

Laparoscopic cholecystectomy with harmonic scalpel

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Abstract:

Background: The Harmonic scalpel (HS) has been proven to be an effective, efficient, and safe instrument for dissection and hemostasis in both open and laparoscopic surgical procedures. The primary use of the HS in laparoscopic cholecystectomy (LC) has been for the division of the cystic artery and liver bed dissection. Advancements in the Harmonic scalpel blade tip now provide for the reliable ultrasonic division and closure of the cystic duct.

Objectives: This study was planned to compare the clips and cautery (CC) method of laparoscopic cholecystectomy (LC) versus LC using HS as regard to the safety and efficacy for symptomatic gallstone disease.

Patients and methods: This is a prospective study conducted in Baghdad Teaching Hospital/ 1st Surgical Unit at the Medical City, done on (120) patients within the period between 1st October 2010 and 1st October 2011 who underwent LC for symptomatic gallstone disease. These patients have been classified into two groups Group A included 60 patients who underwent the (CC) method, and Group B included 60 patients done by (HS) method. The intraoperative and postoperative parameters were collected including duration of operation, intraoperative blood loss, gallbladder perforation rate, postoperative pain, and complications.

Results: HS provides a shorter operative duration than CC (34.85±6.2 min vs. 49.75±9.49 min, respectively, $p=0.0001$), with a significant less incidence of gallbladder perforation (6.6% vs. 20%; $p=0.032$). There was no statistical difference in the conversion rate between both groups. The amount of postoperative drainage is significantly less in HS (37.98±17.25 vs. 49.18±22.65 ml; $p=0.003$). No postoperative bile leak was encountered in HS, but it occurred in 3.3% of patients in CC. Visual analog scale (VAS) for pain severity in HS at 24 hours postoperative was (3.95±0.74 vs. 4.94±1.34, $p=0.0001$).

Conclusion: HS provides a complete hemobiliary stasis and is a safe alternative to standard clipping of cystic duct and artery. It provides a shorter operative duration, less incidence of gallbladder perforation, less operative blood loss, less postoperative pain, and less rate of conversion to open cholecystectomy.

Keywords: Laparoscopic cholecystectomy (LC), Clips and Cautery (CC), Harmonic scalpel (HS).

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Introduction:

LC was popularized in the late 1980s by Mouret and Dubois in Europe and Reddick in the United States.¹ As a result of this pioneering work, a dramatic increase in the use of laparoscopic techniques for cholecystectomy occurred during the 1990s. LC is considered worldwide the “gold standard” in the surgical treatment of symptomatic gallstone and acute cholecystitis, because it offers well-known and more definite advantages in comparison with the laparotomy procedure.²

The traditional LC is commonly performed by means of dissector, the electro-surgical hook, spatula, and/or scissors, and this method has been used in most centers. Simple metal clips are frequently used to achieve cystic duct and artery closure.³ Alternative techniques for cystic duct closure have included linear stapler, endoloops, or sutures, which are, however, seldom used.⁴

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Although LC is a safe technique, several reports have pointed out special injuries and postoperative complications inherent in the limits of the current technology and technique.⁵ These include deep tissue damage with possible distant tissue damage by the high-frequency electro-surgery involving vascular and biliary structures in the vicinity of the cystic duct and artery⁶ bile leakage due to slippage of the clips⁶. And visceral and solid organ injuries due to frequent instrument exchange, which is sometimes performed without optic guidance.

There is a possibility that the clips could fall off causing a bile leak⁶. Or migrate causing the formation of common bile duct (CBD) stones. Furthermore, monopolar and bipolar electrocautery can lead to thermal injury to the CBD and liver. It has been reported that 90% of visceral injuries and 15% of bile duct injuries during LC have been associated with monopolar electrocautery.⁷ Also there is a possibility of electro-surgical burn during a laparoscopic procedure.⁸

