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FREQUENCY OF FECAL INCONTINENCE AND RECURRENCE IN PATIENTS WITH HIGH FISTULA INANO TREATED WITH POLYPROPYLENE (PROLENE-1) AS LOOSE SETON AT TERTIARY CARE HOSPITAL, KARACHI

Original Research

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ABSTRACT

Background: High trans-sphincteric fistula-in-ano remains a challenging surgical condition due to the complex anatomy and risk of compromising sphincter function. Loose setons offering a balance between healing and continence preservation. Polypropylene (Prolene-1) setons are widely used due to their strength, affordability, and biocompatibility. However, concerns persist regarding recurrence and fecal incontinence, particularly in resource-constrained healthcare settings.

Objective: To determine the frequency of fecal incontinence and recurrence in patients with high fistula-in-ano treated with polypropylene (Prolene-1) as a loose seton at a tertiary care hospital in Karachi.

Methods: This cross-sectional study was conducted over six months at the Department of Surgery, Jinnah Postgraduate Medical Centre (JPMC), Karachi. A total of 104 patients aged 30–70 years with high trans-sphincteric fistula-in-ano were included using non-probability consecutive sampling. All underwent surgery under general or spinal anesthesia with Prolene-1 setons were placed and left in situ for three months. Patients were followed every two weeks postoperatively for evaluation of wound healing recurrence and fecal incontinence. Data were analyzed using SPSS version 22, with stratification and chi-square tests applied to assess associations.

Results: Among the 104 patients, 71 (68.3%) were aged 51–70 years, while 33 (31.7%) were 30–50 years old. There were 54 males (51.9%) and 50 females (48.1%). Recurrence was observed in 10 patients (9.6%), and fecal incontinence occurred in 16 patients (15.4%). Recurrence showed no significant association with age (p=0.12), gender (p=0.59), diabetes (p=0.60), hypertension (p=0.28), smoking (p=0.75), or duration of surgery (p=0.37). Fecal incontinence was significantly more common among non-diabetics (21.1% vs 0%, p=0.01) and non-hypertensives (20.8% vs 0%, p=0.01), and occurred only among urban residents (p=0.05).

Conclusion: Polypropylene (Prolene-1) as a loose seton is a safe and effective option for managing high fistula-in-ano, demonstrating low recurrence and acceptable incontinence rates. Clinical outcomes may be further optimized through appropriate patient selection and structured follow-up.

Keywords: Anal fistula, Loose seton, Fecal incontinence, High fistula-in-ano, Prolene-1, Recurrence, Seton treatment.

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INTRODUCTION

Fistula-in-ano is a common yet distressing anorectal disorder that significantly impairs patients' quality of life due to pain, recurrent discharge, and the psychological burden associated with the condition. Characterized by a chronically epithelialized tract lined with granulation tissue, it connects a primary internal opening in the anal canal to a secondary external opening on the perianal skin (1). The majority of cases are idiopathic or cryptoglandular in origin, typically arising from infection of an anal gland situated in the intersphincteric space, which triggers an acute inflammatory process that may evolve into a persistent fistulous tract (2). Although the cryptoglandular pathway remains the predominant etiology, a wide array of secondary causes must also be considered, including Crohn's disease, tuberculosis, malignancies, lymphogranuloma venereum, presacral dermoid cysts, rectal duplication, actinomycosis, traumatic injury, and foreign body reactions (3,4). These varied etiologies complicate both diagnosis and management, necessitating a comprehensive clinical assessment. The condition often represents the chronic sequela of an unresolved or inadequately treated anorectal abscess. When such an abscess either ruptures spontaneously or is incised surgically, there is a tendency for a fistulous tract to develop, forming a persistent communication between the rectum or anal canal and the perineal skin (5,6). Among the different types, high transsphincteric fistulas pose a distinct surgical challenge, as the tract crosses the upper or middle third of the external anal sphincter or the mid-anal canal (7). Surgical intervention in these cases carries a heightened risk of complications, particularly fecal incontinence, due to potential injury to the sphincter complex.

The loose seton, a technique that involves threading a non-absorbable suture material through the fistulous tract and leaving it in place without tightening, has been employed in managing high fistulas, it allows for effective drainage and helps prevent to abscess formation. Conventional approaches such as fistulotomy and fistulectomy are effective for low anal fistulas but are less suitable for high or complex cases due to the risk of prolonged healing, open wounds, recurrence, and incontinence (10,11). Studies have reported recurrence rates of up to 2.4% and fecal incontinence in 15.6% of cases following traditional procedures, highlighting the need for safer and more effective alternatives (12).

