

Evaluation the Role of Harmonic Scalpel in Open and Closed Hemorrhoidectomy, Comparative Study

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Introduction: One of the most common symptoms that patients have in any hospital in surgery departments is hemorrhoids. There are several ways of treating them. Many different types of energy devices have recently been used for hemorrhoidectomy to improve intraoperative hemostasis and lessen postoperative pain.

Ain of work: Evaluation of the role of harmonic scalpel versus an open and closed hemorrhoidectomy.

Patients and methods: Twenty patients with hemorrhoids underwent open hemorrhoidectomy without the use of a harmonic scalpel in group 1, twenty patients with hemorrhoids underwent closed hemorrhoidectomy without the use of a harmonic scalpel in group 2, and twenty patients with hemorrhoids underwent hemorrhoidectomy using a harmonic scalpel in group 3. Sixty patients of both genders had investigatory support for hemorrhoids grades 3 or 4 for surgical management. Assessment of intraoperative bleeding was done. The pain we evaluated during the recovery time using a visual analogue scale (VAS), which has a scoring system from 0 to 10. And blood loss assisting by vitality as heart rate, respiration rate, blood pressure, mental state, and urine output were used to classify hemorrhagic shock and assess post-operative bleeding.

Results: Harmonic scalpel had short visual analog scale (0-1) while open method (1-2) and closed method (2-3) after 24 hours, the harmonic scalpel group also experienced less intra- and post-operative hemorrhage.

Conclusion: Using a harmonic scalpel for a hemorrhoidectomy is a safe operation. As less postoperative pain, intraoperative and postoperative blood loss, and operative time.

Key words: Harmonic scalpel, hemorrhoidectomy, role of harmonic scalpel in hemorrhoidectomy.

Introduction

Venule dilatation causes hemorrhoids, which are defined as the downward displacement of submucosal connective tissue including venules and smooth muscle fibers of anal cushions.¹

Hemorrhoids and associated symptoms comprise the majority of patients seen in general surgery clinics. When choosing a hemorrhoid's management strategy, three key factors must be taken into account. Assessing the patient's symptoms, such as protrusion, pain, or bleeding, is essential first.²

Reducing postoperative pain is the second point. Cutting down on the recurrence rate is the third point. Numerous methods, from food and lifestyle changes to surgery, have been tested for the treatment of hemorrhoids.²

Hemorrhoids can be treated surgically using a variety of techniques, including banding, sclerotherapy, and hemorrhoidectomy techniques like Ferguson's (Closed) and Milligan-Morgan (Open).³

The most frequent surgical treatment for treating internal hemorrhoids is called a closed hemorrhoidectomy. Using a sharp instrument, such as a scalpel, scissors, electrocautery, or even a laser, hemorrhoidal bundles are excised, and the incision is then completely closed with absorbable suture.⁴

Usually, treatment is given to all three hemorrhoidal

columns at once. Frequent sitz baths, low-dose painkillers, and preventing constipation are all part of postoperative treatment. 95 percent of closed hemorrhoidectomy cases are successful.⁵

Anal stricture, urinary retention/UTI, fecal impaction, discomfort, delayed bleeding, and, very infrequently, infection, wound breakdown, and fecal incontinence are examples of potential consequences. This procedure has the highest rates of pain and discomfort following surgery, but it also has the best long-term outcomes and the lowest rates of recurrence. Innovative techniques are being developed to lessen surgical pain, which should improve patient outcomes.⁶

Hemorrhoidal tissue is removed during an open hemorrhoidectomy in the same way as during a closed surgery, but with the incision left open. When the location or severity of the disease makes wound closure challenging or when there is a high risk of postoperative infection, surgeons may choose to perform an open hemorrhoidectomy. Open and closed techniques are frequently combined complications from open hemorrhoidectomy are comparable to those from closed hemorrhoidectomy.⁷

Numerous studies have documented the benefits of the harmonic scalpel technique in treating hemorrhoids, including a reduction in intraoperative time, a decrease in blood loss, and improved outcomes following surgery, including reduced pain,

decreased tissue oedema, a lower risk of infection, and improved wound healing.⁸

The harmonic scalpel is an ultrasonically actuated device that vibrates at a rate of 55,000 per second using sound waves as its power source. It has a reputation for coagulating small and medium-sized arteries, which means that it might lessen tissue edema and swelling during surgery.⁹

