

Outcome Comparison in Stapled Hemorrhoidopexy and Conventional Open Hemorrhoidectomy

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Abstract

Objective: To compare the outcome of stapled hemorrhoidopexy with that of the Milligan-Morgan technique. **Method:** Prospective study conducted on 186 patients, 93 stapled and 93 open with a follow up period was minimum of 1 month and maximum was 2 years. The two groups were compared for duration of surgery, hospital stay, cost of treatment, return to work and post-operative complications. **Results:** The stapled group had statistically significant ($P < 0.001$) lesser operative bleedings, shorter duration of surgery, less post-operative pain and hence need for analgesia. The time taken for the patients to first post-operative defecation, post-operative hospital stay and duration to normal activity was significantly lesser ($P < 0.001$) in the stapled group compared to open group. In the first week of follow up mucoid discharge and pain at defecation was significantly higher in all the 186 patients followed up from the open group. At 6 months, 166 patients, at 1 year, 114 patients, at 1.5 years, 52 patients, at 2 years, 22 patients were available for follow-up. No statistical significance in the complications was found between the 2 groups. **Conclusion:** Stapled hemorrhoidopexy is a safer alternative to open hemorrhoidectomy with many short-term benefits.

Keywords: Hemorrhoids; Milligan-Morgan Hemorrhoidectomy; Stapled Hemorrhoidopexy.

Introduction

There are a few diseases more chronicled on human history than symptomatic hemorrhoids. Varied treatments have been tried for hemorrhoids

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(sclerotherapy, rubber band ligation) but with short lasting effects with increased chances of recurrences and repeated procedures. The conventional Milligan Morgan Hemorrhoidectomy provides a permanent relief, however the patients experience a considerable amount of post-operative pain in view of the wound created at the end of surgery and it often leads to delayed recovery.

Stapled Hemorrhoidopexy as initially advocated by Longo and colleagues, has emerged as a potentially less painful alternative and has met with great enthusiasm by some surgeons, but with cold skepticism by others. It has been hailed as a significant breakthrough in the way surgical excision of hemorrhoids is performed, it dramatically decreases the level of postoperative pain and hastens the speed of healing after the operation. However some surgeons worry about leaving large skin tags behind and long term sequelae such as strictures [1]. It seems clear, therefore, that several important questions need to be answered before this new procedure can be welcomed unreservedly.

Hence this study was designed to compare the outcomes of the conventional Milligan Morgan Hemorrhoidectomy vs Stapled Hemorrhoidopexy at our tertiary care Centre, with an attempt to answer a few of the above questions.

Aims and Objectives

This study has been done prospectively to assess:

- To compare the outcomes of Stapled hemorrhoidopexy and Open Hemorrhoidectomy with regards to post-operative pain and duration of normal activity
- To analyze short term complications of the stapled hemorrhoidopexy and to compare with the conventional open operation.

Materials and Methods

The study was a prospective study conducted under the department of general surgery, Kasturba Hospital, Manipal for a period of two years from July 2014 to May 2016

All patients between 20-60 years of age who were diagnosed to have internal hemorrhoids (grade 2-4) and underwent either the Conventional Milligan Morgan's hemorrhoidectomy or Stapled hemorrhoidopexy were included in the study.

Patients with thrombosed external hemorrhoids, previous anorectal surgery, anal stenosis, associated anal pathologies like anal fissure, fistula, abscess and rectal prolapse and patients with deranged coagulation profile were excluded from the study. Patients with secondary causes of hemorrhoids like portal hypertension, pregnancy and rectal malignancy were also excluded from the study.

Patients were admitted and preoperative work up were done which included complete blood picture, coagulation profile and flexible sigmoidoscopy to rule out co-existing conditions.

Patients were educated about both types of surgery and the type of surgery the patient underwent was as per the choice of patient and affordability. Informed consent was taken from all patients.

Patients were divided into two groups, the stapled group and the open group. Stapled group underwent stapled Hemorrhoidopexy and Open group

underwent Milligan Morgan's hemorrhoidectomy. Stapled Hemorrhoidopexy was performed according to the standard method described by Dr. Antonio Longo and the open procedure was performed according to that mentioned by Dr. Milligan and Morgan.

