Dissection by ultrasonic energy versus monopolar electrosurgical energy in laparoscopic cholecystectomy Mahmoud A. Mahmoud^a, Heba T.A. Aziz El-Atar^b

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Background

Gallstones remain one of the commonest surgical problems in the developed world, and despite major therapeutic advances in recent years, there has been no progress in the prevention of gallstone development, and it may lead to serious complications that may affect patients' quality of life. Laparoscopic cholecystectomy currently is accepted as the gold standard treatment of gallstones. The advantages of such a surgical approach have been reported by a number of authors, showing both the positive effect of this method on the postoperative quality of life of the patients and its optimal short-term and longterm results.

Objective

To assess the safety and efficacy of ultrasonic energy as a single alternative tool in the dissection of the gallbladder during laparoscopic cholecystectomy.

Patients and methods

This is a prospective study that included 60 patients with gallbladder stones who were operated upon for laparoscopic cholecystectomy over 1 year starting from August 2016 till August 2017. Approval from the Ethical Committee of Faculty of Medicine, Ain Shams University, was obtained before commencement of this study. The patients upon whom the study was based were operated on in El Demerdash Hospital and Ain Shams University Specialized Hospital.

Results

A total of 60 patients were included in this study. Group A included 30 patients for whom laparoscopic cholecystectomy had been done using a harmonic scalpel. Group B included 30 patient for whom laparoscopic cholecystectomy had been done using electrocautery tools (hook, grasper, and scissors) and surgical clips. For both groups, data were collected and analyzed: demographic data (sex, age, BMI, comorbidities, and previous surgeries).

Conclusion

The main advantages of ultrasonic dissection include the following: (a) utilization of a single instrument for both dissection of the gallbladder and dissection of the artery and dust, (b) shorter operating time, and (c) improved laparoscopic view and possibly a reduction of postoperative pain. The main disadvantage of ultrasonic dissection is instrument cost, which is particularly high if the surgical unit is equipped with reusable instruments.

Keywords:

cystic artery, cystic duct, extracorporeal shock wave lithotripsy

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Introduction

Gallstones remain one of the commonest surgical problems in the developed world, and despite major therapeutic advances in recent years, there has been no progress in the prevention of gallstone development. The prevalence in North America is comparable to that in the UK. In the UK, more than 40 000 cholecystectomies are performed each year, whereas in the USA 500 000 operations are performed annually [1].

In Egypt, although there are no national incidence figures about the prevalence of cholelithiasis among Egyptians, yet various reports have shown that the incidence is also increasing in Egypt [2].

Proper removal of the diseased gallbladder and ensuring patent pathway for the bile to drain into the gastrointestinal tract has been the goal of all treatment options. In the era of minimally invasive therapy, laparoscopic cholecystectomy is vital adjunct to overall management of cholelithiasis [3].

The standard laparoscopic cholecystectomy is commonly performed by means of specialized

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instruments. For gallbladder dissection, the electrosurgical hook, spatula, and/or scissors, using high-frequency monopolar technology, have been used in most centers. Occlusion by simple metal clips was the most frequently used technique to achieve both cystic duct and artery closure [4].

In laparoscopic surgery, instruments using a variety of energy sources to cut and coagulate tissue have been used, including monopolar and bipolar cautery, CO_2 laser, and the ultrasonic scalpel. The exact incidence of collateral injury is difficult to be assessed; however, 18% of physicians responding to a survey from the society of monopolar electrocautery use have been directly associated with 90% of visceral injuries and 15% of biliary tract injuries during laparoscopic cholecystectomy [5].

Electrosurgical devices can also cause injury owing to insulation failure of the active electrode, direct coupling between the active electrode and metal instruments or tissue, and stray electrical currents. Because of these risks for patient injury, alternative devices such as ultrasonic scalpels have been investigated further [6].

The ultrasonically activated scalpel (Harmonic; Ethicon Endo-Surgery Inc., Johnson and Johnson Medical SPA, Somerville, New Jersey, USA) was introduced into clinical use more than a decade ago. Its technology relies on the application of ultrasound within the harmonic frequency range to tissues and allows three effects that act synergistically: coagulation, cutting, and cavitation. 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. The harmonic scalpel is also an effective tool for closure of biliary ducts and vessels whose diameter is 4–6 mm [7].

Applied with sufficient power, ultrasound waves fragment tissue. Fragmentation is strictly related to the water content of tissue: the higher the water content, the easier the fragmentation [8].

The cavitational effect is due to the backstroke of the blade, which creates low pressure in cells and tissues. Hence, fluids in cells and tissues vaporize, cells explode, and tissues expand [7].

Coagulation is accomplished by conversion of ultrasonic energy into localized heat, which has been reported to range from 60 to 100°C, is a function of time-power-pressure-tension, and is improved by decreasing the power output [9].

The harmonic dissector seems to be the ultimate answer to these troubles because it is the most versatile multipurpose instrument and an efficient substitute for the diathermic hook or scissors, the dissector, and even the clip applier. The manufacturer assures that it is able to seal ducts up to 4 mm [10].

Aim

The aim of this study is to assess the safety and efficacy of ultrasonic energy as a single alternative tool in the dissection of the gallbladder during laparoscopic cholecystectomy.

Patients and methods

This is a prospective study that included 60 patients with gallbladder stones who were operated upon for laparoscopic cholecystectomy over 1 year starting from August 2016 till August 2017.

Approval from the Ethical Committee of Faculty of Medicine, Ain Shams University, was obtained before commencement of this study.

The patients on whom the study was based were operated upon in El Demerdash Hospital and Ain Shams University Specialized Hospital.

Patients

Patients were divided into two groups. Group A included 30 patients who underwent laparoscopic cholecystectomy with the use of harmonic ultrasonic dissector. Group B included 30 patients who underwent laparoscopic cholecystectomy with the use of electrosurgical monopolar energy.

Allocation of the patients into each group had been done by closed envelopes

Inclusion criteria

Both male and female with no age limits, patients fit for general anesthesia, and patients with chronic calculous cholecystitis were the inclusion criteria.

Exclusion criteria

Patients unfit for general anesthesia, patients with medical condition interfering with the use of laparoscope (cardiac diseases, chronic liver diseases, and chest diseases), patients in whom laparoscopic cholecystectomy was converted to open cholecystectomy, patients with gallbladder carcinoma, and patients with previous upper abdominal surgery were excluded.

Methods

Preoperative assessment: All patients had been subjected to full laboratory analysis (complete blood count – full coagulation profile – full liver function – kidney function – viral markers), pelvi-abdominal ultrasound with full comment on biliary system and liver status, chest radiograph, ECG, and echocardiography for those who are older than 60 years old or with significant cardiac history.

