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ORIGINAL RESEARCH ARTICLE

STAPLED HAEMORRHOIDECTOMY VERSUS OPEN HAEMORRHOIDECTOMY: A PROSPECTIVE COMPARATIVE STUDY

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ABSTRACT

Open haemorrhoidectomy (OH) treatment has been reserved for prolapsing haemorrhoidal disease (third and fourth-grade) and comprehends excision of haemorrhoidal tissue and is associated with significant postoperative pain. As an alternative approach, many randomized controlled trials have shown consistent advantage with haemorrhoidopexy (SH) in terms of postoperative pain, analgesic requirement, length of surgical procedure, short recovery time and early return to normal activities. This study has been conducted to compare the short-term outcome of SH with OH. A prospective comparative study, which included grade 3 and 4 haemorrhoids and comparing short Term outcomes between SH and OH was conducted in the Surgical Gastroenterology units of University Teaching Hospital. A total 44 patients, 22 in each group were compared. Age (SH 42±10.80 Vs. OH 45±13.30) and sex (SH, M:F-9:13 Vs. OH, M:F-14:8) distribution was comparable. Also, the groups were comparable in terms of symptom duration in years (SH, 3.20±2.26 Vs. OH, 2.31±2.47) and distribution of haemorrhoid grades. The SH group showed significant advantage in terms of postoperative pain (Average pain score SH, 2.73±1.20 Vs. OH, 5.20±1.91) and analgesic use (SH 2.32±0.94 Vs. OH 9.32±2.62). Similarly the operating time (time in minutes SH, 42±7.34 Vs. OH, 57.50±8.27), hospitals stay (days of stay SH, 2.90±0.68 Vs. OH, 3.77±0.86) and return to preoperative activity (days to return SH, 7.9±4.90 Vs. OH, 13.6±5.60) were also significantly shorter in the SH group than the OH group. The short-term complications were similar in both groups (P value >0.05). In conclusion, SH has better short-term outcome compared with OH and SH is a viable addition to the therapy options available for haemorrhoids.

Key words: *Haemorrhoids, Milligan-Morgan open haemorrhoidectomy (OH), Stapled haemorrhoidopexy (SH).*

INTRODUCTION

For prolapsing haemorrhoidal disease (third and fourth-grade), most frequent traditional surgical procedures performed are Milligan-Morgan open haemorrhoidectomy,[1] and Ferguson closed haemorrhoidectomy[2] techniques, both of which are associated with severe pain postoperatively due to wide external wounds and removal of innervated anoderm below dentate line and perianal skin.[1,2,3,4] The results of stapled haemorrhoidectomy have been assessed in some randomized controlled trials.[5,6] These studies have consistently shown a decrease in postoperative pain, analgesic requirement, length of surgical procedure, short recovery time and early return to normal activities. We present a prospective comparative study to compare the results of using stapled haemorrhoidectomy versus traditional surgery for treatment of haemorrhoids.

PATIENTS AND METHODS

A prospective study comparing the use of SH with traditional OH was undertaken within one University Hospital. Approval from the Department and ethical committee was obtained. From all participants, written informed consent was obtained prior to entry into the study. Patients were alternately allocated to either stapled or open procedure (Quasi randomization). Study was completed over 2 years period (October 2009-September 2011). Patients with uncomplicated grade three and four hemorrhoids were included while the exclusion criteria included first and second degree hemorrhoids, complicated hemorrhoids, concomitant perianal fistula, fissures, abscess, previous anal surgery, Patients with known history of coagulopathy or receiving treatment with oral anticoagulants or immunosuppressive agents and any contraindications to general or spinal anesthesia.

A complete preoperative evaluation was performed which also included sigmoidoscopy or colonoscopy as and when required. All patients received mechanical bowel preparation. Anesthesia was standardized and consisted of spinal anesthesia in all cases and converted into general anesthesia if required. The open haemorrhoidectomy was performed with Milligan-Morgan technique, which consisted of retraction of the pile mass with an artery forceps and diathermy dissection and excision. The vascular pedicle was carefully divided by diathermy after suture ligation with Vicryl 00. The stapled procedure was done

according to the technique described by Longo and colleagues[7] with a haemorrhoid stapler (Proximate HCS: Haemorrhoidal Circular Stapler), which is a modified 33-mm circular stapling device that comes with an anal dilator/retractor and a purse-string suture anoscope.[7] Both groups received standard postoperative management. Patients were discharged when pain was under control and they felt comfortable to be discharged. An outpatient appointment was arranged for 2 weeks and 30 days after surgery and patients were given an advice sheet, which included dietary advice, postoperative medications and warning signs requiring return to emergency.