Recent interest has emerged in the use of polypropylene (Prolene-1) as a loose seton material for high fistula-in-ano. Its biocompatibility, tensile strength, and ability to maintain tract patency may offer a balance between efficacy and safety. Prolene-1 is hypothesized to reduce the risk of abscess formation and improve tract superficialization without causing excessive trauma to the sphincter complex. However, robust evidence regarding its long-term impact on recurrence and continence outcomes remains limited. Moreover, there exists a widespread public misconception that surgical management of fistula-in-ano invariably results in foul smelling, bleeding wounds and permanent loss of control over bowel movements, including flatus. These concerns often deter patients from seeking timely surgical intervention, emphasizing the need for evidence-based reassurance and refinement in treatment strategies. Given these clinical challenges and social perceptions, the present study aims to assess the frequency of fecal incontinence and recurrence following the use of Prolene1 loose seton in high transsphincteric anal fistulas. The findings are intended to contribute to improving surgical decision-making and optimizing patient outcomes through safer and more acceptable treatment protocols.

METHODS

This cross-sectional study was conducted at the Department of Surgery, Jinnah Postgraduate Medical Centre (JPMC), Karachi, over a duration of six months, following the approval of the research synopsis. Ethical clearance was granted by the College of Physicians and Surgeons Pakistan and the institutional ethics review committee. The sample size was calculated using the WHO sample size calculator, based on an estimated 15.6% prevalence of fecal incontinence, with a 95% confidence interval and a 7% margin of error, resulting in a required sample of 104 participants. A non-probability consecutive sampling technique was employed to enroll eligible patients. Inclusion criteria consisted of patients aged 30 to 70 years, of either gender, presenting with high trans-sphincteric fistula-in-ano persisting for more than six weeks (as per operational definition), and having an ASA (American Society of Anesthesiologists) physical status score of I or II. Patients were excluded if they had a diagnosis of anorectal malignancy, a history of pelvic or perianal radiotherapy, inflammatory bowel disease, recurrent anal fistula, or systemic comorbidities such as congestive heart failure, chronic liver disease, chronic obstructive pulmonary disease (COPD), asthma, myocardial infarction, chronic kidney disease, or cerebrovascular accident (3,5). Eligible patients were counseled and informed written consent was obtained in the local language. Baseline demographic data

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including age, gender, and place of residence were recorded. Surgical intervention was performed under spinal or general anesthesia, with the patient placed in the lithotomy position. An experienced surgeon (with more than 10 years of clinical experience) conducted a detailed assessment of the fistulous tract using methylene blue dye and a malleable probe, taking meticulous care to avoid the creation of false tracts. Once the internal opening was precisely located, three non-absorbable Prolene No. 1 sutures were inserted through the external opening using a buttonhole probe and looped through the tract to act as a loose seton.

The rationale for using three separate Prolene-1 sutures, rather than a single loop, was based on practical surgical experience and biomechanical considerations. Multiple sutures help maintain tract patency and prevent premature loosening of the seton and reduce the likelihood of track migration or asymmetric cutting, thereby improving control over the rate of superficialization and minimizing the risk of incontinence. Moreover, in anatomically wide or angulated tracts, a single suture may be insufficient to maintain stable contact across the entire length of the fistula, especially in high trans-sphincteric variants. Although this practice is not universally standardized, it reflects a modification grounded in local surgical expertise and favorable clinical outcomes observed in preliminary cases. Nevertheless, uniform technique application was maintained throughout the study to avoid variability in outcomes. Postoperatively, all patients received standard care including twice-daily sitz baths, analgesics, and stool-bulking agents to support wound hygiene and defecation ease. Patients were followed up every two weeks to evaluate seton integrity, wound healing progress, recurrence of fistula, and any symptoms of fecal incontinence, all documented as per operational definitions. Statistical analysis was carried out using IBM SPSS version 22. Quantitative variables such as age and duration of surgery were tested for normal distribution using the KolmogorovSmirnov test. Variables with normal distribution were expressed as mean ± standard deviation (SD), while non-normally distributed variables were presented as median with interquartile range (IQR). Categorical variables, including gender, residence, comorbidities, recurrence, and fecal incontinence, were summarized as frequencies and percentages. To control for potential confounders, data were stratified by demographic and clinical characteristics, and the chi-square or Fisher's exact test was applied post-stratification. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

