

The Effectiveness of Harmonic Scalpel compared to Metal Clips in Ligating the Cystic Duct during Laparoscopic Cholecystectomy: A Meta-Analysis

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Background

During the course of laparoscopic cholecystectomy, ligation of the cystic duct is a necessary step in performing the procedure. Traditionally, the ligation of the cystic duct is carried out using metal clips. Even though this has been the standard tool for ligation, there are still reports of post-operative bile leaks leading to peritonitis.^{1,2} One of the reasons noted is laceration of cystic duct by the metal clips, which was attributed to necrosis of the clamped tissue and the ability of the metal clips to conduct electricity when electrocautery was used.³ Another reason is the occlusion and eventual necrosis of the cystic duct and erosion of the metal clips into the common bile duct.⁴ With the recent invention of ultrasonically activated scalpel or harmonic scalpel, this device was also used as an alternative to the traditional way of ligating the cystic duct. However, the efficacy of this alternative has not been proven. For this reason, the authors aim to present the best current evidence on the effectiveness of harmonic scalpel compared to metal clips in ligating the cystic duct during laparoscopic cholecystectomy.

Objectives

The authors aimed to determine the effectiveness of ultrasonically activated scalpel compared to metal clips during ligation of the cystic duct during laparoscopic cholecystectomy.

The specific objectives of this study includes:

1. To compare the operative time when either of the tools was used
2. To compare the duration of hospital stay when either of the tools was used
3. To compare the rate of post-operative complications of both methods

Methodology

A computer assisted literature search was done on electronic databases online such as Pubmed and Cochrane Central Register of Controlled Trials (CENTRAL). The electronic databases were identically searched using the following key words: "clipless cholecystectomy", "harmonic scalpel", "ultrasonically activated scalpel", "laparoscopic cholecystectomy." The search strategy used for both PUBMED and Cochrane CENTRAL are as follow: (((((((clipless) OR harmonic scalpel) OR ultrasonically activated scalpel) OR ligature) OR suture) OR intracorporeal ligation) OR absorbable clip) OR absorbable lock) AND cystic duct) AND laparoscopic cholecystectomy. The inclusion criteria used in this review were primarily randomized controlled trials that were written in the English language and published on 2014 or earlier.

Criteria for Considering Studies for this Review

Type of studies included were limited to randomized controlled trial, with patients who underwent laparoscopic cholecystectomy for symptomatic gallstones and were written in English. The interventions compared are use of harmonic scalpel and metal clips in ligation of cystic duct during laparoscopic cholecystectomy. The primary outcome measure was the rate of post-operative complications. Secondly, the operative time when either of the tools were used.

Results

A total of 73 studies were collected after a computer assisted literature search using the above mentioned key words. After review and evaluation of the studies searched, 3 studies met the set criteria for this study. A total of 492 patients were included in this review. Out of the 492 patients, 246 patients underwent laparoscopic cholecystectomy using Harmonic scalpel while 492 underwent conventional laparoscopic cholecystectomy. The age range of patients in the 3 trials was 18-66 (Kandil 2009), 18-83 (Kandil 2011) and less than 20 to more than 60 years old (Redwan 2010). The percentage of male in the 3 trials was 42% (Kandil 2009), 37.5% (Redwan 2010), and 9% (Jain 2011).

Different complications were reported in the 3 studies. However, there was no complication noted that was similar for all 3 studies. Two studies (Redwan 2010, Kandil 2009) reported a total of 3 postoperative bile leak in patients who underwent conventional laparoscopic cholecystectomy. In the study by Kandil (2009), 3 patients who underwent conventional laparoscopic cholecystectomy experienced post-operative pulmonary complications while there was 1 patient who experienced the same complication who

underwent laparoscopic cholecystectomy using harmonic scalpel. Also in the same study, 4 patients in the conventional group were noted to have experienced port site infection while there was 1 in the harmonic scalpel group.

In the conventional laparoscopic cholecystectomy, the duration of surgery are 64.7 (Jain 2011), 44.01 (Redwan 2010), and 51.7 minutes (Kandil 2009) while in the laparoscopic cholecystectomy using harmonic scalpel, the duration of surgery are 50 (Jain 2001), 16.8 (Redwan 2010), and 33.2 minutes (Kandil 2009).

The length of hospital stay in the conventional group are 2.52 (Jain 2011), 1.53 (Redwan 2010), and 1.12 days (Kandil 2009), while in the harmonic scalpel group are 1.89 (Jain 2009), 1 (Redwan 2010), and 0.98 days (Kandil 2009).

The risk of bias is summarized in Figure 1 and Figure 2. Three of the trials (100%) had adequate random sequence generation and all outcome data were reported. None of the trials discussed allocation concealment, blinding of participants and personnel, blinding of outcome assessment, and selective reporting of data.

