

Assessment of Safety and Efficacy of Harmonic Scalpel in Laparoscopic Cholecystectomy

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Abstract

Objective To achieving safe closure and prevention of post-operative complications by using harmonic Scalpel. **Methods:** This Clinical trial study was carried out in Zagazig university hospital. It included 24 patients with uncomplicated gallstone diseases who attended to general surgery department outpatients clinic. All patients included in this study were diagnosed to be uncomplicated gallstone disease patients. Patients were operated within 6 months duration in Zagazig University Hospital, during the period from Feb 2020 to Aug 2020. All patients were subjected to Demographic data taking, complete clinical examination, Laboratory investigations and Abdominal ultrasound. **Results:** Neither major complications regarding the gallbladder perforation nor bile duct injuries were detected, there were no post-operative complications, However, the mean operative time was significantly shorter. **Conclusion:** Harmonic scalpel in general is an efficient tool for complete hemobiliary sealing with high safety profile.

Key words: Laparoscopic cholecystectomy, Ultrasound, Harmonic Scalpel, Gallstones

I. Introduction:

Gallstones (cholelithiasis) are stones that are caused by abnormally high levels of either cholesterol or bilirubin (haem breakdown product) in the bile in the gallbladder or biliary tract. Gallstones are prevalent (10-20% of the global adult population) and more than 20% of people with gallstones will experience symptoms (including biliary colic or infections) during their lifetime, typically in adulthood[1]. Open cholecystectomy being performed for more than 100 years, has been an effective method of treating symptomatic gallbladder stone disease and has demonstrated an acceptable low morbidity and mortality, with a variation from 0 to 0.8 percent[2].

Laparoscopic cholecystectomy is the gold standard procedure for symptomatic gallbladder stone disease. The procedure was first performed in France and United States in 1980's. There have been various

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technical modifications since then; improving the outcome of surgery by scientific innovations. Modern energy devices used to dissect and coagulate tissue in laparoscopic surgery has made surgery safer and less invasive [3] .

Advantages of laparoscopic cholecystectomy have been clearly proved as less post-operative pain, minimal tissue trauma, improved cosmesis, shorter hospital stay, earlier return to work and possibly greater cost effectiveness[4].

Laparoscopic cholecystectomies using the conventional tools like monopolar diathermy and liga-clips are associated with two to three times more frequent injuries to common bile duct and/or collateral organ injuries as compared to open cholecystectomy [5].

There are several techniques of securing cystic duct and artery in laparoscopic cholecystectomy, like clips, intra or extra corporeal ligation, harmonic scalpel [6].

Harmonic scalpel is being used in a number of complex operations other than cholecystectomy, owing to its effective sealing capabilities [7].

Several studies have described the use of ultrasonic technology in laparoscopic cholecystectomy, where the harmonic shears were used as the sole instrument (apart from the camera and retraction forceps) to achieve both dissection of the gallbladder and closure/division of the cystic duct and artery[8].

The harmonic shears provided a superior alternative to the currently used high-frequency monopolar technology in terms of shorter operative time and lower incidence of gallbladder perforation. Further, the harmonic shears were as safe and effective as the commonly used metallic clips in achieving safe closure and division of the cystic duct in laparoscopic cholecystectomy [9]. The aim of the current study was achieving safe closure and prevention of post-operative complications by using harmonic Scalpel during laparoscopic cholecystectomy.

II. Patients and methods:

This Clinical trial study was carried out in Zagazig university hospital. It included patients with gallstone diseases who visited Zagazig University Hospital outpatients clinic. All included patients were informed about the study and informed consent was taken from all of them. All patients included in this study were diagnosed to be uncomplicated gallstone disease patients. This study included 24 patients, operated within 6 months duration in Zagazig University Hospital, during the period from Feb 2020 to Aug 2020. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Inclusion criteria: Patients with uncomplicated gallstones disease. Exclusion criteria: Choledocholithiasis. Manifestation of acute cholecystitis (History, Examination & Radiological). Evidence of Mirrizi syndrome (Radiological). Cirrhotic Liver diseases/ malignancy. Age less than 18 years. Cystic duct diameter more than 6 mm (Assessed by preoperative ultrasound or intra-operatively by blades of harmonic scalpel). Previous upper abdominal surgery. Uncontrolled Coagulation abnormalities& Sever cardio-pulmonary diseases.

