

# A CONTROLLED RANDOMIZED TRIAL COMPARING HARMONIC SCALPEL HEMORRHOIDECTOMY VERSUS DIATHERMY HEMORRHOIDECTOMY

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## ABSTRACT

**Objective:** To compare between the results Milligan-Morgan's operation using the Harmonic Scalpel (HSH) and diathermy (DH) in the surgical treatment of grade III and IV hemorrhoids. **Methods:** The comparative study was conducted at Kafr El Sheikh University Hospital, Egypt, from December 2018 to December 2019, 40 patients presented with grade III and IV hemorrhoids were enrolled in the study and were divided into 2 groups; DH group (20 patients) and HSH group (20 patients). **Results:** The mean age of patients who underwent DH was  $39.8 \pm 11.34$  years and  $42.8 \pm 10.67$  years in HSH group. The mean operative time of the DH and HSH groups was  $18.95 \pm 6.85$  minutes and  $14.75 \pm 4.93$  minutes, respectively ( $p < 0.001$ ). There was statistically significant difference between both groups regarding postoperative pain and amount of analgesia used. On day of the surgery, postoperative pain ranged from 4.5 to 6 with a median of 5 according to VAS score in HSH group compared to 6.5 to 8 with a median of 7 in DH group. **Conclusion:** Harmonic Scalpel is better than diathermy in terms of reduced postoperative pain, reduced doses of analgesia needed postoperatively and excellent hemostasis despite being slightly costly in terms of treating hemorrhoids. **Clinical Trial Number:** MKSU 50-5-18

## Introduction

Hemorrhoids are one of the most common anorectal disorders with a reported prevalence of 4.4% up to 36.4% of general population and a peak prevalence occurs between 45 and 65 years of age.<sup>1</sup> Patients are usually presented by a prolapsed lump, which may require manual reduction or is constantly prolapsed. Other clinical manifestations include painless bleeding, discomfort, discharge, hygiene problems, soiling, and pruritus. Internal hemorrhoids are further graded according to Goligher's classification which depends on the degree of prolapse into: (1) Grade I hemorrhoids: Anal cushions bleed without prolapse; (2) Grade II hemorrhoids: Anal cushions prolapse on straining but reduce spontaneously; (3) Grade III hemorrhoids: Anal cushions prolapse on straining or exertion and require manual reduction; and (4) Grade IV hemorrhoids: The prolapse is irreducible and remains out all the time.<sup>2</sup>

The Milligan Morgan hemorrhoidectomy (MM) is still considered the gold standard surgical intervention for Grade III- IV hemorrhoids with the lowest recurrence rate as compared to other procedures, yet considered inadequate due to the severe post-operative pain.<sup>3</sup>

Regarding diathermy hemorrhoidectomy, coagulation occurs at temperatures higher than  $150^{\circ}\text{C}$ . This results in the formation of an eschar that seals the bleeding area. Compared with conventional hemorrhoidectomy (CH), diathermy hemorrhoidectomy has been shown to be associated with less bleeding, shorter operating time but with similar post-operative pain.

The harmonic scalpel® (Johnson and Johnson Medical KK, Ethicon Endo-Surgery, Cincinnati, OH) is an ultrasonically activated instrument, which vibrates at a rate of 55000 MHz per second. It is acknowledged for its capacity to coagulate small- and medium-sized vessels by converting electrical energy to a mechanical one. Thus, ultrasonic cutting and coagulating device has advantages such as causing minimal lateral tissue injury (the HS causes lateral thermal injury 1-3 mm wide), less fumes, not making neuromuscular simulation, and more localized impact, with no passage of electricity to or through the patient, resulting in greater safety and less pain for the patients.<sup>4</sup>

The current study was planned to compare DH and HSH techniques in patients undergoing MM hemorrhoidectomy.

## Keywords:

Harmonic scalpel, Milligan Morgan, Haemorrhoidectomy, Haemorrhoids, Diathermy.

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**Patients and methods**

This double-blind randomized trial was approved by the Ethical Committee at Kafr El Sheikh University. 40 patients complaining from Grade III and Grade IV hemorrhoids were enrolled in the study performed at General Surgery Department, Kafr El Sheikh University hospital between December 2018 to December 2019 and a written informed consent from all the participants was obtained.

