

**Prospective Study Comparing The Efficacy Of Cyanoacrylate Glue Injection
Versus Conventional Fistulectomy In Management Of Patients With Fistula
In Ano
by**

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LIST OF ABBREVIATIONS

- DM - DIABETES MELLITUS
- HTN - HYPERTENSION
- HIV - HUMAN IMMUNO DEFICIENCY VIRUS
- AIDS - ACQUIRED IMMUNE DEFICIENCY SYNDROME
- VAS - VISUAL ANALOGUE SCALE
- NO - NUMBER
- CM - CENTIMETRE
- FIG. - FIGURE
- RBS - RANDOM BLOOD SUGAR
- WBC - WHITE BLOOD CELL COUNT
- ESR - ERYTHROCYTE SEDIMENTATION RATE
- FBS - FASTING BLOOD SUGAR
- PPBS - POST PRANDIAL BLOOD SUGAR
- SIS - SMALL INTESTINAL SUBMUCOSA
- MSC – MESENCHYMAL STEM CELLS
- LIFT - LIGATION OF INTERSPHINCTERIC FISTULA TRACT
- VAAFT - VIDEO ASSISTED ANAL FISTULA TREATMENT
- GROUP A : CYANOACRYLATE GLUE INJECTION
- GROUP B : FISTUECTOMY

ABSTRACT

BACKGROUND :

Fistula in ano is amongst one of the earliest lesions to be recognized. It is accepted that majority of them occur due to suppuration of anal glands which open into the anal crypts. Fistula-in-Ano is the most common and an intriguing problem of the Ano-rectal region in general population. Cyanoacrylate glue injection for fistula in ano is beneficial as one of the modalities of treatment with respect to ease of applicability, cost effectiveness, less pain, sparing of sphincters, early recovery and low complications compared to conventional procedures like fistulectomy.

OBJECTIVES: To compare the efficacy of cyanoacrylate glue versus conventional fistulectomy in patients with fistula in ano with respect to

- Post operative Pain
- Perianal wound/scar
- Duration of hospital stay
- Maintenance of continence
- Recurrence of fistula at 6 months follow-up time
- Cost effectiveness of the procedure

MATERIAL AND METHODS:

Patients admitted with fistula in ano were allocated to study group (Cyanoacrylate glue injection) and control group (Fistulectomy) alternatively.

- Detailed history was taken, thorough clinical examination was done and relevant investigations were performed for all the patients in both the study and control groups.
- A Proforma was used to collect all the relevant data from the patients both preoperatively and post operatively.

- All cases were followed up to discharge and subsequently at 1st month, 3rd month and 6th month.

RESULTS: Mean age for fistula in ano was found to be 35.8years , male is to female ratio is 2:1 , Intersphincteric fistula is most common type of fistula,,there is significant difference between mean pain score in patient treated with glue injection (1.3)and those treated with fistulectomy(6.4).No complication was seen in patients treated with cyanoacrylate glue injection where as patients treated with fistulectomy had complications.Success rate of both procedures is about 90.2%.

CONCLUSION: Given its safety profile ,ease of application ,simplicity ,less postoperative pain, reduced duration of hospital stay, early recovery , low complication rate and post operative morbidity cyanoacrylate glue injection should be considered in the management of fistula in ano and is better than fistulectomy in these aspects.

KEYWORDS: Fistulectomy , Fistula in Ano, Cyanoacrylate glue

CONTENTS

Particulars	Page no
1. Introduction.....	1
2. Aims and Objectives.....	3
3. Review of Literature.....	5
4. Materials and Methods.....	48
5. Results.....	54
6. Discussion.....	75
7. Summary.....	78
8. Conclusion	79
9. Bibliography.....	80
10. Annexures	
a) Consent Form.....	85
b) Proforma.....	91
c) Master Chart.....	97

LIST OF TABLES

SERIAL NO	PARTICULARS	PAGE NO
1.	DISTRIBUTION OF AGE BETWEEN STUDY GROUPS	54
2.	MEAN AGE BETWEEN STUDY GROUPS	55
3.	DISTRIBUTION OF SEX BETWEEN STUDY GROUPS	56
4.	DISTRIBUTION OF OCCUPATION BETWEEN STUDY GROUPS	57
5.	MEAN PARAMETERS BETWEEN STUDY GROUPS	58
6.	PRESENCE OF PAIN AS SYMPTOM BETWEEN STUDY GROUPS	59
7.	POST OPERATIVE COMPLICATIONS	60
8.	TYPE OF FISTULA BETWEEN STUDY GROUPS	61
9.	HISTORY OF PREVIOUS SURGERY BETWEEN THE STUDY GROUPS	62
10.	TYPE OF FISTULA BASED ON MRI BETWEEN TWO GROUPS	63
11.	TYPE OF ANAL FISTULA BETWEEN STUDY GROUPS BASED ON CLINICAL EXAMINATION	64
12.	DISTRIBUTION OF POST OPERATIVE PAIN SCORE BETWEEN STUDY GROUP BASED ON VAS	65
13.	MEAN POSTOPERATIVE PAIN SCORE BETWEEN STUDY GROUPS	66
14.	INCONTINENCE BETWEEN STUDY GROUPS	67
15.	RECCURENCE RATE AT SIX MONTHS FOLLOW UP	68

LIST OF GRAPHS

SERIAL NO	PARTICULARS	PAGE NO
1.	DISTRIBUTION OF AGE BETWEEN STUDY GROUPS	54
2.	MEAN AGE BETWEEN STUDY GROUPS	55
3.	DISTRIBUTION OF SEX BETWEEN STUDY GROUPS	56
4.	DISTRIBUTION OF OCCUPATION BETWEEN STUDY GROUPS	57
5.	MEAN PARAMETERS BETWEEN STUDY GROUPS	58
6.	PRESENCE OF PAIN AS SYMPTOM BETWEEN STUDY GROUPS	59
7.	POST OPERATIVE COMPLICATIONS	60
8.	TYPE OF FISTULA BETWEEN STUDY GROUPS	61
9.	HISTORY OF PREVIOUS SURGERY BETWEEN THE STUDY GROUPS	62
10.	TYPE OF FISTULA BASED ON MRI BETWEEN TWO GROUPS	63
11.	TYPE OF ANAL FISTULA BETWEEN STUDY GROUPS BASED ON CLINICAL EXAMINATION	64
12.	DISTRIBUTION OF POST OPERATIVE PAIN SCORE BETWEEN STUDY GROUP BASED ON VAS	65
13.	MEAN POSTOPERATIVE PAIN SCORE BETWEEN STUDY GROUPS	66
14.	INCONTINENCE BETWEEN STUDY GROUPS	67
15.	RECCURENCE RATE AT SIX MONTHS FOLLOW UP	68

LIST OF PHOTOGRAPHS

FIGURE	IMAGE	PAGE NO
1	Le Bistouri ala Royale instrument used in ancient times to treat Anal fistula	5
2	Anatomy of Anal canal and rectum	11
3	The lining of Anal canal	12
4	Distil Rectum and Anal canal	12
5	Arterial supply of Rectum and Anal canal	18
6	Venous and lymphatic drainage of Anal canal	19
7	Nerve supply of rectum and anal canal	20
8	Cryptoglandular infections and abscess	22
9	Classification of Anal Fistula described by Park	27
10	Goodsall's Rule	29
11	Histopathology image of fistula tract	33
12	X – Ray Fistulogram	69
13	MRI Fistulogram	70
14	Image showing figure of 8 closure of internal opening	71
15	Image showing injection of cyanoacrylate glue into the fistulous tract	72
16	Post operative image following glue injection	73
17	Post operative image following fistulectomy	74

INTRODUCTION

Fistula in Ano was amongst the earliest disease to be recognized. It is generally accepted that the majority of them follow suppuration of glands which are present within the crypts of anal mucosa.¹

Fistula-in-Ano is the most common and an intriguing problem of the Ano-rectal region in general population. The patient's first visit, accurate initial surgical treatment plays an important role in healing of the fistulous tract. The accurate identification of the internal opening and the identification of possible chronic abscesses or secondary tracks are universally considered the keys for successful treatment of fistula in ano. Fistula-in-Ano is a disease which can be to a extent prevented provided the perianal – perirectal suppurations are treated timely and in a appropriate manner. The location of the diseased part makes the patient refrain from early consultation. The common pathogenesis associated with this disease is the bursting open of an acute or inadequately treated abscess involving anal canal and rectum and spaces surrounding the anal canal and rectum into the skin of the perianal region.²

The chronicity of the disease process with its annoying symptoms like soiling of the under garments, itching, repeated abscess formation, discharge makes an otherwise healthy and active person lose their earning capacity, with lowered self-esteem.

Combating Anal fistulas meticulously is a difficult task for surgeons and dealing with the disease process and its chronicity is very frustrating for both surgeons and patients. Fistulectomy is one of the standard procedure practiced since ages for treatment of fistula in ano and it is to this procedure that any new management procedure invented should be compared. Though the variety of procedures have been explained in treatment of anal fistulas it is also important to note whether the procedure adds to any impairment in continence⁶⁷. Recently array of methodologies are followed in the management of fistula in ano, but none of them are free from complications such as delayed wound healing, extensive perianal wounds /scar, incontinence, recurrence.³

Conventional fistulectomy is done for most simple anal fistulae and has low recurrence and agreeable morbidity. However, complications such as scar and incontinence have always posed a significant problem to the patient. On the other hand complex anal fistulae treated with conventional fistulectomy and with cutting seton placement was associated with significant discomfort from seton placement and an increased risk of incontinence and abscess formation.⁴

Ardis in 1949 for the first time discovered the chemical 'Cyanoacrylate'. But it was applied in Surgery for the first time by Coover in the year 1959. Few years later researchers developed a

non toxic form of cyanoacrylate known as 'N-butyl-2-cyanoacrylate, which has ability to glue even in wet environments.

When cyanoacrylate comes in contact with wet surfaces it breaks down into cyanoacetate and formaldehyde which is an exothermic reaction⁶⁸

Various types of Cyanoacrylate include methyl cyanoacrylate, ethyl cyanoacrylate, butyl and isobutyl cyanoacrylate which differ from each other with respect to the length of their lateral chain. It is said that more is the length of side chain, more rapidly it degrades and more are the adverse effects. Methyl cyanoacrylate glue has got largest side chain and has got highest toxicity such as edema and necrosis of tissue and hence is not available for clinical use. N butyl-2-cyanoacrylate, which acquires excellent tissue gluing properties, promotes faster healing, and is also bacteriostatic and haemostatic⁶⁸. It is recently being used in surgeries by orthopaedic surgeons⁶, ophthalmologists⁷, neurosurgeons⁸, urologists⁹ and endoscopists¹⁰ for varieties of surgical procedures.

Cyanoacrylate glue injection is simple, easy to use, cost effective, and repeatable. Hence we intend to find out the efficacy of cyanoacrylate glue injection as compared with conventional fistulectomy in cases of fistula in ano.

AIMS AND OBJECTIVES OF THE STUDY:

To compare the efficacy of cyanoacrylate glue versus conventional fistulectomy in patients with fistula in ano with respect to :-

- Post operative Pain
- Perianal wound/scar
- Duration of hospital stay
- Maintenance of continence
- Recurrence of of fistula at 6 months follow-up time
- Cost effectiveness of the procedure

RESEARCH HYPOTHESIS:

Cyanoacrylate glue injection for management of Anal fistula is a safe procedure and is equally effective in treating fistula in ano and preventing recurrences and spares sphincters and reduces post operative scarring as compared to conventional fistulectomy.

REVIEW OF LITERATURE

“Fistula” in latin term means a flute.. It means a tract which is lined by granulation tissue which connect two surfaces which are lined by epithelium.¹

The history of Fistula in Ano dates back past 2500 years.. The term ‘Fistula’ is was first given by John Arderne whole classical work on anal fistula is still in available in history¹

Hippocrates in around 460BC in Greece presented a paper on fistula in Ano. In his paper he described application of horsehair known as ‘**seta**’ for curing anal fistulas⁶⁷.

Sushruta (b~800BC) in his treatise Shushruta Samhita described both fistulotomy and fistulectomy and about the chemical seton using ‘**Kshara Sutra**’¹¹

Sushruta conducted surgeries on Anal fistulas , known as “**Salya tantra**”. Sushruta traced the source of origin of fistula in ano known as “**Murma**” to the abscess in the perianal region. He had various instruments in his armamentarium for the surgery on fistula in ano. Even though the details of fistula operation are not available in Egyptian medicine, the instrument which might have been used for the surgery of fistula-in ano, have been unearthed from the ruins of Pompeii. There are records to show that the surgery was carried out during the middle ages. The actual record available in the history of medicine for fistula in ano is during the 14th century.

In 1300 **John Ardene** was famous for his technique for operating anal fistulas . **King Louis XIV** had developed an anal fistula as declared officially by his court of physicians and surgeons and he was operated for the same on November 17 ,1686 by Charles Francois Felix by using his own instrument called “Le Bistouri ala Royale”.



Figure 1 Le Bistouri ala Royale instrument used to treat anal fistula

The king was operated successfully again on 10th December 1686 by the same surgeon. At a later stage the method of opening the fistula by cutting was replaced by a tight ligature which was passed along the tract with a strong silk in order to produce necrosis of the overlying tissue. Percival Pott (1714-88) worked in Bartholomew's hospital and produced a paper on fistula-in-ano in 1765.

In 1779, Sir Percival Pott advocated strongly with his vast experience, that simple incision of fistula in ano and careful dressing by packing the wound was better than tight ligature. Fredric Soloman modified this by adding another incision at the outer end of the wound in the form of "T". This is known as "Soloman's back cut". This was designed to prevent the premature healing of the wound.

In 1854 Sir Fredrick Salmon opened a Hospital specifically meant for treatment of Fistula in Ano known as St. Mark's Hospital for Fistula.

Goodsal and Miles (1900), Atwington (1901), Tuffer (1903) and Mummery (1934) contributed very much to the surgery for fistula-in-ano specifying the extent of sphincters that may be sacrificed without causing incontinence, which is one of the dreaded complication of fistula surgery.

More recently the methods of primary suture and skin grafting came into Existence. Hughes (1953-61) emphasized on primary or delayed primary grafting and claimed 80% success.¹²

. While performing Fistulectomy for Anal fistulas we put patient at varing risk of anal incontinence depending on the amount of external sphincter sacrificed during the procedure. Not only this this procedure also leaves a wound in perianal region to be taken care of till it heals and also puts patient into varying amount of discomfort and pain due to surgery. In order to combat all these shortcomings of the procedure researchers have been studying and evaluating different procedure for treatment of anal fistulas which avoid excising sphincters, less painful, early recovery and have got low recurrence rate.

Since then a variety of procedures have been developed for treatment of anal fistulas such as use of Fibrin sealant, application of Biologic and synthetic fistula plugs, Endorectal advancement flaps, dermal advancement flaps, LIFT, VAAFT, Stem cell application, which are being used as alternatives to fistulectomy with different success rates.

The ultimate aim in treating any case of Fistula in ano requires efficient healing, it should be less painful, it should spare the sphincters, providing early recovery from the surgery without complications and should have low recurrence rate. These objectives led evolution of minimally invasive approaches, one of them being use of cyanoacrylate glue in treatment of anorectal fistulae.

There are probably **three papers** reporting the efficiency of N-butyl cyanoacrylate glue in treatment of Fistula in Ano.

Barillari *et al.* managed patients with anal fistulas with cyanoacrylate glue injection .He studied it in 21 patients. Seven of these patients had simple anal fistula and 14 had complex anal fistula. They followed these patients for 18 months.At 18 months of follow up they obtained cure rate of 90.2%. No complications such as bleeding, abscess formation or fistula recurrence were observed in this study period.^{13,69}

Queralto *et al.* used Glubran-2 (N-butyl-2-cyanoacrylate and Metacrilosisolfolano)for treatment of high anal fistula. Their study included 34 patients. They followed patients at 1st month post procedure and at 3rd month and 6 months by direct physical examination. They again followed up patients at the end of one year and again after two years post procedure by phone contacts. At the end of one month follow up they obtained success rate of 67.6% with this procedure. At the end of two year follow up period none of them had any incontinence neither any recurrence of fistula^{14, 69}

Jain *et al.* managed patients with low anal fistulas by cyanoacrylate glue injection into the fistulous tract. He studied about 20 patients and followed them for six months. He obtained success rate of 85% with this procedure.^{15, 69}

Meinro and Mori have applied cyanoacrylate glue to strengthen closure of internal opening during VAAFT. From May 2006 till May2011 they operated on 136 patients using VAAFT, patients were followed up 6 months. Primary healing was achieved in 72 patients within 2 to 3 months of surgery. Cure rate at the end of one year was 87.1 % .¹⁶.

Cyanoacrylate glue is being used and has proved to be benefiaciale in many other surgeries in other branches.

Yilmaz *et al.* studied that in comminuted fractures cyanoacrylate glue provided sufficient rigidity for bone healing and was easy to apply. This glue did not affect the healing of the bone as compared to fixation done with K wiring after examination of biopsies from the healed bone. But due to the low viscosity of the glue posed a difficulty in adhering the osteotomy surfaces.⁶

A study done by **Sharma A *et al.*** found that fibrin glue and cyanoacrylate tissue adhesive were both effective in the closure of corneal perforations up to 3 mm in diameter. Fibrin glue provided faster healing, with less corneal vascularization, but required a significantly longer time for adhesive plug formation compared with cyanoacrylate glue.⁷

A neuro-endovascular study done by **Wakhloo AK *et al.*** found that cyanoacrylate glue infusion can be used as primary alternative or in addition to coil embolization for treatment of dural carotico cavernous fistula.⁸

Aslan G *et al.* used cyanoacrylate glue for closure of calyceal fistula following partial nephrectomy. Closure of calyceal fistula by conventional and endoscopic methods had been unsuccessful previously. This study concluded that usage of tissue adhesives can be useful in the management and prevention of persistent urinary leakage from calyceal fistula.⁹

Surgical Anatomy of the Anorectal Region

A complete knowledge of the anatomy of the rectum and anal canal is absolutely Necessary to understand the surgery of fistula-in-ano.

DEVELOPMENT OF ANAL CANAL AND RECTUM ¹⁷

The hindgut is formed from the secondary yolk sac as the result of the Development of the tail fold. It gives origin to the left third of transverse colon, the rectum, the upper part of the anal canal and to a considerable part of the genitourinary system. The part of the hindgut caudal to the allantois dilates to form a pouch termed as 'endodermal cloaca' and in its ventral wall the cloacal membrane is formed. Later the cloacal membrane comes to lie at the bottom of a shallow depression termed the 'Ectodermal cloaca'. The hindgut and allantois open into the endodermal cloaca. Its wall is pierced by mesonephric ducts in the fifth week of intrauterine life. After the development of urorectal septum the cloaca is divided into a dorsal segment which forms the rectum and a ventral segment which forms the urinary bladder and the urogenital sinus which are covered caudally by anal membrane and urogenital membrane, respectively. The lower part of the anal canal is formed from the proctodeum but its upper part is endodermal in origin. The line of union corresponds with the edges of the anal valves in the adult.¹⁸

RECTUM ¹⁹

The rectum begins from the recto sigmoid junction opposite 3rd sacral vertebra and ends 2 – 3 cms in front and below the tip of the coccyx. It bends backwards and slightly downwards all the way through the Levator ani to continue as anal canal almost 4 cms from the anal verge. It makes an angle of about 120 degrees with the anus with the convexity directed anteriorly due to pull of the puborectalis muscle sling. This is called carrying angle or anorectal angle.

CURVATURES

Though the term "Rectum" means straight, the rectum is straight only in infants. The rectum fits into the hollow of the sacrum forming the sacral curvature. In infants this curvature of the rectum is not developed. The rectum also has three curvatures towards the lateral aspect. The upper and lower curvature have convexity towards right where as the middle curvature has convexity towards the left.

INTERNAL STRUCTURES

Opposite lateral convexities of the rectum the mucosa shows prominent semicircular folds called the “Valves of Houston”. Two such valves are present on the left and one on the right side. The middle valve is most prominent and is called “Kohlrausch’s fold”. The middle third of the rectum just below the middle valve is quite wide and hence is referred as ‘Ampulla’.

PERITONIAL RELATIONS:

In adults the length of rectum ranges from 18 cms to about 20 cms . It is divided into upper, middle and lower thirds. The upper one third of the rectum has peritoneal lining on its anterior surface as well as on its lateral surface. The middle third has peritoneal lining only on anterior surface , while the lower third is devoid of any peritoneal covering. However the lower third of the rectum has two fascial condensations, anteriorly the fascia of “Denonvilliers” and posteriorly the fascia of “Waldeyer”. Denonvilliers fascia separates rectum from the prostate in front and Waldeyers fascia separates it from the coccyx and last two vertebra of sacrum. These fascial layers are tough and prevent infiltration of surrounding tissues in cases of malignancy and hence are important surgically. They are also of valuable guides during surgery.

RELATIONS

- Anteriorly the rectum is related to the bladder, ureter, prostate, seminal vesicle in males and uterus and vagina in females. Laterally it is allied to Ischiorectal fossa and levator ani.
- Posteriorly, it is related to S3, S4, S5 vertebrae, median sacral vessels and mesorectum.

FASCIA AROUND RECTUM

The parietal layer of pelvic fascia is condensed laterally, attaching the rectum to the 3rd piece of the sacrum. This is called the lateral ligament of the rectum. The visceral layer of pelvic fascia investing the rectum is called the fascia propria.

ANAL CANAL ^{19, 20}

The anal canal (Milligan et al 1937, Gabriel 1945, Wilde 1949, Goligher et al 1955, Fowler 1957) commences when the widened portion of rectum the ampulla , suddenly narrows, and traverses down and backwards to form the anal canal. It is about 4 cms long in adults, its anterior wall being slightly shorter than its posterior. When empty its lumen is a sagittal or triradiate longitudinal slit.

- Posteriorly: The canal is separated from the tip of the coccyx by fibro fatty and muscle tissue known as coccygeal ligament.
- Anteriorly : It is separated by the perineal body from the membranous urethra and penile bulb or from the lower vagina. Laterally are the ischiorectal fossae and over its whole length it is surrounded by sphincters which normally keep it closed.

