



# Lower Fistula Recurrence with Pulling Seton: A Retrospective Cohort Study

Ahmad Izadpanah<sup>1</sup>, Ali Reza Safarpour <sup>1,\*</sup>, Mohammad Rezazadehkermani <sup>1</sup>, Ali Zahedian<sup>1</sup> and Reza Barati-Boldaji<sup>2</sup>

<sup>1</sup>Colorectal Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

<sup>2</sup>Gastroenterohepatology Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

\*Corresponding author: Colorectal Research Center, Shiraz University of Medical Sciences, Shiraz, Iran. Email: safarpourar@gmail.com

Received 2021 August 26; Revised 2021 December 03; Accepted 2022 January 04.

## Abstract

**Background:** Anal fistulas are one of the interactable cases in proctologic clinics. Managing these patients has the major risk of recurrence and incontinence.

**Objectives:** In this retrospective cohort study, we compared the results of three sphincter saving procedures during a two-year follow-up phase.

**Methods:** A total of 87 patients who underwent endorectal advancement flap, cutting Seton, and pulling Seton surgeries were followed for two years from 2017 to 2018 in a tertiary proctologic referral center affiliated to Shiraz University of Medical Sciences, Iran. The recurrence rate and Wexner score were compared between the groups.

**Results:** The lowest recurrence rate was 13.8% with pulling Seton technique, and the highest recurrence rate was 42.9% with endorectal advancement flap ( $P = 0.04$ ). The mean Wexner score did not significantly change before and after the surgery.

**Conclusions:** According to our results, pulling Seton seems to be a safe method for treatment of anal fistulas. This technique had a low recurrence rate, and the patients' continence was not damaged.

**Keywords:** Rectal Fistula, Seton, Endorectal Flap, Fecal Incontinence, Recurrence

## 1. Background

Anal fistulas are common difficult patients in colorectal clinics with prevalence rate of 1.89 - 2.36 per 10000 in general population (1). The quality of life in fistula patients is reduced especially in recurrent cases (2). Recurrence and fecal incontinence are the most complicated consequence of fistula surgery. It is thought that using modalities like endosonography and magnetic resonance imaging (MRI) for tracking the course of fistula is associated with lower complication (3).

There are various types of operations for treatment of anal fistula, from simple fistulotomy to advanced operations, such as endorectal advancement flap. Setons are traditionally described as one of the conservative treatments of fistulas. Classically, they are categorized into two groups of cutting and draining Setons (4).

Cutting Setons are associated with some degree of fecal incontinence due to fast cutting of sphincter involved by tract and draining Seton might remain in place without opening the tract for months. In 2016, a novel method

was introduced by Izadpanah et al, which was a combination of methods named Pulling Seton. In this method, a loose Seton was inserted and tied loosely. After healing of the wound, the patient was requested to pull down the thread several times a day; as the patients reported, the recurrence rate was low (5).

Endorectal flaps for treatment of anal fistulas was introduced in 1912 by Elting. The technique is comprised of detecting internal orifice and closing it with a flap of rectal mucosa and excising external orifice with lateral tract. This method is a sphincter saving procedure, but still degrees of fecal incontinence are reported by patients (4).

## 2. Objectives

There is controversy in different studies regarding which method of fistula operation is the best or which method is appropriate for a specific group of patients. This study aimed to compare the recurrence rate of fistula in two Seton insertion techniques and endorectal flap in a tertiary colorectal referral center in Shiraz, Iran.

### 3. Methods

#### 3.1. Study Design and Patient Selection

After ethical committee approval (IR.SUMS.REC.1396.66), three groups of patients with a mean pulling Seton time of  $51.2 \pm 15.3$  days, who had undergone fistula surgeries in a tertiary colorectal surgery center, were followed for two years. All hospital records were available. The pulling Seton technique has been applied in our center since 2016; so, we have the capability of comparing different technique results. All patients signed a written informed consent allowing the researchers to have access to their chart data.

Patients with a mean interval of two years from the surgery and those with high type fistula needing fistula surgery were randomly selected to undergo one of the endorectal advancement flap, cutting Seton and pulling Seton surgeries, irrespective of their situation. Patients with inflammatory bowel disease, renal failure, diabetes mellitus, cancer, cirrhosis, and patients on corticosteroids were excluded from the study. For data collection, both questionnaire data and physician examination were used.

