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Original Article

Assessment of Post-operative Complications, Recurrence Rate, and Patient Satisfaction After Undergoing Stapled Hemorrhoidopexy Intervention for Grades III and IV Hemorrhoids among Adult Patients of North India

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Abstract:

Introduction: Hemorrhoids are one of the most frequent anorectal disorders encountered by clinicians in day-to-day practice and constitute about 50% of colorectal investigations. Stapled hemorrhoidopexy (SH) represents the first dramatic change in the treatment of hemorrhoids. Since its introduction, some researchers have raised concerns about the recurrence rate as well as patient satisfaction. Hence, the present study was carried out to evaluate recurrence rate and patient overall satisfaction with SH procedure at a tertiary care center in North India.

Materials and Methods: Ethical clearance was obtained at the start of the study from the Institutional Review Board. A total of 100 patients with Grade III/IV hemorrhoids were included. SH was performed as per the standard procedures. Data were collected on complications developed post operatively at different follow-ups and an overall patient satisfaction. The data were coded and entered into Microsoft Excel 2010.

Results: Post-operative complications we observed at the 1st week were bleeding and discharge in 5%, pain in 9%, and urinary retention in 11% of enrolled cohorts. At 1 month, hematoma formation was observed in 7.3% of total remaining patients (n = 96) and 5.2% still had post-operative pain. At 6 months, pruritus and stenosis were witnessed in 4.3% and 1.1%, respectively, of total remaining patients (n = 93). Recurrence rate was found 4.3% at the end of 6 months. The overall complication rates at 1 week, 1 month, and 6 months follow-up were 25%, 12.5%, and 9.7%, respectively.

Conclusion: The findings of our study confirm that SH is associated with a high patient satisfaction and with a lesser post-operative complications. We conclude that SH is safe with many short-term benefits.

Key words: Complications, Hemorrhoids, Stapled hemorrhoidopexy, Surgery

INTRODUCTION

Hemorrhoids are one of the most frequent anorectal disorders encountered by clinicians in day-to-day practice and constitute about 50% of colorectal investigations.[1] Hemorrhoids are characterized by pathological changes of anal cushions and include rupture of supportive connective tissues within the cushions, resulting in enlargement of venous plexus.[2] The exact incidence of this common condition is difficult to estimate as many people are reluctant to seek medical advice for various personal, cultural, and socioeconomic reasons. It has been estimated that 58% of people over 40 years have hemorrhoids in the United States. One million new cases are reported annually, at the rate of 47/1000 and this rate increases with age.[3-5] The

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etiological factors responsible for hemorrhoid development include constipation, prolonged straining, pregnancy, obesity, aging, hereditary, derangement of the internal anal sphincter, weak blood vessels, and absent valves in the portal vein.[5-8] Today, most patients with low-grade hemorrhoidal disease in whom medical treatment fails may be effectively treated with office-based procedures, such as banding, sclerotherapy, and infrared coagulation.[10-12] However, surgical hemorrhoidectomy is reserved for patients who are refractory to office procedures, who are unable to tolerate office procedures, who have large external hemorrhoids, or who have combined internal and external hemorrhoids with significant prolapse (Grades III to IV).[13] Excisional hemorrhoidectomy (EH) using Milligan-Morgan open hemorrhoidectomy and Ferguson closed hemorrhoidectomy are two most commonly used techniques for surgical correction, however, both the techniques have shown to be associated with severe pain postoperatively.[14-17] Stapled hemorrhoidopexy (SH) represents the first dramatic change in the treatment of hemorrhoids in many years introduced in 1997 by Longo.[18,19] If feasible, it is recommended as the first-choice procedure when post-operative pain is considered.[20] The results of SH have been assessed in some randomized controlled trials.[21,22] These studies have consistently shown a decrease in post-operative pain, analgesic requirement, length of surgical procedure, short recovery time, and early return to normal activities. However, despite these promising results, some recently published reviews showed data that there is no conclusive evidence for the long-term benefit of stapled procedure, despite patient acceptance being high.[23,24] Since its introduction, some researchers have raised concerns about the recurrence rate as well as patient satisfaction. 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 recurrence rate and patient overall satisfaction with SH procedure at a tertiary care center in North India.

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 as suggested by Snedecor and Cochran (1989), and the calculated sample size was 100. This observational study was undertaken in the Department of General Surgery at Asian Institute of Medical Science at Faridabad. A total of 100 subjects who were undergoing SH and fulfilled the inclusion and exclusion criteria were enrolled in the study. All subjects were followed up at 1 week, 1 month, and at 6 months periods. There were four patients lost to follow up at 1 month and 7 patients lost to follow up at 6 months; and remaining 93 patients successfully completed the study.

