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STAPLED HEMORRHOIDECTOMY;

IS IT REALLY SUPERIOR TO CONVENTIONAL HEMORRHOIDECTOMY? A LONG-TERM ANALYSIS

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ABSTRACT: Stapled hemorrhoidectomy has been recently advocated as a procedure of choice for prolapsed hemorrhoids. Studies consistently show that this newer technique is associated with less postoperative pain and may be cost effective; however others have questioned its more generalized application. Study Design: Randomized controlled trial. Setting: Tertiary hospital settings at Services Institute of Medical Sciences, and Ittefag Hopsital Trust, Lahore. Period: 2002 to 2007. Patients & Methods: Short and long-term outcomes of stapled and conventional hemorrhoidectomy were compared. 538 patients with Grade II, III & IV hemorrhoids were randomized to undergo either stapled (n=251) or conventional hemorrhoidectomy (n=287). Perioperative and postoperative complications, length of hospital stay, patient satisfaction and long-term recurrence rates for at least 5 postoperative years were analyzed. Results: In the short term, patients undergoing stapled hemorrhoidectomy (n=251) were associated with less operative time, less postoperative pain, shorter hospital stay and acceptable overall first post-op year patient satisfaction score as compared to patients undergoing conventional hemorrhoidectomy (n=287). In the long-term however; there were significantly higher rates of recurrence and tenesmus in stapled group. Over the postoperative years, these rates of complications increased significantly among patients undergoing stapled hemorrhoidectomy. The subgroup analysis showed that Grade IV patients undergoing stapled hemorrhoidectomy had higher long term postoperative complication rate and poor patient satisfaction scores as opposed to Grade III hemorrhoid patients and had to undergo secondary surgical interventions. Conclusions: The stapled hemorrhoidectomy is an acceptable treatment for selected patients with Grade II & III hemorrhoids in terms of less postoperative pain and shorter hospital stay at expense of mildly higher long- term recurrence rate; however for grade IV hemorrhoids stapled hemorrhoidectomy is clearly is an 'under treatment' in the long-term as opposed to conventional hemorrhoidectomy.

Key words: Stapled Hemorrhoidectomy; Milligan Morgan Hemorrhoidectomy; Ferguson Hemorrhoidectomy; Long-term analysis

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INTRODUCTION

Hemorrhoids, abnormally dilated tortuous anal cushion veins which lead to fresh bleeding per rectum, still remain an important surgical problem.^{1,2} Traditional treatments include dietary advice, Mitchell's Injection Sclerotherapy, Banding and Open Milligan Morgan's or Closed Ferguson's Hemorrhoidectomy. These hemorrhoidectomy techniques have stood the test of time and still remain gold standard.^{3,4}

Recently, stapled hemorrhoidectomy (SH) has been increasingly coined as a treatment of choice for prolapsing hemorrhoids as an alternative to Ferguson and Milligan–Morgan techniques.¹⁻⁶ This newer technique has been received with much enthusiasm because it could offer patients a significantly improved postoperative comfort level.¹⁻⁹ This is attributable to the fact that the mucosal incision and staple lines are positioned well above the dentate line, and the highly sensitive perianal skin. Many randomized trials and their resultant meta-analysis have demonstrated less postoperative pain and earlier return to work in patients having undergone stapled hemorrhoidectomy, compared with conventional hemorrhoidectomy.¹⁻⁹ Although the short term benefits have been clearly documented in multiple clinical trials comparing these two techniques; questions have been raised regarding long term outcome of this newer approach.¹⁰⁻¹² Recent studies including a recent meta-analysis suggest that long term recurrence rates are higher with stapled hemorrhoidectomy as opposed to the conventional hemorrhoidectomy.¹⁰⁻¹²

This study is a prospective randomized trial comparing the patients undergoing stapled hemorrhoidectomy vs. conventional hemorrhoidectomy to answer particular questions regarding its efficacy and failure rates on a longterm follow up. To our knowledge this is the largest trial till now comparing the long term outcomes spanning over 5 years of follow up.

