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Stapled Hemorrhoidopexy Versus Classical Hemorrhoidectomy – A Prospective Comparative Study with 3 Years Follow-up

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ABSTRACT

Hemorrhoids are the common benign anal problems in rural India and usually the patients present to the surgical outpatient department at late stage. This prospective randomized clinical trial is aimed to compare the results of classical versus stapled hemorrhoidopexy for treatment of third and fourth degree hemorrhoids.

Objective: We report our experience on surgical treatment focusing on postoperative pain, complications and days to return normal activities after the procedure

Methods: 106 patients admitted for surgical treatment with class III/IV hemorrhoids from June 2011 to May 2013 were randomly assigned to classical (n=53) or stapled hemorrhoidopexy (n=53). The outcomes included in form of post operative pain, procedure time, number of days taken to return to work, post-operative bleeding, acute urinary retention, need of dressings, and anal stricture were compared. The patients were followed up to 3 years for recurrence of symptoms.

Results: Stapled procedure group had less postoperative pain, earlier return to normal activity and less recurrence after 3 years of the study. There is no need of Seitz bath after stapled procedure

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

Key Words: Classical Milligan- Morgan hemorrhoidectomy (CH), Third and fourth degree hemorrhoids, Stapled hemorrhoidopexy(SH)

INTRODUCTION

Hemorrhoids – bleeding piles are the commonest benign anorectal problem attending to the surgical OPD. In the modern laparoscopic era there are major advances in the treatment of colorectal diseases but only few modifications are available in the management of hemorrhoid disease. Surgical hemorrhoidectomy has been reserved for third and fourth-grade hemorrhoids and the most frequent traditional surgical procedures performed are Milligan-Morgan open hemorrhoidectomy and Ferguson closed hemorrhoidectomy [1,2]. Stapled hemorrhoidopexy, as designed by Dr Antonio Longo made the surgeon to think for an alternative method of conventional excisional hemorrhoidectomy.

In contrast to the traditional approach of removing hemorrhoid tissue, SH involves excising a circumferential ring of mucosa three to four centimeters above the dentate line using a circular stapler which interrupts the superior hemorrhoidal vessels and restores the hemorrhoid tissues back to their anatomic position [3].

We present a prospective randomized clinical trial to compare the results of using stapled hemorrhoidopexy versus classical hemorrhoid surgery for treatment of third and fourth degree hemorrhoids at department of surgery, GSL medical college with follow-up of 3 years.

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PATIENTS AND METHODS

The present study was prospective randomized clinical study comparing the use of stapled hemorrhoidopexy with traditional hemorrhoidectomy in department of surgery, GSL medical college and General Hospital from June 2011 to may 2013 by surgeons from two units.

The study protocol was approved by the *ethical committee* and written informed consent was obtained from all participants prior to entry into the trial.

The outcome of the study was to compare

1. Duration of surgery 2. Postoperative pain 3. post surgery complications (bleeding, urinary retention, infection) 5. Duration of hospital stay. 6. Days return to work 7. Cost between the procedures and 8. Follow up anal stenosis /recurrence

The study population included 106 patients with symptomatic third degree hemorrhoids (prolapsed upon defecation or straining, but must be manually reduced) and fourth degree hemorrhoids (prolapsed and cannot be manually reduced) internal hemorrhoids, who are fit for anesthesia. Randomization was performed prior to commencement of the study as follows:

Patient admitted on Monday are planned for classical hemorrhoidectomy, and admitted on Thursday for stapled hemorrhoidopexy. First group (53 patients) was randomized to Milligan-Morgan traditional hemorrhoidectomy and second group (53 patients) was randomized to stapled hemorrhoidopexy procedure.

Exclusion criteria in the study group

1. First and second degree hemorrhoids or thrombosed hemorrhoids
2. Concomitant perianal fistula, fissures, abscess
3. Previous anal surgery
4. Patients with known history of bleeding disorder
5. Having psychiatric illness
6. Patient not giving consent

The surgery was performed by two unit surgeons experienced in hemorrhoid surgery, both open and stapler hemorrhoidopexy.

Preoperative evaluations: Preoperative evaluations included a detailed medical history, physical examination, proctoscopy/ sigmoidoscopy, and routine laboratory tests in all patients. Patients over 40 years underwent cardiologic evaluation preoperatively. As the study was conducted in a medical college patient was evaluated only after admission.

