

# Treatment of Fistula-in-Ano with Tight (Cutting) Seton: Analysis of Outcomes and Efficacy Assessment

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## ABSTRACT

**Introduction:** Management of fistula-in-ano is a surgical challenge. Various methods for the treatment of anal fistulas have a range of success rates and use of the cutting seton is still questionable.

**Aim:** The aim of this study was to assess the effectiveness and suitability of the tight (cutting) seton as a surgical treatment of anal fistula.

**Materials and Methods:** This was a prospective study of 68 patients (59 males and 9 females) with an anal fistula, mainly of high variety were treated with cutting seton over a 3 year period. Follow up for at least 12 months to record the duration of complete wound healing, fistula recurrence and incontinence

was done. Statistical analysis was performed using SPSS version 18.00. A  $p < 0.05$  was considered statistically significant.

**Results:** Complete healing was achieved in 55 patients within 3 months (success rate =80.9%). The treatment was failed in 13 (19.1%) patients. 9 (13.2%) patients have presented minor incontinence 6 (8.8%) with gas incontinence and 3 (4.4%) with liquid stool incontinence and there were no cases of solid stool incontinence. The recurrent fistula was noted in 2 (2.9%) patients during the follow up period.

**Conclusion:** Cutting seton yields fairly good results in regard to the cure of fistula with good continence in the majority, but the risk of failure or persistence fistula was relatively high so we recommend the routine use of cutting seton for all anal fistulas.

**Keywords:** Anal fistula, Recurrence, Surgery

## INTRODUCTION

Fistula-in-ano is one of the common surgical dilemmas with recorded incidence of 1.2 to 2.8/10,000 with prevalence in men higher than in women (2:1 male/female) [1]. An anal fistula is an abnormal track between the anal canal mucosa and the perianal skin. The usual history of this condition consists of an intermittent pain, itching, and discharge of pus, faeces or blood [2,3]. In the view of the relation of the primary fistula track to the external anal sphincter, Parks AG et al., classified the anal fistula into four major types, these are intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric [4]. This classification is an essential manual to the surgical arrangement.

The treatment of high fistula-in-ano exhibits a curative challenge [5]. Fistulotomy cannot be performed in such cases due to the danger of sphincter injury and consequent faecal incontinence [6]. The standards of anal fistula surgery are to obliterate the fistula, prevent recurrence and maintain sphincter work [7,8]. Many alternative therapeutic procedures have been followed in order to maintain the sphincter components such as setons, infill substances such as fibrin glue or collagen plug and the rectal mucosal advancement flap [9,10]. The choice planning of the proper surgical procedure is widely dependent on the type of the fistula, the presence of concomitant local diseases such as inflammatory bowel disease and the surgeon's favourite [10].

For several decades, seton has been practiced to manage anal fistula; though, in the literature, setons were principally used just for high or complex anal fistula in order to avoid faecal incontinence and recurrence [11]. Currently, several different materials have been used as setons, including silk, braided silk, rubber band, silastic tube, linen, polypropylene, braided polyester, vascular loop, nylon, cable tie, and others [12]. The reported incontinence and recurrence

rate varies from 0-62% [13] and from 0-16% [14], respectively, with different materials used as seton. There is a continuing demand to decrease the complications associated with seton use. The most common weak points of this technique are the high rates of continence disturbances, prolonged discharge and numerous visits to check and adjust the seton. The tight (cutting) seton is any string-like material which when passed and tied within the fistula track develops gradual transection of the external sphincter muscle as a result of pressure necrosis with a negligible splitting of the cut ends. In this way, it preserves sphincter continuity during the cutting process [15].

The aim of this prospective study was to determine the outcomes of the tight (cutting) seton placement for the treatment of anal fistula over a three years period by calculating the healing, failure, recurrence and incontinence rates with a surgical plan that aims to produce cure of the fistula without division of any portion of the anal sphincter complex.

## MATERIALS AND METHODS

This was a prospective interventional study conducted on 68 patients with primary fistula-in-ano at Al-kindy teaching hospital over a 3-years period from February 2013 to January 2016. Informed consent for all patients, as well as Ethical approval for the study from the hospital scientific committee, was obtained. All patients (males and females) in the age group 20-80 years, who present with primary fistula-in-ano were incorporated in this study. Exclusion criteria was patients with existing preoperative incontinence, patients with difficult follow-up and not ready to participate in the study, patients with fistula secondary to inflammatory bowel disease, malignancy, tuberculosis or trauma, patients with a horseshoe or multiple fistulas, and patients with synchronous anorectal problems like hemorrhoids.