Out of the 104 patients included in the study, the majority were between 51 and 70 years of age (68.3%), while the remaining 31.7% fell within the 30 to 50-year age range. The gender distribution was nearly balanced, with 54 males (51.9%) and 50 females (48.1%). Most participants were urban residents (83.7%), whereas 16.3% were from rural areas. Regarding operative duration, 56.7% of the procedures exceeded 2.5 hours, while 43.3% lasted 2.5 hours or less. A total of 28 patients (26.9%) had type II diabetes mellitus, and 27 (26%) were hypertensive. Among the participants, 35.6% reported being smokers. Postoperatively, 9.6% of the patients experienced recurrence of the fistula, while fecal incontinence was reported in 15.4% of the cohort. Analysis of recurrence patterns revealed no statistically significant association with any of the demographic or clinical variables. Although recurrence was more frequently observed among patients aged 51 to 70 years (12.7%) compared to those aged 30 to 50 years (3.0%), the difference was not statistically significant ($p = 0.12$).Similarly, recurrence did not show significant associations with gender ($p = 0.59$), residence ($p = 0.56$), duration of surgery ($p = 0.37$), diabetes status ($p = 0.60$), hypertension ($p = 0.28$), or smoking ($p = 0.75$).

Fecal incontinence, however, showed more distinct patterns. Notably, none of the patients with diabetes or hypertension developed incontinence, whereas 21.1% of non-diabetic and 20.8% of non-hypertensive patients did, with both associations reaching statistical significance ($p = 0.01$). Additionally, fecal incontinence occurred exclusively among urban residents (18.4%), while no rural patients reported this complication, a result that approached statistical significance ($p = 0.05$). No meaningful relationship was observed between fecal incontinence and age ($p = 0.22$), gender ($p = 0.86$), duration of surgery ($p = 0.55$), or smoking status ($p = 0.69$). Based on additional stratified analysis, the relationship between fecal incontinence and surgical duration was further examined. Among the 45 patients who underwent surgery lasting ≤2.5 hours, 8 (17.8%) developed fecal incontinence, while among the 59 patients whose surgeries exceeded 2.5 hours, 8 (13.6%) experienced this complication. The difference was not statistically significant ($p = 0.55$), suggesting that surgical duration alone did not have a clear impact on the incidence of incontinence.

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Table 1: Distribution of baseline characteristics among the study participants.

Variables	n (%)
Age	
30–50 years	33 (31.7%)
51–70 years	71 (68.3%)
Gender	
Male	54 (51.9%)
Female	50 (48.1%)
Residence Status	
Urban	87 (83.7%)
Rural	17 (16.3%)
Duration of Surgery	
≤ 2.5 hours	45 (43.3%)
> 2.5 hours	59 (56.7%)
Diabetes Mellitus	
Yes	28 (26.9%)
No	76 (73.1%)
Hypertension	
Yes	27 (26.0%)
No	77 (74.0%)
Smoking Status	
Yes	37 (35.6%)
No	67 (64.4%)
Recurrence	
Yes	10 (9.6%)
No	94 (90.4%)
Fecal Incontinence	
Yes	16 (15.4%)
No	88 (84.6%)

Table 2: Distribution of patient characteristics according to the Recurrence groups.

Variables	Recurrence (n = 10)	No Recurrence (n = 94)	p-value
Age			
30–50 years	1 (3.0%)	32 (97.0%)	0.12
51–70 years	9 (12.7%)	62 (87.3%)	
Gender			
Male	6 (11.1%)	48 (88.9%)	0.59
Female	4 (8.0%)	46 (92.0%)	
Residence Status			
Urban	9 (10.3%)	78 (89.7%)	0.56
Rural	1 (5.9%)	16 (94.1%)	
Duration of Surgery			
≤ 2.5 hours	3 (6.7%)	42 (93.3%)	0.37
> 2.5 hours	7 (11.9%)	52 (88.1%)	
Diabetes Mellitus			
Yes	2 (7.1%)	26 (92.9%)	0.60
No	8 (10.5%)	68 (89.5%)	
Hypertension			

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Variables	Recurrence (n = 10)	No Recurrence (n = 94)	p-value
Yes	4 (14.8%)	23 (85.2%)	0.28
No	6 (7.8%)	71 (92.2%)	
Smoking Status			
Yes	4 (10.8%)	33 (89.2%)	0.75
No	6 (9.0%)	61 (91.0%)	

Table 3: Distribution of patient characteristics according to the Fecal incontinence groups.

