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Original Research Article

Comparative study of management of grade III hemorrhoids by Harmonic Scalpel technique versus conventional surgical technique (Milligan Morgan method)

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ABSTRACT

Background: The study aimed to compare the management of Grade III hemorrhoids by conventional Milligan Morgan versus Harmonic scalpel hemorrhoidectomy with respect to the intraoperative time, intra operative blood loss, length of hospital stays, postoperative outcome based on immediate and late complications and activity resumption, recurrence and cost.
Methods: In this prospective study, a total of 60 patients, 30 patients undergoing Harmonic Scalpel hemorrhoidectomy and 30 patients undergoing Milligan Morgan hemorrhoidectomy, were studied. Operated patients were monitored for bleeding, pain, retention of urine, fecal incontinence ambulatory time and recurrence.
Results: Symptoms such as pain during defecation, bleeding PR were significantly reduced at follow up in patients undergoing Harmonic scalpel hemorrhoidectomy over Milligan Morgan technique. Fecal incontinence was present in 8 cases following Milligan Morgan method over 3 months follow up. Recurrence was highest in (26.08%) in Milligan Morgan group while lowest in (4.34%) in Harmonic Scalpel group. No of days absent from work is more Milligan Morgan group and significantly less in Harmonic Scalpel group.
Conclusions: This study showed significant difference in operative time, blood loss during surgery and pain score on postoperative days 15, 1 month, 3 months and 6 months and postoperative analgesic requirement for Harmonic scalpel assisted hemorrhoidectomy as compared to conventional Milligan Morgan, which were statistically significant. Harmonic scalpel hemorrhoidectomy is a newer, safer, more effective, faster and bloodless operative technique with minimal tissue damage and further larger sample studies and required to establish its complete efficacy and benefit over other modalities of hemorrhoidectomy.

Keywords: Harmonic Scalpel hemorrhoidectomy, Hemorrhoidectomy, Milligan Morgan hemorrhoidectomy

INTRODUCTION

Hemorrhoidectomy is the most definitive way of treating 3rd degree hemorrhoids.[1] Two well-established methods are the Milligan-Morgan excision and the Ferguson techniques. Various techniques have been previously described and Milligan-Morgan operation has stood the challenge of time and is the basis for evolution of different operations.[2,4] Pain, per rectal bleeding, fecal incontinence and anal stricture are the commonest post-operative complications.[2,3] The main causes for postoperative pain are related to the incision performed during the surgery, the sutures applied to approximate

anal mucosa, cauterization, and possible surgical site infection.[4]

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 edema to the surrounding tissue.[5]

The Harmonic Scalpel possesses the unique advantage of causing very little lateral thermal injury in the tissues. A decreased lateral thermal injury (<1.5 mm) at the surgical site is translated into decreased postoperative pain.[6] In an attempt to compare the procedure and results of hemorrhoidectomy using ordinary scissors and Harmonic Scalpel, a prospective study was therefore performed.

Aims and objectives

To compare techniques of management of Grade III hemorrhoids using harmonic scalpel versus conventional surgical techniques (Milligan-Morgan procedure) with respect to:

- Operative time
- Intra operative blood loss
- Post-operative complications

A. Immediate-
   a. Bleeding
   b. Pain

B. Late-
   a. Infection
   b. Fecal and flatus incontinence

- Duration of stay in hospital
- Recurrence
- Cost of surgery.

METHODS

Type of study was prospective study. Place of study was Dr. D Y Patil medical college and hospital and research center, Pimpri, Pune-18, Maharashtra, India. Plan of study was all the patients who presented to surgical OPD with history or complaints of Grade III were admitted and evaluated. Period of study was from July 2014 to September 2016. Sample size involved 60 cases. Patients were divided into Group A and B.

- Group A: 30 patients with Grade III hemorrhoids corrected by open hemorrhoidectomy (Milligan-Morgan procedure- Group A)
- Group B: 30 patients with Grade III hemorrhoids corrected by hemorrhoidectomy using Harmonic Scalpel- Group B.

