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A Prospective Single Centre Observational Study on Energy Devices in Colorectal Surgery

(Проспективное одноцентровое наблюдательное исследование энергетических устройств в колоректальной хирургии)

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ABSTRACT *BACKGROUND: Advances in colorectal surgery include energy devices for precise dissection and hemostasis. This observational study evaluates the ultrasonic scalpel and electrocautery in colorectal surgeries, analyzing intra- and postoperative parameters to inform decisions and best practices.*
METHODS: Prospective observational study at a tertiary center (12/19/2022–09/30/2024). Data collected and analyzed with SPSS 23.
RESULTS: Comparable groups in baseline characteristics. There were no significant differences in operative time, intraoperative bleeding, postoperative drainage (48h), or hospital stay between the ultrasonic scalpel and electrocautery.
CONCLUSION: The ultrasonic scalpel and electrocautery are valuable tools for dissection and hemostasis in colorectal surgery, crucial for effective and safe minimally invasive approaches. Long-term effects should be determined. Study approved (IEC2:474/2022) and registered (CTRI/2022/12/048254).

KEYWORDS: *harmonic, electrosurgery, colorectal, monopolar*

LIMITATIONS: *this was a single center study with limited sample size and unequal distribution between the two groups. There was no follow up of the patients. Further studies to determine the cost benefit and long-term effects of various energy devices are required.*

CONFLICT OF INTEREST: *all the others declare that they have gone through the manuscript and have no conflict of interest.*

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CONSENT TO PARTICIPATE: *all the individuals included in the study have been explained about the study -the aims, objectives, methodology- in the best possible way in a language that they understand and have consented to the same.*

HUMAN ETHICS AND PARTICIPATION CONSENT: *the study has been carried as per the Declaration of Helsinki and has been scrutinized and approved at multiple levels by the institutional ethics committee — IEC2:474/2022 and has been registered with the Clinical Trails Registry of India CTRI/2022/12/048254*

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INTRODUCTION

Understanding the anatomy and development of the large intestine is essential for comprehending the pathophysiology of various colorectal diseases and for performing surgical interventions. Colorectal surgeries often require the resection of parts of the colon or rectum and the creation of an anastomosis to restore bowel continuity. The choice between laparoscopic and conventional surgical approaches depends on multiple factors, including the surgeon's experience and the patient's specific condition.

Advancements in surgical techniques, particularly the use of energy devices, have revolutionized colorectal surgeries. Electrosurgery, employing high-frequency electrical current, and ultrasonic devices,

which utilize mechanical energy, offer precise tissue dissection and effective hemostasis. Monopolar and bipolar electrocautery, along with advanced systems like the Radiofrequency Vessel Sealing System and Ultrasonic Scalpel, have enhanced the safety and efficiency of these procedures.

The advent of advanced energy devices, such as the Ultrasonic Scalpel and electrocautery, has significantly enhanced the precision and effectiveness of these surgical procedures. These devices offer distinct advantages in tissue dissection and hemostasis, crucial for minimizing intraoperative blood loss and reducing postoperative complications.

The Ultrasonic Scalpel utilizes ultrasonic energy to simultaneously cut and coagulate tissues, providing a unique blend of mechanical and thermal energy that results in precise tissue handling with minimal lateral thermal damage. In contrast, electrocautery, which can be used in monopolar or bipolar modes, employs high-frequency electrical currents to achieve tissue dissection and hemostasis through controlled thermal effects. Both technologies have become integral to modern surgical practice, yet their comparative efficacy and safety in colorectal surgeries remain areas of active investigation.

This observational study aims to evaluate the use of the Ultrasonic Scalpel and electrocautery in colorectal surgeries, focusing on various intraoperative and postoperative parameters. By examining factors such as operative time, blood loss, complication rates, and overall patient outcomes, the study seeks to provide a comprehensive assessment of these energy devices in clinical practice. Through this analysis, the study intends to offer valuable insights into the advantages and limitations of each device, thereby informing surgical decision-making and potentially guiding the development of best practices in colorectal surgery.

