Original Article

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Harmonic Scalpel versus Electrocautery and its Outcome in Laparoscopic Cholecystectomy: A Prospective Interventional Study

Surgery Section

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ABSTRACT

Introduction: Laparoscopic cholecystectomy can now be performed safely and effectively due to various surgical tools that have significantly reduced intraoperative and postoperative problems. The Harmonic® Scalpel (HS) is a superior option to more conventional Electrocautery (EC) because it reduces temperatures, smoke, and lateral tissue damage. The Harmonic® Scalpel also lowers the risk of injury due to minimal heat dispersion. Due to less trauma, there is a decrease in both moderate and severe bleeding. It is hypothesised that the HS might be a more cost-effective alternative to employing a variety of disposable tools, such as scissors, a clipper, an EC hook, and a grasper.

Aim: To compare the effectiveness and safety of the HS compared to traditional EC in achieving complete dissection and haemostasis during laparoscopic cholecystectomies.

Materials and Methods: A prospective interventional study was conducted with 300 patients diagnosed with chronic calculous cholecystitis, admitted to a tertiary care hospital under Department of General Surgery, from November 2020 to October 2022. Patients were allocated to two groups, and the outcomes of laparoscopic cholecystectomy were compared between the usage of a HS and EC in Calot's triangle dissection and Gallbladder (GB) dissection from the GB fossa. Descriptive data were represented through frequencies and percentages. The means of the two groups were compared using t-test, and categorical variables were compared using chi-square test.

Results: The mean age was 46.53±13.740 years in the HS group, while it was 45.3±13.961 years in the EC group. The average duration of dissection with a HS was 52.84±6.167 minutes and 56.79±5.582 minutes in the EC group (p-value 0.001). A total of 67 (44.7%) patients in the HS group had minimal or no bleeding, while it was 23 (15.3%) patients in the EC group. GB perforation occurred in 13 (8.7%) patients in the HS group and in 26 (17.3%) patients in the EC group. Liver injury occurred in 2 (1.3%) patients in the HS group and in 6 (4%) patients in the EC group. Postoperative nausea and vomiting were reported in 20 (13.3%) and 72 (48%) patients in the HS and EC groups, respectively, in the first 48 hours. All these associations were found to be statistically significant (p-value 0.001).

Conclusion: The present study found that the HS offers a hassle-free dissection without much incidence of intraoperative bleeding or surrounding tissue damage.

Keywords: Calot's triangle, Chronic calculous cholecystitis, Gallbladder fossa, Intraoperative bleeding

INTRODUCTION

Laparoscopic cholecystectomy can now be performed effectively and safely because of a variety of surgical tools that have been created to reduce intraoperative and postoperative problems significantly [1]. Numerous ultrasonic scalpels, water jet dissectors, laser systems, and specially designed suction devices have been employed in addition to EC. All of these tools have varying degrees of success in their ability to completely stop bleeding during dissection [2]. The most common tool for achieving a bloodless operative field during laparoscopic cholecystectomy is the electric hook. However, both monopolar and bipolar electric coagulation can harm surrounding organs, the small bowel or stomach, with local complications like liver or Common Bile Duct (CBD) damage, perforation of the gallbladder, and bile or stone spilling into the peritoneal cavity [3].

The ultrasonically activated HS has served as a safe alternative to EC for the haemostatic dissection of tissues. The division of the artery to the cystic duct and the separation of the GB from the liver bed have been the main uses of the HS in laparoscopic cholecystectomy. This groundbreaking technique for slicing tissues was built on the coagulating and cavitation effects produced when different tissues were in touch with a rapidly vibrating blade [1].

The HS is a superior option to more conventional EC because of the reduction in temperatures, smoke, and lateral tissue damage that it causes. The HS has acquired extensive physician acceptance and usage since its inception [4]. Low temperatures, lower than those employed by electrosurgery or lasers, are used by the ultrasonic generator to cut and coagulate tissue. Ultrasound technology manages bleeding by coaptive coagulation at low temperatures between 50 and 100° Celsius, creating a protein coagulum that coapts (tamponades) and seals vessels [5]. Long-lasting effects generate secondary heat that seals larger vessels [6].

