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To evaluate and compare Stapled Haemorrhoidopexy and Milligan-Morgan Haemorrhoidectomy with respect to patient outcome

Sumit Kumar[1], Ankit Verma[2], Pranava Dutta Verma[3], Sanjeev Kumar Bharti[4]
Abhineet Kumar[5], Manoj Kumar[6]

[1](Department of surgery/ NMCH, Patna.Bihar,India)
[2](IPJMR & SSKM Hospital , Kollkata,India))
[3](Associate professor/ NMCH,Patna,Bihar ,India)
[4](Post Graduate Student/ NMCH,Patna,Bihar ,India)
[5](Post Graduate Student/ NMCH,Patna,Bihar ,India)
[6](Post Graduate Student/ NMCH,Patna,Bihar ,India)

Abstract:
***Background*:-** *Haemorrhoids, also known as piles, are one of the most common anorectal disorders and they are characterized by dilated veins of the anal canal. Common predisposing factors are obesity, constipation and pregnancy. They affect millions of people around the world, and represent a major medical and socioeconomic problem. Different studies showed that about 5%-10% of patients suffering from haemorrhoids do not respond to conservative treatments, so surgical procedures become the treatment of choice in such cases. Symptomatic third and fourth degree haemorrhoids result in considerable morbidity to the patient, and require excision of the offending venous cushion to provide any degree of relief to the patient. Milligan-Morgan open haemorrhoidectomy is the most widely practiced surgical technique used for the management of third and fourth degree haemorrhoids but it has it's own complication. Now we will compare Milligan-Morgan open haemorrhoidectomy with staple haemorrhoidopexy in last 2 years with promising results.*
Materials and Methods*: In this prospective, observational, comparative study conducted in NMCH Patna we include 120 patients and divided in 2 groups randomly, each fulfilling the inclusion and exclusion criteria who were followed up for 6 months post-operatively were included using convenient sampling. Data was collected and entered into Microsoft excel sheet. Data was analyzed using MedCalc for Windows, version 17.5.5:*
Results*: Stapled Haemorrhoidopexy is superior to Milligan Morgan haemorrhoidectomy over duration of surgery and intra-operative bleeding. SH has an edge on MMH over post-operative pain, duration of hospital stay and time to return to work.*
Conclusion: - *Stapled haemorrhoidopexy appears to have advantage of less post-operative pain and less time to return to work over Milligan Morgan haemorrhoidectomy*.
Key Word*:* ***Haemorrhoids, Milligan Morgan haemorrhoidectomy, Stapled haemorrhoidopexy, Rectal Prolapse.***

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I. Introduction

Haemorrhoids, also known as piles, are one of the most common anorectal disorders. They are fibrovascular cushions containing arteriovenous communications that are located in the sub epithelial space of anal canal and are a normal part of human anatomy.[1]

Haemorrhoids are characterized by dilated veins of the anal canal, classically occurring at the 3, 7 and 11 o'clock position with the patient in lithotomy position. Common predisposing factors are obesity, constipation and pregnancy. Symptoms of haemorrhoids are painless per-rectal bleeding, during passage with stools and separate from stool. Other clinical manifestations include discomfort, discharge, hygiene problems, soiling, and pruritus.[2,3]

Long standing haemorrhoids with a history of straining can lead to prolapse. Prolapsed haemorrhoids can present as something lying outside the anus, thrombosis leading to pain, and abscess formation.

They affect millions of people around the world, and represent a major medical and socioeconomic problem.[4] The frequency peaks between the age of 45 and 65 years and is more common in men.[5] There is a decline in the incidence after the age of 65.

Haemorrhoids can be classified into according to their size and degree of mucosal prolapse. Most colorectal surgeons use the grading system by Banov et al –
Grade Ⅰ: Anal cushions bleed without prolapse;
Grade Ⅱ: Anal cushions prolapse on straining but reduce spontaneously;
Grade Ⅲ: Anal cushions prolapse on straining or exertion and require manual reduction;
Grade Ⅳ: The prolapse is irreducible and remains out all the time.[6]

Approximately one-third of patients affected by haemorrhoids seeks medical advice.

Different studies showed that about 5%-10% of patients suffering from hemorrhoids do not respond to conservative treatments, so surgical procedures become the treatment of choice in such cases.[7]

Treatment of hemorrhoids depends on symptomatic discomfort and degree of hemorrhoids. Injection sclerotherapy and banding are the usual treatment for first degree and second degree hemorrhoids. These are simple OPD procedures and work by occluding the lumen of the veins. They provide effective relief to patients of early grade hemorrhoids.

Symptomatic third and fourth degree hemorrhoids result in considerable morbidity to the patient, and require excision of the offending venous cushion to provide any degree of relief to the patient. Milligan-Morgan open hemorrhoidectomy is the most widely practiced surgical technique used for the management of third and fourth degree hemorrhoids and is currently considered the "gold standard" though some early and late postoperative complications like anal pain, acute retention of urine, anal stenosis and incontinence are evident.[8,9]

Circular stapled haemorrhoidopexy was first described by Longo in 1998 as an alternative to conventional excisional haemorrhoidectomy.[10] The principle of Stapled haemorrhoidopexy is excision of a strip of mucosa and submucosa, leading to disruption of vascular supply of the hemorrhoids, as well as pulling up of the prolapsed tissue. Some randomized controlled trials comparing stapled haemorrhoidopexy with traditional excisional hemorrhoidectomy have shown it to be less painful and associated with quicker recovery.[11-14]The reports also suggest a better patient acceptance and a higher compliance with day-case procedures potentially making it more economical. Some other studies has reported that patients undergoing circular stapled haemorrhoidopexy were significantly more likely to have recurrent hemorrhoids in long term follow up as well as significantly higher proportion of patients with stapled hemorrhoidectomy complained of symptoms of prolapse than those receiving conventional haemorrhoidectomy.[15-18] None of these studies have gained universal acceptance.

At our institute, we have traditionally done Milligan-Morgan hemorrhoidectomy with good results. However, we have also begun stapled haemorrhoidopexy in the last one year with promising results. But there was still a lot of controversy over patient selection and outcomes of the two methods. Hence, we conducted this study to compare the two procedures with respect to patient outcome.

II. Material And Methods

My study is a prospective, observational, comparative study conducted in the Department of General Surgery, Nalanda Medical College, Patna, Bihar after obtaining clearance from the institutional ethics committee and an informed consent from the patients from March 2019 to February 2021.

All patients presenting with grade III/IV hemorrhoids to our department. According to previous data of past three years, the average number of patients who underwent hemorrhoidal surgery in our hospital was 90 per year.

Study design:

Prospective, observational, comparative study

Sample size with justification:

Using data from study C. Ammaturo et al.[19] and with G*power 3.1.9.2, I calculated sample size to be 59 patients in each arm to get adequate effect of study.

Hence, I have taken sample size of 120 patients, with 60 in each arm.

Time frame to address the study:

March2019 – February, 2021

Inclusion criteria:

All patients above 14 years of age presenting with grade three/four haemorrhoids to our department and underwent surgical intervention.

Exclusion criteria:

1 Patients of bleeding diathesis, liver disease or patient on anticoagulants.
2 Patients with other concomitant gastrointestinal diseases such as ulcerative colitis, Crohn's disease, anal fissure.
3 Pregnant patients

Study work up:

All patients were diagnosed with grade III/IV hemorrhoids by senior surgeons, either in OPD or emergency setting. Patients were admitted a day before surgery. Thorough history taking was done, all relevant details were noted.

Patients were given option about the surgical procedures including MMH and SH, all advantages and disadvantages of both procedure explained to patient. Patient was posted for procedure according to their informed preference.

Selection of patients in this study was based on strict inclusion and exclusion criteria. Only patients with clinical diagnosis of symptomatic Grade III and IV hemorrhoids were included. Patients were advised to undergo surgery and patients who gave consent for surgery were taken up. Patients were explained in detail about participating in this study and its purpose, in a language he/she understood. Patient information sheet was provided and written informed consent was taken from all the patients included in the study. For all patients agreeing to participation in the study, thorough history was taken and all relevant details were noted.