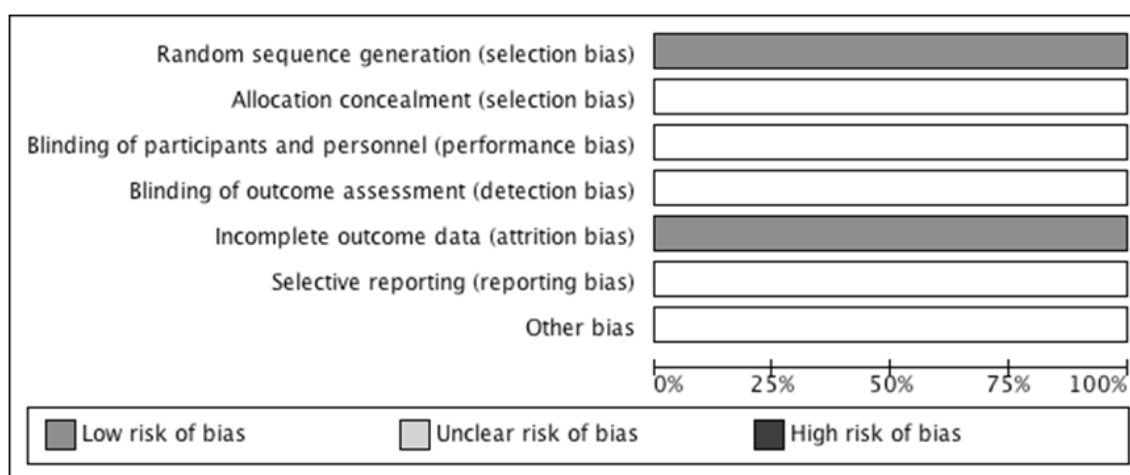


Figure 1. Risk of bias graph: review author's judgments about each risk of bias item presented as percentages across all included studies

Redwan 2010	Kandil 2009	Jain 2011	
+	+	+	Random sequence generation (selection bias)
			Allocation concealment (selection bias)
			Blinding of participants and personnel (performance bias)
			Blinding of outcome assessment (detection bias)
+	+	+	Incomplete outcome data (attrition bias)
			Selective reporting (reporting bias)
			Other bias

Figure 2. Risk of bias summary: review author's judgments about each risk of bias item for each included study

DISCUSSION

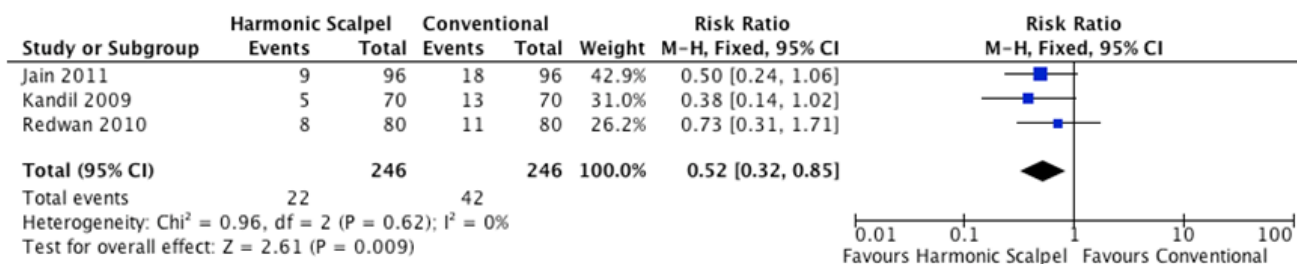


Figure 3. Gallbladder perforation

The three trials consistently showed a tendency towards a higher risk of gallbladder perforation with conventional cholecystectomy. However, metaanalysis of the results showed that there is a significantly higher risk of gallbladder perforation with conventional cholecystectomy. The risk of the complication with the use of harmonic scalpel is only half that with the use of conventional technique ($RR=0.52$, 95%CI 0.32, 0.85)

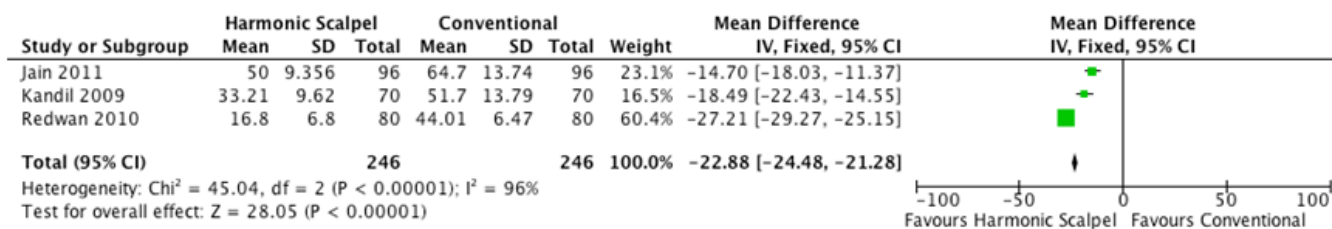


Figure 4. Duration of Surgery (minutes)

