Original Article

Ultrasonic Sealing Versus Titanium Clip Ligation of the Cystic Duct and Cystic Artery Measuring Less Than 5 mm in Laparoscopic Cholecystectomy: A Prospective Randomized Comparative Study

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Abstract

Background: Titanium clips are the standard method for securing the cystic duct and artery in laparoscopic cholecystectomy (LC). The harmonic scalpel can seal and divide them without clips. We compared the two for structures under 5 mm. **Material and Methods:** In this prospective randomized study at a tertiary hospital in Chandigarh, India, 58 adults with symptomatic cholelithiasis were allocated to titanium clips (n = 29) or harmonic scalpel closure (n = 29). The primary outcome was operative time. Secondary outcomes were conversion, complications, day-1 pain, liver function tests and hospital stay. **Results:** Groups were similar at baseline. Mean operative time was 52.1 ± 15.0 min with clips and 57.4 ± 12.6 min with the harmonic scalpel, a difference of 5.3 min (95% CI −2.0 to 12.6; p = 0.150). Conversion to open surgery occurred in 3/29 (10.3%) and 2/29 (6.9%) patients (p = 1.000), all for a frozen Calot's triangle. There was no bile leak, duct injury or haemorrhage. Wound infection (6.9% vs 13.8%; p = 0.670), pain (p = 0.366) and hospital stay (3.4 ± 0.7 vs 3.5 ± 0.7 days; p = 0.487) did not differ. The postoperative rise in AST was smaller after harmonic closure (+2.4 vs +7.5 IU/L; p < 0.001). **Conclusion:** For a cystic duct and artery under 5 mm, harmonic scalpel closure was as safe as clip ligation in the early postoperative period. It did not shorten the operation during the unit's early experience with the device. Larger multicentre trials with longer follow-up are needed.

Keywords: Ultrasonic sealing, Titanium clips, Cystic duct, Cystic artery, Laparoscopic cholecystectomy, Biliary complications, Surgical outcomes, Randomized comparative study.

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Introduction

Gallstone disease is one of the most frequent reasons for surgical admission. Its prevalence in adults approaches 20%, and roughly 2% of asymptomatic carriers develop symptoms each year.[1–3] The rise in reported cases has been linked to sedentary living, lower fibre intake and diets rich in calories and cholesterol.[1,2] Untreated symptomatic disease can progress to acute cholecystitis, choledocholithiasis, cholangitis, biliary pancreatitis and gallstone ileus.[3]

Laparoscopic cholecystectomy (LC) has been the standard treatment for symptomatic cholelithiasis since the late 1980s.[4] Its key steps are still not fully standardised. After the critical view of safety is achieved, the cystic duct and cystic artery are most often secured with titanium clips.[5,6] Clips are simple to apply and widely available, but they can slip or migrate, may contribute to bile leak and add instrument exchanges.[6]

The harmonic scalpel converts high-frequency ultrasonic energy into mechanical vibration at the blade, which coagulates and cuts tissue with limited lateral thermal spread and little smoke.[7,8] Its use in LC was first reported in 1999, and it is approved by the United States Food and Drug Administration for sealing vessels up to 5 mm in diameter.[8] The cystic duct normally measures about 3 mm and averages 4.6 ± 1.1 mm in patients with gallstones, so most ducts fall within this range.[9]

Randomized trials and systematic reviews report that clipless LC with the harmonic scalpel has bile leak rates similar to clip ligation and, in several series, a shorter operation and fewer gallbladder perforations.[10–14] Experimental porcine data, however, showed frequent seal failure when ultrasonic shears were used on the common bile duct.[15] Evidence from Indian centres is limited, and performance during a unit's early experience with the device is rarely reported.

This study compared ultrasonic closure and division with

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titanium clip ligation of a cystic duct and cystic artery measuring less than 5 mm. The primary objective was operative time. Secondary objectives were postoperative complications and conversion to open surgery.

