ORIGINAL RESEARCH

Stapled Haemorrhoidectomy versus Open Haemorrhoidectomy (Miligan Morgan) For Grade Iv Haemorrhoids A Randomized Controlled Trial

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ABSTRACT

Background: The present study aimed to compare the Stapled Haemorrhoidectomy versus Open Haemorrhoidectomy (Milligan Morgan) for Grade IV Haemorrhoids. Methods: A randomised controlled trial study was carried out in the General Surgery department of Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh. 60 patients, aged of 18 years and above with grade IV haemorrhoids admitted to the Department of General Surgery of Rohilkhand Medical College and Hospital Bareilly were recruited for the study. Patients were randomly divided into two groups in a 1:1 allocation ratio, each compromising 30 patients. The outcome measures were postoperative pain, postoperative bleeding, analgesic requirement, operative time, hospital stay, time to return to normal activity and complications. Appropriate statistical tests were applied depending on the distribution and type of data. A p-value of < 0.05 was considered as statistically significant. Result: Mean Age being 35.3±9.5 years for stapler haemorrhoidectomy (group A) and 37.8±9.8 years for open haemorrhoidectomy (group B). Higher proportion of patients were seen in 31-50 years age group. Both treatment groups demonstrated a predominantly male patient population. 46.7% of patients in the Stapler group and 40.0% in the Open group reported experiencing pain pre operatively. No significant difference was observed with p value 0.602. Stapler Haemorrhoidectomy had a significantly shorter operative time (32.9 minutes) (p<0.001), less blood loss (5.3 mL) (p<0.001), significantly less pain during the first stool passage (p<0.001), shorter hospital stay (1 day) (p<0.001) and returned to work significantly faster (5 days) (p<0.001) than Open Haemorrhoidectomy patients. On the 0th day, the Stapler group had a mean pain score of 3.2 ± 0.5 , significantly lower than the Open group, which had a mean score of 6.3 ± 0.5 (p < 0.001) with highly significant p-values (< 0.001). Stapler Haemorrhoidectomy had a significantly lower incidence of post-operative urinary retention (16.7%), post-operative bleeding (10.0%) and post-operative incontinence (0%). Conclusion: Stapler haemorrhoidopexy is a viable alternative to open haemorrhoidectomy. The procedure is simple to execute, reproducible and diverse operators can achieve comparable results as long as they adhere to the fundamental principles and possess an adequate level of experience.

Key words: Haemorrhoids, Stapler Haemorrhoidectomy, Open haemorrhoidectomy.

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INTRODUCTION

A prevalent anorectal condition Haemorrhoids is characterized by the symptomatic growth and distal shift of the normal anal cushions. They are a significant medical and socioeconomic issue that affects millions of individuals worldwide.¹Hematochezia is the most prevalent cause of rectal haemorrhage which is attributed to them.

The three primary cushions are situated at the left lateral, right posterior and right anterior positions.

They are made up of connective tissue, smooth muscle, and blood vessels known as sinusoids. The term "haemorrhoids" may be reserved to characterise these "cushions" when they become abnormal and cause symptoms for practical purposes.²

It is estimated to have a global prevalence of approximately 4.4%. A condition may be present in 58% of individuals over the age of 40. Haemorrhoids are more prevalent in males than in women.³ In 44.74% of patients, haemorrhoids induce symptoms.

Haemorrhoids affect approximately 50% to 66% of individuals at some point in their lives.⁴

Haemorrhoids are commonly caused by constipation and protracted straining, as hard stool and elevated intraabdominal pressure may obstruct venous return, leading to engorgement of the haemorrhoidal plexus.5Pregnancy can increase the likelihood of symptomatic haemorrhoids and congestion of the anal cushion, which will resolve autonomously shortly after birth. While numerous dietary factors, such as a low fibre diet, piquant foods, and alcohol consumption, have been implicated, the data that has been reported is inconsistent.⁶ Haemorrhoids are most frequently associated with painless rectal bleeding that occurs during bowel movements.Because haemorrhoidal tissue has direct arteriovenous communication, the blood appear typically vibrant red.