The majority of electro-surgical injuries manifests late or goes unrecognized. The incidence of accidental burns caused

by unintentional energy transmission during a LC ranges between 0.06% and 0.3%. However, only one or two patients in 1,000 are recognized.⁹ The ultrasonically activated device (USAD) was invented in 1994 by Amaral¹⁰ to simultaneously perform hemostasis and dissection. This device is excellent for coagulating dissection of soft tissues and is currently employed for numerous kinds of endoscopic surgery, such as cholecystectomy¹¹, large-intestine operations¹², gastrectomy¹³ and liver resection¹⁴. A USAD consists of a transducer to generate ultrasonic vibration, an acoustic transmitting section of titanium alloy that transmits ultrasonic vibration generated by the transducer, and a treatment unit called the blade installed at the tip of the device. Vibration of the blade generates frictional heat, denaturing proteins in blood to arrest hemorrhage. At the same time, the mechanical action of the ultrasonic vibration performs dissection¹⁵.

The principle is transforming of the electric power into mechanical longitudinal movement of the working part of the instrument, by piezo electrical transducer situated in the hand piece. The primary use of the Harmonic scalpel in laparoscopic cholecystectomy has been for the division of the cystic artery and liver bed dissection. Advancements in the Harmonic scalpel blade tip now provide for the reliable ultrasonic division and closure of the cystic duct.¹⁶

Harmonic scalpel contains 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.¹⁷ 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.¹⁸⁻¹⁹ The Harmonic scalpel is also an effective tool for closure of biliary ducts and vessels whose diameter is <4mm to 5mm (as certified by the FDA in 2006).

In addition to the direct cutting action of the vibrating blade, ultrasound waves cause cavitations fragmentation of tissues and additional cutting effect^{20, 21}. The coagulation effect occurs due to tissue protein denaturation²². In contrast to electrical or laser coagulation, working with harmonic scalpel is associated with a considerably lower production of thermal energy (up to 80°C), thus causing significantly less damage to the adjacent tissue^{23,24}.

Patients and methods:

This prospective interventional study was carried out from October 2010 to October 2011. (120) patients were treated by laparoscopic cholecystectomy (LC) for symptomatic gallstone disease at Baghdad Teaching Hospital/ 1st Surgical Unit and were included in this prospective randomized study. The exclusion criteria included patients with history of upper abdominal laparotomy, common bile duct stones, suspicion of gallbladder malignancy (based on radiologic features of

ultrasound or CT scan), and pregnant women.

All patients were subjected to thorough history and clinical examination focused on manifestation of gallstone disease. The following investigations were performed [whole blood picture, liver function tests (total serum bilirubin, ALT, AST, alkaline phosphatase, serum albumin, and prothrombine time), HCV and HBV markers, and abdominal ultrasound] to show the state of the liver, portal vein, gallbladder, and CBD. CT scan for suspicion of gallbladder malignancy and CBD stones. No Intraoperative cholangiograms were performed. The following preoperative data were collected in preformed design for this study: age, sex, clinical presentation (biliary colic, acute cholecystitis) and associated comorbidities as diabetes, hypertension (DM, HT). Patients were randomized into two groups: Group A, LC was done using clips and cautery (CC) method, which included (60) patients and group B, LC was done using harmonic scalpel (HS), which included (60) patients.

Operative procedures were performed with the patient under general anesthesia, same antibiotics (Intravenous ceftriaxone 1g (2 doses): one dose 1hour (hr) before induction and another dose postoperatively), placed in supine, reverse-trendelenburg position with the right shoulder up. A uniform technique of the laparoscopic cholecystectomy was performed using conventional four ports, namely, the umbilical port, port below xiphoid, and two ports below right costal margin. Pneumoperitoneum by CO₂ gas at maximum pressure of 12 mmHg was used. Dissection of the gallbladder was initiated at the triangle of Calot with the identification and skeletonization of both the cystic duct and artery. In group A, LC was done by using clips and cautery method: dissection of Calot's triangle was performed with an atraumatic dissecting forceps. Clipping of both cystic duct and artery were done by metal clips, whereas the division of cystic duct was achieved by scissor and cystic artery by electrocautery hook. After that, dissection of the gallbladder from its bed was performed by using electrocautery hook. Finally, the gallbladder was subsequently removed through the subxiphoid port, and a subhepatic tube drain was inserted through the most lateral port. In group B, LC was done by using the harmonic scalpel (SÖRING) (for dissection of Calot's triangle and then occlusion of both cystic duct and artery) and the harmonic hook (SÖRING) for dissection of the gallbladder for liver bed. The Harmonic scalpel (SÖRING) was used for dissection in the triangle of Calot, with the power level set at "5," which translated into more cutting and less coagulation. For the closure and division of both the cystic duct and artery, the instrument was set at the power level "2," which translated into less cutting and more coagulation. Closure and division of the cystic duct proceeded as follows. First, it was ascertained that there were no micro calculi in the lumen of the cystic duct by moving the jaws of the Harmonic scalpel (SÖRING) up and down. Second, the

