

Definitive Healing Through Simplicity - Evaluating Draining Seton Alone in the Management of Fistula-in-Ano: Outcomes in Healing and Postoperative Morbidity

Khan RK¹, Islam MR², Lima IJ³, Bahar M⁴, Talukdar MI⁵, Sarker RD⁶

Conflict of Interest: None

Received: 05.02.2024

Accepted: 05.03.2024

www.banglajol.info/index.php/JSSMC

ABSTRACT:

Background: The prime goal and challenge in combating fistula-in-ano is to achieve complete tract closure while preserving continence. Surgical techniques vary based on fistula complexity and surgeon expertise, with conventional methods like fistulotomy and fistulectomy posing a risk of incontinence, particularly in high trans-sphincteric cases. Low trans-sphincteric fistulas are generally amenable to fistulotomy, whereas SETON placement has long served as a drainage-focused, sphincter-sparing alternative. This technique facilitates abscess resolution and promotes tract healing through controlled inflammation.

Result: In this study, we encountered 30 patients with fistula-in-ano who were treated with draining seton, the mean age was 41.5 ± 12.2 years, with a male predominance (83.3%). The majority of patients (76.7%) achieved complete healing, while 23.3% showed no improvement. Postoperative complications were minimal, with 9.9% experiencing pain, 3.3% reporting bleeding, and 3.3% developing incontinence, indicating draining seton as a highly effective and well-tolerated treatment option.

Conclusion: This study demonstrated that draining seton achieved favourable outcomes in the treatment of fistula-in-ano, with the majority of patients experiencing complete healing. The overall complication rate remained low, with minimal occurrences of pain, bleeding, and incontinence. These findings position draining seton as a highly effective and well-tolerated therapeutic approach for fistula-in-ano.

Key Words:

Seton, fistula, per-rectal, healing.

[J Shaheed Suhrawardy Med Coll 2024; 16(1): 58-63]

DOI: <https://doi.org/10.3329/jssmc.v16i1.85267>

Authors:

1. Dr. Rafiul Karim Khan. Associate Professor, Dept. of Surgery, Shaheed Suhrawardy Medical College, Dhaka
2. Dr. Md. Rashidul Islam, Associate Prof. Dept. of Colorectal Surgery, Shaheed Suhrawardy Medical College, Dhaka.
3. Dr. Ismat Jahan Lima, Associate Prof. Dept. of Colorectal Surgery, Shaheed Suhrawardy Medical College, Dhaka.
4. Dr. Mejbahul Bahar, Assistant Professor, Dept. of Surgery, Shaheed Suhrawardy Medical College, Dhaka
5. Dr. Monoarul Islam Talukdar, Consultant, Dept. of Surgery, Shaheed Suhrawardy Medical College, Dhaka
6. Dr. Rajib Dey Sarker, Assistant Surgeon, District Sadar Hospital, Rajbari

Correspondence:

Dr. Rafiul Karim Khan. Associate Professor, Dept. of Surgery, Shaheed Suhrawardy Medical College, Dhaka,
Mobile: 01752477745, Email: rafiulronyaz@gmail.com.

Introduction

Fistula, derived from the Latin word for a reed or pipe, refers to an abnormal communication between two epithelium-lined surfaces. Anal fistulas, in particular, are abnormal channels between the anal canal and the perianal skin or perineum, causing significant discom-

fort and morbidity. Patients with anal fistulas often experience cyclic episodes, where the external opening closes temporarily, leading to pain, swelling, and the subsequent release of purulent material or blood once the opening reopens. The incidence of anal fistulas ranges from 0.86 to 2.32 per 10,000 people per year,

with a male predominance, showing a ratio of 2:1 to 5:1, and most affected individuals are between the ages of 30 and 50. The condition is generally considered troublesome and requires effective treatment.