A meticulous clinical examination and a precise patient history are the foundations for the definitive diagnosis of haemorrhoidal disease.⁷ treatments for 1st and 2nd degree haemorrhoids include cryosurgery, infra-red photocoagulation, sclerotherapy and rubber band ligation. The most effective therapeutic approach for third and fourth-degree haemorrhoidal disease is surgical intervention. The most frequently employed traditional options are open and closed haemorrhoidectomy.

The current Gold Standard for the treatment of third and fourth-degree haemorrhoids is the Milligan-Morgan haemorrhoidectomy, which is the most popular surgical method due to its economic efficiency, minimal postoperative complications, and superior long-term outcomes. Nevertheless, the treatment for haemorrhoids. standard open haemorrhoidectomy, is known to be an unpleasant procedure that requires a 2- to 3-day hospital stay, postoperative discomfort and a minimum of onemonth of recuperation.⁸ Many surgeons now employ stapled hemorrhoidopexy as an alternative to these conventional methods. This method is less traumatic, safe and fast and it improves postoperative pain control.It also has the advantage of being able to be performed on a day-care basis for certain patients.⁹ Haemorrhoids continue to be the subject of significant debate regarding their precise treatment.

Therefore a present study was conducted to compare the Stapled Haemorrhoidectomy versus Open Haemorrhoidectomy (Milligan Morgan) for Grade IV Haemorrhoids.

MATERIALS AND METHODS

A randomised controlled trial study was carried out in the General Surgery department of Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh.60 patients, aged of 18 years and above with grade IV haemorrhoids admitted to the Department of General Surgery of Rohilkhand Medical College and Hospital Bareilly were recruited for the study.Patients were randomly divided into two groups in a 1:1 allocation ratio, each compromising 30 patients. Informed consent and approval of each patient for participation in the study was taken.In Group (A) 30 patient for Stapler Haemorrhoidectomy and in Group (B) 30 patient for Open Haemorrhoidectomy (Milligan Morgan) were taken.

Inclusion Criteria

• All patients of 18 years and above with Grade IV haemorrhoids admitted in the department of surgery of Rohilkhand Medical College and Hospital Bareilly, Uttar Pradesh.

Exclusion Criteria

- Patients with colorectal malignancy anal fistula.
- Acute haemorrhoidal oedema, Perianal sepsis.
- Patients with acute or chronic diarrhoea or inflammatory bowel disease.
- Patients with previous history of surgery for haemorrhoids, a pre-existing sphincteric injury, or complete rectal prolapse or perianal dermatosis.
- Patients with symptomatic incontinence, diabetes, anaemia, malnutrition, or immunodeficiency; patients with serious heart, liver, or kidney disease, or blood coagulation dysfunction.
- Pregnant or menstruating.

Methodology

After screening of patients presenting to department of general surgery with grade IV Haemorrhoids, appropriate patients were enrolled in the study after obtaining written informed consent. Patients were subjected to clinical examination and routine laboratory investigations preoperatively. Then randomly (lottery method) these patients were placed in 2 groups. Group A contained (30 patients) patients went for Stapled haemorrhoidectomy while those in Group B (30 patients) went for Open (Milligan-Morgan) haemorrhoidectomy.

Operating time was defined as the time from the start of the operation to the application of the endoanal dressing. All patients were admitted before surgery. The patient's hospital stay for analysis was calculated starting from the day of surgery. Preoperatively patients were kept nil per oral overnight prior to surgery. One dose of antibiotics was given at the time of anaesthesia for surgery. All operations were performed in the lithotomy position under spinal anaesthesia. Patients were again examined under anaesthesia to rule out associated anal pathologies like anal fissures and fistula in ano and to confirm the grade of haemorrhoids. A patient was operated on by prefixed operative procedure as per group. A patient was on a soft oral diet within 4 hours postoperatively. The dressing was removed on the morning after surgery and a local external visual examination was done. Postoperative pain was managed according to the guidelines.