PATIENTS & METHODS

This study was conducted in tertiary hospital settings at Services Institute of Medical Sciences, and Ittefaq Hopsital Trust, Lahore, Pakistan from 2002 to 2007 after approval from ethical committees. A total 697 patients with prolapsing hemorrhoids were initially enrolled in study after an informed consent in a blinded fashion. The patients with significant co-morbidities or other causes of bleeding per rectum, proctalgia or perianal pathology were not included in the study. Due to various causes including deaths, 159 patients were excluded from the study as the long term follow up was lost. Total 538 patients were randomized by lottery method to undergo either stapled hemorrhoidectomy (SH; n=251) or conventional hemorrhoidectomy (CH; n=287). Per-operatively blood loss was monitored and operative time was also recorded. During early postoperative period, pain was monitored with Visual Analogue Scoring (VAS) on a scale of 0-10. Postoperative clinical visits, complications and hospital stay were recorded. The long term follow up was also done on yearly basis. Complications were recorded and further surgical decisions were made for any secondary surgical intervention required subsequently. Patient satisfaction with surgical intervention was assessed by a modified questionnaire PSQ-18 developed by RAND corporation. The record of long term complications was also made along with mode of intervention or type of intervention required.

Data Collection and Statistical Analysis

Data was retrieved from all the patients at each clinical visit and were processed, plotted and tabulated as described in detail in the legends of the figures of this report. Appropriate statistical analysis was done using SPSS version 12 (Chicago, IL) and also has been described along with figure legends.

Open hemorrhoidectomy technique

Patients were placed in the lithotomy position after induction of general anesthesia. The external and internal hemorrhoidal components were excised entirely from the apex to the base with electrocautery. The pedicle was suture-ligated, and necessary hemostasis was achieved with diathermy coagulation. One to 3 hemorrhoidal cushions were excised after ligation with 2–0/ 1-0 Vicryl (Ethicon). A packing was left in the anal canal. A perianal block was administered with 15 mL of 0.5% bupivicaine with 1:200 000 epinephrine. Patients were discharged subsequently on the following day or a day after. Follow-up at 2 weeks was arranged for an office visit, interview and perineal examination.

Stapled hemorrhoidectomy technique

Patients were given Ceftriaxone 1g and metronidazole 500 mg intravenously in the operating room and were placed in the lithotomy position. The procedure was performed with the PPH[™] (Ethicon Endosurgery[®], Cincinnati, Ohio) according to instructions of the manual. Briefly, pursestring anoscope was gently inserted into the anus to reveal the hemorrhoidal cushions. The gap in the anoscope was rotated around the circumference of the anus for the application of the pursestring stitch. This was done with a 2-0 PDS[®] (Ethicon, Inc., Somerville, NJ) suture, and careful attention was paid to include only mucosa and submucosa in each bite. The pursestring was started and ended at the 6 o'clock (posterior) position, was placed 3-4 cm proximal to the dentate line In female patients, a finger was inserted in the vagina to ensure that the posterior wall was not drawn into the head of the stapler. The stapler was fired and held closed for 3 minutes to provide hemostasis. The specimen was retrieved from the stapler and was examined to ensure that a complete donut of mucosa was obtained. The purse-string anoscope was reintroduced and rotated to visualize the staple line for proper hemostasis. If present, bleeding points were oversewn with a figure-of-8 stitch with a 3–0 Vicryl[®] (Ethicon, Inc., Somerville, NJ) suture. The anal canal was packed and a perianal block was administered with 15 mL of 0.5% bupivicaine with 1:200 000 epinephrine.

RESULTS

In this clinical trial out of 697 initially enrolled patients, 159 patients were excluded because of loss of follow up either due to death, migration or co-morbidities which could act as confounding variables (Figure-1).





Rest of 538 patients was randomized to undergo either stapled hemorrhoidectomy (SH) or conventional hemorrhoidectomy (CH). Patients undergoing stapled hemorrhoidectomy and conventional hemorrhoidectomy had a mean age of 45 (range 31-65) and 48 (33-59) respectively (Table-I). Out of 251 patients undergoing stapled hemorrhoidectomy 37, 142 and 72 had grade II, III and IV hemorrhoids respectively, while 287 patients undergoing conventional hemorrhoidectomy 8, 130 and 149 patients had grade II,III, IV hemorrhoids respectively (Table-I).

