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Original Research Article

Harmonic scalpel versus conventional haemorrhoidectomy for grade III and IV haemorrhoids: a randomized controlled trial

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ABSTRACT

Background: Haemorrhoidal disease is one of the most frequently encountered anorectal condition in the clinical practice of a surgeon. Haemorrhoidectomy is the treatment of choice for grade III and IV haemorrhoids but is associated with significant postoperative pain and complications. Harmonic dissection causes less lateral tissue injury and thus less intra-operative bleeding and post-operative complications. The present study compares Harmonic Haemorrhoidectomy with conventional Haemorrhoidectomy.
Methods: In a randomized controlled trial, patients with grade III and IV haemorrhoids satisfying inclusion and exclusion criteria were allocated to Harmonic scalpel haemorrhoidectomy or conventional Milligan Morgan open haemorrhoidectomy by block randomisation of 4. The outcome factors were intra operative blood loss, postoperative pain on VAS scale, urinary retention and anal stenosis after one month of follow up.
Results: Total of 40 cases were enrolled. Of them, 22 were allocated to Harmonic haemorrhoidectomy, the rest 18 patients underwent conventional haemorrhoidectomy. The mean age of patients was 47.03 years with a Male to Female ratio of 1.35:1. Intraoperative blood loss measured by number of soaked gauze pieces and pain score measured on visual analogue scale at 12, 24 and 48hours was seen to be statistically significant ($p<0.001$) lesser in patients who underwent Harmonic scalpel haemorrhoidectomy. There was no statistically significant difference in operative time urinary retention or anal stenosis.
Conclusions: Harmonic scalpel haemorrhoidectomy appears to be a better procedure for symptomatic grade III and grade IV haemorrhoids with ease of operating due to less bleeding, good postoperative recovery and patient acceptance.

Keywords: Harmonic scalpel, Haemorrhoidectomy, Haemorrhoids, Milligan Morgan

INTRODUCTION

Haemorrhoids have been afflicting mankind since the dawn of history and is said to be the price paid by humans for their erect posture.[1] It is one of the most frequently encountered ano-rectal disease in the clinical practice of a surgeon. Haemorrhoidectomy is one of the most commonly performed anorectal surgery in general surgical practice. Postoperative pain is protracted and post-operative complications are not negligible. For treating Grade III and Grade IV haemorrhoids, conventional Milligan-Morgan technique is one of the time-tested method but is associated with significant post-operative pain and complications like urinary retention, constipation, postoperative haemorrhage and in long term anal stenosis. Labelling surgical haemorrhoidectomy as a notoriously painful procedure, lots of research has been concentrated upon reducing the intra-operative bleeding and postoperative complications.

The operative procedures vary from conventional cautery dissection to vessel-sealers, harmonic scalpel, laser

haemorrhoidectomy and stapling devices. All these are being tried with each individual procedure having its own merits and demerits.

The rationale for using Harmonic Scalpel® for carrying out Harmonic Haemorrhoidectomy is that it divides the tissues through the high frequency ultrasonic energy that disrupts protein hydrogen bonds. The relatively low temperature (80ºC) leads to minimum lateral thermal energy(<1.5mm) as compared to electro-cautery which causes significant lateral injury and burns several millimetres in depth.[2]

This difference causes less post-operative pain and long term complications like anal stenosis. Hence the present study used Harmonic Scalpel® to carry out traditional Milligan-Morgan surgery and compared it with conventional electro-cautery Milligan-Morgan operation.

METHODS

The present study was carried out in a tertiary care teaching hospital for a two-year period. A total of 40 cases were recruited in this study based on inclusion and exclusion criteria on accrual basis. All patients presenting to surgery OPD with bleeding per rectum formed the study population. All patients of age ranging between 18-70 years, both genders, clinically and anoscopically diagnosed as grade III and grade IV haemorrhoids willing for surgical intervention were selected as subjects. Patients with grade I and II haemorrhoids, with infected or thrombosed haemorrhoid, those who have undergone previous ano-rectal surgeries, those with co-existing anorectal conditions like anal fissures/anal fistulas/ perianal sepsis, those having co-morbid conditions like Diabetes Mellitus, Hypertension, HIV etc., those declared unfit for anesthesia as ASA III, IV and those not consenting for surgical intervention were excluded from the study.