Materials and Methods

Study design and setting: This prospective randomized comparative study was carried out in the Department of General Surgery, Government Medical College and Hospital (GMCH), Chandigarh, India, a public tertiary teaching hospital. The study period was 18 months, and the operations took place between October 2023 and April 2024. The Institutional Ethics Committee of GMCH Chandigarh (registration ECR/658/Inst/PB/RR-20) approved the protocol prospectively with effect from 16 September 2023 (Ref. GMCH/IEC/2023/1037R); all operations took place after this date. Each patient received a written information sheet, which stated that the results might be published without identifying participants, and gave written informed consent before enrolment. Participants could withdraw at any time without affecting their care. The study followed the Declaration of Helsinki and the ethical guidelines of the Indian Council of Medical Research. The report follows the CONSORT 2010 statement where applicable.

Participants: Adults older than 18 years with cholelithiasis scheduled for LC at GMCH were screened. Patients whose cystic duct and cystic artery measured less than 5 mm in diameter were eligible. Patients who declined participation, pregnant women and patients with Mirizzi syndrome were excluded.

Sample size: The sample size was based on operative time. Assuming mean operative times of 41.8 min with the harmonic scalpel and 58.9 min with clips (a difference of 17.1 min), a power of 95% and a two-sided α of 0.05, 29 patients were required in each group. This calculation corresponds to a standard deviation of about 17.5 min.

Randomization: Patients were allocated in a 1:1 ratio using a computer-generated random sequence. Group 1 underwent clip ligation and division of the cystic duct and artery with titanium clips. Group 2 underwent closure and division of both structures with the harmonic scalpel. Patients, surgeons and outcome assessors were not blinded.

Preoperative assessment: Each patient underwent history, clinical examination, complete blood count, coagulation profile, renal function tests and liver function tests: total serum bilirubin (TSB), alkaline phosphatase (ALP), aspartate aminotransferase (AST) and alanine aminotransferase (ALT). The diagnosis was confirmed on abdominal ultrasonography, which recorded gallbladder wall thickness, distension, common bile duct (CBD) diameter, pericholecystic fluid, number and size of calculi, mucocele, empyema and cystic duct diameter. Magnetic resonance cholangiopancreatography (MRCP) was performed when clinically indicated.

Surgical technique: All patients received intravenous ceftriaxone 1 g and intramuscular diclofenac 75 mg one hour before surgery. Under general anaesthesia, pneumoperitoneum was created by direct trocar entry, Veress needle or open technique, and a three-port or four-port LC was performed after the critical view of safety was achieved.

- **Group 1 (clips):** The cystic duct was secured with two titanium clips (size 300 or 400, chosen by duct diameter) on the CBD side and one clip on the gallbladder side, then divided. The cystic artery was secured with three clips and divided in the same way.
- **Group 2 (harmonic scalpel):** The cystic duct and cystic artery were sealed and divided with the harmonic scalpel, without clips.

A second dose of ceftriaxone 1 g was given intravenously after surgery.

Outcome measures: The primary outcome was operative time, from skin incision to the final closing stitch. Secondary outcomes were conversion to open surgery; intraoperative and postoperative complications (trocar or Veress needle injury, haemorrhage, CBD injury or bile leak, wound infection, ileus, gallstone or bile spillage and bowel injury); pain on postoperative day 1 (POD1) scored on a 0–10 visual analog scale (VAS) and graded as mild, moderate or severe; liver function tests on POD1; and length of hospital stay. Ultrasonography or MRCP was arranged after surgery when clinically indicated. Patients were followed up until discharge.

Statistical analysis: Analysis was by allocated group. Continuous variables are shown as mean ± standard deviation (SD) and, where skewed, as median (interquartile range). Normality was checked with the Shapiro–Wilk test. Normally distributed variables were compared with Welch's t test and skewed variables with the Mann–Whitney U test. Categorical variables are shown as number (percentage) and were compared with the chi-square test, or Fisher's exact test when any expected cell count was below 5. Pain grade, an ordinal variable, was compared with the Mann–Whitney U test. Change in each liver function test (POD1 minus preoperative) was compared between groups with the Mann–Whitney U test. The difference in mean operative time is reported with its 95% confidence interval (CI). An exploratory analysis, not prespecified, compared operative time in operations completed laparoscopically. Analyses used only recorded values; missing data were not imputed. A two-sided p value below 0.05 was considered significant. The original analysis used SPSS version 26.0; all values reported here were recalculated from the patient-level master chart in Python 3 (SciPy 1.18).

