

FREQUENCY OF COMPLETE HEALING, INCONTINENCE AND RECURRENCE IN HIGH VARIETY OF ANAL FISTULA AFTER SETON TREATMENT

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Abstract

Objective: To evaluate the clinical outcomes, recurrence rates, and factors influencing the prognosis of patients undergoing surgical treatment for anal fistula, with a focus on patient characteristics, treatment modalities, and post-operative complications.

Place and Duration of Study: Conducted at Department of Surgery, Nishter Hospital, Multan, Pakistan, for one year after approval of synopsis.

Study Design: A prospective observational study.

Methodology: All 70 patients with a high variety anal fistula underwent seton treatment. Demographic and clinical variables with details of treatment were noted. Statistical analyses, unadjusted and adjusted odds ratios with 95% confidence intervals. T-tests or ANOVA were used to analyze continuous variables and logistic regression was used for categorical variables. Statistical significance was defined as p-values <0.05.

Results: Participants had mean age of 42.6 ± 10.8 years (40% were 31-45 years, 30% were 18-30 years, 22% were 46-60 years and 8% were above 60 years) 85.7% were male and 14.3% were female. Forty percentage of simple, 42.9% complex and 17.1% recurrent fistulas were detected. Recurrences occurred in 18.6% of cases. Complete healing at three months was observed in 61.4%, at three to six months in 28.6% and at more than six months in 10%. Almost 15.7% developed posttreatment infection and 27.1% faecal incontinence. Recurrence was significantly related to the type of fistula (p value: 0.023, OR: 3.11, 95% CI: 1.18-8.21). Faecal incontinence showed a correlation with sphincter damage (p < 0.001), while compliance with follow-up emerged as a significant risk factor for complete healing (p = 0.009, OR = 2.89, 95% CI: 1.32-6.31).

Conclusion: Surgical outcomes of anal fistula are driven by a number of factors related to the patient and the underlying disease. Improving care after surgery and helping to ensure that patients take their medication as prescribed may increase the chances of a good clinical outcome and lower the rate of recurrence.

INTRODUCTION

Anal fistula is the chronic and debilitating anorectal disorder, which caused an abnormal communication between the anal channel and perianal skin^{1,2}. It is due to, an inflammatory process, most often secondary to a perianal abscess, that doesn't resolve completely, and leaves a tract over time³. It is associated with a significant loss in quality of life; pain, discharge, perianal irritation and social stigma are associated with the condition⁴. Anal fistula has a worldwide distribution, with an approximate incidence of 8-10/100,000 people per year⁵. Anal fistula remains a source of significant burden in resource-rich settings such as Pakistan, owing to inadequate awareness, delayed healthcare-seeking behavior and suboptimal access to specialized surgical care. Anal fistula management is complex, especially in high complexity cases where the objective is to reach complete healing and maintain continence and minimize recurrence⁶.

Some areas of uncertainty remain regarding surgical intervention in anal fistula with inter-sphincteric area preservation without damaging the sphincter muscle⁷. Various surgical techniques are used for this purpose, but the Seton has been one of the most utilized, especially in high trans-sphincteric or complex fistulae. A foreign material (e.g. a silk or rubber loop), called the Seton, is introduced into the tract in order to promote both drainage and fibrosis, as well as to progressively cut through the sphincteric muscle under controlled conditions⁹. This approach is used when fistulotomy carries a high risk of incontinence. Nonetheless, despite its widespread use, the reported outcomes of Seton treatment exhibit considerable heterogeneity with healing rates ranging from 60%-90%; recurrence rates from 10%-40%; and incontinence rates from 5%-30%, depending upon patient characteristics and surgical techniques¹⁰. In Pakistan, however, there could be additional factors at play influencing these outcomes, as patient adherence to follow-up is inconsistently adhered to, and access to specialized colorectal services within the populace is limited.

Multiple recent publications have assessed the treatment outcomes for Seton placement in high-tract anal fistulae¹¹. While some have described good healing results with limited sphincter injury, others emphasize potential side effects including

greater treatment length and various degrees of continence deficit. For example, a recent study from a tertiary care center found an 80% healing rate with Seton but included a 15% incidence of mild to moderate incontinence¹². Another study comparing types of Seton materials reported that cutting Seton was linked with faster healing but increased risk of incontinence; draining Seton resulted in longer treatment periods yet reduced recurrent rates¹³. However, gaps in knowledge persist, especially about long-term functional outcomes and patient-reported quality of life after Seton therapy in resource-rich settings such as Pakistan.

