"A PROSPECTIVE RANDOMIZED OPEN LABEL TRIAL TO COMPARE EFFECTS OF CREAM CONTAINING ALOE VERA VERSUS 2% XYLOCAINE JELLY ON POST HEMORRHOIDECTOMY PAIN"

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ENDORSEMENT

This is to certify that the dissertation entitled **"A PROSPECTIVE RANDOMIZED OPEN LABEL TRIAL TO COMPARE EFFECTS OF CREAM CONTAINING ALOE VERA VERSUS 2% XYLOCAINE JELLY ON POST HEMORRHOIDECTOMY PAIN"** is a bonafide research work done by **REG NO. BH0110002.**

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LIST OF ABBREVIATIONS USED

ECG → Electrocardiogram

AIDS → Acquired immuno deficiency syndrome

DM → Diabetes Mellitus

PPH → Procedure for prolapsing haemorrhoids

CS → Circular Stapler

CAD → Circular anal dilator

PSA → Purse string suture anoscope

HIV → Human Immuno deficiency virus

NSAIDS—Non stearoidal Anti- Inflamatory Drugs

ESR—Erythrocyte Sedimentation Rate

TNF- Tumour Necrosis Factor

ABSTRACT

Background and objectives

Open haemorrhoidectomy although safe routinely carried out surgery, post haemorrhoidectomy pain is frequent complaint. Our study aims at reduction of post haemorrhoidectomy pain. The objective of this study is to compare the efficacy of peri anal application of Aloe vera cream versus 2% xylocaine in post haemorrhoidectomy defecation pain.

Methodology

50 adult patients admitted to department of surgery posted for elective open haemorrhoidectomy in KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum between age group 18 to 60 years suffering from grade 3 and grade 4 haemorrhoids were included in the study. 50 patients undergoing open haemorrhoidectomy were prospectively randomized into 2 groups. **Group (A) – Study group:** Patients applied Aloe vera cream post surgery three times daily. **Group (B) - Control group:** Patients applied 2% xylocaine jelly three times daily at the same location. The treatment was carried out till post operative day 7. The evaluation of postoperative pain was done at fixed time interval according VAS. Analgesic requirements were analyzed.

Results

Mean pain scores were significantly lower in Aloe vera group on 48 hrs, Day 3 , Day 7 post surgery($p=<0.0001$) as compared with group B. . The mean total NSAID's usage in group A was lower as compared to group B and was found to be statistically significant ($p<0.001$).

Conclusion

To conclude, Aloe vera cream is effective in post haemorrhoidectomy pain and it significantly reduced post defecation pain when compared with conventional 2% xylocaine jelly

Key words

Open Haemorrhoidectomy; Aloe vera cream; Post operative pain relief;

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INTRODUCTION

Haemorrhoids are one of the most common chronic anorectal diseases known.[1]

Haemorrhoids the word is derived from Greek, haima meaning blood and rhoos meaning flowing. The common man's term piles is derived from Latin word pila meaning ball.[2]

Treatment of hemorrhoidal disease depends on the stage of the disorder and the symptoms. Surgical hemorrhoidectomy is indicated for the treatment of third- and fourth-degree symptomatic hemorrhoids.[3]

However, surgery is associated with severe postoperative pain that is a source of such anxiety that some patients decide not to undergo the operation. Continuous internal anal spasm is considered a major factor in inducing pain.[3]

Nonsteroidal anti-inflammatory drugs (NSAIDs) and opiates have often been used to control pain, but their use is confined to a short period of time and is associated with frequent side effects.[3]

Consequently, the introduction of novel methods for the control of pain after hemorrhoidectomy is required. With regard to the effect of pain on discomfort of patients, several pharmacological agents have been assessed for relieving pain in patients including diltiazem , glycerol trinitrate ointment, lidocaine and prilocaine ointment, sucralfate cream and perineal block with ropivacaine.[1]

Ineffective analgesia is the main cause of prolonged hospital stay and patients returning to an ambulatory care facility after haemorrhoidectomy [4]

Aloe Vera has been used in traditional medicine for a long time. It is one of the most recognizable herbs in the world and the medicinal part is the succulent leaves. A topical skin gel provides wonderful healing support for the skin.[5-8]

Aloe Vera contains many important nutrients for the body, including amino acids, B vitamins, and other nutrients that support general health. It also has pharmacological properties including antioxidant, woundhealing, antibacterial, antifungal, and immunomodulatingeffects.[5-8]

The literature on effect of aloe vera in reducing post haemorroidectomy pain is limited. Hence the present study is undertaken to compare the effect of aloe vera versus 2% xylocaine jelly on post haemorroidectomy pain and post defecation pain.

OBJECTIVES

To compare the efficacy of Aloe Vera cream over 2% xylocaine jelly in post hemorrhoidectomy Patients for

1. Post operative pain relief.
2. Post defecation pain relief in comparison with conventional 2% Xylocaine jelly.

REVIEW OF LITERATURE

HISTORY

A haemorrhoid is one of the oldest diseases suffered by mankind well recorded in ancient texts of Greeks, Egyptians, Hindus, and Bible. Many great personalities have suffered from haemorrhoids like the Philistines, Napolean Bonaparte, Don Juan Demoranna. It is said Napolean Bonaparte lost his battle of Waterloo because of the delay in launching the attack due to a bad attack of bleeding haemorrhoids.

Hippocrates thought haemorrhoidal disease facilitates purification of various organisms expelling petrified matter. He also correlated Liver disease, portal hypertension and haemorrhoids. He proposed stopping of excess flow with ligation, excision and cauterization with hot iron rod.[10]

In John of Ardernes writings in 1370, in his treatise on haemorrhoids mentions that the common people call them piles, the aristocracy[2]call them haemorrhoids and the French call them figs.

Maimonoides the ancient popular Physician in his early writings pointed out the composition of ones food should always produce stool softening. In his treatise he recommended a host of concoctions in the form of suppositories, ointments, enemas for alleviation and even prevention of haemorrhoids. He also regarded operative excision with skepticism as he thought surgery does not remove the underlying cause.[9]

In olden days the controversy in treatment was to whether stop haemorrhoidal flow or not. Celsus believed if flow stopped the infected blood can travel to heart and

other viscera. Ambroise Paré proposed that if haemorrhoidal blood flow was moderate then it was better not to stop it as it avoids psychological depression.

Duret suggested increase in portal venous pressure due to straining during defecation as the cause of haemorrhoids. James proposed that the presence of caustic and acid matter in colon, rectum causes spasm of anal muscles producing stasis in rectal veins predisposing to haemorrhoids.

John Morgan first attempted sclerotherapy to obliterate haemorrhoids in 1869 with iron persulphate.[11]Anderson (1924) and Bacon (1949) outlined injection treatment and later Albright used 5% phenol in almond oil.

In 1774 John Louie Petit proposed submucosal method of ligation of haemorrhoids. In 1835, Salmon was the first to isolate the pedicle of haemorrhoid. In 1882 Whit head described the circumferential amputation of haemorrhoids. In 1903 Mitchell described a method of clamping of haemorrhoids and excision with partial wound closure. Earl and Bacon popularized the technique later. In 1919, Miles modified Salmons original technique of high excision with open haemorrhoidectomy by suggesting a lower ligation to reduce the amount of raw tissue in the anal canal. In 1959 Ferguson and Heaton described a technique of closed haemorrhoidectomy.

Blaisdell in 1954 invented the instrument and technique for outpatient ligation of internal haemorrhoids using silk thread for ligation[12] .This instrument was later modified by Barron in 1963 who used rubber bands for ligation.[13]Lords in 1968 described anal dilatation for haemorrhoids and Noratas in 1971 proposed lateral subcutaneous sphincterotomy to reduce the activity of internal sphincter, over activity of which was proposed as a cause.[10]

Lewis introduced cryosurgery in treatment of haemorrhoids[14], which was later followed by Frazer and Gill (1967), Lewis et al (1969), Lloyd Willing et al (1973).

Neiger introduced photocoagulation in 1979. Most recently laser haemorrhoidectomy has been tried. Longo in 1998 has described stapled haemorrhoidopexy for painless treatment of haemorrhoids.[15]

ANATOMY

The anal canal is the terminal portion of gastrointestinal tract, begins at the anorectal junction. It is about 4 cms long and terminates at the anal verge. The anorectal junction is angulated in relation to the rectum due to pull of puborectalis muscle producing anorectal angle.[16]It lies 2-3 cms in front of and slightly below tip of coccyx, where the ampulla of rectum suddenly narrows and pierces the pelvic diaphragm, which is opposite apex of prostrate in males. The anal verge is marked by a sharp turn where the squamous epithelium which lines the lower anal canal becomes continuous with skin of perineum.[16]

Embryologically the superior two thirds of the anorectal canal forms from the distal part of hindgut, whereas the inferior one third of anorectal canal is derived from ectodermal pit called the anal pit or proctodeum.[17]The pit is created when the mesenchyme around anal membrane proliferates to form a raised border. The anal membrane thus separates the endodermal and ectodermal portions of anorectal canal, the former location of this membrane is marked in adult by irregular folding of mucosa called pectinate line.[17]

The anal canal consists of an inner lining epithelium, a vascular sub epithelium, the internal and external anal sphincters and fibromuscular supporting

tissue[16].The anal canal is attached posteriorly to coccyx by the anococcygeal ligament, a midline fibro muscular structure which may possess some skeletal muscle elements, which runs between the posterior aspect of external sphincter and coccyx. Just above this is the raphe of the levator plate, the fusion of two halves of iliococcygeus muscle, which merges anteriorly with the puborectalis muscle. Between these two structures is the potential post anal space.[16]

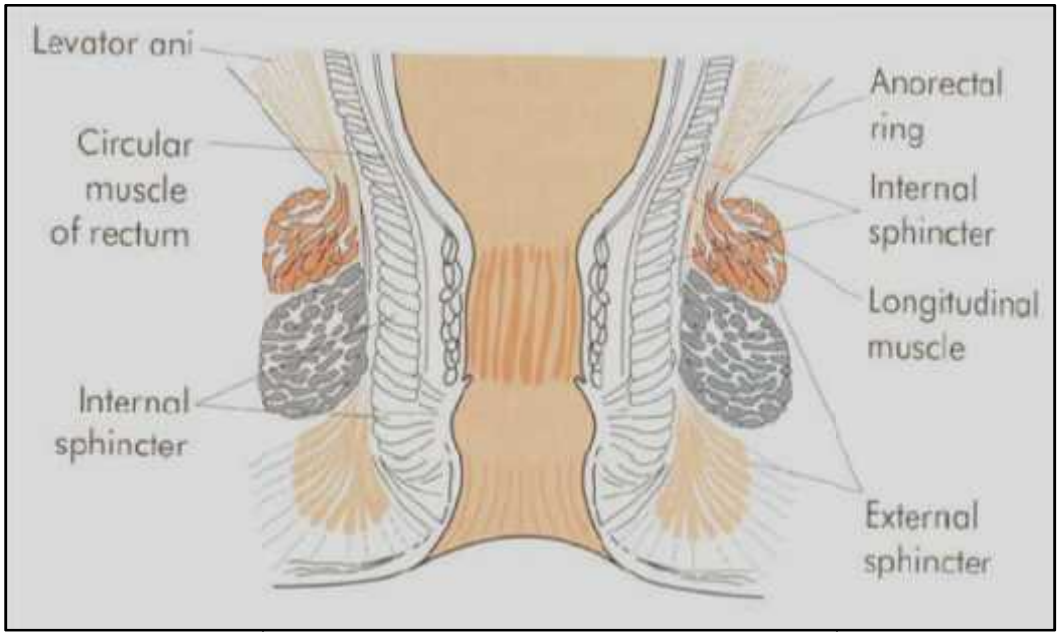


Fig1: Musculature of the anal canal

RELATIONS OF ANAL CANAL

In both sexes the anal canal is related anteriorly to the perineal body. Perineal body in males separates anal canal from membranous urethra and penile bulb, and separates it from lower vagina in females. Posteriorly the anal canal is related to the tip of the coccyx and anococcygeal ligament and laterally to loose adipose tissue of ischiorectal fossa.

INTERIOR OF THE ANAL CANAL

Divided into 3 parts

1. Upper part – about 15 mm long

2. Middle part – about 15 mm long

3. Lower part – about 8 mm long.

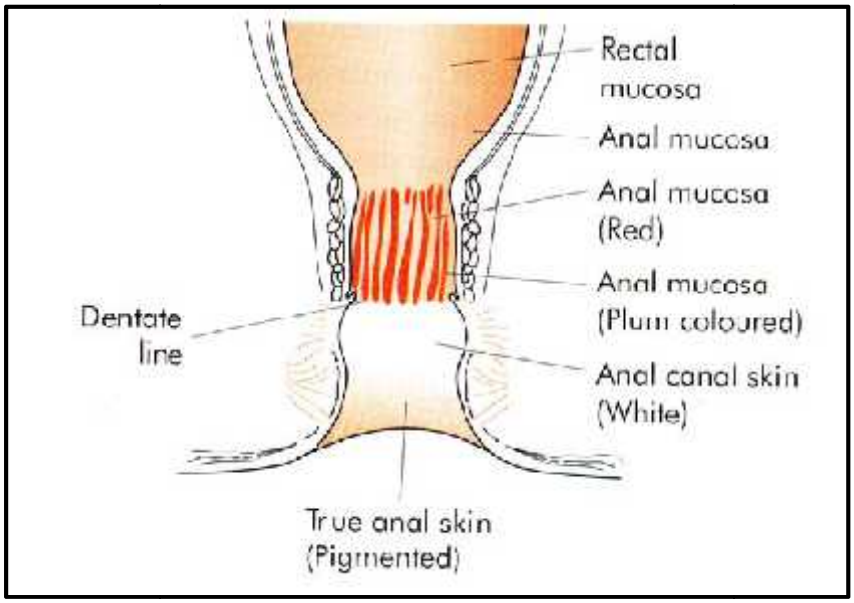


Fig 2: Lining membrane of anal canal

Upper part – 15 mm long (Mucous)

The upper part is lined by columnar epithelium similar to the rectum. It contains secretory and absorptive cells with numerous tubular glands or crypts. The subepithelial tissues are mobile and relatively distensible and possess profuse submucosal arterial and venous plexus. Terminal branches of superior rectal vessels pass downwards towards anal columns. The submucosal veins drain into submucosal rectal venous plexus and also through fibres of upper internal anal sphincter into a inter muscular venous plexus.

There are 6-10 vertical folds in the mucosa called the anal columns[16]. Each column contains a terminal radical of superior rectal artery and vein. The vessels are largest in left lateral, right posterior, right anterior quadrants of wall of anal canal, where subepithelial tissues expand into three anal cushions.[16] The lower end of columns form small cresenteric folds called anal valves, between which lie small recesses referred as anal sinuses. The anal valves and sinuses together form the dentate or (pectinate) line. About six anal glands open into small depressions in anal valves called anal crypts.

Middle part (15 mm long) (Pecten)

The middle part is a transitional zone, also lined by bluish appearing mucosa because of a dense venous plexus that lie between it and muscle coat. It is nonkeratinized stratified squamous epithelium lacking sweat/sebaceous glands, hair follicles but contains numerous somatic nerve endings extending down to inter sphincteric groove[16] which is the lower limit of pectin. It often has a whitish appearance referred to as the whiteline (of Hilton).

Lower part (cutaneous)

The lower part is lined by hair bearing, keratinsing squamous epithelium continuous with perianal skin

Muscles of anal canal

The anal canal is encircled by internal and external anal sphincters separated by the longitudinal layer and has connection superiorly to puborectalis and transverse perinea muscles.[16]

Internal anal sphincter

The internal anal sphincter is a well-defined ring of obliquely oriented smooth muscle fibres continuous with circular muscles of the rectum, terminating at the junction of superficial and subcutaneous component of external sphincter, Thickness of internal sphincter varies between 1.5 to 3.5 mm. The lower portion of sphincter is crossed by fibres from conjoint longitudinal coat which passes into submucosa of the lower canal.

Vascular supply

The vascular supply of internal sphincter is from the terminal branches of superior rectal vessels and branches of inferior rectal vessels.

Innervation

The internal sphincter has both sympathetic and parasympathetic innervation. The sympathetic innervation originate in the lower two lumbar segments via inferior hypogastric plexus. The parasympathetic innervation originates in second to fourth sacral segments via inferior hypogastric plexus.

External anal sphincter

The external anal sphincter is a elliptical cylinder of skeletal muscle surrounding the anal canal originally described as 3 divisions which was proved invalid by Goligher[9], He demonstrated that a sheet of muscle runs continuously upwards with the puborectalis and levatorani. The lowest portion occupies a position below and slightly lateral to internal sphincter, a palpable groove at this level has been referred to as inter sphincteric groove.[9]

The lowest part is traversed by the conjoint longitudinal muscle. The intermediate portion is attached to coccyx by posterior extension of muscle fibres forming the anococcygeal ligament. The deep portion of external sphincter is devoid of posterior attachment and proximally becomes continuous with puborectalis muscle. Anteriorly the high fibres of external sphincter is attached to perineal body.[9]

Vascular supply

Terminal branches of inferior rectal vessels with contribution from median sacral artery.

Innervation

Inferior rectal nerve, a branch of pudendal nerve originating, in anterior division of second to fourth sacral nerve roots.

Conjoint longitudinal muscle

At the level of anorectal ring the longitudinal muscle coat of rectum is joined by fibres of levator ani and puborectalis, The conjoint muscle thus formed descends between internal and external anal sphincter. Many of these fibres traverse the lower portion of external sphincter to gain insertion into perianal skin referred as corrugator cutis ani[9]- some fibres of conjoint longitudinal muscle may form a longitudinal layer of muscle on the inner aspect of internal sphincter named it as muscularis sub mucosa ani. Some fibres that traverse the internal sphincter and become inserted just below anal valves and returned as mucosal suspensory ligament. It has been suggested that the role of conjoint longitudinal muscle is to affix the anal canal and avert the anus during defecation.

Anorectal ring

This is a muscular ring present at the anorectal junction, formed by fusion of puborectalis muscle, deep external sphincter and internal sphincter, less marked anteriorly where fibres of the puborectalis are absent.[9]

Surgical spaces related to anal canal.[18]

- Ischiorectal space on each side of anal canal.
- Perianal space surrounds the anal canal below the white line and contains superficial part of external sphincter. External rectal venous plexus, terminal branches of inferior rectal vessels and nerves.
- Submucous space of the canal lies above the white line between mucous membrane and internal sphincter.It contains internal rectal venous plexus and lymphatics.

Arterial supply of anal canal

The arterial supply of anal canal above pectinate line is by the superior and middle rectal arteries. The arterial supply below pectinate line is by the inferior rectal artery.