Calculations

Total number of cases 60.

$$n = \frac{Z^2\, p\, q}{E^2}$$

where, Z= Standard normal variation at 95% α, p = prevalence of symptoms of acute appendicitis, q = 1- p, E = allowable error in this study.

Analysis of data and interpretation of results were based on parametric and non-parametric statistical techniques like Kendel's Tau test of correlating different scales and Z test for large samples.

P = 50% confidence level = 95% and absolute precision = 10% i.e., E number of cases n =Z^2pq/E^2 = 56. Each group was of 30 cases.

Inclusion criteria

All patients coming to the surgery outpatient department (OPD) with: Grade III hemorrhoids (aged above 18 years)

Exclusion criteria

Patients found to have any co morbid medical conditions such as:

- Immunocompromised patients
- Inflammatory bowel disease (Crohn's disease, ulcerative colitis)
- Anal stricture
- Patients who had secondary hemorrhoids due to intra-abdominal pathology
- Alcoholic liver disease
- Portal hypertension
- Recurrent hemorrhoids
- Piles with growth in anal canal or rectum
- Diabetes mellitus.

Detailed history, clinical examination and routine hematological examinations were carried out in all cases. The patient was regularly reviewed 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 postoperatively on day 1 ,15th and 1 month, 3 months and 6 months.

The measured outcomes

- Operation time
- Blood loss
- Pain score after postop day 15th, 1 month, 3 months and 6 months
- Analgesic requirement
- Hospital stays.

RESULTS

Symptoms in both groups have p value of > 0.05 which is statistically insignificant. In present study 93.3% patients in the HSH group showed minimum intra operative bleeding while in MMH group 60 % patients showed minimum intra operative bleeding. 40% from Group B had significant bleeding. P value was < 0.0001 which was statistically significant.

Figure 1: Milligan Morgan Hemorrhoidectomy.

Comparison of pain score at 15 days, 1 month, 3 months and 6 months in study groups: in current study, there was a significant decrease in pain score in Harmonic Scalpel hemorrhoidectomy (mean 2.03 with SD 0.65) as compared with Milligan Morgan hemorrhoidectomy (Mean 5.86 with SD 0.74) with p value < 0.0001, which was statistically significant. Significant reduction in pain score is seen after 15th day and 1 month following Harmonic Scalpel hemorrhoidectomy (mean was 1.84 on 15th day and 0.42 after 1 month) as compared to Milligan Morgan hemorrhoidectomy (mean was 5.02 on 15th day and 2.13 after 1 month) with p value <0.0001 which is statistically significant. At the end of 3rd month and 6th month the pain score was less than 1 in both the groups with P value of >0.05 which was statistically insignificant.

Current study showed that the time required for harmonic scalpel hemorrhoidectomy was less than 30 minutes in 66.7% of patients and was between 30-60 minutes in 33.34% of patients. The time required for Milligan Morgan hemorrhoidectomy was less than 30 mins in 13.3% of patients, between 30-60 minutes in 83.4% of patients and > 60 minutes in 1.7% of patients. The p value was < 0.0001 which was statistically significant.

Comparison of bleeding per rectum at follow up in study groups: significant reduction in bleeding PR was seen on POD 1, 15th day and after 1 month in Harmonic Scalpel group when compared with Milligan Morgan group with p value <0.0001 and < 0.05 respectively which is statistically significant. At 3rd month and 6th month the number of cases with bleeding PR were less than two in both groups with P value of >0.05 which is not statistically significant.

Figure 2: Milligan Morgan Hemorrhoidectomy.

Figure 3: Harmonic Scalpel Hemorrhoidectomy.

In this study, incidence of incontinence was higher following Milligan Morgan procedure. On 15th day 2 patients from Group A and 1 patient from Group B had developed incontinence, P value <0.0001. In 1 month follow up, 1 case from groups gained continence. At the end of 6 months, incontinence percentage in Milligan Morgan group and Harmonic Scalpel group was 10% and 3.3% respectively.