The pain was assessed using a visual analogue scale (vas) where 0 represents no pain and 10 represents the worst pain ever. The pain score was recorded on postoperative day 1 with the effect of analgesia. Postoperatively, patients were advised antibiotics, analgesics, and syrup lactulose 20 ml at bedtime for two weeks. Patients underwent open hemorrhoidectomy advised sitz bath twice daily for two weeks. Patients were discharged when pain control and home circumstances permit. An outpatient appointment for review was given one week after surgery. Patients were advised to report immediately in cases of emergency. On follow up patients were asked, to rate the control of their symptoms i.e., degree of continence to flatus and faeces, duration to return to normal activities, and any other problems they had. A physical examination was carried out at each follow-up. The outcome measures were postoperative pain, postoperative bleeding, analgesic requirement, operative time, hospital stay, time to return to normal activity, and complications. Patient data collection sheet for data collection.

Statistical Analysis

Data was entered in SPSS-23.0. Descriptive analysis was done by calculating proportions, means and standard deviation. Appropriate statistical tests were applied depending on the distribution and type of data. A p-value of < 0.05 was considered as statistically significant.

RESULT

Stapler Haemorrhoidectomy group showed a slightly higher proportion of patients in the 31-40 age range (43.3%), the Open Haemorrhoidectomy group had a marginally higher percentage in the 41-50 age range (40.0%). Mean Age being 35.3 ± 9.5 years for stapler haemorrhoidectomy (group A) and 37.8 ± 9.8 years for open haemorrhoidectomy (group B). Both treatment groups demonstrated a predominantly male patient population, with approximately 80% of patients being

male and remaining 20% were females. Both treatment groups had a similar distribution of urban and rural residents, with approximately 55% of patients residing in urban areas and 45% residing in rural areas. Approximately 60% of Stapler Haemorrhoidectomy patients and 73.3% of Open Haemorrhoidectomy patients reported Smoking/Alcohol habits. Majority of patients, 60% of stapler group and 70% of open group, were non vegetarians. No statistically significant difference was observed between above parameters. (Table 1)

46.7% of patients in the Stapler group and 40.0% in the Open group reported experiencing pain pre operatively. All patients in both groups (100%) experienced bleeding, itching, mass per rectum, mucous discharge, and constipation, with no difference between the groups in these symptoms. No significant difference was observed with p value 0.602. (Table 2)

Stapler Haemorrhoidectomy had a significantly shorter operative time (32.9 minutes) (p<0.001), significantly less blood loss (5.3 mL) (p<0.001), significantly less pain during the first stool passage (p<0.001), shorter hospital stay (1 day) (p<0.001) and returned to work significantly faster (5 days) (p<0.001) than Open Haemorrhoidectomy patients. (Table 3)

On the 0th day, the Stapler group had a mean pain score of 3.2 ± 0.5 , significantly lower than the Open group, which had a mean score of 6.3 ± 0.5 (p < 0.001). Similar trends were observed on the 1st, 3rd, 5th, and 7th days, with the Stapler group consistently reporting lower pain scores compared to the Open group, all with highly significant p-values (< 0.001). (Table 4)

Stapler Haemorrhoidectomy had a significantly lower incidence of post-operative urinary retention (16.7%), post-operative bleeding (10.0%) and post-operative incontinence (0%). (Figure 1).

		Stapler	Open	[p value]
		Haemorrhoidectomy [N=30]	Haemorrhoidectomy [N=30]	-
Age (years)	11-20	2 (6.7)	1 (3.3)	2.734
	21-30	6 (20.0)	7 (23.3)	[0.603]
	31-40	13 (43.3)	8 (26.7)	
	41-50	8 (26.7)	12 (40.0)	
	51-60	1 (3.3)	2 (6.7)	
Gender	Male	24 (80.0)	23 (76.7)	0.098
	Female	6 (20.0)	7 (23.3)	[0.754]
Residence	Urban	17 (56.7)	16 (53.3)	0.067
	Rural	13 (43.3)	14 (46.7)	[0.795]
Past history		0 (0.0)	0 (0.0)	-
Smoking/Alcohol		18 (60.0)	22 (73.3)	1.200 [0.273]
Diet status	Vegetarian	12 (40.0)	9 (30.0)	0.659

 Table 1: Demographic distribution of study population

Non-	18 (60.0)	21 (70.0)	[0.417]
Vegetarian			

Table 2: Distribution of symptoms in both groups			
	Treatment		Test value [p value]
	Stapler Haemorrhoidectomy	Open Haemorrhoidectomy	_
	[N=30]	[N=30]	
Pain (Pre-	14 (46.7)	12 (40.0)	0.271 [0.602]
operative)			
Bleeding	30 (100.0)	30 (100.0)	-
Itching	30 (100.0)	30 (100.0)	-
Mass per Rectum	30 (100.0)	30 (100.0)	-
Mucous Discharge	30 (100.0)	30 (100.0)	-
Constipation	30 (100.0)	30 (100.0)	-

