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Research Article

Comparative Study between Harmonic Scalpel and Diathermy in the Surgical Treatment of Grade III and IV Hemorrhoids

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Abstract

Introduction: Surgical excision using Harmonic Scalpel is a modern technique used for ablation of symptomatic third degree and all fourth-degree hemorrhoids. Compared with diathermy, Harmonic Scalpel causes minimal lateral thermal injury during tissue dissection. The resulting mucosal defect then left open. The aim of this work is to compare between Harmonic Scalpel hemorrhoidectomy and diathermy hemorrhoidectomy in the surgical treatment of grade III and IV haemorrhoids.

Patients and Methods: This is a prospective randomized study done at Alexandria University hospital during the period from November 2014 to April 2015. Forty patients underwent surgical excision of complex grade III or grade IV hemorrhoids. They were divided into two groups: (1) Harmonic Scalpel Hemorrhoidectomy group (n=20) and (2) Diathermy Hemorrhoidectomy group (n=20). Operative time and bleeding, postoperative pain and analgesic requirements, early and late postoperative complications, hospital stay, and time to return to normal activity all were recorded and statistically analysed.

Results: Postoperative pain in Group (1) was significantly less with less analgesic requirement in the first 24 hours postoperatively. There was no significant difference between both groups regarding other postoperative complications.

Conclusion: This study demonstrates significantly reduced postoperative pain after Harmonic Scalpel Hemorrhoidectomy compared with Diathermy Hemorrhoidectomy. Most likely, this result came from the avoidance of excessive lateral thermal injury caused by monopolar electrocautery.

Keywords: Hemorrhoidectomy; Haemorrhoids

Introduction

Hemorrhoids are one of the most common anorectal disorders with a reported prevalence of 4.4% up to 36.4% of general population [1]. Different studies showed that about 5%-10% of patients suffering from hemorrhoids do not respond to conservative treatments, so surgical procedures become the treatment of choice in such cases [2]. The pathogenesis of hemorrhoids is not completely clear [3]. A number of possible contributing factors leading to migration of the hemorrhoidal cushions have been suggested, including lack of dietary fiber, prolonged straining, spending excess time on the commode, constipation, diarrhea, pregnancy, sedentary lifestyle, and a family history. Apart from pregnancy, none of these etiologies are supported by good evidence [4-6]. 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 [7].

The first item of conservative treatment of hemorrhoid is to modify life style so that the patient can avoid prolonged straining mainly by decrease formation of hard stool, which can be achieved by increasing the intake of dietary fiber and oral fluids. Other factors that may help to decrease straining include improving anal hygiene, avoiding unnecessary straining and medications, which cause either constipation or diarrhea [8-10]. Office procedures include the following: (1) rubber band ligation (RBL), (2) sclerotherapy, (3) infrared coagulation, (4) radiofrequency coagulation, (5) bipolar diathermy and direct- current electrotherapy, (6) cryosurgery, and (7) laser therapy. Although these procedures are all relatively well tolerated and cause minimal pain, they have variable rates of recurrence. A meta-analysis of 18 randomized trials showed that RBL is the most effective of all office procedures as it is associated with a lower rate of recurrence, albeit with a more overall pain than other procedures [11]. Excisional hemorrhoidectomy is considered to be the most effective treatment modality for hemorrhoids with the lowest recurrence rate as compared to other modalities; however, the main drawbacks are the marked post-operative pain and the highest complication rate [12]. With diathermy hemorrhoidectomy, coagulation occurs at temperatures higher than 150°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 and lower postoperative analgesic requirement, but with similar post- operative pain [13].

The ideal intraoperative hemostatic energy source would accurately coagulate, cut like a knife without charring or sticking to tissue, have minimal smoke production, and keep the patient out of the electrical circuit. Ultrasonic coagulating shears or the Harmonic Scalpel (Ethicon Endo-Surgery, Cincinnati, OH) was developed as an alternative to electrical energy for surgical use [14]. In this study, we present our experience in using Harmoinc Scalpel in hemorroidectom and evaluating the postoperative results in comparison to the use of diathermy.

