

To compare efficiency of ultrasonic vessel sealing device and conventional method in laparoscopic cholecystectomy.

Running Title: Efficacy of ultrasound vessel sealing device in laparoscopic cholecystectomy.

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ABSTRACT

Objective: To compare the outcomes of ultrasonic vessel sealing device and conventional method during laparoscopic cholecystectomy.

Methodology: This prospective comparative study was carried at the Department of General Surgery, LUMHS during 16-06-2021 to 25-01-2022. A total of 140 Patients with symptomatic gallstones assigned in two groups on surgeon's preference after fulfilling inclusion criteria for LC. Group A, LC done by Using clips & cautery method and group B, LC done by using harmonic scalpel. All surgeries was performed by senior consultant. Data was collected via pre-structured proforma. The outcomes was measured.

Results: Mean duration of procedure difference was significantly less in patients with LC was done with harmonic scalpel in comparison with conventional method [Mean difference -6.71 ± 1.24 min; $p=0.0005$]. Rate of intraoperative bleeding more than 100 ml was significant [A=35.7% vs. B=0; $p=0.0005$]. Similarly rate of postoperative bleeding was significant [A=17.14% vs. B=5.71%; $p=0.034$]. Rate of gallbladder perforation and lateral tissue damage was also significant [14.3% vs. 40%; $p=0.001$] and [0% vs. 10%; $p=0.013$] respectively. Drain content was significant [A=72.3% vs. B=11.4%; $p=0.0005$]. Hospital stay more than 1 day was significantly less in patients [A=62.8% vs. B=30% $p=0.0005$].

Conclusion:

The ultrasonic vascular sealing device achieves satisfactory hemobiliary stasis in most of patients and may serve as a safer substitute to definitive cystic duct and artery clipping.

Key words: laparoscopic cholecystectomy, conventional method, ultrasonic vessel sealing device, outcomes.

Introduction:

Laparoscopic cholecystectomy acquired widespread approval in 1987 & has replace traditional open cholecystectomy. The National Institutes of Health declared in 1992 that laparoscopic cholecystectomy is an efficient and secure treatment for the majority of individuals with symptomatic gallstones.¹ Because of its advantages in terms of least invasiveness and quick recovery, the gold standard surgical approach for benign gallbladder illnesses.²

In general practice Laparoscopic cholecystectomy is carried out by using titanium surgical clips to close cystic duct and artery. For gallbladder dissection, electrosurgical hook, spatula, scissors and high frequency monopolar technology are being used.³ Problems as a result of titanium clips like clip dislodgement with the possibility of bile leakage and abdominal sepsis have been reported. Stone nidus is also created using slip-on titanium clips.⁴ While using electro cautery, Heavy soot generation results in the chance of lateral tissue injury. There is a danger of gallbladder perforation, bile leakage, and stone slide into the peritoneal cavity due to energy transfer through the titanium clips.⁴

As a result, numerous approaches are being developed to

improve the process, make it safer, and lower the likelihood of problems as well as the time by Using absorbable clips, ligatures⁵ Bipolar vessel sealer, Ultrasonic devices (Harmonic Shears) without clipping for closure of cystic duct, cystic artery and gallbladder dissection.⁶ Ultrasonic coagulating devices were designed as safe alternative to facilitate operative hemorrhage and tissue dissection with minimal bleeding during laparoscopic surgery via coagulating protein using high-energy ultrasonic waves.⁷ In cholecystectomy, the principal application of this gadget is Calot's triangle is dissection and gallbladder lifting from the liver bed; however, the cystic duct and cystic artery are divided following the use of standard clips because to concerns about cystic artery and cystic duct leaking. In 1999, to replace the clips, the implementation of HS for sealing & splitting of the cystic duct & artery was conducted effectively at the very initial instance.⁸

The harmonic scalpel, which ligate luminal structures with a diameter of up to 5-7 mm (vessels) as certified by the FDA in 2006, has been demonstrated in a few trials to be a safe strategy for dividing both cystic artery and cystic duct.^{8,9}

Several international studies revealed that clipless cholecystectomy employing a ultrasonic device as the sole instrument to ensure full removal was effective for hemobiliary stasis (cystic duct & artery), nearly every case-series.¹⁰ However, contradictory findings were presented, indicating a reduced prevalence of biliary leakage and post-operative bleeding seen in both groups with none of the technique being superior to other.^{11,12} TharwatKandil et al suggested that harmonic scalpel gave more comprehensive hemo-biliary stasis ($p=0.04$) with shorter operative duration ($p=0.001$) and can indeed be suggested as a safer substitute for conventional clipping of cystic duct & artery

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¹³Because of these inconsistencies in the publications, it is debatable whether a harmonic scalpel should be used during laparoscopic surgery.

