



COMPARATIVE OUTCOMES AND PARAMETERS OF DRAINING SETON VERSUS FISTULOTOMY IN TREATING ANAL FISTULAS

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ABSTRACT

Background: Anal fistula is a common anorectal condition associated with significant morbidity and recurrence. Draining seton placement and fistulotomy are widely used surgical treatment options, but their comparative outcomes remain a subject of clinical interest.

Aim: To compare the clinical outcomes and parameters of draining seton and fistulotomy in the management of anal fistulas.

Materials and Methods: This prospective comparative observational study was conducted in the Department of General Surgery of a tertiary care hospital in Mumbai over a period of 12 months. A total of 40 patients diagnosed with anal fistula were included, with 20 patients each undergoing draining seton placement and fistulotomy. Baseline demographic characteristics, fistula type, postoperative pain, wound infection, recurrence, and reintervention rates were evaluated and compared between the two groups.

Results: The mean age was comparable between the draining seton and fistulotomy groups (37.10 ± 9.48 vs. 35.25 ± 12.06 years; $p=0.59$). Postoperative pain scores and wound infection rates showed no significant differences between groups ($p>0.05$). Recurrence was significantly higher in the draining seton group than in the fistulotomy group (40.0% vs. 5.0%; $p=0.008$). Similarly, reintervention was required more frequently following draining seton placement (65.0% vs. 30.0%; $p=0.027$).

Conclusion: Both procedures demonstrated acceptable safety profiles; however, fistulotomy was associated with lower recurrence and reintervention rates. Fistulotomy appears to provide superior long-term outcomes in appropriately selected patients, while draining seton remains a useful sphincter-preserving option for selected complex fistulas.

Keywords: Anal Fistula, Draining Seton, Fistulotomy, Recurrence, Postoperative Complications, Wound Infection, Reintervention, Parks Classification.

INTRODUCTION

Anal fistula is a common anorectal disorder characterized by an abnormal epithelialized tract connecting the anal canal or rectum to the perianal skin. It is frequently associated with recurrent perianal abscesses and chronic inflammation, leading to significant discomfort, pain, purulent discharge, and impairment in quality of life.

The majority of anal fistulas arise from cryptoglandular infections of the anal glands, although they may also occur secondary to conditions such as Crohn's disease, tuberculosis, trauma, radiation exposure, or malignancy. The disease predominantly affects young and middle-aged adults, with a higher incidence among males, and continues to pose a considerable challenge to colorectal surgeons due to its tendency for recurrence and the risk of postoperative fecal incontinence following treatment [1,2].

The primary goal of anal fistula management is eradication of the fistulous tract while preserving the integrity and function of the anal sphincter complex. Achieving this balance remains difficult, particularly in complex fistulas that involve a significant portion of the sphincter muscles. Over the years, numerous surgical techniques have been developed, including fistulotomy, fistulectomy, advancement flap procedures, ligation of



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intersphincteric fistula tract (LIFT), fibrin glue injection, video-assisted techniques, and seton placement. Among these, fistulotomy and draining seton placement remain widely practiced owing to their effectiveness, simplicity, and accessibility [3,4].

Fistulotomy is considered the gold standard treatment for simple low anal fistulas. The procedure involves laying open the fistulous tract to allow healing by secondary intention. It is associated with high healing rates and relatively low recurrence rates in appropriately selected patients. However, division of sphincter muscle during the procedure may increase the risk of postoperative continence disturbances, particularly in high or complex fistulas. Consequently, careful patient selection is essential to maximize therapeutic success while minimizing complications [5,6].

Draining setons, on the other hand, are commonly employed in the management of complex anal fistulas, especially those traversing substantial portions of the sphincter apparatus. A seton consists of a thread or similar material passed through the fistulous tract to facilitate continuous drainage, reduce sepsis, and promote fibrosis around the tract. This technique helps preserve sphincter function and is often used as either a definitive treatment or a preliminary stage before further surgical intervention. Although draining setons are associated with lower risks of incontinence, concerns remain regarding prolonged healing times, patient discomfort, and variable recurrence rates [7,8].

