

COMPARISON BETWEEN CLIPLESS LAPAROSCOPIC CHOLECYSTECTOMY VERSUS CONVENTIONAL METHODS IN PATIENTS OF SYMPTOMATIC GALLSTONES

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ABSTRACT

Background: Laparoscopic cholecystectomy is the worldwide gold standard treatment of symptomatic gallbladder lithiasis. The sealing device has been used safely in other general surgical operations. The primary use of clipless with sealing device in laparoscopic cholecystectomy was for the division of the cystic artery. Now, Blade tip provide for the reliable ultrasonic division and closure of the cystic duct. The aim of the current study was achieving safe closure and prevention of post-operative complications by using clipless laparoscopic cholecystectomy. **Patients and methods:** This study included 30 patients with uncomplicated gallstone diseases. All patients were diagnosed to be uncomplicated gallstone disease patients. Patients were operated within 6 months duration in Zagazig University Hospital. History taking, clinical examination and full investigations were done. A definite diagnosis is confirmed by using ultrasonography. All patients with comorbid diseases were fully optimized and well prepared for the surgery. **Results:** There is statistically significant difference between the studied groups regarding operative time. Mean operative time is significantly higher among conventional laparoscopic cholecystectomy group. There is statistically highly significant difference between the studied groups regarding length of hospital stay (significantly longer among patients underwent Clipless Laparoscopic harmonic Cholecystectomy). There is statistically non-significant difference between the studied groups regarding VAS preoperatively. There is statistically significant difference between the studied groups regarding VAS postoperatively (significantly lower in Clipless Laparoscopic harmonic Cholecystectomy). In each group, VAS significantly decreased postoperatively. There is statistically significant difference between the studied groups regarding need for conversion to conventional technique by clipping cystic duct. No conversion to open cholecystectomy in both groups. **Conclusion:** Sealing device provides complete hepatobiliary 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, and less rate of conversion to open cholecystectomy avoiding clip failure less thermal effect on the liver especially fatty or early cirrhotic.

Keywords: **Clipless Laparoscopic; Cholecystectomy, Gallstones**

INTRODUCTION:

Gallstone disease is one of the most common problems affecting the digestive tract. The prevalence of gallstones is related to many factors, including age, gender, and ethnic background. Obesity, pregnancy, dietary factors, Crohn's disease, terminal ileal resection, gastric surgery, hereditary spherocytosis, sickle cell disease, and thalassemia are all associated with an increased risk of developing gallstones. Women are three times more likely to develop gallstones than men, and first-degree relatives of patients with gallstones have a twofold greater prevalence (1).

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

The traditional LC is usually performed by mean of the dissector, the electrosurgical hook, and spatula and /or scissor, this method has been used in most centers. Deep tissue damage with possible distant tissue damage by the high frequency electrosurgery involving vascular and biliary structure in the vicinity of cystic duct and artery, bile leakage due to slippage of clips, and collateral injuries i.e. visceral and solid organ injury due to frequent instrument exchange, which is sometimes performed without optic guidance (3).

The electrosurgical devices has become in use for all surgical specialities, including general surgery, urology and gynaecology (4). UCS devices (e.g. Harmonic Scalpel, Ethicon Endo-Surgery) use electric power to generate high frequency ultrasonic mechanical vibrations, which drive the active blade of the device. Hydrogen bonds in tissue proteins are denatured, thus forming a coagulum, enabling sealing of vessels up to 7mm in diameter (5). EBVS devices on the other hand, (e.g. Ligasure™, Valleylab) use a combination of pressure and energy (high current and low voltage) to create tissue fusion. Collagen and elastin in vessel walls are denatured, thus forming a seal, with studies showing capability of sealing vessels of up to 7mm in diameter (6). **Ahmed and Muhammad (7)** evaluated the safety, efficacy and clinical outcome of LC using harmonic scalpel for securing cystic duct and artery compared with conventional laparoscopic cholecystectomy. They found that the harmonic scalpel provides complete hemostasis for all patients and is a safe alternative to standard clipping of cystic duct and artery. It provide a shorter operation time, less evidence of gallbladder perforation, less postoperative time and less rate of conversion to open surgery.