Various parameters were noted and compared intra operatively and post operatively according to standard proforma. Pain was assessed using a visual analogue scale (VAS). Post-operative analgesia was given as per the standard protocol approved by the ethics committee of hospital.

Various parameters which were compared were – duration of surgery, per operative bleeding, post-operative pain, analgesic requirements, bleeding urinary retention, anal incontinence, time to first post-operative bowel movement, defecatory pain, tenderness on per rectal examination at discharge, duration of hospital stay, cost of treatment and satisfaction level of patients. Post-operative reviews were done at the end of 1 week, one month and 6 months with a minimum of 6 months follow up, 2 year follow up based on the time they got operated.

Results

Total 186 patients were included in the study (93 stapled and 93 open). The follow up period was minimum of 1 month and maximum was 2 years as shown in Table 1.

Table 1: Showing number of patients studied in each group in different time interval

| Follow up period | | 1 month | 6 months | 12 months | 18 months | 24 months |
|-------------------|---------|---------|----------|-----------|-----------|-----------|
| Cases followed up | Stapled | 90 | 83 | 57 | 21 | 11 |
| | Open | 90 | 83 | 57 | 21 | 11 |
| | Total | 180 | 166 | 114 | 52 | 22 |

Table 2: Comparing need of analgesics, drug and dosage between two groups

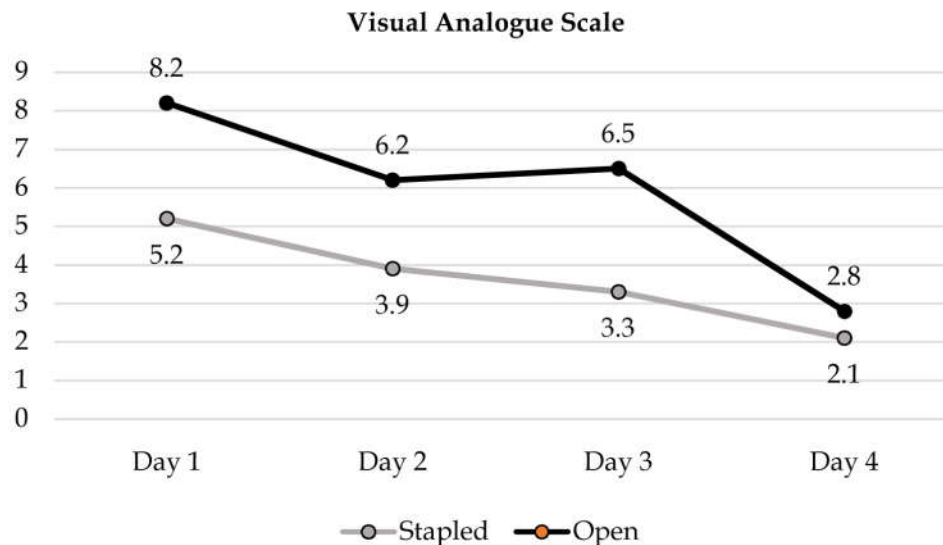
| PCM/DICLO/TRAMA Tab | Stapled group | Open group |
|-------------------------|---------------|------------|
| "0" dose | 2 (2%) | 0 |
| "1" dose | 41 (44%) | 2 (2%) |
| "2" doses | 36 (39%) | 13 (14%) |
| "3" doses | 7 (8%) | 78 (84%) |
| TRAMA/DICLO Inj. | | |
| "0" dose | 0 | 0 |
| "1" dose | 48 (52%) | 0 |
| "2" doses | 7 (8%) | 0 |
| "3" doses | 38 (40%) | 13 (14%) |
| "4" doses | 0 | 80 (86%) |
| PETHIDINE Inj. | | |
| "1" dose | 5 | 52 (62%) |
| "2" dose | 2 | 30 (32%) |
| "3" doses | 0 | 6 (6%) |