Inclusion Criteria

The following criteria were included in the study:

- Clinically diagnosed cases of Grades 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 previous history of hemorrhoidectomy
- Patients with associated fistula in ano, fissure in ano, thrombosed piles, growth per rectum, anal stenosis, and 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 lithotomy position preferably under spinal anesthesia. In case of failure to achieve adequate anesthesia using spinal anesthesia, alternate anesthetic technique/ general anesthesia was tried. A 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: Post-operative pain, bleeding, discharge per rectum, and infection were recorded. Post-operative bleeding was recorded in terms of ml/number of dressings changed, discharge per rectum and/or infection were monitored as event and recorded whenever occurred. Patients were asked to confirm if they were satisfied with the overall procedure and its outcome at the end of the study as satisfied and not satisfied. The data collected was coded into Microsoft Excel 2013.

RESULTS

There were in all 100 participants in the study. Figure 1 shows the age distribution of the study population.

The studied group had male preponderance and male: female ratio was 3:1. Table 1 shows the sex distribution of the study population.

Table 1: Sex distribution of the study population

Gender	Frequency (%)
Female	25 (25)
Male	75 (75)
Total	100 (100)

In the study group, 73% of subjects had Grade III and 27% had Grade IV hemorrhoids. Out of 93 subjects, 5.4% had bleeding and discharge, 7.5% had hematoma formation, and 11.8% suffered urinary retention. Figure 2 shows the recurrence of the hemorrhoid with respect to time.

We successfully followed up all the enrolled patients at the 1st week; however, four patients at 1 month and total 7 patients at 6 months lost to follow up and remaining 93 patients successfully completed the study. Post-operative complications we observed at the 1st week were bleeding and discharge in 5%, pain in 9%, and urinary retention in 11% of enrolled cohorts (n = 100). About 75% of patients did not experience any complication post-SH. At 1 month, hematoma formation was observed in 7.3% of total remaining patients (n = 96) and 5.2% still had post-operative pain. At 6 months, we lost 7 patients to follow up. About 83.9% had no complication, on the other hand, pruritus and stenosis were witnessed in 4.3% and 1.1%, respectively, of total remaining patients (n = 93). Recurrence rate was found 4.3% at the end of 6 months. The overall complication rates at 1 week, 1 month, and 6 months follow-up were 25%, 12.5%, and 9.7%, respectively. Figure 3 shows distribution of the study participants as per the satisfaction rate.

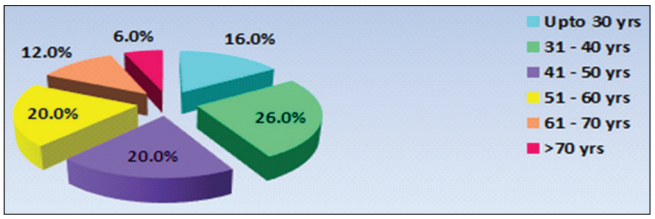

Figure 1: Age distribution of study population

Post op complications	1 week		1 month		6 month	
	Frequency	%	Frequency	%	Frequency	%
None	75	75.0%	84	87.5%	84	90.3%
Bleeding	5	5.0%				
Pain	9	9.0%	5	5.2%		
Urinary retention	11	11.0%				
Hematoma			7	7.3%		
Pruritis					4	4.3%
Recurrence					4	4.3%
Stenosis					1	1.1%
Total	100		96	100.0%	93	100.0%