The aim of the present study was to compare the laparoscopic conventional cholecystectomy and clipless cholecystectomy using a Sealing device in terms of the duration of the operation, intraoperative blood loss, postoperative complications, postoperative pain, and hospital stay.

PATIENTS AND METHODS:

This comparative clinical study was conducted in General Surgery Department, Zagazig University Hospitals. Thirty patients with gallstone diseases were included.

Inclusion criteria:

All medically fits patient with nocontraindication for laparoscopy between 15 to 70 years of age, if they did not fall in exclusion criteria and Cystic duct diameter < 6 mm (measured preoperatively by ultrasound, MRCP and intra-operatively by comparing with tip of Maryland's dissector). Symptomatic cholelithiasis with BMI under 35 and ASA I or II.

Exclusion criteria:

Patients in age of < 15 years and > 70 years, cystic duct diameter > 6 mm, pregnancy, gallbladder malignancy, history of recent acute attack and history of recent or remote obstructive jaundice or attacks biliary colic.

The patients were assessed according to the following scheme: thorough history, complete physical examination, laboratory investigations including Complete Blood Count (CBC), liver function tests (serum albumin, ALT, AST, prothrombin time, total and direct bilirubin and alkaline phosphatase), renal function tests (urea and creatinine) and HCV and HBV markers to show the state of the liver, portal vein, gallbladder, and CBD. Abdominal ultrasonography was the preliminary investigation for all patients.

Examination by an experienced ultrasonographer, and good preparation of the patient through fasting and repeated enemas was a matter of concern to ensure extraction of reliable information about the extent of intrahepatic biliary radicles dilatation, possible site of stricture, length of proximal bile duct stump, presence of intra-abdominal free fluid collection, presence of liver cirrhosis, portal hypertension and other abdominal abnormalities in general.

Operative strategy:

The patient was placed in the supine position on the operating table with both lower extremities apposed. Using standard laparoscopic cholecystectomy equipments include two laparoscopic monitors, one telescope (5/10 mm, 0/30 degrees) including camera cord and light source. 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. During this study period. First, insufflation of the abdomen by veress needle is achieved to 12-15mmHg using carbon dioxide. 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. Harmonic scalpel blade was used to separate the gallbladder from the liver bed completely. Hemostasis is achieved after the abdomen is allowed to deflate to 8mmHg for 2 minutes. This technique is employed to avoid missing potential venous bleeding that can be tamponaded by elevated intra-abdominal pressure (15mmHg). 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. Subcuticular suture or interrupted dermo-epidermal stitching was done (**Figure 1**).

Outcome measure:

Effectiveness closure of the cystic duct (time frame at one month) is assessed on the presence or not of cystic duct bile leak. The efficacy and safety of the use of sealing device performing cholecystectomy is assessed by evaluating the operative time, the presence of major or minor intraoperative complications.

