

Post-operative Complications of stapled versus Ferguson Hemorrhoidectomy at Mulago Hospital. A Randomized Comparative Study.

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Background: Hemorrhoids are a common anorectal condition. New surgical treatments have led to a reappraisal of hemorrhoid disease over the last few decades and despite a range of treatment modalities, the options are limited in their effectiveness and can lead to a number of complications. This study set out to compare post operative complications between stapled haemorrhoidopexy (SH) and Ferguson haemorrhoidectomy (FH) for patients with Grade III and IV in Mulago National Referral and teaching Hospital.

Methods: Following ethical approval 48 consenting participants with Grade III/IV hemorrhoids were randomized to either FH or SH under regional anesthesia on 1:1 allocation. Early and short term post-operative complications were analyzed. .

Results: We enrolled 24 participants in each arm with equal sex allocation and mean age of 39 years with 100% follow up. There was largely no difference in early and short term complications between FH and SH save for bleeding in the short term follow up which occurred more frequently in the FH group (p-value 0.045). The bleeding was mild and did not require transfusion.

Conclusion: There was no major difference in short term complication rates between SH and FH. SH is a safe alternative to FH in Mulago Hospital.

Key words: Ferguson hemorrhoidectomy. Stapled hemorrhoidopexy. Hemorrhoids.PPH, Mulago Hospital, colorectal surgery

Introduction

Worldwide Hemorrhoidal disease is one of the most frequent anorectal disorders ¹. In Uganda hemorrhoids are the second commonest benign anal condition, M : F 2.5:1 ^{2,3}. Treatment includes; Conservative, minimally invasive procedures and Operative procedures such as Ferguson hemorrhoidectomy and Stapled haemorrhoidopexy ⁴. SH was conceived and developed in Europe, with the aim of making hemorrhoidectomy a less painful and yet quick and safe procedure⁵. In spite of that, reports of high pain scores and adverse complications have been reported ⁵. Further research is required to study the complications and safety of SH to inform its use in our in our setting. We therefore sought to compare the early and short term post operative outcomes between SH and FH at our hospital.

Methods

Following Ethical approval this single blinded RCT was conducted at Mulago National Referral and Teaching Hospital from August 2014 to January 2015. Sample size of 48 was calculated using a statistical method by Pocock(6). Participants ≥ 18 years with Grade III/IV hemorrhoids and no other anorectal pathology were conservatively recruited from the colorectal clinic. Simple randomization was done upon entering theatre by selecting a coupon from a sealed opaque envelope in a ratio of 1:1. Pre-

operative preparation included a 3 day course of low residue diet and an enema on the morning of surgery. Operations were performed in lithotomy position under regional anesthesia according to Longo(7) for SH and Ferguson(8) for FH by the surgical resident under supervision of a more experienced surgeon. Post operatively all respondents received analgesics, antibiotics and laxatives and were prospectively followed up for 28 days. Existence of short and intermediate term complications; - bleeding, urinary retention, pain, wound sepsis, anal stricture, incontinence, constipation were noted. Severity of pain was scored with the aid of a visual analogue scale ranging from 0-10 (10cm line)(9).

