COMPARATIVE STUDY OF MINIMAL INVASIVE PROCEDURE FOR HEMORRHOIDS VS CONVENTIONAL HEMORRHOIDECTOMY IN MANAGEMENT OF HEMORRHOIDS

By

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Dissertation Submitted to
Sumandeep Vidyapeeth, Pipariya, Vadodara.
In partial fulfilment
of the requirements for the degree of

"MASTER OF SURGERY"

(BRANCH-I)

GENERAL SURGERY

Under the guidance of:

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I hereby declare that this dissertation/thesis entitled **"Comparative study of Minimal Invasive Procedure for Hemorrhoids Vs. Conventional Hemorrhoidectomy in Management of Hemorrhoids"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. Vipul Gurjar (Professor).**

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It is certified that the study is original.

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ABSTRACT

Introduction: Till recently Milligan – Morgan hemorrhoidectomy i.e. conventional or open hemorrhoidectomy is the most popular surgical treatment for hemorrhoids. With the advent of minimal invasive surgery, the scenario has changed. More recently, stapler hemorrhoidectomy is becoming popular as a day care procedure with minimal post-operative pain and early return to work. The present study is designed to compare make a comparative assessment of the Stapled hemorrhoidectomy against Conventional hemorrhoidectomy in the surgical treatment of hemorrhoids.

Material & Methods: A hospital based Non-randomised comparative study was conducted in Dept. of Surgery of at a tertiary care hospital. A total of 50 eligible cases scheduled for haemorrhoidectomy in our hospital were included in the study. These 50 patients were then divided into two groups i.e. 25 for stapled procedure and other 25 patients for conventional procedure Data was analyzed using statistical software SPSS ver. 21.

Results: Mean operative time was significantly less in stapler group (39.12 vs 45.75 mins; $p<0.01$) while mean hospital stay was significantly longer in conventional surgery group (7.02 vs 3.01 days; $p<0.01$). Post-op complains of pain, immediately after surgery (6 hrs.) and at day 1 and day 3 was significantly less in stapler group ($p<0.01$). Post-op complications after conventional surgery include bleeding (28%), urinary retention (12%), wound infection, anal incontinence (8% each) and anal stenosis (4%). Complications of stapler surgery include bleeding (16%) and urinary retention (4%). Mean time for return to work was significantly less in stapler group as compared to conventional surgery group (4.91 vs 13.8 days; $p<0.01$).

Conclusion: Stapler hemorrhoidectomy requires less operative time, reduces hospital stay and decreases post-operative pain. Return to normal activity is also significantly faster with stapler surgery. Stapler hemorrhoidectomy is thus recommended for all patients undergoing surgery of hemorrhoids. However, there is a need to conduct larger prospective double-blind trials with longer period of follow-up to study rate of recurrence along with trials for cost effectiveness.

Keywords: Conventional hemorrhoidectomy, Hemorrhoids, Stapler hemorrhoidectomy, Post-operative pain, Return to work

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Hemorrhoids are one of the commonest ailment that afflicts mankind, and their treatment has been subject of consideration in medical literature since Egyptian papyruses earlier than 3000 BC. Hippocrates in 400 BC mentioned burning, strangling and excision [1]. The word '**hemorrhoid'** is derived from the Greek adjective hemorrhoids, meaning bleeding (haima- blood, rhoos- flowing) which is most prominent symptom. The word '**piles'** is derived from the Latin word pila- meaning a ball which refers to a swelling around the anus. These terms are often used synonymously.

In 83 BC a famous Latin poet, Marziale, has described hemorrhoids in a poem. He found that the disease was common in the poor as well as in rich, in the young as well as in the old:

(Fig (pile) is seen in wife, fig is seen in husband, neither the governor, not the peasant is spared by the disease, also not the rich or the poor. It affects young and old ones equally, which is prodigious and these figs are seen all around)

This stands true till today as, it is difficult to obtain any accurate idea of their incidence, but rate of surgery for hemorrhoids vary form of their incidence, but rate of surgery hemorrhoids varies from 35/ 100,000 population/ year in UK to 50-60 /100,000 population / year in US [2] Prevalence in US population is 4.4% [3].

Many alternative treatment methods have been developed for hemorrhoids. Milligan – Morgan hemorrhoidectomy i.e. conventional or open hemorrhoidectomy was described in 1937, and is still the most popular surgical treatment for hemorrhoids. It has good result but is a very painful procedure resulting in increase hospital stay and having complications like immediate hemorrhage, urinary retention and late complication like incontinence, stenosis [5].

With the advent of minimal invasive surgery, the scenario has changed. More recently, Dr. Antonio Longo (1998) has advocated circular stapler hemorrhoidectomy for hemorrhoids [6]. This technique has been named "Procedure for Prolapse and Hemorrhoids (PPH)" and should be referred to as stapled hemorrhoidectomy. It has come up as a day care procedure with minimal post-operative pain and early return to work. Although it showed early promising results, expensive instrument, specialized training and a long learning curve limits the use of stapler hemorrhoidectomy.

The present study is designed to compare make a comparative assessment of the Stapled hemorrhoidectomy against Conventional hemorrhoidectomy in the surgical treatment of hemorrhoids.

Hemorrhoids are one of the most frequent and familiar anorectal problems seen in the general population. The exact incidence of this condition is difficult to estimate as many people are reluctant to seek medical advice for various personal, cultural, and socioeconomic reasons. However, it is common in both the sexes, and although seen more prevalent in adults, it also affects children. About 50% of people have hemorrhoids by the time they reach age 50 and the peak age being between 45 and 65 years. Hemorrhoids are usually asymptomatic and are often not considered as a disease unless they become symptomatic. Hemorrhoids are a frequent complaint among pregnant women, and become more common with increased age and parity.

Hemorrhoids are the varicosities of the veins of the hemorrhoidal plexus, often complicated by inflammation, thrombosis, and bleeding. It is an oversimplification of the nature of hemorrhoids. Normal hemorrhoidal tissue accounts for 15-20% of resting anal pressure and helps in important sensory information, enabling the differentiation between solid, liquid, and gas. As the hemorrhoidal cushion is a normal anatomic structure, all adults are prone to the development of symptomatic hemorrhoids. Abnormal swelling of the anal cushions leads to dilatation and engorgement of the arteriovenous plexuses and this in turn leads to stretching of the suspensory muscles and eventual prolapse of rectal tissue through the anal canal.

Hemorrhoids are one of the commonest afflictions of mankind from time immemorial.[4] It is said that 40 percent of population have symptoms due to hemorrhoids at some time of their lives, a price possibly man has had to pay following the evolution of his erect posture.[5] Terrel, in his words expresses it as “Man is a victim of a capricious creator, there is no doubt that man was intended to walk on all limbs, and having perhaps frustrated his’, creator’s plan by walking on two has

created several problems. Hemorrhoids are one of them. The assumption of an erect posture was a prodigious accomplishment and man pays for his arrogance by the pain and humility that go with hemorrhoids. Morgagni [6] (1749) attributed the upright posture of man as the causative factor of hemorrhoids.

By common consent the terms hemorrhoids and piles are used quite interchangeably, but etymologically the word have entirely different meaning. Hippocrates [7] in his treatise but it cannot be accurately applied to all the conditions diagnosed as hemorrhoids. The word pile is derived from 'pila", a ball. This term was first used by John Ardene [8] (1910) and can be aptly used for all form of hemorrhoids or pile, for literally every such condition does produce a swelling of some kind, even though it may not show externally.

Vascular cushions within the anal canal do not differ anatomically in normal individuals from those in symptomatic patients. It is therefore probably illogical to talk about the incidence of vascular cushions since they are ubiquitous. Both sexes, all races and all ages have anal cushions. If the cushions are omnipresent then it is only the existence of symptoms that merits classification as a disease. Hundred percent of population has hemorrhoids but only fifty percent are symptomatic. [9]

The treatment of hemorrhoids dates back to antiquity for the two chief symptoms of bleeding and protrusion. The methods of treatment date back to the Babylonian era, Hippocrates described the treatment by, cautery, which must have been extremely painful in the pre-anesthetic era. [10] This has been mentioned in "Sushruta Samhita" of the ancient Indian medicine. At present a wide variety of treatment is available for hemorrhoidal disease, ranging from advice on diet and bowel habit, through a number of non-operative methods of mucosal fixation and

widening of the anus, to a host of different techniques of excision of the internal anal vascular cushions and the external vascular cushions and the external vascular channels. The choice of method depends on the severity and type of the symptoms, on the degree of prolapse and on the expertise of the operator and equipment available.

About 40% of the patients suffering from hemorrhoids require surgery. [11] Conventional hemorrhoidectomy is a commonly performed operation for hemorrhoids, it has good results but is a very painful procedure resulting in a hospital stay for four to ten days and time off work for two to six weeks. [12] The patient also faces the complications of hemorrhage immediate, reactionary or secondary, urinary retention, and late complications like stenosis or incontinence. In search of a surgical technique to treat the common condition of hemorrhoids, stapler has been introduced for hemorrhoidectomy. Stapled hemorrhoidectomy has come up as a new and promising procedure causing minimal post-operative pain, early discharge and quick return to work.

The Review of Literature has been discussed under following headings:

1. Anatomy
2. Etiology
3. Pathogenesis
4. Clinical features
5. Treatment

ANATOMY

Anal canal, a tubular passage, is about 3.8cm long in adults and starts where lower end to the ampoule of rectum suddenly narrows, passing downwards and backwards to end at the anus. Its anterior wall is slightly shorter than its posterior and in the empty condition its lumen has the form of an antero-posterior longitudinal slit.

Anteriorly, it is separated by the perineal body from the membranous part of the urethra and the bulb of penis in males, and from the lower end of vagina in females. Posterior relations are coccyx with a certain amount of fatty tissue and come fibrous and muscular tissue termed the anococcygeal ligament, laterally, it is related to is chi rectal fosse with their contained fat and the inferior hemorrhoid nerves and vessels which cross them to reach the anal Canal.

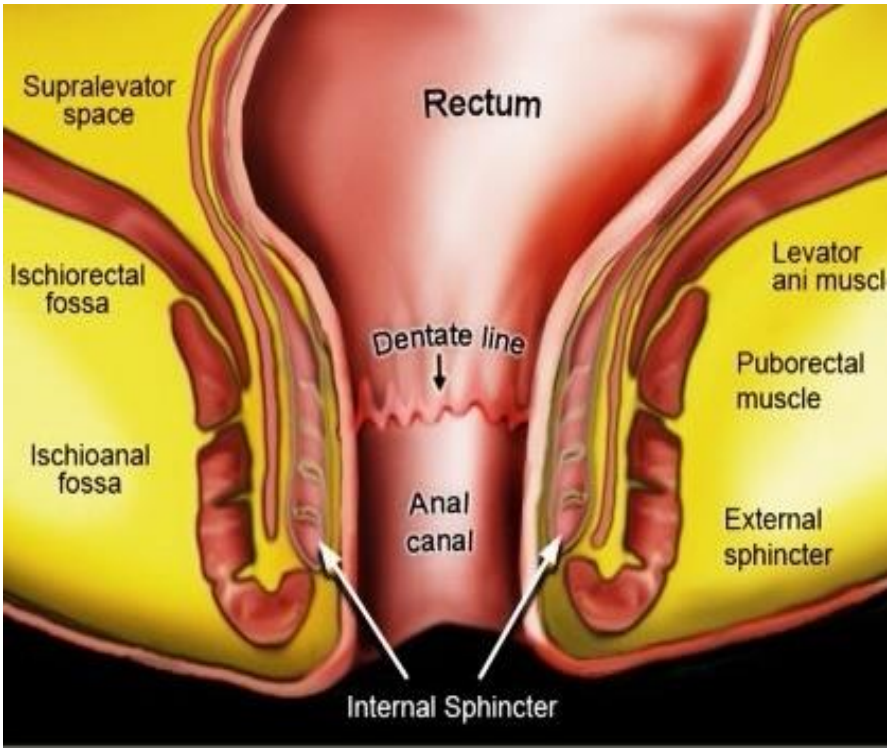


FIGURE -1: ANATOMY OF ANAL CANAL

LINING OF THE ANAL CANAL

Lining of the anal canal consists of an upper mucosal and a lower cutaneous part, the junction being marked by the "dentate" or "pectinate" line, which lies about 2 cm from the anal verge. Above the dentate line, anal canal is lined by mucous membrane and is plum coloured due to the presence of blood in the internal rectal venous plexus. The epithelium of this region is variable in character being stratified columnar in some cases, single layer of simple columnar epithelium in other and having a patchy distribution of stratified columnar, stratified squamous and polyhedral cell in yet other cases.

Mucosa in this region is thrown into 8-14 longitudinal folds, the "anal columns" or "Rectal columns of Morgagni" (Goligher 1986) [4]'. They are well defined in adults; each column contains a terminal branch of the superior rectal artery and vein, these radicals being largest in the left lateral, right anterior and posterior quadrants. Lower ends of these columns are joined by a series of transversely placed semilunar folds called anal valves behind which lie the anal sinuses. However, it has been said that the junction of the ectodermal and endodermal parts of the anal canal is situated lower down at the lower border of posteriorly (Johnson 1914) [13]. The crypts of Morgagni are small pockets between the inferior extremities of the columns of Morgagni. Into several of these crypts, mostly those situated posteriorly, opens one anal gland by a narrow duct. Below the white line, the squamous epithelium lining the lower anal canal is thin and shiny, and is known as the anoderm. This squamous epithelium differs from the true skin in that it has no epidermal appendages, i.e. hair and sweat glands.

ANAL INTRAMUSCULAR GLANDS

Parks [14] (1961) studied the anatomy of these glands with particular reference to their role in the pathogenesis of infections in the anal region. They arc 4-8 in number and open directly into an anal crypt, occasionally two opening into the same crypt. Traced outwards, it has a short-tubular portion in the submucosa, which branches in a racemose structure of widely ramifying ducts. Though some anal glands are present entirely in the submucosa in about two-thirds of them, one or more brandies may enter the internal sphincter, some even going further to enter the ischiorectal fossa. Parks in none of his specimens found them to he extending beyond the longitudinal intersphincteric muscle.

Their secretory function is highly doubtful. In some lower animals, these glands secrete an odoriferous substance during the rutting season; in humans, their function, if any, is obscure. Surgical significance lies in the fact that they may provide an avenue of infection from anal canal to sub mucosa and intersphincteric spaces. They may also be the sites of an adenocarcinoma.

ANAL MUSCULATURE

The surgical anatomy of this region was stated by Milligan [15] (1934. 1937 and 1942) and Morgan'[16] (1934, 1936).

Internal anal sphincter superiorly is continuous with the circular muscle coat- of the rectum, and inferiorly it is rounded and lies 6-8 mm above the anal verge or 8 - 12 mm below the dentate line. The fibers are grouped into discrete elliptical bundles, with an imbricate arrangement. External anal sphincter It extends further downwards than the internal sphincter, the lowest portion curving medially to lie below and

slightly lateral to the lower edge of the internal sphincter. Though originally described as being divided into three parts - deep, superficial and subcutaneous (Milligan and Morgan 1934).no such distinction was found by Goligheret al1 (1955) who states that it is one continuous muscular sheet. This is transversely divided by a fan shaped expansion of the longitudinal muscle fibers of the anal canal which splits it into 8-12 discrete bundles. At its upper end, external sphincter fuses with the puborectalis.

Longitudinal muscle fibers: These lie mainly between the internal and external sphincters and are the continuation of longitudinal muscle of the rectum, intermingled with fibrously puborectalis and pubo-coccygcus. This muscle become largely fibro elastic as it proceeds distally and terminates at the lower border of the internal sphincter when it breaks up into its terminal medial and lateral fibro-elastic muscle extensions. The medial one encircles the lower rounded border of the internal sphincter. The lateral terminal branch passes outwards encircling the lower, inner and distal surface of the lowest part of external sphincter to its lateral extremity where it attaches to the skin forming the external outer boundary of the marginal space which encloses the external hemorrhoidal plexus. The distal part of the conjoint longitudinal muscle gives off lateral septa that pass downwards and inwards, dividing the subcutaneous external sphincter into longitudinal bundles. I hey gain attachment to the skin and are called the "corrugator cutis ani Fowler [17] (1957) failed to find muscle fibres at these sites and suggested that the puckering of the perianal skin is due to the combined effects of the levator and pulling on the longitudinal coat and the tone of the subcutaneous external sphincter.

Attachments of external anal sphincter - Posteriorly, the external sphincter is attached to the skin to the perianal region and coccyx by the anococcygeal raphe. Behind the

anal canal, between the upper raphe of the levators and the lower one formed by the external sphincter, lies a space filled with fatty tissue" Retrosphincteric space of Courtney". Anteriorly, the external sphincter is attached to the perianal skin and the perineal body.

The Levator ani muscle: This is a broad thin muscle attached peripherally to the inner surface of the side of the pelvis and medially unites with its fellow of the opposite side to from the greater part of the pelvic floor. Levator is divided into three parts:

a. Ileococcygeus
b. Pubococcygeus
c. Puborectalis

Puborectalis is an important component of the sphincter mechanism and contributes towards the formation of anorectal ring.

Milligan and Morgan (103-1) first coined the term anorectal ring. This is composed of the upper borders of internal and external sphincter and puborectails and is strong posteriorly and laterally.

NERVE SUPPLY

Internal sphincter the sympathetic motor supply to the internal sphincter comes from the Superior hemorrhoidal plexus and from hypogastric nerves. The parasympathetic supply which is inhibitory to the sphincter comes from the second, third and fourth sacral nerve trunks. Internal sphincter is normally involuntarily contracted.

External sphincter: The voluntary external sphincter has two sources of supply on either side the inferior hemorrhoidal branch of the internal pudendal and the perineal branch of the fourth sacral nerve.

Cutaneous supply: It is present below the level of the anal valves and has afferent pathway via the inferior hemorrhoidal nerve.

ARTERIAL SUPPLY

There are three main arteries:

1. Superior rectal artery. It is a direct continuation of the inferior mesenteric artery and constitutes the chief arterial supply to the anorectum. Its left branch supplies the left half of the canal by a single terminal branch, while its right has two terminal branches.

2. Middle rectal arteries are the branches of internal iliac artery, one on each side and pass along the lateral ligament of the rectum. Their terminal branches anastomose with the terminal branches of superior and inferior rectal arteries to form a rich submucous and intramural plexus.

3. Inferior rectal artery is a branch of internal pudendal artery. It supplies the anal sphincters, anal canal and the skin of anal margins.

VENOUS DRAINAGE

Venous-drainage is in:

a. Superior hemorrhoidal vein which drains into the inferior mesenteric and portal system.

b. Middle and inferior hemorrhoidal veins, both of which enter systemic venous Circulation via the internal iliac veins

LYMPHATIC DRAINAGE

Lymph from upper half of anal canal flows upwards to drain into the post rectal lymph nodes and from there goes to the para-aortic nodes via the inferior mesenteric chain. Lymph from below the mucocutaneous junction descend to the anal margin, and pass laterally to the most medial of the superficial and then into deep inguinal group of lymph nodes.

ETIOLOGY

Majority of the piles arc idiopathic, though sometimes they can be symptomatic of some other underlying pathology. Many predisposing factors have been mentioned: heredity, temperature, climate, age, sex, pregnancy and puerperal state.B Akande[18](1989) states the importance to recognize the presence of hemorrhoids in elderly male, as they may be due to prostatism. Various factors which have been considered to play a role in the development of idiopathic hemorrhoids are:

(I) Heredity

Certain families are predisposed, to the development of hemorrhoids so that many or all of its members become affected and often at an early age (Goligher 1980)'. This is presumably as a result some structural weakness of the wall of the hemorrhoidal veins. It is well known that hemorrhoids and varicose veins of the legs often 'coexist suggesting a more widespread defect of venous structure.

