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Original Research Article

Harmonic scalpel versus bipolar diathermy in Milligan-Morgan haemorrhoidectomy: a randomized controlled study

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ABSTRACT

Background: Post-operative pain and bleeding are two major dilemmas associated with haemorrhoidectomy. Recent advances in energy sources have provided an alternative in reducing both the issues. This study was conducted with an aim to compare use of ultrasonic scalpel (Harmonic Scalpel) and bipolar diathermy in reducing post-operative pain and bleeding in Milligan-Morgan haemorrhoidectomy (MMH).
Methods: Sixty patients with grade III and IV haemorrhoids underwent MMH, after being randomized into two groups, one half of them using Harmonic Scalpel and other group, using Bipolar diathermy scissors over a period of one year at Department of General Surgery at Sir Sayajirao Gaekwad (SSG) Hospital, Baroda. Operative data were recorded, and the patients were followed-up accordingly. Independent assessors were assigned to obtain blood loss, post-operative pain scores, analgesic requirements and other secondary outcomes.
Results: Intra-operative bleeding, post-operative pain scores and duration of hospital stay were significantly lower with Harmonic scalpel as compared to bipolar diathermy scissors. However, there was no significant difference in both the groups with respect to first bowel movement and early or late complications.
Conclusions: Harmonic scalpel can be used as an alternative to bipolar diathermy, in view of its good haemostatic capability, reduced post-operative pain and analgesic requirements.

Keywords: Bipolar diathermy, Blood loss, Haemorrhoidectomy, Harmonic scalpel, Post-operative pain

INTRODUCTION

Haemorrhoidectomy is the most definitive way of treating 3rd and 4th degree haemorrhoids.[1] It is one of the most commonly performed ano-rectal operations. Although it is considered a minor procedure, the postoperative course is protracted, and the postoperative complications are not negligible.

Postoperative pain is a major concern, and the surgery itself is not without complications, including notably bleeding and anal stricture.[2-4] Recent advances in instrumental technology have provided new alternatives in haemorrhoidectomy.[5-7] The Harmonic Scalpel is an ultrasonically activated instrument with sound waves as its source of power, which vibrates at a rate of 55,000 per second. It is known for its ability to coagulate small and medium-sized vessels thus, potentially it may minimize postoperative swelling and oedema to the surrounding tissue.[5]

The Harmonic Scalpel possesses the unique advantage of causing very little injury in the tissues. A decreased injury (<1.5 mm) at the surgical site is translated into decreased postoperative pain.[8] In different procedures it was found that harmonic scalpel offers many benefits,

including smaller incision, shorter hospital stays, less damage to tissues, quicker recovery and reduced scarring (Figure 1).[9]

Figure 1: Harmonic Scalpel device.

Similarly, a bipolar electrothermal device is a novel hemostatic device and can deliver the precise amount of electrocautery energy across the vascular structures with minimal surrounding thermal spread. Haemorrhoidectomy with a bipolar diathermy has been shown to reduce operating time and postoperative pain or analgesic requirements (Figure 2).

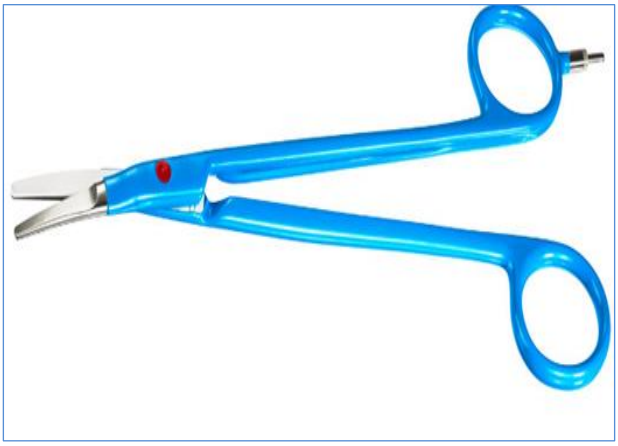

Figure 2: Bipolar diathermy scissors

This prompted a randomized control study of postoperative pain and analgesic requirements after using Harmonic Scalpel and Bipolar diathermy in Milligan-Morgan haemorrhoidectomy.

METHODS

This study was performed on a total of 60 patients presenting at Department of General Surgery at SSG hospital with haemorrhoids during the period of September 2016 to December 2017. The study was approved by the Institutional Research and Ethical Committee.

Inclusion criteria

- All patients with grade III and IV haemorrhoids were included.

Exclusion criteria

- Patients with acute thrombosed piles, previous history of anorectal surgery
- patients taking NSAIDs, opiods, or other analgesics before surgery
- patients with coagulopathies
- and those not giving informed consent.