Procedure

All patients received a dose of 1 g of third-generation cephalosporin before induction of anesthesia. In group A, harmonic ultrasonic dissector was used in cystic duct and artery dissection and gallbladder dissection from liver, whereas in group B, traditional monopolar electrosurgical energy dissector was used in cystic duct and artery dissection and gallbladder dissection from liver. Subhepatic tube drain (18 size) was used in all patients. Any intraoperative event was documented regarding operative time, confirm diagnosis, gallbladder perforation, bile duct injury, bleeding, biliary spillage, and liver or intestinal injury.

Surgery techniques

Operative procedures were performed with the patient under general anesthesia and placed in the standard supine reverse Trendelenburg position with 15° tilt to the left. A uniform technique of laparoscopic cholecystectomy was applied including the use of four trocar ports and pneumoperitoneum with a maximized pressure of 14 mmHg and a 30° camera lens. The pneumoperitoneum was achieved by using Hasson's technique (open method) to all patients of group A and all patients of group B. For all patients, a nasogastric tube was inserted to decompress the stomach. It was removed at the end of the operation. By decompression of the stomach, the view was improved especially during the cystic duct dissection and the risk of trocar trauma to the stomach was decreased. A four-port approach was adopted, and the first trocar (10 mm) was inserted above.

In group A patients, after dissection of the hepatocystic triangle using the harmonic shear with the power level set at '5', which translated into more cutting and less coagulation, cutting of the cystic ducts after application of single safety metallic clip was done using the minimal power option at the power level '3', 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 microcalculi in the lumen of the cystic duct by moving the jaws of the Harmonic ultrasonic dissector 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 until a click was heard after application of safety metal clip. Third, the instrument was activated at the power level '3', 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. Finally, the cut points of the cystic duct were checked for any bile leakage. Dissection of cystic artery was also done by harmonic ultrasonic dissector.

Visual confirmation that there is no leaking point from the stump of the dissected cystic duct was done after that.

In group A, dissection of the gallbladder from the liver was done by the harmonic shear using maximum power level.

In group B, clipping and cutting of the cystic duct and cystic artery using hemostatic clips after completion of the dissection of the hepatocystic triangle had been done using electrocautery hook and or grasper or scissors.

The duration of operative procedure was recorded for all patients within the two groups.

Intraoperative difficulties and complications were recorded for both groups.

Postoperative

All patients received 1 g of third-generation cephalosporin intravenously.

Follow-up

Follow-up was done regarding drain amount, drain color, time of drain removal (when<50 ml serous within 24 h), time of return of peristalsis (all patients started clear fluid when audible intestinal sound shifted to solid diet after 24 h if no suspected complications), and hospital stay (patient discharge after drain removal). Postoperative pelvi abdominal ultrasound was done after 2 weeks and 3 months to document any collection and biliary system status. Postoperative full laboratory assessment (full liver profile and bilirubin) was done after 1, 2 weeks, and 3 months. Stitch removal time and status of wound were recorded. Pain control was done through injection of 50 mg pethidine with monitoring of the response (Figs 1 and 2).



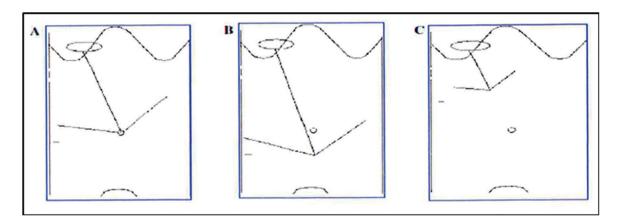
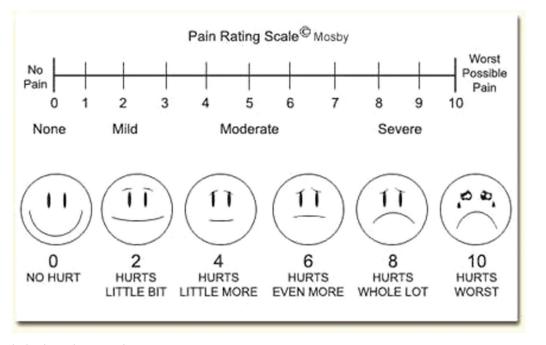


Diagram of trocar insertions in (a) normal sized abdomen, (b) very small sized abdomen, and (c) very large sized abdomen [3].



Showing numerical pain analogue scoring system.

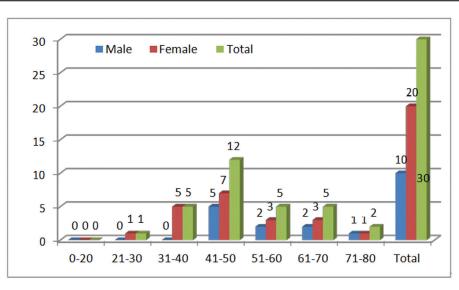
All data analyses were performed with the statistical package for the social sciences version 11.5 software (SPSS Inc., Chicago, Illinois, USA). The Mann–Whitney *U*-test and the Student's *t*-test were used for continuous variables. The χ^2 and the Fisher's exact test were used for categorical variables. All *P* values were two sided. A value of *P* 0.05 was considered statistically significant.

Results

A total of 60 patients were included in this study. Group A included 30 patients for whom laparoscopic cholecystectomy had been done using a harmonic scalpel. Group B included 30 patients for whom laparoscopic cholecystectomy had been done using electrocautery tools (hook, grasper, and scissors) and surgical clips.

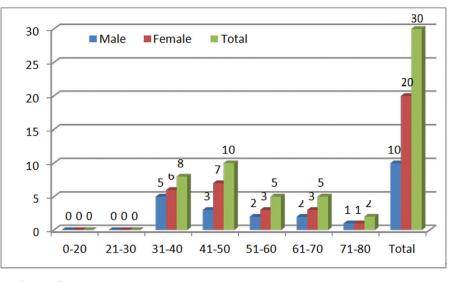
For both groups, data were collected and analyzed, such as demographic data (sex, age, BMI, comorbidities and previous surgeries), indications of cholecystectomy, surgical procedure data (associated procedures, intraoperative incidents, operative time and conversion to open), and postoperative course data (postoperative morbidities, postoperative hospital stay and re-interventions). Furthermore, biliary complications were analyzed as a single parameter comparing the incidence within A and B groups.





Demographic distribution of group A.

Figure 4



Demographic distribution of group B.