Recurrence was higher in Milligan Morgan group compared to Harmonic Scalpel group. 6.7% was the recurrence rate following Milligan Morgan procedure in 6 months follow up, while recurrence rate was nil in HSH group. P value < 0.005 which was statistically significant.

Comparison of post-operative stay in groups: mean operative stay in Milligan Morgan group was 4.04 days while in Harmonic Scalpel group it was 1.46 days; with F value 74.02 and p value <0.0001 which is statistically significant. Cost of treatment is higher in Harmonic

Scalpel group with p value of <0.0001 which is statistically significant.

Duration of treatment was higher in Milligan Morgan group with a mean duration of 8.13 days when compared to Harmonic Scalpel group where the mean duration was 4.02 days, with p value of <0.0001.

Number of days absent from work was higher in Milligan Morgan group which was 8.24 days with SD 1.53 while it was an average 3.32 days with SD 1.02 in Harmonic scalpel group. P value was <0.0001 which was statistically significant. Bleeding during surgery was quantitated measuring the mops used. <2 mops as minimum bleeding, >2mops as significant. 93.3% of cases in HSH group and 60% of cases in MMH group had minimum bleeding, with p value <0.0001 which was significant as shown in Table 1. 40% of cases in MMH group had significant bleeding intra operatively. The mean operation time for HSH was 15.7+/- 9.20 mins and for MMH was 42.8+/16.7 minutes which was significant as shown in (Table 1).

Table 1: Comparing measured outcomes in both groups.

	Harmonic Scalpel technique (n=30)	Milligan Morgan technique (n=30)	P value
Operation time (minutes)	15.7± 9.20	42.8±16.7	<0.0001
Intra operative bleeding			
Minimum bleeding (<2 mops soaked)	93.3% cases	60% cases	<0.0001
Significant bleeding (>2 mops soaked)	6.7% cases	40% cases	<0.0001
High analgesic requirement			
Post-operative day 1	20%	66.7%	<0.0001
Post-operative day 15	0	26.7%	<0.0001
At 1 month	0	10%	<0.0001
Duration of treatment (days)	4.02±1.62	8.13±2.65	<0.0001
Postoperative hospital stays (days)	1.46±0.88	4.04±0.84	<0.0001
Number of days absent from work	3.32±1.02	8.24±1.53	<0.0001
Recurrence			
Post-operative day 15	0	0	<0.005
1 Month	0	0	<0.005
3 Months	0	1 case (3.33%)	<0.005
6 Months	0	1 case (3.33%)	<0.005

Table 2: Comparing post-operative symptoms in both the groups.

Symptoms		Milligan Morgan technique	Harmonic Scalpel technique	Total
Painful defecation	Present	29	25	2.04
	Absent	1	5	>0.05
Bleeding per rectum	Present	27	23	3.61
	Absent	3	7	>0.05
Constipation	Present	21	16	2.71
	Absent	9	14	>0.05
Pruritus	Present	4	3	3.04
	Absent	26	27	>0.05

The pain score was calculated from post-operative day 1, was higher following MMH (mean was 5.86), while it was lower after HSH (mean was 1.98). Decrease in pain score was seen in both groups on 15th day and was 1.84 in HSH group and 5.02 in MMH group, with p value <0.05. At end of 1-month pain score was mean 0.42 in HSH group and mean 2.13 in MMH group. In 3 months and 6 months follow up pain score was less than 1 in both groups with p >0.05 (Table 3).

Higher analgesic requirement on the post op day 1 was in 66.7% of cases following MMH and 20% in HSH group, which was requirement of injection diclofenac 75mg additional to the oral analgesics. Shown in (Table 1).

On discharge the analgesic requirement following the harmonic scalpel hemorrhoidectomy was lower compared to Milligan Morgan method and was significant. Hospital stay average for HSH was 4.02±1.62 days, and for MMH

was 8.13±2.65 with p value of <0.0001 which was significant (Table 1).

Table 3: Comparing bleeding per rectum in both the groups.

