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Randomized trial of open hemorrhoidectomy verses stapled hemorrhoidectomy in Grade II / III Hemorrhoids

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Abstract

The management of third and fourth degree hemorrhoids is usually surgical.[7] The most commonly performed operation is hemorrhoidectomy.[8]Milligan-Morgan hemorrhoidectomy has been the most popular among the various surgical techniques performed This study is planned to compare the results and patient satisfaction in stapled hemorrhoidectomy and open hemorrhoidectomy in Grade II / III Hemorrhoids by randomized controlled trial **Objectives:**To compare treatment outcome in stapled hemorrhoidectomy and open hemorrhoidectomy in Grade II / III Hemorrhoidsandthe complications in stapled hemorrhoidectomy and opehemorrhoidectomy I Grade II / III Hemorrhoids In the present study, 60 patients were included **.Results**10 patients (16.7%) suffered from anemia. 30 patients each were operated by Open hemorrhoidectomy and Stapled hemorrhoidectomy. The mean score at 6 hours by open hemorrhoidectomy (8.4±1.5) was significantly higher as compared to by Stapled hemorrhoidectomy (7.5±1). No statistical difference was found between pain. at 12 hours, 24 hours and first defecation with respect to type of surgery performed. **Conclusion** In our study we came to a conclusion that stapled heamarrhoidectomy is comparatively better as compare to open heamarrhopidectomy considering the duration of surgery ,duration of hospital stay and related complications

KEYWORDS: Hemorrhoidectomy, Stapled Hemorrhoidopexy, Postoperative Outcomes

INTRODUCTION

The management of third and fourth degree hemorrhoids is usually surgical.[7] The most commonly performed operation is hemorrhoidectomy.[8]Milligan-Morgan hemorrhoidectomy has been the most popular among the various surgical techniques performed.[9]Inmodern times, surgical management of hemorrhoids shouldaim to provide a definite cure or long-term relief of symptoms using techniques that are safe, preserve the anorectal function, and make the patient's quality of life an important priority. In 1998, a transanal circular staplinginstrument, initially used on mucosalprolapses,[10] was used to treat hemorrhoids via a procedure called stapledhemorrhoidopexy (SH).[11]The technique introduced a completely new concept for treating hemorrhoidal disease. It consisted of a circumferential rectal mucosectomy that performed a mucosal lifting(anopexy), aimed not at excision of the"diseased" hemorrhoidal cushions but rather at reconstitution of the healthy anatomical and physiological aspects of thehemorrhoidal plexus.[11] It is thought that the stapling device works by repositioning the rectal mucosa higher (mucosallifting), [10, 11]restoring the normal anatomy of the anal canal and enabling the hemorrhoidal
cushions to perform their role incontinence, as opposed to hemorrhoidectomy techniques that only excise abundant issues. However, the stapler operation also influences the blood flow ,affecting venous vessels and leading to an improvement of the venous reflux.[12]

Surgical hemorrhoidectomy has been reputed as being a painful procedure for a benign disease, and causes postoperative pain which needs about 2- 3 days hospital stay and a convalescence of at least one month.[13,14] Stapled hemorrhoidopexy is a newer modality that represents a paradigm change in the treatment of hemorrhoids.[15] However it has been met with both skepticism and interest.[16] Stapled hemorrhoidectomy has better short-term outcomes, including shorter operating times, less postoperative pain, early return to work and greater patient satisfaction.[13,14,17-19]

This study is planned to compare the results and patient satisfaction in stapled hemorrhoidectomy and open hemorrhoidectomy in Grade II / III Hemorrhoids by randomized controlled trial

AIM & OBJECTIVES

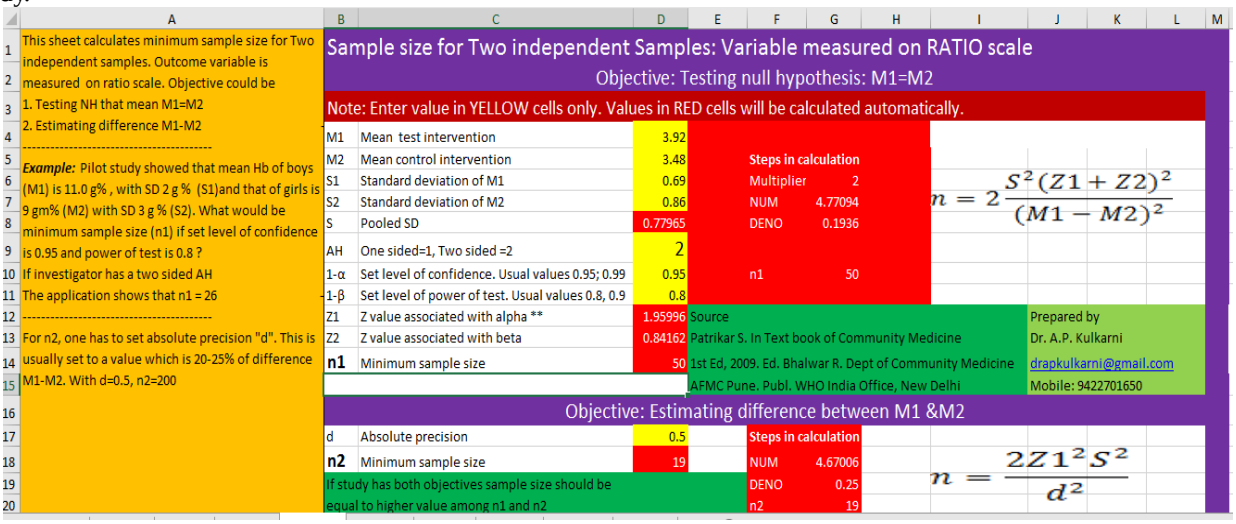
Aim: Randomized trial of open hemorrhoidectomy verses vs stapled hemorrhoidectomy in Grade II / III Hemorrhoids

Objectives:
To compare Treatment outcome in stapled hemorrhoidectomy and open hemorrhoidectomy in Grade II / III Hemorrhoids
To compare the complications in stapled hemorrhoidectomy and open hemorrhoidectomy in Grade II / III Hemorrhoids
To compare the patient satisfaction in stapled hemorrhoidectomy and open hemorrhoidectomy in Grade II / III Hemorrhoids

Hypothesis: Stapled hemorrhoidectomy offers several advantages over open hemorrhoidectomy, including reduced postoperative pain, a reduced hospital stay, and an earlier recovery time.

MATERIAL AND METHODS
Study design: Randomized controlled trialsingle blind
Study population: patients diagnosed with grade 2 and grade 3 hemorrhoids requiring surgical treatment

Study period:2 years
Sample size: Minimum calculated sample size is 50 based on patient satisfaction score for two groups from previous study.[1]



Ethical clearance: The study will be initiated after approval of Institutional Ethical committee.