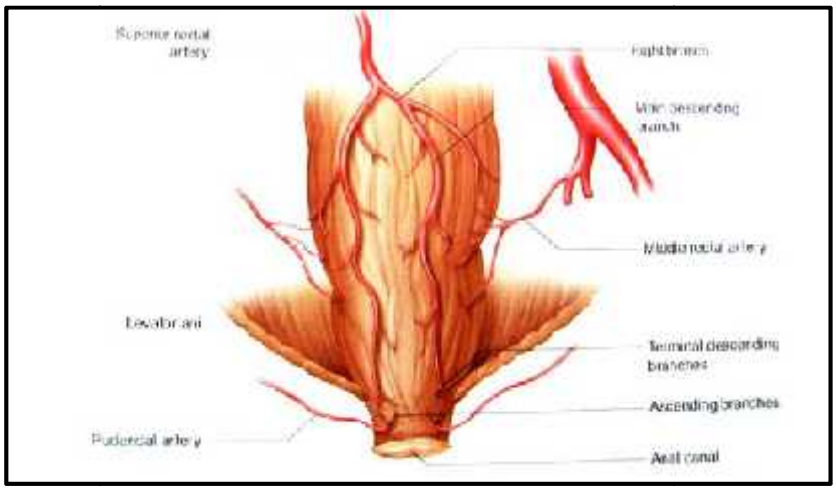


Fig 3: Arterial supply of anal canal

Venous drainage of anal canal

The venous drainage of the upper anal canal mucosa, internal anal sphincter and conjoint longitudinal coat passes via terminal branches of the superior rectal veins into the inferior mesentric vein to portal system. The lower anal canal and external sphincter drain via inferior rectal branch of pudendal vein into internal iliac vein[16].

Internal rectal venous plexus (haemorrhoidal plexus)

The haemorrhoidal plexus lie in submucosa of anal canal and drains mainly in superior rectal vein but communicates freely with external plexus and thus with middle and inferior rectal veins. Hence the internal plexus is a important site for porto-systemic anastomosis. Veins present in three anal columns at 3, 7, 11^{0} clock positions are large and they constitute potential sites for primary internal piles.

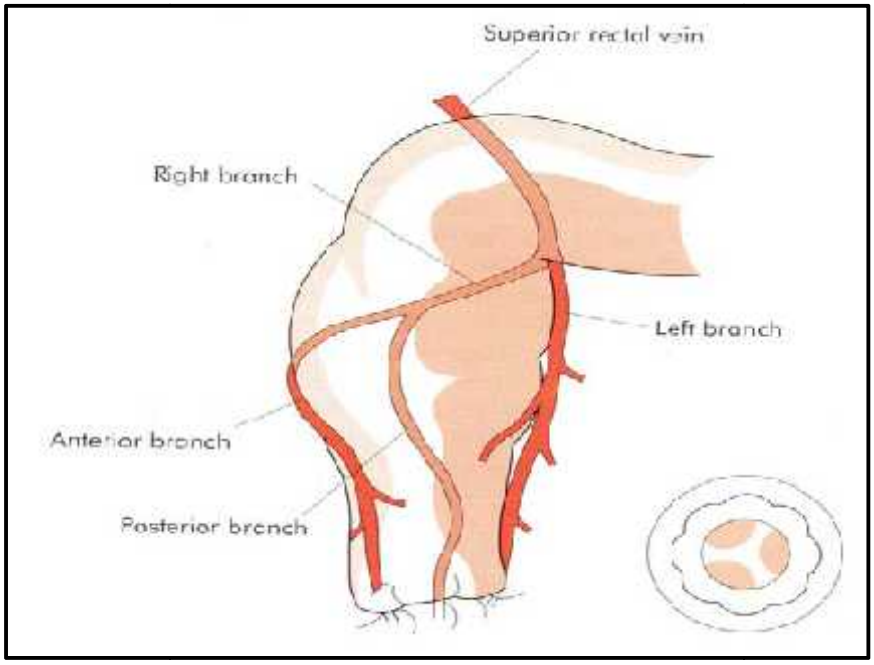


Fig. 4: Disposition of anal venous vasculature

External rectal venous plexus

The external rectal venous plexus lie outside the muscular coat of rectum and anal canal, communicating freely with internal plexus, the lower part of external plexus is drained by inferior rectal vein into internal pudendal vein, the middle part by middle rectal vein into internal iliac vein, upper part by superior rectal vein which continues as inferior mesentric vein a tributary of the portal vein[18]

Anal veins

The anal veins are arranged radially around the anal margin. They communicate with internal rectal plexus and inferior rectal veins.[18]

Lymphatic drainage of anal canal

Lymphatics from the upper anal mucosa, internal anal sphincter and conjoint longitudinal coat drain upwards into the submucosa and intramural lymphatics of the rectum. The lower anal canal epithelium and external anal sphincter lymphatics drain downwards via perianal plexus into vessels, which drain into external inguinal lymph nodes. The lymphatics of Puborectalis muscle drain into internal iliac lymph nodes[16].

NERVE SUPPLY OF ANAL CANAL

The sympathetic nerve supply of anal canal above the pectinate line is from the inferior hypogastric plexus ($L_{1, 2}$), and the parasympathetic nerve supply is from pelvic splanchnic nerves ($S_{2,3,4}$) (Pain sensations carried by both)[11].The somatic nerve supplybelow the pectinate line is from Inferior rectal ($S_{2,3,4}$) nerves[18].

PHYSIOLOGY

The function of the anorectal region is not only to act as a reservoir for faeces but also to facilitate effortless, unimpeded voiding during defecation. The physiology of anorectal region is very complex, better understood by systematic and fundamental study utilizing anorectalmanometry, defecography, continence tests, electromyography of the anal sphincters and pelvic floor, nerve stimulation tests. Combining proctography, with simultaneous pressure recordings and electromyography permits these investigations to present a more dynamic and physiological account of the state of anorectal region[9]

Anal continence

Maintaining anal continence is a complex matter because it is controlled by local reflex mechanisms as well as conscious will. Normal continence depends on highly integrated series of complicated events

Mechanisms of continence

Stool volume and consistency

Stool weights and volume; vary from individual to individual and from time to time in the same individual, from one geographic region to another. The frequency of passing stools may play some role, as colonic transit time is rapid when large bowel content is liquid because left colon doesn't store fluid well. Ability to maintain normal control may depend on whether rectal contents are solid, liquid or gas. This fact is important as just changing the consistency may be enough to regain control[9]

Reservoir function of rectum

The distal part of large intestine has a reservoir function that is important for continence. The lateral angulations of sigmoid colon and the valves of Houston provide a mechanical barrier and retard progressions of stools.[9] The adaptive compliance of rectum along with rectal capacity and dispensability also contribute to differences in pressure patterns between distal and proximal levels of anal canal resulting in development of force vector in the direction of rectum. This continuous differential activity may be important in controlling the retention of small amounts of liquid matter and flatus in rectum. Angulation between the rectum and anal canal due to continuous tonic activity of puborectalis muscle as well as high-pressure zone in anal canal contribute to the reservoir function.

Sphincteric factors

Activity of the anal sphincters is believed to be the most important factor for continence. They are responsible for the high-pressure zone (average 25-120 mmHg) in anal canal that appears to provide a barrier against high rectal pressure (average 5-20 mmHg). The high-pressure zones as demonstrated by pull through recordings have an average length of 3.5 cm and results from continuous tonic activity of both sphincters[9].

Internal sphincter

The internal sphincter contributes majorly to the high-pressure zone and is estimated to account for 55-85% of pressure recorded. Lestar et al concluded that when a 0.3 cm diameter probe was used 30% of maximum anal basal pressure is made up by striated sphincteric tone activity, 45% due to nerve induced internal sphincteric

activity, 10% due to purely myogenic internal sphincter activity and 15% due to expansion of haemorrhoidal plexus.[9]However when external sphincter is paralyzed the pressure is not significantly changed so resting pressure would seem to be largely due to internal sphincter.

External sphincter

Continuous tonic activity at rest and even during sleep has been recorded in pelvic floor muscles and in external sphincter. External sphincter is unique in this regard because other striated muscles are electrically silent at rest.

But basal tone of the externalsphincter shows considerable variation, it is increased in upright posture, also augmented by perianal stimulation (anal reflex) and increases in intra abdominal pressure like coughing, sneezing and Valsalva manoeuvre and rectal distension with initial small volumes of feaces. Permanent activity of external sphincter is modulated by second sacral spinal segment.

Sensory components

Extrinsic sensory receptors

The awareness of rectal distension as produced by feacal matter arrival is characterized by a distinct rectal sensation. Though stretch receptors are there in rectal wall itself there is evidence to suggest these receptors are located in puborectalis and pelvic floor muscles. Because the receptors for this proprioceptive reflex lie in pararectal tissues, this reflex remains intact even after resection of rectum.[9]

Intrinsic sensory receptors

A more precise perception of nature of rectal contents is achieved by receptors within the anal canal. Careful histologic studies have demonstrated free and organized nerve endings in epithelium of anal canal primarily in distal half of anal canal but may extend to 5-15 mm above dentate line

Neuropathway

Internal sphincter is supplied by a dual extrinsic innervation containing a motor supply from the sympathetic outflow via hypogastric nerve and an inhibitory supply from parasympathetic outflow. The sympathetic nerves have a direct effect on the internal sphincter muscle cells, which possess α and β adrenoreceptors, the α receptors mediate contractions, β receptors mediate relaxation. It is suggested that there is a dominant population of α- adrenoreceptors explaining the overall excitatory effect.[9]

Reflexes

The reflex response of external sphincter is represented by transient increase in activity initiated by postural changes, perianal scratch and increased intraabdominal pressure. The reflex response of internal sphincter consists of transient relaxation stimulated by rectal distension or Valsalva maneuver; this does not involve peristalisis because the sphincter relaxes before peristaltic wave reaches the sphincter. The transient relaxation of internal sphincter allows rectal contents to be sampled by sensory epithelium of anal canal. During this sampling, continence is maintained by synchronous contraction of external sphincter.

The inhibition induced by rectal distension was thought to be under parasympathetic control. However recent evidence suggests reflex is predominantly of intramural origin.[9]

Mechanical factors

Angulation between rectum and anal canal

The angulation between rectum and anal canal is the most important component for gross fecal continence due to continuous tonic activity of puborectalis muscle. As measured by defecography the angle between axis of anal canal and rectum in resting state is about 90 degree and radiographic studies have elucidated changes duringdefecation.[9]

Flutter valve

It has been suggested that additional protection of continence might be afforded by intra abdominal pressure being transmitted laterally to the side of the anal canal just at the level of the anorectal junction. The anal canal is an anteroposterior slit like aperture and any increased intra abdominal pressure tends to compress it in a fashion similar to a flutter valve[9].The flutter valve mechanism is controversial because the highest pressure is found in the middle part of the anal canal rather than in the upper part, and therefore intra abdominal forces should act at an infralevator level.

Flap valve theory

The flap valve theory was advanced by Parks et al and the theory proposed any increase in the intraabdominal pressure tends to accentuate the anorectal angle and forces the anterior rectal wall to lie firmly over upper end of anal canal producing a flap valve effect. For defecation to occur the flap valve must be broken,and this

breakage takes place by lengthening of the puborectalis muscle, lowering pelvic floor and obliterating the angle.[9]

Corpus cavernosum of anus

Stelzner postulated that the vascular architecture in submucosal and subcutaneous tissues of anal canal really represent what he called corpus cavernosum of rectum. This cushion consists of masses of blood vessels, smooth muscle fibres, and elastic connective tissue with constant configurative of left lateral, right anterolateral, right posterolateral segments. These cushions have a physiological ability to expand and contract taking up slack contributing to finest degree of continence. This is supported by the fact that some patients after haemorrhoidectomy have minor alteration in continence.[9]

AETIOLOGY AND PATHOPHYSIOLOGY

Several theories have been postulated regarding the cause of haemorrhoids, however the precise etiology still remains elusive.[11]Frequency of haemorrhoids in general population according to Buie (1960) is 52% in a large series of unselected patients at the Mayo clinic.[10]

Age Incidence

The age distribution of haemorrhoids demonstrated a hyperbolic pattern with a peak between age 45 to 65 years and a subsequent decline after the age of 65 years.[9]The presence of haemorrhoids in patients less than 20 years was unusual.

Sex Incidence

Taking both symptomatic and asymptomatic haemorrhoids into concern the prevalence of haemorrhoids is marginally more in male[19].

Socio-economic status and diet

Haemorrhoids are particularly rare in communities which have departed least from their traditional manner of life but more in economically developed communities[20]. There is a close relationship with western type of diet, which is more refined and low in fibre which increases bowel transit time and resulting in formation of hard stools.

Occupation

People whose occupation required prolonged sitting or standing are more prone for haemorrhoids. Washaw LJ and Turell noted a number of patients in whom occupation strain or stress played a important role in precipitating prolapse of existing internalhaemorrhoids.[20]

Varicose vein theory

The varicose vein theory stemmed from assumptions that dilatations of veins of internal rectal plexus result from pathological change. This has been shown as invalid by confirming the dilatations are in fact normal.[9]The fact that haemorrhoids are no more common in patients with portal hypertension than in population at large is additional evidence against this theory. This theory also fails to account for the fact that haemorrhoids frequently occur singly and more common in right anterior position.

Vascular hyperplasia theory

The vascular hyperplasia theory proposes that the principal cause of haemorrhoids seem to be congestion and hypertrophy of internal anal cushions as they fail to empty during defecation, the theory they are abnormally mobile and trapped by tight anal sphincter, is also obsolete. The histologic studies by Thomson showed no vascular hyperplasia.[9]

Sliding downwards of anal cushions theory

Sliding downwards of anal cushions is the latest proposed theory. The association of haemorrhoids with straining and with irregular bowel habits is compatible with this theory. Repeated stretching of submucosal muscle of Treitz causes disruption and results in prolapse. The studies of Haas, Fox, and Haas[21]and Bernstein[19]support this theory. These authors found that the anchoring and supporting connective tissue in haemorrhoids is integrated and fragmented.

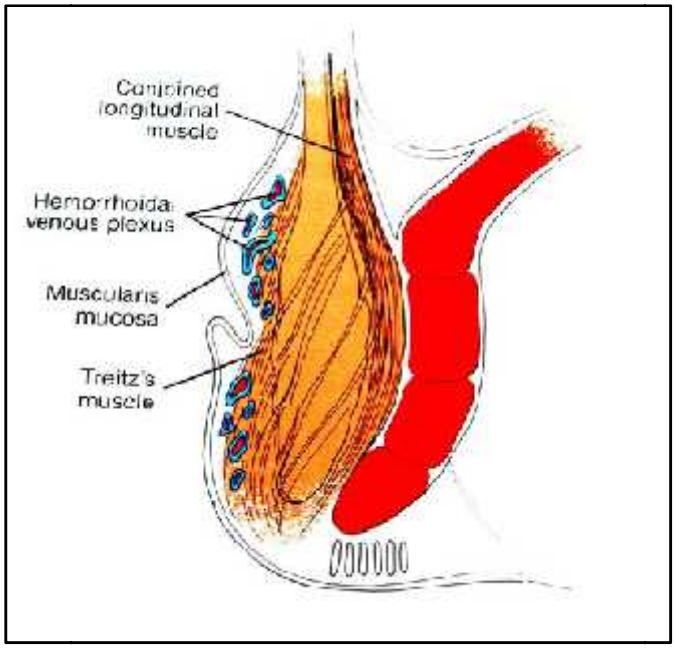


Fig. 5: Anatomy of anal cushion

Internal anal dysfunction theory

Dysrythmia within the internal sphincter[22]and higher anal resting pressures have been demonstrated in patients with haemorrhoids.[9] Hancock believed that an internal sphincter abnormality may be a causative factor. Roe et al found a reduction in anal pressure after haemorrhoidectomy and believed it might be possible that haemorrhoidal tissue itself is responsible for rise in pressure. Sun, Read and Shorthouse suggested that abnormally high pressures in anal canal in patients with haemorrhoids may be due to increased vascular pressures in the anal cushions

Predisposing and associated factors

Many factors has been implicated in the causation of haemorrhoidal disease like chronic constipation,[9]Heredity, erect posture, absence of valves in haemorrhoidal plexus and draining veins, obstruction of venous return from raised intraabdominal pressure. Portal hypertension may lead to venous engorgement in haemorrhoidal plexus and on rare occasions result in true varices[9]. Pregnancy undoubtedly aggravates preexisting disease, and it usually becomes asymptomatic after delivery suggesting hormonal changes in addition to direct pressure effects. Paradoxically diarrheal states also predispose to development of haemorrhoids, patients with inflammatory bowel disease may in fact present with true haemorrhoidal symptoms.

CLASSIFICATION OF HAEMORRHOIDS

Internal haemorrhoids

Internal haemorrhoids are symptomatic, exaggerated, submucosal vascular tissue located above the dentate line and covered by transitional and columnar epithelium. They can be divided into 4 categories.

1) First-degree internal haemorrhoids

They bulge into the lumen of anal canal and produce painless bleeding.[9]

2) Second-degree internal haemorrhoids

They protrude at the time of bowel movement and reduce spontaneously

3) Third degree internal haemorrhoids

They are those that protrude spontaneously or at time of bowel movements and require manual reduction.

4) Fourth degree internal haemorrhoids

They are those that are permanently prolapsed and irreducible despite attempts at manual reduction

External haemorrhoids

External haemorrhoids comprise the dilated vascular plexus that is located below the dentate line and covered by squamous epithelium, multiple skin tags usually accompany.

Interno-Externo (mixed) haemorrhoids

Are those with elements of internal and external haemorrhoids.

PATHOLOGY

Histologically, haemorrhoids consist of dilated veins in the mucosa and submucosa. There may be evidence of hemosiderin deposition from a previous episode of bleeding[23]depending on whether the haemorrhoids arise above or below the dentate line.They may be covered by columnar, transitional or non-keratinzing squamous epithelium. The organization and re-canalization of thrombi can lead to florid papillary endothelial hyperplasia.[24]

Microscopic examination of tissue submitted with clinical diagnosis of haemorrhoids, rarely may show non-specific granulomas, tuberculosis, malignant lymphomas, koilocytotic changes, dysplasia/carcinoma in situ, invasive squamous cellcarcinoma or even malignant melanoma.[24]

CLINICAL MANIFESTATIONS

Bleeding

As the name haemorrhoids, implies bleeding.It is the principal and earliest symptom[2].At first it is slight and bright red and occurs during defecation as splash in the pan and may continue intermittently for months to years, Bleeding usually occurs at the end of defecation and rarely may also be occult as guiac positive stools.

Prolapse

Prolapse is a much later symptom; To start with protrusion is slight and occurs only at stool and reduces spontaneously. As time progresses it does not reduce spontaneously but has to be replaced digitally. Still later prolapse occurs during day, often during exertion and may go on to become permanently prolapsed.

