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**Citation this Article:** Dr. Upendra Kumar Pandey, Dr. Darshita Sharma, "Comparative study of open hemorrhoidectomy versus stapler hemorrhoidopexy in patients of grade 3 and 4 hemorrhoids", IJMSIR- March - 2021, Vol – 6, Issue - 2, P. No. 357 – 365.

**Type of Publication:** Original Research Article

**Conflicts of Interest:** Nil

## Abstract

Haemorrhoids is one of common anorectal disease, which is seen as bleeding from anal canal and is known for its complications. The management depends on the type and severity of the symptoms, on the degree of prolapse and resources available. A prospective study conducted on 64 patients with grade 3 and 4 haemorrhoids visiting the outpatient department of General Surgery, R.D. Gardi medical college and hospital from November 2018 to February 2020. After routine investigations and optimisation of the clinical condition, the patients were randomly allocated for one of the surgeries after taking an informed consent.

Out of 64 patients 32 underwent open 32 haemorrhoidectomy and underwent stapler haemorrhoidopexy. There was a significant difference (p< 0.001) between the two groups in terms of Operative time  $(47\pm13.9 \text{ min vs } 39\pm7.2 \text{ min})$ , Total hospital stay (8.2 $\pm$ 2.1 days vs 3.2  $\pm$  1.4 days), post operative pain, time to return work(10.7±2.7 days vs 4.0±1.3 days), post - operative complications, level of satisfaction and recurrence. Stapler hemorrhoidopexy is superior to Milligan-Morgan haemorrhoidectomy in terms of operative time, total hospital stay, Time to return to work, pain, patient's satisfaction, recurrence and in terms of other complications. Thus, it can be used as a better alternative to open procedure.

**Keywords**: Milligan-Morgan Haemorrhoidectomy, Stapler Haemorrhoidopexy, Haemorrhoids, Surgical Procedure.

#### Introduction

Haemorrhoids are one of the commonest benign anorectal problems encountered in the primary care setting worldwide. The rectum serves the function of a temporary reservoir for faeces and unfortunately when haemorrhoids raise their ugly heads, the natural process of eliminating waste from the body causes discomfort to the patient.<sup>1</sup>

Haemorrhoids (Greek: haima = blood, rhoos = flowing; synonym: piles, Latin; pila = a ball) are two types internal and external. Internal haemorrhoids are symptomatic anal cushions and characteristically lie in

the 3,7 and 11 o'clock positions when patient in lithotomy position. In addition, haemorrhoids may be observed between the main pile mass in which case they are called the internal haemorrhoids at the secondary position.<sup>2</sup> In both sexes, all races and all ages have anal cushions. Not all patients are symptomatic for haemorrhoids.<sup>3</sup>

External haemorrhoids relate to venous channels of the inferior haemorrhoidal plexus deep in the skin surrounding the anal verge and not true haemorrhoids; they are only recognised as a result of a complication, which is most typically painful solitary acute thrombosis. External haemorrhoids associated with internal haemorrhoids (intero-external piles) result from progression of the latter to involve both haemorrhoidal plexuses, and are best thought of as being external extensions of line and are, therefore, painless.<sup>2</sup> They bleed profusely on staining at stool. The primary piles occur in 3, 7 and 11 O'clock positions of the anal wall when viewed in the lithotomy position. They are formed by the enlargement of 3 main radicles of the superior rectal vein which lies in the anal columns, which occupy the left lateral, right posterior, and right anterior positions. Varicosities in other positions of the lumen are called secondary piles.<sup>2</sup>

External piles or false piles occur below the pectinate line and are, therefore, very painful. They do not bleed on straining at stool.<sup>4</sup>

The treatment of haemorrhoids dates back to antiquity for the two chief symptoms of bleeding and protrusion. Hippocrates used cautery treatment, which was an extremely painful when anaesthesia was not discovered.<sup>5</sup> This has been mentioned in "Sushruta Samhita" of the ancient Indian medicine.