All included patients were subjected to history taking regarding the main complaint (Classical biliary colicky pain such as onset, Duration, Site of pain, Type of pain, Radiation of pain, Aggravating & relieving factors), Clinical examination and Laboratory investigations were done for all patients including complete blood count (CBC), and ABO blood grouping. Liver function tests including serum bilirubin, serum albumin, International Normalized Ratio (INR), serum alkaline phosphatase, gamma-glutamyl transferase (GGT), Serum glutamic pyruvic transaminase (SGPT), Serum glutamic oxaloacetic transaminase (SGOT), Random blood sugar, ECG & Echocardiogram for patients with co-morbidity. Ultrasonography was routinely performed to all patients to confirm the clinical diagnosis of cholelithiasis with number of stones, size, gallbladder wall thickness (up to 6 mm), pericholecystic collection, diameter of cystic duct & common bile duct.

All patients were diagnosed as gallbladder stone diseased patients underwent laparoscopic cholecystectomy within 24 hours after admission. Patients received medical care till the operation.

Operative strategy:

The patient was placed in the supine position on the operating table with both lower extremities apposed, Preoperative single dose antibiotics such as ceftriaxone or ceflexin 1 gram is given within 30 minutes of incision per protocol, General anaesthesia were used for all included patients.

Surgical Procedure:

After induction of general anaesthesia and in presence of expert surgeons, an aseptic surgical field is created from just above the bilateral costal margins to the pubic tubercle and laterally to the right and left flanks. The sterile surgical field allowed for the possibility of an open procedure if needed. Veress needle technique was performed in all cases. First, insufflation of the abdomen by veress needle is achieved to 12-15 mmHg using carbon dioxide. The four small incisions are made in the abdomen for trocar placement (Supraumbilical or infraumbilical, Subxiphoid, Right subcostal & right ant axillary line). Utilizing a camera (telescope) for exploratory laparoscopy. The preliminary overall step is the careful diagnostic laparoscopy which is done to all included patients, particular attention to the area around the umbilicus to exclude unsuspected omental or bowel adhesions or injuries. After exploratory laparoscopy positioning the patient in reverse trendelenburg position. The gallbladder is retracted over the liver by long instruments. This allows for exposure of the proposed region of the hepatocystic triangle.

The standard four-trocars operative technique was used for laparoscopic cholecystectomy. To create a critical view of safety **Figure (1)**, Calot's triangle was dissected from fat and fibrous tissue and the lower end of the gallbladder was dissected off the liver bed.

Triangle of Calot dissection: Opening of anterior & posterior peritoneal leaflets is done. Careful dissection is carried out to achieve the critical view of safety.

Once this view is adequately achieved, the operating surgeon proceeded with confidence. Both structures are carefully sealed and transected by harmonic scalpel. **Figure (2)**

Harmonic scalpel blade was used to separate the gallbladder from the liver bed completely **Figure (3)**. Hemostasis is achieved after the abdomen is allowed to deflate to 8 mmHg for 2 minutes. This technique is employed to avoid missing potential venous bleeding that can be tamponaded by elevated intra-abdominal pressure (15 mmHg). The gallbladder is removed from the abdomen in a specimen pouch. Intraperitoneal

(gallbladder bed) redivac suction drain No.14 was kept in all cases then all trocars removed under direct visualization.

