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Harmonic Scalpel® treatment of haemorrhoidectomy versus Milligan–Morgan's method

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Abstract--Haemorrhoidal disease develops slowly. In comparison to electrocautery, surgical intervention with the Harmonic Scalpel® shear is a revolutionary approach for ablation of symptomatic fourth and third degree haemorrhoids. In contrast to electrocautery, Harmonic Scalpel® causes less discomfort because of its restricted lateral thermal injury during tissue dissection. The purpose of this study was to observe how effective Harmonic Scalpel® is at reducing postoperative problems after a haemorrhoidectomy. A harmonic US scalpel device was utilized to do the hemorrhoidectomy in group A, while a monopolar electrocautery device was employed in group B, which included 82 individuals. In this study, postoperative pain was more statistically significant in the Harmonic haemorrhoidectomy group A than in group B haemorrhoidectomy, in keeping with a pain numerical analogue scale of 1 to 10. The postoperative pain in group A was statistically significant on the 1st, 2nd, 4th, 7th, 14th, and 28th days of follow up, $p < 0.001$. Time off work and patient satisfaction were statistically significant in the harmonic group, 2.50 ± 0.066 compared to the surgery group, 3.56 ± 0.070 ($p < 0.05$). Healing of postoperative ulcers was statistically significant in the harmonic group ($2.640.062$ vs. $4.120.062$ in surgery) ($p < 0.037$). Haemorrhoidectomy using a harmonic scalpel is more safe and effective surgical technique for the treatment of haemorrhoids in grades III and IV. The postoperative

pain, time of the procedure, the postoperative complications, and wound healing are lower compared with conventional haemorrhoidectomy.

Keywords---harmonic US scalpel, conventional haemorrhoidectomy, electrocautery, tissue dissection.

Introduction

Haemorrhoidal disease is one of the most prevalent anorectal disorders seen in general practice, but the true frequency in the general population is unknown, mainly due to the fact that many patients do not seek treatment. Haemorrhoidal disease was shown to be prevalent in 4 and 7% of adult patients attending general practice clinics in two French studies (Tournu et al., 2017). In contrast, population-based surveys in the United States, Spain, and Japan found prevalence rates of 4, 13, and 17%, respectively. Specific groups, such as pregnant or postpartum women, have a greater prevalence of haemorrhoidal disease, with a prevalence of between 12% and 41% (Perry et al., 2010)

Haemorrhoids develop slowly over a long period of time (Gentile et al., 2011) They are associated with constipation, can be made worse by pregnancy, and often run in families (Bakhtiar et al., 2016). Piles are usually painless and, when inflamed or enlarged, become a disease, termed "haemorrhoid". The symptoms usually range from bleeding per rectum, pain, discharge, itching, and disordered anorectal function, even incontinence (Simillis et al., 2015).

Haemorrhoids are usually divided into internal and external, or combined internal and external. The dentate (pectinate) line is the landmark that differentiates the types of hemorrhoids. The internal haemorrhoids usually start above it, whereas the external haemorrhoids start below it (Margetis, 2019). The Goligher classification method, which is based on the degree of prolapse through the anus, is commonly used to determine the severity of haemorrhoidal disease. A hemorrhoid that bleeds but does not prolapse is classified as Grade 1; a hemorrhoid that proleptes during straining but spontaneously reduces or reverts is classified as Grade 2; a hemorrhoid that prolapses during straining or exertion but can be manually pushed back into the anal canal is classified as Grade 3; and a hemorrhoid that is permanently prolapsed is classified as Grade 4 (Lohsiriwat, 2012). This system, in particular, does not take into account the symptoms of patients. In addition to bleeding, patients may also experience pain, faecal soiling, rectal irritation or swelling, and a feeling of fullness. This is especially true if the haemorrhoids are prolapsed. Hemorrhoids that have prolapsed might become thrombosed or strangulated, causing severe anal pain (Setiyaningsih et al., 2020). Depending on the prolapse severity, internal haemorrhoids were divided into four grades (Khanna et al., 2010). Patients with internal haemorrhoids of grade 3 or 4, as well as severe external haemorrhoids or a mix of the two, appear to be surgical candidates (Mott et al., 2018). Although haemorrhoidectomy is a simple operation, most patients fear the postoperative complications, mainly postoperative pain; so many patients believe hemorrhoidectomy is the last option

