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ORIGINAL ARTICLE

STAPLED HEMORRHOIDECTOMY VERSUS TRADITIONAL HEMORRHOIDECTOMY FOR THE TREATMENT OF HEMORRHOIDS

Gouda El-Iabban
Department of General Surgery, Faculty of Medicine, Suez Canal University, Ismailia, Egypt

Email: ellabbang@yahoo.com

Abstract

Aim: We aimed in this randomized clinical trial to compare the results of traditional versus stapled hemorrhoidectomy for treatment of third and fourth degree hemorrhoids.

Methods: Thirty patients admitted for surgical treatment of prolapsing hemorrhoids were randomly assigned to traditional (n=15) or stapled hemorrhoidectomy (n=15). All patients received standardized preoperative and postoperative analgesic and laxative regimens. Postoperative pain measured by Visual Analog Scale (VAS) was used as the primary outcome measure. Secondary outcome measures were; operative time, use of analgesia, postoperative complications, hospital stay duration, time to first bowel motion, and return to normal activity.

Results: Stapled procedure for hemorrhoids is associated with a significant improvement in postoperative pain control and with an earlier return to normal activity. Operative time and duration of hospital stay were shorter for the stapled procedure. . A trend towards earlier bowel function after the stapled procedure, although not significant in this study, would be consistent with less perianal pain and spasm.

Conclusion: Stapled hemorrhoidectomy is an effective treatment for third and fourth degree hemorrhoids with significant advantages for patients compared with traditional hemorrhoidectomy.

Keywords: Circumferential mucosectomy, conventional technique, stapled hemorrhoidopexy

INTRODUCTION

Despite the major advances that have occurred in the treatment of colorectal diseases, there have been few modifications in the management of hemorrhoidal disease in the last decades.[1-6] Surgical hemorrhoidectomy treatment has been reserved for prolapsing hemorrhoidal disease (third and fourth-grade) and comprehends excision of hemorrhoidal tissue.[7-9] Most frequent traditional surgical procedures performed are Milligan-Morgan open hemorrhoidectomy[10], and Ferguson closed hemorrhoidectomytechniques[11], both of which are associated with low complications and excellent results in terms of relief of symptoms, but severe pain may arise postoperatively due to wide external wounds and removal of innervated anoderm below dentate line and perianal skin.[1,2,12] Considerable postoperative nursing care is needed, with a convalescence of at least 1 month.[13]

Several modifications to traditional techniques have been proposed aiming to reduce postoperative pain including lateral internal sphincterotomy, anal

dilatation, diathermy hemorrhoidectomy, use of anal sphincter relaxants or metronidazole and the haemorrhoidal artery ligation operation (HALO).[14-17] However, none have resulted in a significant decrease in postoperative pain to gain universal acceptance.[18]

Stapled hemorrhoidectomy was introduced in 1993 as an alternative to traditional techniques for operative management of hemorrhoidal disease. This method was described and refined by Longo[19] in 1998. It uses a transanal circular stapler to excise a complete circular strip of rectal mucosa above the dentate line which lifts the prolapsed hemorrhoidal tissue, removing the redundant mucosa and stapling off the end branches of the superior hemorrhoidal artery.[19,20] By avoiding multiple excisions and suture lines on the sensitive anal mucosa below the dentate line, the initial experience of several authors has shown that pain appears to be far less with stapled hemorrhoidectomy than with traditional techniques.[1,2,4,5,21,22]

The introduction of the stapled hemorrhoidectomy was received with much enthusiasm because it could offer patients a significantly improved postoperative comfort level. This is attributable to the fact that the mucosal incision and staple lines are positioned well above dentate line and the highly sensitive perianal skin is left intact.[23] The results of stapled hemorrhoidectomy have been assessed in some randomized controlled trials.[7,12,16,19,24] 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. The complications and postoperative recurrence rates are similar to those reported after excisional technique.[7,9,11,16]

In this study we present a randomized clinical trial to compare the results of using stapled hemorrhoidectomy versus traditional surgery for treatment of third and fourth degree hemorrhoids.

