# **Original Research Paper**



# **General Surgery**

# TO OPEN HEMORRHOIDOPEXY A BETTER AND SAFER ALTERNATIVE TO OPEN HEMORRHOIDECTOMY IN THE MANAGEMENT OF GRADE III & IV HEMORRHOIDS- A HOSPITAL BASED STUDY

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**ABSTRACT** 

**Background:** Surgical hemorrhoidectomy is usual method for management in hemorrhoid grade III and IV. It is generally associated with postoperative pain, long hospital stay and a longer convalescence. Stapled hemorrhoid

a newer minimally invasive alternative for the treatment of hemorrhoids. **Aims:** In this study, the above two methods were compared with respect to short term outcomes.

**Settings and Design:** This was a prospective and randomized study.

Methods: 60 patients having grade 3 or 4 hemorrhoids and who fulfilled the criteria were included in the study. Thirty patients underwent stapled hemorrhoidopexy and other thirty underwent open hemorrhoidectomy. All patients were reviewed immediately after surgery and at 1, 3 and6 weeks post-operatively. The two groups were compared in terms of duration of surgery, hospital stay, return to work and post-operative level of satisfaction.

Statistical Analysis: The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. Significance was assessed at 5% level of significance. Student t-test was used to find the significance of study parameters on continuous scale in parametric condition between two groups (inter group analysis) and Mann Whitney U test was used to find the significance of study parameters on continuous scale in non-parametric condition within each group. Chi-square/ Fisher Exact test were used to find the significance of study parameters on categorical scale between two groups.

**Results:** The overall mean age of patients in our study was  $41.35 \pm 12.80$ . The majority of patients in the study were males (78.3%) and had grade 3 haemorrhoids (93.3%). Stapled hemorrhoidopexy group had shorter duration of surgery, less postoperative pain and need for analgesia, shorter duration of hospital stay and earlier return to work and a high patient satisfaction as compared with open hemorrhoidectomy group.

**Conclusions:** Stapled hemorrhoidopexy is a minimally invasive, better and safer alternative to open hemorrhoidectomy with many short-term benefits.

# KEYWORDS: Stapled hemorrhoidopexy, open hemorrhoidectomy

#### INTRODUCTION

Hemorrhoids are the most common benign anorectal problems. Third and fourth degree hemorrhoids usually require surgical intervention. Open hemorrhoidectomy by Milligan-Morgan technique has been the most popular among the various open surgical techniques performed. However, post-operative pain is the most dreaded complication of this technique which leads to a longer hospital stay and a convalescence of at least one month. A

Stapled hemorrhoidopexy is a newer minimal invasive modality in the treatment of grade III and IV degree hemorrhoids<sup>5</sup>, which has been met with both skepticism and interest<sup>6</sup>. Stapled hemorrhoidectomy has shown better short-term outcomes, including shorter operating times, lesser postoperative pain, early return to work and a greater patient satisfaction.<sup>3,4,7-9</sup>

The present study was designed to compare the short term outcomes of stapled hemorrhoidopexy with Milligan-Morgan open hemorrhoidectomy in terms of:

- Duration of surgery
- · Post-operative pain and requirement of analgesics
- · Duration of hospital stay
- Post-operative complications
- Days taken for return to work
- Patient satisfaction

#### MATERIAL & METHODS

The study was conducted in the Department of General Surgery, LLR and Associated Hospitals, GSVM MEDICAL COLLEGE, KANPUR, U.P., from January 2019 to October 2020, on patients of hemorrhoid who were admitted in to wards.

A total of 60 patients were included in the study – 30 underwent stapled

hemorrhoidopexy and 30 underwent open hemorrhoidectomy by Milligan Morgan technique, allocated randomly after taking a proper informed consent.

The study was performed after obtaining clearance from the Institutional Ethical Committee, based on its guidelines.

#### INCLUSION CRITERIA-

All patients of age group  $\geq$  18 years with grade III and IV hemorrhoids who were willing to give consent for open hemorrhoidopexy /stapled hemorrhoidopexy.

#### **EXCLUSION CRITERIA-**

Patients with recurrent haemorrhoids and thrombosed grade IV hemorrhoids were excluded. Patient with other disease like portal hypertension and associated peri-anal conditions like abscess, anal fissure, rectal ulcer and rectal prolapse were also excluded from the study.