Research by Daodu et al. (2018) demonstrated that the draining seton technique could effectively manage fistula-in-ano, with 73.7% of patients experiencing complete resolution of symptoms after an average of 36.6 weeks of seton placement [1]. Similarly, Kelly et al. (2014) confirmed the effectiveness of loose seton placement, reporting successful fistula clearance in 96% of patients, although recurrence occurred in 6% of cases [2]. Ramachandra and Garg (2018) compared several treatment modalities, highlighting the LIFT procedure and fistulotomy as promising options for both low and high lying fistulas [3]. Alam and Abbasi (2017) further supported the use of setons for managing high anal fistulas, demonstrating a high healing rate with minimal incontinence [4].

Additionally, Pearl et al. (1993) observed that staged fistulotomy with seton placement provided effective long-term resolution with low rates of fecal incontinence and recurrence [5]. Other studies, such as those by Yildirim and Bakir (2021), Gurer et al. (2007), and Zheng et al. (2020), explored various aspects of seton techniques and materials, comparing the efficacy, recurrence rates, and postoperative outcomes [7, 8]. Yildirim and Bakir found that the use of elastic materials for setons yielded acceptable results [6], while Gurer et al. introduced self-locking cable ties as an inexpensive and effective option. Furthermore, Zheng et al. concluded that loose combined cutting setons (LCCS) achieved a 100% healing rate with minimal incontinence and postoperative pain. Tumer and Altioek (2023) found that both loose and cutting setons were effective, though the latter was associated with higher incidences of pain and incontinence [9]. Overall, the treatment of anal fistulas remains a complex area, but various surgical approaches, particularly seton placement, have shown significant success in managing the condition. These findings underscore the importance of individualized treatment strategies based on the type and complexity of the fistula.

Materials And Methods

This prospective observational study successfully included 30 patients with trans-sphincteric

fistula-in-ano, treated at the Department of Colorectal Surgery, Shaheed Suhrawardy Medical College, Dhaka, and District Sadar Hospital, Rajbari, between January 2023 to December 2023. The treatment demonstrated high efficacy, with most patients achieving complete healing, reflecting the positive outcomes of seton placement as a viable management option. Despite a smaller sample size due to time constraints, the findings provide valuable insights into the effectiveness of this approach.

Selection Criteria of Subjects

Inclusion criteria

- Patients with Fistula-in-Ano (Transsphincteric)
- Age > 18 years
- Both sexes
- Patients who gave consent

Exclusion criteria

Patients with existing preoperative incontinence, inflammatory bowel disease, intestinal tuberculosis, malignancies and anorectal tumor, simple fistula.

Sample size formation

Sample size determination:

The sample size was determined by following formula

$$n = \frac{Z^2 p \times q}{d^2}$$

Where,

n = the desired sample size which would help to measure the different indicators

z = the standard normal deviate, usually set at 1.96 at 5% level which corresponds to 95% confidence level.

Here p = 0.895 (Completely healed of fistula-in-ano was 89.5% [Noor and Abbasi, 2017])

q = 1 - 0.895 = 0.105

d = allowable error (normally from 1 – 10%) = 0.01 (assumed 1.0%)

So, the sample size for this study will be

n = 36 (Due to time constraints and a lack of willing patients in this procedure, only 30 patients were selected instead of the intended 36)

Sampling technique: Purposive sampling was done.

Variables

Independent variables:

- Age
- Sex
- Height
- Weight
- BMI

Dependent variables:

- Duration of operation
- Post-operative pain
- Hospital stay
- Return to daily activity
- Complete healing
- Non- healing group
- Incontinence rate

Operational definitions

Complete healing: Healing has been progressed and completed in usual and expected course.

Non-healing: Healing has not been progressed and not completed in usual and expected course of time. Even not within 6 months.

Results

As mentioned earlier, the study included 30 patients, with a mean age of 41.5 ± 12.2 years, ranging from 24 to 75 years. The largest proportion of patients fell within the 31-40 (30.0%) and 41-50 (33.3%) age groups, while 23.3% were in the 18-30 age group. A smaller percentage of patients were in the 51-60 (6.7%) and over 60 (6.7%) age groups. The findings suggest that the majority of patients affected by fistula-in-ano were middle-aged, reflecting the common age range for this condition. [Table RDS1]

Table RDS1: Distribution of the patients by their age group (N=30)

Age (years)	Number (n)	Percentage (%)
18 - 30	7	23.3
31 - 40	9	30.0
41 - 50	10	33.3
51 - 60	2	6.7
>60	2	6.7
Gender		
Mean $\pm$ SD	41.5 ± 12.2	83.3
Min – max	24 - 75	16.7

Mean age of the patients was 41.5 ± 12.2 years ranged from **24 years to 75 years**.