Variables	Fecal Incontinence (n = 16)	No Incontinence (n = 88)	p-value
Age			
30–50 years	3 (9.1%)	30 (90.9%)	0.22
51–70 years	13 (18.3%)	58 (81.7%)	
Gender			
Male	8 (14.8%)	46 (85.2%)	0.86
Female	8 (16.0%)	42 (84.0%)	
Residence Status			
Urban	16 (18.4%)	71 (81.6%)	0.05
Rural	0 (0.0%)	17 (100.0%)	
Duration of Surgery			
≤ 2.5 hours	8 (17.8%)	37 (82.2%)	0.55
> 2.5 hours	8 (13.6%)	51 (86.4%)	
Diabetes Mellitus			
Yes	0 (0.0%)	28 (100.0%)	0.01
No	16 (21.1%)	60 (78.9%)	
Hypertension			
Yes	0 (0.0%)	27 (100.0%)	0.01
No	16 (20.8%)	61 (79.2%)	
Smoking Status			
Yes	5 (13.5%)	32 (86.5%)	0.69
No	11 (16.4%)	56 (83.6%)	

Table 4: Stratified Assessment of Fecal Incontinence by Surgical Duration and Seton Factors

Variables	Yes Fecal Incontinence n (%)	No Fecal Incontinence n (%)	p-value
Duration of Surgery ≤ 2.5 hrs	08 (17.8%)	37 (82.2%)	0.55
Duration of Surgery > 2.5 hrs	08 (13.6%)	51 (86.4%)	
Seton Threads Used (n=3 in all cases)	Not variable	Not variable	N/A
Seton Tightening Schedule	Not recorded	Not recorded	N/A

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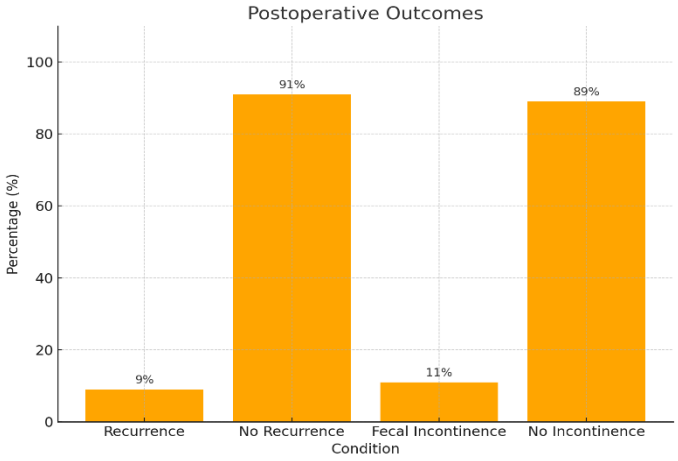