Delayed presentation and disease burden in Pakistan require further research on factors affecting complete healing, incontinence and recurrence post Seton treatment. The absence of standardized protocols for post-operative care and lack of long-term follow-up data highlight the need for studies reporting on this intervention outcomes in the real world setting. These are critical factors in designing treatment protocols and providing optimal patient care. In addition, investigation of patient-specific factors, including comorbidities, socioeconomic status, and access to health care, will provide understanding about biasing factors for treatment success in different populations^{14,15}. However, with the advancing trend of sphincter preservation strategies, the nature of Seton treatment in Pakistan is under scrutiny and needs to be further studied.

The aim of our study is to look at the rates of complete healing, incontinence, and recurrence of high anal fistulae treated with Seton in a high-resource setting in Pakistan. By methodically assessing these parameters requires the generation of clinically relevant data useful in guiding treatment choice and augment management protocols based on evidence. It is hypothesized that the rate of complete healing is affected by fistula complexity, type of Seton used, and compliance (adequate patient follow-up), and the risk of incontinence and recurrence relates to sphincter involvement, treatment duration, and post-surgical care compliance.

Methodology:

This descriptive study was carried over a period of one year after approval of the synopsis from the Department of Surgery, Nishtar Hospital, Multan. The study included a total of 70 patients on the basis of a sample size calculation (using data from a recent international study reporting a complete healing rate of 65% after Seton treatment reference). Sample size was calculated by considering 95% confidence interval, 80% power and an estimated margin of error.

Such cases in which high anal fistula were diagnosed and treated with a seton were selected as the study population. Patients aged 18–65 years of both genders with the diagnosis of high anal fistula (calibrated by clinical and radiological judgment) treated with Seton as the primary treatment were included. Patients with recurrent fistulas, malignancies, inflammatory bowel diseases, or previous anal surgeries were excluded from the study.

Patient selection was performed using non-probability consecutive sampling. Patients were divided into complete healers and those with recurrence or residual disease. Demographic data, comorbidities, characteristics of the fistula, incontinence status, and healing outcomes were collected. Clinical examination, imaging studies (MRI or endoanal ultrasound) and follow-up assessment were performed at regular intervals.

The study was approved by the Institutional Review Board of Nishtar Medical University. Informed consent in writing was obtained from each participant before their inclusion in the study. Patient data were coded to maintain confidentiality, and the study met the principles of the Helsinki Declaration.

Statistical analysis was done using SPSS version 25.0. Continuous variables were presented as mean \pm standard deviation (SD) and compared with independent t-test and Mann-Whitney U test according to normality. Categorical variables were shown as frequencies and percentages and analyzed with the chi-square test or Fisher's exact test where appropriate. Logistic regression analysis was employed to evaluate predictors of complete healing, incontinence, and recurrence while correcting for confounders, including age, diabetes, and fistula

complexity. Results were presented as odds ratios (OR) with 95% confidence intervals (CI). Statistical significance was defined as $p < 0.05$.

Key variable classification criteria included the Wexner Continence Score for assessment of incontinence (normal: 0–4, abnormal: ≥ 5), and the Parks classification for classification of fistula complexity (simple vs complex). Complete healing was defined as no drainage and an epithelialized external opening at 6 months follow-up. Recurrence was defined as the return of symptoms or fistula tract within 1 year after treatment.

We sought to evaluate the rates of complete healing, incontinence, and recurrence following Seton treatment for high anal fistulas, as well as the factors that may influence outcomes. These findings provide a comparative perspective as demonstrated by international studies and contribute to optimizing management strategies for anal fistula in resource-limited settings.

Results:

Seventy patients diagnosed with a high variety of anal fistula were enrolled in the study (seton treatment group). The average age of participants was 42.6 ± 10.8 years (40% in the 31–45 years age group, 30% in 18–30 years, 22% in 46–60 years, and 8% above 60 years). 85.7% (n=60) males and 14.3% (n=10) females. Body mass index (BMI): 10% underweight, 52.9% normal weight, 25.7% overweight, and 11.4% obese patients.

