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Randomized comparison of stapled haemorrhoidopexy and open haemorrhoidectomy

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ABSTRACT

Background: Surgical management of haemorrhoids is reserved for stage III and IV haemorrhoids. Both Milligan-Morgan technique (CH-Conventional Haemorrhoidectomy) and stapled haemorrhoidopexy technique are used as surgical therapy. Our prospective, comparative study of conventional haemorrhoidectomy versus stapled haemorrhoidectomy was designed in present institution.

Methods: This prospective randomised comparative study was carried out in present Surgery Dept from July 2016 to December 2017 with total 60 sample size. All data were analysed according to applicable statistical methods. The results were compared to previous studies so as to arrive at a conclusion.

Results: The mean duration of surgery with stapled method was 30.76 ± 3.13 minutes and with conventional method was 49.36 ± 4.08 minutes which was significantly high in conventional method. VAS scores for pain at 12 hours, 24 hours, 72 hours and 7 days for stapled group were 2.63 ± 0.76 , 1.66 ± 0.88 , 0.90 ± 0.71 and 0.50 ± 0.43 while that for the conventional group were 5.63 ± 0.72 , 4.56 ± 1.22 , 3.26 ± 1.25 and 2.00 ± 0.69 . At all points of time the VAS was significantly lower in stapled group. The mean duration of hospital stay of the patients with stapled method was 3.10 ± 0.75 days and with conventional method was 6.06 ± 0.94 days, which was significantly high in conventional method. The mean time to return to normal activities of the patients with stapled method was 8.16 ± 1.93 days and with conventional method was 12.60 ± 1.67 days, which also significantly high in conventional method.

Conclusions: Present study inferred that stapled haemorrhoidopexy is faster, minimally invasive for treatment of haemorrhoids as compared to Conventional haemorrhoidectomy. It is associated less pain and provides a more satisfactory alternative to Conventional surgery because of reduced hospitalisation and earlier return of patient to daily activities, with no significant differences in short term follow up.

Keywords: Hemorrhoids, Open (Milligan-Morgan) hemorrhoidectomy, Stapled hemorrhoidopexy

INTRODUCTION

Haemorrhoids are one of the most common benign anorectal problems presenting in the surgical OPD. Estimates of people in United States suffering from symptomatic haemorrhoids shows a prevalence rate of 4.4%, an approximately 10 million people. The words haemorrhoids and piles are often used synonymously but are different etymologically. Haemorrhoids comes from

Greek meaning bleeding (haima-blood, rhoid-flow) whereas piles comes from Latin 'pila' meaning ball.² According to Parks, internal haemorrhoids are saccular dilatation of terminal part of haemorrhoidal venous plexus lying in sub mucosa of the upper anal canal just above the mucocutaneous junction.³

Surgical management of haemorrhoids is reserved for stage III and IV haemorrhoids. The Milligan-Morgan

technique (CH-Conventional Haemorrhoidectomy) is the most popular and widely used technique making it the gold standard surgical therapy. But it has its drawbacks like post-operative pain; wound dressing which is required for long time including a long time required for wound healing which may take 3-6 weeks. For this reason, many people prefer conservative management over surgery.

In 1998 Longo developed the stapled haemorrhoidectomy or haemorrhoidopexy (SH-Stapled Haemorrhoidopexy), which has less post-operative pain and less wound soiling compared to conventional haemorrhoidectomy. But the long-term superiority of haemorrhoidopexy over conventional haemorrhoidectomy is yet to be established.⁴

And hence this study, a prospective, comparative study of Conventional Milligan-Morgan Haemorrhoidectomy versus Stapled Haemorrhoidectomy was designed in present institution.

METHODS

The study was a prospective, comparative, randomised study and Subjects were selected from all patients coming to the OPD of present department from July 2016 to December 2017 with total 60 sample size. Sampling Techniques by the help of computer generated random numbers by the process of randomization.

Intervention: All patients underwent a thorough history taking and clinical evaluation as per proforma. Patients with third and fourth degree haemorrhoids were selected on the basis of random number generated by the computer.

Pre-anaesthetic checkup and operative fitness were obtained for all patients. Preoperative bowel preparation done with one P. enema at night.