All three studies consistently showed significantly shorter duration of surgery with the use of harmonic scalpel. Combined results showed that the use of harmonic scalpel shortened the surgery by 23 minutes compared to conventional cholecystectomy (95% CI -24.5, -21.3)

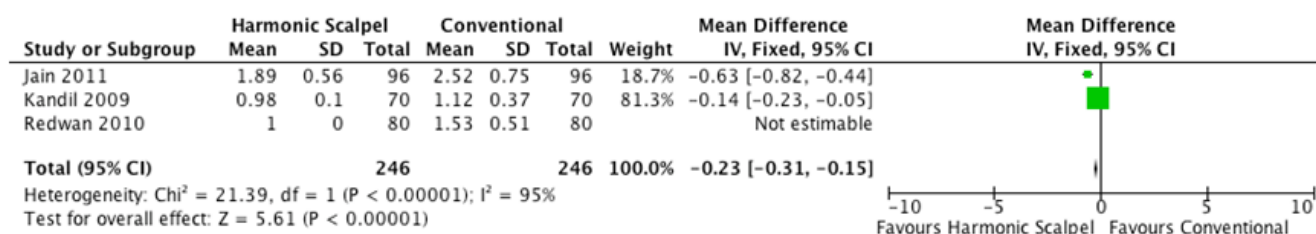


Figure 5. Duration of hospital stay

This review which consisted of 3 trials with a total of 492 patients compared the effectiveness of harmonic scalpel compared to metal clips in ligating the cystic duct during laparoscopic cholecystectomy.

All 3 trials were consistent in their results showing the advantages of using harmonic scalpel during laparoscopic cholecystectomy. Pooled analysis of the trials showed that utilization of harmonic scalpel is significantly associated with less risk of gallbladder perforation during dissection, lesser duration of operation, and lesser duration of hospital stay. As for the duration of duration hospital stay, although it was deemed significant, the difference between the two interventions is only a few hours.

Two studies were able to report post-operative bile leakage (Kandil 2009, Redwan 2010). In the conventional laparoscopic cholecystectomy, 2 out of 70 patients (Kandil 2009) and 1 out of 80 patients (Redwan 2010) experienced post-operative bile leakage while there was none in the harmonic scalpel group.

Conclusion

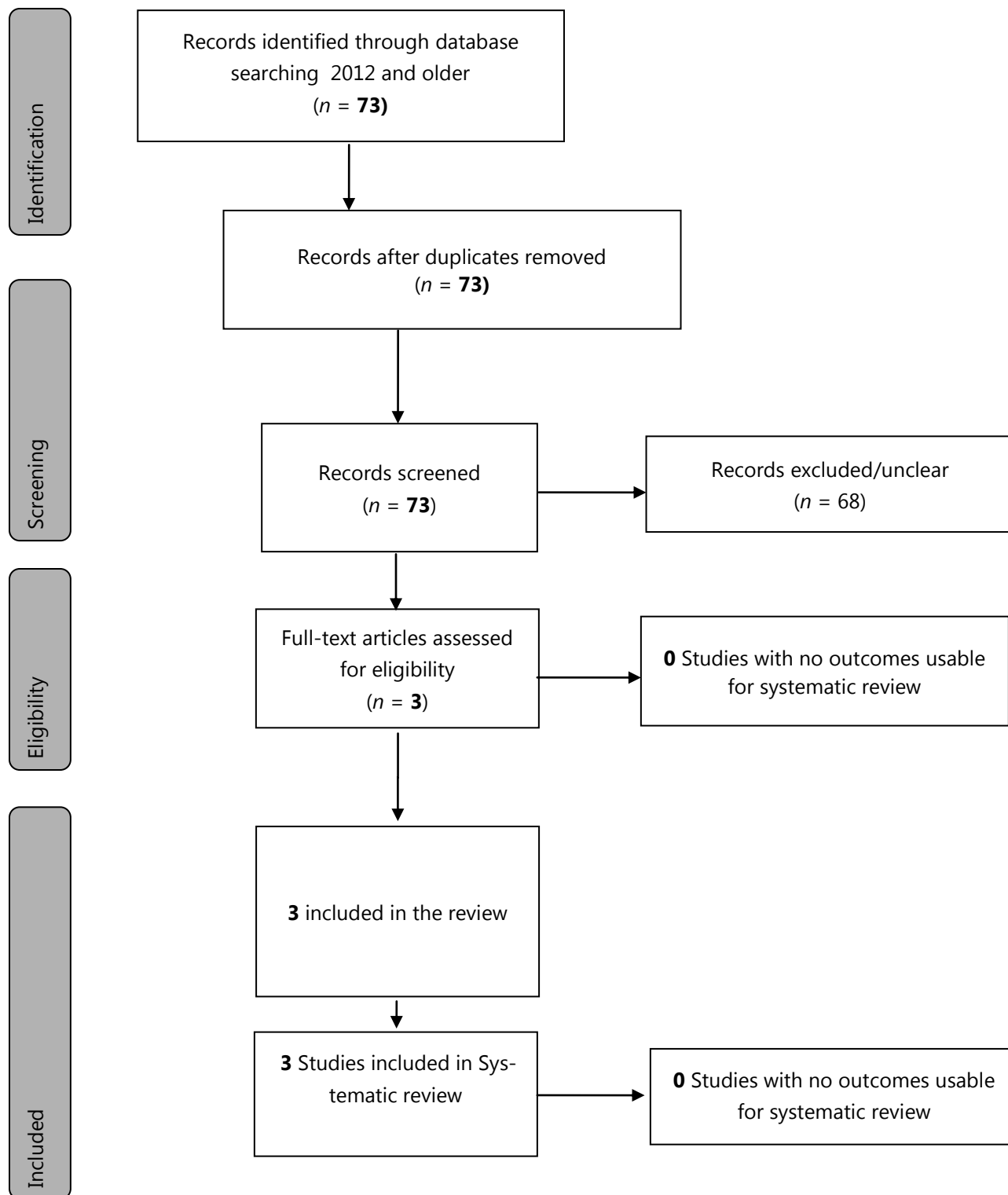
There is a lesser risk of gallbladder perforation and, shorter operative time when harmonic scalpel is used during laparoscopic cholecystectomy. The use of harmonic scalpel during laparoscopic cholecystectomy may be recommended. However, due to the lack of evidence of the advantages of harmonic scalpel in preventing post-operative complications, more trials with similar design and longer follow up should be done and reviewed to assess its advantage over conventional cholecystectomy in this respect.