Table 3: Comparing level of satisfaction between two groups

| | Stapled group (n=93) | Open group (n=93) |
|---------------|----------------------|-------------------|
| Excellent | 33 (42%) | 11 (18%) |
| Good | 39 (42%) | 39 (42%) |
| Satisfied | 11 (12%) | 28 (30%) |
| Not satisfied | 4 (4%) | 5 (10%) |

Table 4: Comparison of short term results with various other studies

| | No of patients | Duration of surgery(min) | Average pain score | Duration of stay(days) | Duration of normal activity(days) | Time to first defecation |
|--|----------------|--------------------------|--------------------|------------------------|-----------------------------------|--------------------------|
| Our study | 93 Vs 93 | 35 Vs 50 | 3.6 Vs 6.2 | 2 Vs 3 | 3 Vs 7 | 12 Vs 29 |
| Mehigan et al ⁹ 2000 | 20 Vs 20 | 18 Vs 22 | 2.1 Vs 6.5 | - | 17 Vs 34 | - |
| RowSELL et al ¹¹ 2000 | 11 Vs 11 | 14.1 Vs 14.8 | 20.6 Vs 44.3 | 1.09 Vs 2.8 | 8.1 Vs 16.9 | - |
| Jean francoius et al ⁴ 2005 | 63 Vs 63 | 21 Vs 31 | 2.7 Vs 4.2 | 2.2 Vs 3.1 | 14 Vs 24 | 38 Vs 50 |



Graph 1: Comparing post-operative pain in the two groups of patients

The study included 66% males and 34% females. The minimum age of patient was 20 years and maximum was 76 years; mean age of presentation is 46 years.

The commonest complaint in the study found was bleeding per rectum in 143 patients. Mass per rectum was found to be present in 74 patients of the stapled group and 31 patients of open group. The other complaints such as pain, constipation and itching was seen in 54, 23 and 23 patients respectively. The mean duration of symptoms was 14.5 months for bleeding and mass per rectum.

The number of patients who had grade 2 or 3 hemorrhoids were 169. Prolapsed grade 4 hemorrhoids was seen in 6 patients from stapled group and 11 from open group.

The per operative bleeding which was measured in terms of number of soaked 4 x 4 cm gauze pieces were significantly lower in stapled group (10 ml) compared to open group (40 ml). This was statistically significant with P value <0.001 as per Mann Whitney’s test.

The duration of surgery was also significantly lower in stapled (25 minutes) compared to open group (35 minutes). This was statistically significant with P value <0.001 as per Mann Whitney’s test.

The post-operative pain was calculated in the form of a quantitative analysis using Visual Analogue Scale (VAS) as shown in graph 1. There was significant difference in the mean VAS at each day between the 2 groups (P <0.001 as per Mann Whitney’s test) indicating that stapled group experienced lesser pain.

The time taken for the patients to first post-operative defecation was statistically significantly lower in stapled group (12 hours) as compared to open group (29 hours) with P value <0.001 as per Mann Whitney's test.

The post-operative hospital stay was significantly lower in stapled group (2 days) compared to open group (3 days) with P value <0.001 as per Mann Whitney's test.

The immediate post-operative complications experienced during hospital stay were bleeding, urinary retention and anal incontinence. There was a significant difference in the mean found for urinary retention in the 2 groups using the Chi Square Test $p=0.022$. Post-operative bleeding and anal incontinence did not show any statistical significance.

There was a lesser post-operative need for analgesics seen in stapled group compared to open group as shown in Table 2.

The duration to normal activity was significantly lesser in the stapled group compared to open group. It took an average of 3 days for patients in stapled group and 7 days in patients of open group. This was statistically significant with P value <0.001 as per Mann Whitney's test.

The post-operative review at week-1 was possible in all 186 patients. There was no statistical significance in stapled and open groups with respect to bleeding 6 (6%) and 28 (30%), rate of perianal wound infection 2 (2%) and 7 (8%) and mucoid discharge 32 (34%) and 26 (28%) respectively. Statistically significant rate of increased pain at defecation seen in 69 (74%) and 19 (20%) of patients and tenderness at per-rectal examination were found 86 (92%) and 13 (14%) in the open group compared to stapled group respectively. The perianal wound infection post stapled surgery progressed to septicemia, pulmonary edema and eventually death in one patient with pre-existing co-morbidities of diabetes and hypertension.