(II) Dietary Factors

A low residue diet was demonstrated to be responsible for raised pressure within the lumen of the colon (Cleave et al 1969) [20]. A fiber adequate diet reduces the need to strain at stools. Elimination of cereal fibers from the diet has been thought to be a cause of high incidence of piles in American Negroes and urban population of Africa as compared to rural and primitive African communities {Burkitt 1972) [21]

(III) Anatomical Factors

Complete absence of valves in the portal system of veins results in the pressure of entire column of blood in the portal venous system to be transmitted to the internal hemorrhoidal

(IV) Morphological Factors

The weight of the column of blood unassisted by valves produces a high venous pressure in the lower rectum because of the upright posture of man.

(V) Bowel Habits

Cleave et al (1969) considers the basic cause to be the direct pressure of hard fecal masses on the hemorrhoidal veins. The distending effect of normal defecation on the hemorrhoidal plexus may be greatly magnified if the patient is constipated and has to 'engage in prolonged straining to pass large hard motions. According to Goligher1 (1980) this can give rise to retrograde flow of blood in hemorrhoidal veins. Diarrhea if associated with much tenesmus and futile straining may be associated with similar but slightly less injurious effects. G. Mattana [22] (1989) states that the recurrence in constipated patients is much higher, up to 75%, than those with normal bowel habits.

(VI) Deficiency of the anal sphincters, alteration of sphincter tone

In anal pressure studies, comparing patients with piles and normal control subjects, Hancock and Smith (1975) [23], and J. K Iin [24] (1989) observed significantly higher pressures in the former though how this raised pressure could be etiologically relevant is difficult to understand

(VII) Occupation- This could be a contributing but not a primary factor

(VIII) Pregnancy: Piles may develop during pregnancy due to large uterus obstructing the venous return from the rectum, the effects of progesterone which causes laxity of smooth muscles in the walls of the veins and pelvic tissues and increase in circulating volume in pelvis.

(IX) Straining during micturition due to lower urinary tract obstruction

Portal hypertension and hemorrhoids

Goenka [25] and associates performed a prospective study to evaluate the prevalence of this finding in 75 individuals with portal hypertension. It has failed to demonstrate an increased incidence of hemorrhoids in patients with portal hypertension. However, rectal varices may be seen as enlarged portal systemic collateral veins in patients of portal hypertension.

Hemorrhoids and rectal varices must be recognized as two separate entities because the treatment is so obviously different.

PATHOGENESIS

Various theories have been proposed to explain the exact pathogenesis of hemorrhoids.

THE VARICOSE VEIN THEORY

Internal piles have traditionally been regarded as essentially varicosities of the venous plexuses in the wall of the anal canal and lowermost centimeter or so of the rectum. The basis of this is discrete dilatations in the course of veins within the tissues of the hemorrhoids 20 They have been explained by

(i) Localised increase in venous pressure and

(ii) Localised weakness in the vein wall.

The increase in the venous pressure had been attributed to the valveless portal vein and its tributaries and sites of communication between the portal and systemic circulation. Morgagni (1949) attributed raised pressure to upright human posture.

It was suggested that venous dilatation were the result of obstruction to the venous return at the point where the veins pass through the unprotected muscular 'button-holes' in the rectal wall. Queni (1895), said that the fault lay in the weakened walls of the veins due to destruction by recurrent infections resulting from minor trauma at defecation. This theory holds no good as dilatations have been shown to be normally present. The fact that piles arc no more common in patients with portal hypertension is evidence against this theory.

THE VASCULAR HYPERPLASIA THEORY

Straubesand [26] et al (1963) demonstrated arteriovenous communications in anal submucosa and called them "Corpus Cavernosum recti" having erectile properties. Steizner [26] (1963) stimulated them to suggest that hemorrhoids might result from "Hyperplasia of Corpus Cavernsum recti". In support, they cited the bright red colour of the bleeding explicable if venous spaces were arterialized by direct communications.

Thomson [26] (1975) in an interesting study, injected the superior rectal vein in cadavere. he demonstrated that fusiform, saccular or serpiginous dilatations of the veins of the submucous plexus of the anal canal the so-called corpus cavernosum recti of Steizner (1963) were a regular feature of normal anatomy.

THE SLIDING ANAL LINING THEORY

Trietz (1853) and Thomson (1975) have shown that the submucosa docs not form a continuous ring of thickened tissue in the anal canal but a discontinuous series of cushions, the three mains in the constant positions, submucosal smooth muscle, contributes greatly to their bulk. They believe that they are mainly displaced and prolapsed cushions, the extrusion resulting from degeneration of the supporting tissue, previously noted by Gass and Adams (1950) [27]. Irregular bowel habits associated with hard bulky stools cause straining, which pushes the cushions out of the anal canal disrupting muscularis submucosa resulting in intermittent and later permanent prolapse. These may become associated with venous engorgement and thrombosis when they get gripped by the active internal sphincter and cannot slide back into the anal canal. Bleeding in hemorrhoids is due to abrasion of anal canal mucosa while passage of hard fecal matter. One difficulty on this basis of etiology is to explain

adequately the frequent occurrence of bleeding first-degree piles, detected only on proctoscopy and unassociated with descent of the mucosa to the anal orifice.

CLINICAL FEATURES

There are two cardinal symptoms of internal hemorrhoids, bleeding and prolapse, and it is on account of these that the patient usually reports to his doctor.

SYMPTOMS

1. Bleeding is usually initial symptom and occurs as a slight streak of blood on the motion usually when the patient strains at stool.
2. Prolapsing mass per rectum
3. Mucoid discharge from the rectum can occur in prolapsing piles.
4. Anal irritation of the perianal skin
5. Pain is usually considered to be a symptom of complicated hemorrhoids. E.g. thrombosed piles.
6. Chronic anemia

DEGREES OF HEMORRHOID FORMATION

1. First degree hemorrhoids: Merely project slightly into the lumen of the anal canal when the veins are congested at defecation.
2. Second degree hemorrhoids: The mucosal surface, corresponding to the piles, appears externally while patient is straining, but returns spontaneously when straining ceases.

3. Third degree: These piles prolapse even more readily and not only protrude during defecation but remain prolapsed afterwards until they are digitally reposited. Further exertion of any kind is liable to force the piles down once more. Hanock cl al'° (1975) classified third degree hemorrhoids that prolapse only at defecation, requiring digital replacement into III A. and those which prolapse even at times other than defecation is III B.

4. Fourth degree: These piles become so large and develop such considerable skin covered component that they cannot be returned to the anal canal, but instead remain as a permanent projection of anal mucosa. Previously this was known as interno-external hemorrhoids. -

TREATMENT

The treatment of piles is based on stage of piles. Stage I and II piles, if asymptomatic does not require active treatment apart from dietary & lifestyle modifications. If they are symptomatic, active treatment by injection or rubber band ligation should be advised. Treatment is to be given in Grade III and IV piles along with dietary & lifestyle modifications.

Available treatment modality are:

1. Conservative treatment
2. Sclerotherapy
3. Rubber band ligation
4. Manual dilation
5. Cryosurgery
6. Infrared coagulation

7. Conventional hemorrhoidectomy
8. Laser hemorrhoidectomy
9. Stapled hemorrhoidectomy

HISTORICAL REVIEW

Event Timeline

- 2250 BC; Babylon Code of King Hammurabi described the symptoms of hemorrhoids
- 1700 BC; Egyptian papyrus pronounced a topical astringent lotion.
- 1552 BC; Egyptian medical record detailed remedies for hemorrhoids.
- 1046 BC; Old Testament, 1 Samuel 5:9 Philistines punished with "emerods", and in 1 Samuel 5:12 People who moved the Ark to Ekron were punished with "emerods".
- 460–375 BC; Hippocratic Treatises described hemorrhoid treatment by cautery and excision, and first recorded use of speculum to inspect the rectum (endoscopy).
- 25 BC–AD 50; Celsus describes Pile ligation.
- 41–68; Roman physician Dioscorides defined Aloe Vera use for easing hemorrhoids.
- 130–200; Roman Emperor Marcus Aurelius's physician Galen pronounced hemorrhoids treatment ointment containing laxatives and leeches. He also explained thread use to tie off piles causing them to shrivel up.
- 4th–5th Century; Indian Susruta Samhita text defined clamp and cautery use.

- 5th–10th Century; Arab physician El-Zahrawy defined cautery irons use, whilst Byzantine physicians ligated with thread on the hemorrhoid base, before amputating.
- 1307–1370; John of Ardene's exposition transcribed hemorrhoids and fistula treatment, and enemas use.
- 1806; Modern era of endoscopy was piloted by Bozzini with his aluminum tube to expose the genitourinary tract.
- 1835; St.Marks Hospital London was founded by Frederick Salmon providing modern hemorrhoids and fistula treatment.
- 1849; Introduction of anal dilation for hemorrhoids treatment.
- 1935; St.Marks Hospital further developed excision and ligation methods at the hands of ETC Milligan and C Naughton Morgan – nowadays defined as the gold in hemorrhoidectomy standard.
- 1952; Modification to the Milligan-Morgan procedure introduced by Ferguson.
- 1955; A.G. Parks' developed his closed method surgical treatment the hemorrhoidectomy.
- 1963; J Barron developed an out-patient rubber band procedure to tie hemorrhoids.
- 1970; Development of cryotherapy, diathermy, infrared coagulation and laser cauteries.
- 1975; PH Lord developed his anal dilation hemorrhoid treatment method, whilst WHF Thompson postulated that hemorrhoids developed from anal cushions that are part of the normal anatomical structures.

- 1997; Italian A Longo introduced his stapled hemorrhoidectomy procedure for prolapsed hemorrhoids.

Surgery of hemorrhoids gas back a long-time hut has fundamentally changed very little. Hippocrates in his medical treatise described a surgical method consisting of a ligature operation and cauterization. Parks (1955) suggests Amida of the Byzantine and Paul of Aegina gave a good description of ligation and excision. Even ShrutaSamhita of the fifth century A. D. gives description of cautery and excision as a method for treatment of hemorrhoids.

As practiced by the ancient and most surgeons in the middle ages down to the first part of the nineteenth century this operation consisted at applying a ligature to the entire hemorrhoid, including skin and mucosa Covered portions, and cutting of some of the part distal to the ligature.

In 1835, Salmon modified the procedure by making a cut at the mucocutaneous junction and. Stripping the mucosa covered portion to the top of the anal canal, thereby, isolating the vascular pedicle for the first time. This was, however, criticized by Milligan[12] (1930) and Gabriel [29] (1939), as extensive raw areas lead to wide scarring and anal stenosis.

Milligan et al (1939)'", described a low ligation technique also known as Gabriel's operation. Whitehead [30] in 1882 advocated excision of the entire pile bearing area of the anal canal as a tubular segment, continuity of the fining being restored by suturing the rectal mucosa to the skin margin. The main objective was seldom achieved, also the loss of sensitivity of the anal mucosa interfered with continence of the patient. It also leads to ectropion of the rectum which came to be known as Whitehead deformity.

Fanslers [31] (1931) pioneered a technique of intra anal operation by means of his operating anoscope. He described a modification of Whitehead's operation in which flaps were raised radially and redundant mucosa was removed. Closure is done by stitching skin to mucosa. The operation was also performed for inflamed and thrombosed piles.

Ferguson and Heaton [9] (1959) and Ganchrow [32] et al (1971) used a method of so called closed hemorrhoidectomy using a modified Sim's speculum with the patient in the left lateral position. A complete hemorrhoidectomy with high ligation is carried out. Ferguson et al (1971) claimed good results in an analysis of 2038 cases treated by closed hemorrhoidectomy. 96% of the pis were totally asymptomatic white 1.32% had postoperative bleeding and 0.2% had post- operative infection. However, post-operative pain was more and one third required catheterization. Golighcr et al. (1980) performs preliminary stretching of the anal-canal and docs not advocate the use of Sim's speculum. Parks (1956) described 'submucosal hemorrhoidectomy, as the method with reduced pain and anal stenosis. Postoperative pain was markedly diminished as compared to the pure ligature type of procedure, thus reducing the number of days of hospitalization. Eisenhammer[41] (1969) and Singh[42] (1976) adopted submucosal hemorrhoidectomy similar to those performed by Park. The results were good and the complications of mucosal prolapse can be prevented by careful replacement, and suture of mucosa.

Anoderm preserving hemorrhoidectomy has been described by Takano [33] (1980). Following this there is no possibility of postoperative bleeding and post-operative evacuation is not so painful. Suprasphincteric hemorrhoidectomy a new technique by Wanderman [34] (1981) has been claimed to be physiologically sound,

practically blood less and comparatively less painful. A Trietz muscle preserving hemorrhoidectomy has been described by GansenJager[35](1982) and he considers the procedure to be an accurate reconstruction of the anatomy and function and reports excellent functional results. Farag [36] (1978) described a new -technique of pile suture where three catgut sutures arc applied to the hemorrhoidal mass above the dentate tine, tied and left as such without excising the hemorrhoid. Hemorrhoids are replaced by fibrous cords within 3-6 months. He claims marked reduction in the severity of postoperative pain. There is no incidence of urinary retention of recurrence of bleeding. Awojobi [37] (1983) has further modified this and performed it as an outpatient procedure under local anesthesia. Bleeding stopped in all cases while prolapse reduced in 96% of cases.

Micturition difficulties following Milligan's hemorrhoidectomy as were noted by Connie and McNair [38] (1959) were found in 28% of cases. The need for catheter post-operatively was however, found in 2 to 5%. Mclntyre [39] (1961), Baradnal [40] (1974) gave a cure rate of 74%, 9.3% complained of periodic bleeding, pain and incontinence.

Excision of (lie external hemorrhoids is extremely painful and surgeons have been trying out new methods to lessen the pain of hemorrhoidectomy. Ixnral application and injection of long or ting anesthetic agents have been employed. Use of glucofuranoside derivatives, Meripons medicated contact dressings, local infiltration of lignocaine viscous, Novocain and saline.

Many other methods of treating hemorrhoids have been introduced notably rubber band cryosurgery, laser surgery.

Ligation of hemorrhoids without excising them was practiced in middle ages. Blaisdell [45] (1968) introduced this method in the form of rubber band ligation. Barron [46] (1963) simplified banding apparatus, which could be used on outpatients. Van Hoom [47] introduced a modified proctoscope with bands stretched over an inner drum and pushed advancing the outer drum of proctoscope over it. Thomson (19S0) used a device, which could be used single handed as it had ligator in the proctoscope.

Carden [48] (1969) reports a high success rate after rubber band ligation. Recurrence been reported as 4%. Correlation between the discomfort and the number of ligations perfumed m one sitting has noted by Gehanyand Healey (1974) [49]. However, Alexander [50] et al (1975) had no such correlation in their series of 200 patients. A fatal case of clostridial septicemia was reported by O'Hara [51] (1980) and another ease of tetanus following rubber band ligation by Murphy [52] (1978).

Denker el al. [53] (1973) in a series compares the results of rubber band ligation and hemorrhoidectomy by Milligan's technique, and considers both equally efficacious. Murie [54] (1980) reported that when used for prolapsing hemorrhoids rubber band ligation had an acceptable outcome in 88% of the patients as compared to 93% following hemorrhoidectomy [60]. In third degree hemorrhoids, good results were not obtained by band ligation, though it is effective in 70% of cases.

A study comparing cryosurgery with hemorrhoidectomy showed that the pain of cryodestruction lasted longer. At one year 65% of the patients preferred surgery and 35% preferred cryotherapy. JC Verma [55] (1991) found that current coagulation leads to more discomfort, less tolerance and is a more tedious procedure compared to sclerotherapy.

CONSERVATIVE TREATMENT

Perhaps the development of hemorrhoids can be prevented by avoidance of constipation and straining. The more general adoption of high residue diet may have a prophylactic effect, but once established, there is no evidence that the process is really reversible. Patients' bowel habits can be regulated by diet and addition of bulk laxatives. During an attack of piles some relief of discomfort may be obtained by the use of suppositories and ointments but their use is highly doubtful.

Sclerotherapy

This technique was probably used for the first time by Morgan (1869) who used iron persulphate as the sclerosing agent. Historical aspects of sclerosant injection therapy have already been reviewed above. Presently the injection of 5% phenol in almond or arachis oil into the submucosa of the hemorrhoid is the preferred method of treatment (Gabriel 1963)? Ponsky [56] (1991) used endoscopic retrograde hemorrhoidal sclerotherapy with good results.

The objective of injection is to produce a submucosal fibrosis which constricts the internal hemorrhoidal plexus and to produce a fibrous reaction in the submucous layer which will fix tin loose redundant mucous membrane to the inner muscle layer and draw up the pile so that it no longer prolapses or is grasped by the sphincters. Injection sclerotherapy has become the treatment of choice for first degree hemorrhoids.

Band Ligation

Rubber banding for hemorrhoids was first described by Blaisdell (1958) and further simplified by Barron (1963). It is an ideal method of treating large first or second-degree hemorrhoids in the absence of associated tags or external hemorrhoidal component.

The principle of this method is to apply a rubber band though a proctoscope to the mucosa covered part of the internal hemorrhoid. Over a period of seven to ten days, this elastic band gradually cuts through the tissues and the pile sloughs off spontaneously.

Various ligators as Barron's ligator, McGivney ligator, have been used. Some modification obviating an assistant needed to hold the proctoscope have been developed. These are Van Hoom ligating proctoscope and Thomson's ligator. All these have been used ideally for second degree -hemorrhoids. It is indicated and is the choice of treatment in large second degree or small third degree internal piles with little external component or skin tag enlargement. Post-banding pain is usually minor and rubber band ligation is associated with the lowest recurrence rate of the non-operative techniques[81].

Manual Dilatation (Lord's Procedure)

Lord [57] (1968, 1969) described a day care procedure for the cure of third degree hemorrhoids consisting of forcible anal dilatation. The role of Lord's procedure in the current times for the management of hemorrhoids is controversial.

Cryosurgery

This painless method making it an outpatient procedure was first used by Lewis [58] in 1969. Cooling is produced to -70°C degree Celsius by using nitrous oxides using a cryoprobe. It leads to rapid destruction of cell membrane, and thrombosis of the microcirculation. Although this procedure can be performed without any anesthesia with less post-operative pain, it is rarely used these days due to persistent anal discharge that is extremely irritating for the patient.

Infrared Coagulation

It was developed for coagulating bleeding points and was further used for electric treatment of hemorrhoids. This is administered by a gun like device, which can be applied without assistance. Each application is for 1 to 2 seconds as programmed in the device by the surgeon. The bum is only 2 to 3 mm in diameter. Usually three or four bums are needed for each hemorrhoidal column. Unfortunately, each of the application is acutely painful while the infrared light is on. First and second-degree hemorrhoids respond to this treatment. Third degree hemorrhoids arc less responsive [60]

Hemorrhoidectomy

The surgical treatment of piles is one of the earliest exercises in operative surgery and was practiced even in ancient Greece and Rome (Parks 1955) [11]. However, the credit of development of the present procedure goes to Salmon. There are two basic varieties, open and closed, depending on whether or not the, anorectal mucosa and perineal skin are closed after the hemorrhoids have been excised and ligated.

Indications of hemorrhoidectomy are:

1) Large third-degree hemorrhoids particularly those associated with skin tags and an external hemorrhoidal component.

2) Failure of conservative treatment of second degree hemorrhoids

3) Recurring thrombosis in internal hemorrhoids with or without strangulation

4) Fibrosed hemorrhoids.

Surgeons to lessen post-operative discomfort and complications have made continuous attempts to improve the technique of hemorrhoidectomy. Surgical treatment, reserved for patients with prolapsing hemorrhoids can be done by the following techniques: -

- **Milligan-Morgan Gabriel's operation** (ligation and excision – Open hemorrhoidectomy).

