

## A Clinicopathological Study with Evaluation of Different Operative Techniques for Fistula-in-Ano on Patients: An Observational Study

### ABSTRACT

**Introduction:** Fistula-in-ano form a good majority of benign treatable lesions of rectum and anal canal. Anal fistulas are considered as one of the commonest cause for a persistent seropurulent discharge that irritates the skin in the neighbourhood and causes discomfort. Anal fistulas develop secondary to perianal abscess. Complex fistula can have a characteristic of the following: multiple tracts, recurrence, pre-existing incontinence, fistula in Crohn's disease. Most of these fistula-in-ano are easy to diagnose with a good source of light, a proctoscope, and a meticulous digital rectal examination. Managing fistula in ano is a challenge since it carries a significant recurrence rate after the operation. Management of fistula in ano includes control of sepsis, closure of fistulous tract, maintenance of continence and preventing recurrence. Surgical techniques like fistulotomy, fistulectomy, primary closure after excision of tract, seton use and staged operations have rendered the postoperative period uneventful, short and steep fall in recurrence rate. Complications of fistula surgery are myriad, like fecal soiling, mucus discharge, varying degrees of incontinence and recurrent abscess and fistula. Clearly the surgeon who has the first opportunity to treat the patient is the one most likely to effect a cure, to minimize disability and to limit morbidity. In this dissertation, an attempt is made to study the presenting symptoms, the findings on clinical examination and the various surgical procedures.

**Key words:** Case series, fistula-in-ano, surgery, recurrence, Goodsall's rule, observational study.

### INTRODUCTION

Fistula is defined as an abnormal communication between two epithelial surfaces and it is usually lined by granulation tissue. A fistula-in-ano is a granulation tissue lined tract, which connects an opening on the perianal skin (external) to another opening inside the anal canal or the lower rectum (internal). It is a benign anorectal condition which is mostly due to cryptoglandular infections.<sup>1</sup> Park's classification<sup>2</sup> is used to determine the type: inter-sphincteric, trans-sphincteric, supra-sphincteric and extra-sphincteric.

Fistula-in-ano form a good majority of benign treatable lesions of rectum and anal canal. Anal fistulas are considered as one of the commonest cause for a persistent seropurulent discharge that irritates the skin in the neighbourhood and causes discomfort. Anal fistulas develop secondary to perianal abscess. Pain is experienced till the abscess ruptures which gives immediate relief. Soreness and itching of perianal skin are common due to moist swollen condition of the skin. Complex fistula can have a characteristic of the following: multiple tracts, recurrence, pre-existing incontinence, fistula in Crohn's disease.

The late 19th and 20th century saw substantial research and various treatment options developed by the likes of Milligan-Morgan, and Goodsall.<sup>3,4</sup> Sir James Parks introduced his classification system in 1976, which is used worldwide even today.<sup>5</sup> David Henry Goodsall in 1900 described a rule (now called as Goodsall's rule), which predicts the position of the external opening of the fistula-in-ano in relation to its internal opening.<sup>6</sup>

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Most of these fistula-in-ano are easy to diagnose with a good source of light, a proctoscope, and a meticulous digital rectal examination. Managing fistula in ano is a challenge since it carries a significant recurrence rate after the operation. Management of fistula in ano includes control of sepsis, closure of fistulous tract, maintenance of continence and preventing recurrence. Factors associated with recurrence include complex type of fistula, horseshoe extension, lack of identification or lateral location of the internal fistulous opening, previous fistula surgery and the surgeon performing the procedure.

There has been a lot of progress in the understanding of the anatomy of the anal canal and the mechanism of continence of rectum and anal canal. This has allowed the surgeon to deal with keeping the spastic anorectal ring intact without interfering with the continence and eradicating the disease. Traditional method has been laying open of the fistulous tract in part or whole, in one or more stages and letting the wound

heal by secondary intention. Rarely a fistula in ano heals spontaneously and often requires a surgical therapy. Surgical techniques like fistulotomy, fistulectomy, primary closure after excision of tract, seton use and staged operations have rendered the postoperative period uneventful, short and steep fall in recurrence rate. Complications of fistula surgery are myriad, like fecal soiling, mucus discharge, varying degrees of incontinence and recurrent abscess and fistula. Hence a careful discussion with the patient regarding the surgical options and potential risks must be performed preoperatively because the precise procedure may not be clear until operative examination. Clearly the surgeon who has the first opportunity to treat the patient is the one most likely to effect a cure, to minimize disability and to limit morbidity.