The choice between fistulotomy and draining seton placement depends on multiple factors, including fistula anatomy, sphincter involvement, patient comorbidities, and surgeon expertise. Despite extensive clinical experience, there remains ongoing debate regarding the comparative effectiveness of these approaches in terms of healing, recurrence, postoperative complications, continence preservation, and patient satisfaction. Comparative studies evaluating these outcomes are therefore essential to guide evidence-based decision-making and optimize patient care [9,10].

The present study aims to compare the clinical outcomes and treatment parameters of draining seton and fistulotomy in the management of anal fistulas. The objectives are to evaluate healing time, determine recurrence rates following each treatment modality, and assess postoperative complications, particularly fecal incontinence and wound infection, to identify the safer and more effective surgical approach.

MATERIALS AND METHODS

Study Design: Prospective comparative observational study.

Study Population: Patients aged 18 years and above diagnosed with anal fistula and undergoing

either draining seton placement or fistulotomy in the Department of General Surgery.

Sample Size: A total of 40 patients were included in the study, with patients allocated to either the draining seton group or the fistulotomy group based on clinical indications and surgeon preference. The sample size was determined using power analysis for comparing two independent proportions, assuming a healing rate of 85% for fistulotomy and 60% for draining seton, with a significance level (α) of 0.05 and power of 80%.

Study Duration: 12 months.

Study Place: Department of General Surgery, tertiary care hospital, Mumbai, Maharashtra, India.

Inclusion Criteria

1. Patients aged 18 years and above diagnosed with anal fistula.
2. Patients with primary fistula-in-ano (simple/low or complex/high fistula).
3. Patients considered suitable for either draining seton placement or fistulotomy based on clinical and radiological evaluation.
4. Patients willing to provide written informed consent for participation in the study.

Exclusion Criteria

1. Patients with recurrent anal fistulas or previous surgery for fistula-in-ano.
2. Patients with fistulas secondary to Crohn's disease, tuberculosis, malignancy, or other systemic diseases.
3. Patients with multiple fistulous tracts not amenable to either fistulotomy or draining seton placement.
4. Patients with pre-existing anal sphincter dysfunction or fecal incontinence.
5. Pregnant women.
6. Patients with severe comorbid conditions contraindicating surgical intervention.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were assessed for normality using the Shapiro–Wilk test and summarized as mean \pm standard deviation (SD) for normally distributed data and as median with interquartile range (IQR) for non-normally distributed data. Categorical variables were expressed as frequencies and percentages. Comparisons between the Draining Seton and Fistulotomy groups were performed using the independent samples Student's t-test for normally distributed continuous variables and the Mann–Whitney U test for non-normally distributed variables. Categorical variables were compared using the Chi-square test or Fisher's exact test whenever the expected cell frequency was less than five. Postoperative outcomes including pain scores, wound infection, recurrence, and requirement for reintervention were compared between the two

treatment groups. All statistical tests were two-tailed, and a p-value <0.05 was considered statistically significant.

RESULT

Table 1. Baseline Demographic and Clinical Characteristics of the Study Population

| Variable | Draining Seton (n=20) | Fistulotomy (n=20) | p-value |
|---|-----------------------|--------------------|---------|
| Age (years), Mean ± SD | 37.10 ± 9.48 | 35.25 ± 12.06 | 0.59 |
| BMI (kg/m ²), Mean ± SD | 23.51 ± 4.32 | 26.77 ± 7.82 | 0.11 |
| Male Sex, n (%) | 14 (70.0) | 12 (60.0) | 0.51 |
| Female Sex, n (%) | 6 (30.0) | 8 (40.0) | |
| Previous Fistula Surgery, n (%) | 11 (55.0) | 7 (35.0) | 0.2 |
| Duration of Symptoms ≤3 Months, n (%) | 7 (35.0) | 13 (65.0) | 0.477 |
| Duration of Symptoms 4–6 Months, n (%) | 11 (55.0) | 4 (20.0) | |
| Duration of Symptoms 7–12 Months, n (%) | 2 (10.0) | 3 (15.0) | |

Table 2. Distribution of Fistula Type According to Parks' Classification

| Parks' Classification | Draining Seton n (%) | Fistulotomy n (%) | Total n (%) | p-value |
|--------------------------|----------------------|-------------------|-------------|---------|
| Intersphincteric Fistula | 11 (55.0) | 4 (20.0) | 15 (37.5) | <0.001 |
| Transsphincteric Fistula | 2 (10.0) | 14 (70.0) | 16 (40.0) | |
| Extrasphincteric Fistula | 7 (35.0) | 2 (10.0) | 9 (22.5) | |
| Total | 20 (100.0) | 20 (100.0) | 40 (100.0) | |