All patients meeting the previously mentioned determination criteria were treated with cutting seton. Fistulas were grouped in relation to anal sphincter involvement, hence, it regarded as suprasphinctric, when the internal opening of the fistula was positioned above the external sphincter, high transsphincteric, when the internal opening of the fistula lies within the upper half of the external sphincter and it was supposed a low transsphincteric fistula when the internal opening opened at lower half of the external sphincter.

Data gathered included patients demographic data and the presence of past anal surgery. Proctoscopy was performed in all the patients. Fistulography or Magnetic Resonance Imaging (MRI) of the pelvis was done preoperatively for all the patients to outline the fistula anatomy.

The patients were instructed about the offered procedure of dealing with the fistula and the point that follow-up and healing are likely to be prolonged.

For all patients, bowel preparation was arranged with pure liquid diet for 24 hours earlier to surgery and the distal bowel was cleared by an enema approximately an hour before the operation. All patients received a single-shot antibiotic with ceftriaxone (1g) and metronidazole (15 mg/kg) injection.

### Operative Technique

The operations were made under general or spinal anaesthesia in the lithotomy situation. All operations were done by the same set of surgeons. Primary examination of the ano rectum was done to evaluate the internal openings of fistula, concomitant abscesses, and to eliminate additional anorectal pathology.

Following an initial examination, the fistula track was recognised using 3mm blunt-tipped metallic malleable probe. If the internal opening showed hard to find, an alcoholic solution of gentian violet or diluted hydrogen peroxide was used to determine the whole track obviously by injecting into the external opening. The region around the external opening was dissected around the track up to the sphincter; this core of tissues was then divided and removed. The procedure was achieved without division of any portion of the anal sphincter muscle fibres.

To guarantee that the seton sufficiently cuts the tissue it is surrounding, a constant tension was applied. We used the looped seton technique, reported by Jain BK and Gupta A [16]. A suture (silk 1 Ethicon) was located along the track, using the probe to pull it through. The suture was then knotted and tightened against the skin to create a small loop within the seton. When the seton becomes loose due to cutting through and migration of track, a new silk suture is threaded through the loop to re-thread the fistula track and replacing the old seton. Lastly, a dry wound pad was put to cover the wound.

### Postoperative

All of the patients were discharged home within 24 hours post procedure. None required readmission or required opiate analgesics following discharge. No infective complications or vital bleeding were seen. Instructions were presented to all patients upon their discharge. The patients were encouraged to avoid heavy physical activities for two weeks. Care at home consisted of regular hot soaks, dry gauze cover, analgesics, and stool bulking agents. The patients were examined at 2-week intervals at the outpatient department. On every visit, an elective changing of seton was made until the seton has completely dropped. Patients were then followed up for at least 12 months to check for complete healing of the fistula, operative failure, postoperative incontinence, and postoperative septic complications.

Healing of the fistula was defined as complete closure of the internal opening and healing of the external wound with complete resolving of indurations and perianal sepsis discharge. Operative failure was considered as the persistence of fistula within 12 months of

intervention. At each visit, patients were asked about the faecal incontinence.

## STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for Social Sciences for Windows (SPSS, version 18.00). Continuously measured results are presented in mean or median and categorically measured results are presented in number (%). A  $p < 0.05$  was considered statistically significant.

## RESULTS

During the study period, 68 consecutive patients met the selection criteria were treated with cutting seton. Out of these, 59 (86.8%) were males and 9 (13.2%) females. The median age at the time of presentation with the fistula was 40 years (range: 26–67 years). Peak occurrence was noted between 30 to 39 years. 48 (70.6%) patients did not have any prior surgical history of perianal problem, while 12 (17.6%) patients had undergone previous surgery for drainage for either perianal or ischio-rectal abscess, and eight (11.8%) patients had undergone previous surgery for fistula (fistulotomy) and presented with recurrent fistulae [Table/Fig-1]. After MRI and fistulographic assessment, all patients had a single fistula. A high transsphincteric fistula was the most common type and found in 31 (45.6%) patients, the low-level transsphincteric fistula was present in 28 (41.2%) patients, while suprasphincteric type was found in 9 (13.2%) patients as presented in [Table/Fig-1].

All the patients were followed up for a minimum period of one year. No patient was lost to follow up. The median duration of postoperative clinical follow up was 15 months (range: 12–18 months). During the total follow up period, the seton was tightened with a median of 4 times (3–6 times range). Most of the patients tolerated the tightening session well with no or minimal analgesia.