Patients were randomly subdivided into two groups: (1) DH Group: 20 patients who underwent hemorrhoidectomy performed with monopolar diathermy, which represented the traditional technique and (2) HSH Group: 20 patients who underwent harmonic scalpel hemorrhoidectomy. Patients with previous anorectal surgery; associated anorectal pathology such as perianal fistula or anal fissure; acute thrombosed hemorrhoids, uncontrolled diabetes mellitus, or previous cerebrovascular accidents; and patients with liver cirrhosis were excluded from this study.

Patients were admitted to in general surgery department in the hospital one day before the operation and enema was performed twice (12 hours and 6 hour) prior to the operation. Patients without complications after the operation were discharged from hospital 1 day after the surgery. Spinal anesthesia was administered for all patients. Patients were placed in the lithotomy position and the perineal area was exposed by attaching tape to both sides of the buttocks. After manual dilatation of anal canal, situation of hemorrhoids was determined with an anoscope.

Regarding DH, open MM hemorrhoidectomy using diathermy with pedicle ligation. The diathermy forceps were applied across the skin tags, then the hemorrhoids, and finally the hemorrhoidal pedicle which was secured by transfixing suture with 2/0 Vicryl suture. The haemorrhoid was then excised then bleeding was controlled by the means of monopolar cautery. Haemostasis was secured and the wound was left open. (Figure 1)

In HSH group, the scalpel was applied across the skin tags and the hemorrhoids; the pedicle was controlled by coagulation. The power set at level 3 (minimum level). The internal and external components of each hemorrhoidal complex was grasped and elevated by an artery forceps and the hemorrhoid bundle was carefully dissected off the internal anal sphincter. Care was exercised in

avoiding violation of the circular fibres of the internal sphincter. Control of the pedicle and hemostasis were achieved. The technique of Harmonic Scalpel hemorrhoidectomy was the same as diathermy, except that the dissection and haemostasis were purely performed with the ultrasonic scalpel. (Figure 2)

Postoperative pain was assessed on a visual analogue scale (VAS) on day 1,2,7,14,28 and total amount of analgesia administered by the patients were recorded over the same days. Operative time was recorded as the time between the incision and ligation of the pedicle. Intraoperative bleeding amount was included in the study as well. Patients were assessed for early and late complication when they came back for follow up.

All data were collected and analyzed using SPSS version 25 (SPSS Inc., Chicago, IL, USA). Chi-square test and Student t test were performed for comparison of the groups as appropriate. A p value <0.05 was considered as statistically significant.

**Results:**

The mean age of patients who underwent DH and HSH was 39.8 ± 11.34 years and 42.8±10.67 years, respectively. The male/female ratio of the DH and HSH groups was 15/5 and 16/4, respectively. (Table 1)

There is statistically significant difference between the studied groups regarding operative time. Mean operative time in HSH group was 14.75 ± 4.93 minutes compared to 18.95 ± 6.85 minutes in DH group. On pairwise comparison, the difference is significant regarding intraoperative bleeding amount; the median for bleeding was 2 (1 - 2) ml in HSH group as opposed to 3.5 (2.25 - 5) ml in DH group. (Table 2)

There is statistically significant difference between the studied groups regarding VAS pain scores over postoperative follow up period. On doing pairwise comparison concerning VAS on day 1, 2 and 7, the difference is significant between the two groups towards HSH group. On day of the surgery, postoperative pain ranged from 4.5 to 6 with a median of 5 according to VAS score in HSH group compared to 6.5 to 8 with a median of 7 in DH group. Similarly, length of hospital stay in HSH group had a mean of 1.05 ± 0.22 days in comparison with 1.10 ± 0.31 days in DH group. (Table 3)

**Table 1:** [Comparison between the studied groups regarding demographic data]

Parameters	Groups		Test	
	DH Group N=20(%)	HSH Group N=20(%)	x2	p
Gender: Male Female	15 (75%) 5 (25%)	14 (70%) 6 (30%)	0.476	0.788
	Mean ± SD	Mean ± SD	F	p
Age (year)	39.8 ± 11.34	42.8±10.67	0.696	0.503
BMI (kg/m2)	27.2 ±2.88	26.8 ±2.38	0.925	0.403

