



ORIGINAL ARTICLE

HARMONIC SCALPEL® VERSUS CONVENTIONAL DIATHERMY HAEMORRHOIDECTOMY; GAIN OR PAIN?

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Abstract

Aim: Postoperative pain is the most distressing drawbacks of surgical hemorrhoidectomy. We will compare harmonic scalpel hemorrhoidectomy with diathermy hemorrhoidectomy as regard postoperative pain, analgesic requirements duration of healing and other complications.

Methods: Seventy-two patients having symptomatic grade III & IV hemorrhoids were randomly classified into two groups; the first group (group I) (36 patients) were operated upon using harmonic scalpel® and the second group (group II) (36 patients) were operated upon using conventional monopolar diathermy. Operative time & postoperative pain severity and analgesic requirements were recorded 6, 12, 24, 48 hours, 7, 14 and 28 days. Incidence of bleeding and wound infection was recorded in 1, 2, 3 & 4 weeks. The patients were followed up for 6 months where late complications as delayed wound healing, anal stenosis, incontinence and persistent pain, all were recorded in both groups.

Results: Operative time was significantly shorter in harmonic scalpel group, also, there was no blood loss. Postoperatively, pain scoring was significantly lower in group I and subsequently daily analgesic requirements. Healing was faster in first group. Secondary infection and bleeding occurred in second group with no incidence in first group, also, temporary minor fecal incontinence occurred in second group only.

Conclusion: Harmonic scalpel hemorrhoidectomy can be used safely for treatment of grade III & IV hemorrhoids and is better in most of aspects than conventional diathermy. Its cost is overcome by shorter operation, rapid healing and early return to work.

Keywords: Hemorrhoids, hemorrhoidectomy, harmonic scalpel®, diathermy.

INTRODUCTION

Hemorrhoidectomy is the most effective approach for hemorrhoidal disease especially for grade III and grade IV disease.⁽¹⁾ However, postoperative pain⁽²⁾ is a major concern, and the surgery itself is not without complication, including notably bleeding,⁽³⁾ wound sepsis and anal stenosis⁽⁴⁾ resulting in a protracted

period of recovery for the patient.

Diathermy hemorrhoidectomy has been shown to be associated with less bleeding, shorter operating time and lower postoperative analgesic requirement, but this technique is not less painful than conventional hemorrhoidectomy.⁽⁵⁾

Recent advances in surgical instruments, including the stapling devices,⁽⁶⁾ the ultrasonic scalpel⁽⁷⁾ and bipolar electrothermal device,⁽⁸⁾ have revived the hope for an improved technique for radical treatment of hemorrhoids with less postoperative pain.

The harmonic scalpel® (Johnson & Johnson Medical K.K., Ethicon Endo-Surgery, Cincinnati, OH) is an ultrasonically activated instrument which vibrates at a rate of 55,000 MHz per second. It is known for its ability to coagulate small and medium sized vessels by converting electrical energy to mechanical one. There is less lateral thermal damage, with no passage of electricity to or through the patient, resulting in greater safety for the patient. In theory, the reliable haemostatic effect and the associated decreased tissue trauma should make harmonic scalpel® a superior instrument for hemorrhoidectomy.

There have been several randomized trials to date comparing harmonic scalpel® hemorrhoidectomy with other various open⁽⁹⁻¹⁰⁾ and closed techniques^(7,10) and the results were inconstant. Some studies showed clear cut benefit of harmonic scalpel hemorrhoidectomy with respect to operative time, blood loss, postoperative pain, length of hospital stay and return to normal activity^(9,10,11) whereas others showed no advantages.^(7,12)

Motivated by results of these studies, this prospective, randomized study was designed to compare the surgical outcomes of hemorrhoidectomy performed by harmonic scalpel® with that performed by conventional open diathermy hemorrhoidectomy.

PATIENTS AND METHODS

Patients having symptomatic grade III & IV hemorrhoids were included in the study. Patients with associated anorectal disease as anal fissure, fistula in ano, associated mucosal prolapse, anal incontinence, rectocele, obstructed defecation and previous anal surgery were excluded from the study.