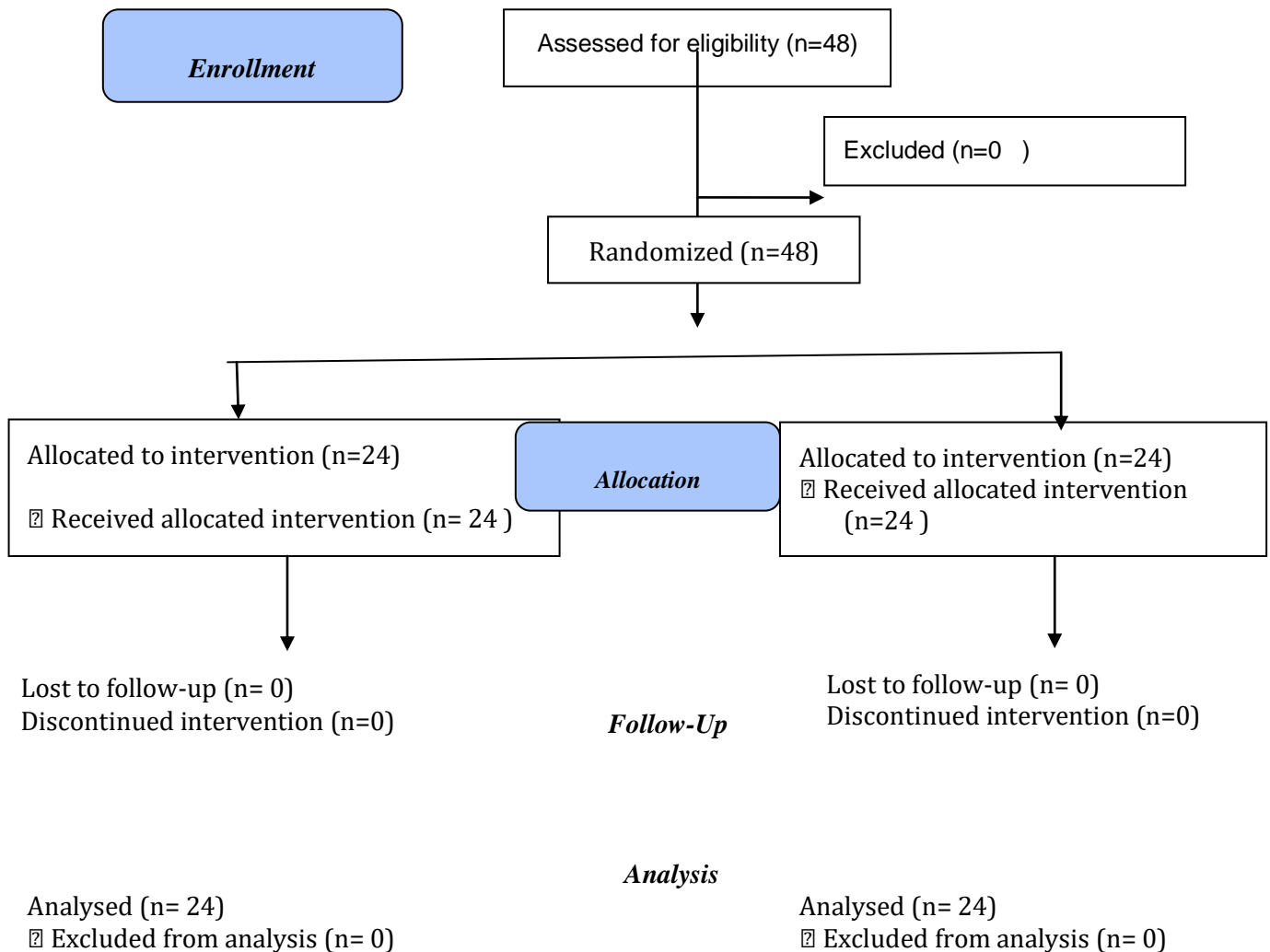
Results

We enrolled 48 participants to this randomized trial with 100% follow up.

Participant

Flow

Diagram



Data were double entered into EPIDATA Version 3.1 and exported to STATA Version 11.2 for analysis. The continuous variables were tested with Shapiro Wilks tests for normality and if normally distributed, two sample student t-test with unequal variance was used to establish whether there is a difference between the means of stapled hemorrhoidopexy and Ferguson hemorrhoidectomy. For the categorical variables, non-parametric methods were utilized for a two sample proportion specifically the Wilcoxon rank sum test to establish whether there was a difference in the complications within the groups. P-values < 0.05 at a 95% confidence level were considered statistically significant.

