

# Assessment of the Success Rates of Stapled Hemorrhoidopexy Intervention for Grade III and IV Hemorrhoids among Adult Patients of North India: An Observational Hospital-based Study

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## Abstract

**Introduction:** Hemorrhoid disease therapy is effectively been treated with conventional excisional hemorrhoidectomy. Stapled hemorrhoidopexy (SH) revolutionized the traditional surgical approach by the introduction of the theory of dealing with the rectal mucosal prolapse by resecting a mucosal cylinder above the dentate line by means of mechanical stapling. It is a non-excisional approach for the surgical treatment of hemorrhoid disease.

**Materials and Methods:** Ethical clearance was obtained from the institution. A total of 100 adult patients with Grade III/IV hemorrhoids indicated for surgery were recruited for the study purpose. Data collected were post-operative pain in the form of VAS scale, immediate complications, duration, or length of stay in the hospital along with the time to resume work again. SPSS 17.0 was used to carry out the analysis. All  $P < 0.05$  were considered to be statistically significant.

**Results:** The mean age of the study group was  $45 \pm 14.93$  years. The mean length of hospital stays, postoperatively for 21% subjects, was mere 1 day; however, it was 2 days for the rest of population studied. The only complication was with 2% of the study population having excessive intraoperative bleeding. The mean time to return to work was 8 days. About 77% of the patients resumed their work within 8 days of surgery.

**Conclusion:** Within the given limitations of the study, we can conclude that SH is a successful procedure for Grade-III/IV hemorrhoids in terms of immediate post-operative complications, pain as well as the duration of hospital stay.

**Key words:** Bleeding, Hemorrhoids, Pain, Stapled hemorrhoidectomy

## INTRODUCTION

Hemorrhoid disease therapy is effectively been treated with conventional excisional hemorrhoidectomy. The Milligan-Morgan operation is the standard approach for hemorrhoid prolapse in Europe, while the Ferguson

closed hemorrhoidectomy is the operation of choice in North America.<sup>[1]</sup> Excisional hemorrhoidectomy is associated with significant post-operative pain, leading to deferral of treatment. This pain also results in an increased hospital stay and late resumption of the daily chores or work. Stapled hemorrhoidectomy (SH) was introduced in 1998 as an alternative.<sup>[2]</sup> It revolutionized the traditional surgical approach by the introduction of the theory of dealing with the rectal mucosal prolapse by resecting a mucosal cylinder above the dentate line by means of mechanical stapling.<sup>[3]</sup> It is a non-excisional approach for the surgical treatment of hemorrhoid disease.<sup>[1]</sup> It aims at repositioning the prolapsed hemorrhoid tissue through a circular resection of the inner layers (mucosa,

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submucosa, and part of the muscularis propria).<sup>[2-4]</sup> SH was studied in several randomized controlled trials in which its safety and early-term efficacy have been demonstrated.<sup>[4-7]</sup> Systematic reviews have demonstrated that the short-term outcomes result favor SH when compared to the traditional excisional method.<sup>[8,9]</sup> SH is associated with shorter operative time, reduced inpatient stay, less pain, and earlier return to normal activities.<sup>[10]</sup> However, systematic analyses of literature evidence have shown that SH is associated with a high symptomatic recurrence rate.<sup>[8,11]</sup> This conflict resulted in Giordano *et al.* to conclude that patients should choose whether to accept a higher risk of recurrence and additional operation for the sake of the short-term benefits of SH compared with conventional hemorrhoidectomy.<sup>[12]</sup> There are important issues to be considered when reviewing the studies included in the systematic reviews concluding for higher recurrence associated with SH when compared to a conventional hemorrhoidectomy. One derives from the heterogeneity in the diagnosis of hemorrhoid disease grade. The second is that it must be noted that many of the randomized trials included in these reviews recruited very few patients. In these studies, the previous clinical experience (learning curve) with SH was not declared. On the other hand, participating surgeons entering these trials could possibly have reached an expert level by performing conventional techniques. In spite of this controversy, SH has been successfully used for the surgical management of hemorrhoids.<sup>[1-6]</sup> Considering conflict in reports, it is essential that to resolve this debate, evidence-based clinical studies should be carried out, and clinical evidence be recorded to settle the issue. Hence, the present study was carried out to evaluate the functional results among patients undergoing staple hemorrhoidectomy for Grade-III/IV hemorrhoids postoperatively.

