

## Clinical Outcome of Clip-Less Cholecystectomy Versus Conventional Laparoscopic Cholecystectomy

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### Abstract

**Background:** Laparoscopic cholecystectomy is the gold standard worldwide in the surgical treatment of cholecystitis and symptomatic gallstone because it gives well known and more definite advantages if compared with the open procedure. The traditional Laparoscopic cholecystectomy is usually performed by mean of the dissector, the electrosurgical hook, spatula and /or scissor, this method has been used in most centers. Now Harmonic scalpel is used widely to include surgery of head and neck, chest and liver, spleen kidney, adrenal glands colon, rectum and others.**Aim:** We present this paper in a trial to evaluate the safety, efficacy and clinical outcome of Laparoscopic cholecystectomy using harmonic scalpel for securing cystic duct and artery compared with conventional laparoscopic cholecystectomy. **Patients and method:** Prospective interventional study was carried out from 1st February 2012 to 14th January 2013, 60 patients were included by laparoscopic cholecystectomy for symptomatic gallstone disease at Slemani Teaching Hospital. The primary outcome was the duration of the operation .the second outcome was the conversion rate .The third outcome was perforation of gallbladder during dissection .the fourth outcome was bleeding during the operation and all were reported intra operatively. All possible complications and clinical outcomes in 30 days period compared in both groups.**Results:** This study was conducted in a period from 1st February 2012 to 14th January 2013, during this time sixty patients were included to this prospective randomized study, the patients were divided in to two groups each with 30 patients with the mean age 39.0 ranging from 22 to 66 years. They were 85 % female and the remainder were males with non-significant results statistically regarding age and gender. We found; The mean operative time was (33.17±8.23) in group A and (18.53±2.37) in group B ; p = <0.001, The incidence of gall bladder perforation was 43.33% in group A and 13.33% in group B; p= 0.010, The incidence of pain at 24 hour postoperatively is significantly more in group A compared with group B; p= 0.021. **Conclusion:** We found that harmonic scalpel cholecystectomy is comparable to conventional laparoscopic cholecystectomy in, shortening the time of the procedure and has less sequels and complications in comparison to conventional laparoscopic cholecystectomy.

**Key Words:** Conventional laparoscopic cholecystectomy, harmonic scalpel laparoscopic cholecystectomy, pain, gallbladder perforation and duration of operation.

### INTRODUCTION

Laparoscopic cholecystectomy (LC) is the gold standard worldwide in the surgical treatment of cholecystitis and symptomatic gallstone because it gives well known and more definite advantages if compared with the open procedure (1, 2).

From the late 1980s LC was popularize by Mouret and Dubois, in the Europe and United States (3) and a dramatic increase in its use for cholecystectomy occurred during the 1990s.

The ultrasonic activated device (USAD) was invented in 1994 by Amaral(4) to simultaneously perform hemostasis and dissection, this device is excellent for coagulation dissection of soft tissue and is currently used for numerous kind of endoscopic surgery, such as cholecystectomy (5), large intestine operations (6)gastrectomy(7) and liver resection (8).

The traditional LC is usually performed by mean of the dissector, the electrosurgical hook, and spatula and /or scissor, this method has been used in most centers.

Deep tissue damage with possible distant tissue damage by the high frequency electro surgery involving vascular and biliary structure in the vicinity of cystic duct and artery(9-10), bile leakage due to slippage of clips(11-12), and collateral injuries i.e. visceral and solid organ injury due to frequent instrument exchange, which is sometimes performed without optic guidance.

There is possibility that the clips could migrate or fall off and cause bile leakage(13,14),further more monopolar and bipolar electro cautery can lead to thermal injury to the CBD and liver.

It has been reported that 90% of visceral injuries and 15% of bile ducts injuries and electrosurgical burn during LC have been associated with monopolar electro cautery.(15,16)

The majority of electrosurgical injuries manifest late or goes unrecognized. Ultracision Harmonic scalpel, Ethicon end surgery contain a generator producing acoustic waves at a frequency of 55,000 Hz , the waves are transferred to the active blade of the instrument , vibrating harmoniously at the same frequency allows 3 effects that act synergistically , coagulation, cutting and cavitation, It is also an effective tool for closure of biliary tract and vessels whose diameter is less than 4mm to 5mm as certified by FDA in 2006.The primary use of harmonic scalpel in the LC is for the division of cystic duct and artery and liver bed dissection.(15, 16)

Vibration of the blade generate frictional heat ,denaturing protein in blood to arrest hemorrhage , at the same time the mechanical action of the ultrasonic vibration perform dissection(17).