PATIENTS AND METHODS

Study design: A single-blinded randomized clinical trial comparing the use of stapled hemorrhoidectomy with traditional hemorrhoidectomy was undertaken at Suez Canal University Hospital from March 2006 to March 2007. The trial was approved by the Faculty of Medicine, Suez Canal University Research Ethics Committee, and a written informed consent was obtained from all participants prior to entry into the trial. The study population included 30 patients with symptomatic third (hemorrhoids prolapsed upon defecation or straining, but must be manually reduced) and fourth (hemorrhoids prolapsed and cannot be manually reduced) degree internal hemorrhoids, according to the grading system developed by Banov,[25] with or without redundant rectal mucosa, who are fit for anesthesia. The included patients were randomly allocated into one of two groups; the first group (15 patients) was randomized to Milligan-Morgan[10] traditional hemorrhoidectomy and the second group (15 patients) was randomized to stapled hemorrhoidectomy procedure.

Patients with first and second degree or thrombosed hemorrhoids, concomitant perianal fistula, fissures, abscess, or previous anal surgery disorders were excluded. Patients with known history of coagulopathy or receiving treatment with oral anticoagulants or immunosuppressive agents or had psychiatric disorders were also excluded.

Randomization: Randomization was performed prior to commencement of the study as follows: opaque envelopes were numbered sequentially from 1 to 30. A table of random numbers was generated by a computer program and used for group assignment; if the last digit of the random number was from 0 to 4, the assignment was to group 1 (traditional hemorrhoidectomy), and if the last digit was from 5 to 9, the assignment was to group 2 (stapled hemorrhoidectomy). The assignments were then placed into the opaque envelopes and the envelopes sealed. As eligible participants were entered into the trial, these envelopes were opened in sequential order to give each patient his or her random group assignment. The envelopes were opened by the operating surgeon following patient consent and just prior to the surgical procedure. The operation was performed by a single surgeon experienced in colorectal surgery. Patients were unaware which treatment they will receive while the surgeon was aware of treatment allocation from the start.

Preoperative evaluations: Preoperative evaluations included a medical history, physical and proctological examinations, and routine laboratorial tests for all patients. Patients over 45 underwent cardiologic evaluation preoperatively. Colonoscopy was performed preoperatively for patients with important changes in bowel habit, a previous history of colorectal cancer or polyps and for all patients over 50.

Operative technique: Anesthesia was standardized and consisted in all cases of general anesthesia maintaining the airway with a laryngeal mask. Analgesia consisted of diclofenac 1 mg/kg administered intravenously intra-operatively, and a regimen of intravenous morphine (0.1 mg/kg intravenous rescue analgesia in the first 24 h), regular diclofenac (50 mg three times a day by mouth for 1 week), and local 0.2% glyceryl trinitrate (to anal margin three times a day for 1 month).

All patients were also given metronidazole (500 mg intravenously) at induction of the procedure and were prescribed oral metronidazole (500 mg three times a day by mouth for 7 days).[14] Patients had two phosphate enemas before the operation (one at night and the other at the morning of surgery) and were prescribed lactulose 20 mL twice daily until return of normal bowel function.

We chose the lithotomy position to perform the operations for all patients. The operative technique for

the Milligan-Morgan group consisted of retraction of the pile mass with an artery forceps and diathermy dissection and excision. The vascular pedicle was carefully divided by diathermy. Suture ligation of the pedicle was avoided and only done if diathermy failed to secure satisfactory haemostasis. An absorbable gelatine sponge dressing was placed in the anal canal when the procedure was completed.

The stapled procedure was done according to the technique described by Longo and colleagues.[19] The hemorrhoid stapler (Proximate HCS: Hemorrhoidal Circular Stapler) is a modified 33-mm circular stapling device that comes with an anal dilator/retractor and a purse-string suture anoscope.

The circular anal dilator with the transparent anal retractor is then inserted right up to the hilt. Although the retractor has 4 suture apertures, it usually suffices to secure it to the buttocks with 2 opposing lateral stitches.

Proper insertion and affixation assures that the dentate line can be identified through the transparent retractor. The purse string anoscope is introduced through its center. A 2/0 monofilament suture on a tapered 5/8th needle is used. By rotating the anoscope, a mucosa-only purse string suture is placed 4 to 5 cm above the dentate line that will draw a circumferential ring of mucosal tissue into the stapling device. The excision of a 2-cm tissue ring and the simultaneous reanastomosing of the mucosa with 2 rows of staples will result in a circumferential surgical wound about 2 cm above the dentate line (i.e. in an insensitive area). Mark the inside of suture anoscope with a water-resistant marking pen at the level of 4 to 5 cm proximal to the visible dentate line.[26]

After the purse suture has been placed, a digital rectal examination was performed to check that the purse string tightens easily, smoothly, and circumferentially around the finger. The circular stapler was then opened to its maximum position and the head introduced and positioned proximal to the purse string suture.