Many prospective studies have been done in recent times to assess the outcomes of surgeries using different energy devices. Short-term outcomes of energy devices like the Radiofrequency scalpel and Ultrasonic Scalpel have been observed to be better than conventional electrosurgery. Certain authors have found that the use of Radiofrequency scalpel during laparoscopic colorectal surgery results in shorter surgical times and reduced blood loss compared to the use of ultrasonic coagulating shears (UCS). In contrast, a recent study showed that during laparoscopic colorectal surgery, there were no appreciable variations in the short-term results between UCS and Radiofrequency scalpel. Ultimately, the choice of device used must be as per the surgeon's preference [1].

In a study by Campagnacci et al. in 2007 (Italy), electrothermal bipolar vessel sealing (EBVS) and UCS were compared in laparoscopic colectomies. Right colectomy, left colectomy, and low anterior resections were the surgeries performed. No statistically significant differences in the mean duration of surgery or in the mean post-operative stay were observed among the two groups. However, there were differences in the mean blood loss for each of the surgeries for the two groups [1,2].

In a study by Takada et al. in 2005 (Japan), 30 patients were included who underwent transverse colectomy and sigmoidectomy by laparoscopic method for malignancy. Either the EBVS (Radiofrequency scalpel) or UCS (Ultrasonic Scalpel) were used during the surgery. These devices were used in dissection of the mesocolon. For both surgical procedures, rebleeding was considerably reduced for the group in which EBVS was used compared to the group in which UCS was used. When EBVS was utilized during either of the procedures, the amount of time needed for mesocolon dissection was also significantly reduced [2,3].

These results were associated with a decrease in blood loss during surgery, which was statistically significant. The conventional group experienced a higher rate of conversion to other methods. There were no significant differences in immediate outcomes, like morbidity, mortality and hospital stay. The cost analysis was similar between the three groups [2,4].

In summary, this study endeavors to contribute to the growing body of knowledge on energy devices in surgery, with the goal of enhancing surgical efficacy and patient safety in the management of colorectal diseases.

AIM AND OBJECTIVES

- To assess the outcome of various energy sources like ultrasonic scalpel and electrocautery in colorectal surgeries
- To measure the operative time, intraoperative blood loss, drain output and hospital stay

METHODOLOGY

The current study is a prospective, single-center, observational study conducted in the department of General Surgery. The study period extends from 19.12.2022 to 30.09.2024. The number of participants included in the study is 68. Approval was sought from the Institutional Ethics Committee and patients were

Table 1. *Distribution of operative variables among the two groups in the study*

Variables		Device Used			
		Electrocautery		Ultrasonic Scalpel	
		n	%	n	%
Approach	Open	11	35.5%	18	48.6%
	Laparoscopy	20	64.5%	19	51.4%
Incision/Ports	4 ports + minilaparotomy	1	3.2%	1	2.7%
	5 ports	6	19.4%	2	5.4%
	5 ports + minilaparotomy	13	41.9%	16	43.2%
	Midline vertical	11	35.5%	18	48.6%
Procedure	Anterior resection	17	54.8%	14	37.8%
	Right hemicolectomy	12	38.7%	17	45.9%
	Sigmoid colectomy	2	6.5%	3	8.1%
	Left hemicolectomy	0	0.0%	2	5.4%
	Left hemicolectomy + sigmoid colectomy	0	0.0%	1	2.7%
Type of anastomosis	End to End	18	58.1%	17	45.9%
	Side to Side	13	41.9%	20	54.1%
Technique of anastomosis	Hand-sewn	7	22.6%	9	24.3%
	Stapler	24	77.4%	28	75.7%
Skin closure	Staples	27	87.1%	25	67.6%
	Sutures	4	12.9%	12	32.4%
Stoma	Yes	3	9.7%	6	16.2%
	No	28	90.3%	31	83.8%

recruited according to the inclusion and exclusion criteria. A participant information sheet was handed over and informed consent was taken. Data was collected using a proforma.

This study included patients above the age of 18 years, undergoing elective colorectal surgery for various benign and malignant pathologies. It included both an open and laparoscopic approach. Any patient with unsatisfactory data was excluded from the study.