Table 1: Baseline demographic and clinical characteristics of the study population

Characteristic	SH (N=24)	(%)	FH (N=24)	(%)	P - Value
Mean age in years (SD)	39.5(SD9.9)		38.4(SD13.5)		0.734
Gender					
Male	13	44.8	16	55.1	0.381
Female	11	57.9	8	42.1	
Occupation					
None	2	66.7	1	33.3	0.059
Civil duties	7	63.6	4	36.4	
Casual laborer	9	56.2	7	43.8	
Housewife	2	40.0	3	60.0	
Business	4	36.4	7	63.6	
Student	0	0.0	2	100	
Smoking					
No	22	53.7	19	46.3	0.225
Yes	2	28.6	5	71.4	
HIV/AIDS					
No	23	52.3	21	47.7	0.301
Yes	1	25.0	3	75.0	
Diabetes					
No	23	48.9	24	51.1	0.317
Yes	1	100	0	0.0	
Grade of hemorrhoid					
III	18	50.0	18	50.0	1
IV	6	50.0	6	50.0	
Body Mass Index					
< 18.4kg/m ²	4		2		0.322
18.5 – 25 kg/m ²	16		16		
> 25 kg/m ²	4		6		
Chronic Constipation					
No	13	65.0	7	35.0	0.082
Yes	11	39.3	17	60.7	

NB Wilcoxon rank-sum (Mann-Whitney) test was used for P-Values while α Mean and SD.

The two study arms were similar in baseline demographic and clinical characteristics.

Table 2. Comparison of the early post-operative complications between SH and FH.

Complication	SH (N=24)	(%)	FH (N=24)	(%)	P - Value
Bleeding					
No	20	83.3	20	83.3	1
Yes	4	16.7	4	16.7	
Urinary retention					
No	22	91.7	24	100	0.153
Yes	2	8.3	0	0.0	
Pain (mean VAS)	3.75		4.35		0.67

Table 3. Comparison of the short term post-operative complications between SH and FH.

Complication	SH (N=24)	(%)	FH (N=24)	(%)	P - Value
Bleeding					
No	16	66.7	9	37.5	0.045
Yes	8	33.3	15	62.5	
Wound Sepsis*					
No	22	91.7	23	95.8	0.555
Yes	2	8.3	1	4.2	
Stool Incontinence					
No	24	100	22	91.7	0.153
Yes	0	0.0	2	8.3	
Constipation					
No	21	87.5	17	70.8	0.157
Yes	3	12.5	7	29.2	
Skin Tags					
No	16	66.7	17	70.8	0.758
Yes	8	33.3	7	29.2	
Pain on defecation					
No	22	91.4	22	91.4	1
Yes	2	8.3	2	8.3	
Persistence of hemorrhoids					
No	21	87.5	23	95.8	0.976
Yes	3	12.5	1	4.1	

NB Wilcoxon rank-sum (Mann-Whitney) test was used for P-Values. Follow up for 28 days.

There was a significantly more occurrence of bleeding in the SH than the FH group. The bleeding that was recorded however was mild and did not require blood transfusion.

Discussion

This randomized trial revealed there was largely no difference in early and short term complications between FH and SH save for bleeding in the short term follow up which occurred more frequently in the FH group. Our study recruited 48 patients with grade III and IV hemorrhoids with a male: female ratio of 1:1 and a mean age of 39 years. This population is comparable in characteristics to that studied by Nassali et al in the same institution some 14 years earlier.

Early Complications

In the early (first 48 hours) post operative period, there was no significant difference in pain scores, and frequency of urine retention and bleeding between FH and SH group.

Pain

Most perianal procedures including hemorrhoid surgery carry a significant amount of post operative pain. Advocates of SH have pushed for it on the account of the significantly lower post operative pain than most other procedures for hemorrhoid surgery. However in our study there was no significant difference in VAS between the FH and SH group. It is important to mention that in our study pain scores were generally low. The mean score for FH group was interestingly low at 4.35 compared to most other studies¹⁰⁻¹². One study had previously reported pain score of up to 5.6 for SH¹³. Overall, the pain score from these two procedures were low with none offering an advantage of the other as far as post operative pain is concerned.