Pre-operative evaluation:

Blood investigations including haemoglobin, total counts, differential counts, random blood sugar, serum urea, serum creatinine, urine routine and microscopic examination, electrocardiogram, serum electrolytes, Chest x-ray PA view, HIV 1 and 2, HBsAg, HCV were also done. After pre-operative work up the patients were sent for pre-anaesthetic checkup where the provisional fitness for surgery was declared.

Patient were asked to come for admission one day prior to the date of surgery with all investigation reports along with pre-anaesthetic check-up fitness card. Review is done by anaesthetist the day before surgery again as a second check and final fitness for surgery was declared and any special precautions during surgery were documented. Risk consent for the surgery was taken.

Risk consent includes consent about information regarding procedure of MMH and SH and risk involved in surgery which includes risk of bleeding and anal sphincter injury. Consent was signed in person by the patient and guardian's signature was taken in case the patient was below 18 years.

All patients were explained about VAS for charting of post-operative pain. All the patients were given a dose of 0.5 mg alprazolam and 150 mg of ranitidine night before surgery as preanesthetic medication. All patients were kept nil per orally from midnight on the day of surgery. However, any regular medicine taken by the patient such as antihypertensive drugs and thyroid hormones were given on the morning of surgery as per normal schedule. Antiplatelet drugs and oral hypoglycemic drugs were discontinued before surgery. Diabetic patients were kept on glucose insulin drip titrated to their blood sugar level.

Pre-operative preparation was done in all cases (hair clipping, bathing, betadine painting and covering of surgical site before taking to operation theatre). Test dose of Injection (Inj.) Cefuroxime was given in the ward 1 hour before surgery. Patients were shifted to pre-operative care room half hour before surgery for immediate pre-operative assessment about maintenance of nil per oral, patency of intravenous cannula, vitals checked, weight measured and all events documented. All surgeries were done in operation theatre in lithotomy position under standard operating conditions by senior consultant surgeons. All surgeries were done under spinal or general anesthesia. All patients were given Inj. Cefuroxime 1.5 gm intravenously just prior to skin incision. All patients were catheterized just prior to skin incision. Operative time was noted from start of skin incision to end of skin closure.

Operative procedure

In Milligan Morgan haemorrhoidectomy, a gentle two fingers dilatation of the anal canal is performed. Artery forceps are placed on the perianal skin just outside the muco-cutaneous junction opposite to each primary haemorrhoid cushion at 3, 7 and 11 O' clock position. Gentle traction is applied to the forceps to bring the internal haemorrhoids into view.

As the internal haemorrhoids are pulled down, a second pair of artery forceps are placed on the main bulk of each haemorrhoidal mass. Further traction on forceps exposes the haemorrhoidal pedicles and the haemorrhoids are ready to be dissected.

The haemorrhoids are divide in turn, starting with no. 3 o' clock. The two artery forceps are held in the left hand of the surgeon with his left index finger in the anal canal pressing on the pedicle to the out. By the right hand using scissors, the skin at muco-cutaneous junction is cut in 'V'- shape manner, then the dissection of subcutaneous space is done till the pedicle of the haemorrhoids is reached. Beware not to injure the external or internal sphincter during the process.

After traction is applied on the haemorrhoids, transfixation and ligation of the pedicle by No. 0 catgut with the knot tied on the lumen side. Control the bleeding and oozing from subcutaneous raw area by ligation or cauterization. Now the second transfixation to the pedicle is applied proximal to the first one and sutured. The pedicle is cut through, leaving sufficient cuff.

The other haemorrhoids are removed in a similar fashion leaving intact bridge of perianal skin and anal mucosa between each dissection side should not be less than one centimetre wide. The three pedicles of haemorrhoids are sutured to the skin and the final appearance of the operation area are presence of 3 pedicles covering the three raw areas of dissection

MMH in our hospital

Figure 24: Pre-operative grade 3 hemorrhoids

Figure 25: Excised same hemorrhoid after MMH

Figure 26: Same case Post MMH.

In stapled haemorrhoidopexy, a specialized circular stapler kit is used having the following components-

- A 33mm hemorrhoidal circular stapler
- Suture threader- hook tip to catch suture ends while threader passes through casing ports.
- Circular Anal Dilator with obturator- Clear obturator provides smooth insertion and view of dentate line.
- Purse-String Suture Anoscope.

SH is also performed in lithotomy position under general or regional anesthesia. It involves the following steps-

Prolapse reduction and Instrument introduction- The anal verge is gently massaged and dilated before inserting the dilator. The obturator is inserted alone for dilatation to prevent damage to the internal sphincter. The obturator is then removed and circular anal dilator along with the obturator is inserted. This pushes the mucosal prolapse back into the anal canal. The tubing aspect of the dilator which s 3cm in length should overlies the dentate line to prevent damage to the dentate line and the internal sphincter. The skin is then milked out and the tissue is flattened to ensure complete insertion of the dilator and prevent damage to dentate line. The circular anal dilator is fixed by suturing the dilator on perianal skin through the four slots on flange of circular anal dilator. This transparent circular anal dilator allows easy instrumentation and proper vision of dentate line and internal sphincter, so that they could be prevented from damage.

Taking Purse-string sutures- The new, clear purse-string suture anoscope is inserted through the circular anal dilator and circumferential purse string sutures using 2-0 Prolene are placed at the correct height (around 2 to 3 cm above the apex of haemorrhoids at the tip of the anoscope) and depth should include only mucosa and submucosa. Clear purse string suture is completely extracted, then rotated and inserted again before taking each purse string suture. Rotating anoscope while it is fully inserted in the circular anal dilator can twist the mucosa and can leads to an improper asymmetric purse-string suture. A finger is placed in the anus and the purse-string suture is tightened to check that there is uniform circumferential closure and no skins or gaps in between. The location of the purse-string suture ultimately must result in a staple line that resides at least 2cm above the dentate line. The circular anal dilator preserves the unstriated sphincter and permits the atraumatic placement of a purse-string suture.

Circular stapler and suture threader- After the purse-string sutures are complete, the ends of the suture are knotted externally. Now, the entire casing of stapler is introduced into the anal canal after partial opening of the stapler along the axis of anal canal and moderate traction is maintained on the purse-string sutures to draw complete prolapsed mucosa into stapler casing. When the circular stapler is completely inside the anal canal it is opened completely and the both ends of purse-string sutures are fed into the stapler using the threader.

Closing and Firing- Prior to firing, the 4cm mark on the stapler casing is positioned at the level of the anal verge, placing the staple line at the proper height. If the patient is female, check the posterior vaginal wall to certain that it has not been incorporated in the staple line. After ascertaining the position of stapler and prolapse mucosa in it, safety is removed and stapler is fired. As the stapler is closed completely, the orange indicator will advance to the low end of the green gap setting scale, toward the smaller "B". Tighter stapler compression reduces the risk of bleeding from the staple line. The safety should not be touched until the device is ready to fire. Whenever ready, the safety is released and stapler is fired in one fluid motion. The stapler is kept fully closed for approximately 30 seconds before and 20 seconds after firing. It act as a tamponade, which may help promote haemostasis. A one-half to three-quarters turn of the adjusting kb of the stapler facilitates the extraction of stapler with complete doughnut. Additional turns should be avoided as it can cause interposition of mucosa between the anvil head and the upper edge of the circular anal dilator.

Post-firing- After the firing, open the circular stapler one half to three-quarters of a turn for easy extraction. The purse-string suture anoscope is reinserted and careful inspection of the staple line is done. Make sure the staple line is completely intact. Any bleeding is handled by suturing with vicryl 2.0. Anal packing is done. Doughnut is checked and it should contain a 3cm wide strip of rectal mucosa and possibly haemorrhoid tissue with no or minimal muscle. Correct placement of the muco-mucous suture over the anorectal ring should be at least 2 to 4 cm above the dentate line.