## MATERIALS AND METHODS

Ethical clearance was obtained at the start of the study from the Institutional Review Board. The SH technique is a regularly carried out procedure for indicated cases as a part of the treatment regime. The data of the same cases were used for the study purpose. The sample size has been calculated using the formula suggested by Snedecor and Cochran (1989) to prove the hypothesis:  $n = C^2$ .

For this study, “*P*” was taken as 0.5, *C* a constant at a certain confidence level (its value at 95% confidence limit and 80% power is 1.96) while was the allowed error (taken as 10% or 0.10). Hence,  $n = 96.04 \sim 96$ . Thus, the calculated sample size is 96. After adding for a contingency of 4%, we had an assumed sample size of 100.

### Inclusion Criteria

The following criteria were included in the study:

- Clinically diagnosed cases of Grade III and IV hemorrhoids (symptomatic).
- Patients of either sex
- Patients aged 18–70 years

### Exclusion Criteria

The following criteria were excluded from the study:

- Patients with Grades I and II hemorrhoids
- Patients with a previous history of hemorrhoidectomy
- Patients with associated
- Fistula in ano, Fissure in ano
- Thrombosed piles
- Growth per rectum
- Anal stenosis
- Prolapse of single anal cushion
- Pregnant females
- Patients with portal hypertension

### Operative Evaluations

One dose of ciprofloxacin and metronidazole was given at the time of anesthesia for surgery. All operations were performed in a lithotomy position, preferably under spinal anesthesia. In case of failure to achieve adequate anesthesia using spinal anesthesia, alternate anesthetic technique/general anesthesia were tried. Written informed consent was taken separately from the patients to include their details as a part of the study. The surgical procedure, as detailed by Altomare (Ellesmore and Windsor, 2002), was followed.

### Post-operative Evaluation

#### *Method of measurement of outcome of interest*

Intraoperative complications, difficulty – intraoperative complications such as difficulty in accessing and locating anatomical structures, blood loss, and damage to adjoining vasculature, were noted in categorical terms. The pain was assessed using a visual analog scale (VAS), where a score of 0 represented no pain and a score of 10 represented the worst pain ever. The pain score was recorded every 6 h during the 1<sup>st</sup> post-operative day. Duration of hospital stay was recorded in the number of days and time to return to work was recorded in days. The data were collected on a semi-structured questionnaire. The data collected were coded into Microsoft Excel 2013. Descriptive statistics were performed with SPSS version 17.0 (IBM Analytics, New York, U.S.A). Pearson’s Chi-square test was used to determine if there is a relationship between two categorical variables.  $P < 0.05$  was considered statistically significant.

## RESULTS

The mean age of the study group was  $45 \pm 14.93$  years. The studied pathology was more prevalent (62%) in younger

(21–30 years) and middle age groups (31–50 years) than the older age group. Of the total 100 participants, 75 were male and 25 were female. In the study group, 73% subjects had Grade III and 27% had Grade IV hemorrhoids. Table 1 shows the overall mean length of hospital stay and the VAS score (pain assessment).

The mean length of hospital stays, postoperatively for 21% subjects, was mere 1 day; however, it was 2 days for the rest of the population studied. Table 2 shows the frequency distribution of the study population based on the VAS scale.

The only complication was with 2% of study population having excessive intraoperative bleeding. The mean time to return to work was 8 days. About 77% of the patients resumed their work within 8 days of surgery.

## DISCUSSION

Ideally, the surgical intervention for hemorrhoids should be less invasive, painless, safe to perform, and effective in nature. The success rates of SH have been a point of discussion for long. SH was found to be associated with lesser pain in the immediate post-operative period.<sup>[1]</sup> SH is one among many new techniques that have appeared on the scene of hemorrhoid management at the turn of the 20<sup>th</sup> century that has yielded promising and good short-term results. It has gained popularity over the last decade for the management of Grade-III/IV hemorrhoidal disease,<sup>[1]</sup> as an alternative to open hemorrhoidectomy, long considered to be the gold standard. The technique has been standardized and the indications, contraindications, and operative technique have been defined. The results of SH have been weighed across multiple randomized trials.<sup>[13-23]</sup> In terms of age distribution, this study found that hemorrhoids affect the most active age group of 20–49 years, accounting for a total of 62% of those affected in