Detailed history and clinical examination was carried out in all cases. Routine haematological evaluation was done in all the patients and a written informed consent was taken. Eighty sealed envelopes containing a number indicative of the group assignment (even number = Bipolar Diathermy, uneven = Harmonic Scalpel) was used to randomly allocate patients into two groups: A) Harmonic Scalpel™ haemorrhoidectomy (HSH), and B) Milligan-Morgan haemorrhoidectomy with bipolar diathermy (BD) scissors. The surgeon was not blinded to the method used.

Patients were admitted one day before operation and were started on a standard laxative regimen. They were put on a normal diet and kept nil by mouth (NBM) 10 hours prior to surgery. Sodium biphosphate proctolysis enema was given 10 hours and 2 hours prior to the surgery.

Operative Technique

Under spinal or general anaesthesia, the operation was performed with the patient in the lithotomy position. At the start of operation, effluent from the rectum was first carefully sucked away, and a dry cotton gauze-piece was then placed beneath the anal canal to collect blood during operation. The cotton gauze-piece was weighed at the end of the procedure to estimate the blood loss. Increase in one gram of its weight was corresponded to one millilitre of blood loss.

In BDH group, anoderm and subcutaneous tissues between the haemorrhoids was injected with 20 ml of 0.5 percent lidocaine with 1:20000 adrenaline to reduce bleeding and aid preservation of skin bridges left following excision. In our study, the power of the cautery was set at 40W. After putting skin incision, using bipolar diathermy scissors, the haemorrhoidal bundle was carefully dissected off the internal sphincter, up to the pedicle at the anorectal ring. Care was taken to make sure the tissue turned “white” before incising. Whenever necessary, a polyglactin suture was applied at the apex. Bleeding, if any, was controlled by the bipolar cautery. The pedicle of each haemorrhoid was grasped and

coagulated between the scissors rather than being transfixed. Each haemorrhoid was dissected in a similar manner and after ensuring proper haemostasis, a soft absorbable anal dressing was inserted.

Post-operative Care and Follow-up

A high fibre diet was given in the immediate postoperative period and a standard laxative regimen was continued for four weeks. Patients were instructed to take warm sitz bath three to four times a day to keep the perianal area hygienic. The patient was regularly reviewed by an independent assessor in the postoperative period. Postoperative pain was evaluated by means of a visual analogue scale that was explained to patients. Pain was evaluated by a score of 0 (no pain) to 10 (worst pain possible). Patients were asked to rate their pain both preoperatively (in the outpatient clinic) and in post-operative period on day 1, day 2, day 3, day 7, week 4 and week 6. For pain relief, oral analgesic (Tab. Voveran 50mg) was given twice a day. Injection Contramol 50mg IV diluted in 10 cc of distilled water was given as rescue medication when VAS score $\geq$ 5 was appreciated. Required analgesic doses were recorded and analysed as a marker for pain severity. Also, the day of his first bowel movement and any early or late complications, if any, were noted.

Patients were discharged on the basis of the following criteria that, no significant postoperative complications, including fever, have occurred; wound was satisfactory; at least one bowel movement has occurred; and there is no longer requirement of Contramol injection to the patient.

Patients were followed up telephonically at 4 and 6 weeks to record any late complications such as urinary retention or flatus incontinence.

Primary outcomes included post-operative pain and blood loss. Secondary outcomes included analgesic requirements, first bowel movement, duration of hospital stay and early and late complications.

Statistical analysis

Data analysis was performed using MedCalc version 17.9.5 software. Categorical variables were analyzed with chi-squared test and continuous variables were analyzed with 't' test. Values were reported as mean ± standard deviation or median (extremes) or percentages as and when required. P value of less than 0.05 was considered significant.

RESULTS

Total 60 patients with grade III and IV were randomized for the study. Adequacy of randomization was evident from similarity in patient characteristics in both the groups (Table 1). No protocol violations were recorded during the study.

Blood loss during the surgery was significantly less (p=0.0001) in the HSH group compared to BDH group. The mean blood loss in HSH group was 5.93±1.96 ml, while in BDH group, it was 7.23±2.81 ml (Table 1).

Table 1: Comparison of outcomes in HSH group and BDH group.