Patient characteristics

Figure 3 shows the demographic distribution in group A. There were 20 females and 10 males, and their age ranged from 26 to 80 years, with a mean of 45.5 ± 5.74 years. Most of the patients were in their fourth and fifth decades. The BMI ranged from 26 to 39 kg/m², with a mean of 33.6 ± 3.24 kg/m².

Figure 4 shows the demographic distribution in group B. There were 20 females and 10 males, and their age ranged from 32 to 80 years, with a mean of 46.5 ± 2.41 years. Most of the patients were in their fourth decade. The BMI ranged from 24 and 37 kg/m², with a mean of 30.6 ± 4.61 kg/m².

Table 1 shows the age, sex, BMI, associated comorbidities, and previous surgeries in both study groups. For group A, four (13.3%) patients were diabetic, five (16.7%) patients were hypertensive, three (10%) patients had chronic asthmatic bronchitis, and two (6.7%) patients had ischemic heart disease. Moreover, 20 (66.7%) patients were obese.

Eighteen (60%) patients had previous abdominal operations done, including five (16.7%) patients had appendectomy, 11 (36.7%) patients had caesarian section, and two (6.7%) patients had abdominoplasty (Table 1). Moreover, two (6.7%) patients had

Table 1 The age, sex, BMI, associated comorbidities, and	
previous surgeries in both study groups	

	Group A	Group B	P value
Age			
Range	26–77	32–74	NS
Mean±SD	33.6±3.24	30.6±4.61	
Sex			
Female	20	20	NS
Male	10	10	NS
BMI (kg/m ²)			
Range	26–39	24–37	NS
Mean±SD	33.6±3.24	30.6±4.61	NS
Obesity	20	13	NS
Associated comorbidities			
Diabetes	4	7	NS
Hypertension	5	6	NS
Ischemic heart disease	2	2	NS
Bronchial asthma	3	4	NS
Previous surgeries			
Appendectomy	5	4	NS
Cesarean section	11	10	NS
Abdominoplasty	2	1	NS
ERCP	1	0	NS

ERCP, endoscopic retrograde cholangiopancreatography.

endoscopic retrograde cholangiopancreatography (ERCP) and sphincterotomy and CBD stone extraction.

As for group B, seven (23.3%) patients were diabetic, six (20%) patients were hypertensive, four (13.3%) patients had chronic asthmatic bronchitis, and two (6.7%) patients had ischemic heart disease. A total of 13 (43.3%) patients were obese. Overall, 15 (50%) patients had previous abdominal operations done for them: four (13.4%) patients had appendectomy, 10 (33.4%) patients had caesarian section, one (3.3%) patient had abdominoplasty (Table 1).

No significant difference was found between the age, sex, BMI (BMI=weight/height square), associated comorbidities, and previous surgeries in both groups, as shown in Table 2.

Clinical presentation

Table 3 and Fig. 5 show clinical presentation of the study patients. In group A, 25 (833.3%) patients presented with clinically evident chronic right hypochondrial pain especially with fatty meals, two (6.7%) patients presented with epigastric pain, three (10%) patients presented only with dyspepsia after fatty meals, and two (6.7%) patients presented after ERCP and sphincterotomy and CBD stone extraction. None of the patient had clear previous history of acute cholecystitis.

Table 2 Operative data

Operative data	Group	Group B	P
	A	D	value
Abnormal anatomy	4	1	
Phrygian cap	2	1	0.001
Sessile gallbladder	1	0	
Accessory cystic duct of Luschka	1	0	
Inflammatory adhesions	5	7	
Mild adhesions	3	4	0.001
Massive adhesions	1	3	
Intraoperative bleeding	0	2	
Cystic artery	0	1	0.001
Omental bleeder	0	1	
Liver	0	0	
Bowel injury	0	0	0.001
Gallbladder perforation and bile leak (%)	20	30	
	2	0	0.001
Fundus traction, grasping	_	U U	0.001
Cystic duct clip slippage	1 ^a	0	
Accessory cystic duct of Luschka	1	0	
Gallbladder dissection	2	9	
Gallbladder sealed stump	0	1	

^aSessile cystic duct in group A patients, not applicable to apply harmonic shear with a trail to clip it, but bile leak continued and ended by endoloop application.

Table 3 Clinical presentation

Clinical presentation	Group A	Group B
Biliary pain	25	24
Dyspepsia	3	4
Epigastric pain	2	3
Post-ERCP	2	0

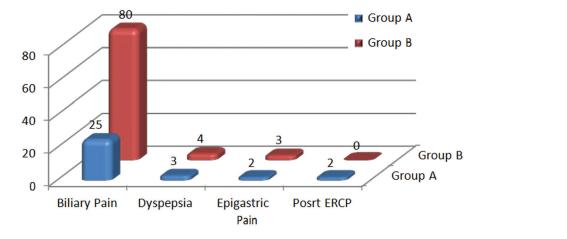
ERCP, endoscopic retrograde cholangiopancreatography.

In group B, 24 (80%) patients presented with clinically evident chronic right hypochondrial pain especially with fatty meals, three (10%) patients presented with epigastric pain, and four (13.3%) patients presented only with dyspepsia after fatty meals. None of the patient had evident previous history of acute cholecystitis. No significant difference was detected regarding clinical presentation in both the study groups.

Preoperative findings

For both groups, laboratory studies stressing upon the liver function tests were done. The results were for all patients in both groups showing values within the normal ranges. In group A, one patient had positive test for hepatitis C virus, but none within group B patients.

Table 4 and Fig. 6 show the preoperative finding in both groups. In group A, the ultrasonic examination showed seven (23.3%) patients with mild liver enlargement and mild fatty infiltration, and two



Clinical presentation.

Preoperative findings	Group A (%)	Group B (%)
Gallbladder ultrasound	100	100
Single stone	46.7	33.3
Multiple stones	53.3	66.7
Upper gastrointestinal endoscopy	6.7	10
ERCP	6.7	0
MRCP	0	0

ERCP, endoscopic retrograde cholangiopancreatography; MRCP, magnetic resonance cholangiopancreatography.

(6.7%) patients with liver cirrhosis. Regarding the gallbladder, all patients showed thickened wall with multiple stones of variable sizes in 16 (53.3%) patients and 14 (46.7%) patients with single gallbladder stones. Regarding the common bile duct, ultrasonic examination was normal for all patients of the study. Two (6.7%) patients of the study group were referred to the surgery department following ERCP. ERCP showed one case with a single impacted stone and one case with multiple CBD stones. For the aforementioned two patients, sphincterotomy and CBD stone extraction was done. After ERCP, laboratory and ultrasonography studies were done with no more laboratory or radiological signs of obstructive jaundice. Upper gastrointestinal endoscopy was done for two (6.7%) patients who presented with epigastric pain, and gastric cause of the pain was excluded.