Selection criteria: Patients diagnosed with hemorrhoids visitingmedical college and hospital
, will be subjected to the following inclusion and exclusion criteria.

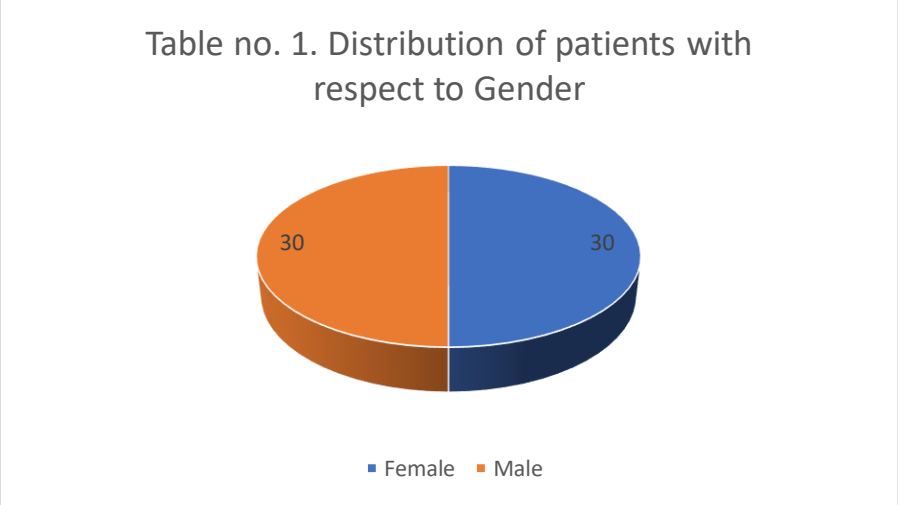
Inclusion criteria:
Patients visiting maheshwara medical college and hospital
Patients diagnosed with Grade 2 and grade 3 hemorrhoids
Patients of age 18 years or above of either gender.
Patients willing to give written informed consent to participate in the study.

Exclusion criteria:
Acute hemorrhoidal episodes with thrombosis
Prior hemorrhoidectomy
Anal pathology other than hemorrhoids like fistula in ano and anal fissure
Prolapse of single anal cushion
Anal stenosis
Patients who will satisfy the above inclusion and exclusion criteria will be included in the study. Written informed consent will be taken in all patients.

Study procedure:
After taking consent, patient's demographic data will be collected. All the patients will be randomly allocated to two groups, one group study group will undergo stapled hemorrhoidectomy and other group control group will undergo open hemorrhoidectomy. In both the groups data regarding grae of hemorrhoids, comorbidities, Duration of surgery, Post-operative pain and analgesics requirement, Duration of hospital stay, Post-operative complications, Days taken for Return to work, Anorectal physiological functions and recurrence, Patient satisfaction will be collected.

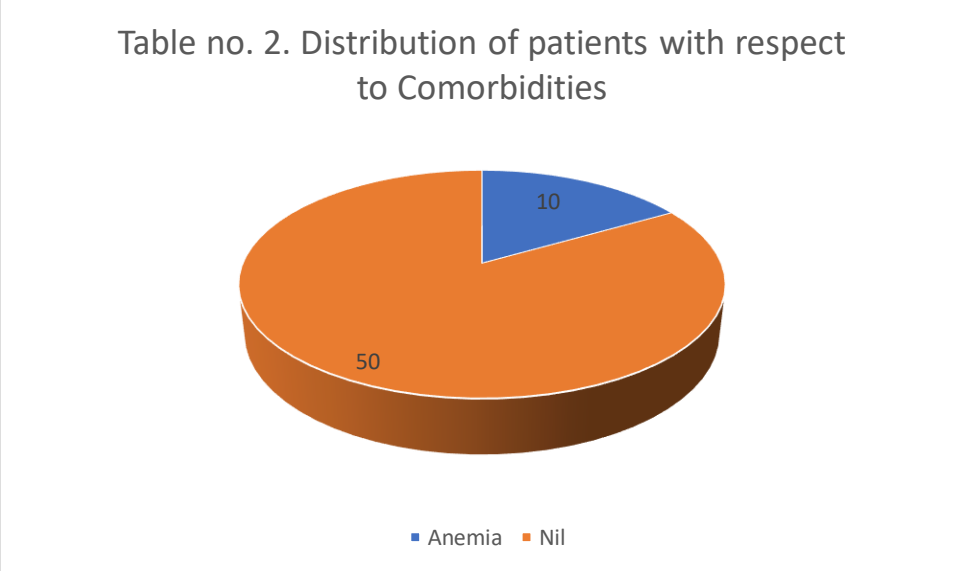
In the present study, 60 patients were included.

Table no. 1. Distribution of patients with respect to Gender			
		Frequency	Percent
Gender	Female	30	50.0
	Male	30	50.0
	Total	60	100.0



30 each patients of the study were males and females.

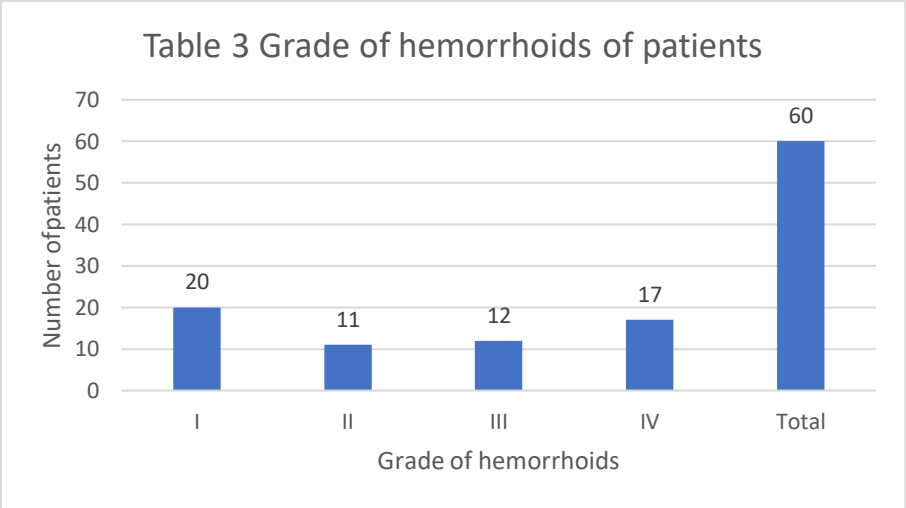
Table no. 2. Distribution of patients with respect to Comorbidities			
		Frequency	Percent
Comorbidity	Anemia	10	16.7
	Nil	50	83.3
	Total	60	100.0



10 patients (16.7%) suffered from anemia.

