

## Original research article

**A study to evaluate the efficacy of seton vs traditional procedures in the therapy of anorectal fistulas: a prospective clinical study****Dr. Kumar Chandra Kant<sup>1\*</sup>, Dr. Md Noman<sup>2</sup>, Dr. Kumar Shashi Kant<sup>3</sup>**<sup>1</sup>Senior Resident, Department of General Surgery, All India Institute of Medical Science, Patna, Bihar, India<sup>2</sup>Senior Resident, Department of General Surgery, A. N. Magadh Medical College & Hospital, Gaya, Bihar, India<sup>3</sup>Assistant professor, Department of Orthopaedics, Patna medical college & Hospital, Patna, Bihar, India**Corresponding Author: Dr. Kumar Chandra Kant****Abstract****Aim:** The aim of the present study to determine the role of seton versus conventional techniques in the management of anorectal fistulas.**Methods:** Total 100 patients with age group 18-65 years presented with primary fistula-in-ano and patients giving consent for the procedure were included in this study. Out of 100, 54 (54%) patients were placed in the group to be treated with seton placement in which 24 patients had a cutting seton placed through the fistulous tract and 30 patients had non-cutting seton made of rubber gloves placed through the fistulous opening. Remaining 46 (46%) patients were placed in another group to be treated by other means either with fistulotomy alone in 18 out of 46 patients or with fistulectomy done in 28 out of 46 patients.**Results:** Out of 100 patients studied, 81 patients were males and 19 patients were females, with male to female ratio of 4.26:1. 54 patients out of 100 (54%) had a simple fistula, 25 (25%) had multiple fistulae and 21 (21%) had complex fistulae. 54 patients who had a simple fistula and 25 patients who had a complex fistula were selected and treated with seton placement (54%) in which cutting seton was placed in 24 patients and seton made of rubber glove was placed in 30 patients. At the end of 1 month, 14 out of 18 patients (77.78%) who underwent fistulotomy had their wounds healed while in seton group, 37 out of 54 patients (68.52%) had their wounds healed. In fistulectomy group, 20 out of 28 patients (71.43%) had their wounds healed and the results were not found to be statistically significant ( $p=0.82$ ). At the end of 3 months, 15 out of 18 (83.33%) patients had their wound healed who underwent fistulotomy, 47 out of 54 (87.04%) in patients of seton as the treatment modality, while with fistulectomy alone, complete wound healing was seen in 20 out of 28 patients (71.43%) but the results were not statistically significant ( $p=0.14$ ). Recurrence was observed in 3 out of 18 patients of fistulotomy, 8 out of 54 patients of seton use and 4 out of 28 patients who underwent fistulectomy, but the results were comparable ( $p=0.79$ ). 5 out of 18 patients (27.78%) were observed as having incontinence who underwent fistulotomy alone, 5 out of 54 (9.26%) in patients of seton group and 6 out of 28 (21.43%) had incontinence in fistulectomy group but the results were statistically insignificant ( $p=0.08$ ).**Conclusion:** Setons are safe, low-cost, less invasive, precise, and cost-effective option for treating simple and complex fistula-in-ano.**Keywords:** Anorectal fistulas, Fistulectomy, Fistulotomy, Perianal abscess, Setons

## Introduction

Fistula-in-ano is one of the commonly encountered surgical problems with prevalence of 1.2 to 2.8/10000.<sup>1</sup> It is characterized by severe pain and discharge. They arise following infection near the anal canal, or secondary to specific conditions of the intestines like Crohn's disease, tuberculosis. By meaning 'crypto glandular abscess' means abscess arising from the anal glands. Because of the close association of abscess and fistula in aetiology, anatomy, pathophysiology, therapy and morbidity, it is appropriate to consider both entities as one, i.e., abscess– fistula or a fistulous abscess. It is also appropriate to consider an abscess as the acute and a fistula as the chronic state of anorectal suppuration. The classification of fistula-in-ano, as described by Parks et al. is based on the location of its tract in relation to anal sphincter muscle: intersphincteric, transsphincteric, suprasphincteric, or extrasphincteric.<sup>2</sup> The term complex fistula is modification of the Park's classification, which falls in any one of these conditions, that is, the tract crosses >30% to 50% of the external sphincter, anterior tracts in females, multiple tracts, recurrent, or the patient has pre-existing incontinence, local irradiation, or Crohn's Disease. Due to the involvement of the anal sphincter, the treatment of complex fistula poses a high risk for impairment of continence.<sup>3,4</sup> The treatment of perianal fistulas is diverse because no single technique is universally effective. Surgery is the mainstay of treatment of anal fistulas. The principles of anal fistula surgery are to eliminate the fistula, prevent recurrence and preserve sphincter function.<sup>5</sup> Fistulotomy can treat simple and low anal fistulas safely, but in case of complex fistulas management needs to be balanced between the outcome of cure of fistula and anal continence. During fistulotomy there is a risk of sphincter muscle damage, and this might lead to varying degrees of an unacceptable risk of anal incontinence (AI).<sup>6-8</sup> The amount of damaged muscle, pre-existing sphincter damage, and scarring of the anal canal are the main dependent factors which decide the degree of anal incontinence. Several alternative treatment strategies have been practiced in order to preserve the sphincter mechanism, including draining setons, cutting setons,<sup>8-11</sup> rectal mucosal or full-thickness advancement flaps,<sup>12-14</sup> rerouting,<sup>15</sup> two-stage seton fistulotomy,<sup>16</sup> fistulectomy, anal fistula plug,<sup>17-19</sup> ligation of the intersphincteric fistula tract (LIFT),<sup>20,21</sup> fistulotomy with reconstruction of the sphincter mechanism,<sup>22</sup> or fibrin glue.<sup>23</sup> Recently, Video- assisted Anal Fistula Treatment (VAAFT) have been introduced, which is a minimally invasive and sphincter saving technique for treating complex fistulas.<sup>24</sup> The studies related to this, are still preliminary and need longer follow-up for validation.