cystic duct was put between the jaws at a safe distance from the common bile duct to avoid damage to this structure, and the jaws were then closed. Third, the instrument was activated at the power level "2," and during this phase, great care was taken not to stretch the cystic duct or rotate the instrument, 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. For dissecting the gallbladder from its bed, we use the harmonic hook (SÖRING) and set it to level 5, i.e., more cutting power. No electrocautery was used, and control of oozing from the liver bed was easily achieved by applying the harmonic hook (SÖRING) and set it to level 2, i.e., more coagulation power tangentially to the tissue. Finally, the gallbladder was subsequently removed through the subxiphoid port, and a subhepatic tube drain was inserted through the most lateral port. The primary outcome was the duration of the operation. The secondary outcomes were the conversion rate, the amount of blood loss during the operation, the hospital stay, and the rate of complications. The conversion rate and Intraoperative findings were documented. The Intraoperative parameter observed included duration of the operation, bile escape, saline irrigation during operation, and volume of blood loss were all recorded.

Operative time was measured from the insertion of the last port to the removal of the gall bladder and was expressed in minutes. Blood loss was measured from the suction device. A value of 0 was given, if suction was not required owing to the negligible amount of bleeding. Gallbladder perforation during dissection from the liver bed was expressed by number of patients affected. Conversion rate to open surgery was assessed by number of patients in whom LC was converted to open cholecystectomy. The subhepatic closed drain was left for all patients in the study. Postoperative bile leakage was defined as bile continuing to be observed in the subhepatic drain during the postoperative stage. The patients were usually discharged after removal of drain and had uneventful recovery. Postoperative pain (PP) was evaluated at 24hrs. and 1 week after operation using a visual analog scale (VAS) (with which each patient noted the severity of pain at each evaluated time using a linear between 0 (no pain) and 10 (severe pain) and further analyzing pain as either incisional or shoulder pain. Postoperative analgesia in the form of tramadol 100 mg was administered intramuscularly when required. If the patients still complained of pain, strong analgesic (Pethidine 1 mg/kg intramuscularly) was administered. The total dose of these medications was recorded.

Postoperative body temperatures were recorded at (24 and 48 hrs.) for all patients. Postoperative vomiting "POV" were assessed after 48 hrs. by the number of patients suffering from postoperative vomiting as an outcome indicator for paralytic ileus. Metoclopramide was given if the patients developed nausea or vomiting, and the total doses of this medication

were recorded. The length of hospital stay was described as the number of hours during which patients stayed in hospital. It was determined by the patients' needs and the speed of postoperative recovery at the end of the 1st postoperative week, patients underwent a clinical examination and an abdominal ultrasound, with special attention to the presence or absence of any subhepatic (or otherwise) fluid collections. At the end of the 1st and 6th postoperative months, the clinical examination and abdominal ultrasound were repeated.

Statistical analysis: The statistical analysis of the data in this study was performed using the SPSS version 18. For continuous variables, descriptive statistics were calculated and reported as mean±SD. Categorical variables were described using frequency distributions. The Students' test for paired samples was used to detect differences in the means of continuous variables, and chi-square test was used in cases with low expected frequencies ($p < 0.05$ was considered to be significant).