Table 3. Postoperative Pain Outcomes

| Variable | Draining Seton (n=20) | Fistulotomy (n=20) | p-value |
|----------------------------|-----------------------|--------------------|---------|
| POD-1 VAS Score, Mean ± SD | 4.10 ± 1.37 | 3.65 ± 1.53 | 0.33 |
| VAS 1–3, n (%) | 5 (26.3) | 9 (47.4) | |
| VAS 3–5, n (%) | 12 (63.2) | 8 (42.1) | 0.28 |
| VAS 5–7, n (%) | 2 (10.5) | 2 (10.5) | |

Table 4. Postoperative Complications

| Variable | Draining Seton (n=20) | Fistulotomy (n=20) | p-value |
|--------------------------------|-----------------------|--------------------|---------|
| Wound Infection Present, n (%) | 2 (10.0) | 4 (20.0) | 0.38 |
| Wound Infection Absent, n (%) | 18 (90.0) | 16 (80.0) | |

Table 5. Treatment Outcomes during Follow-up

| Outcome | Draining Seton (n=20) | Fistulotomy (n=20) | p-value |
|-----------------------------------|-----------------------|--------------------|---------|
| Recurrence Present, n (%) | 8 (40.0) | 1 (5.0) | 0.008 |
| Recurrence Absent, n (%) | 12 (60.0) | 19 (95.0) | |
| Reintervention Required, n (%) | 13 (65.0) | 6 (30.0) | 0.027 |
| No Reintervention Required, n (%) | 7 (35.0) | 14 (70.0) | |

Table 6. Overall Characteristics of the Study Population (N=40)

| Variable | Value |
|--------------------------|------------------|
| Age (years), Mean ± SD | 36.17 ± 10.74 |
| Median Age (IQR) | 33.0 (28.0–48.0) |
| Age Range | 19–53 |
| Intersphincteric Fistula | 15 (37.5%) |
| Transsphincteric Fistula | 16 (40.0%) |
| Extrasphincteric Fistula | 9 (22.5%) |
| Male Sex | 26 (65.0%) |
| Female Sex | 14 (35.0%) |

Figure: 1. Comparison of Parks' Classification between Draining Seton and Fistulotomy Groups