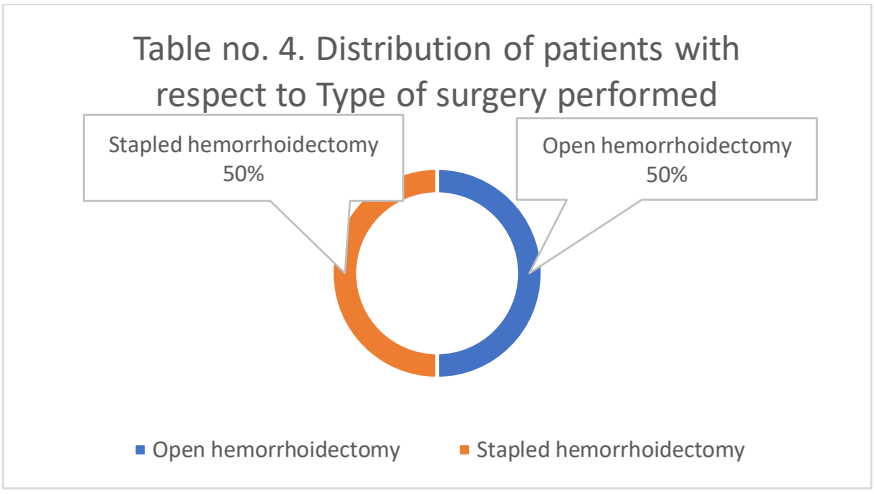
The study title mentions only Grade III and IV while data mentions all types of grades.

Table 3 Grade of hemorrhoids of patients			
		Frequency	Percent
Grade of hemorrhoids	I	20	33.3
	II	11	18.3
	III	12	20.0
	IV	17	28.3
	Total	60	100.0



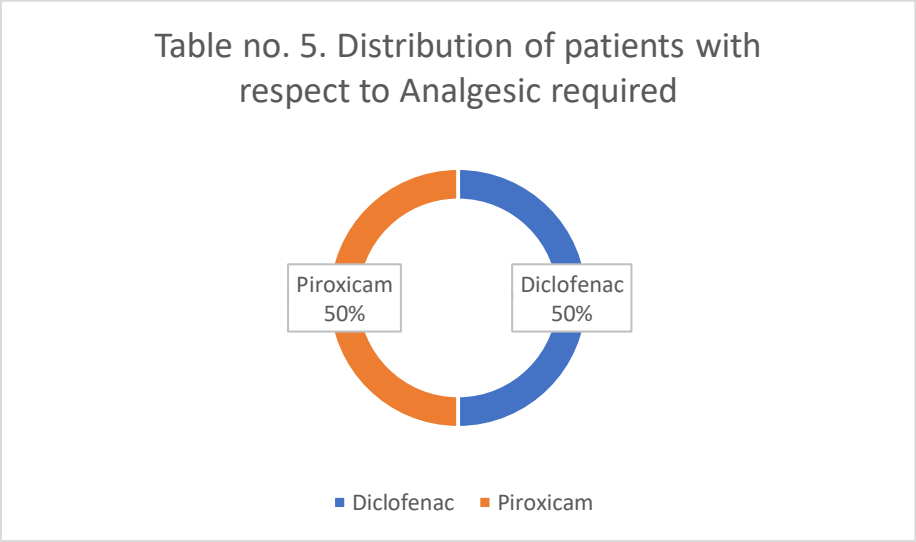
20, 11, 12 and 17 patients belonged to Grade I, II, III and IV of hemorrhoids, respectively.

Table no. 4. Distribution of patients with respect to Type of surgery performed			
		Frequency	Percent
Type of surgery performed	Open hemorrhoidectomy	30	50.0
	Stapled hemorrhoidectomy	30	50.0
	Total	60	100.0



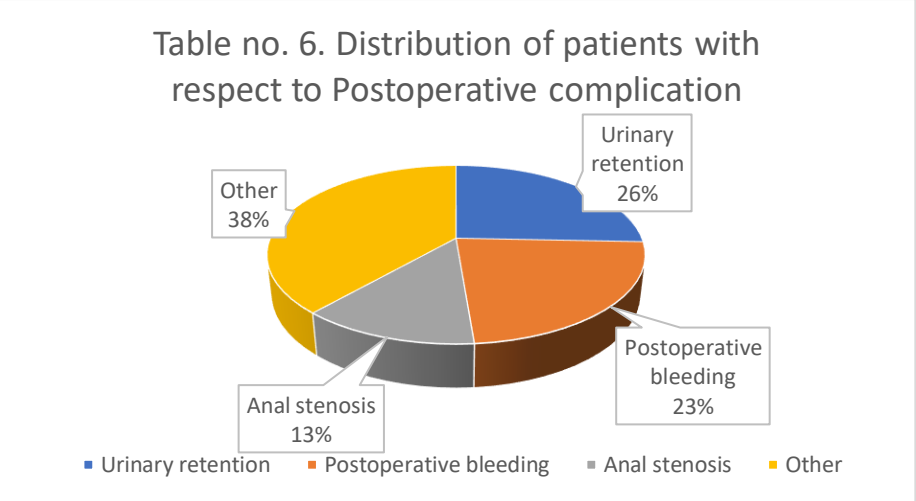
30 patients each were operated by Open hemorrhoidectomy and Stapled hemorrhoidectomy.

Table no. 5. Distribution of patients with respect to Analgesic required			
		Frequency	Percent
Analgesic required	Diclofenac	30	50.0
	Piroxicam	30	50.0
	Total	60	100.0



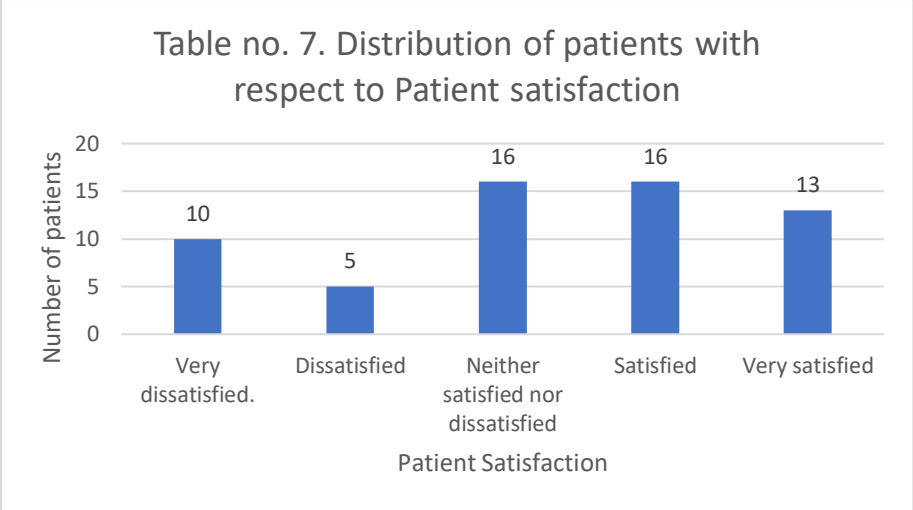
30 patientseachrequiredDiclofenac and Piroxicam as analgesic after surgery.