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APPENDICES

APPENDIX 1. PRISMA Flow Diagram



APPENDIX 2. CHARACTERISTICS OF INCLUDED STUDIES

STUDY IDENTIFIER	Jain 2011
STUDY TITLE	A Prospective, Randomized Study of Comparison of Clipless Cholecystectomy with Conventional Laparoscopic Cholecystectomy
AUTHORS	Sudhir Kumar Jain, MS, FRCS, Raman Tanwar, MBBS, Ram Chandra Murti Kaza, MS, and Prem Narayan Agarwal, MS
CITATION	JOURNAL OF LAPAROENDOSCOPIC & ADVANCED SURGICAL TECHNIQUES Volume 21, Number 3, 2011
PARTICIPANTS	
Description	Laparoscopic cholecystectomy has become a gold standard in the treatment of symptomatic gallstone disease. Amalgamation with upcoming technology makes the present-day procedure faster and safer. Ultrasonic shears, which perform dissection and ligation by cavitation and coaptation of vessels, are the latest addition to the armamentarium of laparoscopic surgeons. Acceptance of its safety and efficacy awaits its use as the sole instrument in the widely accepted procedure.
Total number enrolled (exp/ctrl)	200 patients with symptomatic gallstone disease, who were randomly divided into two comparable groups, one undergoing cholecystectomy using ultrasonically activated shears and the other using conventional clip and electrocautery One hundred patients were included in each group
Total number analyzed	200 patients
INTERVENTION	Harmonic scalpel vs Conventional
Experimental	Harmonic scalpel
Description	Ultrasonically activated shears
Number	100
Control	Conventional
Description	Surgical clips and Cautery
Number	100
OUTCOMES (list all outcomes)	Duration of stay (in days) Stay range (in days) Fall in Hemoglobin (in g%) Fall in Hematocrit (in %) Duration of Surgery (in minutes) Duration range (in minutes) Time taken to remove gallbladder from bed (in minutes) VAS day 0 VAS day 1 Analgesic requirement – day 1 (number of 50 mg diclofenac tablets consumed) Gallbladder perforation Number of patients requiring drains