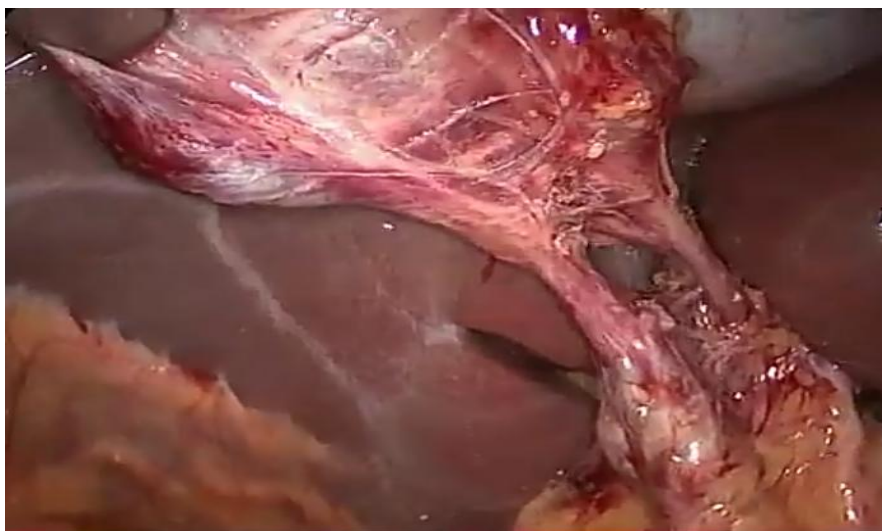


Figure (1): Critical view of safety achievement

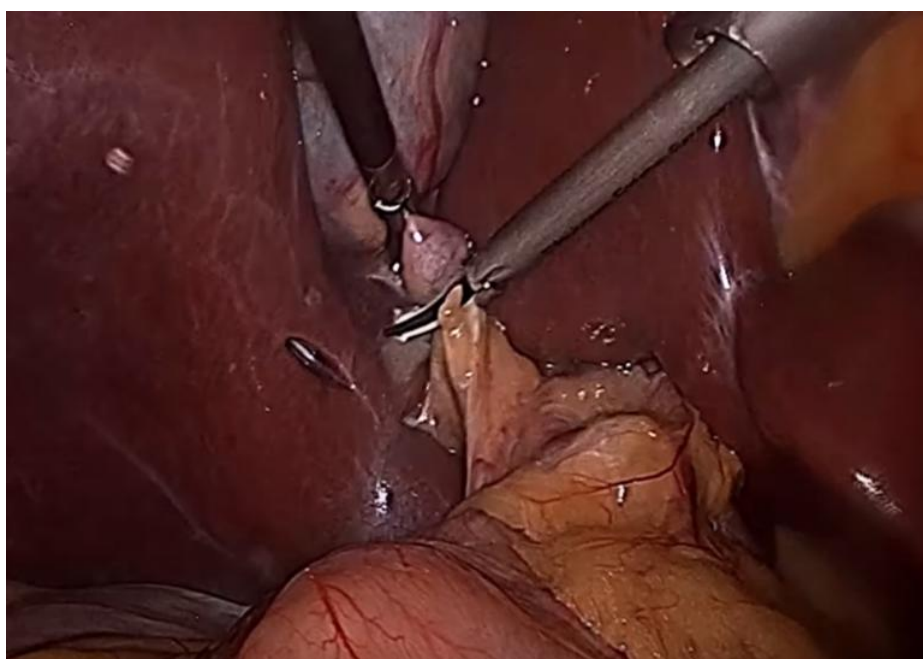


Figure (2): Application of scalpel blade for sealing the cystic duct.