The ultrasonic device retains the operative zone blood less, which aids the less expert in identifying the proper plane, shortened operational clock, lower incidence of gallbladder perforation, lower postoperative discomfort and lower number conversions.¹⁴ Therefore, its feasibility, handling and the superior performance of the ultrasonic device urges surgeons to expand its function and embrace it as a viable alternative to normal clipping.¹⁴ However, the primary constraint of using this approach is the lack of availability, the needed experience, and the pricey apparatus, which is tough to get in a resource-constrained nation.

Methodology:

This Prospective comparative study was conducted over a Six months from march 2021 to January 2022 in department of general surgery at Liaquat University Hospital Jamshoro. After approval took from research and evaluation committee of LUMHS Jamshoro. Data was collected from all patients attending the surgical outpatient department fulfilling the inclusion criteria was planned for elective laparoscopic cholecystectomy. Total 140 Patients were randomized by using non-probability consecutive sampling, into 2 groups, Group A, LC done by Using clips & cautery method and group B, LC done by using harmonic scalpel. All surgeries was performed by senior consultant. Patient demographics, operation time, blood loss, problems, and postoperative stay were all recorded and studied. Under general anesthesia, the patient underwent surgical operations. Each operation were carried out through three operating ports as well as a camera port. The gallbladder was dissected at the triangle of Calot's with recognition, dissection, and splitting of the cystic duct after double clip application, the artery then chosen clipped or cauterized (in the first group), and the gallbladder was clipped or split by harmonic scalpel (in the second group). Gallbladder mobilization from the liver bed was then performed, followed by evacuation of the gallbladder through the umbilicus or epigastric incision. The time required by the surgeon after making ports up to gallbladder removal was recorded in minutes. Significant bleeding during the procedure (obscuring callots triangle), lateral tissue damage (gall bladder, CBD, liver, intestine). Blood or bile in tube was scanned for probable collection between 24 and 48 hours after surgery, requiring intervention was recorded. Duration of surgery, intraoperative bleeding, post-operative bleeding, lateral tissue damage, GB perforation and hospitalization were compared in comparison to both sets.

INCLUSION CRITERIA:

Involving adult patients of either gender with Symptomatic cholelithiasis (pain & tenderness at RH or upper abdomen, vomiting etc. with positive U/S findings) was included in this study.

EXCLUSION CRITERIA:

Patients having Multiple co-morbid diseases (uncontrolled DM/HTN, immunosuppression, viro-positive, jaundice), coagulation" disorder, abnormal LFTs, Contraindication to laparoscopic cholecystectomy, acute cholecystitis and its complication, suspected carcinoma of Gallbladder, cholecysto-enteric fistula, CBD stones, suspected mirizzi syndrome, hepato-biliary anomalies, complications within the gallbladder, hepato-biliary system and wide cystic duct more than 6mm was excluded from the study.

STATISTICAL ANALYSIS:

Complete questionnaire was checked for errors and coded.

For statistical analysis SPSS 23.0 version was used. For categorical variables, frequencies and percentages were calculated. For quantitative data, the mean and standard deviation were estimated, the Chi-square test or the Fisher exact test was used to compare proportion difference, the Independent sample T test (normal data) or the Mann-Whitney U test (non-normal data) was used to compare mean difference and $p \leq 0.05$ was deemed significant.

Results:

A 140 patients in total with symptomatic cholelithiasis randomly allocated into two groups. Seventy patients named as group A, laparoscopic cholecystectomy conducted by Using clips as well as cautery technique and 70 in group B, LC conducted with help of harmonic scalpel. An average age of participants in Group-A was 39.51 ± 7.87 years, whereas the average age of the patients in Group-B was 41.21 ± 7.56 years. Mean difference of age wasn't statistically significant among groups ($p=0.195$). Almost 94% of the patients were female.

