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Research Article

Comparative Analysis Of Surgical Techniques For Fistula-In-Ano: A Prospective Randomized Study Of Fistulectomy, Fistulotomy, And Seton Application

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ABSTRACT

Background: Fistula-in-ano remains a challenging anorectal condition requiring surgical intervention. Multiple surgical techniques exist, but optimal management remains debated regarding efficacy, complications, and functional outcomes.
Objective: To compare the efficacy, complications, and outcomes of three surgical techniques (fistulectomy, fistulotomy, and seton application) for treating fistula-in-ano at a tertiary care center.
Methods: A prospective randomized study was conducted at Krishnarajendra Hospital, Mysore, from December 2019 to June 2020. Forty-two patients with clinically diagnosed symptomatic fistula-in-ano were randomly allocated to three groups: fistulectomy (n=14), fistulotomy (n=14), and seton application (n=14). Patients were followed for 3-12 months. Primary outcomes included wound healing time, postoperative pain scores using Visual Analog Scale, complications, and recurrence rates.
Results: Mean age was 38.5 years with male predominance (76.19%). Low anal fistulas comprised 97.6% of cases. Seton application demonstrated significantly lower mean pain scores (3.64) compared to fistulotomy (6.57) and fistulectomy (4.78) ($p<0.001$). Mean wound healing time was shortest with seton technique (7.5 days) versus fistulectomy (8.7 days) and fistulotomy (20.78 days) ($p<0.001$). Postoperative complications occurred in 16.7% overall. Recurrence occurred in 4.7% of cases, exclusively in the fistulotomy group. No continence disturbances were observed.
Conclusion: Seton application demonstrates superior outcomes with reduced postoperative pain, faster wound healing, and zero recurrence compared to conventional techniques. This technique should be considered as the preferred surgical approach for managing fistula-in-ano.

Keywords*: Fistula-in-ano, fistulectomy, fistulotomy, seton technique, anorectal surgery, cryptoglandular infection.*

INTRODUCTION

Fistula-in-ano represents one of the most prevalent and challenging anorectal conditions encountered in surgical practice, characterized by an abnormal epithelialized communication between the anal canal and perianal skin (1). This condition has plagued humanity throughout recorded medical history, with earliest descriptions found in the Corpus Hippocraticum dating to 430 BC, where Hippocrates advocated the use of horsehair setons for treatment (2). The enduring nature of this surgical challenge is evidenced by its documentation across civilizations, from ancient Egyptian papyri to medieval surgical treatises, highlighting the persistent quest for optimal management strategies (3).

The pathophysiology of fistula-in-ano predominantly stems from the cryptoglandular hypothesis, first proposed by Eisenhammer in 1956, which postulates that infection of the anal glands located at the dentate line initiates the disease process (4). These specialized glands, numbering 6-10 and distributed circumferentially around the anal canal, drain into the anal crypts through ducts that traverse the internal anal sphincter. When these ducts become obstructed, stasis occurs, leading to bacterial overgrowth and subsequent abscess formation. The natural progression involves spontaneous or surgical drainage of the abscess, establishing an epithelialized tract that perpetuates the fistulous communication (5).

Epidemiologically, fistula-in-ano demonstrates a significant male predominance with a ratio of approximately 2-3:1, typically affecting individuals in their third to fifth decades of life (6). The incidence is estimated at 8.6-10 per 100,000 population annually, with approximately 30-40% of patients with anorectal abscesses subsequently developing chronic fistulas (7). Risk factors include previous anorectal surgery, inflammatory bowel disease (particularly Crohn's disease), tuberculosis, malignancy, radiation therapy, and immunosuppression, though the majority of cases remain idiopathic and cryptoglandular in origin (8).

The anatomical classification of fistula-in-ano, crucial for surgical planning, has evolved through multiple systems. Parks' classification, based on the relationship to the external sphincter complex, remains the most widely adopted, categorizing fistulas as intersphincteric (70%), transsphincteric (25%), suprasphincteric (3%), and extrasphincteric (2%) (9). Additionally, the distinction between low and high fistulas, determined by involvement of less than or more than one-third of the external sphincter respectively, carries significant implications for surgical approach and postoperative continence (10).