- **Closed hemorrhoidectomy** described by Fansler (1933) and later adopted by Ferguson and Heaton (1959) [61]. The wound is closed using a continuous Catgut suture. Healing is by primary intention, thus causing less pain. Ferguson and Heaton developed the closed hemorrhoidectomy technique. Three principal objectives are:

  - To remove as much vascular tissue as possible without sacrificing anoderm;

  - To minimize postoperative serous discharge by prompt healing with immediate lining of the anal canal with stratified squamous epithelium (anoderm) and;

- To prevent the stenosis that may complicate healing of large raw wounds by granulation tissue. However, no appreciable difference in postoperative pain or healing was seen after closed hemorrhoidectomy as compared to open technique.

- **Submucosal hemorrhoidectomy:** Park popularized the method originally conceived by Petit (1974). A vertical incision is made through the mucosa over the hemorrhoid and mucosal flaps arc raised on either side to complete uncover the hemorrhoid. It is then dissected away from the underlying internal sphincter, and the pedicle is transfixed, ligated and the pile is excised. The mucosal flaps are approximated using interrupted catgut stitches. The incidence of postoperative pain and stenosis is reduced (Goligher, 1980)1. However, this is a more difficult operation taking a longer time than simple ligation excision. Recurrence rates are 14% (Watts ct al 1964) [62]. Improper suturing of mucosa can lead to mucosal prolapse.

- **Whitehead hemorrhoidectomy:** The operation involves the circumferential excision of the hemorrhoids and often the anodcrm with anchoring of perianal skin and rectal mucosa to a region at or above the previous dentate line [30,63]. Many surgeons misinterpreted Whitehead's original operation and sutured the rectal mucosa Ectropion, the so-called wet anus or whitehead's deformity. The late complication rates are in the region of 10-13%, particularly stenosis and incontinence, and suggest that this is not a technique to he used [63]. In the present times, there is no role of white head hemorrhoidectomy.

- **Laser hemorrhoidectomy:** The procedure has been performed using Carbon-dioxide laser and Nd: YAG laser using both contact and non-contact technique.

This procedure has also been used as an outpatient procedure [64]. The laser beam produces vaporization of tissue and coagulation necrosis of blood vessels and lymphatics. Lasers may be used to perform the dissection in conventional "hemorrhoidectomy. Eddy et al. [65] have performed 150 hemorrhoidectomies using C02 laser and they claim that the incidence of post-operative pain was considerably reduced, and therefore narcotics were seldom needed. Wand et al. [66] have carried out 88 cases. Results show fewer long term complication (bleeding, anal stenosis, skin tag) and excellent patient acceptance. Left [67] used the CO_2 laser to perform hemorrhoidectomy on an outpatient basis on 102 patients. In their study, none of the parameters assessed showed any difference between laser and the more traditional hemorrhoidectomy.

- **Stapled hemorrhoidectomy:** hemorrhoidectomy or circumferential mucosectomy.

Milligan-Morgan (Open) Hemorrhoidectomy

The first descriptions of open hemorrhoidectomy are from 2 centuries ago; the technique was made popular in the United Kingdom by Milligan and Morgan, in 1937, and is still widely used in Europe. In this procedure, hemorrhoidal tissue and vessels involved are excised in the same manner as in Ferguson's procedure, including the placement of a suture at the hemorrhoid pedicle, but the incisions are left open. Often, because of location, technical difficulties, or extensive disease with gangrenous hemorrhoidal tissue, an open approach is required; this technique also may be more useful for avoiding subsequent anal stenosis. To achieve hemostasis, electrocautery is often used. Even when using the open technique, it is important to

maintain adequate bridges of normal anoderm because primary wound healing can also result in stricture and anal stenosis.

Complications

- Pain
- Urinary retention
- Hemorrhage
- Constipation
- Fissure
- Abscess
- Skin tag
- Pseudo polyp
- Anal stricture
- Fistula, rectovaginal fistula
- Sepsis
- Perforation
- Incontinence

Stapled hemorrhoidectomy

The technique of stapled hemorrhoidectomy or circumferential mucosectomy has received much recent enthusiasm as a novel technique in the surgical treatment of hemorrhoids. If the pathological condition leading to hemorrhoidal complication is the prolapse of anal mucosa, it is rational to hypothesize that reduction of such

disturbance could be an effective therapy or symptoms. Reduction of the prolapse restoring the normal topographic relationship between anal mucous membrane and the anal sphincters induces an improvement in venous outflow, eliminating the risk of complications. In this procedure, the blood supply to the hemorrhoids is interrupted but the actual A-V malformations are left in-situ.

The technique of stapling for hemorrhoids was initially presented by Donald Peck [68] from San Jose, CA approximately fourteen years ago in which the hemorrhoidal tissue was removed by application of two circumferential purse string sutures and subsequent firing of a circular stapler. However, this technique was standardized in 1993 by Dr. Antonio Longo [68] at the University of Palermo.

Longo has accumulated the most experience, but he has not yet published his results [69]. Longo worked on the basis that stapling interruption of the feeding superior hemorrhoidal arteries above the base of the hemorrhoids was adequate for complete treatment of hemorrhoidal symptoms. Pescatori [70] et al have reported on the tans-anal introduction of a circular stapling instrument to excise redundant rectal mucosa.

The technique described by Peck had the theoretical risk of both anal canal stenosis and anal mucosal prolapse (White head deformity). The Longo-Milito technique obviated these concerns by placing the staple approximately 4 cm cephalad to dentate line. This placement and retention of hemorrhoids should allow significantly better post-operative sensory function for the patient with fewer disturbances, incontinence, a lower chance of anal stenosis and less pain. Because the procedure does not involve any surgery on the sensate anal mucosa below the dentate line, it is supposed to be less painful that traditional hemorrhoidectomy.

Circular stapled hemorrhoidectomy is quite rapid and technically easy and can be performed even by trainees. Results were independent of the experience of the surgeon [71]. By means of a circling stapling gun, a low rectal mucosal resection and mucosal – mucosal anastomosis act to remove redundant rectal mucosa above the hemorrhoids, correcting the previous down ward displacement of the anal cushions and interrupting the vessels in the submucosal plane.

Unlike excision ligation techniques the external hemorrhoidal components are not dealt with directly, these are observed to regress in the early post-operative period, eventually, forming radial cutaneous folds. When questioned, most patients thought the external component was considerably resolved. No attempt should be made to excise the cutaneous component.

Indications of Stapled hemorrhoidectomy [85]

- Prolapsing hemorrhoids requiring manual reduction (Grade III);
- Uncomplicated hemorrhoids, irreducible by the patient but reducible at surgery (Grade IV);
- Selected prolapsing hemorrhoids with spontaneous reduction (Grade II);
- Failure to alleviate hemorrhoidal symptoms by other methods (e.g. rubber band ligation)

Contra-indications

- Abscess;
- Gangrene;
- Anal stenosis;
- Full-thickness rectal prolapse.

FIGURE 2: PPH SET

FIGURE 3: PLACING PURSE STRING SUTURES

FIGURE 4: PPH DEVICE THROUGH PURSE STRING SUTURE

FIGURE 5: SCHEMATIC OF APPROXIMATED MUCOSA

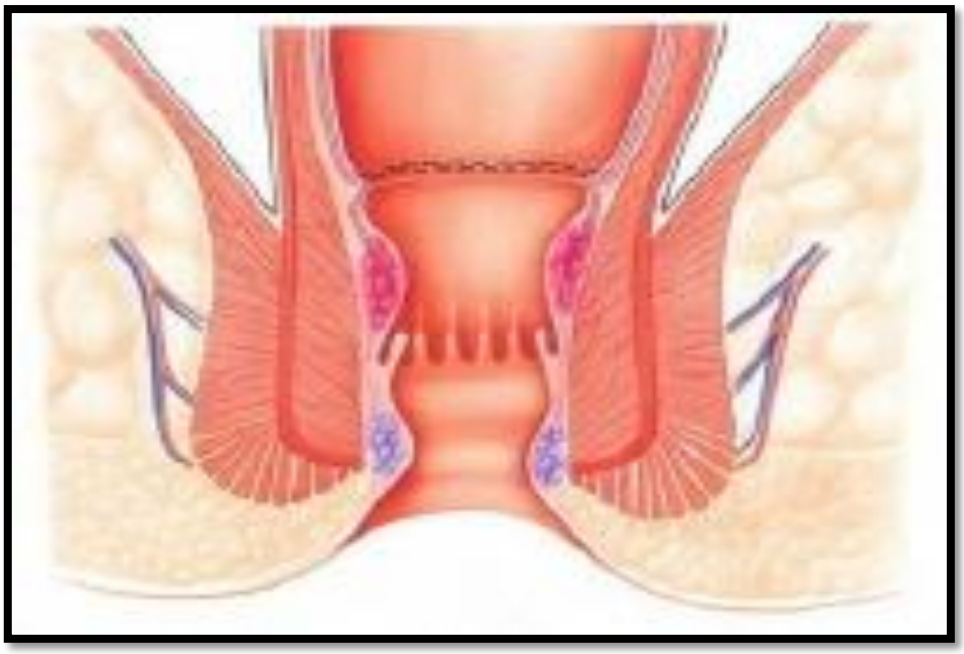


FIGURE 6: COMPLETED PROCEDURE

Complications

Many of the complications of stapled hemorrhoidectomy are similar to those of hemorrhoidectomy or any anorectal operation, such as pain, urinary retention. [58-63] However, there are several serious complications, some unique to this procedure, that warrant discussion. There have been anastomotic dehiscence necessitating colostomy following stapled hemorrhoidectomy. Rectovaginal fistula has been reported after stapled hemorrhoidectomy. Perforation of the rectum has been reported and was likely caused by a very low peritoneal reflection incorporated in to the anastomosis. [64,65]

Pneumo-retroperitoneum has been reported as well as pelvic sepsis. [66] Rectal obstructions have also been reported because the lumen was obliterated by the staples[67]. Most complications are most likely related to faulty application of the purse string, emphasizing the precision required when placing the suture. Due to these potentially devastating complications, training before use of stapled hemorrhoidectomy is strongly recommended.

- To make a comparative assessment of the Stapled hemorrhoidectomy against Conventional hemorrhoidectomy in the surgical treatment of hemorrhoids.

- To compare stapler hemorrhoidectomy with conventional hemorrhoidectomy in term of:

  a) Operative time

  b) Post-operative pain

  c) Bleeding

  d) Duration of hospital stay

  e) Anal Incontinence/ Stenosis

  f) Other post-op complications.

Study Design

Non-randomised comparative study

Study Duration

October 2015 to September 2017

Study Area

Department of General Surgery, Dhiraj General Hospital, Pipariya, Vadodara

Study Population

All eligible cases undergoing conventional haemorrhoidectomy and stapled hemorrhoidectomy in the Department of surgery, Dhiraj General Hospital, Pipariya, Vadodara during the study period.

Inclusion Criteria

1. Age more than 18 years
2. Symptomatic hemorrhoids

Exclusion criteria

3. Asymptomatic hemorrhoids
4. Thrombosed haemorrhoids
5. Hemorrhoids with fistula in ano
6. Other ano rectal pathology

Sample size: Sample size for stapled and conventional haemorrhoidectomy was 25 each (Total 50).

Sample design: Compare 2 Proportions: 2-Sample, 2-Sided Equality

Methodology of Study:

The institutional ethical committee clearance was taken before the study. All patients admitted at Dhiraj general Hospital with haemorrhoids explained about the cost factor. If the patient agrees, then only Patient was operated. A detailed history was taken and all patients were subjected to thorough clinical examination including per rectal and proctoscopic examination by which further hemorrhoids was graded. According to the grades of hemorrhoids 1st grade was excluded from the surgical treatment as they were not indicated and so Grade II, Grade III, and Grade IV were included in the study for surgical treatment. Routine lab investigations like blood and screening of chest were done. A total of 25 patients underwent stapled procedure and other 25 patients underwent conventional procedure according to the patients will after explaining the procedure. The study group was analyzed post operatively on factors such as:

1) Post-operative pain: assessed by visual analogue scale
2) Bleeding
3) Wound infections
4) Urinary retention
5) Anal incontinence
6) Anal stenosis

All patients were assessed during the first post-operative day, day of discharge, and at follow up visits at 1st week and 3rd week post operatively.

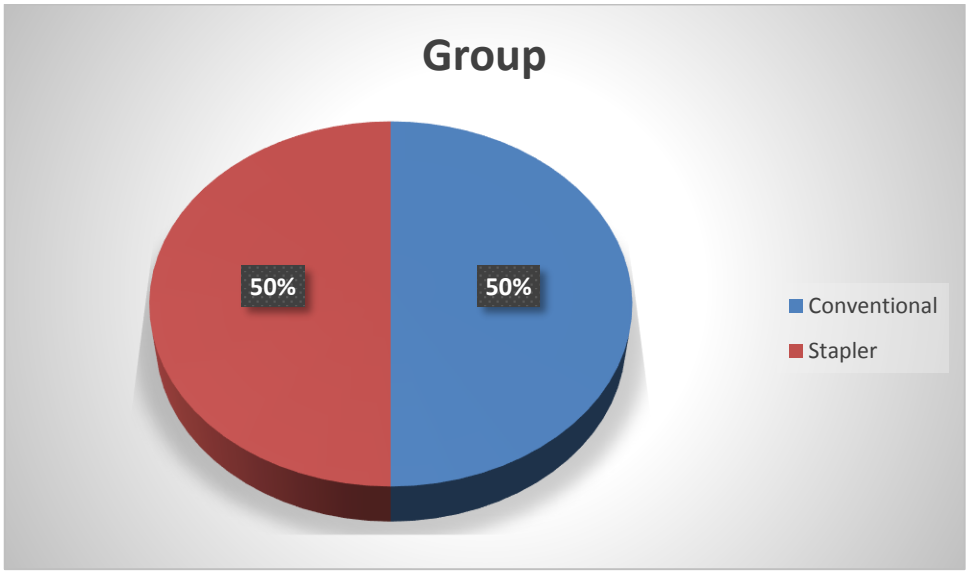
Data were statistically described in terms of mean (±SD), frequencies (number of cases) and percentages when appropriate. Data were tested first for normal distribution by Klomogorov– Smirnov test. Comparison of quantitative variables between the study groups was done using Student t test for independent samples if normally distributed. Mann–Whitney U test was used for non-normally distributed quantitative data. For comparing categorical data, Chi square test was performed. Exact test was used instead when the expected frequency is less than 5. A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations were done using computer programs Microsoft Excel 2007 (Microsoft Corporation, NY, USA) and SPSS (Statistical Package for the Social Science; SPSS Inc.,Chicago, IL, USA) version 21.

1) GROUP DISTRIBUTION: -

TABLE 1. DISTRIBUTION OF SUBJECTS BASED ON STUDY GROUPS

Group	N	%
Conventional	25	50.0%
Stapler	25	50.0%
Total	50	100.0%

Present study aimed to make a comparative assessment of the Stapled hemorrhoidectomy against Conventional hemorrhoidectomy in the surgical treatment of hemorrhoids. The study group included 25 subjects in each group.



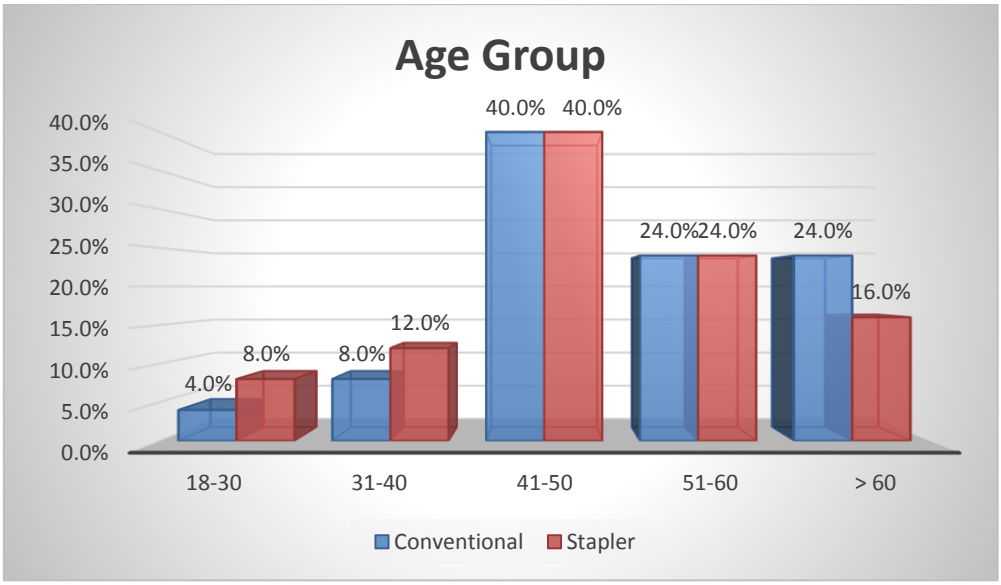
GRAPH 1: - GROUP DISTRIBUTION

2) AGE DISTRIBUTION: -

TABLE 2. COMPARISON OF STUDY GROUPS BASED ON AGE

Age Group	Group		Total
	Conventional	Stapler	
18-30	1	2	3
	4.0%	8.0%	6.0%
31-40	2	3	5
	8.0%	12.0%	10.0%
41-50	10	10	20
	40.0%	40.0%	40.0%
51-60	6	6	12
	24.0%	24.0%	24.0%
> 60	6	4	10
	24.0%	16.0%	20.0%
Total	25	25	50
	100.0%	100.0%	100.0%
p- value - 0.82			

Most common age group affected by Hemorrhoids was between 41-60 years of age with mean age of 48.9 years. No difference was observed between the study groups as per age (p>0.05).



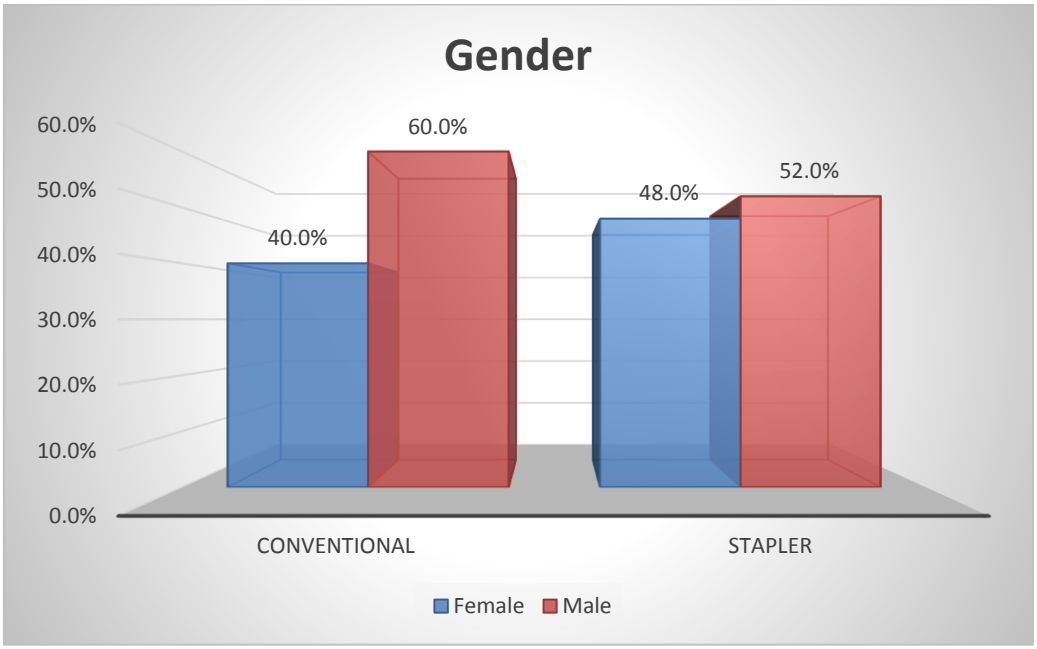
GRAPH 2 : - GRAPH SHOWING AGE DISTRIBUTION

3) SEX DISTRIBUTION

TABLE 3. COMPARISON OF STUDY GROUPS BASED ON GENDER

Gender	Group		Total
	Conventional	Stapler	
Female	10	12	22
	40.0%	48.0%	44.0%
Male	15	13	28
	60.0%	52.0%	56.0%
Total	25	25	50
	100.0%	100.0%	100.0%
p- value - 0.77			

Males are more commonly affected than females (56% vs 44%). No difference was observed between the study groups as per gender (p>0.05).