Seventy-two patients fulfilled the study criteria and agreed to randomization (Consort E-flowchart). The Ethics Committee of Mansoura University approved the study protocol. All patients in the study gave written informed consent. Patients were randomly classified according to a simple closed envelope method into two groups; the first group (group I) (36 patients) were operated upon using harmonic scalpel® and the second group (group II) (36 patients) were operated upon using conventional monopolar diathermy.

Standardized surgical techniques were applied for each patient in each group. Under spinal anesthesia, the patient was placed in lithotomy position. A modified

Ferguson hemorrhoidectomy for mother piles (3 quadrants) was applied for each patient.

On using harmonic scalpel®, each hemorrhoidal cushion was dealt with as follow: three to five applications of the harmonic scalpel® blade were required to excise the cushion. Harmonic scalpel® uses the scissor configuration (Coagulation Shears), so there was no need to use surgical scissors. The first application included the perianal skin, including the external component of hemorrhoidal cushion, the second included part of cushion overlying the internal sphincter, and the last included the pedicle 0.5 cm above the dentate line (Figs. 1-3).

With diathermy hemorrhoidectomy, each hemorrhoidal cushion was managed starting by a V- shaped incision in perianal skin including external component of the cushion by using diathermy in cutting mode. Dissection using diathermy in coagulation mode is continued cephalade up to 0.5cm above dentate line taking care not to jeopardize internal sphincter muscle fibers. Bleeding points were cauterized with diathermy. Transfixion-excision of the dissected hemorrhoid was done 0.5 cm above dentate line using Vicryl 2/0 and the resultant wound was left open.

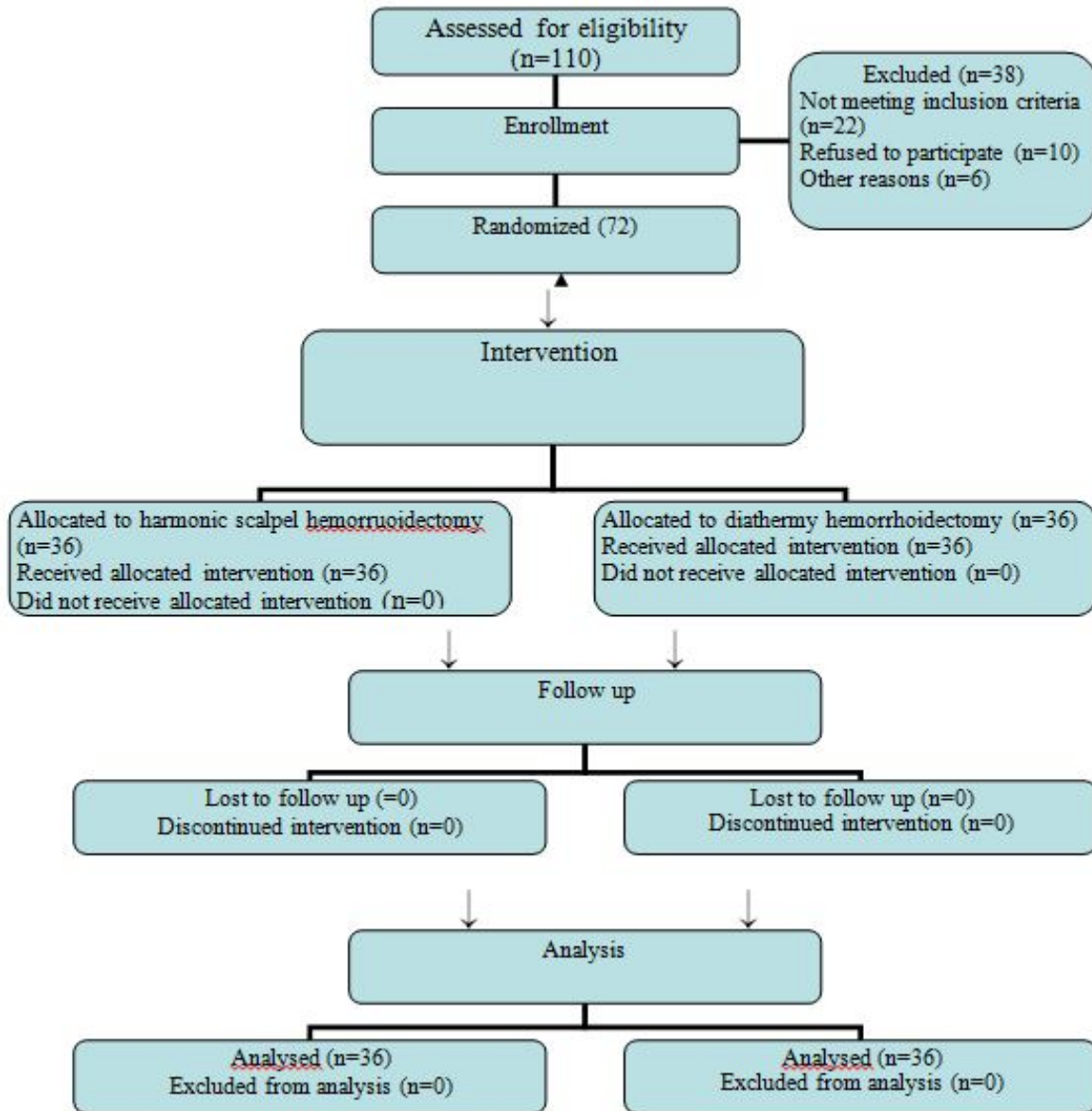
The wound was covered with light gauze impregnated with gentamycin ointment with no packing.