Fig. 2.1 Overview of the pelvic floor muscles and anal sphincters seen from below

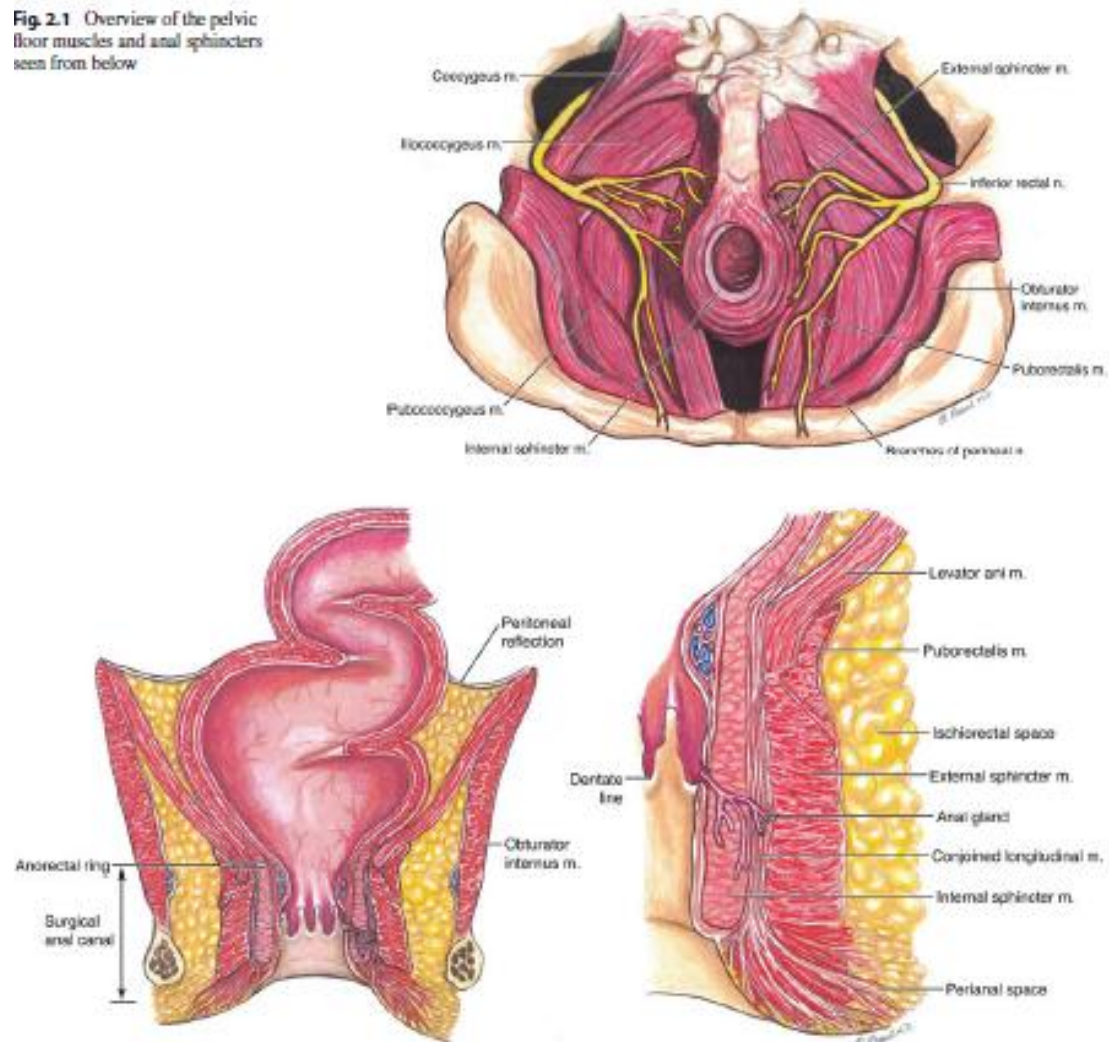


Figure 2. Gross Anatomy of Anal canal and Rectum

THE MUCOSAL LINING OF ANAL CANAL ²¹

The mucosa of the lower part of the rectum is pale pink and semitransparent, the branching pattern of the superior rectal vessels being visible through it. The upper half(15mm) of the canal is also lined by mucosa, plum red in colour due to blood in the subjacent internal rectal venous plexus.

The epithelium is variable in the upper part, it is similar to that of the rectum, consisting of simple columnar cells, some secretory and other absorptive, with numerous tubular glands or crypts. In the lower half, this gives way to non-keratinized stratified squamous

epithelium, finally merging with the keratinized stratified squamous epithelium of perianal epidermis.

In this part of the canal, there six to ten vertical folds, the anal columns, well marked in children but sometimes less defined in adults. Each column contains a terminal radical of the superior rectal artery and vein, these radicals being largest in the left lateral, right posterior and right anterior quadrants of the wall of the canal. Enlargements of venous radicles in these three sites constitute primary internal haemorrhoids. The lower ends of the columns are linked by small crescentic mucous folds, and valves, above each of which is a small recess or anal sinus. The anal canal extends about 15mm below the anal valves as the transitional zone, whose epithelium is non-keratinized stratified squamous epithelium.

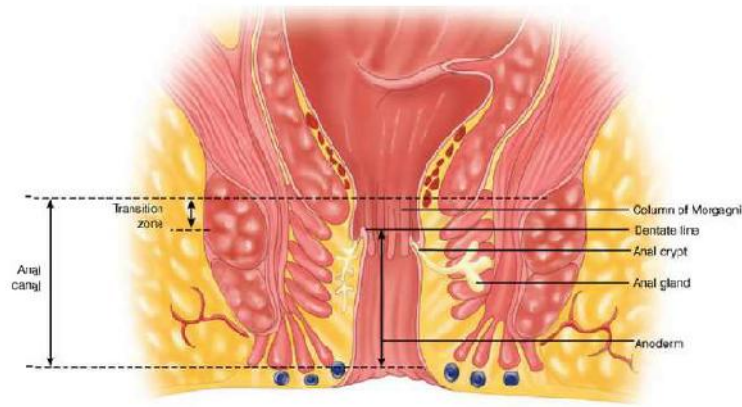


Fig 3 The lining of Anal canal

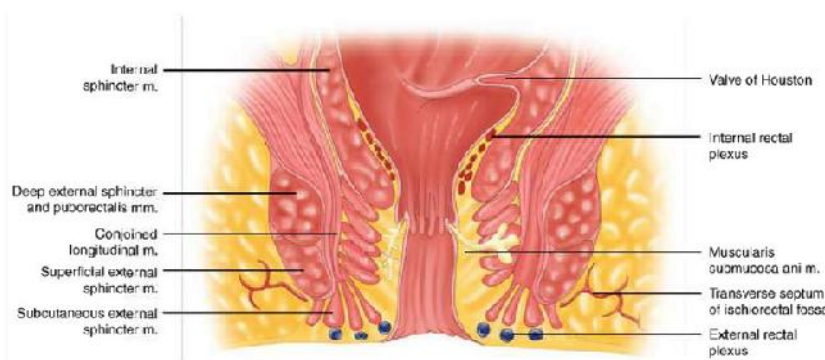


Figure 4 Distil Rectum And Anal Canal

THE DENTATE LINE: - SURGICAL IMPORTANCE

Dentate line is a very important land mark.

- It acts as embryological watershed. Above this line are visceral structures above and below are somatic structures .
- The mucosa above the dentate line is insensitive to pain as it has nerve supply from autonomic nervous system where as skin below the dentate line is sensitive to pain as it has got nerve supply from somatic nervous system.
- The mucosa above this line of dentate is drained by the inferior mesenteric and portal circulation where as below this line the mucosa is drained by the systemic veins.
- The lymphatic drainage above the dentate line is upwards as that of rectum. Below the dentate line lymphatics drain into the inguinal group of lymph nodes. Its significance lies in spread of malignancy from these regions.
- Internal haemorrhoids develop just above this line.
- The anal glands open into sinuses at the anal valves at this level. Any suppuration of these anal glands results in formation of anal abscess which may extend into the spaces surrounding rectum and anal canal
- . Stimulation of nerve endings in the region of the dentate line may initiate reflex changes in sphincter tone.

ANAL VALVES OF BALL:

Transversely placed folds of mucous membrane which link the Columns of Morgagni to one another are known as anal valves. They are responsible for waviness of the dentate line. They represent remnants of fusion of post-allantotic gut with the proctodeum.

ANAL CRYPTS OF MORGAGNI²²

These crypts are placed in the anal columns as small pockets. The anal glands open into the crypts mostly those situated posteriorly by a narrow duct. The duct bifurcates and the branches pass outwards to enter the internal sphincter muscle in 60% of people. Issuing from the ampulla, there are 3-6 tubular sub-branches that extend into the intramuscular connective tissue where they end blindly. Infection of an anal gland can give rise to an abscess and they may also be site of origin of adenocarcinoma according to Dukes and Galvin.

MUSCLES OF ANAL CANAL

Sphincter Ani Internal

It is continuation of inner circular muscle layer of the rectum. It is involuntary. It commences as the rectum passes through the pelvic diaphragm and ends at the anal orifice, it is at this location where its lower border can be felt. It is about 2.5cm in length and 2.5 mm in thickness. It appears pearly white in colour. Spasm and contracture of this muscle occurs in fissure and other anal infections. Internal anal sphincter is under control of the autonomic nervous system. It is partly muscular and partly fibrous, it extends downwards to end as fibrous band traversing via peri-anal fatty tissue and lower part of sphincter Ani externus, and gets attached to the skin.

Sphincter Ani Externus

Sphincter ani externus surrounds the whole anal canal, it is usually described as consisting of three parts, all composed of skeletal muscle. These are the subcutaneous, the superficial and the deep portions.

Subcutaneous part

The subcutaneous part is a flat band, about 15mm, broad, around the lower anal canal and lies horizontally below the lower borders of the internal sphincter and superficial part of the external sphincter. It lies beneath the skin at the anal orifice and is inferior to the Dentate line.

Superficial part

Is elliptical and superior to the subcutaneous, it is the only part attached to bone, arising from the posterior surface of the terminal coccygeal segment by the median anococcygeal raphe. Anteriorly it surrounds the lower part of the internal sphincter and is chiefly attached to the perineal body.

Deep part:

The deep part is a thick annular band around the upper part of the internal sphincter; its deeper fibers blend inseparably with the puborectalis. Anterior to the anal canal many fibers decussate into the superficial transverse perineal muscles, especially in females. Some posterior fibers are usually attached to the ano coccygeal raphe. The external sphincter can voluntarily contract to occlude the anus firmly. Nerve supply is derived from the inferior rectal branch of the pudendal nerve (S2 and S3) and the perineal branch of the fourth sacral nerve.

Levator ani muscle

A transverse line at the level of the ischial tuberosity, divides the diamond shaped perineum into an anterior urogenital triangle and posterior anal triangle.

The levator ani muscle is the chief muscle of the anal triangle and forms the pelvic diaphragm. It consists of 3 parts namely, the pubo coccygeus, arising from the back of the pubis, the Iliococcygeus, arising from the back of the ilium and the coccygeus arising from the ischium. All groups insert into the anococcygeal body and coccyx bone. Of these the puborectalis is the most important muscle and is the inner most part of pubococcygeus muscle. It forms a sling at the anorectal junction and can be palpated along with the sphincteric muscles as per rectal examination, as the ano rectal ring.

Ano Rectal Ring ²²

It demarcates the intersection between the ano-Rectum. The puborectalis, external sphincter, conjoined longitudinal muscle and internal sphincter together fuse to form the ano rectal ring. It is palpable in the anal canal. The ring is more strengthened in posterior aspect than and lateral, and anteriorly. It can be clearly felt digitally especially in its posterior and lateral aspects. Inadvertent division of this ring during surgery results in permanent anal incontinence.

SPACES IN RELATION TO ANAL CANAL ²³

Perinanal Space

It contains finely lobulated fat. Laterally it becomes continuous with the subcutaneous fat of the buttocks. Medially it may be considered as extending into the lower part of the anal canal where it is lined by modified skin probably as far proximally as the site of Parks mucosal suspensory ligament. The space may also be said to contain the lower part of external sphincter.

Subcutaneous Space

This space lies between the internal sphincter and the mucocutaneous lining of the proximal two-thirds of the anal canal. Below, it probably extends down to the level of Park's mucosal suspensory ligament and above it becomes continuous with the sub mucous layer of the rectum. It contains internal haemorrhoidal plexus and related terminal branches of the superior haemorrhoidal artery.

Pelvi Rectal Space:

There lies a potential space between the pelvic peritoneal floor and the levator ani partly on either side of the rectum. This space is filled with loose connective tissue. The pelvi-rectal space communicates with the Ischio rectal space through the hiatus of Schwalbe which is a gap in the attachment of the levator ani to the obturator internus fascia laterally.

Ischiorectal Fossa:

This is a wedge shaped space filled with fibrous fat lying on either sides of lower part of rectum and anal canal. The fossae communicate with each other behind the anal canal. The fossa is pyramidal in shape. It is 5cm deep and 2.5cm wide.

Boundaries:

- Laterally: The fascia covering the obturator internus muscles and the ischial tuberosity.
- Medially: The fascia covering the levator ani muscle; the external sphincter of the anus.
- Posteriorly: Sacrotuberous ligament, on the posterior surface of which is the gluteus maximus muscle.
- Anteriorly: Urogenital diaphragm. Under the skin is a large pad of fat filling the fossa. Here there is no deep fascia such as exists elsewhere just under the skin. The deep fascia is separated from the skin by the whole thickness of the pad of fat filling the fossa. This fascia is named the 'Fascia lunata'. The two ischiorectal fossae communicate with each other behind the anal canal, below the levator ani and above the external sphincter by the retro sphincteric space of Courtney. Hence infection from one ischiorectal space can spread to the other, to form a horse shoe abscess or fistula. A thin transverse fascia at the level of the white line of Hilton, divides ischiorectal fossae into an ischiorectal space superiorly, forming upper 2/3, filled and the perianal space below.

FASCIA LUNATA

Relations

- Medially: It covers the fascia on the levator (anal fascia) and ends at the lower end of the levator.
- Laterally: Covers fascia on obturator internus (obturator fascia) and is attached to the ischium. The internal pudendal vessels and nerves are between these two layers which form the pudendal canal.
- Anteriorly: The fascia fuses with the urogenital diaphragm.
- Superiorly: The upper arched portion of the fascia is called the tegmentum. There is a space between this tegmentum and the apex of the fossa, which is the suprategmental space and contains fat.

THE PUDENDAL CANAL

The pudendal canal runs forwards on the lateral wall of the fossa 3-8cm above the lower border of the ischial tuberosity, leading from the lesser sciatic foramen posteriorly to the perineal membrane anteriorly. It contains the internal pudendal vessels and pudendal nerve. The artery

gives the inferior rectal branch at the posterior part of the canal and the perineal branch at the anterior end.

ARTERIAL SUPPLY OF RECTUM

Superior Rectal Artery

Main arterial supply to the rectum is from superior rectal artery. It is continuation of inferior mesenteric artery. At the level of 3rd sacral vertebra it divides into right and left branches. The right branch again divides into an anterior and a posterior branch about half way down the rectum. Each column of Morgagni within the anal canal receives terminal branches from the superior rectal artery. At the level of internal sphincter this artery anastomoses with branches of middle and inferior rectal arteries.

Inferior Rectal Artery

This is a branch of internal pudendal artery. It crosses the upper part of the ischiorectal fossa. Its branches supply sphincter ani externi, sphincter ani interni, anal canal and anoderm.

Middle Rectal Artery

This is a branch of internal iliac artery, which runs in close proximity to the lateral ligament of the mid rectum. This supplies the lower rectum and the upper anal canal.

Middle Sacral Artery

It is a small vessel arising from the back of the aorta just above the bifurcation. The branches of it supply the posterior surface of the rectum (anorectal junction and anal canal). An additional source of blood supply to the lower rectum may be from branches of internal pudendal artery that ramify in the pubococcygeus and transverse perineal muscle.

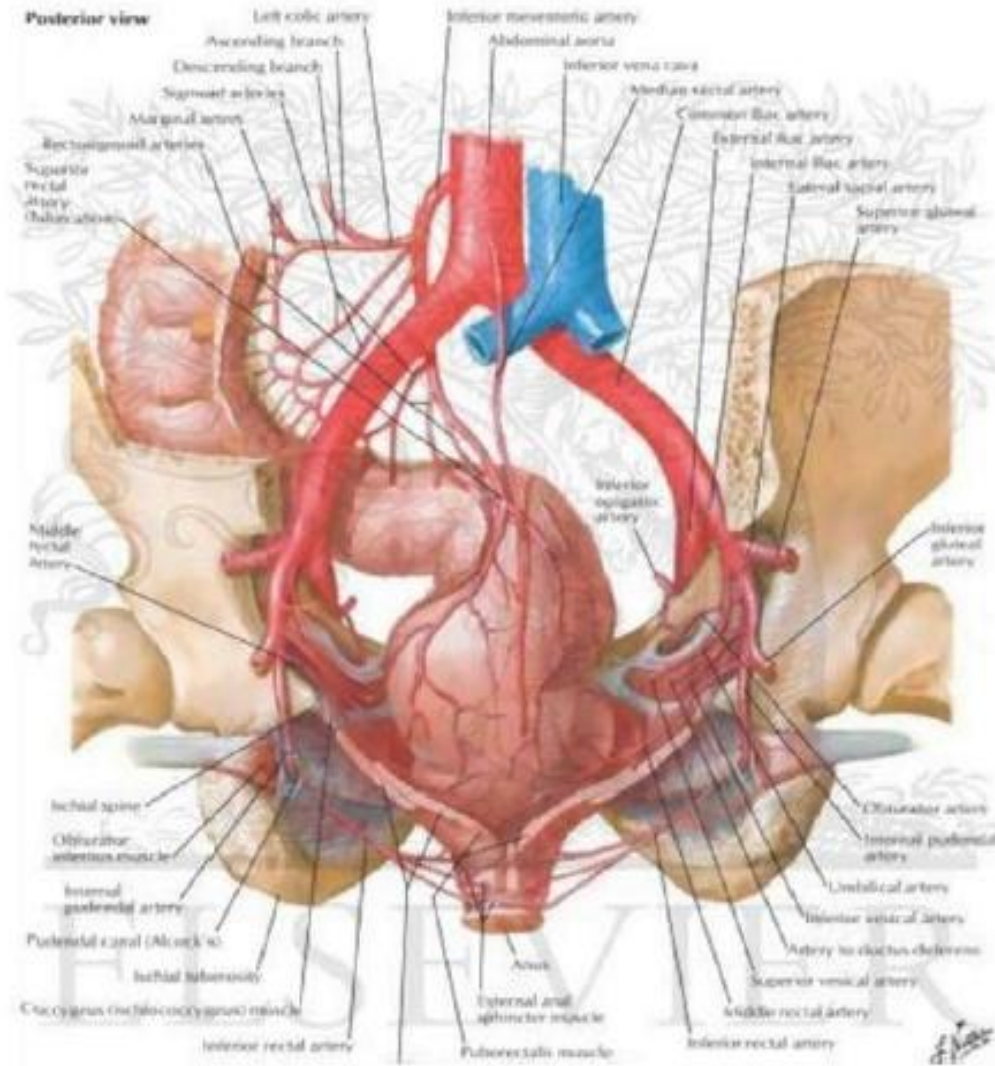


Figure 5 Arterial Supply of Rectum and Anal canal

VENOUS DRAINAGE OF THE RECTUM AND ANAL CANAL

Internal Rectal Plexus Of Veins

These venous plexus begin from line of dentate and extend till anorectal ring. These inturn drain into veins situated within the sub mucosal layer of the rectum. The tributaries penetrate the rectal wall and join outside to form superior rectal vein which in turn finally drains into the portal system of veins. The internal iliac veins are the one which receive middle rectal veins.

External Rectal Plexus of Veins

External plexus of veins are located below the dentate line within the skin of anal margin. These plexus communicate with the internal rectal plexus beneath the endoderm through communicating veins. The internal iliac veins and the internal pudendal veins drains the lower region of the plexus, These veins form part of portosystemic anastomosis.

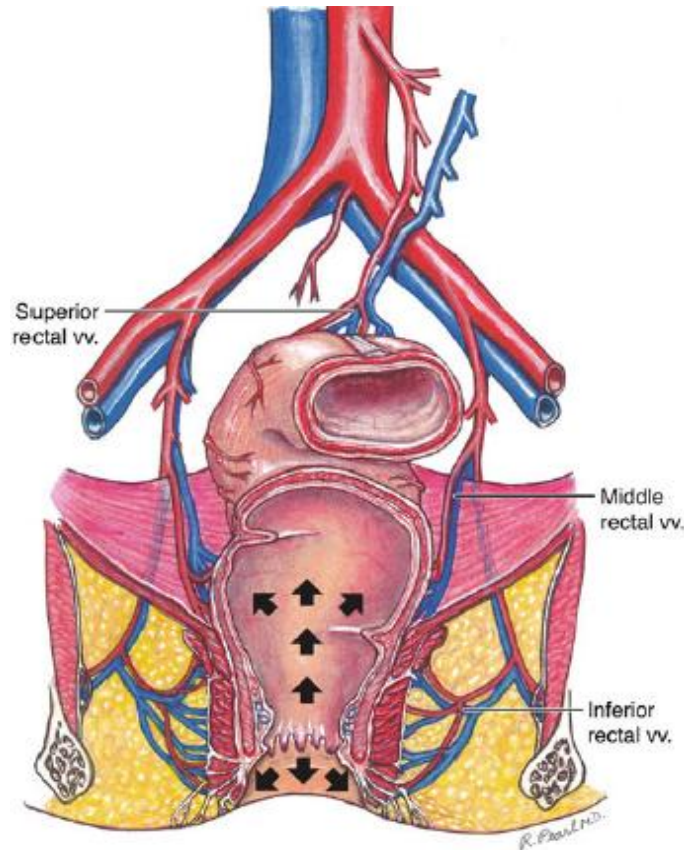


Figure 6 Venous and Lymphatic drainage of anal canal and rectum

Lymphatic Drainage of the Rectum and the Canal:

The lymphatic of the mucocutaneous lining and that of the muscle coats intercommunicate freely. There are three main sets of lymph nodes:

1. Superior Rectal Lymph nodes

These nodes lie close to the superior rectal vessels. The lymph nodes placed close to the rectal wall, in the region of ampulla, just above the levator ani muscle are also known by name lymph nodes of Gerota.

