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Original Research Article

A randomized prospective study to evaluate the efficacy of ultrasonic shears (Harmonic scalpel®) and monopolar electrocautery in dissection of gall bladder from the gall bladder bed during laparoscopic cholecystectomy

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ABSTRACT

Background: Laparoscopic cholecystectomy is the gold-standard treatment for symptomatic gallstones. Advances in technology have made it faster and safer. Ultrasonic shears enable dissection and vessel sealing via cavitation and coaptation, though their safety and efficacy as a sole instrument require further validation.
Methods: A prospective randomized controlled study was conducted in 100 patients with symptomatic gallstones, divided into two groups: laparoscopic cholecystectomy using ultrasonically activated shears or monopolar electrocautery. Operative time, gallbladder removal, blood loss, postoperative pain scores, analgesic requirement, hospital stay, and complications were compared.
Results: Patients who had a laparoscopic cholecystectomy with ultrasonic shears experienced less pain and a quicker procedure (44.18±14.03 minutes versus 54.48±16.34 minutes; $p<0.001$) and gallbladder removal from the gallbladder bed (9.66±4.54 minutes versus 14.18±4.67 minutes; $p<0.001$). They had a lower risk of gallbladder perforation (4 versus 13) and a shorter hospital stay. Additionally, on the first postoperative day, fewer analgesics were needed. The study population included 85% females and 15% males, presented in demographic analysis.
Conclusions: There is no risk of serious injuries or leaks while using an ultrasonically triggered scalpel during a laparoscopic cholecystectomy. In terms of quicker and safer operation, lower related morbidity, less pain, and an earlier return to home, it performs better than electrocautery.

Keywords: Laparoscopic cholecystectomy, Ultrasonic shears (Harmonic scalpel®), Monopolar electrocautery

INTRODUCTION

Laparoscopic cholecystectomy (LC) is widely regarded as the gold standard for the surgical management of symptomatic gallstone disease and acute cholecystitis worldwide, as it provides several well-established advantages compared with the traditional open (laparotomic) approach.

Standard laparoscopic cholecystectomy is typically performed using a monopolar electrosurgical hook for dissection and clips to occlude the cystic duct and cystic artery. Other methods for duct ligation, such as linear staplers, endoloops, or sutures, have been described but are rarely used in practice.[1,2]

Even if laparoscopic cholecystectomy is considered a safe procedure. Electric current as an energy source bears numerous harmful effects such as the high risk of thermal

damage and considerably more frequent biliary problems following surgery. Additionally, visceral and solid organ damage brought on by frequent instrument switching should not be undervalued, such as bile leakage from clips slipping.[4-7]

The ultrasonically activated scalpel (Harmonic, Ethicon Endo-Surgery Inc., Johnson & Johnson Medical S.p.A., Somerville, NJ) was initially introduced for use in clinical settings. Its method allows for three effects that work in concert: coagulation, cutting, and cavitation. It does this by applying ultrasound within the harmonic frequency range to tissues.[8] The danger of tissue damage is decreased since the temperature obtained and the lateral energy spread are smaller than those found when the monopolar hook is employed.[9-11] According to an FDA certification from 2006, the Harmonic scalpel is also a useful instrument for closing biliary ducts and arteries with a diameter of 4 to 5 mm.

The proposed study aims to evaluate the effectiveness of the ultrasonically activated scalpel (Harmonic Scalpel®) compared with monopolar electrocautery in the removal of the gallbladder from the gallbladder bed during laparoscopic cholecystectomy in terms of duration of surgery, intra-operative complications, post-operative complications, postoperative pain assessed using the visual analogue scale, analgesic requirement, duration of hospital stay, and time taken to return to normal activity.

METHODS

Over the course of two years, this study was carried out in the general surgery department of JLN Medical College and Hospital in Ajmer, Rajasthan, India. One hundred consecutive patients who were admitted for laparoscopic cholecystectomy due to confirmed gallbladder stone illness based on ultrasound and clinical findings were included in the study (study period: September 2014 to October 2015).

Study design

Patients of chronic cholecystitis with cholelithiasis were randomly divided into two groups of 50 each using a computer-generated randomization system.

Group A (n=50): laparoscopic cholecystectomy was performed using ultrasonically activated scalpel (Harmonic scalpel®, ACE+ model from Johnson and Johnson) for removal of gallbladder from gallbladder bed.

Group B (n=50): laparoscopic cholecystectomy was performed using monopolar electrocautery for removal of gallbladder from the gallbladder bed.

Inclusion criteria

All patients of symptomatic gallbladder stone disease undergoing laparoscopic cholecystectomy, ≥13 years of age who did not fall under exclusion criteria were included.