Average operative time for patients undergoing stapled hemorrhoidectomy was significantly (p 0.04) lower as opposed to conventional hemorrhoidectomy (35.5 ± 15 vs. 45.6 ± 17). Similarly, postoperative hospital stay (1.2 ± 0.5 vs. 2.1 ± 0.9) and postoperative clinical visits (2.2 ± 0.94 vs. 4.2 ± 2.1) were lesser in stapled group (SH) as opposed to conventional hemorrhoidectomy (CH). Per-operative bleeding was not significantly different between the two groups (p 0.12).

Postoperative complications were analyzed at various time points. Stark contrast noted between the two groups was lower postoperative pain associated with stapling technique. The postoperative pain was significantly lower at 4, 24 hours and at the time of first defecation (Figure-2). Other short term complications like hemorrhage, urinary retention, local infection and perianal sepsis were not statistically different (Table-III). Among long term complications listed in Table III, only tenesmus (14.4% vs. 8.4%; p value <0.0003), recurrent bleeding (5.9% vs. 2.1%; p <0.034) and recurrent prolapse (15.5% vs. 3.1%; p <0.0012)

		Treatment Group; Number (n=538)						
	Sta	Stapled Hemorrhoidectomy N=251			Conventional Hemorrhoidectomy N=287			
	Grade II	Grade III	Grade IV	Total	Grade II	Grade III	Grade IV	Total
Male	15	57	32	104	4	52	60	116
Female	22	85	40	147	4	78	89	171
Total	37	142	72	251	8	130	149	287
Mean Age (Range)		45 (31-65)			48 (33-59)			

Table-I. Patient demographics and severity of disease for conventional (CH) and stapled hemorrhoidectomy (SH)

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were significantly higher in stapled group. Other long-term postoperative complications like incontinence, anal stenosis, skin tags, prurirtis ani, anal fissure, anal fistula and fecal urgency were not found to be statistically different in two groups.

Table-IV shows the comparison of the long-term postoperative complications in conventional and stapled hemorrhoidectomy at sub group level. In grade III hemorrhoids undergoing two different treatment strategies, tenesmus (12% vs. 6.1%; p <0.001), and recurrent prolapse (12.6%

vs. 3.8%; p<0.004) were significantly higher in stapled group compared with conventional group. The most dissatisfied group was with grade IV hemorrhoids undergoing stapled hemorrhoidectomy. In this group, tenesmus (23.6% vs. 6.7%; p<0.05), recurrent bleeding (8.3% vs. 3.3%; p< 0.05) and recurrent prolapsed (29.1% vs. 5, 4%; p<0.05) were markedly higher as opposed to conventional hemorrhoidectomy.

The non-responders to primary surgical intervention had to undergo secondary surgical intervention/s (Table-V).

Operative time, admission ra	te, length of hospital stay for conventi	onal and stapled hemorrhoidectomy		
	Treatment Group (n=538)			
	Stapled Hemorrhoidectomy N=251	Conventional Hemorrhoidectomy N=287		
Average Operative Time (min)	35.5±15	45.6±17*		
Per-operative bleeding (ml)	19.6±6.1	23.5±9.2		
Postoperative Clinic Visits	2.2±0.94	4.2±2.1*		
Length of Hospital Stay (days)	1.2±0.5	2.1±0.9*		
Mann Whitney U Tes	y is associated with less operative, sho Values have been expressed as Means t was employed to find significant different *p <0.05 was considered statistically significant	nce between the two groups.		



Figure 2. Stapled Hemorrhoidectomy is associated with reduced postoperative pain.

Postoperative Pain Scores measured with Visual Analogue Scoring (VAS) on a scale of 0-10. The measurements were done at 4, 24 hours and at the time of first defecation. Values are expressed in form of inter-quartile ranges. Mann Whitney U t-test was employed to find the significant difference between the two groups and P < 0.05 was considered statistically significant.