2. Middle Rectal Lymph nodes

These are in relation to the middle rectal vessels and lie in the lateral ligament of the rectum. From here they pass to the lymph nodes around the internal iliac vessels.

3. Inguinal Lymph nodes

This group receives the lymphatics from lower portion of the anal canal.

NERVE SUPPLY

The nerve supply of the rectum is derived from both the parts of the autonomic nervous system. The sphincter ani internus receives the sympathetic and parasympathetic of which the previous is motor and the latter is inhibitory to the sphincter. Sympathetic are derived by the way of superior and inferior hypogastric plexus and the parasympathetic is from the sacral outflow via inferior hypogastric plexus. The external sphincter has two sources of supply on either side from the inferior haemorrhoidal branches of internal pudendal nerve and perineal branches of the fourth sacral nerve. The levator ani muscles are supplied by fourth sacral nerve on the pelvic aspects and on the perineal aspect by the perineal branches of pudendal nerves.

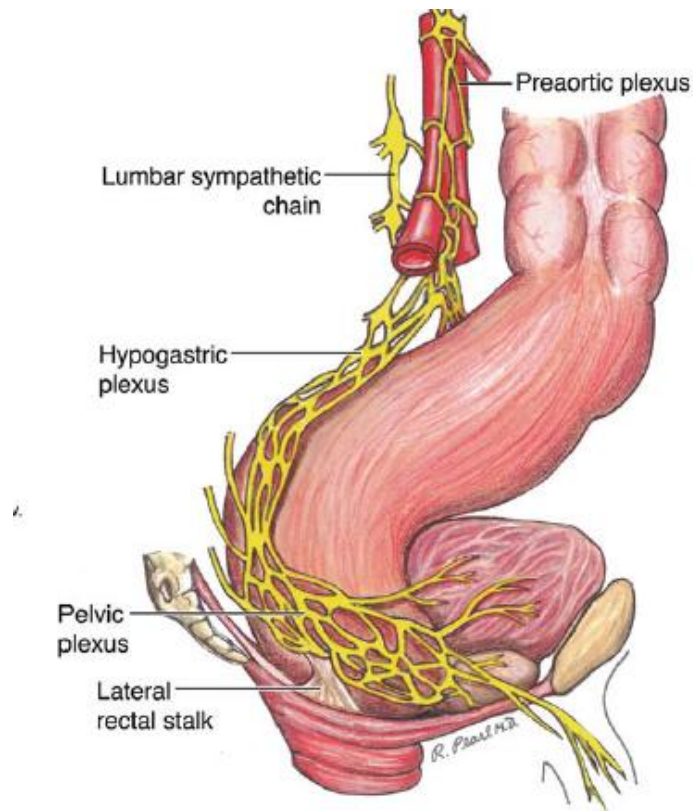


Figure 7 Nerve supply of rectum and anal canal

PHYSIOLOGY²⁴

MECHANISM OF ANORECTAL CONTINENCE:

The anorectal continence is maintained by a series of mechanisms.

Primary mechanism

The puborectalis sling forming the anorectal ring, crosses the rectum anteriorly and plays the most crucial role in maintaining continence. The secondary mechanisms are the intrinsic tone in the internal sphincter ani muscle, the voluntary contraction of the external sphincter ani muscle and the compression of ischioanal and ischioanal fat by the gluteus maximus muscle, which in turn keeps the anal canal and the rectum in a collapsed state.

The three theories of anorectal continence put forth are

1. Pressure zone theory

The intraluminal pressure within the rectum is less than 20mm Hg while that within the anal canal is 20 – 120 mm Hg. This difference in pressures is one mechanism for continence.

2. Flutter valve theory

The levator ani muscle at the anorectal junction is thought to act like a flutter valve and maintain continence.

3. Sling theory

The puborectalis muscle as explained above; forming a sling around the anorectal junction forms the most important mechanism of continence.

4. Crypto glandular theory²⁵

Suppuration of the anal glands at the origin of most anorectal infections in posterior midline empty into the anal canal at level of dentate line and penetrate into surrounding sphincter to variable depth leading to fistula in ano.

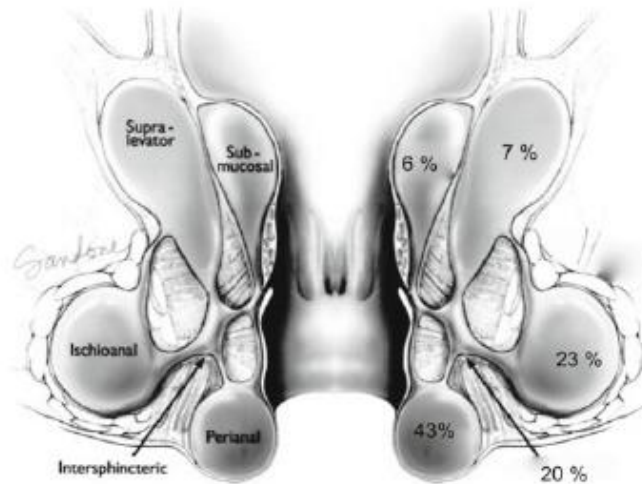


Figure 8 Cryptoglandular infections and abscesses

AETIOLOGY AND CLASSIFICATION ²⁶

Fistula-in-ano is a tract lined by granulation tissue which opens within in the anal canal or rectum and externally onto perianal skin. The fistulous tract is formed of thick layer of fibrous tissue which and is lined inside by a layer of granulation tissue. It is seen to best when the fistulous tract is laid open during surgery. Once the tough inner layer of granulation is worn out by scrapping it exposes the white fibrous base. C.G. Marks et al defined anal fistulas as a tract or a cavity communicating with the rectum or anal canal by an identifiable opening.

Etiology

The etiological factors to be considered here are:

1. Previous pyogenic abscess (perianal abscess).
2. Crohn's Disease (regional enterocolitis)
3. Tuberculosis.
4. Ulcerative colitis.
5. Malignancy of anal canal and rectum
6. Lymphogranuloma venereum.
7. Actinomycosis involving ano-rectal region.
8. Other rectal conditions following obstetrics and gynecological surgeries.
9. Pelvic inflammation.

Age and Sex²⁷

Fistula in ano is most commonly seen between 20yrs- 40 yrs of age group with mean age of 40yrs in both genders⁶⁷.

Race²⁸

Read and Abcarian reported a case series in which 92% of the patients belonged to African-American race. No statistical significance is observed between personal hygiene and sedentary lifestyle with occurrence of fistula in ano.

PATHOLOGY²⁹

The fistulous tract has got two openings. The internal opening in the rectum or the anal canal is the primary opening and the external opening on the skin is the secondary opening. The fistulous tract is made of fibrous tissue, layered by unhealthy granulation tissue on its internal surface. Since the primary opening is communicating internally with the anal canal, the presence of fecal particles and anal microorganisms maintains the chronicity of the fistula. Also, the high adipose content associated with relatively low vascularity in the region contributes to the chronicity. Since more than 1 gland can open into a crypt, a fistula tract may have several external openings but the internal opening is almost always single. Furthermore, presence of multiple external openings is pathognomonic of conditions like tuberculosis, inflammatory bowel disorders and sometimes LGV infections. The density of anal glands is more in the posterior part of the anal canal and this accounts for the higher incidence in the posterior half of the perianal region.

1. Previous Pyogenic Abscess

Anorectal abscess arises in the anal crypts and in the intermuscular glands. Because of the anatomical specificities of the anal canal, suppuration seldom clears spontaneously, and may persist even if drained inadequately. Thus recurrent infection is the primary cause of chronicity of fistula (Park). However for this chronicity certain hypothetical explanations have been given.

- Anal glands within the anal columns may get infected occasionally as these track into surrounding perianal spaces repeated low grade infections of these glands results in formation of perianal abscesses. , Inadvertent drainage of these abscess many a time may lead to fistula formation connecting the offending gland with perianal skin resulting in persistent discharge. In some instances certain foreign bodies like fish bone may get incorporated within the abscess cavity and result in chronic low grade infection with results in recurrent abscesses.

- The fatty tissues around the anus have a poor resistance to infection, or that repeated retrograde infection has occurred from the opening in the external anal verge in the highly contaminated perianal skin.
- Anal sphincters may impede the drainage of the abscess cavity. In children under 5 years, the congenital cyst of the anal glands is the cause of the perianal abscess. In adults the fistula-in – ano is quite common.

2. Crohn's Disease³⁰

An important predisposing cause for anal abscesses and fistulae is Crohn's . In a study done on 332 cases of Crohn's managed at the Leeds General infirmary, 16% had anorectal abscesses and 20% anal fistulae. Small intestinal primary Crohn's complication of fistula was 10%, but when the large bowel was involved, the incidence of abscess rose to 21% and fistula to 25%. When the rectum itself was implicated the figures rose to abscess 23% and fistula 35%.

Mornon and Lockhart – Mummery have pointed out, the characteristic histological appearance of Crohn's disease, with non – caseating giant cell follicles are often seen in the granulation tissue of secondary anal abscesses and fistulae studied.

3. Tuberculosis

It has long been known that anorectal abscess and fistula – in – ano may be due to a tuberculosis infection. This occurs as a well – recognized complication in patients with known pulmonary tuberculosis lesions. Granet has reported from the Sea View sanatorium of New York about 16% incidence of abscess and fistulae due to tuberculosis. The method of infection of the anal region in these cases is presumably that tubercle bacilli are swallowed in the sputum and enter the perianal tissue through minute abrasions of the lining of the anal canal.

Nowadays in developed countries the incidence of tuberculosis as etiopathological cause has come down.

4. Ulcerative Colitis

Another predisposing cause for development of anorectal abscess and fistula is ulcerative colitis. In Goligher series of 465 cases of ulcerative colitis 82 patients suffered from the ano – rectal complication and 25 of them (i.e.5.48% presented with fistula –in-ano Dombel et al. Sloan et al, Jackman (1954) Highower et al (1958), Edward and Truelove (1964), Waugh et al (1964) all reported ulcerative colitis as one of the cause for the fistula-in-ano with almost same percentage as that of Goligher. Edwards and Truelove (1964) found that abscess and fistula may occur at any stage of the disease.

5. Carcinoma of Rectum and Anal Canal

Carcinomas of colon or rectum are occasionally complicated by the occurrence of per colonic or perirectal abscesses. If the growth lies in the lower rectum or in the anal canal and an overlying abscess develops, it will be situated in one of the tissue spaces around the anal canal, and when it ruptures it gives rise to fistula-in-ano (Dukes and Galvin, 1956). Carcinomata of the anorectal region may arise, not in the mucosa of the rectum or anal canal, but in the epithelial lining of the anal inter – muscular glands, when there may be no growth evident in the rectal or anal lumen, but may be seen in the fistulous track.

6. Lymphogranuloma Venerum

These are seen commonly in female. Strictures due to lymphogranuloma venereum are frequently accompanied by abscess and a fistula in the anal region. Lymphogranuloma is due to infection with a virus of psittacosis group, which is introduced into the body by sexual intercourse.

7. Actinomycosis of the Anorectal region

This condition is very rare, but when it occurs it is often associated with the development of the anal fistula discharging typical actinomycotic pus. The infection may occur anywhere from ileo ceecal region to the anus.

This may be primary in the rectum or may be found as a chronic anorectal abscess secondarily to the actinomycotic lesion anywhere in the alimentary tract.

8. Previous Rectal, obstetrical or Gynecological operation

Fistula may develop as a consequence of operation such as evacuation of the anal hematoma. In female patient anterior fistula may be as a result of perineal tear during parturition or perineorrhaphy. Sometimes fistula in ano may also result due to infection or due to the injuries to the perineal region by accident

CLASSIFICATION

Fistula-in-ano has been classified on the basis of morbid anatomy.

Anal fistula are best thought of in relation to the vertical and horizontal axis to the canal. Milligan and Morgan in 1934 classified fistulae in relationship to sphincters especially with respect to the anal ring. They are sub mucous, low anal and high anal anorectal and pelvi rectal²⁰ Charles Rob and Rodney Smith have classified the fistula as low anal, high anal, subcutaneous, sub mucous, ischiorectal and pelvi-rectal. H.R.Thompson (1962) has described the fistulae as simple and easy to treat (95%) or complex and difficult to treat (5%)³¹.

It was considered as difficult when the internal opening was above the anorectal ring or when the fistulous tract was more than three- fourths of the circumference of the external sphincter.

In 1959, Steizen classified the fistulas into 3 groups:

1. Intermuscular or intersphincteric – here the tract lies between the sphincter ani internus and sphincter ani externus.
2. Trans – sphincteric – where the fistulous tract crosses the external sphincter into the ischiorectal fossa.
3. Extra sphincteric – the tract directly passes from the rectum through the levator ani and outside external sphincter to the skin.

A.G. Parks et al had formulated a new classification on the basis of pathogenesis and course of anal fistula²⁹.

Park's classification of Anal fistulas is most commonly employed classification now a days and it includes following four fistula types based on his study in group of 400 patients with fistula in ano⁶⁷ - intersphincteric includes 45 %, is most common type followed by transphincteric includes 29 %, which in then is followed by suprasphincteric involving 20% and Extrasphincteric includes 5 %. Extrasphincteric fistulas are least common and most commonly results from inadequate or inadvertent drainage of perianal abscess.

J.C.Goligher has modified the classification of Milligan and Morgan and by comparing to that of Park et al classifies the anal fistula as follows:

1. Subcutaneous fistula 5%
2. Low anal (low inter – sphincteric) fistula 75%
3. High anal (Trans – Sphincteric) fistulae 8%
4. Anorectal fistula 7%
 - a) Ischiorectal or intra – levator
 - b) Pelvirectal or supralelevator.
5. Sub mucous or intramuscular(High intersphincteric) fistula 4%

Today, these percentages of different types of anal fistulas have changed and are classified based on studies done on large series.⁶⁷. Intersphincteric includes 70 %, Transphincteric ranging from 20% –25 % , suprasphincteric ranging from 1% –3 % , extrasphincteric ranging from 1%– 2 %)

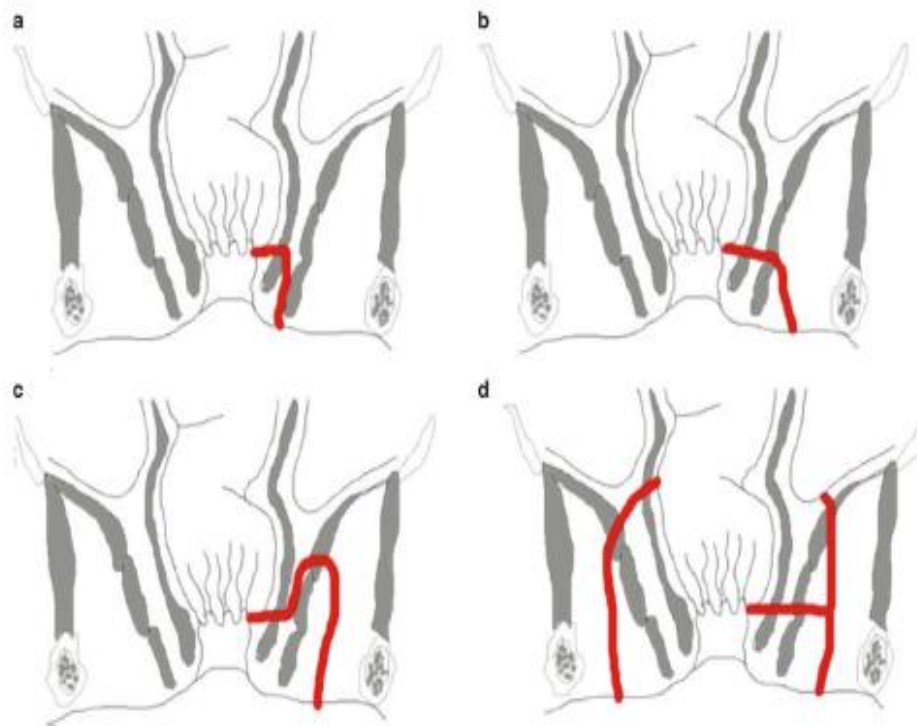


Figure 9Classification of fistula in ano according to Park et al . a.intersphincteric; b. transsphincteric ;c supralelevator ;d. extrasphincteric

Most common type of fistula in ano is intersphincteric type . Internal opening is usually seen at the intersphincteric groove and they tend to have a very short course ,they usually open at perianal skin externally near anal verge . Intersphincteric fistulas occur following drainage of perianal abscess which are located within the confine of external anal sphincter .³³

Following intersphincteric fistulas transsphincteric fistulas are more common. These type of fistulas traverse through both internal anal sphincter and external anal sphincter and they tend to extend till ischioanal fossa. As seen with other type of anal fistulas they occurs as a result of perianal abscess drainage. Site of spontaneous decompression and the site of previous incision taken for treatment of perianal abscess determine the actual length of these fistulas.

The third type of fistulas are the suprasphincteric, they are less common type of fistulas.. They have a complicated course within the perianal region. They usually begin at the level of dentate line,and ascend above most of the time crossing the puborectalis, they traverse the ischioanal fossa and finally end in the perianal skin.

Extrasphincteric fistulas are the least common type of fistulas..They tend to occur as a result of inadvertent probing during drainage of perianal abscess or during fistula surgery where a surgeon accidentally tend to create false passage .They too are complex anal fistulas with internal opening above the level of anorectal ring.These are difficult to treat due to high internal opening and tend to have high recurrence rate after surgery.

Complex fistula is used to define any type of fistula other than intersphincteric or low transsphincteric type of fistula. It also includes recurrent fistulas, anterior fistulas in females, those with multiple tracts, and fistulas associated with crohns disease, ulcerative colitis, tubercular fistulas and HIV.⁶⁷

These are named as complex fistulas because they are difficult to treat with traditional procedures such as fistulectomy and fistulotomy. They require thorough clinical and radiological evaluation to access the tract of the fistula, its extension, and treatment should be tailored accordingly.

HORIZONTAL DISPOSITION

Goodsall's rule³⁵

In the year 1900, Goodsall pointed out that if a imaginary transverse line was drawn across the midpoint of the anus, fistulae with their external opening posterior to this line or anterior to this line but beyond 1½ inches from the anus, have their internal opening in the midline posteriorly between the sphincters and the fistula's track is curved. When the external opening is situated in front of the transverse line, but within 1½ inches from the anus, the internal opening lies in the same radial line as the external orifice, the fistula track being straight. This is known as Goodsall's rule. The curved track of a posterior fistula may be present on one side only, or may be bilateral, the two fistulae then converging on a single midline internal opening.

These are known as single and double horseshoe fistulae may occur at different levels relative to the anus, anal canal and lower rectum. Sometimes there is possibility to come across exemption to this rule. It is said horseshoe fistula hugs the puborectalis muscle as it forms a sling round the sides and the back of the anorectal junction, lying external to the upper most part of the external sphincter and below or external to the lower most part of the levator ani muscle.

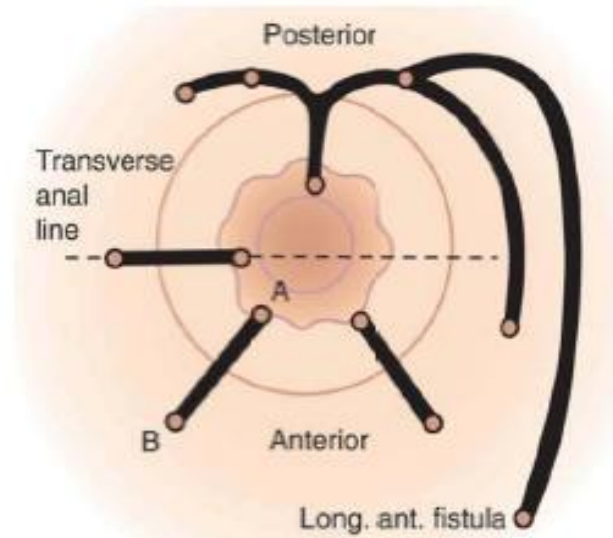


Figure 10 Goodsall's Rule

CLINICAL MANIFESTATIONS

- Most commonly a patient with fistula in ano presents with a swelling in perianal region associated with persistent discharge which causes discomfort . occasionally perianal itching.
- A patient with anal fistula may give a history of perianal abscess which may have burst open spontaneously or may give a history of surgery for perianal abscess.It may happen that the patient would not give any previous history of any surgery as it might be a remote event and patient would have forgotten about it. The discharge may be purulent or serous and sometimes blood stained. Soiling of the under-clothes may be another annoying complaint. Patient may complain of soreness and itching of the perianal skin, it occurs due to pruritis resulting from the moist , sodden state of the perianal skin.

Inspection³⁵

- On inspection one can easily make out the external opening which is seen as 1mm-2mm size hemispherical swelling in perianal region. One can also make out serous or pus discharge from the external opening.
- In the chronic state, external opening usually can be seen as a reddish swelling of extruded granulation tissue with purulent serosanguinous discharge on compression. Sometimes the opening is so small that it can be detected only when palpation around the anus expresses a few beads of pus from an otherwise inconspicuous opening and their relationship to the anal canal may reveal much more information.

- Not infrequently the sinus is temporarily healed over, though its position is marked by a raised papilla by a scar. On examination should look for scars in perianal region which might be due to spontaneous rupture of the abscess or due to surgical drainage and left open to be healed by secondary intention. Sometimes perianal skin may reveal erosion due to pruritis, and skin may be thickened in chronic cases which may obscure the external opening of the fistula.

Palpation

- Palpation helps us to confirm the external opening of fistula, it is usually felt as firm swelling which may extrude pus on pressing surrounding perianal region.
- Simple anal fistulas (low anal or subcutaneous) can be easily palpated as band of induration below the perianal region with distinct button like consistency internal opening and a distinct external opening.
- Horse shoe fistulas are the type of fistula which have external opening in either side of anal verge and traverse behind the anal canal or the rectum. It is difficult to delineate the entire tract clinically in such conditions due to relative depth of these tracts from the perianal skin.
- Palpation of the anal canal internal opening is identified as button like consistency which is usually felt in posterior midline in case of posterior fistulas and are felt along the line of external opening in anterior fistulas in accordance with the Goodsalls rule. The internal opening is invariably detected in the midline on the posterior wall of the anal canal in posterior single or double horse-shoe fistulae at or above the ano – rectal ring.
- In sub mucous track, the induration can easily be made out, reaching down till pectinate, and may extend beyond the anorectal ring. It may be low or high anal fistulae with an extension into the sub mucosa after penetrating the sphincter.