Operative procedure: Either conventional haemorrhoidectomy or stapled haemorrhoidopexy was done as per the group to which the patient belonged.

Post-operative care

- Patients were observed periodically for any anorectal bleeding.
- Patient remained hospitalized till satisfactory control of pain was achieved without need of injectable analgesics.
- Warm sitz baths were taken by patients belonging to conventional haemorrhoidectomy group thrice daily.
- Bulk laxatives were given once daily.
- Proper analgesia.
- Advice regarding regular follow up to detect and deal with stenosis, stricture or any other complication was given to all patients and
- Anal dilatation if stenosis was observed.

Statistical analysis

Chi-square test was used to test the association between different study variables under study. Test of proportion (Z-test) was used to test the significant difference between two proportions. t-test was used to test the significant difference between means.

Also, One Way Analysis of Variance (ANOVA) followed by post hoc Tukey's Test was performed with the help of Critical Difference (CD) or Least Significant Difference (LSD) at 5% and 1% level of significance to compare the mean values. Odds ratio (OR) with 95% Confidence Interval (CI) was calculated to measure the different risk factor. $p \le 0.05$ was considered statistically significant.

RESULTS

The mean age (mean±S.D.) of the patients in the whole population was 45.03±12.37 years with range 22-69 years and the median age was 44.5 years.

Table 1: Age and treatment groups.

Age Group (in years)	Stapled (n=30)	Conventional (n=30)	Total
20-29	4	2	6
Row %	66.7	33.3	100.0
Col %	13.3	6.7	10.0
30-39	8	9	17
Row %	47.1	52.9	100.0
Col %	26.7	30.0	28.3
40-49	8	7	15
Row %	53.3	46.7	100.0
Col %	26.7	23.3	25.0
50-59	7	7	14
Row %	50.0	50.0	100.0
Col %	23.3	23.3	23.3
60-69	3	5	8
Row %	37.5	62.5	100.0
Col %	10.0	16.7	13.3
Total	30	30	60
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±S.D.	43.30±12.50	46.76±12.20	
Median	44	45.5	
Range	22 - 68	27 - 69	

 $\chi^2 = 1.29$; p = 0.86; NS: Not Significant

Most of the patients were in the age group 30-59 years (76.6%) which was significantly higher. The mean age (mean±S.D.) of the patients with stapled method was 43.30±12.50 years and that of the patients with conventional method was 46.76±12.20 years. The mean duration of surgery (mean±S.D.) of the patients with stapled method was 30.76±3.13 minutes and that of the patients with conventional method was 49.36±4.08 minutes. The mean duration of surgery for conventional

method was significantly higher than that of stapled method.

Table 2: Duration of surgery and treatment groups.

Duration of surgery (in minutes)	Stapled (n=30)	Conventional (n=30)	Total
25-29	8	0	8
Row %	100.0	0.0	100.0
Col %	26.7	0.0	13.3
30-39	21	0	21
Row %	100.0	0.0	100.0
Col %	70.0	0.0	35.0
40-49	1	14	15
Row %	6.7	93.3	100.0
Col %	3.3	46.7	25.0
50-60	0	16	16
Row %	0.0	100.0	100.0
Col %	0.0	53.3	26.7
Total	30	30	60
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±S.D.	30.76±3.13	49.36±4.08	
Median	30	50	
Range	25-40	40-60	

 $\chi^2 = 1.29$; p = 0.86; NS: Not Significant

Table 3: Comparison of VAS at post-operative (PO) different times.

