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ORIGINAL RESEARCH

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Evaluation surgical strategies in perianal fistulas treatment: Efficacy draining seton compared to other surgical approaches; a case-control study

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Abstract

Background and Aims: Perianal fistula is a prevalent anorectal condition originating from an infectious crypt extending to the external opening. Multiple surgical methods exist for treating perianal fistulas; however, selecting the appropriate options is still controversial. Our study aims to evaluate seton replacement versus other surgical methods in treating perianal fistula.

Methods: This study recruited 72 patients presenting with perianal discharge and diagnosed with perianal fistula through intra-sphincteric, trans-sphincteric, and supra-sphincteric examinations at Imam Reza and Besat Hospitals from July 2022 up to March 2023. Regarding case-control design, patients were divided into two groups: the first group ($n = 36$) underwent seton insertion, while the control group ($n = 36$) received alternative surgical methods. Follow-up was conducted for 1 month post-discharge, with monthly visits for 6 months. Patients were evaluated for fistula tract healing, seton loosening, and daily secretion rate (based on infected pads) during each visit. Finally, the two groups were compared in terms of improvement rates.

Results: In the seton group, approximately 94.4% of patients showed improvement. However, the difference between the groups was insignificant ($p = 0.494$). Seton replacement was performed in 52% of patients, with the majority requiring replacement twice (61%). Improvement rates were highest among cases with two seton replacements, although the difference was not statistically significant ($p = 0.073$). Following seton replacement, the most common treatment methods were endoanal flap and fistulotomy, with observed improvement in 10 cases for each procedure.

Conclusion: This study highlights that draining seton remains a primary choice for intermediate treatment due to its satisfactory improvement rate and lower requirement for replacement, especially up to two times.

KEYWORDS

perianal fistula, perianal fistula treatment, seton replacement

1 | INTRODUCTION

Perianal fistula is a disabling clinical condition characterized by localized pain and inflammation correlated with purulent discharge, negatively affecting the quality of life.[1] The disease usually develops between the ages of 20 and 50 years.[2] The incidence of fistula after perianal abscess surgery was reported as 45.58%, with a higher prevalence rate in males and the young population.[3,4] Moreover, perianal fistula could occur in 20%–50% of Crohn's disease (CD) patients.[5,6] In addition, cryptoglandular theory can be considered one of the explanations for perianal fistula etiology.[7] Besides, like several diseases, it is imperative to recognize that other risk factors, including a history of smoking and alcohol consumption, high salt intake, diabetes, and metabolic disorders, can contribute to developing this disease.[8–11]

A perianal fistula usually arises from an infection adjacent to the anus. This results in stocking puss in surrounding tissues, eventually creating a tunnel covered in granulomatosis tissue between the rectum and the anus.[12] This condition is categorized into four groups based on Park classification: (I) inter-sphincteric, (II) trans-sphincteric, (III) supra-sphincteric, and (IV) extra-sphincteric.[12] Newly, another assortment according to the dentate line is utilized for preanal fistula classification: (I) low fistula develops in the below dentate line, and (II) high fistula originates from the above dentate line.[2] The most severe complications following preanal fistula include fecal incontinence, recurrence of infection or sepsis, psychological problems such as anxiety and depression, restrictions on sexual activity, reduced pregnancy, and limited employment opportunities.[13]

Various techniques have been developed to reduce fecal incontinence in fistula subjects, including fistulotomy, fistulectomy, seton insertion (cutting and draining), endoanal flap, ligation of intersphincteric fistula tract (LIFT), expanded adipose-derived stem cells (ASC), fistula laser closure (FiLaC), video-assisted anal fistula treatment (VAAFT), and glue injection.[2,14] Seton insertion is a traditional technique of treating perianal fistulas, particularly in high-grade fistula, serving as an intermediate step to prepare the fistula for other therapeutic options by multiple mechanisms such as draining the pus and controlling sepsis, stimulating fibrosis and advancing slow transaction of the external sphincter muscle.[14] Seton method is divided into short-term and long-term based on the duration. Short-term is applied for 1–2 weeks before definitive treatment choice when the perianal abscess is connected to the inside of the anus, while in the long-term type, the seton is used for at least more than 1–2 months. However, it may be necessary to replace the seton frequently if the patient's condition does not allow for other procedures. Besides, the seton technique is a more effective alternative than a single-stage fistulotomy in preserving functionality through the slow division of the sphincter muscles along with the low risk of developing incontinence.[2,14] Moreover, based on the Motamedi et al.[15] investigation, long-term seton management was a practical option in CD patients due to proper healing and recurrence rates. Additionally, CD patients under regular follow-up with symptomatic anal fistula can benefit from ambulatory exploration of the anal canal and rectum (outpatient exploration) to reduce waiting times for surgical exploration.[16] It is important to note that this approach was reported to be valuable during the COVID-19 pandemic, in which all vulnerable groups and patients with comorbidities shall be taken into consideration.[16,17]