One special benefit of the Harmonic Scalpel is that it leaves very minimal lateral thermal damage to the tissues. Reduction in postoperative discomfort correlates with reduction in lateral thermal injury (<1.5 mm) at the surgery site.¹⁰

Patinet and methods

From December 2022 to July 2023, a prospective randomized controlled clinical trial was carried out at the Ain Shams University Hospitals' general surgery department under the Faculty of Medicine.

Study population

Patients attended outpatient clinic with the following criteria:

Inclusion criteria

Patient with grade 3,4 hemorrhoids and willingness for the surgical management for both sexes were included .

Exclusion criteria

Patients with inflammatory bowel disease, sentinel piles (Skin tags), recurrent hemorrhoids, anal Fistula, malignancy, cirrhosis and portal hypertension, pregnancy and blood diseases.

Sampling Method "randomization"

Systematic random sampling men and women fulfilled the inclusion criteria were randomly assigned to either group. Sixty opaque envelopes were numbered serially and, in each envelope, the corresponding letter, which denoted the allocated group, was put according to randomization table. Then all envelopes were closed and put in one box. Randomization was done using computer generated randomization sheet using MedCalc © version 13.

Sample size

A total of 60 patients were enrolled, after consenting to each of them.

Ethical considerations

Patient information and informed consent: before being enrolled into the study, the patient consented to participate after the nature, scope and possible

consequences of the clinical study had been explained in a form understandable to them.

Confidentiality: only the patient initials were recorded in the case report form, and when the patient's name appeared on any other document, it was kept in a secure place by the investigators. The investigators maintained a personal patient identification list (Patient initials with the corresponding patient names) to enable records to be identified.

Protocol approval: before the beginning of the study and any accordance with the local regulation followed, the protocol and all the corresponding documents were declared for ethical and research approval by the council of general surgery department, Ain Shams University.

Concerning safety and efficacy: The patient could anticipate pain and anal fullness within the first week following hemorrhoidectomy and hemorrhoidopexy. Adequate pain control, as well as the use of stool softeners, is a priority in the postoperative period. Early complications included bleeding, urinary retention and thrombosed external hemorrhoids. Rare but life-threatening complications that could be recognized early include sepsis, abscess formation and massive bleeding. Late complications included anal stenosis, skin tags, recurrent hemorrhoids, delayed hemorrhage and fecal incontinence.

Study interventions and procedures

The demographic characteristics were extracted from a questionnaire during their first visit to an outpatient clinic.

According to inclusion and exclusion criteria; patients were subjected to:

Complete history taking of clinical importance including

Demographic data: age, sex, marital status, and residence.

History of previous medications especially thromboembolic medications.

Past and family history of blood diseases, malignancy, recurrent hemorrhoids and other excluded conditions.

Clinical examination with special emphasis on General examination as vital signs, BMI, pallor, etc.

Local examination of the anus: for detection of the grade of hemorrhoids, bleeding, fissure, fistula and malignancy.

Investigation: Routine laboratory investigation and specific investigations as coagulation and

bleeding profile. Colonoscopy was done in cases suspecting malignancy, and inflammatory bowel diseases.

The study was conducted on (60) patients who were divided into 3 groups:

Group 1: 20 patients with hemorrhoids who underwent open hemorrhoidectomy without harmonic scalpel.

Group 2: 20 patients with hemorrhoids who underwent closed hemorrhoidectomy without harmonic scalpel.

Group 3: 20 patients with hemorrhoids who underwent hemorrhoidectomy using harmonic scalpel.

Equipment

The classic instrument used for an excisional hemorrhoidectomy is the scalpel with or without the aid of scissors or diathermy for dissection. This approach is highly effective and of low cost.

Harmonic scalpels are modern-day energy devices that have slowly come onto the medical scene. The added expense can negatively impact economic efficiency in the current reimbursement milieu.