Patients and Methods

A prospective study was carried out in Alexandria Faculty of Medicine; Department of Surgery and in Alexandria Police Hospital; Department of Surgery after approval of the Ethics Committee had been obtained. Patients who fulfilled the inclusion and exclusion criteria and completed the follow-up for 6 weeks were included in the study; they were 40 consecutive patients during a period of six months from November 2014 through April 2015. Eligible patients were randomly assigned using sealed opaque envelopes in the operating room into one of two groups: Group 1, (HSH, n=20): Haemorrhoidectomy with the Harmonic Scalpel® (Johnson and Johnson Medical KK, Ethicon Endo Surgery, Cincinnati, OH). Group 2, (DH, n=20): Open Haemorrhoidectomy (Milligan-Morgan's Operation) with Diathermy. A written informed consent was obtained from all participants prior to enrolment, after explanation of the associated risks and benefits and description of the study protocol. Inclusion criteria included patients with symptomatic Grade III internal haemorrhoids in association with large external components or prolapsed Grade IV haemorrhoids. Exclusion criteria included Coexisting anorectal disease and patients complicated with fistula-in-ano, anal fissure, or abscess. Previous history of anorectal surgery. The regular use of immunosuppressant or analgesics. Patients with neurologic deficit (paraplegia or previous cerebrovascular accident) or chronic pain syndrome and patients already taking narcotic analgesics. No informed consent or unwillingness of the patient. Patient considered anaesthetically unfit for surgery or poor general condition. Hematologic disorders or a bleeding diathesis. Patients with liver cirrhosis, uncontrolled diabetes.

The procedures were standardized as far as possible to allow comparability. The operations were performed under standardized spinal anaesthesia with the patient in the lithotomy position. An elective three-quadrant surgical haemorrhoidectomy was used in both groups. Follow-up was performed by inspection of the wound in the outpatient clinic after 1, 2, 4 and 6 postoperative weeks assessing patients' outcome, symptoms control and complications.

Operative Time was measured from the beginning of excision of the first pile until excision of the last one. Intraoperative Bleeding was measure by counting number of small gauzes soaked with blood during the operation.

Pain was assessed post-operatively using a visual analogue scale (VAS) [15] from 0 to 10. A score of zero (no pain) evaluated pain to 10 (very severe pain). All patients were given intra-muscular injections of Pethidine (0.5 mg/kg according to body weight) as postoperative Narcotic Analgesia (NA), as required while the patients were still in the hospital. Number of Pethidine injections required during the first 24 h post- operatively was recorded. Postoperative

urinary retention, early postoperative bleeding were recorded as early postoperative complications. In addition to late postoperative complications as haemorrhage, excessive discharge from the wound, anal stenosis and anal incontinence. Length of postoperative hospital stay and time to return to normal activity were measured.

Results

Demographics of the study population were 18 males and 2 females in-group 1, patients' age ranged from 26.0 to 53.0 with a mean of 33.30 ± 7.58 years. While in- group 2, patients were 17 males and 3 females, patients age ranged from 26.0 to 51.0 with a mean of 33.10 ± 6.72 years. There was no statistically significant difference between both groups as regards the patients' sex and age distribution (P value = 1.000, P value = 0.930, respectively). Grade of hemorrhoids was III in 16 patients and IV in 4 patients in group 1. While in-group 2, Grade of hemorrhoids was III in 15 patients and IV in 5 patients. There was no statistically significant difference between both groups as regards grade of hemorrhoids (P value = 1.000).

In-group 1, operative time was statistically significant shorter than group 2. Operative time ranged from 15.0 to 24.0 minutes with a mean of 18.30 ± 2.75 minutes in-group 1. While in-group 2, operative time ranged from 18.0 to 33.0 minutes with a mean of 20.95 ± 4.22 minutes. (P value = 0.024). In-group 1, intraoperative bleeding (blood loss) was statistically significant less in blood loss than group 2. Number of small gauzes soaked with blood intraoperatively ranged from 3.0 to 5.0 with a mean of 3.35 ± 0.67 small gauzes soaked with blood in group 1. While in group 2, Number of small gauzes soaked with blood intraoperatively ranged from 4.0 to 8.0 with a mean of 4.85 ± 0.93 small gauzes soaked with blood. (P value < 0.001). Most of patients stayed postoperatively for 24 hours in the hospital. No statistically significant difference in length of postoperative hospital stay between both groups (P value = 0.560).

