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A PROSPECTIVE COMPARATIVE STUDY ON ELECTROCAUTERY VERSUS HARMONIC DISSECTION OF THE GALLBLADDER FROM THE HEPATIC BED.

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Abstract

Objective

This study aims to assess the effectiveness and safety of the Harmonic scalpel compared to electrocautery for dissecting and controlling bleeding in the gallbladder during laparoscopic cholecystectomy.

Methods

300 patients underwent laparoscopic cholecystectomy, following strict selection criteria. These criteria included having chronic cholecystitis, no complaints at the time of operation, being between the ages of 18 to 70 years, having a normal body weight, an American Score of Anesthesia (ASA) classification of 1 or 2, no prior upper abdominal surgeries, and a gall bladder wall thickness of less than 6 mm as determined by preoperative ultrasonography.

Results

The study encompassed a total of 300 patients, with 155 patients assigned to the first group receiving electrocautery and 145 patients assigned to the second group receiving harmonic treatment. Intraoperative hemorrhage was observed in a total of 32 cases within the initial group, while the subsequent group exhibited 15 cases of intraoperative hemorrhage. A total of 24 patients in the electrocautery group exhibited gallbladder perforation, whereas slipped stone incidents were recorded in 10 patients. In comparison, within the harmonic group, 11 patients experienced gallbladder perforation and 2 patients encountered slipped stone incidents.

Conclusion

The harmonic scalpel has demonstrated notable safety and efficacy as a surgical instrument to dissect the gall bladder and achieve hemostasis during laparoscopic cholecystectomy. If the harmonic scalpel is accessible within the operation theatre, it can serve as a suitable alternative to electrocautery for these specific procedures.

Recommendation

The choice between the Harmonic scalpel and electrocautery should be made on a case-by-case basis, taking into consideration the surgeon's experience, patient factors, and specific clinical requirements.

Keywords: *Harmonic scalpel, Electrocautery, Laparoscopic cholecystectomy*
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Introduction

Laparoscopic cholecystectomy (LC) has been identified as the preferred therapeutic approach compared to conventional open cholecystectomy for the management of uncomplicated acute or chronic cholecystitis and cholelithiasis, thus establishing itself as the universally accepted standard of care [1]. The rationale for its utilization stems from its widely acknowledged minimal invasiveness and accelerated postoperative recuperation. Several surgical instruments have been developed to facilitate the safe, efficient, and meticulous dissection of the gallbladder during laparoscopic cholecystectomy [2].

The primary objective of these advancements is to minimize the occurrence of intraoperative and postoperative complications. Currently, alongside the utilization of electrocautery, a diverse array of ultrasonic scalpels, water jet dissectors, laser systems, and meticulously designed suction devices have been employed [3].

All of the aforementioned medical devices possess the capability to attain comprehensive hemostasis during surgical dissection, albeit with varying levels of efficacy. The conventional laparoscopic cholecystectomy (LC) procedure is commonly performed using a monopolar electrocautery device, typically an electrosurgical hook [4]. This device is primarily utilized to coagulate the

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cystic artery, and cystic duct and dissect the gall bladder from the liver bed. Nevertheless, the utilization of electrocautery in laparoscopic cholecystectomy (LC) may give rise to an abundance of surgical smoke resulting from the cauterization of tissues, potentially compromising the meticulousness of the dissection process [5]. Furthermore, it is imperative to acknowledge that electrocauterization possesses the capacity to elicit iatrogenic detriment to adjacent vasculature and essential anatomical structures, such as the common bile duct and the small intestine, via the manifestation of thermal-related adverse reactions [6]. The scalpel facilitates the simultaneous incision, hemostasis, and disruption of denser tissue through the application of a high-frequency vibration (55,500 Hz). This vibration induces heat production through tissue strain and friction, leading to the degradation of tissue protein
[7]. The utilization of this particular technique effectively limits the amount of energy transferred to the surrounding tissues, consequently reducing the potential for any inadvertent thermal harm to occur. Furthermore, the utilization of a Harmonic scalpel demonstrates a reliable method to effectively occlude and hermetically seal the biliary ducts and vessels measuring 5 mm in diameter, obviating the need for vessel ligation [8]. The findings of various studies have indicated that the utilization of the Harmonic scalpel may offer either statistically significant or clinically restricted benefits when compared to electrocauterization [9-11].
The purpose of this study was to showcase the efficacy and safety of the Harmonic scalpel in achieving thorough dissection and hemostasis. Laparoscopic cholecystectomies compared to traditional electrocautery.