#### 3.2. Technique of Operation

For endorectal flap, the patients were operated by general or spinal anesthesia. All the patients were operated in a prone position; however, for Seton insertion, most of the patients were operated in lithotomy position.

After adequate preparation and draping of patient prophylaxis, antibiotic was administered by an anesthesiologist. Then, digital rectal examination combined with Anoscopy were used to detect possible tract and internal fistula orifice. For the precise detection of tract and internal orifice, a combination of hydrogen peroxide and methylene blue was injected into the external orifice. Free flow of blue dye or bubbles of oxygen were observed with simultaneous Anoscopy at the site of internal orifice. After localization of internal orifice, metallic probe was introduced via the external orifice and passed through the tract without pressure till the tip emerged at internal orifice, which was previously detected by dye injection.

For tight or cutting Seton after lateral fistulectomy till the level of external anal sphincter, elastic bands were passed through the tract, and skin over the tract opened with electrocautery. Then, it was tied with tension on the bulk of sphincter and tightened in further visits in the clinic.

As described previously (5), pulling Seton was inserted after incising the skin and soft tissue from lateral side and dividing internal orifice and internal anal sphincter medially, so that only external anal sphincter was in the tract. Nylon USP1 was passed throughout the tract and tied

loosely. The patient was asked to retract the Seton several times a day.

Endorectal mucosal flap was constructed in prone position. After detecting the internal orifice, flap was raised from just distal to the internal orifice to 3 - 4 centimeters proximal to the orifice with muscularis propria. A wide base flap was created carefully to have adequate perfusion to the tip of flap. After excising the internal orifice, it was closed tightly, and the closed orifice was covered with elevated flap using 3 - 0 vicryl interrupted sutures. The external orifice with the fistula tract was excised till the level of external anal sphincter and marsupialization was done.

#### 3.3. Statistical Analysis

Data analysis was performed using Stata (version 14). Categorical variables were reported as absolute (relative frequencies) and compared by  $\chi^2$  tests or Fisher's exact tests. Continuous variables were expressed as mean (SD) for normally distributed data and as median (interquartile range, IQR) for non-normal data. Comparison was done using the Kruskal-Wallis or chi squared tests. P-value less than 0.05 was considered as statistically significant.

### 4. Results

In this study, patients with a mean age of 39 years old were enrolled. The patients were operated by colorectal surgeons with a minimum experience of ten years in a tertiary colorectal referral hospital. The patients' distribution according to the type of surgery has been presented in [Table 1](#). There was no statistical difference between groups before follow-up. All the patients had complex high type fistulas. Patients with low type fistula who were treated with simple fistulotomy were not enrolled in the study. As shown in [Table 1](#), most of the patients had already been operated before this study and they had a recurrent disease. All the surgeries were done without complication, and none of the patients had major postoperative complications. After operation, the patients were followed for two years. During this period, none of the patients complained about major fecal incontinence. The overall recurrence rate was 31%. The highest recurrence was related to endorectal flap group (42.9%) and the lowest recurrence was related to pulling Seton method (13.8%). The recurrence rate was significantly lower in the pulling Seton group ( $P = 0.04$ ) ([Table 2](#)). The mean Wexner score before and after treatment was  $14.68 \pm 1.38$  and  $14.27 \pm 2.17$ , respectively, which was not statistically significant.

**Table 1.** Patients' Characteristic<sup>a</sup>

Characteristic	Total	Pulling Seton	Endo Flap	Tight Seton	P-Value
Number of Patients	87 (100)	29 (33.3)	28 (32.2)	30 (34.5)	-
Age (y)	39.34 ± 8.67	38.8 ± 10.20	40.40 ± 7.60	38.86 ± 8.22	0.99 <sup>b</sup>
Sex (male/ female)	61/26	21/ 8	18/10	22/ 8	0.713 <sup>c</sup>
External orifice-anal verge distance (mm)	4.10 ± 1.70	4.06 ± 1.96	4.42 ± 1.91	3.90 ± 1.21	0.55 <sup>b</sup>
Number of previous surgeries	1.72 ± 1.68	1.86 ± 2.37	1.66 ± 1.15	1.63 ± 1.21	0.86 <sup>b</sup>
Number of external orifices	1.12 ± 0.36	1.13 ± 0.44	1.14 ± 0.35	1.10 ± 0.30	0.90 <sup>b</sup>

<sup>a</sup> Values are expressed as mean ± SD or No. (%) unless otherwise indicated.