Figure 27: Instruments in stapler haemorrhoidopexy Kit

Stapled haemorrhoidopexy performed in our hospital

Figure 28: Pre-op Grade 3 hemorrhoids

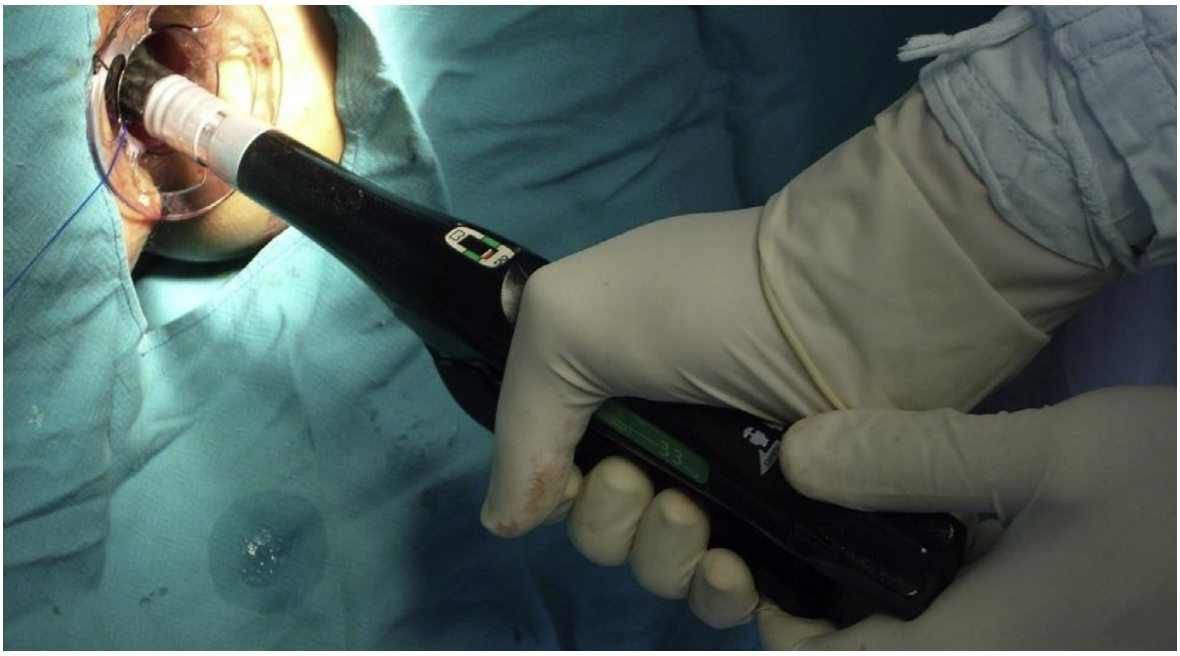


Figure. 29: Stapler being fired

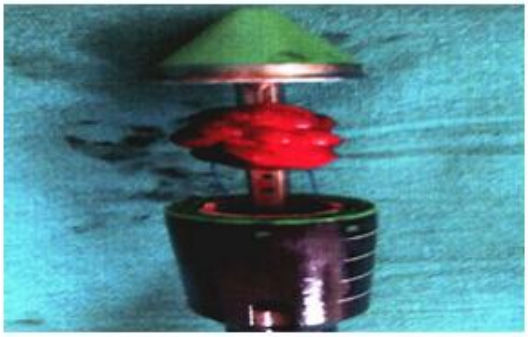


Figure 30 : Doughnut after stapler haemorrhoidopexy

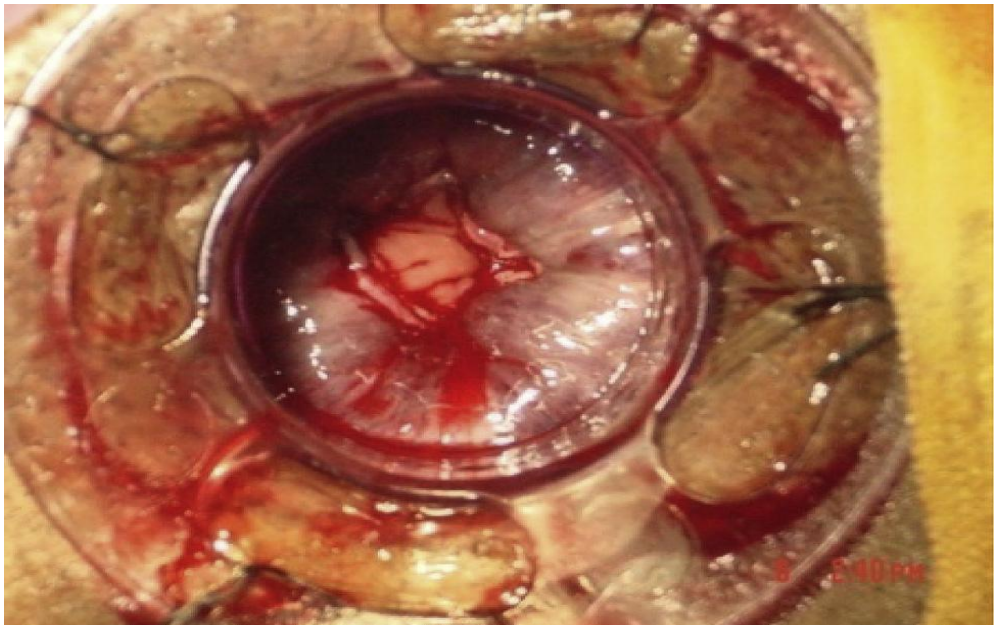


Figure 31: Inspection of stapler line for bleeding

Figure 32: Post-op picture of same patient after Stapler haemorrhoidopexy

Intra-operative assessment

Operative time was recorded for each patient and defined as from the point of first digital rectal examination to insertion of anal pack. Anal packing was done in all cases with betadine soaked gauge. Bleeding during surgery was assessed on the basis of number of and percent of soakage of sponges that is of 4×4 cm in size. Soakage of one 4×4 centimetre gauze piece was considered as 30 ml blood loss, as per Bakhtiar N et al.[20]

Post-operative assessment

Post-operatively all patients were examined on evening of surgery by operating surgeon. Patients were allowed orally after patients were out of the effects of general or spinal anaesthesia. Patients were managed suitably in the ward. Two doses of Inj. Cefuroxime 1.5 gm intravenously were given. One at 8 hours after surgery and 2nd dose at 16 hours after surgery. All the patients were administered Inj. Diclofenac 75 mg intramuscularly one immediately at the end of procedure and second dose at 12 hours after surgery. Patients were advised to do day to day activities immediately after recovering from effects of anaesthesia. Catheter was removed in next morning after surgery. Wound inspection was done on post-operative day one after removal of pack and patients were advised to take Sitz bath three times a day. Stool softeners such as Syrup Lactulose is given in a dose of 15ml at night, from the night of surgery, to prevent constipation and straining.

Patient were asked about VAS which consist of a 0-10 mm line scale with 0 at one end depicting 'no pain' and 10 at the other end depicting 'worst pain imaginable'. All the patients were counselled and demonstrated when and how to express the pain intensity at the time of first evaluation on day of surgery. They were asked to move the marker present over the scale to a point which represents their pain intensity best. VAS pain score chart was filled by each patient as explained at 6 hours, 24 hours and 48 hours from completion of surgery.

