation by FDA.

A sample size of 150 cases (75 in each group) was calculated with 80% power of study, 5% level of significance and taking expected percentage of gall bladder perforation upto 2.72% in laparoscopic clipless cholecystectomy using harmonic scalpel group versus 18.6% in conventional laparoscopic cholecystectomy group using clips and monopolar cautery.

Patients were randomized prospectively into harmonic scalpel group (HSG, Group A; n=75) or conventional laparoscopic cholecystectomy group or CLC (Group B; n=75). Randomization was done by pulling-in-an-envelope-method upon the patient's arrival in the operating suite. The allocation was made into equal groups of 30 (15 from each group) to ensure uniformity; and mid-term assessment could have been possible by the internal auditors. An informed written consent was obtained from all the participating cases. The study was registered with [www.researchregistry.org](http://www.researchregistry.org) registration UIN research registry 2219.

The standard laparoscopic cholecystectomy was performed using standard four ports, CO<sub>2</sub> insufflations, tissue dissection along with dissection of liver bed and coagulation and division of the cystic duct and artery with harmonic scalpel in Group A. The settings of the harmonic generator generation 4<sup>®</sup> was set to 2 on the coagulation paddle as recommended by the manufacturer. An indelible marker was used to mark the 4 mm on the blade of harmonic shear. Any duct, where the diameter of the cystic duct was larger than the ink marker, were coagulated with the device; but an additional intracorporeal knot was placed to add security. The cystic duct was sealed at two places approximately 0.5 - 1.0 cm apart depending on the length of the cystic duct available. After confirmation that the sealed sites are visibly collapsed, cutting was done in the middle first coagulating and then cutting the duct. A picture of each case was recorded for later review. Cystic artery was simply coagulated at one place and cut approximately after sealing 5-10 mm distal to the distal sealed site.

In group B, tissue dissection along with dissection of liver bed was done with electrocautery and clipping or ligation and division of the cystic duct and cystic artery with titanium clips would be done. A Redivac suction drain No.14 was kept in all cases in harmonic scalpel group.

Operation time was recorded from creating pneumoperitoneum to complete hemostasis and removal of gall bladder. Time taken to place first port, placement of drain and closure of the port sites were excluded to reduce any bias. All the patients received 3 doses of intravenous antibiotic (cefuroxime 750 mg) one dose at the time of induction and next two doses eight hours apart. All the patients were discharged on first postoperative day and drain removed on the third postoperative day when there was no reveal.

The statistical analysis was performed in SPSS Version 11.0 (Chicago, IL, USA) and a p-value  $\leq 0.05$  was considered statistically significant. Descriptive analyses were performed for demographic data. Mean with standard deviation, calculated for age, frequencies with percentages, were determined for qualitative variables. Tests for normality were applied. The dependent variables were analyzed for normal distribution. The data for age, blood loss and drain output were positively skewed as calculated using the Shapiro-Wilk test. The histograms, Q-Q plots and box plots were analyzed for all the dependent variables. Skewed qualitative continuous data was analyzed using the Mann-Whitney U-Test.

Chi-square test was used to compare categorical variables including gender and rate of perforation. Data analyses were done on 'intention to treat' basis.

## RESULTS

A total of 150 consecutive cases were included for elective laparoscopic cholecystectomy. The demographic statistics are tabulated in Table I.

Operative time was significantly lower in group A as compared to conventional electrocautery group B. Median operative time for group A was 30 minutes (IQR 10) versus 35 minutes (IQR 10,  $p < 0.001$ , Table II) In Group-A only 5/75 (6.67%) patients had gallbladder perforation, whereas in Group-B 16/75 (21.33%) patients had gallbladder perforation using the L-hook electrocautery, respectively ( $p = 0.010$ ).

Intraoperative blood loss in group A was significantly lower than in group B ( $p = 0.001$ ). Postoperative pain in both groups were calculated using the Visual Analogue score from 1 - 10. Median pain score was 3 (IQR 2) versus 3 (IQR 3) in HSG versus CLC, respectively.

None of the patients in either group had bile leaks or sub-hepatic fluid collection defined as any fluid in excess of 10 ml, on follow-up ultrasonography at 2 and 4 weeks.