In contrast, obliterative coagulation, or burning at greater temperatures (150-400°C), is a procedure offered by electrosurgery and lasers. Eschar is created by the desiccation and oxidation of blood and tissue, which covers and seals the bleeding spot [3,7,8]. When electrosurgical blades are withdrawn and adhere to tissue, interrupting the eschar, rebleeding can be dangerous. Additionally, the ultrasonic scalpel exhibits a zone of denatured tissue surrounding the ultrasonic incision of about one millimeter, which is comparable to the lateral energy dispersion seen with ultrasonic instrumentation in porcine models [9]. The usage of Harmonic® also lowers the danger of injury due to the minimum heat dispersion [10]. Additionally, because the electronically operated HS creates almost no smoke, the sight of the operating field is maintained during the whole process, negating the need to repeatedly clean the lens or expel smoke to recreate the pneumoperitoneum [11].

The major drawback of ultrasonic dissection is the high cost of the equipment. However, it can be argued that the HS might be a more affordable alternative than employing a variety of disposable tools, such as scissors, a clipper, an EC hook, and a grasper [12]. There is a paucity of literature on the advantages of an HS in laparoscopic

cholecystectomies. The sample size of previous studies was also limited, which weakens the validity and reliability of the proposed hypothesis [13,14]. This study was conducted at a tertiary care hospital, with 300 patients, to compare the effectiveness and safety of the HS to traditional EC in achieving complete dissection and haemostasis during laparoscopic cholecystectomies.

MATERIALS AND METHODS

A prospective interventional study was carried out in Department of General Surgery, Kalinga Institute of Medical Sciences in Bhubaneswar, Odisha, India, from November 2020 to October 2022. Institutional Ethical Clearance (IEC) (Approval number KIIT/KIMS/IEC/492/2020) was obtained before commencing the study.

Inclusion criteria: Patients diagnosed with uncomplicated gallstone disease, specifically chronic calculous cholecystitis or asymptomatic cholelithiasis without features of complications such as perforation or gangrene on imaging, with GB wall thickness <4 mm, and age >18 years were included in the study.

Exclusion criteria: Patients being operated on for acute cholecystitis, complicated gallstone diseases such as gangrenous cholecystitis or GB perforation, and post-Endoscopic Retrograde Cholangiopancreatography (ERCP) patients were excluded due to thick, fibrotic, and sometimes contracted GB with dense adhesions.

A total of 300 patients admitted during the study period were selected through consecutive sampling. They were divided into two groups by random allocation: HS (Group A) and EC (Group B), with 150 patients in each group. An odd number was assigned to the HS group using the Ultrascision® Harmonic® Scalpel (Model: Generator 300 of Ethicon® Endosurgery®), and an even number was assigned to the EC group using the Covidien® Valley LabTM Model: FT10 energy platform.

Study Procedure

The protocol and procedure were clearly explained, and informed consent was obtained. After creating a pneumoperitoneum and placing ports, Calot's triangle dissection was carried out, and the critical view of safety was achieved. The cystic artery was then clipped and cut, and haemostasis was ensured. The cystic duct was clipped and cut. No intraoperative cholangiogram was performed, as advocated by some surgeons. The GB was then dissected out from the GB fossa, and the specimen was delivered in an endo bag.

Patients in both groups underwent laparoscopic cholecystectomy, and the outcomes were assessed. In group A, the HS was used for Calot's triangle dissection and dissection of the GB from the GB fossa. In group B, EC was used for Calot's triangle dissection and separation of the GB from the GB fossa.

The following variables or outcomes were assessed:

1. **Duration of dissection:** The duration of dissection was recorded using a stopwatch in both groups in minutes. This included the time taken for Calot's triangle dissection, any adhesiolysis if present, and separation of the GB from the GB fossa. Any time lags associated with technical difficulties such as loss of pneumoperitoneum, control of bleeding, or equipment failure were excluded. The outcomes in both groups were assessed and compared separately. Cases that required conversion to an open procedure due to technical difficulties were not included as part of the study.
2. **Intraoperative bleeding:** Intraoperative bleeding was defined as bleeding occurring during Calot's triangle dissection or GB dissection. Bleeding from various factors, such as liver or cystic artery injury, or bleeding after posterior wall separation, was considered cumulatively and quantified. The amount of bleeding was calculated as the total output in the suction drain minus the total irrigation fluid used. Bleeding less than 50 mL was categorised as nil or minimal, 50 mL or more but less than 100 mL as mild, 100 mL or more but less than 200 mL as moderate, and 200 mL or more as severe. All types of bleeding were controlled either by pressure or with the help of an energy source. Cases of torrential or uncontrollable bleeding that required conversion to an open procedure were not included in the study unless the bleeding was a result of the energy source used.
3. **GB perforation:** GB perforation leading to intraperitoneal bile or calculi spillage was recorded and compared between both groups. Perforation due to blunt or sharp dissection was excluded. Spilled stones were extracted and thorough peritoneal lavage was performed post-bile spillage. Patients were kept on empirical antibiotic coverage postoperatively.
4. **Liver injury:** Liver injuries, ranging form minor tears of Glisson's capsule to major lacerations, caused by the energy sources used were studied. Injuries caused during blunt or sharp dissection were excluded. Liver injuries were primarily managed by controlling bleeding using pressure or an energy source, unless a forced conversion to an open procedure was required.
5. **Common Bile Duct (CBD) injury:** Injuries to the CBD resulting from lateral spread of current were recorded. Transection of the CBD during dissection or mistakingly ligation the CBD instead of the cystic duct were not considered. Injuries were managed based on their severity.
6. **Conversion to open procedure:** Forced conversions due to cystic artery injury and uncontrollable bleeding, major liver lacerations, and major biliary trauma caused by the energy source were noted. Elective conversions due to technical difficulties or surgeon preference were excluded.
7. **Postoperative pain:** Postoperative pain was assessed using a numeric pain scoring system at 24 and 48 hours postsurgery. The Numeric Rating Scale (NRS-11) was used for self-reporting of pain by patients [13]. Patients who required additional analgesia beyond the prescribed dosage were considered. The results at 24 and 48 hours were compared.
8. **Postoperative nausea and vomiting:** The occurrence of nausea and vomiting up to 48 hours postsurgery was monitored. Any intolerance to food or patients not wanting to eat were also included in this category.

STATISTICAL ANALYSIS

The data were analysed using Statistical Package for the Social Sciences (SPSS) statistical software version 20.0 Descriptive data were presented as mean, standard deviation, and frequencies. A t-test was used to compare mean scores for the duration of dissection. The Chi-square test was employed to test the association of categorical variables. A p-value of <0.005 was considered statistically significant.

RESULTS

Among the 300 operated cases, 203 (67.7%) were females and 97 (32.3%) were males. The mean age of patients in the HS group was 46.53±13.740 years, and 45.3±13.961 years in the EC group (p-value 0.44). The mean duration of dissection with HS was 52.84±6.167 minutes, while it was 56.79±5.582 for the EC group. The t-test showed a significant difference with p-value 0.001.

When assessing intraoperative bleeding, 67 (44.7%) patients in the HS group had nil/minimal bleeding, compared to 23 (15.3%) patients in the EC group [Table/Fig-1]. Bleeding was effectively controlled in all these patients, and proper haemostasis was ensured before the end of the procedure. There were no instances of CBD injury or forced conversions in either group throughout the study, likely due to the exclusion of complicated gallstone diseases.

GB perforation was observed more frequently in the EC group compared to the HS group, and the association was statistically

Variable		Study groups n (%)		Total	χ^2	p-value
		Harmonic®	Electrocautery (EC)			
Intraoperative bleeding	Nil/Minimal	67 (44.7)	23 (15.3)	90 (30)	30.953	0.001
	Mild	44 (29.3)	63 (42)	107 (35.7)		
	Moderate	25 (16.7)	41 (27.3)	66 (22)		
	Severe	14 (9.3)	23 (15.3)	37 (12.3)		
	Total	150 (100)	150 (100)	300 (100)		

[Table/Fig-1]: Outcome of intraoperative bleeding.

significant (p-value 0.026). Postoperative pain at 24 and 48 hours was higher in the EC group, and the association was statistically significant (p-value 0.001). Postoperative nausea was also more prevalent in the EC group, with a statistically significant association (p-value 0.001) [Table/Fig-2].