Patients were clinically examined and routine laboratory investigations were done preoperatively. All patients were operated on an in-patient basis. Patients' hospital stay for analysis was calculated from the day of surgery. Preoperatively patients were kept nil per oral overnight and received proctoclysis enema in the morning of the day of surgery.

At the time of induction, injection Ceftriaxone 1gm i.v. and injection Metronidazole 500mg i.v. were injected for prophylactic antibiotic coverage All patients were operated in lithotomy position under saddle/spinal anaesthesia, in the operation theatre of GSVM MEDICAL COLLEGE, KANPUR, U.P. Patients were reexamined under anaesthesia to confirm the grade of hemorrhoids and to rule out associated anal pathologies like anal fissure and fistula in ano .

Post-operative management consisted of standard nursing care and analgesia. Patients were started on a soft oral diet within 6 hours post-operatively. Dressing was removed on the morning after surgery and a local external visual examination was done. Pain was assessed in terms of the Visual Analog Score (VAS) with maximum imaginable pain as 10 and least as 1. In the postoperative period the parameters recorded were-

- · Duration of surgery
- Episode of urinary retention
- Soakage of pad with blood
- Post op perianal itching
- Time for passage of first stool
- Pain on VAS during passage of first stool
- Duration of Hospital stay
- · Time to return to normal work
- Pain on VAS during follow up at 3<sup>rd</sup>day, 7<sup>th</sup>day and 15<sup>th</sup>day post op.
- Level of satisfaction

Patients undergoing open hemorrhoidectomy were also advised Sitz bath twice daily for two weeks. Patients were discharged when pain control and home circumstances permitted. The patients were discharged when there was no requirement for analgesia in the last 12 hours.

On each follow up visit the patient was subjected to VAS. In the second and subsequent visit, a gentle digital rectal examination and proctoscopic evaluation was done. Level of patient satisfaction was assessed against a score of 10. A note on the number of days to return back to work was made. After the initial visits the patients were advised to follow up every 3 months.

#### **OPEN HAEMORRHOIDECTOMY**





Pre-operative photograph

Result

#### STAPLED HAEMORRHOIDECTOMY





Pre-operative photograph

Result

#### STATISTICALANALYSIS:

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. Significance was assessed at 5% level of significance. Student t-test was used to find the significance of study parameters on continuous scale in parametric condition between two groups (inter group analysis) and Mann Whitney U test was used to find the significance of study parameters on continuous scale in non-parametric condition within each group. Chi-square/Fisher Exact test were used to find the significance of study parameters on categorical scale between two groups.

#### **OBSERVATIONS AND RESULTS:**

Out of 60 patients, 50% (n=30) underwent hemorrhoidectomy by Open Milligan-Morgan's method (Group A) while the remaining 50% (n=30) patients underwent stapled hemorrhoidopexy (Group B). The following results were observed and statistically analyzed. In the present study, both the groups were comparable with respect to mean age and sex.

Table 1: Distribution Of Study Population According To Age:

	Group A	A (n=30)	Group B	(n=30)	Total (N=60)		
	No.	%	No.	%	No.	%	
≤30 yrs	3	10.0	10	33.3	13	21.7	

31-40	12	40.0	11	36.7	23	38.3
41-50	9	30.0	4	13.3	13	21.7
51-60	3	10.0	3	10.0	6	10.0
>60	3	10.0	2	6.7	5	8.3
	$X^2 = 5.93$	36 (df=4	); p=.20	)4		
Min - Max (Median)	19-75 (	41.0)	21-84 (	37.0)	19-84 (40.0)	
Mean±SD	43.73±	11.85	38.97±	13.46	41.35±	12.80

## Table 2. Distribution of Study Population according to Gender:

Gender	Group A (n=30)		Group E	3 (n=30)	Total (N=60)	
	No. %		No.	%	No.	%
Female	4	4 13.3		30.0	13	21.7
Male	26	86.7	21	70.0	47	78.3
	$X^2$	=2.455 (d				

#### Table 3. Grade of Hemorrhoids:

	Grade of	1	A (n=30)	Grou	up B (n=30)	Total (N=60)		
	Hemorrhoids	No.	%	No.	%	No.	%	
	Grade III	26	86.7	30	100.0	56	93.3	
	Grade IV	4	13.3	4	6.7			
Ī		X2	=4.286(df=	=.038				

## Table 4. Duration of Surgery:

	Group.	A (n=30)	Group E	3 (n=30)	Total (N=60)		
	No. %		No.	No. %		%	
<30 min	0.0		24	80.0	24	40.0	
30-40 min	5	16.7	6	6 20.0		41.7	
>40 min	25	83.3	0	0.0	11	18.3	
	$X^{2}$	=49.091(d					