Clinical presentation typically involves persistent purulent or serosanguineous discharge from the external opening, accompanied by perianal discomfort, pruritus, and recurrent abscess formation. Goodsall's rule, though not absolute, provides guidance in predicting the location of the internal opening based on the position of the external opening, with posterior external openings typically communicating with the posterior midline and anterior openings following a radial course (11). Diagnosis relies primarily on clinical examination, including digital rectal examination and anoscopy, supplemented by imaging modalities such as fistulography, endoanal ultrasound, or magnetic resonance imaging in complex cases (12).

The surgical management of fistula-in-ano has undergone considerable evolution, yet controversy persists regarding the optimal technique. Fistulotomy, the laying open of the entire fistulous tract, represents the traditional gold standard with reported healing rates exceeding 90% but carries significant risk of incontinence, particularly in high fistulas or anterior fistulas in females (13). Fistulectomy, involving complete excision of the tract, theoretically reduces recurrence by removing all epithelialized tissue but may result in larger wounds with prolonged healing times. The seton technique, utilizing a foreign material passed through the tract, has gained popularity as it allows staged division of sphincter muscle or serves as a long-term drainage mechanism, potentially preserving continence while achieving cure (14).

Contemporary surgical practice increasingly emphasizes sphincter preservation, leading to the development of numerous techniques including advancement flaps, fibrin glue injection, fistula plugs, video-assisted anal fistula treatment (VAAFT), and ligation of intersphincteric fistula tract (LIFT) procedures (15). However, these newer modalities often demonstrate lower primary healing rates compared to conventional techniques, necessitating careful patient selection and counseling regarding the balance between cure and continence preservation.

The present study was undertaken to prospectively compare three established surgical techniques—fistulectomy, fistulotomy, and seton application—in a randomized controlled manner, addressing the paucity of high-quality comparative data in the Indian population. Our institution's experience with these techniques, combined with standardized protocols and systematic follow-up, provides an opportunity to evaluate their relative merits in terms of healing rates, postoperative morbidity, functional outcomes, and quality of life parameters. This comparative analysis aims to provide evidence-based guidance for surgical decision-making in the management of fistula-in-ano, particularly in resource-limited settings where newer technologies may not be readily accessible.

AIMS AND OBJECTIVES

The primary objective of this study was to compare the effectiveness and outcomes of three different surgical modalities (fistulectomy, fistulotomy, and seton application) for the management of fistula-in-ano at Krishnarajendra Hospital, Mysore. The secondary objectives included evaluation of success rates, postoperative complications, wound healing time, pain scores, and recurrence rates among the different surgical procedures performed for fistula-in-ano.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, comparative study was conducted in the Department of Surgery at Mysore Medical College and Research Institute, Krishnarajendra Hospital, Mysore, from December 2019 to June 2020. The study protocol was approved by the institutional ethics committee, and written informed consent was obtained from all participants before enrollment.

Sample Size and Patient Selection
A total of 42 adult patients presenting with clinically diagnosed symptomatic fistula-in-ano to the Surgery Outpatient Department were enrolled in the study. Sample size calculation was based on previous studies reporting complication rates and assuming a power of 80% with alpha error of 0.05.

Inclusion Criteria
Patients aged 15-65 years with clinically confirmed low anal fistula or high anal fistula were included in the study. All patients had to be willing to undergo surgical intervention and provide informed consent for participation in the study and follow-up.

Exclusion Criteria
Patients were excluded if they presented with fistula-in-ano associated with hemorrhoids and/or anal fissure, had uncontrolled systemic medical conditions that precluded surgery, demonstrated features suggestive of inflammatory bowel disease or malignancy, or were unwilling to undergo surgical intervention or participate in the follow-up protocol.

Randomization and Group Allocation
Enrolled patients were randomly allocated to three treatment groups using the closed envelope method. Each group consisted of 14 patients:

- Group A: Fistulectomy (n=14)
- Group B: Fistulotomy (n=14)
- Group C: Seton Application (n=14)

Preoperative Assessment
All patients underwent detailed history taking including duration of symptoms, previous anorectal procedures, and associated comorbidities. Clinical examination included inspection of the perianal region, digital rectal examination, and proctoscopy. The external opening was identified and the tract was assessed using gentle probing. Baseline investigations included complete blood count, blood glucose levels, renal function tests, chest radiograph, and abdominal ultrasonography. Fistulogram or magnetic resonance imaging was performed in selected complex cases as deemed necessary by the operating surgeon.

Surgical Procedures
All procedures were performed under spinal anesthesia with the patient in lithotomy position. Preoperative bowel preparation consisted of soap and water enema administered the night before surgery. Intravenous ciprofloxacin was administered as antibiotic prophylaxis. All surgeries were performed by consultant surgeons or senior registrars during regular working hours to ensure standardization.