Results:

Ten patients were excluded from the study due to different reasons: (2) patients had common bile duct stones, (5) patients had previous history of upper abdominal surgery ; (1) patient had suspicion of gallbladder malignancy, and (2) pregnant women. Consequently, (120) patients were included in this prospective randomized study and randomly divided into two groups. Group A, (60) patients underwent LC using the clips and cautery method (CC) with a mean age of 41.68 ± 7.28 years (range, 34-50 years), and group B, (60) patients underwent LC using the harmonic scalpel (HS) with a mean age 40.87 ± 8.85 years (range, 32-50 years).

There were 86 females and 34 males. No statistically significant difference was found between the age, sex, and clinical presentation and associated comorbidities in both groups. The demographic data for the patients in both groups are shown in Table 1.

Table 1 Patients' demographic data and clinical presentation

Variables	Group A	Group B	P value
Age	41.68±7.28 (34-50)	40.87±8.85 (32-50)	0.582
Male / female	16/44	18/42	0.683
Clinical presentation			
Biliary colic	50(83.3%)	52(86.7%)	0.609
Acute cholecystitis	10(16.7%)	8(13.3%)	0.609
Comorbid disease			
DM	10(16.7%)	12(20%)	0.637
HT	9(15%)	10(16.7%)	0.803

The mean operative time was significantly shorter in the HS group than in the CC group (34.85±6.2 min vs. 49.75±9.49 min; $p = 0.0001$). The Intraoperative blood loss was significantly greater in the CC group than in the HS group (86.25±31.16ml vs. 58.88±12.93 ml; $p = 0.0001$). The incidence of gallbladder perforation was significantly higher in the CC group than in the HS group (20% vs. 6.6%; $p = 0.032$). In the CC group, three patients (5%) were converted to open surgery (two due to unclear anatomy and one due to bleeding) but in the HS group, all cases were completed laparoscopically. Drainage tube was positioned in all patients, and it was maintained for at least 24 hours.

Table 2 Operative variables between the two groups

Variables	Group A	Group B	P value	
Operative time (min)	49.75±9.49	34.85±6.2	0.0001	Sig.
Intraoperative blood loss (ml)	86.25±31.16	58.88±12.93	0.0001	Sig.
Gall bladder perforation (Pts.)	12(20%)	4(6.6%)	0.032	Sig.
Conversion rate (Pts.)	3(5%)	0	0.079	N.S

The mean amount of postoperative drainage was significantly more in the CC group than in the HS group (49.18±22.65 vs. 37.98±17.25ml; $p = 0.003$). The hospital stay was shorter in the HS group (23.73±1.7 vs. 27.15±6.55hrs; $p = 0.0001$). The incidence of pain is significantly more in the CC group at 24hrs. Postoperatively (81.6% vs. 60%, $p=0.009$), but the incidence of PP at 1 week differs but did not reach a significance between both groups. VAS in HS group was lower than in the CC group; the difference is significant at 24hrs. Postoperative (3.95±0.74 vs. 4.94±1.34, $p=0.0001$), but the difference was insignificant at 1 week postoperative.

Table 3 Postoperative course variables between the two groups

Variables	Group A	Group B	P value	
Postoperative drainage (ml)	49.18±22.65	37.98±17.25	0.003	Sig.
Hospital stay (hr.)	27.15±6.55	23.73±1.7	0.0001	Sig.
Presence of Postoperative Pain				
Day 1	49(81.6%)	36(60%)	0.009	Sig.
Day 7	6(10%)	4(6.6%)	0.509	N.S
Postoperative pain severity (VAS)				
Day 1	4.94±1.34	3.95±0.74	0.0001	Sig.
Day 7	0.95±0.17	0.94±0.17	0.82	N.S
Postoperative pain site				
Day 1 (Incisional/shoulder)	43/5	31/5	0.627	N.S
Day 7 (Incisional/shoulder)	4/2	3/1		

The overall morbidity rate was 21.7 % (13/60) in the CC group versus 5 % (3/60) in the HS group, with the difference being statistically insignificant. No operative mortality occurred in either group. No major bile duct injuries were encountered in the current study. Bile leak was occurred into patients (3.3%) in the CC group (one from the accessory duct and one from the cystic duct), but no postoperative bile leak occurred in the HS group. All these bile leaks stopped spontaneously without need for any interference. The time course of changes in body temperature from preoperative (baseline) values is shown in Table 4. There was no observed significant change in temperatures in both groups.