**Table (2)** Comparison between the studied groups regarding intraoperative events

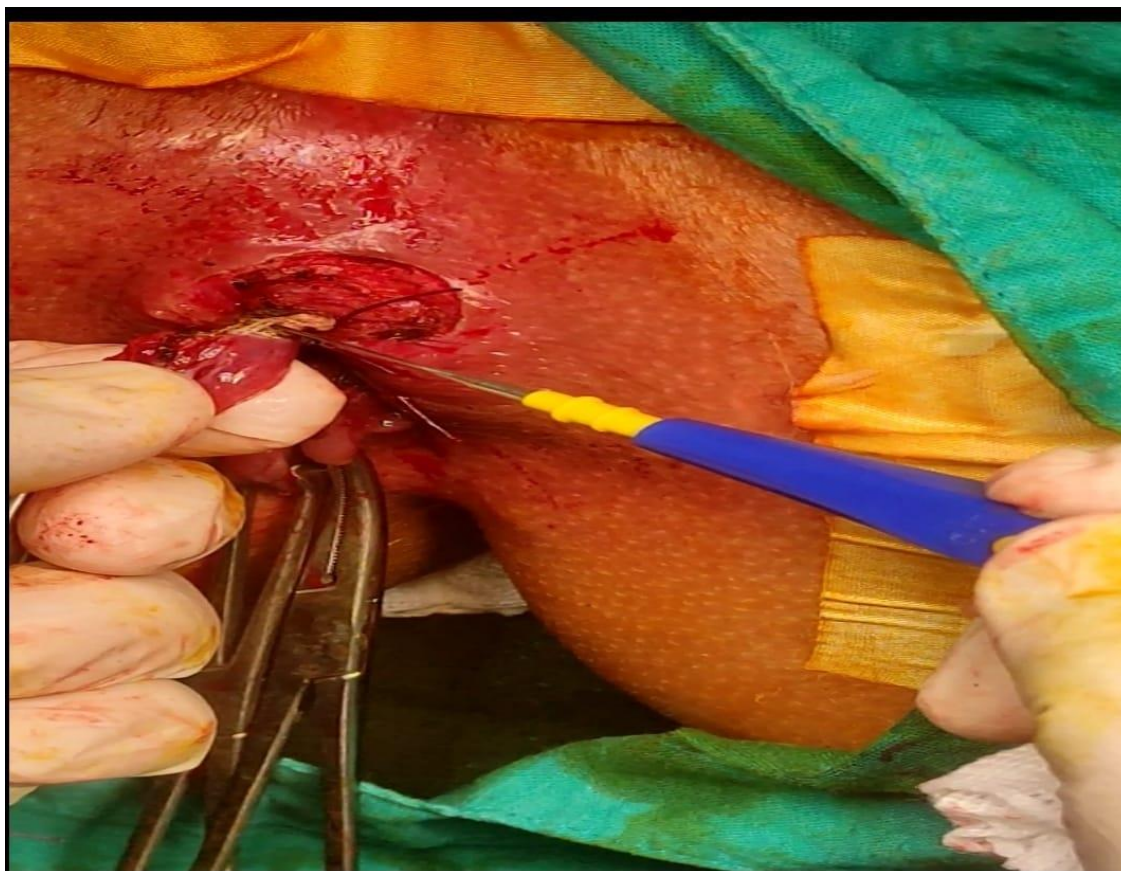
Parameters	Group		Test	
	Group A	Group B	F	p
	Mean ± SD	Mean ± SD		
Operative time (minutes)	18.95 ± 6.85	14.75 ± 4.93	46.195	<0.001**
Tukey HSD test	P1 0.024*	P2<0.001**		
	Media (IQR)	Media (IQR)	Z	p
Bleeding	3.5 (2.25 - 5)	2 (1 - 2)	19.305	<0.001**
Pairwise comparison	P1 0.001**	P20.739		

