



## Potential application of Harmonic Scalpel in Laparoscopic Cholecystectomy as an alternative to Monopolar electrocautery

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### ABSTRACT

*The Laparoscopic Cholecystectomy (LC) is the gold standard treatment modality for uncomplicated acute or chronic cholecystitis with cholelithiasis. Conventional LC is normally performed with a Monopolar electrocautery which can cause iatrogenic injury of adjacent viscera via thermal side effects. The Harmonic scalpel (HS) is an advanced minimally invasive surgical tool with minimal peripheral tissue damage. The main objective of this study is to evaluate the beneficial aspects and disadvantages of Harmonic scalpel compared with Monopolar electrocautery.*

**Keywords:** Lap Cholecystectomy, Harmonic Scalpel, Monopolar Electrocautery.

### INTRODUCTION

The Laparoscopic Cholecystectomy (LC) is the gold standard treatment modality for uncomplicated acute or chronic cholecystitis with cholelithiasis<sup>1</sup>. The conventional LC is normally performed with a Monopolar electrocautery for the dissection and coagulation of the gall bladder, cholecystic duct, and the cholecystic artery. The use of Monopolar electrocautery in LC may cause iatrogenic injury of adjacent vessels and solid organs, such as the common bile duct<sup>2</sup> and the small intestine<sup>3</sup> via thermal side effects. Also Monopolar electrocautery in LC results in excessive smoke which may compromise the precision of dissection. However, because of its documented risks, especially those related to visceral injury, search for alternative forms of energy that can be used in laparoscopic dissection.

Among these alternative energy sources are ultrasonic energy and laser energy.

The Harmonic scalpel (HS) is an advanced minimally invasive surgical tool<sup>4</sup>. The HS is based on the mechanism of ultrasound<sup>5</sup>. The scalpel enables synchronous cutting, coagulation, and cavitations of the thicker tissue by a high-frequency (55,500 Hz) vibration, which generates heat by tissue stress and friction to degenerate tissue protein<sup>6</sup>. This technique transfers minimal energy to the tissues in proximity and thereby minimizes the risk of collateral thermal damage<sup>6</sup>. The HS enables protein denaturation within the vessel by means of ultrasonic vibrations and closes and cuts vessels up to 5 mm in diameter without requiring vessel clipping<sup>7,8</sup>. Although vessel sealing time with HS is dependent on the user, the sealing times of both devices are

similar<sup>9</sup>. After activation, tip temperature is higher in HS, but less peripheral tissue damage has been reported for HS.<sup>2</sup>

The main objective of this study was to evaluate the possible beneficial aspects and disadvantages of Harmonic scalpel.

## MATERIAL AND METHODS

### STUDY DESIGN

This study was an open-label, assessor-blinded, randomized, controlled trial conducted at a single academic tertiary care institute. The investigators and patients were not blinded. The study protocol was approved by the Ethical committee of King George Medical College and Hospital, affiliated to King George Medical University, Lucknow, India. From October 2015 to June 2016, a total of 150 patients were prospectively and consecutively hospitalized for emergency or elective LC and screened for eligibility for this study. Of these patients, 120 were found to be eligible for this study. All the patients voluntarily gave written informed consent, before participating in this study. All eligible patients were equally and randomly assigned to LC, with open-label Harmonic scalpel (the experimental group, 65 patients) or conventional Monopolar electrocautery (the control group, 55 patients). Patients were randomly divided into treatment groups using computer-generated assignments. The results of the randomized assignments were sealed in numbered envelopes, concealing the enclosed contents. If all inclusion criteria were adequately met, patients diagnosed with acute Cholecystitis were asked to participate in the study. If the patient agreed, he/she would review and sign Committee-approved Informed Consent documents. Following verification of consent, the patient was randomly assigned to one of two treatment groups. The attending surgeon recorded the patient's name and treatment number. All eligible patients were recorded. All LC procedures were performed by led by certified laparoscopic surgeons with a previous total case volume of

more than 500 conventional LC procedures and ~200 LC procedures with the Harmonic scalpel.