Results

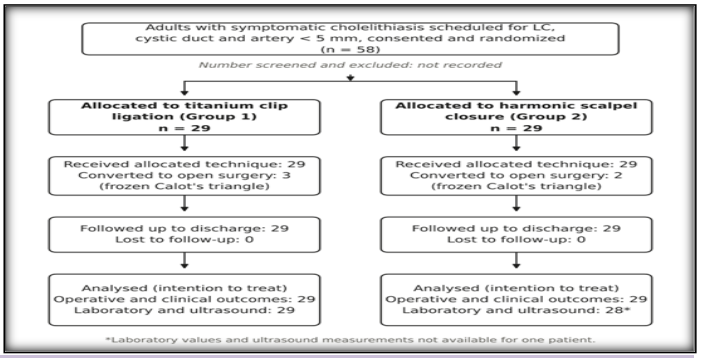


Figure 1: Flow of participants through the study. LC, laparoscopic cholecystectomy.

Fifty-eight patients were randomized, 29 to each group [Figure 1]. All received the allocated technique, and none was lost to follow-up before discharge. The mean age was 41.9 ± 14.9 years and 39 patients (67.2%) were women. All operations were elective. For one patient in Group 2, laboratory values, ultrasound measurements and some intraoperative event fields were not available; these variables are reported for 28 patients in that group.

Baseline characteristics: The groups were similar in demographic and clinical features [Table 1]. Median duration of symptoms was 6.0 months in Group 1 and 7.0 months in Group 2. Acute-onset upper abdominal pain at presentation was recorded in one patient, and nine patients (15.5%) had fever. No patient with recorded findings had right hypochondrial tenderness, a positive Murphy's sign or a palpable gallbladder at admission.

Imaging findings: Ultrasonographic findings did not differ between groups [Table 2]. The gallbladder was distended in 41 of 58 patients (70.7%), pericholecystic fluid was present in 34 (58.6%) and multiple calculi in 42 (72.4%). No patient with recorded data had empyema. MRCP was done in three patients: it showed distal CBD tapering in two patients in Group 1 and no CBD stone in one patient in Group 2.

Table 1: Demographic and clinical characteristics at baseline

Variable	Group 1: Clips (n = 29)	Group 2: Harmonic (n = 29)	p value
Age (years), mean ± SD	43.1 ± 14.4	40.8 ± 15.5	0.571
Female sex, n (%)	20 (69.0)	19 (65.5)	0.780
Weight (kg), mean ± SD	63.1 ± 12.6	65.8 ± 10.8	0.399
Height (cm), mean ± SD	158.7 ± 8.8	161.9 ± 8.6	0.168
BMI (kg/m²), mean ± SD[a]	25.0 ± 4.5	25.1 ± 3.7	0.619
Duration of symptoms (months), median (IQR)	6.0 (4.5–9.0)	7.0 (5.5–9.5)	0.478
Acute-onset abdominal pain, n (%)	1 (3.4)	0	1.000
Fever, n (%)	6 (20.7)	3 (10.3)	0.470
Supraumbilical scar, n (%)	3 (10.3)	0	0.237
Infraumbilical scar, n (%)	6 (20.7)	7 (24.1)	0.753
Diabetes mellitus, n (%)	4 (13.8)	2 (6.9)	0.670
Previous pancreatitis, n (%)	1 (3.4)	1 (3.4)	1.000

BMI, body mass index; IQR, interquartile range; SD, standard deviation. p values: Welch's t test or Mann–Whitney U test for continuous variables; chi-square or Fisher's exact test for categorical variables. [a] Calculated from recorded weight and height.