In addition to the direct cutting action of the vibrating blade ultrasound waves cause cavitation fragmentation of tissue and additional cutting effect (18) .The coagulation effect occur due to protein denaturation (19). In contrast to electrical and laser coagulation working with harmonic scalpel produce lower production of thermal energy 80Co thus causing significantly less damage to the adjacent tissue (20).

The temperature obtained and lateral energy spread are lower than those detected when monopolar hook is used thus reducing the risk of tissue damage (21-22).

Now Harmonic scalpel is used widely to include surgery of head and neck, chest and liver, spleen kidney, adrenal glands colon, rectum and others (23, 24).

This paper is a trial to evaluate the safety, efficacy and clinical outcome of LC using harmonic scalpel for securing cystic duct and artery compared with conventional laparoscopic cholecystectomy.

### **PATIENTS, MATERIALS AND METHODS**

Prospective interventional study was carried out from 1st February 2012 to 14th January 2013, 60 patients were included by laparoscopic cholecystectomy for symptomatic gallstone disease at Slemani Teaching Hospital. The exclusion criteria included patient with history of upper abdominal laparotomy, suspicion of gallbladder malignancy (based on radiological feature of ultra sound or CT scan) and pregnant women. The subject of this work approved by the ethical committee of Iraqi board of medical specialization in general surgery.

All patients were signed the informed consent and subjected to thorough history and clinical examination focusing on manifestation of gallstone disease. The following investigations were performed liver function tests (total serum bilirubin, alkaline phosphatase, SGPT), HCV, HBsAg and HIV markers and abdominal ultrasound to show the state of liver, portal vein, gallbladder and common bile duct and CT scan and MRCP for suspected cases of CBD stone and malignancy of gallbladder, but intraoperative cholangiography is not performed and not available in our center. The patients were randomized into two groups: group A, LC was done using clips and cautery method and group B, LC was done using harmonic scalpel. Each group included 30 patients.

Operative procedures were performed with the patient under general anesthesia, placed in supine position, reversed Trendelenburg position with the right shoulder up and tilted to left. A uniform laparoscopic technique was performed using conventional four ports namely the supra-umbilical port, a port 6 cm below xiphoid in the midline and two ports below right costal margin, one at right midclavicular line and the other at anterior axillary line. Pneumoperitoneum by CO<sub>2</sub> gas at maximum pressure of 14 mmHg was used. Dissection of the gallbladder was initiated at the triangle of Calot with identification and skeletonization of both cystic duct and artery.

In group A LC was done using clips and cautery method: using non-traumatic dissecting forceps for dissection of Calot's triangle. Clipping of both cystic duct and artery by metal clips whereas the division of cystic duct and artery achieved by scissor after that dissection of gallbladder from its bed done with electro cautery hook finally the gallbladder was delivered through the supra-umbilical port.

In group B, LC was done by harmonic scalpel which is used for dissection of Calot's triangle and then occlusion of both cystic duct and artery. The harmonic scalpel was used in dissecting of Calot's triangle with the power level set at (5) which translated into more cutting and less coagulation. For the closure of both cystic duct and artery the instrument was set at power level (3) which translated into less cutting and higher coagulation. The cutting end of cystic duct was checked for presence of any bile leakage or stone.

The primary outcome was the duration of the operation. The second outcome was the conversion rate. The third outcome was perforation of gallbladder during dissection. The fourth outcome was bleeding during the operation and all were reported intra operatively.

Operative time was measured from the insertion of last port to delivery of the gallbladder. The post-operative pain was observed during the first 24hour.

Post-operative analgesia was given in the form of paracetamol 600 mg IV injection bid and hyoscine injection 20 mg bid. Post-operative vomiting assessed during the first (24) hour .The length of hospital stay was determined by the patients' needs and post-operative recovery. In the first post-operative day liver function tests were done and repeated in visits on 7th and 28th days.