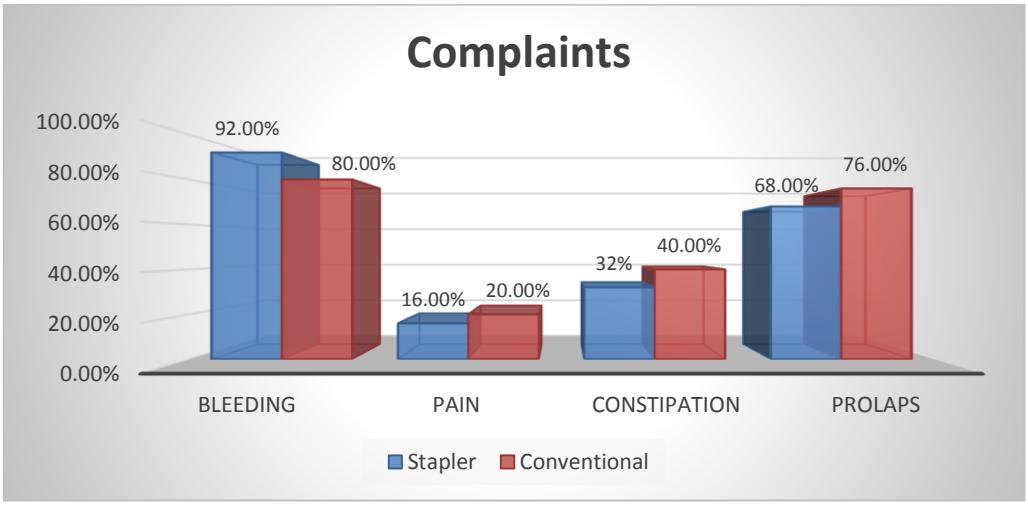
GRAPH 3 : - GRAPH SHOWING GENDER DISTRIBUTION

4) PRESENTING COMPLAIN: -

TABLE 4. COMPARISON OF STUDY GROUPS BASED ON PRESENTING COMPLAINTS

Complaints	Group		Total	P- value
	Conventional	Stapler		
Bleeding	23	20	43	**0.42**
	92.0%	80.0%	86.0%	
Pain	4	5	9	**1.0**
	16.0%	20.0%	18.0%	
Constipation	8	10	18	**0.77**
	32%	40.0%	36.0%	
Prolapse	17	19	36	**0.75**
	68.0%	76.0%	72.0%	

Most common presenting complaint in patients of hemorrhoids was bleeding (86%) followed by something coming out of rectum (prolapse 72%), Constipation (36%) and pain (18%). No difference was observed between the study groups as per presenting complaints($p>0.05$).



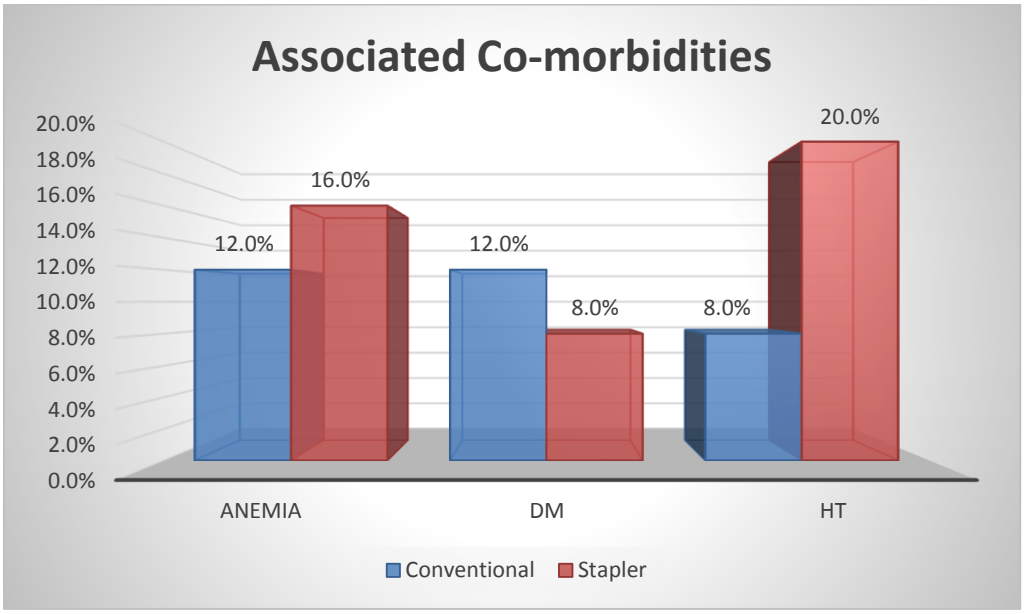
GRAPH 4: - GRAPH SHOWING PRESENTING COMPLAINS

5) ASSOCIATED CO-MORBIDIRIES

TABLE 5. COMPARISON OF STUDY GROUPS BASED ON ASSOCIATED CO-MORBIDITIES

Associated Co-morbidities	Group		Total	Total
	Conventional	Stapler		
Anemia	3	4	7	1.00
	12.0%	16.0%	14.0%	
DM	3	2	5	1.00
	12.0%	8.0%	10.0%	
HT	2	5	7	0.42
	8.0%	20.0%	14.0%	

Associated co-morbidities included Anemia (14%), diabetes (10%) and hypertension (14%). No difference was observed between the study groups as per associated co-morbidities (p>0.05).



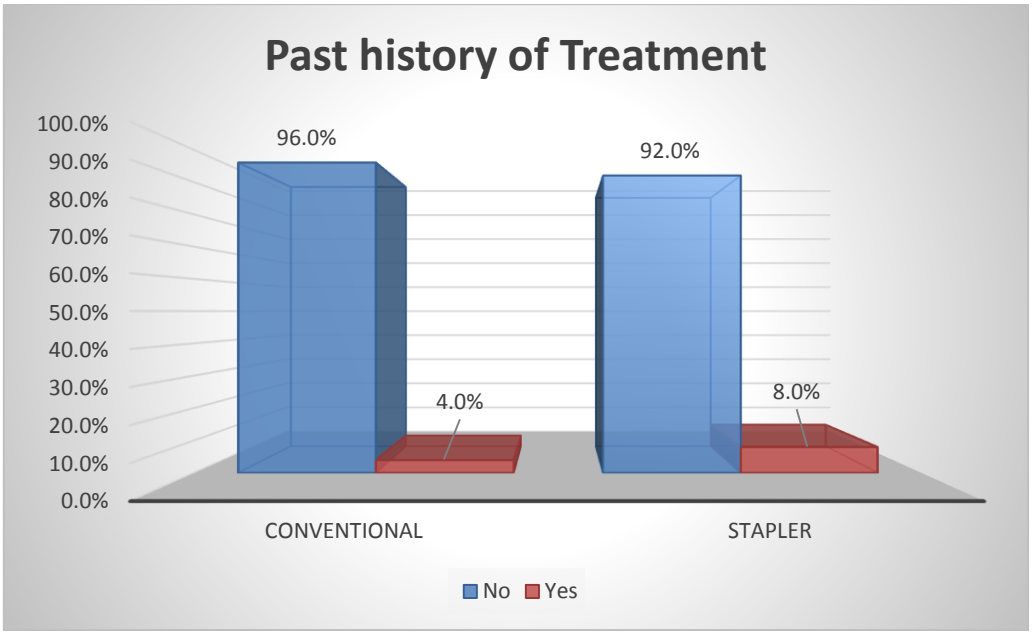
GRAPH 5 : - GRAPH SHOWING ASSOCIATED CO-MORBIDITIES

6) PAST HISTORY OF TREATMENT

TABLE 6. COMPARISON OF STUDY GROUPS BASED ON PAST HISTORY OF TREATMENT

Past history of Treatment	Group		Total
	Conventional	Stapler	
No	24	23	47
	96.0%	92.0%	94.0%
Yes	1	2	3
	4.0%	8.0%	6.0%
Total	25	25	50
	100.0%	100.0%	100.0%
p- value - 1.0			

Past history of treatment for hemorrhoids was given by only 3 patients (1 in conventional and 2 in stapler group).



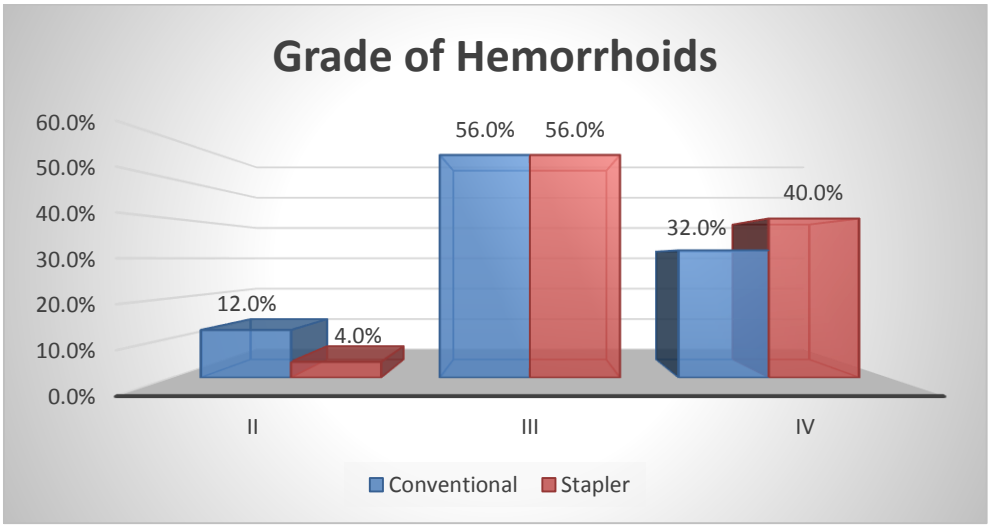
GRAPH 6 : - GRAPH SHOWING PAST HISTORY OF TREATMENT

7) GRADE OF HEMORRHOIDS

TABLE 7. COMPARISON OF STUDY GROUPS BASED ON GRADE OF HEMORRHOIDS

Grade of Hemorrhoids	Group		Total
	Conventional	**Stapler**	
II	3	1	4
	12.0%	4.0%	8.0%
III	14	14	28
	56.0%	56.0%	56.0%
IV	8	10	18
	32.0%	40.0%	36.0%
Total	25	25	50
	100.0%	100.0%	100.0%
p- value - 0.54			

Out of the 50 study cases, 8% were of grade 2 hemorrhoids while remaining 56% and 36% had grade III and IV hemorrhoids. No difference was observed between the study groups as per grade of hemorrhoids (p>0.05).



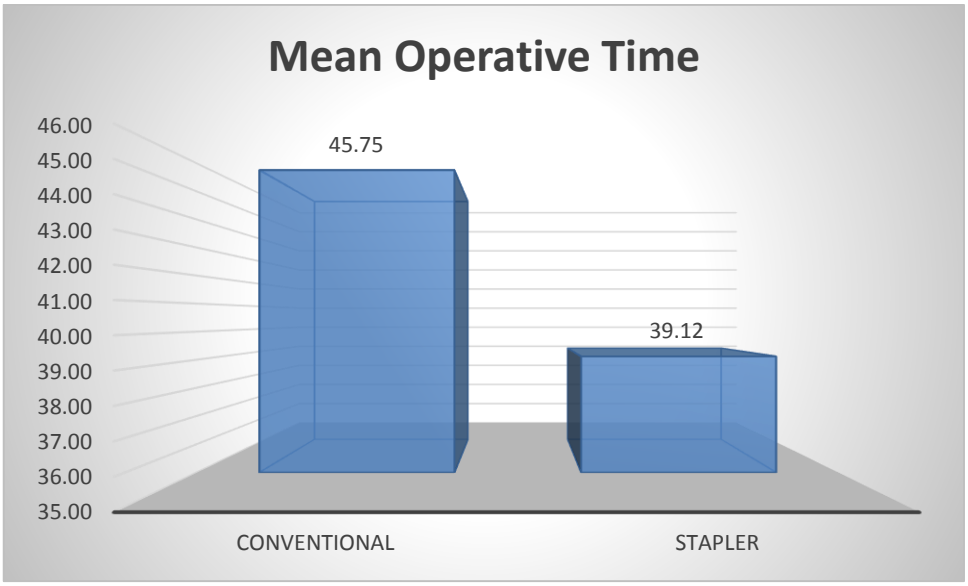
GRAPH 7 : - GRAPH SHOWING GRADE OF HEMORRHOIDS

8) OPERATIVE TIME

TABLE 8. MEAN COMPARISON OF OPERATION TIME

Variables	Group	N	Mean	SD	p- value
Operative Time (mins)	**Conventional**	25	45.75	6.73	**<0.01**
	Stapler	25	39.12	3.82	

Mean operative time was significantly less in stapler group as compared to conventional surgery group (39.12 vs 45.75 mins; p<0.01).



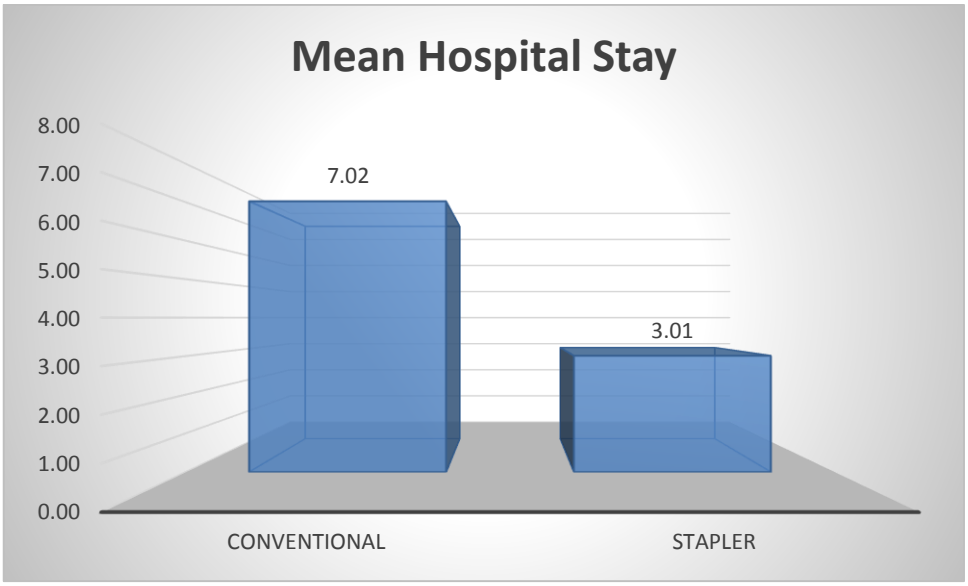
GRAPH 8 : - GRAPH SHOWING OPERATIVE TIME

9) HOSPITAL STAY

TABLE 9. MEAN COMPARISON OF HOSPITAL STAY

Variables	Group	N	Mean	SD	p- value
Hospital stay (days)	**Conventional**	25	7.02	1.90	**<0.01**
	Stapler	25	3.01	1.10	

Mean hospital stay was significantly longer in conventional surgery group as compared to stapler group (7.02 vs 3.01 days; p<0.01).



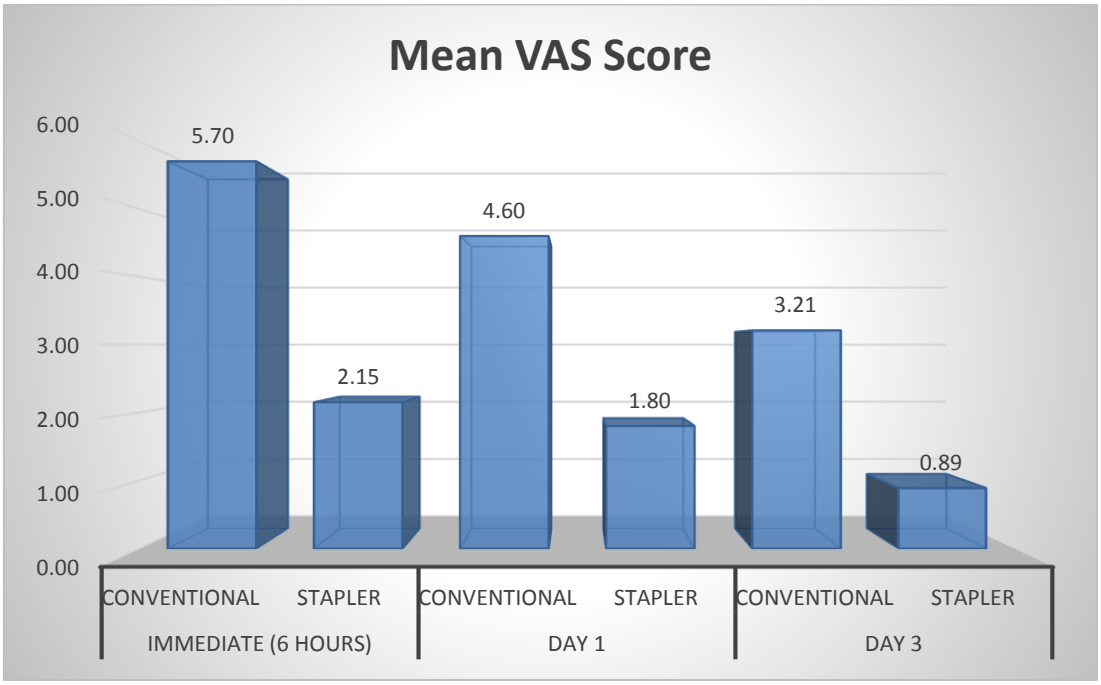
GRAPH 9 : - GRAPH SHOWING HOSPITAL STAY

10) POST OPERATIVE PAIN SCORE (VAS SCORE)

TABLE 10. MEAN COMPARISON OF VAS SCORES

VAS Score	Group	N	Mean	SD	p- value
Immediate (6 hours)	**Conventional**	25	5.70	1.26	**<0.01**
	Stapler	25	2.15	0.93	
Day 1	**Conventional**	25	4.60	1.09	**< 0.01**
	Stapler	25	1.80	1.03	
Day 3	**Conventional**	25	3.21	1.19	**< 0.01**
	Stapler	25	0.89	0.17	

Post-op complain of pain (as measured by VAS score) immediately after surgery (6 hrs.) and at day 1 and day 3 was significantly less in stapler group as compared to conventional surgery group (p<0.01).