### INCLUSION AND EXCLUSION CRITERIA

The inclusion criteria were diagnosis of simple acute or chronic cholecystitis, cholelithiasis, or gallbladder polypoid lesion on abdominal ultrasound or computed tomography (CT) scan, aged 18–75 years with symptomatic gallstones or polyps documented by imaging were enrolled.; physical status class I or II, according to American Society of Anesthesiologists (ASA); The exclusion criteria were as follows: age <18 years or >75 years; pregnant or lactating women; pre-existing morbid obesity (body mass index [BMI, measure of weight in kilograms divided by the height in meters squared] >40 kg/m<sup>2</sup>); ASA class III or IV; complicated intrahepatic or extrahepatic bile duct stones; complicated acute pancreatitis; suspected gallbladder malignancy; history of previous upper abdominal open surgery; concomitant serious cardiopulmonary (New York Heart Association class III or IV) or refusal to participate.

### OPERATIVE PROCEDURES

All the patients received premedication general anesthesia with endotracheal intubation and intravenous antimicrobial prophylaxis with ceftriaxone sodium as a routine surgical prophylaxis. Laparoscopic cholecystectomy was performed with the standard 4-port technique, as reported earlier<sup>10</sup>; a fourth port was made below the right-side subcostal margin, if necessary. In brief, pneumoperitoneum was established with carbon dioxide insufflation and maintained at 12 mm Hg. Calot's triangle (hepatobiliary triangle or cystohepatic triangle) was dissected with the Harmonic scalpel in the experimental group or by laparoscopic Monopolar electrocautery in the control group. Closure and sealing of the cystic duct was performed with Hem-o-lok clips in both groups. Closure and sealing of the cholecystic artery was performed with Hem-o-lok clips in Monopolar electrocautery in the control group.

Closure and sealing of the cholecystic artery was performed with Harmonic scalpel in the experimental group without Hem-o-lok clips. The gallbladder was mobilized from the gallbladder bed with Harmonic scalpel in the experimental group and with Monopolar electrocautery in the control group, and any obvious oozing blood or bile leak was controlled. A peritoneal drain was inserted into the Morrison's pouch (hepatorenal recess of subhepatic space). The adjustments of the working gear of the Harmonic scalpel were at the sole discretion of the surgeons, and the parameters of Monopolar electrocautery were set at 40 W for exposing and separating the cystic duct and artery, and 40–50 W for separating the gallbladder from the gallbladder bed.

#### **POSTOPERATIVE CARE AND FOLLOW-UP**

Patients received analgesics as required. Six hours after surgery, patients were encouraged to begin oral intake and mobilize. Duration of hospitalization and date of discharge from hospital were set according to routine practice of the hospital and discretion of the treating surgeon. The first follow-up examination (6 h after surgery) was undertaken in the surgical ward. All subsequent follow-ups were conducted in the outpatient department.

#### **MAIN OUTCOME MEASURES**

The complete data were collected and evaluated by an independent research nurse. The preoperative variables included age, sex, BMI, ASA classification, indication for LC, and concomitant medical and surgical conditions from medical chart review. The operative variables included operative time, estimated blood loss and intra operative incidents. Intra operative bleeding was estimated by measuring blood aspirated from the operative field and weighing gauze used for pressure homeostasis. The postoperative variables included postoperative recovery times, postoperative pain, use of postoperative analgesics, postoperative complications, and length of postoperative hospital stay (PHS). The

postoperative pain was evaluated at 6,24 and 48 hours after the operation, with the help of a linear visual analog scale (VAS) from 0 (no pain) to 10 points (the most severe pain), with a higher score indicating more serious pain.<sup>11</sup> Postoperative analgesia included 1 dose of intramuscular Diclofenac (NSAID) for all patients and an additional dose of NSAID for patients with a VAS score  $\geq 3$  points; intramuscular Tramadol hydrochloride was given otherwise. The use and dose of analgesics were recorded in medical charts.

#### **SAMPLE SIZE CALCULATION AND STATISTICAL ANALYSIS**

The statistical analysis of the data in this study was preferred using the SPSS version 10 (SPSS Inc., Chicago, IL, USA). Analysis of data was by intension to treat. For continuous variables, descriptive statistics were calculated and reported as mean $\pm$ SD. Categorical variables were described using frequency distributions. The Student's t test for paired samples was used to detect differences in the means of continuous variables, and chi-square test was used in cases with low expected frequencies ( $p < 0.05$  was considered to be statistically significant).

