https://doi.org/10.33878/2073-7556-2024-23-4-94-100

Loose seton in the treatment of transsphincteric anal fistulas complicated by additional fistula tracks (randomized trial)

Alexander G. Khitaryan[1,2], Albert Z. Alibekov[1,2], Anastasia A. Golovina[1], Suleiman A. Adizov[1], Xenia S. Oplimakh[2]

[1]Clinical Hospital "RZD-Medicine" (Varfolomeeva st., 92a, Rostov-on-Don, 344011, Russia)
[2]Rostov State Medical University (Nakhichevan Lane, 29, Rostov-on-Don, 344022, Russia)

ABSTRACT *AIM: to evaluate caudal migration of free seton in patients with anal fistulas complicated by additional fistula tracks.*

PATIENTS AND METHODS: the prospective randomized single-center study included 115 patients with transshincteric fistulas, who had one of 2 types of seton installed. The decision to choose a seton was made by randomization in 2 groups: 63 patients with a polyester braided ribbon with a fluoropolymer coating 3 mm wide (Polyester-F Braid 3 mm, "Balumed" LLC, Russian Federation) seton "T", and the 2nd group included 52 patients with a seton polyester braided ribbon with a fluoropolymer coating with a diameter of 0.5 mm of USP conditional number 2 with a diameter of 0.5 mm was installed (Polyester-F Thread USP 2 with a diameter of 0.5 mm, "Balumed" LLC, Russian Federation) — seton "N".

RESULTS: after 12 weeks the largest number of complete caudal migration occurred in 30/63 (47.6%; 95% CI: 34.9–60.6) patients with seton "T", whereas in patients with seton "N" it occurred significantly less often in 7/52 (13.5%; 95% CI: 5.6–25.8) patients (p = 0.0002). Caudal seton migration with sphincter involvement of more than 1/2 was noted only in 1 patient with seton "T", and was completely absent in patients with seton "N".

CONCLUSION: in patients with a fistulas involving less than 1/2 of the external sphincter, it is reasonable to use a 3 mm wide fluoropolymer-coated polyester braided band as a seton, expecting caudal migration in almost half of the cases. Whereas the installation of a 0.5-mm diameter fluoropolymer-coated polyester braided thread, when more than 1/2 of the external sphincter is involved, does not lead to caudal migration.

KEYWORDS: *rectal fistula, loose seton*

CONFLICT OF INTEREST: *the authors declare no conflict of interest*

FOR CITATION: Khitaryan A.G., Alibekov A.Z., Golovina A.A., Adizov S.A., Oplimakh K.S. Loose seton in the treatment of transsphincteric anal fistulas complicated by additional fistula tracks (randomized trial). *Koloproktologia*. 2024;23(4):94–100. (in Russ.). https://doi.org/10.33878/2073-7556-2024-23-4-94-100

ADDRESS FOR CORRESPONDENCE: *Alibekov A.Z., Rostov State Medical University, Nakhichevan Lane, 29, Rostov-on-Don, 344022, Russia; e-mail:albert_alibekov@list.ru*

Received — 22.07.2024 *Revised — 09.09.2024* *Accepted for publication — 01.11.2024*

INTRODUCTION

Treatment of anal fistulas has been one of the most common problems of anorectal surgery for many years.

At the same time, up to 95% of all anal fistulas are cryptoglandular in nature, and in more than 70% of cases they are formed as a result of acute abscess [1,2]. Anal fistula is not a life-threatening condition, but significantly affects the quality of life of patients with negative influence on social, intimate and labor components [3].

Over time and the accumulation of experience in the treatment of fistulas, 2 issues turned out to be fundamental: the prevention of recurrences, and the preservation of continence. In place of the classic excision of the fistula with suturing the sphincter, there are many minimally invasive methods of treatment. The use of such techniques has led to minimizing the development of incontinence; however, there is an increase in recurrences. The use of free seton, as the first stage of treatment, increases the effectiveness of such minimally invasive technologies as FiLaC, LIFT, VAAFT, etc. Moreover, in certain cases, when the fistula passage affects less than 1/3 of the

external sphincter, the use of free seton as an independent method leads to a complete cure.