Once the head of the stapler has passed the purse string level, the suture was tied down to the rod with a closing knot (step A). The suture ends were threaded, pulled through the lateral holes of the stapler gun, and knotted externally. With moderate traction on that suture (step B), the stapler gun was then closed and tightened to the maximum. Step A pulls the tissue towards the center (rod) and step B pulls the tissue into the stapler chamber to maximize the tissue resection.[26]

Before the maximally closed stapler was actually fired, two safety stops were done. The sutures holding the circular anal dilator were divided and thorough circumferential inspection around the stapler was performed to ensure that the dentate line has not accidentally been incorporated into the stapler, this would invariable result in a great deal of postoperative pain. To prevent rectovaginal fistula, vaginal examination was performed in females to ensure that the posterior vaginal wall has not been incorporated/tethered into the staple line.

The closed stapler is held in place for 20 seconds, this prevents bleeding and keeps staple line dry. The stapler is then opened fully and removed. Inspection of the staple line is done by a bivalve retractor and any bleeding points were stopped by electrocautary (as bleeding was minimal and easily controlled). An absorbable gelatine dressing is placed in the anal canal at the end of the procedure. Anesthesia time was recorded.

Postoperative care: Postoperative management consisted of standard nursing care and analgesia according to the above protocol. Each patient was given a discharge prescription for lactulose 20 mL each day. Patients were unaware of which procedure they underwent and were discharged when pain was controlled and home circumstances permitted. An outpatient appointment was arranged for 10 days after surgery and patients were given an advice sheet and telephone number in case of emergency.

Outcome measures: The primary endpoints of the study were measurement of postoperative pain after 24 hours and every day of the first 10 days. Postoperative pain scores were measured using a 100- millimeters VAS. VAS is a horizontal line anchored by word descriptors at each end. The patient marks on the line at the point that they feel represents their perception of their current pain. It was measured in millimeters from the left hand end of the line to the point that the patient marks. A higher numeric pain score represented more severe pain.[27] Patients were unaware of the treatment they had received until pain VAS forms for the first 10 days had been collected.

The secondary outcome measures were operative time, use of analgesia, incidence of postoperative complications, duration of hospital stay, time to first bowel motion, patients' satisfaction and time until return to normal activity. Operative time duration was measured from anesthesia up to final wound dressing. The total analgesic consumption during the first 10 days postoperatively was recorded. Patients were asked to record the first bowel motions. Hemorrhoidal symptoms were assessed preoperatively and at 1 and 3 months follow up outpatient visits. Patients were asked to rate their satisfaction into four categories: unsatisfactory; satisfactory; good; excellent. Specific enquiries into fecal continence were made preoperatively and at each follow-up. Postoperative complications were divided into early and late. Patients were asked how long after the operation they returned to work or their normal activities. The patients were followed up at 1 month and 3 months postoperatively.

Statistical analysis: Serial measurements on VAS were summarized by calculating the average pain over the period for each patient as a summary measure.[28] Analysis of variance (ANOVA) test was used to test significance between mean VAS during follow up

periods. We calculated the observed means by Student's t-test in order to show a difference of one SD in average pain scores between groups. Power calculations suggested that 30 patients should be recruited to identify a 50% reduction in inpatient stay with a power of 80% at the 5% significance level. We used the t-test to compare operative time, duration of hospital stay and time to return to normal activities. Chi square or Fisher's exact tests were used for categorical data. Observed results were calculated by Statistical Package of Social Sciences for Microsoft Windows Version 13 (SPSS v.13 Software).[29]

RESULTS

Patient characteristics: The study was conducted on 30 patients divided into two equal groups; there were 17 males and 13 females. There was a predominance of males in both groups, but without any significant difference. The majority of the cases were in the fourth decade of life. The mean age of the patients was 45 versus 42.2 years in traditional and stapled groups respectively. The majority of the patients had third grade hemorrhoids (21 patients, 70%). The main complaint of the patients was anal bleeding (25 patients, 83.3%). No patients in both groups complained of fecal incontinence preoperatively. The clinical characteristics of patients in the two groups were similar regarding the mean age, gender, hemorrhoids degree and preoperative complaints ($p>0.05$). The clinical characteristics are summarized in Table 1.