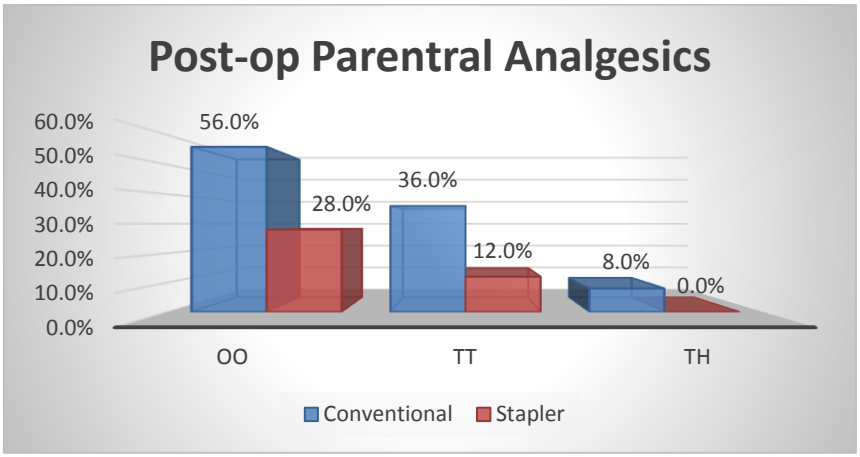
GRAPH 10 : - GRAPH SHOWING POST OPERATIVE PAIN (VAS) SCORE

11) POST OP ANALGESIA REQUIREMENT

TABLE 11. COMPARISON OF STUDY GROUPS BASED ON POST-OP ANALGESIA

Post-op Parentral Analgesics	Group		Total
	Conventional	**Stapler**	
None	0	15	15
	0.0%	60.0%	30.0%
1	14	7	21
	56.0%	28.0%	42.0%
2	9	3	12
	36.0%	12.0%	24.0%
3	2	0	2
	8.0%	0.0%	4.0%
Total	25	25	50
	100.0%	100.0%	100.0%
p- value < 0.01			

No post-op analgesia was required in 60% cases of stapler group compared to none in conventional group. More than one dose of analgesic was required in 44% cases of conventional surgery compared to 12% cases of stapler group (p<0.01).



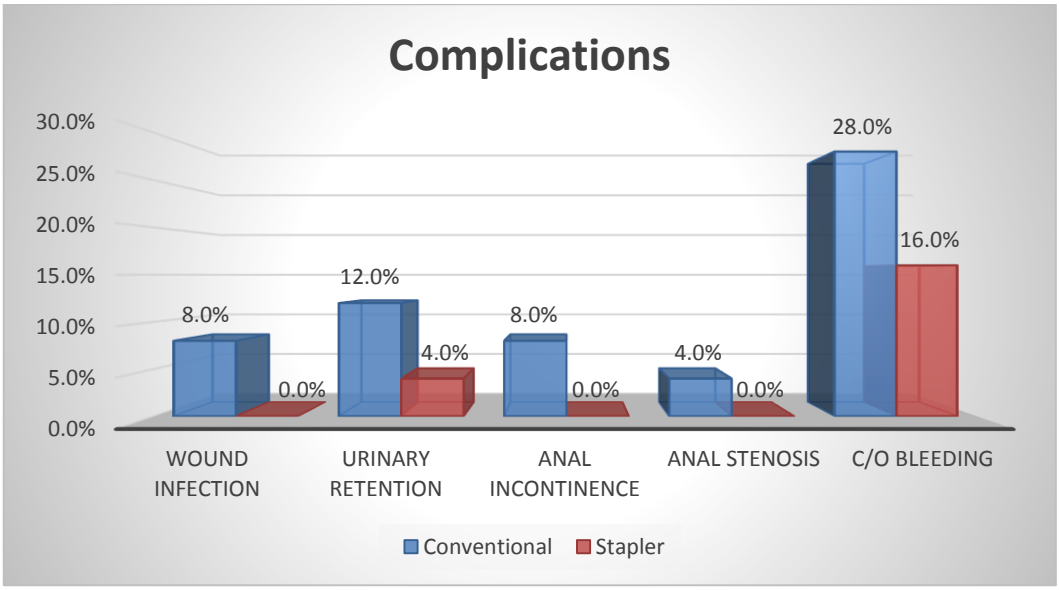
GRAPH 11 : - GRAPH SHOWING REQUIREMENT OF POST- OP ANALGESIA

12) POST OPERATIVE COMPLICATION

TABLE 12. COMPARISON OF STUDY GROUPS BASED ON POST-OPERATIVE COMPLICATIONS

Post-op Complications	Group		Total	Total
	Conventional	**Stapler**		
Wound Infection	2	0	2	**0.49**
	8.0%	0.0%	4.0%	
Urinary Retention	3	1	4	**0.61**
	12.0%	4.0%	8.0%	
Anal Incontinence	2	0	2	**0.49**
	8.0%	0.0%	4.0%	
Anal Stenosis	1	0	1	**1.00**
	4.0%	0.0%	2.0%	
C/o Bleeding	7	4	11	**0.49**
	28.0%	16.0%	22.0%	

Post-op complications after conventional surgery include bleeding (28%), urinary retention (12%), wound infection, anal incontinence (8% each) and anal stenosis (4%). Complications of stapler surgery include bleeding (16%) and urinary retention (4%). No significant difference was noted between the two groups with respect to complications (p>0.05).



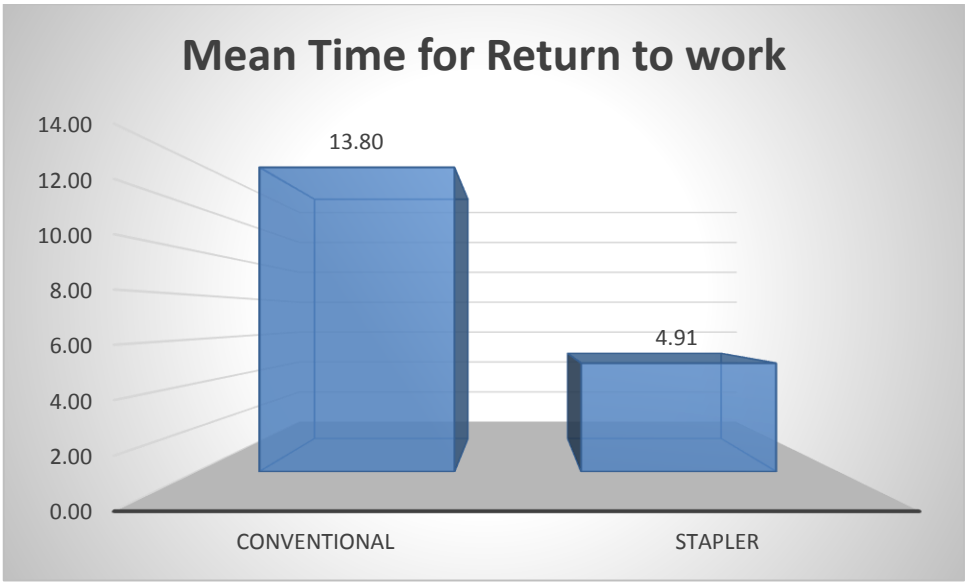
GRAPH 12 : - GRAPH SHOWING POST-OP COMPLICATIONS

13) TIME FOR RETURN TO NORMAL WORK

TABLE 13. MEAN COMPARISON OF TIME FOR RETURN TO NORMAL WORK

Variables	Group	N	Mean	SD	p- value
Time for Return to Normal Work	**Conventional**	25	13.80	3.23	**<0.01**
	Stapler	25	4.91	1.19	

Mean time for return to work was significantly less in stapler group as compared to conventional surgery group (4.91 vs 13.8 days; p<0.01).



GRAPH 13 : - GRAPH SHOWING TIME FOR RETURN TO NORMAL WORK

Hemorrhoidectomy is the accepted method for the treatment of symptomatic piles. Conventional hemorrhoidectomies are effective operations that have withstood the test of time; however, the problem of postoperative pain has never been satisfactorily addressed in conventional hemorrhoidectomy. The postoperative pain related to excisional hemorrhoidectomy is well known. Patients will frequently avoid definitive treatment of their disease for many years so as to avoid this problem. Also, the high postoperative morbidity and long recovery has prompted the need for an alternative procedure. Several techniques, including diathermy hemorrhoidectomy, dilatation with banding and cryo-hemorrhoidectomy have been tried.

Stapled hemorrhoidectomy was introduced in 1995 by Longo [5]. Stapled hemorrhoidectomy offers a significantly less painful alternative that provides patients definitive treatment of their disease in a single sitting [1]. A novel technique in dealing with the management of hemorrhoidal disease, it has emerged as an alternative to open hemorrhoidectomy, long considered the "gold standard". It treats the mucosal prolapse, with concurrent disruption of the blood supply to the hemorrhoidal tissue. The technique has been standardized and the indications, contraindications, and operative technique have been defined. Several randomized trials have shown the efficacy and safety of the procedure. There has been some concern and reluctance in accepting stapled hemorrhoidectomy as few serious complications have been reported. These include fecal urgency, recto-vaginal fistula, rectal obstruction, perforation peritonitis and pelvic sepsis. These have all been seen by most investigators in the early part of the learning curve. Numerous controlled studies have later demonstrated that this technique is associated with less postoperative pain and a quicker recovery [71-82]. To further validate these findings in our set up, present study was designed to compare the short-term results of stapled hemorrhoidectomy with conventional Hemorrhoidectomy.

1) AGE COMPARISION

Most common age group affected by Hemorrhoids was between 41-60 years of age with mean age of 48.9 years.

TABLE 14: - MEAN AGE COMPARISION

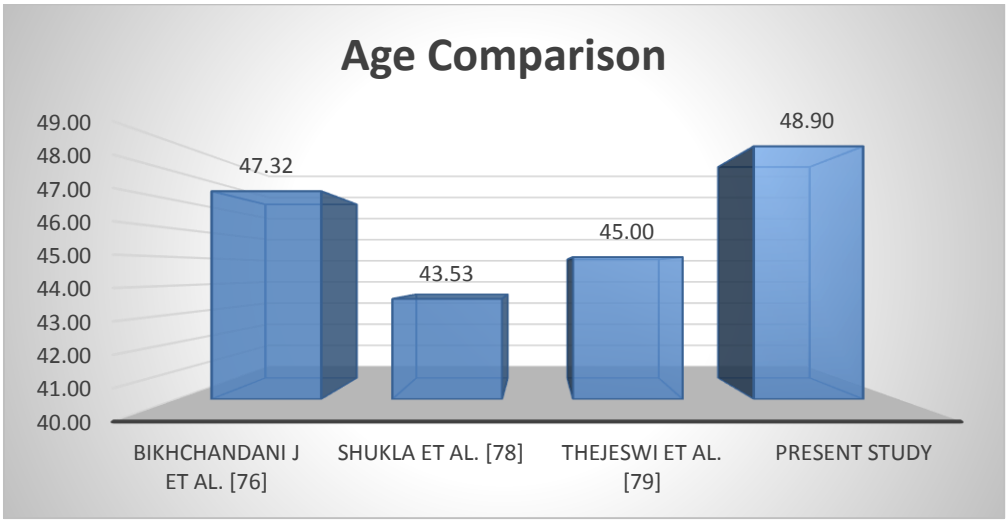
Author	Mean Age (Years)
Bikhchandani J et al. [76]	47.32
Shukla et al. [78]	43.53
Thejeswi et al. [79]	45.00
Present study	48.90

Bikhchandani J et al. [76] mean age of patients was 46.02 years (SD, 12.33) in the stapled group and 48.64 years (14.57) in the open group.

Shukla S et al. [78] most common age group for patients of haemorrhoids was 41-50 years. In the study by

Thejeswi PL et al. [79], mean age was 45 years.

Above findings shows similar age incidence comparable to others study attributing to less fibre and water intake leading to high incidence of constipation and resulting into haemorrhoids.



GRAPH 14: - GRAPH SHOWING MEAN AGE COMPARISION

2) GENDER COMPARISION

Males are more commonly affected than females (56% vs 44%).

TABLE 15: - GENDER COMPARISION

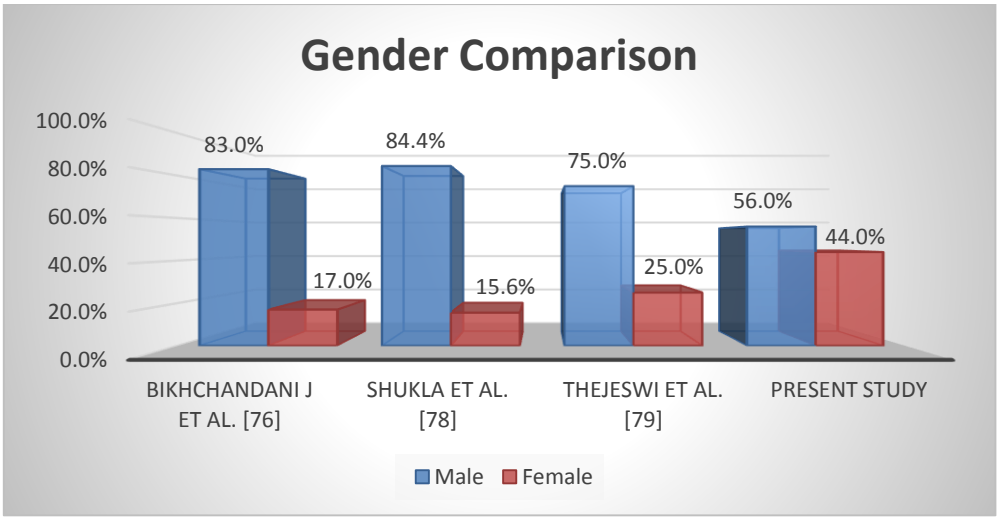
Author	Male	Female
Bikhchandani J et al. [76]	83.0%	17.0%
Shukla et al. [78]	84.4%	15.6%
Thejeswi et al. [79]	75.0%	25.0%
Present study	56.0%	44.0%

Bikhchandani J et al. [76] Hemorrhoids were more common in men (ie, 80.9% and 85.7% in the stapled and open group, respectively).

Shukla S et al. [78] Males are more in number than females in both the study group.

In the study by Thejeswi PL et al. [79], males are more commonly affected than females.

There is male predominance in all the studies as those working population staying away from home and irregular and less fibre and water intake leading to haemorrhoids.



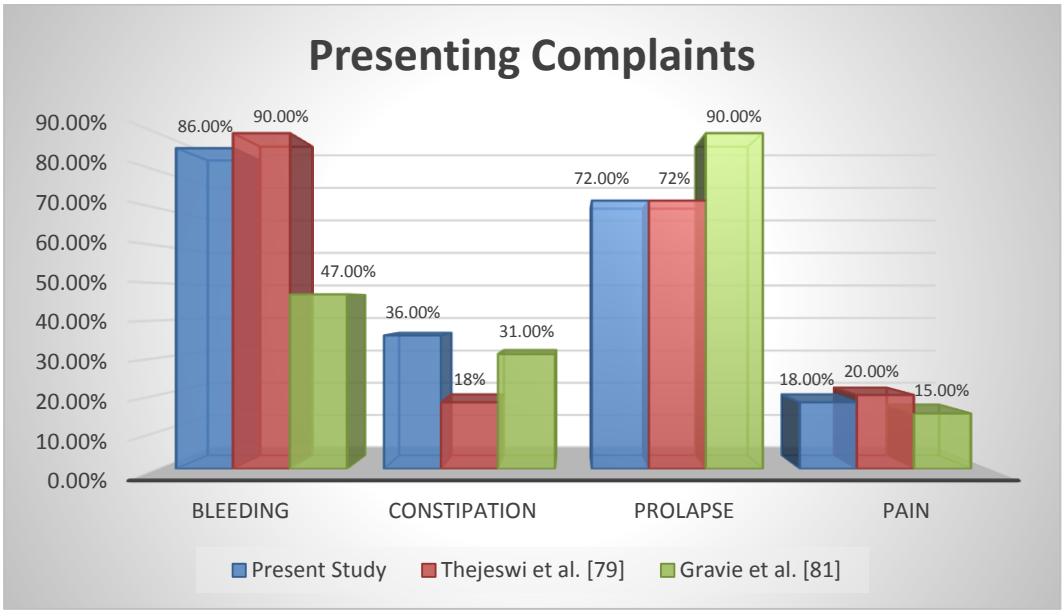
GRAPH 15 : - GRAPH SHOWING GENDER COMPARISION

3) PRESENTING COMPLAIN COMPARISION

Most common presenting complaint in patients of hemorrhoids was bleeding (86%) followed by something coming out of rectum (prolapse 72%), Constipation (36%) and pain (18%).

TABLE 16: - PRESENTING COMPLAIN COMPARISION

Complaints	Present Study	Thejeswi et al. [79]	Gravie et al. [81]
Bleeding	86.0%	90.0%	47.0%
Constipation	36.0%	18.0%	31.0%
Prolapse/ Mass per anum	72.0%	72.0%	90.0%
Pain	18.0%	20.0%	15.0%



GRAPH 16 : - GRAPH SHOWING PRESENTING COMPLAIN COMPARISION

In the study by Henry et al. [83], PR bleeding was the most common symptom and prolapse as second most common.

Thejeswi PL et al. [79] observed bleeding per rectum as the presenting complaint in the majority of the patients with 45 of the 50 patients presenting with it; 26 patients gave complaints of a mass per anus and 10 patients complained of pain during defecation; 13 patients gave other associated symptoms such as constipation (9) and generalised weakness (3).

The most common problem reported by the patients before the operation in the study by Gravie et al. [81] was the impression of a mass at the anus (90%). Other problems included frequent bleeding (47%), itching (35%), constipation (31%), and pain (15%).

Most common presentation of hemorrhoids reported and present in our study is bleeding per rectum and something coming out per rectum as patient feel shy and thus presents late and neglecting their complaints.

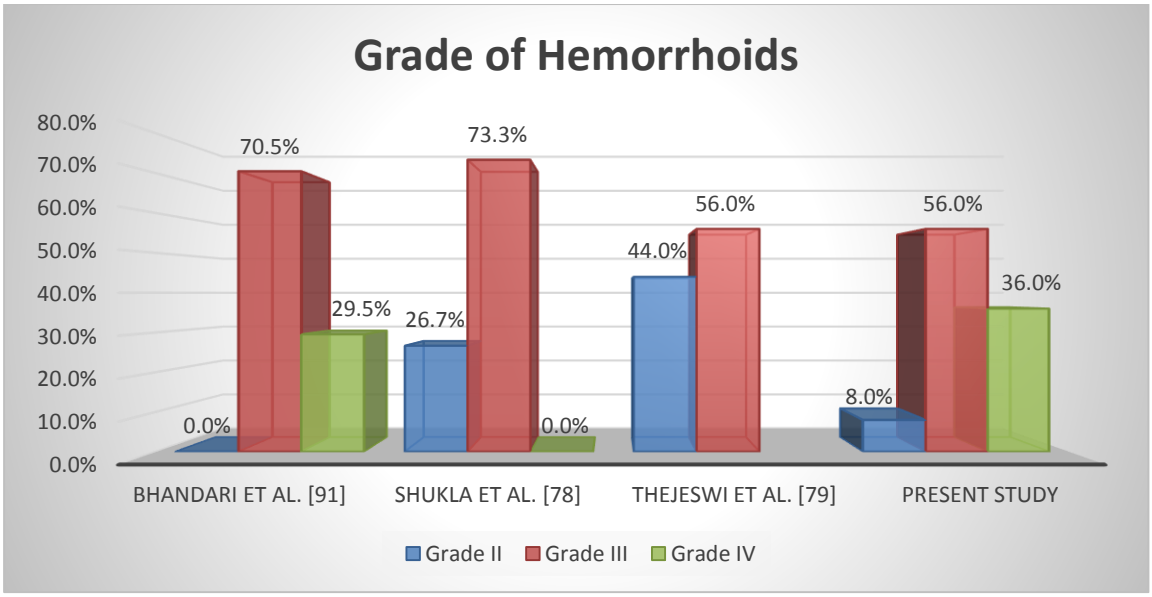
4) GRADE OF HEMORRHOIDS

Out of the 50 study cases, 8% were of grade 2 hemorrhoids while remaining 56% and 36% had grade III and IV hemorrhoids. No difference was observed between the study groups as per grade of hemorrhoids (p>0.05).

