Surgery Section

Stapled Hemorrhoidectomy; Results of a Prospective Clinical Trial in Saudi Arabia

SALMAN YOUSUF GURAYA¹, GAMAL A KHAIRY²

ABSTRACT

Objectives: This study was designed to evaluate the effectiveness of stapled hemorrhoidectomy (SH) in terms of cure of the symptoms and post-operative pain control.

Material and Methods: In this prospective clinical study, SH (Ethicon Endo-surgery, Cincinnati, OH) was performed for all patients with grade III and grade IV hemorrhoids, presenting to the surgical clinics of Ohud and Meeqat Hospitals Almadinah Almunawwarah Saudi Arabia. The results of SH were evaluated by a questionnaire focusing on the relief of symptoms, severity of post operative pain, and complications of SH.

Results: Thirty patients (21 males and 9 females); with a mean age of 39.6 years were recruited in this study. Twenty

six (86%) patients had grade III and 4 (14%) presented with grade IV hemorrhoids. Perianal prolapse was the most frequent presentation reported in 23 (76%). Mean operating time was 21.7 minutes (range; 17-36 minutes) whereas mean hospital stay was 1.9 days. Post-operative pain was tolerable (non-persistent) in 28 (93%) cases whereas 2 (7%) experienced mild pain requiring additional analgesia. Urinary retention was the most common complication found in 5 (16%) patients. All patients were cured of the hemorrhoids

Conclusion: SH is a safe, rapid, and convenient surgical remedy for grade III and grade IV hemorrhoids with low rate of complications, minimal postoepative pain, and early discharge from the hospital.

Key words: Hemorrhoids, Stapled Hemorrhoidectomy, Post-operative pain, Perianal itching

INTRODUCTION

The term "hemorrhoids" refers to anal cushions that swell, bleed, thrombose, and/or prolapse, hence causing clinical symptoms [1]. Around 5% of the general population suffers from symptoms of hemorrhoids, and one third seeks medical treatment [2]. The treatment of symptomatic hemorrhoids varies and ranges from conservative therapy involving dietary and lifestyle changes to use of various pharmacological agents and creams, office-based nonoperative procedures, and operative hemorrhoidectomy [3]. Surgery is indicated in the treatment of combined internal and external hemorrhoids or Grade III and Grade IV hemorrhoids, especially in patients who are unresponsive to other methods of treatment or those with extensive disease [4]. Only surgical remedies allow complete cure and are recommended in the treatment of Grade III and Grade IV symptomatic hemorrhoidal disease [5]. Around 10% to 15% of patients with hemorrhoids eventually require surgical treatment [2].

Historically, the most practiced surgical procedures for hemorrhoids were hemorrhoidectomies according to Milligan Morgan and Fergusson techniques [6,7]. A major innovation has been the introduction of Harmonic Scalpel, monopolar shears (Ethicon Endosurgery, Cincinnati, OH) [8] and Stapled Transanal Rectal Resection (STARR) [9]. The results of Harmonic Scalpel hemorrhoidectomy have not demonstrated consistent improvement in postoperative pain when compared with standard technique [10,11]. The STARR procedure, when complicated or failed, has a poor outcome following surgical reintervention. It requires careful patient selection to determine the associated pelvic floor pathology and pre-existent psychopathology [12]. In 1998, Longo revolutionized the surgical approach to hemorrhoids by introducing the technique of SH [13]. This technique is considered to be more expensive than classic hemorrhoidectomy, but it is less painful and allows a faster recovery [14]. The purpose of this study was to determine the convenience or difficulty in using SH, and to determine the efficacy, safety and postoperative course following this technique.

MATERIAL AND METHODS

This prospective clinical trial was conducted during the period September 2011 to September 2012 in Ohud and Meeqat Hospitals Almadinah Almunawwarah Saudi Arabia. This was a university-granted funded project and prior ethical approval was obtained from the institutional review board. All consecutive patients presenting to the surgical clinics with either grade III or grade IV hemorrhoids were incorporated in the study group. Those with post hemorrhoidectomy recurrent hemorrhoids, refusing procedure by CEEA stapler, associated perianal pathology like fissure or fistula were excluded from the study. A detailed informed consent was taken from all the patients. A routine fleet enema (sodium phosphate enema) was administered at the night before operation and single dose prophylactic injections of ciprofloxacin 200 mg intravenously and metronidazole 500 mg intravenously was administered at the time of induction. All the operations were performed by two senior consultant surgeons and the follow-up was also conducted by the same team.