A well-established approach to prophylaxis and treatment is to regulate the patient defecation and

failing this, to use surgical methods. A wide range of techniques, are currently available for the surgical treatment of haemorrhoids i.e., sclerotherapy, rubber band ligation (Barron1963), anal dilatation (Lord1969), cryosurgery (Lewis1969, Lloyd Williams 1973), photocoagulation (Neiger 1979 and Leicester 1981), Milligan & Morgan open and Ferguson closed method, Stapler haemorrhoidopexy, haemorrhoidectomy using harmonic scalpel, Ligasure, Doppler guided haemorrhoidal artery ligation, Laser haemorrhoidectomy.6

The choice of method depends on the type and severity of the symptoms, on the degree of prolapse and on the expertise of the operator and equipments available. Open haemorrhoidectomy as described by Milligan and associates in 1937 has been accepted worldwide as the best choice of treatment but is often associated with significant post-operative pain, discomfort and lengthy recovery time. Stapler haemorrhoidopexy is a newer modality that represents a paradigm change in the treatment of haemorrhoids with better outcome, shorter operating times, less post-operative pain, early return to work and greater patient satisfaction.

In view of it the current study is designed to compare the results of open haemorrhoidectomy with stapler haemorrhoidopexy in Indian patients of Grade 3 and 4 haemorrhoids admitted in R.D. Gardi medical College, Ujjain.

## Materials and methods

This study was conducted in the Department of General Surgery, R.D. Gardi Medical College and Hospital, Ujjain, from November 2018 to February 2020 on patients attending the outpatient department or emergency department of R.D. Gardi Medical College and Hospital irrespective of their gender, background, socio-economic status. In all 64 patients included in the

study - 32 underwent stapler haemorrhoidopexy and 32 underwent open haemorrhoidectomy. The patients were randomly allocated to one of the two surgeries after taking an informed consent. The advantages and disadvantages of both the procedures were explained to the patient.

## **Inclusion criteria**

Symptomatic patients of Grade III and Grade IV haemorrhoids.

#### **Exclusion criteria**

- 1. Symptomatic and asymptomatic patients of grade I & grade II haemorrhoids.
- 2. Haemorrhoids with fissure in ano.
- 3. Haemorrhoids with fistula in ano.
- 4. Anorectal malignancies.
- 5. Patients with bleeding diathesis.
- 6. Patients who refused to participate in the study.
- 7. Severe proctitis.
- 8. Cirrhosis and portal hypertension.
- 9. Pregnancy.

To assess the general condition of the patient Haemoglobin, Total Leucocyte Count, Differential Leucocyte Count, Urine routine and microscopy, X-ray chest, Blood urea, Serum creatinine, Blood sugar and ECG was done. Following assessment, the cases were randomly allocated to one of the two treatment groups. During the surgery operative time was recorded.

# Operative procedure

All patients were operated in lithotomy position under spinal anaesthesia, in the operation theatre of R.D. Gardi Medical college and Hospital.

# **Open haemorrhoidectomy**

The open technique is based on the procedure originally described by Milligan and Morgan in 1937, is also referred to as the Milligan-Morgan operation.

- 1. The skin covered component of each of the main piles is seized with artery forceps and retracted outwards.
- 2. The purple anal mucosal component of each pile is grasped in another artery forceps and drawn downwards and outwards. This manoeuvre prolapses the pile well out of the anus and brings into view the pink rectal mucosa at its upper pole.
- 3. The traction of the three haemorrhoids is maintained until pink rectal mucosa shows not only at the upper part of the piles but also on the mucosal folds running between the piles. This indicates that the piles have been drawn down to their maximum extent so that the ligatures can be applied at their upper poles rather than in the middle.
- 4. The operator then makes a V shaped incision in the anal and perianal skin. The limbs of the V cross the mucocutaneous junction but do not extend into the mucosa, the point of the V should lie 2.5-3 cm away from the anal verge.
- 5. It is preferred to free the haemorrhoidal venous plexus further by dissecting it off the internal sphincter for a distance of 1.5-2.0 cm.
- 6. The apex of the pedicel is then transfixed with a 0/0 or 1/0 chromic catgut suture on a round-bodied needle. The isolated haemorrhoid is then excised with scissors a few millimeters below the apical ligature, while the transfixion suture remains clamped and left long for further inspection at the end of the operation.
- 7. The transfixion ligatures are then divided and the skin wounds are trimmed if they appear ragged, leaving three pear-shaped raw areas.