The comparison of present study results with other studies is shown in table below:

TABLE 17: - GRADE OF HEMORRHOIDS

Author	Grade II	Grade III	Grade IV
Bhandari et al. [91]	0.0%	70.5%	29.5%
Shukla et al. [78]	26.7%	73.3%	0.0%
Thejeswi et al. [79]	44.0%	56.0%	
Present study	8.0%	56.0%	36.0%



GRAPH 17 : - GRAPH SHOWING GRADE OF HEMORRHOIDS

In most of the cases surgical intervention is required only for grade III or IV hemorrhoids. Grade I and II case were general managed medically. Six cases in our study with grade II hemorrhoids had associated sever bleeding and measures to control the symptoms medically had failed.

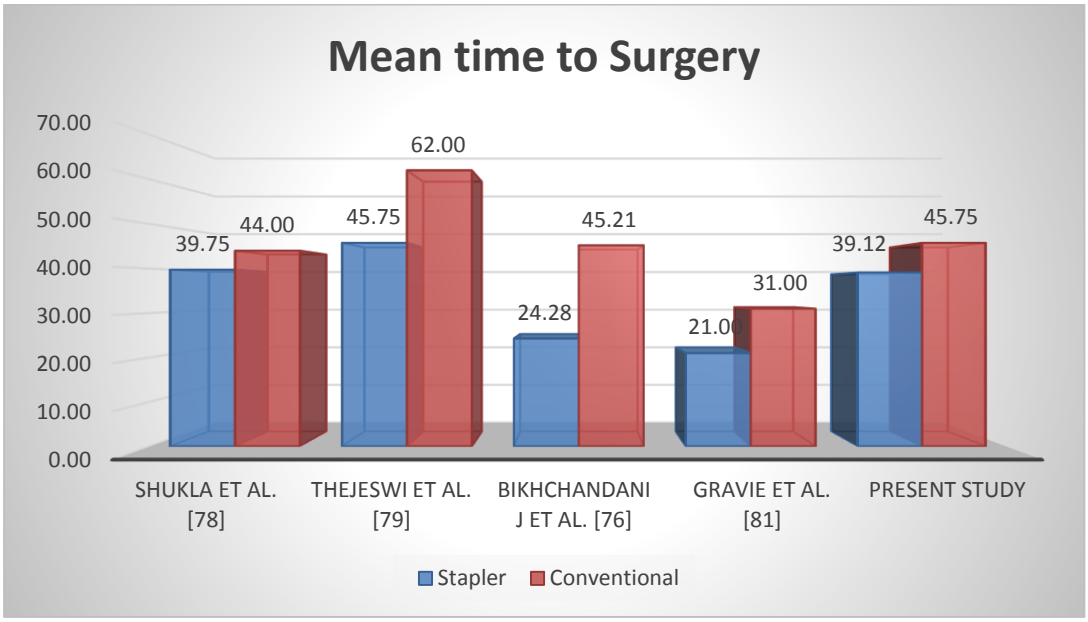
Our is a tertiary institute where patients from far presents with their complaints with most of the patients taking primary treatment elsewhere and presenting at a later stage for their unsuccessful treatment there by higher number of patients of grade III hemorrhoids.

5) TIME REQUIRED FOR SURGERY

In presents study, mean operative time was significantly less in stapler group as compared to conventional surgery group (39.12 vs 45.75 mins; p<0.01).

TABLE 18: - MEAN OPERATIVE TIME

Author	Mean time to Surgery (mins)	
	Stapler	Conventional
Shukla et al. [78]	39.75	44.00
Thejeswi et al. [79]	45.75	62.00
Bikhchandani J et al. [76]	24.28	45.21
Gravie et al. [81]	21.00	31.00
Present study	39.12	45.75



GRAPH 18 :- GRAPH SHOWING MEAN OPERATIVE TIME COMPARISION

Shukla S et al. [78] also observed similar results with mean duration of surgery for patients' having conventional hemorrhoidectomy as 44±5 minutes while patients having stapler hemorrhoidectomy as 39.75±5.73 minutes ($p<0.01$).

Thejeswi PL et al. [79] observed average time taken for a stapled hemorrhoidectomy as 45.75 minutes (30-70min.) while conventional hemorrhoidectomy took an average of 62 minutes (45-80 mins).

Bikhchandani et al. [76] observed the mean operative time to be shorter in the stapled group 24.28 minutes (4.25) versus 45.21 minutes (5.36) in the Milligan-Morgan group ($P < .001$).

Gravie et al. [81] also observed Stapled hemorrhoidectomy to be significantly faster than the Milligan-Morgan technique (21 minutes versus 31 minutes; $P <0.001$).

Metanalysis from china performed by Shao WJ et al, and Tjandra JJ et al, from university of Melbourne also found shorter operating time in stapler group than conventional one [77,84].

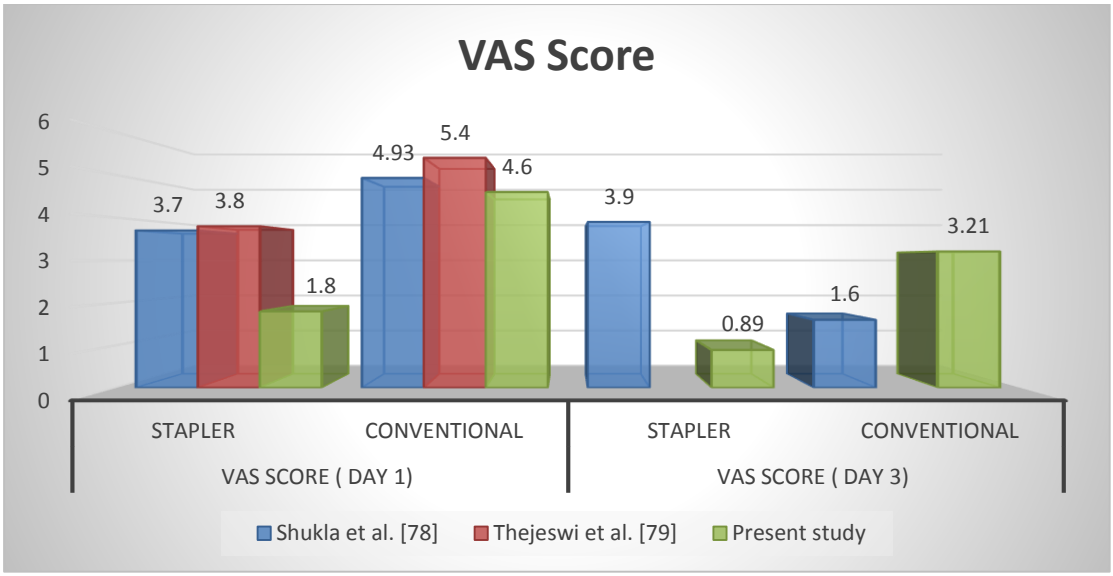
Conventional Hemorrhoidectomy requires clear identification of pedicle and ligation of each pedicles separately and excision of mass thus taking longer interval then stapler hemorrhoidectomy which having single continuous suturing and application of stapler.

6) POST-OPERATIVE PAIN & ANALGESIC REQUIREMENT

Post-op complains of pain (as measured by VAS score) immediately after surgery (6 hrs.) and at day 1 and day 3 was significantly less in stapler group as compared to conventional surgery group ($p<0.01$). No post-op analgesia was required in 60% cases of stapler group compared to none in conventional group. More than one dose of analgesic was required in 44% cases of conventional surgery compared to 12% cases of stapler group ($p<0.01$).

TABLE 19: - POST OPERATIVE PAIN SCORE (VAS SCORE) COMPARISION

Author	VAS score (Day 1)		VAS score (Day 3)	
	Stapler	Conventional	Stapler	Conventional
Shukla et al. [78]	3.70	4.93	3.90	1.60
Thejeswi et al. [79]	3.80	5.40		
Present study	1.80	4.60	0.89	3.21



GRAPH 19 : - GRAPH SHOWING VAS SCORE COMPARISION

Bikhchandani et al. [76] in their study also observed that pain scores and requirement of analgesics to be significantly less in the stapled group.

Gravie JF et al. [81] finds that the patients in the Stapler hemorrhoidectomy group experienced less postoperative pain during bowel movement and had less total analgesics requirement over the first 3 days.

Thejeswi et al. [79] observed the average pain scores on post-op day 1, day 2 and day 3 in the stapled group as 3.8, 2.4 and 1.6 as against 5.4, 4.3 and 3.9 in the conventional group, respectively ($p<0.01$).

Senagore AJ et al. [85], Boccasanta [86] and Shao WJ et al. [84] meta-analysis showed that stapled hemorrhoidectomy was less painful than conventional hemorrhoidectomy with less post-op analgesic requirement.

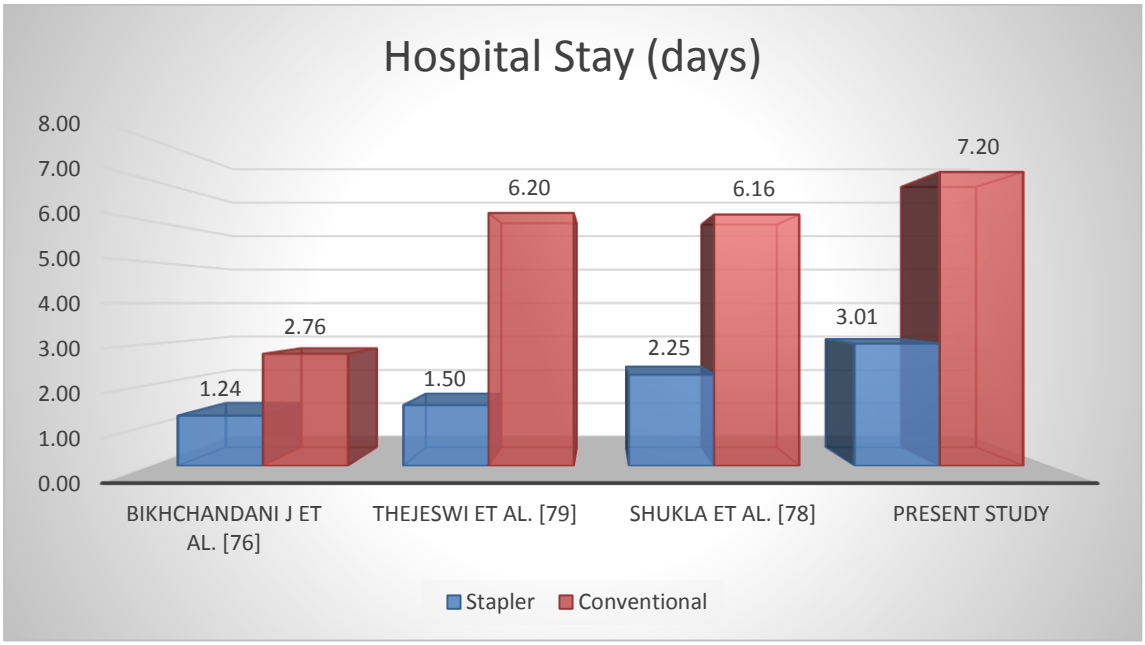
As there is and excision of mass below the dentate line containing nerve endings with open wound compared to stapler hemorrhoidectomy involving mucosal excision above the dentate line causing more pain then stapler hemorrhoidectomy.

7) HOSPITAL STAY

Mean hospital stay was significantly longer in conventional surgery group as compared to stapler group (7.02 vs 3.01 days; $p<0.01$).

TABLE 20:- HOSPITAL STAY COMPARISION

Author	Hospital Stay (Days)	
	Stapler	Conventional
Bikhchandani J et al. [76]	1.24	2.76
Thejeswi et al. [79]	1.50	6.20
Shukla et al. [78]	2.25	6.16
Present study	3.01	7.20



GRAPH 20: - GRAPH SHOWING HOSPITAL STAY COMPARISION

Bikhchandani et al. [76] observed mean hospital stay as 1.24 days (0.62) and 2.76 days (1.01) ($P < .001$) in the stapled and open group, respectively.

Thejeswi et al. [79] observed the average duration of stay in the hospital for the stapled group as 1.5 days, with 13 patients being discharged within 24 hrs of the surgery. The average duration of stay in the hospital for conventional group was 6.2 days ($p<0.01$).

Shukla S et al. [78] observed the mean duration of hospital stay in conventional group as 6.16±2.135 days while in stapler group as 3.25±1.932 days ($p<0.01$).

Gravie et al. [81] observed similar results with mean length of stay varying from 1.00 to 3.50 days in the Stapler group and from 1.67 to 5.00 days in the conventional group.

Conventional hemorrhoidectomy requires post-operative dressing of open wound and injectable analgesics for pain thus longer hospital stay compared to stapler hemorrhoidectomy.

8) COMPLICATIONS

No significant difference was observed in the incidence of complications in the 2 groups (P> 0.05). Post-op complications after conventional surgery includes bleeding (28%), urinary retention (12%), wound infection, anal incontinence (8% each) and anal stenosis (4%). Complications of stapler surgery includes bleeding (16%) and urinary retention (4%).

TABLE 21: - POST OP COMPLICATION COMPARISION

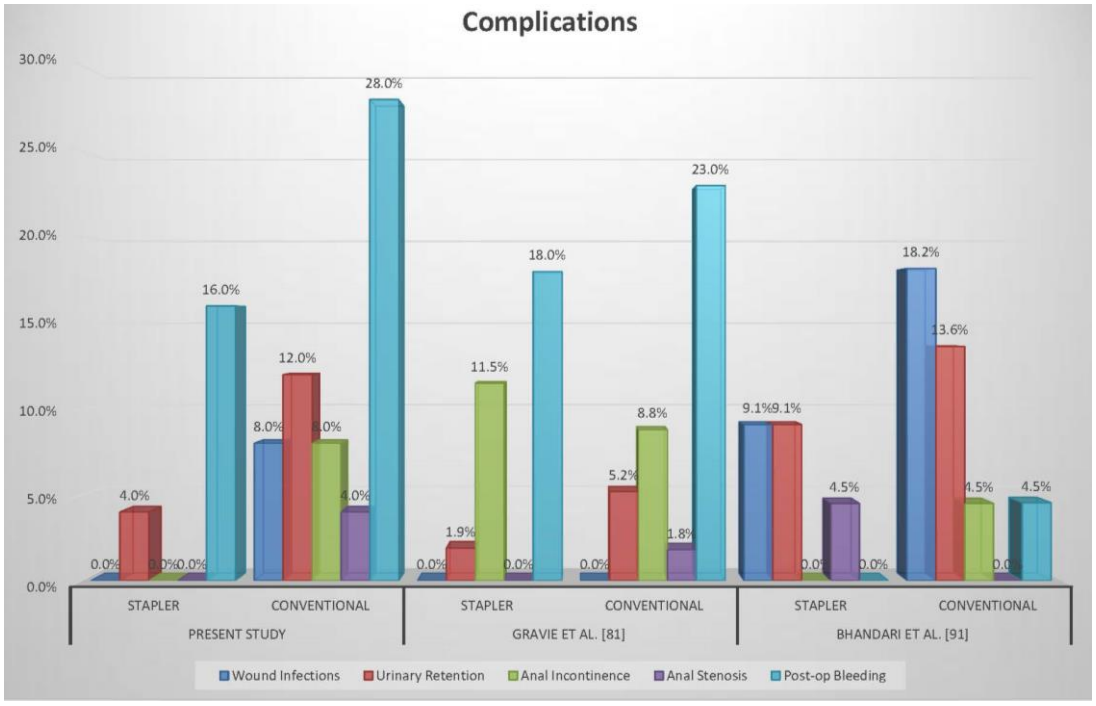
Author	Present Study		Gravie et al. [81]		Bhandari et al. [91]	
	Stapler	Conventional	Stapler	Conventional	Stapler	Conventional
Wound Infections	0.0%	8.0%	0.0%	0.0%	9.1%	18.2%
Urinary Retention	4.0%	12.0%	1.9%	5.2%	9.1%	13.6%
Anal Incontinence	0.0%	8.0%	11.5%	8.8%	0.0%	4.5%
Anal Stenosis	0.0%	4.0%	0.0%	1.8%	4.5%	0.0%
Post-op Bleeding	16.0%	28.0%	18.0%	23.0%	0.0%	4.5%

Shukla et al. [78] also observed bleeding as the most common symptom present in the post-operative period. At the end of 1st month, only 20% of patients with stapler procedure comes with complains of bleeding while it was present in 30% of conventional group patients. Urinary retention and wound infection was seen in 2 patients each in conventional group.

Bickchandani et al. [76], Shalaby et al. [87] and Gravie et al. [81] also found no difference in the rate of complications in the open and stapler groups respectively.

Conventional hemorrhoidectomy has an open wound leading to higher incidence of bleeding and wound infection then stapler hemorrhoidectomy.

Also with stapler which requires expertise there are incidence of bleeding due to improper suture line and donut.



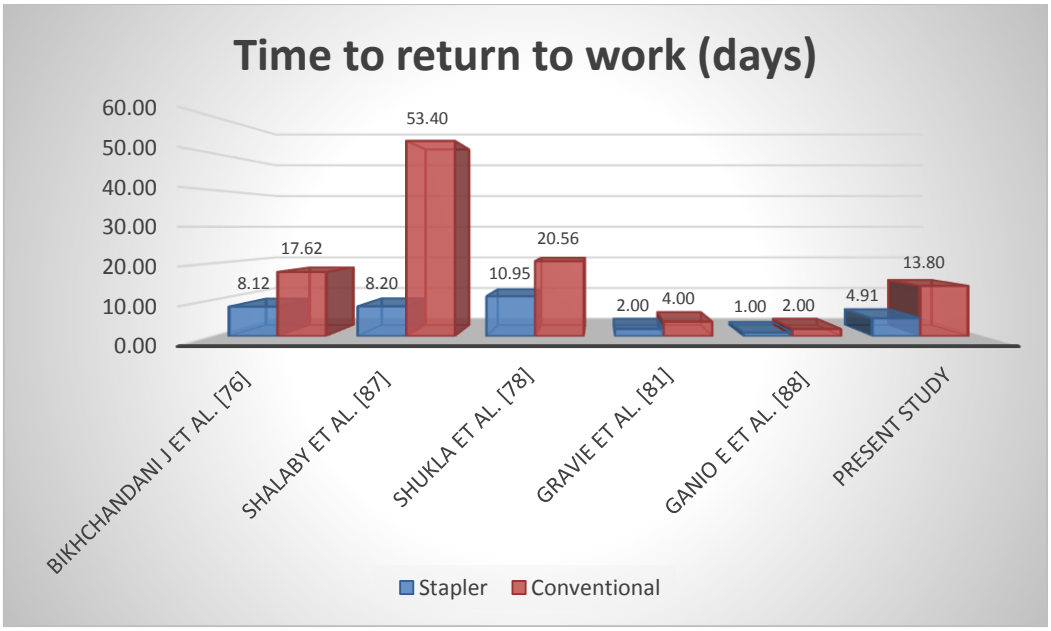
GRAPH 21: - GRAPH SHOWING POST OP COMPLICATION COMPARISION

9) **TIME TO RETURN FOR WORK**

Mean time for return to work was significantly less in stapler group as compared to conventional surgery group (4.91 vs 13.8 days; p<0.01).

TABLE 22: - TIME TO RETURN FOR WORK COMPARISON

Author		Time to return to work (Days)	
		Stapler	Conventional
Bikhchandani J et al. [76]		8.12	17.62
Shalaby et al. [87]		8.20	53.40
Shukla et al. [78]		10.95	20.56
Gravie et al. [81]		2.00	4.00
Ganio E et al. [88]		1.00	2.00
Present study	4.91	13.80	



GRAPH 22: - GRAPH SHOWING TIME TO RETURN TO WORK COMPARISION

Bikhchandani et al. [76] in their study observed that patients in the stapled group returned to work or routine activities earlier (ie, within 8.12 days [2.48]) as compared with 17.62 (5.59) in the conventional group ($p<0.01$).