Due to inadequate anal sphincter protection by cutting seton, drainage seton (loose seton) was proposed as a primary improvement method. To prevent abscess formation, loose seton continuously drains the fistula via medical thread, rubber band, and other materials. Additionally, the loose seton application is recommended as the gold standard for complex fistulas.[18] Of note, the correct choice of seton material is necessary to ensure a high chance of recovery and maintain quality of life.[19] Considering the prevalence of perianal fistula among military people and the lack of access to advanced surgical services in border areas, in this study, we aimed to examine seton placement in these patients referred to military medical sciences hospitals (Imam Reza and Besat hospitals) and evaluate the need for other treatment methods.

2 | MATERIALS AND METHODS

A case-control design study was conducted to investigate the outcomes of different treatment methods in patients with perianal fistula. The study included a total of 72 patients who presented with complaints of perianal secretion and were diagnosed with intra-sphincteric, trans-sphincteric, or supra-sphincteric perianal fistula based on examinations conducted at Imam Reza and Besat Hospitals from July 2022 up to March 2023. The inclusion criteria are based on patients who are above 16 years of age at the time of study enrollment. Additionally, patients with extra-sphincteric fistulas, those who had previously undergone fistulotomy due to superficial fistula depth, individuals with perianal fistula associated with inflammatory bowel disease, underlying diseases, or cancer in the perianal region, and those with a history of seton placement were excluded from the study.

The enrolled patients were divided into two groups: the case group (36 patients treated with seton insertion) and the control group (36 patients treated with other methods). All patients were followed up for 1 month after discharge, and subsequent monthly outpatient visits were scheduled for a total follow-up period of 6 months after the surgical intervention. During each visit, the patients were assessed by two blinded surgeons for fistula tract improvement, loosening of the thread, and secretion rate (based on the number of infected pads used daily). Based on their progress, patients were categorized into three groups: (1) those who showed significant improvement with seton insertion, suggesting the possibility of future treatment with a simple fistulotomy; (2) those who did not achieve complete resolution and required reinsertion of the seton; and (3) those who have deemed candidates for alternative treatment methods. Finally, the two groups were compared in terms of treatment outcomes.

2.1 | Definition(s)

"Improvement" is defined as disappeared or diminished discharge, disappeared tenderness, enhanced induration, and reduced perianal pain assessed by two blind surgeons.

2.2 | Ethical statements

We conducted this study in compliance with the principles of the Declaration of Helsinki. The study's protocol was reviewed and approved by the Institutional Review Board of AJA University of Medical Sciences (IR.AJAUMS.REC.1401.088). Written informed consent was obtained from the patients.

2.3 | Statistical analysis

Categorical variables were presented as frequencies and percentages. The Student *t*-test was used to compare the continuous variables between study groups after ensuring the variables were normally distributed. Data analyses were performed using SPSS version 23.0 (IBM) software. A *p*-value less than 0.05 was considered statistically significant for all tests.

3 | RESULTS

The study involved 72 patients with perianal fistula. Of these, 36 patients underwent treatment with seton, while the remaining 36 patients received other surgical methods (control group). The average age of the patients was 46 ± 13.6 years, with an average age of 53 ± 14.6 years for those treated with seton and 43 ± 12.3 years for the control group. The mean age differed significantly between the two groups ($p = 0.003$). Additional patient information for each group is presented in Table 1. Our results showed a significant difference in the primary track between the two groups ($p = 0.027$). Seton-treated patients had a higher rate of improvement in trans-sphincteric fistulae compared to the control group.