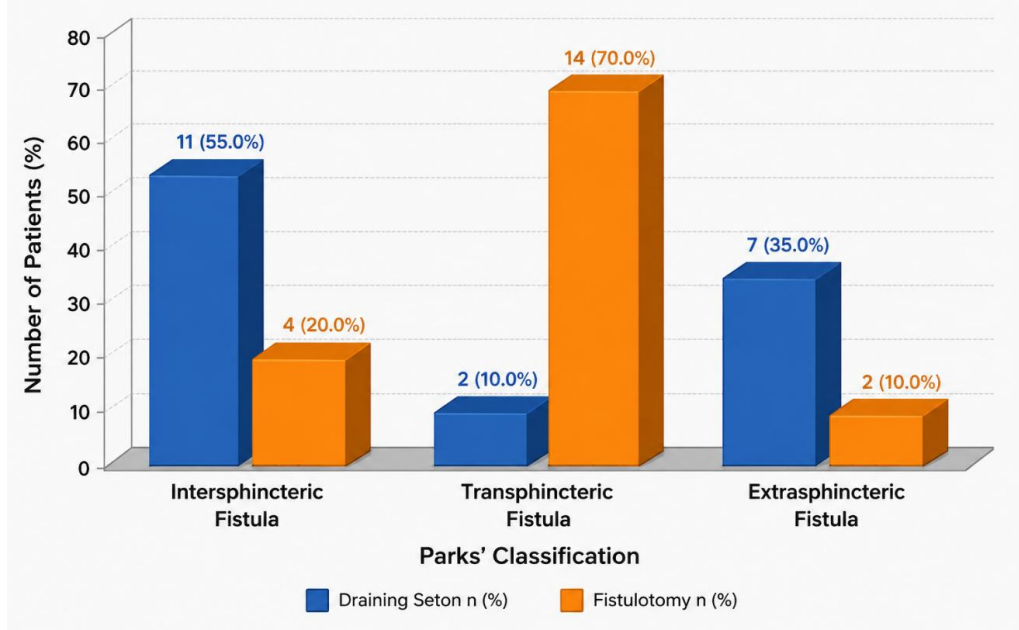
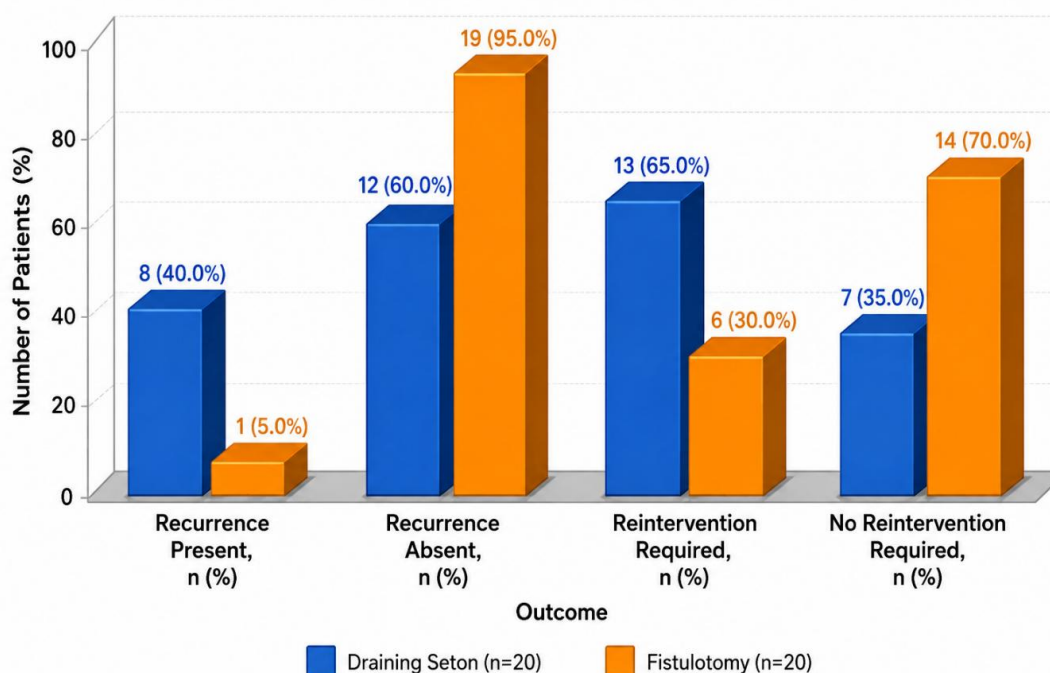


Figure: 2. Comparison of Recurrence and Reintervention Outcomes between Draining Seton and Fistulotomy Groups



A total of 40 patients were included in the study, with 20 patients each in the draining seton and fistulotomy groups. The mean age of patients in the draining seton group was 37.10 ± 9.48 years compared to 35.25 ± 12.06 years in the fistulotomy group. The difference was not statistically significant ($p=0.59$), indicating comparable age distribution between the groups. Similarly, the mean BMI was 23.51 ± 4.32 kg/m² in the draining seton group and 26.77 ± 7.82 kg/m² in the fistulotomy

group, with no significant difference observed ($p=0.11$).

Male patients constituted the majority of the study population, accounting for 70.0% ($n=14$) of the draining seton group and 60.0% ($n=12$) of the fistulotomy group, while females represented 30.0% ($n=6$) and 40.0% ($n=8$), respectively. This gender distribution was comparable between groups ($p=0.51$). Previous fistula surgery was reported in 55.0% ($n=11$) of patients undergoing draining seton placement and 35.0% ($n=7$) of those treated with

fistulotomy, although this difference did not reach statistical significance ($p=0.20$).