Table 2: Preoperative ultrasonographic findings

Variable	Group 1: Clips (n = 29)	Group 2: Harmonic (n = 29)	p value
GB wall thickness (mm), median (IQR)[c]	2.5 (2.2–2.8)	2.7 (2.4–3.0)	0.174
Distended gallbladder, n (%)	19 (65.5)	22 (75.9)	0.387
Dilated CBD, n (%)	2 (6.9)	1 (3.4)	1.000
Pericholecystic fluid, n (%)	15 (51.7)	19 (65.5)	0.286
Multiple calculi, n (%)	20 (69.0)	22 (75.9)	0.557
Largest calculus (mm), mean ± SD[a c]	15.5 ± 5.2	15.8 ± 5.3	0.831
Mucocele, n (%)	3 (10.3)	2 (6.9)	1.000
Cystic duct diameter (mm), mean ± SD[b]	3.0 ± 0.4	2.8 ± 0.5	0.147

CBD, common bile duct; GB, gallbladder; IQR, interquartile range. [a] Group 1, n = 28 (one unreadable value). [b] Group 2, n = 27: measurement not available for one patient, and one recorded value of 33.2 mm excluded as a probable entry error. [c] Group 2, n = 28 (measurement not available for one patient).

Operative outcomes: Mean operative time was 5.3 min longer with the harmonic scalpel (57.4 ± 12.6 min) than with clips (52.1 ± 15.0 min). The difference was not significant (95% CI −2.0 to 12.6 min; p = 0.150; Table 3, Figure 2). The confidence interval excludes the 17-minute saving with the harmonic scalpel that was assumed in the sample size calculation. In an exploratory analysis that was not prespecified, limited to operations completed laparoscopically, the harmonic scalpel group took longer (57.8 ± 13.0 vs 50.0 ± 14.2 min; n = 27 vs 26; p = 0.043).

Five patients (8.6%) required conversion to open surgery, three with clips and two with the harmonic scalpel (p = 1.000). Every conversion was due to a frozen Calot's triangle, and 4 of the 5 converted patients were men. No bile leak occurred in either group. No trocar or Veress needle injury, haemorrhage, CBD injury, bowel injury, ileus, or gallstone or bile spillage was recorded [Table 3, Figure 3].

Table 3: Operative and postoperative outcomes

Outcome	Group 1: Clips (n = 29)	Group 2: Harmonic (n = 29)	p value
Operative time (min), mean ± SD	52.1 ± 15.0	57.4 ± 12.6	0.150
Operative time (min), median (IQR)	50 (45–60)	55 (50–65)	
Difference in mean (95% CI)	Reference	+5.3 (−2.0 to 12.6)	
Hospital stay (days), mean ± SD	3.4 ± 0.7	3.5 ± 0.7	0.487
Conversion to open surgery, n (%)	3 (10.3)	2 (6.9)	1.000
Wound infection, n (%)	2 (6.9)	4 (13.8)	0.670
Bile leak, n (%)	0	0	—

CBD injury, n (%)[a]	0	0	—
Haemorrhage, n (%)[a]	0	0	—
Gallstone or bile spillage, n (%)[a]	0	0	—
Bowel injury, trocar injury or ileus, n (%)[a]	0	0	—
POD1 pain, mild, n (%)	14 (48.3)	17 (58.6)	0.366
POD1 pain, moderate, n (%)	11 (37.9)	10 (34.5)	
POD1 pain, severe, n (%)	4 (13.8)	2 (6.9)	

CBD, common bile duct; CI, confidence interval; IQR, interquartile range; POD1, postoperative day 1. p values: Welch's t test (operative time), Mann–Whitney U test (hospital stay and pain grade), Fisher's exact test (complications). [a] Group 2, n = 28 (field not available for one patient).

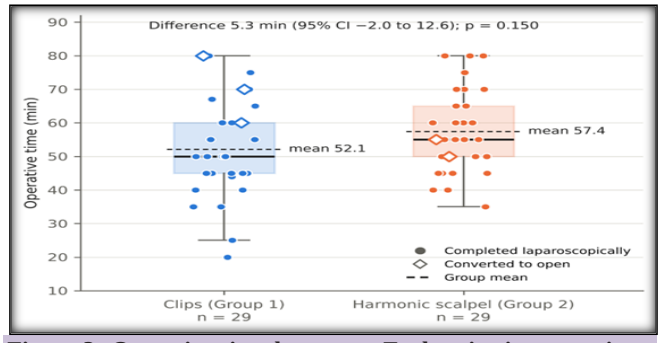


Figure 2: Operative time by group. Each point is one patient; diamonds mark operations converted to open surgery. Boxes show median and interquartile range; whiskers show the range; dashed lines show group means. p value from Welch's t test.