Males (83.3%) were predominant than females (16.7%). Male to female ratio was 5:1.

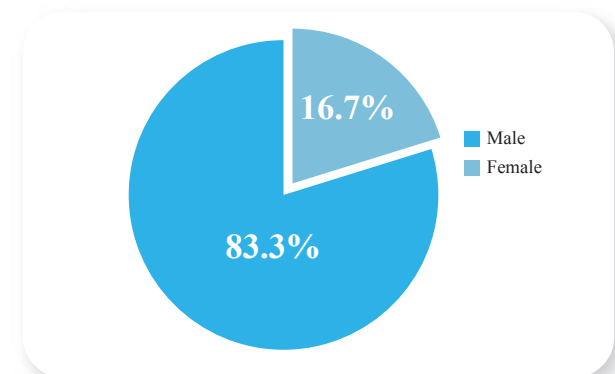


Figure RDS2: Pie chart showing gender distribution of the study subjects

The study found that among the 30 patients, 53.3% (16 patients) had a normal weight (BMI 18.5-24.9 kg/m²), while 46.7% (14 patients) were classified as overweight (BMI 25.0-29.9 kg/m²). The mean BMI of the patients was 24.7 ± 2.6 kg/m², with values ranging from 19.1 to 29.0 kg/m². These findings indicate that the majority of patients had a BMI within the normal to overweight range, with a notable proportion falling into the overweight category. [Table RDS3]

Table RDS3: Distribution of the patients by BMI (N=30)

BMI (kg/m ²)	Number (n)	Percentage (%)
1 Normal weight (18.5-24.9)	16	53.3
Over weight (25.0 – 29.9)	14	46.7
Mean $\pm$ SD	24.7 ± 2.6	
Min – max	19.1 – 29.0	

Among 30 patients 16 (53.3%) had normal weight and 14 (46.7%) had overweight. Mean BMI was 24.7 ± 2.6 kg/m² ranged from 19.1 to 29.0.

The mean duration of disease among the study participants was 4.35 ± 1.19 years, with a range spanning from 1 to 7 years. This suggests that most patients had been living with the condition for a considerable period prior to intervention, highlighting the chronic nature of trans-sphincteric fistula-in-ano in this cohort. [Table RDS4]

Table RDS4: Duration of disease (N=30)

Duration of disease (years)	
Mean $\pm$ SD	4.35 ± 1.19
Min – max	1 – 7

Mean duration of disease was 4.35 ± 1.19 years ranged from 1 to 7 years.

Postoperative pain following draining seton placement was reported in only 3 patients (9.9%), while the majority, 27 patients (90.1%), experienced no postoperative pain. This indicates that the procedure was generally well tolerated with minimal discomfort among most patients. [Table RDS5]

Table RDS5: Postoperative pain of draining seton as treatment of Fistula in Ano (N=30)

Pain	Number (n)	Percentage (%)
Yes	3	9.9
No	27	90.1

Postoperative pain was present in 3 patients (9.9%).

Postoperative bleeding occurred in only 1 patient (3.3%), while 29 patients (96.7%) experienced no bleeding, indicating that draining seton treatment is associated with minimal postoperative bleeding and is generally a safe procedure in terms of hemostatic outcomes. [Table RDS6]

Table RDS6: Postoperative bleeding of draining seton as treatment of Fistula in Ano (N=30)

Bleeding	Number (n)	Percentage (%)
Yes	1	3.3
No	29	96.7

Postoperative bleeding was observed in 1 patient (3.3%).

Postoperative incontinence was reported in only 1 patient (3.3%), while the remaining 29 patients (96.7%) retained

full continence, suggesting that the draining seton procedure preserves anal sphincter function in the vast majority of cases. [Table RDS7]

Table RDS7: Postoperative incontinence of draining seton as treatment of Fistula in Ano (N=30)

Incontinence	Number (n)	Percentage (%)
Yes	1	3.3
No	29	96.7

Postoperative incontinence was found in 1 patient (3.3%).