**Table (3)** Comparison between the studied groups preoperative VAS pain scores over time

VAS	Group		Test	
	DH Group	HSH Group	KW	p
	Median (IQR)	Median (IQR)		
First day	7 (6.5 - 8)	5 (4.5 - 6)	49.632	<0.001**
Second day	7.5 (6 - 8)	5 (5 - 6)	44.897	<0.001**
Seventh day	6 (5 - 6)	4 (4 - 5)	36.704	<0.001**
Fourteen day	3 (3 - 4.5)	2.5 (3 - 4)	31.933	<0.001**
VAS 28 days	2 (1 - 2)	1 (1 - 2)	15.815	<0.001**

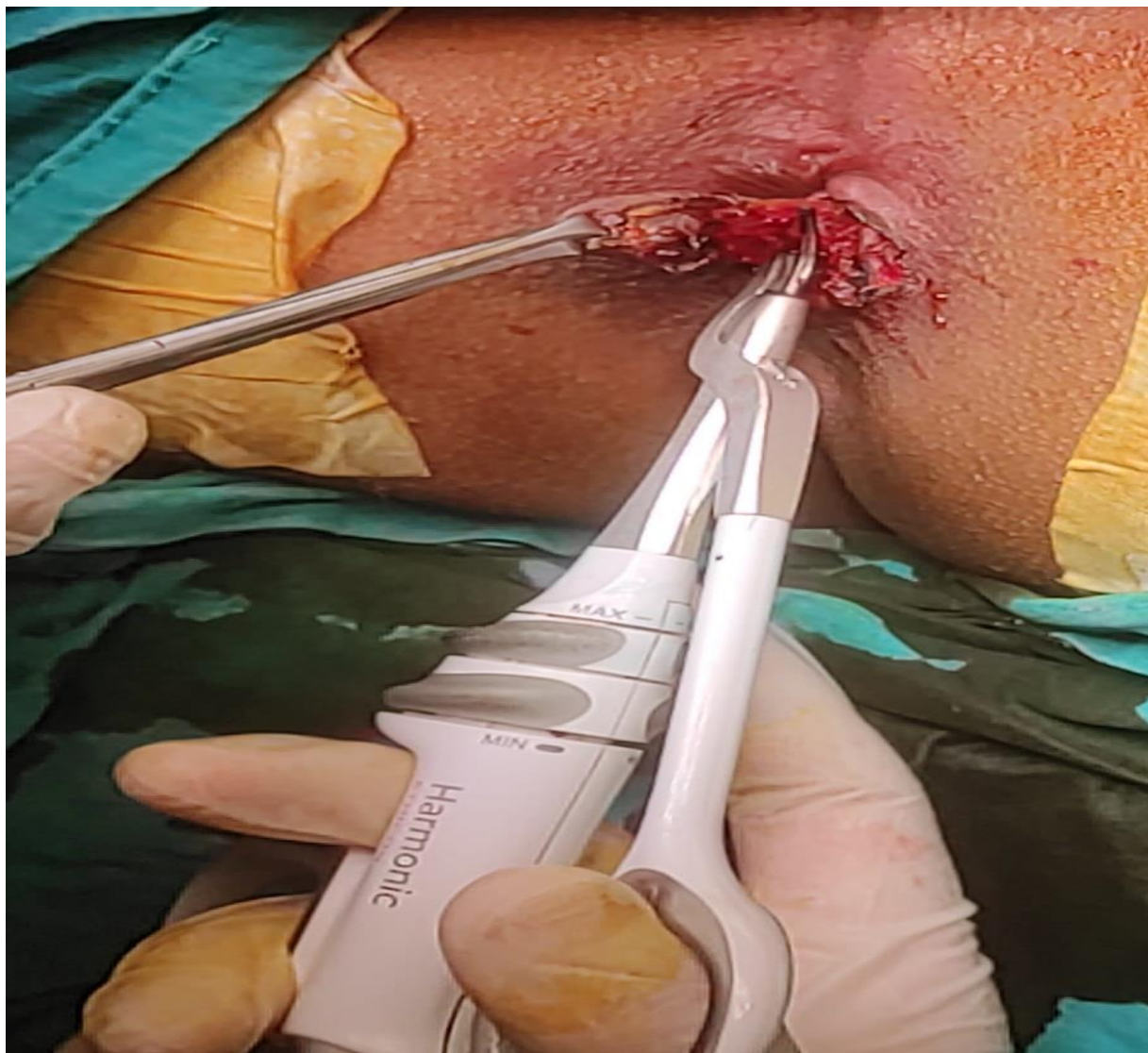
**Table (4)** Comparison between the studied groups preoperative amount of postoperative analgesia over time