Anesthesia was standardized for all cases under spinal anesthesia. Laxative 2 packets in 200ml water given at bed time before the day of surgery. The procedures were performed in the lithotomy position for all patients. After anal dilation

anoscope was kept for evaluation. Operative technique for the Milligan-Morgan group consists of retraction of the pile mass with a forceps and diathermy dissection and excision. The vascular pedicle was ligated with vicryl 1-0. The stapled procedure was done according to the technique described by Longo and colleagues. The hemorrhoid stapler PPH 03 33mm Johnson and Johnson was used for all the case of stapler hemorrhoidopexy. Post procedure in both the group diclofenac suppository and then anal pack covered with paraffin gauze dressing was kept.

Procedure time was recorded from starting of anesthesia till the anal pack placement.

Postoperative management consisted of standard nursing care and analgesia. All patients kept nil orally only for 6 hrs. The anal packs was removed after 1 hrs of surgery. Local external examination was done day 1 and on day of discharge.

Each patient was given a discharge prescription for lactulose 20 ml each day. An outpatient appointment was arranged for 7 days after surgery and patients were given an advice sheet and telephone number in case of emergency.

Outcome measures

The primary and most important endpoints of the study were measurement of postoperative pain after 24 hours of surgery and every day till discharge. The pain scores were measured using Visual analog scale where score of 0 represents no pain and score 10 represents the worst unbearable pain. Analgesic was administered to keep pain below 3 or 4.

The secondary outcome measures were procedural time, incidence of postoperative bleed, duration of hospital stay, need of dressings, patients satisfaction and time until return to normal activity. Operative time duration was measured from anesthesia up to final wound dressing. The total cost of the procedures also documented. The total analgesic consumption during the first 7 days of postoperative period was recorded. Patients were asked to record the first bowel movements.

Hemorrhoidal symptoms were assessed postoperatively and at 1 and 3 months on follow up outpatient visits. On 2nd year and 3rd year patient was contacted on phone for the wellbeing and any recurrence of symptoms. Patients were asked to rate their satisfaction into four categories: unsatisfactory; satisfactory; good; excellent.

All data observed means by Student's t test in order to show a difference of one SD in average pain scores between groups. We used the student 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.

RESULTS

The study conducted on 106 patients divided into two equal groups, 60males and 46 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 majority of the patients had third grade hemorrhoids (71/106--66.9%). The main complaint of the patients was anal bleeding. No patients in both groups complained of fecal incontinence preoperatively. .

Age

The mean age of the patients was 45.11 versus 42.94 years in classical and stapled groups respectively.

Table 1: Comparison of age distribution in study population

Total Procedure		Classical Hemorrhoidectomy		Stapled Hemorrhoidectomy		Age in Years
No	percentage	No	Percentage	No	percentage	
17	16.03	9	16.98	10	18.86	21- 30
27	25.47	10	18.86	14	26.41	31-40
38	35.84	17	32.07	14	26.41	41-50
17	16.03	9	16.98	9	16.98	51-60
14	13.2	8	15.09	6	11.32	>60
106		53		53		Total
44.02±12.83		45.11±12.944		42.94±12.63		MEAN±SD

Grade of disease

In the study group 71% had grade III hemorrhoids in stapled group and 62.2 % in the open group.

Table 2: Grade of disease in study population

Grade	Stapled		Classical		Total	
Grade III	38	71.6 %	33	62.2%	71	66.9%
Grade IV	15	28.3%	20	37.7%	35	33.01%
Total	53	100%	53	100%	106	100%

Procedure time

All patients were operated on lithotomy position under Spinal anesthesia. Intraoperative additional homeostasis was required for 5 cases. The operative time was longer in the traditional group (mean = 40.056±7.001minutes) than the stapled group (mean of 34.9±6.11 minutes).

P value and statistical significance

The two-tailed P value equals 0.0001 by conventional criteria, this difference is considered to be extremely statistically

significant. **Confidence interval**

The mean of Group One minus Group Two equals -5.16000
95% confidence interval of this difference: From -7.69113 to -2.62887

Intermediate values used in calculations:

t = 4.0427

df = 104

standard error of difference = 1.276

Pain scoring post hemorrhoidectomy

Post surgery diclofenac suppository kept in all patients. The pain score was significantly higher in classical surgery group.

Table 3: Pain Scoring Comparison Between Both the Procedure- mean VAS rank

Postoperative pain VAS score	Stapled	Classical	P value
12hrs	1.76 ±0.72	2.88±0.81	Less than 0.0001
day1	1.84± 0.69	2.24±0.78	0.0062
day3	1.38±0.61	1.76±0.81	0.0075
days`	1.12±0.65	1.52±0.88	0.0090

The p values are statistically highly significant, postoperative pain is significantly high in classical hemorrhoidectomy group

Post surgery immediate complications

Bleeding was seen in 11.2% of patients with stapled hemorrhoidectomy as compare to 26.41% in classical group(table -4). Supportive stitches required for 3 patients in stapled group and 7 cases in open group. Rests of cases were managed with anal pack. In one case after removal of pack patient had major bleed, shifted to OR and local site suturing done

Urinary retention was the common postoperative findings as seen in other pelvic surgery. In the study group urinary retention was seen in 15.09 % in stapled group as compare to 20.75% in classical group. These patients were managed with temporary urinary bladder drainage

Residual prolapse seen in 28.3% in classical group as compare to 7.4 % in stapled group. All the cases were in follow up with medication of Calcium Dobesilate, and Troxerutin as active ingredients for 1 month. 2 cases in stapled group required the excision of prolapsed external hemorrhoids. The residual prolapsed seen in grade IV hemorrhoids.