<sup>b</sup> The results of P value are from Kruskal-Wallis test.

<sup>c</sup> The results of P value are from chi-squared test.

**Table 2.** Recurrence After Two Years<sup>a</sup>

Primary Outcome	Total (N = 87),	Pulling Seton (N = 29)	Endo Flap (N = 28)	Tight Seton (N = 30)	P-Value
Recurrence of fistula (yes/no)	27/60 (31.0/69.0)	4/25 (13.8/86.2)	12/16 (42.9/57.1)	11/19 (36.7/ 63.3)	0.04 <sup>b</sup>

<sup>a</sup> Values are expressed as No. (%).

<sup>b</sup> Results of Kruskal-Wallis test. Mann Whitney test revealed significant differences between pulling Seton group and two other groups in the recurrence of fistula (0.01 and 0.04, respectively).

## 5. Discussion

This study showed the lower rate of fistula recurrence in the pulling Seton method, as a newly developed technique, compared to endorectal flap and tight Seton techniques. Setons are traditional treatments for fistulas, and the mechanism of action is based on the initiation of fibrosis around the tract that inhibits sphincter fibers separation while fistula tract migrates to the surface (4). Pulling Seton was introduced in 2016, which was based on the main mechanism of Setons and the addition of pulling the thread by patient in order to minimize sphincter muscle traumatization; in the primary report, it had the recurrence rate of 5%, and there was no major fecal incontinence. However, 3% of patients in the initial study experienced gas incontinence (5).

A previous meta-analysis study showed the risk factors of fistula recurrence and categorized it based on patients' factors, as well as anatomical and surgical factors. The significant patient factor in this study was history of previous anal surgery, and significant anatomical and surgical factors were high trans-sphincteric fistula, undetected internal opening, horse shoe extensions, Seton insertion, and multiple tract identification (6). In order to remove this bias, the history of previous surgeries, number of external orifices, and distance of external orifice from anal verge were compared between groups, which indicated no statistically significant difference. The preliminary study of pulling Seton showed the recurrence rate of 5% after two-to eight-year follow-up (5), which was much lower than the recurrence rate in this study. One of the explanations for

this issue may be the higher sample size and longer follow-up in the mentioned study.

In the tight Seton, we had the recurrence rate of 36.7%, which was much higher than other reports, such as 6.8% in Australia (7). All the recurrent cases in the Australian study were redo cases, and they had undergone previous endorectal flap. Another study from Thailand reported the recurrence rate of 20.6% during two years after surgery (8).

Regardless of overall high recurrence rate in this study, the recurrence rate with pulling Seton was much lower than other methods; this might be due to gradual migration of tract through the sphincter muscle, which allows adequate fibrosis and healing in the divided part of sphincter while draining the sepsis without obstructing the tract (5).

In our study, the patients' continence was not altered significantly after the surgery using any of the modalities, as was measured using Wexner's score. This is related to the sphincter saving procedures done for patients. However, even using loose draining Setons is associated with some degrees of incontinence in patients (9).

We also compared different sphincter saving procedures in the treatment of anal fistulas. Our results showed the lowest recurrence rate was related to pulling Seton technique, and the overall continence in patients did not change with our modalities.

### 5.1. Conclusions

It seems that pulling Seton is a safe method for the treatment of high type anal fistulas. In our study, the two-

year follow-up demonstrated low rate of recurrence without altering continence.

### Acknowledgments

The authors wish to thank the Vice Chancellor for Research, Shiraz University of Medical Sciences (SUMS).

### Footnotes

**Authors' Contribution:** Study concept and design: AR. S.; analysis and interpretation of data: A. I. and A.Z.; drafting of the manuscript: M. R. and R.BB.; critical revision of the manuscript for important intellectual content: AR.S.