Group	n = number if cases	Pain score at									
		POD 1		15 days		1 month		3 months		6 months	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Milligan Morgan	30	5.86	0.74	5.02	0.43	2.13	0.79	0.43	1.36	0.47	1.43
Harmonic Scalpel	30	2.03	0.65	1.84	0.69	0.42	0.58	0.21	1.02	0	0
F Value		82.06		81.01		34.36		0.24		1.86	
P Value		<0.0001		<0.0001		<0.0001		>0.05		>0.05	

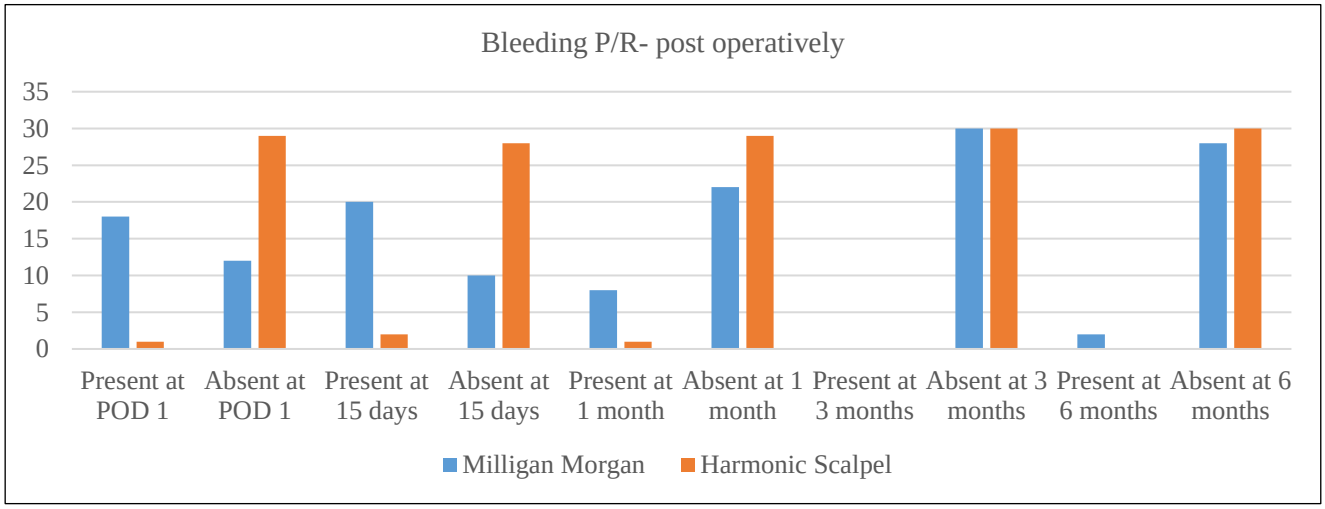

Figure 4: Number of days bleeding p/r present post op in both groups.

Recurrence was seen in 3 cases at different intervals from 15 days to 6 months following MMH and nil recurrence following HSH in 6 months follow up period. P value was <0.005 and was statistically significant. Procedure cost was more than 2 folds lower for MMH as compared to HSH. Mean cost was Rs. 400 with SD of 137.59 for MMH and Rs. 1050 with SD 201.08 for HSH. The p value was <0.0001 which was significant.

Table 4: Incontinence - wise distribution of cases in study groups.

Incontinence at		Milligan Morgan	Harmonic Scalpel	Chi-square	P value
POD 1	Present	0	0	0.27	>0.05
	Absent	30	30		
15 days	Present	2	1	22.07	<0.0001
	Absent	28	29		
1 month	Present	1	0	17.14	>0.05
	Absent	29	30		
3 months	Present	0	0	0.10	>0.05
	Absent	30	30		
6 months	Present	0	0	0.57	>0.05
	Absent	30	30		

DISCUSSION

Hemorrhoidectomy is the most effective and definitive treatment for symptomatic third and fourth degree hemorrhoids.[7] The Harmonic Scalpel (HS) possesses the unique advantage of causing very little lateral thermal injury in the tissues. A decreased lateral thermal injury (<1.5mm) at the surgical site is translated into decreased

postoperative pain.[8] In the present study minimum intra operative bleeding was seen in HSH group (93.3%). Incidence in MMH group was 60%. This was statistically significant.