Probing of Track

- Probing when done must be performed with a feather like touch to prevent false channels therefore it is best to avoid such probing outside the operating room. Even in the operating room with the patient under anesthesia, great care must be taken to avoid the creation of false passages into the anal canal or into the rectum.
- After a probe has been gently introduced into the track it can follow the path of a 'low' fistula towards the anus at an angle of approximately 30 degree to skin. Passage of the probe at an 80 degree angle to the skin or almost parallel to the anal canal indicates the presence of a high fistula or atleast a supralevator or ischioanal extension of a low fistula. Primary openings are successfully located by a probe in two thirds of patients. In the remainder, methylene blue dye is used.
- A malleable medium sized metal or silver probe with an olive tip, capable of being bent in the terminal inch and a half into a straight curve as required is used to probe the horse-shoe fistula.

If the internal opening is very small then a lacrimal probe is useful. These should be used very carefully as the false passages are easily produced. For simple straight forward fistula, St. Marks Hospital pattern of probe (pointed director) is sufficient.

Proctoscopy

- Importance of proctoscopy examination cannot be denied in cases of fistula in ano. Proctoscopy examination can help us visualize internal opening of fistula which is seen as button like induration,. Sometimes it can reveal discharge of pus on slight pressure. It also helps us to differentiate high anal fistula from low anal fistula from the level of internal opening. Proctoscopy shows the state of the rectal mucosa and evidence of underlying proctocolitis.

Sigmoidoscopy

- It is used to rule out any abnormal ano-rectal pathology in the recto sigmoid or sigmoid colon, as the instrument can be passed up to 25 cm. It is desirable particularly in patients over 45 years of age. A rectal biopsy is performed if Crohn's disease is suspected.

Radiological Examinations^{36,37,38,67}

There are varieties of modalities of radiological investigation options for treatment of fistula in ano which include fistulography, CT, Endorectal ultrasound, MRI with each of them having their advantages and disadvantages.

Fistulography is one of the commonly done procedure for anal fistula. It is done either using barium contrast or using fluoroscopy which gives a real time X ray image. It gives information about the length of tract and information regarding whether it is high anal or low anal type of fistula. It doesn't give relation of the tract with respect to sphincter muscles. Not only this patient is exposed to radiation and image provided by fistulography is suboptimal. Hence in most of the centers this modality is not being used commonly.

CT image gives additional information regarding the relation of the tract with respect to sphincter muscles but imaging is suboptimal in delineating soft tissues as compared to MRI. It also contributes to radiation exposure which is higher than x ray fistulogram. It is more informative when fistula is associated with abscess.

Endorectal ultrasound is most commonly used method of imaging fistula tract, it give clear delineation of the tract, its relation with the sphincter muscles, levator ani and the spaces around the anal canal and rectum. Radiologists use hydrogen peroxide for enhancement of the tract during imaging. Most commonly used frequency for fistula tract examination is either 7 MHz or sometimes 10MHz probe is also used. It also gives information regarding associated abscess,

and multiple tracts. Its use is free from exposure to radiation. Its sensitivity in delineating fistulous tract ranges from 90-94%.^{37, 38}. Only disadvantages is that it is real time and user dependent and not accurate for internal openings above the anorectal ring.

- MRI^{39, 67} : MRI Fistulogram is one of the important investigations in evaluating anal fistulas. It gives accurate information regarding the architecture of sphincter muscles , course of the fistula tract, any associated abscesses. MRI is more accurate compared to CT in delineating soft tissues. It is done either with or without gadolinium contrast Contrast requires insertion of gadolinium coils within the anal canal which might be cumbersome to the patient and patients may not accept it easily. Though MRI is most accurate imaging modality it is not easily available in all centre, it also adds to the cost as it is expensive imaging technique. But it should definitely be used in case of recurrent fistulas where the sphincter architecture is totally distorted due to previous surgery. Simple fistulogram may not delineate the tract accurately and may pose difficulty in tracking the course of the tract during surgery and may result in incomplete surgery and recurrence. • Hence complex fistulas mandate implementation of MRI imaging for proper identification of the course of the fistula tract and to identify the type of fistula based on which a surgeon can categorize the type of surgery which can be appropriate for that patient.

- A barium enema study is indicated in patients with a history of bowel symptoms or in anyone with a recurrent fistula in ano.
- It is important to get a chest Xray done in patients with anal fistula to identify any tubercle foci within the lungs as fistula may be secondary to hematogenous dissemination of tuberculosis of lungs. In that case thorough evaluation of the patient with Mantoux test, Sputum examination for mycobacterium should be carried out meticulously.
- Abdominal examination, general clinical examination is to be done preferably prior to the rectal examination routinely.
- Lung lesions can be detected which is very important for the diagnosis of tuberculosis fistulae.

Laboratory Investigations

- Routine investigations like Hb% , RBS, WBC, ESR, FBS, PPBS, blood urea, serum creatinine are essential. Urine and stool examination are necessary in every case.
- Culture and sensitivity help to know the type of organism and its sensitivity to the antibiotics.
- Examination of sputum, ESR and other routine investigations are necessary.

Histological Examination

- Histological Examination of the fistulous tract after operation has to be routinely done. This helps to assess and appreciate the pathogenesis of fistula-in-ano and helps to exclude the other varieties like tuberculosis or mycotic or carcinomatous causes.

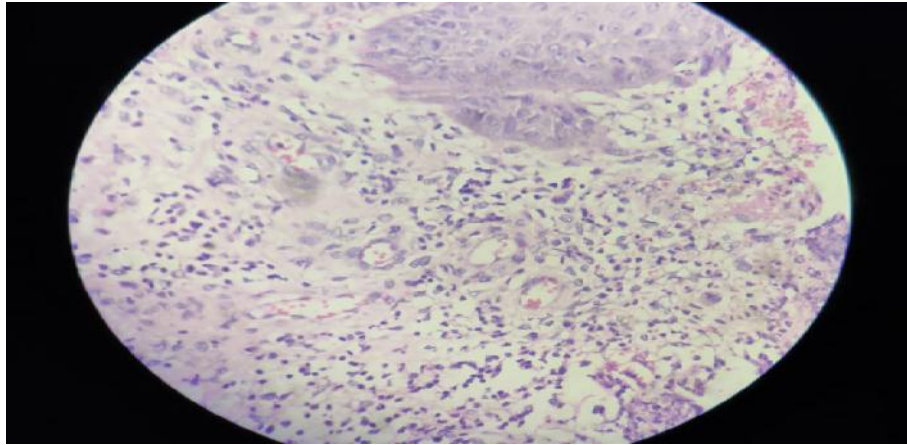


Figure 11 Section studied show tissue lined by stratified squamous epithelium, subepithelium shows fibrocollagenous , fibromuscular tissue lined by granulation tissue-features suggestive of chronic non specific inflammation-FISTULA IN ANO

DIFFERENTIAL DIAGNOSIS

By examination as described, it is usually possible not only to recognize any fistula present, but also to classify it accurately according to its relationship to the sphincter musculature, which is an essential step in planning treatment. However, some other pathological conditions must be kept in mind which mimic fistula-in-ano.

Urethral Fistula

If the fistula extends forwards in a male patient, it may be necessary to consider the possibility of being a urethral fistula rather than an anal one.

In the female, an anterior fistula may originate in the anal canal and also a chronically infected Bartholin's glands. Anterior or low anal intersphincteric fistulous abscess may also involve the scrotum in the male; in the female anterior high intramuscular fistulous abscess is situated deep to the labia majora and if it is not treated, it may result in fistula.

Pilonidal Sinus

Posterior fistulae on the other hand may be confused with pilonidal sinuses, though the latter condition lies a short distance behind the anus and generally contains hairs. On examination of the posterior anal region, opening is in the midline about 5cms or behind the anus with single

opening. The skin enters the opening so that opening has a smooth edge unlike that of an ordinary fistula wherein the fistula is situated at the centre of the exuberant granulation tissue.

Suppurative hydradenitis

This condition may bear a resemblance to fistula-in-ano. It is a chronic indolent inflammation of the apocrine glands which are present in the perianal region. It may be mistaken for fistula-in-ano. This occurs after purplish discoloration of the overlying skin suggesting a sub-acute or chronically inflamed condition. This will also have numerous sinuses which seldom discharge pus.

Concealed Fistulae

In some cases though the patient has complained of discharge, no definite evidence of fistula can be discovered on examination. Occasionally, this may be due to the fact that external fistulous opening is healed and it may be difficult to decide whether the induration is due to scarring or to a concealed active fistulous track.

Idiopathic Pruritus Ani

Another cause for the complaint of a discharge in certain cases, in which no evidence of fistula is found, is a severe degree of idiopathic pruritus ani. This results in a moist oozing perianal skin and the fluid escaping from it soils the patient's underclothes leading to the belief that he has a fistulous discharge. It is hardly necessary to point out that in female patients an alleged anal discharge may be of vaginal origin.

MANAGEMENT OF ANAL FISTULAS

Managing anal fistulas is challenging for surgeons. They are known for their recurrences following surgery. The need for both surgeons and patient is complete cure of anal fistula with no complications. There are various procedures utilized for treating anal fistulas. Some of the surgeries are too aggressive requiring lot of tissue compromise and pain while others are too conservative with no or minimal tissue loss and minimal pain. Both of these have their own benefits and demerits.

If a surgeon adopts a conservative procedure involving less invasiveness and less tissue loss their might be less pain and discomfort experienced by the patient but the chances of recurrence are high. Continence is not affected with such procedures. If a Surgeon adopts too aggressive surgery like fistulotomy and fistulectomy, patient will experience more discomfort, more pain and is also at risk of developing incontinence depending on the amount of sphincters lost during surgery, but recurrence rate is low with such procedure as it ensures complete removal of fistulous tract. Every patient must be evaluated thoroughly to identify the type and course of fistula and the surgery must be tailored on the individual basis.

Surgical Treatment⁴⁰

Surgery is the treatment for anal fistulas. They are not known to get closed or cured by conservative treatment. Though medical like of management with appropriate antibiotics, analgesics may relieve the patient of perianal discharge and itching but the tract remains and may get repeatedly infected with low grade infections which may produce chronic symptoms for months together. Chronic fistulas are also prone to undergo malignant change.

It must be known by both surgeons and patients that anal fistulas are reluctant diseases and are known for their recurrence. The high chances of recurrence and compromise with respect to continence must be explained clearly to the patients and attendees before hand. Complications can be minimized by proper knowledge of anatomy of ano-rectal region, caution, and with the help of experience gained through the practice while managing and skillful techniques particularly in high anal and anorectal fistula.

Depending on the type of surgery used main aim post surgery should be sound healing of the tract from the depth, pain management and appropriate antibiotics to prevent secondary infection. So the standard method of treatment of fistula, depends on the fact that when a tract is underlying an epithelial surface, healing occurs from the epithelial edges. Epithelium spreads over the fistulous track itself. In this way the wound now becomes part of the surface incised.

Buic put forward a few principles in the surgical treatment of anal fistulae.

They are:

1. Primary opening must be found
2. The fistulous tract or tracts must be traced.
3. Structures external to the primary opening and the fistulous tunnel are converted into open ditches throughout their course.
4. Measures must be adopted during and after the operations to ensure that the cavity will heal from within outwards without development of further tracts.

Various Techniques of Fistula Surgery^{1,42,43,36}

1. Laying open the fistula and allowing the wound to heal by granulation. Since the healing of the wound takes a lot of time, the other methods came into existence, though the fundamental laying open of the track is the same(**Fistulotomy**).
2. Excision of the track with primary suturing(**Fistulectomy**).
3. Fistulotomy with primary skin grafting- The relation of fistulous tract to the ano-rectal ring, both pre-operatives as well as on the table, should be determined under light anesthesia. In the subcutaneous, low anal and sub mucous fistulas, there is no danger of incontinence. In the case of complete anorectal or pelvirectal varieties, the classical orthodox method of laying open the

track is not possible. The other alternative method for difficult high fistulae of this type is to use the strong braided silk or braided stainless steel wire which is passed along the external opening and taken out along through internal opening, and ligature is put tightly so that controlled division of sphincters is obtained which also gives then time to heal in the process the fistulous tract also gets divided and heals by formation of granulation tissue(**seton placement**).

Pre-operative Preparation:

The patient should be admitted to the hospital preferably two days prior to the operation.

a) Bowel Preparations: Lower bowel must be thoroughly emptied before the operation as it considerably adds to the comfort of the patient, in postoperative treatment. Emptying of the bowel is done by enema.

b) Diet: A day or two before the operation the patient is given a light diet with low residue. The perineal region, perineum, and the lower abdomen are shaved the evening before operation. If skin grafting is intended to be done, then the thighs should be shaved.

Anesthesia

General anesthesia combined with relevant drugs is suitable for fistulectomy. Spinal anesthesia could be used. By use of general anesthesia, spinal headache and post-operative retention of urine are slight but risk of spinal nervous lesion with resulting paralysis or permanent disturbance of bladder function can be avoided.

Position of the Patient

Lithotomy position is the best suited for fistulectomy. The patient will lie down to the edge of the table so that the buttocks will be beyond the end of the table.

Rectal Toilet

Asepsis is not complete and some contamination is inevitable in the anal region. By free use of weak, watery antiseptic solution such as povidone iodine for swabbing purposes before and during the procedure.

Perianal Fistula

The principle is to lay open the track or sinus. All the findings of pre-operative clinical examination are confirmed by further probing. If the tract is thought to be blind at its inner end, care is taken to establish the fact whether it is blind or not.

Percival Pott (1779) strongly advocated that the fistula should be laid open and the wound subsequently kept open by careful packing.

Frederic Solomon's, modified the classical technique by adding to the main incision, laying open the fistulous tracks further by 'T' shaped incision. This incision became known as Solomon's "Back cut". This was designed to prevent premature healing of the outer part of the

wound before the anal end had a chance to fill with granulations and become soundly epithelialized.

The Management of Sphincter Muscles and Preservation of Continence⁴³

The significant thing in laying open fistulae by the classic method as Milligan and Morgan emphasized is the height at which the track lies in relation with the internal and external anal sphincters and more importantly anorectal ring. They claimed that provided its integrity is preserved the greater part of both sphincters may be divided without loss of continence but if the anorectal ring is inadequately divided the effect is inevitably a total loss of anal control (and usually some degree of complete or partial rectal prolapse as well).

In planning treatment, it is therefore important to define the relationship of the fistulous track to the anorectal ring, both pre-operatively and at the time of operation. If the fistula is of the subcutaneous sub mucous or low anal variety, it's incision will clearly not endanger the anorectal ring in anyway. If the fistula is of complete anorectal variety here the fistulous tract traverses and reaches above the anorectal ring and opens into the rectum above the ring, its treatment by incision would inevitably divide the ring and render the patient incontinent. This type of fistula is to be regarded as inoperable by the classic method and calls for special operative consideration. The really perplexing cases are those with a high anal or anorectal fistula with an opening into the upper part of the anal canal; it may be extremely difficult to decide whether the opening of the fistulous tract internally is situated just above the level of anorectal ring or below it.

(1) Fistulotomy procedure-

A) Low anal fistula:

The findings on pre-operative clinical examination are confirmed by further probing, and if the tract was thought to be blind at its inner end, care is taken to establish whether it is blind or not. Sometimes a minute internal opening hitherto undetected may be demonstrated by a fine lacrimal probe passed from the external opening, or one may be found on inspecting and probing the wall of the anal canal with the aid of a bivalve speculum. Next a pointed probe is passed along from the external opening towards internal opening and skin overlying the probe is gradually divided to reach till the fistulous tract gets laid open. This process also entails division of part of sphincters depending on the depth and course of fistulas. Once the fistulous tract is laid open the edges of the skin are retracted properly, hemostasis should be attained and the underlying floor of the fistulous tract is examined which is seen to be covered with characteristic velvety covering of granulation tissue, the opened up track of the fistula is readily distinguished from the other tissues as a narrow strip running in a radial direction in the deepest part of the wound. Its recognition is useful in confirming that the director was correctly passed along the

fistula and did not make a false passage in the tissue. The floor of the fistulous tract which is covered with granulation tissue is thoroughly scooped to remove all overlying granulation tissue leaving behind the fibrous wall. Its surface should be closely examined throughout its length for any openings and these should be tested with a medium or fine lacrimal probe to determine whether they lead into subsidiary fistulous tracks. Similarly, the surrounding soft tissues should also be examined thoroughly for any induration which may be due to offshoots from the present fistulous tracts. A fine probe may be used gently to examine for any opening through the fistula tract which may lead to extra branches from this tract. Care should be taken to prevent creation of any false passages during probing. Overzealous probing is not acceptable.

Finally if no further fistulous openings are discovered, the margins of wound are excised leaving behind a shallow ulcer to be healed by secondary intention. The wound is again surveyed for hemostasis and general configuration, and again palpated to make sure that no fresh areas of induration have been revealed by the process of trimming. Finally the dressing is applied; this consist of gauze rinsed out in Eusol which are arranged to cover the wound surface, the corner of one square being tucked into the anal canal to provide a dressing for the apical part of the wound. More complicated anal or subcutaneous fistulae with numerous subsidiary tracks and openings of course require additional incisions and when these are amalgamated the effect may be to produce a much more extensive irregular wound. It is possible for a patient to have two entirely separate fistulae but this is excessively rare and it may be taken as a good working rule that all fistulous openings should be found to communicate with one another.

B) Ischiorectal fistula (High posterior horse shoe fistulae) ⁴⁴

This is the commonest type of anorectal fistulae. This is amenable to well planned radical surgical treatment. One external opening always will be present and it is best to commence by using it to lay open the lateral limb of the horse shoe track on that side. From the external opening fistula probe is inserted gently and proceeded gradually along the course of the tract. It may proceed towards the posterior wall of the anal canal and, if a definite internal opening has been identified there below the anorectal ring, it may be made to emerge through it into the canal; this part of the fistula is then laid open by incision, otherwise and usually preferably, the point of the instrument is directed forwards and made to project against and penetrate through the skin at the side of the anus and slightly in front of it. An incision is then made on to the director, releasing it and exposing part of the fistula. The granulation tissue is scraped by a sharp scoop, samples of granulation tissue should be sent for histopathological examination. The fibrous base is now followed forwards, and probing at its anterior end usually reveals prolongation of the tract.

The proximal aspect of fistulous tract is incised and the underlying wound is excised thoroughly to prevent overhanging and undue early approximation of skin edges. If there is no internal opening in the posterior horse-shoe fistulae a very careful search with a lacrimal probe may reveal presence of internal opening which should be laid open. Before this, the anorectal ring should be identified.

(C) Pelvirectal fistula

This type of fistula usually develops when there occurs a small rent within the levator ani due to which the tract tends to extend above the level of levator ani. While managing such cases the rent should be stretched open by blunt artery forceps for drainage of any residual abscesses. This is safely performed in a backward, lateral or forward direction, but not medially, the opening being enlarged as much as required to ensure free drainage of the supralelevator portion of the tract. The tissue obtained after scrapping should always be sent for histopathological examination to rule out other causes of fistula in ano.

The lower portion of the track is dealt with, similar to the other type of fistulae. The external wound is now enlarged by wide trimming of the skin edges and fats especially posteriorly to produce deep gutter extending backward and towards the side of the coccyx. In every high pelvirectal fistula the perineal route is not much help unless it is combined with the abdominal approach as in recto-vaginal fistula.

Goligher advised the preliminary left iliac defunctioning colostomy even though the results with this procedure are not far superior to other methods.

D) High intermuscular fistulae

It is important to make sure that the fistula is only sub mucous fistula. Sometimes the induration that can be felt through the rectal wall of the blind upper end of an anorectal fistula closely mimics that of a high sub mucous or intramuscular tracts; it is important not to confuse these two lesions. For treatment of submucous fistula incision is usually taken within the anal wall and the tract is laid open into the lumen of anal canal. Post-operatively these sub mucous fistulae are liable to give trouble by developing a residual pocket of pus which may require further incision, so the progress after the operation should be specifically reviewed by digital or proctoscopic examination.

Care of the Wound⁴⁵

The main aim post surgery is to take adequate care of the wound as to prevent wound infection and promote healing from the depth of the wound and prevent premature closing of the wound due to premature approximation of skin edges. Dressing is changed twice a day leaving the inner covering gauze. The first bowel movement may be very painful. The dressings are repeated

twice a day. The bowel is kept regular and soft by administration of liquid paraffin at bed time daily. The inner dressing is removed on the morning of the third post-operative day. Fresh dressing is applied loosely.

Periodic review of wound

Usually post surgery the wound should not have much discharge of pus. Any pus discharge from the wound should mandate one to search for underlying unopened pus pockets which acts as persistent source of infection. Subsequently the wound has to be reviewed once a week. Periodic examination of the wound and rectal examination should be done in order to assess the condition of the anus. As the large fistula may heal with great amount of fibrosis, resulting in anal canal stricture. In order to avoid complications (stenosis) regular daily anal dilatation is needed till the wound heals completely and some weeks afterwards also depending upon the case. In the high posterior double horse-shoe fistula both inferior haemorrhoidal nerves may have to be divided resulting in false incontinence. If the anorectal ring is preserved, anal control becomes normal with the regular exercise of the anal sphincter.

Duration for complete healing

The time taken for healing of fistula is usually slow in case of fistulotomy and usually take more time in high anal fistula as compared to low anal fistula. Low anal fistulas usually heal in 4-5 weeks where as high anal fistulas take around 12 weeks to heal. Patients who undergo fistulotomy can be discharged on 10th or 12th post-operative day provided the patient attends the hospital for checkup for first few dressings. In order to minimize the period of convalescence and based on the socio economic problems of the patient, secondary skin grafting may be done as soon as the granulating surface has reached the level of the surroundings skin. The results however are poor due to difficulty of retaining the graft in position and hence this is abandoned now.