#### **RESULTS**

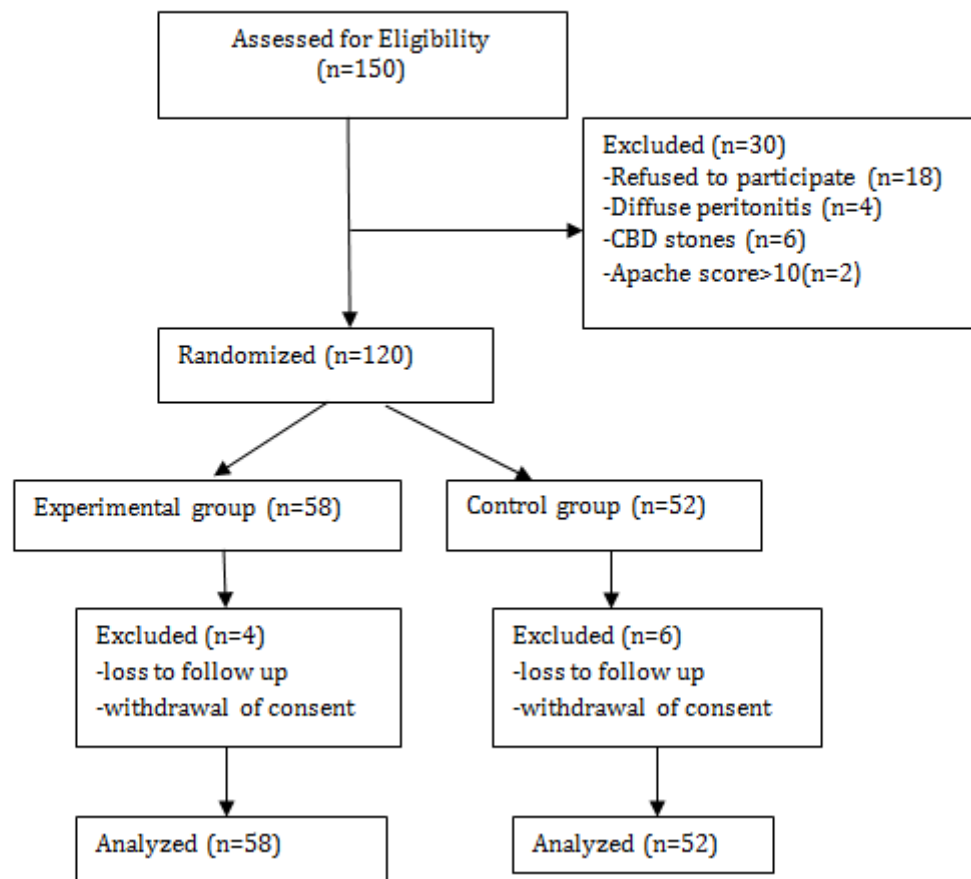
Out of 150 patients screened for eligibility, 120 patients were randomized to undergo LC with the Harmonic scalpel ( $n = 65$ ) or Monopolar electrocautery ( $n = 55$ ); 10 patients were excluded from analysis because of withdrawal of informed consent or loss to follow-up ( $n = 10$ ). Overall, 110 patients were included for the analysis, of whom 58 patients were allocated to the experimental group, and 52 were allocated to the control group. Both the groups were comparable with respect to the baseline patient characteristics, including age, sex, BMI, ASA classification, gallbladder disease, and concomitant medical conditions (all  $P > .05$ ). The intra operative parameters observed including duration of the operation, rate of gallbladder perforation, bile escape or leaks, volume of blood

loss, amount of drainage, occasional visceral injuries and conversion rates were all recorded. The postoperative parameters observed included

postoperative hospital stay and morbidity for each group.

**Figure 1.**

**PATIENT ALLOCATION FLOW CHART:**



**Table 1. BASELINE CHARACTERISTIC DATA**

	Experimental(n=58)	Control(n=52)
Age	38.6±12.2	36±11.6
Sex-males	23	18
Females	35	34
BMI	23.2±2.6	24.4±3.2
Gall Bladder disease-		
Mucocoele	3	2
GB polyp	1	0
Other	2	1
Associated co-morbidity	4	3