Table 5 and Fig. 6 show the preoperative findings. In group B, the ultrasonic examination showed five (16.7%) patients had mild liver enlargement and fatty infiltration and one (3.3%) patient with liver cirrhosis. Regarding the gallbladder, all patients showed thickened wall with multiple stone of variable sizes in 20 (66.7%) patients and 10

(33.3%) patients with single gallbladder stones. Regarding the common bile duct, ultrasonic examination was normal for all patients of the study. Upper gastrointestinal endoscopy was done for three (10%) patients who presented with epigastric pain, and gastric cause of the pain was excluded.

Operative data

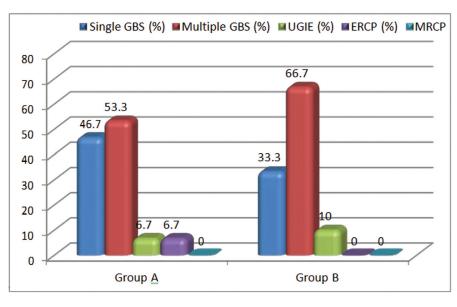
For both groups, operative time, the intraoperative incidences, and postoperative complications were recorded.

In group B, laparoscopic cholecystectomy was successfully completed in 27 (90%) patients. Three (10%) patients were converted to open procedures and were excluded from the study.

In group A, laparoscopic cholecystectomy was successfully completed in 29 (96.7%) patients. One (3.3%) patient was converted to open procedures and was excluded from the study.

Operative details

For group A, in three (10%) patients, some anatomical variations were encountered, and in one (3.3%) patient, a Phrygian cap gallbladder was encountered. In one (1%) patient, an accessory cystic duct of Luschka was accidentally found during dissection of the gallbladder from its bed. The leak from that duct was controlled with the ultrasonic dissecting shear. Another patient (1%) had sessile gallbladder with wide cystic duct insertion for which end loop and metal clip was applied after failed trail to seal the wide cystic duct with harmonic after dissection where cyst artery cutting was done using harmonic ultrasonic dissector (Table 2 and Figs 7–16).



Preoperative findings.

Table 5 Operative time

Operative data	Group A	Group B	P value		
Operative time (mi	Operative time (min)				
Range	25–45	35–88	0.000		
Mean±SD	31	44			
Without gallbladde	Without gallbladder perforation				
Range	25–48	35–59	0.002		
Mean±SD	28.02±5.2	38.94±4.8			
With gallbladder perforation					
Range	28–80	35–88	0.007		
Mean±SD	42.16±8.9	53.07±6.3			

SD, standard deviation.

Regarding group B also, one case with Phrygian cap gallbladder was encountered for which no special maneuvers were done.

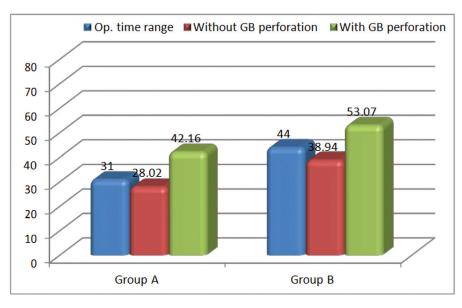
In this study, seven (23.3%) patients of group B showed adhesions; in four (13.3%) patients of them, the adhesions were successfully dealt with using electrocautery with clear visualization of the anatomy of the biliary system. In these patients, adhesiolysis was achieved safely and completely, and in the remaining three (10%) patients, dense adhesions were encountered that were tough and difficult to handle with. In one patient, the presence of dense adhesions around the gallbladder and within the hepatocystic triangle rendered difficult dissection verv with nonvisualized gallbladder; thus, the procedure was converted to open cholecystectomy. In two (6.7%) patients, the presence of such adhesions rendered dissection very difficult and the anatomy very unclear. Dissection ended with uncontrolled bleeding which further

obscured the operative field by the rapidly accumulating blood; thus, the procedure was converted to open cholecystectomy. In one patient, bleeding was from the cystic artery and in the other patient was from an omental bleeder. Conversion to open surgery was done, and after control of bleeding, cholecystectomy was done successful.

For group A, five (16.7%) patients had shown adhesions. In three (10%) patients, the adhesions were successfully dealt with using the harmonic ultrasonic dissector. In the remaining two (6.7%) patients, dense adhesions were seen that were tough and difficult to handle with. In these two patients, the presence of dense adhesions around the gallbladder and within the hepatocystic triangle rendered dissection very difficult with no clear visualized biliary ducts; thus, the procedure was converted to open surgery cholecystectomy.

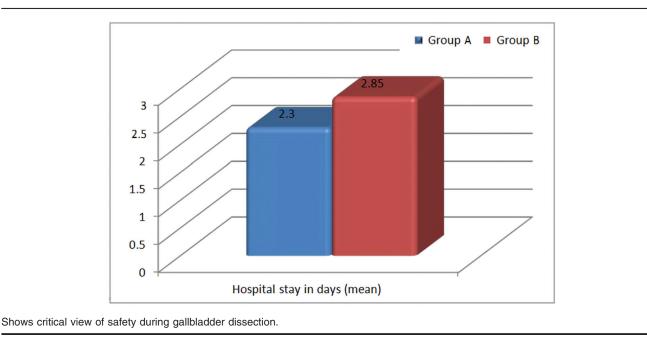
For those patients of both groups in whom conversion to open procedure for adhesions was done, the presence of such adhesions rendered dissection very difficult and the anatomy very unclear. Dissection trails continued for ~ 25 min without any progress. So the decision was taken to convert to open surgery.

Intraoperative bleeding occurred in both groups from the gallbladder bed during dissection as well as during the dissection of adhesions and was controlled by harmonic shear in group A and by electrocautery in group B. No bleeding happened in group A after sealing and cutting of the cystic



Shows dissection of Calot's triangle by electrocautery hook.





artery by the harmonic shear. In group B, two patients had rapid bleeding, obscuring the operative field by the rapidly accumulating blood; one patient had bleeding from the cystic artery transection during adhesiolysis and the other patient had bleeding from omental bleeder during dissection of greater omentum from the gallbladder. Conversion to open surgery was done for both. Another patient of group B had minimal bleeding immediately after cutting the clipped cystic artery, and bleeding stopped after reinforcing the cystic artery stump through sealing by another clip. Gallbladder perforation and intraoperative bile leak in group A during the procedure occurred in six (20%) patients. In two (6.7%) patients, the perforation was at the gallbladder fundus. This was mainly owing to retraction difficulties. In one (3.3%) patient, the leak was from slipped clips of a sessile cystic duct. In one (3.3%) patient, the leak was from an accessory cystic duct which was in the gallbladder bed and injured during dissection of the gallbladder from its bed on the liver surface. For patients in whom perforations (6.7%) were from the posterior surface of the gallbladder during its dissection from its liver bed



Shows clipping of the cystic duct with metallic clip.