(2) Fistulectomy with primary closure^{1,46,47,24}

Eternal opening is probed gently with lacrimal probe and gently inserted through the tract once internal opening is reached incision is taken on the perianal skin overlying the fistulous tract and incision extended to lay open the tract tract is completely excised followed by primary closure of the wound edges. Complicated high fistulae, where tissue may have to be fairly generously removed in order to assist exploration of the tracts, are technically quite unsuitable for primary suture, as are fistulae with numerous off shoots to the main tract. This method is most readily applied to simple direct fistulae. Wound should be prepared for suturing which means the edges of the skin and subcutaneous tissue are not trimmed apart to allow approximation of edges.

It involves layer by layer closure of the wound from the depth and also involves reconstruction of sphincter muscles individually with absorbable suture material. Subcutaneous fat is

approximated using absorbable interrupted suture material followed by skin approximation. The surface stitches comprise of vertical mattress stitches of fine chromic catgut. In the mucosa and the skin of the part of the wound lying in the anal canal, similar stitches of vicryl is put as in the skin of the perianal region. Goligher also practiced primary suturing by taking particular care to excise the fistula on its entirety and leave fresh supple raw surface which was then opposed by two or more layers of buried fine plain catgut sutures. Skin was opposed with Michael clip or silk sutures.

(3)Fistulotomy followed by skin grafting ^{46,48}

It was first advocated by Hughes in 1953. The procedure involves fistulotomy that is laying open of the tract, the skin edges and the subcutaneous tissues are excised in par with the underlying wound. This is followed by application of split thickness skin graft over the wound obtained from thigh and stabilizing it with either sutures or skin staplers. Dressing is applied. These grafts should be prevented from becoming floating. Firm pressure by a moulded pack is therefore essential if good apposition is to be secured. Hughes reports were most impressive. He reported complete take in 30 cases out of 40. Goligher reports that primary Thiersch grafting is less satisfactory. Out of his 22 cases, 100% take in 13 cases and 50 to 70% in the remaining cases. Most common demerit of this procedure is wound infection and graft rejection.

Use of Seton ^{49, 50}

When a tract is of high anal type with extension of the tract above the anorectal ring it is not possible to excise or lay open whole of the tract as it will cause division of the anorectal ring and can result in incontinence. In such condition after partial excision of the tract a silk thread can be passed from the external opening and is brought out via the internal opening and tied together tightly which brings about controlled division of the sphincters and it gives sufficient time for healing of the sphincters by fibrosis which will not affect the continence.

By gradual and periodic tightening of the fistula tract we can achieve laying open of the tract and healing without affecting the sphincter function adversely. Division of the sphincter will be followed by scar formation proximal to the ligature, thus holding the muscle fibers together, which may already have been accomplished by fibrosis of the fistulous track. Another benefit of Seton is that it allows the surgeon to better delineate the amount of muscle beneath the fistulous track. The third advantage of adding a seton is that it helps in external drainage of any abscess within or around the tract. Seton can be changed periodically. While doing it a new sterile seton is tied to the previous seton at external opening and old seton is dragged out through the internal opening, in this process the old seton as it comes out of the tract it positions the new seton into the tract which can be tied as cutting seton. This method of placing new seton is known as 'rail road technique'. Usually however the muscle is divided at a second stage 6-8 weeks later.

Appropriate timing of transaction of the sphincter subsequent to Seton placement is essential for sufficient fibrosis to ensure sphincter function.

When a large portion of muscle is included, it might be wise to divide the remaining muscle in more than one stage. If the wound does heal well, removal of the Seton without division of the contained muscle can be considered. Gradual pressure necrosis will sever the muscle after the Seton is tightened three or four times. Clinical situations in which use of a seton should be considered are – high fistula, anterior fistula in women, co-existent inflammatory bowel disease (especially Crohn's disease), a marked weakened sphincter in elderly individuals, extensive scarring in individuals who have had previous operations and the presence of simultaneous fistulas.

Managing complex fistulas

Pelviorectal fistula:

If the fistulous tract passing above the anorectal ring ends in an internal opening in the lower rectum, is unsuitable for treatment by an orthodox laying open operation which would render the patient incontinent. In the experience of Goligher there are five ways which a surgeon can follow in managing such cases.

1) Conservative management

Leaving alone the fistulous tract with initial antibiotics and analgesics with frequent sitz bath may help patient relieve of persistent discharge and soiling of clothes. But this mode of treatment is neither curative nor satisfactory for patient as it results in recurrence of symptoms once the medications are discontinued. The patient may continue indefinitely along expectant lines, keeping the part clean by regular baths, morning and evening and possibly wearing a dry dressing or piece of cotton wool to protect his underclothes from soiling.

2) Establishment of a temporary colostomy

Temporary colostomy as a procedure results in temporary defunctioning of anorectum and helps the fistula to heal and also prevents abscess formation, but Williams reported some prospect of healing the fistulas, so that the colostomy may eventually be closed. The possible curative value of a simple colostomy is something to be borne in mind in the management of these worrying cases. Here left iliac colostomy is preferred. This colostomy is to be maintained at least for 6-12 months, before complete closure.

3) Fistula repair

Most of the times the expectant management causes failure of treatment because of repeated low grade infection which causes persistence of symptoms unless the infected anal gland is not treated the disease always recurs. Goligher has undertaken it only 9 times successfully in 6, unsuccessfully in 3. Sphincter muscle may be divided below the subsidiary internal opening into

the anal canal, but the upper region of the muscles is not disturbed. The fistulous tract which is seen to have high internal opening into the rectum is excised sufficiently till the levators, the rent within the levators is then sutured with non-absorbable sutures. The side of the entire hole is trimmed. Gauze dressings are laid on the raw surface of the top. Post-operative management is same as in other conditions. The patient lies on the side opposite to that of the internal opening or in the prone jack-knife position.

4) Use of a Seton

Another possibility is to use a Seton as described previously

5) Excision of the rectum with permanent iliac colostomy.

If recurrent sepsis and discharge persists despite a defunctioning iliac colostomy and a direct attack on the fistula has failed or been decided against, the only alternative is rectal excision. Treatment of tuberculous anal fistula Gabriel strongly condemns the operation on superficial tuberculosis fistula and advocates conservative treatment⁵¹.

.It is clearly stated that the overall results in any large series of cases of tuberculosis fistula will be considerably influenced by the success in controlling the chest condition. The first requirement in the treatment of tuberculosis anal fistulae is an accurate assessment by the chest physician of the activity of any pulmonary tuberculosis focus present. Operative and post-operative management does not differ. If at the time of initial examination the pulmonary lesion is not made out, or the chest condition is considered to be clear, surgical treatment can be undertaken, provided there is no other focus in the hip or seminal vesicles, to account for the fistula.

6) VAAFT (Video Assisted Anal Fistula Treatment)^{16,67}

This procedure was first described by Meinro and Moori. This procedure is done using an endoscope specially designed for anal fistulas known as fistuloscope. The equipment used consists of a fistuloscope, an obturator and an electrode. Also available in the kit is an endobrush for thorough scooping out the fistula tract. The fistuloscope is designed with angle of 8 degrees and diameter is about 3.3mm x 4.7mm. Length of the fistuloscope is about 14 cm. The procedure is done with patient in lithotomy position and under spinal anaesthesia. It can be both diagnostic and therapeutic. The scope is introduced through the external opening. Fistuloscope is connected to a bag containing 5000 ml of 1% glycine – mannitol solution which helps in dilation of the tract and helps in easy passage of the fistuloscope through the tract.

During diagnostic phase a surgeon tries to visualize presence of any secondary tracts and should identify the internal opening of the fistula. Once this is done the unipolar electrode is inserted from the external opening and the tract is thoroughly cauterized from the internal opening extending till external opening. Glycine mannitol solution helps in clearing up of the debris. Once

complete cauterization of the tract is done all the necrotic substance within the tract is removed using an endobrush. At a final step the internal opening is closed either with stapler or figure of 8 sutures using vicryl and about 0.5 ml of cyanoacrylate glue is applied within the internal opening which helps in complete closure of internal opening. The remaining cauterized tract is left open which helps in drainage of any secretions left behind.

This is a sphincter saving procedure, and doesn't leave behind painful wounds to the patient to be taken care of, no complication of incontinence, and procedure remains same and can be applied for any kind of fistula. Only demerit being equipment used is expensive and so the procedure and also needs a wide learning curve to the surgeon.

7) Fibrin glue for the treatment of fistulae in ano^{52,53,67}

Fibrin glue acts as a natural adhesive and when applied activates the later steps of coagulation cascade. . Two essential components are fibrinogen and thrombin. It comes in a dual component syringe with a single nozzle where the components from two syringes meet .One syringe contains fibrinogen, factor XIII and bovine aprotinin while the other syringe contains thrombin and calcium. Once external and internal opening are identified by gentle probing the tract is scooped thoroughly and peroxide wash is given fibrin glue is applied from internal opening till external opening . At the tip of the nozzle the two components mix up, thrombin converts fibrinogen into fibrin ,factor XIII causes cross linking of fibrin. This cross linked fibrin provides a scaffold into which native tissues grow in which is followed by neovascularization and epithelialization.

.It causes. It is a simple treatment strategy, preserves sphincter function with minimal adverse side effects. It should therefore be considered as possible first line treatment in simple fistulae but it is less likely to be successful in complex or those fistulae associated with inflammatory bowel disease. Repeat gluing is unlikely to be successful. Fistulae that have failed to heal by 3 months will need further evaluation.

Synthetic and Biologic Fistula Plugs^{54,55,67}

Fistula plugs are substances used in treatment of anal fistulas and are usually prepared from bovine intestinal submucosa. It allows good tissue ingrowth as well as neovascularisation. Ideal qualities should be that it should be resistant to infection should not induce allergic reactions. It should fit aptly into the fistulous tract. It should support native tissue ingrowth and help in obliteration of the tract. Advantages of using fistula plugs is that they are easy to apply, sphincter saving procedure, hence incontinence does not occur, there is less perianal pain, no external wound ,it can be done as a day care procedure and patient can resume to his daily work immediately. Only disadvantage is that it is very costly and many times plug extrusion may occur which may cause recurrence.

Endorectal Advancement Flaps⁶⁷

Endorectal advancement flap for management for fistulas was for the first time applied for treatment of rectovaginal fistulas by Noble. It is a sphincter sparing procedure. Recently they are also being used for treatment of anal fistulas . This procedure can be applied even in complex anal fistulas such as those associated with crohns disease and recurrent fistulas. The procedure is done under spinal anaesthesia and patient in lithotomy position .It involves raising of flaps containing mucosa, submucosa and few muscle fibres. Once flap is raised the internal opening is excised ,the flap is advanced to cover the internal opening and sutured in place using interrupted absorbable suture material. As the internal opening which marks the location of infected anal glands is excised and closed using advancement flap, the source of infection is removed , hence it promotes healing of the remaining tract with fibrosis.

Dermal Advancement Flaps^{57,58,59,67}

Procedure is similar to endorectal advancement flap only difference is in this procedure dermal flap is raised to cover both internal and external opening instead of endorectal flap .Procedure is done under spinal anaesthesia with patient in lithotomy position after painting and draping internal opening is identified with probe, once it is identified the internal opening is excised partially. skin incision is taken area and flap raised, flap is advanced to cover both the internal and external opening and sutured using absorbable interrupted sutures . Surrounding subcutaneous fat is left open and is allowed to heal by secondary intention. Most common complication is that the flap may get separated at the base at exterior portion and second most complication is urinary retention. Modification of dermal flaps are also being used such as V-Y flap. Success rate of this procedure is reported to be around 70-80%.

LIFT^{60,67}

LIFT was first adopted as treatment for anal fistula by Rojanasakul in the year 2007.This procedure is done under spinal anaesthesia .It is most useful in transsphincteric type of anal fistulas.It involves gentle probing of the fistula tract, identification of internal opening and external opening. Once this is done skin incision is taken at the level if intersphincteric groove, incision is extended to identify the fistulous tract within the intersphincteric plane with probe in situ, once the course of tract is identified in the intersphincteric plane , probe is removed two ligatures are place on either sie ,one towards the internal opening and the other towards the external opening. The ligature put towards the internal opening obliterates the internal opening. The remaining tract beyond the ligature placed distally heals by fibrosis. Internal and external

sphincters are re approximated and skin closure is done. dressing applied. It is also a sphincter sparing procedure with no complication of incontinence.

Stem Cell Application in Fistula Disease^{61,67}

Most recent advancement in treatment of anal fistulas is application of stem cells for management of fistulas. It can be used as treatment modality in recurrent fistulas and complex fistulas such as those associated with inflammatory bowel disease. Stem cells are the type of cells which have potential to develop into varied kind of cells and they are being studied with their application in wound healing. This procedure for usage in treatment of anal fistulas is still under study and clinical trials are being carried out. Till date for treatment of anal fistulas only mesenchymal stem cells are being tried, obtained from bone marrow and fat. They have ability to migrate at the site of inflammation and tend to stimulate secretion of growth factors which in turn stimulate proliferation of native cells to that region and promote healing. They also promote matrix remodeling.

Management of Fistula in Ano associated with Crohns disease

Treatment required for these lesions depends on the site of the underlying enteritis in the intestinal tract. If it is located in the small bowel or proximal colon, with the distal large bowel normal, the surgical attack is also two fold. First step is the excision of the diseased intestinal segment. Secondly, an appropriate 'deroofting' operation for the fistula is to be done. Often main lesion is missed and only fistula is treated, and treatment will be failure of the wound to heal or early recurrence of the condition has lead to the suspicion and eventual diagnosis of the regional ileitis.

Anal fistula with ulcerative colitis

It is said that local surgical treatment of these fistulae, by ignoring the underlying bowel condition is fragile and even dangerous as it may be followed by an exacerbation of the colitis. Sometimes these fistulae temporarily heal as the ulcerative colitis improves to reopen again. Usually for these conditions, radical surgical treatment involving total proctocolectomy and ileostomy is required. Anal fistula with carcinoma has got poor prognosis as a result of wide spread to the principal region, and to the inguinal lymph nodes.

Occasionally however, removal is possible by means of an abdominoperineal excision of the rectum with wide ablation of the surroundings tissues on the affected side, and a subsequent block dissection of the glands of the groin. This may give a good palliative result for one or two years before recurrence takes place. In in-operable cases, super-voltage radiotherapy may be of

some value, especially in cases of squamous epithelioma. Paul Bellireau et al⁴¹ (1983) recommends the preservation of external sphincter muscle mass in treating trans sphincteric and supra sphincteric fistulae and his studies support the attempts at sphincter preservation in fistula surgery. Carol Ann Vasilevsky et al has conducted a retrospective study of 117 patients. These patients underwent incision and drainage of anorectal abscess. None of the patients who had intersphincter abscess developed recurrence. Of the 83 patients with perianal or ischioanal abscess, 9(11%) developed recurrent abscess and 31(37%) developed persistent fistula –in-ano to constitute a total recurrence rate of 48%. Han Kuypers says that the extra sphincteric anal fistulas remain a cause of concern because they may have a secondary internal opening above the pectinate line. He has treated 10 cases of extra sphincteric fistulas by two stage procedure without a diverting colostomy and had no recurrences. In this study, fistula was first laid open, then braided nylon thread was put through the extra sphincteric extension and the rectal opening and tied loosely, thus enclosing and puborectalis muscle. The deep part of the external wound heals by granulation tissue. The remaining fistulous tract drains around the seton.

MATERIAL AND METHODS:

Source of Data:

- All patients, admitted and have been diagnosed with fistula in ano.
- Period of study was from october2017 till may 2019

Method of Collection Of Data:

- Patients admitted with fistula in ano were allocated to study group and control group alternatively.
- Detailed history was taken and thorough clinical examination was done and relevant investigations performed for all the patients in both the study and control groups.
- A Proforma was used to collect all the relevant data from the patients i.e. pre and post operatively.
- All cases were followed up to discharge and subsequently at 1st month, 3rd month and 6th month

INCLUSION CRITERIA:

- 1) All Patients planned for fistula in ano repair either with cyanoacrylate glue injection or conventional fistulectomy will be included in the study.
- 2) High and low anal fistulas diagnosed clinically and radiologically
- 3) Cases of recurrences after previous surgeries/conservative attempts
- 4) HIV infected patients with CD4 count > 200 cells/cumm

EXCLUSION CRITERIA:

- 1) Fistulae associated with abscess
- 2) Fistula in ano due to other causes like Crohn's disease, Ulcerative colitis, Tuberculosis, Actinomycosis,
- 3) Fistulas associated with carcinoma anal canal or carcinoma rectum
- 4) HIV infected patients with CD4 count < 200 cells/cumm

PROCEDURE

CYANOACRYLATE GLUE INJECTION FOR TREATMENT OF FISTULA IN ANO

Informed written consent was obtained from each patient for the procedure after explaining then regarding the methodology implemented in procedure and explaining them regarding post operative care .

- Careful clinical examination was done in all patients to identify the anal fistula, its external opening . Per rectal and proctoscopy examination was done to identify the internal opening, and to classify it as low anal or high anal clinically.
- Patients in study group were planned for treatment with injection of N-butyl-cyanoacrylate.
- All patients were treated with oral antibiotics (ofloxacin and ornidazole orally) for 5 days before hand.
- Patients were admitted and the procedure was planned under spinal anaesthesia with patient placed in lithotomy position.
- Parts were painted with povidone iodine 10% and draped .On table per rectal examination and proctoscopy examination was done to confirm internal opening.
- About 2ml of methylene blue dye was injected from external opening with syringe nozzle into the tract and its spillage from internal opening confirmed. The tract was scooped thoroughly of all granulation tissue. Hydrogen peroxide wash was given.
- Internal opening was identified and offending anal gland at internal opening destroyed using monopolar dithermy. Internal opening was ligated loosely with figure of 8 sutures using vicryl no 1 . Once this is done 0.5 ml of cyanoacrylate glue was loaded into 2 ml syringe under all aseptic precautions which was connected to a 5 french urothelial catheter. Catheter tip was introduced gently into the fistula tract till internal opening is reached and glue was injected gradually.
- Bubbling of glue was confirmed at the internal opening, catheter was gradually withdrawn till bubbling is noted at the external opening. The loosely sutured vicryl at internal opening is then tightened. This procedure does not require any dressing. The glue gets polymerized and gets stabilized within 5-10 seconds.
- Oral Ofloxacin and Ornidazole was prescribed daily for 1 week . Laxatives were prescribed for ten days. Patients were advised to avoid straining at stools.
- Patients were asked to rate their pain score on the visual analogue scale ranging from 0 -10.

- The patients were reexamined every week for the first month, and then at 3rd month and 6th month.
- If a patient had recurrence at 4 week follow up , they were allocated for one more glue injection for second time and were followed up subsequently.

PROCEDURE

FISTULECTOMY IN FISTULA IN ANO

- The patients were operated under regional anesthesia. An anorectal examination was performed to verify the findings of the clinical examination.
- A dye study of the fistula tract was performed by placing moist gauze in the anal canal and injecting about 2 mL of methylene blue through the external opening. Staining of the gauze piece denoted patency of the fistula tract.
- A probe was gently passed into the fistulous tract through the external opening.
- Fistulectomy was begun by taking a keyhole skin incision over the fistulous tract and encircling the external opening.
- The incision was deepened through the subcutaneous tissue, and the tract removed from surrounding tissues. While the tract was being removed, attention was paid to identifying secondary tracts, if any. Hemostasis achieved. The operating time for the procedure was calculated from the start of the dye test to the beginning of dressing of the postoperative wound.

Statistical analysis used

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean± standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square (χ^2) test was used for association between two categorical variables.

The formula for the chi-square statistic used in the chi square test is:

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

The subscript “c” are the degrees of freedom. “O” is observed value and E is expected value.

$$C = (\text{number of rows}-1) * (\text{number of columns}-1)$$

The difference of the means of analysis variables between two independent groups was tested by unpaired t test.

The t statistic to test whether the means are different can be calculated as follows:

$$t = \frac{(\bar{x}_1 - \bar{x}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

where \bar{x}_1 = mean of sample 1

\bar{x}_2 = mean of sample 2

n_1 = number of subjects in sample 1

n_2 = number of subjects in sample 2

$$s_1^2 = \text{variance of sample 1} = \frac{\sum(x_1 - \bar{x}_1)^2}{n_1}$$

$$s_2^2 = \text{variance of sample 2} = \frac{\sum(x_2 - \bar{x}_2)^2}{n_2}$$

If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analyzed using SPSS software v.23.0. and Microsoft office 2007.