Table no. 6. Distribution of patients with respect to Postoperative complication		
	Frequency	Percent
Urinary retention	10	25.6
Postoperative bleeding	9	23.1
Anal stenosis	5	12.8
Other	15	38.5
Total	39	100.0



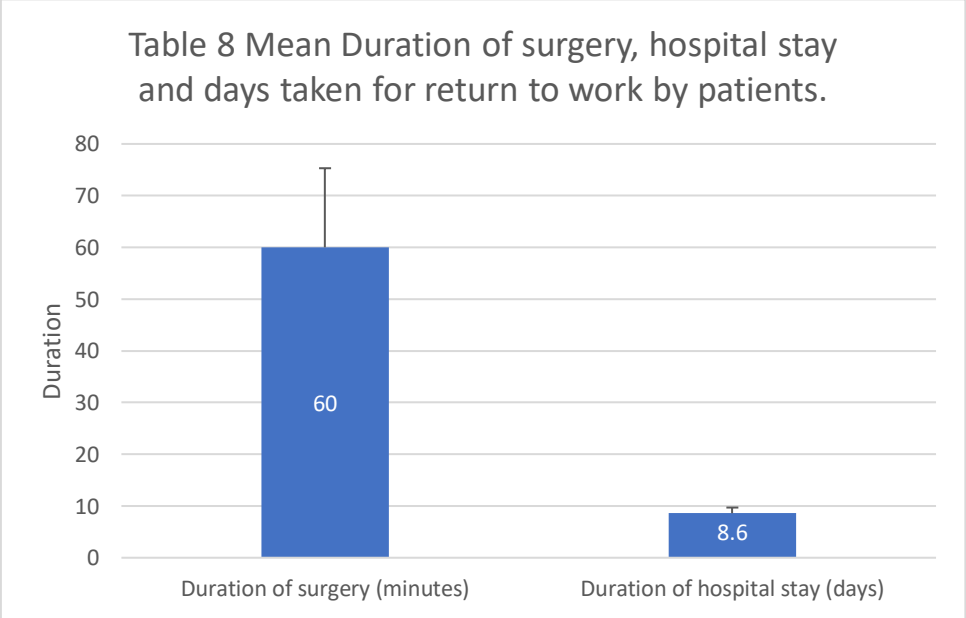
Postoperative complications were seen in 39 patients. Of these Urinary retention (10, 25.6%), Postoperative bleeding (9, 23%) and Anal stenosis (5, 12.8%) were common.

Table no. 7. Distribution of patients with respect to Patient satisfaction			
		Frequency	Percent
Patient satisfaction	Very dissatisfied.	10	16.7
	Dissatisfied	5	8.3
	Neither satisfied nor dissatisfied	16	26.7
	Satisfied	16	26.7
	Very satisfied	13	21.7
	Total	60	100.0



Mean age of the patients was 37.1 ± 12.8 years. Most of the patients were either neutral or satisfied (16, 26.7% each) with the surgery.

Table 8 Mean Duration of surgery, hospital stay and days taken for return to work by patients.			
	N	Mean	Std. Deviation
Duration of surgery (minutes)	60	60.0	15.3
Duration of hospital stay (Days)	60	8.6	1.1

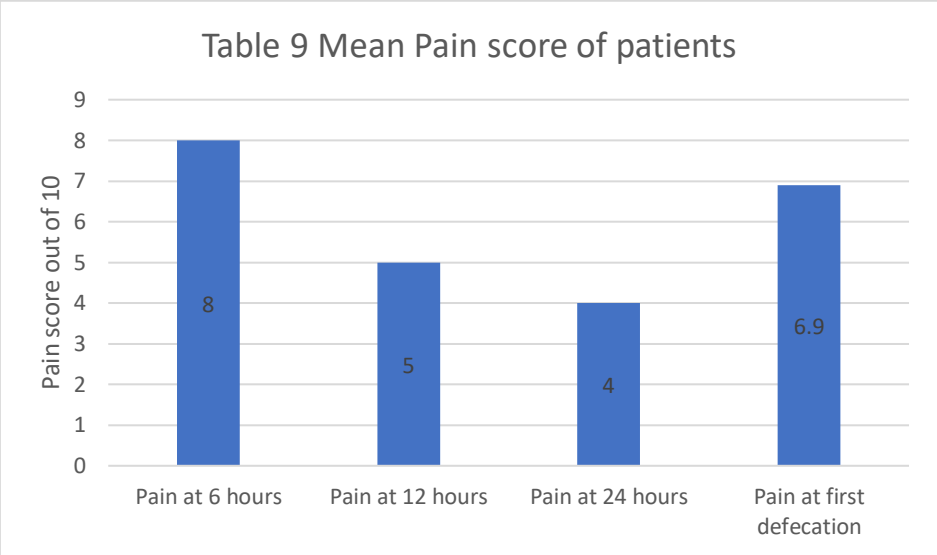


All patients took 15 days to return to work from the day of surgery. The mean duration of surgery was 60 ± 15.3 minutes, while the Mean duration of surgery was 8.6 ± 1.1 days.