Moreover, our findings depicted a significant difference in the surgery rates between the two groups ($p < 0.001$). A lower surgery rate was observed in patients who had been treated with seton compared to the control group. According to Figure 1, fistulotomy (alone) and fistulectomy after seton removal were more common among patients treated with seton. Furthermore, Figure 2 demonstrates that fistulotomies, lifts and sphincteroplasty, fistulectomy, and flaps were the most frequently used treatment methods in the control group, respectively.

Table 2 shows an overall improvement in 67 patients (97%), with 34 patients (94.4%) improving in the seton group and 33 (91.6%) patients in the control group. However, the difference between the groups was not statistically significant ($p = 0.494$).

Regarding Table 3, among the cases in the seton group, seton replacement was performed in 52% of patients. Most replacements occurred twice (61%), and the most common treatment method after seton replacement was endo-anal flap and fistulotomy. Improvement was observed with all treatment methods used after the replacement. Specifically, ten cases improved with the flap method, ten with the fistulotomy method, seven with the fistulectomy method, and one with the sphincteroplasty option.

A total of 22 cases (100% success rate) improved after two times seton replacement, nine patients (90%) improved after three times, and three (75%) improved after four times, as shown in Table 4. The optimum improvement rate for seton's replacement was more than two

TABLE 1 Baseline characteristics of all participants.

Baseline characteristics	Case ($n = 36$)	Control ($n = 36$)	*p*-value*
Primary track, *n* (%)			0.027
Inter	24 (66.7%)	16 (44.4%)	
Superficial	2 (5.6%)	0 (0%)	
Supra	0 (0%)	1 (2.8%)	
Trans	10 (27.8%)	19 (52.8%)	
Internal opening level, *n* (%)			0.666
Below	5 (13.9%)	7 (19.4%)	
At	22 (61.1%)	22 (61.1%)	
Inside fissure bed	0 (0%)	1 (2.8%)	
Above	9 (25%)	6 (16.7%)	
Number of external openings, *n* (%)			0.865
0	1 (2.8%)	1 (2.8%)	
1	31 (86.1%)	29 (80.6%)	
2	4 (11.1%)	5 (13.9%)	
3	0 (0%)	1 (2.8%)	
Horseshoeing, *n* (%)			0.07
Infra-levator	2 (22.2%)	5 (83.3%)	
Inter-sphincteric	6 (66.7%)	1 (16.7%)	
Supra-levator	1 (11.1%)	0 (0%)	
Concomitant abscess, *n* (%)			0.987
None	31 (93.9%)	28 (93.3%)	
Infra-levator	1 (93.3%)	1 (3.3%)	
Inter-sphincteric	1 (3%)	1 (3.3%)	
Other anal conditions, *n* (%)			0.987
Fissure	7 (77.8%)	8 (100%)	
Heamorrohids	1 (11.1%)	0 (0%)	
Submocusal mass	1 (11.1%)	0 (0%)	

*$p < 0.05$ was considered significant.

