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Stapled haemorrhoidopexy versus open haemorrhoidectomy: our initial experience

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ABSTRACT

Background: Haemorrhoids or 'Piles' is a frequently observed disease in surgical practice. Various non-surgical and surgical treatments are available. Open haemorrhoidectomy (Milligan-Morgan) is a widely-used procedure. A recent novel technique called 'Stapled haemorrhoidopexy', first described and performed by Italian surgeon Antonio Longo is gaining worldwide recognition for its benefits.

Methods: A total of 155 patients between the age group of 20 and 65 years, diagnosed to have grade III or IV haemorrhoids were included in the study, divided into 2 groups, Group 1 undergoing Open haemorrhoidectomy (30 patients) and Group 2 undergoing Stapled haemorrhoidectomy (25 patients). Post operatively patients of both groups were reviewed at the time of discharge, at 7 days after discharge, at 1 month and 3 months post-surgery. The significant difference of the percentages between the two groups was tested using the Chi Square test. The significant difference in the mean values between the 2 groups was tested using the Student's t- independent test. For all the tests, level of significance was taken as 0.05.

Results: In present study, the mean operating time for stapled haemorrhoidopexy was 34.96 ± 7.38 minutes with an average of 20-50 minutes, while with open haemorrhoidectomy, the mean operating time was 44.67 ± 11.83 minutes ($p < 0.001$). The mean VAS scores at 6, 12 and 24 hours with stapled haemorrhoidopexy were 1.79 ± 0.76 ; 1.83 ± 0.61 and 1.47 ± 0.66 , respectively, and with open haemorrhoidectomy, the mean VAS scores at 6, 12 and 24 hours were 2.88 ± 0.88 ; 2.13 ± 0.82 and 1.91 ± 0.83 , respectively. The mean hospital stay for patients with stapled haemorrhoidopexy was 1.96 ± 0.55 days in comparison to the open group where the mean hospital stay was 3.51 ± 0.72 days (P -value < 0.001). The time for resumption to routine work was shorter in stapled group 8.61 ± 2.76 as compared to 15.34 ± 2.12 which was statistically significant (P value < 0.001). The mean amount of blood loss during stapled haemorrhoidectomy was statistically less than in open surgery.

Conclusions: Stapled Haemorrhoidectomy is less painful with shorter duration of hospital stay and resumption of daily activity is faster than the open haemorrhoidectomy. However, long term follow-up is required to know the recurrence rate in stapled haemorrhoidectomy.

Keywords: Hemorrhoids, Hemorrhoidopexy, Stapled

INTRODUCTION

Haemorrhoids or commonly 'Piles' (Pila= a ball; Latin - Haima blood; Rheias- flowing in Greek) is a frequently observed day to day disease in surgical practice.

Haemorrhoids are engorged venous plexuses of the anal cushions in anal canal and can be symptomatic as prolapse, bleeding, pain, thrombosis and pruritus.¹ These are one of the oldest illnesses known to humanity. At least 50% of the people over the age of fifty have some

degree of hemorrhoid formation. Ferguson and Heaton said, "Hundred percent of the population does suffer from hemorrhoids at least once in their lifetime".²

The exact cause is unknown. They are classified as internal or external depending on their site of origin with reference to dentate line. External haemorrhoids originate distal to dentate line, lined by modified squamous epithelium, richly innervated with somatic pain fibers (delta type, unmyelinated). Internal haemorrhoids originate proximal to the dentate line and are covered by mucosa and hence painless. Some haemorrhoids may be mixed (internal and external).³

No other single disease entity has so many different treatment modalities advocated from disparate systems of medicine than hemorrhoids. This in itself goes to show that not a single method has escaped from patient dissatisfaction due to difficulty in compliance, painful convalescence, unacceptable complications and persistence of symptoms.

There are various nonsurgical and surgical treatment modalities for haemorrhoids based on the origin, extent of prolapse and symptoms of haemorrhoids. As stated in the revised practice parameters for the management of haemorrhoid⁴, surgical treatment should be offered to patients in whom office procedures were unsuccessful, patients, not capable of tolerating office procedures, patients with large external haemorrhoids, grade III and IV haemorrhoids. Open haemorrhoidectomy (Milligan-Morgan) is a widely-used procedure for haemorrhoids, established as gold standard as it has stood the test of time by virtue of its least postoperative complications, cost effectiveness and better long term effects. A recent novel technique called "Stapled Haemorrhoidectomy or Stapled Haemorrhoidopexy" as first described and performed by Italian surgeon Antonio Longo is gaining worldwide recognition for its benefits⁵. Staplers as a mechanical adjunct to surgery replacing the traditional sutures have revolutionized operative procedures over the last decade worldwide due to its simplicity, ease and standardization to an anastomosis.