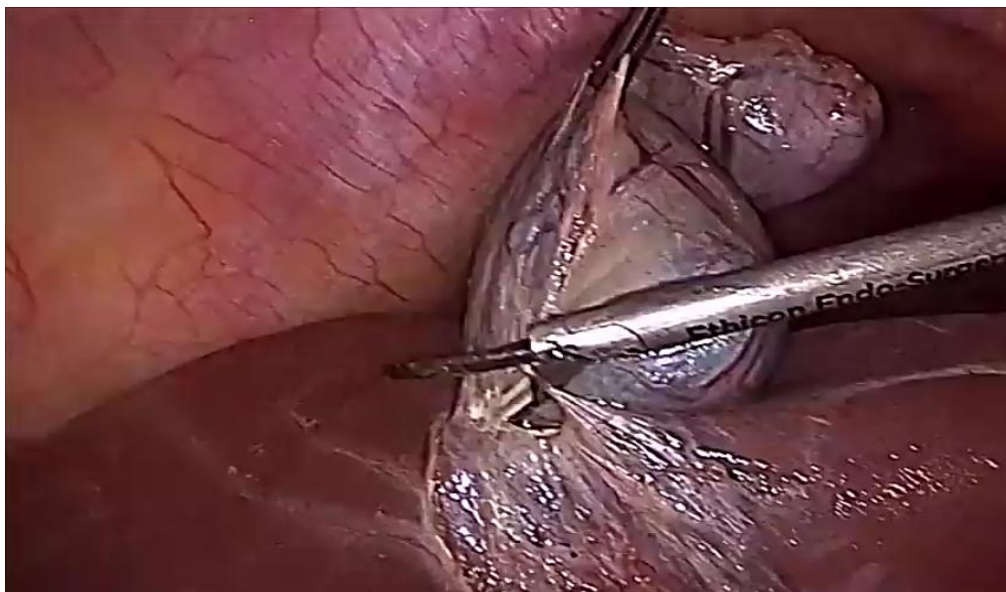


Figure (3): Complete separation of gallbladder from liver as a final step of separation.

Post-operative care:

All patients are shifted postoperatively to ordinary ward beds under close monitoring. The patients were started on orals by the first post-operative day (6-8 hr). All Patients are managed with current enhanced recovery after surgery protocols; patients encouraged for quick ambulation, close observation of pulmonary function, and the intravenous antibiotic was continued for 24h after surgery & postoperative pain assessment using VAS. All patients were discharged on the first post-operative day except who had bile leak or bleeding intraoperatively are discharged on the second day with advice to keep on a fat-free diet and were followed in the outpatient department. Follow up of the patients done after 1 week then after two weeks until patients became fully improved and had no more postoperative complaints.

Postoperative investigations:

All patients were subjected to postoperative CBC, INR & liver function test. The postoperative course was generally uncomplicated (e.g fever, uncontrolled vomiting or extreme pain)

Statistical analysis :

All data were fed to the computer and analyzed using IBM SPSS software package. Qualitative data were described using number and percent. Quantitative data were described using mean and standard deviation for parametric data after testing normality.

III. Results:

Consecutive laparoscopic cholecystectomies were performed in the Department of Surgery, in patients affected by gallbladder lithiasis with no indication for conversion was faced such as difficult manipulation due to adhesions, Intra-operative bleeding uncontrolled laparoscopically, Intra-operative bile duct injury uncontrolled laparoscopically or intra-operative visceral injury. 6 (25%) patients were males, and 18 (75%) were females with an average age of 20-59 years (35.7 ± 10.11).

Pre-operative results of studied patients; This study showed that the mean age of studied group was 35 years and 7 months, ranged from 20 years up to 59 years and the commonest age group found was 20 – 30 years with 37.5% of the studied patients, 29.2% of them represented in age groups 31-40 years and 41-50 years. Also, showed that 75% of studied patients were females and 25% were males. **Table (1)**