	Treatment Group (n=538)			
	Stapled Hemorrhoidectomy N=251	Conventional Hemorrhoidectomy N=287	P Value	
Grade II Hemorrhoids				
Tenesmus	3/37 (8.1%)	1/8 (12.5%)	NS	
Bleeding	1/37 (2.7%)	0/8 (0%)	NS	
Recurrent Prolapse	2/37 (5.4%)	0/8 (0%)	NS	
Grade III Hemorrhoids				
Tenesmus	17/142 (12%)	8/130 (6.1%)	<0.001*	
Bleeding	11/142 (7.7%)	4/130 (3.1%)	NS	
Recurrent Prolapse	18/142 (12.6%)	5/130 (3.8%)	<0.004*	
Grade IV Hemorrhoids				
Tenesmus	17/72 (23.6%)	10/149 (6.7%)	0.000*	
Bleeding	6/72 (8.3%)	5/149 (3.3%)	0.02*	
Recurrent Prolapse	21/72 (29.1%)	8/149 (5.4%)	0.000*	
Over all	96/251 (38.2%)	41/287 (14.2%)	0.0005*	

Table-IV. The comparison of long term postoperative complications in Conventional (CH) and Stapled Hemorrhoidectomy (SH) at subgroup level- The values have been expressed on form of percentages. The significant difference between the two groups was analyzed by Fisher's Exact Test and p < 0.05 was considered statistically different. NS (Non-significant)

	Treatment Group (n=538)				
	Stapled Hemorrhoidectomy N=251	Conventional Hemorrhoidectomy N=287	P Value		
Grade II Hemorrhoids					
Redo -Hemorrhoidectomy	0	0	NS		
Banding	1/37 (2.7%)	1/8 (12.5%)	Small sample		
Injection Sclerotherapy	0	0	size no significant difference		
Miscellaneous¶	1/37 (2.7%)	0			
Grade III Hemorrhoids					
Redo -Hemorrhoidectomy	8/142 (5.6%)	3/130 (2.3%)	<0.03*		
Banding	12/142 (8.4%)	2/130 (1.5%)	<0.002*		
Injection Sclerotherapy	9/142 (6.3%)	4/130 (3.07%)	<0.04*		
Miscellaneous¶	4/142 (2.81%)	5/130 (3.84)	<0.13		
Grade IV Hemorrhoids					
Redo -Hemorrhoidectomy	16/72 (22.2%)	2/149 (1.34%)	0.0001*		
Banding	8/72 (11.11%)	4/149 (2.68%)	0.001*		
Injection Sclerotherapy	3/72 (4.1%)	3/149 (2.01%)	0.006*		
Miscellaneous¶	8/72 (11.11%)	6/149 (4.02%)	0.0045*		
Overall	72/251 (28.68%)	30/287 (10.45%)	0.0007*		

Table V. The comparison of additional procedures done in Conventional (CH) and Stapled Hemorrhoidectomy (SH) at subgroup level- The values have been expressed on form of percentages. The significant difference between the two groups was analyzed by Fisher's Exact Test and p < 0.05 was considered statistically different.

¶ Miscellaneous procedures included incision and drainage, debridement, sphincterotomy, dilatation, fistulectomy etc.

The overall secondary intervention rate was significantly higher (28.68% vs. 10.45%; p0.0007) in stapled group vs. conventional hemorrhoidectomy group in non or partial responders. The patients with grade III hemorrhoids not responding or

partially responding to primary intervention had to undergo secondary surgical intervention significantly higher (Redo hemorrhoidectomy 5.6% vs. 2.3%; banding 8.4% vs. 1.5%; injection sclerotherapy 6.3% vs. 3.07%) in stapled group as opposed to conventional hemorrhoidectomy. The most affected group of non-responders had grade IV hemorrhoids that underwent stapled hemorrhoidectomy. Redo hemorrhoidectomy (22.2% vs. 1.34%), banding (11.1% vs. 2.68%), injection sclerotherapy (4.1% vs. 2.01%) and miscellaneous surgical procedures (11.1% vs. 4.02%) were done in this group significantly higher as opposed to conventional hemorrhoidectomy.

Patient Satisfaction Scores with procedure done was assessed annually. The overall after first postoperative year patient satisfaction score (7.3 ± 1.2 vs. 8.2 ± 0.9) was significantly lower (p0.045) in stapled hemorrhoidectomy as opposed to conventional hemorrhoidectomy. The subgroup analysis convincingly showed that patients having grade IV hemorrhoids were more dissatisfied with the procedure as opposed to grade III hemorrhoids undergoing stapled hemorrhoidectomy (Figure-3).



Figure 3. Patient Satisfaction Score after 1st year after Conventional (CH) and Stapled Hemorrhoidectomy (SH). The scores have been plotted in form of Means±SD and Fisher's Exact Test was applied to see the significant difference between the groups. P value <0.05 was considered statistically significant.