for thoughtful people (Rivadeneira et al., 2011). The two classical techniques involve closed Ferguson's haemorrhoidectomy and open Milligan–Morgan's haemorrhoidectomy, which can be operated with a scalpel or electrocautery (Pillant-Le Moullet et al., 2015). Electrocautery divides tissue by a process of thermal coagulation, which results in a significant lateral thermal injury, or burn, several millimeters deep (Shahmoradi et al., 2020). A harmonic scalpel was initially used in surgery in 1992, using ultrasonic energy to cut and coagulate soft tissue with minimum thermal damage to the surrounding tissues (Bilgin et al., 2015). With high-frequency ultrasonic energy, the Harmonic Scalpel® separates tissue by destroying protein hydrogen connections within the tissue (550000 Hz). Blood vessels are coapted and sealed by denatured proteins in the vessel lumen. Because of the low temperature (80 °C) at which this occurs, no thermal harm occurs (Bulus et al., 2014).

The aim of this study is to compare the outcomes of patients who had harmonic scalpel haemorrhoidectomy with those who had the traditional open Milgan Morgan procedure. This includes the procedure's schedule, postoperative hospitalization, pain score, amount of painkillers used, wound healing, time to resume normal activity, satisfaction score, and postoperative complications such as anal stenosis and faecal or flatus incontinence.

Patient and Methods

A prospective comparative (randomised, blinded) study was conducted on 180 candidates for haemorrhoidectomy from October 2019 to September 2021 in the Theodor Bilharz Research Institute. Demographic data (age, sex, and BMI) were documented. Two groups of patients were included: the first group A includes 98 patients, a harmonic US scalpel device was used to perform the hemorrhoidectomy while in the second group B which includes 82 patients, and a monopolar electrocautery device was used. Patients meeting the inclusion criteria presenting with Grade III internal haemorrhoids with external components or Grade IV disease (aged from 18 to 60 years) and cirrhotic patients are included in the study. Patients with further anorectal pathology (fissure or fistula), persistent anal pain syndrome, and neurologic impairments were excluded.

Examination and diagnosis

Obtaining the patient's medical history, performing a digital rectal examination, and only performing a colonoscopy if the patient is older than 45, shows signs of inflammatory bowel illness, or has risk factors for colorectal cancer. All patients underwent routine laboratory tests according to their ASA anaesthesia score. Patients were informed about the procedures and signed consent forms before surgery.

Operation protocol

The patient was placed in the lithotomy position while under anesthesia. The perianal, perineum, and upper thigh were all sterilized. Before the haemorrhoidectomy operation, an examination under anaesthesia (EUA) was performed to rule out any additional pathology (figure 1A). All patients have open

haemorrhoidectomy, which is performed using a harmonic US scalpel in group A patients and monopolar electrocautery in group B patients. The pedicle is gripped using artery forceps, and the mucocutaneous junction is grasped with Allis forceps. The haemorrhoidal tissue is dissected and removed from the anal sphincter until the pedicle is reached. In group A, the pedicle is dissected, coagulated, and excised with a harmonic US scalpel (figure 1B), whereas in group B, the pedicle is transfixed and ligated with vicryl 2-0. Then small gauze with local anaesthetic ointment was inserted into the anal canal in all patients, and then removed three hours later. Each procedure's operative time, blood loss, and quantity of soaked gauze were all recorded. All patients were given the same instructions in the first week: clean the wound twice a day and take a warm bath twice a day, then once a day after defecation in the second week.