The overall satisfaction levels of patients for the procedures was interviewed and following results were noted as shown in table 3. No statistical test could be applied for these findings.

At one month, Data of 180 patients was available for comparison. Mucoid discharge and pain at defecation was significantly higher in open group compared to stapled group 47 (52%), 14 (16%) and 47 (52%), 14 (16%) with P value <0.001.

At 6 months, Data of 166 cases were available. 1 patient had recurrence of symptoms namely mass and

bleeding per rectum about 5 months after surgery. 1 patient in open group developed anal stenosis. 5 patients in the stapled group continued to have urge at defecation and tenesmus at 6 months following surgery. However it was not statistically significant.

At 1 year, data of 114 cases were available for comparison. No statistical significance in the complications was found between the 2 groups.

At 1.5 years, Data of 52 cases were available. No significant difference in the complications in the 2 groups were noted. 1% of patients in the stapled group and 3% in the open group continued to have fecal urgency/soiling/tenesmus but no statistical significance could be drawn.

At 2 years, Data of 22 patients was available. There were no fresh complications. No added cases of recurrence, stenosis or urgency noted.

Discussion

Since the first description of Stapled Hemorrhoidectomy by Longo in 1998, this procedure has been widely accepted and used in the common clinical practice for the care of mainly third and fourth degree hemorrhoids, as an alternative to other conventional techniques. Stapled hemorrhoidopexy returns the anal cushions to their normal location within the anal canal and secures the position of the internal hemorrhoids with a partial thickness staple line.

At the same time, the interruption of the arterial inflow and restoration of the venous outflow cause the internal hemorrhoids to reduce in size. The prolapse is prevented, and ultimately the symptoms disappear. The demographic and clinical features of the patients in the study are comparable to other studies like Claudio et al [2] and Jean et al [3]. The commonest symptom too in this study is bleeding comparable to the other 2 studies. The occurrence of hemorrhoids increases with age.

In comparison to other studies by Mehigan et al [4] 2000, Rowsell et al [5] 2000 and Jean Francoius et al [3] 2005 which compare the two groups, our study, shown in Table 4, also shows that short term results of stapled hemorrhoidectomy are better in terms of post-operative pain, return to normal activity and incidence of early post-operative complications, and that the procedure can be considered as safe as open hemorrhoidectomy.

On comparing the complications at long follow up period with, Mehigan et al [4], Rowsell et al [5], Hetzer et al [6], Ortiz et al [7], this study showed no significant

increase in the occurrence of complications.

The mean duration of Surgery and per-operative bleeding was significantly lower in the Stapled group compared to open group, comparable to other similar controlled trials [1-4].

The results reported in this study show that stapled hemorrhoidopexy is associated with significantly lesser post-operative pain. In this study, this was proven by the lesser duration to first post-operative defecation, shorter hospital stay, lesser pain during defecation, lesser cases of urinary retention, lesser need for injectable analgesics and lesser duration to normal activity in the stapled group compared to the open group.

There was no significant difference in pain between the 2 groups on days 2 in contrast to other studies [6]. It is also worth noting that a small number of patients in the stapled group developed urinary retention (9/93), needed greater number of analgesic doses and had a higher visual analogue score. This might be attributed to the probable low stapler line in these patients. The same patients also had comparatively slower recovery and had pain at the first follow up at one week with bleeding and pain at defecation. This suggests the importance of a higher staple line.