METHODOLOGY/ DESIGN	A prospective, randomized, control study was undertaken in the Department of Surgery, Maulana Azad Medical College, and associated Lok Nayak Hospital, wherein 200 patients with symptomatic gallstone disease undergoing laparoscopic cholecystectomy between 18 and 70 years of age were included if they did not fall in the exclusion criteria. These patients were randomly divided into two groups using a computer-generated software, one undergoing surgery with electrocautery (group A) and the other with ultrasonic shears (group B). Exclusion criteria included the following: (a) Patients who had impaired liver function tests; (b) History of jaundice or pancreatitis; (c) Suspicion of gallbladder carcinoma; (d) Patients having concomitant common bile duct (CBD) calculi; (e) Acute cholecystitis, cholangitis, and empyema of gallbladder; (f) Pregnant patient; (g) CBD size more than 5mm on ultrasonography. Appropriate clearance from the scientific and ethical committee of the institution was obtained before starting the study. A detailed informed consent was obtained from all patients. All patients were given the option to opt out of the study at any stage without compromising their right for treatment. Laparoscopic cholecystectomy was performed using the four-port American technique. In group B patients, after dissecting the Calots triangle with ultrasonic shears, ligation of the cystic artery and duct was done by ultrasonic shears at the power setting of 2, and shears were not removed till the two ligated ends gave way on their own. Before ligation of cystic duct with ultrasonic shears, the size of the cystic duct was judged by comparing it with the size of CBD. To do this, first the width of CBD was judged by opening the jaws of harmonic shear and then compared with the width of cystic duct. In none of our patients, the width of cystic was found to be more than the width of CBD and we did not include any patient with CBD size >5 mm. The surgeons assessed the cystic duct for any calculi before cutting by moving the jaws of ultrasonic scalpel up and down the duct. The jaws were placed at a safe distance from the CBD to avoid injury to it. The instrument was then activated after fixing the jaws and keeping the instrument still till the two ends got separated at their own without applying traction. Dissection of the gallbladder liver bed was also done using ultrasonic shears at a setting of 5, with minimal bleed. The gallbladder was extracted from the epigastric port and drains were inserted whenever there was significant bleed, ooze from the gallbladder fossa, or bile spillage due to gallbladder perforation. Patients undergoing conventional cholecystectomy in group A underwent dissection with Maryland's dissector and cystic duct and artery were ligated using clips. The gallbladder was extracted from the gallbladder bed using hook and electrocautery. Intraoperatively the time of surgery (starting from skin incision to closure) and the time taken to remove the gallbladder from the gallbladder bed were noted. Postoperative pain scores using visual analog score and analgesic requirement were noted at 6 hours following surgery and at days 1 and 2 by an observer who was unaware of the procedure performed, to eliminate observation bias. Postoperative complications if any and duration of stay were noted. Gallbladder perforation and need for placement of drains were also noted. The amount of blood loss was adjudged by the fall in hemoglobin and hematocrit on postoperative day 1. Patients were followed up at 1 and 3 weeks and at end of 6 months following surgery for completion of data regarding pain score, consumption of analgesics, and complications of surgery if any. Statistical analysis The data collected was analyzed using SPSS software. For quantitative variables such as duration of hospital stay, severity of pain as per visual analog scale, and time taken for surgery, difference between means was analyzed using t-test or Mann-Whitney test. For qualitative data such as requirement of analgesics, difference between proportions was analyzed using chi-square test or Fisher's exact test. P value of less than or equal to .05 was taken as the cutoff point for statistical significance.
CONCLUSIONS	Ultrasonically activated scalpel can be used safely in laparoscopic cholecystectomy without risk of major injuries or leaks. It fairs better than electrocautery in terms of not just a faster and safer surgery but also a surgery with decreased associated morbidity and pain and early return back home.
LIMITATIONS	None

Study Quality Assessment

STUDY IDENTIFIER	Jain 2011
RANDOMIZATION (Description)	Patients were retrospectively divided into 2 groups according to the instruments used for division of the cystic artery and duct as well as for dissection of the liver bed. On the one hand, group 1 consisted of 95 patients who were all treated with the ultrasonically activated scalpel as the sole instrument used in the whole procedure (an additional ligature with clips was performed in 17 patients (17.89%) with a cystic duct of more than 4mm in diameter). On the other hand, group 2 comprised 90 patients in whom dissection and coagulation were performed using monopolar coagulation, and section of the artery and duct with clips.
ALLOCATION CONCEALMENT (Description)	Not applicable
BLINDING (yes/no)	No
WITHDRAWALS	
Yes/No?	No
How many?	Not applicable
Reasons for withdrawal	Not applicable
ALL OUTCOMES REPORTED?	Yes
REMARKS	

Study Data

Study identifier	Jain 2011		
	Harmonic scalpel	Conventional	P value
Duration of stay (in days)	1.89 ± 0.86	2.52 ± 0.75	.001
Stay range (in days)	1 - 3	2 - 7	.001
Fall in Hemoglobin (in g%)	0.53 ± 0.52	1.33 ± 0.85	.001
Fall in Hematocrit (in %)	1.59 ± 2.50	2.60 ± 1.295	.001
Duration of Surgery (in minutes)	50.00 ± 9.356	64.70 ± 13.74	.001
Duration range (in minutes)	31 - 72	42 - 102	.001
Time taken to remove gallbladder from bed (in minutes)	3.94 ± 2.07	7.36 ± 3.43	.001
VAS day 0	2.65 ± 1.04	4.58 ± 1.00	.001
VAS day 1	1.86 ± 0.76	3.01 ± 0.86	.001
Analgesic requirement – day 1 (number of 50 mg diclofenac tablets consumed)	1.86 ± 0.59	2.66 ± 0.66	.001
Gallbladder perforation	9	18	.002
Number of patients requiring drains	12	31	.002