Operative time was recorded for both techniques. Postoperatively, pain severity and analgesic requirements were recorded 6, 12, 24, 48 hours, 7, 14 and 28 days. Pain was assessed using visual analog scale, it was evaluated by a score of 0 (no Pain) to 10 (very severe pain).

Analgesic given was diclofenac sodium with a maximum dose of 3 mg/kg/day (I.M. in the first 48 hours and by oral rout after that). In severe intractable pain, opioid analgesic (pethidine 1 mg/kg) was given in one or two doses in the first day. Incidence of bleeding and wound infection was recorded in 1, 2, 3 & 4 weeks. The patients were followed up for 6 months where late complications as delayed wound healing, anal stenosis, incontinence and persistent pain, all were recorded in both groups.

Statistical analysis: Data was analyzed using SPSS (Statistical Package for Social Sciences) version 10. Qualitative data was presented as number and percent. Comparison between groups was done by Chi-Square test. Quantitative data was tested for normality by Kolmogrov-Smirnov test. Normally distributed data was presented as mean \pm SD. Student t-test was used to compare between two groups. P < 0.05 was considered to be statistically significant.

The Consort E-Flowchart



RESULTS

Seventy-two patients were included in the study, they were 42 females and 30 males with age ranging from 21 to 58 years. Age, sex, disease duration and hemorrhoids grade are enumerated in Table 1.

Operative time, intraoperative blood loss and hospital stay were significantly less in harmonic scalpel® group than diathermy group. Secondary hemorrhage, wound infection and other complications were insignificantly

more in diathermy group. Time off of work was significantly longer in diathermy group. Table 2.

Severity of pain was assessed using visual analogue scale where pain scoring was significantly lower in harmonic group during the first 28 days which showed gradual decrease in intensity. Table 3, Fig. 4.

Subsequently, the daily requirements of analgesics showed significant difference where analgesic demands were much more in diathermy group. Table 4.

Table 1. Clinical characteristics of studied patients.

	Harmonic scalpel® group (n= 36)	Diathermy group (n= 36)	P value
Age: (years)			
Range	22- 57	21- 58	0.373
Mean ± SD	35 ± 4.5	34 ± 5	(NS)
Sex:			
Male	14	16	0.633
Female	22	20	(NS)
Duration of illness:			
< 12 months	8	9	0.887
12- 24 months	13	14	(NS)
> 24 months	15	13	
Grade:			
III	23	22	0.808
IV	13	14	(NS)

Table 2. Operative time and blood loss & post-operative complications.