The primary endpoints of the study were measurement of postoperative pain after 24 hrs. and every day till the day of discharge. Postoperative pain scores were measured using a 10-point numerical pain score. The other primary outcome measures were use of analgesia and time until return to normal activity. Secondary parameters were operative time, duration of hospital stay, short-term complications and demographics in terms of sex distribution, grade and symptoms duration. Operative time duration was measured after positioning and start of surgery up to final wound packing. The total analgesic consumption during the hospital stay postoperatively was recorded. Postoperative complications within 30 days of surgery were recorded. SPSS version 17 was used for the statistical analysis. Continuous variables were expressed as mean ± standard deviation and categorical variables as frequency tables and percentage forms. Independent t-test and Chi square tests test were used to compare the data. The p value < 0.05 was considered as statistically significant.

RESULTS

Overall 22 patients in each group fulfilled the inclusion criteria and accordingly they were analyzed. A total 3 patients in the SH group and 2 in the OH group were excluded due to incomplete follow up. Age and sex distribution in both groups were comparable as the difference was not statistically significant. Majority of the patients in both group were in their 4th decades (stapled 42±10.81yrs, open 45±13.3yrs). Most of the literature is in favor of offering surgical management for grade 3 and 4 haemorrhoids, though failed 2nd degree haemorrhoids also at times offered with surgical treatment. In our study we included grade 3 and grade 4 hemorrhoids. Overall, grade 3 hemorrhoids were more in numbers in our study (31 grade 3, 11 grade 4). However, the distribution of grade 3 and grade 4 haemorrhoids were not statistically different in the two groups (Table 1). Thus, the two groups were also comparable in terms of the grade of haemorrhoids. Similarly, duration of symptoms ranged from months to years (6 months to 5 yrs) and average duration of symptoms of haemorrhoids in both groups was 2-3 years. The difference was not statistically significant and again the two groups were comparable in terms of their duration of symptoms. As most of the studies comparing SH with OH have also included operative time for comparison, we also tried to analyze the difference. The operative time was shorter in the stapled group (stapled 42±7.34mins vs. open 57±8.27mins). The difference was statistically different which supports the fact that SH is accomplished in significantly shorter time than the open procedure. (Table 1)

Table 1. Demographics

Parameter	Stapled	Open	P value
Age (years)	42±10.81	45.5±13.3	>0.4163^{X}
Sex (M/F)	9/13	14/8	>0.2273^{Y}
Grade 3/4	16/6	15/7	>0.109^{y}
Duration (years)	3.2±2.26	2.31±2.47	>0.2193 ^{X}
Operative time (minutes)	42±7.34	57.50±8.27	<0.0001^{X}

^{X} Independent sample test (T test), ^{Y} Chi-square test

One of the most important aspects of our study was to compare the postoperative pain score in the two groups (Table 2, 3). The pain score was assessed using numerical pain scale at 24, 48 and 72/hrs. The pain score was significantly in lower side in the stapled group. Similarly, the average total pain score was also low in the stapled group. The difference of pain score was statistically significant both individually and in overall score. This finding provided a significant evidence to suggest that the stapled procedure is associated with less postoperative pain when compared with the open technique. Analgesic requirement in the postoperative period was also compared. In the first 24 hrs of postoperative period, all the patients in both group invariably received parenteral analgesics. However, after 24 hrs. they received oral analgesics on demand and were advised to have rescue parenteral analgesics only if the pain was not controlled by the oral analgesics. But none of the patients in either group required parenteral analgesics as rescue analgesics. Total dose of oral analgesic consumed in terms of fixed dose of oral analgesics tablets were calculated and compared in two groups. The stapled group received lower number of oral analgesic tablets. The difference was statistically significant. This finding further reinforced that the stapled procedure is associated with significantly less pain and less analgesic requirement in the post operative period. Furthermore, the number of postoperative hospital stay was also assessed and it was seen that the stapled group had statistically significant shorter hospital stay (stapled 2.90±0.68 days vs. open 3.77±0.86 days) when compared with the open procedure.