Thus there are varied features, presentations and treatment modalities for fistula in ano. Hence in this dissertation, an attempt is made to study the presenting symptoms, the findings on clinical examination and the various surgical procedures.

The true prevalence of fistula-in-ano is unknown. The incidence of a fistula-in-ano developing from an anal abscess ranges from 26% to 38%.<sup>7</sup> One study showed that the prevalence of fistula-in-ano is 8.6 cases per 100,000 population. In men, the prevalence is 12.3 cases per 100,000 population, and in women, it is 5.6 cases per 100,000 population. The male-to-female ratio is 1.8:1. The mean patient age is 38.3 years.

In 2009, a retrospective cohort study was conducted in patients with a first-time perianal abscess treated at Kaiser Permanents Los Angeles between 1995 and 2005. Of the 148 patients, during a mean follow up period of 38 months, the incidence of chronic anal fistula or recurrent sepsis was 36.5%. Age <40 years significantly increased risk. Diabetic patients were at increased risk. Gender, smoking history, perioperative antibiotic treatment and HIV status were not risk factors for chronic anal fistula or recurrent anal sepsis.<sup>8</sup>

A single centre study of 80 cases of fistula-in-ano in Sri Ramchandra Medical College, Chennai, it was observed that 90% of the cases were <60 years of age with a very high male preponderance (82.5%). A perianal abscess is the major cause of development of anal fistulae with tuberculosis causing 7.5% of the fistulae in our study. Goodsall's rule was found to be accurate in only about 66% of anterior fistulae and 29% in posterior fistulae.<sup>9</sup>

A study in Stanley Medical College, Chennai in 2016 on 45 patients of fistula in ano revealed the following: majority (82%) belonged to 31- 60 years of age. Male: female = 4:1. 91% fistulas were low anal, 76% of external openings were posterior. Fistulectomy was performed in 31 cases, fistulotomy for 10 cases, seton for 4 cases and the operated wound healed 2-8 weeks. Delayed healing was seen in complex fistulas, intersphincteric and transsphincteric fistula takes longer time to heal about 4-5 weeks. Fistula of tubercular etiology took minimum 3 weeks to heal. 13% cases showed recurrence.<sup>10</sup>

Hiranyakas *et al.* in 2005(21cases) in their study on efficacy of endoanal ultrasound, showed that overall only 58.82% of the cases of fistula-in-ano followed the Goodsall's rule.<sup>11</sup> Mallick and Kamil (71 cases) showed Goodsall's rule accurate in 53% posterior openings and 54% anterior openings.<sup>12</sup>

Besides clinical evaluation commonly done investigations are sigmoidoscopy, colonoscopy, Fistulography, endo-anal/endorectal ultrasound, MRI, CT Scan, barium enema/small bowel series, fistuloscopy.<sup>13</sup> Diagnostic tests such as pelvic MRI or Endo-rectal ultra-sound and treatment by a specialist is helpful in fistula in ano.<sup>14</sup>

The object of surgical treatment of an anal fistula is to eradicate it without disturbing anal continence.<sup>15</sup> The primary determinant of successful treatment of fistulas involves accurate identification of the internal opening and course of the fistulous tract.<sup>16</sup> Anal fistulas are usually treated with the classical lay open technique, fistulotomy. The radiofrequency fistulotomy is performed recently.<sup>17</sup> Some surgeons prefer to excise the fistulous tract along the probe i.e. fistulectomy. High trans-sphincteric fistulas which encircles a greater amount of muscle are more safely treated by initial placement of seton.<sup>18</sup> Difficult and persistent high fistulas can be treated by sliding flap advancement made up of mucosa, submucosa and circular muscle to cover the internal opening. Other methods of treatment include coring and ligation of the external anal fistula tract, fistula plug, fibrin glue, video assisted anal fistula treatment (VAAFT), ligation of inter-sphincteric fistula tract (LIFT).