The conventional hemorrhoidectomy was uniformly the most favored procedure in terms of long-term recurrence and patient satisfaction. Most of the secondary interventions were done during second year postoperatively. Patient satisfaction scores for responders to stapled hemorrhoidectomy were persistently remained lower as opposed to undergoing conventional hemorrhoidectomy both in grade III and IV hemorrhoid patients. The non-responders had to undergo secondary interventions to which they responded well-meaning thereby that especially for grade IV hemorrhoids stapled hemorrhoidectomy is an under treatment.

DISCUSSION

This large Multicenter randomized trial was primarily aimed at comparing long term outcomes of stapled and conventional hemorrhoidectomy in an era where this newer technique is rapidly replacing the conventional one. There is general consensus spanning over many randomized trials that in immediate postoperative period, stapled hemorrhoidectomy has significant advantages over conventional technique.¹⁻⁶ In agreement with these reports, this study clearly shows that stapled hemorrhoidectomy is associated with lesser operative time, blood loss, postoperative pain, hospital stay and post operative visits.¹⁻⁹ Other commonly seen postoperative complications are also not significantly different between these groups. Recently, however, few authors have raised some serious questions about the long term results of this technique and its generalized applications over almost all grades of the prolapsing hemorrhoids.¹⁰⁻¹² This trial has clearly addressed these issues in a systematic way.

The study has shown that stapled hemorrhoidectomy one year postoperatively has significantly higher rates of tenesmus, recurrent bleeding and recurrent prolapse as opposed to conventional technique (38.2% vs. 14.2%). Similarly, these patients with late or persistent complications (non or partial responders to primary surgical intervention) had to undergo additional secondary surgical interventions too (28.7% vs. 10.5%). Patient satisfaction with the procedure was also significantly lower with stapled technique signifying the superiority of the conventional technique in the longer run. Interestingly, this is in agreement with a recent meta-analysis published by Giordano et al.13



Figure 4. The long-term comparison of patient satisfaction scores between Conventional (CH) and Stapled Hemorrhoidectomy (SH) at subgroup level

The figure shows the comparison of patient satisfaction scores with Grade III & IV hemorrhoids who either responded to primary intervention (top panel) or underwent secondary intervention as they were non responders to the primary intervention. The significant difference between the two groups was analyzed by Fisher's Exact Test and p< 0.05 was considered statistically different.



The subgroup analysis of the patients undergoing these two forms of treatment further highlights that grade III hemorrhoids can be managed with stapled technique with acceptable long term recurrence rates however for the grade IV hemorrhoids stapled hemorrhoidectomy is associated with very high recurrent prolapse, tenesmus and recurrent bleeding making it a less favorable technique as opposed to the conventional hemorrhoidectomy. This is further reflected by the fact that these patients require secondary interventions to which they respond effectively. Improvement in patient satisfaction scores after secondary intervention further corroborates these findings.

Grade II hemorrhoids at large are managed on our set up by banding. The patients who agreed for either of the above mentioned technique responded well to it without any apparent difference. Due to smaller sample size, however this comparison remained statistically invalid.

The reason why stapled technique may be used as an alternative to conventional hemorrhoidectomy for grade III hemorrhoids but not for grade IV hemorrhoids lies within pathological anatomy. Stapled technique primarily rectifies mucosal disease and in grade IV hemorrhoids the problem is no longer mucosal alone and patient would often say, "Dr. I am half fixed".¹¹ For these reasons the stapled technique is being modified to increase the area of mucosal resection for better results. One modification is use of EEA instead of PPH and other in application of double purse string suture rather a single with improved outcome.¹⁴

In future, however, with improved technique and instrumentation, the use of this technique holds promise of its broader application but at the moment long term outcomes are best met with conventional technique. In conclusion, conventional hemorrhoidectomy is superior to stapled hemorrhoidectomy in terms of long term outcomes. Stapled hemorrhoidectomy can be good alternative for patients with grade III hemorrhoids with a bit higher recurrence rate, however, for grade IV hemorrhoids stapled hemorrhoidectomy although provides short term benefit over the conventional technique but is clearly under treatment in the long run.

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AUTHORSHIP AND CONTRIBUTION DECLARATION