

Research Article

A Prospective Comparative Study of Stapler Hemorrhoidectomy Vs Open Haemorrhoidectomy (Milligan Morgan) in its Outcome and Postoperative Complications

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Received: 21 December 2020; **Accepted:** 04 January 2021; **Published:** 11 January 2021

Citation: Nambula Malyadri, Veera Jayachandra Allu. A Prospective Comparative Study of Stapler Hemorrhoidectomy Vs Open Haemorrhoidectomy (Milligan Morgan) in its Outcome and Postoperative Complications. Journal of Surgery and Research 4 (2021): 4-13.

Abstract

Introduction: Stapled hemorrhoidectomy has been considered as a novel technique in the surgical treatment of prolapsed hemorrhoids. Although it involves substantial added cost, it resulted in shorter period of convalescence in comparison with Open hemorrhoidectomy.

Aim: To investigate and compare the outcome and post-operative complications in patients with grade III and IV hemorrhoids who underwent hemorrhoidectomy

with either Stapler hemorrhoidectomy or Milligan Morgan hemorrhoidectomy.

Methods: A total of 80 patients between the age group 28 to 40 years who were diagnosed with grade III and IV hemorrhoids, were divided into two groups equally. Group- 1 contains 40 Patients undergoing Stapler hemorrhoidectomy and Group- 2 contains 40 Patients undergoing Open hemorrhoidectomy/Milligan Morgan. Post-operatively patients of both the groups were assessed for bleeding, pain against pre-operative symptom profile, development of recurrence and long-

term complications. Comparative analysis between the two groups were done based on student's T test using SPSS software version. The level of significance was set at 5% ($p < 0.05$).

Results: Stapler hemorrhoidectomy technique was quicker to perform in comparison with Open hemorrhoidectomy (p value < 0.001). Hospitalization and duration of resumption to daily activity was less in Stapler hemorrhoidectomy group as compared to Open hemorrhoidectomy/Milligan Morgan group (p value < 0.001).

Conclusion: Both methods were effective in the treatment of hemorrhoidectomy, however the advantages of Stapler hemorrhoidectomy in terms of lesser operative time and intra and post-operative bleeding and lower incidence of various post-operative complications was observed.

Keywords: Stapler hemorrhoidectomy; Milligan Morgan hemorrhoidectomy; Surgical procedures; Hemorrhoids; Piles

1. Introduction

The term hemorrhoids refer to anal cushions that swell, bleed, and thrombose and prolapse and cause clinical symptoms [1]. External hemorrhoids are aggregations of congested external perianal vascular plexus covered by perianal skin; while, internal hemorrhoids originate from the sub-epithelial plexus of the anal canal above the dentate line [2]. Internal hemorrhoids may be classified according to the degree of prolapse into four degrees, although this may not reflect the severity of a patient's symptoms. The symptoms include discomfort, itching, mucous discharge, bleeding, pain, and prolapse and are associated with a feeling of fullness and

incomplete evacuation [3].

The symptomatic hemorrhoids can be managed with conservative therapy involving dietary and lifestyle changes and by using various pharmacological agents like creams, office-based non-operative procedures etc [4]. Surgery is the treatment of choice for grade III and grade IV hemorrhoids especially in patients who are not responding to other methods of treatment [5-7]. However, the disease is by no means confined to older individual's Male pre-dominance observed [8].

For 1st and 2nd degree hemorrhoids surgery as an option is not viable and better avoided. whereas for the management of 3rd and 4th degree hemorrhoids the most widely practiced surgical technique is the Milligan Morgan hemorrhoidectomy and is considered the current Gold standard and has stood the test of time by virtue of its least postoperative complications, cost effectiveness, and better long-term effects [9, 10].

Although with relatively low complication rates and reduced hospital stays the Stapled hemorrhoidectomy procedure is regarded as a well-established procedure [11], it is an exorbitant procedure Even though cost-effective, the conventional management of hemorrhoids by open hemorrhoidectomy causes post-operative discomfort and other complications to the patients. Hence the aim of the present study was to compare stapler hemorrhoidectomy to Milligan Morgan open hemorrhoidectomy in the management of 3rd/4th degree hemorrhoids in its outcome and post-operative complications.

2. Materials and Methods

A prospective comparative Hospital based study was conducted at a Tertiary care centre, in the Department

of General surgery, Secunderabad, Telangana. A sample size of 80 subjects was estimated by assuming the mean operating time as about 30 minutes in staple group and 43.25 minutes in open group, as per study by Frank H et al. [12]. A statistical power of 90% and 2-sided alpha error of 5% were considered for sample size calculation. The required sample size would be 37 subjects in each group. To account for a loss to follow up of about 5% another 2 subjects were added to each group. The sample size was then rounded off to include 40 subjects in each group.