Table 9 Mean Pain score of patients			
	N	Mean	Std. Deviation
Pain at 6 hours	60	8.0	1.3
Pain at 12 hours	60	5.0***,###	0.9
Pain at 24 hours	60	4.0***,###	0.9
Pain at first defecation	60	6.9	0.8

*** P<0.001 vs Pain at 12 and 24 hours, ###P<0.001 vs Pain at first defecation.

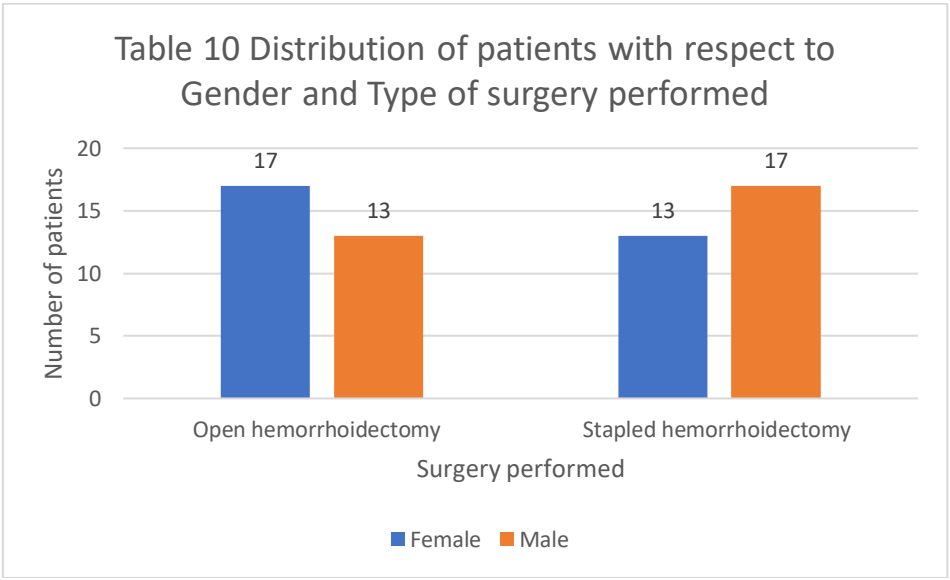
Friedman Test (Nonparametric Repeated Measures ANOVA)



The mean pain score of patients at 6 hours (8±1.3) was significantly higher as compared to that at 12 (5±0.9) and 24 hours (4±0.9). Also the mean pain score of patients at first defecation (6.9±0.8) was significantly higher as compared to that at 12 (5±0.9) and 24 hours (4±0.9)

Table 10 Distribution of patients with respect to Gender and Type of surgery performed				
		Type of surgery performed		Total
		Open hemorrhoidectomy	Stapled hemorrhoidectomy	
Gender	Female	17	13	30
	Male	13	17	30
Total		30	30	60

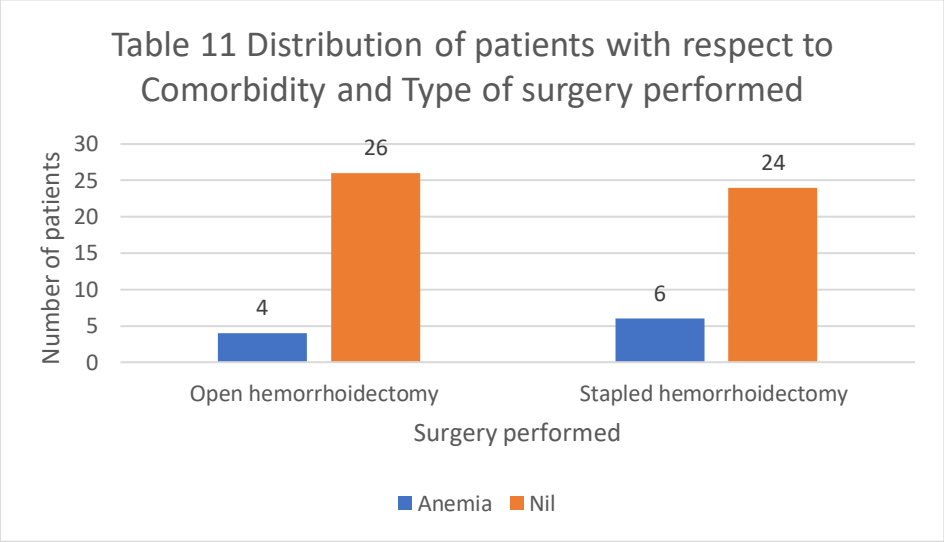
Chi-squared Test for Independence, P value is 0.4884.



No statistical difference between Gender and type of surgery performed was observed.

Table 11 Distribution of patients with respect to Comorbidity and Type of surgery performed				
		Type of surgery performed		Total
		Open hemorrhoidectomy	Stapled hemorrhoidectomy	
Comorbidity	Anemia	4	6	10
	Nil	26	24	50
Total		30	30	60

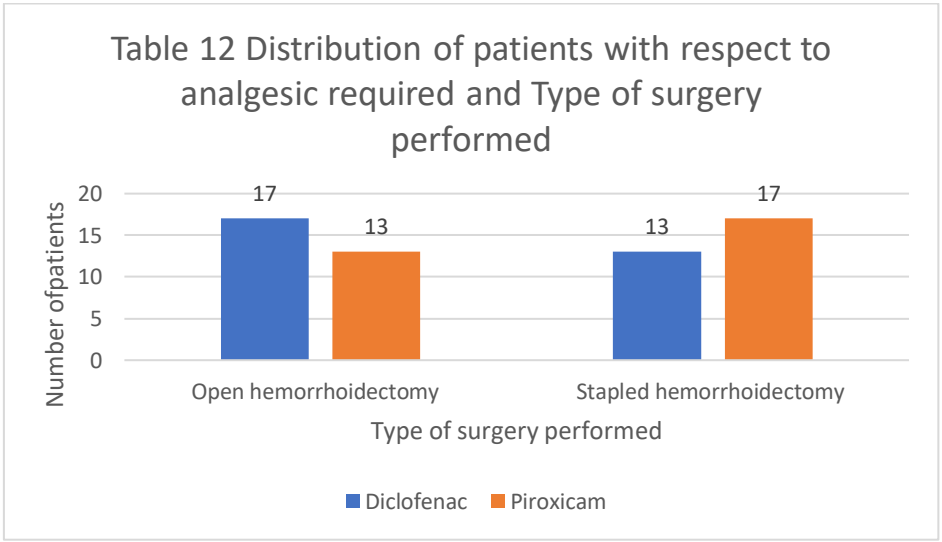
Chi-squared Test for Independence, P value is 0.4884.



No statistical difference between Morbidity and type of surgery performed was observed.

