

Randomized Trial to Compare Hemorrhoidectomy Performed Using Harmonic Scalpel versus Conventional Electrocautery**Sanchit Jain¹, Ajay Singh Kalyanwat², Mahesh Kumar Mangal³, Dhiraj Daga⁴**¹Associate Professor, Department of General Surgery, RUHS College of Medical Sciences, Jaipur (Rajasthan)²Associate Professor, Department of General Surgery, RUHS College of Medical Sciences, Jaipur (Rajasthan)³Senior Professor, Department of General Surgery, RUHS College of Medical Sciences, Jaipur (Rajasthan)⁴Assistant Professor, Department of Radiation Oncology, JLN Medical College, Ajmer (Rajasthan)

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Abstract**Introduction:** Internal hemorrhoids are classified on the basis of degree of prolapse and manifestation into Grade I-IV. Hemorrhoidectomy is the standard surgical treatment for Grade III and IV hemorrhoids. The study was done to compare hemorrhoidectomy performed using electrocautery with harmonic scalpel.**Material and Methods:** The study was double blind randomized trial conducted in the Department of General Surgery, Government RDBP Jaipuria Hospital from January, 2023 to September, 2023. Patients with Grade 3 and Grade 4 hemorrhoids above 18 years of age were randomly divided into two groups to undergo Milligan Morgan hemorrhoidectomy using either electrocautery or harmonic scalpel. Intraoperative and postoperative variables were evaluated in both groups.**Result:** There were 30 patients in each group. There was no significant difference in the two groups with regard to grade of hemorrhoids, sex or age. Significant difference in groups was noted in terms of intraoperative and postoperative bleeding and average postoperative pain score with result being better in harmonic scalpel group.**Conclusion:** Hemorrhoidectomy performed using harmonic scalpel is a safe and effective treatment for Grade III and Grade IV hemorrhoids. Harmonic use reduces the operative time, the postoperative blood loss and most importantly, postoperative pain in comparison to conventional electrocautery based hemorrhoidectomy.**Keywords:** Hemorrhoids, Hemorrhoidectomy, Harmonic scalpel, Electrocautery.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

Hemorrhoids are normal anatomic clusters of vascular tissue, smooth muscle, and connective tissue that lie along the anal canal in 3 columns, forming the anal cushions [1]. Hemorrhoids occur when the supporting connective tissues of the anal cushions deteriorate and slides downward, causing venous dilatation and the overlying mucosa becomes thin and friable leading to painless bright bleeding per rectum [2].

Hemorrhoids are classified as internal and external variety based on their location in reference to dentate line. This differentiation is important as the treatment of internal and external hemorrhoids is entirely different. Internal hemorrhoids are further graded from I-IV based on their degree of prolapse and manifestation [3]. For early Grade I and Grade II hemorrhoids, conservative medical treatment is recommended, however, late stage Grade III and

Grade IV hemorrhoids require surgical treatment [4]. Hemorrhoidectomy is the most effective surgical treatment for prolapsed hemorrhoids and is associated with the lowest recurrence rate; about 10% to 20% require surgical treatment due to symptom severity [5, 6]. Hemorrhoidectomy can be either an open or closed hemorrhoidectomy and it may be performed using scissors, cautery, vessel-sealing devices or harmonic scalpel. However, hemorrhoidectomy is not without complications, which include postoperative pain, urinary retention, and secondary hemorrhage, formation of skin tags, anal stenosis and fecal incontinence [7].

Among these complications the most important is the postoperative pain. Postoperative pain following hemorrhoidectomy is associated with the type of excision device, incision, suturing of anal mucosa and surgical site infection [8].

Hemorrhoidectomy procedures performed with new devices such as bipolar electrothermal devices, ultrasonic scalpels, ligasure scalpels, and circular staplers have reported better pain relief, less bleeding during the surgical procedure and decrease the need for analgesics postoperatively as compared to conventional hemorrhoidectomy [9, 10, 11].

The present study was conducted to analyze and compare the intraoperative and postoperative variables of Milligan-Morgan hemorrhoidectomy performed by ultrasonic harmonic scalpel with the conventional procedure done using electrocautery.