The Harmonic scalpel uses a reciprocating blade to generate heat for tissue division and coagulation. The proposed benefits of using energy devices relative to their cost have not demonstrated significant clinical advantages.

A Hill Ferguson retractor that was inserted into the anal canal to visualize the entire length of the hemorrhoidal complex.

Other equipment that could be needed may include: De Bakey forceps, Mayo scissors, large Kelly clamp and absorbable sutures.

Technique

The patients were admitted to the surgery department in the hospital one day before the operation to be prepared for the operation.

The patients were placed in lithotomy position under spinal or general anesthesia. The anus was exposed by attaching tape to both sides of the buttocks. The situation of hemorrhoids was determined with an anoscope.

Surgical excision occurred primarily through a closed hemorrhoidectomy (Ferguson technique), or open hemorrhoidectomy (Milligan-Morgan).

The Hill Ferguson retractor was inserted in the anal canal to assess all three of the hemorrhoidal

columns.

The excision could be to only one column, or all three were excised during the same operation if clinically indicated.

The clinician addressed the largest of the pathologic columns first.

The enlarged column was compressed at the base with a DeBakey forceps to ensure the anoderm is tension free.

A 10-scalpel blade was used to make an elliptical incision around the hemorrhoidal column.

In closed technique:

The pedicle was dissected off the surface of the internal anal sphincter using unipolar cauterization up to the level of the pedicle.

The pedicle was grasped with a large Kelly and was suture ligated with 2-0 Vicryl on a CT 2 needle.

Deeper suture fixation of 2-0 Vicryl was used at the top of the anorectal ring to reduce the risk of recurrent prolapse.

The suture was then used to close the rectal mucosa, anoderm, and perianal skin in a running fashion.

In open hemorrhoidectomy:

Hemorrhoidal tissue is excised in the same manner as in a closed procedure, but here the incision is left open. Surgeons may opt for open hemorrhoidectomy when the location or amount of disease makes wound closure difficult or the likelihood of postoperative infection.

In harmonic scalpel hemorrhoidectomy:

Excision of hemorrhoids was done with the help of vascular forceps and without damaging the internal anal sphincter. The hemorrhoidal pedicle was coagulated with a harmonic scalpel without ligation of the pedicle.

Intraoperative bleeding was assessed by counting the number of the gauzes (Which required 5: 10 ml of blood loss during the operation) that were used to stop bleeding.

Postoperative assessment

The patient was kept in nil per oral (NPO) for about 6 hours.

The pain in postoperative period was assessed by visual analog scale (VAS) with a rating ranging from 0-10.

Post-operative bleeding was assessed by

classification of hemorrhagic shock through amount of blood loss (<750 ml class I, loss 750-1500 class II, loss 1500- 2000 class III, Loss > 2000 class IV), percentage of blood loss, heart rate, respiratory rate, blood pressure, mental status and urine output.

Regular follow up and examination of the patients was performed 24 hours after surgery.

In case of postoperative infection, this infection was followed up for after one then two weeks and finally up to six weeks.

Study outcomes

Primary outcome: Intra operative bleeding.

Secondary outcomes: Operative time (minutes), hospital stay (hours), post-operative bleeding, post-operative infection from 1 to 6 weeks, post operative pain by visual analog scale (vas) and vitality of patient after surgery.

Statistical analysis

Recorded data were analyzed using the statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were presented as mean± standard deviation and ranges when their distribution was parametric (Normal) while non-normally distributed variables (Non-parametric data) were presented as median with inter-quartile range (IQR). Also, qualitative variables were presented as number and percentages. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk Test.

The following tests were done:

- A one-way analysis of variance (ANOVA) when comparing between more than two means.
- Post Hoc test: Tukey's test was used for multiple comparisons between different variables.
- Kruskal Wallis test: for multiple-group comparisons in non-parametric data & Mann Whitney U test: for two-group comparisons in non-parametric data.
- The Comparison between groups with qualitative data was done by using Chi-square test and Fisher's exact test instead of Chi-square test only when the expected count in any cell less than 5.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

• Probability (P-value):

- P-value <0.05 was considered significant.
- P-value <0.001 was considered as highly significant.
- P-value >0.05 was considered insignificant.