The patients were allocated to Harmonic scalpel haemorrhoidectomy or conventional Milligan Morgan open haemorrhoidectomy by block randomisation of 4. Informed consent was taken for surgery. All the patients were operated under spinal anaesthesia/Saddle block in lithotomy position. The outcome factors included intra-operative bleeding, Post-operative Pain (on VAS scale) and other complications like post-operative bleeding per rectum, urinary retention and anal stenosis. The data was presented as mean, standard deviation, range and percentage for descriptive statistics of age, gender and clinical manifestations.

Comparison of baseline parameters between open haemorrhoidectomy and harmonic haemorrhoidectomy patients and also intra-operative and post-operative complications was done using "student t-test" for continuous variables and "chi square test" or "Fisher exact test" for categorical variables. The statistical software used in the analysis was SPSS version 20, EPI Info software version 7. The study has clinical clearance from Institutional Ethics committee of this institute.

RESULTS

Total 40 patients were recruited in the study following inclusion criteria. The mean age of the patients was 47.03 years SD ±12.797 with a range from 28 years to 70 years. On observing decade-wise distribution, haemorrhoids were most commonly observed in the age group of 41-50 years accounting for 35% of the cases and 57.5% were in the 4th and 5th decade. Male: Female Ratio was found to be 1.35:1. Twenty-two patients (55%) had vegetarian diet and 18 patients (45%) consumed mixed diet. This suggests that consumption of non-vegetarian does not necessarily predispose to grade III & IV haemorrhoidal disease.

Table 1: Comparison of baseline characteristics of the two groups.

		HS (n=22)	MM (n=18)	P value
Mean age #		48.54	45.28	0.442 (NS)
Gender	Male	11	12	
	Female	11	6	0.289 (NS)
Diet	Vegetarian	12	10	0.949 (NS)
	Mixed	10	8	
Bleeding per rectum		22	18	1.00 (NS)
Something protruding per anum		13	9	(S)
Pain while defecation		11	7	(S)
No. of haemorrhoid	1	11	8	0.920 (NS)
	2	6	5	
	3	5	5	
Grade of haemorrhoids	3	14	11	0.87 (NS)
	4	8	7	

Chi-Square test NS=Not Significant.

Table 2: Comparison of operating time.

Intra -Operative Parameter	HS (n=22)	MM (n=18)	T value	P value
Operating Time (mins)	14.14±4.764	15.67±6.212	-0.882	0.384 (NS)
Gauze Pieces soaked in blood (Mean)	1.59±0.734	3.00±1.328	-4.252	<0.001 (HS)

t-test.

Bleeding per rectum was the most common complaint given by all 40 (100%) patients followed by complaints of something protruding per anum in 55% and painful defecation in 45% of the patients. 18 (45%) came with complaint of pain while defecation. Twelve (30%) of the patients gave a history of Constipation. Prolonged straining and hard stools could cause congestion of haemorrhoidal cushions, causing them to prolapse. A majority of 62.5% patients presented with grade III haemorrhoids and the rest 37.5% had Grade IV haemorrhoids. There was a single haemorrhoidal column in 47.5% patients, two haemorrhoidal columns in 27.5% patients and the rest 25% patients had three haemorrhoidal columns.

The basic characteristics of both these groups were similarly(P>0.05) (Table 1). The average operating time for the Harmonic Scalpel Haemorrhoidectomy was 14.14±4.764 minutes whereas the average operating time for the Open Haemorrhoidectomy was 15.67±6.212 minutes. The difference was statistically not significant. The total amount of bleeding caused during the procedure was recorded using number of gauze pieces soaked in blood. An average number of 1.59±0.734 gauze pieces were soaked in blood during the Harmonic Scalpel procedure while 3.00±1.328 gauze pieces were soaked in blood during the Milligan-Morgan procedure. This difference was statistically highly significant (p<0.001) (Table 2).

Table 3: Comparison of post-operative pain.

Post-operative pain		HS (n=22)	MM (n=18)	T value	P value
Pain on VAS score	12 Hours (Mean)	6.50±0.512	7.33±0.485	-5.244	<0.001 (HS)
	24Hours (Mean)	4.86±0.710	5.67±0.485	-4.078	<0.001 (HS)
	48Hours (Mean)	3.14±0.503	4.39±0.608	-5.581	<0.001 (HS)

Independent sample t-test HS=Highly Significant.