Variable		Study groups n (%)		Total	χ^2	p-value
		Harmonic®	Electrocautery (EC)			
Gall Bladder (GB) perforation	Yes	13 (8.7)	26 (17.3)	39 (13)	4.981	0.026
	No	137 (91.3)	124 (82.7)	261 (87)		
Liver injury	Yes	2 (1.3)	6 (4)	8 (2.7)	2.055	0.282
	No	148 (98.7)	144 (96)	292 (97.3)		
Postoperative pain after 24 hours	Yes	20 (13.3)	47 (31.3)	67 (22.3)	14.009	0.001
	No	130 (86.7)	103 (68.7)	233 (77.7)		
Postoperative pain after 48 hours	Yes	7 (4.7)	27 (18)	34 (11.3)	13.268	0.001
	No	143 (95.3)	123 (82)	266 (88.7)		
Postoperative nausea	Yes	20 (13.3)	72 (48)	92 (30.7)	42.391	0.001
	No	130 (86.7)	78 (52)	208 (69.3)		

[Table/Fig-2]: Study of outcomes in HS and EC groups.

DISCUSSION

The goal of gallbladder surgery is to reduce operative blood loss, minimise local thermal harm to tissue, prevent gallbladder perforation, avoid (CBD) injury, decrease intraoperative time, and lower expenses. When the necessary tools, skills, and expertise are at their peak, these goals can be achieved [15]. Ultrasonic generators use low temperatures, lower than those employed by electrosurgery or lasers, to cut and coagulate tissue. Ultrasound technology manages bleeding through coaptive coagulation at temperatures between 50 and 100° Celsius, forming a protein coagulum that seals vessels. Coagulation occurs by denaturation proteins as the blade connects with them, creating a coagulum that eventually compresses and closes tiny capillaries. The long-lasting effect generates secondary heat, which seals larger vessels. In contrast, electrosurgery and lasers offer obliterative coagulation, involving burning at higher temperatures (150-400°C). This process creates eschar through the desiccation and oxidation of blood and tissue, covering and sealing the bleeding spot [7,8,16]. However, rebleeding can be dangerous if electrosurgical blades withdraw and disrupt the eschar [17]. Additionally, the ultrasonic scalpel creates a zone of denatured tissue around the incision, approximately one millimeter in size, which is similar to the lateral energy dispersion observed with ultrasonic instrumentation in porcine models.

The mean age observed in the current study was 46.53 in the HS group and 45.3 in the EC group, with a higher proportion of females in both groups. However, neither age nor sex had any impact on the outcome of the study. Similar findings were reported by Yehia A et al., [13]. A study by Bessa S et al., reported a significant reduction in surgical time favouring ultrasonic instrumentation [11]. In this study, there was a statistically significant difference in the average time for Calot's triangle dissection and the separation of the gallbladder from its bed, including the control of the cystic duct and artery, which are the main procedures during laparoscopic cholecystectomy, between the two groups. The mean duration was 52.84 minutes in the HS group and 56.79 minutes in the EC group. However, it is important to note that operating time is greatly influenced by the education and experience of individual surgeons, and a shorter time does not always translate into a therapeutic advantage.

Monopolar electrosurgery is a technique that most surgeons can refine, reducing the amount of time they spend in operating. In contrast, ultrasonic dissection performed by untrained individuals may result in a prolonged and dangerous dissection process. A slight but statistically significant difference in blood loss was found in a single randomised clinical trial that included 200 patients undergoing laparoscopic cholecystectomy surgery by Janssen I et al., [18]. Present study also showed a decrease in both moderate and severe bleeding due to the decreased trauma caused by the (HS).