Amongst the 30 patients who underwent treatment for trans-sphincteric fistula-in-ano using the draining seton technique, a substantial majority—23 patients (76.7%)—achieved complete healing, demonstrating the effectiveness and clinical reliability of the procedure. However, 7 patients (23.3%) did not attain complete healing during the study period, which may be attributed to factors such as fistula complexity, chronicity of disease, or patient-specific comorbid conditions. These findings support the use of draining seton as a viable and effective treatment modality for achieving satisfactory healing outcomes in the majority of patients with complex fistula-in-ano. [Table RDS8]

Table RDS8: Outcome of draining seton as treatment of Fistula in Ano (N=30)

	Number (n)	Percentage (%)
Completely healed	23	76.7
Not healed	7	23.3

Among the 30 patients 23 (76.7%) were completely healed and 7 (23.3%) were not healed.

Discussion

The principal therapeutic objective in the management of fistula-in-ano is to ensure complete resolution of the fistulous tract while preserving anal continence and minimizing recurrence [10,11]. The choice of surgical technique is often influenced by the surgeon's expertise, the complexity of the fistula, and anatomical considerations. Traditional approaches, such as fistulotomy and fistulectomy, involve the careful dissection of cutaneous, subcutaneous, and sphincteric structures. While these methods are generally effective for low transsphincteric

fistulae, their application in more complex cases—especially those involving the middle to upper third of the sphincter complex—poses a significant risk of postoperative incontinence [12,13]. Consequently, sphincter-sparing techniques, including the use of setons, have re-emerged as valuable alternatives in the management of complex anal fistulae [14].

Seton placement is based on the premise of promoting continuous drainage and controlled fibrosis while minimizing sphincter damage [15]. In our study, the mean age of participants was 41.5 ± 12.2 years (range: 24–75 years), which aligns with previous findings reporting mean ages of 38.2 years [16], 36.1 years [17], 38.7 years [18], and 42 years [19], suggesting that fistula-in-ano commonly affects individuals in mid-adulthood.

Males predominated in our study cohort, with a male-to-female ratio of 5:1. This is comparable to other investigations, such as Alam and Abbasi [16] (4.2:1), and consistent with findings from Kelly et al. [20], Tümer and Altıok [18], Yildirim and Bakir [21], and Zheng et al. [17], indicating a male preponderance in the epidemiology of anal fistulae.

Regarding body mass index (BMI), 53.3% of patients had normal weight and 46.7% were overweight, with a mean BMI of 24.7 ± 2.6 kg/m² (range: 19.1–29.0). Although the relationship between BMI and anal fistula formation remains controversial, emerging data suggest a potential correlation. A recent analysis by Ye et al. [22] revealed that elevated BMI is associated with a higher risk of both anal fistulae and anorectal abscess, with a dose-dependent J-shaped curve indicating progressively increasing risk with rising BMI values.

The mean duration of disease in our cohort was 4.35 ± 1.19 years (range: 1–7 years), underscoring the chronic nature of this condition and the need for timely intervention to prevent prolonged patient morbidity.

Postoperative complications were notably low in this study. Pain was reported by only 3 patients (9.9%), a figure lower than that observed by Şahin et al. [23], who noted pain in 19.2% of cases with VAS scores ranging from 1–5.5. Similarly, Zheng et al. [17] reported minimal pain, with most patients experiencing only mild discomfort. Postoperative bleeding occurred in 1 patient (3.3%), indicating excellent intraoperative hemostasis and favorable surgical outcomes.

Anal incontinence remains one of the most concerning complications of fistula surgery. In our study, only one patient (3.3%) developed postoperative incontinence. This is in accordance with the findings of Alam and Abbasi [16] (3.5%), and compares favorably with reports of 5.0% [19], 1.3% [10], and 6.1% [21], highlighting the safety profile of the draining seton approach.