Depending on the severity of postoperative pain, patients were given oral paracetamol 500 mg every 8 hours for one week, Ibuprofen 400 mg every 8 hours for all patients, and ketolac 30 mg IM when needed. Unless clinically indicated otherwise, all patients were discharged home on the same day following fast track surgery. Follow-up period, all patients were contacted by telephone on postoperative days 1, 2, 4, 7, 14, and 28. They were asked to make a meticulous record of the number of analgesics necessary during each 24-hour period. This was recorded on the patient information sheet.

In the first, second, fourth, and sixth months after discharge, all patients are followed in the outpatient clinic. On days 1, 2, 4, 7, 14, and 28 after surgery, the patients were asked to report their maximum pain score on a visual analogue scale for the day during rest and post-defecation using a numeral analogue pain score from 1 to 10. The pain was evaluated by a score of 0 (no pain) to 10 (very severe pain) at home before going to bed, record postoperative urine retention, early or late bleeding, anal infection, anal stenosis, or anal incontinence in clinical files after 1 week, 2 weeks, 4 weeks, and 6 months.

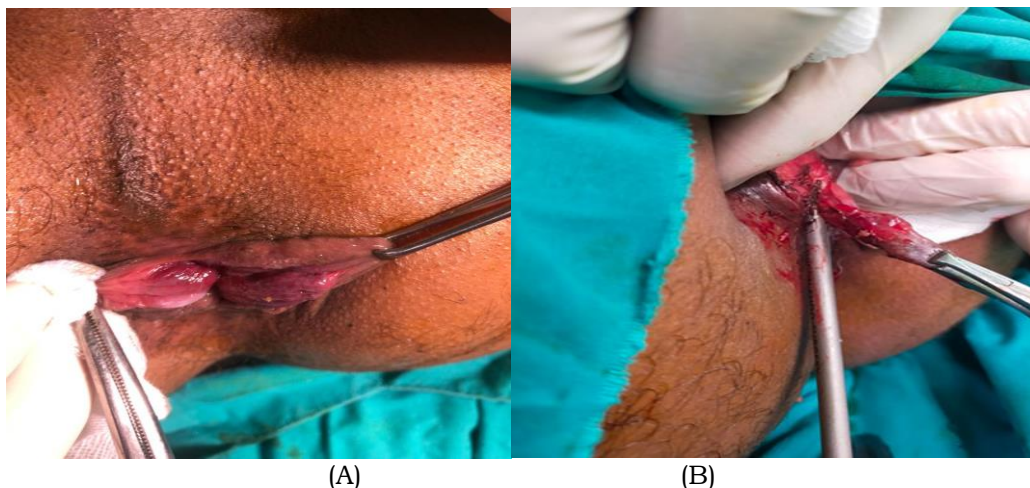


Fig. 1 :(A): shows 4th degree haemorrhoid, (B): dissection using harmonic for 4th degree haemorrhoid at 3 o'clock.

Statistical analysis

Each questionnaire was checked visually for completeness. Data were coded and entered using EPI DATA 5.1 version and statistically analyzed using SPSS v25 for analysis. Data cleaning was done by identifying and correcting missed values and inconsistencies. Descriptive statistics like frequency, percentage, median, and mean \pm SD was done to describe the study population in relation to different variables. A Chi-square test was done for all variables to check the assumptions. Non parametric alternative tests will be used if the data were not normal and the level of significance was set at 5%. Analysis of data and interpretation of results will be based on parametric and non-parametric statistical techniques like Kendel's Tau test of corresponding different scales and Z test for large samples.

Results

A total of 180 patients were included in this study, ranging from 18 to 60 years old; 91 males and 89 females. They were diagnosed with third-or fourth-degree internal haemorrhoids (figure 1A) and divided into two groups. Group A open haemorrhoidectomy was performed with a harmonic US scalpel (figure 1B), including 98 patients, while Group B open haemorrhoidectomy was performed with monopolar electrocautery, including 82 patients. The demographic characteristics of the groups are presented in table (1).