During assessment of postoperative pain, the visual analogue scale was used to score the pain in numbers. The use of the Harmonic Scalpel caused statistically significant less in postoperative pain during the first 24 hours after the surgery and statistically significant less in number of Pethidine injections required postoperatively, while the use of diathermy caused more pain after the surgery and more number of Pethidine injections required postoperatively as depicted in Figure 1 and Figure 2. On day of the surgery, postoperative pain ranged from 6.0 to 9.0 with a mean of 7.10 ± 0.97 according to VAS in group 1. While in group 2, On day of the surgery, postoperative pain ranged from 8.0 to 10.0 with a mean of 8.65 ± 0.75 according to VAS in group 1, Number of Pethidine injections given ranged from 2.0 to 4.0 with a mean of 3.05 ± 0.69 injections. While in group 2, Number of Pethidine injections given ranged from 5.0 to 6.0 with a mean of 5.20 ± 0.41 injections.

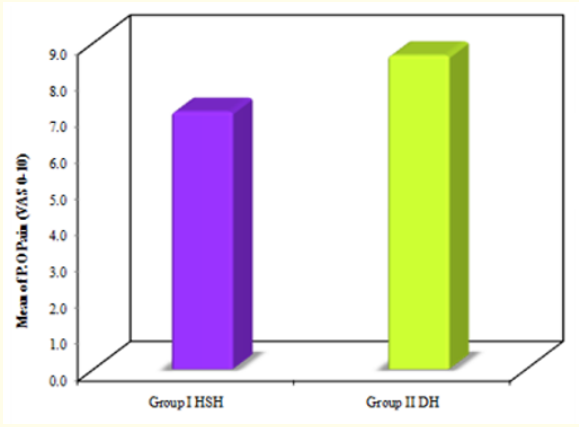

Figure 1: Comparison between the studied groups according to postoperative pain on day of the surgery using VAS (from 0 to 10) (P value < 0.001, using Student t-test).

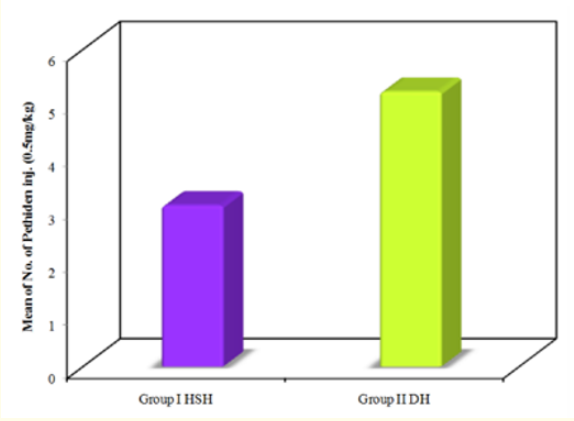

Figure 2: Comparison between the studied groups according to P.O Analgesic Requirement on day of the surgery using No. of Pethidine injections given (P value < 0.001, using Student t-test).

During the follow up period, No statistically significant difference in postoperative pain between both groups as depicted in Table 1 and Figure 3.

	P. O. Week 1	P.O. Week 2	P.O. Week 4	P.O. Week 6
Group I HSH				
Min. – Max.	5.0 – 7.0	4.0 – 7.0	2.0 – 4.0	0.0 – 1.0
Mean ± SD.	5.40 ± 0.68	4.50 ± 0.95	2.55 ± 0.69	0.30 ± 0.47
Median	5.0	4.0	2.0	0.0
Group II DH				
Min. – Max.	5.0 – 9.0	4.0 – 8.0	2.0 – 7.0	0.0 - 1.0
Mean ± SD.	5.90 ± 1.07	4.90 ± 1.07	2.90 ± 1.17	0.60 ± 0.50
Median	6.0	5.0	3.0	1.0
t	1.762	1.252	1.157	1.949
p	0.086	0.218	0.254	0.059

Table 1: Comparison between the studied groups according to postoperative pain using VAS (from 0 to 10) during the follow up period.

t: Student t-test for comparing between the two groups.