Results

Table 1 shows no statistically significant difference between groups according to baseline characteristics, with p-value ($p>0.05$).

Table 2 shows statistically significant higher mean value of operative time "min" in open group, followed by closed group, and the lowest mean value in harmonic scalpel group, with p-value $p<0.001$.

Table 3 shows statistically significant higher mean value of intraoperative bleeding "ml" in open group, followed by closed group, and the lowest mean value in harmonic scalpel group, with p-value $p<0.001$. Tukey's post hoc test revealed no significant difference between closed groups and harmonic scalpel group, with p-value ($p>0.05$).

Table 4 shows statistically significant higher mean value of hospital stay "hrs." in open group, followed by closed group, and the lowest mean value in harmonic scalpel group, with p-value $p<0.001$. Tukey's post hoc test revealed no significant difference between closed groups and harmonic scalpel group, with p-value ($p>0.05$).

Table 5 shows statistically significant higher frequency of post-operative bleeding was 3 patients (15%) in open group, while there is no postoperative bleeding in closed group and harmonic scalpel group, with p-value ($p<0.05$).

Table 6 shows that the 2 patients (15%) had post-operative infection from 1W to 6W in open group, while there is no infection in closed group and harmonic scalpel group, but insignificant difference, with p-value ($p=0.126$).

Table 7 shows that there is decrease pain score in the three groups over the periods, but the most decrease in the harmonic scalpel group, followed by closed group, then open group according to visual analogue scale at 24hrs. After surgery and after one week, there was a statistically significant difference between groups, with p-value ($p<0.001$). While VAS score after 2 weeks and after 6 weeks, insignificant difference between groups, with p-value ($p>0.05$).

Table 8 shows that the all patients 60 (100%) were stable for vitality of patient after surgery, with p-value ($p>0.05$).

Table 1: Comparison between three groups according to demographic data

Baseline characteristics	Open Group (n=20)	Closed Group (n=20)	Harmonic Scalpel Group (n=20)	Test value	P-value
Age (years)					
Mean±SD	40.55±6.69	43.55±6.71	42.20±5.16	1.968	0.142
Range	30-53	34-57	34-50		
Sex					
Female	3 (15.0%)	5 (25.0%)	9 (45.0%)	4.596	0.100
Male	17 (85.0%)	15 (75.0%)	11 (55.0%)		
Grade of hemorrhoids					
Grade 3	7 (35.0%)	5 (25.0%)	10 (50.0%)	2.727	0.256
Grade 4	13 (65.0%)	15 (75.0%)	10 (50.0%)		

Using: One way Analysis of Variance test was performed for Mean±SD.
 x²: Chi-square test for Number (%) or Fisher's exact test, when appropriate.
 p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant.

This table shows no statistically significant difference between groups according to baseline characteristics, with p-value (p>0.05).

Table 2: Comparison between three groups according to operative time (Minutes)

Operative time (minutes)	Open Group (n=20)	Closed Group (n=20)	Harmonic Scalpel Group (n=20)	Test value	P-value
Mean±SD	21.90±3.09A	16.95±1.67B	11.80±1.44C	106.139	<0.001**
Range	18-27	15-20	10-14		

Using: One way Analysis of Variance test was performed for Mean±SD & Multiple comparison between groups through Post Hoc test: Tukey's test.

Different capital letters indicate significant difference at (p<0.05) among means in the same row.

**p-value <0.001 is highly significant.

This table shows statistically significant higher mean value of operative time "min" in open group, followed by closed group, and the lowest mean value in harmonic scalpel group, with p-value p<0.001).

Table 3: Comparison between three groups according to Intra operative bleeding (ml)

Intra operative bleeding (ml)	Open Group (n=20)	Closed Group (n=20)	Harmonic Scalpel Group (n=20)	Test value	P-value
Mean±SD	40.50±10.12A	26.00±4.76B	19.30±4.18B	49.45	<0.001**
Range	30-60	20-35	12-25		

Using: One way Analysis of Variance test was performed for Mean±SD & Multiple comparison between groups through Post Hoc test: Tukey's test.

Different capital letters indicate significant difference at (p<0.05) among means in the same row.