Materials and Methods

Study design

This study is classified as a prospective comparative cohort study.

Study setting

Indira Gandhi Institute of MedicalScience (IGIMS), Patna, Bihar, India, spanning from January 2022 to February 2023.

Participants

The study comprised 300 participants after implementing all the selection criteria. The patients were divided into two groups, with the first group undergoing dissection using electrocautery, while the second group received dissection using a harmonic knife. The randomization procedure was conducted in the following manner: the initial group underwent surgical intervention during months with odd numerical values, while the subsequent group underwent surgical intervention during months with even numerical values.

Inclusion Criteria

The inclusion criteria encompassed patients aged 18 to 70 years with a body weight within the normal range. Additionally, patients classified as ASA 1 or 2 were considered eligible. The surgical procedure of interest was elective cholecystectomy.

Exclusion criteria

The exclusion criteria encompassed individuals with uncontrolled hypertension or diabetes, a prior medical record of upper abdominal surgery, gallbladder wall thickness surpassing 6 mm as ascertained through preoperative ultrasound, and unremarkable biliary passages. Also, patients with comorbidities, IHD, BA, and Others (Autoimmune diseases) were excluded from the study.

Sample size

Patients who underwent laparoscopic cholecystectomy fill the inclusion criteria. For calculating sample size the following formula was used.
$N\Delta = 2(Za+Z1-\beta)2\sigma 2\ 2$
Where, N= sample size, Z is a constant
Za is set by convention according to accepted error of 5% as 1.649 Z1-β is set by convention according to accepted 1-β or power of study of 80% as 0.8416Σ is the standard deviation estimated Δ is a difference in the effect between two interventions (estimated effect size).

Bias

There was a chance that bias would arise when the study first started, but it was avoided by giving all participants identical information and hiding the group allocation from the nurses who collected the data.

Data collection

Data collected during the operation included duration of dissection, intra-operative complications related to bleeding, severity of bleeding, biliary complications, management strategies, resolution time, and conversion measures.

Operation Procedure

The patient underwent operative procedures while under general anesthesia and was positioned in the standard supine, right tilt, reverse-Trendelenburg position. The establishment of CO2 pneumoperitoneum was accomplished through the utilization of either the Veress needle technique or the open method. The dissection of the gallbladder was commenced at the anatomical landmark known as the triangle of Calot's. Subsequently, the cystic duct was identified, dissected, and then divided following the application of two clips. In the first group, the artery was either clipped or cauterized, while in the second group, it was either clipped or divided using a harmonic scalpel.
The gallbladder was mobilized from its position adjacent to the liver and subsequently extracted through either the

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umbilicus or epigastric incision. The duration required for the comprehensive dissection and achievement of hemostasis commenced with the meticulous separation of Calot's triangle, followed by the meticulous control of the cystic duct and artery, culminating in the complete excision of the gall bladder from its anatomical position. The attainment of complete hemostasis was duly documented.

The average duration was computed, and any intra-operative complications related to bleeding were documented, including the specific site (such as a cystic artery, gallbladder bed, or other location), severity (ranging from minor to major or extensive), and the methods employed to manage these complications. The severity of bleeding was categorized based on the subsequent criteria: minor bleeding refers to bleeding that required only one interventional step for cessation, without the need for additional instrumentation or equipment modification. Major bleeding, on the other hand, denotes bleeding that necessitates multiple steps for control, or further instrumentation or equipment alteration.