Since in present institution, we are practising both the procedures, a study was conducted with an aim to report our experience. The aim of the study was to compare the two techniques (Open and Stapled Haemorrhoidectomy) in terms of operative time, post-operative pain, resumption of routine daily activity, Post-operative hospital stay, post-operative bleeding, urinary retention and perianal infections comparing the conventional open haemorrhoidectomy with stapled procedure.

METHODS

This study was a prospective hospital based study comprising of patients admitted for elective surgery for haemorrhoids in department of general surgery at HAHC Hospital of HIMS over a period of 18 months. A total

of 55 patients underwent haemorrhoidectomy during the study period. The study was not randomised, patients were informed about the procedures and they underwent the procedures depending upon their affordability and will.

The patients were taken for haemorrhoidectomy after proper clinical evaluation including flexible sigmoidoscopy. Each patient and his attendants were fully explained about the nature of the procedure in the language which they understood, written consent was taken from the patient before surgery. Patients were informed about the possible complications of the procedures. All patients were given a cleansing enema the night before and on early morning of surgery Single dose of prophylactic antibiotic was given at the time of anaesthesia. The anaesthesia used was general or regional anaesthesia. The procedure was performed with the patient in prone, jack-knife or lithotomy position.

Inclusion criteria

- Grade 3 and grade 4 haemorrhoids

Exclusion criteria

- Uncorrected coagulopathy
- Acute hemorrhoidal episodes with thrombosis
- Prior hemorrhoidectomy
- Intercurrent anal pathology (like fistula in ano and anal fissure)
- Prolapse of single anal cushion
- Anal stenosis

Both procedures were carried out as per standard operative techniques. No packs were left in anal canal at end of this procedure. External dressing was applied which was removed after 8 hours. The operating time was defined as the time from beginning of the surgery until the application of the dressing. All patients received a normal diet postoperatively and were given oral lactulose 30 ml daily at bedtime for preventing hard stools. Patients in both groups were advised same cleaning of the anal region and Sitz baths, and no external dressing was applied. All excised tissue was sent for histopathology.

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 hours during the first postoperative day, at the time of first motion. The aim was to keep the VAS score below 5 with adequate analgesia. Post-operative pain therapy consisted of Intravenous Diclofenac 12 hourly for the 1st post-operative day, followed by oral NSAIDS in the form of Diclofenac 50mg 8th hourly was given for the next 5 post-operative days in both the groups. Additional analgesia was supplemented on patient's request. Post operatively patients of both groups were reviewed for the study at-

- Time of discharge
- Time of first review i.e. after 7 days of discharge
- At 1 month post-surgery
- At 3 months, post-surgery.

Data was analysed using SPSS. For descriptive statistics mean, standard deviation and percentages were computed. The significant difference of the percentages between the two groups was tested using the Chi Square test. The significant difference in the mean values between the 2 groups was tested using the Student's t-independent test. For all the tests, level of significance was taken as 0.05. presented.

RESULTS

A total of 55 consecutive patients were included in this study who fulfilled the preset inclusion criterion. Out of these, 25 opted for stapled haemorrhoidopexy and 30 patients underwent open haemorrhoidectomy.

Age distribution

In present study, the patients were in the range of 21-65 years (Table 1). The mean age in stapled group being 40.88 ± 9.74 while in open group mean age was 38.96 ± 10.93 (p-value=0.885).

Table 1: Age distribution of patients.

| AGE (in years) | Stapled | | Open | |
|----------------------|--------------------|-----|--------------------|------|
| | No. of patients | % | No. of patients | % |
| 21-30 | 6 | 24 | 9 | 25.7 |
| 31-40 | 8 | 32 | 7 | 20 |
| 41-50 | 9 | 36 | 8 | 22.8 |
| 51-60 | 2 | 08 | 4 | 11.4 |
| >60 | 0 | 0.0 | 2 | 5.7 |
| Total | 25 | 100 | 30 | 100 |
| Mean±SD | 40.88 ± 9.74 | | 38.96 ± 10.93 | |

Sex distribution

In our study 14 patients (56%) were male and 11 patients (44%) were females in stapled group while as 20 patients (66.7%) were males and 10 (33.3%) were females in open group (Table 2). The difference however being statistically insignificant. P-value=0.037.