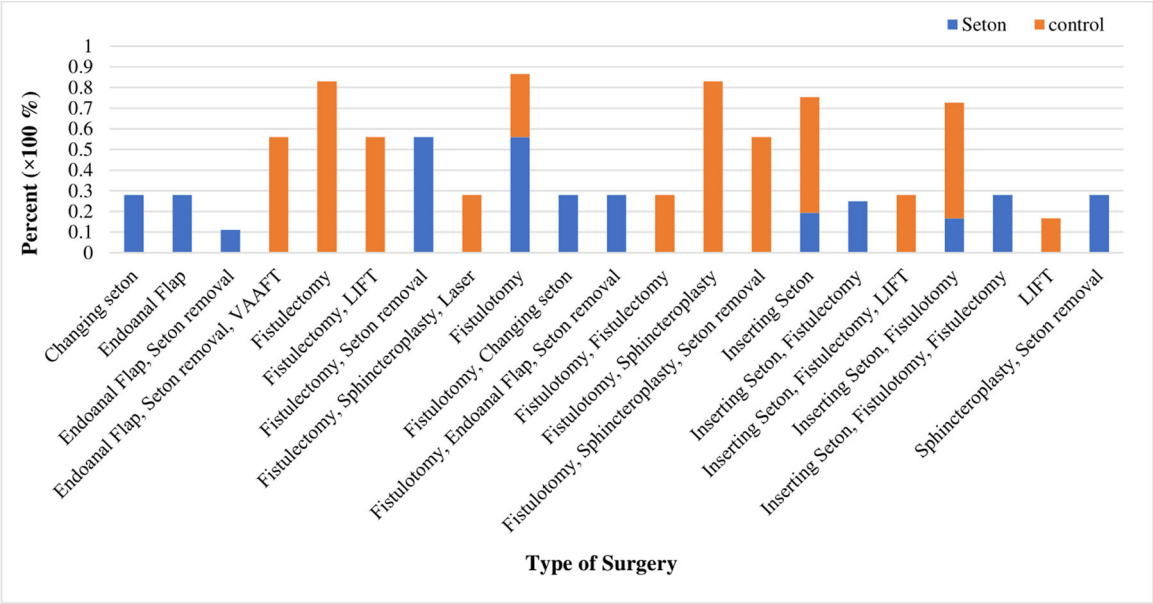

FIGURE 1 A comparison of the frequency of each type of surgery used in the case and control groups.

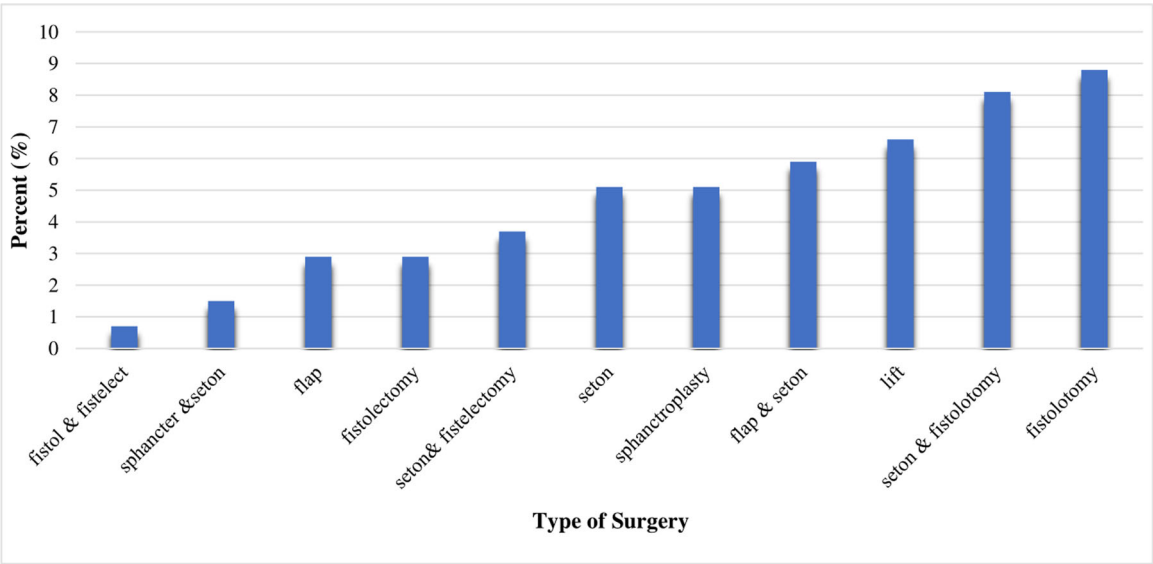

FIGURE 2 The rate of using other standard surgical methods in patients with perianal fistula in our study.

times, although the difference was not statistically significant ($p = 0.073$). A total of seven cases were enhanced by the endoanal flap method, six by fistulectomy and fistulotomy, and one by sphincteroplasty when compared to the two-time seton replacement surgery.