Table 12 Distribution of patients with respect to analgesic required and Type of surgery performed				
		Type of surgery performed		Total
		Open hemorrhoidectomy	Stapled hemorrhoidectomy	
Analgesic required	Diclofenac	17	13	30
	Piroxicam	13	17	30
Total		30	30	60

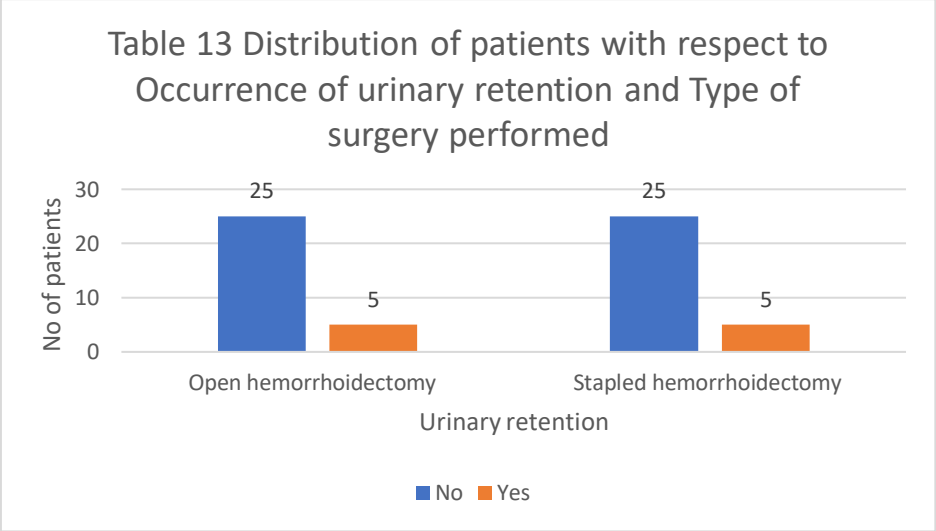
Chi-squared Test for Independence, P value is 0.30.



No statistical difference between analgesic and type of surgery performed was observed.

Table 13 Distribution of patients with respect to Occurrence of urinary retention and Type of surgery performed				
		Type of surgery performed		Total
		Open hemorrhoidectomy	Stapled hemorrhoidectomy	
Urinary retention	No	25	25	50
	Yes	5	5	10
Total		30	30	60

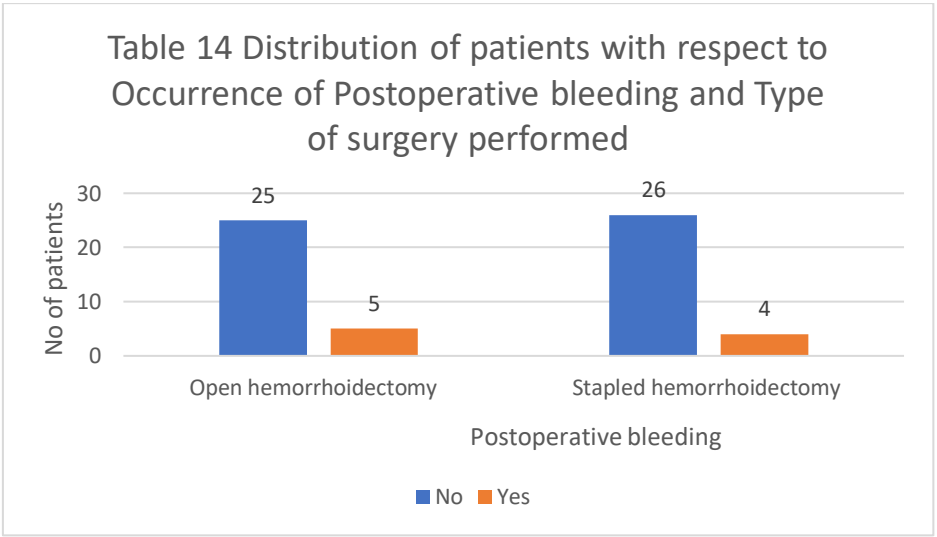
Chi-squared Test for Independence, P value is 1.



No statistical difference between occurrence of urinary retention and type of surgery performed was observed.

Table 14 Distribution of patients with respect to Occurrence of Postoperative bleeding and Type of surgery performed				
		Type of surgery performed		Total
		Open hemorrhoidectomy	Stapled hemorrhoidectomy	
Postoperative bleeding	No	25	26	51
	Yes	5	4	9
Total		30	30	60

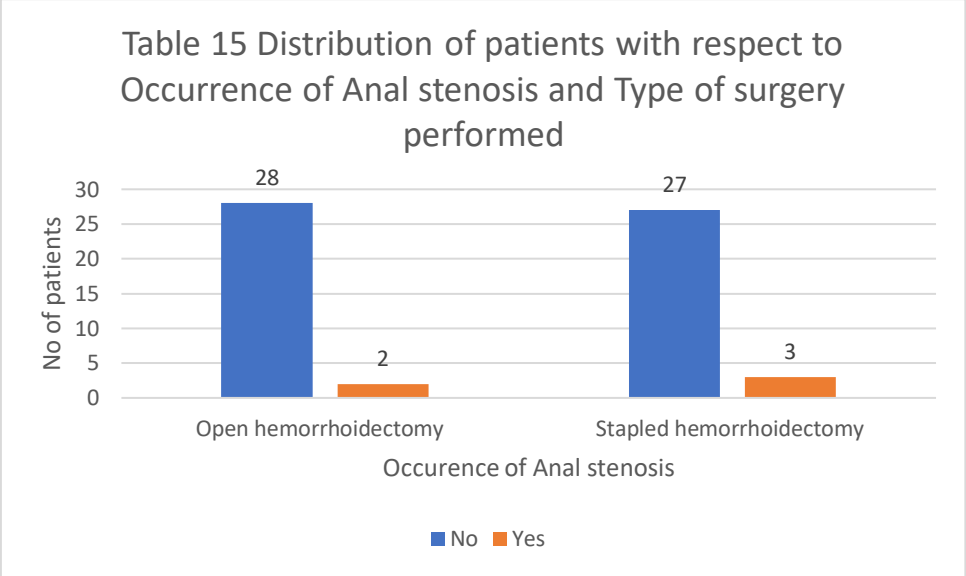
Chi-squared Test for Independence, P value is 0.7177.



No statistical difference between occurrence of Postoperative bleeding and type of surgery performed was observed.

Table 15 Distribution of patients with respect to Occurrence of Anal stenosis and Type of surgery performed				
		Type of surgery performed		Total
		Open hemorrhoidectomy	Stapled hemorrhoidectomy	
Anal stenosis	No	28	27	55
	Yes	2	3	5
Total		30	30	60

Chi-squared Test for Independence, P value is 0.6404.