Figure 10



Shows cystic duct after clip application.

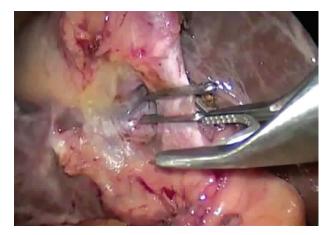
Figure 11



Shows cystic duct stump after cutting by scissor.

owing to direct application of the active blade of the harmonic shear to the gallbladder wall, control of the

Figure 12



Shows dissection of Calot's triangle by harmonic ultrasonic dissector.

Figure 13



Shows critical view of safety exposed by harmonic ultrasonic dissector.

leak from the sessile cystic duct was done by applying endoloop on the cystic duct after failed control by clip application. Regarding the other patients, it was done by applying ultrasonic sealing device upon the dissected duct of Luschka and by grasping the perforated site and clipping it.

Regarding group B, 10 (30%) patients had gallbladder perforation and intraoperative bile leak. Of these 10 patients, nine patients had perforation from the posterior surface of the gallbladder during its dissection from its liver bed owing to direct application of the electrocautery hook, and perforation was clipped. In one patient, the bile leak was from improper sealing of the stump of the dissected gallbladder. Control of the bile leak was achieved by extra clip application to the leaking gallbladder cystic stump.



Shows cutting of cystic duct by harmonic ultrasonic dissector after application of safety clip.

Figure 15

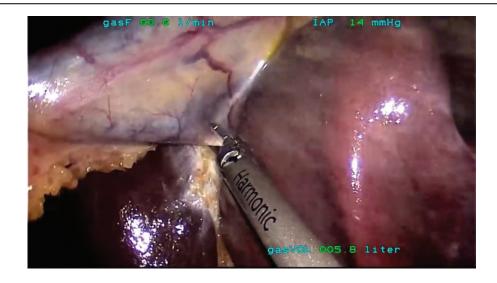


Shows dissection of gallbladder from liver bed by harmonic ultrasonic dissector.

Figure 16



Shows dissection of gallbladder from liver bed by harmonic ultrasonic dissector.



Operative time.

Spillage of stones from perforated gallbladder into the peritoneal cavity occurred in one (3.3%) patient of group A and in two (6.7%) patients of group B. Stones were totally retrieved in all patients. However, this was at the expense of operative time and effort.

Repeated thorough irrigation and suction was done in all patients who had perforated gallbladder or those with slipped cystic duct clips immediately after the perforation and at the end of the procedure. None of these patients experienced any postoperative complications related to this condition.

Regarding group A, five patients had umbilical hernia repair within the same session. The operative time for such procedure was removed from the calculations. Moreover, for group B, two patients had umbilical hernia repair.

Table 5 and Fig. 17 show the operative time details for both groups. In group A, the total time of laparoscopic cholecystectomy per patient without gallbladder perforation ranged from 25 to 48 min, with a mean time of 28.02 ± 5.2 min, whereas with gallbladder perforation ranged from 28 to 80 min, with a mean time of 42.16 ± 8.9 min. The total operative time per patient ranged from 25 to 80 min, with a mean time of 31 min.

In group B, the total time of laparoscopic cholecystectomy per patient without gallbladder perforation ranged from 35 to 59 min, with a mean time of 38.94 ± 4.8 min, whereas with gallbladder perforation ranged from 35 to 88 min, with a mean time of 53.07 ± 6.3 min. The total operative time per

Table 6 Postoperative course in both groups

	Successful laparoscopic cholecystectomy
Amount of analgesia in the first 24 h	0–50 mg pethidine
Return of peristalsis	With 24 h postoperatively
Start of oral feeding	With 24 h postoperatively
Tolerability to solid diet	1 day postoperatively

patient ranged from 35 to 88 min, with a mean time of 44 min.

There is no statistically significant difference between the use of harmonic ultrasonic dissector and the use of monopolar dissector on total operative time; however, the use of harmonic ultrasonic dissector showed shorter time than that of monopolar dissector.

Postoperative course and complications are shown in Tables 6 and 7. Based on the pain analogue score (from 0 to 10), patients of both groups in whom laparoscopic cholecystectomy was successfully done, the analgesic requirements ranged from none to 50 mg of pethidine for patient in the first 4–6 h and during first 24 h postoperatively, as 64% of patients required no analgesia at all and 33% of patients required one ampoule of pethidine 50 mg.

Patients of both groups in whom laparoscopic cholecystectomy was successfully done resumed their normal bowel sounds within the same day of surgery postoperatively.

Patients of both groups in whom laparoscopic cholecystectomy was successfully done started oral

 Table 7 Postoperative complications

Complications/patient	Group A	Group B
Major complication		
lleal perforation	0	0
Bile leaks (surgical management)	0	0
Abscess	0	1 ^a
Pancreatitis	0	0
Chest infection	0	0
CBD injury	0	0
Minor complication		
Bile leak (conservative)	0	0
Bile leak (observation)	0	0
Fluid collection	0	1
Pleural effusion	0	1
Respiratory impairment	0	0
Jaundice	0	0
Urinary retention	0	0
UTI	2	1
Wound sepsis	2	0

CBD, common bile duct; UTI, urinary tract infection. $^{\rm a} {\rm Ultrasound}$ guided drainage.

feeding within the same day postoperatively starting with fluids. After at least 12 h postoperatively, fat-free soft diet was given to the patients.

Regarding group A patients, one patient could not tolerate oral feeding for 1 day with vomiting once, whereas two patients vomited once in group B.

Fever developed within the 1st 24 h postoperatively in two patients in group A and in three patient of group B, which showed complete resolution within the second postoperative day for all patients.

The drain was removed of all patients of both groups, with discharge from hospital after starting oral feeding.

In group B, one patient (one of those who had perforated gallbladder during dissection) had drain obstruction. The drain was kept until full oral feeding was achieved with no change in the color of the discharge. Moreover, abdominal ultrasonic examination was done for that patient and showed minimal subhepatic collection at the first day postoperatively. The collection totally disappeared at the seventh day postoperatively.