#### Table 5. Time of first stool Passage:

0										
	Group A (n=30)		Group E	3 (n=30)	Total (N=60)					
first stool	No.	%	No.	%	No.	%				
4-8 hrs	hrs 1		1	3.3	2	3.3				
8-12 hrs	28	8 93.3 28	28	93.3	56	93.3				
>12 hrs	1	3.3	1	3.3	2	3.3				
	X	<sup>2</sup> =0.000(d								

#### Table 6. Pain in passage of First Stool:

			0				
Pa	in	Group A	A (n=30)	Group E	3 (n=30)	Total (	N=60)
sco	ore	No. %		No.	No. %		%
<	3	2 6.7		29	29 96.7		51.7
3 to	o 6	5	5 16.7		0.0		8.3
≥	7	23	76.7	1	1 3.3		40.0
		$X^{2}$	=48.683(d				

## Table 7. Duration of Hospital Stay:

Duration of	Group A	roup A (n=30) Group B (n=30)			Total (	(N=60)		
hospital stay	No.	%	No.	%	No.	%		
1 day	2	6.7	29	96.7	31	51.7		
2 days	27	90.0	1	3.3	28	46.7		
3 days	1	3.3	0	0.0	1	1.7		
	$X^2=$	<i>X</i> <sup>2</sup> =48.659 (df=2); <b>p&lt;.001</b>						

## Table 8. Pain at different time intervals during Follow Up:

Period of	Group A				Group I	Mann Whitney		
observation	(n=30)			(n=30)			U test	
	Md	Mean	SD	Md	Mean	SD	Z	P
Day 3	3.00	3.50	1.36	2.00	2.10	0.55	6.477	< 0.001
Day 7	2.00	1.87	1.07	0.00	0.47	0.57	5.604	< 0.001
Day 15	0.00				0.00	0.00	2.558	0.011

#### Table 9: Intra-op/Post-op Complications:

Complications	Total	Group A		Group B		Significance	
	(N=60)	(n=30)		(n=30)		of difference	
		No.	%	No.	%	$X^2$	P
Bleeding	9	6	20.0	3	10.0	1.176	0.278
Urinary retention	9	6	20.0	3	10.0	1.176	0.278
Itching	11	7	23.3	4	13.3	1.002	0.317
Wound infection	0	0	0.0	0	0.0	_	_
Re-intervention	0	0	0.0	0	0.0	_	_

#### Table 10. Time to Return to Normal work (Days):

Group	No. of patients	Min.	Max.	Median	Mean	S.D.
Group A	30	7	13	8.00	8.30	1.62
Group B	30	2	7	2.00	2.53	1.36
Total	60	2	13	7.00	5.42	3.26

't'=14.931; p<.001

Table 11: Satisfaction of patients after treatment:

Satisfaction	Group A (n=30)		Group B (n=30)		Total (N=60)	
	No.	%	No.	%	No.	%
Not satisfied	4	13.3	4	13.3	8	13.3
Satisfied	26	86.7	26	86.7	52	86.7
	X <sup>2</sup> =0.000(df=1); p= <b>1.000</b>					

#### DISCUSSION:

The study was a comparative evaluation of stapled hemorrhoidopexy versus open hemorrhoidectomy, designed to determine whether the stapled technique offers any definite advantages over the open method.

The two groups of patients were matched with respect to age. Mean age in group A was  $43.73{\pm}11.85$  years and in group B was  $38.97{\pm}13.46$  years . There was no statistical difference in the mean age group between them. In the study conducted by  $Hetzer\ et\ al.$ , the mean age group was 50.4 yrs in stapled group and 44.8 yrs in open group – with no statistical difference.  $^{10}Mean$  age group was 48 yrs and 47 yrs in the stapled and open groups respectively in the study by  $Ganio\ et\ al.$  Ho and colleagues studied with a mean age group of 44 years in stapled hemorrhoidectomy patients and 46.3 years in open hemorrhoidectomy patients  $^{11}$ . Sachin et al. studied with a mean age of  $39.69{\pm}9.49$  years and  $39.2{\pm}11.03$  years in the stapled hemorrhoidopexy and open hemorrhoidectomy groups respectively.  $^{12}$ 

Out of the 60 patients enrolled in the study only 21.7% (n=13) patients were females, the remaining 78.3% (n=47) were males. Gender ratio was 3.62:1. Proportion of females was higher in Group B (30.0%) as compared to Group A (13.3%), which was statistically not significant (p=.117). The condition of haemorrhoids is more common in males as compared to females. Hetzer et al. reported that the sex distribution of male: female was 15:5 in stapled group and 14:6 in open group in his study. This has also been pointed out in other studies in the literature.