**Numeric Pain scoring system**

Rating	Pain Level
0	No Pain
1 – 3	Mild Pain (nagging, annoying, interfering little with ADLs)
4 – 6	Moderate Pain (interferes significantly with ADLs)
7 – 10	Severe Pain (disabling; unable to perform ADLs)

ADL= Activity of daily living

The Numeric Rating Scale (NRS-11) is an 11–point scale for patient self-reporting of pain. It is for adults and children 10 years old or older. (25)

**RESULTS**

This study was conducted in a period from 1stFebruary 2012 to 14th January2013, during this time sixty patients were included to this prospective randomized study ,with the mean age 39.0 range from 22 to 66 years, with the mean age 39.0 for group A and 41.0 for group B. They were 85 % female and the remainder were males with non-significant results statistically regarding age and gender. The mean operative time was (33.17±8.23) in group A and (18.53±2.37) in group B; p = <0.001

Table 1 explores duration of operation (33.2 minutes) was reported among group A and mean duration (18.5 minutes) was reported for group B, these associations statistically was highly significant p = < 0.001

**Table1 shows association between clip and harmonic scalpel cholecystectomy and duration of operative time.**

Type of operation	Operative time (Minutes) Mean± Std. Deviation	P value
Harmonic scalpel	18.53±2.37	<0.001
Clip	33.17±8.23	

The incidence of gall bladder perforation was 43.33% in group Aand13.33% in the B group; p = 0.010.

In the group Atow patients were converted to open cholecystectomy, one of them due to common bile duct injury and the other due to uncontrolled bleeding, but in the harmonic scalpel group all the cases were completed laparoscopically.

**Table II shows complications in each group of A & B**

Variables	Types of operation		P values
	Group B N 30	Group A N 30	
<b>Conversion to open cholecystectomy</b>	0(0.0)	2(6.66)	<b>0.150</b>
<b>Gall bladder perforation</b>	4(13.33)	13(43.33)	<b>0.010</b>
<b>CBD injury</b>	0(0.0)	1(3.33)	<b>0.313</b>

The incidence of pain at 24 hour postoperatively is significantly more in the group A compared with group B;  $p = 0.021$

Moderate and severe pain was reported in group A (43% and 17%) respectively. Mild postoperative pain was reported in harmonic group B (73%) while largest percentage of these associations statistically were significant;  $p = 0.021$

**Table III shows association of post-operative pain between clip cholecystectomy and harmonic scalpel cholecystectomy**

Severity of abdominal pain	Types of operation		P values
	Harmonic	Clip	
Mild	22(64.7%)	12(35.3%)	<b>0.021</b>
Moderate	7(35.0%)	13(65.0%)	
Sever	1(16.7%)	5(83.3%)	

**Table IV showing Postoperative complications between the two groups**

Variables	Types of operation		P values
	Harmonic No.(%)	Clip No.(%)	
<b>Right shoulder pain</b>	3(50.0)	3(50.0)	1
<b>vomiting</b>	10(41.7)	14(58.3)	0.292
<b>jaundice</b>	0(0.0)	1(100.0)	0.313
<b>postoperative bleeding</b>	0(0.0)	1(100.0)	0.313

**Table V shows perioperative details of the liver function test in both group A & B**

	<b>TSB (0.3 -1.1 )mg/dl Mean± S.D</b>	<b>SGPT Male: (10-40) units/L Female: (8-35) units/L Mean± S.D</b>	<b>S.ALP (40-12) units/L Mean± S.D</b>
<b>Preoperative</b>			
Clip	0.81±0.10	12.6± 3.97	36.72± 14.48
Harmonic	0.80±0.10	11.6± 3.9	43.74± 13.68
<b>Postoperative</b>			
Clip	0.83± 0.09	18.71± 11.36	45.80± 20.81
Harmonic	0.82± 0.09	15.50± 9.18	48.71± 16.05
<b>P values</b>	<b>0.141</b>	<b>&lt;0.631</b>	<b>&lt;0.214</b>

Each returned questionnaire was given an identity number. Prior to data entry and analysis, the questions of study were coded. The data was entered into a Microsoft Excel Spreadsheet, after data cleaning; the data was transported into SPSS (Statistical Package for the Social Sciences-version16.0) package software program for statistical analysis.

Descriptive statistics (numbers and percentage) were calculated for all variables, as well as analytical statistics was done to find the relations between variables. Statistical tests such as Chi-square, and T-test were used. A p-value < 0.05 was considered as significant

### DISCUSSION

The harmonic scalpel has been proven to be effective and safe instrument for hemostasis and dissection in laparoscopic surgical procedure ,to date the primary use of harmonic scalpel in LC has been for the division of cystic artery and liver bed dissection ,advancement in harmonic scalpel blade tip now provide for the reliable ultrasonic division and closure of the cystic duct.(26) In addition harmonic scalpel is also an effective tool for closure of biliary tract and vessels whose diameter is less than 5 mm as certified by FDA in 2006.(15, 16) In contra to conventional laparoscopic cholecystectomy, harmonic scalpel save time and clips, make imaging like MRI possible if needed in the future.