Exclusion criteria

Patients with impaired liver function test, cirrhosis, suspicion of gallbladder carcinoma, portal hypertension, common bile duct calculi, cholangitis, acute cholecystitis, empyema of gallbladder, unfit for general anesthesia, and pregnancy were excluded.

Statistical analysis

For quantitative variables like duration of hospital stay, severity of pain as per visual analogue scale, time taken for surgery difference between means was analyzed using t-test.

For qualitative data like requirement of analgesics, difference between proportional was analyzed using chi-square test. P value of less than or equal to 0.05 was taken as the cut off point for statistical significance.

Surgical technique

Laparoscopic cholecystectomy was performed under general anaesthesia using the standard four-port technique by a single experienced surgeon. In patients assigned to group A, an ultrasonically activated scalpel (Harmonic Scalpel® ACE+; Johnson & Johnson) was used for dissection of the gallbladder from the hepatic bed and served as the primary energy device throughout the procedure.

In group B, conventional electrocautery was used for gallbladder dissection from the hepatic bed. In both groups, the cystic duct and cystic artery were secured and divided using surgical clips.

During the intraoperative period, the total operative time was recorded, measured from the initial port incision to closure of the port site. The time required for gallbladder dissection from the hepatic bed was also noted.

Additional observations included gallbladder perforation during dissection, intraoperative complications such as bile or gallstone spillage, common bile duct or liver injury, bleeding, and the requirement for drain placement.

Postoperatively, patients were evaluated based on the following parameters: pain intensity assessed using the visual analogue scale (VAS), analgesic requirement, duration of hospital stay, and occurrence of any immediate postoperative complications.

Patients were discharged after drain removal and once they were comfortable or free of pain. Follow-up assessments were conducted in the outpatient department at 7 days, 14 days, and 1 month after surgery to evaluate any postoperative pain and the need for analgesic medication.

RESULTS

A total of 100 consecutive patients admitted for laparoscopic cholecystectomy with a diagnosis of gallstone disease confirmed by ultrasound and clinical evaluation were included in the study. The mean age of the study population was 46.39±14.66 years, with ages ranging from 13 to 85 years. The mean age was 46.06±14.13 years in the ultrasonic shears group and 46.72±15.30 years in the electrocautery group, showing comparable age distribution between the two groups (Table 1). The study population included 85% females and 15% males, presented in demographic analysis.

Table 1: Mean age of study population.

Variable	Mean age (years) ±SD	P value
Ultrasonic shears	46.06±14.13	0.8231
Electrocautery	46.72±15.30	

The efficacy of the device was evaluated by comparing operative parameters with those of electrocautery. The mean duration of surgery was 44.18±14.03 minutes in the ultrasonic shears group, compared with 54.48±16.34 minutes in the electrocautery group. Similarly, the mean time required for gallbladder dissection from the hepatic bed was 9.66±4.54 minutes with ultrasonic shears, whereas it was 14.18±4.67 minutes when electrocautery was used. Both operative times were significantly shorter with the use of the ultrasonically activated scalpel (p=0.001). The detailed results are presented in Table 2.

Various factors that complicate laparoscopic cholecystectomy, such as gallbladder perforation, were also significantly less in the ultrasonic shears group (4 versus 13). There was also decreased need of placement of drains after the gallbladder was removed (17 versus 34; p value of .001).

Postoperative pain was evaluated using the VAS on postoperative days 0, 1, 7, and 14, and at 1 month after surgery. Comparison between the two groups revealed significantly lower pain scores in the ultrasonic shears group compared with the electrocautery group at all assessed time points. The mean pain scores at each interval are presented in Table 2 and Figure 1.

Table 2: Comparison of various parameter between two groups.

Variables	Ultrasonic shears	Electrocautery	P value
Mean time (min)±SD to removal of gallbladder	9.66±4.54	14.18±4.67	<0.001
Mean duration (min)±SD of surgery	44.18±14.03	54.48±16.34	<0.001
VAS score day 0	4.24±2.2	6.64±1.73	
VAS score day 1	2.0±1.9	4.4±2.35	
VAS score day 7	0.52±1.05	2.08±1.61	
VAS score day 14	0.24±0.65	1.0±1.35	
VAS score 1 month	0	0.4±0.70	
Number of gall bladder perforation	4	13	
Spillage of bile and gall stones	2	12	0.007
CBD injury	0	1	1
Liver injury	0	2	0.475
Bleeding (minor)	10	19	0.07
Number of patients require drain placement	17	34	0.001