Surgical technique of stapled hemorrhoidectomy

The stapled procedure was performed in lithotomy position under general anesthesia, according to the technique described by Longo [13], with slight modifications [15]. Using the purse string anoscope in the Ethicon Endosurgery stapler set, a circumferential purse string suture with 2-0 polypropylene (on a 30-mm curved, round-bodied needle) was taken starting at 3 o'clock, at least 3 cm proximal to the dentate line. A second simple stitch with the same suture material was placed at 9 o'clock at the same level as the purse string. This ensured that a symmetrical ring of mucosa and submucosa was excised when the staple gun was fired. The hemorrhoidal circular stapler was opened to its maximum position and positioned proximal to the purse string. The purse string was then tightened. The stapler was then fired and held in the same position for 20 seconds to ensure hemostasis. The stapled line was inspected for any bleeding and, if present, hemostatic sutures were taken with 4-0 Vicryl. The doughnut of the tissue

was sent for histological examination. The external hemorrhoidal components of hemorrhoids were not dealt with directly. The criteria of passage of first motion after surgery were considered necessary for discharge.

Patients were prescribed oral analgesia and stool softeners for 2 weeks. Outpatient clinic follow up were timetabled for all patients at 2 weeks and 10 weeks, and a gentle digital rectal examination was performed at both visits. An easy-to-follow standardized questionnaire was administered during their second visit (10 weeks post operative) after taking verbal consent from the participants [Table/Fig-1].

All the data was tabulated and analyzed on Microsoft Excel 2010. The information gathered from the questionnaire were collected, analyzed, and presented for the final evaluation.

Please grade in order the symptoms that most troubled you before the stapled haemorrhoidectomy in the number range of 1 to 7. Please grade your symptoms according to the number 1 to 7: with the symptom graded 1 as being the most troubling and grade 7 being the least troubling.

- 1. Pain
 - □ Constipation
 - □ Bleeding
 - □ Discharges
 - □ Prolapse/swelling
 - □ Diarrhea
 - □ Others (specify)
- Your preoperative symptoms have
- □ Resolved completely
- ☐ Resolved partially
- □ Remain Unchanged
- Worsened
- 3. Which symptoms have not resolved?
- 4. Post-operative anal pain
 - □ No persistent anal pain
 - ☐ Mild anal pain after defecation
 - □ Moderate anal pain that is tolerable
 - ☐ Severe anal pain that affects my life
- 5. Post-operative bleeding during defecation □ Does not occur
- ☐ Is mild with some occasional staining
- п Is moderate
- ☐ Is severe requiring medical attention
- 6. Still experience prolapse of piles
 - □ Never
 - ☐ Piles reduce spontaneously after defecation
 - $\hfill\square$ Piles must be pushed back into the anus after defecation
 - ☐ Piles lie outside the anus all the time
- 7. Incontinence/leakage of feces
 - □ Never
 - ☐ Unable to control gas or flatus
 - □ Unable to control liquid feces
 - ☐ Unable to control solid feces
- 8. Itching around the anus
- □ Never
- ☐ Occasionally (less than once a day)
- □ Frequently
- пAlwavs

[Table/Fig-1]: Standardized stapled hemorrhoidectomy questionnaire

RESULTS

A total of 30 patients constituted this study group; 21 (70%) males and 9 (30%) females with a mean age of 39.6 years. 26 (86%) patients had grade III while 4 (14%) presented with grade IV hemorrhoids; prolapse being the most frequent presentation reported in 23 (76%) patients. Mean operating time was 21.7 minutes (range; 17-36 minutes) whereas mean hospital stay was 1.9 days. Since Ohud and Meegat hospitals did not have day-case surgery units, the procedures were performed as elective cases after admissions in the surgical wards. Intraoperative bleeding at the stapled line was identified in 5 patients which was successfully controlled by hemostatic suture. Urinary retention was the most frequent complication found in 5 (16%) patients. Three (10%) cases complained of perianal itching after the procedure which subsided during the follow up. The results of the questionnaire are displayed in [Table/Fig-2].

Features	Mean
1. Preoperative presentation	
Pain	05 (16%)
Constipation	11 (36%)
Bleeding	21 (70%)
Discharges	10 (33%)
Prolapse/swelling	23 (76%)
Diarrhea	02 (6%)
2. Your preoperative symptoms have	
Resolved completely	27 (90%)
Resolved partially	03 (10%)
Remain Unchanged	00
Worsened	00
3. Post operative anal pain	
No persistent anal pain	28 (93%)
Mild anal pain after defecation	02 (7%)
Moderate anal pain that is tolerable	00
Severe anal pain that affects my life	00
4. Post operative bleeding during defecation	
Does not occur	29 (96%)
Is mild with some occasional staining	1 (3%)
Is moderate	00
Is severe requiring medical attention	00
5. Still experience prolapse of piles	
Never	29 (96%)
Piles reduce spontaneously after defecation	00
Piles must be pushed back into the anus after defecation	00
Piles lie outside the anus all the time	1 (3%)
6. Incontinence/leakage of feces	
Never	30 (100%)
Unable to control gas or flatus	00
Unable to control liquid feces	00
Unable to control solid feces	00
7. Itching around the anus	
Never	27 (90%)
Occasionally (less than once a day)	03 (10%)
Frequently	00
Always	00

[Table/Fig-2]: The analysis of the questionnaire from the post operative patients (No. 30)

DISCUSSION

Many theories have coined the etiopathogenesis of hemorrhoids including 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 [17,18]. SH does not excise hemorrhoidal tissue at the anus, but consists of an excision of a circumferential column of mucosa and submucosa just above the hemorrhoids, followed by a stapling of the defect. The prolapsed hemorrhoidal tissue is drawn back into a physiologic position within the anal canal. SH does not involve dissection and excision of the perianal skin, and this significantly contributes to reduced pain scores. Carrying out a mucomucous anastomosis, in a region with few sensory receptors and mucous somatic fibers, sets the theoretic premises for surgery involving a low level of postoperative pain. However, Mehigan et al., [19], Hetzer et al., [20], and Ho et al

[21], did not find significant difference in the hospital stay between the stapled and open hemorrhoidectomy groups.