*: Statistically significant at p ≤ 0.05.

SD: Standard Deviation

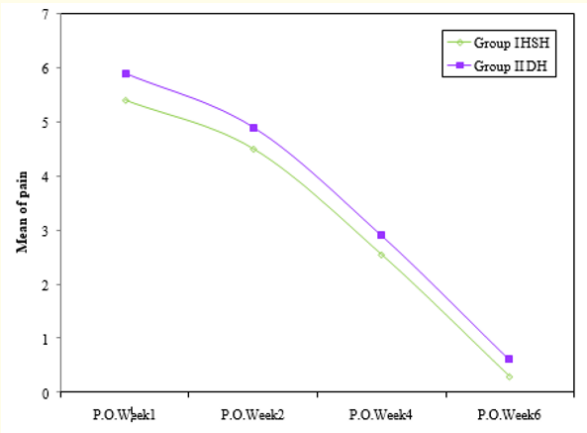

Figure 3: Comparison between the studied groups according to postoperative pain using VAS (from 0 to 10) during the follow up period.

In-group 1, one patient had postoperative urinary retention and the other patient had anal stenosis. In-group 2, two patients had postoperative urinary retention, one patient had early postoperative bleeding, one patient had late hemorrhage during the follow up, one patient had excessive discharge from the wound, and one patient had flatus incontinence. Two patients had postoperative complications in group-1 while six patients had postoperative complications in-group 2. No statistically significant difference in the incidence of postoperative complications between both groups (P value NS). In-group 1, time to return to normal activity was statistically significant shorter in time than in-group 2. 90% of patients in-group 1 restored their normal activity within two weeks postoperatively while only 35% of patients in-group 2 backed to their activity within two weeks postoperatively (P value < 0.001).

Discussion

In the current study, many potential confounders were been avoided by standardizing many variables. Starting with choice of the patients, patients with other anorectal pathology and patients with neurological defects or chronic pain syndromes and those currently taking narcotic analgesics were been excluded. This gave us the advantage of avoiding variation in the results of pain assessment. In addition, patient selection was only to those having symptomatic Grade III internal hemorrhoids with prominent external ones and Grade IV disease.

Our results were similar to those published by Ramadan., *et al*. [21] study. They mentioned that there was statistically significant difference in duration of surgery between the two studied groups. Tan., *et al*. [16], Khan., *et al*. [17], and Chung., *et al*. [18] published different results. They showed that there was no statistically significant difference in duration of surgery between the studied groups. Those results were explained in Chung., *et al*. [18] study by that the operating surgeons were familiar with the use of the Harmonic Scalpel, bipolar scissors, and traditional scissors. Our results were similar to those published by Chung., *et al*. [18] study. They mentioned that there was statistically significant difference in intraoperative bleeding (blood loss) between the HSH group and MMH group.