The rate of pulmonary and port site infections was higher in the CC group than in the HS group but it did not reach statistical significance. Cases of port site infections occurred in 5 patients (8.3%) in the CC group and one patient (1.6%) in the HS group manifested by pain at the port site with signs of erythema, tenderness and indurations. It was treated by oral antibiotics and simple analgesia. Postoperative collection occurred in two patients (3.3%) in the CC group and one patient (1.6%) in the HS group manifested 7th post. op. day by Right hypochondrial or epigastric pain, anorexia, bloating, food intolerance, followed by U/S and treated conservatively by rest, reassurance, oral antibiotics, analgesia and dietary modification. Although, the total incidence of postoperative vomiting (POV) was higher in the CC group, the number of patients who expressed suffering from vomiting did not differ significantly at 48 hrs. (Table 4)

Table 4 Postoperative complications

Variables	Group A	Group B	P value	
Bile leak	2(3.3%)	0	0.159	N.S
Postoperative pulmonary complications	4(6.6%)	1(1.6%)	0.171	N.S
Port site infection	5(8.3%)	1(1.6%)	0.094	N.S
Postoperative collection	2(3.3%)	1(1.6%)	0.559	N.S
Body temperature				
Before the operation	36.61±0.37	36.64±0.39	0.74	N.S
24 hrs.	37.63±0.35	37.37±0.31	0.0001	Sig.
48 hrs.	36.89±0.35	36.83±0.31	0.318	N.S
Presence of postoperative vomiting (POV) at 48hrs.	3(5%)	1(1.6%)	0.309	N.S

Discussion:

The harmonic scalpel has been proven to be an effective and safe instrument for dissection and hemostasis in both open and laparoscopic surgical procedures. To date, the primary use of the harmonic scalpel in LC has been for the division of cystic artery and liver bed dissection. Advancements in the harmonic scalpel blade tip now provide for the reliable ultrasonic

division and closure of cystic duct.^{25,26} In our study, the mean operative time was significantly shorter in the harmonic group than in the clips and cautery group (34.85 ± 6.2 min vs. 49.75 ± 9.49 min, respectively, $p=0.0001$). We have the same result with Samer et al.²⁷ who reported that statistically significant shorter mean operative time in the HS group can be attributed to several factors; (1) the statistically significant lower incidence of gallbladder perforation in the HS group with subsequent avoidance of time loss in abdominal lavage and spilled stones retrieval and (2) the Harmonic ACE® is a multifunctional instrument. It replaces four instruments routinely used in the laparoscopic cholecystectomy, namely, the dissector, clip applier, scissors, and electrosurgical hook or spatula. Its use, therefore, prevents the frequent blind extraction and reinsertion of these different instruments with the subsequent avoidance of time loss. Finally, the activation of the Harmonic (SÖRING) 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. On the other hand, the use of electrosurgery 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. In our study, Intraoperative blood loss was significantly more in the CC group than in the HS group (86.25 ± 31.16 ml vs. 58.88 ± 17.97 ; $p=0.0001$). We feel that the potential benefits of the harmonic scalpel in this respect are that it allows better control of oozing from dissected tissues allowing the surgeon a clearer discrimination of anatomy. Huscher et al.³⁴ reported that harmonic scalpel has been proven to be an effective and safe instrument for dissection and hemostasis. The main finding of our study is the absence of either minor or major bile leaks from the cystic-duct stump in the HS group, denoting that the harmonic scalpel is as safe and efficient as simple metal clips in achieving the closure of the cystic-duct stump in the laparoscopic cholecystectomy. Such a finding provides further evidence to the conclusions of others²⁸⁻²⁹ who demonstrated that the harmonic scalpel is capable of producing a safe and efficient closure and division of the cystic duct in the laparoscopic cholecystectomy. Westervelt reported no bile leaks from the cystic-duct stump in his 100 patients in whom the closure and division of the cystic duct was achieved solely by the harmonic scalpel.²⁴ Similar findings were reported by Samer.²⁶ Huscher et al.²⁷ stated that the blades were first applied 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 grasp until the division of the duct was accomplished. 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 scalpel 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. Effective sealing of the cystic-duct stump by the harmonic scalpel has been confirmed histologically by Huscher et al.³⁵ 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.³⁰⁻³² Further, in the process of application, the metallic clips can fall from the applicator.³³