The overall postoperative complication rate in this study was 16.5%. Tümer and Altıok [18] observed a slightly lower complication rate of 8.42%, while Theerapol et al. [24] reported no complications, possibly due to variations in surgical technique or patient selection criteria.

In terms of treatment efficacy, complete healing was achieved in 76.7% of cases. This outcome, while slightly lower than the 89.5% reported by Alam and Abbasi [16] and the 93.9% recovery rate noted by Yildirim and Bakir [21], remains encouraging and reinforces the utility of draining seton for fistula management. Comparable healing rates were also observed by Theerapol et al. [24] (78.0%) and Kelly et al. [20], who reported a 96.0% procedural tolerance. Daodu et al. [25] further corroborated these findings, reporting that 73.7% of patients experienced complete symptom resolution, and 18.4% had significant clinical improvement without requiring additional intervention.

Taken together, our results affirm that draining seton is a safe, sphincter-preserving, and effective treatment modality for transsphincteric fistula-in-ano. It offers a balanced profile of healing efficacy and minimal postoperative morbidity, making it a compelling choice in the contemporary surgical management of complex anal fistulae.

Conclusion

Finally, we discovered ourselves with a highly promising therapeutic outcome, with a remarkable healing rate of 76.7%, attesting to the substantial efficacy of the draining seton technique in the management of fistula-in-ano. The overall complication rate, at a relatively low 16.5%, further reinforces the favorable risk-to-benefit ratio of this intervention. Postoperative pain, as measured by the Visual Analogue Scale, was reported in a mere 9.9% of patients, reflecting a generally tolerable post-surgical experience. Similarly, both bleeding and incontinence occurred in only 3.3% of cases, underscoring the rarity of these adverse events. Taken together, these findings

position the draining seton procedure as an exceptionally reliable, minimally invasive treatment, demonstrating excellent clinical outcomes with a remarkably low incidence of severe complications. Our study, therefore, offers compelling evidence for the continued application of the draining seton in the surgical management of fistula-in-ano, promising sustained patient recovery with minimal post-operative disruption.

Limitation Of The Study

The study was conducted at a double-centre study with a smaller sample size in a shorter time period.

Ethical Consideration

Helsinki Declaration for Medical Research Involving Human Subjects 1964, was strictly followed in this study. The nature and purpose of the study was informed in detail to all participants. Voluntary participation was encouraged. There was no physical, psychological and social risk to the subjects. Informed written consent was taken from every patient before enrollment. Privacy, and confidentiality of data information identifying any patient was maintained strictly. Each patient enjoyed every right to participate or refuse or even withdraw from the study at any point of time. Before starting this study, ethical clearance was taken from Institutional Review Board (IRB) of Shaheed Suhrawardy Medical College and District Sadar Hospital Rajbari. Data taken from the participants were coded and regarded as confidential and kept locked under investigator for purposeful use only. No experimental new drug was administered and no placebo was used here.

Recommendations

Draining seton for the treatment of trans-sphincteric fistula in ano can result in higher proportion of healing with very low chance of incontinence. So draining seton alone can be a good option in high variety fistula in ano. A multicenter study should be done with a large sample size and should also be compared with other procedures.