The results of the present study were similar to those published by Armstrong., *et al*. [19], Chung., *et al*. [18], Ramadan., *et al*. [21], and Abo-Hashem., *et al*. [20] studies. They mentioned that there was statistically significant difference in postoperative pain; during the first 24 hours after the operation, postoperative narcotic analgesia required and postoperative pain during follow up period, between the two studied groups. In Armstrong., *et al*. [19] study, they reported that postoperative pain was significantly less in the Harmonic Scalpel group on Days 1, 2, 7, 14, and 28 ($P < 0.01$). The number of narcotic analgesics required per 24-hour period was significantly lower in the Harmonic Scalpel group on Days 1, 2, 7, and 14. By Day 28, there was no significant difference between the groups. In Chung., *et al*. [18] study they also reported that There was significant difference between HSH group and MMH group in term of the mean pain scores (PS) in the first postoperative week (Days 1 to 7). ($P = 0.043$). Patients in the HSH group required significantly fewer pethidine injections than those in the MMH group. ($P = 0.022$). In Ramadan., *et al*. [21] study, they reported that the degree of pain was higher in MM group ($P < 0.0001$) even though the types of analgesia given one day after operation were similar. The pain at first defecation and at rest was significantly lower in the HS group. Likewise, similar results were seen in the first and second weeks after surgery Pain in the harmonic scalpel hemorrhoidectomy group was significantly less than that in patients treated by the electronic device, and this difference was recognizable in analgesics usage. In Abo-Hashem., *et al*. [20] study they also reported that Postoperative pain was found to be significantly less in HSH Group in all days of postoperative follow up ($P < 0.01$). The mean dose of narcotic analgesia used in the first three days postoperatively was significantly reduced in Harmonic scalpel group when compared to the bipolar electro- cautery group, ($P < 0.01$). Tan., *et al*. [16], and Khan., *et al*. [17] published different results. They showed that there was no statistically significant difference in postoperative pain; during the first 24 hours after the operation, postoperative narcotic analgesia required and postoperative pain during follow up period between the studied groups. Those results were reported in Tan., *et al*. [16] study showed that there was no statistical difference in severity of postoperative pain between the two groups. There was no significant difference in pain scores between patients undergoing hemorrhoidectomy via diathermy or the Harmonic Scalpel. This was further borne out by the similar results obtained in analysis of the number of pethidine injections. In Khan., *et al*. [17] study they also reported that there was no reduction in postoperative pain when patients whose operations were assisted by electrocautery were compared with those whose surgery was done with the HS. There was no significant difference in pain measurements reported on Day 1 ($P < 0.82$). On postoperative Day 7, the difference in pain between groups approached significance, with pain reported as 3.7 ± 0.3 for CH and 5.1 ± 0.7 for HS ($P < 0.06$). There was no significant difference in pain at six weeks, with both groups being essentially pain-free ($P < 0.36$). However, a significant decrease in pain was found between postoperative Days 1 and 7 in CH patients ($P < 0.001$) that was not seen in HS patients ($P < 0.42$).

The results obtained from this study were similar to those published by Tan., *et al*. [16] study. They mentioned that there was no statistically significant difference in postoperative hospital stay between the HSH group and DH group. Our results were similar to those published by Tan., *et al*. [16], Khan., *et al*. [17], Armstrong., *et al*. [19], and Chung., *et al*. [18] studies. They mentioned that there was no statistically significant difference in postoperative complications rate between the studied groups. Tan., *et al*. [16] mentioned that there was no significant difference between post-hemorrhoidectomy bleeding rates ($P = 0.19$), although there appeared to be more bleeding in DH Group. In Ramadan., *et al*. [21] study, they mentioned that early complications occurred more frequently in the MM group but the difference was not statistically significant overall. Urinary retention was more frequent in the MM group ($P < 0.005$). Constipation was also more frequent in the MM group, but with no statistical significance. In Abo-Hashem., *et al*. [20] study, they mentioned that incidence of postoperative bleeding

was nearly comparable in both groups. They also mentioned that posthemorrhoidectomy bleeding was found statistically significant ($P < 0.05$). In addition, no difference was found between both groups regarding wound infection, major short-term incontinence and swelling of the skin bridges. Our results were similar to those published by Armstrong., *et al*. [19], Ramadan., *et al*. [21], and Abo-Hashem., *et al*. [20] studies. They mentioned that there was statistically significant difference in time to return to normal activity between the two studied groups, (within second week, $P < 0.05$).

Although the use of the Harmonic Scalpel carries some disadvantages increased cost over the electro-cautery hemorrhoidectomy, it carries several advantages. Reduced postoperative pain, reduced doses of Narcotic Analgesia postoperatively, excellent hemostasis and reduced amount of vapour released during the procedure are considered as great advantages. In addition, secondary to the reduced postoperative pain there was significantly reduced incidence of postoperative urine retention and finally reduced time-off work for patients of Group 1 (Harmonic Scalpel hemorrhoidectomy group). So, and for all these merits we recommend using Harmonic Scalpel in hemorrhoidectomy surgery if available in patients with symptomatic grade III internal haemorrhoids in association with large external components and those with prolapsed, thrombosed Grade IV hemorrhoids.

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