The above-mentioned hazards observed in the use of metallic clips were not encountered when closure and division of the cystic duct was achieved with the harmonic scalpel. Further, there was no reported hazard observed in the use of harmonic scalpel in the closure and division of the cystic duct. 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.”^{34,35} Ultrasonic instruments were developed to eliminate the collateral damage associated with electrosurgery.⁴² The lateral energy spread is minimal, and the risk of distant tissue damage is lower than that of high-frequency electrosurgery.^{4,36} Further, ultrasonic devices can coagulate and cut at a lower temperature (100°C) than occurs during electrosurgery (150°C) or laser surgery (200°C).³⁶

The reported incidence of gallbladder perforation during the laparoscopic cholecystectomy ranged from 10 to 30% in some studies.³⁷ In our study, the use of harmonic scalpel was associated with a statistically significant lower incidence of gallbladder perforation compared to electrocautery (6.6% vs. 20%, respectively; $p=0.032$). Janssen et al.³⁸ prospectively randomized 199 patients to either harmonic scalpel or electrocautery in the dissection of the gallbladder from the liver bed in the laparoscopic cholecystectomy. The use of harmonic scalpel was associated with a statistically significant lower incidence of gallbladder perforation, compared to electrocautery (16% vs. 50%, respectively; $P < 0.001$). Further, at logistic regression analysis, the risk of perforation with bile loss was about four times higher (odds ratio 0.26; $P < 0.001$) and that of perforation with stone loss was about six times higher (odds ratio 0.17; $P = 0.007$) in the electrocautery group, compared with the ultrasonic group.³⁸ We concluded that ultrasonic devices are preferable over electrocautery for gallbladder dissection in the laparoscopic cholecystectomy because of the minimal local thermal injury and the lack of electrical current with risk of distant tissue damage. Samer et al. reported that the use of the harmonic ACE® was associated with a statistically significant lower incidence of gallbladder

perforation, compared to electrocautery (10% vs. 30%, respectively; $p=0.002$)²⁶. We feel that gallbladder perforation with loss of bile and stones obscure the laparoscopic view, lead to frequent instrument exchange, and prolong the operative time.

LC has become the standard treatment for gallbladder disease. However, despite its low degree of invasiveness, many patients complain of PP and POV due to residual pneumoperitoneum. Many factors attributed to PP may be due to residual pneumoperitoneum, diaphragmatic stretch during laparoscopy, or duration of the operation with using large volume of gases.³⁸ The use of lower insufflations pressure (7.5 mmHg) has considerably decreased PP.³⁹ In our study and in the use of higher insufflations pressure of (12 mmHg which we think might be the cause), the incidence of pain is significantly more in the clips and cautery group at 24 hrs postoperatively (81.6% vs. 60%, $p=0.009$). VAS in HS group was lower than in CC group; the difference is significant at 24 hrs. postoperative (3.95 ± 0.74 vs. 4.94 ± 1.34 , $p=0.0001$). This statistical difference may be attributed to several factors such as shorter duration of operation, so we use less amount of gasses, and less incidence of perforation of gallbladder in harmonic group so less escape of bile in the peritoneum. The mean amount of postoperative drainage was significantly more in the CC group than in the HS group (49.18 ± 22.65 ml vs. 37.98 ± 17.25 ml, $p=0.003$). The hospital stay was shorter in the HS group (23.73 ± 1.7 hrs vs. 27.15 ± 6.55 hrs, $p=0.0001$) as reported by Huscher et al²³ and Tsimoyannis et al⁴⁰.

Author's Contributions:

Dr. Tariq Ibrahim, Data collection, Main surgeon, Patient follow up, Literature review.

Dr. Walled H. Salman Study Design, Manuscripts writing.

Dr. Hassan F. Aziz, Literature review.

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