STUDY IDENTIFIER	Kandil 2009
STUDY TITLE	Comparative Study between Clipless Laparoscopic Cholecystectomy by Harmonic Scalpel Versus Conventional Method: A Prospective Randomized Study
AUTHORS	Tharwat Kandil & Ayman El Nakeeb & Emad El Hefnawy
CITATION	J Gastrointest Surg (2010) 14:323–328
PARTICIPANTS	
Description	The advantages of laparoscopic cholecystectomy (LC) have been published extensively, and LC has become the gold standard in treating benign gallbladder diseases. LC has largely replaced conventional open cholecystectomy. The traditional LC is commonly performed by means of dissector, the electrosurgical 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. Alternative technique using sutures for cystic duct closure is infrequently used. Various energy sources are routinely used as cutting and coagulating aids in laparoscopic surgery. Risks involved with the use of monopolar electrosurgery are significantly greater. Nonetheless, monopolar electrosurgery is the preferred method in more than 85% of surgeons. Bipolar electrosurgery, being as effective as monopolar electrosurgery, has not been widely used in the LC procedure. The majority of electrosurgical 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. Several studies have described the use of ultrasound dissection technology in the LC, which concluded that ultrasonic dissection was safe and easy to use. Few studies reported the harmonic scalpel, though superior, is not immune from causing undesirable biological effects on the body. However, current available studies on LC using harmonic ultrasonic dissector are too small to determine any statistically significant difference in outcomes between traditional LC and LC with harmonic. This study planned to compare traditional method of LC versus LC using harmonic as regard the safety and efficacy.
Total number enrolled (exp/ctrl)	140 laparoscopic cholecystectomies were performed in the Gastroenterology Surgical Center and Mansoura University General Hospital 70 were all treated with ultrasonically activated scalpel 70 were all treated with dissection and coagulation using monopolar coagulation and clips
Total number analyzed	140 patients
INTERVENTION	Harmonic scalpel vs Conventional
Experimental	Harmonic scalpel
Description	Ultrasonically activated scalpel
Number	70
Control	Conventional
Description	Surgical clips and Cautery
Number	70
OUTCOMES (list all outcomes)	Intraoperative blood loss Bile spillage Duration of operation Conversion rate Amount of drainage Hospital stay Postoperative pulmonary complication Port site infection Postoperative collection Postoperative bile leakage Body temperature Postoperative nausea Postoperative vomiting

METHODOLOGY/ DESIGN	This study was carried out from January 2008 to December 2008. Patients with gallbladder stone were treated by LC at the Gastroenterology Surgical Center and Mansoura University General Hospital and were included in this prospective randomized trial. The exclusion criteria included patients above 80 years old, patients with history of upper laparotomy, patients with common bile duct stones, and pregnant women. All patients were subjected to thorough history and clinical examination focused on manifestation of gallstone disease and chronic liver disease. The following investigations were performed [whole blood picture, liver function tests (serum albumin, ALT, AST, and prothrombine time "INR"), HCV and HBV markers, and abdominal ultrasound] to show the state of the liver, portal vein, gallbladder, and CBD. Informed consent was obtained from all patients to be included in the study, after explaining the nature of the disease and operative steps and possible complications. This study was approved by the local ethical committee. The patients were randomized into two groups using enclosed envelope. The envelopes were drawn and opened by a nurse not otherwise engaged in the study before operation. Group A LC was done using traditional method, which included 70 patients, and group (B) LC was done using harmonic scalpel, which included 70 patients. Under general anesthesia and the same antibiotics (third generation cephalosporin), surgery was performed using conventional four ports umbilical port, port below xiphoid, and two ports below right costal margin. Pneumoperitoneum at pressure 12 mmHg was used. In group A, LC was done using traditional method by dissection of Calot's triangle and clipping of both cystic duct and artery by metal clips. After that, dissecting the gallbladder from its bed by hook using electrocautery technique was performed. Finally, we insert abdominal drain in Morrison pouch. In group B, LC was done using harmonic ACE (Ethicon Endo-Surgery) by dissection of Calot's and then occlusion of both cystic duct and artery using harmonic ACE. For closure and division of cystic pedicle, we set the instrument at power 2, i.e., more coagulation, and do it at two levels and separate the duct at the proximal level toward the gallbladder. When dissecting the gallbladder from its bed, we set it to level 5, i.e., more cutting power, and control of any bleeding from the bed using the active blade of harmonic ACE. Finally, we insert abdominal drain in Morrison pouch. The intraoperative parameter observed included duration of the operation, amount of CO₂ used in the operation, bile escape, saline irrigation during operation, and volume of blood loss were all recorded. The patients started oral feeding 8 h postoperatively; abdominal ultrasound was done for all patients in both groups on day of discharge to show any collection or free fluid in the abdomen. The patients were usually discharged after removal of drain and when the patient is surgically free. Postoperative pain (PP) was evaluated at 12 h, 24 h, 48 h, and 1 week after operation using a visual analog scale (VAS)¹⁸ (with which each patients noted the severity of pain at each evaluated time using a linear between 0 (no pain) and 10 (severe pain). Postoperative analgesia in the form of nonsteroidal anti-inflammatory drug was administered intramuscularly when required. If the patients still complained of pain, strong analgesic (1 mg/kg pethidine intramuscularly) was administered. The total dose of these medications was recorded. Postoperative maximum body temperatures were recorded at (24 and 48 h) for all patients. Postoperative nausea and vomiting "PONV" were assessed after 24 and 48 h. Metoclopramide was given if the patients required reduction of nausea, and the total doses of this medication were recorded. The frequency of vomiting was recorded. At the end of the first postoperative week, first month, and sixth postoperative month, patients underwent a clinical examination and an abdominal ultrasonography. In addition, blood sample was taken to show follow up of liver function. The statistical analysis of the data in this study was preferred using the SPSS version 10. Analysis of data was by intension to treat. For continuous variables, descriptive statistics were calculated and reported as mean+SD.
CONCLUSIONS	The harmonic scalpel provides complete hemobiliary stasis for all patients and is a safe alternative to stander clip of cystic duct and artery. It provides a shorter operative duration, less incidence of gallbladder perforation, less PP, and less rate of conversion to open cholecystectomy.
LIMITATIONS	None