This study showed that 37.5% of studied patients had history of previous abdominal surgery and 25% of them had history of Cesarean section (CS), while 16.7% had history of appendectomy. The commonest US finding among studied group was multiple gallbladder stones (MGBS) 66.7%, while only 33.3% of them presented with solitary gallbladder stone (SGBS). The INR ranged from 0.8 to 1.18 with the mean 0.93, Hb ranged from 10.7 to 16.1 with the mean 12.7 & RBS ranged from 88 to 155 with the mean 113.5. Regarding the pre-operative liver function tests that the mean of total bilirubin was 0.87 ± 0.13 ranged from 0.68 to 1.1, the range of direct bilirubin was 0.2 up to 0.55 with mean of 0.37, while serum ALP ranged from 35 up to 93 with the mean 53.2. range of SGPT from 15 to 33 with mean 24.8 and SGOT were 12 to 31 with mean 19.3 respectively. **Table (2)**

Operative results; This study showed that the mean of operative time was 51.4 minutes ranged from 35 up to 87 minutes and the longest operative time found during first 8 cases with mean of 69.5 minutes, while the shortest time found among last 8 cases with mean of 39.5 minutes. The operation was in good sequence among 87.5% of the studied group, while bleeding occurred in 4.2% and 8.3% of the patients showed intra-operative bile leak from the cystic duct stump after sealing with harmonic scalpel, the commonest action to manage these complications was clipping with classical metal clips just proximal to cystic duct stump as well as artery and it was fair and effective to control among all complicated cases, With all cases needed drainage and without conversion to open approach. **Table (3)**

Post-operative results; This study showed that post-operative pain the mean level of VAS was 6.2 with 25% of patients had VAS score <6 and 75% of them had VAS score ≥ 6 . There were no post-operative complications reported among studied patients. only 12.5% stayed for two days at hospital, that most of the studied patients (87.5%) stayed for only one day at hospital. **Table (4)**

Table (1): Demographic data of age, Gender and comorbidities distribution of the studied patients.

Variables	Studied group N=24
Age/years	
Mean SD	35.7 $\pm$ 10.11
Range	20 – 59
Age distribution	
20-30 years	9 (37.5%)

31-40 years	7 (29.2%)
41-50 years	7 (29.2%)
51 -60 years	1 (4.2%)
Gender	N (%)
Male	6 (25%)
Female	18 (75%)
Comorbidity	
Yes	4 (16.7%)
No	20 (83.3%)
Type of comorbidity	
Hypertension	3 (12.5%) *
DM	(8.3%)

*One of the studied patients had both hypertension and diabetes.

Table (2): Demographic data of the studied patients.

Variables	Studied group N=24 N (%)
Previous abdominal surgery	
Yes	9 (37.5%)
No	15 (62.5%)
Types of previous surgery	
Appendectomy	4 (16.7%)
Cesarean Section	6 (25%)
US	
Solitary gallbladder stone (SGBS)	8 (33.3%)
Multiple gallbladder stones (MGBS)	16 (66.7%)

Pre-operative laboratory data	
INR	0.93 ± 0.11
Range	0.8 – 1.18
Hb (mg/dl)	12.7 ± 1.44
Range	10.7 – 16.1
RBS(mg/dl)	113.5 ± 18.2
Range	88 – 155
Pre-operative liver function tests	
Total bilirubin(mg/dl)	0.87 ± 0.13
Range	0.68 – 1.1
Direct bilirubin(mg/dl)	0.37 ± 0.09
Range	0.2 – 0.55
Serum ALP(u/l)	53.2 ± 15.4
Range	35 – 93
SGPT(u/l)	24.8 ± 5.42
Range	15 – 33
SGOT(u/l)	19.3 ± 5.51
Range	12 – 31

Table (3): Intraoperative Data

Variables	Studied group N=24
Operative time	
Operative time (minutes)	
Mean $\pm$ SD	51.4 ± 15.3
Range	35 – 87