Shalaby et al. [87] observed the mean duration to return to routine work as 53.4 days and 8.2 days in conventional and stapler group respectively ($p<0.01$).

Similarly, Shukla et al. [78] observed average duration of return to work post operatively as 10.95±4.81 days in patient of stapler hemorrhoidectomy as compared to patients of conventional hemorrhoidectomy, where it is 20.56±10.16 days ($p<0.001$).

Gravie JF et al. [81] shown the less duration of hospital stay of 2 days in Stapler as compared from 4 days in conventional one while Ganio E et al. [88] found it to be 1 day in stapler and 2 days in conventional procedure.

Meta-analysis done by Chen JS et al. [89] from Taiwan and Mattana et al. [90] also shows that stapler procedure provides has lesser hospital stay and quicker return to work.

Low incidence of post-operative pain and wound infection favors early recovery and return to work in stapler hemorrhoidectomy.

A hospital based Non-randomised comparative study was conducted at a tertiary care hospital with the objective of comparing stapled hemorrhoidectomy against conventional hemorrhoidectomy in the surgical treatment of hemorrhoids. A total of 50 eligible cases scheduled for haemorrhoidectomy in our hospital were included in the study. These 50 patients were then divided into two groups i.e. 25 for stapled procedure and other 25 patients for conventional procedure. Following observations were made during the study:

1. Most common age group affected by Hemorrhoids was between 41-60 years of age with mean age of 48.9 years.
2. Males are more commonly affected than females (56% vs 44%).
3. Most common presenting complaint in patients of hemorrhoids was bleeding (86%) followed by something coming out of rectum (prolapse 72%), Constipation (36%) and pain (18%).
4. Associated co-morbidities included Anemia (14%), diabetes (10%) and hypertension (14%).
5. Past history of treatment for hemorrhoids was given by only 3 patients (1 in conventional and 2 in stapler group).
6. Out of the 50 study cases, 8% were of grade 2 hemorrhoids while remaining 56% and 36% had grade III and IV hemorrhoids.
7. Mean operative time was significantly less in stapler group as compared to conventional surgery group (39.12 vs 45.75 mins; $p<0.01$).
8. Mean hospital stay was significantly longer in conventional surgery group as compared to stapler group (7.02 vs 3.01 days; $p<0.01$).

9. Post-op complains of pain (as measured by VAS score) immediately after surgery (6 hrs.) and at day 1 and day 3 was significantly less in stapler group as compared to conventional surgery group ($p<0.01$).

10. No post-op analgesia was required in 60% cases of stapler group compared to none in conventional group. More than one dose of analgesic was required in 44% cases of conventional surgery compared to 12% cases of stapler group ($p<0.01$).

11. Post-op complications after conventional surgery include bleeding (28%), urinary retention (12%), wound infection, anal incontinence (8% each) and anal stenosis (4%). Complications of stapler surgery include bleeding (16%) and urinary retention (4%).

12. Mean time for return to work was significantly less in stapler group as compared to conventional surgery group (4.91 vs 13.8 days; $p<0.01$).

- Most common age group affected by Hemorrhoids was between 41-60 years of age with mean age of 48.9 years. Age incidence comparable to others study attributing to less fibre and water intake leading to high incidence of constipation and resulting into haemorrhoids.
- Males are more commonly affected than females (56% vs 44%). There is male predominance in all the studies as those working population staying away from home and irregular and less fibre and water intake leading to haemorrhoids.
- Most common presentation of hemorrhoids reported and present in our study is bleeding per rectum and something coming out per rectum as patient feel shy and thus presents late and neglecting their complaints.
- In most of the cases surgical intervention is required only for grade III or IV hemorrhoids. Grade I and II case were general managed medically. Six cases in our study with grade II hemorrhoids had associated sever bleeding and measures to control the symptoms medically had failed. Our is a tertiary institute where patients from far presents with their complaints with most of the patients taking primary treatment elsewhere and presenting at a later stage for their unsuccessful treatment there by higher number of patients of grade III hemorrhoids.
- In presents study, mean operative time was significantly less in stapler group as compared to conventional surgery group because Conventional Hemorrhoidectomy requires clear identification of pedicle and ligation of each pedicles separately and excision of mass thus taking longer interval then stapler hemorrhoidectomy which having single continuous suturing and application of stapler.

- Post-op complains of pain (as measured by VAS score) was significantly less in stapler group as compared to conventional surgery group. No post-op analgesia was required in 60% cases of stapler group compared to none in conventional group As there is and excision of mass below the dentate line containing nerve endings with open wound compared to stapler hemorrhoidectomy involving mucosal excision above the dentate line causing more pain then stapler hemorrhoidectomy.
- Mean hospital stay was significantly longer in conventional surgery group as compared to stapler group as because Conventional hemorrhoidectomy requires post-operative dressing of open wound and injectable analgesics for pain thus longer hospital stay compared to stapler hemorrhoidectomy.
- No significant difference was observed in the incidence of complications in the 2 groups (P> 0.05). Post-op complications after conventional surgery includes bleeding, urinary retention, wound infection, anal incontinence and anal stenosis. Conventional hemorrhoidectomy has an open wound leading to higher incidence of bleeding and wound infection then stapler hemorrhoidectomy. Also with stapler which requires expertise there are incidence of bleeding due to improper suture line and donut.
- Mean time for return to work was significantly less in stapler group as compared to conventional surgery group because of Low incidence of post-operative pain and wound infection favors early recovery and return to work in stapler hemorrhoidectomy.
- The finding of our study confirms that conventional hemorrhoidectomy is associated with more post-operative pain, longer duration of surgery, longer duration of hospital stays, longer duration to return to work, higher chances of

wound infection and post-operative bleeding as compared to stapler hemorrhoidectomy.

- Although stapled hemorrhoidectomy offers much less pain when compared to the conventional methods, it requires skills to perform it and the cost of the procedure is much higher. So, it cannot be offered to all patients as an option.
- So, it is up to the treating surgeon to use his experience, skill and acumen in selecting the procedure for treating his patient with hemorrhoids, which is suitable to the patient economically, socially and curatively.
- We conclude that stapler hemorrhoidectomy is safe with many short-term benefits. It is a novel technique and has emerged as an alternative to conventional hemorrhoidectomy.
- However, there is a need to conduct larger prospective double-blind trials with longer period of follow-up to study rate of recurrence along with trials for cost effectiveness.

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ANNEXURE I:

LIST OF ABBREVIATIONS

VAS	:	VISIUAL ANALOGE SCORE
PPH	:	PROCEDURE FOR PROLAPS HEMORRHOIDS
MIPH	:	MINIMAL INVASIVE PROCEDURE FOR HEMORRHOIDS
DM	:	DIABETIS MELLITUS
HT	:	HYPERTENSION
B.P	:	BLOOD PRESSURE
R.S	:	RESPIRATORY SYSTEM
C.V.S	:	CARDIO VASCULAR SYSTEM
C.N.S	:	CENTRAL NERVOUS SYSTEM
CBC	:	COMPLETE BLOOD COUNT
RFT	:	RENAL FUNCTION TEST
RBS	:	RANDOM BLOOD SUGAR
HIV	:	HUMAN IMMUNO VIRUS
ECG	:	ELECTROCARDIOGRAPHY
SPSS	:	STATISTICAL PACKAGE FOR THE SOCIAL SCIENCE

ANNEXURE II

PARTICIPANT INFORMATION SHEET

Study Title: "COMPARATIVE STUDY OF MINIMAL INVASIVE PROCEDURE FOR HAEMORRHOIDS VS CONVENTIONAL HAEMORRHOIDECTOMY IN MANAGEMENT OF HAEMORRHOIDS"

1. Introduction: Hemorrhoidal disease that results from the hypertrophy of the hemorrhoidal plexus with the pathological changes in the anal cushions is most common anorectal disease & it has various modalities for treatment like conservative management, conventional & stapler hemorrhoidectomy etc.
2. What is the purpose of this study?

- So here we are comparing 2 methods of surgery for the best management with less post-operative pain & early recovery.

3. Why have I been chosen?

- You are being chosen for comparative study amongst 2 surgeries as you have hemorrhoids which on conservative treatment cannot be treated.

4. Do I have to take part?

- Yes, but on voluntary basis. Surgery would be operated as per the choice of participant after informing about both surgeries in detail.

5. How long will the study last?

- Around 2 years.

6. What will happen to me if I take part?

- ***Screening Period****: Per- rectal examination would be done & on the basis of hemorrhoids grading if needed participant would be informed about the surgery.*

- ***Treatment Period****: During this participant would be taken for surgery under anesthesia- Conventional/ Stapler hemorrhoidectomy & regarding medical treatment would be given pre-&post-operative.*
- ***Follow-up period***: Post-operative day 5, 15th day.

7. What do I have to do?

- Cooperate with the treating doctor & provide actual facts and allow to investigate regardingly for the procedure.

8. What are the benefits of the study?

- This study has both individual and community benefits. This study will provide data about the benefits of MINIMAL INVASIVE PROCEDURE FOR HEMORRHOIDS for patients having HEMORRHOIDS.

9. What are the alternatives for treatment?

- Conservative treatment, Sclerotherapy, Cryotherapy, rubber Band ligation, Bipolar Diathermy, Direct-Current electrotherapy, Infrared photocoagulation (IRC)

10. What are the side effects of the treatment received during the study?

- Less chances of Post-operative pain, bleeding per rectum, wound infection, urinary retention, anal incontinence, and anal stenosis.

11. What if new information becomes available?

- Till now various methods are already available & chances of exploring new method is less likely. If any new information gets updated the participant would be informed & accordingly actions would be taken.

12. What happens when the study stops?

- When the study stops we would get the inference about better method with less complications & feasible.

13. What if something goes wrong?

- If any type of threat or untoward event, consequent to present study, is met with, the patient will be provided every type of protection. Nature of this protection can be decided when such an event actually is faced with.

14. Will my taking part be kept confidential?

- Yes. Every detail would be kept confidential & patient would be given codes for identification.

15. What else should I know?

- About anesthesia risk, other complications of co-morbidities not related to surgery. Participant can be called for having additional information if needed.

16. Who to call with questions?

- Dr. MOSAM I SHAH
  Department of Surgery, Dhiraj General Hospital.
  Piparia, Tal: Waghodia, Dist: Vadodara.
  MOBILE NO: 9712530851

ભાગીદારી માહિતી શીટ

અભ્યાસ શીર્ષક: કમ્પેરેટિવ સ્ટડી ઓફ મીનીમલ ઈન્વેસીવ પ્રોસિજર ફોર હેમરોઈડ્સ વિરુદ્ધ કનવેન્સનલ હેમરોઈડેકટોમી ઇન મેનેજમેંટ ઓફ હેમરોઇડ્સ

પરિચય: મસા નો રોગ એ મસા ની નાડી મોટી થાવાથી અને ગુદા ની ગાદી મા રોગવિજ્ઞાનવિષયક ફેરફારો થવાથી થાય છે. મસા નો રોગ સૌથી સામાન્ય એનોરેક્ટ્લ રોગ છે. જેના સારવાર માટે વિવિધ પદ્ધતિઓ છે જેમા રૂઢિચુસ્ત મેનેજમેન્ટ, પરંપરાગત હેમરોઈડેકટોમી ,સ્ટેપલર હેમરોઇડેક્ટોમી, વિગેરે નો સમાવેશ થાય છે

1. આ અભ્યાસ નો હેતુ શું છે?

- અમે અહીં આ અભ્યાસ મા ઓછી સર્જરી પછી ની પીડા અને પ્રારંભિક પુનઃપ્રાપ્તિ સાથે શ્રેષ્ઠ વ્યવસ્થાપન માટે સર્જરી ની 2 પદ્ધતિઓ સરખામણી કરવામાં આવે છે.

2. શા માટે હું પસંદ કરવામાં આવી/ આવ્યો છું?

- તમારી પસંદગી 2 શસ્ત્રક્રિયા ના તુલનાત્મક અભ્યાસ માટે કરવામાં આવી છે કારણકે તમારી સારવાર રૂઢિચુસ્ત સારવાર થી થઈ શકે તેમ નથી.

3. શું મારે ભાગ લેવાની જરુર છે?

- હા. પરંતુ સ્વૈચ્છિક ધોરણે, બંને શસ્ત્રક્રિયા ની વિગતવાર માહિતી સહભાગી ને સમજાયા પછી સહભાગી ની પસંદગી પ્રમાણે સંચાલિત કરવામાં આવશે.

4. અભ્યાસ કેટલો લાંબો ચાલશે?

- આસપાસ 2 વર્ષ.

5. હું ભાગ લઉં તો મને શું થશે?

- સ્ક્રીનીંગ પીરિયડ: ગુદા પરીક્ષણ ના આધારે મસા નુ ગ્રેડિંગ કરવામાં આવશે અને જરુરી લાગશે તો સહભાગી ને સર્જરી વિશે જાણ કરવામાં આવશે.

- સારવાર સમયગાળાના : આ દરમિયાન ભાગ લેનાર ને નિશ્ચેતના હેઠળ પરંપરાગત/ સ્ટેપલર હેમરોઇડેક્ટોમી સર્જરી લેવામાં આવશે અને દર્દી ને શસ્ત્રક્રિયા ની પૂર્વ અને પછી તબીબી સારવાર આપવામાં આવશે.
- અનુસરો અપ સમય: શસ્ત્રક્રિયા પછી નો દિવસ 5, દિવસ 15

6. મારે શું કરવાનું છે?

- સારવાર ડૉક્ટર સાથે સહકાર અને વાસ્તવિક હકીકતો પૂરી પાડવી અને પ્રક્રિયા માટે સંબંધિત તપાસ કરવા માટે પરવાનગી આપવી.

7. અભ્યાસ માં શું ફાયદા છે.?

- આ અભ્યાસ વ્યક્તિગત અને સમુદાય લાભ ધરાવે છે. આ અભ્યાસ મસા ના દર્દીઓ માટે એમ.આઇ.પી.એચ ના ફાયદાઓ વિશે માહિતી પૂરી પાડે છે.

8. સારવાર માટે વિકલ્પો શું છે?

- રૂઢિચુસ્ત સારવાર, સ્લ્કેરોથેરાપી, ક્રાયોથેરાપી, રબર બેન્ડ લાઈગેશેન, સીધા-પ્રવાહ ઇલેક્ટ્રોચિકિત્સા, બાઈપોલર ડાઇથરમી, ઇન્ફ્રારેડ ફોટોકોએગુલ્શન.

9. અભ્યાસ દરમિયાન પ્રાપ્ત સારવાર ની આડઅસરો શું છે?

- પોસ્ટ ઓપરેટિવ દુખાવો, મળાશય રક્તસ્રાવ, ઘા ચેપ, પેશાબ રોકઈ જવો, ગુદા અસંયમ, ગુદા સંકીર્ણતા.

10. નવી માહિતી ઉપલબ્ધ બને ત્યારે શું કરવા માં આવશે?

- અત્યાર સુધી વિવિધ પદ્ધતિઓ પહેલેથી જ ઉપલબ્ધ છે અને નવી પદ્ધતિ અન્વેષણ તકો ની શક્યતા ઓછી છે. કોઈપણ નવી માહિતી સુધારાશે, તો સહભાગી ને જાણ કરવામાં આવશે અને તે મુજબ ક્રિયાઓ લેવામાં આવશે.

11. અભ્યાસ ના અંતે તેનું શું થશે?

- અભ્યાસ ના અંતે આપણ ને ઓછી જટિલતાઓ વાળી અને વધુ સારી રીતે પદ્ધતિ વિશે અનુમાન થશે.

12. જો કોઈ ખોટું થાય તો?

- આ અભ્યાસ ને લગતી કોઈપણ પ્રકારની ધમકી અથવા કમનસીબ ઘટના દદીે સાથે થશે ત્યારે તેને તેની સામે રક્ષણ આપવામા આવશે. આવી ઘટના નો ખરેખર સામનો થશે ત્યારે આ રક્ષણ નક્કી કરવામાં આવશે.

13. મારો ભાગ લેવા ની બાબત ગુપ્ત રાખવામાં આવશે?

- હા. એકત્રિત તમામ માહિતી ગુપ્ત રાખવામાં આવશે.

14. મારે બીજું શું જાણવું જોઈએ?

- નિશ્ચેતના જોખમ વિશે, સર્જરી સિવાય ની અન્ય જટિલતાઓ. અગર જરુર જનાય તો વધારાની માહિતી માટે ભાગીદાર ને બોલાવી શકાય છે.

15. પ્રશ્નો માટે કોને કૉલ કરવાનો?

- ડૉ મોસમ શાહ.

  સર્જરી વિભાગ, ધીરજ જનરલ હોસ્પિટલ, પીપરીયા જિલ્લો: વાઘોડીયા, વડોદરા

  મોબાઈલ નં: 9712530851

अभ्यास का शीर्षक :– "कम्पेरेटिव स्टडी ओफ मीनीमल इन्वेसीव प्रोसिजर फोर हेमरोइड्स विरुध्ध कनवेन्सनल हेमरोइडेकटोमी इन मेनेजमेन्ट ओफ हेमरोइड्स"

अभ्यासक्रमांक :– ..... *दिनांक :– .....*

(१) परिचय :–

मसा की बीमारी मसा की नाडी बडी होनेसे और गुदें की गादी में चिकित्साविज्ञान विषयक परिवर्तन होने से होता है । मसा की बीमारी सब से सामान्य एनोरेकट्ल बीमारी है । जिसके उपचार के लिए विविध पध्धतिर्या है, जिसमें परंपरागत मेनेजमेन्ट, परंपरागत हेमरोइडेकटोमी, स्टेपलर हेरोइडेकटोमी इत्यादि का समावेश किया जाता है ।

(२) अभ्यास का हेतु क्या है ?

यहा हम सर्जरी के बाद की कम पीडा और प्रारंभिक पुनःप्राप्ति के साथ श्रेष्ठ व्यवस्थापन के लिए सर्जरी की दो पध्धतियों की तुलना करेंगें ।

(३) अभ्यास में मेरी पसंदगी क्यों हुई ?

अभ्यास में दो अलग–अलग शस्त्रक्रिया का तुलनात्मक अभ्यास किया जायेगा, क्योंकि आपकी चिकित्सा परंपरागत तौर से नहीं कि जा सकती ।

(४) क्या मुझे इस अभ्यास में हिस्सा लेना जरुरी है ?

हा, किन्तु स्वेच्छा से । दोनों पध्धतियों के बारे में संपूर्ण जानकारी देने के पश्चात कार्यवाही की जायेगी ।

(५) अभ्यास कितने समय तक चलेगा ?

यह अभ्यास दो साल तक चलेगा ।

(६) इस अभ्यास में भाग लेने के बाद मेरे साथ क्या होगा ?

स्क्रीनिंग समय :– गुदा परीक्षण के आधार पर मसा का ग्रेडिंग किया जायेगा और तत्पश्चात अगर आवश्यकता हुई तो सहभागी को सर्जरी के बारे में विदित किया जायेगा ।

चिकित्सा का समय :– इस दौरान मरीज को बेहोश करके परंपरागत / स्टेपलर हेमरोइडेक्टोमी सर्जरी की जायेगी और उसके बाद शस्त्रक्रिया से पूर्व और पश्चात की ट्रिटमेन्ट दी जायेगी ।

फोलोअप समय :– शस्त्रक्रिया के बाद ७ वे दिन, १५वे दिन ।

(७) मुझे क्या करना होगा ?