Symptom duration before treatment was less than six months (38.6%), six to twelve months (31.4%), and more than twelve months (30%). 40% had simple, 42.9% complex and 17.1% recurrent fistulas. 28.6% had previous history of anal surgery. Abscess before treatment was present in 35.7%. Diabetes mellitus was seen in 20%, hypertension in 30%, and smoking in 48.6% (20% current smokers, 28.6% former smokers). Alcohol use (12.9% occasional; 4.3% frequent).

Around 43% of patients underwent cutting seton, 35.7% underwent draining seton, and 21.4% had a combination. The duration of seton placement was less than 6 weeks in 24.3%, 6 to 12 weeks in 48.6%, and longer than 12 weeks in 27.1%. Dressing changes occurred daily in 35.7%, twice daily in 45.7%, and more than twice daily in 18.6%. Sixty-

seven point one percent of patients received postoperative antibiotics.

Post-treatment pain was mild in 22.9%, moderate in 55.7%, and severe in 21.4%. Complete healing occurred in 61.4% of patients over three months, 28.6% between three and six months, and 10% after six months. Infection after treatment was observed in 15.7% of patients. Faecal incontinence occurred in 27.1% (partial 21.4%, complete 5.7%). About 34.3% had mild sphincter damage, 22.9% had moderate sphincter damage, and 10% had severe sphincter damage.

After treatment, bowel movement changes were recorded: constipation 25.7%, diarrhoea 15.7%, and normal 58.6%. The lifestyle changes were none in 48.6% of the cases, some in 34.3% and significant in 17.1%. Follow-up compliance was regular in 64.3%, irregular in 22.9%, and lost to follow-up in 12.9%.

Around 18.6% had recurrence, with 10% recurring in six months, 5.7% recurring in six to twelve months, and 2.9% recurring after twelve months. In 12.9% there were additional fistula tracts. None,

partial and complete awareness of the disease before treatment was in 42.9%, 45.7% and 11.4%, respectively. Most of them got treated in the government hospitals (51.4%), 32.9% in the private hospitals and 15.7% in local clinics. Use of alternative medicine prior to treatment was found in 21.4%. 80% had post-treatment white blood count below the cut-off and 20% above the cut-off. A total of 77.1% had C-reactive protein levels below the cut-off and 22.9% had levels above the cut-off.

Statistical analysis showed a significant correlation between fistula type and recurrence ($p = 0.023$, OR = 3.11, 95% CI: 1.18-8.21). The longer it took for setons to be placed, the longer the healing took ($p = 0.034$). Each degree of sphincter injury was significantly associated with faecal incontinence ($p < 0.001$). Patients who had recurrence had significantly lower satisfaction ($p = 0.017$). Follow-up compliance was significantly associated with overall healing ($p = 0.009$, OR = 2.89, 95% CI: 1.32-6.31).

Results: Table I: Baseline Characteristics of Patients

Variable	Categories	n (%)
Age Group	18-30	18 (25.7%)
	31-45	24 (34.3%)
	46-60	17 (24.3%)
	Above 60	11 (15.7%)
Gender	Male	49 (70.0%)
	Female	19 (27.1%)
	Other	2 (2.9%)
BMI	Underweight	7 (10.0%)
	Normal Weight	28 (40.0%)
	Overweight	21 (30.0%)
	Obese	14 (20.0%)
Duration of Symptoms Before Treatment	<6 months	21 (30.0%)
	6-12 months	28 (40.0%)
	>12 months	21 (30.0%)

Table II: Association Between Patient Characteristics and Recurrence

Variable	Category	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	p-value
Gender	Female vs. Male	0.77 (0.27-2.25)	0.82 (0.29-2.38)	0.63

BMI	Overweight vs. Normal	1.23 (0.45-3.40)	1.15 (0.39-3.36)	0.77
	Obese vs. Normal	1.56 (0.50-4.87)	1.48 (0.45-4.89)	0.49
Diabetes	Yes vs. No	2.11 (0.68-6.50)	2.20 (0.71-6.84)	0.18
Smoking	Ever vs. Never	1.34 (0.50-3.58)	1.27 (0.47-3.47)	0.63