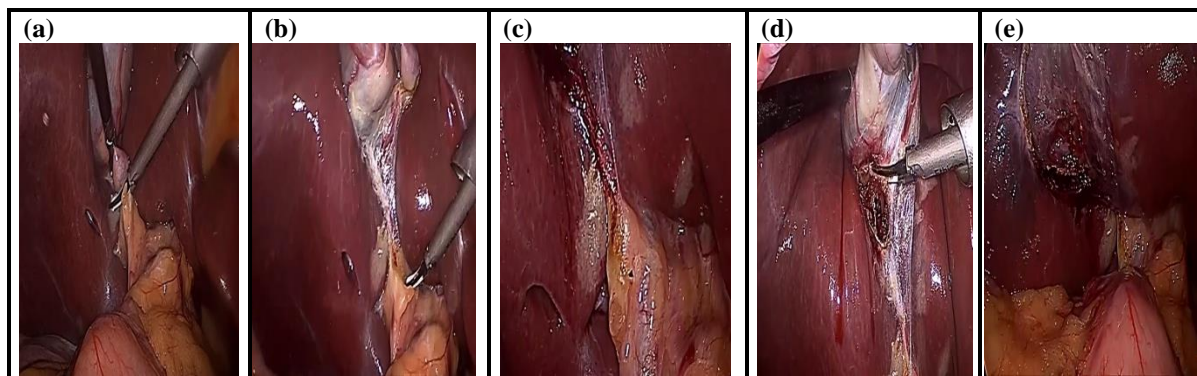


Figure (1): Surgical technique showing (a) application of scalpel blade for sealing the cystic duct, (b) Sealing and dividing the cystic duct and artery by harmonic scalpel, (c) both cystic duct and artery stumps after sealing and division by the harmonic scalpel, (d) Gallbladder dissection; (e) Securing haemostasis and final look on the stump before putting the drain in gallbladder bed and closure.

Statistical analysis:

Data were entered checked and analyzed using Epi-Info version 6 and SPP for Windows version 8. Mann Whitney-U test and Student t test were used when comparing two means. For all above mentioned statistical tests done, the threshold of significance is fixed at 5% level (p -value). The results were considered: Significant when the probability of error is less than 5% ($p < 0.05$). Non-significant when the probability of error is more than 5% ($p > 0.05$). Highly significant when the probability of error is less than 0.1% ($p < 0.001$). The smaller the p -value obtained, the more significant are the results.

RESULTS:

This study is recruited on 30 patients; 15 within each group. There is statistically non-significant difference between the studied groups regarding age, or gender. Females represented 73.3% and 66.7% within groups of clipless laparoscopic cholecystectomy and conventional methods respectively (**Figure 2**).

There is statistically significant difference between the studied groups regarding operative time. Mean operative time is significantly higher among conventional laparoscopic cholecystectomy group (**Figure 3**).

There is statistically highly significant difference between the studied groups regarding length of hospital stay (significantly longer among patients underwent Clipless Laparoscopic harmonic Cholecystectomy) (**Table 1**).

There is statistically non-significant difference between the studied groups regarding VAS preoperatively. There is statistically significant difference between the studied groups regarding VAS postoperatively (significantly lower in Clipless Laparoscopic harmonic Cholecystectomy), In each group, VAS significantly decreased postoperatively (**Table 2**).

There is statistically significant difference between the studied groups regarding need for conversion to conventional technique by clipping cystic duct. No conversion to open cholecystectomy in both groups (**Table 3**).

Five patients from group A underwent conventional technique, one due to bleeding, one due to wide cystic duct, one had intraoperative bile leak and two had short cystic duct (Table 4).

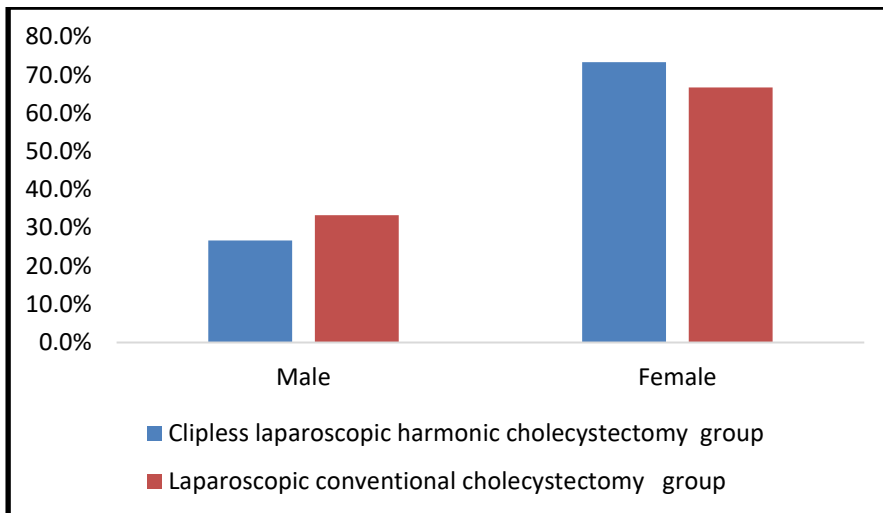


Figure (1): Multiple bar chart showing comparison between the studied groups regarding gender