Urinary retention

There was no significant difference in occurrence of urine retention between FH and SH group in this study. The occurrence of urinary retention after hemorrhoidectomy has been attributed to spasms of the urinary bladder that persists for about 20 hours after the operation, an excess of intra-operative IV fluids and severe post-operative pain. It is also frequently precipitated by presence of a rectal pack or tube or both¹⁴. Considering that pain scores as discussed above were generally low and not different between the groups, it follows quite expectedly that there was also no difference in occurrence of urine retention between the two. The two patients in the SH group who got urine retention were treated one, by reassurance and warm sitz bath and the other by one time urinary catheterization without further complications. In other studies too urinary retention was managed by urinary catheterization^{11, 15} however in Singer et al's study, a muscle relaxant was prescribed to relieve the spasm of levator ani muscle in addition¹⁶.

Bleeding

There was no difference in bleeding in the initial 48 hours post operatively between SH and FH groups. Similar findings have been reported by other authors^{17, 18}. The bleeding was mild and stopped spontaneously within the 48 hours. None of the patients required blood transfusion.

Short term post operative complications

Among the short term (28 days post operation) complications studied, only bleeding occurred more frequently in the SH group than the FH group with no significant difference in occurrence of wound sepsis, incontinence, pain on defecation, constipation, skin tags and persistence of hemorrhoids.

Bleeding

Bleeding in the short term was reported more in the FH group than in the SH group. This was minor and reported during opening of bowels. Ho reported similar findings¹¹. Bleeding may be secondary as a result of infection or as a result of constipation with hard stool opening up suture lines.

Wound sepsis

Post-operative infection and abscess formation have been reported after hemorrhoidectomy¹⁹. The incision wound in SH is hidden and attempts to reduce contamination such as sitz bath may not be effective as compared to FH. One patient in the SH group reported history of foul smelling anal discharge. A course of antibiotics was given with resolution of symptoms as was reported as in other studies²⁰⁻²⁵. Unlike in other reports there was no case of severe sepsis following SH in this study²³.

Incontinence

Incontinence of stool was reported in two patients following FH and none in SH. This difference was not statistically significant. This was however, temporary and patients recovered fully during the study period. This may have been due to overflow as patients feared to evacuate stool because of fear of pain on defecation. One patient had incontinence for only one week and recovered. She had Grade III hemorrhoids. The other was male and had Grade IV hemorrhoids and incontinence persisted until the third week. Ho reported incontinence to gas following SH²⁶ while Senogore reported more incontinence in the FH group¹³.

Persistence of hemorrhoids and Skin tags

Persistence of hemorrhoids was observed more in the SH group than FH group. Since SH does not address external components, external hemorrhoids, including Grade IV internal hemorrhoids, may persist. Singer in his study reported that manufacturer did not recommend SH on Grade IV hemorrhoids¹⁶. Where there is a large volume of prolapsing hemorrhoidal tissue, the stapling technique may fail to remove adequate volume of the prolapsing tissue leading to such persistence²⁷. Also, skin tags that are not excised as part of the SH procedure may persist for longer periods. Some studies have suggested that these tags eventually regress in the long run and perhaps patients may be counseled to that effect^{11, 28-30}. This points out a further need for clear selection criteria for patients who may benefit the most from SH.

Limitations

The operations in this study were performed by a junior surgeon who was new to SH technique albeit under the supervision of more experienced surgeons. However, considering that SH is relatively new in the region, this is a situation many a surgeon will find themselves in and thus the results of this study remain applicable to them.

Conclusion

This randomized study with short term follow up showed that there is generally no difference in complication rates between stapled hemorrhoidopexy and Ferguson hemorrhoidectomy in our setting. Even the bleeding in the short term which occurred more frequently in the SH group was mild and resolved without any further management. SH therefore is

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