There are two main types of seton in the literature: crossing, *cutting seton* (in Latin *"seta"* means a thread)), the roots of which go back to the time of Hippocrates, and the *loose seton*, first proposed in the 70s of the XX century by Parks and Stitz [4,10].

The essence of the is to conduct it through the fistula track with tight tightening of the thread, which leads to "cutting" of the anal sphincter, migration of the course distally and the development of fibrosis in the area of the crossed muscle. Thus, Hippocrates also described the method of using a seton made of linen thread wrapped in horsehair for this purpose [5]. One of the seton options is a silk thread soaked in *Achyranthes aspera* extract, traditionally used in Indian Ayurvedic medicine.

In the late 70s of the XX century, the use of latex seton was proposed [6]. However, the unsatisfactory results of cutting setons including severe pain and anal incontinence [7,8,9,11] led to the search for new variants of the seton.

Data on the effectiveness and disadvantages of free setons are few in the available literature and often contradictory. In particular, there are some interesting studies which described the course of the disease after the installation of a drainage seton for fistulas with perianal additional cavities. In such cases, the use of minimally invasive methods seems impractical, and surgery is restricted to opening and drainage of these cavities. The insertion of a free seton is of a draining nature, and can be used as an independent method of treating fistulas, due to complete subcutaneous submucosal migration, in which the caudal displacement of the seton completely extends beyond the sphincter. Such treatment makes it possible to perform a radical fistulectomy with minimal risk of anal incontinence [12–15].

Many questions on the use of free setons remain debatable, and clearly formulated algorithms and recommendations for using this approach are missing, which requires further analysis and comparative studies.

In connection with the above data and the assumption that there are significant differences in the incidence of caudal migrations in patients with anal fistulas with varying sphincter involvement when using free setons of different types, within the framework of this randomized study, we tested the hypothesis of superiority among free setons of 2 types in the indicated clinical conditions.

THE AIM OF THE STUDY

The aim of the study was to compare caudal migration of free seton in patients with anal fistulas complicated by additional fistula tracks.

PATIENTS AND METHODS

The prospective randomized study (January 2022 — February 2024) included 115 patients with anal fistulas and perianal tracks, in whom internal and external openings were identified intraoperatively.

The inclusion criteria were transsphincteric anal fistula, involving subcutaneous, superficial or deep portions of the external sphincter, with external and internal openings, and perianal additional tracks.

The non-inclusion criteria were: inflammatory bowel diseases, colorectal tumors, severe comorbidities, including diabetes mellitus.

The surgical procedure was performed in the operating room, in lithotomy position, under intravenous sedation. The opening of perianal tracks was performed with ultrasound navigation. If necessary, additional incisions were performed with the installation of draining latex. Randomization was performed by random number generator, a decision was made to install one of 2 types of setons, which were carried out through the external and internal fistula openings, into the anal canal lumen, the free ends of the seton were fixed externally without tension.

The patients were divided into 2 groups: 63 patients had a polyester braided ribbon with a

Table 1. *Distribution of patients*

Indicators	Seton "T" N = 63	Seton "H" N = 52	*p*-value
Gender, abs. *(%)* Male Female	 43 (68.3%) 20 (31.7%)	 36 (69.2%) 16 (30.8%)	0.929*
Age (years), *M (SD)*	54.5 (4.4)	56 (5.2)	0.717**
Disease duration (months), *Me (Q1; Q3)*	7 (5.5; 10.3)	8.5 (6.4; 11.2)	0.607***
Diabetes mellitus, abs. (%)	8 (12.7%)	6 (11.5%)	0.9^
Morbidobe sity, abs. (%)	10 (15.9%)	9 (17.3%)	0.964^
Autopsy of acute paraproctitis, abs. (%)	55 (87.3%)	43 (82.7%)	0.7^