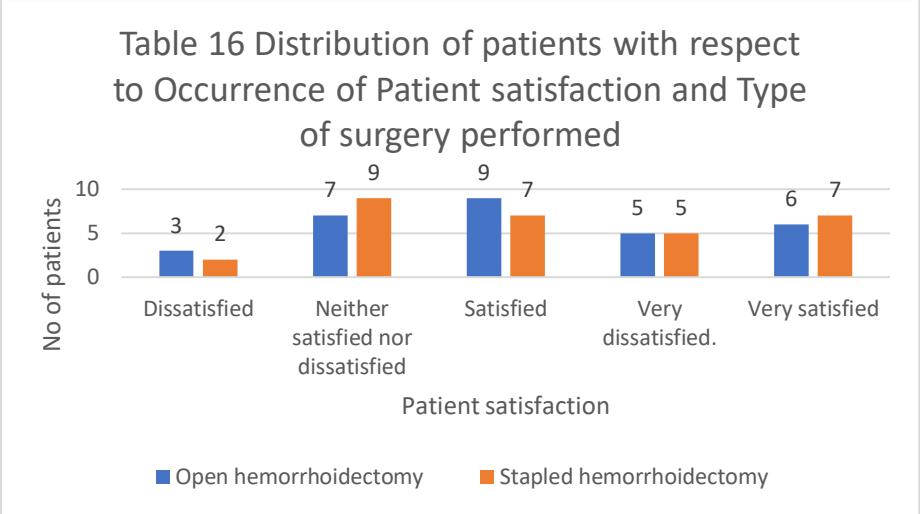


Anorectal physiological functions were normal in all patients irrespective of Type of surgery performed.
No statistical difference between occurrence of anal stenosis and type of surgery performed was observed.

Table 16 Distribution of patients with respect to Occurrence of Patient satisfaction and Type of surgery performed				
		Type of surgery performed		Total
		Open hemorrhoidectomy	Stapled hemorrhoidectomy	
Patient satisfaction	Dissatisfied	3	2	5
	Neither satisfied nor dissatisfied	7	9	16
	Satisfied	9	7	16
	Very dissatisfied.	5	5	10
	Very satisfied	6	7	13
Total		30	30	60

Fisher's Exact Test, P value is 0.6351

Days taken for Return to work were 15 days irrespective of the Type of surgery performed.

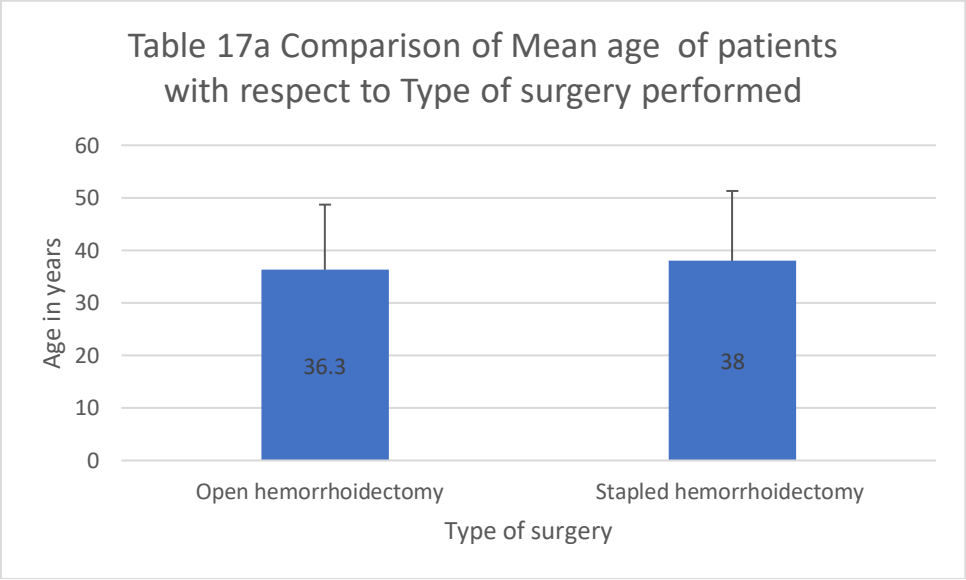


No statistical difference between satisfaction scale and type of surgery performed was observed.

Table 17 Comparison of Mean age and duration of surgery of patients with respect to Type of surgery performed

	Type of surgery performed	Mean	Std. Deviation	P value
Age	Open hemorrhoidectomy	36.3	12.4	0.459
	Stapled hemorrhoidectomy	38.0	13.3	
Duration of surgery	Open hemorrhoidectomy	61.7	16.0	.360
	Stapled hemorrhoidectomy	58.3	14.6	

Independent Samples Test



No statistical difference between mean age and Duration of surgery was found with respect to type of surgery performed was observed.

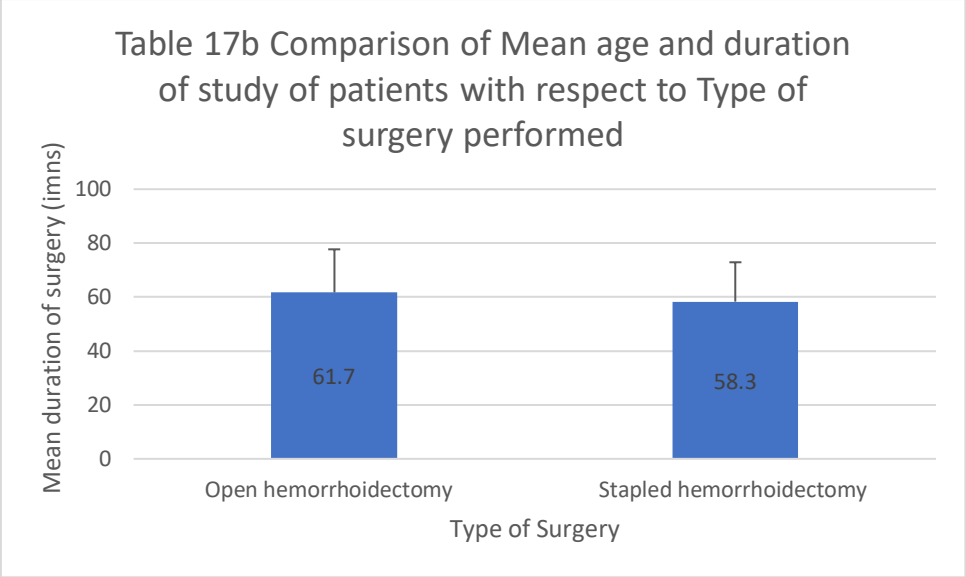
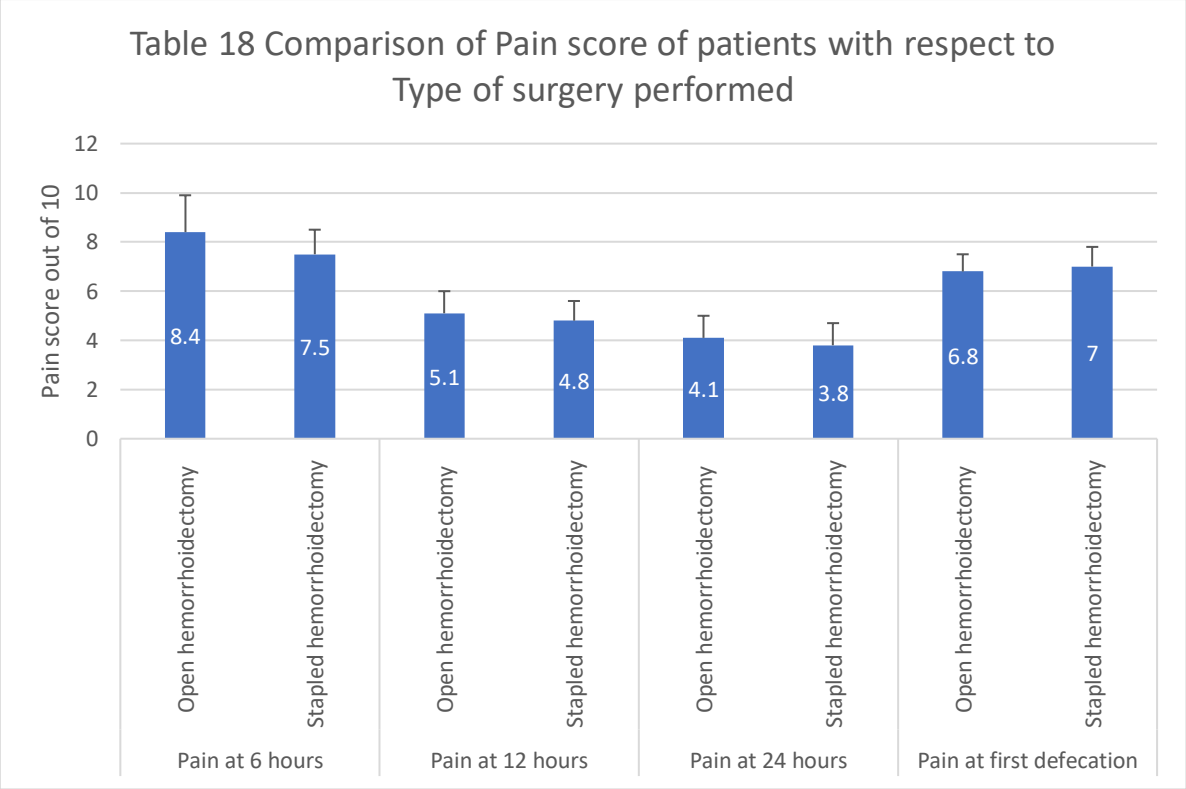