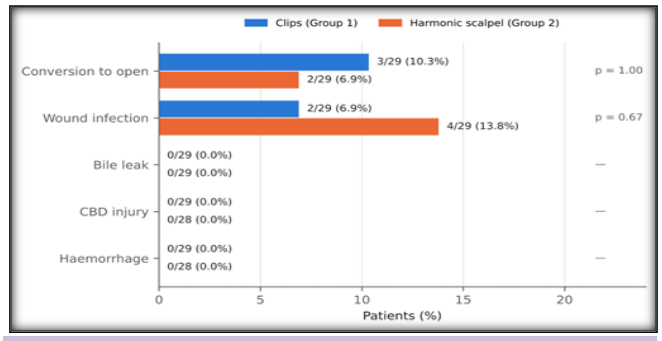


Figure 3: Intraoperative and postoperative events by group. Bars show the percentage of patients; labels give counts. p values from Fisher's exact test. CBD, common bile duct.

Postoperative course: Wound infection developed in six patients (10.3%). Pain on POD1 was mild in 31 patients (53.4%), moderate in 21 (36.2%) and severe in 6 (10.3%), with no difference between groups (p = 0.366; Figure 4). Median hospital stay was 3 days in both groups.

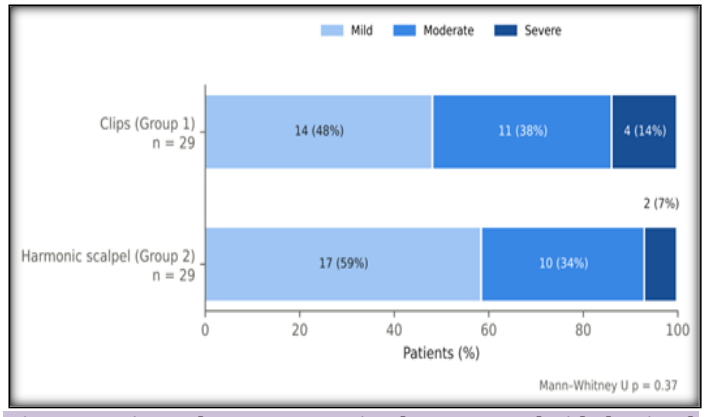


Figure 4: Pain grade on postoperative day 1, assessed with the visual analog scale.

Preoperative TSB was higher in Group 2 (0.63 ± 0.22 vs 0.48 ± 0.19 mg/dL; p = 0.008), a difference without clinical meaning. AST and ALT rose slightly after surgery in both groups, and the rise was smaller after harmonic closure (Table 4, Figure 5). All mean postoperative values were close to baseline, and no patient had a biochemical pattern suggesting bile leak or duct obstruction.

Table 4: Liver function tests before surgery and on postoperative day 1

Parameter	Group 1: Clips (n = 29)	Group 2: Harmonic (n = 28)	p value
Total bilirubin (mg/dL)			
Preoperative	0.48 ± 0.19	0.63 ± 0.22	0.008
POD1	0.54 ± 0.23	0.64 ± 0.23	0.091
Change	+0.07 ± 0.09	+0.01 ± 0.05	0.009
ALP (IU/L)			
Preoperative	82.1 ± 22.0	76.2 ± 19.7	0.291
POD1	86.7 ± 21.1	79.1 ± 18.4	0.151
Change	+4.6 ± 6.9	+2.9 ± 3.1	0.659
AST (IU/L)			
Preoperative	62.8 ± 25.4	64.4 ± 19.6	0.555
POD1	70.3 ± 27.8	66.8 ± 20.6	0.968
Change	+7.5 ± 6.4	+2.4 ± 3.6	<0.001
ALT (IU/L)			
Preoperative	65.7 ± 25.9	68.1 ± 20.1	0.453
POD1	73.2 ± 28.0	70.4 ± 20.5	0.943
Change	+7.6 ± 7.5	+2.2 ± 4.0	0.003

Values are mean ± SD. ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; POD1, postoperative day 1. Change = POD1 minus preoperative. p values: Welch's t test or Mann–Whitney U test according to distribution; Mann–Whitney U test for change.