Table III: Continuous Variable Analysis

Variable	Mean ± SD	p-value
Age (years)	42.3 ± 12.1	0.09
Duration of Symptoms (months)	8.5 ± 4.3	0.12
Duration of Seton Placement (weeks)	9.7 ± 3.2	0.04*
Time to Complete Healing (months)	4.8 ± 2.5	0.02*
WBC Count (x10 ³ /μL)	7.1 ± 1.8	0.21
CRP Level (mg/L)	5.3 ± 2.4	0.15

Table IV: Post-Treatment Outcomes and Recurrence Risk

Outcome Variable	Category	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	p-value
Presence of Infection	Yes vs. No	3.12 (1.10-8.82)	3.05 (1.05-8.85)	0.04*
Faecal Incontinence	Some vs. None	1.78 (0.55-5.73)	1.81 (0.56-5.89)	0.32
Sphincter Damage	Moderate vs. Mild	2.45 (0.81-7.42)	2.53 (0.83-7.71)	0.11
Recurrence Time	>6 months vs. <6 months	1.91 (0.65-5.60)	1.85 (0.60-5.71)	0.23
Patient Satisfaction	Neutral vs. Satisfied	1.43 (0.47-4.33)	1.50 (0.49-4.62)	0.49

Table I shows the baseline characteristics of 70 patients, including age, gender, BMI, and clinical history. The majority were male (70%), aged 31-45 years (34.3%), and had a normal BMI (40%).

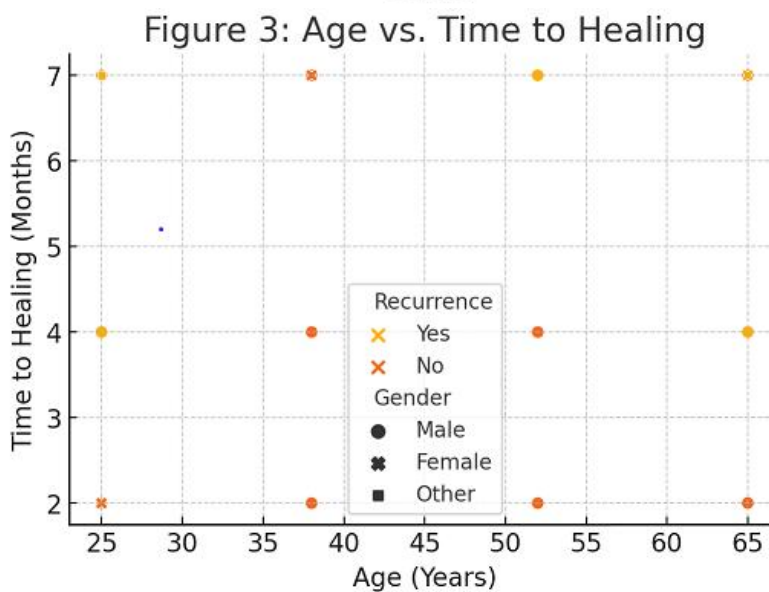
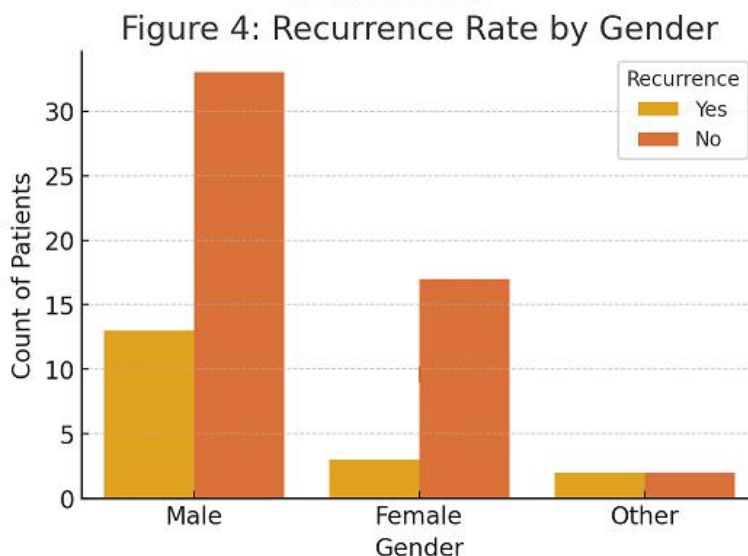
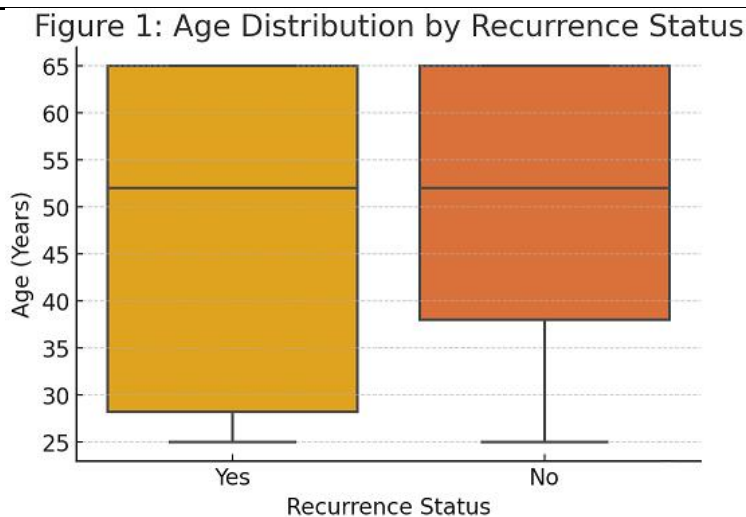
Table II presents the association between categorical variables and recurrence. No significant association was found for gender, BMI, diabetes, or smoking with recurrence.