The mean age of the patients in groups A and B was 43.39 ± 2.02 and 39.00 ± 1.48 , respectively. There were 7 patients in group A who had previous anal operations, while in group B there was only 1 patient. Males represent 53.1% and 47.6% of patients in groups A and B, respectively, while females represent 46.9% and 52.4%, with no significant difference among them (Table 1). In group A, the frequency of 3rd and 4th haemorrhoidal diseases patients was 12.2% and 87.8%, respectively, while in group B, the frequency of 3rd and 4th degree haemorrhoidal disease patients was 13.4% and 86.6%, respectively. There was no significant difference among them (Table 1).

Table 1: Patient demographics and study variable

	group A harmonic	group B) surgery	<i>p-value</i>
Age (mean \pm SD)	43.15 \pm 11.14	39.00 \pm 10.2	
Gender (mean \pm SD)			
Male	52 (53.1%)	39 (47.6%)	NS
Female	46 (46.9%)	43 (52.4%)	
Previous anal surgery (No. & %)			< 0.05
Yes	7 (3.9%)	1 (0.6%)	
No	91(50.6%)*	81(45.0%)	
Grade (No. & %)			NS
III	12 (12.2%)	11 (13.4%)	
IV	86 (87.8%)	71 (86.6%)	

Post operative analgesia	1.02±0.02	1.18±0.05*	< 0.02
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Table 2: comparison of postoperative pain between harmonic and surgery

Variables (Post-operative pain)	Surgery group B Mean±SD	Harmonic group A Mean±SD	p-value
1st day	9.52±0.107	3.61±0.094**	<0.001
2nd day	9.55±0.104	3.73±0.104**	<0.001
4th day	9.54±0.098	3.71±0.125**	<0.001
7th day	7.51±0.113	2.88±0.073**	<0.001
14th day	5.56±0.094	2.27±0.073**	<0.001
28th day	2.46±0.098	1.41±0.074**	<0.001

(All values are presented as mean ± standard deviation; between groups was used Mann-Whitney test (U-test); and Chi square test.

Groups A and B, the postoperative pain on day 1 postoperative was 3.61±0.094 and 9.52±0.107, respectively, which was statistically significant in group A, $p < 0.001$ table (2). Also, the postoperative pain on 2nd day, 4th day, 7th day, 14th day, and 28th day of follow up was statistically significant in group A, $p < 0.001$ table (2).

In the Harmonic Scalpel ® group A, the number of analgesics required per 24-hour period was much lower. On days 1, 2, and 4, we use two types of oral analgesics; after one week, we only use one type, and after the second week, we only use one type on demand. While in Milligan–Morgan's haemorrhoidectomy group B, we use 2 types of oral plus IM injection on days 1, 2, and 4, while on day 7 we use 2 types of oral analgesics, which is continued for 4 weeks (Table 3).

Pain scores (Visual Analog Scale). Figure 2 shows that harmonic scalpel patients experienced significantly less pain than the surgery group on all postoperative days, p -value < 0.05 , using the Wilcoxon rank-sum test.

Table 3: comparison postoperative analgesic between harmonic and surgery

Variable (postoperative analgesia)	Harmonic group A Mean±SD	Surgery group B Mean±SD	p-value
1 st day	4.79±0.074*	6.25±0.024	<0.05
2 nd day	4.87±0.060*	6.37±0.028	<0.037
4 th day	4.81±0.061*	6.35±0.024	<0.039
7 th day	3.68±0.063*	5.42±0.019	<0.030
14 th day	2.78±0.014*	3.72±0.016	<0.01
28 th day	1.71±0.068	1.81±0.068	NS

(All values are presented as mean ± standard deviation; between groups was used Mann-Whitney test (U-test); and Chi square test.