Third degree hemorrhoid is the commonest type requiring surgical treatment as reported in various studies. In the present study, 93.3% (n=56) had grade III haemorrhoids. However, the fourth degree haemorrhoids were more common in the study conducted by **Shalaby** et al. 13

There was a significant difference in the duration of surgery in the two techniques. Duration of surgery among majority of patients of Group B was <30~(80.0%) minutes while in majority of patients of Group A, was >40 minutes (83.3%). Proportion of patients of Group B was higher as compared to Group A having lower duration of surgery i.e. <30 min (80.0% vs. 0.0%) and 30-40 min (20.0% vs. 16.7%) while proportion of patients of Group A was higher as compared to Group B having duration of surgery >40 minutes (83.3% vs. 0.0%). It was seen that the duration of surgery showed a downward trend in the stapled group with the increase in the number of cases operated, probably because of the learning curve. This data was found to be statistically significant. (p=<.001).

This has been reported by a number of previous studies. **Sachin et al.** in their study found that in the stapled hemorrhoidopexy group, 38% underwent surgery within 20 - 30 min<sup>12</sup>. The mean duration of surgery was 33 min, ranging from 25 to 55 minutes. In the open hemorrhoidectomy group, mean duration was 44 minutes, ranging from 25 to 55 minutes. However, **Ho et al.** found that the conventional hemorrhoidectomy required less time as compared to the stapled technique. This is probably because the study by the Ho et al. was conducted between 1999-2000, when the stapled hemorrhoidectomy was still at its earlier stages, the learning curve being the contributing factor

In Group A, hospital stay in most of the patients was of 2 days only (90.0%) followed by 1 day (6.7%) and the rest (3.3%) had 3 days of hospital stay. In Group B duration of hospital stay was 1 day (96.7%) in most of the patients and only 1 patient (3.3%) had a hospital stay of 2 days ( $\mathbf{p}$ <.001). The shorter duration in the stapled group has been well confirmed by a number of studies. According to **Varun Raju et al.** mean post operative hospital stay in MIPH group was  $1.1\pm0.35$  days and  $2.3\pm1.2$  days in Milligan-Morgan group, which is statistically significant with  $\mathbf{p}$  value <  $0.005^{15}$ . This is also supported by the studies of  $\mathbf{Dr}$ . **Jean François Gravié et al.**,  $\mathbf{Dr}$ . **Ammaturo C et al.**,  $\mathbf{Dr}$ . **Nisar PJ et al.**,  $\mathbf{Dr}$ . **Raahave D et al.**, and  $\mathbf{Dr}$ . **Hetezer FH et al**. However the duration of stay was similar in the two groups as according to **Michigan et al.** and **Ho et al**.

Post operative pain was assessed using VAS. On day 3, median pain score of patients of Group A and Group B was 3 and 2 respectively. Mean pain score of patients of Group A (3.50±1.36) was found to be higher as compared to Group B (2.10±0.55). On Day 7, median pain score of patients of Group A and Group B was 2 and 0 respectively. Mean pain score of patients of Group A (1.87±1.36) was found to be higher as compared to Group B (0.47±0.57). This was found to be statistically significant.

The requirement of analgesics during the hospital stay as well as after discharge was less in group B. The pain scours compared between the two groups in various studies conclusively prove that post-operative pain is much less after stapled haemorrhoidectomy than after open haemorrhoidectomy. All studies are unanimous regarding this.

The time of first stool passage in majority of overall as well Group A and Group B patients was 8-12 hours (93.3% each) 1 patient each from Group A and Group B passed first stool at 4-8 hours and >12 hours. Time of first stool passage was similar in both the groups. **P Thejeswi et al.** reported that the average time for the passage of first stools in the stapled, open and the closed group was 20 hrs, 24.9 hrs and 23.4 hrs, respectively<sup>15</sup>.