4 | DISCUSSION

Perianal fistula is one of the most common anorectal diseases with a high correlation with CD.[4] Like many other diseases, perianal fistula can occur following several risk factors, such as smoking, alcohol use, high salt intake, and diabetes.[7–10] To reduce fecal incontinence in perianal fistula cases, seton insertion can be used as a conventional therapeutic option to prepare the fistula for other procedures. It has been found that CD patients with perianal fistula can considerably benefit from long-term management with seton.[15]

As a result of our study, 94.4% of patients in the seton group experienced an improvement in their fistula; however, no significant difference was recorded between the two groups. According to Rosen et al. investigation of 121 patients (80 men) suffering from intra-sphincteric fistula, 98% of patients achieved complete fistula resolving without fecal incontinence under cutting seton treatment.[20] Moreover, the study conducted by Kelly et al.[21] on 200 patients with perianal fistula (139 males, 61 females) under loose seton treatment

TABLE 2 The rate of improvement between the two groups.

Variables	Case (n = 36)	Control (n = 36)	p-value*
Improvement			0.494
No, n (%)	2 (5.6)	–	
Yes, n (%)	34 (94.4)	33 (100)	

*p < 0.05 was considered significant.

TABLE 3 Seton information in the case group (n = 36).

Variables	Number (%)
Seton replacement	
No	34 (47.9)
Yes	37 (52.1)
Number of seton replacement	
Two times	22 (61.1)
Three times	10 (27.8)
Four times	4 (11.1)
Treatment method after seton replacement	
Sphincteroplasty	1 (3.6)
Endo-anal flap	10 (35.7)
Fistulectomy	7 (25)
Fistulotomy	10 (35.7)

TABLE 4 The rate of improvement after seton replacement in the case group.

Variable	2 Times	3 Times	4 Times	p-value*
Improvement, n (%)				
No	–	1 (10)	1 (25)	0.073
Yes	22 (100)	9 (90)	3 (75)	

*p < 0.05 was considered significant.

demonstrated acceptable tolerability in 96% of subjects as well as a low recurrence rate, confirming our findings.[21] Our study's most common treatment option after seton's replacement was endo-anal flap fistulotomy, with a healing rate of ten patients in each method. Wright et al.[22] discovered a recovery rate of 50% with seton placement followed by a fistulotomy or rectal advancement flap in 53 patients who did not respond to LIFT.[22]

Despite developing different surgical techniques to treat perianal fistulas, it is still a major medical issue. Recently, some novel treatment methods for managing perianal fistula have been proposed, which rely on the surgeon's skills, experience, and the complexity of the fistula, all of which contribute to the success of these procedures.[23] Despite this, studies have revealed that they have disadvantages compared with traditional treatments, along with being less cost-effective.[24] However, these various techniques can be employed to treat high fistulas, cutting setons still playing an important role.[23] A seton drainage procedure may be the best option in cases of multiple previous surgeries, compared to other procedures, which are potentially challenging and complicate the patient's current situation. This method is advantageous as it allows the fistula to drain, thus preventing recurrent abscesses. Accordingly, Abdelnaby et al.[25] conducted a randomized trial to compare the efficacy and safety of the drained mucosal flap technique versus rerouting seton around the internal anal sphincter.[26] The findings indicated that two of 48 patients in the seton group and one of 49 in the flap group exhibited fecal incontinence. Also, two patients in the flap group and four in the seton group were unable to respond.[25] Of note, no significant difference was observed between cutting seton and the two-stage seton fistulotomy (TSSF) in the surgical management of high anal fistula.