Time	Stapled (n=30)			Conventional (n=30)		
	Mean±SD	M	R	Mean±SD	M	R
At PO 12 hours	2.63±0.76	3	1-4	5.63±0.72	6	4-7
At PO 24 hours	1.66±0.88	2	0-3	4.56±1.22	5	2-7
At PO 72 hours	0.90±0.71	1	0-3	3.26±1.25	3	1-6
At PO 7 days	0.50±0.50	0.5	0-1	2.00±0.69	2.0	1-3
ANOVA	$F_{3,116} = 49.7$ $p < 0.0001$	0		$F_{3,116} = 69.6$ $p < 0.0001$	3	

M: Median; R: Range

In the whole population VAS score analysis for different post-operative times showed that there was significant difference and there was a significant reduction of VAS at 72 hours and at 7 days in comparison to VAS at 12 hrs. VAS scores at 12 hours, 24 hours, 72 hours and 7 days for stapled group were 2.63±0.76, 1.66±0.88, 0.90±0.71 and 0.50±0.43 while that for the conventional haemorrhoidectomy group were 5.63±0.72, 4.56±1.22, 3.26±1.25 and 2.00±0.69. At all points of time the VAS of stapled haemorrhoidopexy group was significantly lower than that of the conventional group.

Table 4: Gender and different parameters.

		Stapled (n = 30)	Conventional (n = 30)	Total	Chi-square Value	p-value
Gender	Male	16	17	33	0.06	0.79
	Female	14	13	27	0.00	
Degree of	3 rd	17	18	35	0.00	0.79
hemorrhoids	4 th	13	12	25	0.06	
Bleeding at post-	Yes	1	2	3	0.25	0.55
operative 24 hours	No	29	28	57	0.35	
TI	Yes	4	5	9	0.12	0.71
Urinary retention	No	26	25	51	0.13	
A 1.T	Yes	0	0	0		
Anal Incontinence	No	30	30	60		
A 1	Yes	0	0	0		
Anal stricture	No	30	30	60		
	Yes	2	2	4		
	Row %	50.0	50.0	100.0		0.60
Fever	Col %	6.7	6.7	6.7	0.26	
	No	28	28	56	0.26	
	Row %	50.0	50.0	100.0		
	Col %	93.3	93.3	93.3		

Proportion of males (55.0%) was higher than that of females (45.0%) but it was not statistically significant. The ratio of gender was found as Male: Female=1.2:1. Proportion of 3rd degree of hemorrhoids (58.3%) was

significantly higher than that of 4th degree of hemorrhoids. Both the groups respectively had higher number of patients with third degree haemorrhoids. 3 patients in the total group had significant bleeding in

post-operative period and out of them two belonged to conventional group and one belonged to stapled group. 5 patients of conventional group (16.7%) and 4 patients of stapled group (13.3%) had urinary retention. No patient had anal incontinence or stricture. 2 patients of each group had fever.

Table 5: Duration of hospital stay and treatment groups.

Duration of hospital stay (in days)	Stapled (n=30)	Conventional (n=30)	Total
≤7	30	27	57
Row %	52.6	47.4	100.0
Col %	100.0	90.0	95.0
>7	0	3	3
Row %	0.0	100.0	100.0
Col %	0.0	10.0	5.0
Total	30	30	60
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±SD	3.10 ± 0.75	6.06±0.94	
Median	3.0	6.0	
Range	2-5	5 - 8	

 $\chi^2 = 3.73$; p = 0.053; S: Significant

Table 6: Time to return to normal activities and treatment groups.

Time to return to normal activities (in days)	Stapled (n=30)	Conventional (n=30)	Total
≤7	13	0	13
Row %	100.0	0.0	100.0
Col %	43.3	0.0	21.7
8-14	17	27	44
Row %	38.6	61.4	100.0
Col %	56.7	90.0	73.3
>14	0	3	3
Row %	0.0	100.0	100.0
Col %	0.0	10.0	5.0
Total	30	30	60
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean \pm s.d.	8.16±1.93	12.60±1.67	
Median	8	12	
Range	5-14	10-18	

 $\chi^2 = 18.27$; p = 0.001; S: Significant

The mean duration of hospital stay (mean \pm S.D.) of the patients with stapled method was 3.10 \pm 0.75 days and that of the patients with conventional method was 6.06 \pm 0.94 days. Analysis showed the mean duration of hospital stay for conventional method was significantly higher than that of stapled method. The mean time to return to normal

activities (mean \pm S.D.) of the patients with stapled method was 8.16 ± 1.93 days and that of the patients with conventional method was 12.60 ± 1.67 days. Statistical analysis showed that the mean time to return to normal activities for conventional method was significantly higher than that of stapled method.