Although the cost of the stapler device is still relatively high, the length of hospital stay and the period of the patient's incapacity for work are certainly shortened. The absence of local care and less postoperative pain are clear advantages to the patient. SH results in significantly lesser immediate postoperative pain than conventional excision techniques (by 2 to 3 levels on Visual Analogue Scale) and offers more comfort to the patient [22,23]. Similarly, a high level of patients' satisfaction was achieved in the current study in terms of low incidence of pain and complications. Although a study published in Lancet stated that SH incurred severe postoperative pain, those results remained controversial because they were seriously challenged by several letters to the editor and caused heated discussion with no consensus [24].

The technique of SH is considered easy to learn and quick to perform by the surgeons and operations last no more than 20 minutes, with a mean duration of 23 minutes [25]. Our study showed a mean operating time of 21.7 minutes (range; 17-36 minutes). Also we did not encounter any difficulty in mastering the technique which confirms a very short learning curve for SH. The placement of purse-string suture is crucial to the success of the operation. When this suture is placed very high, it may decrease the probability of complete reduction of hemorrhoidal prolapse; if the suture is low, 2 cm or less above the dentate line, postoperative pain is often increased, possibly because a portion of the hemorrhoids may have been included and squamous epithelium may be found in the surgical specimen [26]. Based on the same premise, in the present study, the proximal suture was placed 3 cm above the dentate line resulting in less post operative pain.

A randomized controlled trial compared the early and mid-term results of stapled versus open hemorrhoidectomy reported that the mean operative time was shorter in the stapled group 24.28 minutes (4.25) versus 45.21 minutes (5.36) in the Milligan-Morgan group (p \leq 0.001) (15). On the same note, the blood loss, pain scores and requirement of analgesics was significantly less in the stapled group. Mean hospital stay was 1.24 days (0.62) and 2.76 days (1.01) (p \leq 0.001) in the stapled and open group, respectively. Only 88.1% of patients were satisfied by the open method compared with 97.6% after the stapled technique. The results of the present study are in clear agreement with the reported literature.

The overall complication rate of SH is estimated to be between 12% and 36.4% [27,28] as compared to higher complication (rates (19-46%) of open hemorrhoidectomy [29]. Complications following SH are divided into early (within one week from surgery) and late (one week from surgery) complications. Early complications include bleeding, constipation, urgency defecation, pain, urinary retention, dehiscence of the suture and rectal perforation with sepsis. Main late complications are anal stenosis, pruritus, urgency and anal pain. In the present study, although the overall complication rate was 23%, majority of the complications were mild and were resolved during the follow up. Persistent pain after SH is considered chronic when lasting one week after surgery and it seems that the majority of patient recovers from it [12,27,30]. Prevalence of persistent pain after SH ranges from 1.6% to 31% [31]. Lelpo B et al., reprted 14.3% rate of persistent pain after SH while our study showed a rate of 7% which is still within the reported range [32]. Urinary retention is a common complication of anorectal surgery with an incidence between 1.5 and 32% [33]. In our experience, urinary retention occurred in 16% of cases. The causes of urinary retention are uncertain, but perioperative fluid intake and perioperative pain are the possible precipitating factors [34]. Septic complications including pelvic sepsis after SH have been reported in the literature [35,36] but no such complication occurred in the present study. One theory indicated that the firing of the stapler enables gas-producing organisms in the rectal lumen to enter the pararectal space [37].

LIMITATIONS

The study group is quite small and further similar prospective clinical trials are required to validate the findings in Saudi Arabia.

CONCLUSION

Treatment of grade III and grade IV hemorrhoids with SH offers a safe and effective surgical alternative. The procedure has few post operative complications, short hospital stay and minimal perianal pain.

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PARTICULARS OF CONTRIBUTORS:

- Professor, Department of Surgery, College of Medicine Taibah University, Almadinah Almunawwarah Saudi Arabia.
- 2. Professor, Department of Surgery, College of Medicine Taibah University, Almadinah Almunawwarah Saudi Arabia.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Prof. Salman Yousuf Guraya, FRCS, Cert MedEd (Dundee), Consultant Minimally Invasive Surgeon, College of Medicine Taibah University, Almadinah Almunawwarah Saudi Arabia.

E-mail: drsyg7@yahoo.com

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