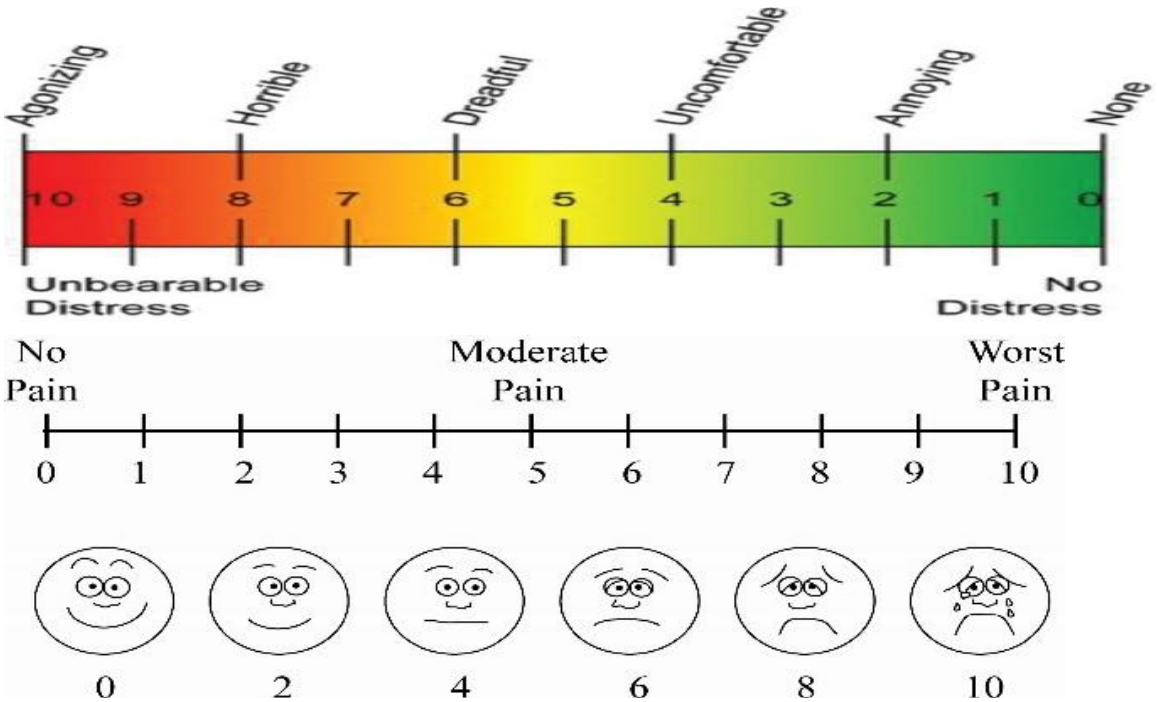


Fig 33: Visual Analogue Scale (VAS) pain score chart.

Patients were restarted on all medications which had been stopped before surgery after 24 hours. Patients were given oral Tablet (Tab.) Cefuroxime 500 mg twice daily, Tab. Diclofenac 50 mg twice daily and Tab. Ranitidine 150 mg twice daily on first post-operative day. Patients were given Inj. Diclofenac 75 mg stat as a rescue analgesic if VAS pain score was greater than 5.

Patients were discharged after recovery and date of discharge was noted. Patients were allowed to go home when they were fully comfortable on oral analgesics, fully mobile, and tolerating normal diet. Diclofenac Sodium 50mg tablets were prescribed for all patients to be taken when required, but not more than twice a day Tab. Cefuroxime 500mg twice daily was continued for 5 days. Sitz bath and laxatives were continued for one week postoperatively. Patients were given a telephone number on discharge to call for queries in emergencies.

Follow up after discharge

After the discharge patient were followed up on OPD basis for the duration of 6 months. The duration required by patient to return to work was recorded by questioning the patient during follow-up visits to the OPD.
Thereafter, OPD follow up was done at:

- 2^{nd} week and 4^{th} week for assessment of:
  1 Pain
  2 Anal incontinence
  3 Anal stenosis
- Every month up to 1^{st} six months for assessment of:
  1 Anal stenosis
  2 Recurrence

Data collection forms:

All the data pertaining to the research were entered into data collection forms as mentioned in Annexures attached directly filled or transcribed from operation theatre after surgery

Statistical Analysis

Data is collected and entered into Microsoft excel sheet and then analyzed using MedCalc for Windows, version 17.5.5. Cases are further divided in two groups namely MMH and SH. Following statistical significance tests are applied:
Mean, variance and standard deviation is calculated.
Student's T-test is used as statistical tool to test for the significance of observed mean differences. 'p'-value of < 0.05 is taken as significant.
Chi-square test is used as test of significance for difference of proportion. 'p'-value of <0.05 is taken as significant

III. Result

A total of 60 patients with clinical diagnosis of Grade 3 and 4 haemorrhoids were included in each of the two study groups.

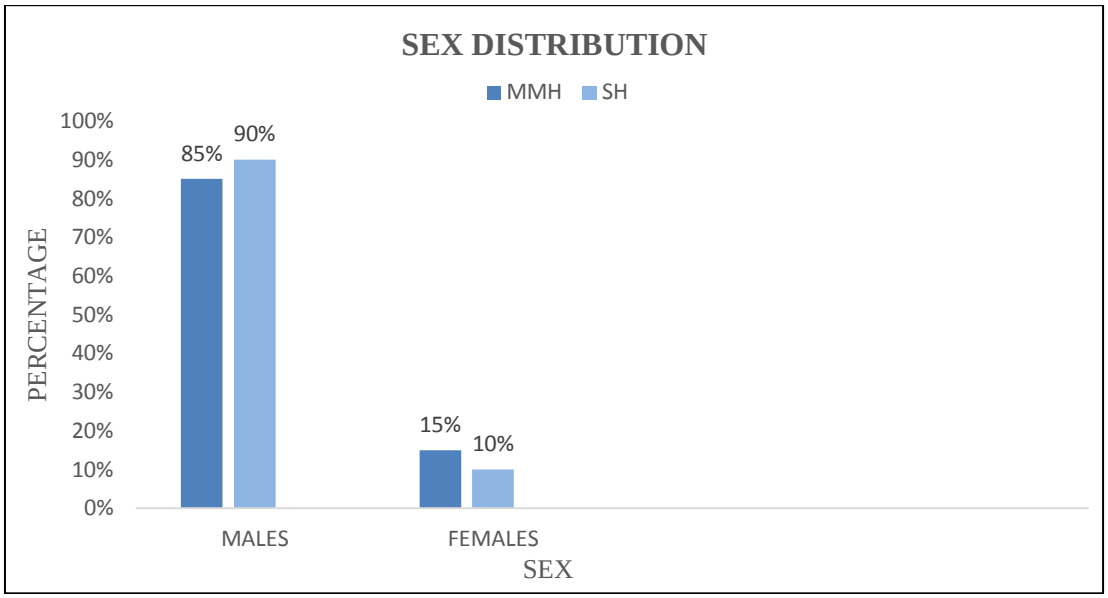
Table no. 3: Patients in two groups.

Group	Number of patients
MMH	60
SH	60
TOTAL	120

Sex distribution

Table no. 4: Sex distribution among two groups

Gender	MMH (n = 60)		SH (n = 60)		'χ2' value	'p' value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)		
Male	51	85.00	54	90.00	0.680	0.4096
Female	9	15.00	6	10.00	0.680	0.4096



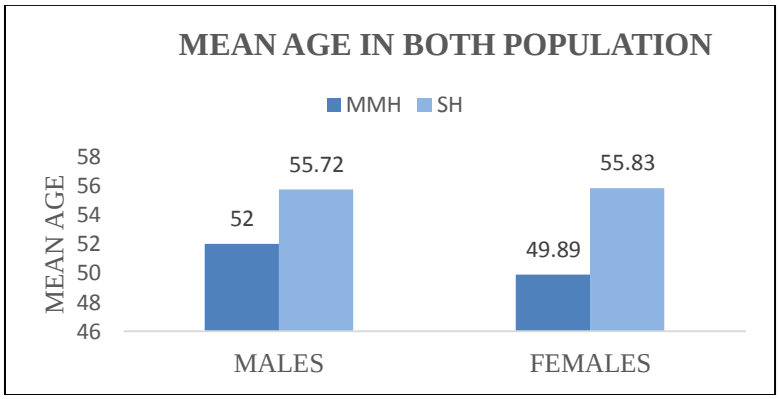
Graph no. 1

In our study males are predominant in both groups with around 85% being males in MMH group and 90% being males in SH group. Proportions of males and females in each group are similar with statistically insignificant difference ($p > 0.05$), which means both the groups are matching on the basis of sex distribution.