RESULTS

TABLE: DISTRIBUTION OF AGE BETWEEN TWO GROUPS

Age (yrs)	Group A		Group B		p value
	Mean	SD	Mean	SD	
20-30	10	33.3%	7	23.3%	0.696
31-40	12	40.0%	14	46.7%	
41-50	6	20.0%	5	16.7%	
>50	2	6.7%	4	13.3%	
Total	30	100.0%	30	100.0%	

FIGURE: DISTRIBUTION OF AGE BETWEEN TWO GROUPS

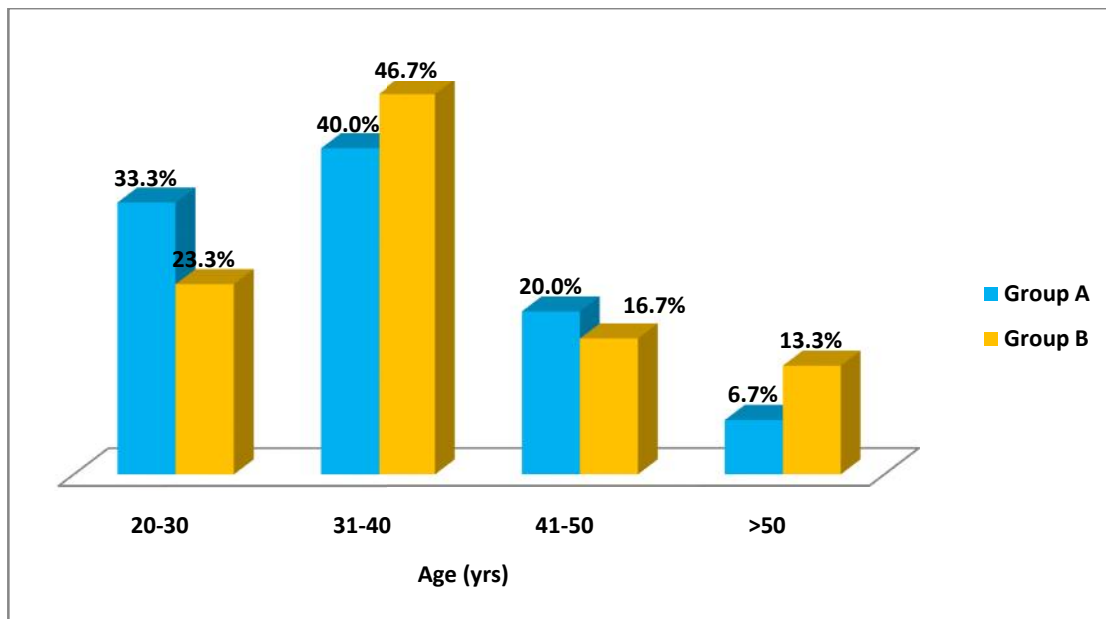


TABLE: MEAN AGE BETWEEN TWO GROUPS

Parameters	Group A		Group B		p value
	Mean	SD	Mean	SD	
Age (yrs)	35.8	10.2	38.9	10.2	0.239

FIGURE: MEAN AGE BETWEEN TWO GROUPS

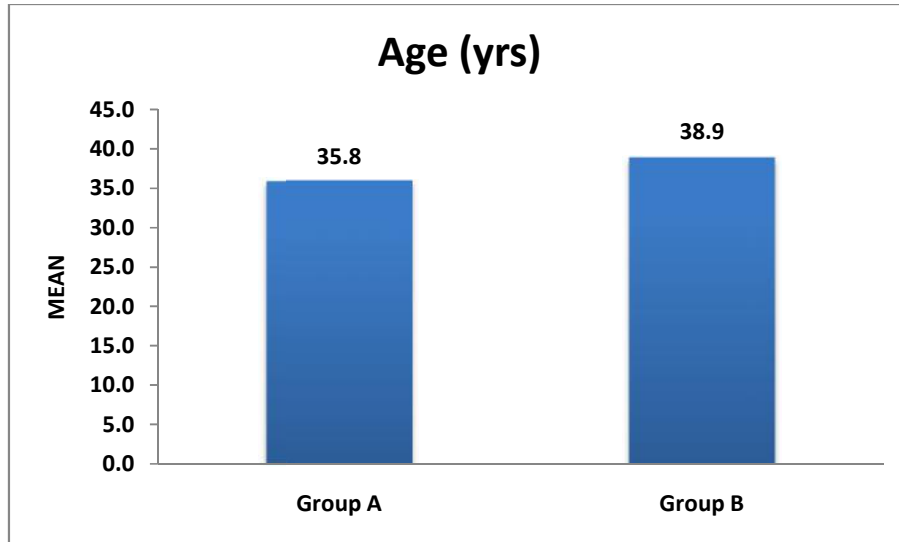


TABLE: DISTRIBUTION OF SEX BETWEEN STUDY GROUPS

Sex	Group A		Group B		p value
	Mean	SD	Mean	SD	
Male	21	70.0%	21	70.0%	-
Female	9	30.0%	9	30.0%	
Total	30	100.0%	30	100.0%	

FIGURE: DISTRIBUTION OF SEX BETWEEN STUDY GROUPS

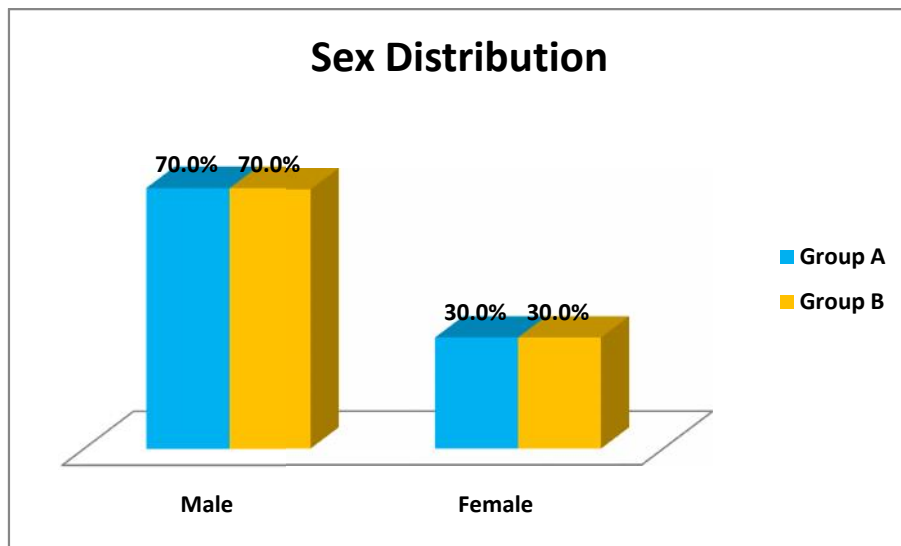


TABLE: DISTRIBUTION OF OCCUPATION BETWEEN STUDY GROUPS

Occupation	Group A		Group B		p value
	Mean	SD	Mean	SD	
Buisness	1	3.3%	3	10.0%	0.287
Farmer	8	26.7%	11	36.7%	
Housewife	5	16.7%	3	10.0%	
Labourer	6	20.0%	1	3.3%	
Retired	1	3.3%	1	3.3%	
Service	4	13.3%	8	26.7%	
Student	5	16.7%	3	10.0%	
Total	30	100.0%	30	100.0%	

FIGURE: DISTRIBUTION OF OCCUPATION BETWEEN STUDY GROUPS

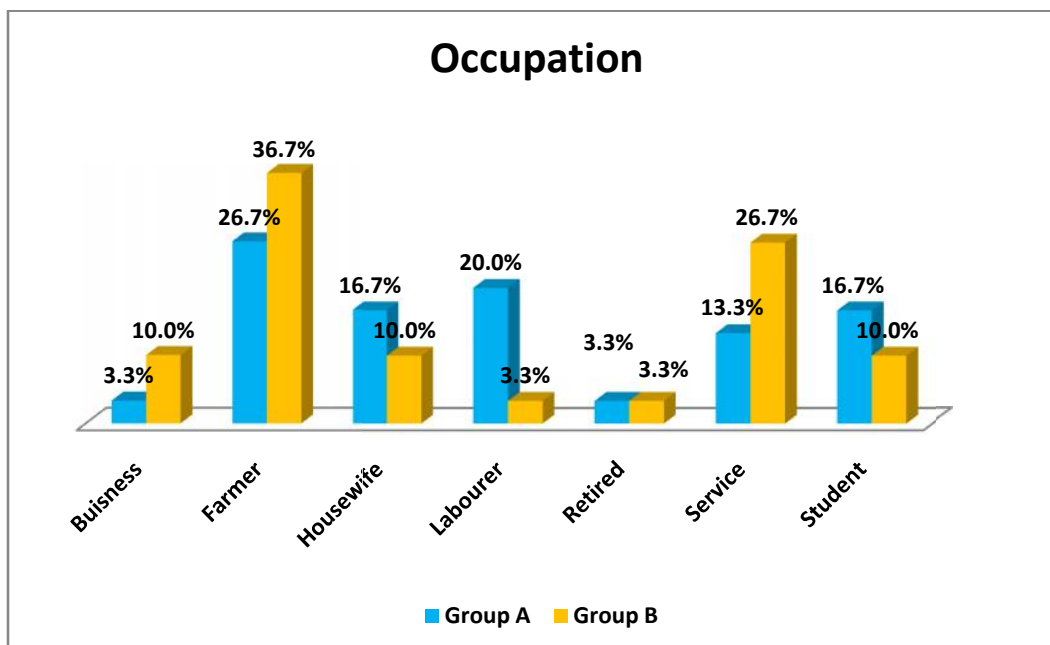


TABLE: MEAN PARAMETERS BETWEEN STUDY GROUPS

Parameters	Group A		Group B		p value
	Mean	SD	Mean	SD	
Swelling (Duration in months)	6.0	7.3	5.9	5.1	0.967
Discharge (Duration in months)	5.7	7.4	5.9	5.1	0.887
Duration of Hospital Stay(Days)	5.5	0.7	9.2	1.4	<0.001*

Note: * significant at 5% level of significance ($p < 0.05$)

FIGURE: MEAN PARAMETERS BETWEEN STUDY GROUPS

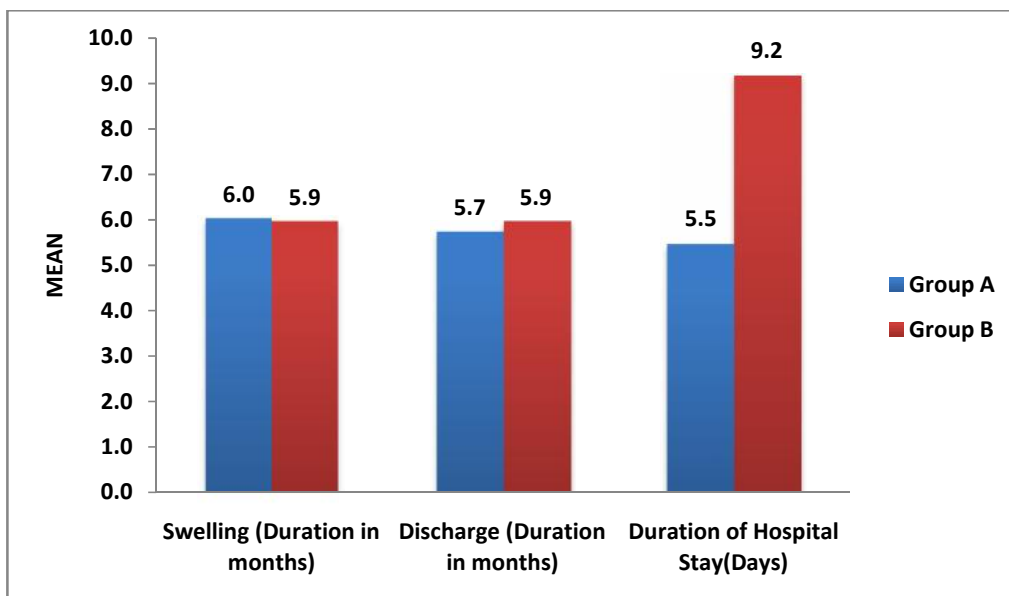


TABLE: PRESENCE OF PAIN AS SYMPTOM BETWEEN STUDY GROUPS

Pain	Group A		Group B		p value
	Mean	SD	Mean	SD	
Yes	5	16.7%	2	6.7%	0.228
No	25	83.3%	28	93.3%	
Total	30	100.0%	30	100.0%	

FIGURE: PRESENCE OF PAIN AS SYMPTOM BETWEEN STUDY GROUPS

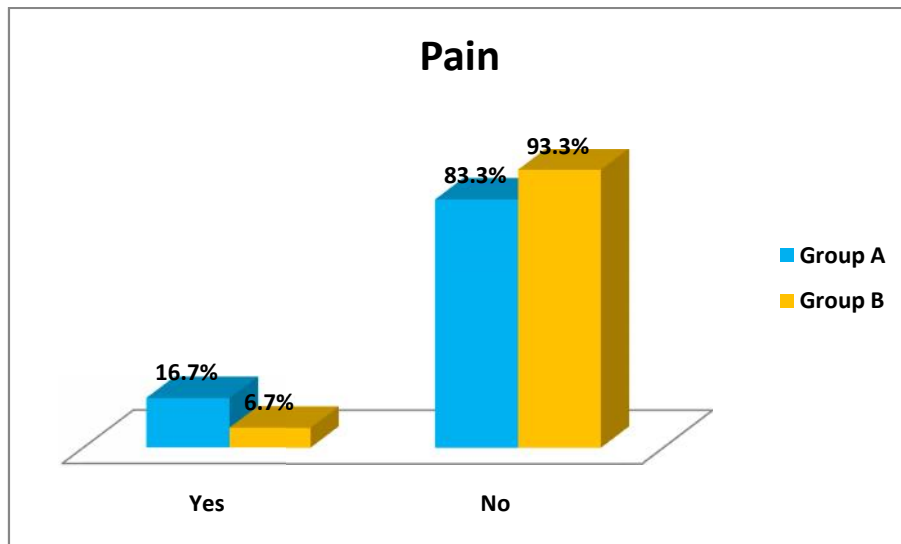


TABLE: POSTOPERATIVE COMPLICATIONS BETWEEN STUDY GROUPS

Postoperative Complication	Group A		Group B		p value
	Mean	SD	Mean	SD	
Nil	30	100.0%	27	90.0%	0.076
Wound Infection	0	0.0%	3	10.0%	
Total	30	100.0%	30	100.0%	

FIGURE: POSTOPERATIVE COMPLICATIONS BETWEEN STUDY GROUPS

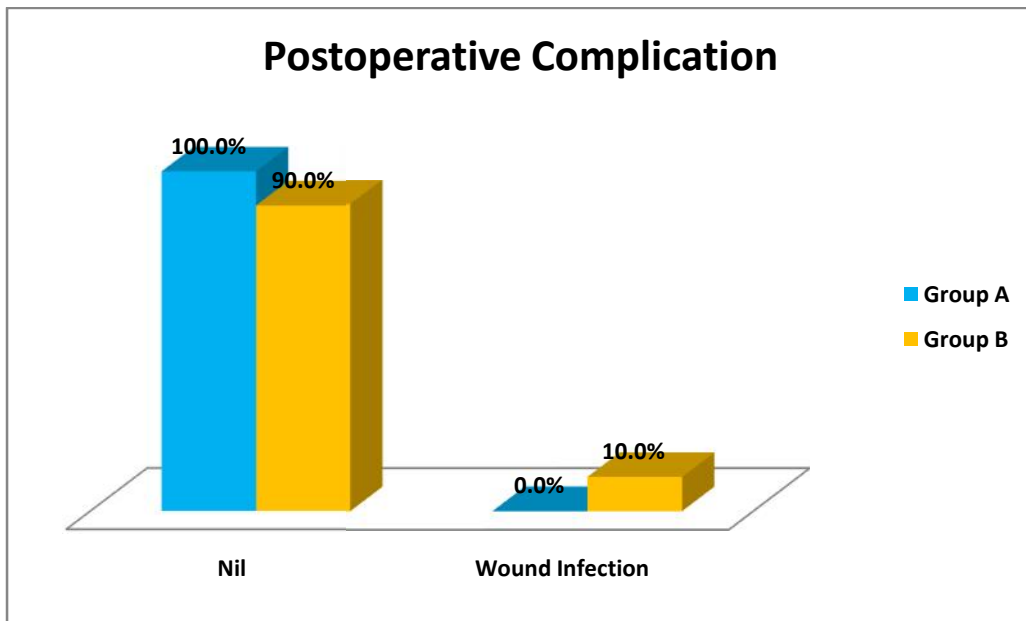


TABLE: TYPE OF FISTULA BETWEEN STUDY GROUPS

Type of fistula	Group A		Group B		p value
	Mean	SD	Mean	SD	
Anterior	3	10.0%	5	16.7%	0.448
Posterior	27	90.0%	25	83.3%	
Total	30	100.0%	30	100.0%	

FIGURE: TYPE OF FISTULA E BETWEEN STUDY GROUPS

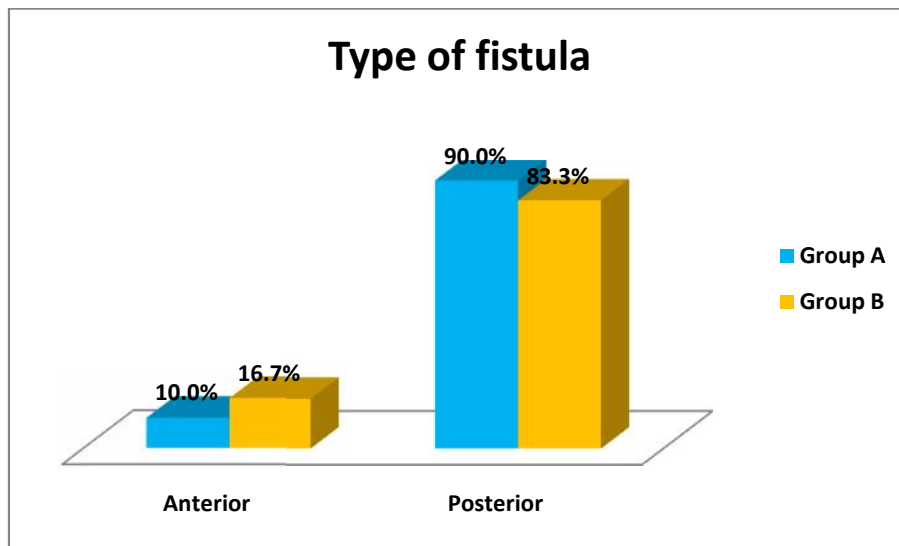


TABLE: HISTORY OF PREVIOUS SURGERY BETWEEN STUDY GROUPS

Previous Surgery	Group A		Group B		p value
	Mean	SD	Mean	SD	
Yes	11	36.7%	8	26.7%	0.485
No	19	63.3%	22	73.3%	
Total	30	100.0%	30	100.0%	

FIGURE: HISTORY OF PREVIOUS SURGERY BETWEEN STUDY GROUPS

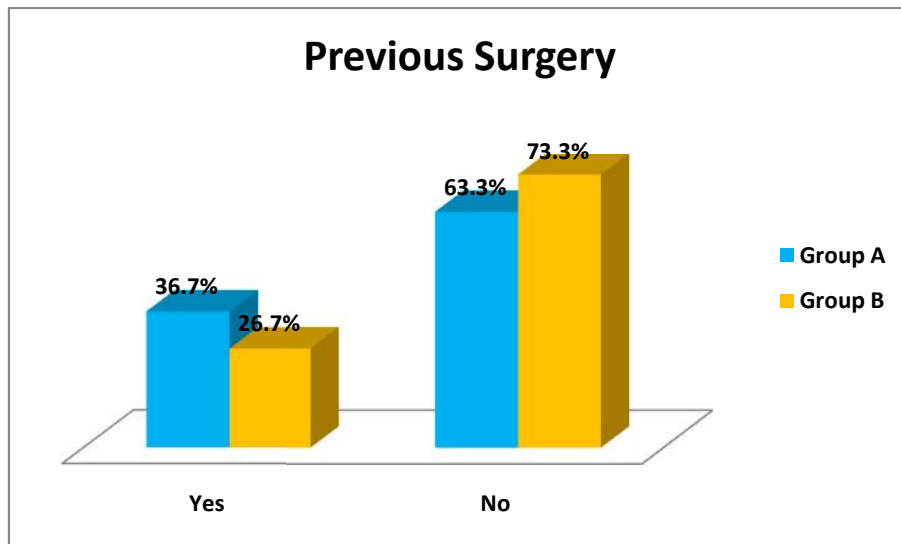


TABLE: TYPE OF FISTULA BASED ON MRI BETWEEN STUDY GROUPS

MRI	Group A		Group B		p value
	Mean	SD	Mean	SD	
Extrasphincteric	3	10.0%	2	6.7%	0.191
Intersphincteric	20	66.7%	25	83.3%	
Suprasphincteric	3	10.0%	3	10.0%	
Transsphincteric	4	13.3%	0	0.0%	
Total	30	100.0%	30	100.0%	

FIGURE: TYPE OF FISTULA BASED ON MRI BETWEEN STUDY GROUPS

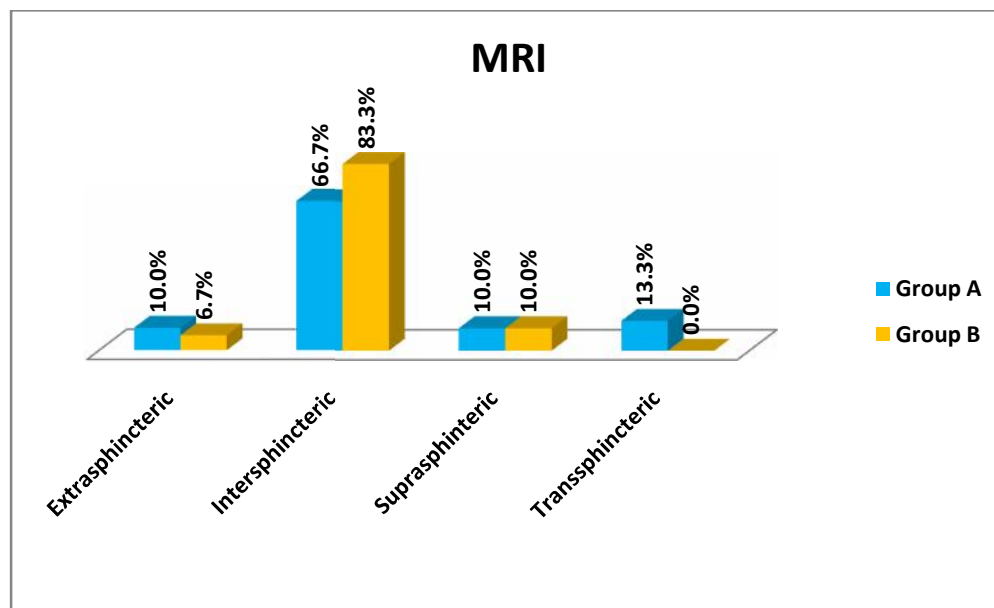
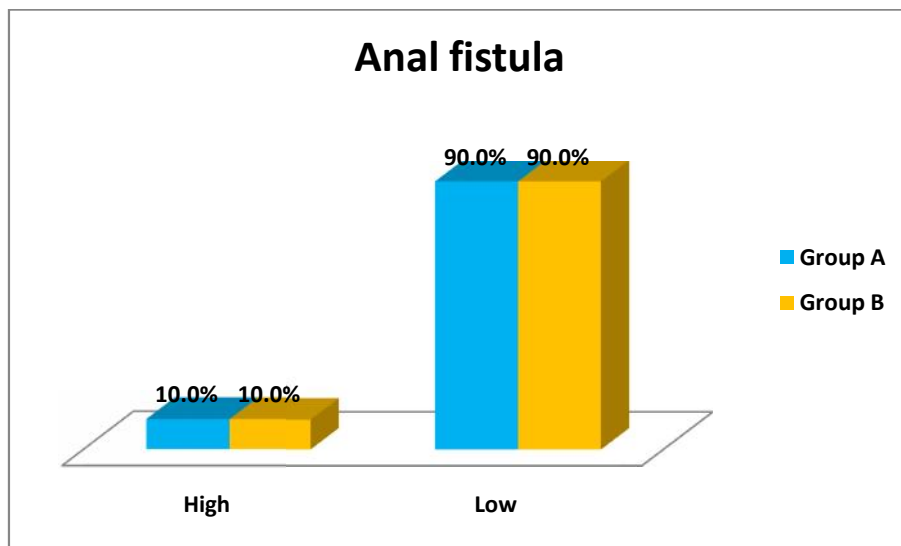