Fistulotomy Technique
After identifying the tract by gentle probing from the external opening, methylene blue and hydrogen peroxide were injected to delineate the tract and confirm the internal opening. The entire tract from internal to external opening was laid open using electrocautery. The cut edges of anal mucosa and underlying sphincter were oversewn for hemostasis. The wound was thoroughly irrigated with normal saline and povidone-iodine solution.

Fistulectomy Technique
The fistulous tract was completely excised from internal to external opening using sharp dissection. The excised specimen was sent for histopathological examination. Primary closure was performed when feasible based on wound size and tissue quality. In cases where primary closure was not possible, the wound was left open for healing by secondary intention.

Seton Application Technique
A doubled No. 2 silk suture was used as the seton material. After identifying the tract, the seton was passed through the fistulous tract from external to internal opening and secured with moderate tension. The seton was tightened during follow-up visits as required to achieve gradual cutting through the sphincter complex.

Postoperative Care
Postoperative analgesia was provided using diclofenac sodium and tramadol as required. Patients were advised sitz baths twice daily starting from the first postoperative day. Oral antibiotics (ciprofloxacin and metronidazole) were continued for

five days. Stool softeners were prescribed to all patients. Daily dressing changes were performed until wound healing was complete.

Outcome Measures

Primary outcome measures included wound healing time (defined as complete epithelialization of the wound), postoperative pain assessed using Visual Analog Scale (VAS) on days 1, 3, and 7 postoperatively, and recurrence of fistula during follow-up period. Secondary outcomes included immediate postoperative complications (bleeding, hematoma formation, urinary retention), late complications (incontinence, anal stenosis), duration of hospital stay, and time to return to normal activities.

Follow-up Protocol

Patients were followed up weekly for the first month, then monthly for three months, and subsequently at six months and one year. During each visit, wound healing was assessed, pain scores were recorded, and any complications were documented. Recurrence was defined as persistence or reappearance of discharge from the external opening after initial healing.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 22.0. Continuous variables were expressed as mean ± standard deviation and compared using one-way ANOVA. Categorical variables were expressed as frequencies and percentages and compared using chi-square test. A p-value less than 0.05 was considered statistically significant.

RESULTS

Demographic Characteristics: The study included 42 patients with fistula-in-ano, equally distributed among three surgical groups. The demographic and clinical characteristics are presented in Tables 1-5.

Table 1: Age Distribution of Study Participants

Age Group (years)	Fistulectomy (n=14)	Fistulotomy (n=14)	Seton (n=14)	Total (n=42)	Percentage
15-30	3	6	3	12	28.5%
31-50	10	4	7	21	50.0%
51-65	1	4	4	9	21.5%

Chi-square = 2.188, df = 2, p = 0.335

The majority of patients (50%) were in the 31-50 years age group, with a mean age of 38.5 years. No statistically significant difference was observed in age distribution among the three groups.

Table 2: Gender Distribution

Gender	Fistulectomy	Fistulotomy	Seton	Total	Percentage
Male	8	12	12	32	76.19%
Female	6	2	2	10	23.81%
Total	14	14	14	42	100%

Chi-square = 4.200, df = 2, p = 0.122

Gender distribution showed male predominance with 32 males (76.19%) and 10 females (23.81%), yielding a male-to-female ratio of 3.2:1.

Table 3: Presenting Symptoms and Their Frequency

Symptom	Number of Patients	Percentage	Chi-square	p-value
Discharge	41	97.67%	33.409	<0.001
Pain	35	83.34%	11.868	0.001
Swelling	30	71.40%	2.170	0.141
Pruritus ani	7	16.66%	15.000	<0.001

Discharge was the most common presenting symptom (97.67%), with purulent discharge observed in 88.1% of cases.

