

# A Prospective Randomized Control Trial to Assess the Efficacy of Ultrasonic Dissection without Cystic Artery Clipping Versus Classical Electro Dissection in Laparoscopic Cholecystectomy

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## Abstract

**Aim:** Ultrasonic Dissection without Cystic Artery Clipping Versus Classical Electro Dissection in Laparoscopic Cholecystectomy

**Material and Methods:** The prospective randomized control trial study was conducted in the Department of General Surgery, ESIC Medical College and Hospital, Faridabad, Haryana, India from April 2018 to Feb 2019. The study included 40 patients.

**Result:** The operative time was significantly less in the ultrasonic group (p-value 0.017). VAS score for postoperative pain in the harmonic group was significantly less compared to the classic group (p-value 0.001). The incidence of gallbladder perforation was almost double in the classic group compared to the ultrasonic group, but it was statistically not significant (p-value 0.74). The drain was inserted in 7 (35%) patients in the classic group while it was inserted in 5 (25%) patients in the harmonic group, but this difference was not statistically significant. The length of hospital stay was not significantly different in the two groups (p=0.89). All patients had no complications and conversion to open surgery

**Conclusion:** Ultrasonic dissection of Callot's triangle and division of the cystic artery without clipping is safe in laparoscopic cholecystectomy. It has certain advantages over electrocautery like shorter operative time and less postoperative pain. However, no additional benefits to decrease the chances of gallbladder perforation, requirement of drain insertion and hospital stay.

**Keywords:** Cholecystectomy, Electrocautery, Gallbladder perforation, Harmonic, Pain.

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## Introduction

Laparoscopic cholecystectomy is the revolutionary new method for the treatment of gallstone disease and has now become the gold standard for the surgical treatment of symptomatic cholelithiasis[1,2]. The traditional laparoscopic cholecystectomy is

commonly performed by means of dissector, the electrosurgical hook, spatula, and/or scissors, and this method has been used in most centers. Simple metal clips are frequently used to achieve cystic duct and artery closure[3]. Although the surgical clip was known to be a safe closure method, bile

leakage due to clip displacement from the cystic duct stump is a potential complication of laparoscopic cholecystectomy[4]. There are many other complications that have been found to be associated with the use of the clips like accidental clipping of common bile duct leading to obstruction, strictures, slippage of clips etc[5]. Therefore, various new methods are now used to control the cystic artery like absorbable or non-absorbable sutures, Monopolar or Bipolar electro coagulation and Harmonic scalpel have also been used for this purpose but due to its high cost Harmonic scalpel has been used less frequently[6]. Designed as a safe alternative to electro cautery for the haemostatic dissection of tissue, the ultrasonically activated Harmonic scalpel was introduced into clinical use nearly a decade ago. Several studies have described the use of ultrasound dissection technology in the LC, which concluded that ultrasonic dissection was safe and easy to use. Its technology relies on the application of ultrasound within the harmonic frequency range to tissues and allows two effects: ultrasonic coagulation and cavitation effects provided by a rapidly vibrating blade contacting various tissues[7].

### Material and methods

The prospective randomized control trial study was conducted in the Department of General Surgery, ESIC Medical College and Hospital, Faridabad, Haryana, India from April 2018 to Feb 2019.

### Methodology

A total of 40 patients were included in the study. All patients were planned for laparoscopy and randomly divided into group A (classical electrocautery) and group B (harmonic group). The final sample size was 20 patients in each group. All patients underwent the standard protocol for preoperative evaluation. A complete case history, physical examination, routine blood investigation

and ultrasonographic evaluation of the abdomen were done. Informed and written consent was taken before the procedure. Randomization was done on the day of surgery. A prophylactic dose of Ceftriaxone 1gm was given 30 minutes prior to skin incision. All procedures were performed under general anaesthesia with the patient in a reverse Trendelenburg position by conventional four-port technique.

### Inclusion and exclusion criteria

The study included all patients who were planned for elective laparoscopic cholecystectomy in the department of General Surgery and excluded all patients with acute cholecystitis, gangrenous cholecystitis, and perforated gall bladder and on anticoagulant drugs.

### Statistical analysis

The Statistical analysis was done by using the SPSS software (IBM SPSS for windows version 25.0, 2015, Armonk, NY: IBM Corp.).