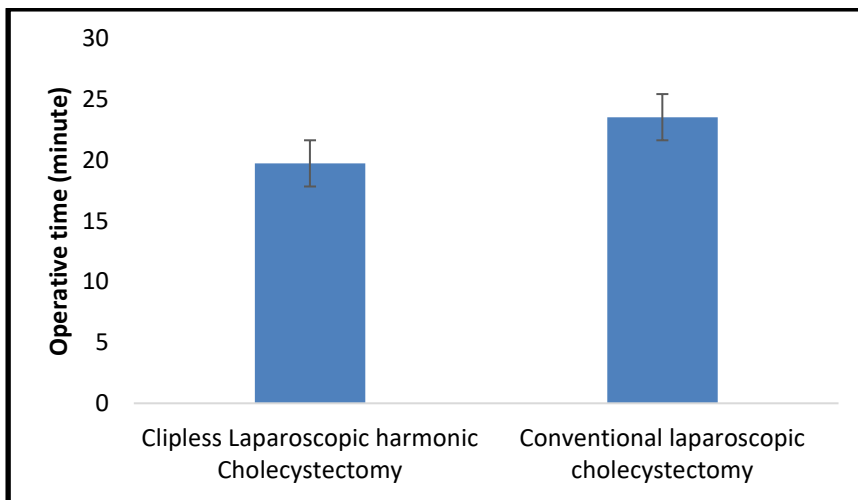


Figure (3) Simple bar chart showing comparison between the studied groups regarding operative time

Table (1) Comparison between the studied groups regarding length of hospital stay:

Parameters	Groups		Test	
	Group A	Group B	t	p
	N=15	N=15		
LOS (hour) Mean ± SD Range	47.89 ± 8.77 24 – 72	28.2 ± 7.93 20 – 48	6.45	<0.001**

t independent sample t test *p<0.05 is statistically significant

Table (2) Comparison between the studied groups regarding VAS score pre and postoperatively:

	Groups		Test	
	Group A	Group B	Z	p
	Mean ± SD	Mean ± SD		
VAS Preoperatively Postoperatively	6 (5 – 8) 2 (1 – 3)	6 (5 – 8) 3 (1 – 5)	-0.179 -2.442	0.858 0.015*
P (Wx)	<0.001**	<0.001**		

Z Mann Whitney test Wx Wilcoxon signed rank test *p<0.05 is statistically significant

**p≤0.001 is statistically highly significant

Table (3) Comparison between the studied groups regarding need for conversion to conventional:

	Groups		Test	
	Group A	Group B	χ^2	p
	N=15	N=15		
Conversion to B [conventional] No Yes	10 (66.7) 5 (33.3)	15 (100) 0 (0)	Fisher	0.042*

*p<0.05 is statistically significant

Table (4) cause of conversion in group A to group B:

	N=5	%
Bleeding	1	20
Wide cystic duct	1	20
Intraoperative bile leak	1	20
Short cystic duct	2	40

DISCUSSION:

In laparoscopic cholecystectomy (LC), cystic duct and cystic artery are normally secured with Titanium clips. 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 (8).

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 (9).

Little reports were performed on this subject before. Therefore, we compared the laparoscopic conventional cholecystectomy and clipless cholecystectomy using a sealing device. This study is recruited on 30 patients with gallstone diseases divided into two groups using closed envelopes; group A (conventional) and group B (clipless); 15 within each group.