TABLE: TYPE OF ANAL FISTULA BETWEEN STUDY GROUPS (BASED ON CLINICAL EXAMINATION)

Anal fistula	Group A		Group B		p value
	Mean	SD	Mean	SD	
High	3	10.0%	3	10.0%	-
Low	27	90.0%	27	90.0%	
Total	30	100.0%	30	100.0%	

FIGURE: ANAL FISTULA BETWEEN STUDY GROUPS



**TABLE: DISTRIBUTION OF POSTOPERATIVE PAIN SCORE
BETWEEN STUDY GROUPS (BASED ON VAS)**

Pain Score	Group A		Group B		p value
	Mean	SD	Mean	SD	
1	21	70.0%	0	0.0%	<0.001*
2	9	30.0%	0	0.0%	
5	0	0.0%	4	13.3%	
6	0	0.0%	14	46.7%	
7	0	0.0%	9	30.0%	
8	0	0.0%	3	10.0%	
Total	30	100.0%	30	100.0%	

Note: * significant at 5% level of significance (p<0.05)

FIGURE: DISTRIBUTION OF PAIN SCORE BETWEEN STUDY GROUPS

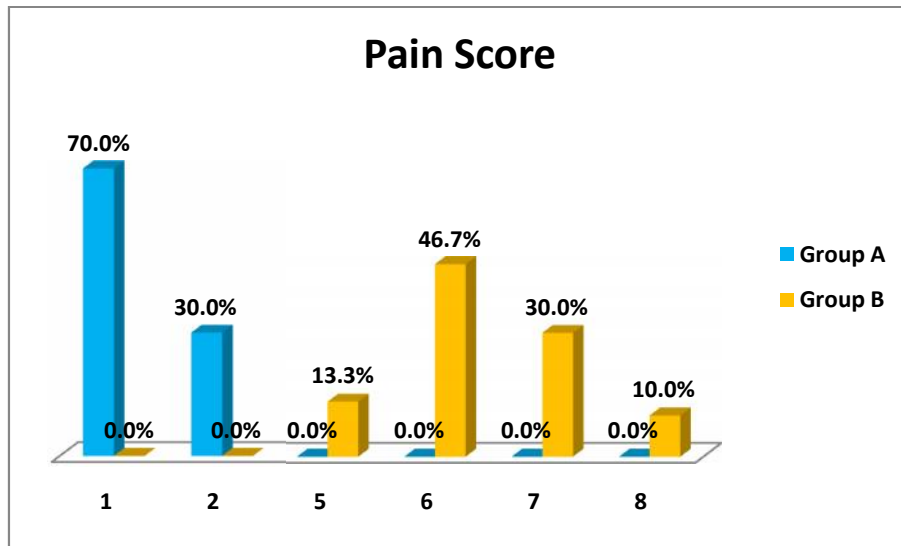


TABLE: MEAN POST OPERATIVE PAIN SCORE BETWEEN STUDY GROUPS

Parameters	Group A		Group B		p value
	Mean	SD	Mean	SD	
Pain Score	1.3	0.5	6.4	0.9	<0.001*

Note: * significant at 5% level of significance (p<0.05)

FIGURE: MEAN PAIN SCORE BETWEEN STUDY GROUPS

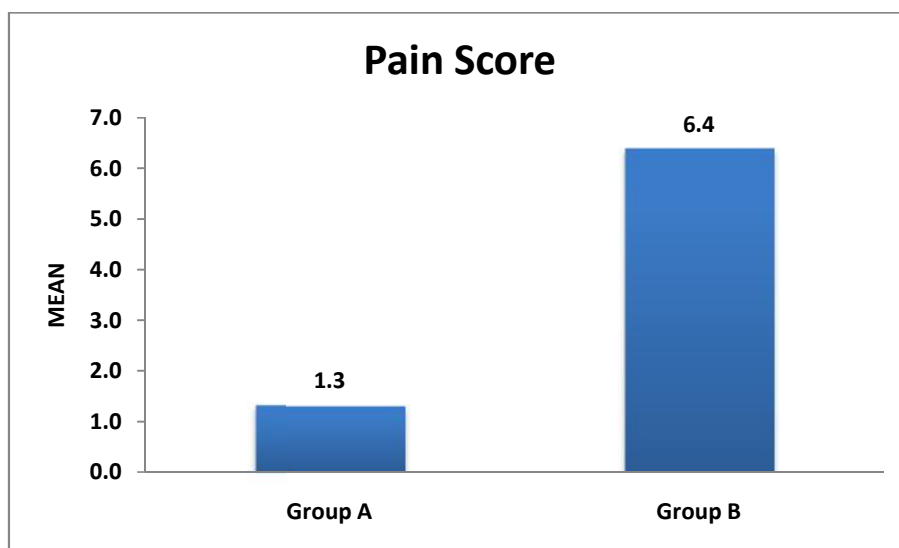
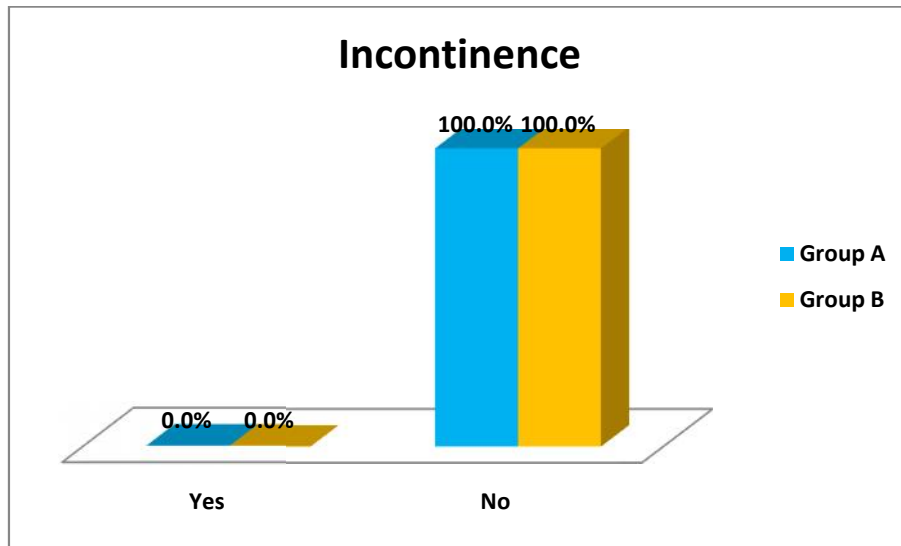


TABLE: INCONTINENCE BETWEEN STUDY GROUPS

Incontinence	Group A		Group B		p value
	Mean	SD	Mean	SD	
Yes	0	0.0%	0	0.0%	-
No	30	100.0%	30	100.0%	
Total	30	100.0%	30	100.0%	

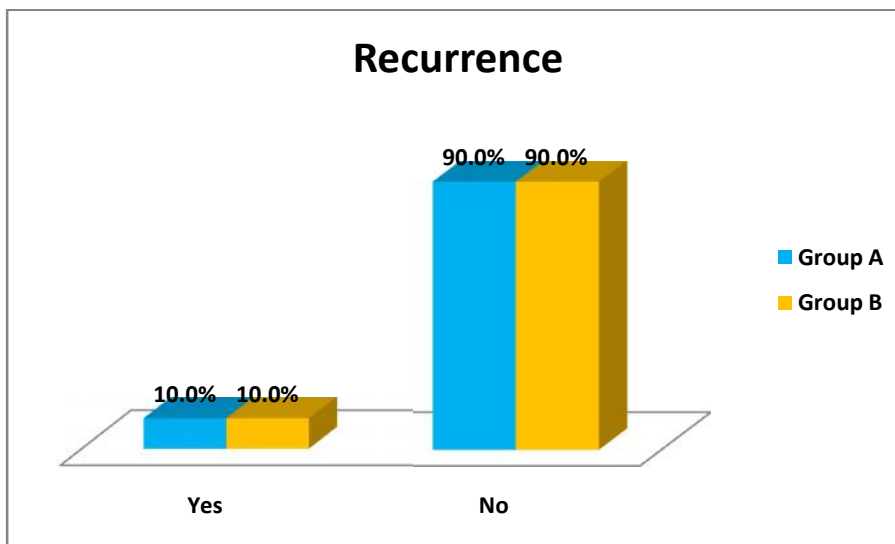
FIGURE: INCONTINENCE BETWEEN STUDY GROUPS



**TABLE: RECURRENCE RATE AT 6 MONTHS FOLLOW UP PERIOD
BETWEEN STUDY GROUPS**

Recurrence	Group A		Group B		p value
	Mean	SD	Mean	SD	
Yes	3	10.0%	3	10.0%	-
No	27	90.0%	27	90.0%	
Total	30	100.0%	30	100.0%	

FIGURE: RECURRENCE RATE AT 6 MONTHS FOLLOW UP PERIOD BETWEEN STUDY GROUPS



PHOTOGRAPHS

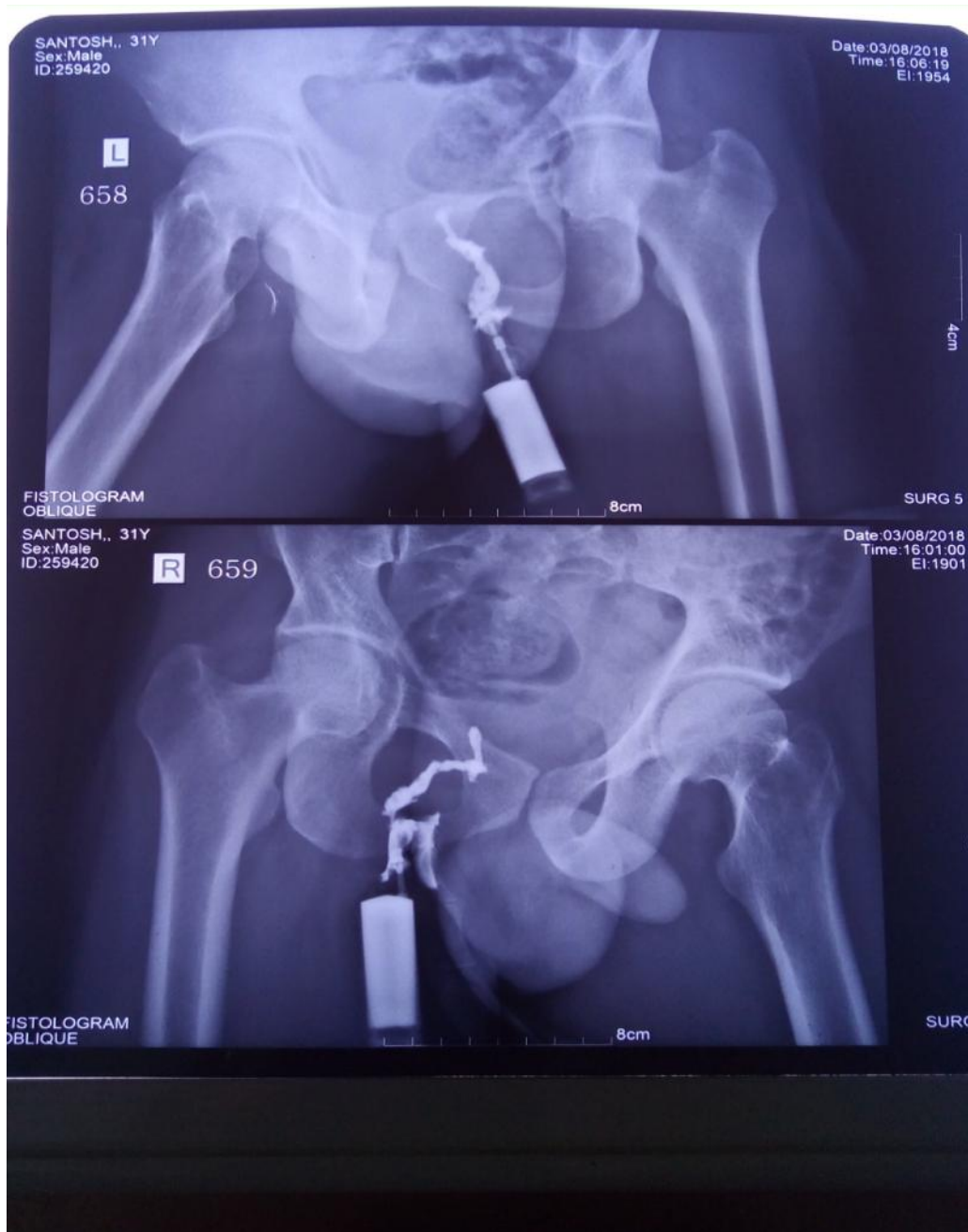


Figure 12 X RAY Fistulogram showing dye in the Rectum



Figure 13a coronal section of MRI Fistulogram



Figure 13b Sagittal section of MRI Fistulogram

Fig 13-Fistulous track seen arising from posterior aspect(5'oclock position) ,left side, hyperintense on T1/T2/STIR WI with surrounding inflammatory changes. Track runs posterolaterally through left ischioanal fossa(7.6 cm). There is evidence of T1 hypointense and T2 WI hyperintense collection measuring about 30 x 15 mm seen communicating with the fistulous tract in left ischioanal fossa - suggestive of Abscess. The tract traverses both layers of sphincter and opens into anus [at 4'0 clock position].

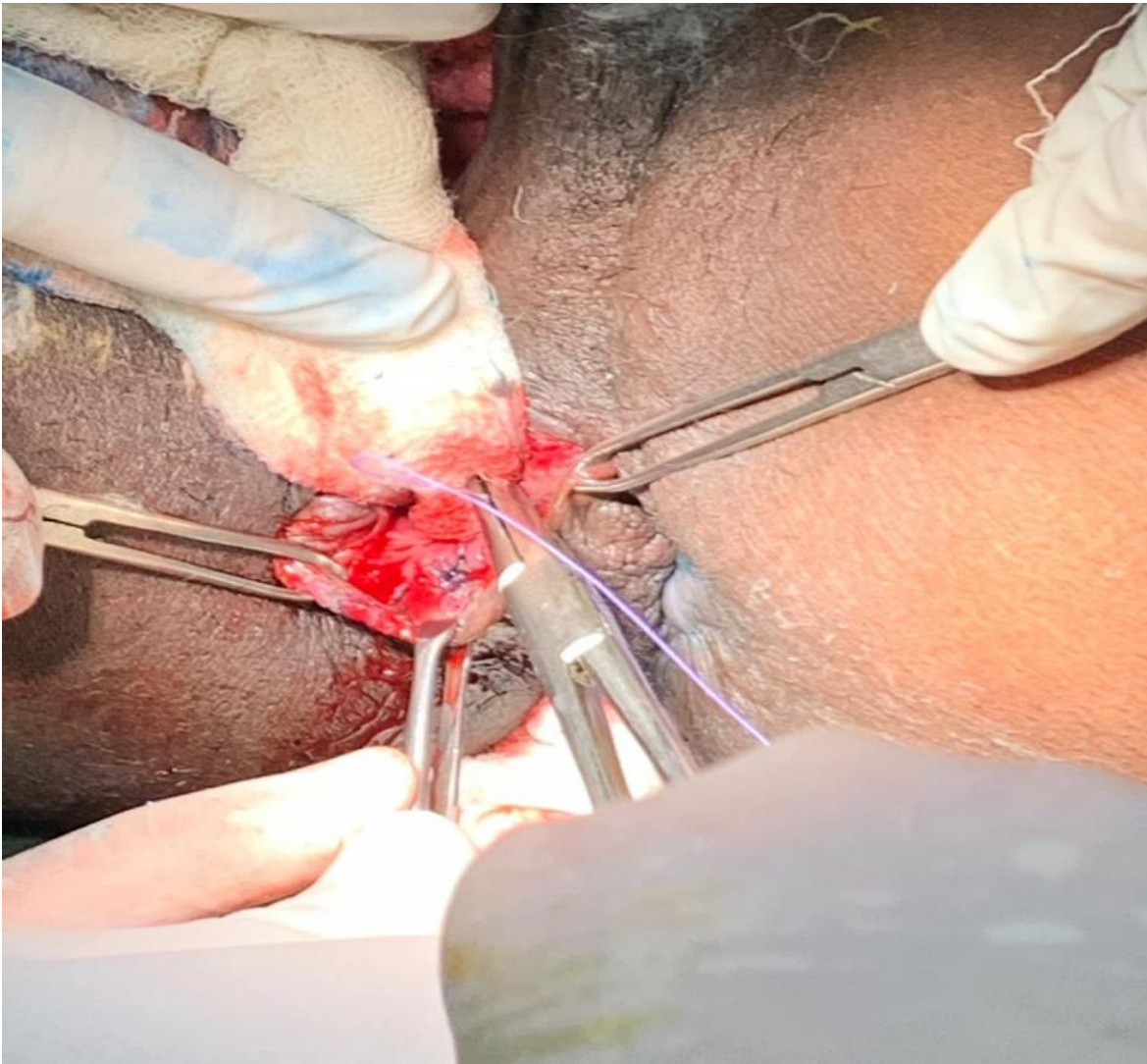


Figure 14 . Closure of Internal Opening with figure of '8' sutures

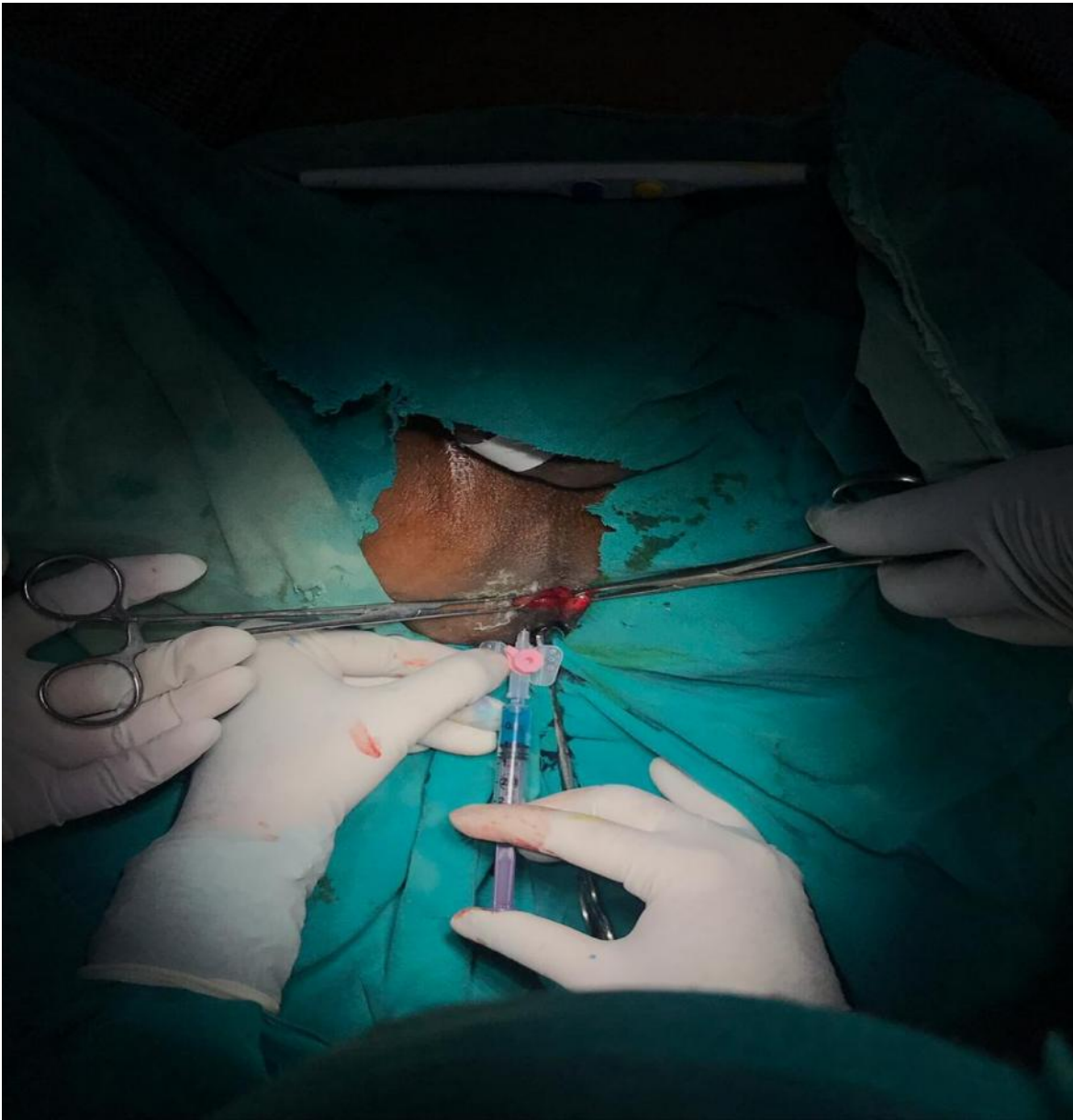


Figure 15. Injection of Cyanoacrylate Glue into the fistulous tract



Figure 16. Post Operative Image following Glue Injection, No External wound, Polymerized glue visible through external opening



Figure 17. Post operative image of Fistulectomy showing scar

DISCUSSION

The patients in our study were allocated randomly into study group (group A) treated with Cyanoacrylate glue injection and Control group (group B) treated with fistulectomy.

In Study group i.e. patients allocated for cyanoacrylate glue injection majority of patients were seen between the age group 31-40 years (SD 40%) followed by 20-30 years of age group (SD 33.32%) around 6 patients belonged to 41-50 years (SD 20.0%) and only 2 patients belonged to age above 50 years. In control group i.e. patients allocated for fistulectomy showed similar results with about 14 patients from age group 31-40 years (SD 46.7%) followed by 7 patients between age group 20-30 years (SD 23.3%). About 5 patients (SD 16.7%) were between age group 41-50 years (SD 16.7%) and only 4 patients were above 50 years of age (SD 13.3%).