Study Quality Assessment

STUDY IDENTIFIER	Kandil 2009
RANDOMIZATION (Description)	The patients were randomized into two groups using enclosed envelope. The envelopes were drawn and opened by a nurse not otherwise engaged in the study before operation. Group A LC was done using traditional method, which included 70 patients, and group (B) LC was done using harmonic scalpel, which included 70 patients.
ALLOCATION CONCEALMENT (Description)	Not applicable
BLINDING (yes/no)	Not applicable
WITHDRAWALS	
Yes/No?	Not applicable
How many?	Not applicable
Reasons for withdrawal	Not applicable
ALL OUTCOMES REPORTED?	Yes
REMARKS	

Study Data

Study identifier	Kandil 2009		
	Conventional	Harmonic scalpel	P value
Intraoperative blood loss (mL)	83.31 +46.23	43.28 +31.27	0.0001
Bile spillage	13 (18.6%)	5 (7.1%)	0.04
Duration of operation (min)	51.7 +13.79	33.21 +9.62	0.0001
Conversion rate	2 (2.9%)	0	0.156
Amount of drainage	47.78 +31.54	29 +30.79	0.001
Hospital stay (hours)	26.95 +8.94	23.44 +2.29	0.002
Postoperative pulmonary complication	3 (4.3%)	1 (1.4%)	0.312
Port site infection	4 (5.7%)	1 (1.4%)	0.173
Postoperative collection	2 (2.9%)	1 (1.4%)	0.561
Postoperative bile leakage	2 (2.9%)	0	0.156
Body temperature			
Before operation	36.6 +0.5	36.74 +0.4	0.310
24 h	37.6 +0.6	37.29 +0.4	0.01
48 h	37.6 +0.6	37.36 +0.4	0.01
Presence of postoperative nausea			
24 h	24 (34.3%)	16 (22.9%)	0.462
48 h	5 (7.1%)	3 (4.3%)	0.136
Presence of postoperative vomiting			
24 h	4 (5.7%)	2 (2.9%)	0.4
48 h	2 (2.9%)	1 (1.4%)	0.56

STUDY IDENTIFIER	Redwan 2010
STUDY TITLE	Single-Working-Instrument, Double-Trocae, Clipless Cholecystectomy using Harmonic Scalpel: A Feasible, Safe, and Less Invasive Technique
AUTHORS	Alaa A. Redwan, MD
CITATION	JOURNAL OF LAPAROENDOSCOPIC & ADVANCED SURGICAL TECHNIQUES Volume 20, Number 7, 2010
PARTICIPANTS	
Description	Laparoscopic cholecystectomy is a commonly performed operation for patients diagnosed with gallstones. Usually, the procedure involves electrosurgery and sealing of the gallbladder duct and arteries with titanium clips. Dissection with concomitant hemostasis can be performed with the use of ultrasonic instruments, such as the Harmonic scalpel, (Ethicon Endo-Surgery, Cincinnati, OH), and can radically simplify the whole operation and offer good hemostasis, so ultrasonically activated devices have been used for dissection with encouraging results. 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 of 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. Recently, ultrasonic energy has been used to seal the cystic duct during successful clipless cholecystectomy. So, total Harmonic scalpel dissection, in the performance of a laparoscopic cholecystectomy, is described in this article. The resulting decrease in temperature, smoke, and lateral tissue damage has placed the Harmonic scalpel in contrast to the effects seen with more traditional electrocautery. In addition, the elimination of inadvertent, sometimes unrecognized, electrical arcing injuries, with their potentially hazardous sequelae, has supported the role of the Harmonic scalpel as a potentially safer instrument for tissue dissection. It tackles the concerns regarding smoke production, and inadvertent injuries to the abdominal organs and structures.
Total number enrolled (exp/ctrl)	160 patients underwent laparoscopic cholecystectomy 80 were all treated with ultrasonically activated scalpel (Harmonic scalpel) 80 were all treated with dissection and coagulation using monopolar coagulation and clips
Total number analyzed	160 patients
INTERVENTION	Harmonic scalpel vs Conventional
Experimental	Harmonic scalpel
Description	Ultrasonically activated scalpel
Number	80
Control	Conventional
Description	Surgical clips and Cautery
Number	80
OUTCOMES (list all outcomes)	Duration of stay Duration of surgery Intraoperative complications Postoperative complications