In our study, there is statistically non-significant difference between the studied groups regarding age or gender. Females represented 73.3% and 66.7% within groups of clipless laparoscopic cholecystectomy and conventional methods respectively. **Alam et al. (10)** in their study on 120 patients were operated laparoscopically through standard four ports technique and ultrasonic device (harmonic) 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%). **Mohammed and Asaad (11)** 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%).

The current study showed that there is statistically significant difference between the studied groups regarding operative time. Mean operative time is significantly higher among conventional laparoscopic cholecystectomy group. **Bulus et al. (12)** reported on the safety of instruments used for LC in 60 patients. The duration of surgery was 33.1 ± 10 minutes when clips were used (Group A), 31.5 ± 11.1 minutes when Harmonic scalpel was used (Group B), and 36.5 ± 9.9 when bipolar vessel sealer was used (Group C). The difference between Group B and Group C was statistically significant ($P < 0.04$). There was a statistically significant longer operating time (mean difference 12.00 minutes) in the ligature group than in the non-absorbable clips group.

Sharma et al. (13) reported that the time from skin incision to closure of wound was 46.6 minutes in the clip group and 70.7 minutes in the ligature group. They observed that the operative time was longer when using intracorporeal knotting as compared with clip application, but the difference was not statistically significant ($P = 0.493$). **Singh et al. (14)** found that the mean operative time in the study group was 37.28 ± 7.860 minutes (range 20-56 min). **Sanawan et al. (15)** reported that the mean operating time was 30 min in the harmonic scalpel group.

In our study, there is statistically highly difference between the studied groups regarding length of hospital stay, being significantly longer among patients undergoing clipless laparoscopic cholecystectomy. **Alam et al. (10)** in their study on 120 patients 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.

Singh et al. (14) reported that the mean duration of hospital stay in Study group was 2.24 ± 1.154 days (mean 1-7 days). **Sanawan et al., (15)** concluded that Hospital stay in hours was 32.9 ± 5.53 hours in harmonic scalpel group.

There is statistically non-significant difference between the studied groups regarding VAS preoperatively. There is statistically significant difference between the studied groups regarding VAS

postoperatively (significantly lower in clipless laparoscopic cholecystectomy). In each group, VAS significantly decreased postoperatively.

There was no significant difference in the visual analogue scale score between the two groups (16). **Singh et al. (14)** reported that mean postoperative pain score on VAS scale for the study group was (mean 6.18 ± 0.54) and **Sanawan et al. (15)** 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.

In our study, there is statistically significant difference between the studied groups regarding need for conversion to conventional technique by clipping cystic duct. No conversion to open cholecystectomy was found in both groups. Five patients from group A underwent conventional technique; one due to bleeding from cystic artery, one due to wide cystic duct, one had intraoperative bile leak and two had short cystic duct. **Ahmed and Muhammad (7)** found that two patients were converted to open cholecystectomy, one of them due to common bile duct injury and the other due to uncontrolled bleeding, but in the harmonic scalpel group all the cases were completed laparoscopically.

Cystic duct leakage with metal clips persists after laparoscopic cholecystectomy. Use of locking clips on leaks from the cystic duct stump after LC is an alternative to metal clips (17). **Rawal (18)** noted the migration of two clips into the common bile duct (CBD) along with retained stones as rare complications of LC, and highlighted that it should be kept in mind as differential diagnosis of recurrent cholangitis in post-cholecystectomy cases.

Cookson et al. (19) described an intraductal migration of surgical clips into the CBD after 10 years of LC, which was unusual and could result in gallstone formation clip cholelithiasis. **Photi et al. (20)** have done the ligation of the cystic duct with surgical clips, and reported a case of cholangitis secondary to clip migration into the CBD.

Conclusion:

From our study we can conclude the sealing device provides complete hepatobiliary 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, and less rate of conversion to open cholecystectomy avoiding clip failure less thermal effect on the liver especially fatty or early cirrhotic.

No conflict of interest.

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