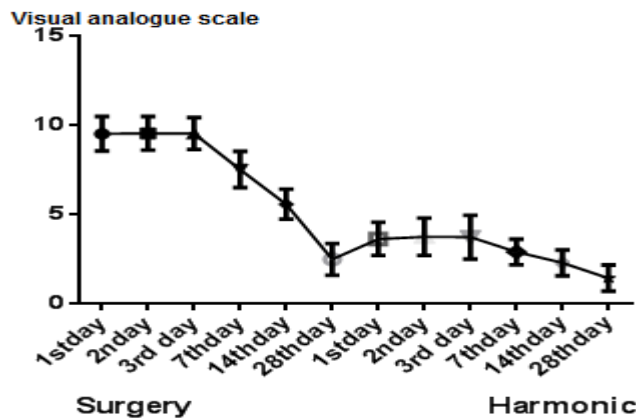


Fig. 2: Repeated-measures analysis Wilcoxon rank-sum test) a significant $p < 0.05$ effect of postoperative analgesic between harmonic and surgery

Wound healing was evaluated using a pain scale, a clinical examination, patient satisfaction, and time off work (table 4). Time off work and patient satisfaction were statistically significant in harmonic group 2.50 ± 0.066 compared to surgery group 3.56 ± 0.070 ($p < 0.05$). Healing of postoperative ulcer was statistically significant in the harmonic group 2.64 ± 0.062 , compared to surgery group 4.12 ± 0.062 ($p < 0.037$). Except for one patient in the surgery group who was discharged after two days due to postoperative bleeding, all patients stayed in the hospital for less than 24 hours.

Table 4: comparison time of return to work and healing of post-operative ulcer between harmonic and surgery

Variables	Surgery n=90 Mean \pm SD	Harmonic n=90 Mean \pm SD	p-value
Time off work	3.56 \pm 0.070	2.50 \pm 0.066*	<0.05
Healing of post-operative ulcer	4.12 \pm 0.062	2.64 \pm 0.062*	<0.037

There was no statistical difference among both groups A and B, regarding the hospital stay, and blood loss, while the operation time in the Harmonic Scalpel® group A ranged from 25 minutes to 40 minutes with a mean operative time of 32 minutes, while in Milligan–Morgan's haemorrhoidectomy group B it ranged from 35 minutes to 60 minutes with a mean operative time of 47 minutes. Postoperative urine retention affected two patients in group A and five patients in group B. The urinary catheter was removed 2 hours before discharge from the hospital for all patients with urine retention. There was no statistical difference between the two groups.

One patient in group A had little bleeding (secondary haemorrhage) one week after the operation, which was treated conservatively. Four patients in group B experienced postoperative bleeding, one within 24 hours (primary haemorrhage) that necessitated examination under anaesthesia to control the cause of bleeding, and the other three bleeding occurred after seven days (secondary haemorrhage) that were treated conservatively with no statistical difference among both groups.

In the current study, there were two cases of anal stenosis in group B that appeared four weeks after the operation and were treated with anal dilation under general anesthesia, as well as two cases of flatus incontinence in group B that improved after one month. There were no cases of faecal incontinence.

Discussion

Internal haemorrhoids of grades III or IV are usually treated surgically. After a haemorrhoidectomy, pain and discomfort are still a major problem (Lee et al., 2019). Various devices, such as harmonic, have been enhanced to prevent intraoperative and postoperative haemorrhage, bleeding, anal incontinence, and anal stenosis (Tan et al., 2007). Harmonic scalpels are ultrasonic scalpels with automatic vessel-sealing mechanisms that have recently been upgraded. Tissue charring and full cutting and coagulation of vessels up to 7 mm in diameter with minimal heat spread less than 2 mm (Sayfan et al., 2001).