Surgical treatment and secondary outcome measures: All patients were operated on lithotomy position under general anesthesia. No intraoperative additional hemostasis was required in any case. The operative time was significantly longer in the traditional group (mean = 38 minutes) than the stapled group (ranged between 15 and 40 minutes with a mean of 35 minutes), ($p<0.007$). Hospitalization time ranged between 1 and 3 days. There was a significantly shorter mean duration of the hospital stay in the stapled group than in the traditional group (1.09 versus 2.8 days, respectively) ($p<0.001$). In 14 cases (46.7%) the first bowel movement occurred while patients were still in hospital. There was a trend toward earlier bowel motions in the stapled group with 8 (53.3%) patients opening their bowels within 24 h of surgery in the stapled group and 6 (40%) in the traditional group but without significant difference ($p=0.72$). Earlier complications consisted of acute urinary retention in two patients, one in each treatment group. Seven patients (23.3%) of both groups complained of discrete bleeding that stopped spontaneous by in up to 3 days. No patient required intervention for bleeding control and no recurrent bleeding was reported. Temporary incontinence to flatus and liquid stool was reported by two patients in the stapled group and one patient after the traditional; this has been resolved after stopping the glyceryl trinitrate cream after 1 month follow-up. No persistent incontinence had been reported in either group. Late complications include; anal stenosis, prolapse recurrence, fissure and persistence pain, which were insignificantly different between both groups. The operative details and complication rates are summarized in Table 2.

Pain outcome measures: Pain scores as assessed by VAS are shown in (Fig. 1). Average pain in the stapled group was significantly lower than the Milligan-Morgan group [mean 2.5±0.5 (range 0.3–6.9) versus 7±2.3 (2.5–7.8), $p<0.0001$, Student's t test). This effect remained significant when analyzed for females [3.2±0.3 (range 0.7–6.6] versus 4.9±1.0 (range 3.5–6.2), $p=0.002$) and for males [3.8±0.7 (range 0.9–6.5) versus 5.9±1.5 (range 2.8–7.4), $p=0.0018$].

Patients in the stapled group required none (n=11 patients), one (n=3), and three (n=1) injections of opiates and the traditional group required none (n=5 patients), one (n=6), two (n=3), three (n=1), and four (n=1) injections. The outcome data for pain scores and the consumption of analgesia are summarized in Table 3.

Follow-up of both studied groups: At the review after 1 month, traditional hemorrhoidectomy controlled symptoms in nine patients (60%). Stapled hemorrhoidectomy controlled symptoms in 10 out of 15 patients (66.7%) at the 1-month review. After 3 months follow up, only one patient in each group had unsatisfactory control of the symptoms due to persistent pain. Satisfaction with symptom control was similar in both groups in all follow up periods without any significant differences. Patients' assessment of time to return to normal activity varied widely between patients. There was, however, a significantly earlier return in the stapled group in comparison to the traditional group [mean 18 (8-45) versus 31 (14–70) days, $p=0.0005$, Student's t-test]. These results are summarized in Table 4.

DISCUSSION

We have shown that the stapled procedure for hemorrhoids is associated with a significant improvement in postoperative pain control and with an earlier return to normal activity, as defined by the patient. The use of VAS scores is well accepted and although the scores for the Milligan-Morgan group remain high at the end of the 10 days it should be noted that there was wide variation. Operative time is in addition shorter for the stapled procedure. A trend towards earlier bowel function after the stapled procedure, although not significant in this study, would be consistent with less perianal pain and spasm.

The patients of stapled group have shown a significant shorter duration of hospital stay than the other group, early discharge from hospital which was secondary endpoint of the study. We feel that the marked decrease in the severity of postoperative pain with the stapled procedure may facilitate a move towards day case surgery.

Table 1. Clinical characteristics of both studied groups.

Clinical characteristic	Stapled group (n=15)	Traditional group (n=15)	P value
Age (years):			
Mean ±SD	42.2±8.1	45±10.2	0.41
Gender:			
Male / female (%)	9 / 6 (60 / 40)	8 / 7 (53.3 / 46.7)	0.72
Hemorrhoids degree:			
Third / fourth (%)	10 / 5 (66.7 / 33.3)	11 / 4 (73.3 / 26.7)	0.69
Preoperative complaints:			
Anal bleeding (%)	12 (80)	13 (86.7)	0.78
Perianal pain (%)	6 (40)	8 (53.3)	0.46
Constipation (%)	3 (20)	4 (26.7)	0.81
Itching & discharge (%)	6 (40)	6 (40)	1.00
Incontinence (%)	0	0	1.00

Table 2. Details of surgical treatment and secondary outcomes in both studied groups.