	Harmonic	Diathermy	P value
Operative time: (minutes)			
Range	9- 16	17- 28	< 0.001 (S)
Mean ± SD	11 ± 3	20 ± 4	
Intraoperative blood loss:			
- Range	0 - 20 (cc)	20 - 40 (cc)	< 0.001 (S)
- Mean ± SD	(13 ± 3) cc	(25 ± 4) cc	
Urine retention	3	7	0.022 (S)
Hospital stay	24 – 48 h	36 – 96 h	< 0.001 (S)
Secondary hemorrhage	1	2	NS
Infection	1	3	NS
Incontinence	0	1	NS
Stenosis	0	1	NS
Return to work after operation:			
- One week	18 (50%)	3 (8.3%)	< 0.001 (S)
- two weeks	10 (27.8%)	9 (25%)	< 0.563 (NS)
- three weeks	4 (11.1%)	11 (30.6%)	< 0.001 (S)
- four weeks	4 (11.1%)	9 (25%)	< 0.001 (S)

Table 3. Pain score (VAS) in first 4 weeks in both groups.

	Harmonic	Diathermy	P value
Preoperative:			
Range	1.0 - 3.0	1.5 - 3.5	0.444
Mean	1.7 ± 0.5	1.8 ± 0.6	NS
Day 1			
Range	4.5 - 6	7.5 - 9.5	< 0.001
Mean	4.7 ± 0.6	7.8 ± 1.0	S
Day 2			
Range	4.3 - 5.7	7.2 - 9.5	< 0.001
Mean	4.5 ± 0.4	7.5 ± 1.0	S
Day 7			
Range	2.7 - 3.0	5.7 - 7.3	< 0.001
Mean	2.5 ± 0.4	5.8 ± 0.8	S
Day 14			
Range	1.5 - 2.0	3.5 - 4.6	< 0.001
Mean	1.6 ± 0.2	3.7 ± 0.5	S
Day 28			
Range	0.3 - 0.7	0.5 - 0.9	< 0.001
Mean	0.4 ± 0.1	0.6 ± 0.2	S

Table 4. Range of Analgesic requirements in both groups.

	Harmonic	Diathermy	P value
Day 1	120 - 160	250 - 300	< 0.001 S
Day 2	100 - 150	225 - 300	< 0.001 S
Day 7	50 - 100	120 - 160	< 0.001 S
Day 14	25 - 50	80 - 100	< 0.001 S
Day 28	0 - 25	0 - 50	< 0.001 S

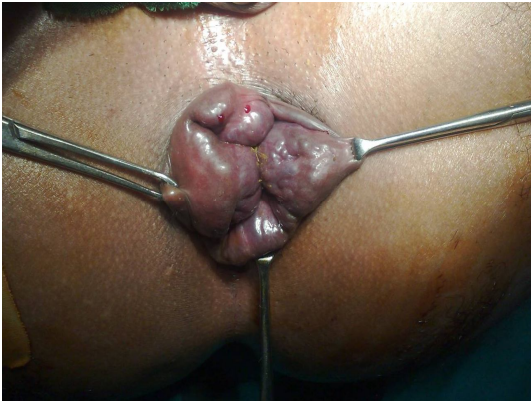


Fig 1. Hemorrhoidal cushions.



Fig 3. Final result after harmonic scalpel hemorrhoidectomy.

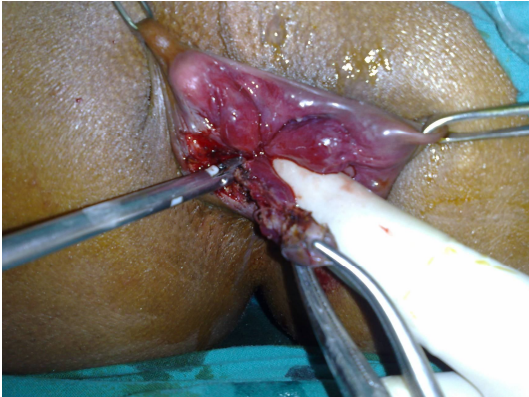


Fig 2. Harmonic scalpel dissection.