Outcomes	HSH group	BDH group	P value
Blood loss (ml)	5.93±1.96	7.23±2.81	P=0.0001
Post-op pain scores(VAS)			
Day 1	4.40±3.72	6.13±3.31	P = 0.0003
Day 2	2.67±2.19	3.80±2.99	P = 0.0014
Day 3	1.67 2.12	2.50±2.08	P = 0.0033
Day 7	0.5 1.72	0.8±2.06	P = 0.2261
No. of rescue analgesics injections	0.63±1.23	1.27±1.81	P = 0.0026
Day of first bowel movement (day)	1.26 0.90	1.4±0.99	P = 0.2811
Duration of hospital stay (days)	3.23±0.86	3.97±1.11	P < 0.0001

Similarly, the mean pain scores in BDH group were seen consistently higher compared to HSH group on post-operative day 1, day 2, day 3 and day 7. On day 1, the mean pain score in HSH group was 4.40±3.72, compared to BDH group, which was 6.13±3.31. By day 7, the mean pain scores in both groups had become similar with no significant statistical difference. There was no pain noted in the patients on follow-up during week 4 and week 6 in both the groups respectively. There was a highly significant statistical difference seen amongst the pain scores in both the groups on all post-operative days (Table 1). There was no requirement of triple dosage of rescue analgesics in HSH group as compared to the BDH group (Table 1). The mean requirement of rescue

analgesic dosages in BDH group (1.27±1.81) was found to be more compared to the HSH group (0.63±1.23), and it was found to be statistically significant (p=0.0026). First day bowel movement was achieved in 22 of 30 patients in HSH group, compared to 18 patients in BDH group. The mean day of first bowel movement in BDH group (1.4±0.99) was higher compared to HSH group (1.26±0.90), but it was statistically insignificant (p = 0.2811) (Table 1).

Hospital stay was seen to be longer in BDH group, with 4 patients having 4 days hospital stay, whereas no patient had such a longer stay in HSH group. 23 out of 30 patients in HSH group had an overall hospital stay of 3 days. The mean duration of hospital stay in HSH group was 3.23±0.86 days whereas in BDH group, it was 3.97±1.11 days, and it was statistically significant (Table 1). There were total 4 cases of post-op bleeding noted, one in HSH group and three in BDH group.

All of them were managed by keeping soft absorbable haemostatic anal sponges. One case of urinary retention was noted in BDH group, which was managed by per-urethral catheterization.

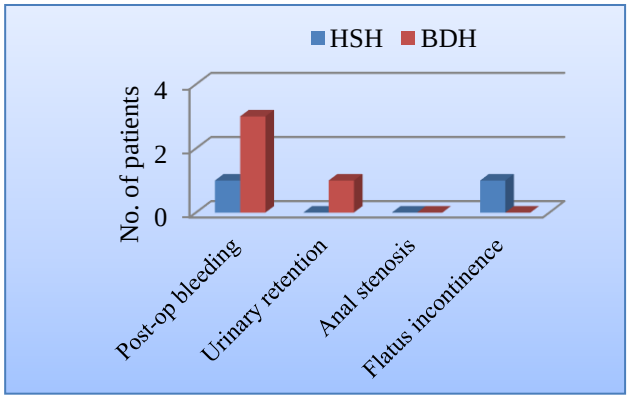

Figure 3: Complications in HSH and BDH groups after haemorrhoidectomy

One case of flatus incontinence was seen in HSH group, for which patient was advised high fibre diet and pelvic floor exercises. The complications in both the groups didn't show any statistically significant difference (p = 0.3679) (Figure 3).

DISCUSSION

Surgical haemorrhoidectomy is generally reserved for symptomatic Grade III internal haemorrhoids with prominent external ones or for Grade IV disease.[1,2] The obvious disadvantage of surgical haemorrhoidectomy is the postoperative pain resulting from the surgical raw area in the sensitive peri-anal skin and the anoderm. Much of this discomfort arises from the thermal injury induced by the electrocautery or laser machines.[7-9]

The Harmonic Scalpel possesses the unique advantage of causing very little injury in the tissues.[10] A decreased injury (<1.5 mm) at the surgical site is translated into decreased postoperative pain. The depth of thermal injury in porcine small bowel mesentery was found to be up to 9mm with bipolar electrocautery. The difference in the degree of lateral thermal damage that occurs when using bi-polar electrocautery is due to the fact that bipolar system places the tissue between two electrodes allowing the current to pass from one electrode to the other without excessive spread laterally.

Present study clearly demonstrates the superior pain control profile of Harmonic Scalpel in haemorrhoidectomy and also the less need for analgesics, both narcotic and NSAIDs. Armstrong et al published a similar study but they used both open and closed techniques in haemorrhoidectomy in their series.[11] In authors opinion, this was a potential flaw in their study, although it did not affect their final conclusion. This was the reason we standardized the technique to the open one to avoid such flaw. Also, in the same study done by Armstrong et al, they used the narcotic analgesics (NA) for the whole period of postoperative follow up.[11] Authors believed that long term use of such NA may lead to habituation or even drug addiction. So, we replaced the NA from the third day on by using Diclofenac sodium (DS) for the rest of the period of postoperative follow up.