Table 18 Comparison of Pain score of patients with respect to Type of surgery performed				
	Type of surgery performed	Mean	Std. Deviation	P value
Pain at 6 hours	Open hemorrhoidectomy	8.4	1.5	.004
	Stapled hemorrhoidectomy	7.5	1.0	
Pain at 12 hours	Open hemorrhoidectomy	5.1	0.9	.571
	Stapled hemorrhoidectomy	4.8	0.8	
Pain at 24 hours	Open hemorrhoidectomy	4.1	0.9	.836
	Stapled hemorrhoidectomy	3.8	0.9	
Pain at first defecation	Open hemorrhoidectomy	6.8	0.7	.925
	Stapled hemorrhoidectomy	7.0	0.8	



The mean score at 6 hours by open hemorrhoidectomy (8.4±1.5) was significantly higher as compared to by Stapled hemorrhoidectomy (7.5±1). No statistical difference was found between pain. at 12 hours, 24 hours and first defecation with respect to type of surgery perfo

DISCUSSION

Hemorrhoids are one of the commonest benign anorectal problems worldwide.[1]Haemorrhoids, also referred as piles are a pathological condition occurring at the anorectal region. Globally the incidence ranges from 50-80% and in India it affects around 75% of the population[2]. Haemorrhoids, generally has the peak prevalence at the age of 45 to 65 years and affects both the genders. Based on the degree of prolapse, Goligher has graded the Haemorrhoids for the accurate treatment. Thus, first degree Haemorrhoids has visible vessels, second degree haemorrhoids prolapse with defecation and restore instantly, third degree lesions prolapse but requires manual replacement and fourth degree lesions prolapse out of the anal canal[3]. Based on the degree of haemorrhoids, the treatment strategies include dietary restriction, injection sclerotherapy, rubber band ligation, scalpel and laser surgery[4,5,6].

In the present study, 60 patients were included **.** 10 patients (16.7%) suffered from anemia. 30 patients each were operated by Open hemorrhoidectomy and Stapled hemorrhoidectomy.30 patients each required Diclofenac and Piroxicam as analgesic after surgery. 30 patients eachrequiredDiclofenac and Piroxicam as analgesic after surgery. Postoperative complications were seen in 39 patients. Of these Urinary retention (10, 25.6%), Postoperative bleeding (9, 23%) and Anal stenosis (5, 12.8%) were common. All patients took 15 days to return to work from the day of surgery. The mean duration of surgery was 60 ± 15.3 minutes, while the Mean duration of surgery was 8.6 ± 1.1 days. All patients took 15 days to return to work from the day of surgery. The mean duration of surgery was 60 ± 15.3 minutes, while the Mean duration of surgery was 8.6 ± 1.1 days. *** P<0.001 vs Pain at 12 and 24 hours, ###P<0.001 vs Pain at first defecation. Friedman Test (Nonparametric Repeated Measures ANOVA. The mean pain score of patients at 6 hours (8±1.3) was significantly higher as compared to that at 12 (5±0.9) and 24 hours (4±0.9). Also the mean pain score of patients at first defecation (6.9±0.8) was significantly higher as compared to that at 12 (5±0.9) and 24 hours (4±0.9) No statistical difference between Morbidity and type of surgery performed was observed. No statistical difference between analgesic and type of surgery performed was observed. Chi-squared Test for Independence, P value is 0.7177Anorectal physiological functions were normal in all patients irrespective of Type of surgery performed. Chi-squared Test for Independence, P value is 0.7177. Anorectal physiological functions were normal in all patients irrespective of Type of surgery performed.No statistical difference between occurrence of anal stenosis and type of surgery performed was observed. Fisher's Exact Test, P value is 0.6351Days taken for Return to work were 15 days irrespective of the Type of surgery performed.No statistical difference between mean age and Duration of surgery was found with respect to type of surgery performed was observed. The mean score at 6 hours by open hemorrhoidectomy (8.4±1.5) was significantly higher as compared to by Stapled hemorrhoidectomy (7.5±1). No statistical difference was found between pain. at 12 hours, 24 hours and first defecation with respect to type of surgery performed

CONCLUSION

In our study we came to a conclusion that stapled heamarrhoidectomy is comparatively better as compare to open heamarrhopidectomy considering the duration of surgery ,duration of hospital stay and related complications

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