### Results

The sample size of 40 patients randomly allocated into two groups by the SNOSE technique: Group A- Classic cholecystectomy group, Group B- cholecystectomy was done using the harmonic scalpel. All procedures were performed under general anaesthesia with the patient in a reverse Trendelenburg position by conventional four-port technique. The patient's in-group A underwent classical laparoscopic cholecystectomy. In this method, dissection of Calot's triangle was done in a conventional manner using Maryland dissector or hook and cautery, and then, after identification of cystic duct and cystic artery, one clip was applied over the cystic artery towards its origin, and one clip applied towards the gallbladder and then it was divided in between using scissor. Two clips were applied on cystic duct towards CBD, and one clip was applied towards the

gallbladder, and then it was divided using scissor. The gallbladder was dissected out from the liver bed by using hook and monopolar cautery. The patient's in-group B underwent the other technique of laparoscopic cholecystectomy. In this technique, the harmonic scalpel was used to dissect Calot's triangle, divide the cystic artery and dissect GB from the liver bed. After the division of the cystic artery by harmonic, two clips were applied on the cystic duct towards the CBD, and one clip applied towards the GB, then the cystic duct was between using scissors. Then the gallbladder was dissected from the liver bed using the harmonic scalpel. The median age in the classic cholecystectomy group was 44.5 years, and in the harmonic group, it was 45 years ( $p=0.783$ ). The sex distribution was comparable in both groups. In the classic group, it was 14 females (70%) and 6 males (30%) while in the harmonic group, it was 16 females (80%) and 4 males (20%). There is a female preponderance of the gallstone diseases with a reported ratio of 3:1(F: M). In the present study, this ratio is 3.5:1(F: M) ( $p=0.441$ ).

In the harmonic group, the median operative time was 46 minutes, and in the classic group, it was 60 minutes. It was 14 minutes shorter in a harmonic group compared to the classic group. The operative time was significantly less in the harmonic group ( $p=0.017$ ). The age and sex distribution in both groups were comparable in the study.

The incidence of gallbladder perforation was almost double in the classic group compared to the harmonic group. In the classic group, the incidence of GB

perforation was 5 (25%) out of 20. while in the harmonic group, it was 3 (15%) out of 20. However, it was statistically not significant ( $p=0.74$ ), perhaps because the study was underpowered.

The pain was evaluated by the Visual Analogue Scale (VAS) score after 12 hours of surgery. In the harmonic group, the median VAS score was 3, while in the electrocautery group, it was 5 ( $p$ -value 0.001). The harmonic group had a lower number of patients requiring intra-abdominal drain compared to the classic group, but this difference was not statistically significant ( $p$ -value 0.086).

The harmonic group required drain insertion in 5 patients out of 20 (25%) whereas the classical group required to drain in 7 patients out of 20 (35%). In our study, the difference in drain volume in both groups was not significant ( $p$ -value 0.077). The classic group had a median value of 30 ml, while the harmonic group had a median value of 20 ml. The drain volume and character were noted on postoperative day 1. The drain character was serosanguinous to serous in nature. There was no postoperative bile leak in any case.

The length of hospital stay was similar in both the groups. There was a median difference of 5 hours, wherein, the harmonic group had an earlier discharge, but it was not statistically significant ( $p$ -value-0.89). The harmonic group had an average of 33 hours of postoperative hospital stay while the classic group had a postoperative hospital stay of 42 hours. [Table]

**Table 1: Comparison of classic and harmonic operative group with variables.**

	Classic	Harmonic	p-value
Median intraoperative time- defined as skin incision to skin closure (Minutes)	60	46	0.017
Intraoperative gallbladder perforation	5 (25%)	3 (15%)	0.74
Median postoperative pain (VAS Score) after 12 hours of surgery	5	3	0.001
No of patients required intraoperative drain insertion	7 (35%)	5 (25%)	0.086
Median length of hospital stays after surgery (Hours)	42	33	0.89

### Discussion

In our study, a statistically significant difference was observed in operative time between the two groups. The operative time in the harmonic group was 14 minutes shorter as compared to the classic group ( $p=0.017$ ). Our study results are consistent with those of previous studies[8-11].

The lesser operative time in the harmonic group can be attributed to several factors, like, for the division of cystic artery and dissection of the gallbladder from liver bed, harmonic scalpel replaces multiple instruments. This leads to reduced operative time as the frequency of instrument exchange is drastically decreased. The use of harmonic helps to achieve better hemostasis while dissecting Calot's triangle and gallbladder from the liver bed. Harmonic produce minimal smoke which leads to the clearer operative field, and because of this, there is also a less frequent need for cleaning the camera lens[9,11-14]. The increased incidence of gallbladder perforation is another factor for an increased operative time as it leads to poor operative field and requires irrigation, suctioning and sometimes drain insertion[12]. In the study by Jansen et al., less experienced surgeons operated several cases in the ultrasonic group. Surgeons with experience of less than 10 laparoscopic cholecystectomies did 23 cases in an

ultrasonic group, whereas only 12 cases in electrocautery group. In contrast, surgeons with experience of more than 22 laparoscopic cholecystectomies did 65 cases in the ultrasonic group and 75 cases in the electrocautery group. These could have been the reasons for not having a significant difference in operative duration between the two groups[11]. Rajnish et al. did not find any significant difference in the operative duration. He did a non-randomized study with smaller sample sizes which could have underpowered the study[15,16].