this study. This is in accordance with other workers.<sup>[18,23]</sup> The present study showed that hemorrhoids affect mainly the productive members of society. There were more males than females comparable to previous studies,<sup>[18,23]</sup> the reason for male preponderance is not clear. Risk factors to females are similar to their male counterparts. If fact, pregnancy being the most common cause of abdominal distention in female should have exacerbated the hemorrhoids formation. One of possibility for a lesser prevalence of hemorrhoids among female could be the shielding effect of pregnancy against hemorrhoids development for an unclear reason and requires further studies for confirmation. In our study group, 73% subjects had Grade III and 27% had Grade IV hemorrhoids. Literature also showed that Grade III hemorrhoids are more common than Grade IV disease.<sup>[24,25]</sup> Intraoperative bleeding of 6–7 ml at the stapled line was identified in 2% patients only which was successfully controlled by hemostatic suture. The amount of bleeding was comparatively less than conventional hemorrhoidectomy in the previous study.<sup>[23]</sup> The mean length of hospital stay in our study was 1.79 days. Our study supports the earlier findings of shorter hospital stay post SH as reported by Bhandari *et al.* (2.9 days),<sup>[19]</sup> Voigtsberger *et al.* (3 days),<sup>[22]</sup> and Kishore *et al.* (3 days)<sup>[23]</sup> in their respective studies. The pain was assessed using the visual analog scale (VAS score). Our aim was to keep VAS score <5 using adequate analgesia classified using the world health organization (WHO). The mean VAS score of our study group was 4.42. Picchio *et al.*,<sup>[21]</sup> Sachin *et al.*,<sup>[26]</sup> and Watson *et al.*<sup>[27]</sup> in large multicenter trials have reported mild degree of post-operative pain with SH than open hemorrhoidectomy. We also found pain score was significantly less for SH. In our study group, mean time to return to work was found 8 days. About 79% of the study population returned to work in 8 or lesser days, similar to other studies.<sup>[28]</sup> It is estimated that the general complication rate for SH varies from 12% to 36.4% in comparison to 19–49% for open hemorrhoidectomy.<sup>[29-31]</sup> The intraoperative bleeding and discharge were witnessed in 2% of patients which was almost nil to exist, whereas Kishore *et al.* stated that it occurred in all the cases of open hemorrhoidectomy ranged from dressing soakage to about few drops during defecation in their study.<sup>[23]</sup> Persistence of pain after SH is considered chronic if it lasts one week after SH. The prevalence of persistent pain ranges from 1.6% to 31%.<sup>[23]</sup> Lelpo *et al.* reported that a prevalence rate of persistent pain after SH was 14.3%, while in our study, it was 5.2%, which is still within the reported range.<sup>[32]</sup> Although the cost of the stapler device is still relatively high, the length of hospital stay and the period of the patient's incapacity for work are undoubtedly reduced. The absence of local care and less post-operative pain is clear advantages to the patient. SH results in significantly lesser immediate post-operative pain than conventional

**Table 1: The mean length of hospital stay and VAS score**

	Mean±SD	Median	Min–Max
Length of hospital stay	1.79±0.41	2.00	1–2
VAS score	4.42±0.81	4.00	2–7

**Table 2: Visual analog scale**

VAS score	Frequency	Percentage
3	12	12.0
4	42	42.0
5	38	38.0
6	8	8.0
Total	100	100

excision techniques (by 2–3 levels on the visual analog scale) and offers more comfort to the patient.<sup>[18]</sup> In contrast, a study stated that SH caused more post-operative pain; those results remained controversial because they were seriously challenged by several letters to the editor and caused heated discussion with no consensus.<sup>[33]</sup> In this descriptive study of shorter duration, we found positive functional outcomes as shown in previous studies but needed further longer duration study for recurrence and longer duration outcomes. SH represents a simple and fast operation when compared to the procedure of transanal dearterialization. With the existing evidence, one cannot fail to appreciate that technical errors may play a pivotal role in the high recurrence rate (especially symptomatic) as compared to other conventional procedures.<sup>[34-36]</sup> There is always some difficulty in estimating the amount of mucosal prolapse that needs to be removed. It is, however, reasonable to assume that a higher degree of hemorrhoid prolapse requires a larger resection of rectal mucosa. As a result, there is increasing consensus among experts about the concept that fourth-degree hemorrhoid disease should not be a valid indication of SH. More in-depth analysis is therefore needed in overlapping cases with respect to the subjectivity of the technique being performed.

## CONCLUSION

Within the given limitations of the study, we can conclude that SH is a successful procedure for Grade-III/IV hemorrhoids in terms of immediate post-operative complications, pain as well as the duration of hospital stay.

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