Pain score in passage of first stool among majority of patients of Group B (96.7%) was <3 and rest 3.3% had pain score  $\geq$ 7 (3.3%). Pain score of majority of patients of Group A was  $\geq$ 7 (76.7%), only 6.7% had pain score <3 and rest 16.7% had pain score 3 to 6. This was also statistically significant (**p<.001**). In the study by **Sachin et al.** a significant difference in the pain at the passage of stools was obtained between the stapled and the open group. <sup>12</sup>

Incidence of urinary retention was reported by higher proportion of patients of Group A (20.0%) as compared to Group B (10.0%) in this study, but this was statistically found to be not significant. **Shelby et al.** reported urinary retention in 14 out of 100 patients (14%) in open group as compared to 7 out of 100 (7%) in stapled Group<sup>13</sup>. **Ganio** reports that retention developed in 5 out of 50 (10%) after open hamenorrhoidectomy<sup>11</sup>. **Sachin et al.** reported urinary retention in 15 out of 50 patients (30%) in open group as compared to 8 out of 50 (16%) in the stapled group<sup>12</sup>. **Smith et al.** stated that urinary retention is the most common problem after hemorrhoidectomy, with its degree related to the amount of surgery and the incisions required. The anal sphincter has the same nerve root origin as the bladder sphincter.

Incidence of bleeding was reported by higher proportion of patients of Group A (20.0%) as compared to Group B (10.0%). In the study by **Ganio et al.** secondary hemorrhage occurred in 3 patients each in both group (of 100 patients each). 1. 1 out of 100 patient (1%) in stapled group and 2 out of 100 (2%) in open group had significant bleeding as reported by **Shalaby et al.** 12 Secondary haemorrhage was reported in only one of 28 patients in the conventional haemorrhoidectomy group and non in stapled group by **Ortiz et al.** Post-surgery 7 (14%). Patients in stapled group had bleeding as compared to 11 in the open group (22%) as found by **Sachin et al.** 12

Complaints of itching was reported by higher proportion of patients of Group A (23.3%) as compared to Group B (13.3%) but difference in incidence of itching among patients of above two groups was not found to be statistically significant. **Kim et al.** In their study demonstrated less burning/itching sensation 4 weeks after surgery in the stapled group compared to the Milligan-Morgan group (4.9 vs. 19.7%; p<0.001)<sup>17</sup>.

Time to return to normal work of patients of Group A was 7-13 days while that of Group B was 2-7 days. Median duration of time to return to normal work was 2 days in Group B and 7 days in Group A. Time to return to normal work was earlier in Group B (2.53±1.36 days) as compared to Group A (8.30±1.62 days). Most of the studies reported that the return to work or routine activities is much earlier after stapled hemorrhoidectomy in comparison to the open group. Sachin et al. in their study stated that a mean of 8 days in stapled group and 15 days in open group was noted. About 50 % of stapled group had returned to work at the end of one week and the rest by second week 12. Only one patient took 16 days to return to work. In the open group, 38% patients returned to work by 2 weeks and rest after 2 weeks. However Ortiz et al. reported that there was no statistical difference in the mean time to return to work. He said that social and cultural factors need to be taken into account in the assessment of return to work.

As regards patients evaluation and level of satisfaction, In both the groups, 86.7% patients were satisfied with their treatment and rest 13.3% were not satisfied. Proportion of dissatisfied patients in both the groups was similar. Shalaby et al. reported that 92% of patients in stapled group as against 80% in open group were satisfied with the procedure<sup>13</sup>. Mehigan et al. reported that 85% of patients were satisfied with stapled haemorrhoidectomy wheres 75% with open hemorrhoidectomy. Sachin et al. reported significantly high level of satisfaction among stapler group<sup>12</sup>. However in the study by **Ortiz et** al. patients' satisfaction was higher in open hemorrhoidectomy group as compared to stapled group on a scale of 10 16

#### CONCLUSION:

In the present study, an attempt has been made to compare the traditional Milligan-Morgan open hemorrhoidectomy with the new modality of stapled hemorrhoidopexy for the treatment of distressing and widely prevalent disease of hemorrhoids. An attempt has been made to assess to role of staplers in the treatment of Grade III and IV haemorrhoids.

The stapled procedure for hemorrhoids is superior to Milligan-Morgan technique in terms of postoperative pain, operative time and return to normal activity. It is straightforward and easy to learn. Early functional and symptomatic outcomes have been satisfactory and appear similar or better to those achieved using conventional technique. However, long term follow-up with respect to these factors is necessary. Also, a longer follow up period is necessary to compare the recurrence rates of the two groups.

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