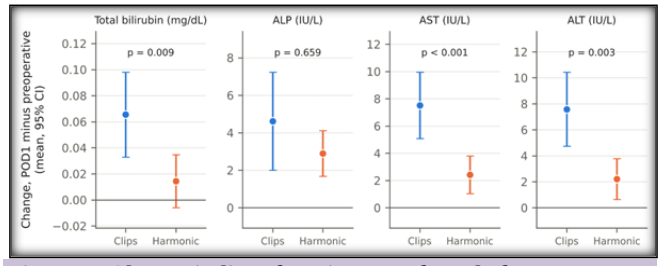


Figure 5: Change in liver function tests from before surgery to postoperative day 1 (mean and 95% confidence interval). p values from the Mann–Whitney U test. ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase.

Discussion

In this randomized comparison, harmonic scalpel closure of a cystic duct and artery under 5 mm was as safe as titanium clip ligation in the early postoperative period. There was no bile leak or duct injury in either group, and conversion, wound infection, pain and hospital stay were similar. The harmonic scalpel did not shorten the operation, which differs from most published series.

Operative time: Several trials report a shorter operation with the harmonic scalpel. Abdelhady and Salama randomized 60 patients and found 48.4 vs 58.6 min (p = 0.032),[16] and Yehia et al. reported a significant reduction in a 60-patient trial.[13] In the 112-patient trial by Awale et al., the overall difference (35.9 vs 41.1 min) did not reach significance (p = 0.054) and was significant only in cases without gallbladder perforation.[12] Pooled analyses have also favoured the harmonic scalpel.[14,17,18] The usual explanation is that one instrument dissects, seals and divides, which removes repeated instrument exchanges.[11]

In our study, the harmonic scalpel group took 5.3 min longer on average. The 95% CI (−2.0 to 12.6 min) excludes any meaningful time saving, and in the exploratory analysis of operations completed laparoscopically the harmonic scalpel group took significantly longer (57.8 vs 50.0 min; p = 0.043), although that comparison was not prespecified. Two factors may explain this. The study coincided with the unit's first use of the device, and technical issues with it were noted during some procedures, so a learning curve is likely. In addition, Group 2 had numerically more distended gallbladders (75.9% vs 65.5%) and pericholecystic fluid (65.5% vs 51.7%), which suggest more inflammation and harder dissection. Neither difference was significant. Table 5 places these results beside earlier work.

Table 5: Comparison with published studies

Study	Design, n	Operative time, clips vs HS (min)	Bile leak	Other findings
Present study	RCT, 58	52.1 ± 15.0 vs 57.4 ± 12.6 (p = 0.150)	None in either group	Conversion 10.3% vs 6.9%
Awale et al. 2019,[12]	RCT, 112	41.1 ± 14.2 vs 35.9 ± 11.7 (p = 0.054)	Not reported	Conversion 3.2% vs 1.85%
Abdelhady and Salama 2017,[16]	RCT, 60	58.6 ± 19.0 vs 48.4 ± 16.9 (p = 0.032)	None in either group	GB perforation 10% vs 3.3%
Yehia et al. 2019,[13]	RCT, 60	Shorter with HS (significant)	None in either group	No conversions
Aboelela et al. 2022,[19]	Prospective, 42 children (HS only)	40 ± 10.4	None	No conversions
Nishant et al. 2019,[20]	Ex vivo, 100 GB	—	Burst pressure 162.3 vs 166.0 mmHg (p = 0.362)	Minimum 102 mmHg
Hope et al. 2010,[15]	Porcine CBD model	—	Seal failure 50% with shears	Larger ducts than cystic duct

CBD, common bile duct; GB, gallbladder; HS, harmonic scalpel; RCT, randomized controlled trial; —, not applicable.