Post-operative pain was measured on Visual Analogue Scale (VAS) in all the patients at 12 hours, 24 hours and 48 hours postoperatively. The average post-operative pain score on VAS 12 hrs post op was 6.50±0.512 in the Harmonic Haemorrhoidectomy group and 7.33±0.48 in the Open Haemorrhoidectomy group. The average post-operative pain score on VAS 24 hrs after surgery was 4.86±0.71 in the Harmonic Haemorrhoidectomy group and 5.67±0.485 in the Open Haemorrhoidectomy group. The average post-operative pain score on VAS 2 days after surgery was 3.14±0.503 in the Harmonic Haemorrhoidectomy group and 4.39±0.603 in the Open Haemorrhoidectomy group. This difference in pain score between both procedures 12, 24 and 48 hrs after surgery was statistically highly significant (p<0.001) (Table 3).

Looking at the post-operative complications, post-operative bleeding managed conservatively was observed in two patients 2 patients who underwent the Harmonic Scalpel procedure and 4 patients in the open procedure, the difference was not statistically significant overall. None of the patients who underwent either of the procedure had urinary retention in the post-operative period and anal stenosis after follow up of one month.

DISCUSSION

Haemorrhoids arise from congestion of internal or external vascular plexuses around anal canal. They are classified into four degrees based on their severity. Most cases of haemorrhoidal disease can be treated by dietary modification, topical medication and warm water bath. In a certain percentage of cases mainly restricted to symptomatic grade III and Grade IV haemorrhoids, surgical procedures are necessary to give satisfactory long term relief.[3] Excision of haemorrhoidal complex is the basic of all surgical procedure but the greatest drawback of surgical haemorrhoidectomy is post-operative pain. Modification of surgical technique and use of newer surgical modalities have been tried in the hope of decreasing post-operative pain.[4]

Considerable researches in the last few decades were concentrated on pain reduction following operative procedures. The present study was an effort in the same direction with additional research into the associated predisposing factors and clinical presentation in the local population. The results are discussed as under. The mean age of the patient was 47.03 years which is quite

consistent with studies from India and literature available. The male: female ratio was 1.35:1 with a slight increase in occurrence in males. This male preponderance is also consistent with the studies available in literature.[5-7]

While evaluating the clinical presentation and specifically looking at symptoms all patients (100%) in the present study had bleeding per rectum. This presentation is quite consistent with literature showing a range from 77.5% - 100%. And in Indian studies it was on the higher side as patients usually do not come for surgical treatment unless they are losing blood in stools. Something coming out from the anus during defecation or without straining and pain during defecation specially noted in Grade IV haemorrhoids was observed in 55% and 45% patients respectively in present study. These results are also consistent with literature except one study La Bella et al which had almost all patients with swelling coming out of anus and 86% patients having pain during defecation, probably due to selection of Grade IV haemorrhoids.[8]

A total of 62.5%patients in the present study had Grade III haemorrhoids and 37.5% had Grade IV haemorrhoids. This data is quite consistent with other studies in literature.[8-11] The intraoperative blood loss was 1.59 gauzes in harmonic haemorrhoidectomy as against 3 to 4 gauzes in open haemorrhoidectomy this difference was statistically significant in the present study and if we were to consider one completely soaked gauze piece to be equal to 5 ml of blood 9 the average blood loss in harmonic haemorrhoidectomy was 5ml as against 15 to 20 ml in open haemorrhoidectomy. The present study did not do weighing of gauze pieces to calculate blood loss. No other study in literature showed a comparison between Harmonic vs Electrocautery open haemorrhoidectomy. However, the losses in the harmonic haemorrhoidectomy range from 2 ml to 4.5 ml which is quite consistent with our study. Blood loss in traditional Milligan Morgan procedure is ranging from 5 to 11 gauzes this also depends on the use of electrocautery and individual surgical technique.