1 st 8 cases	Mean ± SD (Range)
2 nd 8 cases	69.5 ± 12.99 (53 – 87)
Last 8 cases	45.3 ± 3.37 (40 – 50)
	39.5 ± 2.21 (35 – 43)
Intra-operative sequence and management of complications	
Intra-operative sequence	N (%)
Good	21 (87.5%)
Bile leak	2 (8.3%)
Bleeding	1 (4.2%)
Management of complications	N =3
Clipping	3 (12.5%)
Conversion	
No	24 (100%)
Drainage	
Yes	24 (100%)

Table (4). Postoperative Data

Variables	Studied group N=24
Post-operative visual analogue scale (VAS) of pain	
Mean ± SD	6.2 ± 1.18
Range	4 – 8
VAS score	N (%)
<6 score	6 (25%)
≥6 score	18 (75%)
Complications	

Bile leak	0 (0.0%)
Bleeding	0 (0.0%)
Hospital stay duration	
1 day	21 (87.5)
2 days	3 (12.5%)

IV. Discussion:

Laparoscopic cholecystectomy (LC) is a well-known benchmark in the surgical management of symptomatic gallbladder stones as well as acute cholecystitis. (LC) has numerous advantages when compared to conventional surgical laparotomy, yet the most important of these merits are its minimal invasiveness and faster recovery for patients. The titanium clips used for clipping the cystic artery and cystic duct have a risk of slippage, which may lead to bleeding, and an increased risk for bile leakage [10]. Advanced energy sources, such as the harmonic scalpel, though expensive, may provide the advantage of shorter operating time by reducing smoke, bloodless dissection in the gallbladder bed, lower risk of bleeding from the cystic artery due to secure vessel sealing and avoiding the use of a larger number of titanium clips [11].

The current study showed that the mean age of studied group was 35 years and 7months, ranged from 20 years up to 59 years and the commonest age group found was 20 – 30 years with 37.5% of the studied patients, 29.2% of them represented in age groups 31-40 years and 41-50 years. Also, showed that 75% of studied patients were females and 25% were males.

While **Mahmoud andEl-Atar**[12] in their study on a Group included 30 patients whom laparoscopic cholecystectomy had been done using a harmonic scalpel, found that their age ranged from 26 to 77 years, with a mean of 33.6 ± 3.24 and They were 20 females (66.7%) and 10 males (33.3). Most of the patients were in their fourth and fifth decades.

But **Mohammed and Asaad** [13] in a study included 30 patients who subjected to clipless cholecystectomy using harmonic scalpel, reported that the mean age was 38.8 ± 12.7 years (19–79 years), they were 22 females (73.3%) and 8 males (26.7%).

Also **Alam et al.**, [14] in their study on 120 patients were operated laparoscopically through standard four ports technique and ultrasonic device (hormonic) reported that the age of the patients ranged from 25 to 68 years with the maximum number in the 4th decade and the mean age was 42.4 ± 13.29 years, they were 102 females (85%) and 18 males (15%) .

Attri et al., [15] in a study included 114 patients, found that the majority of the patients were females 82 (71.92%) and 32 (28.07%) were males. The age of their studied group ranged between 16 years to 72 years, with average age of 41.4 years, majority of the patients were between 35-44 year range (42.10%).

The current study showed that 4 patients (16.7%) had comorbid diseases commonly hypertension (12.5%) and 8.3% had diabetes, One patient had both hypertension and diabetes . Which in agreement with the

study of **Bessa et al.**, [16] who reported that hypertension was found in 5 (8.3%) and 7 patients (11.7%) had Diabetes mellitus.

In contrast to our results the study of **Amer et al.**, [17] on 30 patients who underwent laparoscopic cholecystectomy using harmonic scalpel reported that 6 patients (20%) had hypertension, while 10 patients (30%) had DM.

Meanwhile **Kumar et al.**, [18] reported that 4 patients (20%) had hypertension, while 3 patients (15%) had DM. **Liao et al.**, [19] reported that hypertension was found in 5 patients (4.3%) while Diabetes mellitus was found in 2 patients (1.7%).