Seitz bath was advised for all classical groups for relief of pain and dressing. It was the major concern for treatment in classical hemorrhoidectomy

Table 4. Complications following the stapled and classical hemorrhoidectomy surgery

Complications	Stapled		classical	
Bleeding	6	11.42%	14	26.41%
Retention of urine	8	15.09%	11	20.75%
Residual prolapse after 5 th day	4	7.54%	15	28.3%
Seitz bath	0		50	94.33%

DURATION OF HOSPITAL STAY

Hospitalization time ranged between 5 and 7 days. As this study was conducted in the general hospital attached to medical college, the investigations were done after admission. On second day medical/ cardiology evaluation and pre anesthesia checkup was done. The surgery was conducted on the 3rd day of hospital admission.

56.6 % of Stapled hemorrhoidectomy cases were discharged on 2nd postoperative day as compare to 37.7 % in classical group. As there is no need of major wound examination and dressing the stapled group were discharged on 2nd or 3rd post operative day after the bowel movements. Duration of hospital stay is significantly low in stapled group

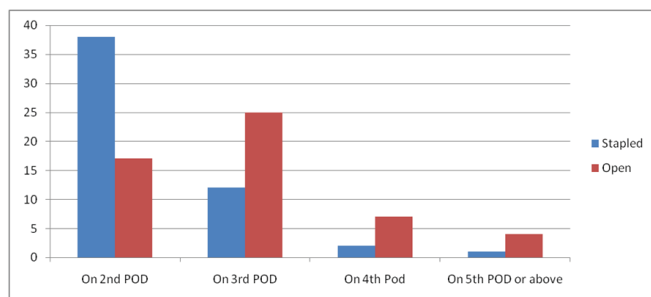


Figure 1: Bar Diagram showing the Mean duration of hospital stay between stapled hemorrhoidectomy and classical hemorrhoidectomy procedure.

Return to the regular activities

In the study group stapled patient returned to their regular activities within the 10 days of surgery where as the classical group attend the activities at the end of second week. The mean days to return to the regular activities is 6 days in stapled group and 12 days in the classical group.

Table 5: Return to work after stapled and classical hemorrhoidectomy- comparative study

Return to work in days	Stapled		Open	
Within 7 days	27	50.94%	0	0%
7-10 days	25	47.16%	21	39.62%
>10 days	10	1.88%	32	60.37%
Total	53	100%	53	100%

Patient satisfaction score

Patient with stapled group were having maximum level of satisfaction as compare to classical hemorrhoidectomy.

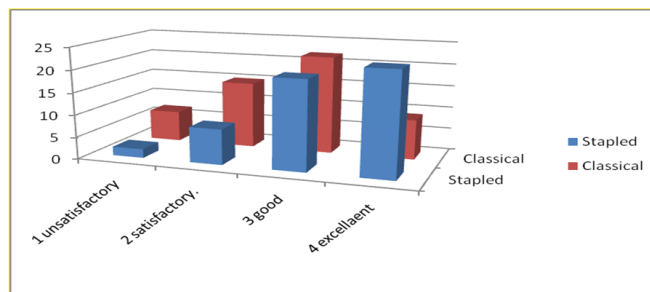


Figure 2: Bar diagram showing Patients satisfaction after classical and stapled hemorrhoidectomy procedure.

Follow-up status

From the study group we called the patient for the follow-up as per their availability. We noticed 5 cases from stapled group and seven cases from classical group were having residual prolapsed managed surgically. 2 cases in open group developed anal stenosis for which anal dilation was done. There was no incontinence in any group.