Figure 1 Postoperative Outcomes

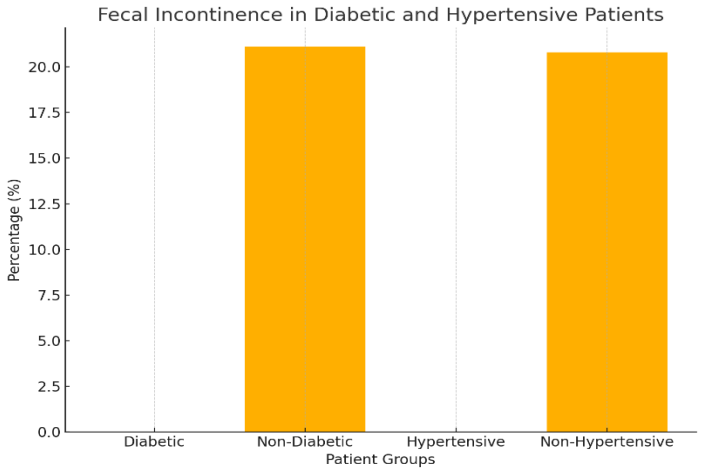

Figure 2 Fecal Incontinence in Diabetic and Hypertension Patients

DISCUSSION

Managing high trans-sphincteric fistula-in-ano presents an enduring surgical challenge due to the delicate balance between achieving complete healing and preserving anal continence. The findings of this study reaffirm the clinical value of polypropylene (Prolene-1) cutting seton as a practical therapeutic option, particularly in resource-limited environments. With a recurrence rate of 9.6% and fecal incontinence observed in 15.4% of patients, the outcomes are consistent with those reported in previous literature, where recurrence typically ranges between 7% and 15% and incontinence falls within a 12% to 18% range depending on surgical technique and case complexity (13,14). These recurrence rates emphasize the importance of precise tract identification and complete surgical dissection. Prior investigations have consistently highlighted that failure to identify the internal opening remains a leading cause of recurrence, underscoring the need for meticulous intraoperative exploration (15). In this study, recurrence did not show statistically significant associations with age, gender, comorbidities such as diabetes or hypertension, or smoking status, which supports the argument made by several authors that patient-related variables alone are insufficient predictors of recurrence (16). The uniform technique used and surgeon experience in this study likely contributed to the relatively low recurrence rate.

Fecal incontinence remains a key concern in seton therapy due to its direct relationship with sphincter integrity. Although the use of Prolene allows for continuous drainage of the tract and fibrosis, thereby minimizing abrupt sphincter disruption, the incidence of incontinence in this study, while within the expected range, requires careful scrutiny. Surprisingly, incontinence was only noted in patients without diabetes or hypertension, which contrasts with general assumptions that these comorbidities compromise wound healing and tissue repair (17,18). This paradox may be attributable to confounding factors such as protective lifestyle adaptations, underreporting, or sample size limitations. These unexpected findings warrant more granular investigation in future prospective studies with broader representation. The association of urban residency with incontinence, although borderline significant, could reflect disparities in followup compliance, access to postoperative care, or sociocultural attitudes toward symptom reporting (19). In broader surgical outcomes research, similar patterns have been observed where urban populations exhibited higher complication reporting rates, possibly due to greater health literacy or accessibility to specialist services. These considerations highlight the multifactorial nature of postoperative outcomes and the importance of tailoring care pathways to individual contexts (20).

The duration of surgery did not significantly influence recurrence or continence outcomes in this cohort, though longer procedures may inherently reflect more anatomically complex cases. A key procedural constant in this study was the use of three Prolene sutures for all patients. While this uniformity aided in standardization, data on the force and frequency of seton tightening were not recorded, limiting the ability to analyze how mechanical variables influenced continence or healing. As tension dynamics play a pivotal role in seton performance, future studies should incorporate these parameters to better assess procedural nuances. The primary strength of this study lies in its real-world relevance, offering insight into outcomes achieved with a low-cost, accessible technique in a high-volume publicsector hospital. The inclusion of a well-defined cohort and the use of consistent surgical methodology strengthen the internal validity of the findings. However, certain limitations must be acknowledged. The use of a non-probability consecutive sampling

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technique introduces potential selection bias, which may limit the generalizability of the findings. As a single-center study conducted at JPMC, results may be reflective of specific institutional protocols or surgeon expertise, which may not translate across diverse settings. The cross-sectional design restricts long-term outcome assessment, particularly regarding delayed recurrence or late-onset continence disturbances. Additionally, reliance on patient-reported continence outcomes may have introduced reporting bias, particularly for minor or socially stigmatized symptoms.

Future studies should aim for multicenter recruitment with probabilistic sampling and longer follow-up intervals to evaluate delayed outcomes. Incorporation of validated continence scoring systems and objective assessment tools, such as anorectal manometry, could enhance diagnostic precision. Moreover, structured documentation of seton management practices, including placement technique and material properties, would offer a deeper understanding of the procedural determinants of success. Overall, the findings support the continued use of Prolene-1 loose seton as a viable and effective treatment for high fistula-in-ano, particularly where resource constraints preclude more advanced modalities. Despite the inherent risks of recurrence and incontinence, these can be mitigated with skilled surgical technique, rigorous follow-up, and individualized patient care protocols.

CONCLUSION

The use of polypropylene (Prolene-1) loose setons in the management of high fistula-in-ano demonstrated favorable outcomes, offering a reliable balance between effective healing and continence preservation. While a few patients developed fecal incontinence, most recovered without major complications or recurrence, reaffirming the value of this technique in complex fistula cases. The absence of strong associations with common risk factors suggests that outcomes are more likely influenced by procedural consistency and postoperative care. Given its simplicity, cost-effectiveness, and accessibility, this approach remains a practical and efficient solution, particularly in resource-constrained surgical settings.

AUTHOR CONTRIBUTION

Author	Contribution
Muhammad Osama Iqbal*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Sarkhail Ahmed Sayar	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Kanwal Gul Bhellar	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Sakeena Fayaz	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published

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