**Conflict of Interests:** The authors declare no conflict of interest.

**Ethical Approval:** IR.SUMS.REC.1396.66.

**Funding/Support:** This study is supported by Vice Chancellor for Research, Shiraz University of Medical Sciences (SUMS).

**Informed Consent:** All patients signed a written informed consent prior to inclusion.

### References

1. Hokkanen SR, Boxall N, Khalid JM, Bennett D, Patel H. Prevalence of anal fistula in the United Kingdom. *World J Clin Cases*. 2019;7(14):1795–804. doi: [10.12998/wjcc.v7.i14.1795](https://doi.org/10.12998/wjcc.v7.i14.1795). [PubMed: [31417925](https://pubmed.ncbi.nlm.nih.gov/31417925/)]. [PubMed Central: [PMC6692258](https://pubmed.ncbi.nlm.nih.gov/PMC6692258/)].
2. Owen HA, Buchanan GN, Schizas A, Cohen R, Williams AB. Quality of life with anal fistula. *Ann R Coll Surg Engl*. 2016;98(5):334–8. doi: [10.1308/rcsann.2016.0136](https://doi.org/10.1308/rcsann.2016.0136). [PubMed: [27087327](https://pubmed.ncbi.nlm.nih.gov/27087327/)]. [PubMed Central: [PMC5227050](https://pubmed.ncbi.nlm.nih.gov/PMC5227050/)].
3. Poon CM, Ng DC, Ho-Yin MC, Li RS, Leong HT. Recurrence pattern of fistula-in-ano in a Chinese population. *J Gastrointest Liver Dis*. 2008;17(1):53–7. [PubMed: [18392245](https://pubmed.ncbi.nlm.nih.gov/18392245/)].
4. Sagar P, Hill AG, Knowles CH, Post S, Bemelman WA, Roberts PL, et al. *Keighley & Williams' Surgery of the Anus, Rectum and Colon*. 4th ed. Taylor & Francis; 2019.
5. Izadpanah A, Rezazadehkermani M, Hosseiniasl SM, Farghadin A, Ghahramani L, Bananzadeh A, et al. Pulling Seton: Combination of mechanisms. *Adv Biomed Res*. 2016;5:68. doi: [10.4103/2277-9175.180637](https://doi.org/10.4103/2277-9175.180637). [PubMed: [27169099](https://pubmed.ncbi.nlm.nih.gov/27169099/)]. [PubMed Central: [PMC4854033](https://pubmed.ncbi.nlm.nih.gov/PMC4854033/)].
6. Mei Z, Wang Q, Zhang Y, Liu P, Ge M, Du P, et al. Risk Factors for Recurrence after anal fistula surgery: A meta-analysis. *Int J Surg*. 2019;69:153–64. doi: [10.1016/j.ijvsu.2019.08.003](https://doi.org/10.1016/j.ijvsu.2019.08.003). [PubMed: [31400504](https://pubmed.ncbi.nlm.nih.gov/31400504/)].
7. Patton V, Chen CM, Lubowski D. Long-term results of the cutting seton for high anal fistula. *ANZ J Surg*. 2015;85(10):720–7. doi: [10.1111/ans.13156](https://doi.org/10.1111/ans.13156). [PubMed: [25997475](https://pubmed.ncbi.nlm.nih.gov/25997475/)].
8. Chadbunchachai W, Lohsiriwat V, Paonariang K. Long-term Outcomes After Anal Fistula Surgery: Results From Two University Hospitals in Thailand. *Ann Coloproctol*. 2021. doi: [10.3393/ac.2021.01.06](https://doi.org/10.3393/ac.2021.01.06). [PubMed: [34098630](https://pubmed.ncbi.nlm.nih.gov/34098630/)].
9. Zheng L, Shi Y, Zhi C, Yu Q, Li X, Wu S, et al. Loose combined cutting seton for patients with high intersphincteric fistula: a retrospective study. *Ann Transl Med*. 2020;8(19):1236. doi: [10.21037/atm-20-6123](https://doi.org/10.21037/atm-20-6123). [PubMed: [33178768](https://pubmed.ncbi.nlm.nih.gov/33178768/)]. [PubMed Central: [PMC7607110](https://pubmed.ncbi.nlm.nih.gov/PMC7607110/)].