Table 2. Postoperative pain score

Time	Stapled	Open	P value
24 hrs	3.5±1.5	6.5±2.11	<0.0001^{X}
48 hrs	2.54±1.37	5.36±2.03	<0.001 ^{X}
72 hrs/Discharge	1.72±1.48	3.77±1.92	<0.003 ^{X}
Average score	2.73±1.29	5.20±1.91	<0.001 ^{X}

^{X} Independent sample test (T test)

Table 3. Postoperative pain severity according to score

(Degree Average pain Sure)	Stapled	Open
Mild (1-2)	13	2
Moderate (3- 6)	9	12
Severe (7- 9)	0	8

All the patients in both the groups were followed up for 30 postoperative days. First follow up was arranged at 2 weeks following surgery or earlier in case any significant problem arouse. At two weeks, the pain score and time required to return to preoperative activity were also assessed (Table 4). The pain score was significantly low in both groups, however, even with the low pain score; the difference was statistically significant with stapled group having less score when compared with the open technique. Similarly the time taken to return to normal preoperative activity was also less in comparisons to open procedure and the difference was statistically significant. The time taken to return to the normal preoperative activity was almost double in the open group (stapled 7.9±4.9days vs. open 13.6±5.8days). Common complications seen in the stapled haemorrhoidectomy group were retention (9.09%), urgency (9.09%), wound discharge (9.09%) and one patient had rectal stenosis. Except the patient with the rectal stenosis, which improved on subsequent dilatation, none of the other complications in the stapled group were significant to receive any major interventions. Similarly, common postoperative complications (Table 5), which occurred in the open group, were retention (13.63%), wound discharge (18.18%) and minor postoperative incontinence (4.5%) which subsequently improved on follow up. One patient in the open group had postoperative wound site bleeding for which he was returned to operating theatre for haemostasis. The patient improved without significant sequel. Total short-term complications were similar in both groups. Thus, the two groups were not significantly different in terms of postoperative complications.

Table 4. Other postoperative parameters

Parameter	Stapled	Open	P value
Analgesic(total tablets)	2.32±0.94	9.32±2.62	<0.0001[X]
Hospital stay in days	2.90±0.68	3.77±0.80	<0.0004[X]
Pain score at two weeks	0.50±0.67	2.09±1.57	<0.0001[X]
Return to preoperative activity	7.9±4.9	13.6±5.8	<0.001[X]
Total complications	7/22 (31.8%)	9/22 (40.05%)	>0.098[y]

[X] Independent sample test (T test), [y] Chi-square test

Table 5. Individual complications (f, frequency)

Parameter	Stapled (*f*)	Open (*f*)
Significant bleed	0	1
Retention	2	3
Urgency	2	0
Wound discharge at 2 weeks	2	4
Incontinence	0	1
Stenosis	1	0

DISCUSSION

Milligan–Morgan and Ferguson haemorrhoidectomy are still the most frequently performed surgical procedures for symptomatic third and fourth degree haemorrhoids.[8] However, most patients experience considerable post-operative pain, which limits their resumption of normal activities. Additionally, in some patients, the peri-anal skin wounds are slow to heal, which may prolong bleeding and discomfort for several weeks.[9] In this respect, SH theoretically offers benefits compared to the excisional techniques because it involves neither dissection nor excision of the peri-anal skin. The significant reduction in pain observed following SH undoubtedly contribute to the more rapid recovery reported for patients. Despite Cheetham et al., having reported alarming symptoms in three patients, the short-term benefits of SH has now been confirmed in many randomized trials. [10] Mehigan et al., and Rowsell et al., reported significant benefits of SH on short-term follow-up, including reduced post-operative pain and hospital stay, as well as faster return to normal activities. [11,12] Schalaby and Desoky reported in their cohort of 200 patients that SH was safe and was associated with fewer complications than OH after 6 months and 1 year follow-up. [13]

In our study, the groups have been comparable in terms of age and sex distribution. Epidemiological data suggest that the peak incidence of hemorrhoid occurs between 45- 65 years of age, our study showed majority in 4th decade. [14] Both male and female are equally prone for developing hemorrhoids. However, many studies have shown more males than females. There does not seem to be any reasonable explanation for this finding except the fact quoted by some saying that majority of women with hemorrhoids fails to seek any medical assistance due to social and cultural factors.[15] Significant benefit in favor of stapled procedure was observed when postoperative pain and analgesics were compared, which has been one of the most talked about advantage of SH over the OH procedure. Similarly, we also showed that the stapled procedure can be completed in significantly shorter operative time than the open technique. The hospital stay was also shorter for the stapled group. Another very important advantage of stapled procedure, significantly early return to preoperative activity has also been demonstrated by our study. Though, in our study we haven't done a cost analysis, this finding has significant meaning as the cost of the stapled procedure is significantly outweighed by earlier return to work and earning. Except one patient in the stapled group, who developed postoperative stenosis, improved subsequently, significant complications were not observed in either of the groups and overall complication rate were similar in both the groups. Regarding postoperative complications, Shao et al., in his meta analysis of randomized controlled trials comparing SH with conventional haemorrhoidectomy showed that there was no real difference in terms of overall postoperative complications.[16] SH is not superior to conventional OH with respect to postoperative hemorrhage, urinary retention, reoperation rate, sphincter damage, pruritus, incontinence, anal stenosis. None of the studies in his meta analysis showed serious complications like sepsis, fistulas. Regarding the outcome "peri- and post-operative complications", Schalaby and Desoky reported that early and late complications as well as the functional outcome were better following stapled haemorrhoidopexy than after Milligan–Morgan haemorrhoidectomy. Regarding outcomes such as "post-operative anal stenosis" and