The mean VAS score used for evaluation of pain in the present study was 6.5 in the harmonic haemorrhoidectomy group and 7.3 in the open haemorrhoidectomy group after 12 hours which got reduced to 4.8 and 3.14 in 24 and 48 hours respectively in the harmonic haemorrhoidectomy group. These findings in our study were statistically significant suggesting less severity of pain in patients undergoing harmonic haemorrhoidectomy the pain score of 4.86 at 24 hours was quite consistent with the range of 3 to 5.1 in literature the pain score of 3.14 after 48 hours was also consistent with the range of 2.5 to 5 in literature. The present study had a policy of giving on demand analgesia for both the studies. However, we did not calculate the amount of analgesia required in post-operative period.

Post-operative bleeding after harmonic haemorrhoidectomy was observed in 10% patients mainly due to capillary ooze from the raw surfaces these findings are quite consistent with the study by Kwok in 200512 with similar post-operative bleeding the other studies in literature showed post-operative bleeding range from 0.6 to 3.5 %.

This post-operative bleeding was blood found on the pad in the post-operative period upto 48 hours and none of the patients required reexploration. No comparative studies are available in literature however the post op bleeding in the open Milligan Morgan group showed quite a high incidence which could be due to poor haemostatic technique in controlling local haemorrhage as this was a primary bleed. None of the patients in this study had secondary bleeding there was no incidence of sepsis or anal stenosis in any of the patients in this study.

CONCLUSION

The result of the present study showed that Harmonic Haemorrhoidectomy appears to be a better procedure for symptomatic Grade III & Grade IV haemorrhoids as a surgical procedure with ease of operating due to less bleeding, good post-operative recovery and patient acceptance. Further randomised control trial with formal sample size calculated with estimation of blood loss by gauze weighing techniques, estimation of post-operative analgesia requirement and a long follow up is recommended to obtain grade 1 evidence in favour of harmonic haemorrhoidectomy.

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REFERENCES

1. Bansal D, Singh RR, Sachdeva K, Shah AS. Conventional versus diathermy coagulation haemorrhoidectomy-a prospective study. Int Surg J. 2016;3(4):1920-4.
2. Abo-Hashem AA, Sarhan A, Aly AM. Harmonic Scalpel® compared with bipolar electro-cautery Haemorrhoidectomy: A randomized controlled trial. Int Surg J. 2010;8(3):243-7.
3. Ho YH, Seow-Choen F, Tan M, Leong AF. Randomized controlled trial of open and closed haemorrhoidectomy. Br J Surg. 1997;84(12):1729-30.
4. Armstrong DN, Frankum C, Schertzer ME, Ambroze WL, Orangio GR. Harmonic Scalpel® Haemorrhoidectomy. Dis Colon Rectum. 2002;45(3):354-9.
5. Saxena D, Akhtar M, Rode A, Tandon M. Harmonic Scalpel® haemorroidectomy at rural tertiary care centre: a review of 52 cases. Int Surg J. 2015;2(3):366-8.
6. Lau WY, Chow HP, Poon GP, Wong SH. Rubber band ligation of three primary Haemorrhoids in a

single session. Dis Colon Rectum. 1982;25(4):336-9.
7. Sayfan J, Becker A, Koltun L. Sutureless closed Haemorrhoidectomy: a new technique. Ann Surg. 2001;234(1):21-4.
8. LaBella GD, Main WP, Hussain LR. Evaluation of transanal Haemorrhoidal dearterialization: a single surgeon experience. Tech Coloproctol. 2015;19(3):153-7.
9. Wang ZG, Zhang Y, Zeng XD, Zhang TH, Zhu QD, Liu DL, et al. Clinical observations on the treatment of prolapsing Haemorrhoids with tissue selecting therapy. World J Gastroenterol. 2015;21(8):2490.
10. Tsunoda A, Sada H, Sugimoto T, Kano N, Kawana M, Sasaki T, et al. Randomized controlled trial of bipolar diathermy vs ultrasonic scalpel for closed Haemorrhoidectomy. World J Gastrointest Surg. 2011;3(10):147.
11. Ahire MK, Rathod CM, Baghadia S, Nandu B. A comparison study between vessel sealing technique and conventional (Milligan Morgan) excisional Haemorrhoidectomy. Int Surg J. 2016;3(4):1844-9
12. 12. Kwok SY, Chung CC, Tsui KK, Li MK. A double-blind, randomized trial comparing Ligasure TM and Harmonic Scalpel TM Haemorrhoidectomy. Dis Colon Rectum. 2005;48(2):344-8.

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