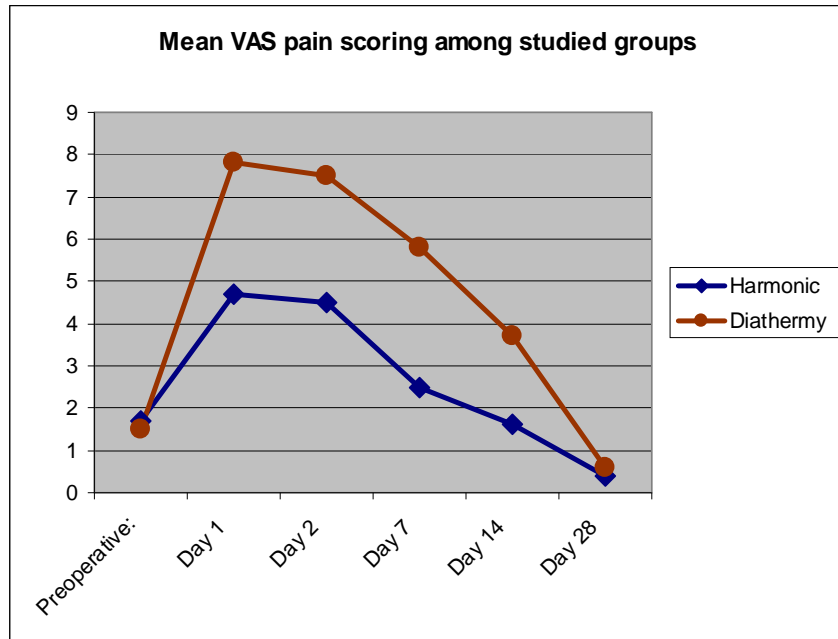


Fig 4. Mean VAS pain scoring among studied groups.

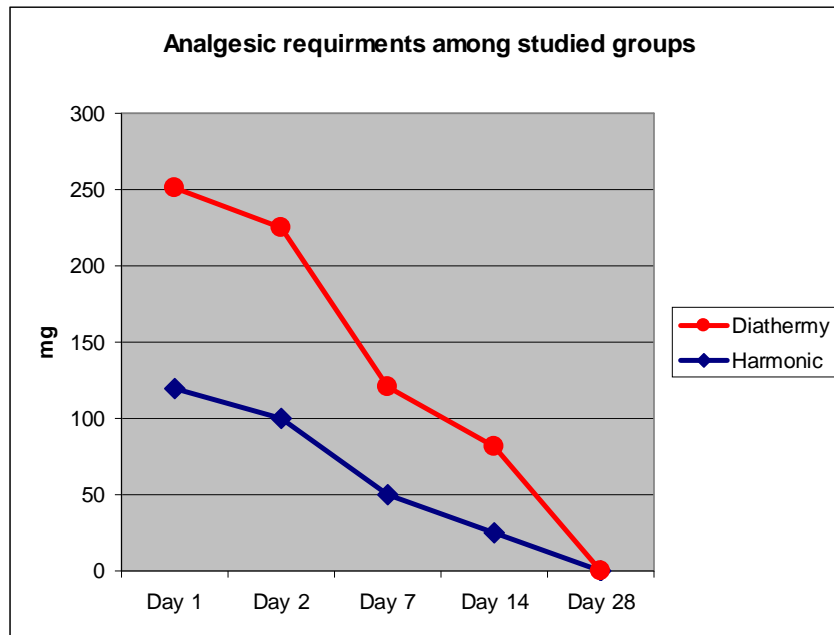


Fig 5. Analgesic requirements among studied groups.

DISCUSSION

The combination of external hemorrhoids and grade III or IV hemorrhoids is most effectively treated by excision of the hemorrhoidal complex.⁽¹⁾

The current study included only grade III & IV hemorrhoids; accordingly, variability introduced by operating on lesser grades is avoided. Also, exclusion of patients with coexisting anorectal pathology (fissure or fistula) makes both groups homogenous. Patients with neurological deficits, chronic pain and patients currently using narcotic analgesics were also excluded to avoid variabilities in pain assessment.