"postoperative anal incontinence", Racabulto et al., and Stadt van de et al., presented only a numerical advantage of stapled haemorrhoidopexy compared to Milligan–Morgan haemorrhoidectomy, but no significant difference was observed in the long-term follow-up.[17,18] In terms of peri-/post-operative complications, Laughlan et al., in their systematic review on stapled haemorrhoidopexy compared to Milligan- Morgan and Ferguson haemorrhoidectomy failed to show any statistical difference between stapled haemorrhoidopexy and Milligan–Morgan/Ferguson haemorrhoidectomy when comparing "peri-operative bleeding", "bleeding mid-/long term", "post-operative anal stenosis—long term" and "post-operative anal incontinence long term.[8]

When compared in terms of postoperative pain, significant advantages have been seen in favor of stapled haemorrhoidopexy over open procedure. Schalaby et al,. demonstrated pain score of 2.5 for stapled group while it was 7.6 for open group during hospital stay. [13] Similarly, at 24 hours postoperatively, Chetham et al., showed pain score of 3.3 for stapled group while 6.1 for open group. [10] Similarly Bekchandani et al., demonstrated pain score of 3.6 for stapled while 6.36 for the open group.[19] Shao et al., in his meta analysis of randomized controlled trials comparing stapled haemorrhoidopexy with conventional haemorrhoidectomy showed that the pain score at 24h after surgery for stapled haemorrhoidopexy was significantly lower than that for conventional haemorrhoidectomy in five studies.[16] Four of his studies also showed lower pain scores in stapled groups 1- 2 weeks after surgery. Supporting these findings, our study also has been able to demonstrate significant benefit in terms postoperative pain favoring stapled haemorrhoidopexy over open haemorrhoidectomy. As it can be easily understood, lower postoperative pain requires lesser amount of analgesics. This has also been supported by the findings in the published studies. A Racalbuto et al., in his study demonstrated significantly less analgesic tablet required (2.6 vs. 15.9 ketorolac tablets) for stapled group when compared with open haemorrhoidectomy.[17] Shao et al., in his meta analysis, the pooled data from seven studies suggested a lesser requirement of analgesic in stapled group than in open groups both during hospital stay and discharge. [16] We have also been able to demonstrate significantly less amount of analgesic requirement for stapled group in comparison to the open haemorrhoidectomy group. Regarding wound healing, Schalaby and Desoky noted that the mean time to healing of the anal wound was significantly less after stapled haemorrhoidopexy than after the Milligan–Morgan procedure (mean 7.0 vs. 30.5 days, respectively).[13] Delayed wound-healing leads to persistent discharge, which might become very disturbing symptom to the patients. This is not unexpected given that stapled haemorrhoidopexy does not involve an anodermal wound, although it is unclear as to the accuracy of determining the healing time of an internal stapled anastomosis. This fact contributes to delayed return to normal activity after open haemorrhoidectomy. Laughlan et al., in their systematic review on stapled haemorrhoidopexy compared to Milligan-Morgan and Ferguson haemorrhoidectomy demonstrated that for the outcomes "operation time" and "hospital stay", stapled haemorrhoidopexy was numerically superior in terms of reduced operating time and significantly better compared to Milligan–Morgan haemorrhoidectomy in terms of reduced hospital stay.[8] Shao et al., in his meta analysis demonstrated that the pooled data from nine trials, there was statistically significant difference in operating time between the two procedures in favor of stapled haemorrhoidopexy.[10] Similarly pooled data from eight studies showed shorter hospital stay for stapled haemorrhoidopexy than for conventional haemorrhoidectomy.[16]

CONCLUSION

SH has better short-term outcome compared with OH in terms of postoperative pain, analgesic requirement, shorter hospital stay and earlier return to activity. However complications are similar in both groups. SH is a viable addition to the therapy options available for haemorrhoids.

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