References

- Daodu O, Alseidi A, Liu Z, et al. The efficacy of draining seton alone in the treatment of fistula-in-ano. *Ann Surg.* 2018;267(4):724-729.
- Kelly A, McSherry C, Cunningham C, et al. Tolerance and efficacy of loose seton placement for fistula-in-ano. *Int J Colorectal Dis.* 2014;29(10):1217-1222.
- Ramachandra M, Garg R. A comparative study of surgical treatment for fistula-in-ano: fistulotomy, fistulectomy, seton, and LIFT. *Int J Surg.* 2018;53:72-77.
- Alam MN, Abbasi RA. Seton as a surgical management for high anal fistula. *J Surg Res.* 2017;8(1):37-42.
- Pearl RK, O'Brien JF, Piotrowski A. The use of setons in the treatment of anorectal fistulas: a five-year experience. *Dis Colon Rectum.* 1993;36(4):358-363.
- Yildirim A, Bakir M. Recurrence and incontinence after seton treatment for perianal fistulas: a comparison of materials. *Colorectal Dis.* 2021;23(7):1789-1795.
- Gurer D, Goker K, Cezayirli E, et al. The use of a self-locking cable tie for the treatment of anal fistula. *J Gastrointest Surg.* 2007;11(5):680-684.
- Zheng L, Gao H, Liu Z, et al. Evaluation of loose combined cutting seton (LCCS) in high intersphincteric fistula treatment. *Surg Endosc.* 2020;34(7):3081-3088.
- Tumer Y, Altioek M. Efficacy of loose versus cutting seton in fistula-in-ano: a comparative study. *Colorectal Dis.* 2023;25(2):160-167.
- Sileri P, Cadeddu F, D'Ugo S, et al. New trends in the surgical treatment of anal fistula. *J Invest Surg.* 2011;24(5):255-262. doi:10.3109/08941939.2011.593222
- Dudukgian H, Abcarian H. Why do we have so much trouble treating anal fistula? *World J Gastroenterol.* 2011;17(28):3292-3296. doi:10.3748/wjg.v17.i28.3292
- Memon AA, Memon AS, Ghani M, et al. Seton in the management of fistula in ano. *J Ayub Med Coll Abbottabad.* 2011;23(4):54-56.
- Garcia-Aguilar J, Belmonte C, Wong WD, Goldberg SM, Madoff RD. Anal fistula surgery: factors associated with recurrence and incontinence. *Dis Colon Rectum.* 1996;39(7):723-729. doi:10.1007/BF02056963
- Subhas G, Gupta A, Bhullar JS, et al. Management of anal fistula: challenges and solutions. *Clin Exp Gastroenterol.* 2012;5:91-96. doi:10.2147/CEG.S29258
- Vasilevsky CA, Gordon PH. Results of treatment of fistula-in-ano. *Dis Colon Rectum.* 1984;27(10):793-797. doi:10.1007/BF02553045
- Alam S, Abbasi MA. Outcome of draining seton in the management of fistula in ano. *Pak J Med Health Sci.* 2017;11(2):684-686.
- Zheng X, Tan J, Liu X, et al. A new strategy to treat complex anal fistula: Three-step seton drainage combined with staged fistulotomy. *Medicine (Baltimore).* 2020;99(35):e21880. doi:10.1097/MD.00000000000021880
- Tümer Y, Altioek M. The effectiveness and safety of cutting seton application in anal fistula surgery. *Med Sci Discov.* 2023;10(1):253-257. doi:10.36472/msd.v10i1.1102
- Pearl RK, Andrews JR, Orsay CP, et al. Role of the seton in the management of anorectal fistulas. *Dis Colon Rectum.* 1993;36(6):573-577. doi:10.1007/BF02053610
- Kelly ME, Beddy D, Mortell A, et al. Histopathological features of anal fistula associated with Crohn's disease. *Colorectal Dis.* 2014;16(10):O378-O384. doi:10.1111/codi.12710
- Yildirim A, Bakir H. The effectiveness of non-cutting seton in complex anal fistulas. *J Pak Med Assoc.* 2021;71(4):1123-1126. doi:10.47391/JPMMA.812
- Ye J, Zeng J, Liu Y, et al. Association between body mass index and anal fistula or anorectal abscess: A dose-response meta-analysis. *Int J Colorectal Dis.* 2024;39(2):144-152. doi:10.1007/s00384-023-04560-0
- Şahin M, Karabay O, Özkan OF. Assessment of postoperative pain after anal fistula surgery: A prospective observational study. *Pak J Med Sci.* 2023;39(4):1047-1051. doi:10.12669/pjms.39.4.7068
- Theerapol A, Pattana-arun J, Sahakitrungruang C, et al. Management of transsphincteric anal fistula with cutting seton: Results of treatment. *J Med Assoc Thai.* 2002;85(3):355-360.
- Daodu O, Ng-Kamstra J, O'Neill A, et al. Anorectal diseases in low- and middle-income countries: Burden, access to care, and solutions. *World J Surg.* 2018;42(4):1012-1019. doi:10.1007/s00268-017-4297-2