DISCUSSION

Both the groups were comparable with respect to patient profiles, baseline clinical and other parameters. From the pooled data authors determined the age distribution, sex distribution, and degree of haemorrhoids, operative time, and VAS scores at different times, length of hospital stay, time required to return to normal daily activities and incidence of complications if any. Authors got these results for all patients in the study and also for the different groups for comparison.

The mean age (mean±S.D.) of the patients was 45.03±12.37 years with range 22-69 years and the median age was 44.5 years. Most of the patients were in the age group 30-59 years (76.6%) which was significantly higher. Gordon in his book has stated the age distribution of haemorrhoids exhibited a hyperbolic pattern, with a peak age of 45 to 65 years with a subsequent decline after that age.⁵ Hiremath B and others in their study found the mean age of the patients in present group was 44.1 years with a range of 20-76 years. The mean age (mean±S.D.) of the patients with stapled method was 43.30±12.50 years with range 22-68 years and the median age was 44.0 years. The mean age (mean±S.D.) of the patients with conventional method was 46.76±12.20 years with range 27-69 years and the median age was 45.5 years. There was no significant association or difference in the mean age of two groups. Thus, the two groups were matched for age.

Test of proportion showed that proportion of males (55.0%) was higher than that of females (45.0%) but it was not statistically significant. The ratio of gender was found as Male: Female=1.2: 1. There was no association between the groups and gender, making the groups comparable. In the total population proportion of 3rd degree of hemorrhoids (58.3%) was significantly higher than that of 4th degree of hemorrhoids (41.7%). Both the groups respectively had higher number of patients with third degree haemorrhoids. There was no association found between degree of haemorrhoids in the two groups. Thus, the two groups were comparable with respect to the degree of haemorrhoids.

Bikhchandani J et al in their study, found men were more commonly affected by haemorrhoids. Overall, grade III haemorrhoids were more common a problem than grade IV.⁷ In the total study population authors found the mean duration of surgery (mean±S.D.) of the patients was 40.06 ± 10.05 minutes. When authors compared the two groups separately authors found that the mean duration of surgery (mean±S.D.) of the patients with stapled method

was 30.76±3.13 minutes with range 25-40 minutes and the median was 30.0 minutes and the mean duration of surgery (mean±S.D.) of the patients with conventional method was 49.36±4.08 minutes with range 40-60 minutes and the median was 50.0 minutes. The mean duration of surgery for conventional method was significantly higher than that of stapled method.

In a study by Boccasanta P et al, mean operative time was 50±5.3 minutes in open haemorrhoidectomy group and 25±3.1 minutes in stapled haemorrhoidopexy group.⁸ Hetzer FH et al in their study found that mean operating time was 30 minutes (range 15 to 45 minutes) in the stapler group and 43 minutes (range 25 to 60 minutes) in the excision group.⁹ In a study published by Ho YH et al, he stated that Conventional haemorrhoidectomy was quicker to perform.¹⁰ When the two groups were compared authors found that VAS at 12 hours for stapled group was 2.63±0.76 with range 1-4 and the median was 3.0 and that for conventional haemorrhoidectomy group was 5.63±0.72 with range 4-7 and the median was 6.0. The mean VAS for stapled group at 12 hours was significantly lower than the conventional group.

The mean VAS for pain at post-operative 24 hours (mean±S.D.) of the patients with stapled method was 1.66±0.88 with range 0-3 and median was 2.0 and in the patients with conventional method it was 4.56±1.22 with range 2-7 and median was 5.0. Here also the mean VAS for stapled group was significantly lower than that of conventional group. At 72 hours the VAS of the patients with stapled method was 0.90±0.71 with range 0-3 and the median was 1.0 while in the patients of conventional group the VAS was 3.26±1.25 with range 1-6 and the median was 3.0, which was significantly higher.

The mean VAS at post-operative 7 days (mean±S.D.) of the patients with stapled method was 0.50±0.43 with range 0-1 and the median was 0.5 while the mean VAS at post-operative 7 days (mean±S.D.) of the patients with conventional method was 2.00±0.69 with range 1-3 and the median was 2.0. The mean VAS at 7 days was significantly higher in the conventional group. The decrease of VAS was more rapid in the stapled method than the conventional method. The stapled procedure did not involve any anal mucosa below the dentate line and hence was less painful. VAS scores were significantly lower in the stapled group as has been proved by various studies.