In our study, post-operative pain levels were minimal on days 1, 2, 4, 7, 14, and 28, with a significant value of importance for group A ($p < 0.001$). In 2017, Ravi Kumar and his colleagues conducted a study on 60 patients comparing harmonic scalpel haemorrhoidectomy to the traditional open procedure (Milligan–Morgan); they discovered that visual analogue pain scores were minimal in the harmonic scalpel group compared to the Milligan–Morgan group at days 1, 7, and 14 postoperatively (G. V. et al., 2017). Our study is also consistent with a study done in 2020 by Elhorbity and his colleagues on 60 patients that were divided into three groups: harmonic, ligaSure, and surgical, the post-operative pain scores based on numerical analogue scores for pain being minimum in the harmonic scalpel and ligaSure groups compared to Milligan–Morgan (Elhorbity et al., 2020). In this study there was significant difference between usages of analgesics in group A than group B patients that is directly proportional to pain scores in both groups. This is consistent with a prospective study done on 192 patients, comparing Harmonic Scalpel with Ferguson's Haemorrhoidectomy, Harmonic scalpel haemorrhoidectomy resulted in much less postoperative discomfort and painkiller use (Ece et al., 2014). In terms of operational time, postoperative discomfort, and analgesic intake, Talha and colleagues discovered that both harmonic scalpel and ligaSure were superior to traditional diathermy in haemorrhoidectomy (Talha et al., 2017).

In our study time off return to work and wound healing is between 1 – 2 weeks in harmonic group A while it is more than 3 weeks in surgery group B patients. This is in accordance with the findings of Abo-Hashem and colleagues, who discovered that harmonic scalpel haemorrhoidectomy resulted in considerably faster wound healing due to reduced tissue stress, charring, minimal local edema in the surrounding tissues, and the absence of tissue necrosis in a 2010 study (Abo-hashem et al., 2010).

In this study patients satisfaction is excellent with harmonic scalpel group A than Milligan Morgan group B and this is consistent with comparative study done on 60 patients by A. Thiyagarajan compared Harmonic Scalpel haemorrhoidectomy versus Milligan Morgan haemorrhoidectomy, he concluded that harmonic Scalpel

had the lowest pain score and the highest satisfaction score (Thiyagarajan & Bhatnagar, 2017).

Two of the most important factors influencing patient comfort and satisfaction are incontinence and anal stenosis. Two cases of anal stenosis in group B developed four weeks following surgery and were treated with anal dilation under anaesthesia, as well as two cases of flatus incontinence in group B that improved after one month. In group A, there were no cases of faecal incontinence or stenosis. These findings are in line with a study done on 50 patients by Armstrong and his group which found no cases of faecal incontinence in the harmonic scalpel group and just one case of anal stenosis in the Milligan Morgan group (Armstrong et al., 2001).

Warnings of the study

The procedure's learning curve and higher cost were two of the earliest drawbacks of Harmonic Scalpel® haemorrhoidectomy. The technique of harmonic haemorrhoidectomy is not commonly used in our country as it is a costly operation in comparison with the Milligan Morgan method, so we are trying to use this technology for the first time in our hospital. The Harmonic Scalpel divides the haemorrhoidal tissue significantly slower than electrocautery. This necessitates patience and the avoidance of excessive traction on the surgical specimen. Excessive traction on the surgical end of the specimen invariably leads to tissue dissection and bleeding.

Conclusion

For surgical treatment of grade III and grade IV haemorrhoids, haemorrhoidectomy with a Harmonic scalpel is a successful and safe method. In comparison to traditional haemorrhoidectomy, postoperative discomfort, pain, operation time, postoperative complications, and wound healing are all reduced.

Funding statement

This study received no financing from public, private, or non-profit organizations.

Ethical approval

The study's protocol was approved by the TBRI institutional review board under Federal Wide Assurance (FWA 00010609), and the work was carried out in accordance with the World Medical Association's Code of Ethics for Human Experiments (Declaration of Helsinki) and its later amendments (GCP guidelines) or comparable ethical standards.

Conflicts of interest

Authors declared that they have no competing interests

Availability of the data and materials

Data and materials are available with corresponding author upon reasonable request.

Authors' contribution

All authors made significant contributions to conception, design, acquisition, analysis and interpretation of data. All authors agreed to submit to the current journal; gave final approval of the version to be published; and agreed to be responsible for all aspects of the work.

Consent for publication

Not applicable

Acknowledgment

General: Not applicable

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