**Table I:** Basic demographic details.

	Total n = 150	Group A n = 75	Group B n = 75
Male/female	22/128 (1:5.8)	7/68 (1:9.7)	15/60 (1:4)
Median age (IQR)	40 (11)	40 (9.9)	39 (12.78)
Conversions	0/150	0/75	0/75

Key: Group-A = Harmonic scalpel group; Group-B = Conventional laparoscopic cholecystectomy

**Table II:** Comparative details of variables in each group.

	Total	Group A n = 75 Median (IQR)	Group B n = 75 Median (IQR)	p-value (Mann-Whitney U-test)
Intraoperative blood loss (ml) median (IQR)	5.00 (15)	5.00 (10)	10.0 (20)	0.001*
Operative time (in minutes) median (IQR)	35 (11)	30 (10)	35 (10)	<0.0001*
Hospital stay (hours) median (IQR)	30 (6)	30 (06)	36 (16)	0.708
Drain output (day 1) median (IQR)	20 (75)	15 (10)	30 (20)	<0.0001*
Drain output (day 2) median (IQR)	00 (25)	00 (00)	00 (25)	<0.0001*
Bleeding from liver bed	24 (16%)	1/75 (1.3%)	23/75 (31%)	<0.0001**
Stone spillage	19 (12.7%)	5/75 (6.7%)	14/75 (18.7%)	<0.0001**

Key: \*p-value=0.000 (Significant: p-value<0.05); \*\* Chi-squared test applied.  
Group-A= Harmonic scalpel group (HSG); Group-B= Electro-Cautery group (ECG).

## DISCUSSION

The introduction of new laparoscopic instruments and advanced coagulation devices have improved treatment outcome in patients with gall stone disease. Conventional laparoscopic cholecystectomy uses electrocautery to coagulate, dissect and metallic clips ligate tubular structures.<sup>1</sup> The gall bladder has to be

dissected off its vascular liver bed. Use of unipolar electrocautery is associated with arching, coupling, collateral thermal injury to adjacent organs and increased rate of perforation of gall bladder during dissection of its bed. Metal clips applied to cystic artery and duct have been reported to get loose or dislodge, can result in partial injury/occlusion of CBD and later present as stricture or a biliary fistula due to necrosis of the wall.<sup>1,4,10</sup>

Harmonic shears use ultrasound energy at high frequency to coagulate, dissect, ligate as well as cut tissues. This energy source is believed to have a safer profile for dissection, coagulation as well as sealing of cystic duct and artery. The instrument is FDA approved for ligation of blood vessels up to 5 mm.<sup>3,10</sup> The instrument has gradually gained acceptance for use other than ligation of blood vessels. This study evaluated the efficacy of ultrasound shear in performing all three steps for laparoscopic cholecystectomy; ligation of cystic artery as well as duct and taking off gall bladder of its fossa (clipless laparoscopic cholecystectomy). The results were compared with outcome measures used to conventional unipolar electrocautery, surgical liga-clips and Maryland dissector forceps (conventional laparoscopic cholecystectomy).

Majority of authors have studied use of ultrasound shears only to dissect the gall bladder of its bed.<sup>4,10-14</sup> The ability to perform all the key steps in the procedure using the same instrument can reduce the operative time by reducing the number of times instruments were changed, prevents dissipation of heat, arcing of electrical current, thermal injuries to surrounding structures specially in the Callot's triangle. Other benefits include prevention of injuries related to liga-clips including its slippage, inadvertent application on the common bile duct or the common hepatic duct.

We enrolled 150 cases, divided into two equal groups to reach a power of study of 80%. Primary and secondary outcome measures showed better results in the harmonic scalpel group with significant lesser bleeding and gall bladder perforations as well as lesser operative time.

Use of harmonic scalpel has been studied to report efficacy of the instrument to dissect the gall bladder from its fossa.<sup>4,11-15</sup> However, fewer randomized studies have determined outcome of use of instrument to ligate the cystic artery without use of clips as well.<sup>3,8,15-17</sup> In this study, a drain was placed in the hepatorenal pouch as part of the protocol to determine any leakage from the ligated cystic duct in the harmonic scalpel group which can further reduce the time of stay and postoperatively pain associated with drain.

Gall bladder perforation with use of harmonic scalpel in terms was significantly lower in HSG group (6.7% versus 21.3%). Blood loss during the dissection 5.0 ml (IQR 10)



was significantly lower in HSG 10 ml (IQR 20). The amount of intraoperative blood loss was markedly different with means ranging from approximately 10 ml in the HSG to more than 160 ml of intraoperative blood loss in conservative group.