Table 2: Sex distribution.

| Gender | Stapled | | Open | |
|--------|--------------------|-----|--------------------|------|
| | No. of patients | % | No. of patients | % |
| Male | 14 | 56 | 20 | 66.7 |
| Female | 11 | 44 | 10 | 33.3 |
| Total | 25 | 100 | 30 | 100 |

p-value=0.037

Duration of surgery

In present study, the mean operating time for stapled haemorrhoidopexy was 34.96 ± 7.38 minutes with average of 20-50 minutes: while as in open haemorrhoidectomy, the mean operating time was 44.67 ± 11.83 minutes (Table 3). The difference being statistically significant with p-value of <0.001.

Table 3: Duration of surgery.

| Duration of surgery (in minutes) | Stapled | | Open | |
|--|--------------------|-----|--------------------|------|
| | No. of patients | % | No. of patients | % |
| 20-30 | 09 | 36 | 03 | 10 |
| 31-40 | 12 | 48 | 09 | 30 |
| 41-50 | 03 | 8 | 11 | 36.7 |
| >50 | 01 | 4 | 07 | 23.3 |
| Total | 25 | 100 | 30 | 100 |
| Mean±sd | 34.96 ± 7.38 | | 44.67 ± 11.83 | |

p-value <0.001

Post-operative pain

The pain scores were aimed to be below 5 in all patients. The pain scores were significantly higher in the open group at 6 hours, 12 hours, 24 hours as tabulated below (Table 4). The difference was statistically significant.

Table 4: Post-operative pain.

| Pain score (VAS) | Stapled | Open | P-value |
|------------------|-----------------|-----------------|---------|
| 6 Hours | 1.79 ± 0.76 | 2.88 ± 0.88 | <0.001 |
| 12 Hours | 1.83 ± 0.61 | 2.13 ± 0.82 | 0.048 |
| 24 Hours | 1.47 ± 0.66 | 1.91 ± 0.83 | 0.003 |

Duration of hospital stay

In present study, the mean hospital stay in patients with Stapled haemorrhoidopexy was 1.96 ± 0.55 days in comparison to open group, were the mean hospital stay was 3.51 ± 0.72 days (Table 5). The difference was statistically significant with a p-value<0.001.

Table 5: Duration of hospital stay.

| Duration of hospital stay (in days) | Stapled | | Open | |
|---|--------------------|-----|--------------------|------|
| | No. of patients | % | No. of patients | % |
| Upto 2 | 20 | 80 | 1 | 2.8 |
| 2-4 | 5 | 20 | 27 | 77.1 |
| >4 | 0 | 0 | 7 | 20. |
| Total | 25 | 100 | 35 | 100 |
| Mean±SD | 1.96 ± 0.55 | | 3.51 ± 0.72 | |

Resumption of routine work

In present study, nearly all the patients resumed work by around 14th day in stapled group while as in open group

only 40% resumed work by same time. Evidently from the data tabulated below (Table 6), mean number of days to resume routine work was 8.61 days in stapled group as against to 15.34 days in open group, with a statistically significant difference ($p < 0.001$).

Table 6: Resumption of routine work.

| Return to work (in days) | Stapled | | Open | |
|--------------------------|-----------------|-----|-----------------|-----|
| | No. of patients | % | No. of patients | % |
| <7 | 12 | 48 | 0.0 | 0.0 |
| 7-14 | 12 | 48 | 12 | 40 |
| >14 | 01 | 02 | 18 | 60. |
| Total | 25 | 100 | 35 | 100 |
| Mean±sd | 8.61±2.76 | | 15.34±2.12 | |

Postoperative complications

Bleeding

In our Study, we found that there was more incidence of intraoperative bleeding in stapled group as compared to conventional open group but this difference was not statistically significant as shown in table under (Table 7).