Postoperative rates of recurrence and incontinence vary according to the procedure performed, as follows:

- **Standard fistulotomy:** The reported rate of recurrence is 0-18%, and the rate of any stool incontinence is 3-7%
- **Seton use:** The reported rate of recurrence is 0-17%, and the rate of any incontinence of stool is 0-17%
- **Mucosal advancement flap:** The reported rate of recurrence is 1-17%, and the rate of any incontinence of stool is 6-8%.<sup>19</sup>

#### Primary Research Question:

To study the clinical presentations and evaluation of different operative techniques for fistula-in-ano.

**Primary Hypothesis:** No hypothesis could be formulated since it is an observational study.

#### Primary Objectives:

1. To study age and sex distribution of fistula-in-ano.
2. To study clinical presentation of fistula-in-ano.
3. To study predisposing factors if any for the development of fistula-in-ano.
4. To study co-morbid factors associated with fistula-in-ano.
5. To study different modalities of surgical approach and efficacy with special reference to sphincter incontinence in the immediate post-op period.

**METHODS**

1. Study design: Observational study.
2. Study setting: Tertiary health care center.
3. Study population: Patients.
4. Duration of study: 18 months, January 2019 to July 2020

Name of milestone	Starting date	Expected submission
IEC-HR Approval	October 2018	November 2018
Enrollment of cases	January 2019	June 2020
Analysis of Data	August 2020	September 2020
Writing and submission	November 2020	December 2020

5. Sample size: 50
6. Sampling technique: Non-random, Purposive.
7. Method of selection of study subjects: After having obtained permission from Institutional Ethics Committee and Institutional Scientific Review Committee approval, patients with fistula-in-ano will be included in the study as per the following criteria:

- **Inclusion criteria:** The patients who are clinically diagnosed as fistula-in-ano and admitted to the hospital, will be included in this study.
- **Exclusion criteria:** -All fistulas and sinuses occurring elsewhere in the body are excluded. -All congenital fistulas are excluded. -All fistulas due to perineal injuries are excluded.
- **Subject withdrawal criteria:** unwillingness on part of the patient is the only withdrawal criteria.

8. Methods of data collection relevant to objective: Data will be collected by pre-tested structured questionnaire from all the respondents by direct interview after getting informed written consent from them or from their legal guardian.

(Variables studied:

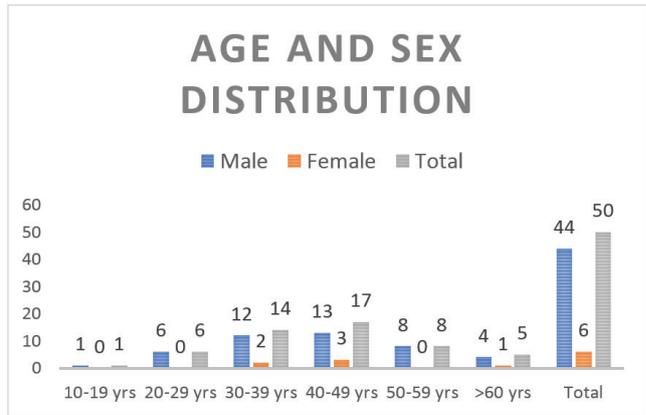
- Age
- Sex
- Symptoms
- Co-morbidities
- Local examination
- Blood parameters, urine R/M
- Chest X-Ray
- MRI Fistulogram
- Examination findings in operation theatre
- Operative technique
- Pus C/S
- Histopathological investigation)

9. Appropriate data management & analysis procedure: Data will be collected as per the Case Record Proforma attached in the appendices and assembled in the master chart attached in the appendices.

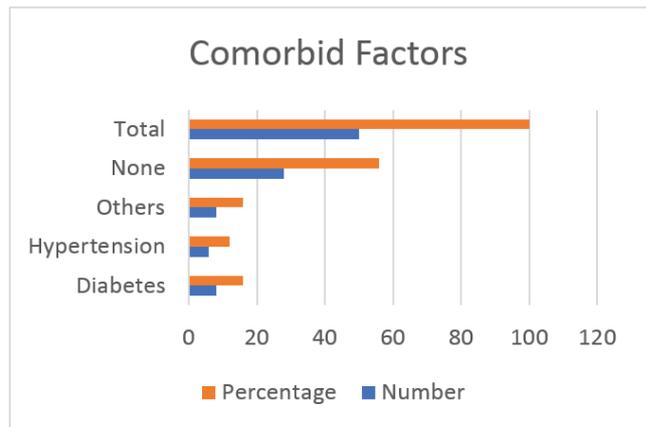
10. Appropriate data analysis plan and methods: Data analysis will be done both manually and by using computer.