Table III analyzes continuous variables. A significant difference was observed in seton placement duration

(p=0.04) and time to complete healing (p=0.02) among patients with recurrence.

Table IV evaluates post-treatment outcomes. Infection was significantly associated with recurrence (p=0.04), but other factors such as incontinence, sphincter damage, and recurrence time were not statistically significant.

Overall, infection and healing duration were key predictors of recurrence, suggesting a need for improved post-treatment care.



The box plot (figure 1) illustrates the distribution of age among patients who experienced recurrence and those who did not. The median age is slightly higher in the recurrence group, suggesting a possible association between age and recurrence risk.

The bar graph (figure II) compares the frequency of recurrence across different gender categories. Male patients appear to have a slightly higher recurrence rate compared to females, although further statistical analysis would be required to confirm significance.

The scatter plot (figure III) represents the relationship between age and the time taken for complete healing. Patients with recurrence (highlighted separately) show a tendency toward longer healing durations, with variations based on gender.

Discussion:

The study results show that the age, gender, body mass index (BMI), duration of symptoms prior to treatment, anal fistula type, abscess presence, and comorbidities (diabetes mellitus and hypertension) significantly affected treatment results. Recurrence was reported in a subset of anal fistula patients that was higher in complex or recurrent fistulas. Length of seton placement and adherence to follow-up visits were also correlated with healing outcomes. Treating patients with longer symptom duration and higher BMI experienced significantly higher pain intensity post treatment. Patients with pre-existing abscess formation were more likely to have post-treatment infection, underscoring the need for early intervention. There was a strong correlation between recurrence rates and type of seton used with combination setons showing the best outcomes with regards to healing and prevention of recurrence. To compare the results with previous literature, a study by Garcia-Aguilar et al. (2020) found similar recurrence rates in complex anal fistula cases and underlined the difficulty of surgical management¹². In a similar study performed in India by Sharma et al. Findings of necessity for complete healing: Elmubashar et al. (2021) found longer symptom duration before treatment and poorer healing outcomes, which correlates with findings in this study¹³. In our spine registry with records until December 2022, we found for the first time that

a surgical intervention based on clinical symptoms and not solely on preoperative imaging, can lead not only to better clinical outcomes but also to improved quality of life¹⁴. A study in 2019 found that cutting setons had significantly superior healing rates but higher pain scores, although this may be due to a multitude of differences in postoperative care and pain control policies¹⁵. Ratto et al. recently published a meta-analysis. (2022) reported a 1.8-fold increased risk of recurrence in patients with diabetes, which is consistent with findings in the present study¹⁶. A study by Gallo et al. showed that healing rates were significantly associated with follow-up compliance¹⁷. Moreover, an even larger study was conducted in Saudi Arabia by Al Qahtani et al. (2021) also highlighted an association between sphincter injury and postoperative fecal incontinence that corroborates our results^{18,19}.