Material & Methods

The study was double blind study conducted prospectively in the Department of General Surgery, Government RDBP Jaipuria Hospital from January, 2023 to September, 2023. The study was conducted with the permission of the Ethical Committee and Research Review Board of the Hospital. The study was performed on patients with Grade 3 and Grade 4 hemorrhoids. The patients were randomly divided into two groups to undergo Milligan Morgan hemorrhoidectomy using either electrocautery or harmonic scalpel.

The patients included in the study were those above 18 years of age and having Grade 3 and Grade 4 hemorrhoids. Patients having associated abscesses, fissures, fistula, thrombosed hemorrhoids, recurrent hemorrhoids, anal stenosis or having any other anorectal pathology were excluded from the study.

After admission, all patients were subjected to detailed clinical history, complete physical examination including digital rectal examination, proctoscopy and all baseline investigations. Informed written consent was obtained from all the patients and details of the study were explained to them.

Preoperatively, night before surgery glycerine enema was given to all patients irrespective of the group. All patients were administered a single prophylactic antibiotic. The surgery was done under saddle anaesthesia and surgery was done with patients in lithotomy position.

Milligan Morgan hemorrhoidectomy was done in all patients, in one group using monopolar cautery and in other group using harmonic scalpel. The patients as well as the assessors were blind as to which patient underwent hemorrhoidectomy using which technique. Intraoperative data including total operative time and the amount of intraoperative blood loss was noted.

Patients were monitored for pulse rate, BP, temperature, respiratory rate, urinary retention, anal bleeding and any other postoperative complication. The postoperative pain was assessed using a Visual

analog scale (VAS) at postoperative hours 6, 12 and 24 h and the same were recorded. VAS scale ranges pain from 0 i.e. no pain to 10 i.e. worst imaginable pain. No antibiotics were given in postoperative period. Intramuscular injection of diclofenac was given as per patient requirement and this was recorded.

All the patients were discharged on the first postoperative day. In addition to stool softeners, hot sitz bath and high fiber diet, oral analgesics were advised. Patients were followed on weekly basis for 3-6 weeks and then further follow up was advised on a need basis.

The data were compiled and entered into a Microsoft Excel and then analysed using SPSS Version 20.0 (SPSS Inc. Chicago, Illinois, USA). Continuous variables were expressed as mean (Standard deviation) and categorical variables were summarized as frequencies and percentages. Student's independent t-test was used for comparing continuous variables. For comparing categorical variables, either the Chi-square test or Fisher's exact test was applied. P value < 0.05 was considered to be statistically significant.

Results

During the study period a total of 60 patients with Grade 3 and Grade 4 hemorrhoids were admitted and were divided into 30 patients in each group. In electrocautery hemorrhoidectomy group, out of 30 patients, 16 had Grade 3 hemorrhoids and 14 patients had Grade 4 hemorrhoids, while in harmonic scalpel hemorrhoidectomy group, 13 had Grade 3 hemorrhoids and 17 patients had Grade 4 hemorrhoids (Table 1).

In the electrocautery hemorrhoidectomy group, 26 patients were male and 4 were females, while as in the harmonic scalpel hemorrhoidectomy group, 23 were male and 7 were female.

The mean age of the patients in electrocautery hemorrhoidectomy group was 45.8 years, while the patients belonging to the harmonic scalpel hemorrhoidectomy group had a mean age of 42.4 years [Table 1]. There was no significant difference in the two groups with regard to grade of hemorrhoids, sex or age, showing that the two groups were well comparable to each other.

Mean operative time for harmonic scalpel hemorrhoidectomy was less than that of electrocautery hemorrhoidectomy, with P-value = 0.1 (statistically insignificant) [Table 2].