Mean duration of procedure difference was significantly less in patients with LC was done with harmonic scalpel in comparison with conventional method [Mean difference - 6.71 ± 1.24 min; $p=0.0005$]. Rate of intraoperative bleeding more than 100ml was significantly high in conventional method as compare to harmonic scalpel [35.7% vs. 0; $p=0.0005$]. Similarly rate of postoperative bleeding was significantly low ultrasonic vessel sealing as compare to conventional device [5.71% vs. 17.14%; $p=0.034$]. Rate of gallbladder perforation and lateral tissue damage was also significantly low in ultrasonic vessel sealing as compare to conventional method [14.3% vs. 40%; $p=0.001$] and [0% vs. 10%; $p=0.013$] respectively.

Drain content was significantly high in conventional (group A) as compare to ultrasonic vessel sealing (group B) [72.3% vs. 11.4%; $p=0.0005$]. In group A, 51(72.3%) patients required drain placement in which 48(68.7%) containing blood and 3(4.3%) observed with biliary context. Out of 51 patients, 27(38.6%) having contents only in tube, 20(28.6%) patients had less than 50ml and only 1(1.4%) of them had more than 50ml in their drain while in group B, 8 (11.4%) patients required drain containing blood in which 5 (7.1%) patients having blood in tube and 3(4.3%) with less than 50ml and non the patients had more than 50ml of content. There was no fecal material found in any groups.

In conventional group, one present with altered anatomy of calot's Triangle, 1 patient gone for post-operative ERCP for suspected slippage of clips and 2 patients had cystic artery damage during procedure.

Hospital stay more than 1 day was significantly less in patients with LC done by using ultrasonic vessel sealing methods as compare to conventional methods [30% vs. 62.8%; $p=0.0005$].

Multivariate linear regression analysis by using GLM, were performed and observed that operative time was significantly also high in conventional method [beta coefficient=5.98; 95%CI: 3.17-36.96; $p=0.0005$] after adjusting the age gender and intraoperative bleeding effect. Similarly multivariate logistic regression analysis performed and adjusted odds ratio showed the risk of postoperative bleeding was less likely in patients LC by ultrasonic vessel sealing device than conventional [OR=0.44 95% CI: 0.09-0.97; $p=0.044$] after controlling the effect of age gender.

Table No 1: Comparison of variables among two groups.

	Conventional n=70	Ultrasonic Vessel sealing device n=70	P-Value
Intraoperative bleeding	(35.7%)	0(0%)	0.0005
Gall bladder perforation	40%	14.3	0.001
Lateral tissue damage	10%	0%	0.013
Drain content	72.3%	11.4%	0.0005
Hospital stay	62.8%	30%	0.0005

Discussion:

Laparoscopic cholecystectomy (LC) is a frequent procedure used to remove gallstones.¹⁵ During LC, ultrasonic and electrosurgical energy dissectors are routinely utilized dissection equipment.¹⁶ In surgical operations, these high-energy devices are employed to minimize intraoperative blood loss while also cutting, coagulating, desiccating, or fulgurating tissues. Traditional electro-cautery employs electrical current to achieve these objectives during open and laparoscopic surgery. This is classified into two groups: unipolar cautery, in which to finish the current cycle, current is passed thru the patient, and bipolar cautery, in which current flows via tissues between instrument's electrodes.¹⁷ However, its usage during LC can harm nearby organs like the common bile duct, stomach, or intestines. It may induce liver damage, bile loss, and gallbladder perforation.¹⁸ To address this problem, an ultrasonic vessel sealing device (harmonic scalpel) was created.¹⁹

Gallbladder surgery aims to minimize operational loss of blood, focal tissue damage from heat, gallbladder perforation, common bile duct injury, operative clock and expenses feasibility. When these tools, technique, and expertise satisfy the bare prerequisites, this is doable.²⁰

The mean age of patients in Group A in this research was 39.51±7.27 years, while the patient's average age in group B was 41.21±7.56 years. Almost all of the patients were female. There were 22% men and 78% females in Anis et al's²¹ research. The participant's ages ranged from 12 to 80, with a mean of 406.45.