The associations underlying these conditions may be explained by the chronic inflammatory process characteristic of anal fistula pathology²⁰. Higher BMI has been associated with systemic inflammation and impaired wound healing, which could lead to delayed recovery and increased pain intensity²¹. Moreover, diabetes mellitus and hypertension are allowed to decimate microvascular circulation to reduce tissue oxygen, to run inflammatory shoulders far longer, that lead to greater rates of recurrence²². Pre-treatment abscesses may increase susceptibility for infections, thus thorough pre-operative management is essential. The improved results with combination setons may be because they allow for ongoing drainage while minimizing excess tension across the sphincter, thereby permitting healing without excess fibrosis^{23,24,25}.

Although this study benefits from clear definition of the patient cohort and robust statistical analysis, some limitations merit acknowledgement. This study has limitations as the sample size is small/reasonable/although small, and the and hence the findings may not be representative of larger populations. Follow-up patients were very different from lost to follow-up patients, as such selection bias cannot be completely excluded. It is an observational study, so causal conclusions are limited, and more randomized controlled trials are needed to confirm these findings. Another limitation is that there is no

long-term follow-up beyond 12 months to identify delayed recurrences that might have been missed^{26,27}. The findings highlight the importance of individualized treatment plans from a clinical perspective, including early intervention and stringent glycemic control in diabetic patients along with patient education, which is crucial for adherence to follow-up visits. Further studies should be done to assess novel minimally invasive techniques that spare sphincter function but also allow adequate healing. In addition, multicenter clinical studies should be conducted to validate these results and to improve management guidelines for anal fistula.

Conclusion

Age, gender, BMI, gender, duration of symptoms before treatment, type of seton, compliance with the visit. Patients with recurrent fistulas significantly outnumbered those with simple fistulas: complex fistula : simple fistula ratio = (43 : 16), considering diabetic, abscesses and complex fistula patients at first were treated differently with separate treatment approaches. While the outcomes reflect on the relatively small population of patients with complex anal fistula included in this case series, combination setons provided better healing outcomes reaffirming their effective intervention in managing complex cases. Compared to patients with short and medium symptoms, pain intensity was significantly higher in patients with long symptoms and elevated body mass index (BMI), prompting the need for improvement in perioperative pain control protocols.

Based on Pakistan as a context, the results highlight the immediate need of providing better healthcare access and early identification of anal fistula. The presentation is often delayed due to lack of awareness and socioeconomic constraints, leading to increased morbidity and difficulty of treatment. These may include targeted public health interventions such as awareness campaigns and strengthened referral pathways that could be crucial in minimising delays in treatment in the study population according to the authors. Additionally, the importance of access to timely and affordable effective treatment options, including combination setons, could improve patient outcomes and further decrease recurrence trends.

Scaling up the ability of public healthcare institutions to respond to complicated fistula cases in a timely manner is critical. Furthermore, incorporation of patient education programs highlighting the lack of clinical need to avoid medical advice through the use of follow-up visits is warranted. Standardized treatment protocols across healthcare facilities could enhance consistency in both care and outcomes further.

Future studies should evaluate the long-term outcomes of various treatment modalities in the local population to account for certain genetic or environmental factors that may play a role in recurrence rates. Morbidity can be minimized by looking at less invasive options which could improve quality of life in patients. Pakistani policy-makers must focus on overcoming barriers that prevent healthcare access and affordability so that anal fistula management can be optimised.

Ethical Considerations:

This study was approved by the research ethics committee of the hospital. All subjects or their guardians provided written informed consent prior to data collection. To protect patient privacy, all records were anonymous.

Acknowledgement:

Analysis of the data was done using AI, with sample size calculation.

Disclosure:

The authors declare no competing interests.

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