The obvious disadvantage of surgical hemorrhoidectomy is the postoperative pain resulting from the surgical defect in the sensitive perianal skin and anoderm. Much of this discomfort may arise from the thermal injury of electrocautery.⁽¹⁰⁾

Harmonic scalpel® offers an excellent method for achieving bloodless dissection of vascular tissue. Localized coagulation with decreased lateral thermal injury (0 – 1.5 mm deep) makes it an ideal instrument for hemorrhoidectomy. Using the sharp blade, on full power mode, and applying a firm grip to the scissor handle maximize cutting of tissues by harmonic scalpel, on the other hand, coagulation is maximized using the blunt blade, variable power mode, and a light grip.⁽¹⁰⁾ Hemostasis is accomplished by coaptation of the vessels which are sealed by denaturated protein. Full power mode was applied for cutting tough perianal skin and

variable mode for vascular anal cushions for good hemostasis. Undue traction on surgical cut margins almost invariably lead to bleeding, so, the key of success is to avoid any traction on tissue during application.

Studies examining the depth of thermal injuries reported a lateral thermal injury up to 15 mm deep using monopolar diathermy whereas bipolar electrocautery caused thermal damage up to 9 mm.⁽¹¹⁾

The significant reduction in both the postoperative pain and the analgesic requirements experienced by the Harmonic scalpel® patients confirm the initial concept that the elimination of lateral thermal injury does indeed translate into significantly less postoperative pain.⁽¹⁰⁾ To obviate the effect of lateral thermal injury, an obvious comparison could be made between hemorrhoidectomy using scissor or knife. If bleeding sites are individually ligated, a time consuming and infrequent surgical practice, no thermal injury whatsoever is imparted.

Supplemental electrocautery is used to some extent during scissor hemorrhoidectomy to coagulate individual bleeders resulting in some degrees of third degree burn. The deep burn of electrocautery is sometimes invoked as a potentially beneficial feature as thermal destruction of dermal pain fibers results in less pain. This argument defies the clinical experience of observing the discomfort, surrounding inflammation and healing time of a clean incised wound compared with deep burns.⁽¹⁰⁾

The reported operative time for Ligasure™ hemorrhoidectomy in different studies was 5.2-15 minutes⁽¹²⁾, which approximates the operative time in the current study. Lateral thermal spread of Ligasure™ is 0.5-2 mm⁽¹³⁾ compared with harmonic scalpel (0-1.5 mm).

In this study there have been no unexpected complications. In contrast circular stapling hemorrhoidectomy has been followed by reports of serious complications including serious pelvic sepsis⁽¹⁴⁾ and anastomotic stenosis⁽¹⁵⁾. Furthermore, failure to deal with external hemorrhoidal components and skin tags can lead to unsatisfactory results in patients treated with circular stapler. This problem is avoided with the use of harmonic scalpel which can deal effectively with both internal and external hemorrhoidal components giving good cosmeses.

There was no statistically significant difference in incidence of postoperative hemorrhage but diathermy operated patients needed reoperation for control. With diathermy, an intravascular clot is formed and is responsible for hemostasis, dislodgement of clots may cause bleeding, while with harmonic, a complete and permanent fusion of the vessel lumen is achieved.

Cost-effectiveness of harmonic scalpel hemorrhoidectomy is to be evaluated by patient's hospital stay and testing time off of work after operation. Dramatic decrease in the number of hospital days in harmonic scalpel hemorrhoidectomy made it an outpatient procedure as reflected in the current study and other studies^(16, 17). Also, earlier return to work could overcome the cost of using the machine. Half of the patients in harmonic scalpel group returned to work within one week in contrary to less than ten percent in diathermy group.

In conclusion, the present study suggests that harmonic scalpel® hemorrhoidectomy is safe, fast, and easy to perform. The cost can be overcome by the advantage of rapid wound healing and earlier return to usual lifestyle.

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