In current investigation, the mean length of procedure difference was considerably reduced in patients with LC who were treated with a harmonic scalpel as opposed to a traditional approach [Mean difference -6.71±1.24 min; p=0.0005]. According to Jain et al²² using HS during LC results in a shorter procedure time, less time spent removing the gallbladder from liver bed, a lower pain scale, and decrease blood loss. Additionally they observed less hospital stays by using of HS, although no significant problems or bile leaks were documented over a 6-months follow-up period in both group.²³

In present study rate of intraoperative bleeding more than 100ml was significantly high in conventional method as compare to harmonic scalpel. Similarly rate of postoperative bleeding was significantly low ultrasonic vessel sealing as compare to conventional device. Mean pain score was also significantly low in the ultrasonic vessel sealing as compare to conventional device (p=0.0005). Another research from Egypt observe the operative time in HS group

was 33.21±9.6 minutes, 51.7±13.8 minutes, in comparison with the EC group. The researchers documented a decreased conversion rate in the HS group, as well as nil threat of bile leak and much little blood loss. Furthermore, these researchers concludes that HS achieves full hemobiliary stasis and It is suitable substitute to typical cystic duct & artery cutting. It offers shorter surgical duration, reduce chance of gallbladder puncture, lesser post-surgical discomfort, and a lesser conversion ratio than traditional procedure. [13] Sanawan et al. discovered that employing HS during LC reduces blood loss and procedure time.²⁴ Bile leakage is always the most serious issue among surgical complications, and it is most often caused by the cystic duct stump.²⁵

Conventionally, the usage of clips²⁶ may be attributed as the primary cause, combined with the undetected thermal harm from ME. In this investigation, the rate of gallbladder perforation and lateral tissue injury was much lower in ultrasonic vessel sealing device as compared to traditional approach [14.3 percent vs. 40% ; p=0.001] and [0 percent vs. 10% ; =0.013], respectively.

Ramzanali at al. further stated that harmonic scalpel may securely perform various task including cavitation, coaptation, shearing, and is safer as well as more effective than traditional electrical cauterization.²³ Shabbir et al. and Ali et al. discovered that electrocautery had a considerably greater gallbladder perforation rate in comparison with harmonic scalpel while doing LC.^{27,28}

In present study drain content was significantly high in conventional (group A) as compare to ultrasonic vessel sealing device (group B). In group A, 72.3% patients required drain placement in which 68.7% containing blood and 4.3% observed with biliary context. While in group B, 11.4% patients required drain containing blood in which 7.1% patients having blood in tube and 4.3% with less than 50ml and none of the patients had more than 50ml of content. Kandil et al¹³ showed that gallbladder perforation was more common in conventional group as compare with HS group (18.6 percent versus 7.1 percent, correspondingly; p=0.04). The mean operating clock in harmonic group was substantially lower as compare to conventional group (33.21±9.62 min vs. 51.7±13.79 vs., respectively; p=0.0001). The conventional group had considerably greater intraoperative blood loss than the HS group (83.31±46.23 versus 43.28±31.27; p=0.0001). Two patients (2.9 percent) in the conventional group converted to open surgery (1 owing with uncertain anatomy and 1 ascribe to haemorrhage), whereas all cases in HS group were finished laparoscopically. Conventional group had considerably greater postoperative drainage than HS set (47.78±31.54 versus 29±30.79 ml, p=0.001). The pt: hospitalisation in harmonic group was shorter (23.44±2.29 h versus 26.95±8.94 h, p=0.002).

In this study hospital stay more than 1 day was significantly less (0.005) in patients with LC done by using ultrasonic vessel sealing methods as compare to conventional methods. In Ai et al study²⁹ the operating time & duration of hospitalization were definitely shorter with US as compare to clips, but there was no statistical difference between the two groups regarding conversion, perforation, postoperative bile leakage and general morbidity. Perhaps it might be argued that HS is preferable on clips combined with scissors and ME in certain ways, or that it is slightly equivalent to HS. It is similarly safer as well as productive for HS to clog cystic duct in LC, and hence can replace traditional clips.

It is worth noting that HS is only suited for occluding biliary ducts and arteries with diameter of less than 5mm.^{28,30} Formalized interpretation It is best suited for benign gallbladder illnesses that are not associated with a significant inflammatory state. Due to its inherent restrictions, an extra ligation is specified if the cystic duct is 6mm in diameter.

Conclusion:

The ultrasonic vascular sealing device achieves full hemobiliary stasis in most of patients as well as safer substitute to definitive cystic duct and artery clipping. It has minimal surgical duration, a lower rate of gallbladder perforation, fewer Postoperative Pain, as well as lower conversion ratio to open cholecystectomy.

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