**Table 2.** OPERATIVE AND POST OPERATIVE DATA

	Experimental(n=58)	Control(n=52)
Operative time, min, mean±SD	53.3±15.2	56.2±13.4
Blood loss, ml, mean±SD	12.6±5.2	14.5±4.7
Gall bladder perforation n(%)	2(3.44%)	5(9.61%)
Conversion to open laparotomy, n(%)	1(1.71%)	2(3.84%)
Post operative drainage, ml, mean±SD	19±3.4	23±6.4
Post operative Complication (%)		
Surgical site infection	1(1.71%)	2(3.84%)
Post operative pneumonia	0(0%)	1(3.84%)
Bile leak	1(1.71%)	0(0%)
CBD injury	1(1.71%)	0(0%)
Visceral injury	0(0%)	0(0%)
Jaundice	0(0%)	0(0%)
Postoperative hospital stay, hour, mean±SD	48.5±3.4	48.3±2.5

**Table 3.** POST OPERATIVE PAIN DATA

	Experimental(n=58)	Control(n=52)
6 hours	3.2	3.4
24 hours	2.2	2.4
48 hours	1.3	1.2

## DISCUSSION

Both operative and postoperative data are shown in Table 2. Both the groups had similar operative time and blood loss (both  $P > .05$ ). However the mean operative time for Harmonic scalpel group was shorter than the Monopolar electrocautery group (18,19). According to a retrospective case series by Gelmini et al,<sup>12</sup> the use of the Harmonic scalpel in LC is associated with a significantly shorter median operative time, as compared to that of conventional monopolar electrocautery coagulation: 60 min (range, 20–205 min) vs 85 min (45–150 min);  $P < .001$ . Zanghi et al<sup>13</sup> also reported in a retrospective study of 164 patients that the use of the Harmonic scalpel is associated with a significantly shorter mean operative time ( $35 \pm 10$  vs  $56 \pm 12$  min,  $P < .001$ ); and Kandil et al<sup>14</sup> reported in a prospective, randomized study that the use of the Harmonic scalpel alone for dissection and sealing in LC resulted in almost half the mean operative time ( $33.2 \pm 9.6$  vs.  $51.7 \pm 13.8$  min,  $P = .001$ ). The reduction in operative time with HS is due to decrease smoke production during dissection as well as better homeostasis.

The conversion to open Cholecystectomy was required in 3 patients (1 patient in the experimental group caused by common bile duct injury and 2 patients in the control group for dense

adhesion). According to some previous studies, the use of the Harmonic scalpel may be associated with a reduced risk of conversion to open procedure and overall surgical morbidity, compared with conventional Monopolar electrocautery. However, the lower risk was not statistically or clinically significant in these studies.<sup>15–17</sup> This study results reaffirmed that the use of conventional Monopolar electrocautery was not associated with a significantly higher risk of open conversion. The major factors contributing to LC conversion to laparotomy includes laparoscopic difficulty or gallbladder perforation caused by adhesion, uncontrollable bleeding, bile leak, missed coexisting bile duct stones, or gallbladder cancer on preoperative assessment.<sup>18</sup> The major postoperative complications included surgical site infection (2 patient in the control group and 1 patient in the experimental group), postoperative pneumonia (1 patient in the control group), and bile leak (1 patient in the experimental group), CBD injury (1 patient in the experimental group). There were no visceral or postoperative jaundice in any patient. Both the groups had a similar time postoperative pain profile, requirement for analgesics (all  $P > .05$ ; Table 3). In previous studies reporting the use of the Harmonic scalpel with less postoperative



pain, the major cause may be a significantly shorter operative time for LC with a Harmonic scalpel than with Monopolar electrocautery.<sup>14</sup>

## CONCLUSION

The use of the Harmonic scalpel for LC in the treatment of uncomplicated cases was associated with similar operative time, conversion risk, blood loss, and postoperative recovery when compared with LC using conventional Monopolar electrocautery in the hands of experienced surgeons. The HS and MC yielded similar clinical data in LC. The HS had lower smoking-induced desufflation rates. The selection of the energy devices should be based on the preference of the surgeon and the condition of the hospital.

The major limitation in using the Harmonic scalpel is its relatively high cost, especially in underprivileged practices. Nevertheless, some authors believe that compared with combined cost of using multiple disposable instruments (scissors, a clipper, an Monopolar electrocautery hook, and a grasper), the Harmonic scalpel may provide a cost-effective option.<sup>19</sup> Another limitation for the use of the Harmonic scalpel with its inability to performing fine dissection with the bulky tip and difficulty in manipulation of the tissue plane with a straight tip also carries potential risks.

## CONFLICT OF INTEREST

The Authors declare that they have no conflict of interests.

## ACKNOWLEDGEMENT

None

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