Complete healing was achieved in 55 patients at the time of the 3rd and subsequent follow up and tightening visits (success rate =80.9%) while 13 patients were failed to be treated by this method (failure rate =19.1%) as shown in [Table/Fig-2].

Of the 13 fistulas that persisted and failed to be healed, 6 (46.2%) patients had received no previous history of surgery at the anal region while four (30.8%) patients had received previous incision and drainage of an abscess, and three (23%) patients had previous surgery for fistulas. Eight (61.6%) patients had high transsphincteric and three (23%) patients had a suprasphincteric fistula and 2 (15.4%) patients had low transsphincteric fistulas [Table/Fig-3].

Variables	N (%)
<b>Sex</b>	
Male	59 (86.8%)
Female	9 (13.2%)
<b>Age group</b>	
20-29	11 (16.2%)
30-39	29 (42.6%)
40-49	18 (26.5%)
50-59	8 (11.8%)
>60	2 (2.9%)
<b>Past anal surgical history</b>	
No prior surgical history	48 (70.6%)
Past surgery for pus drainage	12 (17.6%)
Past history of fistulotomy	8 (11.8%)
<b>Type of fistula</b>	
High transsphincteric fistula	31 (45.6%)
Low transsphincteric fistula	28 (41.2%)
Supra sphincteric	9 (13.2%)

**[Table/Fig-1]:** Data of 68 patients with anal fistula included in the present study.

Postoperative visit	No. of patients with healed fistula (%)	No. of patients with non-healed fistula (%)
1st visit (2 wks)	0 (0.0%)	68 (100.0%)
2nd visit (4 wks)	0 (0.0%)	68 (100.0%)
3rd visit (6 wks)	31 (45.6%)	37 (54.4%)
4th visit (8 wks)	51 (75.0%)	17 (25.0%)
5th visit (3 months)	55 (80.9%)	13 (19.1%)
6th visit (6 months)	55 (80.9%)	13 (19.1%)
7th visit (12 months)	55 (80.9%)	13 (19.1%)

**[Table/Fig-2]:** Time durations for healing of 68 patients with anal fistula after cutting seton placement.

Variable	No.	Outcome			
		Healing		Failure	
		No.	p-value	No.	p-value
<b>Age</b>					
<50	58	48	0.154	10	0.290
>50	10	7		3	
<b>Sex</b>					
Male	59	47	0.079	12	0.002
Female	9	8		1	
<b>Previous operation</b>					
No	48	42	0.220	6	0.088
Yes	20	13		7	
<b>Fistula type</b>					
Low transsphincteric	28	26	0.045	2	0.001
High transsphincteric	31	23		8	
Suprasphincteric	9	6		3	

**[Table/Fig-3]:** The association of the individual variables with the outcomes of cutting seton placement.

Variable	No.	Complications					
		Recurrence No. p-value		Incontinence No. p-value		Abscess formation No. p-value	
		No.	p-value	No.	p-value	No.	p-value
<b>Age</b>							
<50	58	1	0.066	5	0.179	1	0.068
>50	10	1		4		2	
<b>Sex</b>							
Male	59	2	0.110	9	0.056	3	0.004
Female	9	0		0		0	
<b>Previous operation</b>							
No	48	1	0.050	6	0.069	1	0.099
Yes	20	1		3		2	
<b>Fistula type</b>							
Low transsphincteric	28	0		1		0	
High transsphincteric	31	2	0.001	6	0.002	2	0.010
Suprasphincteric	9	0		2		1	

**[Table/Fig-4]:** The association of the individual variables with the postoperative complications.

Recurrent fistula appeared in two (2.9%) patients, six months after seton placement. Three (4.4%) patients represented with an abscess that required incision and drainage but no further treatment of the fistula was required.

Among the 68 patients treated in this study, 59 (86.8%) patients were completely continent, only 9 (13.2%) patients have presented minor incontinence 6 (8.8%) with gas incontinence and 3 (4.4%) with liquid stool intermittent incontinence persisted

for 1-6 weeks and resolved spontaneously and no solid stool incontinence was noticed in any patient.

Our results show that there was no significant association between the patient's age or sex as well as the history of the previous operation and the outcomes of this treatment. While the type of fistula affect significantly the healing rate ( $p=0.045$ ), failure rate ( $p=0.001$ ), the recurrence ( $p=0.001$ ) and incontinence ( $p=0.002$ ). All these observations are summarised in [Table/Fig-3,4] which present the association of the individual variables with the treatment outcomes and postoperative complications.