One patient of group B developed fever during the second day postoperatively and was persistent with increased demand of analgesia owing to persistent abdominal pain. The drain drained minimal serosanguinous discharge with no oozing around it. Abdominal ultrasonic examination was done for that patient and showed mild subhepatic collection related Table 8 Length of hospital stays (days)

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Hospital stay	Group A	Group B	P value
Range	2–3	2–3	0.008
Mean±SD	2.3±1.77	2.85±1.43	

to the gallbladder fossa at the third day postoperatively. A conservative management decision was taken including intravenous antibiotic and follow-up laboratory investigations and repeated abdominal ultrasound study. Repeated laboratory investigations third and fourth day postoperatively showed no abnormal deviation from the normal values of the liver functions. On the fifth day postoperatively, abdominal ultrasound-guided drainage was done for the collection with regain of the temperature to normal. In the ninth day postoperatively, another ultrasound study showed traces of subhepatic collection. Follow-up abdominal ultrasound was done after 1 month and showed no residual collection.

In group A, wound sepsis at the port from which the gallbladder was removed through occurred in two (6.7%) patients. One patient developed fever 2 days postoperatively and was diagnosed as having urinary tract infection based on urine analysis, which showed pus cells. Another patient developed fever from superficial thrombophlebitis at the site of intraoperatively inserted cannula on the second day postoperatively.

However, for group B, two patients developed wound sepsis.

Abdominal ultrasonography had been done for all patients 2 weeks postoperatively on outpatient patient scheduled arrangement, except for those who were converted to open cholecystectomy and those who developed complication within the same admission. Patients of both groups showed no intra-abdominal collection or dilation of the biliary system.

No re-intervention was recorded in the study for both groups. No mortality was also recorded.

Hospital stay (including the day of surgery and afterward).

Table 8 and Fig. 18 show the length of hospital stay in both groups. The hospital stay for group A patients ranged from 2 to 3 days, with a mean of 2.31 ± 1.77 days, and for group B, it ranged from 2 to 3 days, with a mean of 2.85 ± 1.43 days.



Length of hospital stays (days).

There was statistically nonsignificant difference between both groups.

Follow-up after discharge (6-month follow-up)

Patients of both groups were followed up for 6 months postoperatively based on monthly visits with complete liver function tests and abdominal ultrasound studies. All patients were in good health, and the follow-up was uneventful.

Discussion

Laparoscopic cholecystectomy is accepted as the gold standard surgical treatment of gallstones owing to postoperative quality of life of the patients and its optimal short-term and long-term result. Several benefits were gained, such as less postoperative pain, early ambulation, less analgesia, early return to normal daily activity, less hospital stay, and of course, the great benefit of no large abdominal scar, which is highly demanded [11].

Electrocautery remains the main energy form used during laparoscopic dissection. However, because of its documented risks, especially those related to visceral injury, search for alternative forms of energy that can be used in laparoscopic dissection and even coagulation and sealing vessels and ducts began very early during the evolution of laparoscopic cholecystectomy itself. Among these alternative energy sources are ultrasonic energy and laser energy [12].

In contrast to high-frequency electrodiathermy, harmonic scalpel technology does not cause electromagnetic interference with electro sensible implants or other instruments in the operation theater. Therefore, it is recommended for use in patients with a pacemaker, implanted cardiac devices, or cochlear implants, which may malfunction during the use of high-frequency electrosurgery [4].

In contrast to the aforementioned suggestions, the harmonic scalpel helps to achieve 'bloodless; vision during the operation, which in turn facilitates identification of the anatomic structures and thus helps not to injure structures of interest. Therefore, based on both aspects, the use of the harmonic scalpel does not exclude surgeon from having to be aware of surgical anatomy during all stages of the operation. The design of the blades of the shears of the harmonic scalpel allows blunt dissection, which is recommended for gaining adequate vision of surgical anatomy [11].

It has been reported that with ultrasonic energy, there is minimal lateral spread of vibration current in the surrounding tissues, minimizing the risk of injury compared with monopolar electrocautery, which is associated with 90% of visceral injuries and 15% of biliary tract injuries during laparoscopic cholecystectomy [13].

In this study, 60 patients who presented with symptomatic cholelithiasis were operated upon for laparoscopic cholecystectomy through two techniques. In group А, laparoscopic cholecystectomy was done using harmonic ultrasonic dissector as the sole dissecting tool, and in the group B, laparoscopic cholecystectomy was done using the ordinary monopolar electrocautery tools and

hemostatic clips for both cystic duct and artery (as the standard method currently used in practice) [7].

Tsimoyiannis performed their study on 200 patients who were divided into two groups, and Bessa did their study upon 120 patients, again divided into two groups. Cengis et al. did their study upon two groups, where group A included 40 patients and group B included 33 patients. Wetter did their study on two groups, where group A included 37 patients and group B included 21 patients. Sietses performed their study upon 18 patients divided into two groups. Fullum performed their study upon 105 patients in a single group. Kavalakoglu performed their study upon 60 patients divided into two groups. Gelmini performed their study upon 95 patients within a single group. Westervelt performed their study on 100 patients within a single group. Janseen did their study upon two groups, where group A included 96 patients and group B included 103 patients. Buscher did their study upon two groups, where group A included 331 patients who underwent the procedure with the harmonic ultrasonic dissector as the sole tool, and group B included 130 patients. Particularly for this study, for the patients of group A, the author used endoloop for cystic duct after coagulation division by the harmonic shear [7].

In this study, regarding groups A and B, five (16.7%) patients and seven (23.3%) patients, respectively, showed adhesions. As for group B, in four (13.3%) patients, the adhesions were mild and easily dealt with electrocautery. In these patients, adhesiolysis was achieved safely and completely. The remaining three (10%)patients showed massive inflammatory adhesions that were tough and difficult to handle with. In one of these patients, the presence of dense adhesions around the gallbladder and within the hepatocystic triangle rendered dissection very difficult and with intraoperative bleeding. In the other two (6.7%) patients, dissection ended with uncontrolled bleeding and further obscured the operative fields by the rapidly accumulating blood; thus, the procedure was converted to open surgery.

As for group A, three (3.3%) patients had adhesions that were mild and easily dealt with harmonic shear. In these patients, adhesiolysis was achieved safely and completely. The remaining two (6.7%) patients showed massive inflammatory adhesions that were tough and difficult to handle with. Dissection trails continued for ~25 min without any progress. So the decision was taken to convert to open surgery. Titanium clips are a mainstay in open surgery and have been widely used in minimally invasive procedure. Clips create a seal by mechanical compression and pose little risk to surrounding tissues when accurately applied. Although clips achieve reliable seals, they carry the risk of dislodgment with tissue manipulation. Clips require precise dissection of vessels before application [14].