### Stapled haemorrhoidopexy

PPH set (PPH01) consists of:

1. 33 mm Ethicon End surgery circular Stapler (HCS33).

- 2. Circular Anal Dilator (CAD33).
- 3. Purse-string Suture Anoscope (PSA33).
- 4. Suture Threader (ST100).

### **Procedure**

- 1. The anal verge is held by three atraumatic forceps at the three points where the prolapse is smaller and the anoderm is slightly averted. The introduction of the CAD 33 causes the reduction of the prolapsed mucous membrane falls into the lumen of the CAD33.
- 2. The CAD 33 should be affixed to the perineal skin through the four windows of the CAD 33 with silk or linen stiches on a cutting needle, all remaining prolapsing tissues should be pushed back with a atraumatic forceps through the windows of the CAD33.
- 3. The purse string suture anoscope (PSA33) is now introduced through the CAD33. The suture is to be taken at least 4 cm above the dentate line, the distance to be increased in proportion to the degree of the prolapse.
- 4. The purse string is initiated at 3'O clock position. By rotating the PSA33, it will be possible to complete a purse-string both ends of the suture will be 3'O clock position.
- 5. The PSA in now introduced to visualize the 9'O clock window and a second simple stitch with the same suture material is placed at 9 0' clock at the same level as the purse string stitch. This is to ensure equal pull down of mucosa into the hollow stapler housing along its entire circumference.
- 6. There should be approx. three bites in each quadrant of exposed mucosa. The anoscope is rotated clockwise to expose subsequent quadrants. The haemorrhoidal circular stapler (HCS 33) is opened to its maximum position. Its head is lubricated, introduced and positioned proximal to the purse string.

- 7. With the help of the suture threader (ST 100) both ends of the purse string suture are pulled through the 3-0 clock hole of the HCS33.)
- 8. Surgeon must ensure correct placement of the mucomucous suture over the anaorectal ring, at least 2 cm from the dentate line. The instrument is then tightened adequately by clockwise rotation till the orange indicator reaches as close as possible to the distal end of the green firing zone. It is then fired.
- 9. Keeping the HCS 33 in the closed position for 20 seconds before and after firing acts as a tamponade, which promote haemostasis.
- 10. The stapler is opened completely by anticlockwise rotation of the dial, till it comes out of the anus.
- 11. After removal of the stapler, the anus should be packed with a gauze piece and light pressure should be applied at the anastomotic site.
- 12. Finally the staple, line is examined using the PSA33, and additional stitches, if needed should be taken. Post-operative care Patient was allowed fully oral after 6 hrs of surgery. Then patient was on oral antibiotics.

Then patient was advised as follows

- 1. Sitz bath (at least thrice a day and after every motion).
- 2. Syrup Lactulose 3tsf HS for 1 week.

In the postoperative period the parameters recorded were:

- 1. Analgesia required (injectable/oral, non-opiod/opiod)
- 2. Soakage of the pad with blood
- 3. Any episode of moderately severe bleeding per rectum
- 4. Episode of urinary retention
- 5. Visual analogue score at 24 hours
- 6. Patient satisfaction Visual Analogue score

7. The concept of Visual analogue score<sup>7</sup> was explained to each patient in the pre-operative period with the maximum imaginable pain as 10 and least as 1. The patient was assessed for by VAS at 24 hrs, 3 days, and 7 days. One each below up visit the patient was subject to visual analogue pain score. On 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 at 6 months to look for recurrence. The patients who were unable to come for follow up (due to any reason) were inquired telephonically. Statistical

Tests Computerised analysis of the data was done with the help of SPSS SOFTWARE. Significance levels were determined by using averages, standard deviation, unpaired student test, Chi square test and ANOVA test. If p value < 0.01 or < 0.001, the difference is highly significant. If p value < 0.05, the difference is significant.