Table 7: Bleeding.

| Type of surgery | No. of patients (%) | P value |
|-----------------|---------------------|---------|
| Stapled group | 04 (20%) | |
| Open group | 04 (13%) | 0.50 |

However, at the same time, an important observation was that mean amount of blood loss during stapled haemorrhoidopexy was statistically less than in open surgery, depicted in table below (Table 8);

Table 8: Blood loss during stapled haemorrhoidopexy.

| Operative blood loss (in gms) | Stapled | Open | P-value |
|-------------------------------|---------|-------|---------|
| Range | 6-22 | 15-70 | |
| Average | 13 | 46 | <0.001 |

Table 9: Post operative complications.

| Complications | Stapled | | Open | | P-value |
|---------------|-----------------|----|-----------------|----|---------|
| | No. of patients | % | No. of patients | % | |
| Retention | 4 | 16 | 10 | 30 | 0.076 |
| Bleeding | 2 | 8 | 6 | 20 | 0.326 |
| Infection | 0 | 0 | 0 | 0 | 0 |

In present study, we found urinary retention as the most common complication seen in 30% and 16% of open and stapled patients respectively; difference being however statistically insignificant. Bleeding occurred in 20% and 8% of patients in open and stapled groups respectively;

difference being insignificant. No post-operative infection was noted in any of the patients in any of the groups in our study (Table 9).

DISCUSSION

Haemorrhoidectomy is the accepted method for the treatment of large symptomatic haemorrhoids. Conventional haemorrhoidectomies are effective operations that have withstood the test of time; however, the problem of postoperative pain has never been satisfactorily addressed. The postoperative pain related to excisional haemorrhoidectomy is well known. Patients will frequently avoid definitive treatment of their disease for many years so as to avoid this very problem. Also, the high postoperative morbidity and long recovery time has prompted the need for an alternative procedure. Several techniques, including diathermy haemorrhoidectomy, dilatation with banding and cryohaemorrhoidectomy, have been attempted.

Stapled haemorrhoidopexy offers a significantly less painful alternative that provides patients definitive treatment for their disease in a single setting. Stapled haemorrhoidopexy was introduced in 1995 by Longo; a novel technique in dealing with the management of haemorrhoidal disease, it has emerged as an alternative to open haemorrhoidectomy, long considered the "gold standard". It corrects the mucosal prolapse, with simultaneous disruption of blood supply to haemorrhoidal tissue. The technique has been standardized and the indications, contraindications, and operative technique have all been defined. Several randomized trials have shown the efficacy and safety of procedure. There has been concern and reluctance in accepting stapled haemorrhoidopexy, as several serious complications have been reported. These include persistent postoperative pain, fecal urgency, rectovaginal fistula, rectal obstruction, perforation peritonitis and pelvic sepsis. These have all been seen by most investigators during the early part of the procedure's learning curve. Various controlled studies have indicated that stapled haemorrhoidopexy is associated with minimal postoperative pain and early recovery. Right from the earliest research, there has been a high patient satisfaction rate.

However, most of these studies were conducted in highly specialized centers, and the present study was designed to compare the short-term results of stapled haemorrhoidopexy with the Milligan-Morgan haemorrhoidectomy. Our aim was to ascertain if the stapled haemorrhoidopexy performs similarly as is reported in the literature when the procedure was conducted at independent centers. 55 patients that underwent surgery for haemorrhoids at HAHC hospital, fulfilled the criteria and were included in this study. Twenty-five (25) underwent the Longo technique of stapled haemorrhoidopexy and thirty (30) had the Milligan Morgan technique of open haemorrhoidectomy.

In our study, the patients were in the age range of 21-65 years. Most of the patients in the stapled group were in the age group of 41- 50 years, while in the open group, the majority were in the range of 21-30 years. The mean age in the stapled group was 40.8 ± 9.74 while in the open group, the mean age was 38.96 ± 10.93 . (P value=0.759). Pergel [6] found that the mean age was 38 ± 11.9 (range: 23-76) years. In our study, 14 patients (56%) were male and 11 patients (44%) were females in the stapled group, while 20 patients (66.7%) were males and 10 (3.3%) were females in the open group. The difference was statistically insignificant.

The duration of surgery (minutes) was compared between the two groups. In the stapled group, 36% underwent surgery within 20-30 min. The mean duration of surgery was 34.98 min, ranging from 25-55 min. In the open group, the mean duration of surgery was 44.67 min, ranging from 25-55 min. Duration of surgery was significantly low in the stapled group with $t=5.018$; $p<0.001$. This is similar that observed in other studies. However, the duration was 5-10 minutes different than observed by others Khalil KH Bikhchandani J.^{7,8} Tjandra JJ published a systemic review on stapled haemorrhoidopexy of all randomized, controlled trials until August 2006.⁹

Stapled haemorrhoidopexy was highly associated with less operating time (weighted mean difference being 11.35 minutes; $p=0.006$). In our study, the mean difference was comparable (11 min). Stolfi et al, in a study involving one hundred and seventy-one (171) patients comparing the stapler haemorrhoidopexy and Milligan-Morgan technique, found mean surgical time was 28 min.¹⁰ Hetzer et al also observed a mean of 30 min.¹¹ Dilatation of the anal sphincter before stapler introduction was routinely performed.