Bile leak and duct safety: Bile leak is the main concern with any clipless technique. We recorded none in either group, and POD1 bilirubin and enzyme levels gave no sign of a missed leak. This agrees with randomized trials by Abdelhady and Salama, Yehia et al., Bessa et al. and Jain et al,[11,13,16,21] with a paediatric series by Aboelela et al,[19] and with a review by Abounozha et al. and a cohort study by Wills and Crawford, both of which found leak rates comparable to clip ligation.[22,23] Kandil et al. and El Nakeeb et al. reached similar conclusions.[10,24]

Laboratory work supports these findings. In an ex vivo study of 100 gallbladders, Nishant et al. found similar burst pressures after harmonic closure and clip ligation, with a minimum of 102 mmHg, far above physiological biliary pressure.[20] Surel et al. reported comparable results with energy sealers.[25] In contrast, Hope et al. reported a 50% seal failure rate when ultrasonic shears were applied to the porcine common bile duct.[15] The likely reason is duct size. The harmonic scalpel is approved for structures up to 5 mm, and our inclusion criterion kept every duct within that limit; the mean recorded diameter was about 3 mm in both groups. Clips or ligatures remain the safer choice for wide or thick-walled ducts.

Conversion to open surgery: Conversion occurred in 8.6% of patients, all because of a frozen Calot's triangle, and the rate did not differ by technique. This is higher than the 1.85–3.8% reported in other series,[12,26] and probably reflects case mix in a public referral centre. Median symptom duration was 6–7 months, more than half the patients had pericholecystic fluid, and 4 of the 5 converted patients were men. Conversions were made for difficult anatomy at Calot's triangle rather than for a problem with duct closure.

Postoperative pain and recovery: Pain on POD1 was similar; mild pain was reported by 48.3% of patients with clips and 58.6% with the harmonic scalpel. Awale et al. and Yehia et al. found less pain after harmonic dissection and attributed it to less thermal injury and tissue handling.[12,13] In our study, the harmonic scalpel was used only to seal and divide the cystic

structures, and the rest of the dissection was the same in both groups. That narrower use may explain why pain did not differ.

Liver function after surgery: Small rises in transaminases are commonly seen after LC. The rise in AST and ALT was smaller after harmonic closure. The absolute differences were about 5 IU/L, mean values stayed close to baseline, and the finding came from several secondary comparisons, so it should be read as hypothesis-generating. The difference in bilirubin change is harder to interpret because baseline bilirubin was already higher in Group 2.

Practical implications

The harmonic scalpel removes the risk of clip slippage and migration and simplifies the instrument set. Its main drawback is cost, which matters in high-volume public hospitals in India.[27] Low-cost clipless options, such as the intracorporeal triple-ligation technique described by Mukesh et al., remain useful where energy devices are not available.[26] Units adopting the harmonic scalpel should expect a learning period before any time saving appears.

Strengths and Limitations: The study was randomized, used a single defined duct-size threshold, and the analysis was recalculated from patient-level data. It also has several limitations. It was a single-centre study with 29 patients per group, powered only for operative time, and too small to detect differences in rare events such as bile leak or duct injury. Follow-up ended at discharge, so late leaks, collections and strictures could not be captured. Patients, surgeons and assessors were not blinded, and more than one surgeon operated during the unit's early experience with the harmonic scalpel. The number of patients screened was not recorded, and laboratory values and ultrasound measurements were missing for one patient. Gallbladder perforation, blood loss, analgesic use and device cost were not recorded.

Conclusion

For a cystic duct and artery under 5 mm, closure and division with the harmonic scalpel was as safe as titanium clip ligation in the early postoperative period. No bile leak occurred in either group, and conversion, wound infection, pain and hospital stay were similar. The harmonic scalpel did not shorten the operation during early use of the device. Multicentre trials with longer follow-up, a learning-curve analysis and cost data should define its routine role.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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