The outcomes were measured in terms of the following parameters

- Operative time in minutes (time of skin incision to skin closure)
- Intra-operative blood loss in milliliters (gauze + mop + suction volume)
- Post-operative drain volume for the first 48 hours in milliliters
- Duration of hospital stay in days (day of surgery to the day of discharge)

The collected data was entered into an Excel sheet and was analyzed using SPSS version 23. Categorical data was summarised by frequency and percentages. Quantitative data was summarised by mean, standard deviation. Comparison of categorical data between the groups was performed by Chi square test and Fishers exact test. Mann-Whitney U test was done to check if the two groups (Electrocautery and Ultrasonic Scalpel) differ significantly or not with respect to the four outcome variables.

RESULTS

In the current study, 68 patients were grouped into the electrocautery (EC) group and the ultrasonic scalpel (US) group, based on the energy device used during the surgery. The EC group consisted of 31 (45.6%) patients and the US group had 37 (54.4%) patients.

The baseline characteristics were comparable between the two groups. This study included 41 (60.3%) males and 27 (39.7%) females. The mean age in the study was 59.81 + /-14.56 years. Most of the patients were in the age group of 61–70 years (30.9%). The most common presenting complaint was pain abdomen (44.1%) followed by bleeding per rectum (30.9%). Diabetes mellitus and hypertension were the common comorbidities among the patients.

Operative characteristics were similar between the two groups as shown in Table 1. Surgical approach was open in 29 (42.6%) and laparoscopic in 39 (57.6%) cases. In open surgeries, midline vertical was the most common incision used. In laparoscopic surgeries, a hybrid approach with three to five ports along with a minilaparotomy incision was used in most of the patients.

This study included colorectal surgeries like right hemicolectomy (RH), left hemicolectomy (LH), sigmoid colectomy (SC) and anterior resection (AR). Among these, 31 (45.6%) procedures were AR, which was the most performed procedure followed by RH, which was 27 (39.7%).

Following resection, anastomosis was performed between the proximal and distal ends of the bowel.

Table 2. *Distribution of outcome variables among the two groups in the study (mean)*

Variables	Electrocautery		Ultrasonic Scalpel		Unpaired t test P value
	Mean	SD	Mean	SD	
Duration of surgery (minutes)	270.8	95.5	280.7	101.5	0.683
Intra-operative blood loss (ml)	219.4	150.4	275.4	265.4	0.301
Drain output (ml)	148.1	63.9	149.0	51.0	0.947
Duration of stay (days)	7.2	1.9	7.6	3.1	0.500
Duration of ICU stay (days)	2.0	0.0	3.6	3.4	0.681
Hb change	.15	1.33	.61	1.45	0.179

The type of anastomosis performed was either end to end in 35 (51.5%) or side to side in 33 (48.5%). The technique used for anastomosis was either hand-sewn in 16 (23.5%) or stapler in 52 (76.5%). Among the laparoscopic procedures, 28 (71.8%) of the anastomosis were extracorporeal, while 11 (28.2%) were intracorporeal. Skin closure was done using staples in 52 (76.5%) of the surgeries and sutures in 16 (23.5%). A diversion stoma was created in 9 (13.2%) of the procedures, out of which, all of them were loop ileostomies. Malignancy of the colon and rectum was the most common indication for which surgery was performed. Only 6 (8.8%) surgeries were performed for benign pathology. The most common malignant histopathology was adenocarcinoma, seen in 56 (82.4%) cases. Other conditions seen were non-Hodgkins's lymphoma (Diffuse large B-cell lymphoma) and neuroendocrine tumor.

The outcomes studied were the duration of the surgery (minutes), drain output in the first 48 hours (mL), duration of hospital stay (days) and duration of ICU stay (days) as shown in Table 2. The mean duration of surgery, as plotted in Figure 1, the EC group was 270.8 ± 95.5 minutes and in the US group it was 280.7 ± 101.5 minutes. Figure 2 shows the mean blood loss in the EC group was 219.4 ± 150.4 mL and in the US group it was 275.4 ± 265.4 mL. The mean value of the drain output in the first 48 hours was 148.1 ± 63.9 mL in the EC group. In the US group, it was 149 ± 51 mL, the same has been depicted in Figure 3. The mean duration of hospital stay in the EC group was 7.2 ± 1.9 days and in the US group it was 7.6 ± 3.1 days and the same is evident from Figure 4. In our study, there was no statistically significant difference between the two groups with respect to the above parameters.