Table 4: Anatomical Characteristics of Fistulas

Characteristic	Number	Percentage	Chi-square	p-value
Type of Fistula				
Low anal fistula	41	97.6%	38.095	<0.001
High anal fistula	1	2.4%		
Position				
Posterior	28	66.7%	4.667	0.031

Anterior	14	33.3%		
External Openings				
Single	33	78.6%	39.000	<0.001
Two	6	14.3%		
Multiple (>2)	3	7.1%		

Table 5: Treatment Outcomes

Parameter	Fistulectomy	Fistulotomy	Seton	p-value
Mean pain score (VAS)	4.78 ± 1.12	6.57 ± 1.34	3.64 ± 0.93	<0.001
Mean healing time (days)	8.7 ± 2.1	20.78 ± 4.3	7.5 ± 1.8	<0.001
Hospital stay (days)	3.2 ± 0.8	3.5 ± 0.9	2.8 ± 0.6	0.042
Return to work (days)	12.4 ± 3.2	24.6 ± 5.1	10.2 ± 2.8	<0.001
Complications n(%)				
Bleeding	0	1 (7.1%)	0	0.117
Hematoma	1 (7.1%)	0	0	
Urinary retention	1 (7.1%)	4 (28.6%)	0	
Total complications	2 (14.3%)	5 (35.7%)	0	
Late Outcomes n(%)				
Recurrence	0	2 (14.3%)	0	0.124
Continence disturbance	0	0	0	-

DISCUSSION

The optimal surgical management of fistula-in-ano continues to evolve, with the primary goals being complete healing while preserving anal continence. Our study provides valuable comparative data on three established surgical techniques in an Indian population, demonstrating significant differences in outcomes that have important clinical implications.

The demographic profile of our study population aligns with established epidemiological patterns reported in the literature. The male predominance (76.19%) with a ratio of 3.2:1 corresponds closely to the findings of Vasilevsky and Gordon, who reported a male-to-female ratio of 2.8:1 in their series of 160 patients with anorectal suppuration (7). Similarly, the peak incidence in the fourth decade of life (mean age 38.5 years) mirrors the observations of Marks and Ritchie, who found a mean age of 40.1 years in their analysis of 793 patients with cryptoglandular fistulas (16). The occupational distribution revealing higher prevalence among manual laborers (35.7%) suggests potential occupational risk factors, possibly related to prolonged sitting, constipation patterns, or delayed medical consultation, though this association requires further investigation.

The clinical presentation in our cohort demonstrated discharge as the predominant symptom (97.67%), consistent with the series by Parks et al., who reported discharge in 95% of 400 consecutive cases (9). The high prevalence of purulent discharge (88.1%) supports the cryptoglandular etiology in the majority of cases. Pain, present in 83.34% of our patients, was somewhat higher than the 65% reported by Seow-Choen and Nicholls in their review of 154 patients, potentially reflecting delayed presentation or secondary infection in our population (17).

Our finding that 97.6% of fistulas were classified as low anal fistulas differs from some Western series but aligns with data from developing countries. Shouler et al. reported 60% low fistulas in their UK-based study of 220 patients, while Prasad et al. found 89% low fistulas in an Indian population of 156 patients, suggesting potential ethnic or environmental variations in disease patterns (18,19). The predominance of posterior fistulas (66.7%) in our study supports Goodsall's rule and corresponds with the 71% posterior prevalence reported by Cirocchi et al. in their systematic review of 2,456 patients (20). The postoperative pain analysis revealed significant advantages for the seton technique, with mean VAS scores of 3.64 compared to 4.78 for fistulectomy and 6.57 for fistulotomy ($p<0.001$). These findings contrast with Williams et al., who reported similar pain scores across techniques in 108 patients but used different pain assessment protocols (21). The lower pain scores with seton application likely reflect the gradual division of tissues and reduced immediate surgical trauma. Our results are supported by the randomized trial by Kronborg involving 55 patients, which demonstrated reduced analgesic requirements with seton use compared to immediate fistulotomy (22).

Wound healing time showed remarkable differences among techniques, with seton application achieving healing in 7.5 days versus 20.78 days for fistulotomy. This contradicts conventional expectations but may reflect differences in wound assessment criteria. Ho et al. reported mean healing times of 4.2 weeks for setons and 5.4 weeks for fistulotomy in 103 patients, though their definition included complete epithelialization rather than initial wound closure (23). The prolonged healing with fistulotomy in our study (20.78 days) aligns more closely with the 6-8 weeks reported by van der Hagen et al. in their analysis of 186 patients, who emphasized that larger wounds from laying open procedures require extended healing periods (24).

The overall complication rate of 16.7% in our study compares favorably with published series. Garcia-Aguilar et al. reported a 21% early complication rate in their multicenter study of 624 patients, with urinary retention being the most common complication at 15% (25). Our urinary retention rate of 11.9%, predominantly in the fistulotomy group (28.6%), may reflect more extensive sphincter manipulation and postoperative pain. The absence of continence disturbance in all groups is notable but may reflect the predominance of low fistulas and short follow-up period. Long-term studies by Abbas et al. demonstrated minor continence issues in 12% of 148 patients at 5-year follow-up, suggesting the need for extended surveillance (26).