Amount of analgesia	Group		Test	
	Group A	Group B	KW	p
	Median (IQR)	Median (IQR)		
First day	1.5 (1 - 2)	1.5 (1 - 2)	14.75	<0.001**
Second day	2.5 (2 - 3)	2 (2 - 3)	18.174	<0.001**
Seventh day	2 (2 - 3)	1 (1 - 2)	13.212	<0.001**
Fourteen day	2 (1 - 2)	1 (1 - 1)	15.065	<0.001**
28 days	1 (0 - 1)	1 (1 - 1)	38.896	<0.001**



**Figure 1:** Excision of the hemorrhoidal mass after ligation of the pedicle by monopolar diathermy





**Figure 2:** Harmonic scalpel in action during hemorrhoidectomy (hemorrhoidal tissue grasped by Allis forceps)

**Discussion:**

Conventional hemorrhoidectomy, including open and closed techniques, is accepted as the gold standard for surgical treatment of hemorrhoids worldwide. Conventional hemorrhoidectomy for Grade III and Grade IV hemorrhoids is a hectic procedure associated with serious morbidity and a prolonged recovery period.<sup>1,2</sup>

The Harmonic Scalpel possesses the unique advantage of causing minimal lateral thermal injury in the tissues. A decreased lateral thermal injury (<1.5 mm) at the surgical site is translated into decreased postoperative pain in contrast with a 15 mm depth of thermal injury with monopolar electrocautery.<sup>3,4</sup>

These results were similar to those published by Chung et al. who reported that mean operative time in HSH group was 15.9 ± 5.7 minutes and mean operative time in MMH with diathermy group was 17.6 ± 8.3 minutes.<sup>5</sup>

In the current study regarding to postoperative pain and analgesic requirements. Pain score was measured using VAS from zero (no pain) to 10 (very severe pain) on postoperative days 1, 2, 7, 14 and 28. The frequency of analgesia (diclofenac sodium 50 mg tablets) given to the patients during the same period was measured by number of tablets per day.

In HSH group, postoperative pain in the first 24 hours after the surgery was a median of 5 (4.5 - 6) according to VAS with analgesic usage median of 1.5 (1 - 2) tablets. On day 2: the pain median was 5 (5 - 6) according to VAS with diclofenac intake median of 2 (2 - 3). By day 7 and 14; pain median was 4 (4 - 5) and 2.5 (4 - 4) respectively while amount of analgesia use was the same; a median of 1 (1 - 1).

On the contrary, DH group, postoperative pain median was 7 (6.5 - 8) on 1st day and pain killer use median was 1.5 (1 - 2). Pain score slightly increased on the 2nd day with a median of 7.5 (6 - 8) and then slight descend on 7th day 6 (5 - 6). This was reflected on the amount of administered analgesic which had a median of 2.5 (2 - 3), 2 (2 - 3) and 2 (1 - 2) on days 2, 7 and 14 respectively. (Table 4)

Comparison between the two studied groups in the present study showed that; there was statistically significant difference between both groups as regards to postoperative pain on follow up period, where the patients underwent hemorrhoidectomy using Harmonic Scalpel had less postoperative pain than Diathermy, (P<0.001). These results were similar to those published by Armstrong et al.<sup>6</sup>

As stated in previous randomized studies, total analgesic need was the highest in first 24 hours and then decreased gradually, and was lower in HSH group than

DH group at postoperative Day 1, 2, 7, 14 and Day 28. 7,8,9 This could be attributed to the fact that the harmonic scalpel cuts and coagulates tissues simultaneously and there was no transfixing suture at the hemorrhoidal pedicle which was used in DH group.

**Conclusion:**

Hemorrhoidectomy using Harmonic Scalpel is as safe and effective, with similar efficacy as diathermy hemorrhoidectomy. Moreover, it carries several advantages of reduced postoperative pain, reduced doses of analgesia needed postoperatively, excellent hemostasis and reduced amount of vapour released.

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**Conflict of interest:** None.

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