Discharge

A mucoid discharge is a frequent accompaniment of prolapsed haemorrhoids. It is composed of mucous from engorged mucous membrane sometimes augmented by leakage of ingested liquid paraffin.[2] Pruritis almost certainly follows the discharge with excoriation of perianal skin with accompanying discomfort.[9]

Pain and anemia

Pain per se is not a symptom of uncomplicated haemorrhoids. It may indicate associated disease such as anal fissure, perianal abscess, or inter sphincteric abscess. Anemia can be caused by bleeding haemorrhoids very rarely, so this can be called as a complication rather than symptom

DIFFERENTIAL DIAGNOSIS

Rectal mucosal prolapsed

Rectal mucosal prolapse is frequently confused with prolapsing haemorrhoids. Patients with this condition present with prolapse of rectal mucosa below dentate line.[9]Bleeding may occur from trauma to this displaced vascular mucosa. Precipitating factors are the same as haemorrhoids, especially chronic straining at stools; however in many cases haemorrhoids cushions are small. It may progress to complete mucosal prolapse. Causes include Anal sphincteric dysfunction (primarily due to trauma especially surgical like internalsphincterotomy, or lords dilatation).

Hypertrophied anal papillae usually due to underlying anal fissure occasionally papillae may enlarge to huge proportions to form fibrous anal polyp (but are not true colorectal polyps). Rectal polyps[11], melanoma, carcinoma, rectal prolapse,

fissure, inter sphincteric abscess and perianal endometroma should be excluded while diagnosis.

Clinical Examination

Should be aimed at several aspects

- General patient assessment to ascertain general health status and in particular to exclude associated disease[9]. Notably bleeding disorders, liver disease with portal hypertension, Neoplastic growth in abdomen and pelvis, hepatosplenomegaly, presence of free fluid in the peritoneal cavity should be assessed. Other cardiovascular or respiratory disease those are responsible for causation of haemorrhoids should be ruled out.
- Rectal examination

Position

Left lateral (Sim's position): This is the most popular position for anorectal examination with patient lying on left side buttocks projecting over the edge of the table with hips and knees well flexed.[25]

Inspection

Anal tags and fourth degree haemorrhoids are usually visible. Third degree haemorrhoids become visible on making the patient strain as in passing stools. Thrombosed and strangulated external haemorrhoids can never be missed on local examination.[25]

Digital examination

This should be done gently explaining to the patientwhat is being done, with clear instructions to the patient to open his mouth and breathe in and out deeply. After wearing gloves and applying local anaesthetic jelly the right Index finger is laid flat on anal verge, gentle pressure is exerted till sphincter yields and finger in slowly pushed in by rotatory movement.[25]

Uncomplicated piles are not usually felt unless thrombosed or fibrosed or sometime may be felt as a longitudinal fold when finger is swept around lower rectum.

Proctoscopy

It is crucial for diagnosis of haemorrhoids. The proctoscope is well lubricated and gently inserted in the rectum. It is first introduced in the direction of umbilicus till anal canal is passed and later directed posteriorly to enter the rectum.[25]Now the obturator is withdrawn and interior examined with light. The haemorrhoids will protrude into the proctoscope as the instrument is being withdrawn. Note the position of haemorrhoids imagining a watch held against the anus when the patient is in lithotomy position will correspond to 3, 7 and 11^0 clock positions

Sigmoidoscopy, colonoscopy, and barium enema

These investigations may not be possible in all cases but in cases suspicious of sigmoid/rectal neoplasms, polyps, patients may have to go through these investigations mandatorily.[25]

Complications of haemorrhoids

Haemorrhage

Profuse haemorrhage is not rare, most often it occurs in early stages of second degree haemorrhoids; Bleeding mainly occurs externally but it may continue internally after haemorrhoids has retracted, in which case rectum is found to contain blood. Occasionally it can lead to severe anemia.[2]

Strangulation

One or more of the internal haemorrhoids prolapse and become gripped by the external sphincter. Further, congestion follows because the venous return is impended. Second-degree haemorrhoids are most often complicated in this manner and accompanied by considerable pain. Unless the internal haemorrhoids can be reduced within 1 or 2 hours strangulation is followed by thrombosis.[2]

Thrombosis

The affected haemorrhoid or haemorrhoids become dark purple and black and feel solid. Considerable oedemas of anal margins accompany thrombosis. Once thrombosis has occurred the pain of strangulation largely passes off but tenderness persists.

Ulceration

Superficial ulceration of exposed mucous membrane often accompanies strangulation with thrombosis.

Gangrene

Gangrene occurs when strangulation is sufficiently tight to constrict arterial supply to haemorrhoid. The resulting sloughing is usually superficial and localized. Occasionally a whole haemorrhoid sloughs off leaving a slow healing ulcer.

Very occasionally massive gangrene extends to mucous membrane within anal canal and rectum and can cause spreading anaerobic infection and portal pyemia.

Fibrosis

After thrombosis, internal haemorrhoids sometime become converted into fibrous tissue, which is earlier sessile but repeated traction during defecation causes it to pedunculate to constitute a fibrous polyp.[2] Fibrosis commonly occurs in subcutaneous part of primary haemorrhoid. Fibrosis of an external haemorrhoid favours prolapse of an associated internal haemorrhoid

Suppuration

Suppuration is uncommon, occurs due to infection of thrombosed haemorrhoid. Throbbing pain followed by perianal swelling and a perianal or submucous abscess results.[2]

Pyelephlebitis(Syn. Portal pyemia)

Portal pyemia is surprisingly infrequent, theoretically infected haemorrhoids should be a potent cause of portal pyemia.[2] It can occur when strangulated haemorrhoids are taken for surgery and has even been reported following banding.

INVESTIGATIONS

Blood examination

To rule out anemia haemoglobin percent is done; If anemia is found it is usually microcytic hypochromic. Total and differential counts should be noted and ESR should be done. Fasting blood sugar, postprandial blood sugar, blood urea, serum creatinine should be done.

Urine examination

To rule out infection or diabetes, sugar, microscopy of urine should be done.

Stool examination

To rule out occult blood in anemic cases.

Chest x-ray

To rule out causes of chronic cough like chronic bronchitis, pulmonary tuberculosis this may secondarily cause haemorrhoids.

ECG

To rule out cardiovascular diseases

MANAGEMENT OF HAEMORRHOIDS

Medical treatment or non-operative management

Conservative management of haemorrhoids can be accomplished in majority of patients. These vary from advice with respect to

- Defecation habits
- Local hygiene
- Dietary manipulations
- Topical applications

Defecation habits[11]

Neglecting the first urge to defecate, Spending a prolonged time at the toilet, Straining are common defecation errors, which must be corrected.[11]

Local hygiene

Haemorrhoids particularly 3rd and 4th degrees are associated with mucous staining and itching. These symptoms require advice about anal hygiene to prevent perianal dermatitis and to ameliorate symptoms. The use of sitz bath and warm soaks also ameliorate symptomatic haemorrhoids.[11]

Dietary manipulations

The rationale of adding bulk to diet is to eliminate straining at defecation. Burkilt and Graham – Stewart[9] observed that stools lacking in adequate fibre are small, hard and difficult to evacuate requiring prolonged straining. Consumption of plenty of fruits and vegetables, consuming raw unprocessed wheat or oat barn (1/3 cup per day), psyllium seed (2 teaspoons per day) and an adequate volume of fluids must be consumed each day.

Topical applications

A large variety of topical agents as creams, lotions, suppositories and local anaesthetics have been employed with the purpose of improving haemorrhoidal symptoms. Anecdotal evidence suggests symptomatic relief has been achieved by topical medications. Topical nitric oxide has been reported as alternative for managing strangulated internal haemorrhoids by decreasing internal anal sphincter tone.[11]Patients undergoing medical management should be reviewed frequently for

upto 1 year to be sure that their symptoms are improving and bleeding has decreased. If complaints still persist or increase other treatment modalities should be considered

SURGICAL PROCEDURES

Anal stretch (Lords anal dilatation)

In 1968 Lord reported treating haemorrhoids by manual dilatation of the anus. Anal dilatation is based on the belief that haemorrhoids constitute a reversible conditioncaused by narrowing of lower anal canal by a fibrous deposit that Lord called "Pecten Band".[9]The procedure is performed for third degree haemorrhoids under Intravenous sedation or general anaesthesia. It is usually necessary to stretch the anal canal and lower rectum until four fingers of each hand are inserted. Anal dilator is provided for next 6 months to prevent recurrent anal stenosis. Lord claimed that pain and complications were low.[9]

But significant complications like anal incontinence may be for flatus, faeces, which occurs after 4-6 weeks. Also splitting of perianal skin, mucosal prolapse were noted.

Complications

- Bleeding and bruising
- Splitting of skin usually posterior quadrant – may lead to cellulitis.
- Mucosal prolapse
- Incontinence upto 10% - and has gained medico-legal importance

Lateral internal sphincterotomy

Lateral internal sphincterotomy is used widely for the management of patients with anal fissures, where the underlying problem is thought to be hyperfunction of internal sphincter. Some authors claim similar dysfunction accounts for haemorrhoids too. Partial Internal sphincterotomy unlike anal dilatation has the advantage of division of sphincter under direct vision it is done under local, regional or general anaesthesia. Incontinence of varying degrees occur in 25% patients and is usually minor, however prolapse of redundant mucosa is common. This procedure has no effect on external haemorrhoids and skin tags. Postoperative care is simple and is aimed at providing patient comfort and ensuring early bowel movement.

Although relatively simple, this technique should not be used as a sole treatment for haemorrhoids and may be recommended if the patient has concomitant fissure.[11]

Complications

- Prolapse
- Perianal haematoma

HAEMORRHOIDECTOMY

Indications

- Third degree haemorrhoids.[2]
- Fourth degree haemorrhoids[27]
- Second-degree haemorrhoids which have not been cured by non-operative treatment.[2]
- Fibrosedhaemorrhoids

- Interno external haemorrhoids when external haemorrhoid is well defined.
- Haemorrhoids complicated by ulceration, fissure, fistula, large hypertrophied anal papilla and extensive skin tags[9]

Types

- Closed haemorrhoidectomy
- Open haemorrhoidectomy
- Submucoushaemorrhoidectomy
- Laser haemorrhoidectomy

Closed haemorrhoidectomy

In 1931 Fansler[9] described a technique where intra anal anatomic dissection was conducted which was later developed and modified by Ferguson and Heaton in 1959.

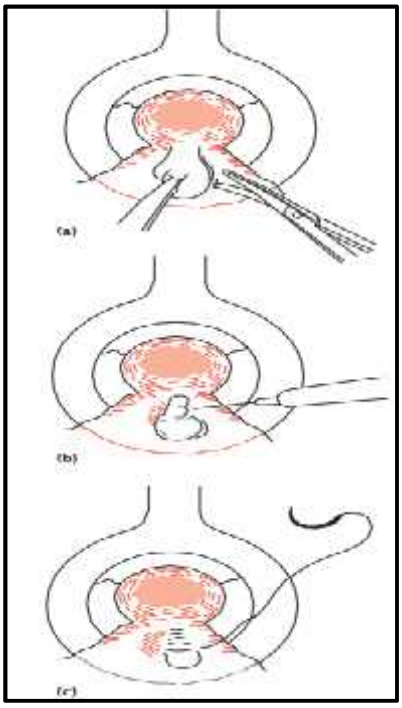


Fig. 6: Closed technique of haemorrhoidectemomy

a) The haemorrhoidal tissue is excised. b) Bleeding is controlled by diathermy. c)The defect is closed with a continuous suture after first undermining the anoderm on each side

Technique

A packaged sodium biphosphate enema is given 1 to 2 hours before the procedure. Under General, spinal anaesthesia the patient is put in Jacknife position with cheeks of buttocks taped apart. A suitable retractor as Hill Ferguson type is used. With scissors an elliptical excision is started at the perianal skin to include external and internal haemorrhoids and is ended at the anorectal ring. The mucosa and submucosa are dissected from the underlying internal sphincter with care taken not to injure the muscle. The pedicle is transfixed and ligated with 3/0 vicryl or Dexon[2].

The entire wound isclosed with running 3/o chromic catgut. The strip of excision should not be more than1 – 1.5 cm so that closure is without tension[9]. If too much tissue is excised wound should be marsupial zed and left open. The largest and most redundant haemorrhoid should be excised first. With this approach the original plans to excise three quadrants may be modified so that only two-quadrant haemorrhoidectomy is necessary.

Open haemorrhoidectomy

Open haemorrhoidectomy is most commonly used in UK known as Milligan – Morgan operation named after surgeons who described it.

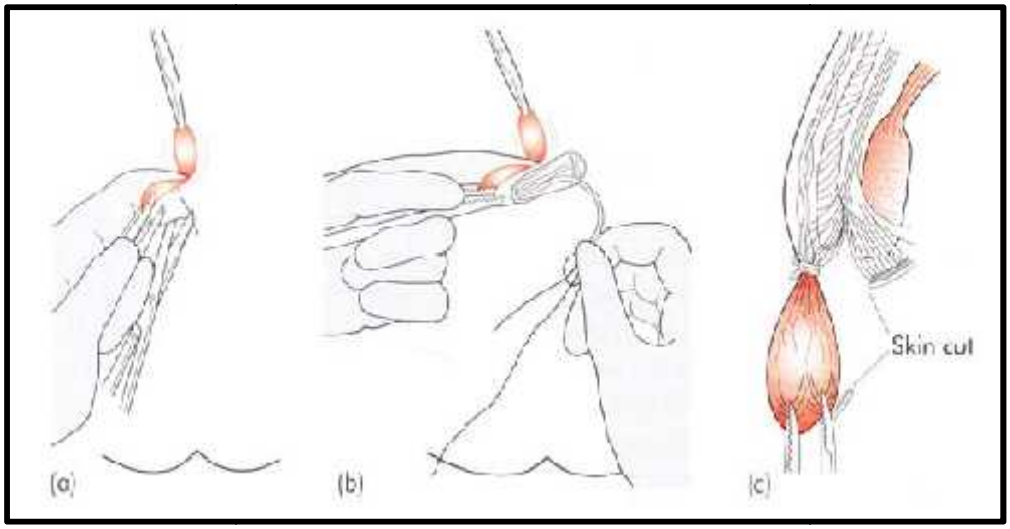


Fig. 7: Ligation and excision of haemorrhoids – By open technique

(a) The skin is cut to the left lateral haemorrhoid; (b) Transfixation of the pedicle; (c) ligation

Technique

Under general or spinal anaesthesia the patient is put in lithotomy position, Anal sphincter is gently stretched and the internal haemorrhoids are then prolapsed by traction on skin tags or skin of anal margin. Each haemorrhoid is picked up with dissecting forceps and traction exerted. Traction displays a longitudinal fold (pedicle) above haemorrhoid, which is grasped with hemostat. The external haemorrhoid or skin tag connected to internal haemorrhoid is also held with hemostat. These pair of hemostats when held out by assistants forms a triangle. The operator takes the left lateral pair of hemostats in his palm and places the extended fore finger in anal canal to support internal haemorrhoid.[9]

In this way traction is applied to anal margin, and with scissors a V shaped cut is made on either side of the skin holding hemostat, the cut traversing the skin and corrugator cutis ani. Exerting further traction and little blunt dissection exposes lower

border of internal sphincter. A transfixing ligature of Vicryl is applied to pedicle at this level. Each haemorrhoid is dealt in this manner and is excised 1.25 cm above knot. The stumps of ligated haemorrhoids are returned into rectum by tucking with a piece ofgauze.

The margins of skin wounds are trimmed so as not to leave overhanging edges. Bleeding subcutaneous arteries are secured, at the corners the three pieces of petroleum jelly gauze are tucked into the anus so as to cover the area denuded of skin.[2]

Complications

1. Pain – 71%

2. Acute retention of urine – 16.4%

3. Reactionary or secondary haemorrhage – 7.6%,

Those requiring re-operation – 1%

4. Other rare complications include:

•Anal stenosis – 2.9%

•Anal fissure – 0.5%

•Abscess – 0.6%

•Fistula in ano – 1.2%

•Long-term incontinence

Other complications include skin tags, pseudopolyps and epidermal cysts. Anal leakage and soiling is common (50%) during early postoperative period but settles in 6-8 weeks. Causes of the above include anal dilatation, loss of sensation and transient reduction in anal canal pressures. Return of anal canal pressure to normal has been described.

Submucous Haemorrhoidectomy

The operation is carried out in lithotomy position with a special self-retaining retractor. The sub mucous plane is infiltrated with saline and adrenaline, which controls bleeding and helps dissection. A vertical incision is made through the mucosa from top ofthe anal canal to the anal margin where any skin tag or external haemorrhoidal component is removed. The mucosal flaps are lifted on both sides so that the haemorrhoid is completely exposed. It is then dissected away from the internal sphincter muscle.

The pedicle is transfixed; ligated and excised .The mucosal flaps are allowed to pull back in place and are approximated with several interrupted catgut sutures. Prolapseof mucosa must be prevented by including part of the internal sphincter muscle in the suture.

Though this technique has advantages such as a less postoperative pain and less chances of postoperative anal stenosis, drawbacks like longer time to perform the surgery, considerable haemorrhage, and higher recurrence rate has withheld its wider adoption.

Postoperative care

Dressings are changed after 24 hours. Patient is advised washing the area and new dressings are applied after each bowel evacuation. Laxative in the dose of 15 ml, 8th hourly is started the next day of surgery and if there is no bowel movement by 3rd postoperative day, sodium hydrogen phosphate enema is given. On 5th postoperative day a digital per rectal examination is done to see the progress of healing. Patient can be discharged on 6th post operative day but healing may prolong till 6 weeks. Patients are advised on discharge to take high fibre diet, plenty of oral fluids, laxatives and sitz bath daily. Patients are advised to return for review after three weeks.[2]

On review digital per rectal examination is done to check for stenosis.[2]Proctoscopy is not advised as it may injure the healing wounds and precipitate development of acute fissure.

Haemorrhoidectomy complications

May be early or late:

Early complications of haemorrhoidectomy

Pain

Pain may demand analgesics, xylocaine jelly repeatedly.[2]

Retention of urine

Retention of urine is not unusual, frequently precipitated due to presence of rectal tube or pack. Before restoring to catheterization the patient should be reassured and given an analgesic, allowed to stand in privacy at side of bed or be assisted with hot bath to help him voluntarily pass urine.

Reactionary hemorrhage

Reactionary hemorrhage is more common than secondary haemorrhage. It may be mainly or entirely concealed. Treatment include suitable analgesics for pain relief and bleeding points secured with diathermy or under running with ligature on a needle. If no bleeding point is found suspected areas are underrun with sutures and rectum and anal canal packed.

Secondary hemorrhage

Secondary hemorrhage is uncommon, occurs around 7th-8th day, and occurs due to sepsis in pedicles, It is usually controlled by morphine but if severe a catgut suture is used to occlude bleeding vessel.[2]

Late postoperative complications of haemorrhoidectomy

Anal stricture

Anal stricture is a rare complication and may need anal dilatation under general anaesthesia with daily use of anal dilators.