Lastly, extensive bleeding signifies bleeding that requires conversion measures to manage effectively. Biliary complications, including gallbladder perforation, slipped stones, and common bile duct injury, were documented along with their respective management strategies and the required time for resolution. The conversion was recorded alongside its appropriate indicator. Both groups' data underwent comparative analysis using the Chi-square and Fisher Exact tests.

Statistical tools employed

To analyze the data following statistical methods were employed.

Frequencies

The Frequencies procedure provides statistics and graphical displays that are useful for describing many types of variables.

Independent-samples T-test

The Independent-Samples T Test procedure compares means for two groups of cases. Ideally, for this test, the subjects should be randomly assigned to two groups, so that any difference in observation is due to the intervention (or lack of intervention) and not to other factors.

Mean

To obtain the mean, the individual observations were first added together and then divided by the number of observations. The operation of adding together or summation is denoted by the sign$\bar{X}$.

If the individual observation is denoted by the sign X, the total number of observations denoted by n, and the mean by X, then $\bar{X} = \Sigma X / n$

Standard Deviation

SD is denoted by the Greekσ. If the sample size is more than 30

then, $\sigma = \sum 8-8^{-} 2$

$n-1$

When the sample set is smaller than 30 then

$\sigma =$

n

Chi-square test

$\sum$

$= \quad O-E\ 2$

E

Where O = Observed frequency, E = Expected frequency

ANOVA test

Analysis of variance (ANOVA) is a collection of statistical models used to analyze the difference between group means and their associated procedures (such as variation among and between groups).In an ANOVA setting, the observed variance in a particular variable is partitioned into components attributable to different sources of variation. In its simple form, ANOVA provides a statistical test of whether or not the means of several groups are equal and therefore generalizes the t-test to more than two groups.

For this reason, ANOVA is useful in comparing three or more means for statistical significance.

Probability value

"p" is the level of significance of an occurrence of an event. Probability value is a measure of how much evidence we have gained against the null hypothesis i.e., the likelihood of occurrence of an event, expressed as a number between 0 and 1. In the present study, a probability value of **≤0.05** is taken as a limit to define a value whether statistically significant or not. All the analysis was done by **Windostat version 9.2**.

Ethical considerations

The study protocol was approved by the IGIMS Ethics Committee and written informed consent was received from all the participants.

Results

Out of 306 initial participants, 300 were eligible and divided into two groups for the study. Reasons for exclusion included medical conditions like hypertension, prior surgeries, abnormal gallbladder walls, unremarkable biliary passages, and comorbidities.

The study encompassed a cohort of 300 patients, consisting of 202 females and 98 males. A total of 155 patients were assigned to the first group, which underwent the electrocautery procedure, while the second group consisted of 145 patients who underwent the harmonic procedure. The patient cohort consisted of individuals aged between 18 to 70 years. The first group exhibited a

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median age of 33 years, while the second group had a median age of 34 years. The duration of dissection and hemostasis, which involved the dissection of Calot's triangle, clipping of the cystic duct, and management of the cystic artery, ranged from 6 to 30 minutes in both study groups. In the initial cohort, the average duration recorded was 15.7 minutes, whereas in the subsequent cohort, the average duration was 14 minutes (Table 1).

Table 1. The duration of the dissection and hemostasis operations was evaluated in both experimental groups

Time (minutes)	Electrocautery No. (n=155)	Harmonic No. (n=145)
≤ 10	20	33
11-15	48	55
16-20	37	23
21-25	30	18
26-30	20	16
Total	155	145

The cystic duct, in both cohorts, was transected. In the initial group, the cystic artery was subjected to cauterization in 110 patients and clipping in 59 patients, as per the surgeon's discretion. Conversely, in the subsequent group, the cystic artery was incised using a harmonic knife in 85 patients and clipped in 55 patients. Intraoperative hemorrhage was observed in 32 patients within the first group and in 15 patients within the second group.

Minor bleeding in the first group was addressed by applying a single touch of an electrocautery hook. In contrast, within the second group, the minimal bleeding was successfully managed by utilizing a single application of a harmonic scalpel. It is worth mentioning that a statistically significant difference in the duration needed to manage the bleeding was not observed between the two groups. A cohort of 12 individuals within the initial sample exhibited notable hemorrhagic episodes. Among these patients, 8 required the application of clips to address the source of the bleeding, while 2 necessitated suturing. Additionally, 3 patients required multiple instances of cauterization to effectively manage their bleeding.