A total of 80 patients aged 28 - 40 years (median age - 34 (Group-1), 35 (Group-2) respectively) diagnosed with grade III and grade IV hemorrhoids were recruited in the study consecutively by convenient sampling till the sample size is reached. A signed informed consent was obtained for all subjects, confidentiality of the study participants was maintained. The hospital's ethics committee approved the research protocol. The data collection for the study was done between June 2016 to February 2018 for a period of 1.8 years including follow-up. Group-1 included patients undergoing Stapler hemorrhoidectomy (40 patients) and Group-2 included patients undergoing Open hemorrhoidectomy/Milligan Morgan (40 patients). The participants were evaluated by thorough clinical history, clinical examination and proctoscopy. The choice of the surgical procedure was based on the hospital protocol and choice of the participants.

2.1 Technique

Surgery was performed under spinal anesthesia, with patient in lithotomy position. SH was performed after preparing the anal canal (operating surface), and Proctoscopy examination. A transparent anal dilator was gently inserted and secured by suturing to the

perianal skin, then the suture anoscope was inserted by making a mucosal purse-string suture measuring about 3-4 cms above the dentate line. Later the purse-string suture was anchored to the fully opened stapling device guiding its two ends through the lateral openings of the stapler. Stapler was closed with continued traction to the sutures until the maximum was reached. The stapler was deployed and held in place for 2 minutes after which it was opened with one and a half turn and gently removed. The donut was verified. Staple line was checked for its position above the dentate line, and hemostasis for bleeding sites was attained using cautery or suture ligatures.

In the open hemorrhoidectomy a Kelly clamp was placed over one haemorrhoidal pedicle and an absorbable suture ligature was made at the apex of the haemorrhoidal pedicle. A V-shaped incision was made to the external skin and extended to a narrow eye shaped incision towards the ligated vascular pedicle and dissected using sharp scissors and electrocautery was done once the dissection reached the ligated pedicle. The hemorrhoid was amputated and the wound left open to heal. The procedure was repeated for the remaining hemorrhoid pedicles.

During the surgery, intra operative time and intra operative bleeding were assessed and recorded. All complications and their response to treatment were recorded during the period. The cost was assessed by the duration of hospital stay, time to resume to normal activities in both the groups and all the patients were followed up for 6 months after the surgery to assess development of recurrence and long-term complications like anal stenosis and anal incontinence.

2.2 Statistical analysis

Data was recorded and analyzed using SPSS software version 22.0. Descriptive statistics were presented for all variables. Comparative analysis between the two groups was done based on Student’s t test with a p-value less than 0.05 as significant.

3. Results

A total of 80 patients were included. the patients were

divided into two groups, group-1 and group-2. The patients in group-1 underwent stapler haemorrhoidectomy and whereas patients in group-2 underwent open hemorrhoidectomy. The median age of the patients was 34(IQR 28 to 40.75) for those who underwent stapler haemorrhoidectomy and 35 (IQR 28 to 38) for those with open hemorrhoidectomy respectively. There was a predominance of males in both groups. (Table 1).

Gender	Group		P-value
	Stapler haemorrhoidectomy (N=40)	Open hemorrhoidectomy (N=40)	
Male	25 (62.5%)	24 (60%)	0.818**
Female	15 (37.5%)	16 (40%)	
Age in years Median (IQR)	34(28 to 40.75)	35 (28 to 38)	0.667
Height Cm, Median (IQR)	166(160 to 168)	165 (156 to 168)	0.086
Weight kg Median (IQR)	65(62 to 69.50)	67(60 to 68)	0.692
BMI Mean ± Std	23.97 ± 1.15	24.17 ± 1.02	0.398

Table 1: Demographic Profile.

The majority of the patients had third-grade hemorrhoids (60%). Among the stapler haemorrhoidectomy group, 23 (57.5%) participants were in the 3rd degree and remaining 17 (42.5%) participants were in the 4th degree. Among the open hemorrhoidectomy group, 24 (60%) participants presented with 3rd degree, 16 (40%) participants presented with 4th degree. The difference in the

proportion of degree of hemorrhoids between the groups was statistically not significant (p-value 0.894) (Table 2). The main complaint of the patients was anal bleeding. All the participants from both groups complained of mass per rectum, pain during defecation and constipation.