Anal Incontinence

Anal incontinence may occur rarely if there is injury to internal sphincter, which might have been inadvertently damaged. Incontinence is a serious problem and is very difficult to treat.

Anal fissure

Anal fissure is a rare complication, and occurs in posterior midline or anteriorly in connection with right anterior or right posterior haemorrhoidal wounds.

Anal fissure can be treated under general anaesthesia with lateral internal sphincterotomy or sphincter stretch.

Abscess or fistula

Abscess or fistula may rarely develop if the patient is left with narrow external wounds, and redundant skin edges may become adherent and lead to pocketing or purse resulting in abscess or fistula. They may require reshaping of the wound under general or local anaesthesia.

Stapled haemorrhoidopexy[11]

Most recently a modified circular stapler approach has been advocated for surgical management of haemorrhoids. The so-called procedure for prolapsed haemorrhoids (PPH) was described initially by Longo in1998.[15]

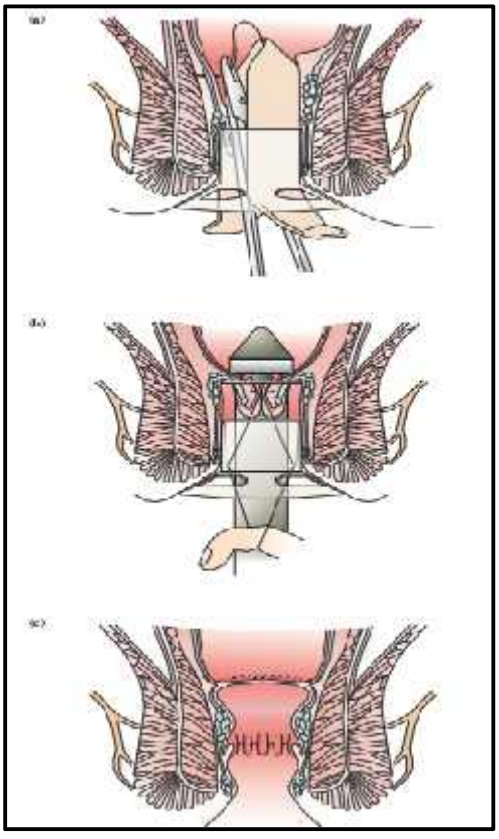


Fig 8: Staple haemorrhoidopexy

Rationale

It is based on the concept of interruption of the superior and middle haemorrhoidal vessels and upward lifting of the prolapsed anorectal mucosa and repositioning of thevascular cushions back into the anal canal which causes the haemorrhoidal tissue to atrophy.

Indications

It is mainly advocated for third and fourth degree internal haemorrhoids.

Technique

A modified 33 mm circular stapler is used to perform the stapled haemorrhoidopexy. This operation is facilitated by the use of the PPH procedural set consisting of a circular stapler (HCS 33), a suture threader (ST 100) a circular anal dilator (CAD 33), and a purse string suture anoscope (PSA 33). The technique of PPH involves placement of a purse string suture using non absorbable monofilament material approximately 2-4 cm cephalad to the dentate line.

The suture is placed into the mucosa and sub mucosa of the lower rectum avoiding the muscular layer and vagina. Care must be taken to place the purse string sufficiently high so that when fired it does not incorporate the anal mucosa and underlying internal sphincter. If this were to occur, severe pain might ensure, in addition to the risk of stricture and mucosal ectropion; these complications are avoided if purse string is placed at least 2 cm above the dentate line. The single greatest advantage of stapled haemorrhoidopexy is reduction in postoperative pain. The pain after PPH is described as Vague and dull and analogous to tenesmus. Michigan and coworkers prospectively randomized 40 patients to undergo PPH

haemorrhoidopexy versus Milligan Morgan haemorrhoidectomy. The average postoperative pain score from day zero to day ten was significantly lower in PPH and also patients had shorter hospital stay and a faster return to full activity. Postoperative complication rates have been similar with that of conventional haemorrhoidectomy. One downslide is the cost of the equipment. But undoubtedly this new technique is a exciting development in the search of a relatively painless procedure to treat haemorrhoidal disease.

Treatment of complications of haemorrhoids

Strangulation, thrombosis and gangrene

In cases of strangulation and thrombosis it was earlier believed that surgery would promote Pylephlebitis. If adequate antibiotic cover is given earlier Pylephlebitis does not occur and immediate surgery is justified. Besides adequate pain relief, bed rest with frequent hot baths and warm saline compress usually cause pile masses to shrink considerably in 3-4 days, when standard ligation and excision can be carried out. Some surgeons consider operation at this stage increases the risk of postoperative stenosis and delay surgery for a month or so. Inspite of low risk of pylephlebitis caution should dictate a non-interventional[2]policy whenever practical.

Severe haemorrhage

The cause of severe haemorrhage usually lies in a bleeding diathesis or use of a anticoagulant. Such cases need local compress containing adrenaline with an injection of morphine; blood is transfused if found necessary. Hemorrhage is to be controlled after which ligation and excision of piles may be required.[2]

Thrombosed external haemorrhoid

Commonly termed perianal haematoma, It is a small clot occurring in perianal subcutaneous connective tissue usually superficial to corrugator cutis ani muscle. This condition appears suddenly and is very painful. On examination a tense, tender swelling in lateral region of anal margin is noted. Untreated it may resolve, suppurate, fibrose,[2] or burst to extrude the clot or continue bleeding. In majority resolution or fibrosis occurs. Thrombosed haemorrhoids if noticed within first 36 hours is treated as an emergency, Under local anaesthesia the haemorrhoid is bisected and excised with 1.25 cm of adjacent skin. The pear shaped wound is left to granulate, the relief of pain is immediate and a permanent cure is certain.[2]

Special situations

Haemorrhoids in pregnancy

Haemorrhoidal symptoms commonly occur and intensify during pregnancy and in most instances they resolve after delivery. Haemorrhoidectomy is indicated in pregnancy only if acute prolapse and thrombosis occur. Haemorrhoidectomy is done under local anaesthesia in the second and third trimester with patient put in left antero-lateral[9]position.Prolapse and thromboses, which occur during delivery, is an indication for operation in immediate postpartum period.

Haemorrhoids in portal hypertension

The incidence of haemorrhoids in portal hypertension is no greater than normal population. Although massive bleeding is uncommon, it can be life threatening. Most commonly it occurs during treatment of encephalopathy with administration of non absorbable antibiotics and potassium supplements which cause

severe diarrhoea causing breakdown of anal canal lining. The bleeding site is spotted with a anoscope under local anaesthesia (0.25% bupivacaine with 1:200,000 epinephrines) and a stick tie figure[9]ofeight suture with 3-0 vicryl incorporating mucosa, sub mucosa and internal sphincter is placed. The associated coagulopathy should be corrected. Haemorrhoidectomy should be reserved for rare cases when stick tie method fails to control bleeding.

Haemorrhoids in inflammatory bowel diseases

Haemorrhoids are uncommon in inflammatory bowel disease. Most anal problems result from perianal irritation and swelling caused by diarrhoea rather than haemorrhoids themselves. Surgical treatment may be indicated if necessary in ulcerative colitis but is relatively contraindicated in Crohn's disease as the rate of severe complications are high.[9]

Haemorrhoids in patients with HIV and AIDS

Haemorrhoids in HIV and AIDS cases can be safely managed as in non-infected patients in early stages. Patients with AIDS however are at high risk of complication (infection, non-healing wounds) and probably should not undergo surgery except under well-controlled circumstances.[11]

XYLOCAINE® JELLY (2%)

Xylocaine (lidocaineHCl) 2% Jelly is a sterile aqueous product that contains a local anesthetic agent and is administered topically. Xylocaine 2% Jelly contains lidocaineHCl which is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride and has the following structural formula.[32]

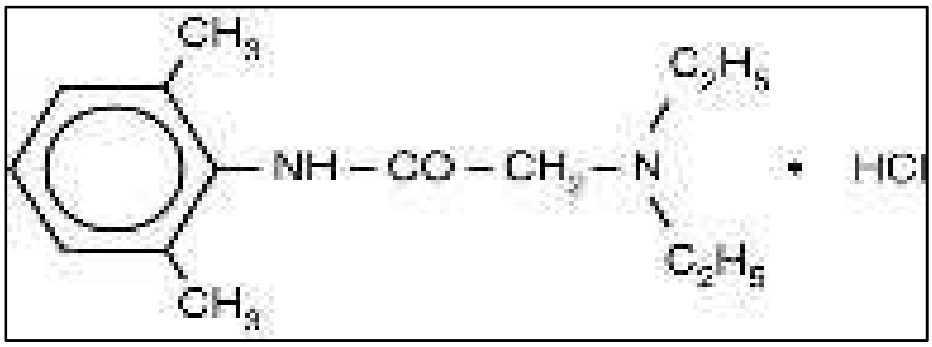


Fig 9: Chemical Structure

PHARMOCOLOGY

Mechanism of Action:

Lidocaine stabilizes the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses, thereby effecting local anesthetic action.

Onset of Action:

The onset of action is 3−5 minutes. It is ineffective when applied to intact skin

Pharmacokinetics and Metabolism:

Lidocaine may be absorbed following topical administration to mucous membranes, its rate and extent of absorption depending upon concentration and total

dose administered the specific site of application, and duration of exposure. In general, the rate of absorption of local anesthetic agents following topical application occurs most rapidly after intratracheal administration. Lidocaine is also well-absorbed from the gastrointestinal tract, but little intact drug may appear in the circulation because of biotransformation in the liver.

Lidocaine is metabolized rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Biotransformation includes oxidative N-dealkylation, ring hydroxylation, cleavage of the amide linkage, and conjugation. N-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycinexylidide and glycinexylidide. Approximately 90% of lidocaine administered is excreted in the form of various metabolites, and less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-hydroxy-2,6-dimethylaniline.[32]

The plasma binding of lidocaine is dependent on drug concentration, and the fraction bound decreases with increasing concentration. At concentrations of 1 to 4 µg of free base per mL, 60 to 80 percent of lidocaine is protein bound. Binding is also dependent on the plasma concentration of the alpha-l-acid glycoprotein. Lidocaine crosses the blood-brain and placental barriers, presumably by passive diffusion.

The half-life may be prolonged twofold or more in patients with liver dysfunction. Renal dysfunction does not affect lidocaine kinetics but may increase the accumulation of metabolites.

INDICATIONS

Surface anaesthesia and lubrication: of the male and female urethra during cystoscopy, catheterisation, exploration by sound and other endourethral operations, of nasal and pharyngeal cavities in endoscopic procedures such as gastroscopy and bronchoscopy, during proctoscopy and rectoscopy, during intubation.

For the relief of pain after circumcision in children.

CONTRAINDICATIONS

Known history of hypersensitivity to local anaesthetics of the amide type or other components of the jelly. Hypersensitivity to methyl and/or propyl hyroxybenzoate or to their metabolite paraaminobenzoic acid.[32]

ADVERSE REACTIONS

Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy, or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

Central Nervous System:

CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or

numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, and arrest. The excitatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

Cardiovascular System:

Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Allergic:

Allergic reactions are characterized by cutaneous lesions, urticaria, edema, or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to the local anesthetic agent or to other components in the formulation. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.[32]

ALOE VERA

Aloe vera (Aloe vera Linn, synonym: aloe verabarbadensis Mill.) is in family Liliaceae, which is a tropical plant and easily grown in hot and dry climates. Numerous cosmetics and medicinal products are made from the mucilaginous tissue, called aloe vera gel, located in the center of the aloe vera leaf. Aloe vera gel has been used for many indications since the Roman era or even long before.[5]

Aloveravera has been used for many centuries for its curative and therapeutic properties and although over 75 active ingredients from the inner gel have been identified, therapeutic effects have not been correlated well with each individual component. Many of the medicinal effects of aloe leaf extracts have been attributed to the polysaccharides found in the inner leaf parenchymatous tissue, but it is believed that these biological activities should be assigned to a synergistic action of the compounds contained therein rather than a single chemical substance.

Medicinal properties of Aloe vera have been recognised for a long time[34]. The antiseptic and antimicrobial agents present in Aloe vera provide the ability to attack, reduce, control, or even eliminate infections as the gel penetrates directly into the deeper layers of the skin. The analgesic property helps to be a fast and effective painkiller. The polysaccharides in Aloe vera are an important stimulus to the immune system, and also act as a catalyst for the healing properties of Aloe vera.[35]

Structural composition

The aloe leaf can be divided into two major parts, namely the outer green rind, including the vascular bundles, and the inner colourless parenchyma containing the aloe gel. The three structural components of the Aloe verapulp are the cell walls, the degenerated organelles and the viscous liquid contained within the cells. These three components of the inner leaf pulp have been shown to be distinctive from each other both in terms of morphology and sugar composition as shown in Figure 10. The raw pulp of A. veracontains approximately 98.5% water, while the mucilage or gel consists of about 99.5% water. The remaining 0.5 – 1% solid material consists of a range of compounds including water-soluble and fat-soluble vitamins, minerals, enzymes, polysaccharides, phenolic compounds and organic acids It has been

hypothesized that this heterogenous composition of the Aloe verapulp may contribute to the diverse pharmacological and therapeutic activities which have been observed for aloe gel products.[5]

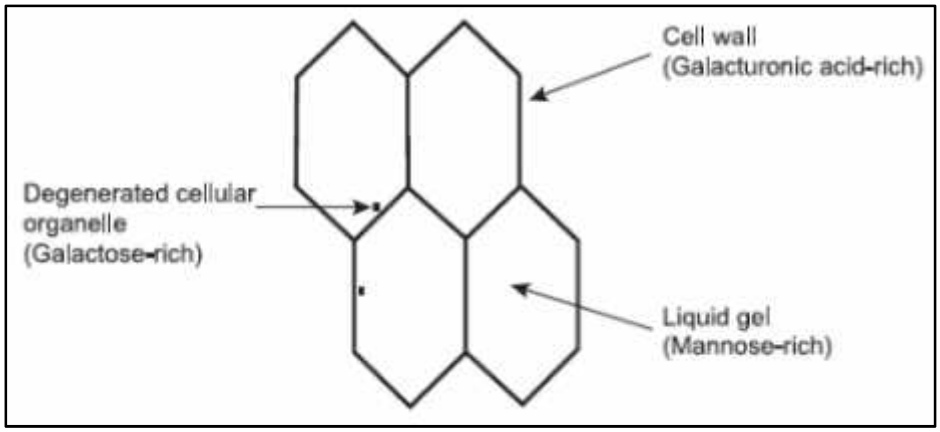


Fig10: Structural Formula

Effect of Aloe vera gel on biological membrane permeation

Intestinal drug absorption enhancement

The effect of Aloe vera gel and whole leaf extract on the oral bioavailability of vitamins C and E was investigated in humans in a randomised, double-blind, cross-over clinical trial. Both the gel and whole leaf extract decreased the rate of vitamin C absorption, but the overall bioavailability (area-under curve) of vitamin C was 3 times higher when administered with the aloe gel as compared to the control and the gel kept the level of this vitamin significantly higher ($p \leq 0.05$) than the baseline even after 24 hours. The bioavailability of vitamin C administered in conjunction with the whole leaf extract was only 80 % compared to the control and the level returned to baseline after 24 hours. For vitamin E, the bioavailability was 3.7 times higher when administered with aloe gel and 2 times higher with the aloe whole leaf extract. The mechanism of action of the aloe products to improve the bioavailability of the

vitamins was explained to be a possible protection effect against the degradation of the vitamins in the intestinal tract as well as binding of the polysaccharides to the vitamins and thereby slowing down the absorption rate.[5]

Skin penetration enhancement

Although there is a high interest in transdermal drug delivery, the poor penetration of drugs into the skin and low permeation across the skin severely hamper the use of this route of drug administration. Techniques for improving the transdermal delivery of drugs are based on the use of chemical penetration enhancers, novel vehicle systems and physical enhancement strategies such as iontophoresis, sonophoresis, ultrasound, microneedles, velocity based techniques and electro oration.

Aloe Vera gel increased the in vitro skin penetration of compounds depending on their molecular weights, with an apparent inverse correlation between enhancement ratio and molecular weight of the compound. This penetration enhancement effect of the aloe gel was explained by a probable pull effect of complexes formed between the compound and the enhancing agent within the aloe gel, but it was stated that the proposed mechanism of action has to be further investigated and confirmed. Some constituents of the Aloe vera gel itself also penetrated the skin and this was interestingly dependent on the molecular weight of the co-applied compounds.

The higher the molecular weight of the co-appliedcompound, the less of the gel components were transported across the skin. This was explained by the probable displacement of Aloe vera components from the penetration pathways and thereby it inhibits permeation of the gel components more effectively than the smaller compounds. Similar to the discussion for intestinal drug absorption enhancement,

Aloe vera gel could potentially be used as a penetration enhancement agent for the transdermal delivery of drugs if proven to be effective and safe

Biological activities of Aloe vera leaf gel

It has been claimed that the polysaccharides in Aloe vera gel have therapeutic properties such as immunostimulation, anti-inflammatory effects; wound healing, promotion of radiation damage repair, anti-bacterial, anti-viral, anti-fungal, anti-diabetic and anti-neoplastic activities, and stimulation of hematopoiesis and anti-oxidant effects. On the other hand, there are a number of clinical reports that have found

Aloe vera gel not effective in terms of the above mentioned therapeutic activities or even to cause undesirable effects such as retardation of wound healing.

Immunomodulatory effects

A number of studies indicated immunomodulating activities of the polysaccharides in Aloe vera gel, and suggested that these effects occur via activation of macrophage cells to generate nitric oxide, secrete cytokines (e.g. tumour necrosis factor-alpha or TNF-α, interleukin-1 or IL-1, interleukin-6 or IL-6 and interferon-γ or INF-γ) and present cell surface markers.[5]

Anti-inflammatory effects

Inflammation is a reaction by the body due to injury and is characterised by swelling, pain, redness, heat and loss of function. This natural response can delay healing, but it may also be detrimental to suppress inflammation before its purpose is accomplished. The anti-inflammatory activity of mannose6-phosphate is believed to resemble the effects observed for acetylated mannan in aloe gel. Aloe gel reduces

inflammation that is induced by agents via promotion of prostaglandin synthesis as well as increased infiltration of leucocytes.

The effects of aqueous, chloroform and ethanol extracts of Aloe vera gel were investigated on oedema in the rat paw as well as neutrophil migration into the peritoneal cavity induced by carrageenan. Both the aqueous and chloroform extracts were found to inhibit the oedema formation close to that of well established anti-inflammatory agents (i.e. indomethacin and dexamethasone). Furthermore, the antioedema effects of these two extracts correlated well with their abilities to decrease the number of neutrophils migrating into the peritoneal cavity. The ethanol extract did not show an effect on the oedema, but reduced the number of migrating neutrophils. Further experimentation on the mechanism of action suggested that the anti-inflammatory activity of the extracts of Aloe vera gel probably occurs via an inhibitory action on the arachidonic acid pathway through cyclooxygenase. A study on Helicobacter pylori-infected rats showed that treatment with A. verasignificantly reduced leukocyte adhesion and tumour necrosis factor α (TNF-α) levels. The results therefore suggest that Aloe vera show potential in the treatment of the inflammatory response of the gastric mucosa due to H. pylori infection.