METHODOLOGY/ DESIGN	All patients were subjected to 1) full history taking, 2) clinical examination, and 3) investigations that included routine lab tests (i.e., blood count, random sugar, and serum creatinine), routine chest X-ray, electrocardiography, etc., liver function tests, prothrombine time, and abdominal ultrasonography. Additional investigations were needed sometimes, in some doubtful cases, such as computed tomography and magnetic resonance cholangiopancreatography. All patients were randomly assigned for laparoscopic cholecystectomy. Group 1 (the clipless Harmonic group) included 80 cases. The Harmonic scalpel was used as a single working instrument, with only two working trocars. Patients were positioned in an anti-Trendelenburg position, with some rotation to the left side to help in good visualization and manipulation of the gallbladder, if difficulty was still encountered. Thereafter, a curved Kirschner wire (1mm) was introduced in the subcostal area and hooked the gallbladder fundus, with gentle retraction upward, or by the direct introduction of the laparoscopic trocar wound-closure forceps through the subcostal region, with gentle retraction of the gallbladder upward. However, these maneuvers were rarely resolved to during the work. An ultrasonic shear (Olympus Keymed Sono surg version G2 220–240V 3A, 50/60 Hz; Tokyo, Japan) was used as the only working instrument during the procedure, through a 10-mm epigastric port, for the dissection and cutting of the cystic artery and duct. Then, gallbladder dissection from the liver bed was helped by a grasper, through the right midclavicular 5-mm port, to attain complete hemobiliary stasis. Last, the gall bladder was retrieved from the epigastric 10-mm trocar site. Group 2 (the clip/cautery group) included 80 cases. The conventional instruments were used with the application of clips and the use of cautery in a three-working-trocar laparoscopic cholecystectomy technique. One small catheter drain was inserted in all cases, which was removed a few hours later. All patients were followed up in the General Surgery Department at Assuit University Hospitals, with the appropriate postoperative treatment in the form of broad-spectrum antibiotic prophylaxis, and analgesics, according to the amplitude of pain, using a “pain scoring system,” where a single shot of narcotics was sufficient to kill pain of a moderate type, but more doses were needed (double) with severe types of pain, until being discharged from the hospital. The recording of all patient data was done and categorized as follows: intraoperative difficulty, intraoperative perforation of the bladder and biliary spillage, intraoperative injuries or complications, operative time, as well as postoperative complications, postoperative pain and the need for analgesics, and hospital stay. Patients were followed up in the outpatient clinic for the detection of any complications, with an assessment of the cosmetic results and, also, patient satisfaction of the surgery.
CONCLUSIONS	The Harmonic scalpel is a safe, efficient, and practical instrument to use during laparoscopic cholecystectomy, especially if used as a sole working instrument, with complete hemobiliary stasis. Its application shortens operative time and decreases accidental bile spillage; consequently, it decreases postoperative complications and may shorten length of hospitalization. Downsizing the number or size of laparoscopy trocars improved the results of minimal invasiveness that may lead to better recovery, less pain, improved cosmesis, and better patient satisfaction.
LIMITATIONS	None

Study Quality Assessment

STUDY IDENTIFIER	Redwan 2010
RANDOMIZATION (Description)	Patients were divided into SC and HS groups (n=160)
ALLOCATION CONCEALMENT (Description)	All patients were randomly assigned
BLINDING (yes/no)	Not mentioned
WITHDRAWALS	
Yes/No?	No
How many?	Not applicable
Reasons for withdrawal	Not applicable
ALL OUTCOMES REPORTED?	Yes
REMARKS	

Study Data

Study identifier		
	Harmonic scalpel	Conventional
Duration of stay (in days)		
Range	1	1-2
Mean $\pm$ SD	1 $\pm$ 0	1.53 $\pm$ 0.51
Duration of surgery (in minutes)		
Range	9-30	35-55
Mean $\pm$ SD	16.8 $\pm$ 6.8	44.01 $\pm$ 6.47
Gallbladder Perforation	8	11
Biliary soaking	1	0