In our study, the incidence of intraoperative gallbladder perforation was higher in the classic group in comparison to the harmonic group. The number of patients who had gallbladder perforation was 5 out of 20 in the classic group, while in the harmonic group; it was 3 out of 20. GB perforation is the most common complication of laparoscopic cholecystectomy. Previous studies concluded that a significantly less incidence of gallbladder perforation in harmonic group compared to the electrocautery group[8,17-19]. The lowest incidence of GB perforation in the harmonic group is probably because of factors like lesser lateral thermal tissue damage by harmonic as compared to electrocautery (1.5 mm Versus 5 mm). Few studies did not find a statistically significant

difference in GB perforation between the two groups, probably because of the smaller sample size[15,16].

Pain is one of the commonest and troublesome complaints during the postoperative period. In our study, we observed significantly lesser pain in a harmonic group of laparoscopic cholecystectomy compared to a classic group where monopolar electrocautery was used. The pain was evaluated by VAS (Visual Analogue Scale) score after 12 hours of surgery. In the harmonic group, the median VAS score was 3, while in the electrocautery group, it was 5 (p-value 0.001). On follow-up after two weeks, pain in both the groups was similar. These results are consistent with those of previous studies[8,12,19]. Harmonic causes lesser lateral thermal damage, up to 1.5 mm while electrocautery causes more lateral thermal damage, up to 5 mm. Harmonic scalpel also causes lesser charring and damage to the surrounding nerves because of its less collateral energy transfer. Hence there could be less inflammation and less release of inflammatory mediators leading to lesser pain as compared to the electrocautery group[12,17,18]. One study has shown that there was no significant difference in pain score between the two groups. This was probably because it was a non-randomized study with small sample size[15,16].

In our study, the length of hospital stay was similar in both the groups. There was a median difference of 5 hours, wherein, the harmonic group had an earlier discharge, but it was not statistically significant (p value-0.89). The reason for no significant difference in hospital stay in our study could be because of two reasons, firstly, most of our patients were from far away and remote places so they were not discharged at the earliest in both the groups. Secondly, it was also influenced by the workload of the residents. Our results were consistent with two other studies[10,20]. One study reported a significantly shorter hospital stay

in the harmonic group as compared to the electrocautery group. The reason for a longer hospital stay was due to a greater number of patients requiring drain and higher pain score in the electrocautery group[12]. Our study also showed a difference in the number of patients requiring intra-abdominal drain insertion between the two groups. The harmonic group had a lower number of patients, who required intra-abdominal drain compared to the classic group, but this difference was not statistically significant (p-value 0.086). There are some studies which showed a significantly lower requirement of drain insertion in the harmonic group[10,12]. Few studies showed no significant difference in the requirement of drain insertion, which was similar to our study.<sup>15</sup> The increased requirement for drain insertion in the classic group could be due to a higher incidence of gall bladder perforation in the classic cholecystectomy group compared to the harmonic group. In our study, the difference in drain volume in both groups was not significant (p-value 0.067). There is one study, which reported a significant difference in the amount of drain volume between the harmonic group and the electrocautery group[19].

All forty cases were operated by laparoscopically, and there was no conversion to open surgery. This result was consistent with the existing literature[15,19,21]. Two studies have reported conversion to open surgery. Liao et al. reported the conversion of one case to open because of CBD injury in the harmonic group. Gelmini et al. reported one conversion to open surgery because of dense adhesions[10,20].

All the patients did well in the second week and one months of follow up. The strength of our study is that it is a single blinded, randomized control trial in which intention to treat (ITT) principle was followed. The patients were unaware of the allocated group. There are certain limitations of this

study like it is a single centre study with a short duration of follow up. The harmonic used in group B is an expensive instrument and not easily available at all the centres. But this was not a limitation for us as no extra cost was charged from the patient for its use. In the future, a multi-centric study with a larger sample size can be done in definitively establishing a recommendation based on the results.

### Conclusions

The harmonic scalpel can be safely used for the dissection of Calot's triangle and division of the cystic artery without clipping. It has certain advantages over electrocautery in the laparoscopic cholecystectomy like shorter operative time and less postoperative pain. However, no significant differences were seen in the chance of gall bladder perforation, the requirement of abdominal drain insertion, drain volume on day 1 and postoperative hospital stay.

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