## DISCUSSION

The principle challenge to colorectal surgeons in the management of anal fistulas is the manner by which to adjust the results of cure and the continence. There is a danger of sphincter muscle injury during fistulotomy, and this may prompt an unacceptable risk of anal incontinence of different grades [17]. So the goal of anal fistula treatment is to close the track with maintaining continence [18]. The use of setons allowed to preserve the majority of internal and external muscular sphincters fibres involved by anal fistula. Setons are useful in the treatment of trans-sphincteric anal fistula because they permit the drainage of acute inflammation and maintain anal sphincters [19].

In the present study, our operative plan concentrates on two fundamental standards: firstly, laying-open the subcutaneous part of the fistula track to make the fistula track as short as could be allowed and secondly, no part of the internal or external anal sphincter is divided.

For many decades, a division of the internal sphincter was practised routinely during treatment of low transsphincteric fistula until many authors highlighted the dangers related to this work; they reported 50–53% incidence of faecal incontinence after surgery for intersphincteric and transsphincteric fistulas [13]. Naturally, numerous patients are unwilling to get the smallest danger of faecal incontinence and they wanted that no portion of the sphincter complex should be divided during their operation. These considerations led us to manage all patients with transsphincteric fistula whether high or low variety by cutting seton technique.

In this study, the gradual, steady, and constant 'cut through' produced by the silk seton as well as the controlled and progressive tightening resulted in a fairly good healing rate and minimal complications.

Looking into the literature, a broad extent of incontinence rates and recurrence is reported after cutting seton treatment. Gurer A et al., reported 0% recurrence and incontinence in 17 patients treated with the cutting seton using a cable tie [19]. Vatanssev C et al., presented a series of 32 patients managed with cutting seton and they reported that none of the patients had recurrence or solid stool incontinence [20], and these may be explained by small sample size, however other series had reported higher incidence of incontinence (up to 62%) [13].

Our results were better than the results of Ibester WH and AlSanea N as 47% of their patients developed incontinence (23 patients); 17 (36.2%) patients to gas, 4 (8.5%) patients to liquid, 1 (2.3%) patient to solid stool, and one patient developed recurrence [21].

Our results were comparable to Chuang-Wei C et al., who treated 112 patients with complex anal fistulas by applying cutting setons with an elastic band from a surgical glove was utilised as the seton material. In their study, recurrence was found in one (0.9%) patient. 27 (24.1%) patients were noted with continence disorders, including gas incontinence in 21 (18.7%) patients and liquid stool incontinence in 6 (5.4%) patients [22], however our results were different from Kamrava and Collins who used silk cutting seton for treatment of 47 patients with 2% of patients developed incontinence and 9% developed a recurrent or persistent fistula in the same place [23].

Ritchie RD et al., concluded that the average rate of incontinence

after cutting seton utilise was 12% and this rate expanded as the level of the interior opening of the fistula moved more proximally [13]. We agree with this author in regards to the relation between incontinence and kind of fistula, as we found that the high transsphincteric and suprasphincteric fistulas were more probably associated with incontinence compared with low transsphincteric fistulas ( $p=0.002$ ). In this way, we presumed that the more proximal the level of the internal opening the higher was the incontinence rate.

The elements associated with fistula persistence or recurrence incorporate the complexity and level of the fistula, horseshoe extension, the level of laterality of the outside opening, disappointment of the surgeon to identify the inside opening, and the general surgical skill of the operator [24]. In our study, we found that the level of the fistula was a significant indicator of failure subsequent to setting for every single other variable ( $p=0.001$ ).

## LIMITATION

Our study excluded patients with complex multiple fistulas, Crohn's fistulas and patients with preoperative major incontinence. There is no difference in incontinence rates between the cutting seton and fistulotomy for complex multiple fistulas. Crohn's disease is not treated by the cutting seton. Patients with major incontinence will be made worse with the cutting seton.

## CONCLUSION

Cutting seton yields fairly good results in regard to the cure of fistula (healing rate =80.9%) with good continence in the majority, but the risk of failure or persistence fistula which was approximately 19.1%, seems to be high to advise the routine use of cutting seton for all anal fistulas. The suprasphincteric fistulas and high transsphincteric fistulas are difficult to treat unless other methods of treatment (preferably those in which sphincter division can be avoided and the risk of anal canal deformity and incontinence are minimised) are supported. Multicentre prospective studies are required to sufficiently compare between cutting seton and other surgical treatments.

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FINANCIAL OR OTHER COMPETING INTERESTS: None.

Date of Submission: **May 11, 2017**

Date of Peer Review: **Jun 20, 2017**

Date of Acceptance: **Sep 06, 2017**

Date of Publishing: **Nov 01, 2017**