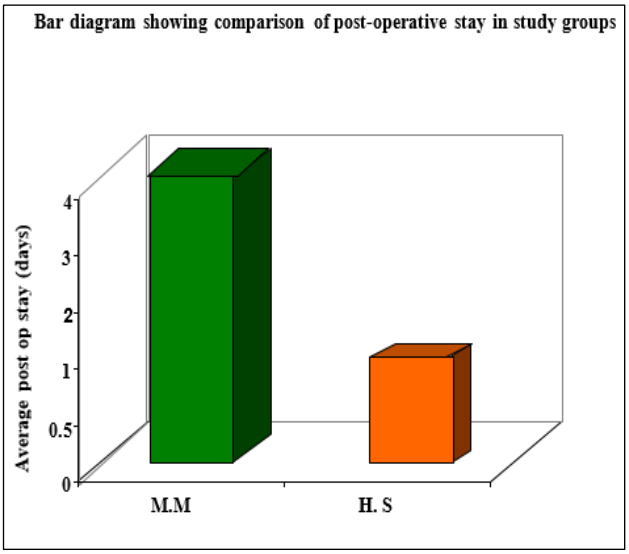

Figure 5: Mean post-op duration of stay in days.

Morri A et al in their study of 50 patients showed that 31 patients (62 %) had insignificant bleeding (less than one gauze) following Harmonic scalpel hemorrhoidectomy.[9] A study by Tsunoda et al showed that the average blood loss during Harmonic scalpel hemorrhoidectomy was less than 5 ml which makes this procedure almost bloodless.[10] The results in these two studies were similar to the results in present study.

In a study done by Di Vita G, Patti R et al, it was observed that a reduced time to healing with reduced spread of necrosis and inflammatory pattern, associated with reduced post-operative pain and the lower analgesic consumption was seen in the group which underwent hemorrhoidectomy with harmonic scalpel and they concluded that the use of ultrasonic scalpel to perform Milligan-Morgan haemorrhoidectomy, compared with conventional instruments, reduce post-operative pain making more shorter time of healing and a precocious time to return to normal activity.[11]

In our study, there was a statistically significant decrease in post-operative pain score in the HSH group compared with the MMH group especially after 15 days and 1 month. (mean was 5.02 on 15th day and 2.13 after 1 month) with p value <0.0001 which is statistically significant. At the end of 3rd month and 6th month the pain score was less than 1 in both the groups with P value of >0.05 which was statistically insignificant.

It was also seen that high analgesic requirement was seen in 66.7% of cases on POD 1, 33.3% of cases on POD 15 and 10% cases at 1 month follow up after Milligan Morgan hemorrhoidectomy compared with Harmonic Scalpel technique where only 20% of the total cases required high analgesics on POD 1. P value was <0.0001 which was statistically significant. Ramadan et al reported post-operative pain in only 4.3% of patients undergoing HSH, whereas in prospective study Armstrong et al showed significantly less post-operative pain in HSH compared to conventional hemorrhoidectomy.[12]

Dae Ro Lim et al in his study involving 50 patients showed post-operative pain score of 6.5±1.7 following conventional hemorrhoidectomy compared to 3.8±1.4 following HSH. Follow up pain score was 1.5±1.2 versus 0.8±0.8 in conventional method group and HSH group respectively and these differences had statistical significance (p <0.05).[13]

In a meta-analysis of the random trials in literature comparing harmonic scalpel hemorrhoidectomy and traditional surgical procedures done by Mushaya et al where 8 randomized controlled trials were compared, they observed significant decrease in postoperative pain score and decreased analgesia post operatively following Harmonic scalpel hemorrhoidectomy as compared to conventional methods (p <0.005).[14] All these studies had similar percentage of pain score post-operatively after hemorrhoidectomy and were comparable to present study.