Among the stapler hemorrhoidectomy group, 38 (95%)

participants had bleeding per rectum and 40 (100%) participants had bleeding per rectum among the open hemorrhoidectomy group. Both groups reported a median duration of BPR at eight days (IQR 7 to 10). No significant difference in the duration of BPR in days between groups was observed. (P value 0.879) (Table

2). Among the stapler haemorrhoidopexy group, 38(95%) participants had pain during defecation, with 35(87.5%) presenting with a mass per anum. However, 40 (100%) participants had pain during defecation, with 100% participants presenting with a mass per anum among the open hemorrhoidectomy group (Table 2).

	Group		P value
	Stapler haemorrhoidopexy (N=40)	Open hemorrhoidectomy (N=40)	
Bleeding per rectum	38 (95%)	40 (100%)	**
Duration of BPR (in days) Median (IQR)	8(7to 10)	8 (7 to 10)	0.879
Pain during defecation	38 (95%)	40 (100%)	**
Mass per arum	35 (87.5%)	40 (100%)	**
3rd degree	23 (57.5%)	24 (60%)	**
4th degree	17 (42.5%)	16 (40%)	

**No statistical test was applied- due to 0 subjects in the cells

Table 2: Comparing the signs and symptoms in both the groups.

	Group		P – value
	Stapler haemorrhoidopexy (N=40)	Open hemorrhoidectomy (N=40)	
Median time of procedure (min)	40 (38 to 40)	50 (48 to 51)	<0.001*
Intraoperative bleeding (ml) Median (IQR)	5 (4.25 to 6)	38 (36 to 40)	<0.001*

*Significant (P<0.05)

Table 3: Comparing the intra-operative parameters in both the groups.

The median operating time for stapler hemorrhoidectomy procedure was 40 min (IQR 38 to 40) whereas for open hemorrhoidectomy, it was 50 min

(IQR 48 to 51). The difference in the time procedure between groups was statistically significant (P value <0.001) (Table 3). Among the patients with stapler

hemorrhoidectomy the median intra operative bleeding was 5ml (IQR 4.25 to 6) whereas it was 38ml (36 to 40) with open hemorrhoidectomy patients and statistically

significant difference in the intra operative bleeding between groups was observed (P value <0.001) (Table 3).

	Group		P Value
	Stapler haemorrhoidopexy (N=40)	Open hemorrhoidectomy (N=40)	
Post-operative bleeding(ml) Median (IQR)	2(1 to 2)	12 (10 to14)	<001*
Post-operative pain-VAS score Median (IQR)	3(3 to 4)	5 (5 to 6)	<0001*
Post-operative Hospital stay in days Median (IQR)	1(1 to 1)	3 (3 to 3)	<0001*
Resumption of daily activity (in days) Median (IQR)	3 (3 to 4)	5 (4 to 5)	<0001*
Recurrence	2 (5%)	1(2.5%)	0.556
Incontinence	0 (0%)	3 (7.5%)	**
Anal stenosis	0 (0%)	2 (5%)	**

**No statistical test was applied- due to 0 subjects in the cells

Table 4: Comparing the post operative parameters in both the groups.

In the SH group, median post-operative bleeding was 2ml (IQR 1 to 2), and in the CH it was 12ml (IQR 10 to14). The difference between groups was statistically significant (P value <0.001) (Table 4). However, the patients who underwent stapler haemorrhoidectomy has a median VAS score was 3 (IQR 3 to 4) and, with open hemorrhoidectomy, the median VAS score was 5 (IQR 5 to 6). The difference in the VAS score between the groups was statistically significant (P value <0.001) (Table 4).

On the other hand, the median hospital stay among the

people with stapler haemorrhoidectomy in days was 1(IQR 1 to 1) and among people with open hemorrhoidectomy, was 3 (IQR 3 to 3). The difference between groups was statistically significant (P value <0.001) (Table 4). Among the people with stapler haemorrhoidopexy median follows up a return to normal activity (in days) was 3 (IQR 3 to 4), and among people, with open hemorrhoidectomy, it was 5 (IQR 4 to 5). The difference in the follow-up a return to normal activity (in days) between groups was statistically significant (P value <0.001) (Table 4). Recurrence was observed in 2 (5%) participants in the stapler

haemorrhoidopexy group, and 1(2.5%) participant in the open hemorrhoidectomy group. No statistically significant difference was observed (P value 0.556) (Table 4).