Since one of the main effect of inflammation is pain, Anti inflammatory action of alovera causes reduction of pain. which is the outcome measured in our study in post Haemorrhoidectomy patients. [5]

Anti-oxidant effects

It has been reported by several authors that different fractions of Aloe vera as well as unfractionated whole gel have anti-oxidant effects. Glutathione peroxidise activity, superoxide dismutase enzymes and a phenolic anti-oxidant were found to be

present in Aloe vera gel, which may be responsible for these anti-oxidant effects. It was shown in two cell-free in vitro systems and by incubation with inflamed colorectal mucosal biopsies that Aloe vera gel has a dose-dependent anti-oxidant effect. The cell-free techniques used in this study assessed the scavenging of both superoxide and peroxyl radicals. The Aloe vera gel in a concentration of 1 in 50 also inhibited prostaglandin E2 production from inflamed colorectal biopsies, but had no effect on thromboxane B2 release.[5]

Wound healing effects

Wound healing is a response to injured tissue that results in the restoration of tissue integrity. It was shown that aloe gel could improve wound healing after topical and systemic administration in several studies, while others claimed no effect or even a delay in wound healing. Conflicting results may be explained by stability of the active ingredients as it was shown that the time of treatment after harvesting was an important factor that determined activity. Several mechanisms have been proposed for the wound healing effects of aloe gel, which include keeping the wound moist, increase epithelial cell migration, more rapid maturation of collagen and reduction in inflammation.[5]

Antimicrobial activities

The activity of Aloe vera inner gel against both Gram-positive and Gram-negative bacteria has been demonstrated by several different methods .Anthraquinones isolated from the exudate of Aloe vera have shown wide antimicrobial activity. The antibacterial activity of emodin against Escherichia coli was proposed to be mediated through inhibition of solute transport in membranes.

Many anthraquinones have shown antiviral and/or virucidal effects on enveloped viruses.

Aloe vera has found to be significantly effective in treatment of multidrug resistant bacterial infections namely infected leg ulcers.[33]

In a study by Bashir et al, Aloevera is found to be significantly effective against Methicilin Resistant Staphylococcus aureus.[34]

Further, considerable clinical improvement was noticed in the form of rapid diminution of inflammation and hence pain, discharge and deodarisation of the wound by the end of 10 days along with the appearance of healthy granulation tissue.[35]

METHODOLOGY

The present study was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period from January 2011 to December 2011 on 50 patients undergoing open haemorrhoidectomy .

Study design

One year prospective randomized open label trial.

Study period and duration

The present one year study was conducted during the period of January 2011 to December 2011.

Source of data

Patients undergoing open haemorrhoidectomy in Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Sample size

A total of 50 patients undergoing open haemorrhoidectomy were studied.

Sampling procedure

Based on 80% of the average three years hospital data the sample size was determined as 50 cases undergoing open haemorrhoidectomy.

Selection Criteria

Inclusion

- Age between 18 to 60 years.
- Patients undergoing Open haemorroidectomy

Exclusion

- Diabetic and immuno-compromized patients.
- Associated with fissure and fistula in Ano
- Patient's with ano-rectal malignancy
- Mentally deranged patients

Ethical clearance

Before the commencement of the study Ethical Clearance was obtained from the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belgaum.

Informed Consent

All the patients fulfilling selection criteria were explained about the purpose of study and a written informed consent was obtained before enrollment (Annexure I).

Method of collection of data

Patients admitted in the wards of Department of General Surgery at KLES Dr.Prabhakar Kore Hospital and Medical Research Centre, Belgaum undergoing elective open haemorrhoidectomy were evaluated based on selection criteria.

Demographic data such as age and sex were recorded. Patients were interviewed for the history and a thorough physical examination was conducted including vitals and systemic examination. These findings were recorded on a predesigned and pretested proforma (Annexure II).

Randomization

Based on the computer generated blocked random numbers patient were randomized into two groups that is;

Group A–Aloe Vera

Group B – 2% Xylocaine Jelly

Investigations

Routine investigations such as Complete blood count, RBS, Blood urea, Serum Creatinine, Bleeding time, Clotting time, Urine routine and microscopy, Chest X-ray and ECG

Procedure:

50 patients were randomized in to two groups. Patients had cream/xylocaine jelly applied immediately after surgery, then at 12 hrs, 48 hrs, Day 3 and Day 7 post surgery. This treatment was continued on the surgery site 3 times a day up to 7 days post operatively. Group A patients applied approximately 3g of aloe cream to the surgical wounds.Group B patients applied same quantity of xylocaine jelly in similar fashion.

The initial application of cream/jelly was performed as a part of post operative dressing. Patients were instructed to apply the cream/jelly with the tip of the index finger to the wounds 3 times daily.All patients were supplied with analgesic drugs as needed. Enrolled patients were explained about the use of visual analogue scale employed in this study.

VAS Score:

Visual analogue scale consists of a 10 cm scale representing varying intensity of pain from 0 (no pain) to 10 (worst pain). All patients were supplied with analgesics (Tab Diclofenac 50 mg) as needed. The patients recorded their analgesic requirement. Then the analgesics requirement was assessed at the end of 12hrs, 48hrs, Day 3 and Day 7.

Statistical analysis

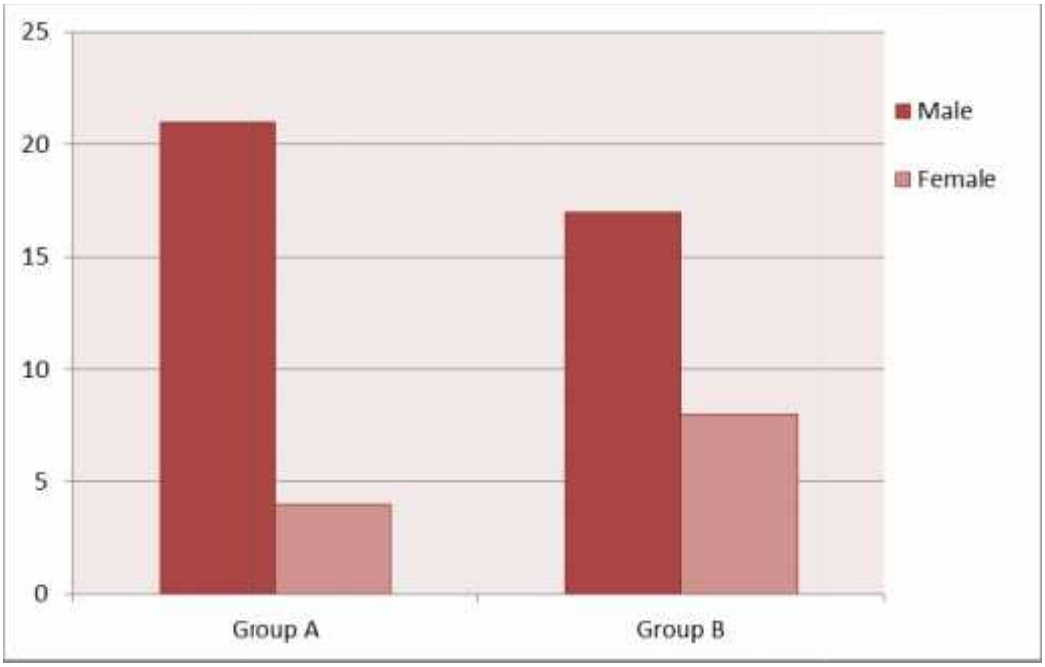
The data obtained was tabulated, categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test. Continuous data was expressed as mean ± standard deviation and comparison was done using unpaired‘t’ test. A ‘p’ value of less than or equal to 0.05 was considered as statistically significant.

RESULTS

Table 1: Male- Female Distribution

Sex	Group A (n =25)		Group B (n= 25)	
	Number	**Percentage**	**Number**	**Percentage**
Male	21	84.0	17	68.0
Female	4	16.0	8	32.0

Graph 1: Male- Female Distribution

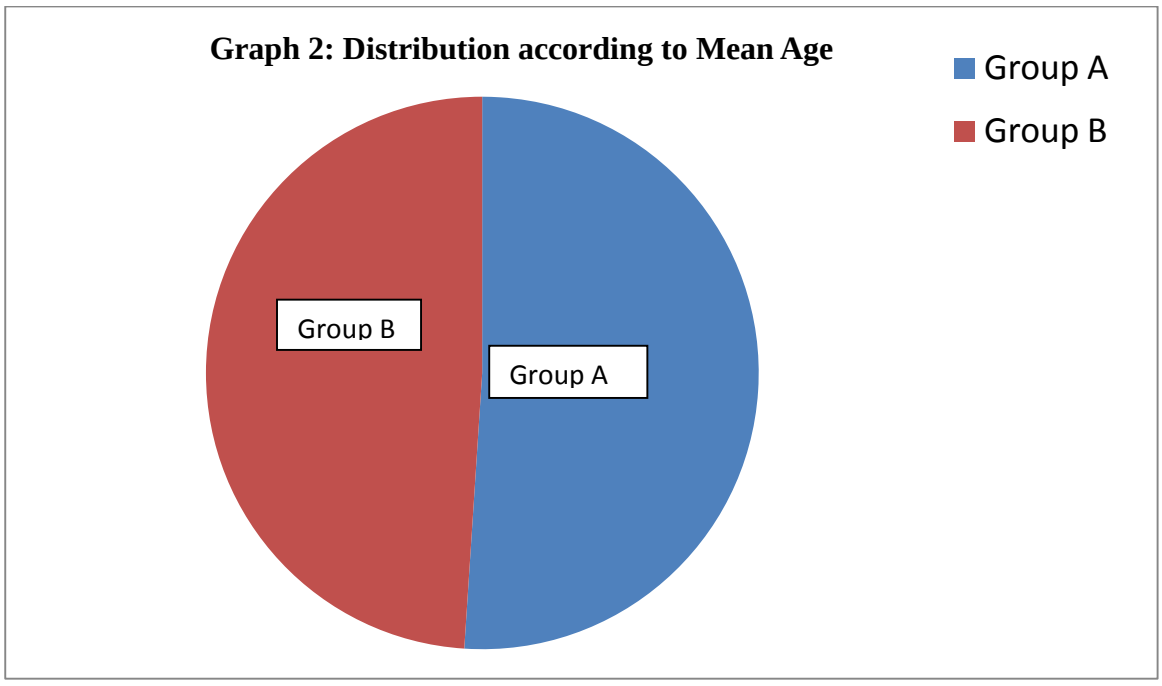


In this study overall, out of 50 patients, 38 were male and 12 were female. In group A, 84% were male and 16% were female. In group B 68% were male and 32% were female .Hence gender distribution in both the groups are comparable.

Table 2: Distribution according to Mean Age

Groups	Mean Age		p Value
	Mean	SD	
Group A	47.32	10.05	0.514
Group B	45.4	10.61	

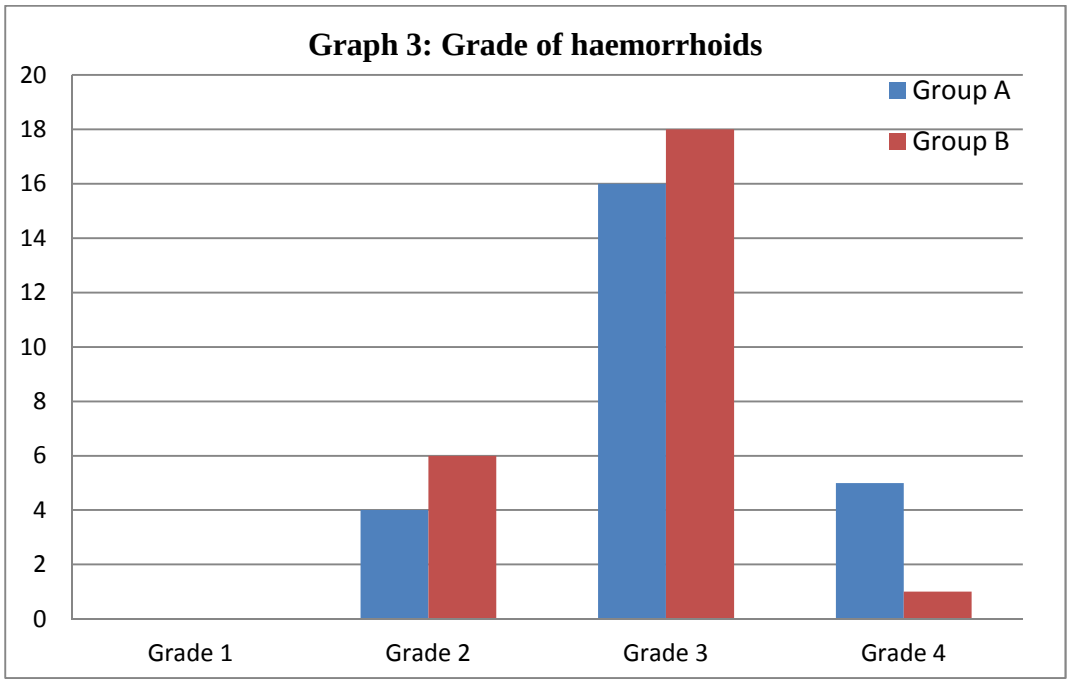
Graph 2: Distribution according to mean age



The mean age in Group A was 47.32±10.05 and in Group B mean age was 45.40±10.61 years suggesting the demographic characteristics of the study population were comparable in both the groups.

Table 3: Distribution of Grades of Haemorrhoids

Groups	Grades of Haemorrhoids			
	Grade 1	**Grade 2**	**Grade 3**	**Grade 4**
Group A	0	4	16	5
Group B	0	6	18	1
Total	0	10	34	6



In present study, distribution of patients according to grades of haemorrhoids, 10 patients were operated for grade-2 haemorrhoids. Out of 10 patients,4 were in group A and 6 were in group B.34 patients were operated for grade-3hemorrhoids which comprises maximum number of patients. Out of 34 patients, 16 were in group A and 18 were in group B. 6 patients operated for grade-4 haemorrhoids, 5 were in group A and 1 patient in group B.

Table 4: Pain Score of Post- Haemorrhoidectomy at 12 hours

Pain Score	Group A		Group B	
	Number	Percentage	Number	Percentage
0	-	-	-	-
1	-	-	-	-
2	-	-	-	-
3	-	-	-	-
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
7	-	-	-	-
8	10	40%	4	16%
9	15	60%	21	84%
10	-	-	-	-
Total	25	100%	25	100%

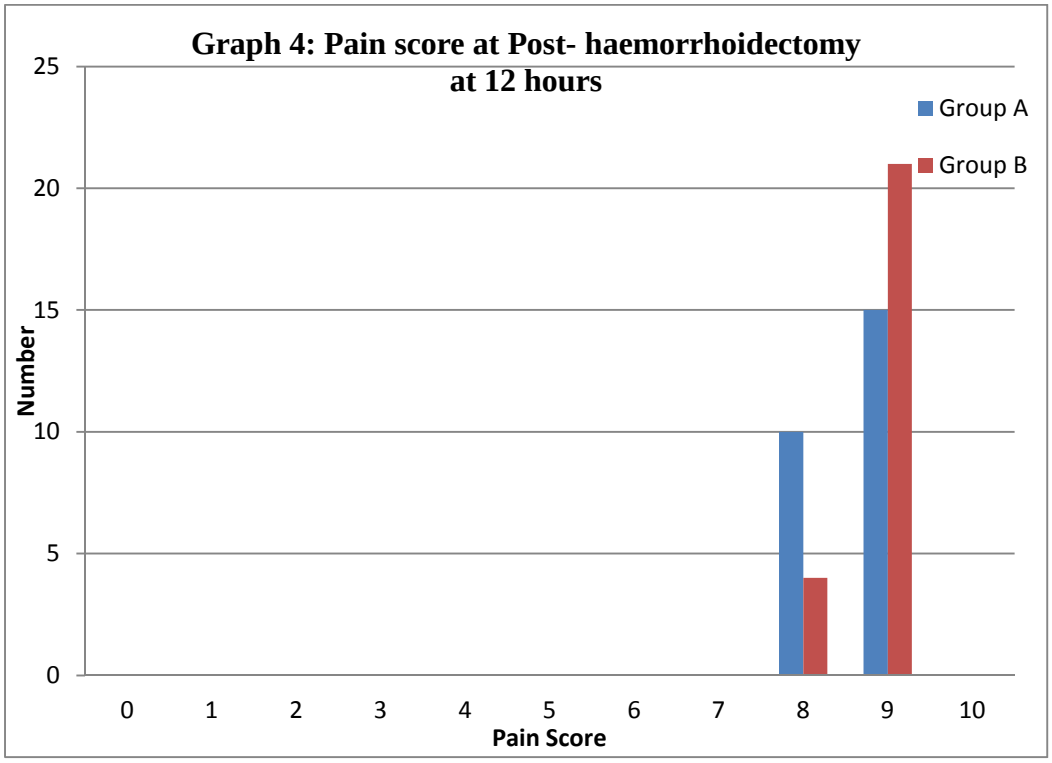
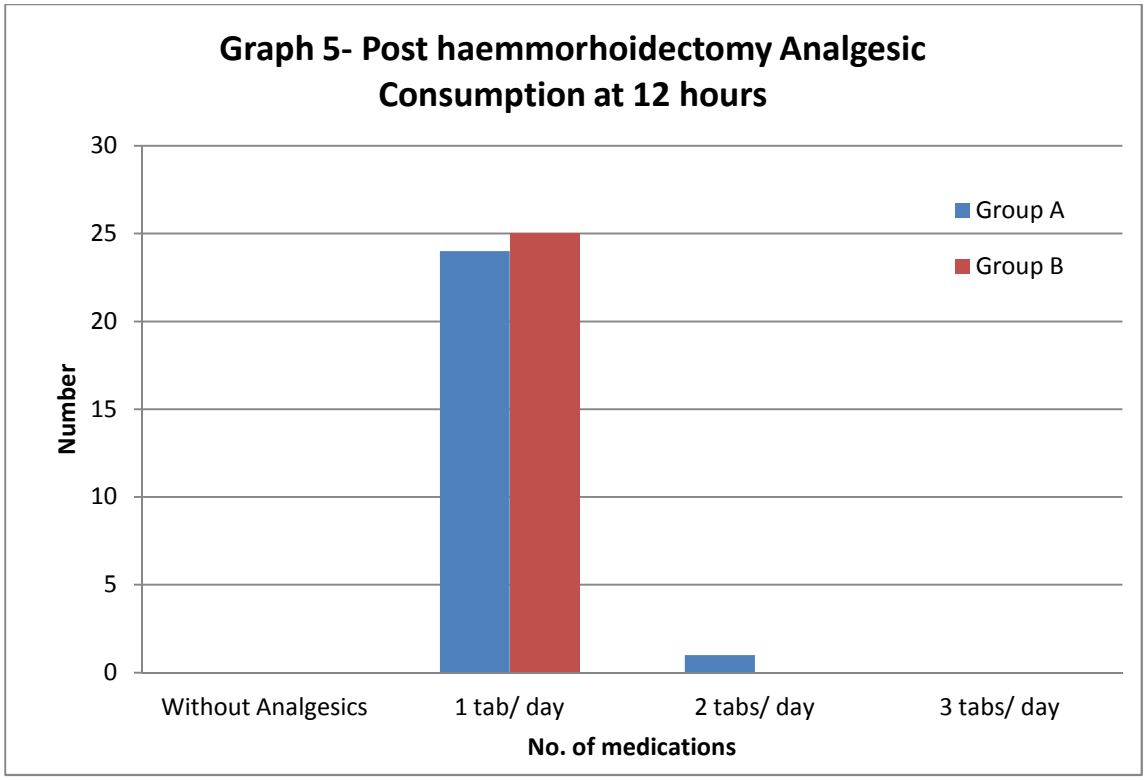


Table 5: Posthemorrhoidectomy Analgesic Consumption at 12 hours

Number Of Medications	Group A		Group B		p Value
	Number	Percentage	Number	Percentage	
Without analgesic	-	-	-	-	-
One tablet/ day	24	96%	25	100%	0.012
Two tablets/ day	1	4%	-	-	-
Three tablets/ day	-	-	-	-	-



Mean pain scores at the end of 12 hrs were low in Aloe vera group. The Analgesic requirement was also significantly lower in Aloe era group with p value of 0.012.