Regarding symptom duration, 35.0% ($n=7$) of patients in the draining seton group presented within 3 months of symptom onset compared to 65.0% ($n=13$) in the fistulotomy group. Symptoms lasting 4–6 months were observed in 55.0% ($n=11$) and 20.0% ($n=4$) of patients in the draining seton and fistulotomy groups, respectively, while symptoms lasting 7–12 months were reported in 10.0% ($n=2$) and 15.0% ($n=3$) of patients. No statistically significant difference was found in symptom duration between the two groups ($p=0.477$).

Analysis of fistula characteristics according to Parks' classification demonstrated a significant difference in fistula type distribution between the two treatment groups ($p<0.001$). In the draining seton group, intersphincteric fistulas were the most common subtype, accounting for 55.0% ($n=11$) of cases, followed by extrasphincteric fistulas at 35.0% ($n=7$) and transphincteric fistulas at 10.0% ($n=2$).

Conversely, transphincteric fistulas predominated in the fistulotomy group, representing 70.0% ($n=14$) of cases. Intersphincteric and extrasphincteric fistulas accounted for 20.0% ($n=4$) and 10.0% ($n=2$) of patients, respectively. Overall, transphincteric fistulas constituted the largest proportion of the study population (40.0%), followed by intersphincteric (37.5%) and extrasphincteric fistulas (22.5%).

Postoperative pain was assessed using the Visual Analog Scale (VAS) on postoperative day one. The mean VAS score was slightly higher in the draining seton group (4.10 ± 1.37) compared to the fistulotomy group (3.65 ± 1.53); however, this difference was not statistically significant ($p=0.33$). Among patients treated with draining seton, 26.3% ($n=5$) reported mild pain (VAS 1–3), 63.2% ($n=12$) reported moderate pain (VAS 3–5), and 10.5% ($n=2$) experienced severe pain (VAS 5–7). In the fistulotomy group, 47.4% ($n=9$) reported mild pain, 42.1% ($n=8$) reported moderate pain, and 10.5% ($n=2$) reported severe pain. The distribution of pain severity did not differ significantly between groups ($p=0.28$), indicating comparable early postoperative pain profiles.

Postoperative wound infection occurred in 10.0% ($n=2$) of patients in the draining seton group and 20.0% ($n=4$) of patients in the fistulotomy group. The majority of patients remained free from wound infection, accounting for 90.0% ($n=18$) and 80.0% ($n=16$) in the draining seton and fistulotomy groups, respectively.

Although wound infection was numerically more frequent following fistulotomy, the difference between groups was not statistically significant ($p=0.38$), suggesting a similar postoperative infection risk with both treatment modalities.

Follow-up evaluation revealed significant differences in recurrence and reintervention rates

between the two treatment groups. Recurrence was observed in 40.0% ($n=8$) of patients treated with draining seton compared with only 5.0% ($n=1$) of those undergoing fistulotomy. Conversely, recurrence-free outcomes were achieved in 60.0% ($n=12$) and 95.0% ($n=19$) of patients, respectively. This difference was statistically significant ($p=0.008$), indicating superior disease control following fistulotomy.

Similarly, reintervention was required in 65.0% ($n=13$) of patients in the draining seton group compared with 30.0% ($n=6$) in the fistulotomy group. No additional intervention was required in 35.0% ($n=7$) and 70.0% ($n=14$) of patients, respectively. The difference in reintervention rates was statistically significant ($p=0.027$), demonstrating a lower need for subsequent procedures among patients managed with fistulotomy.

The overall study population consisted of 40 patients with a mean age of 36.17 ± 10.74 years. The median age was 33.0 years, with an interquartile range of 28.0–48.0 years, while the age range extended from 19 to 53 years.

Based on Parks' classification, transphincteric fistulas were the most common subtype, accounting for 40.0% ($n=16$) of cases. Intersphincteric fistulas represented 37.5% ($n=15$), while extrasphincteric fistulas accounted for 22.5% ($n=9$). Male patients constituted 65.0% ($n=26$) of the study population, whereas females accounted for 35.0% ($n=14$), indicating a clear male predominance among patients presenting with anal fistula.