**p-value <0.001 is highly significant.

Table 4: Comparison between three groups according to Hospital stay (hours)

Hospital stay (hours)	Open Group (n=20)	Closed Group (n=20)	Harmonic Scalpel Group (n=20)	Test value	P-value
Mean±SD	25.15±2.23A	24.00±0.00B	24.00±0.00B	5.315	0.008*
Range	24-30	24-24	24-24		

Using: One way Analysis of Variance test was performed for Mean±SD & Multiple comparison between groups through Post Hoc test: Tukey's test.

Different capital letters indicate significant difference at (p<0.05) among means in the same row.

*p-value <0.05 is significant.

Table 5: Comparison between three groups according to Post operative bleeding

Post operative bleeding	Open Group (n=20)	Closed Group (n=20)	Harmonic Scalpel Group (n=20)	Test value	P-value
No	17 (85.0%)	20 (100.0%)	20 (100.0%)		
Yes	3 (15.0%)A	0 (0.0%)B	0 (0.0%)B	6.316	0.043*
Total	20 (100.0%)	20 (100.0%)	20 (100.0%)		

x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate.
p-value >0.05 is insignificant.

Table 6: Comparison between three groups according to Post operative infection from 1W to 6W

Post-operative infection from 1W to 6W	Open Group (n=20)	Closed Group (n=20)	Harmonic Scalpel Group (n=20)	Test value	P-value
No	18 (90.0%)	20 (100.0%)	20 (100.0%)		
Yes	2 (10.0%)	0 (0.0%)	0 (0.0%)	4.138	0.126
Total	20 (100.0%)	20 (100.0%)	20 (100.0%)		

x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate.
p-value <0.05 is significant.

Table 7: Comparison between three groups according to Visual Analog Scale (VAS)

Visual Analog Scale (VAS)	Open Group (n=20)	Closed Group (n=20)	Harmonic Scalpel Group (n=20)	Test value	P-value
24 hrs. after surgery					
Median (IQR)	4 (3-5)A	3 (3-4)B	2 (1-3)C	28.592	<0.001**
Range	2-6	2-5	1-3		
After one week					
Median (IQR)	2 (1-3)A	2 (1-2)A	0 (0-0)B	29.929	<0.001**
Range	0-4	0-3	0-1		
After 2 weeks					
Median (IQR)	0 (0-0)	0 (0-0)	0 (0-0)	2.000	0.368
Range	0-1	0-0	0-0		
After 6 weeks					
Median (IQR)	0 (0-0)	0 (0-0)	0 (0-0)	2.000	0.368
Range	0-1	0-0	0-0		

IQR: Interquartile range.

Kruskal-Wallis was performed for Median (IQR) & Multiple comparison between groups through Mann-Whitney test.

Different capital letters indicate significant difference at (p<0.05) among means in the same row.

p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant.

Table 8: Comparison between three groups according to Vitality of patient after surgery

Vitality of patient after surgery	Open Group (n=20)	Closed Group (n=20)	Harmonic Scalpel Group (n=20)	Test value	P-value
Stable	20 (100.0%)	20 (100.0%)	20 (100.0%)		
Unstable	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.000	1.000
Total	20 (100.0%)	20 (100.0%)	20 (100.0%)		

x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate.

p-value >0.05 is insignificant.

This table shows that the all patients 60 (100%) were stable for vitality of patient after surgery, with p-value (p>0.05).

Discussion

Baseline variables (Age, sex, and grade of hemorrhoids) did not show statistically significant variations between groups, as per our study. The group that used harmonic scalpels experienced a shorter surgical duration, reduced intra- and post-operative hemorrhage, shorter hospital stays, and a lower post-operative Visual Analog Scale score after 24 and 72 hours. Lastly, there were no changes observed in the patient's vitality or post-operative infection across the study groups.

In 2021, Abdullah et al.¹¹ conducted a comparison between electrocautery with pedicle ligation and harmonic scalpel hemorrhoidectomy in terms of cost, operating time, pain, and healing. They concurred with us and stated that, in comparison to electrocautery controls, post-operative discomfort was much lower following Harmonic Scalpel hemorrhoidectomy. The absence of lateral thermal injury is probably the reason for the reduced post-operative pain in the Harmonic Scalpel group.