DISCUSSION

Table 3 shows the comparison between our study and other similar studies carried out at a national and international level. It depicts the energy devices studied, and the outcome parameters observed in each group.

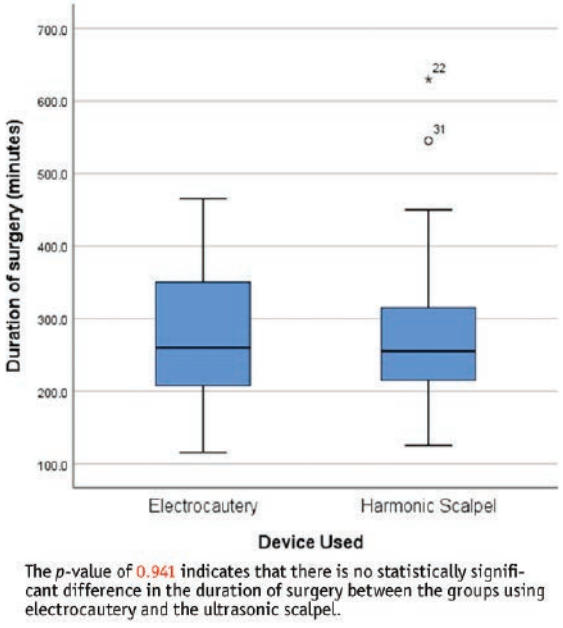

Figure 1. *Box plot for duration of surgery between the two groups.*

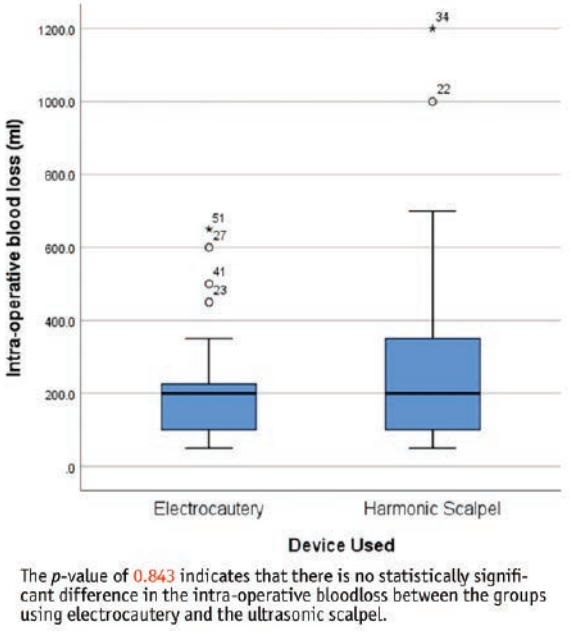

Figure 2. *Box plot for intra-operative blood loss between the two groups.*

Table 3. *Comparison of similar studies*

Study	Kalari et al. RCT		Sista et al. RCT		Rimonda et al. RCT		Current study	
Study setting / Study period	Pune 2022		Italy 2013		Italy 2009		2022	
Sample size	50		211		140		68	
Procedure	RH, LH, AR, APR		RH		Laparoscopic RH, LH, AR		RH, LH, AR, SC	
Energy source	Bipolar (25)	Ultrasonic scalpel (25)	NUS (108)	CH (103)	Ultracision (70)	LigaSure (70)	EC (31)	US (37)
Operative time (minutes)	175.6 ± 27.4	137 ± 26.7	103 ± 21	131 ± 27	114.8 ± 47.6	116.3 ± 44.0	270.8 ± 95.5	280.7 ± 101.5
Blood loss (ml)	271.8 ± 80.6	184 ± 68.1	NA	NA	107.9 ± 42.0	111.2 ± 51.5	219.4 ± 150.4	275.4 ± 265.4
Duration of hospital stay (days)	12.3 ± 2.6	9.7 ± 2.2	8	11	7.4 ± 2.2	6.9 ± 3.3	7.2 ± 1.9	7.6 ± 3.1
Drain output (ml)	NA	NA	D1:125 ± 40 D2:70 ± 30	D1:155 ± 50 D2:110 ± 35	NA	NA	148.7 ± 63.9	149 ± 51

Studies conducted by Kalari et al. and Rimonda et al. also included the same range of procedures. In Kalari et al., AR was the most common procedure performed, which is like our study [5,7]. Sista et al. included only patients undergoing RH as the surgical steps allowed comparison between the energy devices in terms of their ability to cut, coagulation and speed of tissue dissection [5].