Continued persisting pain was experienced by 2 patients up to 5 months following surgery. The cause of persisting pain is difficult to explain. The importance of avoiding the inclusion of the smooth muscles in the fixation of the vascular pedicles in a correctly done open hemorrhoidectomy procedure to reduce the pain, is well known [8]. Cheetham et al [9], refers to this pathogenic theory to explain the persistence of the symptom in the stapled group/ in almost all the cases of their series in which this complication occurred, the doughnuts included smooth muscle fibres, probably suggesting the deeper bites of sutures through the muscular layer as the cause of pain. Other possible theories for the pain could be a lower staple line and fissure in ano. Jean Francois Gravie et al [3] 2005, reported that a small number of patients (10%) in the stapled group needed prolonged analgesic relief. He did not find any correlation in the stapled group between the intensity of pain and the height of the staple line.

Immediate post-operative bleeding, which is mentioned as a frequent possible complication of stapled hemorrhoidectomy [10], was not seen in this study. Spontaneous onset bleeding on post-operative Day 1 was noted in one case of stapled hemorrhoidectomy which was managed conservatively by anal packing.

Most of the complications arise in the first few

weeks following surgery. At the first review, a week after surgery, significant increase in the pain at defecation and mucoid discharge were found in the open group accounted by the large exposed wound at the perianal region. At the review of 1 month following surgery, pain and mucoid discharge were significantly higher in the open group confirming the slow healing rate of perianal wound cause by the open technique and the inconvenience caused by it.

Though there was no statistical significance in the complications between the 2 groups at 6 months post-operative period, points worth a mention are, the fact that 10% of patients in the stapled group continued to have mucoid discharge and a constant urge to defecate. These complaints continued till the 1 year follow up (3/57) and 1.5 year follow up (2/22). Ortiz et al [7], experienced in his study, 40% stapled patients having tenesmus compared to none in the open group. He attributed it to the presence of low rectal suture or post-operative anatomic remodeling of the anal canal. Numerous manometric and ultrasound studies have detected such modifications to the sphincter, although no correlation has ever been defined in terms of clinical outcome [3].

The complications like anal incontinence, sphincter damage or rectovaginal fistula, was not seen in this study. George et al [11], 2002 and Bruscianno et al [12], 2004 showed concerns relating to internal sphincter damage and long term continence problems. This complication has been attributed to the anatomical remodeling after the procedure and anal sphincter fragmentation consequent to anal dilatation by 35mm diameter anoscope or by the Lord's dilatation carried out by some before inserting the anoscope.

There have been no statistically significant advantages of the open group over stapled group in the long term as seen in this study. Stapled hemorrhoidopexy is probably more dependent on the operator skills than previously believed. The practical difficulty is in identifying the amount of mucosa to be removed because this parameter varies according to the extent of the prolapse [12].

This explains why most instances of residual prolapse in the stapled hemorrhoidopexy within this study have involved anterior hemorrhoids.

In comparison to a multicentric study comparing the two groups by Ganio et al [13] in 2007, our study also found no significant differences in the outcomes and recurrence rates.

It is also difficult to establish the optimum duration of long term follow up for the risk of recurrences of

hemorrhoidal disease to be revealed, but a follow up shorter than 2 year should be considered early or medium post-operative period [2].

This study has a follow up of 2 years and hence needs further follow up to definitely conclude on the long term effects of stapled hemorrhoidopexy and to justify the superiority of this procedure over open hemorrhoidectomy, though to a certain extent it has proved to be superior in the first 2 post-operative years. A properly designed, adequately powered randomized trial that comprehensively determines the long term efficacy of stapled hemorrhoidopexy is required for definitive opinion.

Conclusion

Stapled hemorrhoidopexy can be considered as a safe procedure that guarantees extremely satisfactory results in the short term period.

It is superior to the conventional open hemorrhoidectomy in terms of duration of surgery, intraoperative bleeding, post-operative pain scores, need for analgesia, duration of stay at the hospital and return to normal activities in addition to faster recovery. At the end of 2 years of follow up there is no significant differences in the complications between the two procedures. Nevertheless, the results from some studies with long term follow up, noticed to have high incidence of persistent pain, tenesmus and bleeding.

Further prospective and longer term follow up from well-designed studies are required to ascertain the efficacy of stapled hemorrhoidopexy in the long term. Finally, an accurate assessment of the impact on cost and quality of life is needed to properly understand the implications of this novel method of treating hemorrhoids.

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