*Note: abs. — absolute value of observations, "T" — seton "T" (polyester braided ribbon with fluoropolymer coating3 mm wide (Polyester-F Braid 3 mm, LLC "Balumed", RF), "H" — seton "H" (polyester braided thread with fluoropolymer coating 0.5 mm in diameter of the conditional number 2 according to USP with a diameter of 0.5 mm (Polyester Thread USP 2 with a diameter of 0.5 mm, Balumed LLC, Russia) * Pearson's χ^2 test; ** t-Student's test; *** U-Mann-Whitney's test; ^ Pearson's χ^2 test with Yates' correction*

fluoropolymer coating 3 mm wide (Polyester-F Braid 3 mm, LLC Balumed, RF) (seton "T") installed as a seton. Fifty-two patients had a polyester seton braided with a fluoropolymer coating 0.5 mm, conditional number 2 according to USP with a diameter of 0.5 mm (Polyester-F Thread USP 2 with a diameter of 0.5 mm, Balumed LLC, RF) (seton "H").

The mean age of patients in the "T" group was 54.5 (4.4) years, and in the "H" group — 56 (5.2) years. It should be noted that in the group of patients with the installed seton "T", 55 (87.3%) patients had a history of surgery for acute perianal abscess or its spontaneous opening, whereas in the group of patients with the installed seton "H", 43 (82.7%) patients had. Patients of both groups were comparable in gender, age, duration of the disease, comrobidities, as well as surgical history (Table 1).

In 2 weeks after surgery, all patients underwent 3D transanal ultrasound with an assessment of the sphincter involvement degree (SID) (Fig.1).

Based on the results of 3D ultrasound, patients, depending on SID, were divided into 3 groups: less than 1/3 of the external sphincter (group 1); more than 1/3, but less than 1/2 of the external sphincter (group 2); more than 1/2 of the external sphincter (group 3), which corresponded to the involvement of subcutaneous, superficial and deep portions of the external sphincter accordingly. The data obtained were considered the starting point for further study of the degree of caudal migration of the installed setons.

The overall design of the study is shown in Figure 2. The study was approved by the local Ethics Committee (Protocol No. 12 dated 07.12.2021).

Statistical Analysis

Statistical processing of the obtained data was performed on a personal computer using the Statistica 10.0 program (StatSoft Inc., USA).

The analysis of quantitative data for compliance with the normal distribution law was performed

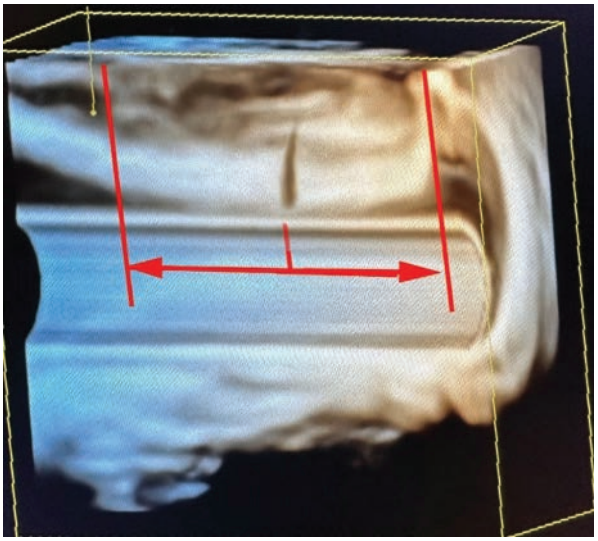

Figure 1. *3D ultrasound picture of a fistula involving more than 50% of the external sphincter*

Table 2. *Distribution of patients depending on the sphincter involvement and the type of seton installed 2 weeks after surgery*

Sphincter involvement degree (SID)	All patients N = 115		
	"T" (*n* = 63)	"H" (*n* = 52)	*p*
Group 1: SID < 1/3	14 (22.2%)	16 (30.8%)	0.4
Group 2: 1/3 < SID < 1/2	41 (65.1%)	27 (51.9%)	0.2
Group 3: SID > 1/2	8 (12.7%)	9 (17.3%)	0.7