Table 3: Comparison of various factors in both groups

	Treatment		Test value [p
	Stapler	Open	value]
	Haemorrhoidectomy	Haemorrhoidectomy	
	[N=30]	[N=30]	
Operative time (minutes)	32.9±4.2	42.5±5.3	-8.26 [<0.001]
Intraoperative Blood Loss	5.3±0.5	35.9±4.0	-41.3 [<0.001]
(in ML)			
Time of First Stool	10.4±1.2	10.2±1.6	0.63 [0.529]
Passage(hrs)			
Pain in passage of First	1.9±0.3	6.9±1.6	-17.15 [<0.001]
Stool (VAS)			
Duration of Hospital Stay	1.0±0.0	2.1±0.3	-23.03 [<0.001]
(Day's)			
Time to Return to Normal	5.0±1.1	14.2±2.4	-19.17 [<0.001]
Work (Days)			

Table 4: Comparison of post-operative pain in both groups

	Treatment		Test value [p
	Stapler	Open	value]
	Haemorrhoidectomy	Haemorrhoidectomy	
	[N=30]	[N=30]	
0 day	3.2±0.5	6.3±0.5	-25.185 [< 0.001]
1 st day	3.1±0.3	5.1±0.3	-28.065 [< 0.001]
3 rd day	2.0±0.2	3.3±0.5	-13.916 [<0.001]
5 th day	1.0±0.0	2.2±0.4	-15.703 [<0.001]
-			
7 th day	0.4±0.5	1.4±0.5	-8.310 [< 0.001]
15 th day	0.0±0.0	0.2±0.4	-2.408 [0.019]



Figure 1: Distribution of post-operative complications in both groups

DISCUSSION

A newer minimally invasive modality in the treatment of grade III and IV degree haemorrhoids, stapled hemorrhoidopexy, has been met with both scepticism and interest. The short-term outcomes of stapled haemorrhoidectomy have been superior, as evidenced by shorter operating times, reduced postoperative discomfort, earlier return to work, and increased patient satisfaction.¹⁰

In the present study, both groups exhibit a similar age range, with most patients falling within the 31-50 years age bracket.Mean Age being 35.3±9.5 years for stapler haemorrhoidectomy (group A) and 37.8±9.8 haemorrhoidectomy vears for open (group B).Mohammed S et al¹¹ showed mean age for 35.7 years for open haemorrhoidectomy and 33.6 years for stapler haemorrhoidectomy group. These results were comparable to our study. Another study conducted by Abid KJ et al¹² showed variation in their age range. The average age was 39.0 years in stapled and 44.20 years in open group respectively.

In the present study, both treatment groups demonstrate a predominantly male patient population, with approximately 80% of patients being male. A similar research conducted by different authors^{13,12,8} showed predominance of males in both the treatment groups. The reason for this may be that women are humiliated to seek medical attention for anorectal issues.

Both treatment groups have a similar distribution of urban and rural residents, with approximately 55% of patients residing in urban areas and 45% residing in rural areas. The statistical analysis, indicated a nonsignificant difference.

The present study showed 46.7% of patients in the Stapler group and 40.0% in the Open group reported pain. All patients in both groups (100%) experienced bleeding, itching, mass per rectum, mucous discharge, and constipation, with no difference between the groups in these symptoms. Abid KJ et al¹². They found bleeding and mucosal prolapsed in 100% patients of both the treatment groups. Another study conducted by Rahman A et al⁸ observed constipation was the most common symptom (69%). The results of all the literatures were in correlation with our study.

Approximately 60% of Stapler haemorrhoidectomy patients and 73.3% of Open haemorrhoidectomy patients reported smoking and alcohol habits. The statistical analysis showed non-significant difference. Nagraj SV et al^{14} found the similar results. The likelihood of haemorrhoids developing can be elevated by smoking and drinking alcohol. In our study, diet status (vegetarian or non-vegetarian) was not significantly associated with the type of hemorrhoidectomy performed.