Figure 2: Post-operative complications at different time of follow-up

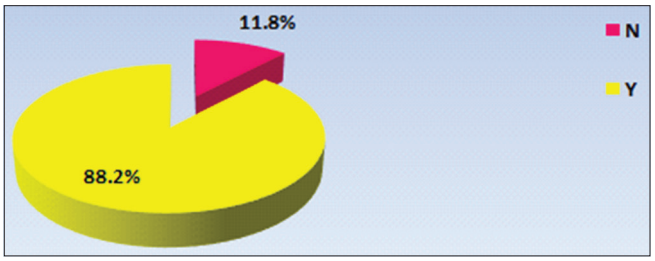

Figure 3: Patient's satisfaction rate. Y: Satisfied, N: Not satisfied

DISCUSSION

Hemorrhoidal disease is one of most frequent anorectal diseases encountered at Asian Institute of Medical Science at Faridabad and in general population at large. It is a significant cause of admissions and outpatient follow-up attendance at our hospital. SH, first introduced in 1997 by Longo, has gained popularity over the past decade for the management of Grade III/IV hemorrhoidal disease.[18] It has emerged as an alternative to open hemorrhoidectomy, long considered "gold standard." The technique has been standardized and the indications, contraindications, and operative technique have been defined. The results of SH have been weighed in many randomized trails.[21-26] Few Indian studies have also been documented.[27-31] In terms of age distribution, this study found that hemorrhoids affect most active age group of 20–49 years accounting for total of 62% of those affected in this study. This is in accordance with other workers.[30,32] Risk factors to females are similar to their male counterpart. If fact, pregnancy being the most common cause of abdominal distention in female should have exacerbated the hemorrhoids formation. One of possibility for lesser prevalence of hemorrhoids among female could be shielding effect of pregnancy against hemorrhoids development for unclear reason and requires further studies for confirmation. It is estimated that the general complication rate for SH varies from 12% to 36.4% in comparison to 19 to 49% for open hemorrhoidectomy.[33-35] Complications can be early (within 1 week after surgery) or late (1 week post-surgery). Early complications include bleeding, constipation, urgency defecation, pain, urinary retention, dehiscence of the suture, and rectal perforation with sepsis. Main late complications are anal stenosis, pruritus, urgency, and anal pain. In our study, the overall complication rates at 1 week, 1 month, and 6 months follow-up were 25%, 12.5%, and 9.7%, respectively. The early complications we observed were bleeding and discharge in 5%, pain in 9%, and urinary retention in 11% of the study group (n = 100). The post-operative bleeding and discharge was witnessed in 5% of patients (n = 100) 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.[30] As per randomized control trials

in different centers in the United Kingdom, significantly lowered post-operative bleeding was associated with SH group than open group.[23] Urinary retention is a common complication in anorectal surgery with an incidence of 1.5–32%. In our experience, urinary retention occurred in 11% of cases. The reasons for urinary retention are uncertain, but precipitating factors could be related to perioperative pain and perioperative fluid intake.[36] The overall recurrence rate in our study group was 4.3%. The recurrence rate for Grade III subjects was 1.4% as compared to 13% for Grade IV subjects. Giordano *et al.* in his meta-analysis of 15 studies reported incidences of recurrence in follow-up period of 12 months to 84 months.[25] Watson *et al.* in a multicenter, randomized controlled trial – eTHoS showed that 32% of patients in SH group at 12 months after randomization and 42% of patients in SH group at 24 months of randomization had recurrence of hemorrhoidal disease and incidence of recurrence was more in SH group than excision group.[26] The low recurrence rate in our study was probably because of short follow-up in our study. Pelvis sepsis has also been reported in literature but no such complication occurred in our study. The absence of local care and less post-operative pain is clear advantages to the patient. A study published in Lancet 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.[37] Minor complications following surgical procedures for hemorrhoidal disease are quite common and include pain, rectal bleeding, vasovagal reaction, micturition disturbances, anal fissures, and ulcers in the anal canal. Analgesics of the nonsteroidal anti-inflammatory drug group and others are used to treat mild pain. Observation and/or surgical hemostasis are relevant in case of minor rectal bleeding. Micturition disturbances should be monitored with bladder scans and catheterization if necessary. The pathophysiologic background of the treatment of hemorrhoidal disease by stapler is different than the pathophysiologic basis for excision hemorrhoidectomy and is being controversially discussed. The complete circular mucosa cranial to the hemorrhoidal plexus is resected, allowing reduction of mucosa prolapse by mucosa lifting and by fixing the prolapsed mucosa at the rectum wall. The reduction of arterial blood flow to the hemorrhoidal plexus is probably not the main point of the treatment. In this descriptive study of shorter duration, we found positive functional outcomes as shown in the previous studies but needed further longer duration study for recurrence and longer duration outcomes. Majority of the patients were satisfied with the outcome of the study. The hemorrhoids may prolapse and result in other symptoms of mucus seepage, pruritus, loss of discrimination and continence to flatus, and occasional fecal incontinence. The latter may cause social embarrassment. Patients with permanent prolapsed hemorrhoids may also face difficulty in maintaining local hygiene. These symptoms impact the quality of life of patients. A study by Garg *et al.* reported that SH improved the physical and the psychological domains of the quality of life of the patients.[38] The present study had certain limitations. We did not compare the outcome with the conventional surgical technique. Furthermore, the sample size was small and relatively equal number of men and women were not involved. Even though the study showed lesser complications, the long-term follow-up for Grades III and IV separately is required.

CONCLUSION

Overall recurrence rate in our study was 4.3% which was lower than previously published study probably because of shorter follow-up of our study. The findings of our study confirm that SH is associated with a high patient satisfaction and with a lesser post-operative complications. We conclude that SH is safe with many short-term benefits. It is a novel technique and has emerged as an alternative to open hemorrhoidectomy, long considered the "gold standard."

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