Age distribution

Table no.5: Mean age of patients among two groups

Gender	MMH (n = 60)	SH (n = 60)	|t| cal	'p' value
	Mean ± standard deviation	Mean ± standard deviation		
Male	52 ± 15.26	55.72 ± 14.11	1.386	0.1682
Female	49.89 ± 12.67	52.84 ± 16.30	1.107	0.2706
Overall	51.68 ± 14.92	55.43 ± 14.37	1.402	0.1635



Graph no. 2

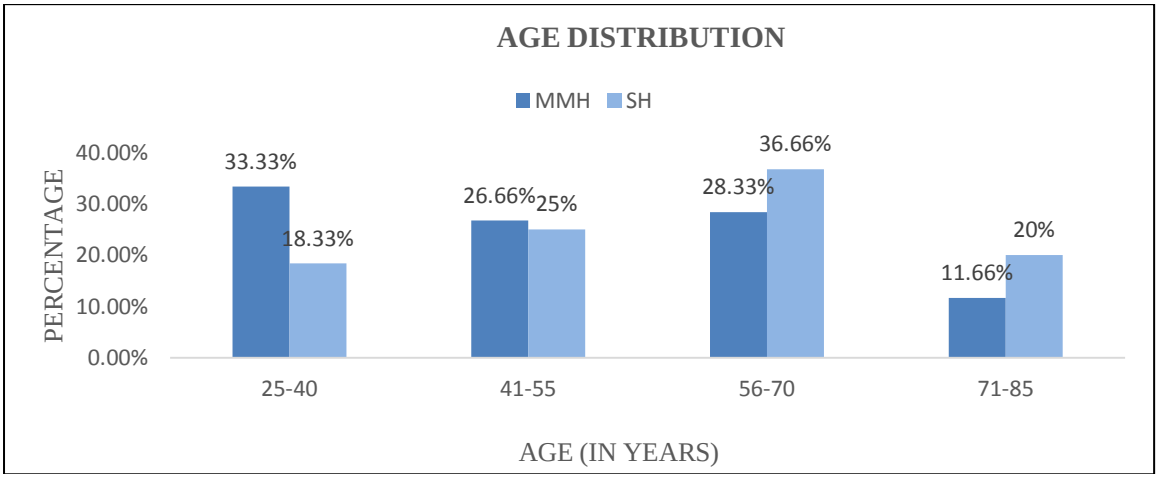
Overall, mean age for MMH is 51.68 and mean age for SH is 55.43. The difference is insignificant with p- value > 0.1635.

Mean age for males in MMH is 52 while mean age for males in SH is 55.72 with insignificant difference and p-value of 0.1682.

Similarly, mean age for females in MMH is 49.89 and mean age for females in SH is 52.84 The difference is insignificant with p- value of 0.2706.

Table no.6: Age distribution among two groups

Age (in years)	MMH(n = 60)		SH(n = 60)		'χ2' value	'p' value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)		
25-40	20	33.33	11	18.33	3.494	0.0616
41-55	16	26.67	15	25.00	0.043	0.8361
56-70	17	28.33	22	36.67	0.941	0.3320
71-85	7	11.67	12	20.00	1.553	0.2127



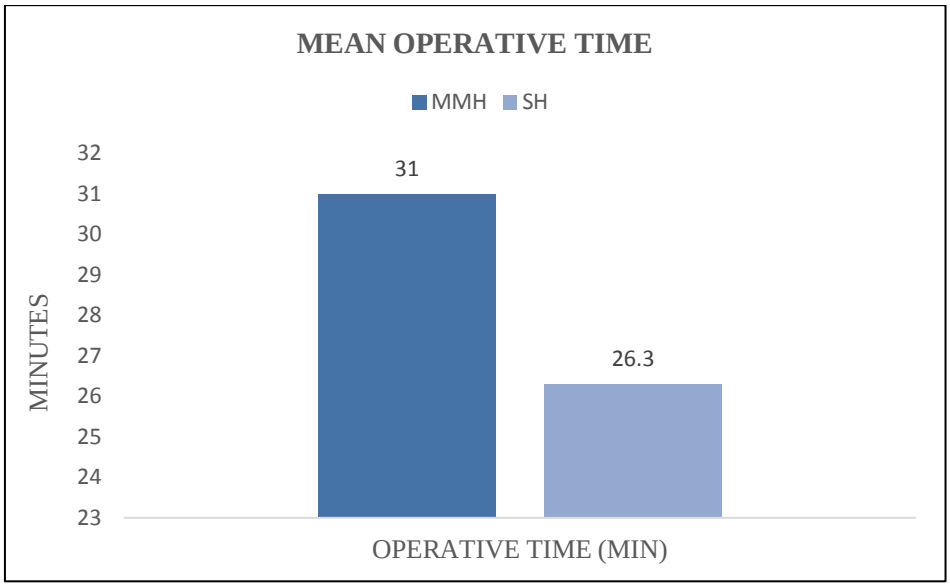
Graph no. 3

The patients who underwent hemorrhoidectomy are in age group ranging from 25-85 years in both groups. The maximum number of patients undergoing MMH are in age group of 25-40 years while maximum number of patients undergoing SH are in age group of 56-70 years.

Operative time

Table no.7: Operative time.

Parameter	MMH (n = 60)	SH (n = 60)	|t| cal	'p' value
	Mean ± standard deviation	Mean ± standard deviation		
Operative Time (Minutes)	31 ± 7.06	26.30 ± 5.83	- 3.976	0.0001



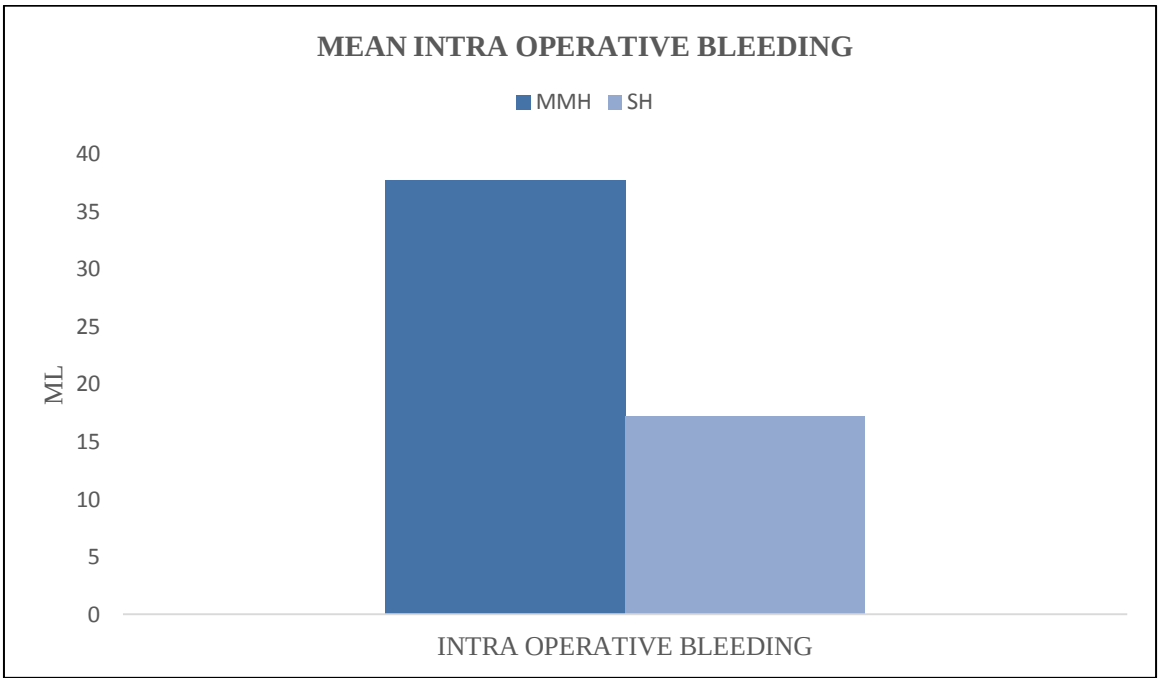
Graph no. 4

Mean operative time (in minutes) for SH (26.30 ± 5.83) is lesser than MMH (31±7.06). The mean time difference is significant with p- value of 0.0001.