मरीज को उसकी चिकित्सा करनेवाले डोक्टर को जाँचने की अनुमति देगा और अपने बारे में संपूर्ण एवम् सच्ची जानकारी देना ।

(८) इस अभ्यास से क्या लाभ है ?

इस अभ्यास से व्यक्तिगत और सामुहिक लाभ प्रदान होगे । इस अभ्यास से मसा के दर्दीओ के लिए एम.आइ.पी.एच.के प्रभाव की प्रदान की जायेगी ।

(९) सारवार का अन्य कोइ विकल्प है ?

परंपरागत सारवार, स्क्लेरोथेरापी, क्रायाथेरापी, रबर बेन्ड लाइगेशेन, सीधा–प्रवाह इलेक्ट्रोचिकित्सा, बाइपोलर डाइथरमी, इन्फ्रारेड फोटोकोएगुल्शन ।

(१०) इस अभ्यास में होने वाली चिकित्सा के क्या नुकशान है ?

ओपरेशन के बाद दर्द, मलाशय में रक्तस्त्राव, इन्फेकशन, मूत्रमार्ग में रुकावट, मळमार्ग का असंयमीत होना, गुदे का संकिर्ण होना, इत्यादि ।

(११) अगर इस अभ्यास के दौरान कोई नई नानकारी प्राप्त होती है तो क्या करेंगे ?

प्रवर्तमान समय में काफी पध्धतिया अस्तित्व में है, किन्तु अगर कोइ नई जानकारी प्राप्त होती है तो उसके बारे में मरीज को अवगत किया जायेगा और उसी अनुसार प्रक्रिया की जायेगी ।

(१२) अभ्यास के अंत में क्या होगा ?

इस अभ्यास के अंत में कौन सी पध्धति कम कोम्प्लीकेशनवाली और सरल है, यह विदित होगा ।

(१३) यदि अभ्यास को दौरान कोई दुर्घटना होती है तो क्या होगा ?

यदि अभ्यास के दौरान कोई दुर्घटना होगी, तो मरीज को सभी प्रकार का रक्षण मोहीया करवाया जायेगा, रक्षण का मतलब स्थिति को ध्यान में रखकर और दुर्घटना की गंभीरता को देखकर तय किया जायेगा ।

(१४) क्या मेरा परिचय गुप्त रखा जायेगा ?

हा, प्रत्येक जानकारी को गुप्त रखा जायेगा और मरीज की पहचान के लिए संकेत दिए जायेंगे ।

(१५) मुझे ओर क्या जानना जरुरी है ?

बेहोश करने का खतरा, अन्य बिमारीयों के कोम्प्लीकेशन ओपरेशन के साथ संबंधित नही है, अगर जरुरत होती है तो मरीज को ज्यादा जानकारी के लिए बुलाया जायेगा ।

(१६) अगर कोई भी नानकारी प्राप्त करनी हो तो किसका संपर्क करे ?

डो.मोसम शाह, जनरल सर्जरी विभाग, एस.बी.के.एस. मेडिकल इन्स्टीटयुट एन्ड रिसर्च सेन्टर–पीपरिया, तह.वाघोडिया जि.वडोदरा मोबाइल नंबर 97125 30851

ANNEXURE III

INFORMED CONSENT FORM

SUMANDEEP VIDYAPEETH UNIVERSITY

Piparia, Ta. Waghodia, Dist. Vadodara Pin: 391760

Informed Consent Form (ICF) for Participants in Research Programmes involving studies on human beings

Study Title: **COMPARATIVE STUDY OF MINIMAL INVASIVE PROCEDURE FOR HAEMORRHOIDS VS CONVENTIONAL HAEMORRHOIDECTOMY IN MANEGMENT OF HAEMORRHOIDS**

Study No: SVU/SBKS/_____ /2011-_____

Participants Initials: _____ Participants Name: _____

Date of Birth: _____ Age: _____Years

1. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that the investigator of this study, others working on the investigators behalf, the Ethics committee and the regulatory authorities will not need my permission to look at my health records, both in respect of the current study and further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information related to the third party or get published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
5. I agree to take part in the above study.

Signature/Thumb impression of the participant _____

Legally acceptable representative _____

Signatory's Name _____ Date _____

Signature of the investigator _____ Date _____

Study Investigator's Name _____ Date _____

Signature of the impartial witness _____Date _____

Name of the witness _____

સુમનદીપવિદ્યાપીઠયુનીવર્સિટી

એસ.બી.કે.એસ. મેડિકલ ઈન્સ્ટટ્યુટ એન્ડ રીસર્ચ સેન્ટર

પીપરીયા, તા. વાઘોડીયા, જી. વડોદરા.

અભ્યાસ માં ભાગ લેવા માટે (સંશોધન)સહભાગી દ્વારા સમજી વિચારીને આપેલી પરવાનગીનુ સંમતિ પત્રક

અભ્યાસનું નામ:"ધિરજ જનરલ હોસ્પિટલ, પિપરિયા ખાતે "કમ્પેરેટિવ સ્ટડી ઓફ મીનીમલ ઈન્વેસીવ પ્રોસિજર ફોર હેમરોઈડ્સ વિરુદ્ધ કનવેન્સનલ હેંરોઇડેક્ટોમી ઇન મેનેજમેંટ ઓફ હેમરોઇડ્સ"

અભ્યાસ ક્રમાંક :SVU/SBKS/ /૨૦૧૨-___

સહભાગીનું પુરુ નામ:

સહભાગીનું ટુંકુ નામ:

સહભાગીની જન્મતારીખ વર્ષ_____ / _____ **:ઉંમર /**

૧) મેંઆ અભ્યાસ(સંશોધન)સંબંધીતારીખ: / /નીમાહિતીપત્રિકાવાંચેલઅનેસમજેલછેતેમજમનેમારાડોકટર (તપાસકર્તા) નેપ્રશ્નોપુછવાનીઅનેચર્ચાકરવાનીપણતકમળીછે.

૨) મનેસમજાવેલછેકેઆઅભ્યાસ (સંશોધન)માંભાગલેવોએસંપૂર્ણમારીમરજીઉપરછેતેમજહુંગમેત્યારેકારણઆપ્યાવગરપણઆમાંથીનીકળીશકું છું, અને આમ કરવાથી મારી તબીબી સારવાર કે કાયદેસરના હક્કોને કોઇ અસર નહીં થાય.

૩) હું જાણુ છું કે આ અભ્યાસ (સંશોધન)ના તપાસકર્તા, તેમના મદદનીશો, એથિકલટીમ અને તેના ઉપર દેખરેખ રાખતા અધિકારીઓને મારા સ્વાસ્થ્યની કોઇપણ જાતની માહિતી, સદર અભ્યાસ (સંશોધન)ને લગતી કે તે સિવાયની, મેળવવા માટે મારી પરવાનગીની જરૂર રહેશે નહીં, ભલે પછી હું અભ્યાસ (સંશોધન)માંથી ખસી જાઉં. હું જાણું છું કે મારી આ પ્રકારની માહિતી અન્ય કોઇને જાણ કે પ્રસિધ્ધ નહીં કરવામાં આવે.

૪) આ અભ્યાસ (સંશોધન) દરમ્યાન, અથવા તેના અંતે પ્રાપ્ત થતી માહિતી, કોઇપણ જાતની વૈજ્ઞાનિક શોધ માટે ઉપયોગ કરવા માટે હું સ્વૈચ્છિક રીતે છુટ આપું છું

૫) હુંઆઅભ્યાસ (સંશોધન)માંભાગલેવા/ જોડાવામાટેમારીસંમતિઆપુંછું.

સહભાગીનું નામ:_____સહભાગીનીસહીઅથવાડાબાઅંગુઠાનુંનિશાન:_____

સંમતિલેનારનુંનામ:_____સંમતિલેનારનીસહી:_____

સાક્ષીનુંનામ:_____સાક્ષીનીસહીઅથવાડાબાઅંગુઠાનુંનિશાન:_____

સ્થળ:_____તારીખ:_____

सुमनदीप विद्यापीठ युनिवर्सिटी

एस.बी.के.एस. मेडिकल इन्स्टीटयुट एन्ड रिसर्च सेन्टर

पीपरिया, ता.वाघोडिया जि.वडोदरा – 391760

अभ्यास का नाम :– "कम्पेरेटिव स्टडी ओफ मीनीमल इन्वेसीव प्रोसिजर फोर हेमरोइड्स विरुध्ध कनवेन्सनल हेमरोइडेकटोमी इन मेनेजमेन्ट ओफ हेमरोइड्स"

अभ्यासक्रमांक :– ..... *दिनांक :–*

.....

(१) *मैं पूष्टि करता हूँ कि, उपरोक्त अभ्यास की (दिनांक.....) की जानकारी पढी है और ठीक से समजी है, और इस विषय में अपूर्ण जानकारी के सवाल करने के लिए मुझे मौका दिया गया था ।*

(२) *साथ ही मुझे यह भी विदित है, कि इस अभ्यास में भाग लेना वैकल्पिक है और किसी भी प्रकार की नोटिस दिये बगैर उसमें से दूर होने का मुझे अबाधित अधिकार है । ऐसा करने से मेरे चिकित्सा संबंधी अधिकारो को कोई असर नहि होगा ।*

(३) *मुझे यह भी ज्ञात है, कि अभ्यास के चिकित्सक, उसके सहयोगी, एथिकल टीम और उसके उपरी अधिकारियों को मेरे स्वास्थ्य संबंधी सभी जानकारी इस अभ्यास के संदर्भ में प्राप्त करने में मेरी रजामंदी की कोई जरुरत नहीं रहेंगी । चाहे मैं इस अभ्यास से दूर हो जाऊ, मुझे अच्छी तरह विदित है कि यह जानकारी कहीं पर भी प्रसिध्ध नहीं होगी ।*

(४) *इस अभ्यास के दौरान और उसके अंत में प्राप्त होनेवाली किसी भी जानकारी का वैज्ञानिक शोध के लिए उपयोग करने के लिए मैं पूर्ण रुप से सहमत हूँ ।*

(५) *इस अभ्यास में जूडने के लिए मैं पूर्ण होशोंहवाश में सहमति प्रदान करता हूँ ।*

प्रतिभागी के हस्ताक्षर या अंगूठे का निशान .....

कानूनी तौर पर स्वीकार्य प्रतिनिधि .....

हस्ताक्षरकर्ता का नाम ..... दिनांक .....

अन्वेषक के हस्ताक्षर ..... दिनांक .....

अन्वेषक का नाम ..... दिनांक .....

निष्पक्ष गवाह के हस्ताक्षर ..... दिनांक .....

निष्पक्ष गवाह का नाम .....

ANNEXURE IV:

PROFORMA:

1. Name:
2. Reg. No.:
3. Age/Sex:
4. Ward:
5. Address:
6. Date of Admission:
7. Date of Operation:
8. Date of Discharge:
9. Clinical History:

PRESENT COMPLAINTS

- Bleeding Per Rectum
- Constipation
- Pain while passing stool
- Something coming out from anus

PAST HISTORY

- H/O Similar complaints / DM / HT / Trauma / Dietary Habits / Addiction (Alcohol/ Other).

OPERATIVE HISTORY

- H/O any surgery in past

CLINICAL EXAMINATION

- Vitals
    - General Condition
    - B.P
    - Pulse
    - Temperature
    - Respiratory Rate

- Pallor / Icterus / Cyanosis / Clubbing / Edema / Lymphadenopathy
- **Per rectal examination**
    - Skin Tag
    - Anal sphincter tone
    - Hard stool
    - Prostate Size
    - Any mass is present or not
- **Proctoscopy Examination**
    - Active Bleeding is present or not
    - Hemorrhoids
- System Review
    - PER ABDOMEN
    - RS
    - CVS
    - CNS

INVESTIGATIONS

- CBC
- RFT
- RBS
- HbsAg
- HIV
- ECG
- Radiological
    - X-ray – Chest

- **MANAGEMENT**
    - Type of Operation:
    - Type of Anesthesia:
    - Position:
    - Operative Time:
- **SURGICAL COMPLICATION**

    - Operative
    - Post –operative
        - Immediate Post-Operative Complication
            - Post-Operative Pain
            - First Defecation Post Surgery
        - Early Complication
            - Urinary retention
            - Secondary Bleed
            - Incontinence
            - Others
        - Late Complication
            - Anal Stenosis
            - Stricture
            - Anal Incontinence
            - Recurrence
            - Others
- **Hospital Stay**
- **TIME TO RETURN TO NORMAL WORK**
- **REMARKS**

ANNEXURE V:

MASTER CHART

KEY TO MASTER CHART

M	:	Male
F	:	Female
DM	:	DIABETIS MELLITUS
HT	:	HYPERTENSION
CH	:	CONVENTIONAL HEMORRHOIDECTOMY
SH	:	STAPLER HEMORRHOIDECTOMY

MASTER CHART

			Complaints										VAS Score				Post-op Complications					
SR NO	Age	Gender	Bleeding	Pain	Constipation	Prolapse	Grade of Hemorrhoids	Associated Co-morbidity	Past History of Treatment	Management	Operative Time (mins)	Hospital Stay	6 hours	Day 1	Day 3	Postop Analgesic	Wound Infection	Urinary Retention	Anal Incontinence	Anal Stenosis	Bleeding	Return to Work
1	48	M	Yes	No	No	No	III	None	No	CH	50	8	7	5	4	2	No	No	No	No	No	12
2	36	F	Yes	No	Yes	No	III	None	No	CH	52	7	6	4	2	1	No	No	No	No	No	13
3	38	M	No	Yes	Yes	Yes	IV	None	No	CH	40	7	6	4	3	2	Yes	Yes	No	No	Yes	18
4	63	F	Yes	No	No	No	II	Anemia	No	CH	43	6	5	3	2	1	No	No	No	No	No	14
5	47	M	No	No	Yes	No	III	HT	Yes	CH	44	7	5	3	2	1	No	No	No	No	No	12
6	50	F	Yes	No	Yes	Yes	IV	None	No	CH	42	8	6	4	1	1	No	No	No	No	Yes	20
7	53	M	No	No	Yes	No	III	DM	No	CH	45	7	7	5	4	2	No	No	No	No	No	11
8	48	M	Yes	No	No	No	III	None	No	CH	41	8	5	4	3	1	No	No	No	No	No	12
9	51	F	Yes	No	No	No	III	None	No	CH	46	8	8	5	3	3	No	No	No	No	No	14
10	60	M	No	Yes	Yes	Yes	IV	None	No	CH	45	9	6	4	3	2	No	Yes	No	Yes	Yes	19
11	42	F	Yes	No	Yes	No	III	Anemia	No	CH	48	8	7	3	2	2	No	No	No	No	No	12
12	67	M	No	Yes	Yes	Yes	IV	None	No	CH	52	7	5	4	3	1	No	No	Yes	No	No	15
13	45	M	Yes	No	No	No	III	None	No	CH	50	6	6	3	1	2	No	No	No	No	No	12
14	50	F	Yes	No	Yes	No	III	DM, HT	No	CH	42	7	5	5	4	1	No	No	No	No	No	13
15	52	M	Yes	No	Yes	Yes	IV	None	No	CH	41	8	5	4	3	1	No	No	No	No	Yes	17
16	68	M	Yes	No	No	No	II	None	No	CH	46	9	6	4	2	2	No	No	No	No	No	12
17	68	F	No	No	Yes	Yes	IV	None	No	CH	40	6	6	5	4	2	Yes	No	Yes	No	Yes	19
18	65	M	Yes	No	Yes	No	III	None	No	CH	47	7	6	5	4	2	No	No	No	No	No	10
19	50	M	Yes	No	Yes	No	III	None	No	CH	41	6	6	4	3	3	No	No	No	No	No	11
20	60	F	Yes	No	Yes	Yes	IV	None	No	CH	48	7	5	3	0	1	No	Yes	No	No	Yes	18
21	49	M	Yes	No	Yes	No	II	None	No	CH	43	6	7	5	4	2	No	No	No	No	No	12
22	42	M	No	Yes	Yes	Yes	IV	DM	No	CH	50	7	5	4	3	1	No	No	No	No	Yes	21
23	46	F	Yes	No	No	No	III	None	No	CH	50	7	6	5	2	2	No	No	No	No	No	14
24	65	F	Yes	No	Yes	No	III	None	No	CH	52	6	6	4	3	2	No	No	No	No	No	12
25	25	M	Yes	No	No	No	III	None	Yes	CH	49	7	3	2	1	1	No	No	No	No	No	12
26	44	M	Yes	No	Yes	No	III	HT	No	SH	34	3	2	1	1	None	No	No	No	No	No	5
27	65	M	Yes	No	No	No	III	None	No	SH	36	3	2	1	0	None	No	No	No	No	No	6
28	75	F	No	Yes	Yes	No	III	None	No	SH	39	4	3	2	1	1	No	No	No	No	No	7
29	41	F	Yes	No	Yes	Yes	IV	Anemia	No	SH	44	4	2	1	1	None	No	No	No	No	No	4
30	55	M	No	No	Yes	Yes	IV	None	No	SH	40	2	3	2	2	1	No	No	No	No	Yes	11
31	28	F	Yes	No	No	No	III	None	No	SH	42	3	4	2	1	1	No	No	No	No	No	4
32	45	M	No	No	Yes	Yes	IV	HT	No	SH	43	2	3	2	1	2	No	Yes	No	No	Yes	10
33	30	F	No	Yes	Yes	No	III	None	No	SH	40	2	2	2	1	None	No	No	No	No	No	5
34	38	M	Yes	No	Yes	Yes	IV	None	No	SH	39	3	2	1	0	None	No	No	No	No	No	3
35	35	F	Yes	No	Yes	No	III	Anemia	No	SH	38	4	4	2	1	1	No	No	No	No	No	6
36	42	M	Yes	No	No	No	III	None	No	SH	40	4	3	2	1	2	No	No	No	No	No	7
37	61	F	No	No	Yes	Yes	IV	DM	Yes	SH	42	3	3	2	1	1	No	No	No	No	Yes	13
38	70	F	Yes	No	Yes	Yes	IV	Anemia, HT	No	SH	44	3	2	1	1	None	No	No	No	No	No	3
39	59	M	No	Yes	Yes	No	III	None	No	SH	41	3	2	1	0	None	No	No	No	No	No	4
40	54	M	Yes	No	Yes	Yes	IV	None	No	SH	45	3	1	2	1	None	No	No	No	No	No	4
41	51	F	Yes	No	Yes	No	III	Anemia	No	SH	43	2	2	2	2	None	No	No	No	No	No	5
42	50	F	No	No	Yes	Yes	IV	HT	No	SH	42	3	1	2	1	None	No	No	No	No	Yes	12
43	45	M	Yes	No	Yes	No	III	None	No	SH	41	4	3	1	0	1	No	No	No	No	No	4
44	52	M	Yes	No	No	No	III	None	No	SH	43	3	2	1	1	None	No	No	No	No	No	3
45	37	F	No	Yes	Yes	Yes	IV	None	No	SH	34	4	2	1	0	None	No	No	No	No	No	4
46	45	M	Yes	No	Yes	No	II	DM, HT	No	SH	38	3	3	2	2	2	No	No	No	No	No	4
47	42	M	Yes	No	No	No	III	None	No	SH	37	3	2	0	1	None	No	No	No	No	No	3
48	57	F	No	No	Yes	Yes	IV	None	No	SH	39	3	1	0	0	None	No	No	No	No	No	4
49	45	F	Yes	No	Yes	No	III	Anemia	No	SH	40	4	2	1	0	None	No	No	No	No	No	3
50	48	M	No	No	Yes	No	III	None	No	SH	41	2	3	2	1	1	No	No	No	No	No	6