Surgical details	Stapled group (n=15)	Traditional group (n=15)	P value
Duration of procedure (minutes):			
Mean ±SD	35±3.2	38±2.4	<0.007**
Duration of hospital stay (days):			
Mean ±SD (range)	1.09±0.3 (1-2)	2.8±0.06 (1-4)	<0.0001**
First bowel sound:			
In hospital / after discharge(%)	8 / 7 (53.3 / 46.7)	6 / 9 (40 / 60)	0.72
Early postoperative complications:			
Minor bleeding (%)	3 (20)	4 (26.7)	0.81
Partial fecal incontinence (%)	2 (13.3)	1 (6.7)	0.89
Urine retention (%)	1 (6.7)	1 (6.7)	1.00
Late postoperative complications:			
Anal stenosis (%)	0	1 (6.7)	1.00
Prolapse recurrence (%)	1 (6.7)	2 (13.3)	0.89
Fissure (%)	1 (6.7)	0	1.00
Persistence pain (%)	3 (20)	1 (6.7)	0.60
Recurrent bleeding (%)	0	0	1.00
Hemorrhoidal thrombosis (%)	0	0	1.00
Persistent incontinence (%)	0	0	1.00

Table 3. Outcome data for pain scores and the consumption of analgesia in both studied groups.

Outcome data	Stapled group (n=15)	Traditional group (n=15)	P value
Average pain by VAS:			
Mean ±SD	2.5±0.5	7±2.3	<0.0001**
Average pain by VAS in females:			
Mean ±SD	3.2±0.3	4.9±1.0	0.002**
Average pain by VAS in males:			
Mean ±SD	3.8±0.7	5.9±1.5	0.0018**
Injections of opiates:			
None (%)	11	5	
One (%)	3	6	0.033*
Three (%)	1	3	
Four (%)	0	1	

Table 4. Follow-up of both studied groups regarding patients' satisfaction and returned to normal activities.

Patients satisfaction	Stapled group (n=15)	Traditional group (n=15)	P value
At 1 month follow up:			
Unsatisfactory (%)	5 (33.3)	6 (40)	
Satisfactory (%)	2 (13.3)	2 (13.3)	0.78
Good (%)	2 (13.3)	3 (20)	
Excellent (%)	6 (40)	4 (26.7)	
At 3 months follow up:			
Unsatisfactory (%)	1 (6.7)	1 (6.7)	
Satisfactory (%)	1 (6.7)	3 (20)	1.00
Good (%)	4 (26.7)	5 (33.3)	
Excellent (%)	9 (60)	7 (46.7)	
Return to normal activity:			
At 10 days follow up:	5 (33.3)	0	
At 1 month follow up:	4 (26.7)	8 (53.3)	-
At 3 months follow up:	4 (26.7)	2 (13.3)	
After follow up periods:	2 (13.3)	5 (33.3)	
Mean ±SD	18±6.4 (8-45)	31±11.1 (14-70)	0.0005**