In his study by Bikhchandani J and associates they compared VAS scores at 12hrs, 24hrs, 72 hours, 7 days and 15 days and found that post-operative pain was significantly lower in stapled group compared to conventional group. At 7 days their study showed VAS scores at 0.57 for stapled group and 2.31 for conventional group. Ortiz also reports that stapled haemorrhoidopexy is a far less painful procedure when compared to conventional surgeries. Mehigan BJ found that the

average pain in stapled method was significantly lower than it was in Milligan-Morgan haemorrhoidectomy.¹²

In present study 3 patients in the total group had significant bleeding in post-operative period and out of them two belonged to conventional group and one belonged to stapled group. The patients were taken to the operating room and haemostasis was secured under anaesthesia. There was no significant association between bleeding at 24 hours in the two groups although it was analysed that risk was twice in the conventional group as compared to the stapled group. 5 patients of conventional group (16.7%) and 4 patients of stapled group (13.3%) had urinary retention treated by catheterisation of the patients. Analysis showed there was no association between the two groups although an increased risk of 1.3 times was present in the conventional group. 2 patients of each group had fever which was treated with paracetamol only. There was no association between the two groups nor was there any excess risk of post-operative fever found in the groups.

Authors did not get any patient with fecal incontinence or stricture in present follow up period. Bikhchandani J, states that early complication rate after the two procedures were comparable. In his study 11.9% patients in stapled group and 16.7% patients in open group had urinary retention. One patient in each group had severe bleeding in the first 24 hours after surgery. The mean duration of hospital stay (mean \pm S.D.) of the patients with stapled method was 3.10 \pm 0.75 days with range 2 – 5 days and the median was 3.0 days and that of the patients with conventional method was 6.06 \pm 0.94 days with range 5 – 8 days and the median was 6.0 days. Analysis showed the mean duration of hospital stay for conventional method was significantly higher than that of stapled method.

The mean time to return to normal activities (mean±S.D.) of the patients with stapled method was 8.16 ± 1.93 days with range 5-14 days and the median was 8.0 days and that of the patients with conventional method was 12.60 ± 1.67 days with range 10-18 days and the median was 12.0 days. Statistical analysis showed that the mean time to return to normal activities for conventional method was significantly higher than that of stapled method. Bikhchandani J in his study found that mean duration of hospital stay was 1.24 days for stapled group and that for conventional group was 2.76 days. Stapled group patients had earlier return to daily activities with a mean period of 8.12 days compared to 17.62 days for conventional group.

Jayaram S in his systematic review states both stapled and conventional methods are safe, effective methods for treatment of haemorrhoids. But stapled method is associated with higher risk of prolapse and long-term recurrence, although it is associated with significant short-term advantages like less post-operative pain, bleeding and an earlier return to normal daily activities with reduced hospital stay.¹³ Similis C et al. in their

systematic review and meta-analysis state that stapled procedure has better outcomes with regard to operating time, post-operative pain, length of hospital stay and time to return to normal activity. However, stapled haemorrhoidectomy was also reported to have higher rate of skin tags, haemorrhoid recurrence and recurrent prolapse than conventional haemorrhoidectomy.¹⁴

CONCLUSION

Authors conclude that Stapled haemorrhoidopexy is faster, minimally invasive technique for treatment of haemorrhoids as compared to Conventional Milligan-Morgan haemorrhoidectomy. It is associated with much less pain in the post-operative period. It also provides a more satisfactory alternative to Conventional surgery because of reduced hospitalisation and earlier return of patient to daily activities, with no significant differences in short term follow up.

Recommendations

Stapled Haemorrhoidopexy should be considered as the procedure of choice when dealing with third and fourth degree haemorrhoids. The economic burden of stapled procedure should be lessened so as to make the procedure universally acceptable. A proper long term follow up of a patient undergoing stapled haemorrhoidopexy has to be ensured.

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