In our study the surgical procedures were performed by multiple surgeons with different levels of experience. In studies conducted by Sista et al. and Rimonda et al., the surgical procedures were standardized and performed by designated surgeons [5,6].

The study by Kalari et al. included patients with proven malignancy of the colon and rectum, whereas Sista el at included patients with the right colon malignancy. The surgical procedure was performed in accordance with oncological principles. This maintained uniformity in the technique of the procedure. Kalari et al., also included a two-year follow-up period to look for recurrence. Our study included colorectal diseases of benign and malignant pathology and there was no follow-up period [6,7].

Drain output was not considered in studies by Rimonda et al. and Kalari et al. Blood loss was not considered in the study by Sista et al.

A study conducted by Sista et al., in Italy in 2013, with a sample size of 211 was a prospective randomized controlled double-blind study. Patients who underwent hemicolectomy, open surgery for cancer of the right colon (carcinomas of the cecum, ascending colon, hepatic flexure or transverse colon) were included in the study.

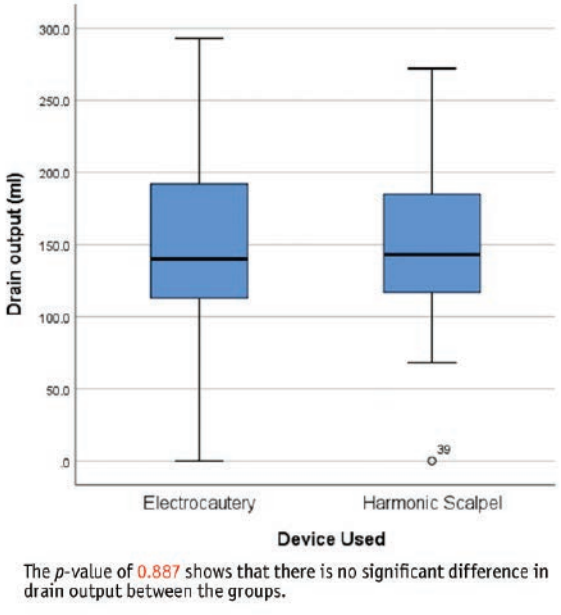

Figure 3. *Box plot for drain output between the two groups.*

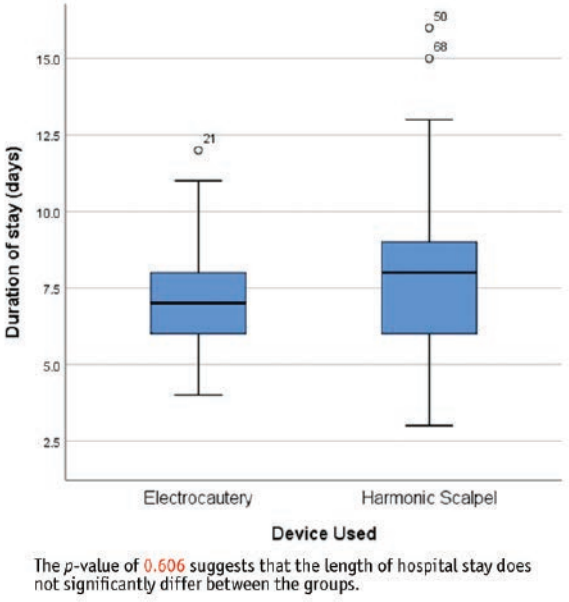

Figure 4. *Box plot for duration of hospital stay between the two groups.*

This study compared outcomes between the New Ultrasonic Scalpel (NUS) and Conventional Hemostasis (CH) [5].

NUS refers to a new US handpiece (NUS; FOCUS Long Curved Shears, Ethicon Endo-Surgery Inc., Cincinnati, Ohio, USA), with a tip smaller than 5 mm, that has been available since 2009 [5].