Calculated data will be arranged in a systemic manner, presented in a table. Statistical analysis to evaluate the objectives of this study would be done with the help of Statistical Package for Social Sciences (SPSS).

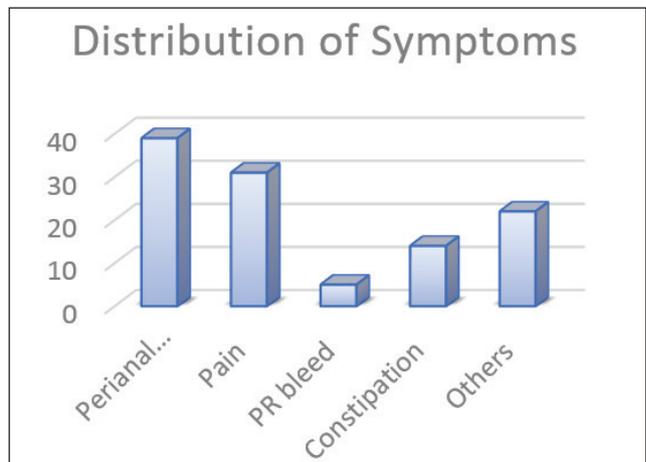
**RESULTS**



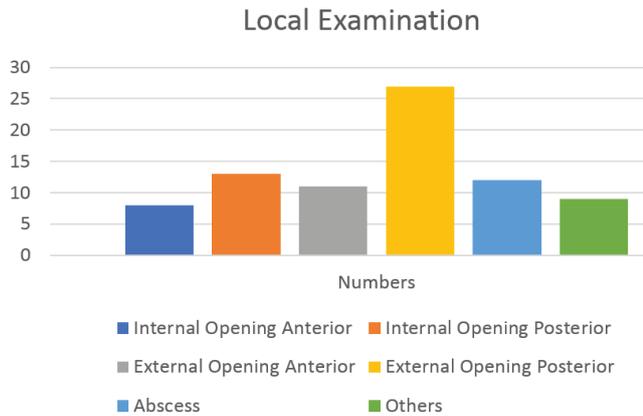
**Graph 1 Age & Sex distribution of patients of fistula in ano**



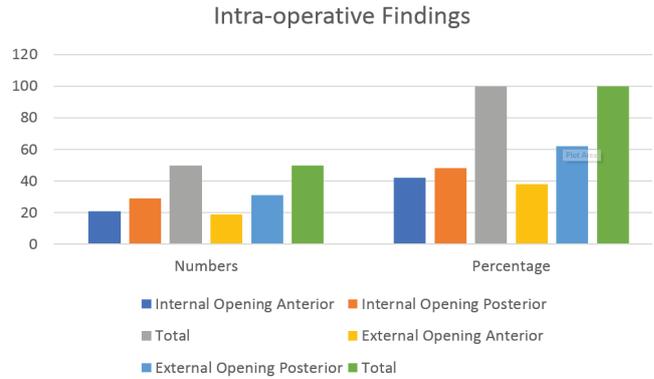
**Graph 2 for associated comorbid factors**



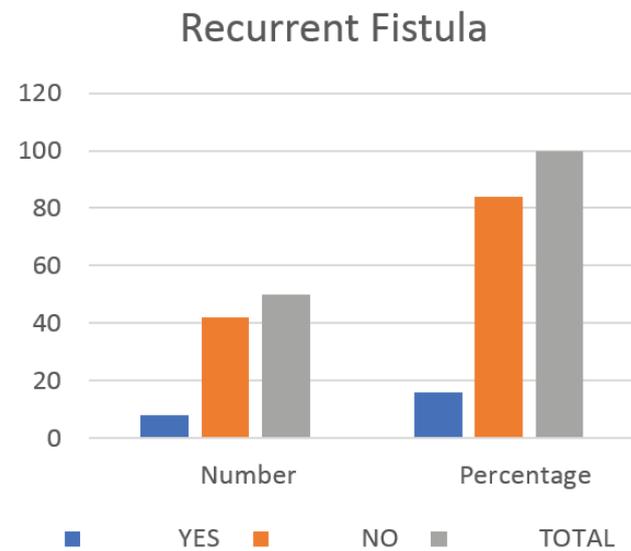
**Graph 3 Distribution of Symptoms**



Graph 4 Findings on PR examination.