The current study showed that 37.5% of studied patients had history of previous abdominal surgery and 25% of them had history of Cesarean section (CS), while 16.7% had history of appendectomy. While **Mahabaleshwar et al.**, [20] reported that previous abdominal surgery was found in 3 patients (9.9%).

In contrast to **Mahmoud and El-Atar**[12] in their study on a Group included 30 patients whom laparoscopic cholecystectomy had been done using a harmonic scalpel, found that 53.2% of studied patients had history of previous abdominal surgery and 16.6% of them had history of appendectomy while 36.6% had history of Cesarean section.

And **Bessa et al.**, [8] in their study on a Group included 20 patients whom laparoscopic cholecystectomy had been done using a harmonic scalpel 20% of studied patients had history of previous abdominal surgery and 10% of them had history of appendectomy while 10% had history of Cesarean section.

We found that the commonest US finding among studied group was multiple gallbladder stones (MGBS) 66.7%, while only 33.3% of them presented with solitary gallbladder stone (SGBS). Which is nearly similar to the study of **Gelmini et al.**, [21] who reported that 76 % of patients were with Multiple gallbladder stones and 24% of patients with Solitary gallbladder stone.

Which in contrast to the study of **Mahmoud and El-Atar**[12] who reported that regarding the gallbladder in harmonic scalpel group, patients showed multiple stones of variable sizes in 16 (53.3%) patients and 14 (46.7%) patients with solitary gallbladder stone. Also, **Mahabaleshwar et al.**, [20] reported that in harmonic scalpel group, 18 patients (60%) had multiple calculi and 9 patients (30%) had single calculus. **Ramzanali and Shah** [22] reported that the pre-operative ultrasound showed multiple stones in gall bladder in 68 (73.9%) cases while on the other hand solitary stone was seen in 24 (26.1%) patients.

The current study showed that the INR ranged from 0.8 to 1.18 with the mean 0.93, Hb ranged from 10.7 to 16.1 with the mean 12.7 & RBS ranged from 88 to 155 with the mean 113.5. On the other hand **Kumar et al.**, [18] found that preoperative INR, CBC & RBS of the studied patients in their study were in the average of the normal values.

Regarding the pre-operative liver function tests we found that the mean of total bilirubin was 0.87 ± 0.13 ranged from 0.68 to 1.1, the range of direct bilirubin was 0.2 up to 0.55 with mean of 0.37, while serum ALP ranged from 35 up to 93 with the mean 53.2. range of SGPT from 15 to 33 with mean 24.8 and SGOT were 12 to 31 with mean 19.3 respectively. While **Orsaria et al.**, [23] found that total bilirubin was 1.2 mg/dL, direct bilirubin 0.6 mg/dL, alkaline phosphatase 110 u/L and SGPT 23 u/L.

Sumer et al. [24] reported that the mean of total bilirubin was 0.48 mg/dL, direct bilirubin 0.25 mg/dL and alkaline phosphatase 139 U/L. **Nishant et al.**, [25] showed that the mean of total bilirubin was 0.88 & the mean direct bilirubin was 0.46.

The current study showed that the mean of operative time was 51.4 minutes ranged from 35 up to 87 minutes and the longest operative time found during first 8 cases with mean of 69.5 minutes, while the shortest time found among last 8 cases with mean of 39.5 minutes. **Ramos et al.**, [26] reported that the mean operative time was 26 min (range 12 to 52) and no associated procedure was required. Which is relatively the same as **Sanawan et al.**, [3] whom reported that the mean operating time was 30 min in the harmonic scalpel group.

In contrast to **Anis et al.**, [27] they reported that the mean operative time was 35.7 ± 4.9 min in the harmonic scalpel group, In agreement with **Singh et al.**, [28] as they found that the mean operative time in the study group was 37.28 ± 7.860 minutes (range 20-56 min). **Jung et al.**, [29], noted that the learning curve was optimum for training personnel with less number of cases in comparison with other electrocautery devices. Time in our study was longer than similar studies, this explained by our early experience in using harmonic scalpel.