The authors suggested this as a possible cause for prolonged operating time. The largest trial describing the experience with 3,711 stapled haemorrhoidopexies was published by Ng et al.¹² The median operation duration was 15 min (range: 5-45 min), much lower than most studies. In this study, postoperative pain was managed according to the guidelines of the French Anaesthesia Society. Pain was assessed using a visual analog scale (VAS). The aim was to keep the VAS score below 5 with adequate analgesia as classified by the World Health Organization (WHO). Analgesics were administered on the basis of VAS score. Comparison of pain scores in the two groups of patients was carried out, and they were maintained below five in all patients. The pain scores were significantly higher in the open group at 6 hours, 12 hours, and 24 hours and were statistically significant at every time of assessment. Similar conclusions were drawn from previous studies by Tjandra et al that found there was less pain after stapled haemorrhoidopexy as evidenced by lower pain scores at rest and on defecation and less analgesic requirements.⁹ Stolfi et al were also in agreement with this.¹⁰

In present study, the mean hospital stay for patients with stapled haemorrhoidopexy was 1.96 ± 0.55 days in comparison to the open group, where the mean hospital stay was 3.51 ± 0.72 days. The difference was statistically significant with a P-value < 0.001 . 80% of patients were discharged within 2 days from the stapled group, whereas only 2% were discharged within 2 days from the open group. Duration of hospital stay was significantly low in the stapled group with $t=11.462$; $p<0.0004$. In our study, nearly all the patients resumed work by around 14th day in stapled group while as in open group only 40% resumed work by same time. Evidently, mean number of days to resume routine work was 8.61 days in stapled group as against to 15.34 days in open group, with a statistically significant difference ($p <0.001$). The time taken for return to work was shorter in stapled group as compared to open group. Studies by Hetzer FH et al, Khan NF et al have reported similar findings.^{11,13}

In the work presented here, we found that there was an increased incidence of intraoperative bleeding in the stapled haemorrhoidectomy group versus the conventional open group; however, the difference was not statistically significant. Bleeding occurred in 20% and 13% of patients in the open and stapled groups, respectively, and the difference was statistically insignificant. Our results were in line with previous studies conducted by Koh et al that reported a high incidence of staple line bleeding, up to 44% with various reasons put forth.¹⁴ When the stapler is deployed in an intact bowel lumen during the Longo technique, the stapler actually cuts across well-vascularised tissue, including submucosal blood vessels, under relatively high pressure. The rectal wall is notoriously vascular, with vessels situated just beneath the mucosa. Similar intraoperative bleeding results have been noted by Manfredelli et al that observed a high percentage of staple line bleeding compared to an open group.¹⁵

In this study, most of the staple line bleeding was from an active arterial spurt that was managed by electocautery initially and, if deemed necessary, was controlled by suture reinforcement by a figure-of-eight suture. The rest of the bleedings were ooze-managed by topical hemostats and gauze packings. We conclude that it is imperative to review the staple line after completion of the procedure to avoid any bothersome after effects from bleeding of the suture line. At the same time, one considerable observation of our study was that the amount of blood loss in the stapled haemorrhoidectomy group was significantly lower than the open group. The difference in the amount of blood between the two procedures was statistically significant. These observations were similar to previous studies with results that depicted a similar trend. Only a couple of investigations reported intraoperative blood loss, each significantly favouring stapled haemorrhoidopexy (Wilson et al - 7 versus 39 g, $p<0.001$).¹⁶

In present study, we found urinary retention as the most common complication seen in 31.1% and 15.6% of open and stapled patients, respectively; the difference was statistically insignificant, however. No postoperative infection was noted in any of the patients in any of the groups of this study. Moreover, there was no statistically significant difference in terms of other postoperative complications. This is similar to findings of other previous studies (ex. Gravie et al).¹⁷

CONCLUSION

Stapled haemorrhoidopexy is associated with lesser post-operative pain than the conventional open haemorrhoidectomy. It is associated with shorter duration of hospital stay following surgery when compared to open haemorrhoidectomy. Patients resume their routine daily activity faster than patients with open haemorrhoidectomy. It is associated with almost same rate of immediate post-operative bleeding, urinary retention. However, it is difficult to recommend stapled haemorrhoidopexy as a procedure of choice for all patients in view of economic considerations. However, for those who can afford the procedure, it offers a benefit.

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