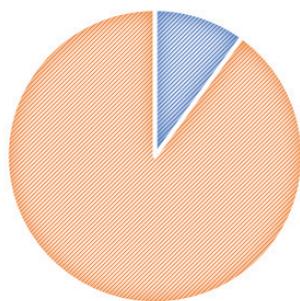
Graph 7 Intraoperative findings



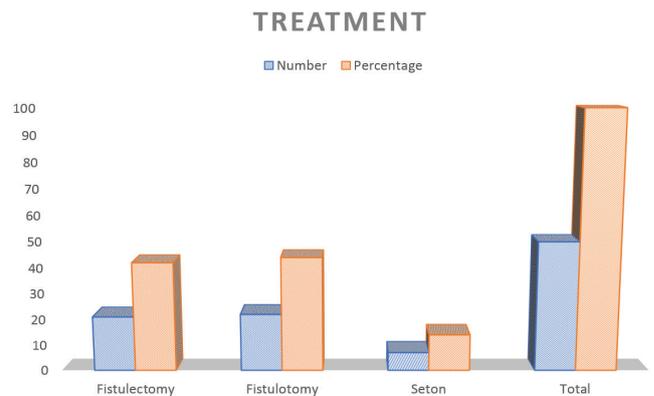
Graph 5 Patients with recurrent fistula

### ANALYSIS OF PUS C/S

Legend: E.coli (blue), C/S not sent (orange)



Graph 6 Organism isolated on Pus culture



Graph 8 Treatment modalities undertaken

### DISCUSSION

Despite being a common problem, perianal fistula has poor standardisation of the treatment protocols. The optimal surgical treatment for anorectal fistulae would be one that is associated with least recurrence rates, minimal incontinence and a good quality of life. Fistula in ano seems to be affecting males predominantly as evidenced by the present study population. This study showed that out of the 50 cases, 44 were males. So, 88% were males and 12% were females. The middle-age group from 30-59 years had maximum number of cases i.e.78%. [Graph 1] 90% of the patients are less than 60 years of age. This is comparable with the study carried out by Fabiano Roberto Fugita et. al.<sup>20</sup>

The most common co-morbid illness found in the patients of fistula in ano is diabetes mellitus. 16% of the patients in our study group had diabetes mellitus, 12% had hypertension. Rest patients had ischemic heart disease, hypothyroidism, leukaemia, cirrhosis of liver as comorbidity. [Graph 2] In the study of Fabiano Roberto Fugita et. al.<sup>20</sup> A no statistical differences were found regarding procedures performed and number of surgeries, since in fact there are no reports of a direct relationship between arterial hypertension or diabetes mellitus

with anal fistulas, although diabetic patients may have a worse outcome regarding anal abscess, which does not extend to the chronic phase of the disease.

Perianal discharge was the most common symptom seen in 78% of the cases this is comparable with the study of Abraham Jebakumar *et. al.* where discharge was the most common symptom.<sup>21</sup> 62% patients had perianal pain. Constipation was seen 28%. Hence the most common symptom in patients of fistula in ano was perianal discharge followed by pain. Other associated symptoms were perianal swelling, per rectal bleed, fever, painful defecation. [Graph 3]