Intra-operative bleeding

Table no.8: Intraoperative bleeding among two groups

Parameter	MMH (n = 60)	SH (n = 60)	|t |cal	'p' value
	Mean ± standard deviation	Mean ± standard deviation		
Intraoperative bleeding (ml)	37.67 ± 9.41	17.17 ± 5.16	- 14.796	<0.0001



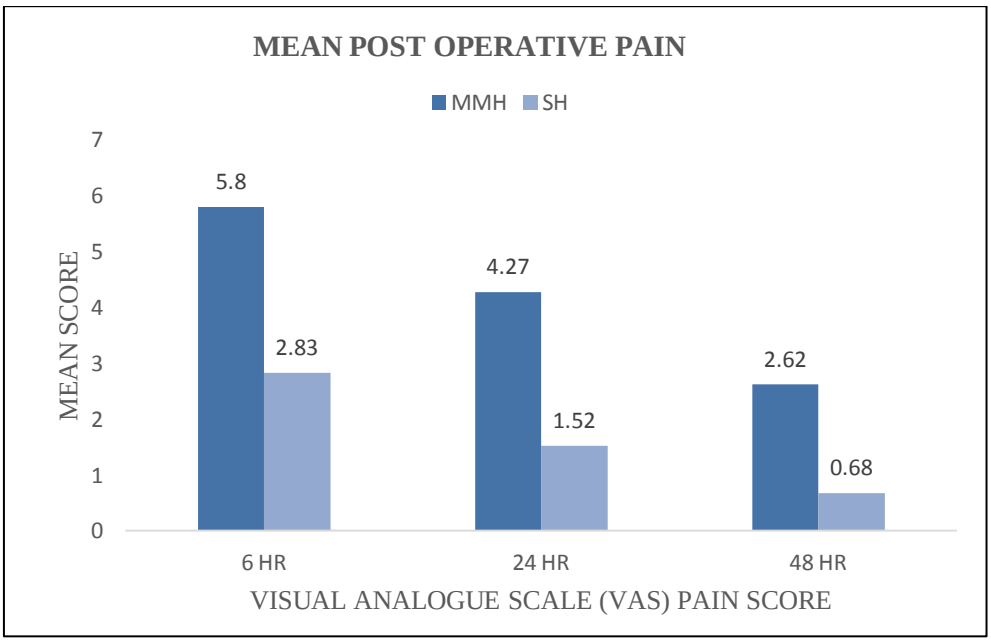
Graph no. 5

Intra operative bleeding (in ML) is more in MMH (37.67 ± 9.41) than that of SH (17.17 ± 5.16). This difference is significant with p- value of <0.0001.

Post-operative pain

Table no. 9: Visual analogue scale (VAS) pain score among two groups.

Time After Operation	MMH (n = 60)	SH (n = 60)	|t|cal	'p' value
	Mean ± standard deviation	Mean ± standard deviation		
6 hrs.	5.80 ± 2.05	2.83 ± 1.08	-9.929	< 0.0001
24 hrs.	4.27 ± 1.66	1.52 ± 0.67	-11.899	< 0.0001
48 hrs.	2.62 ± 1.38	0.68 ± 0.65	-9.851	< 0.0001



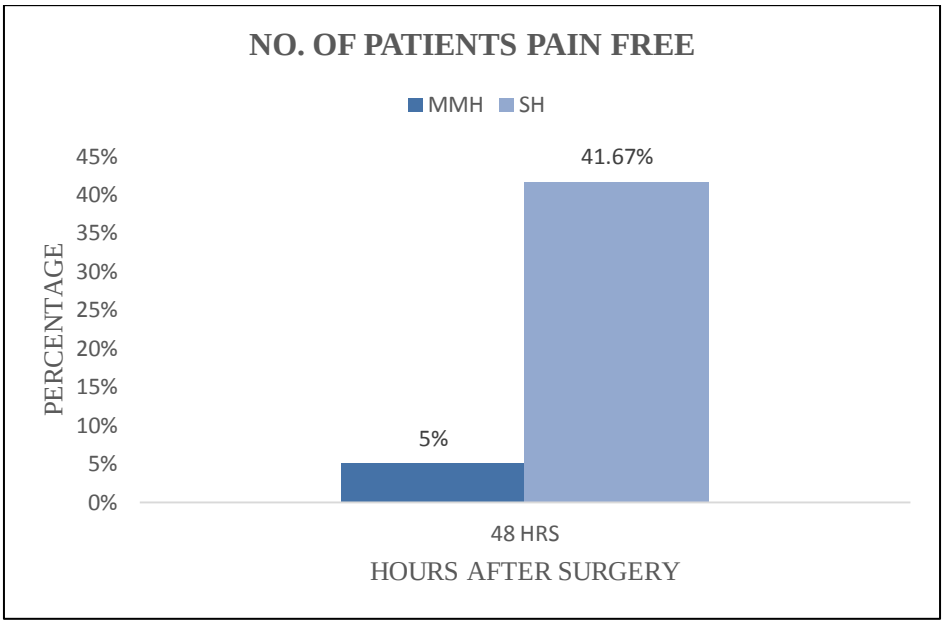
Graph no. 6

The mean post- operative pain on visual analogue scale at 6th hour is 5.80 ± 2.05 in MMH and 2.83 ± 1.08 in SH has significant difference with p- value <0.0001. Pain after 24 hours is 4.27 ± 1.66 in MMH and 1.52 ± 0.67 in SH with significant difference and p- value of <0.0001. Pain after 48 hours of surgery in MMH is 2.62 ± 1.38 and in SH is 0.68 ± 0.65, having significant difference and p- value of <0.0001.
Thus, overall immediate post-operative pain is significantly more in MMH as compared to SH.

Number of patients pain free

Table no.10: Number of patients pain free among two groups

Time after operation	MMH (n = 60)		SH (n = 60)		'χ2' value	'p' value
	No. of patients	Percentage (%)	No. of patients	Percentage (%)		
48 hrs.	3	5	25	41.67	22.362	<0.0001



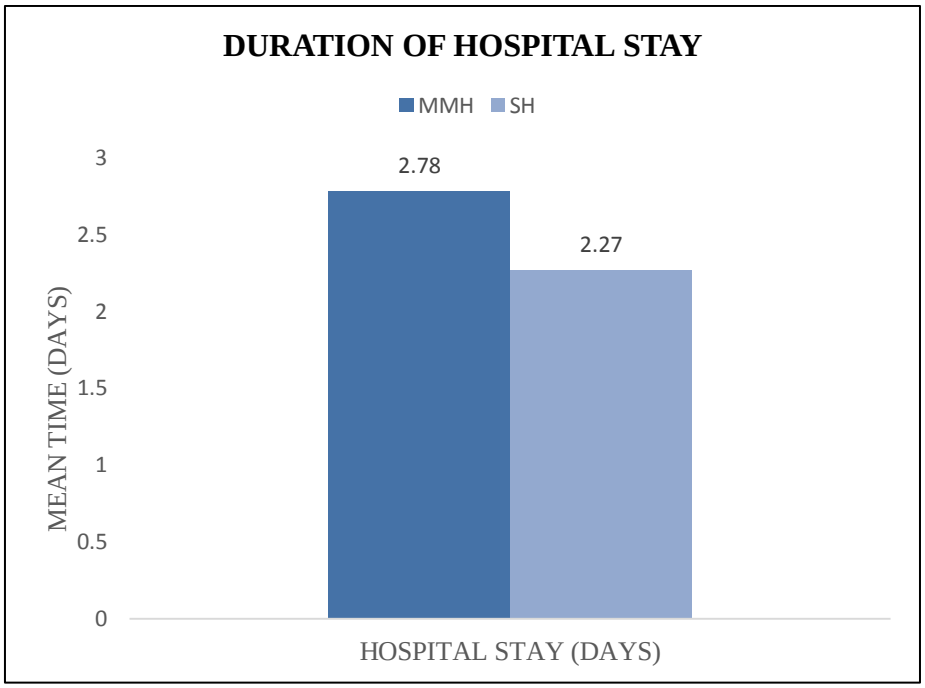
Graph no. 7

Total number of patients which are pain free post- operatively after 48 hours are 3 out of 60 patients in MMH constituting 5% of the group and 25 out of 60 patients in SH group constituting 41.67%. The difference in proportion of patients having no pain after 48 hours is significant with p- value of <0.0001.