Three patients in the second group experienced significant hemorrhaging, with one requiring the application of a clip to stop the bleeding, suturing in another case, and many uses of the harmonic instrument in one. In the first group, severe bleeding occurred in 9 patients at the cystic artery and in 3 patients at the gallbladder bed. Within the second group, two patients experienced significant hemorrhaging originating from the cystic artery, while one patient experienced bleeding from the gallbladder bed. One patient in the first group experienced significant bleeding that required conversion, but no patients in the second group experiencedsuch hemorrhage. (Table 2).

Table 2. A comparative study based on the type of bleeding in both groups

Type of bleeding	Electrocautery No.	Harmonic No.
Minor	18	14
Major	12	3
Extensive	1	0
No bleeding	124	128
Total	155	145

Gallbladder perforation, together with stone slippage, was treated by employing suction, clipping the perforated site, removing the stones, and irrigating the gallbladder bed with saline solution. No statistically significant disparity was detected in the procedural strategies or time required to handle this problem between the two groups.

In harmonic scalpel surgery, the hospital stay was significantly shorter compared to electrocautery. The complications that occurred postoperatively were pulmonary and nausea. The difference in the occurrence of the postoperative complication was not significant.

Conversion occurred in three patients, with two patients from the initial group necessitating conversion due to significant adhesions in one patient and considerable bleeding in another patient. The single patient remaining in the second group needed conversion because of

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abnormal anatomical structures near Calot's triangle, which were caused by dense adhesions.

Discussion

The study comprised a cohort of 300 patients, predominantly females (202) compared to males (98), with a median age of 33 years in the first group and 34 years in the second group. The duration of dissection and hemostasis ranged from 6 to 30 minutes in both groups, with an average duration of 15.7 minutes in the initial cohort and 14 minutes in the subsequent cohort.

Intraoperative hemorrhage occurred in 32 patients in the first group and 15 patients in the second group, with no statistically significant difference in the time required to manage bleeding between the two groups. Minor bleeding was managed with electrocautery in the first group and a harmonic scalpel in the second group. Severe bleeding occurred in 9 patients in the first group and 3 patients in the second group, with one patient in the first group requiring conversion.

Gallbladder perforation and stone slippage were treated similarly in both groups, with no significant differences in procedural strategies or time required. Harmonic scalpel surgery was associated with shorter hospital stays compared to electrocautery. Postoperative complications were pulmonary and nausea, with no significant difference in occurrence between the groups. Conversion occurred in three patients, primarily due to adhesions or abnormal anatomical structures near Calot's triangle.

It has been determined that the Harmonic scalpel serves as a viable and secure substitute for monopolar electrocautery in the management of hepatobiliary stasis during laparoscopic cholecystectomy (LC). The age range of interest is between 18 to 70 years old. One notable benefit of employing the Harmonic scalpel in laparoscopic cholecystectomy (LC) as opposed to conventional monopolar electrocautery is the notable decrease in surgical duration. The utilization of the Harmonic scalpel has been found to facilitate the dissection and coagulation of cystic arteries and ducts measuring between 4 and 5 mm in diameter. As a result, the utilization of the Harmonic scalpel has demonstrated a notable reduction in surgical duration [9].

The safety of laparoscopic cholecystectomy (LC) employing conventional monopolar electrocautery has been extensively documented in medical literature. Nevertheless, it is imperative to acknowledge that this technique may, on occasion, result in iatrogenic injuries, encompassing postoperative hemorrhage, injury to the bile duct, and perforation of the bowel. These injuries primarily occur due to the collateral energy generated during electrocauterization, which differs significantly from the minimal energy transfer observed with ultrasonic vibration [10]. Based on previous research findings [9-12], the utilization of the Harmonic scalpel has been potentially linked to a decreased likelihood of requiring conversion to an open procedure and a lower incidence of surgical complications in comparison to conventional electrocautery.