A very important part of every perianal case is per rectal examination to find the external and internal opening of fistula in ano. In this study position of these openings has been mentioned twice. The first one is the location of the external and internal opening in per rectal examination done preoperatively. In these group out of the 50 patients external opening could be located in 38 patients i.e. 76% cases and internal opening in 21 patients i.e. 42% cases [Graph 4]. The other findings were perianal abscess seen in 24% patients and haemorrhoids seen in 14% patients. Comparing these with intra-operative findings of these patients [Graph 7] internal opening could be located in all patients on examination under anaesthesia using techniques such as methylene blue dye injection, hydrogen peroxide injection, probing. Out the 50 patients, 21 had internal opening anteriorly and 29 had posteriorly, i.e. 42% and 58% respectively. External opening was located anteriorly in 19 patients i.e. 38% and posteriorly in 31 patients i.e. 62%. This is comparable with study carried out by Abraham Jebakumar *et. al.* where external opening was located posteriorly in 68% of cases and anteriorly in 24%.<sup>21</sup>

Fistula in ano rather than being difficult to treat are more notorious to recur again. Of the 50 patients in our study 8 patients had past history of taking surgical treatment for fistula in ano, so there were 16% patients with recurrent fistula in ano [Graph 5]. This is also comparable with the study of Abraham Jebakumar *et. al.* in which 13% of patients had recurrent fistula in ano.<sup>21</sup>

Out of 12 cases of perianal abscess pus was sent for culture and sensitivity in 5 patients. Culture grew *E.coli*, suggesting that it is the most common organism to be isolated from perianal abscess. [Graph 6]

There is still lack of general consensus as to which operative procedure to be undertaken in a particular patient. In our study fistulotomy was performed most commonly in 44% of cases, next was fistulectomy performed in 42% cases. Seton placement was done in 14% patients. This is comparable with the study of Fabiano Roberto Fugita *et. al.* 20 where 92% of the patients underwent fistulotomy or fistulectomy, whereas in our study 86% underwent the two procedures. In the study of Abraham Jebakumar *et. al.*<sup>21</sup> 90% patients underwent fistulotomy or fistulectomy and 8% underwent seton placement.

It is a routine practice to send the fistula tract or granulation tissue for histopathological evaluation for etiological correlation. 42% had chronic pyogenic inflammation whereas 46% had non-specific inflammatory findings. Foreign body giant cells were found in 12% of cases suggestive of possible tuberculosis. In the study of Abraham Jebakumar *et. al.* 21 62% had non-specific inflammation and 6% had tuberculosis.

In the immediate postoperative period, the patients were observed for pain and incontinence. Most common postoperative symptom was minimal pain seen in all the patients. Incontinence to flatus was seen in 6% cases.

In the analysis performed here between age group, procedures performed, and number of procedures, there was no difference on procedure selection depending on age or gender of the patient, this fact need not be given greater relevance. The indication of the technique depends on the characteristics of each fistula as well as its complexity, which would result in a greater number of procedures. This record is important because this information has not been reported much in the literature.

## LIMITATIONS OF THE STUDY

1. Short term follow-up of patients, so difficult to comment on recurrence after surgery and long-term morbidity and mortality.
2. Sample size is limited and study duration is not large enough to be of reasonable precision.
3. To determine the pathophysiology of disease more number of patients need to be analysed.
4. Newer modalities of treatment need to be assessed and compared to comment on the efficacy of each these in the long run.

The cases of this study were collected from a tertiary level hospital, all the facts and figures mentioned in this study have been rigorously studied and hence this study reflects the facts regarding age, gender distribution of perianal fistula, associated symptoms, comorbidities and the efficacy of various treatment modalities.

## CONCLUSION

This subject of fistula in ano in has been a matter of debate since centuries. There is no standard consensus regarding the treatment of choice. Optimum treatment depends on the type of fistula, its exact location, extent, experience of the surgeon with a particular procedure and fitness of the patient from the point of view of various types of anaesthesia.

### The points of conclusion are as follows:

1. Fistula in ano is commonly seen in the age group of 30-60 yrs.
2. Gender-wise higher incidence of anal fistula is seen in males.

3. Most common clinical presentation is perianal discharge followed by perianal pain, swelling, constipation, per rectal bleed.
4. There are no specific predisposing factors associated. Chronic constipation and a past history of perianal abscess may be found in these patients.
5. The most common co-morbidity found in these patients is diabetes.
6. Fistulotomy and fistulectomy are the two most commonly performed procedures. The efficacy of both these procedures in terms of immediate postoperative measure in terms of incontinence is very good, and the patients remained continent postoperatively.

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