# Results

A total of 64 patients were included in the study.

Group A: Those who underwent open haemorrhoidectomy (n1=32)

Group B: Those who underwent stapled haemorrhoidopexy (n2=32)

Table 1: Age Distribution in Study

(	Group A Gro	up B
Range (year)	22 – 75	24 – 80
Mean ± SD (year)	$43.7 \pm 11.6$	$41.7 \pm 10.2$

p value = 0.005

Table 2: Gender Distribution

	Group A Gro	oup B
Males	25	27
Females	7	5

In the study, 52 patients were males and 12 were females.

Table 3: Operative Time

Group	Mean ± SD (min)	Range (min)
A	$47 \pm 13.9$	40 – 80
В	$39 \pm 7.2$	20 – 36

p value < 0.001. Hence the difference in operative time between the two groups was statistically significant.

Table 4: Total hospital stay\*

Group	Mean ± SD (days)	Range (days)
A	$8.2 \pm 2.1$	5 – 7
В	$3.2 \pm 1.4$	1 – 3

\*The calculation of the hospital stay was made from the day of admission.

p value < 0.001. The difference in hospital stay between the two groups was statistically significant.

Table 5: Comparison of post - op pain scores

Post - op Pain (VAS score)	Group A	Group B
0	0	8
1 to 3	0	19
4 to 6	17	5
7 to 10	15	0
Total	32	32

p value < 0.001. Hence the difference in pain between the two groups is significant.

Table 6: VAS score interpretation

VAS Score for pain	Interpretation
0	No Pain
1 – 3	Mild Pain
4 – 6	Moderate Pain
7 – 10	Severe Pain

Table 7: Days to return to work

Group	Mean ± SD (days)	Range (days)
A	$10.7 \pm 2.7$	8 – 14
В	$4.0 \pm 1.3$	3 – 7

p value = 0.000. Hence the difference between the days to return to work in the two groups is highly significant.

Table 8: Comparison of complications

Complications	Open (N = 32)		Stapler $(N = 32)$		p value
	N	%	N	%	
Discharge	27	84.38	3	9.37	0.32
Bleeding	21	65.63	5	15.63	0.35
Urinary retention	23	71.87	5	15.63	0.33
Ulceration	18	56.25	2	6.25	0.42

Follow up of patients of 6 months

Table 9: Evaluation of patients based on level of satisfaction

Group	Excellent		Average		Not satisfied	
	N	%	N	%	N	%
A	2	6.2	18	56.3	12	37.5
В	26	81.0	6	19.0	0	-

Recurrence	Open (N = 32)  N %		Stapler ( $N = 32$ )	
			N	%
Present	27	84.4	3	9
Absent	5	15.6	29	91

p value = 0.000. Hence the difference in recurrence in the two groups is highly significant.

# **Discussion**

Various methods for the management of hemorrhoids - Rubber band ligation, Injection sclerotherapy, Infra-red coagulation and cryosurgery have been used with success but all are inferior to the surgery in the management of third and fourth degree haemorrhoids.<sup>8</sup> The criticism for open haemorrhoidectomy was related to the post-operative pain, and to be absent from work for at least 2 to 3 weeks afterwards with a perineal wound which requires regular dressing<sup>9</sup>. Introduction of stapler for haemorrhoids has eliminated most of the above challenges<sup>10</sup>.