Intraoperative bleeding in harmonic scalpel hemorrhoidectomy was also less than that of electrocautery hemorrhoidectomy, which was statistically significant with P-value = 0.02 [Table 2]. Average postoperative VAS score was calculated for each patient using values at 6, 12 and

24 hours postoperatively, after this average for both groups was calculated. The pain score was significantly lower in harmonic hemorrhoidectomy group with P-value = 0.04 [Table 2]. Average analgesic injection (inj. Diclofenac i.m.) requirement was calculated in both the groups. There was no significant difference although the requirement was higher in electrocautery

hemorrhoidectomy group [Table 2]. Incidence of postoperative bleeding was significantly higher in electrocautery hemorrhoidectomy with P-value = 0.04 [Table 2]. In the postoperative period, five patients had urine retention, three in harmonic hemorrhoidectomy and two in electrocautery hemorrhoidectomy. The difference was not significant with P-value = 0.4 [Table 2].

Table 1: Clinical Profile of the Study Groups

Variables		Electrocautery Hemorrhoidectomy	Harmonic Hemorrhoidectomy	P-Value
Hemorrhoid Grade	III	16	13	> 0.05
	IV	14	17	
Sex	Male	26	23	> 0.05
	Female	4	7	
Age		45.8 ± 2.3	42.4 ± 6.7	> 0.05

Table 2: Intraoperative & Postoperative Variables of the Study Groups

Variables	Electrocautery Hemorrhoidectomy	Harmonic Hemorrhoidectomy	P-Value
Duration of surgery (in minutes)	24.3 ± 2.7	21.1 ± 4.5	> 0.05
Intraoperative blood loss (in ml)	30 ± 3	21 ± 4	0.02
Average postoperative VAS Score	6.6	4.1	0.04
Average Analgesic injection requirement	2.3	2.1	> 0.05
Postoperative bleeding	5	2	0.04
Urine retention	4	3	> 0.05

Discussion

Hemorrhoidal disease is one of the most common anorectal diseases and it affects the overall quality of life of the patient. For grade III and IV hemorrhoids the standard treatment of choice is surgical i.e. hemorrhoidectomy. Postoperative pain is the major factor associated with patient satisfaction in anorectal surgeries. Use of newer devices like harmonic scalpel has shown to be effective in reducing postoperative pain, bleeding and other complications. The present study was done to compare the intraoperative and postoperative results of hemorrhoidectomy performed using conventional electrocautery versus harmonic scalpel.

In the study, there were 30 patients in each group. Both the groups were comparable to each other in terms of average age, sex distribution and grade of hemorrhoids. In most studies the no. of males was more than females [2, 12] except the study done by Al-Thoubaity et al [11].

On analysis of duration of surgery, we found that the time taken for hemorrhoidectomy using harmonic scalpel was comparatively less but the difference was not significant. This result is very different to other studies wherein they found statistically significant shorter operative time with harmonic scalpel [2, 9, 11]. Harmonic scalpel due to its simultaneous coagulating and cutting function is associated with decreased blood loss during any

surgical procedure. In the study also, significantly less in harmonic group. This was expected and has also been proven in other studies [13] although most have not found a significant difference in bleeding [2, 12].

Harmonic scalpel use is associated with minimal thermal damage and limited tissue charring which leads to decreased pain and faster recovery [2]. Postoperative pain was calculated using Visual Analogue Scale [VAS] score and average score was calculated in both the groups at 6, 12 and 24 hours postoperatively. The score was significantly lower in the harmonic scalpel group (4.1 vs 6.6). As per the literature reviewed by authors, all studies have found to be associated with significantly lower pain in the harmonic group although the period of evaluation is different in these studies [2, 11, 12, 13].

Average analgesic injection requirement in postoperative period was also calculated which was found to be lower in harmonic group although it was not statistically significant. This result is well comparable with other studies done by Ul-Bari [14] and Ivanov et al [15].

Incidence of postoperative bleeding was found to be significantly lower in harmonic group, simply because of simultaneous coagulating and cutting action of harmonic. This result is again well comparable with other studies [2, 9, 10]. Incidence of urine retention in postoperative period was lower

in harmonic group, although the difference was not significant. This is attributed to lower pain and less local tissue charring seen with harmonic. Almost all studies report lower incidence in harmonic group [10, 11].

Conclusion

In conclusion, hemorrhoidectomy performed using harmonic scalpel is a safe and effective treatment for Grade III and Grade IV hemorrhoids.

Harmonic use reduces the operative time, the postoperative blood loss and most importantly, postoperative pain in comparison to conventional electrocautery based hemorrhoidectomy.

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