Note: p is the significance level according to Pearson's χ2criterion with Yates's correction; "T" is the seton "T" (polyester braided ribbon with a fluoropolymer coating 3 mm wide (Polyester-F Braid 3 mm, LLC Balumed, RF), "H" is the seton "H" (polyester braided thread with a fluoropolymer coating with a diameter of 0.5 mm, conditional number 2 according to USP with a diameter of 0.5 mm (Polyester-F Thread USP 2 with a diameter of 0.5 mm, Balumed LLC, Russia)

Table 3. *Degree of caudal migration in both groups 12 weeks after surgery*

Sphincter involvement degree (SID)	Total patients N = 115		
	"T" (*n* = 63)	"H" (*n* = 52)	*p*
Subcutaneous-submucosal migration	30 (47.6%)	7 (13.5%)	**0.0002**
Group 1: < 1/3 SID	11 (17.5%)	16 (30.7%)	0.15
Group 2: 1/3 < SID < 1/2	15 (23.8%)	20 (38.5%)	0.14
Group 3: SID > 1/2	7 (11.1%)	9 (17.3%)	0.5

Note: p is the significance level according to Pearson's χ^2 test with Yates's correction; "T" is the seton "T" (polyester braided ribbon with a fluoropolymer coating 3 mm wide (Polyester-F Braid 3 mm, LLC Balumed, RF), "H" is the seton "H" (polyester braided thread with a fluoropolymer coating with a diameter of 0.5 mm of the conditional number 2 according to USP with a diameter of 0.5 mm (Polyester-F Thread USP 2 with a diameter of 0.5 mm, Balumed LLC, RF).

using the Lilliefors test. With a normal distribution of quantitative data, they were represented as M (SD), where M is the mean, SD is the standard deviation; when the normal distribution law does not match, they were represented as Me (Q1; Q3), where Me is the median, (Q1; Q3) are the lower and upper quartiles.

Depending on the type of distribution of quantitative indicators, Student's t-test or Mann-Whitney's U-test were used to compare the indicators of 2 independent samples. To compare the nominal characteristics, Pearson's χ^2-test and Pearson's χ^2-test with Yates' correction were used (with expected values < 5).

The 95% coincidence interval (95% CI) was calculated using Klopper-Pearson's method. The differences were considered statistically significant at $p < 0.05$.

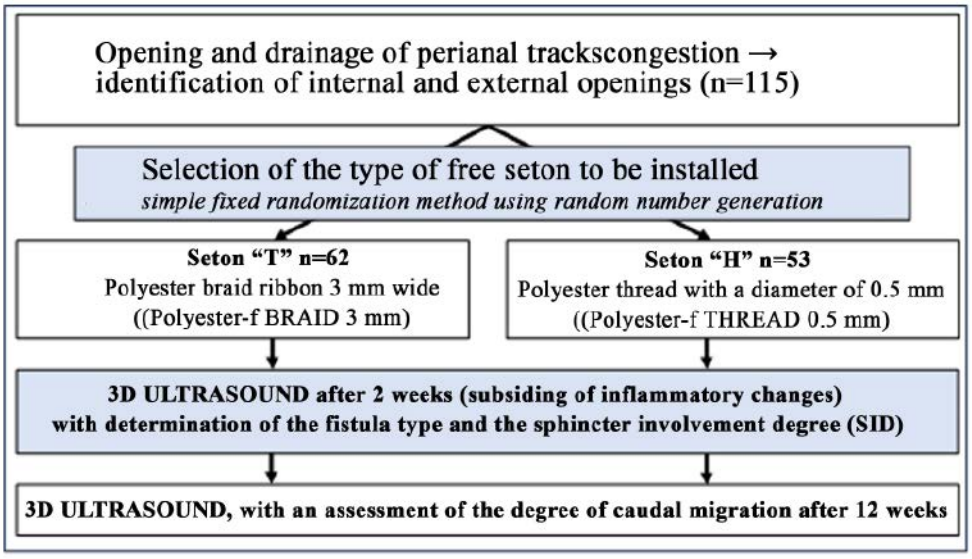

Figure 2. *Design of the study*

RESULTS

The results of the distribution of patients depending on the sphincter involvement by 3D ultrasound 2 weeks after surgery, are presented in Table 2.