These patients were randomized into two groups based on the energy device used. The NUS group included 108 patients, and the CH group had 103 patients. A group of four consultant surgeons with training in colorectal cancer resections carried out all surgical procedures in an open surgical setting. The two surgical groups were compared regarding patients' age (mean age 64 years) and sex (113 men, 98 women), tumor size, location, histotype and local invasiveness assessed by American Joint Cancer Committee stage [5].

The parameters that were studied included: operative time, drainage volume (first 1–3 days after surgery), hospital stay and complications as primary outcomes; serum albumin on post-operative days 1, 2, 3, 6 and C-reactive protein (CRP) on post-operative days 1, 2, 3, 6 as secondary outcomes. Post-operative serum albumin concentration was measured to detect protein depletion due to lymphorrhea. CRP concentration was utilized as an indicator of inflammation, which frequently serves as an indirect cause of hypoalbuminemia [5].

It was observed that the use of the NUS resulted in a decrease in the operative time, post-operative drainage volume and overall hospital stay. All these differences were statistically significant between the two groups. It was also noted that there is a significant decrease in albumin levels on post-operative days 1, 2, 3 in the CH group compared to the NUS group [5].

In summary, the NUS is a helpful tool for colon surgery because it makes surgical procedures easier, cuts down on operating times, blood, and lymphatic losses, and enables adequate protein storage maintenance. Patients recover more quickly as a result, and complications are less common [5].

Another similar study was conducted by Rimonda et al., in Italy in 2009. This was a prospective randomized controlled double-blind study with a sample size of 140 patients (70 in each group). It included patients undergoing laparoscopic right hemicolectomy (RH), left hemicolectomy (LH), and anterior resection (AR). The comparison was between the ultrasonically activated scalpel versus the Radiofrequency scalpel vessel sealing system. The primary end point of the study was intraoperative reduction of blood loss. The secondary end points were intra and postoperative morbidity and operative time [6].

The procedures performed were standardized before starting the protocol. Two experienced surgeons, each with experience of more than 400 laparoscopic colorectal surgeries, performed the procedures for the study [6].

The overall intraoperative blood loss and operative time were similar in the two groups. The overall postoperative complications rate was 10.7%, which was similar in the two groups. This study concluded that there was no significant advantage of the use of the Radiofrequency scalpel device when compared with the ultrasonic scalpel device in laparoscopic colorectal surgery [6].

Since the two devices have different features, their resemblance does not affect the equivalency of the results. While Radiofrequency scalpel has superior hemostatic power, ultrasonic scalpel helps with the dissection phase. The choice of energy device should be according to individual preference [6].

Recently, a similar study was conducted in a tertiary hospital in India by Kalari et al. This study aimed to compare the use of bipolar electrocautery and ultrasonic scalpels in colorectal surgeries. In this study patients with proven colorectal malignancy of stages I and II were included. 50 patients were divided equally into two groups by block randomization, and bipolar electrocautery was used in one group, and ultrasonic scalpel was used in the second group during surgery [7].

Surgical procedures performed included RH, LH, AR, and abdominoperineal resection (APR) based on site, extent, and stage of the tumour. The patients were followed up at regular intervals of three months. This continued to two years to check for any recurrence and stoma complications [7].

The parameters studied were the mean operative time, blood loss, and hospital stay. The ultrasonic scalpel group had a lower mean operating time, which was statistically significant. The mean blood loss in the ultrasonic scalpel group was statistically lower than in the electrocautery group. The hospital stay was longer in the electrocautery group and was statistically significant [7].

This study concluded that the ultrasonic scalpel is an invaluable instrument in colorectal surgery. In terms of operative time, blood loss, and length of hospital stay, the ultrasonic scalpel performed better than the bipolar electrocautery during colorectal cancer surgeries.

CONCLUSION

There is no statistical significance in the outcomes between the two groups. Ultrasonicscalpel as well as electrocautery are valuable tools in colorectal surgeries with respect to tissue dissection and haemostasis and are indispensable tools in the operating theatre.

The use of these devices has made minimally invasive approaches efficacious and safe in complex colorectal surgeries. The long-term effects of these devices on the disease process and outcomes are yet to be determined. Newer energy devices that combine the benefits are available; but the evidence of their superiority is yet to be proved.

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