This study population was younger as compared to reported studies and all patients with signs and symptoms of acute cholecystitis were excluded to reduce bias and risk of injury to extrahepatic biliary channels using harmonic scalpel.<sup>3,4,18</sup>

The difference between mean operation time for HSG (28.93 ±6.892 minutes) was statistically significant as compared to LCC (40.07 ±10.67 min) ( $p < 0.05$ ). The difference in duration is due to number of times the instruments have to be switched, taken out of the operation field and replaced by another one. One study reported no difference in time to perform the procedure using two techniques with a study group of only 20 cases each (31.5 ±11.1 with harmonic dissection versus 33.1 ±10 minutes electrocautery) group.<sup>20</sup> However, the reported total time was longer than our study in both groups, owing to the fact that the study included acute cholecystitis cases as well.<sup>19</sup>

The presently reported operation time is comparable to Janssen *et al.* and Kandil *et al.* (33.21 ±9.6 vs. 51.7 ±13.79 min).<sup>9,20</sup> The amount of smoke created in harmonic scalpel group is generally lesser as compared to the electrocautery group. However, there is no direct mean to objectively measure the variable. Janssen *et al.* indirectly compared smoke produced by calculating number of times camera head had to be cleaned during the procedure in two groups.<sup>9</sup>

Three patients in the HSG were excluded from the study since the size of cystic duct was more than 5 mm and based on the recommendation of FDA, deemed unsafe for the closure of cystic duct. Clip applicators were used in two cases; whereas, in one case intracorporeal knot with vicryl was applied.

Hospital stay in hours (HSG 32.9 ±5.53 versus group B 38.95 ±16.58) was extended in group A due to placement of a drain as per study protocol in group A cases. Gelmini *et al.* reports additional procedures done in several of the patients in their study which creates bias and parameters cannot be compared to efficacy of harmonic scalpel dissection in laparoscopic cholecystectomy alone.<sup>3</sup> There was no conversion to open surgery in either of these two groups, which is down from 4.9% for harmonic scalpel and 14% for conventional laparoscopic cholecystectomy.<sup>18</sup> However, these studies have included acute cholecystitis patients as well.

The authors understand that the placement of the drain was a precautionary measure for the novel procedure due to lack of level I evidence. The hospital stay can further be reduced if the drain is placed selectively in

patients who have any indication to place the drain rather than the part of a protocol. Harmonic scalpel has been proven safe for open surgery and ligating the blood vessels.<sup>21-23</sup> The efficacy to use this technique to ligate the biliary channels has scarcely been studied. The extent of transfer of heat to adjacent structure, thermodynamic changes in the presence of pneumoperitoneum have not been studied. The stability of the seal formed by the harmonic scalpel is not been investigated as well.

## CONCLUSION

Laparoscopic surgery is in the process of evolution and introduction of new technology and user-friendly gadgets have improved patients outcome and have made procedures safer as compared to conventional procedural steps. Further, scientific evidence regarding efficacy and safety of ultrasonic devices may devise new hand-piece designs which can be user-friendly.