The risk of dislodgment can act as a nidus for adhesion formation. Titanium clips have been shown to be adhesiogenic [14].

Intraoperative bleeding that leads neither to hemodynamic instability nor to increase transfusion requirements may pose a particular problem during laparoscopic cholecystectomy. Even minimal bleeding decreases the visualization and accurate discrimination of structures directly because of the pooling of small volumes of blood and indirectly because of reduced illumination owing to light adsorption by the blood. Because significant concerns have been raised regarding the safety of diathermy in laparoscopic surgery and the use of laser in laparoscopic surgery has failed to gain acceptance, the authors decided to evaluate the potential advantages of ultrasonic dissection performance for the laparoscopic cholecystectomy [15].

In this study, no bleeding happened in group A after sealing and cutting of the cystic artery by the harmonic shear. In group B, during adhesiolysis, two patients had rapid bleeding, obscuring the operative field by the rapidly accumulating blood: one patient had bleeding from the cystic artery transection and the other patient had bleeding from omental bleeder during dissection of greater omentum from the gallbladder; conversion to open surgery was done for both. These results go with the literature, which showed the significance of the ultrasonic dissector over the ordinary titanium clips in securing the cystic artery [15].

Another patient of group B showed immediate postclipping and cutting bleeding from the cystic artery clipped, and reinforcement of the clip was done for controlling the bleeding point [15].

Janssen reported that the level of surgical experience did not affect gallbladder perforation when ultrasonic dissection was used in contrast to electrocautery. This is an important finding taking into account the fact that cholecystectomy is the first laparoscopic procedure taught to residents in the Netherlands, and more than 90% of laparoscopic cholecystectomies are done by residents in teaching hospitals [16].

In this study, the use of the harmonic shear was associated with a statistically significant lower incidence of gallbladder perforation compared with electrocautery (20 vs. 30%, respectively; P=0.05). These results are comparable to other studies published concerned with the gallbladder perforation during laparoscopic cholecystectomy using harmonic scalpel [15].

Gallbladder perforation with loss of bile and stone has been shown to obscure the laparoscopic view. This leads to frequent instrument exchange and prolonged operative time. In this study, in both studied groups, procedures complicated by gallbladder perforation were associated with a statistically significant longer operative time than those in which this complication was not encountered [15].

Repeated thorough irrigation and suction was done in all patients who had perforated gallbladder immediately after the perforation and at the end of the procedure. None of the patients in this study had any postoperative complications related to this condition. Soper and Dunnegan stated that gallbladder perforation is more common in laparoscopic cholecystectomy than in open cholecystectomy. Furthermore, they have indicated that gallbladder perforation did not increase the early postoperative morbidity [17].

In this study, spillage of stones from perforated gallbladder into the peritoneal cavity occurred in one patient in group A and two patients in group B (3.3 and 6.7%, respectively). Stones were totally retrieved in all patients. However, this was at the expense of operative time and effort. Sporadic reports have shown late complications related directly to calculi left in the abdominal cavity, recurrent intra-abdominal, or even abdominal wall abscesses with expulsion of calculi. Larger series, however, have shown that most of these patients remain without sequelae. Hunter stated that the only indication for conversion to remove spilled calculi is when purulent bile is mixed with spilled calculi. These patients are at high risk for the development of an abscess even when the drain is left postoperatively [18].

These results are comparable to other studies published concerned with the gallbladder perforation during laparoscopic cholecystectomy using harmonic scalpel [15]. Since the first silk suture material acting as a nidus for the development of subsequent common bile duct stones after cholecystectomy was described in 1897, several investigators have reported that suture materials may cause choledocholithiasis. Silk, chromic catgut, parasites, and other foreign bodies are known occasionally to form such niduses in the common bile duct. Surgical hemostatic clips have been used widely and generally are considered very safe. The first case of post-cholecystectomy clip migration was reported in 1979. Its exact pathogenesis remains unknown. It generally is agreed that bile duct injuries, inappropriate clip placements, subclinical bile leak, and infections also have been postulated to contribute to clip migration.

One problem with laparoscopic cholecystectomy is the incidence of postoperative cystic duct leakage. This complication may be related to insufficient closure of the cystic duct after the standard closure with two metal clips. It may be speculated that necrosis of the cystic duct central to the metal clips or rubbing of the clips may be the most frequent pathogenesis to leakage of the cystic duct besides residual common bile duct stones.

There was absence of either minor or major bile leaks from the cystic-duct stump in group A, denoting that the harmonic shears are as safe and efficient as simple metal clips in achieving the closure of the cystic-duct stump in the laparoscopic cholecystectomy. In the Bessa trial, no minor or major bile leaks were reported in the drains postoperatively. As described by Tsimoyiannis, there were no patients with postoperative bile leakage in the ultrasonic group, but three patients in the electrocautery group developed postoperative bile leak, which was observed during the first 24 postoperative hours; moreover, in one patient, the bile leakage continued for 6 days. In all ERCP cases, bile leakage was confirmed from the gallbladder's liver bed [2].

Such a finding provides further evidence to the conclusions of others who demonstrated that the harmonic shears are capable of producing a safe and efficient closure and division of the cystic duct during the laparoscopic cholecystectomy [15].

In this study, as well as in the study by Bessa *et al.* [2], the harmonic shears were applied to only one site on the cystic duct where sealing and division were achieved with no bile leaks from the cystic-duct stump encountered in any of the four studies. It seems that a double application of the harmonic

shears to the cystic duct is unnecessary and may be an unsafe practice. This is agreed with the previous mentioned studies.

The absence of bile duct injuries in the present study adds further evidence to the safety of ultrasonic devices in the dissection of biliary structures in the laparoscopic cholecystectomy as pointed out by others [2].

Use of ultrasonic shears may be dangerous in the presence of severe visceral adhesions. In such cases, the hot active blade may cause thermal injuries to the bowel during dissection that are not easily recognized, as there is neither change of color nor charring in damaged tissues. Two of the three bowel injuries that occurred in the surgeon-in-training series were owing to instrument misuse: adhesiolysis performed with the active blade in contact with the bowel wall or bowel grasping immediately after instrument use with a still-hot active blade [13].