DISCUSSION

The present study compared the clinical outcomes of draining seton and fistulotomy in the management of anal fistulas. Baseline demographic characteristics were comparable between the two groups, thereby minimizing the influence of confounding factors on treatment outcomes. The mean age of patients was 37.10 ± 9.48 years in the draining seton group and 35.25 ± 12.06 years in the fistulotomy group, with a predominance of male patients in both groups. These findings are consistent with the observations of Visscher et al., who reported that anal fistulas predominantly affect males in the third to fifth decades of life due to greater exposure to risk factors and the higher incidence of cryptoglandular infections in men [11]. Similarly, Abramowitz et al. found that the majority of patients presenting with fistula-in-ano were middle-aged males, reinforcing the demographic pattern observed in the present study [12].

With regard to fistula characteristics, a significant difference in the distribution of Parks' classification was observed between the treatment groups. Intersphincteric fistulas were more common in the draining seton group, whereas transphincteric fistulas predominated in the fistulotomy group. This

finding is comparable to the study by Ellis, who reported that transphincteric fistulas represent one of the most frequently encountered fistula types in surgical practice and often influence the choice of operative procedure because of sphincter involvement [13]. Likewise, Ritchie et al. demonstrated that fistula anatomy remains a critical determinant of surgical decision-making and postoperative outcomes [14].

Postoperative pain assessment revealed no statistically significant difference between the two groups. The mean VAS score on postoperative day one was slightly higher in patients treated with draining seton than in those undergoing fistulotomy, although the difference was not significant. Similar findings were reported by Mushaya et al., who observed comparable postoperative pain scores between seton-based procedures and conventional fistulotomy during the early recovery period [15]. A systematic review conducted by Stellingwerf et al. also concluded that postoperative discomfort is influenced more by wound characteristics and individual pain perception than by the specific surgical technique employed [16].

The incidence of postoperative wound infection was low in both groups and did not differ significantly. Infection occurred in 10.0% of patients in the draining seton group and 20.0% of patients in the fistulotomy group. These findings are in agreement with those reported by García-Aguilar et al., who demonstrated low postoperative infection rates following both fistulotomy and seton placement when appropriate perioperative care was maintained [17]. Similarly, Buchanan et al. found that wound infection is an uncommon complication after anal fistula surgery and generally responds well to conservative management [18].

One of the most important findings of the present study was the significantly higher recurrence rate observed in the draining seton group compared with the fistulotomy group (40.0% vs. 5.0%). This suggests superior long-term disease control following fistulotomy. Comparable results were reported by van Koperen et al., who demonstrated higher healing rates and lower recurrence rates following fistulotomy in appropriately selected patients with simple and low fistulas [19]. Likewise, Sileri et al. observed that fistulotomy remains associated with excellent long-term success rates, whereas seton-based procedures may require additional interventions before complete disease resolution is achieved [20].

The need for reintervention was also significantly greater among patients treated with draining seton than among those undergoing fistulotomy. This finding likely reflects the staged nature of seton therapy and the persistence of fistulous tracts in a proportion of patients. Similar observations were reported by Sileri et al., who found that patients managed with seton placement frequently required

secondary procedures to achieve definitive healing [20]. Furthermore, van Koperen et al. noted that while seton placement effectively controls sepsis and preserves sphincter function, it may prolong treatment duration and increase the likelihood of subsequent interventions [19].

Overall, the findings of the present study indicate that fistulotomy offers lower recurrence rates and reduced need for reintervention compared with draining seton placement, while postoperative pain and wound infection rates remain comparable between the two approaches. These results support the continued role of fistulotomy as an effective treatment option for appropriately selected anal fistulas, whereas draining seton remains valuable in cases where sphincter preservation is a primary concern.

CONCLUSION

The present study compared the outcomes of draining seton placement and fistulotomy in the management of anal fistulas. Both procedures were found to be safe and effective treatment modalities with comparable postoperative pain scores and wound infection rates. However, significant differences were observed in long-term treatment outcomes. Patients undergoing fistulotomy demonstrated substantially lower recurrence rates and a reduced need for reintervention compared with those treated with draining seton. These findings suggest that fistulotomy provides superior disease control and higher rates of definitive healing in appropriately selected patients. Although draining seton remains an important sphincter-preserving option, particularly in complex fistulas where the risk of incontinence is a concern, it may be associated with prolonged treatment and a greater likelihood of additional procedures. Therefore, careful patient selection based on fistula anatomy and sphincter involvement is essential. Larger multicentric studies with longer follow-up periods are recommended to further validate these findings and optimize treatment strategies for anal fistulas.

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