## REFERENCES

- Huscher CG, Lirici MM, Anastasi A, Sansonetti A, Amini M. Laparoscopic cholecystectomy by harmonic dissection. *Surg Endosc* 1999; **13**:1256-7.
- Fullum TM, Kim S, Dan D, Turner PL. Laparoscopic "Dome-down" cholecystectomy with the LCS-5 harmonic scalpel. *JLS* 2005; **9**:51-7.
- Gelmini R, Franzoni C, Zona S, Andreotti A, Saviano M. Laparoscopic cholecystectomy with harmonic scalpel. *JLS* 2010; **14**:14-9.
- Liao G, Wen S, Xie X, Wu Q. Harmonic scalpel versus monopolar electrocauterization in cholecystectomy. *JLS* 2016; **20**:3.
- Hammad AY, Deniwar A, Al-Qurayshi Z, Mohamed HE, Rizwan A, Kandil E. A prospective study comparing the efficacy and surgical outcomes of harmonic focus scalpel versus ligasure small jaw in thyroid and parathyroid surgery. *Surg Innov* 2016; **23**:486-9.
- Bilgin Y, Hot S, Barlas IS, Akan A, Eryavuz Y. Short- and long-term results of harmonic scalpel hemorrhoidectomy versus stapler hemorrhoidopexy in treatment of hemorrhoidal disease. *Asian J Surg* 2015; **38**:214-9.
- Khan S, Khan S, Chawla T, Murtaza G. Harmonic scalpel versus electrocautery dissection in modified radical mastectomy: a randomized controlled trial. *Ann Surg Oncol* 2014; **21**:808-14.
- Hüscher C, Lirici M, Di Paola M, Crafa F, Napolitano C, Mereu A, *et al.* Laparoscopic cholecystectomy by ultrasonic dissection without cystic duct and artery ligation. *Surg Endoscopy Interv Tech* 2003; **17**:442-51.
- Janssen I, Swank D, Boonstra O, Knipscheer B, Klinkenbijn J, Van Goor H. Randomized clinical trial of ultrasonic versus electrocautery dissection of the gallbladder in laparoscopic cholecystectomy. *Br J Surg* 2003; **90**:799-803.
- Vu T, Aguilo R, Marshall NC. Clipless technique of laparoscopic cholecystectomy using the harmonic scalpel. *Ann R Coll Surg Engl* 2008; **90**:612.
- Li GX. Practical skills of harmonic scalpel in laparoscopic gastro-

- intestinal surgery. *Zhonghua wei chang wai ke za zhi; Chin J Gastrointest Surg* 2013; **16**:919-21.
12. Dutta DK, Dutta I. The harmonic scalpel. *J Obstet Gynaecol India* 2016; **66**:209-10.
  13. Bessa SS, Al-Fayoumi TA, Katri KM, Awad AT. Clipless laparoscopic cholecystectomy by ultrasonic dissection. *J Laparoendosc Adv Surg Tech A* 2008; **18**:593-8.
  14. Catena F, Di Saverio S, Ansaloni L, Coccolini F, Sartelli M, Vallicelli C, *et al.* The HAC trial (harmonic for acute cholecystitis): a randomized, double-blind, controlled trial comparing the use of harmonic scalpel to monopolar diathermy for laparoscopic cholecystectomy in cases of acute cholecystitis. *World J Emerg Surgery* 2014; **9**:53.
  15. Westervelt J. Clipless cholecystectomy: broadening the role of the harmonic scalpel. *JLS: JLS* 2004; **8**:283.
  16. Bulus H, Basar O, Tas A, Yavuz A, Akkoca M, Coskun A, *et al.* Evaluation of three instruments for laparoscopic cholecystectomy: harmonic scalpel, bipolar vessel sealer, and conventional technique. *Minerva Chir* 2013; **68**:537-42.
  17. Tebala GD. Three-port laparoscopic cholecystectomy by harmonic dissection without cystic duct and artery clipping. *Am J Surg* 2006; **191**:718-20.
  18. Catena F, Ansaloni L, Di Saverio S, Gazzotti F, Coccolini F, Pinna AD. Prospective analysis of 101 consecutive cases of laparoscopic cholecystectomy for acute cholecystitis operated with harmonic scalpel. *Surg Laparosc Endosc Percutan Tech* 2009; **19**:312-6.
  19. El-Geidie AA. Single-incision laparoscopic cholecystectomy (SILC) using harmonic scalpel. *J Surg Res* 2012; **176**:50-4.
  20. Kandil T, El Nakeeb A, El Hefnawy E. Comparative study between clipless laparoscopic cholecystectomy by harmonic scalpel versus conventional method: a prospective randomized study. *J Gastrointest Surg* 2010; **14**:323-8.
  21. Zhao JZ, Gao M, Yu Y, Li YG, Li XL, Wei SF, *et al.* [Harmonic scalpel versus conventional resection in thyroid surgery: a meta analysis on the safety outcomes]. *Zhonghua Er Bi Yan Hou Tou Jing Wai Ke Za Zhi* 2013; **48**:752-7.
  22. Sista F, Abruzzese V, Schietroma M, Cecilia EM, Mattei A, Amicucci G. New harmonic scalpel versus conventional hemostasis in right colon surgery: a prospective randomized controlled clinical trial. *Dig Surg* 2013; **30**:355-61.
  23. Shin YS, Koh YW, Kim SH, Choi EC. The efficacy of the harmonic scalpel in neck dissection: a prospective randomized study. *Laryngoscope* 2013; **123**:904-9.