Table 6: Follow up status stapled/ classical hemorrhoidectomy

Follow-up	Stapled hemorrhoidectomy		Classical hemorrhoidectomy	
Anal stenosis at 2 month	0		2	3.77%
Incontinence at 1 month	0		0	
Recurrence of symptoms at 6 month	0		0	
Recurrence of symptoms at 3 year-residual prolapse	5	9.43%	8	15.09%

Cost effectiveness

The study was conducted in medical college and general hospital. Surgery and bed charges and investigations were done with free of cost. The patients were advised to bring the medication

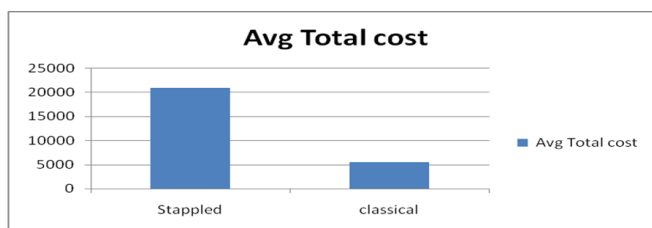


Figure 3: Cost effectiveness between stapled and classical hemorrhoidectomy procedure

DISCUSSION

This was hospital based study conducted in the department of general surgery, GSL medical college and General Hospital, Rajahmundry, Andhrapradesh for duration of 2 years with follow-up for 3 years. It was a prospective study comparing stapled hemorrhoidopexy and classical Milligan Morgan procedure for the management of grade 3 and grade 4 hemorrhoids. 106 patients were included in the study protocol, 53 patients underwent stapled and 53 patients underwent Milligan -Morgan technique

The mean age of the patients was 45.11 versus 42.94 years in classical and stapled groups respectively. In a similar study by Sachin ID *et al* the mean age is 40.05 and 39.50 respectively [2, 10, 16].

There was a predominance of males in both groups; the majority of the cases were in the fourth decade of life. The majority of the patients had third grade hemorrhoids (71 - 66.9%). The main complaint of the patients was anal bleeding [11].

The procedure time longer in the traditional group (mean = 40.05 minutes) than the stapled group (mean of 34.9 minutes).we calculated the procedure time from the starting of spinal anesthesia till anal pack. The P value equals 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant. A series of studies shows duration of surgery is significantly low in stapled group [4, 5, 6].

Intraop/immediate postoperative minor bleed and urinary retention is more common in classical hemorrhoidectomy group compare to stapled, in more than 95% of cases complete circumferential donut of the stapler line achieved at the end of procedure [8,9,11].

Residual hemorrhoidal prolapse seen in 28.3% in classical group as compare to 7.4 % in stapled group. 2 cases in stapled group required the excision of prolapsed external hemorrhoids. Jayram S et al noted that stapler hemorrhoidopexy is associated with higher risk of prolapse[10]. Laughlan k et al reported that stapled hemorrhoidopexy is associated with

reduced pain but an increased rate of recurrent prolapse. In our study even after 3 years no significant prolapsed was seen in stapler group. The residual prolapse noticed in grade IV hemorrhoids only[14,15].

The postoperative pain was assessed by VAS score and the aim was to keep score less than 3 with adequate analgesia. The pain score was high in classical hemorrhoidectomy group at 12 hrs, day one and day 2. Tjandra JJ et al, Laughlan K et al, reported similar findings[12,3,14]. We adopted sitz bath procedure for classical hemorrhoidectomy cases to keep pain score less but the sitz bath was more discomfort for the patient. In comparison Stapler hemorrhoidectomy group experienced less postoperative pain where as cheetham et al reported persistent pain and fecal urgency after stapled hemorrhoidectomy, the explanation may be related to stapled line may be more close to dentate line [4].

In our study stapled group were discharged on 2nd/3rd postoperative day while the classical hemorrhoidectomy patient discharge on 5th/6th POD. Duration of hospital stay was significantly low in the stapled group. This findings supports the report by Tjandra JJ et al, Laughlan K et al.[12,14]

Stapled group returned to their daily activities much faster than classical hemorrhoidectomy patients. Ganio E et al have opined similar finding in their publication [5].

The post procedure satisfaction was significantly higher in the stapled group as compared to classical Milligan -Morgan procedure [15,16].

The procedural cost is higher in stapled group as compare to classical group. For common rural people it is difficult to convince to undergo stapled procedure even if the outcomes are satisfactory.

CONCLUSION

Our experience confirms the validity of both Classical hemorrhoidectomy and Stapled hemorrhoidopexy. Classical hemorrhoidectomy procedure is more invasive and slightly more painful in immediate postoperative period than SH surgery, which is slightly more expensive ones. The costly procedure stapled hemorrhoidopexy is associated with shorter procedural time, less postoperative pain and early recovery with high patient satisfaction as compare to Milligan-Morgan procedure. Compliaction is less if surgical technique is perfect with constant practice. To the safe side SH is the gold standard for III grade hemorrhoids while CH is suggested in IV hemorrhoids to avoid relook surgery for residual prolapse. SH is a novel technique and in the laparoscopic era with advance of insurance policy system in INDIA SH may emerged as alternative to classical hemorrhoidectomy.

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