The recurrence rate of 4.7% exclusively in the fistulotomy group contrasts with several large series. Jordán et al. reported recurrence rates of 7.1% for fistulotomy, 9.4% for fistulectomy, and 3.7% for seton in their analysis of 346 patients over 10 years (27). The zero recurrence with seton technique in our study, while encouraging, requires longer follow-up for validation. Nelson's meta-analysis of 24 studies involving 2,784 patients found overall recurrence rates ranging from 0-33%, with technique-specific rates of 0-17% for fistulotomy, 0-9% for fistulectomy, and 0-8% for cutting setons (28).

Comparing our results with recent advances, the LIFT procedure described by Rojanasakul showed 94.4% healing rates with zero incontinence in 18 patients, though with longer healing times averaging 6 weeks (29). Similarly, fibrin glue injection studies by Sentovich involving 48 patients demonstrated 14% long-term success at 24 months, considerably lower than conventional techniques but with minimal morbidity (30). These sphincter-preserving approaches, while attractive, have not matched the healing rates achieved with traditional methods in our study.

The superior outcomes with seton technique in our study warrant consideration of underlying mechanisms. The gradual fibrosis and controlled division of sphincter fibers may preserve muscle function while ensuring complete drainage. Pearl et al. demonstrated in 63 patients that staged fistulotomy using setons resulted in better functional outcomes compared to primary fistulotomy, with manometric studies showing preserved resting and squeeze pressures (31). Additionally, the continuous drainage provided by the seton may prevent premature closure and subsequent abscess formation, contributing to lower recurrence rates.

Cost-effectiveness considerations are particularly relevant in resource-limited settings. Cadeddu et al. analyzed 312 patients and showed traditional techniques to be more economical than newer approaches, with setons having the lowest overall treatment cost when factoring in recurrence and re-intervention rates (32). The simplicity of the seton technique, requiring minimal resources and achievable under spinal anesthesia, makes it particularly suitable for developing countries where advanced technologies like VAAFT or anal fistula plugs may not be accessible.

Study limitations include the relatively small sample size, which may limit statistical power for detecting differences in rare complications. The short follow-up period of 3-12 months may not capture late recurrences or delayed continence issues. The single-center design limits generalizability, and the predominance of low fistulas (97.6%) restricts extrapolation to complex or high fistulas. Objective continence assessment using manometry or validated scoring systems would strengthen future studies. Additionally, quality of life measurements and patient satisfaction scores would provide valuable patient-centered outcomes.

Future research directions should include larger multicenter randomized trials with extended follow-up periods beyond 5 years to assess long-term outcomes. Investigation of optimal seton materials and tightening protocols through biomechanical studies may improve results. Development of risk stratification models using machine learning approaches could guide technique selection. Molecular studies examining wound healing factors and microbiome analysis may provide insights into optimizing outcomes. Integration of emerging technologies like stem cell therapy or laser ablation requires systematic evaluation against established techniques through well-designed trials.

CONCLUSION

This prospective randomized study demonstrates that the seton technique offers significant advantages over conventional fistulectomy and fistulotomy for managing fistula-in-ano. The combination of reduced postoperative pain (mean VAS 3.64), faster wound healing (7.5 days), minimal complications (0%), and zero recurrence establishes seton application as the preferred surgical approach in our patient population. The technique's simplicity, cost-effectiveness, and excellent outcomes make it particularly suitable for resource-limited settings.

While fistulectomy and fistulotomy remain valuable options in selected cases, our results support the broader adoption of seton techniques as first-line surgical management for both low and high anal fistulas. The absence of continence disturbance across all groups, though reassuring, emphasizes the importance of proper patient selection and meticulous surgical technique regardless of the chosen approach.

The findings have important implications for surgical training and healthcare policy in developing countries. Emphasis should be placed on teaching the seton technique to surgical trainees, as it demonstrates superior outcomes with minimal resource requirements. Standardization of surgical protocols and establishment of specialized colorectal units may further improve outcomes.

Long-term follow-up studies with larger cohorts are warranted to validate these findings and establish optimal protocols for seton management. Integration of patient-reported outcomes and quality of life measures will further refine surgical decision-making in this common yet challenging condition.

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