A total of 64 patients were part of the study. Mean age in group A was  $43.7\pm11.6$  years and in group B was  $41.7\pm10.2$  years (Table 1). There was no statistical difference in the mean age group between the two groups. In a study done by Dr. Idoor D. Sachin<sup>11</sup> at Thiruvalla, Kerala, India in 2016, out of 50 patients in both stapler and open group, maximum (32%, 28%) were in the age group 41-50 years and minimum (2%, 4%) were in the age group > 60 years with a mean age of the patients being  $39.7 \pm 9.5$  years and  $39.2 \pm 11.0$  years, respectively. In another study by P. Thejeswi et al.<sup>12</sup>, the mean age was 45 years.

The condition of haemorrhoids was more common in males as compared to females (Table 2). In the study conducted by Dr. Idoor D. Sachin<sup>11</sup> at Thiruvalla, Kerala, India in 2016, 54% and 64% were males in stapler and open groups respectively. In another study

by P. Thejeswi et al.<sup>12</sup>, 70% and 95% were males in stapler and open groups respectively.

The pain scores compared between the two groups in various studies conclusively prove that the postoperative pain is much less<sup>13</sup> after stapled haemorrhoidopexy than after open haemorrhoidectomy. All studies have been unanimous on this point.

The most common complication seen in Group A was discharge while in Group B was bleeding and urinary retention. In group A, 27 of 32 patients had discharge while in group B, 5 of 32 patients had bleeding and urinary retention (Table 8). Shalaby et al<sup>14</sup> reported urinary retention in 14 out of 100 patients (14%) in open group as compared to 7 out of 100 (7%) in stapled group. Ganio<sup>17</sup> reports that retention developed in 5 out of 50 (10%) after open haemorrhoidecomy whereas in 3 out of 50 patients (6%) after stapled haemorrhoidopexy. Smith<sup>15</sup> have noted that urinary retention is the most common problem after haemorrhoidectomy, its degree related to the amount of surgery and the incisions required.

With regard to return to work there was a significant difference between the two groups. The range in group A was between 8 to 14 days with mean of 10.7±2.7 days, while in group B it ranged between 3- 7 days with a mean of 4.0±1.3 days. The p value was 0.000 (Table 7). Most of the studies reported that the return to work or routine activities is much earlier after stapled haemorrhoidopexy in comparison to the open group. 9,14,16,17,18,19

Of the 64 patients in the current study, in the follow up period 27 out of 32 patients presented with recurrence of haemorrhoids in Group A and only 3 out of 32 presented with recurrence of haemorrhoids in Group B. As regards patient's evaluation and level of satisfaction, 81% patients had excellent satisfaction in Group B as compared to only 6.2 % patients in Group A. Shalaby<sup>14</sup> reports that 92% of patients in stapled group as against 80% in open group were satisfied with the procedure. Mehigan et al<sup>18</sup> reported that 85% of patients were satisfied with stapled haemorrhoidopexy whereas 75% with open haemorrhoidectomy. However, in the study by Ortiz et al<sup>20</sup> satisfaction was higher in open haemorrhoidectomy group as compared to stapled group on a scale of 10.

It has been clearly highlighted in studies that considering the cost of hospital admission with economic loss due to absence from work, stapler procedure is much superior than open procedure.

#### **Conclusion**

The findings of our study confirm that stapler haemorrhoidopexy is associated with shorter duration of surgery, less post operative pain and less need for analgesia, shorter duration of hospital stay, earlier return to work and a high patient satisfaction as compared with Milligan Morgan haemorrhoidectomy. The procedure is not associated with major post operative complications. There is no recurrence, residual prolapse or incontinence in the follow - up period. We conclude that stapler haemorrhoidopexy is safe with many short term benefits. It is a novel technique and has emerged as an haemorrhoidectomy, alternative to open long considered the "gold standard'.

# Acknowledgment

Authors acknowledge their professors, colleagues and juniors for kind help and cooperation.

**Ethical approval**: The study was approved by the institutional ethics committee.

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