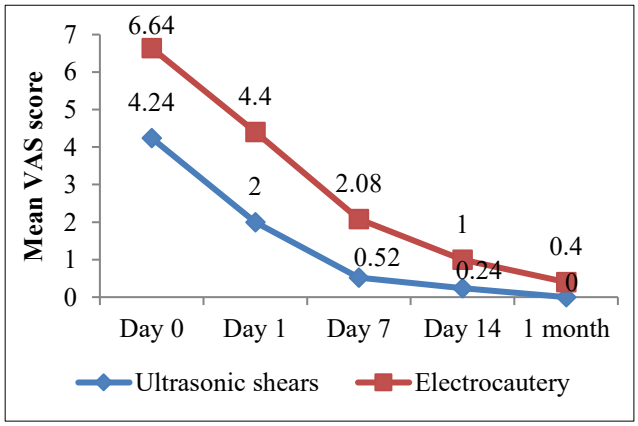

Figure 1: Comparison of pain score (VAS) in between two groups.

Postoperatively, analgesia was administered based on patient-reported pain. On postoperative day 0, patients complaining of pain received intravenous tramadol (one ampule). On days 1, 7, and 14, patients reporting pain were given an oral combination of ibuprofen and paracetamol.

A statistically significant difference in analgesic consumption was observed between the two groups during the postoperative period. The requirement for analgesics was consistently lower in the ultrasonic shears group compared with the electrocautery group. The distribution of analgesic use across different postoperative days is presented in Table 3. The difference in analgesic requirement remained statistically significant on days 1, 7, and 14, indicating reduced postoperative pain in patients treated with ultrasonic shears.

Table 3: Number of patients requires analgesic post-surgery.

Day	Ultrasonic shears	Electrocautery	P value
Day 0	33	48	0.0002
Day 1	22	45	<0.0001
Day 7	3	33	<0.0001
Day 14	0	18	<0.0001

The mean duration of hospital stay was 1.82±0.66 days in the ultrasonic shears group, compared with 2.24±0.92 days in the electrocautery group. This difference was statistically significant (p=0.0099), indicating a shorter postoperative hospital stay among patients in whom ultrasonic shears were used (Figure 2).

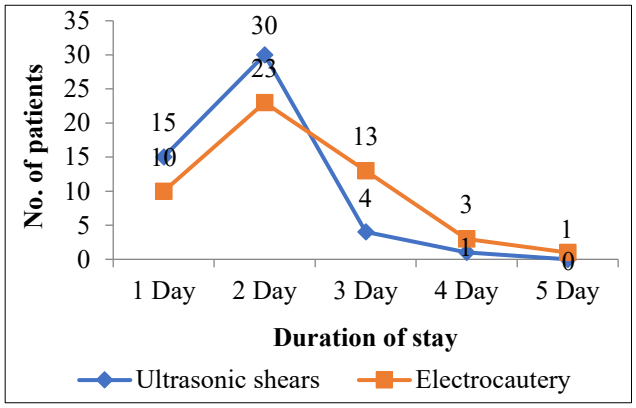

Figure 2: The duration of hospital stays of patients in the two groups after surgery.

DISCUSSION

The cutting-edge technique for treating gallstone disease, laparoscopic cholecystectomy, is currently the gold standard for surgical therapy for cholelithiasis symptoms. Many surgical tools have been created for the safe, efficient, and cautious dissection of the gallbladder during laparoscopic cholecystectomy with the goal of minimizing intraoperative and postoperative problems. These days, a variety of ultrasonic scalpels, water jet dissectors, laser systems, and specifically made suction devices are employed in addition to monopolar electrocautery.

The study's patients ranged in age from 13 to 85 years old, with a mean age of 46.39±14.66 years. The average age was 46.06±14.13 years for the ultrasonic group and 46.72±15.30 years for the electrocautery group. Patients in both groups are comparable, as indicated by the p value of 0.8231. Jain et al also revealed that the study population's mean age group was comparable.[3] The subject profile showed a preponderance of women. Of the study population, 85% were female and only 15% were male. Additionally, Jain et al discovered that the two groups' sex distributions were similar.[3]

In our study, a statistically significant difference in operative time was observed between the two groups. The mean duration of surgery in the ultrasonic shears group was 44.18±14.03 minutes, whereas in the electrocautery group it was 54.48±16.34 minutes, with a p value <0.001. Despite the use of clips in both groups, the ultrasonic shears group demonstrated a notable reduction in operative time, with an average saving of 10.30 minutes. This finding suggests that tissue dissection using ultrasonic shears is comparatively easier and faster. In contrast, Rajnish et al did not report a statistically significant difference in operative time between the two groups.[12] However, studies conducted by Kandil et al (52.14±9.8 versus 61.88±16.17; p<0.001) and Jain et al (50±9.36 versus 64.7±13.74; p=0.001) similarly reported a significantly shorter operative time in the ultrasonic shears group.[3,13]