Current study showed that the time required for harmonic scalpel hemorrhoidectomy was less than 30 minutes in 66.7% of patients and was between 30-60 minutes in 33.34% of patients. Average time required was 15.37±2.4 minutes. The time required for Milligan Morgan hemorrhoidectomy was less than 30 mins in 13% of patients, between 30-60 minutes in 83.4% of patients and > 60 minutes in 1.7% of patients. Average time required was 35.6±4.7 minutes. The p value was < 0.0001 which was statistically significant.

In a study done by Bulus H et al, mean operating time for HSH was 16.8±4.1 while it was 25.5±7.7 for conventional hemorrhoidectomy, p<0.001 for a sample size of 151 patients.[15] In a case control study by Joel Sayfan et al, mean operating time was 11.09 minutes (range 5-15, SD 3.40) in the study group (HSH Group) and 38.76 minutes (range 20-60, SD 11.0) in control group (MMH Group).[16] In our study there was a statistically significant reduction in bleeding PR in HSH group especially at post-operative days 1, 15 and after 1 month compared with the MMH group.

Dae Ro Lim et al in his study showed that 3 patients (12%) following HSH experienced minor bleeding, however in conventional method group 2 patients (8 %) experienced major bleeding and 6 patients (24 %) had minor bleeding. P value was <0.05.[13]

Recurrence was higher in MMH group (6.7% in 6 months follow up) compared with the HSH group (nil). MMH

group showed a higher duration of treatment with mean duration of 8.13 days compared with HSH group (4.02 days). Both these studies were statistically significant. There was a significant difference in the operative time among the two groups. All procedures were performed by the same surgery team. In fact, the longer operation time in the MMH group is likely the result of some extra time spent in hemostasis.

HSH was associated with significantly less blood loss than MMH. This is expected because Harmonic Scalpel™ "coagulate" tissue before cutting, thereby "preventing" bleeding, whereas conventional scissors cut and "induce" bleeding. This kind of coagulation by Harmonic Scalpel was not at the expense of excessive necrosis. The pain on the operation day (POD 0) was not assessed to allow for the effects of anesthesia to wear off. Present study showed HSH to have a decreased pain score and analgesic requirement compared with MMH.

In a study done by Ramadan E et al, 54 consecutive patients with third- and fourth-degree hemorrhoids were prospectively randomized for harmonic scalpel hemorrhoidectomy (HS) and Milligan-Morgan procedure (MM) they concluded that harmonic scalpel hemorrhoidectomy is virtually a bloodless operation with minimal tissue damage. It is associated with significant less postoperative pain and a fast return to normal activity.[12] A study done by Ivanov D, Babovic S, states that "The up-to-date literature, in the experience of authors, has confirmed that the new method of Harmonic Scalpel hemorrhoidectomy reduces postoperative pain. We concluded that Harmonic Scalpel hemorrhoidectomy, due to less thermal damage, statistically significantly reduced postoperative pain with better hemostasis, compared with Milligan-Morgan's method of treating hemorrhoidal disease."[17]

Thus, in comparison with all the above-mentioned trials present study shows a statistically significant decreased operating time, intra-operative blood loss, pain score, analgesic requirement and hospital stay following HSH as compared to MMH. Similar to recent reports on Harmonic Scalpel™ hemorrhoidectomy, the present study shows that HSH is as safe and effective, with decreased complications. In study results, lesser blood loss decreased postoperative pain are upheld, and the HSH can be conducted as day surgery. The major drawback with HSH is its higher cost and learning curve of usage.

The main limitation of the study is the small sample size, short patient follows up. Cost will always be a concern with newer technology.

CONCLUSION

In present study we conclude that, harmonic scalpel hemorrhoidectomy (HSH) is most advantageous method, safe and effective as compared to Milligan Morgan hemorrhoidectomy in terms of operative time, amount of bleeding and post-operative pain. Consequently, harmonic usage is an alternative in the treatment of hemorrhoidectomy which provides a faster and more efficient operation time and minimum blood loss. Although the use of the Harmonic Scalpel carries some disadvantages as prolonged learning curve and increased cost over conventional scissors hemorrhoidectomy, it carries several advantages.

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