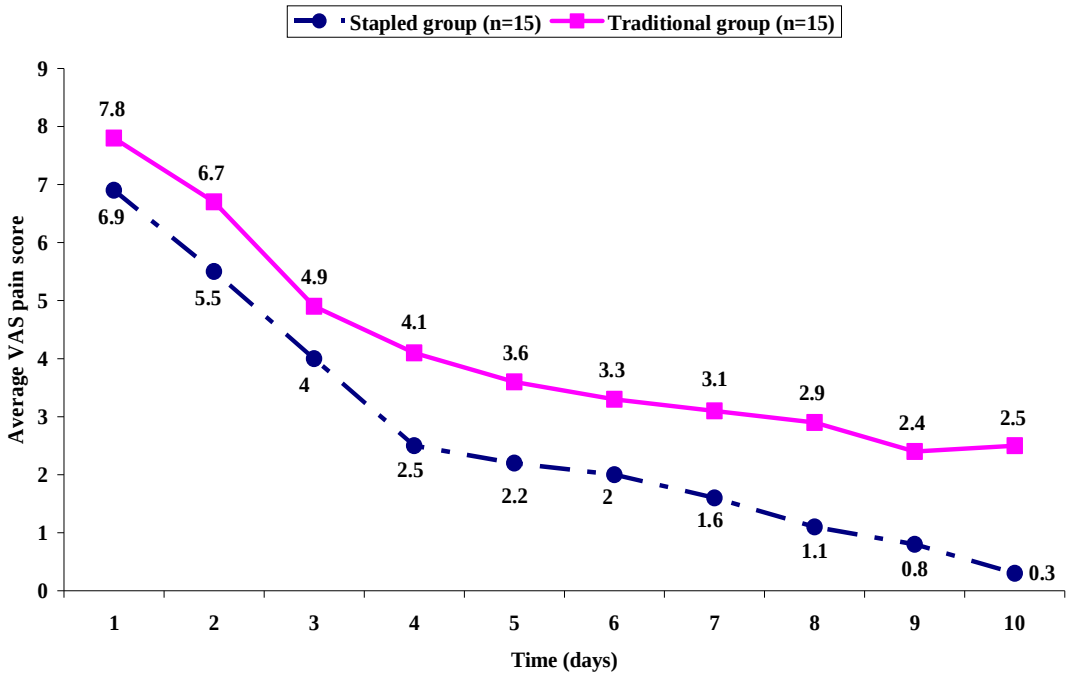

Fig 1. Average VAS pain scores at the first 10 days postoperatively in both studied groups (serial VAS assessed by ANOVA test; Fisher F-value = 117, p-value = 0.000**).

Our study was designed to assess pain as its primary endpoint and it is therefore unwise to draw conclusions about complication rates from such a small sample size. However, early and late postoperative complications in the Milligan-Morgan and stapled groups were as the same without significant difference and were similar to other published studies.[14,30-32] Assessment of long-term results and complications of the operation remains controversial, several studies reported chronic postoperative pain,[4] recurrent prolapse[9,16] and anal stenosis[6,18] but findings in other studies suggest there are no significant differences between stapled hemorrhoidectomy and traditional hemorrhoidectomy in terms of quality of life and functional outcomes.[1,20]

Our data revealed that satisfaction with symptom control was similar in both groups in all follow up periods without any significant differences. There is little information available on the functional outcome and long term symptom control after surgical hemorrhoidectomy. Although some investigators have presented large series of operative hemorrhoidectomy with no adverse functional outcomes,[1,32,33] other studies report no symptomatic follow-up.[31-34] Long-term follow-up of patients following the stapled procedure will be needed to assess the functional outcome satisfactorily. The marked differences in reported incidences of functional disturbances after traditional techniques suggests that further prospective assessment of control groups will also be of importance to define the true functional outcome of current techniques for the treatment of hemorrhoidal disease.[30-34]

Questions have been raised over the mechanism of symptom control and long term durability of stapled hemorrhoidectomy. The cause of hemorrhoids is still debated. Theories have included venous varicosities of the anus, vascular hyperplasia in the hemorrhoidal vascular tissue, and a mucosal prolapse of the anal canal mucosa resulting in elongation and kinking of the upper and middle hemorrhoidal vessels. Observation at operation confirms that this new technique does not excise the hemorrhoidal tissue at the anus, but, by excising a circumferential column of mucosa and submucosa from the lower rectum immediately above the hemorrhoids, and by then stapling the defect, the prolapsed hemorrhoidal tissue is drawn back into a more physiological position within the anal canal. In addition, the blood supply to the hemorrhoidal tissue is interrupted by excision and stapling of the submucosal layer in which these vessels run.

The theoretical benefits of the stapled intervention are threefold. First, the interruption of inflow from the superior hemorrhoidal arteries to the internal hemorrhoids may contribute to improvement of hemorrhoidal symptoms by relieving vascular congestion. Second, the partial excision of the hemorrhoidal cushions themselves reduces the size of the internal hemorrhoids. Third, the resection of rectal

mucosa reduces the tendency to prolapse and restores the internal cushions to their normal physiological position.[1,10] All patients randomized to the stapled hemorrhoidectomy have had effective symptom control (prolapse, bleeding, discharge) at 1-month and 3-months follow-up.

Further long-term follow-up of these patients is planned to determine whether these initial results are durable and to find any long-term sequelae (such as anal stenosis) of either of these techniques, but our initial results suggest that stapled hemorrhoidectomy is an effective treatment for symptomatic third and fourth degree hemorrhoids with significant advantages for patients compared with traditional hemorrhoidectomy.

In conclusion, the stapled procedure for hemorrhoids is superior to Milligan-Morgan hemorrhoidectomy in terms of postoperative pain, operative time, duration of hospital stay and return to normal activity. Early functional and symptomatic outcomes have been satisfactory and appear similar to those achieved using conventional techniques. However, long-term follow-up with respect to these factors is necessary.

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