In our study, the time required for gallbladder dissection from the liver bed was compared between the two techniques. The mean time for gallbladder removal using ultrasonic shears was 9.66±4.54 minutes, whereas it was 14.18±4.67 minutes when electrocautery was used. These findings indicate that ultrasonic shears allow faster dissection of the gallbladder from its bed. Similar observations have been reported by Jain et al and Kandil et al who also documented a significantly shorter time for gallbladder removal using ultrasonic shears.[3,13]

In our study, the incidence of gallbladder perforation was significantly lower in the harmonic group compared with the electrocautery group (4 versus 13; p=0.033). The use of the ultrasonic dissector resulted in an 18% reduction in the perforation rate. Similar findings were reported by Kandil et al and Mahabaleshwar et al (5 versus 12) who also observed a higher incidence of gallbladder perforation in the electrocautery group compared with the harmonic group.[13,14] The results of our study are consistent with these reports, suggesting that ultrasonic shears are safer and more effective than electrocautery for gallbladder dissection with respect to perforation rates.

Common bile duct injury occurred in one patient in the electrocautery group. In this case, dense adhesions were present in Calot's triangle and around the gallbladder. During adhesiolysis, excessive smoke generation and bleeding led to poor visibility, making anatomical identification more difficult. The injury was managed by insertion of a T-tube without conversion to open surgery. In contrast, Liao et al reported common bile duct injury associated with the use of a harmonic scalpel.[15] However, in our study no common bile duct injury occurred in the harmonic scalpel group during laparoscopic cholecystectomy. Additionally, liver injury was observed in two patients in the electrocautery group during dissection with an electrocautery hook. Haemostasis was achieved using electrocautery with a ball tip. No liver injury was recorded in the harmonic scalpel group during cholecystectomy.

Because ultrasonic shears simultaneously cut and coagulate tissue while remaining within anatomical planes, they reduce bleeding and surface oozing during dissection. Consequently, complications such as bile leakage, stone spillage, and gallbladder perforation were observed less frequently. This improved intraoperative control increased procedural confidence and resulted in fewer drains being placed in patients undergoing laparoscopic cholecystectomy with ultrasonic shears compared with electrocautery (17 versus 34; p=0.001). A similar observation was reported by Gelmini et al, who also found that the requirement for drain placement was significantly lower in the ultrasonic shears group.[16]

Our study demonstrated a significant reduction in postoperative pain scores in patients who underwent the procedure using ultrasonic shears. The pain scores in the ultrasonic shears group were consistently lower than those in the electrocautery group at multiple time points: day 0 (4.24±2.2 versus 6.64±1.73; p<0.001), day 1 (2.0±1.9 versus 4.4±2.35; p<0.001), day 7 (0.52±1.05 versus 2.08±1.61; p<0.001), day 14 (0.24±0.65 versus 1.0±1.35; p<0.001), and one month (0 versus 0.4±0.70; p=0.006). Similar findings were reported by Jain et al, who observed significantly lower postoperative pain in the ultrasonic shears group. Likewise, Mahabaleshwar et al also concluded that postoperative pain was reduced when ultrasonic shears were used.[3,14]

The significantly lower pain scores observed in our study were associated with a reduced requirement for postoperative analgesics in the ultrasonic shears group compared with the electrocautery group. Similar findings were reported by Jain et al, who also demonstrated a significantly lower analgesic requirement in the ultrasonic group (1.89±0.59 versus 2.66±0.66; p=0.001).[3]

In our study, the mean postoperative hospital stay was significantly shorter in the ultrasonic shears group compared with the electrocautery group (1.2±0.66 versus 2.24±0.92; p=0.0099). Similar findings have been reported by Mirani et al who also observed a significantly reduced postoperative hospital stay in patients treated with ultrasonic shears.[17]

Limitations

The cost-effectiveness of this device requires further evaluation in the Indian context, where economic considerations play a crucial role in determining the choice of surgical procedure.

CONCLUSION

Our findings are consistent with previous studies showing that ultrasonic shears have clear advantages over electrocautery, including shorter operative time, easier handling in difficult situations, and improved safety. The technique was associated with minimal risk of injury to surrounding structures and less postoperative complications. Postoperatively, patients experienced lower pain scores and reduced analgesic requirements, allowing earlier discharge and faster recovery. Follow-up at one month revealed no complications.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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