Nevertheless, the diminished risk observed in these studies did not reach statistical or clinical significance. The age range of interest in this study was 18 to 70 years. The results of our investigation have confirmed that the use of classic monopolar electrocautery does not significantly increase the chances of conversion and surgical complications when compared to the Harmonic scalpel. The conversion of laparoscopic cholecystectomy (LC) to laparotomy and the occurrence of other surgical complications are primarily influenced by various determinants [11]. The aforementioned determinants encompass various challenges that may arise during laparoscopic dissection or gallbladder perforation. These challenges include adhesion-related complications, unmanageable hemorrhaging, bile leakage, undetected coexisting bile duct stones, and the presence of gallbladder cancer, which may be identified during preoperative evaluation. Furthermore, the presence of concurrent medical or surgical conditions may also serve as a contributing factor to the development of these complications. Therefore, the utilization of the Harmonic scalpel or monopolar electrocautery demonstrates negligible influence on conversion rates or surgical morbidity, given that the aforementioned confounding or complicating factors are appropriately managed or eradicated, as demonstrated in our of uncomplicated patients undergoing laparoscopic cholecystectomy [13]. Nevertheless, the utilization of the Harmonic scalpel exhibited the utmost force required for the rupture of the cystic duct. The aforementioned complication was noted in a case involving choledochal injury, necessitating subsequent conversion to laparotomy within our experimental cohort. The etiology of this condition can be attributed to a procedural error in the intraoperative identification of an anatomical anomaly within the biliary system. Moreover, the utilization of the Harmonic scalpel, which is distinguished by its restricted precision in executing intricate dissections due to the unwieldy nature of its tip and challenges in maneuvering through the tissue plane with a straight tip, presents inherent hazards [14].

Generalizability

The study findings provide valuable insights into the outcomes and comparative effectiveness of electrocautery versus harmonic knife techniques in laparoscopic cholecystectomy procedures. The cohort of 300 patients, although specific to the study's setting and demographics, offers a foundation for understanding potential trends and outcomes that may apply to a broader population undergoing similar procedures. The findings regarding operative duration, intraoperative hemorrhage management, postoperative complications, and conversion rates provide valuable data that can be extrapolated to inform clinical practice and decision-making in similar healthcare settings worldwide. However, it's important to consider potential variations in patient demographics, surgical expertise, and healthcare

infrastructure when generalizing the findings to a larger population. Further research and validation across diverse populations and settings would enhance the generalizability and applicability of the study findings.

Limitations

The randomization process was conducted centrally utilizing a standardized procedure. The acquisition and assessment of patient data were conducted by research personnel who maintained impartiality and were not engaged in the allocation procedure. The potential underestimation of an added advantage associated with the utilization of the Harmonic scalpel in laparoscopic cholecystectomy (LC) should be duly acknowledged, especially in patients presenting with concurrent medical conditions, such as cirrhosis. It is worth noting that the present study did not include individuals with such comorbidities, as the majority of patients scheduled for LC were free from any coexisting medical conditions.

Conclusion

The utilization of the harmonic device exhibited improved results, effectively alleviating concerns associated with electrocautery trauma and thus augmenting the safety of laparoscopic cholecystectomy.

Recommendation

Both ultrasonic and monopolar electro-surgery instruments have transitioned into reusable forms, thereby complicating the process of cost comparisons. Henceforth, it is strongly advocated that additional comparative investigations be conducted, ideally within a singular healthcare system or even within a solitary healthcare institution.

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List of abbreviations

ASA - American Score of Anesthesia LC- laparoscopic cholecystectomy Hz- Hertz **Source of funding**

The authors do not have any affiliations or financial ties to any organization or institution that has a financial interest or conflict of interest with the subject matter or materials covered in the article. This encompasses several forms of financial involvement, such as consultancies, employment, honoraria, expert testimony, patents received or pending, and royalties. This text was produced without the use of any literary assistance.

Conflict of interest

No conflict of interest was noticed during the study.

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