As can be seen from the data presented in Table 2, the groups distinguished by the degree of involvement of the external sphincter (SID < 1/3, 1/3 < SID < 1/2, SID > 1/2) were comparable ($p > 0.05$). The obtained data were considered initial for the assessment of caudal migration of setons.

In 12 weeks after the setons were installed (Table 3), the largest number of complete caudal migration was revealed in patients with seton "T", whereas in patients with seton "H" this phenomenon was recorded significantly less frequently: 30 / 63 (47,6%; 95% DI: 34.9–60.6) vs. 7/52 (13.5%; 95% CI: 5.6–25.8) ($p = 0.0002$). Caudal seton migration with involvement of more than 1/2 of the external sphincter was noted only in 1 patient with seton "T" and was completely absent in patients with seton "H".

After 12 weeks, without expecting further significant caudal migration, the 2nd stage of treatment was performed. Thus, patients with complete subcutaneous submucosal migration and patients with involvement of less than 1/3 of the external sphincter underwent radical fistulectomy after 12 weeks without risk of anal incontinence. Patients with sphincter involvement of more than 1/3, but less than 1/2, underwent various minimally invasive techniques, in particular FiLaC, LIFT. In patients with involvement of the superficial and deep portions of the sphincter, traditional surgeries with fistula excision, anorectal advancement flap and sphincteroplasty were performed. The analysis of the results of the 2nd stage of treatment was not included in the objectives of this study. However, the data obtained are being processed and will be presented in subsequent publications.

DISCUSSION

Recently, the seton as office procedure, is experiencing a kind of renaissance, which also determines the active search for the optimal algorithm for using free seton [7,8]. However, there are no reliable data and recommendations on the use of the free seton. The issues of developing indications for the use of the seton method remain unclear, depending on the type of fistula and the involvement of the sphincter; the timing of seton; its physical and metric characteristics. It is extremely important and requires further study of the effectiveness of the seton method in preparation for sphincter-preserving procedures, and the impact of modern minimally invasive techniques.

In the present study, the effectiveness of two types of setons and the degree of their migration in two groups of patients were compared. These are patients who had a polyester braided ribbon with a fluoropolymer coating 3 mm wide (POLYESTER-F BRAID 3 mm, LLC BALUMED, RF) seton "T" as a seton, and patients who had a polyester thread with a fluoropolymer coating 0.5 mm in diameter, conditional number 2 according to USP (POLYESTER-F, USP 2 thread with a diameter of 0.5 mm, BALUMED LLC, Russia) — seton "N". As a result of the comparative analysis, it was revealed that the maximum caudal migration of the seton, which reached 47.6% (95% CI: 34.9–60.6), up to the formation of a subcutaneous or submucosal fistula, was noted in the presence of a fistula involving less than 1/3 of the external sphincter and a 3-mm wide polyester braid ribbon installed as a seton.

On the contrary, when using a polyester thread with a diameter of 0.5 mm as a seton and with more than 1/2 of the external sphincter involved, the effect of caudal migration was not observed in any case. However, it seems logical to predict greater effectiveness of obliterating techniques such as FiLaC and LIFT, due to the formation of a much thinner fistula, which, in our opinion, increases the effectiveness of minimally invasive and hybrid techniques.

CONCLUSIONS

1). The use of a 3-mm wide polyester braid ribbon in patients with less than 1/3 of the external sphincter involvement in transsphincteric fistulas leads to complete caudal subcutaneous submucosal migration in 47.6% of cases.

2). Polyester thread with a diameter of 0.5 mm is an inert material, when used, caudal migration is insignificant, and when more than 1/2 of the external sphincter is involved, there is no migration at all.

Thus, the data obtained made it possible to formulate practical recommendations.

1. With external sphincter involvement of over 1/2, it is advisable to install a polyester thread with a diameter of 0.5 mm as a seton, since in this case the phenomenon of caudal migration of the seton is not expected.

2. In the case of involvement of less than 1/3 of the external sphincter, with polyester braid ribbon installed, caudal migration is expected in almost half of cases, which will allow radical surgeries to be performed with minimal risk of anal incontinence.