Mean age between the two groups was around 35.8 in group A and 38.9 in group B

Our results were comparable to the reports of Sushil Damor et al, according to whom peak incidence is seen at 21-40 years of age⁶³

In the Saino report, most patients were between ages 20-40 years with mean age of 40 years in both genders²⁷

In our study majority of the patients were male in both the groups (SD 70.0%). In the Saino report incidence was twice more in men as compared to women (12.3% vs 5.6%)^{27,67}. Similar large scale studies done in Cook County hospital Chicago it was seen that male to female ratio is 2:1.^{28,67} These results are in accordance with results of our study.

There is no association between the lifestyle/occupation of the patient and the occurrence of fistula in ano (p value 0.287). These results are in accordance with study done by Read DR.²⁸

Majority of patients presented with Swelling with mean duration of 6 months period in Group A and mean 5.9 months in Group B and discharge since mean duration of 5.7 months in group A and 5.9 months in group B.

Mean Duration of hospital stay in group A is 5.5 days whereas in Group B it is 9.2 days which is statistically significant (p value <0.001).

Pain as symptom along with swelling and discharge was noted only in 5 patients of Group A (SD 16.7%) and in 2 patients of Group B (SD 6.7%).

In Group A 11 patients had recurrent fistula in ano(SD 36.7%) where as in group B 8 patients presented with recurrent fistula in ano(SD 26.7%). In a study done by Vander Hagen on fistulotomy he found that 30% of them had recurrent fistulas.⁶⁵

In our study posterior fistulas are more common than anterior fistulas in both group A (SD90.0%) and group B(SD 83.3%)

Based on MRI report in Group A 20 patients had Intersphincteric fistula(SD 66.7%) , about 4 patients had transsphincteric(13.3%) , 3 patients had suprasphincteric(10.0%) and 3 had extrasphincteric(10.0%) type of fistula in ano. Similarly in Group B about 25 patients had intersphincteric(SD 83.3%), suprasphincteric (10.0%) and extrasphincteric (6.7%).This is in accordance with study done by Vasilevsky et al³².

Majority of them were low anal fistula with internal opening below dentate line Group A (SD 90.0%) and group B (SD 90.0%).

Pain score based on visual analogue scale in Froup A patients was rated at 1(70.0%) , 2 (30.0%) none of the patients treated with glue injection opted for pain score beyond 2. Pain score in patients treated with Fistulectomy were rated at 6 (46.7%), 7(30.0%) , 4 (13.3%) and 3 (10.0%).These results were found to be statistically significant (p value <0.001) This can be attributed to long duration of surgery ,lot of tissue dissection and handling in fistulectomy (groupB).

Mean Post operative pain score in Group A was 1.3 where as mean post operative pain score in Group B was 6.4. These results are significant statistically (p value , 0.001).

No post operative complications complication were noted in Group A patients(SD 0.0%) ,where as patients treated with fistulectomy(Group B) had wound infection(SD 10.0%) which was managed with course of antibiotics according to culture sensitivity.

No in continence was observed either in study group or control group.

Equal recurrence was observed in both Group A (10.0%) and Group B (10.0%), with 3 recurrences in each group. Recurrence in Group A was seen in patients with high anal fistulas. One patient had recurrence at two months , where as rest two had recurrence at 6 months post surgery. All these patients were treated with repeat glue injection and so far are asymptomatic at follow up. In Group B recurrence were seen in two patients with high anal fistula and one

patient with low anal fistula. All three patients were treated with fistulectomy with primary sphincter reconstruction. In a study done by Jivapaisarpong et al on 33 patients with fistula in ano he had recurrence rate of about 12 %.^{66,67}

Success rate with Cyanoacrylate glue injection in our study was 90.0% . In a study done by Barillari et al on cyanoacrylate glue injection for anal fistula done on 21 patients he obtained 90.2% cure rate at a follow up period of about 18 months¹³. Similarly Queralto et al. also studied application of cyanoacrylate glue injection in 34 patients for anal fistulas with follow up done for two years. In his study he found cure rate of about 67.78% in first month of injection¹⁴. Jain et al studied application of cyanoacrylate glue in 20 patients of low anal fistulas and obtained 85% cure rate at six months follow up time¹⁵.

SUMMARY

- We included 60 patients with Anal fistulas in our study according to the proposed inclusion and exclusion criteria. They were allocated by randomization into study group and control group respectively.
- Fistula in ano was seen in mean age group of 38.9 years in both sex which is in accordance with previous studies
- In our study incidence is more in males (SD 70%) compared to females with male to female ratio of 2:1.
- No statistical significance noted with respect to fistula in ano and sedentary lifestyle of patient.
- Most common symptoms were swelling and discharge from peri anal region. Pain as symptom was reported by only 6.7% of patients.
- About 36.7% presented with recurrent fistula in ano
- Posterior and low anal fistulas are more common compared with anterior and high anal fistulas.
- Intersphincteric fistulas are most common type of fistulas followed by transsphincteric, suprasphincteric. Extrasphincteric are least common type.
- Mean post operative pain score in patients treated with glue injection is 1.3 where as those treated with fistulectomy is 6.4 which is statistically significant.(p value <0.001)
- Patients treated with Glue injection experienced significantly less pain as compared to patients treated with fistulectomy.
- Complications such as wound infection was observed in fistulectomy patients but patients with glue injection did not experience any post operative complications.
- Mean duration of hospital stay in study group is 5.5 days where as in control group it is 9.2 which is statistically significant (p value <0.001)
- In our study we noted equal recurrence in both study group and control group.

CONCLUSION

- Fistulectomy/Fistulotomy since long time has been the most reliable method of treating most of the anal fistulas, but sacrificing sphincters during this procedure can cause incontinence. This procedure is difficult in patients with high internal opening, anterior fistulas in women, previous ano rectal surgeries and patients who have disturbances of continence beforehand and in those who have preexisting risk of incontinence such as Crohn's disease, HIV, elderly.
- Cyanoacrylate glue injection is easy to apply, does not have a difficult learning curve, can be performed in a short interval of time, as it is a sphincter sparing procedure and thus definitely there is no risk of incontinence post procedure.
- The operative procedure is technically simple and is cost effective and repeatable, hence does not preclude second surgery if required as it will not distort perianal anatomy or muscle architecture.
- Post operative pain following surgery is also minimal.
- In these aspects Cyanoacrylate glue injection is an ideal procedure for anal fistula.
- According to our study success rate of Cyanoacrylate glue injection is similar to that of Fistulectomy with similar recurrence rates in both groups, and hence patients must be explained before hand regarding possibility of recurrence of the fistula.
- Given its safety profile, easy of application, simplicity, less postoperative pain, reduced duration of hospital stay, early recovery, low complication rate and post operative morbidity cyanoacrylate glue injection should be considered in the management of fistula in ano and is better than fistulectomy in these respects.
- As Fistula in ano remains a complex disease, surgeon should become familiar with various surgical procedures including Cyanoacrylate glue injection and treatment should be tailored accordingly to each patient depending on his condition and type of fistula to gain maximum benefit from surgery.

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B) INFORMED CONCENT FORM

I confirm that, _____, has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore, I agree to give my consent to participate as a subject in this research project.

(Participant)

Date

(Witness to above signature)

Date

PURPOSE OF RESEARCH:

I have been informed that this study will analyse the comparison of cyanoacrylate glue injection with conventional fistulectomy for treatment of fistula in ano.

I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

RISKS AND DISCOMFORTS:

I understand that my patient may experience some pain, may be pain at the operated site, there may be discharge from the wound. I understand that necessary measures will be taken to reduce these complications as and when they arise.

BENEFITS:

Safe and feasible, reduced post-operative pain,.day care procedure, sphincter saving procedure, less intraop and post op hemorrhage, early recovery, no post operative anal incontinence, cost effective, better patient compliance.

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time, _____ is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me.

And that a copy of this consent form will be given to me to keep it and for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that _____, will terminate my participation in this study at any time after she has explained the reasons for doing so and has helped arrange for my continued care by my own surgeon or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to _____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date:

(GUIDE)

(INVESTIGATOR)

- **PERSONAL HISTORY:**

- **GENERAL PHYSICAL EXAMINATION**

BUILT: WELL/MODERATE/POOR

NOURISHMENT: WELL/MODERATE/POOR

PALLOR :

ICTERUS:

CYANOSIS:

CLUBBING:

EDEMA:

LYMPHADENOPATHY:

- **VITALS:**

TEMPERATURE:

PULSE:

RESPIRATORY RATE:

BLOOD PRESSURE:

- **LOCAL EXAMINATION: OF PERIANAL REGION**

INSPECTION:

PALPATION:

DIGITAL RECTAL EXAMINATION:

PROCTOSCOPY:

- **SYSTEMIC EXAMINATION:**

PER ABDOMEN:

RESPIRATORY SYSTEM:

CARDIOVASCULAR SYSTEM:

CENTRAL NERVOUS SYSTEM:

CLINICAL DIAGNOSIS:

LABORATORY INVESTIGATIONS:

HB%:

TOTAL COUNT:

DIFFERENTIAL COUNT

N/L/E/B/M:

URINE ROUTINE:

RBS:

B.UREA,:

S.CREATININE:

HIV, HBsAg

- CHEST X RAY:
- XRAY FISTULOGRAM / MAGNETIC RESONANCE IMAGING OF FISTULOUS TRACT

- OPERATIVE PROCEDURE (DATE AND TIME):

- **POST OPERATIVE ASSESSMENT:**

- 1) POST OPERATIVE PAIN
- 2) POST OPERATIVE BLEEDING
- 3) RECOVERY TIME
- 4) INTOLERANCE TO CYANOACRYLATE GLUE
- 5) RECURRENCE OF SYMPTOMS
- 6) FECAL INCONTINANCE

➤ FOLLOW UP AT 1ST WEEK:

➤ FOLLOW UP AT 2ND WEEK

➤ FOLLOW UP AT 3RD WEEK

➤ FOLLOW UP AT 4TH WEEK:

➤ FOLLOW UP AT THE END OF 3 MONTHS:

➤ FOLLOW UP AT THE END OF 6 MONTHS:

➤ CONCLUSION:

Serial Number	Name	Age	Sex	Occupation	IP number	Date of Admission	Date of Procedure	Date of Discharge	Swelling (Duration in months)	Discharge (Duration in months)	Pain (Yes/No)	Duration of Hospital Stay (Days)	Postoperative Compl ication	Type of fistula	Previous Surgerv	MRI	Low/ High Anal fistula	Pain Score	Incontinence (Yes/No)	Recurrence
1	Iranna	40	M	Farmer	32111	10/2/2017	10/4/2017	10/6/2017	6	6	N	5	No	Posterior	Fistulectomy 2 years ago	Intersphincteric	Low	1	No	No
2	Ametepa	42	M	Farmer	30526	10/5/2017	10/18/2017	10/21/2017	12	12	N	7	No	Posterior	Fistulectomy 1 years ago	Suprasphincteric	Low	2	No	No
3	Shivanand	23	M	Student	30527	11/12/2017	11/15/2017	11/18/2017	2	2	N	7	No	Posterior	No	Intersphincteric	High	1	No	At 3rd month
4	Shankar	26	M	Student	40043	11/24/2017	11/27/2017	11/29/2017	8	8	N	6	No	Posterior	No	Intersphincteric	Low	2	No	No
5	Chandrashekhar	40	M	Clerk	40324	11/25/2017	11/27/2017	11/29/2017	2	1	N	5	No	Posterior	No	Transsphincteric	Low	1	No	No
6	Kavva	49	F	Housewife	15071	5/4/2018	5/7/2018	5/10/2018	5	3	N	7	No	Posterior	Fistulectomy 5 years ago	Extrasphincteric	Low	1	No	No
7	Irappa	45	M	Mechanic	306428	5/18/2018	5/20/2018	5/22/2018	1	1	Y	5	No	Posterior	No	Intersphincteric	Low	1	No	No
8	Somaning	41	M	Mason	17697	5/22/2018	5/24/2018	5/27/2018	2	2	Y	5	No	Posterior	Fistulectomy 2 years ago	Suprasphincteric	Low	1	No	No
9	Mallikariun	26	M	Accountant	40632	5/26/2018	5/28/2018	6/1/2018	4	4	N	6	No	Posterior	No	Intersphincteric	Low	2	No	No
10	Bharati	20	F	Student	40650	6/8/2018	6/10/2018	6/12/2018	2	2	Y	5	No	Posterior	No	Intersphincteric	Low	2	No	No
11	Md. Hanif	39	M	Painter	39086	6/10/2018	6/12/2018	6/14/2018	1	1	N	5	No	Posterior	No	Transsphincteric	Low	1	No	No
12	Mahananda	31	F	Housewife	20306	6/15/2018	6/17/2018	6/20/2018	24	24	N	6	No	Posterior	Fistulectomy 4 years ago	Intersphincteric	Low	2	No	No
13	Hanamanth	38	M	Farmer	21218	6/29/2018	6/1/2018	6/3/2018	36	36	N	6	No	Posterior	No	Intersphincteric	Low	1	No	No
14	Jakappa	62	M	Retired	18513	6/1/2018	6/3/2018	6/6/2018	6	5	N	6	No	Anterior	No	Intersphincteric	Low	2	No	No
15	Krishna	40	M	Electronic Repair	19509	6/8/2018	6/10/2018	6/12/2018	2	1	N	5	No	Posterior	Fistulectomy 1 years ago	Transsphincteric	Low	1	No	No
16	Kumar Premu	32	M	Mechanic	40684	7/15/2018	7/17/2018	7/19/2018	3	3	N	5	No	Anterior	No	Intersphincteric	Low	1	No	No
17	Santosh M	22	M	Student	24531	7/20/2018	7/22/2018	7/24/2018	2	2	N	5	No	Posterior	No	Intersphincteric	Low	2	No	No

18	Santosh J	31	M	Mason	27853	8/17/2018	8/19/2018	8/21/2018	6	5	N	5	No	Posterior	Fistulecto my 2 years ago	Extrasphin ctic	Low	1	No	No
19	Mounesh	54	M	Farmer	19424	8/19/2018	8/21/2018	8/23/2018	4	3	N	5	No	Posterior	Fistulecto my 1 years ago	Intersphinc teric	Low	1	No	No
20	Keerthi	22	F	Student	15424	9/28/2018	9/30/2018	10/2/2018	6	5	N	5	No	Posterior	No	Intersphinc teric	Low	1	No	No
21	Sharanappa	50	M	Farmer	15048	10/8/2018	10/10/2018	10/12/2018	5	5	N	5	No	Posterior	No	Intersphinc teric	Low	1	No	No
22	Lakavva	31	F	Farmer	36232	10/23/2018	10/25/2018	10/28/2018	6	6	N	6	No	Anterior	Fistulecto my 2 years ago	Suprasphin ctic	High	1	No	At 6th month
23	Sumati	38	F	Housewife	30783	10/28/2018	10/30/2018	11/2/2018	2	2	Y	5	No	Posterior	No	Intersphinc teric	Low	2	No	No
24	Kulappa	36	M	Farmer	30786	11/1/2018	11/3/2018	11/6/2018	6	6	N	6	No	Posterior	No	Intersphinc teric	Low	1	No	No
25	Fatima	46	F	Housewife	18493	11/6/2018	11/8/2018	11/10/2018	12	12	N	5	No	Posterior	No	Extrasphin ctic	High	2	No	At 3rd month
26	Ramappa	30	M	Mason	22146	12/18/2018	12/20/2018	12/22/2018	1	1	Y	5	No	Posterior	No	Intersphinc teric	Low	1	No	No
27	Keerthana	28	F	Bank Officer	21124	12/22/2018	12/24/2018	12/26/2018	2	2	N	5	No	Posterior	No	Intersphinc teric	Low	1	No	No
28	Vidhya	38	F	Housewife	21226	1/6/2019	1/8/2019	1/10/2019	4	3	N	5	No	Posterior	Fistulecto my 1 years ago	Intersphinc teric	Low	1	No	No
29	Nagappa	26	M	Farmer	21143	1/1/2019	1/3/2019	1/5/2019	2	2	N	5	No	Posterior	No	Intersphinc teric	Low	1	No	No
30	Bhimappa	28	M	Clerk	9557	3/28/2019	3/31/2019	4/2/2019	6	6	N	6	No	Posterior	Twice Fistulecto my 5 years ago, 2 years ago	Transsphinc ctic	Low	1	No	No
31	Jakappa	64	M	Retired	30554	10/12/2017	10/14/2017	10/24/2017	5	5	N	13	No	Wound Infecti on	No	Intersphinc teric	Low	8	No	No
32	Chanamma	46	F	Farmer	11591	10/16/2017	10/18/2017	10/25/2017	8	8	Y	10	No	Posterior	Fistulecto my 2 years ago	Extrasphin ctic	Low	7	No	No
33	Shankarling	25	M	Student	31311	10/18/2017	10/21/2017	10/27/2017	4	4	N	10	No	Posterior	No	Intersphinc teric	Low	6	No	No
34	Kudalappa	40	M	Farmer	21668	11/1/2017	11/30/2017	11/11/2017	12	12	N	11	No	Posterior	No	Intersphinc teric	Low	6	No	No
35	Raikumar	38	M	Teacher	21758	11/20/2017	11/22/2017	11/28/2017	1	1	N	9	No	Posterior	No	Intersphinc teric	Low	5	No	No

36	Mageppa	50	M	Farmer	22220	12/15/2017	12/18/2017	12/24/2017	24	24	N	10	No	Posterior	Fistulectomy 5 years ago	Suprasphincteric	High	8	No	At 4th month
37	Iranna	45	M	Farmer	1776	1/6/2018	1/8/2018	1/16/2018	2	2	N	11	No	Anterior	No	Intersphincteric	Low	7	No	No
38	Siddramavva	35	F	Housewife	1084	1/8/2018	1/11/2018	1/16/2018	5	5	N	9	No	Posterior	No	Intersphincteric	Low	5	No	No
39	Sangavva	56	M	Farmer	2134	1/16/2018	1/18/2018	1/26/2018	2	2	N	11	No	Posterior	No	Intersphincteric	Low	7	No	No
40	Umesh	40	M	Clerk	3725	1/30/2018	2/1/2018	2/6/2018	4	4	N	7	Wound Infection	Posterior	Fistulectomy 2 years ago	Intersphincteric	High	6	No	At 6th month
41	Gaurabai	41	F	Housewife	5451	2/12/2018	2/15/2018	2/20/2018	2	2	N	9	No	Posterior	Fistulectomy 8 months ago	Intersphincteric	Low	6	No	No
42	Yamanappa	32	M	Farmer	6315	2/20/2018	2/22/2018	2/28/2018	8	8	N	9	No	Anterior	No	Intersphincteric	Low	7	No	No
43	Sandepiti	28	F	Teacher	8747	3/12/2018	3/14/2018	3/19/2018	1	1	N	8	No	Posterior	No	Intersphincteric	Low	6	No	No
44	Ravindramma	36	F	Farmer	9647	3/19/2018	3/21/2018	3/26/2018	6	6	N	8	No	Posterior	No	Intersphincteric	Low	6	No	No
45	Aneeta	28	F	Teacher	12214	4/9/2018	4/11/2018	4/19/2018	4	4	N	11	No	Anterior	Fistulectomy 4 years ago	Suprasphincteric	Low	7	No	No
46	Annapurna	38	F	Teacher	6171	5/10/2018	5/13/2018	5/20/2018	5	5	N	11	Wound Infection	Posterior	No	Intersphincteric	Low	8	No	No
47	Siddappa	25	M	Student	17134	5/19/2018	5/21/2018	5/26/2018	1	1	N	8	No	Anterior	No	Intersphincteric	Low	6	No	No
48	Subhash	35	M	Clerk	18077	8/25/2018	5/30/2018	6/4/2018	4	4	Y	10	No	Posterior	No	Intersphincteric	Low	7	No	No
49	Bagawwa	60	F	Farmer	18888	6/2/2018	6/4/2018	6/8/2018	4	4	N	7	No	Posterior	No	Intersphincteric	Low	5	No	No
50	Gireesh	34	M	Buisness	10822	6/10/2018	6/12/2018	6/19/2018	2	2	N	10	No	Posterior	Fistulectomy 2 years ago	Intersphincteric	Low	6	No	No
51	Farooq	30	M	Bank Officer	20840	6/18/2018	6/20/2018	6/25/2018	6	6	N	8	No	Posterior	Fistulectomy 4 years ago	Intersphincteric	High	6	No	At 6th month
52	Gudalappa	55	M	Farmer	21339	6/24/2018	6/26/2018	7/1/2018	2	2	N	8	No	Posterior	No	Extrasphincteric	Low	7	No	No
53	Santosh	38	M	Teacher	12045	8/15/2018	8/17/2018	8/22/2018	12	12	N	8	No	Posterior	No	Intersphincteric	Low	6	No	No

54	Shivamma	38	F	Housewife	36329	9/15/2018	9/17/2018	9/22/2018	6	6	N	8	No	Anterior	Fistulectomy 1 years ago	Suprasphincteric	Low	7	No	No
55	Shankreppa	45	M	Buisness	16495	9/22/2018	9/24/2018	9/30/2018	4	4	N	9	No	Posterior	No	Intersphincteric	Low	6	No	No
56	Basanna	38	M	Buisness	17794	12/10/2018	12/12/2018	12/17/2018	3	3	N	8	No	Posterior	No	Intersphincteric	Low	5	No	No
57	Sangavvva	40	M	Farmer	22462	12/26/2018	12/29/2018	12/3/2018	12	12	N	9	No	Posterior	No	Intersphincteric	Low	6	No	No
58	Shantappa	32	M	Farmer	23441	1/4/2019	1/6/2019	1/11/2019	2	2	N	8	No	Posterior	No	Intersphincteric	Low	7	No	No
59	Naveen kumar	26	M	Student	15092	2/10/2019	2/12/2019	2/17/2019	15	15	N	8	No	Posterior	No	Intersphincteric	Low	6	No	No
60	Baburao	30	M	Milkman	18511	3/13/2019	3/15/2019	3/21/2019	12	12	N	9	No	Posterior	No	Intersphincteric	Low	6	No	No