Table 6: Pain score of post- haemorrhoidectomy at 48 hours

Pain Score	Group A		Group B	
	Number	**Percentage**	**Number**	**Percentage**
0	-	-	-	-
1	-	-	-	
2	-	-	-	-
3	-	-	-	-
4	-	-	-	-
5	3	12	-	-
6	12	58	2	8
7	10	40	14	56
8	-	-	9	45
9	-	-	-	-
10	-	-	-	-
Total	25	100%	25	100%

Graph 6: Pain Score at Post- Hemorrhoidectomy at 48 hours

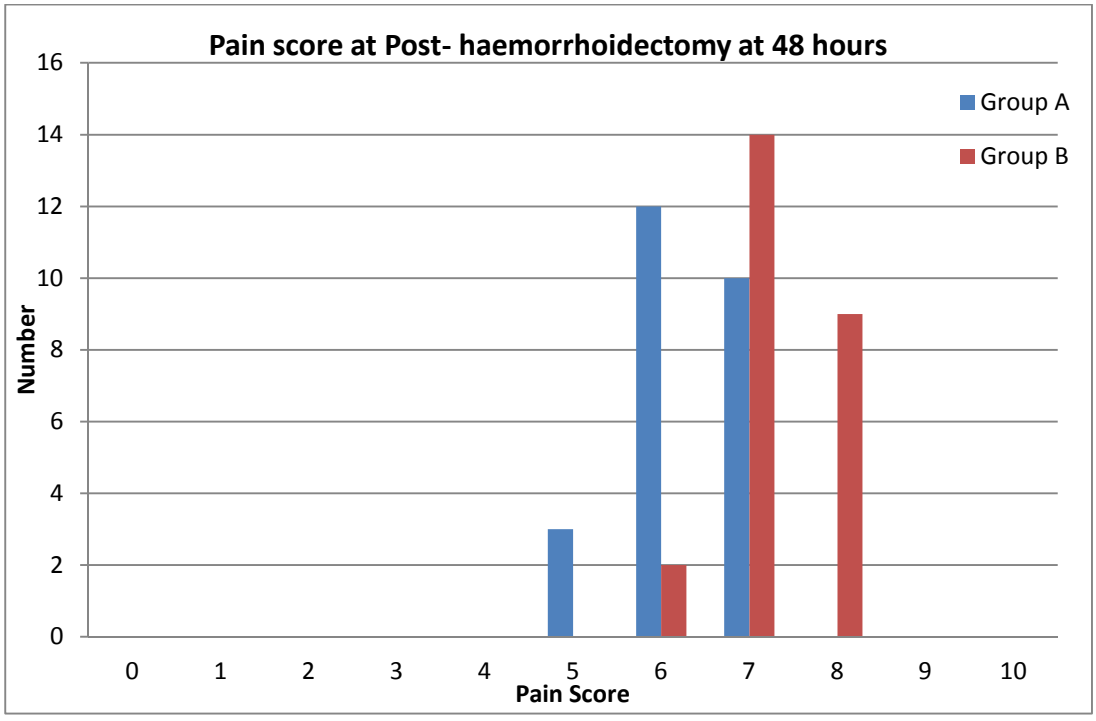


Table 7: Post- defecation pain at 48 hours

Pain Score	Group A		Group B	
	Number	Percentage	Number	Percentage
0	-	-	-	-
1	-	-	-	
2	-	-	-	-
3	-	-	-	-
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
7	2	8%	-	-
8	13	52%	4	16%
9	10	40%	21	84%
10	-	-	-	-
Total	25	100%	25	100%

Graph 7: Pain score at post- operative 48 hours

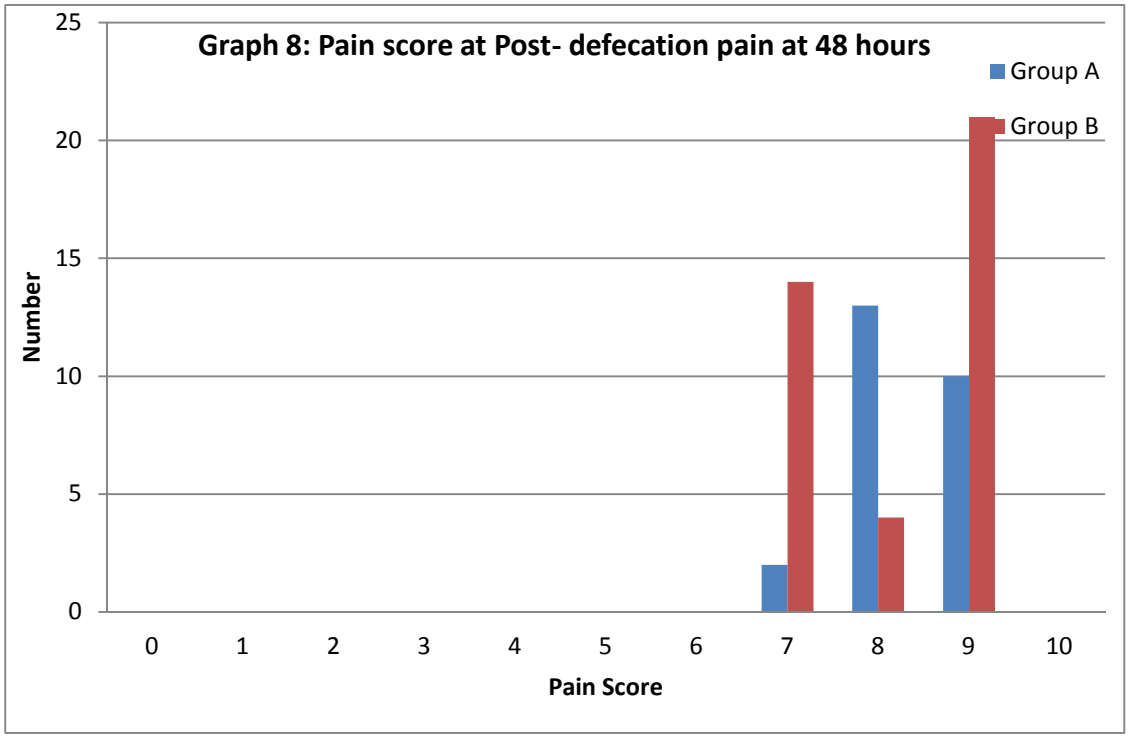
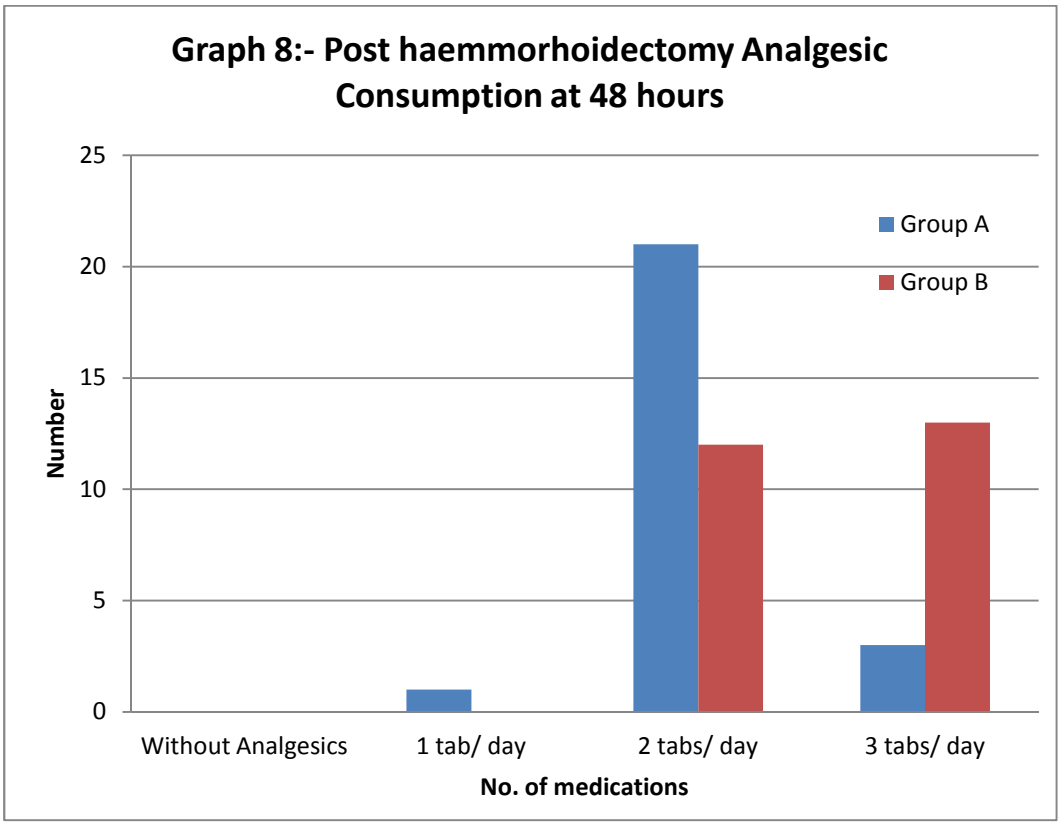


Table 8: Post- Haemorrhoidectomy Analgesic consumption at 48 hours

Number Of Medications	Group A		Group B		p Value
	Number	Percentage	Number	Percentage	
Without analgesic	-	-	-	-	
One tablet/ day	1	4%	-	-	0.0078
Two tablets/ day	21	84%	12	48	
Three tablets/ day	3	12	13	52	



Post Defecation pain was significantly lower in Aloe vera group. Analgesic requirement was also significantly lower in aloe vera group at the end of 48 hrs (p=0.007)

Table 9: Pain score of post- Haemorrhoidectomy at Day 3

Pain Score	Group A		Group B	
	Number	Percentage	Number	Percentage
0	-	-	-	-
1	-	-	-	
2	-	-	-	-
3	8	32%	-	-
4	8	32%	1	4
5	7	28%	6	24
6	2	8%	14	56
7	-	-	4	16
8	-	-	-	-
9	-	-	-	-
10	-	-	-	-
Total	25	100%	25	100%

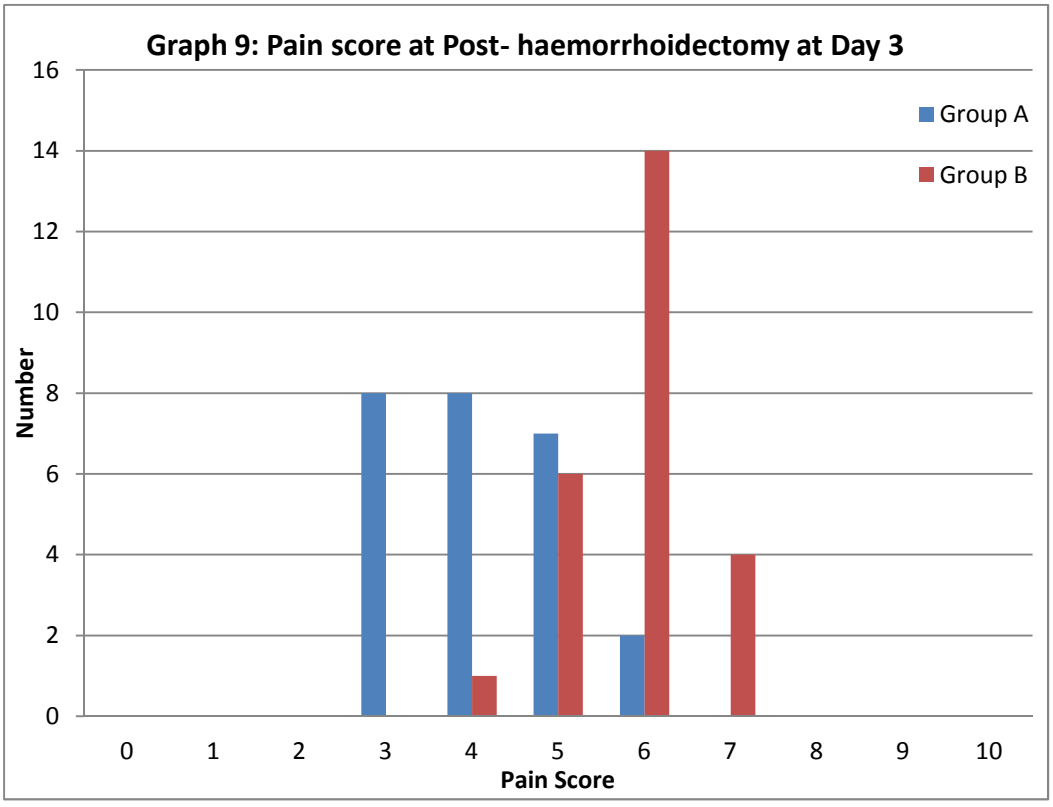


Table 10: Post- defecation pain at Day 3

Pain Score	Group A		Group B	
	Number	Percentage	Number	Percentage
0	-	-	-	-
1	-	-	-	
2	-	-	-	-
3	-	-	-	-
4	7	28%	-	-
5	11	44%	-	-
6	7	28%	8	32%
7	-	-	16	64%
8	-	-	1	4%
9	-	-	-	-
10	-	-	-	-
Total	25	100	25	100

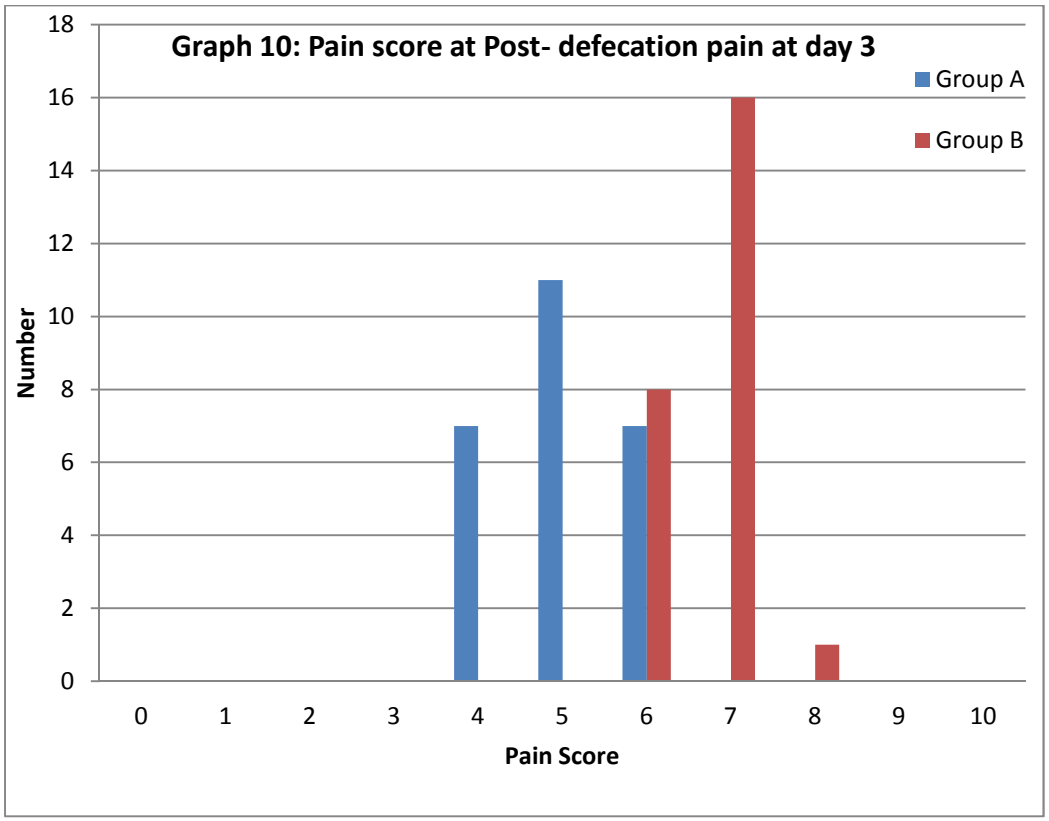
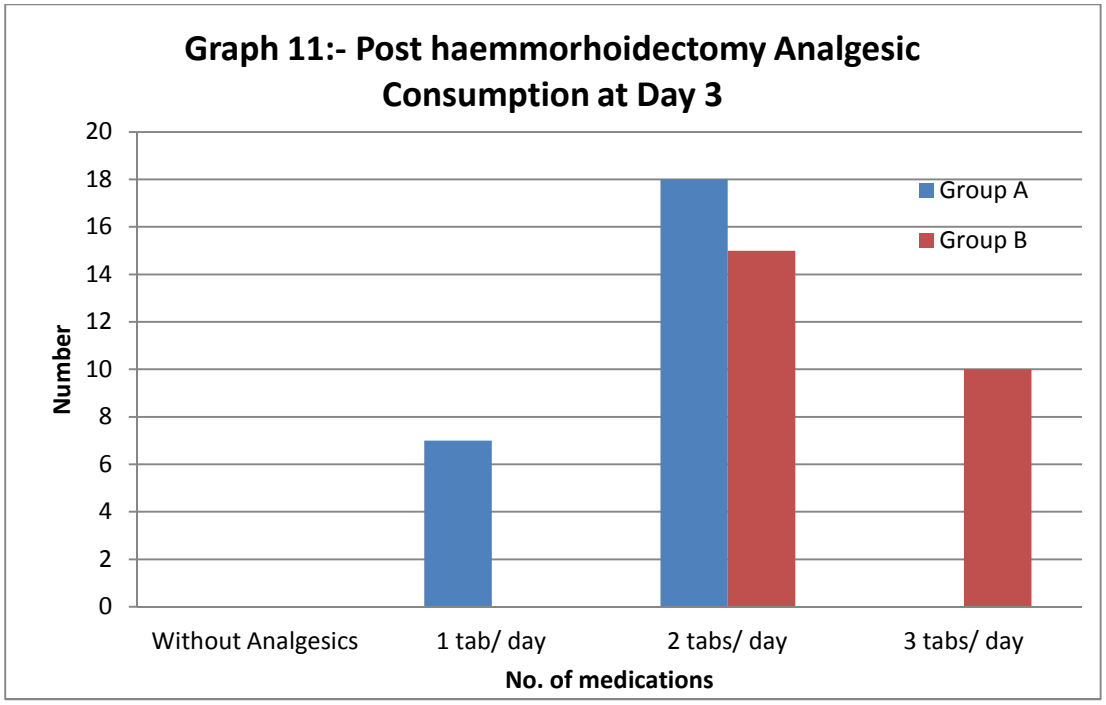


Table 11: Post- Haemorrhoidectomy Analgesic consumption at day 3

Number Of Medications	Group A		Group B		p Value
	Number	Percentage	Number	Percentage	
Without analgesic	-	-	-	-	
One tablet/ day	7	28%	-	-	0.0002
Two tablets/ day	18	72%	15	60%	
Three tablets/ day	0	0	10	40%	



Analgesic requirement significantly reduced in aloe vera group at the end of 3 days. The total doses of analgesics taken were also aignificantly reduced as compared with xylocaine jelly group.