AUTHORS CONTRIBUTION

Concept and design of the study: *Aleksandr G. Khitaryan, Albert Z. Alibekov*

Collection and processing of the material: *Albert Z. Alibekov, Anastasiya A. Golovina, Suleiman A. Adizov, Kseniya S. Oplimakh*

Statistical processing: *Albert Z. Alibekov, Kseniya S. Oplimakh*

Writing of the text: *Albert Z. Alibekov, Anastasiya A. Golovina, Suleiman A. Adizov, Kseniya S. Oplimakh*

Editing: *Aleksandr G. Khitaryan*

INFORMATION ABOUT THE AUTHORS

Aleksandr G. Khitaryan — 0000-0002-2108-2362

Albert Z. Alibekov — 0000-0003-4724-3774

Anastasiya A. Golovina — 0000-0001-5647-1192

Suleiman A. Adizov — 0000-0002-2173-2281

Kseniya S. Oplimakh — 0000-0001-5632-1469

REFERENCES

1. Kryvoruchko I.A., Firsyk T.M.. Modern Minimally Invasive Sphincter-Sparing Techniques of Surgical Treatment of Anal Fistulas. *Novosti Khirurgii*. 2020;28(5):565–576. (in Russ.). doi: 10.18484/2305-0047.2020.5.565

2. Alasari S, Kim NK. Overview of anal fistula and systematic review of ligation of the intersphincteric fistula tract (LIFT). *Tech Coloproctol*. 2014 Jan;18(1):13–22. doi: 10.1007/s10151-013-1050-7

3. Denisenko E.V., Gain Y.M., Denisenko V.L. Rectal fistulas: the current state of the problem. *Surgery. Eastern Europe*. 2022;11(4). (in Russ.).

4. Musin A.I., Antipova E.V., Ulyanov A.A., et al. Ligature in the treatment of rectal fistula: a modern view of the oldest method (literature review). *Bulletin of Surgery named after I.I.Grekov*. 2019;178(2):79–84. (in Russ.). doi: 10.24884/0042-4625-2019-178-2-79-84

5. Adams F. The Genuine Works of Hippocrates. N.-Y.: William Woods &Company. 1939;345–350.

6. Hanley PH. Rubber band seton in the management of abscess-anal fistula. *Ann Surg*. 1978;187:435–437.

7. Williams JG, Farrands PA, Williams AB, et al. The treatment of anal fistula: ACPGBI position statement. *Colorectal Dis*. 2007;9(4):8–50.

8. Patton V, Chen CM, Lubowski D. Long-term results of the cutting seton for high anal fistula. *ANZ J Surg*. 2015;85(10):720–727.

9. Ritchie RD, Sackier JM, Hodde JP. Incontinence rates after cutting seton treatment for anal fistula. *Colorectal Dis*. 2009;11(6):564–571.

10. Lim CH, Shin HK, Kang WH, et al. The use of a staged drainage seton for the treatment of anal fistulae or fistulous abscesse. *J Korean Soc Coloproctol*. 2012;28(6):309–314.

11. Emile SH, Elfeki H, Thabet W, et al. Predictive factors for recurrence of high transsphincteric anal fistula after placement of seton. *Journ Of Surgical Research*. 2017;213:261–268.

12. Subhas G, Gupta A, Balaraman S, et al. Non-cutting setons for progressive migration of complex fistula tracts: a new spin on an old technique. *Int J Colorectal Dis*. 2011;26(6):793–798.

13. Sungurtekin U, Ozban M, Erbis H, et al. Loose Seton: A Misnomer of Cutting Seton. *Surgical Science*. 2016;7:219–225.

14. Kelly ME, Heneghan HM, McDermott FD, et al. The role of loose seton in the management of anal fistula:

a multicenter study of 200 patients. *Tech Coloproctol*. 2014;18(10):915–919.
15. Khitaryan A.G., Alibekov A.Z., Kovalev S.A., et al. Multistage minimally invasive treatment for perianal abscess. *Koloproktologia*. 2020;19(2):83–90. (In Russ.). doi: 10.33878/2073-7556-2020-19-2-83-90