Bowel injury had not occurred in this study. Yet, Hunter stated that many of the lethal complications of laparoscopic surgery have resulted from unrecognized intestinal injury during extensive lysis of adhesions. He indicated that certain findings during trial dissection should trigger the decision to convert specifically dense adhesions of the omentum, duodenum, or the transverse colon to the abdominal wall, the liver, and gallbladder. He had set a time limit on trial of dissection of 30 min after which the surgeon should consider open conversion if no progress was achieved under such circumstances. Open conversion represents good judgment, and a mature laparoscopic surgeon would be the one who has learned to recognize which procedure cannot be completed laparoscopically [19].

It was expected from earlier experience and unfamiliarity with the device that use of the harmonic scalpel would prolong operating time in comparison with electrocautery. On the contrary, the time was shorter when the surgeon or resident was less experienced and when complicating factors were present. An improved laparoscopic view, an uncomplicated course of the procedure without bile and/or stone loss, and a reduced number of lens cleanings explain the shorter operating time [2].

The results of this study corroborate with those of Bessa *et al.* [2] and Janssen *et al.* [13], which demonstrated a shorter operating time and fewer intraoperative complications using ultrasonically activated shears compared with electrocautery in laparoscopic cholecystectomy [13].

The duration of operating time is statistically shorter with ultrasonic dissection. The total time of laparoscopic cholecystectomy for group A per patient ranged from 25 to 80 min, with a mean time of 31 min. The time of laparoscopic cholecystectomy for group A without gallbladder perforation per patient ranged from 25 to 48 min, with a mean time of 28.02 ± 5.2 min. The time of laparoscopic cholecystectomy for group A with gallbladder perforation per patient ranged from 28 to 80 min, with a mean time of 42.16 ± 8.9 min.

The total time of laparoscopic cholecystectomy for group B per patient ranged from 35 to 88 min, with a mean time of 44 min. The time of laparoscopic cholecystectomy for group B without gallbladder perforation per patient ranged from 35 to 59 min, with a mean time was 38.94 ± 4.8 min. The time of laparoscopic cholecystectomy for group B with gallbladder perforation per patient ranged from 35 to 88 min, with a mean time of 53.07±6.3 min.

This results corroborate with those of Bessa et al. [2], Huscher et al., and Janssen et al., which demonstrated a shorter operating time and fewer intraoperative complications using ultrasonically activated dissector. The relative shorter mean operative time in the harmonic group can be attributed to several factors: (a) the statistically significant lower incidence of gallbladder perforation in the harmonic group with subsequent avoidance of time loss in abdominal lavage and spilled stones retrieval and (b) the Harmonic ultrasonic dissector 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 ultrasonic dissector 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 contrary, the use of electrosurgery causes smoke formation in the abdominal cavity, affecting visibility. Moreover, smoke must be evacuated by opening the valves of the trocar, thus causing repeated loss of the pneumoperitoneum and a subsequent loss of time.

The most significant result to emerge from this study is the absence of bile leaks and postoperative hemorrhage in patients who underwent laparoscopic cholecystectomy with the Harmonic scalpel as the sole instrument. In line with Ylimaz *et al.* [20] and Bessa *et al.* [2], this study clearly demonstrates that the harmonic scalpel is an effective and safe tool for the closure of both the cystic duct and artery in patients who undergo laparoscopic cholecystectomy.

In this study, regarding group A, two (6.7%) patients were converted to open cholecystectomy owing to massive adhesions, and in group B, three (10%) patients were converted to open owing to massive adhesions and uncontrollable bleeding.

According to Nashwan *et al.* [11], conversion to open surgery was required in 1.31% of cases. Laparoscopic cholecystectomy done using harmonic ultrasonic dissector as the sole instrument on account of difficulty in dissection and failure to precede, and 2% of cases, laparoscopic cholecystectomy was done using electrocautery-powered instruments [16].

Thus, according to this study and the other studies, the harmonic ultrasonic dissector shows less conversion rates for laparoscopic cholecystectomy than the ordinary technique using the electrocautery power and the metallic clips [16].

The amount of analgesia required in the first 24 h postoperatively was ranging 0–50 mg. Patients who required analgesia in group A represented 65%, and those of group B represented 76% of patients, in whom the surgery was done without open conversion. In the study by Cengiz *et al.*, the first and fourth hours of recovery are statistically lower with ultrasonic dissection. Pain scores at 24 h of recovery from Cengiz and Tsimoyiannis trials were combined with a lower estimate in the ultrasonic dissection group trials is statistically significant [19].

Hospital stay ranged from 2 to 3 days, with a mean of 2.3 \pm 1.77 days for patients within group A. These results were better than the results of group B, in whom hospital stay ranged from 2 to 3, with a mean of 2.85 \pm 1.43 days. The study by Tsimoyiannis *et al.* showed results within the same range of course that short duration was owing to the early return to activity and early ambulation of patients with laparoscopic cholecystectomy.

On follow-up (6 months maximum), none of the study patients experienced postoperative biliary stricture as determined by ultrasound scan. This was in agreement with Bessa *et al.* [2]. Owing to the short postoperative follow-up periods within related literatures and its absence in others, the true risk of delayed biliary complications was unclear. However, there is evidence from the trial by Bessa *et al.* [2], showing the absence of this risk. Moreover, none of the patients in a trial by Huscher *et al.* experienced postoperative biliary stricture during a maximum follow-up period of 6 months as determined by ultrasound scanning, which is in parallel to the results of this study [3].

The main disadvantage of ultrasonic dissection is instrument cost, which is particularly true if the surgical unit is equipped with reusable instruments. Nevertheless, some authors believe that compared with combined cost of using multiple disposable instruments (scissors, a clipper, an electrocautery hook, and a grasper), the harmonic scalpel may provide a cost-effective option [16].

Conclusion

Laparoscopic cholecystectomy using ultrasonic energy is safe and feasible. The method offers several considerable advantages, such as the utilization of a single instrument both for dissection of the gallbladder from the hepatic bed and division of the artery and duct, shorter operating time and an improved laparoscopic view, and possibly a reduction of postoperative pain. The use of ultrasonic technology in the closure of the cystic duct has proved to be as safe and effective as the commonly used simple metal clips. The main obstacle hindering the applicability of the procedure is the cystic duct size: if it exceeds 5-6 mm in diameter, an additional ligature or clip is necessary. Postoperative follow-up for laparoscopic cholecystectomy using ultrasonic energy needs more studies to establish strong evidenced consensus about the late biliary complications. The main disadvantage of the use of ultrasonic technology in laparoscopic cholecystectomy is the cost. Yet within disposable instrument-based centers, it is not a disadvantage. The use of ultrasonic technology in laparoscopic cholecystectomy provides an alternative to the currently used electrocautery and surgical clips.

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Conflicts of interest

There are no conflicts of interest.

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