Table 12: Pain score of post- Haemorrhoidectomy at Day 7

Pain Score	Group A		Group B	
	Number	Percentage	Number	Percentage
0	19	76	5	20
1	4	16	-	-
2	2	8	15	60
3	-	-	5	20
4	-	-	-	-
5	-	-	-	-
6	-	-	-	-
7	-	-	-	-
8	-	-	-	-
9	-	-	-	-
10	-	-	-	-
Total	25	100%	25	100%

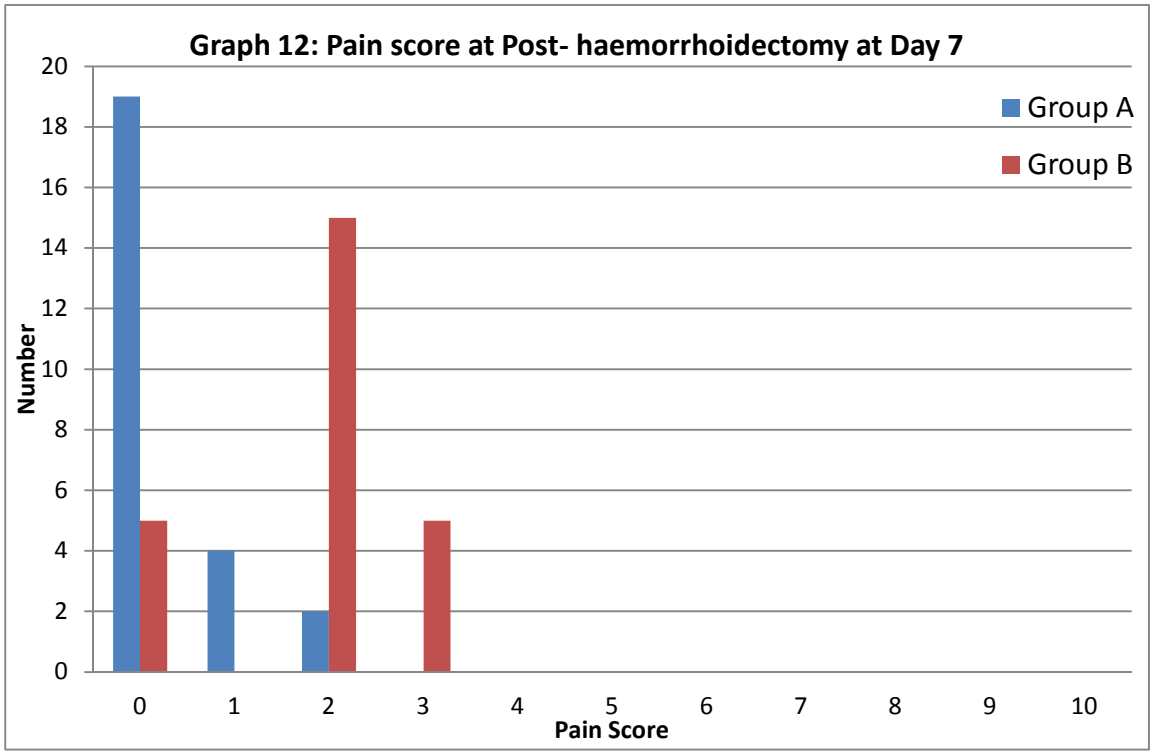


Table 13: Post- defecation pain at Day 7

Pain Score	Group A		Group B	
	Number	**Percentage**	**Number**	**Percentage**
0	17	72	-	-
1	7	28	2	8
2	1	4	11	44
3	-	-	9	36
4	-	-	3	12
5	-	-	-	-
6	-	-	-	-
7	-	-	-	-
8	-	-	-	-
9	-	-	-	-
10	-	-	-	-
Total	25	100%	25	100%

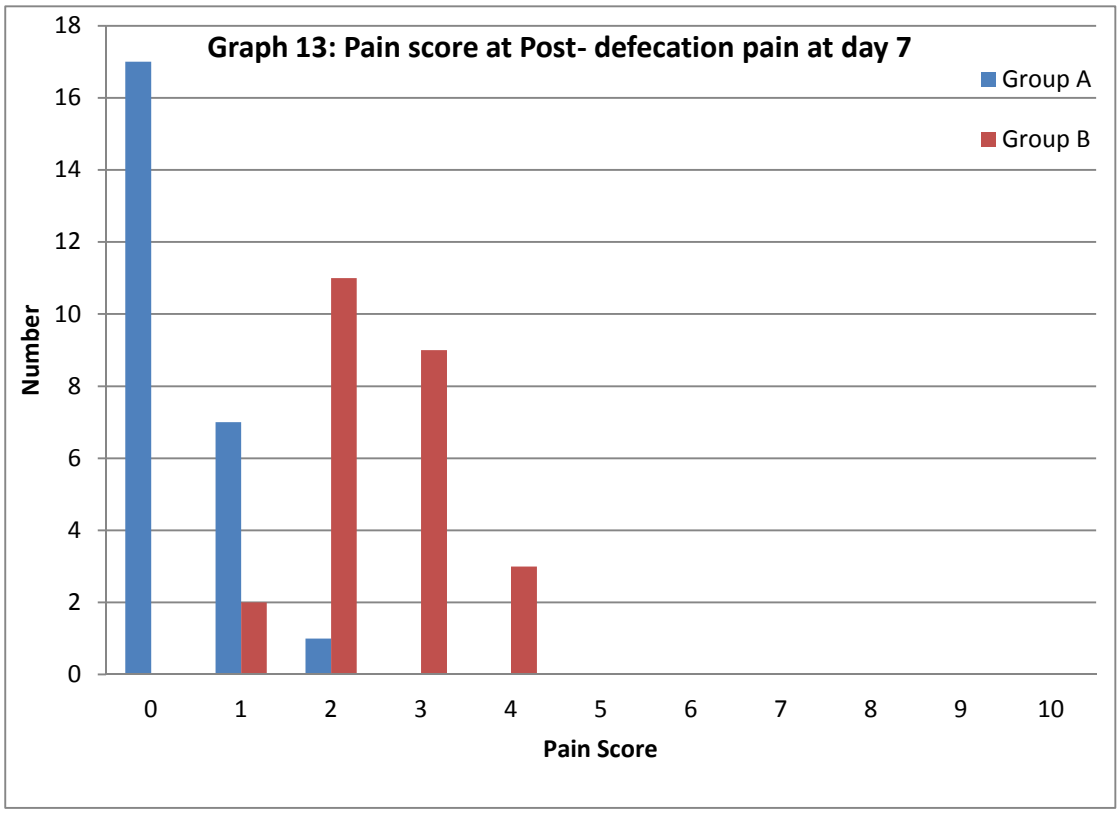
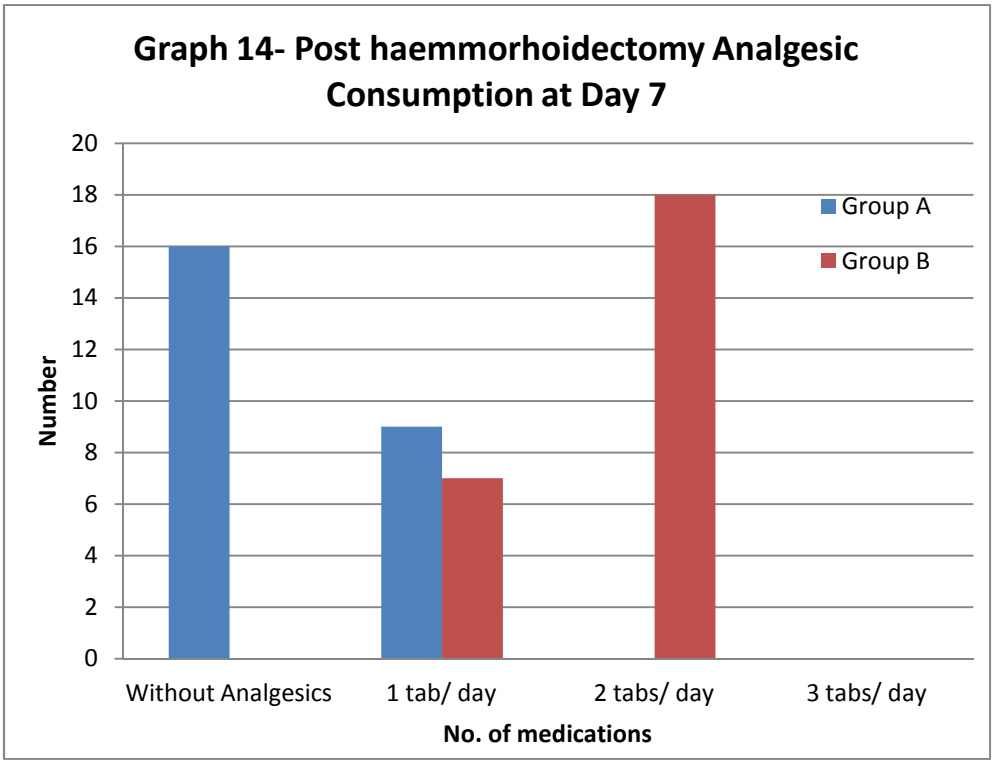


Table 14: Post- haemorrhoidectomy Analgesic consumption at Day 7

Number Of Medications	Group A		Group B		p Value
	Number	Percentage	Number	Percentage	
Without analgesic	16	64	-	-	
One tablet/ day	9	36%	7	28	<0.0001
Two tablets/ day	-	-	18	72%	
Three tablets/ day	-	-	-	-	



Analgesic requirements as well as pain scores were significantly reduced in aloe vera group as compared with xylocaine group with value of <0.0001

Table 15: Post- haemorrhoidectomy pain Score in Aleovera and 2 % Xylocaine Groups

Time	AleoVera (n=25) Mean+ SD	2% Xylocaine (n=25) Mean + SD	p value
12 Hours	8.6 ± 0.5	8.84± 0.37	0.061
48 hours	6.28 ± 0.67	7.28 ± 0.61	<0.0001
Day 3	4.12 ± 0.97	5.84 ± 0.74	<0.0001
Day 7	0.32 ± 0.62	1.8 ± 1.0	<0.0001

Post operative pain scores were significantly reduced in aloe vera group in all the days of assessment proving aloe vera to be superior to xylocaine jelly

Table 16: Pain on defecation in Aleovera and 2% Xylocaine Groups

Time	AleoVera (n=25) Mean+ SD	2% Xylocaine (n=25) Mean + SD	p value
48 hours	8.32 ± 0.62	8.84 ± 0.37	0.0008
Day 3	5 ± 0.76	6.72± 0.54	<0.0001
Day 7	0.36 ± 0.56	2.52 ± 0.82	<0.0001

Table 17: Post Haemorrhoidectomy total Analgesic consumption in AleoVera and 2% Xylocaine groups

Time	AleoVera (n=25) Mean ± SD	2% Xylocaine (n=25) Mean ± SD	P value
Mean	5.2	7.6	<0.0001
SD	0.7	0.64	

Analgesic requirements in aloe vera group were significantly reduced as compared to xylocaine group proving aloe vera to be superior.

DISCUSSION

Pain serves a biological function. It signals the presence of damage or disease within the body. In the case of postoperative pain, it is the result of the surgery. The site of the surgery has a profound effect upon the degree of postoperative pain a patient may suffer. However, any operation involving a body cavity, large joint surfaces or deep tissues should be regarded as painful Management of postoperative pain relieves suffering and leads to earlier mobilization, shortened hospital stay, reduced hospital costs, and increased patient satisfaction.

Haemorrhoidectomy is well known to cause significant post-operative pain and delayed return to daily activities. Both surgical wounds and sphincterial apparatus spasms are likely responsible for the pain. Pain after hemorrhoidectomy can be severe and lasts for 2 to 3 weeks after surgery. Postoperative pain is the main deterrent for patients contemplating surgery for haemorrhoids. In present study, local application of aloe vera has been found to be an effective modality in treatment of post haemorrhoidectomy pain for the first 7 days post surgery

Aloe vera has a long history of popular and traditional use. It is used in traditional Indian medicine for constipation, colic, skin diseases, worm infestation, and infections[44]. According to Lans at al, it is also used in Trinidad and Tobago for hypertension and among Mexican Americans for the treatment of type 2 diabetes mellitus [45,46]. In Chinese medicine, it is often recommended in the treatment of fungal diseases [44].

In Western society, Aloe vera is one of the few herbal medicines in common usage, and it has found widespread use in the cosmetic, pharmaceutical, and food industries. In the case of health, the therapeutic claims for the topical and oral application of Aloe vera cover a wide range of conditions, but few claims have been the subject of robust clinical investigation. The conditions for which clinical trials of Aloe vera have been conducted include skin conditions, management of burn and wound healing, constipation, DM, and gastrointestinal disorders.

The first case report of the beneficial effects of Aloe vera in the treatment of skin and wound healing was published in 1935, with fresh whole-leaf extract reported to provide rapid relief from the itching and burning associated with severe roentgen (radiation) dermatitis and complete skin regeneration. Numerous subsequent reports have explored the role of topical Aloe vera administration in skin conditions and wound healing management, including psoriasis, dermatitis, oral mucositis, burn injuries, and surgical wounds.[12]

In our study is Aloe vera is found to be significantly effective in reduction of post haemorrhoidectomy pain for first seven days post surgery. Veracylglucan B and veracylglucan C, two maloyl glucans isolated from Aloe vera gel, have been demonstrated in vitro to have potent anti-inflammatory effects.[36.] Among the nonpolysaccharide gel constituents, salicylic acid and other antiprostaglandin compounds may contribute to the local anti-inflammatory activity of Aloe vera via the inhibition of cyclooxygenase[37] since pain is one of the main component of inflammation, the anti inflammatory properties of aloe vera are known to significantly reduce pain as well.

A prospective, randomized study conducted by Eshghi et al, has demonstrated that application of Aloe vera cream provided significant pain relief through the 48 hours post open hemorrhoidectomy.[1]

Aloe cream led to significant wound healing at 14 days post surgery. Compared with the placebo group, lower analgesic consumption in the aloe cream group confirms the improved pain management following a hemorrhoidectomy.

Various factors believed to be responsible for the pain after hemorrhoidectomy include spasm of the internal sphincter, and inflammation and bacterial colonization of the hemorrhoidectomy site. Another reason for pain could be the healing of wounds, which was extended up to the anorectal ring[38].

Anti inflammation is the first step in wound healing, and this effect of aloe preparations is believed to play a direct role in facilitating pain and rapid healing[40]. Since inflammation is one of the main causes of pain in patients in the early postsurgery time, the antiinflammatory effects of aloe contribute to relief of postoperative pain in patients treated with aloe cream

Aloe has an antimicrobial effect; this effect is related to its constituents including anthraquinones and aloe-emodin.[5,40] This antimicrobial effect could be contributing to the reduction of pain and promotion of wound healing by Aloe vera. It was demonstrated that oral or topical antimicrobial agents such as metronidazole significantly decreased postoperative pain after open diathermy hemorrhoidectomy.[6,41]

According to study done by East and Isacke in 2002, Polysaccharides isolated from Aloe vera gel are largely composed of sugar mannose. Mannose binds to the certain receptors on the surface of fibroblasts, stimulating them, activating their faster growth and cell replication [42.] Davis et Al in 1994. Reported that mannose-6-phosphate extracted from Aloe vera can remarkably improve wound healing and inhibit inflammation in mice.

Anti-inflammation is the first step in the wound healing and this effect of two Aloe preparations is believed to play a direct role in facilitating the fast healing. Topical administration of the wholeleaf juice preparations, either Aloe arborescens Miller or Aloe ferox Miller, inhibit the growth of all bacterial strains tested.[43]

Aloe vera is known to produce pain relief in various other disorders. Aloe vera is known to cause pain relief in osteoarthritis. According to study conducted by Cowan D et al, oral Aloe vera could be used in the treatment of chronic non cancer pain, particularly that caused by osteoarthritis [6.]

In a recent meta-analysis, a statistically significant benefit of Aloe vera for the treatment of burns was demonstrated. Using the duration of wound healing as an outcome measure, the meta-analysis of the efficacy of Aloe vera in burn wound healing concluded that Aloe vera treatments reduced healing time by approximately 9 days compared to conventional treatment groups ($p = .006$)[6].

Acetylated glucomannan present in aloe vera gel is primarily responsible for the gel's mucilaginous properties and has been found in vitro and in animal studies to modulate immune function (through macrophage activation and cytokine production) and accelerate wound healing[2].

In present study, aloe vera cream significantly reduced the pain post Hemorrhoidectomy for the first seven days post surgery (p=<0.001).Analgesics requirements significantly reduced at 48 hrs (p=0.007), Day 3 (p=0.0002), Day 7 (p=0.0001) post operatively. The beneficial role of topical Aloe vera may be combined effects of antimicrobial, antiinflammatory properties, and positive effects on wound healing.