4. Discussion

Stapled hemorrhoidopexy (SH) procedure invented by Dr Antonio Longo is a novel technique and a considerable modification in the treatment of hemorrhoids, in comparison with the Open hemorrhoidectomy (MM) procedure which is slightly more invasive and painful in the immediate postoperative period than Stapled hemorrhoidopexy (SH) procedure. In the present study we observed that the time taken to perform surgery was significantly shorter in SH 40 min (IQR 38 to 40) than in MM 50 min (IQR 48 to 51) (P value <0.001). The possible reason could be attributed to the surgeon's experience, expertise with the technique, similar observations were reported by Daniel R et al. [13] However, Simone Manfredelli et al. [14] has reported that there is no statistically significant difference in the operating time and recovery time between the two procedures. A statistically significant difference (P value <0.001) was observed when the median intra operative bleeding was compared between the groups (5ml (IQR 4.25 to 6) in SH and 38ml (IQR 36 to 40) in MM groups). With better intra operative hemostasis only 2ml (IQR 1 to 2) of median post-operative bleeding was observed in the stapler haemorrhoidopexy procedure, with a statistically significant difference between groups was (P value <0.001). Similar observations were made by Dr. Mohan S V et al. [15] However, Kim JS et al. [16] (2013) has reported that the postoperative bleeding rate was 4.9 % in both groups.

Gravies J F et al. [17] reported that stapled

hemorrhoidopexy causes significantly less postoperative pain. Bhandari RS et al. [18] postulated that SH has better short-term outcome compared with Open hemorrhoidectomy regarding postoperative pain, analgesic requirement, Kim JS et al. [16] (2013) and Daniel R et al. [13] also noted similar results. Not surprisingly, the results of the present study substantiated the same with a statistically significant difference between the groups (P value <0.001). The reduction in the pain can be associated to the lack of nerve endings above the dentate line, as the procedure was carried out above the dentate line.

Post-operative hospital stay is comparatively less for stapler haemorrhoidopexy group than open hemorrhoidectomy group, with a statistically significant difference (P value <0.001). A study by Daniel R et al. [13] confirmed that hospital stay was significantly shorter in the stapler haemorrhoidopexy group. In contrast, Mehigon BJ et al. [19] found no statistically significant difference for stapled group. However, a systemic review by tjandra JJ et al. [20], a meta-analysis by Nisar PJ et al. [21], a study by RS Bhandari et al. [18] proved that post-operative stay was definitely less for stapler haemorrhoidopexy compared to open hemorrhoidectomy group. The reason for early discharge could be lesser post-operative pain, which is also an important reason for patient's resumption of daily routine activity following the surgery.

The present study has also shown a statistically significant difference (P value <0.001) between the groups when compared in terms of early resumption to normal activity and literature review substantiates this, as a study by Mehigon BJ et al. [19], a systemic review by tjandea JJ et al. [20], a meta-analysis by Nisar PJ et al. [21], confirms the same.

Previous studies have reported higher recurrences following stapler haemorrhoidopexy group in consistent with the present study, 2 (5%) participants in the stapler haemorrhoidopexy group, had a recurrence, and 1 (2.5%) participant in the open hemorrhoidectomy group had a recurrence. The difference in the proportion of recurrence between groups was statistically not significant (P value 0.556).

Giordano P et al. [22] cited the drawback of stapled hemorrhoidectomy in that it carries a significantly higher incidence of recurrence and additional operations compared to open hemorrhoidectomy. Similarly, Kim JS et al. [16] (2013) concluded that stapled hemorrhoidopexy is as effective as the Milligan- Morgan procedure. However, Simone Manfredelli et al. [14] found no differences between open and Stapler hemorrhoidectomy about both pre and post-surgery hospitalization and intraoperative length.

Shalaby and Desky has reported complications after stapled hemorrhoidectomy which includes anal stenosis in 2% on the contrary the present study has found that, 2(5%) participants had anal stenosis, among the open hemorrhoidectomy group. different from the findings by Dr HO Yh et al. [23], our study has found anal inconsistency in 3(7.5%) participants among the open hemorrhoidectomy group.

5. Limitation

Although the present study is prospective, one of the limitations was lack of randomization and blinding. Hence the assessment bias while reporting various outcomes. However, all possible efforts were made to minimize subjectivity in estimating the key outcome parameters. Another important limitation is that the role of residual confounding could not be evaluated by

appropriate regression methods, due to limited sample size. The generalizability of the study findings is limited due to possible variations in the demographic structure, skill level, and experience of the surgeon etc. Despite the limitations, the present hospital based prospective study provides comparison between stapled hemorrhoidectomy procedure to open hemorrhoidectomy procedure in their outcomes and post-operative complications.

6. Conclusion

Though, literature review reveals many surgeons concede to prefer open hemorrhoidectomy technique. The present study has observed the advantages of stapler haemorrhoidopexy procedure associated with operating time, lesser intra and post-operative bleeding, less post-operative pain possibly leading to early recovery and early discharge with patient's perceived satisfaction regardless of other complications. Specialists could safely and readily adapt this technique and offer this option to the patients.

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