The current study showed that the operation was in a good sequence in 87.5% of the studied group, while bleeding occurred in 4.2% and 8.3% of the patients showed intra-operative bile leak, the commonest action to manage these complications was clipping among all complicated cases, All cases needed drainage and without conversion to open approach.

Fullum et al., [30] reported that two gallbladder perforations occurred, but no complications were associated with the extrahepatic biliary tree, viscera, or major blood vessels. Elective conversion occurred in 8 (7.6%) patients due to poor visualization of anatomy because of inflammation and adhesions.

Meanwhile **Singh et al.**, [28], reported that conversion was necessary in one patient in the study group (3.33%) It was due to dense adhesions that critical angle of safety could not be made so they were converted to open, A drainage tube was positioned in subhepatic space in all the cases and was kept till the first postoperative day or 24hrs. None of the cases had any postoperative bile leak, haemorrhage, bleeding and CBD Injury were not present in Study Group.

In concern to the post-operative pain of studied patients in our study the mean level of VAS was 6.2 with 25% of patients had VAS score <6 and 75% of them had VAS score ≥ 6 .

Nearly the same as **Singh et al.**, [28] whom reported that mean postoperative pain score on VAS scale for the study group was (mean 6.18 ± 0.54) & **Sanawan et al.**, [3] reported that postoperative pain in harmonic scalpel group was calculated using the Visual Analogue score from 1 – 10 and the median pain score was 6.

The current study showed that there was no post-operative complication reported in the studied patients. Which in agreement with the study of **Sanawan et al.**, [3] concluded that none of the patients in the harmonic scalpel group had bile leaks or bleeding.

And study of **Sharma et al.**, [2] who reported that there was no bile leaks, bleeding or any other complications, in contrast to **Attri et al.**, [15] Postoperative complications were found in 6 (5.2%) patients with bile leak from duct of Lushka in 1 (0.8%) patient, port site infection in 2 (1.7%) patients and fever in 3 (2.6%) patients but no bleeding reported in patients. **Sanawan et al.**, [3] found that there was one patient (1/75, 1.3%) had bleeding.

The current study showed that most of the studied patients (87.5%) stayed post-operatively for only one day at hospital, while only 12.5% stayed for two days at hospital. which in agreement with the study of **Mohammed & Asaad [13]** found that most of the studied patients (90%) stayed for only one day at hospital, while only 10% stayed for two days at hospital.

Singh et al., [28] reported that the mean duration of hospital stay in Study group was 2.24 ± 1.154 days (mean 1-7 days). **Sanawan et al., [3]** concluded that Hospital stay in hours was 32.9 ± 5.53 hours in harmonic scalpel group. **Abou-Sheishaa et al., [31]** reported that mean postoperative hospital stay was 1.1 day in harmonic scalpel group. **Alam et al., [14]** in their study on 120 patients were operated laparoscopically through standard four ports technique and ultrasonic device (harmonic) reported that the mean hospital stay was 3.37 ± 0.766 days in studied patients.

V. Conclusion:

Harmonic scalpel in general is an efficient tool for complete hemobiliary sealing with high safety profile. The use of harmonic scalpel in the laparoscopic cholecystectomy is associated with a shorter operative time, less post-operative pain and analgesia and shorter hospital stay. The major merit is its relatively high cost and limited use in mega cystic duct sizing more than 6mm. Harmonic shear devices are easy to train and safe at time of training with no fear to get major iatrogenic trauma even to those who are on training level. Laparoscopic cholecystectomy using harmonic scalpel is SAFE and to be used in all cases if available.

Larger studies assessing appropriate plasma transfusion strategies are urgently needed. The study highlights the importance of implementing educational initiatives and the need for stronger evidence from future randomized controlled trials.

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