In terms of efficacy and safety, opical application of Aloe vera gel or extract is safe for the treatment of mild to moderate skin conditions, burns, wounds, and inflammation [2]

Hence, it could be interpreted that it can be used safely for peri anal application in haemorrhoidectomy patients for reduction in inflammation and in turn resulting in reduction of pain.

Future scope of study:

Use of topical Aloe vera gel in wound healing in burns patients is well documented but further long term studies are required in humans to study the effect of Aloe vera on pain relief.

Limitations of the study:

Despite its long history of use, there remains a lack of consistent scientific evidence to support many of the therapeutic claims for Aloe vera. In the present study as well, there is no scientific or objective evidence provided for action of Aloe vera during post operative period.

CONCLUSION

Aloe Vera is found to be significantly effective in preventing post operative pain over a period of seven days after conventional Haemorrhoidectomy when applied at operated site regularly after surgery. Aloe Vera application post operatively significantly reduced the need for Diclofenac compared with 2% xylocaine jelly.

Local application of Aloe vera is safe and effective with minimal side effects. Application of Aloe vera should be considered post operatively in all patients under going Haemorrhoidectomy.

Aloe vera is a better choice as compared with 2 % xylocaine jelly because of

(a) consistant decrease in pain over time as compared with xylocaine jelly

(b) Additional anti inflammatory, anti microbicidal, wound healing actions which eliminate the cause of pain.

SUMMARY

Conventional open haemorrhoidectomy is one of the safe and common anal surgery performed since long time. Even though Haemorrhoidectomy involves less surgical trauma as compared to open abdominal surgeries, post operative pain is often a frequent complaint. Recently, many techniques have come up to combat post haemorrhoidectomy pain. Pain following Haemorrhoidectomy can be either is because of Anal spincter spasm or surgical wound.

Acute pain is typically associated with neuroendocrine stress response that is proportional to the intensity of pain. This suggests that effective postoperative pain management is very important aspect of postoperative care. Uncontrolled postoperative pain is the worst post operative complication and has an adverse sequele of delayed passage of stools and delayed resumption of normal function, restriction of mobility (thus contributing to thromboembolic complications), nausea and vomiting.

It was suggested that peri anal application of Aloe vera cream post operatively after open haemorrhoidectomy may provide consistant pain relief. Unfortunately there are very minimal studies conducted to study the efficacy of peri anal application of aloe vera cream for post operative pain relief and early wound healing.

Aloe Vera is in family Liliaceae, which is a tropical plant easily grown in hot and dry climates. Aloe vera pulp has got heterogenous composition. It contains approximately 98.5% water. The remaining 0.5 – 1% solid material consists of a range of compounds including water-soluble and fat- soluble vitamins, minerals, enzymes, polysaccharides, phenolic compounds and organic acids. This heterogenous

composition of the Aloe vera pulp may contribute to the diverse pharmacological and therapeutic activities.

Aloe vera is found to be significantly effective in wound healing in burns patient's .It is proved to reduce the wound healing time significantly as compared with other agents.

Application of Aloe vera cream on the surgical site has been found to be effective in reducing postoperative pain both on resting and during defecation, healing time, and analgesic requirements in the patients compared with the placebo group. Hence, Aloe vera can be effective modality in treatment of post haemorrhoidectomy pain.

In our study, we have compared the effectiveness of peri anal application of Aloe vera cream versus 2 % Xylocaine jelly for post haemorrhoidectomy pain relief for first 7 days post surgery. The demographic data and duration of surgery were similar in both the groups. Patients who were in Aloe vera group showed significantly reduced pain scores at the end of 48 hrs , day 3 , day 7 post haemorrhoidectomy.(p value<0.0001)

Total analgesic requirement also significantly reduced in Aloe vera group as compared with 2 % xylocaine jelly with p value of <0.0001.

So, we believe that peri anal application of Aloe vera post haemorrhoidectomy is more effective than 2% xylocaine jelly in controlling post operative pain. Hence we recommend its use as a part of standard post haemorrhoidectomy care for open haemorrhoidectomy.

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ANNEXURE I

INFORMED CONSENT

Mr / Mrs / Miss _____ we are requesting you to enrol yourself in study entitled, "**A PROSPECTIVE RANDOMIZED OPEN LABEL TRIAL TO COMPARE EFFECTS OF CREAM CONTAINING ALOE VERA VERSUS 2% XYLOCAINE JELLY ON POST HEMORRHOIDECTOMY PAIN"** is being conducted by Dr. _____, post graduate in Surgery at Jawaharlal Nehru Medical College. Under guidance of Dr. _____, Department of Surgery, Jawaharlal Nehru Medical College, under KLE University.

Respected Sir/Madam, we request you to enrol yourself to participate in our study as you are eligible for participating in this study. During the study you will be asked some questions regarding your present complaints and your are suppose to answer to the best of your knowledge.

Your participation in research is voluntary. If you decide to participate you are free to withdraw at any time.

The purpose of research is to compare the effects of cream containing Aloe vera versus 2% xylocaine jelly on post haemorrhoidectomy pain.

Procedure involved

If you agree to enrol yourself in my study, you will be interviewed regarding your present, past and family history then you will be clinically examined in detail and investigated accordingly. You will be randomly allocated either into study Group

A or Group B, if you are in Group A you will receive Aloe vera gel immediately after surgery and if you are in group B you will receive 2% xylocaine jelly.

Benefits and Risks

The benefits of taking part in this research are you will have reduced post operative pain and post defecation pain after surgery. The no observable risks associated with this study.

Voluntary participation / Withdrawal

Taking part in the study is voluntary. You may choose not to enrol yourself in this study. Your decision will not change present or future health care services offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre.

Alternatives

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and confidentiality

The only people to know that you are a research subject are members of the research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Authorization to Publish Results

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for participation

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation

In the event of injury, related to the study, treatment will be made available at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. There is compensation or payment for such medical treatment by law.

Questions/Contact details

If you have any queries about your rights as a study subject, you may call Dr. _____, Principal and Chairman, J. N. Medical College Institutional Ethical Committee for Human Subjects Research, Ph. 0831-2473777 at J. N. Medical College.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY:

I,Mr./Mrs._____

voluntarily agrees to take part in this study, by signing this consent form I am not giving up my legal rights. I may withdraw at any time. I am signing after having read, or been read to me in the vernacular language including risks and the benefits and having all queries cleared.

Subject Name: _____

Signature of the participant _____ Date _____

Or Left thumb print

Witness name: _____

Signature: _____ Date _____

Investigator's name: _____

Signature: _____ Date _____

Place: _____

ANNEXURE - II

PROFORMA

STUDY: A PROSPECTIVE RANDOMIZED OPEN LABEL TRIAL TO COMPARE EFFECTS OF CREAM CONTAINING ALOE VERA VERSUS 2% XYLOCAINE JELLY ON POST HEMORRHOIDECTOMY PAIN

PATIENT DETAILS

Name : IP No :

Sex : Age :

Date of admission :

Address :

HISTORY:-

Chief Complaints

Bleeding per rectum : Colour :

Duration: Associated with defecation:

Pain during defecation: Mass per rectum:

Reducibility Manually:

Spontaneously: H/o constipation:

EXAMINATION

General Examination

Built and Nourishment: ***Weight:***

Pallor/Icterus/Cyanosis/Clubbing/Edema/Lymphadenopathy

Vitals

Pulse Rate	:	/Min	B.P.	:	mm Hg
Temperature	:	^{0}F	R. R.	:	/Min

Systemic Examination

Respiratory :

Per Abdomen :

CVS :

CNS :

Local examination :

INVESTIGATIONS

Complete blood count

Random blood sugar

Blood urea.

Sr. Creatinine.

Bleeding time

Clotting time

Urine routine and microscopy

Chest X-ray

ECG

GROUP : Group A (or) Group B

OPERATION DETAILS

Date of surgery :

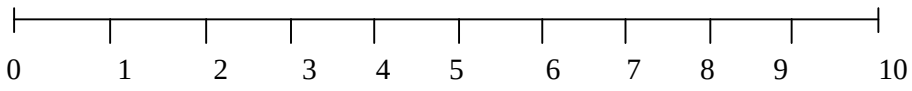
Name of Surgery :

Anaesthesia :

Duration of the surgery :

1. Assessment of postoperative pain Visual Analog Scale

On a scale of 0 – 10 0 – Least Pain 10 – Worst pain



12 hours :

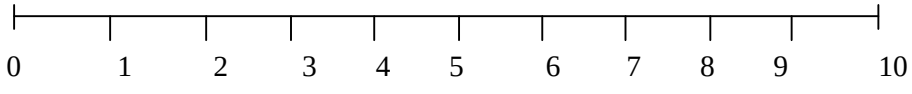
48 hours :

Day 3 :

Day 7 :

2. Assessment of post-defecation pain Visual Analog Scale

On a scale of 0 – 10 0 – Least Pain 10 – Worst pain



12 hours :

48 hours :

Day 3 :

Day 7 :

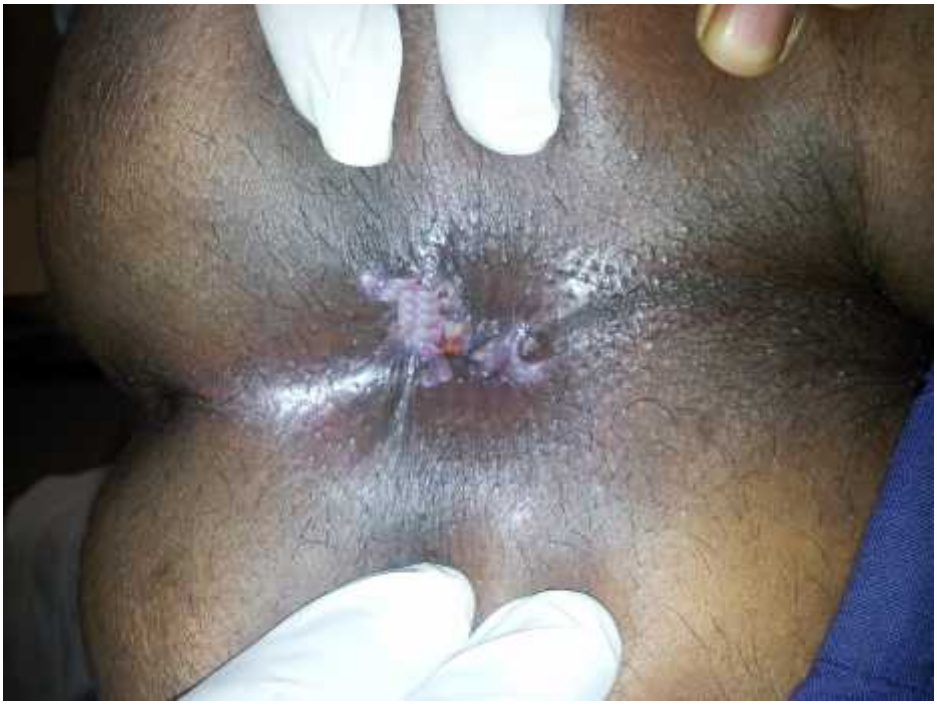
ANNEXURE – III

PHOTOGRAPHS

Photograph 1: Aloe vera cream

Photograph 2: 2 % xylocaine jelly

Photograph 3: Post operative Grade-4 Haemorrhoids



Photograph 4: Post operative Day 7

KEY TO MASTER CHART

IP No: Inpatient Number

Grd : Grade

Ext : External

Int : Internal

M : Male

F : Female

Y : Years

No : Number

Sr. No	IP No	Sex/ Age	Diagnosis	Post Haemorrhoidectomy Pain				Post- Defecation Pain				No. of doses of Analgesic given.				Total Dosage
				12 hrs	48 hrs	Day 3	Day 7	12 hrs	48 hrs	Day 3	Day 7	12 hrs	48 hrs	Day 3	Day 7	
AloeVera																
1	391216	48y/M	Grd 2 Int. Hemorrhoids	9	7	5	0	-	9	5	1	1	2	1	0	4
2	396142	46y/M	Grd 3 Int. Hemorrhoids	9	7	3	1	-	8	4	0	1	3	1	1	6
3	400505	40y/M	Grd 3 Ext. Hemorrhoids	9	7	3	0	-	9	5	0	1	2	2	0	5
4	402433	44y/M	Grd 3 Int-Ext. Hemorrhoids	8	6	3	0	-	9	4	1	1	1	2	0	4
5	402443	44y/M	Grd 3 Ext. Hemorrhoids	9	7	5	0	-	8	6	2	1	2	1	0	4
6	421612	42y/M	Grd 4 Ext. Hemorrhiods	9	7	5	0	-	7	4	0	2	2	1	1	6
7	403617	45y/M	Grd 3 Ext. Hemorrhoids	8	6	4	0	-	8	4	0	1	3	1	1	6
8	418178	49y/M	Grd 3 Int. Hemorrhoids	9	7	3	0	-	9	5	1	1	2	2	0	5
9	446412	48y/M	Grd 3 Int. Hemorrhoids	8	6	6	2	-	8	5	0	1	2	1	1	5
10	401264	48y/M	Grd 3 Int. Hemorrhoids	9	7	6	2	-	9	6	0	1	2	2	0	6
11	426294	36y/M	Grd 3 Int-Ext. Hemorrhoids	8	6	5	1	-	9	5	1	1	2	2	0	5
12	427866	55y/M	Grd 3 Int. Hemorrhoids	8	6	4	0	-	8	4	1	1	2	2	0	5
13	432159	72y/M	Grd 3 Int. Hemorrhoids	9	6	4	0	-	9	6	0	1	2	2	1	6
14	445801	36y/F	Grd 3 Int-Ext. Hemorrhoids	8	6	4	0	-	8	5	0	1	2	2	0	5
15	449500	22y/M	Grd 2 Int. Hemorrhoids	9	7	5	1	-	7	4	0	1	2	2	0	5
16	450824	52y/M	Grd 3 Int. Hemorrhoids	8	5	3	0	-	8	4	1	1	2	2	1	6
17	456371	42y/M	Grd 4 Ext. Hemorrhoids	9	5	3	0	-	9	6	0	1	2	2	1	6
18	464874	60y/M	Grd 3 Int-Ext. Hemorrhoids	9	6	4	0	-	8	6	1	1	2	2	1	6
19	467809	45y/M	Grd 4 Ext. Hemorrhoids	8	5	3	1	-	8	5	0	1	3	2	1	6
20	479079	37y/M	Grd 2 Int. Hemorrhoids	9	7	4	0	-	8	5	0	1	2	2	0	5
21	473428	51y/F	Grd 3 Int. Hemorrhoids	9	6	4	0	-	9	6	0	1	2	2	0	5
22	486074	65y/M	Grd 3 Int. Hemorrhoids	9	6	3	0	-	8	5	0	1	2	1	0	4
23	482490	56y/F	Grd 4 Ext. Hemorrhoids	8	7	5	0	-	8	5	0	1	2	2	0	5
24	483561	48y/M	Grd 2 Int. Hemorrhoids	9	6	5	0	-	9	6	0	1	2	2	0	5
25	486183	52y/F	Grd 4 Ext. Hemorrhoids	8	6	4	0	-	8	5	0	1	2	2	0	5

Sr. No	IP No	Sex/ Age	Diagnosis	Visual Analogue Scale				Post- defecation Pain								
				12 hrs	48 hrs	Day 3	Day 7	12 hrs	48 hrs	Day 3	Day 7					
2% Xylocaine																
1	4E+05	40y/M	Grd 3 Ext. Hemorrhoids	9	7	6	0	-	9	6	2	1	2	3	2	8
2	4E+05	24y/M	Grd 3 Ext. Hemorrhoids	9	7	5	0	-	9	7	2	1	2	2	2	7
3	4E+05	36y/M	Grd 2 Int. Hemorrhoids	9	8	6	2	-	8	6	2	1	3	2	1	7
4	4E+05	54y/M	Grd 3 Int. Hemorrhoids	9	8	6	2	-	9	6	1	1	2	2	2	7
5	4E+05	63y/M	Grd 3 Int. Hemorrhoids	9	7	7	2	-	9	7	2	1	3	2	2	7
6	4E+05	54y/M	Grd 3 Int.l Hemorrhoids	8	6	5	0	-	8	6	1	1	2	2	1	6
7	4E+05	71y/M	Grd 3 Ext. Hemorrhoids	9	7	5	2	-	9	7	2	1	3	3	1	8
8	4E+05	35y/M	Grd 2 Int. Hemorrhoids	9	8	6	2	-	9	6	2	1	2	3	2	8
9	4E+05	46y/F	Grd 3 Int. Hemorrhoids	8	7	5	0	-	8	7	2	1	3	2	1	7
10	4E+05	43y/F	Grd 3 Ext. Hemorrhoids	9	7	5	2	-	9	7	3	1	3	2	2	8
11	4E+05	53y/F	Grd 3 Int. Hemorrhoids	9	8	4	0	-	9	6	4	1	3	2	1	7
12	4E+05	32y/M	Grd 3 Int-Ext. Hemorrhoids	9	7	5	2	-	9	7	2	1	2	2	2	7
13	4E+05	50y/F	Grd 3 Ext. Hemorrhoids	9	8	6	2	-	9	7	3	1	2	3	1	7
14	5E+05	32y/M	Grd 3 Ext. Hemorrhoids	8	7	6	2	-	9	7	3	1	2	3	2	8
15	5E+05	60y/M	Grd 2 Int. Hemorrhoids	9	7	7	2	-	9	7	2	1	3	2	2	8
16	5E+05	45y/F	Grd 3 Int-Ext. Hemorrhoids	9	8	6	2	-	9	7	2	1	2	3	2	8
17	5E+05	51y/M	Grd 2 Int. Hemorrhoids	9	7	6	2	-	9	6	3	1	3	2	1	7
18	5E+05	45y/F	Grd 2 Int. Hemorrhoids	9	7	7	2	-	9	7	3	1	3	3	2	9
19	5E+05	39y/M	Grd 3 Int-Ext. Hemorrhoids	9	7	6	3	-	9	7	3	1	3	2	2	8
20	5E+05	52y/M	Grd 3 Int. Hemorrhoids	9	8	6	3	-	9	7	3	1	2	3	2	8
21	5E+05	49y/M	Grd 4 Ext. Hemorrhoids	8	6	6	2	-	8	6	4	1	3	2	2	8
22	5E+05	42y/F	Grd 3 Int. Hemorrhoids	9	7	6	3	-	9	7	3	1	2	3	2	8
23	5E+05	39y/F	Grd 2 Int. Hemorrhoids	9	7	6	2	-	9	7	2	1	3	2	2	8
24	5E+05	38Y/M	Grd 3 Int. Hemorrhoids	9	8	6	3	-	9	8	3	1	2	3	2	8
25	5E+05	42y/M	Grd 3 Int-Ext. Hemorrhoids	9	8	7	3	-	9	7	4	1	3	2	2	8