The loose seton requires a second procedure in complicated perianal fistulas.[26,27] There is, however, a great deal of conflicting information in research reports. In a study by Daodu et al.,[28] a total of 76 patients with a mean age of 45 years and an average time to seton removal of 36.6 weeks were followed for a mean duration of 63 months. Only about 7% of patients met recurrences after seton removal. Notably, the recurrence rate and symptom resolution were not affected by the time of seton removal. Daodu et al.[28] detected that because draining setons are sphincter and function preserving, placement of draining setons alone is a potential treatment choice for symptomatic management of fistula-in-ano. As a result of the investigation by Shira et al.,[29] complete amelioration occurred in 97.6% of the 372 cases. In addition, flatus incontinence was reported in 15.6% of patients, and fistula recurred in 2.4% of patients. Likewise, Subaşı et al.[30] evaluated a total of 42 patients (15 females, 27 males, mean age 43 years) with a primary or recurrent perianal fistula who underwent a partial fistulectomy with loose seton placement in a 10-month follow-up period. Interestingly, none of the patients displayed fecal incontinence symptoms during the follow-up period. Fistula relapse was also observed in only two patients (4.8%).[30] According to Zhi et al.,[31] 22 subjects (18 males, four females) were examined for a mean of 3.65 years after receiving loosely combined cutting seton (LCCS). All patients were cured, and there were no recurrences during the follow-up period, highlighting the effectiveness, safety, and reliability of LCCS in treating patients with high anal fistulas.[31] Omar et al.[32] implemented a prospective randomized controlled trial to compare the clinical outcomes between the separate drainage seton and drainage seton combined with fistula tract rerouting (EAS-sparing Seton after rerouting). The findings depicted no significant difference in relapse rate and complications between the two groups. However, the combined technique reduced postoperative healing time and the number of patients requiring secondary fistulotomy.[32] Patten et al.[33] carried out a study to peruse the long-term impact of cutting seton in treating high cryptoglandular fistulae. Based on the results, primary and

secondary recovery rates were 93% and 98%, respectively. There were 78% of patients with normal continence or minor incontinence, 13.5% with moderate incontinence, and 8.5% with severe incontinence. It was noted that women had disproportionately more incontinence than men.[33]

We discovered that endo-anal flap and fistulotomy, followed by seton as secondary treatment methods, positively enhanced the improvement rate. However, study results varied based on the severity of the patient's disease and the length of seton's placement. Incontinence, fistula recurrence, and lifestyle effects can also determine satisfaction with the technique.[34] We also detected that seton replacements were applied to 52% of patients. Most Seton replacements were performed twice (61%) in patients. Among different types of Seton replacements, the most dramatic improvement was observed in 22 cases (100%) after two sets of Seton replacements. However, the difference was not statistically significant. The finding has yet to be discussed in any study, or reports are few, so our study is unique in this aspect.

In summary, the study design, inclusion criteria, and short follow-up may have contributed to no statistically significant results. Our findings, however, are consistent with previous investigations.[12,20,32] It is imperative to conduct clinical trials and cohort studies with larger sample sizes, long-term follow-up, and proper subjective and objective evaluation methods to assess optimal procedures for patients suffering from perianal fistulas. Moreover, a previous history of comorbidities and complications, as well as an effective preoperative evaluation, are necessary to diagnose the type of fistula accurately and choose the most appropriate method. Furthermore, improvements in technology and surgical methods should be focused on developing and discovering effective procedures to achieve better results with lower recurrence rates.

5 | CONCLUSION

This study's findings suggest that draining seton as an interim treatment is a favorable approach, as it demonstrated a satisfactory rate of improvement with a relatively low need for replacement, especially up to two times. Moreover, secondary treatment methods such as endo-anal flap and fistulotomy, when combined with seton, showed promising effects on the rate of improvement. However, it is important to note that further comparative studies with larger sample sizes are necessary to obtain more precise and conclusive results.

AUTHOR CONTRIBUTIONS

Amir Ghasemlouei: conceptualization; investigation; validation; visualization; writing—original draft; writing—review and editing. **Amirhosein Naseri**: conceptualization; methodology; project administration; supervision; validation. **Ali Ashjaei**: data curation; validation; writing—review and editing. **Shahryar Sadeghi**: supervision; validation; writing—review and editing. **Amir Keshvari**: data curation; investigation; validation; writing—review and editing.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data underlying this article will be shared on a reasonable request to the corresponding author.

ETHICS STATEMENT

In accordance with our hospital's routine, all patients provided written informed consent upon admission, granting permission for their clinical data to be used anonymously for research purposes. The Institutional Review Board of AJA University of Medical Sciences approved the study protocol (IR.AJAUMS.REC.1401.088). This study conforms to the ethical principles outlined in the Declaration of Helsinki and its updates.

TRANSPARENCY STATEMENT

The lead author Amirhosein Naseri affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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