GB perforation: The incidence of GB perforation contrasts positively with the thermal energy damage associated with monopolar Electrocautery (EC) in the range of 0.24 to 15.0 mm [19]. GB perforations decreased from 17.3% to 8.7% over the course of this series (p-value=0.026). In a randomised clinical trial by Janssen I et al., involving 200 patients comparing ultrasonic versus EC dissection of the gallbladder during laparoscopic cholecystectomy [18], it was claimed that the use of ultrasonic generators significantly decreased the incidence of gallbladder perforation and resulted in a smoother procedure. The ultrasonic dissector facilitated the quick removal of fat at the Calot's triangle, making it safer to expose the cystic duct and artery. Mathur H et al., also reported a higher incidence of GB perforation with monopolar EC compared to the HS [14]. In the Abrar Hussain Z and Abdul Haleem S study, GB perforation and slipped stones occurred in 2.7% and 1.8% of the 100 patients who underwent laparoscopic cholecystectomy using the HS [19]. No significant or uncontrolled bleeding, CBD damage, or postoperative biliary discharge was noted.

Liver injury: Decreased instances of liver injury due to reduced lateral thermal spread have been observed with the HS [10]. However, it should be noted that the occurrence of liver injury is not solely determined by the use of monopolar instruments, as the precision of surgery and control of the instrument largely depend on the individual surgeon. In Present study, liver injury was observed in two cases compared to six cases in the HS and EC groups, respectively.

CBD injury: Similar findings with decreased instances of CBD injury due to reduced lateral thermal spread were observed with the HS. However, no CBD injuries were noted in this study.

Conversion to open procedure: Laparoscopic cholecystectomy using the HS has been shown to be practical and efficient, with minimal blood loss and operating time. The conversion rate was also found to be low. The absence of bile duct damage simplified the dissection process, resulting in a shorter surgical procedure and reduced need for conversion to open surgery. In the Abrar Hussain Z and Abdul Haleem S study, only two cases (1.81%) required conversion to open surgery due to difficulties in dissection and lack of progress, with no fatalities reported. The average dissection time ranged from 17 to 70 minutes [19].

In the current study, none of the individuals in the groups required conversion to open surgery. However, it is important to note that acute cholecystitis was not included in this study. The traditional clipping

technique was used to manage the cystic duct in all cases, rather than using a Harmonic® device or monopolar Electrocautery (EC).

Postoperative pain and nausea: The incidence of postoperative pain was higher with the use of EC, possibly due to heat dispersion and the production of more smoke, which often leads to abdominal discomfort and nausea. However, strong evidence of the efficiency and safety of the Harmonic® device was provided by Westervelt J in a study including 100 cases of total Harmonic® dissection (clipless surgery) and by Tebala GD in another study of 100 cases [12,20].

The main drawback of ultrasonic dissection is the high cost of the equipment, especially when reusable instruments are used. However, some authors argue that the (HS) may be a more cost-effective alternative compared to using a variety of disposable tools such as scissors, a clipper, an EC hook, and a grasper [10,12,21-23]. The cost issue is significant only when disposable technology is used for monopolar EC. Comparing costs becomes more challenging now that both monopolar electrocautery and ultrasonic surgery have reusable tools. Therefore, further comparison studies are recommended, particularly within a single health system or even within a single healthcare facility, to establish findings on a larger scale.

Limitation(s)

The limitation of present study was the exclusion of emergency and complicated cholecystectomy cases due to resource and time constraints. Including those cases could have provided a more comprehensive conclusion.

CONCLUSION(S)

Modern surgical needs and goals have always been patient-oriented. While it is important for us to provide patients with the best outcomes using the best in-house equipment, it should also be kept in mind that a cost-effective approach is suitable for the majority of the population. The sole purpose of this study was to determine whether the extra cost or price tag of the Harmonic® scalpel, compared to monopolar electrocautery (EC), is justified. Harmonic® scalpel offers hassle-free dissection with minimal intraoperative bleeding or damage to surrounding tissues. Although there is not a significant decrease in intraoperative time, there is a notable reduction in postoperative complications such as pain and nausea. The use of the Harmonic® scalpel resulted in a significant reduction in intraoperative bleeding. Furthermore, with the introduction of reusable equipment and safer sterility-maintaining techniques, the cost factor has been greatly reduced. However, it is important to note that regardless of whether the Harmonic® scalpel or EC is used, the training, experience, and expertise of the surgeon play a major role. Therefore, under normal circumstances with all contradictory factors eliminated, it can be concluded from this study that HS is a safer device compared to EC and is truly worth the price and hype.

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