Duration of Hospital Stay

Table no.11: Duration of hospital stay among two groups

Parameter	MMH (n = 60)	SH (n = 60)	|t| cal	'p' value
	Mean ± standard deviation	Mean ± standard deviation		
Duration of hospital stay (days)	2.78 ± 0.82	2.27 ± 0.61	- 3.865	0.0002

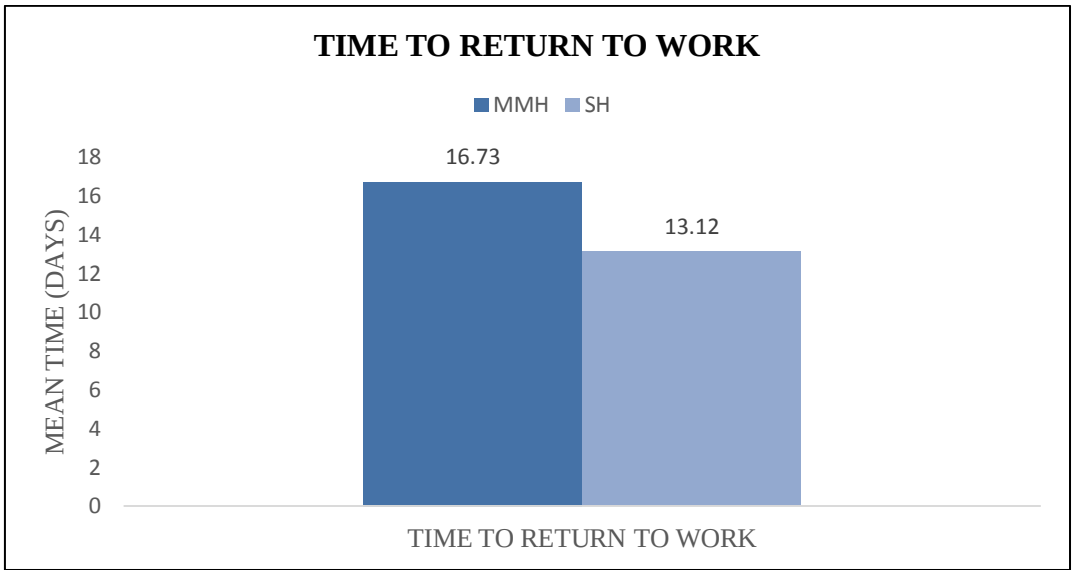


Graph no. 8

Mean duration of hospital stay (no. of days) of is longer for patients undergone MMH (2.78 ± 0.82) than those who undergone SH (2.27 ± 0.61). The mean difference of hospital stay is significant with p- value of 0.0002.

Table no.12: Time to return to work

Parameter	MMH (n = 60)	SH (n = 60)	|t|cal	'p' value
	Mean ± standard deviation	Mean ± standard deviation		
Time for return to work	16.73 ± 2.07	13.12 ± 2.14	- 9.392	< 0.0001



Graph no. 9

Mean time for return to work (no. of days) is 16.73 ± 2.07 for MMH group and 13.12 ± 2.14 for SH group. The difference is significant with p- value of <0.0001.

IV. Discussion

Hemorrhoids, also known as piles, are one of the most common anorectal disorders. They are fibrovascular cushions containing arteriovenous communications that are located in the sub epithelial space of anal canal and are a normal part of human anatomy.[1]

Hemorrhoids are characterized by dilated veins of the anal canal, classically occurring at the 3, 7 and 11 o'clock position with the patient in lithotomy position. Common predisposing factors are obesity, constipation and pregnancy. Symptoms of hemorrhoids are painless per- rectal bleeding, during passage with stools and separate from stool. Other clinical manifestations include discomfort, discharge, hygiene problems, soiling, and pruritus.[2,3]

They affect millions of people around the world, and represent a major medical and socioeconomic problem. The frequency peaks between the age of 45 and 65 years and is more common in men.[1] There is a decline in the incidence after the age of 65.

A total number of 120 patients having undergone Milligan Morgan hemorrhoidectomy and stapled haemorrhoidopexy (60 in each group) fulfilling the inclusion and exclusion criteria are included in the study.

Sex distribution

In present study, 51 males (85%) and 9 females (15%) have undergone Milligan Morgan haemorrhoidectomy and 54 males (90%) and 6 females (10%) have undergone stapled haemorrhoidopexy. Males were predominant because study is carried out in industrial hospital and majority of it is male population. Proportions of males and females in each group are similar with statistically insignificant difference ($p > 0.05$), which means MMH and SH groups are matching on the basis of sex distribution.

Table no. 13: Comparison of sex distribution with other studies

Author and year of study	MMH (%)		SH (%)	
	M	F	M	F
Bhandari RS et al[60] (2014)	63.64	36.36	40.91	59.09
Kashani SMT et al[61] (2011)	75	25	60	40
Baur S et al[62] (2017)	73.3	26.7	53.3	46.7
Bilgin Y et al[63] (2009)			62.75	37.25
Khan NF et al[64] (2009)	80	20	66.7	33.3
Current study	85	15	90	10

The sex distribution in our study is comparable to other studies with predominance of males going under MMH or SH.

Age distribution

Range of age is from 25 to 85 years in both MMH and SH group. Maximum number of patients are found in range of 25- 40 years in MMH group and in range of 56- 70 years in SH group, constituting 33.33% and 36.66% in the groups respectively.). Mean age of males is found to be more than females in both the groups, with males being older than the females in their respective groups. Mean age of MMH and SH patients are 51.68 ± 14.91 and 55.43 ± 14.37 respectively. There are statistically insignificant differences among the males and females according to their age and between the mean ages of the groups; hence the groups are matching on the basis of age distribution

Table no. 14: Comparison of mean age with other studies

Author and year of study	MMH	SH
Bhandari RS et al[61] (2014)	45.5 ± 13.3	42 ± 10.81
Kashani SMT et al[62] (2011)	50.6 ± 17.3	48 ± 12.5
Baur S et al[63] (2017)	39.02 ± 11.03	39.69 ± 9.49
Khan NF et al[65] (2009)	40.1 ± 11.5	41.2 ± 11.8
Current study	51.69 ± 14.92	55.43 ± 14.37

The mean age in our study is comparable with most of the studies.

Mean operative time

In present study, mean operative time for MMH and SH is 31 ± 7.06 and 26.30 ± 5.83 respectively. Thus, SH has significantly less mean operative time than that of MMH with a significant p- value of 0.0001.

Table no. 15: Comparison of operative time with other studies

Author and year of study	MMH	SH
Kashani SMT et al[62] (2011)	23.6 ± 13.5	35 ± 7
Lu M et al[66] (2015)	44.27 ± 6.57	24.36 ± 5.16
Bhandari RS et al[61] (2014)	57.50 ± 8.27	42 ± 7.36
Stolfi VM et al[67] (2008)	28.41 ± 10.78	28.30 ± 13.28
Baur S et al[63] (2017)	45.67 ± 11.94	35.22 ± 7.23
Khan NF et al[65] (2009)	19.6 ± 5.9	22.4 ± 7.2
Sudhir M et al[68] (2014)	47.67 ± 8.28	30.13 ± 5.97
Current study	31 ± 7.06	26.3 ± 5.83

Most of the studies have mean operative time taken for SH is significantly lower than mean operative time for MMH and are comparable to our study. However, in Kashani SMT et al[21] (2011), the mean operative time for SH is significantly higher than MMH while in Stolfi VM et al[23] (2008), there is insignificant difference in mean operative time of two procedures.

Mean intra-operative bleeding

In present study, mean intra- operative bleeding (in ml) for MMH is 109.5 ± 32.32 and for SH is 50.75 ± 22.60. Thus, intra- operative bleeding is significantly higher in MMH group as compare to SH group with a p- value of < 0.0001.

Table no. 16: Comparison of intra- operative bleeding with other studies

Author name and year of study	MMH	SH
Sudhir M et al[68] (2014)	21.83 ± 8.36	12.33 ± 5.53
Wani MD et al[69] (2017)	46 ± 19.96	13 ± 4.24
Current study	37.67 ± 9.41	17.17 ± 5.16

Mean intra operative bleeding in our present study is comparable with above studies in literature. In our study the mean intra operative blood loss is significantly lower in SH group in comparison with that in MMH group.