In the present study, we have observed that Stapler haemorrhoidectomy had a significantly shorter operative time (32.9 minutes) compared to open haemorrhoidectomy (42.5 minutes). Similar studies conducted by Yadav GD et al¹⁰ found more than 40 min for open and less than 30 min for stapled procedure, Surati K et al¹⁵ (40 min and 34 min) and Shukla S et al¹⁶ (50 min and 35.8 min) respectively.Results were consistent with our results. We reported, Stapler Haemorrhoidectomy resulted in significantly less blood loss (5.3 mL) compared to Open Haemorrhoidectomy (35.9 mL). Similar results were observed by Mohammed S et al¹¹. They observed blood loss in open hemorrhoidectomy group

was 39.5ml and in stapled hemorrhoidectomy group was 26ml. Rahman A et al⁸ showed the stapled haemorrhoidopexy group's intraoperative bleeding was 48.44 ml and intraoperative blood loss for the open hemorrhoidectomy group was 72.65 ml.The patients of stapler haemorrhoidectomy had a significantly shorter hospital stay (1 day) compared to Open haemorrhoidectomy patients (2.1 days). Similar study done by Rahman A et al⁸ showed maximum fraction of patients (78.6%) of stapled haemorrhoidectomy had a hospital stay of less than 2 davs. While 73.8% patients of open haemorrhoidectomy had hospital stay of 2-4 days. These results are in accordance to our study.Stapler haemorrhoidectomy patients returned to work significantly faster (5 days) compared to open haemorrhoidectomy patients (14.2 days). Bangaradka N et al¹⁷ in their study also observed return to normal routine was faster in stapler haemorrhoidectomy (3±1.5) as compared to open haemorrhoidectomy (10 ± 3.2) . Similar results were observed by Kumar M et al¹⁸ and Malyadri N et al¹⁹.

In the present study, on the 0th day, the Stapler group had a mean pain score of 3.2 ± 0.5 , significantly lower than the Open group, which had a mean score of $6.3 \pm$ 0.5. Similar trends were observed on the 1st, 3rd, 5th, and 7th days, with the Stapler group consistently reporting significantly lower pain scores compared to the Open group.On the 15th day, the Stapler group had a pain score of 0.0 ± 0.0 , while the Open group had a slightly higher score of 0.2 ± 0.4 .The study done by Gupta R et al²⁰ observed similar pattern of pain reduction in stapler haemorrhoidectomy as compare to open haemorrhoidectomy.Rulaniya SK et al²¹ observed at all times, the VAS of the stapled haemorrhoidopexy group was significantly lower than that of the conventional group.

Stapler Haemorrhoidectomy was associated with a lower incidence of post-operative complications, particularly urinary retention and incontinence, when compared with Open Haemorrhoidectomy. Abid KJ et al^{12} reported 4% cases of open haemorrhoidectomy had anal stenosis. Rahman A et al^8 reported less incidence of post-operative urinary retention in stapler hemorrhoidectomy (16.7%) as compare to open group (31.0%). Less post-operative bleeding in stapler group (14.3%) as compare to open group (21.4%). Post-operative incontinence was observed in 4.8% cases of open group. Similar results were observed by Yadav GD et al^{10} .

The surgical treatment of haemorrhoids has undergone significant changes over time. The gold standard of treatment worldwide remains the timetested open haemorrhoidectomy. The efficacy of each contemporary procedure is evaluated in comparison to that of open haemorrhoidectomy. Shorter operating times, minimal intraoperative bleeding and reduced postoperative complications such as pain, urinary retention, and bleeding are among the unique benefits of stapler haemorrhoidectomy.

CONCLUSION

Stapler haemorrhoidopexy is a viable alternative to open haemorrhoidectomy in the indicated patient population who can afford the stapler, as it offers distinct advantages like Shorter operating times, minimal intraoperative bleeding and reduced postoperative complications such as pain, urinary retention and bleeding. Another advantages are the earlier return to work and the shortened hospital stay. The procedure is simple to execute, reproducible and diverse operators can achieve comparable results as long as they adhere to the fundamental principles and possess an adequate level of experience.

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