Table 2: Comparison of post-op pain (mean ± 2SD/ median in range) with other studies.

Post-op pain (VAS scores)	HSH	BDH	P value
Present study	4.40±3.72	6.13±3.31	0.0003
Armstrong et al	1.1±0.5	5.7±0.4	<0.01
Chung et al	2.8 (1.7)	4.5 (2)	0.042
Tsunoda et al	3 (2.6-4.2)	2(1.8-3.5)	0.135
Talha et al	2.57-6.86	6-8.29	0.0001

Table 3: Comparison of requirement of rescue analgesics with other studies.

No. of rescue analgesics (doses)	HSH	BDH	P value
Present study	0.63±1.23	1.27±1.81	0.0026
Armstrong et al	5.4±0.4	8.5±0.6	<0.01
Chung et al	0.1	0.7	0.026
Tsunoda et al	1(0.9-1.3)	1(0.4-0.9)	0.006
Talha et al	0-3	1-3	0.0001

Meanwhile, present study yielded comparable results to those of Chung et al, Tsunoda et al and Talha et al who mentioned that Harmonic Scalpel haemorrhoidectomy statistically significantly reduced postoperative pain, induced better haemostasis and less analgesic consumption.[10,12,13] This difference may be attributed to the rapid rate of healing in the group of Harmonic scalpel

and improvement in surgical training using such machine in haemorrhoidectomy (Table 2 and 3).

Both HSH and BSH were associated with significantly less blood loss than MMH. This is hardly surprising because Harmonic Scalpel and bipolar diathermy "coagulate" tissue before cutting, thereby "preventing" bleeding, whereas conventional scissors cut and "induce" bleeding. This kind of coagulation by Harmonic Scalpel and bipolar diathermy was not at the expense of excessive necrosis. Chung et al and Tsunoda et al also showed a significant reduction in blood loss in haemorrhoidectomies done using Harmonic Scalpel, similar to present study (Table 4).[10,12]

Table 4: Comparison of amount of blood loss in mean±2SD / median with other studies.

Blood loss (ml)	HSH	BDH	P value
Present study	5.93±1.96	7.23±2.81	0.0001
Chung et al	16.2(37.8)	13.5(27.5)	0.026
Tsunoda et al	4.6(3.8-7)	0.9 (0.83.7)	0.001

Table 5: Comparison of duration of hospital stay in median or mean±2SD with other studies.

Duration of hospital stay (days)	HSH	BDH	P value
Present study	3.23±0.86	3.97±1.11	<0.0001
Chung et al	3.1(1.2)	3.6(2)	NS
Tsunoda et al	2(2.2-2.8)	2(2.2-2.7)	0.275
Talha et al	1	1-2	0.134

Present trial shows that haemorrhoidectomy using Harmonic Scalpel is as safe and effective, as bipolar diathermy (BDH) in terms of reduced blood loss, but is superior because it is associated with less postoperative pain and hence, better patient satisfaction and lesser hospital stay (Table 5).

In present study, there were three cases of post-operative bleeding seen in bipolar diathermy group followed by one such case in Harmonic Scalpel group. This was managed by local haemostatic sponge application. None needed surgical intervention.

There was also a case of urinary retention noted in bipolar diathermy group which was mostly due to intravenous fluid restriction during the surgery or regional anaesthesia. This was overcome by per-urethral catheterization for 24 hours. One case of flatus incontinence was observed in Harmonic Scalpel group which was managed by high fiber diet and advising Kegel exercises to the patient. Similar such findings were found in other studies, but none were found to be statistically significant.

The small number of patients and short follow-up period were only limitations in present study. The long-term results and recurrence rate should be evaluated in larger prospective studies. Also, cost is a concern with the newer technology, but it was provided for free of cost to the patients undergoing haemorrhoidectomy at our institute.

CONCLUSION

Although Milligan - Morgan haemorrhoidectomy by Harmonic Scalpel does produce less post-operative pain in patients, it is comparable to bipolar diathermy in terms of speed and overall efficacy. It does not produce more complications after surgery, and postoperative duration of stay is quite similar. Therefore, the Harmonic Scalpel may be offered as a possible alternative to bipolar diathermy for haemorrhoidectomies for its less pain and good haemostasis. But larger trials are needed to assess its protective effect on postoperative bleeding before it can be recommended routinely.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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