Post-operative pain

In present study, the mean post-operative pain according to visual analogue scale for MMH were 5.8 with SD ± 2.05, 4.27 with SD ± 1.65, 2.62 with SD ± 1.38 and that for SH were 2.83 with SD ± 1.08, 1.52 ± 0.67, 0.68 with SD ± 0.65 at 6hrs, 24hrs and 48hrs post-operative respectively.

The mean VAS post-operative pain is significantly less in SH group than MMH group at 6, 24 and 48hrs with a p- value < 0.0001

Table no. 17: Comparison of post- operative pain with other studies

Author name and year	MMH			SH		
	6hr	24hr	48hr	6hr	24hr	48hr
Lu M et al[66] (2015)		8.3 ± 1.1			2.9 ± 0.9	
Bhandari RS et al[61] (2014)		6.5 ± 2.11	5.36 ± 2.03		3.5 ± 1.5	2.54 ± 1.37
Stolfi VM et al[67] (2017)			4.73 ± 2.91			5.1 ± 3.04
Baur S et al[63] (2017)	2.89 ± 0.86	1.89 ± 0.80		1.78 ± 0.77	1.42 ± 0.62	
Khan NF et al[65] (2009)		7.37 ± 0.72			4.43 ± 1.25	
Sudhir M et al[68] (2014)		5.70 ± 0.65	4.57 ± 0.90		4.63 ± 1.38	2.70 ± 0.92
Ahmad MM et al[70] (2017)	2.88 ± 0.88	1.91 ± 0.83		1.79 ± 0.76	1.47 ± 0.66	
Wani MD et al[69] (2017)	2.89 ± 0.86	1.89 ± 0.80		1.78 ± 0.77	1.42 ± 0.62	
Current study	5.8 ± 2.05	4.27 ± 1.66	2.62 ± 1.38	2.83 ± 1.08	1.52 ± 0.67	0.68 ± 0.65

The mean post-operative pain in accordance with VAS scale in most of the studies in literature is significantly lower in SH group as compared to post-operative pain in MMH group at 6, 24 and 48 hours respectively and are thus comparable to present study except for the controversial study of Stolfi VM et al (2017), where the mean post-operative pain in accordance with Visual Analogue scale is more in SH group than MMH group.

Table no. 18: Comparison of number of patients pain free at 48 hours post-operative

Author name and year of study	MMH	SH
Agarwal S et al [4(2016)]	26.67%	63.33%
Current study	5%	41.67%

Post-operative 48 hours, more number of patients are pain free in SH group as compared to MMH group. This difference is significant with p- value <0.0001.

Duration of hospital stay

In present study, the mean duration of hospital is less in patient undergone SH (2.27 ± 0.60) than those who have undergone MMH (2.78 ± 0.82). The difference is significant with a p- value of 0.0001.

Table no. 19: Comparison of duration of hospital stay with other studies

Author and year of study	MMH	SH
Lu M et al[66] (2015)	3.6 ± 2.3	2.1 ± 1.4
Kashani SMT et al[62] (2011)	1.27 ± 0.6	1.7 ± 0.6
Bhandari RS et al[61] (2014)	3.77 ± 0.80	2.90 ± 0.68
Gravie JF et al[53] (2005)	3.1 ± 1.7	2.2 ± 1.2
Baur S et al[63] (2017)	3.51 ± 0.72	1.96 ± 055
Khan NF et al[65] (2009)	3.37 ± 2.2	2.03 ± 0.81
Ahmad MM et al[70] (2017)	3.51 ± 0.72	1.96 ± 0.55
Sudhir M et al[68] (2014)	6.70 ± 1.82	3.83 ± 0.87
Current study	2.78 ± 0.82	2.26 ± 0.60

The mean duration of post-operative hospital stay in most studies lesser for SH group in compared to MMH group and are comparable with present study.

Time to return to work

In present study, the mean time to return to work is longer in MMH group than in SH group with mean time to return to work (in days) 5.75 ± 1.37 and 4.25 ± 0.79 respectively. This difference is significant with p- value < 0.0001.

Table no. 20: Comparison of time to return to work with other studies

Author and year of study	*MMH*	SH
Bhandari RS et al[61] (2014)	13.6 ± 5.8	7.9 ± 4.9
Gravie JF et al[53] (2005)	24 ± 13	14 ±10
Baur S et al[63] (2017)	16.8 ± 4.19	8.36 ± 3.35
Sudhir M et al[68] (2014)	10.57 ± 3.46	5.43 ± 1.33
Current study	16.73 ± 2.07	13.12 ± 2.14

The mean time to return to work in most of the studies in literature is comparable to present study with time to return to work significantly lower in SH group as compared to MMH group.

Complications on follow up

In present study, patients have been followed for a period of six months. During this period the complications including anal incontinence, anal stenosis and recurrence are noted. Patients who underwent MMH have not developed any of the complications during follow up period of 6 months whereas there is one patient who developed anal stenosis as a late complication during follow up, constituting 1.67 %.

Table no. 21: Comparison of complications on follow up with other studies

Author and year of study	MMH			SH		
	A.I.	A.S.	Recurrence	A.I.	A.S.	Recurrence
Kim JS et al[71] (2013)	3.3%	---	23%	6.6%	---	18%
Baur S et al[63] (2017)	6.7%	---	8.9%	---	---	2.2%
Bilgin Y et al[64] (2015)	---	---	---	---	---	13.7%
Nahas SC et al[72] (2003)	---	---	---	---	2%	5%

Thirumalagiri VR et al[73] (2017)	---	8.5%	4.16%	---	---	4.76%
Thejeswi P et al[74] (2012)	---	---	---	---	---	5%
Current study	---	---	---	---	---	1.6%

The rate of post-operative complications on follow up in studies in literature is significantly higher than the present study. This significant difference may be due to less duration of post-operative follow up.

V. Conclusion

1-Stapled haemorrhoidopexy is associated with significantly less post-operative pain on VAS scale than Milligan Morgan hemorrhoidectomy.

2-Number of patients being pain free after 48 hours post-operatively is significantly higher among patient undergone Stapled haemorrhoidopexy than Milligan Morgan hemorrhoidectomy. Thus, Stapled haemorrhoidopexy has an advantage over Milligan Morgan hemorrhoidectomy with respect to post-operative pain making it a more compliant procedure.

3-In experienced hands, Stapled haemorrhoidopexy is less time taking procedure with less intra-operative time than Milligan Morgan hemorrhoidectomy. However, there is a learning curve for stapled haemorrhoidopexy.

4-Intra-operative bleeding during the procedure is also significantly less in Stapled haemorrhoidopexy than Milligan Morgan hemorrhoidectomy. The bleeding can vary based
on surgical expertise.

5-Duration of hospital stay post-operatively is significantly less in patient underwent Stapled haemorrhoidopexy than those who underwent Milligan Morgan hemorrhoidectomy, thus contributing to less morbidity post-operatively.

6-Patients underwent Stapled haemorrhoidopexy able to return to work in shorter time than those who underwent Milligan Morgan hemorrhoidectomy, making Stapled haemorrhoidopexy more acceptable within the community especially among industrial workers.
Post-operative complications rate cannot be compared between the two groups as the duration for follow up is not sufficient. Longer duration follow up is required for assessing and comparing pot-operative complications between two groups.

VI. Recommendations

1-The purse string sutures should be taken at least 2-3 cm above the dentate line in Stapled haemorrhoidopexy for better results and also to ensure less pain post-operatively.

2- The circumferential purse string should be taken at appropriate depth and at equal distance. The depth of sutures should be appropriate to include mucous and submucous layers. It should not be too deep to involve muscular layer which may lead to anal stenosis, nor be too superficial which may render the procedure ineffective or may cause recurrence in long term.

3- Knowledge of anal canal anatomy and the stapling device along with expertise of surgeon is must for the success of procedure and better results.

4- Stapled haemorrhoidopexy appears to have advantage of less post-operative pain and less time to return to work over Milligan Morgan haemorrhoidectomy.

5- More inclusive study with large sample size and longer follow up is required to ascertain the longterm benefits of stapled hemorrhoidopexy and recommend it in the community.

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