Ultracision Harmonic scalpel, Ethicon end surgery contain a generator producing acoustic waves at a frequency of 55,000 Hz , the waves are transferred to the active blade of the instrument , vibrating harmoniously at the same frequency allows 3 effects that act synergistically , coagulation, cutting and cavitation (27).

In this paper the mean operative time was significantly shorter in the harmonic group (18.53±2.37) versus the clip group (33.17±8.23)as a result reached by Samer et al.(28). Who reported the statistically significant shorter mean operative time in the harmonic group which could be attributed to several factors; the statistically significant lower incidence of gallbladder perforation in the harmonic scalpel group with subsequent avoidance of time loss in abdominal lavage and spilled stone retrieval on the other hand the harmonic scalpel is multifunctional instrument . It replaces the four instrument that used routinely in laparoscopic cholecystectomy , namely the dissector , clip applicator ,scissor and electrosurgical hook or spatula. (28)

Harmonic scalpel prevents the frequent blind extraction and reinsertion of these different instrument with the subsequent avoidance of time loss, also reduce the risk of visceral and solid organ injury associated with multiple instrument exchange and loss of necessary pneumoperitonium. (29)

Finally the activation of the harmonic does not form smoke, so allow the surgeon to work in a clean operative field throughout the operation. While the use of electro cautery causes smoke formation in the abdominal cavity and decrease visibility. Moreover, smoke must be evacuated by opening the valve of the trocars thus causing repeated loss of pneumoperitonium and a subsequent time loss.(30)

The reported incidence of gallbladder perforation during the LC ranged from 10 to 30% in some studies.(31) While we found just (43.33%) in conventional clip cholecystectomy group and (13.33%) in harmonic scalpel group.

Janssen et al(31)prospectively randomized 199 patient to either harmonic scalpel or electro cautery in the dissection of the gallbladder from the liver bed in the LC .The use of harmonic scalpel was associated with a statistically significant lower incidence of gallbladder perforation compared to electro cautery( 16 % vs 50% respectively , p value < 0.001) (32)

So harmonic scalpel devices are preferable over electro cautery in dissection of gallbladder in LC because of minimal local thermal injury no leak of electrical current so no risk of distant tissue damage. In addition the elimination of inadvertent sometimes unrecognized electrical arcing injury with their hazardous squeal supporting the role of harmonic scalpel as potentially safe instrument for dissection. (33, 34)

Samer et al (35) reported that the use of harmonic scalpel was associated with a statistically significant lower incidence of gallbladder perforation compared with clip and electro cautery LC (10 %to 30% respectively p <0.002). (35)

In this paper postoperative pain is significantly lower in harmonic scalpel group in comparison with conventional clip group. P= 0.021. The incidence of pain is significantly more in the clips and cautery group at 24 hours postoperatively when compared with harmonic LC the statistical difference may be related to several factors such as shorter duration of operation so we use less amount of gasses and less incidence of gallbladder perforation in harmonic group so less escape of bile in the peritoneum.(36, 37, 38) The severity of pain was calculated using the numerical pain scoring system.

Factors known to predispose to bile duct damage have included the use of diathermy producing what become known us the diathermy induced bile duct injury.(39,40, 41) The absence of bile duct injury in our study compared to current literature (42-43)adds further evidence to the safety of harmonic scalpel in the dissection of biliary structure in the laparoscopic cholecystectomy thus causing significantly low damage to the adjacent tissue. (44)The greater cost of harmonic scalpel when compared with the cost of electro cautery probe, has been regarded as a potential disadvantage. However in LC using harmonic scalpel is cost effective when considering that we use fewer overall instrument compared with combined cost of using multiple instrument also we are able to carry out more procedure on average list as a result of the shorter operative time and less complication and early hospital discharge and less pain eliminating all these costs makes it cost effective.

## CONCLUSION

The harmonic scalpel provides complete hemostasis for all patients and is a safe alternative to standard clipping of cystic duct and artery. It provide a shorter operation time , less evidence of gallbladder perforation, less postoperative time and less rate of conversion to open surgery.

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