The use of harmonic and electrocautery scalpels for hemorrhoidectomy was compared by Shahmoradi et al. in 2020. They concurred with us and stated that there is a noteworthy correlation between less discomfort following surgery and hemorrhoidectomy performed with a harmonic scalpel. There was no discernible difference in the demographic information between the two groups. $**P < 0.05$ ". The electrocautery group experienced higher rates of bleeding and pain following surgery.

Alhomoud et al. (2018).⁹ examined the results of conventional and harmonic scalpel hemorrhoidectomy techniques. They concurred with us and stated that, in light of reduced bleeding, less discomfort following surgery, and improved patient acceptance, harmonic scalpel hemorrhoidectomy seemed to be a more effective treatment for symptomatic grades III and IV hemorrhoids. Both groups' patient demographic data and clinical traits were comparable. In addition to having a shorter hospital stay, the harmonic group experienced less pain, bleeding, and postoperative discomfort.

Abo-hashem et al. (2010),¹² found similar results, indicating that using a harmonic scalpel during non-conventional hemorrhoidectomy decreased the risk of excessive lateral thermal injury.

In 2014, 151 patients receiving hemorrhoidectomy using harmonic or electrocautery cutting techniques were enrolled in research by Bulus et al. The study's findings showed that electrocautery was linked to longer hospital stays, longer operating times, and a higher usage of postoperative analgesics.

Comparably, a prospective study conducted in 2014 by Hamdy et al.¹³ found that the electrocautery approach is probably linked to a higher risk of anal stenosis, urine retention, longer recovery times, increased blood loss, and pain following surgery.

Fayyaz et al. (2017),¹⁰ included 60 patients undergoing hemorrhoidectomy using either technique, and they reported similar results. The study's findings are consistent with our research, which shows that using a harmonic scalpel is linked to a comparatively shorter hospital stay, less postoperative discomfort and blood loss after surgery, and a lower risk of hemorrhoids returning.

Zeinalinejad et al.'s 2019,¹⁴ study, which was carried out in Kerman and involved 53 patients receiving harmonic or electrocautery hemorrhoidectomy, found that the harmonic scalpel group experienced much less discomfort and bleeding 24 hours and 8 weeks after surgery.

Conversely, the results of the 2015 study by Dumlu et al.¹⁵ suggested that there might not be a difference between the two approaches in terms of complications, bleeding episodes, length of hospital stay, and postoperative discomfort as measured by VAS.

In their 2017 study, Ravi et al.¹⁶ demonstrated that the harmonic scalpel group experienced reduced blood loss throughout the surgery (6.1 ml compared to 19.4 ml for the Milligan-Morgan group). The VAS pain scores at days 1, 7, and 14 post-operatively were lower in the harmonic scalpel group compared to the Milligan-Morgan group, according to a study they conducted on 60 patients to compare harmonic scalpel hemorrhoidectomy with the standard open approach. They revealed that the Milligan-Morgan group had higher rates of post-operative problems such bleeding and urine retention.

Prospective research on fifty patients with grade III or grade IV internal hemorrhoids was carried out by Lim et al in 2016. Every patient had a hemorrhoidectomy procedure performed on them: 25 underwent harmonic scalpel excision, and 25 underwent conventional technique suturing with 3-0 vicryl material. The harmonic scalpel group experienced a shortened operation duration, lower VAS pain scores during the post-operative phase, and lower post-operative hemorrhage ($p=0.034$). The two groups' post-operative complications did not significantly differ from one another.

Conclusion

Using a harmonic scalpel for a hemorrhoidectomy is a safe and successful operation. Reductions in intraoperative and postoperative blood loss,

postoperative pain, and operation duration are achieved with the harmonic scalpel. With less bleeding, less pain after surgery, and higher patient acceptance, harmonic scalpel hemorrhoidectomy seems to be a more effective treatment for symptomatic grades III and IV hemorrhoids. Larger-scale research and extended follow-up are necessary to assess typical activity following a harmonic scalpel hemorrhoidectomy.

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