## Material and methods

This was a retrospective non-randomized study conducted in the Department of General Surgery, Anugrah Narayan Magadh Medical college, Gaya, Bihar, India for 18 months, after taking the approval of the protocol review committee and institutional ethics committee. Total 100 patients with age group 18-65 years presented with primary fistula-in-ano and patients giving consent for the procedure were included in this study. Fistula secondary to Crohn's disease, tuberculosis, malignancy, recurrent fistula at presentation, pregnant females and immuno-suppressed patients were excluded from the study.

## Methodology

Out of 100, 54 (54%) patients were placed in the group to be treated with seton placement in which 24 patients had a cutting seton placed through the fistulous tract and 30 patients had non-cutting seton made of rubber gloves placed through the fistulous opening. Remaining 46 (46%) patients were placed in another group to be treated by other means either with fistulotomy alone in 18 out of 46 patients or with fistulectomy done in 28 out of 46 patients.

### Operative steps

Patients are placed in the prone jack-knife position with the buttocks taped apart to facilitate exposure. Regional anaesthesia is preferred to local anaesthesia for adequate assessment of deep components of complex anorectal abscesses. Malleable blunt probes identify the course of the fistula tract and its internal opening. Any associated abscess cavity is widely unroofed. After the tract has been delineated with the probe, the rectal mucosa and the underlying internal sphincter are divided from the internal opening to the anal verge, along with the cephalad portion of the external sphincter and perianal skin. A seton of heavy, braided, non absorbable suture (cutting) or made by cutting rubber gloves (non-cutting) is looped around the distal half of the intact external sphincter and tied loosely to mark the tract. After six to eight weeks, the proximal fistulotomy wound has usually healed, re-establishing the continuity of the anorectal ring. A probe is placed through the remaining low fistula tract marked by the seton, the remaining external sphincter is divided. In cases of supra-sphincteric fistulas from Crohn's disease or fistulas in patients with AIDS, a Silastic TM vessel loop is used as a seton to promote drainage and prevent recurrent anorectal abscesses. Second stage fistulotomy is not routinely performed. Postoperative care is essentially the same as for other anorectal procedures and includes warm sitz baths four times per day, oral analgesics, and stool softeners.

### Statistical analysis

Statistical analysis was done to compare both the groups by using SPSS 21.0 software. Descriptive studies were presented as mean values with standard deviation for continuous variables. Statistical comparison was performed using chi square test and unpaired "t" test.  $P < 0.05$  was considered to be statistically significant.

### Results

Out of 100 patients studied, 81 patients were males and 19 patients were females, with male to female ratio of 4.26:1.

54 patients out of 100 (54%) had a simple fistula, 25(25%) had multiple fistulae and 21 (21%) had complex fistulae (Table 1).

54 patients who had a simple fistula and 25 patients who had a complex fistula were selected and treated with seton placement (54%) in which cutting seton was placed in 24 patients and seton made of rubber glove was placed in 30 patients. Other patients who had either multiple or complex fistulae were treated with either fistulotomy or fistulectomy (Table 2).

**Table 1: Intra operative findings and procedures performed.**

	No. of patients	Percentage %
<b>Intra-operative findings</b>		
Simple	54	54
Multiple	25	25
Complex	21	21
<b>Procedure done</b>		
Fistulectomy	18	18
<b>Setons</b>		
I: Cutting seton	24	24
II: Non cutting seton	30	30
Fistulectomy	28	28

The mean time for the seton to cut through the sphincter and drop was 1 month. In 24 patients (24%), the seton did not fall, and the patient was readmitted for seton removal in patients with

cutting setons and tightening of loosened seton in patients with non-cutting setons made by cutting rubber gloves (Table 3).

**Table 2: Seton fell on its own after seton placement after 1 month.**

Type of Seton	Seton Fell	No. of Patients (n=54)	Percentage %	P value
<b>Cutting (n=24)</b>	Yes	14	58.33	
	No	10	41.67	
<b>Non-cutting (n=30)</b>	Yes	21	70	0.52
	No	9	30	

At the end of 1 month, 14 out of 18 patients (77.78%) who underwent fistulotomy had their wounds healed while in seton group, 37 out of 54 patients (68.52%) had their wounds healed. In fistulectomy group, 20 out of 28 patients (71.43%) had their wounds healed and the results were not found to be statistically significant ( $p=0.82$ ) (Table 3).

At the end of 3 months, 15 out of 18 (83.33%) patients had their wound healed who underwent fistulotomy, 47 out of 54 (87.04%) in patients of seton as the treatment modality, while with fistulectomy alone, complete wound healing was seen in 20 out of 28 patients (71.43%) but the results were not statistically significant ( $p=0.14$ ) (Table 3).

Recurrence was observed in 3 out of 18 patients of fistulotomy, 8 out of 54 patients of seton use and 4 out of 28 patients who underwent fistulectomy, but the results were comparable ( $p=0.79$ ) (Table 3).

**Table 3: Association of outcomes according to the procedure**

Outcome	Fistulotomy (n=18)	Seton (n=54)		Fistulectomy (n=28)	P value
	N (%)	Cutting (n=24) N (%)	Non-cutting (n=30) N (%)	N (%)	
<b>Healing at 1 month</b>					
Yes	14 (77.78)	13 (54.17)	24 (80)	20 (71.43)	0.82
No	4 (22.22)	11 (45.83)	6 (20)	8 (28.57)	
<b>Healing after 3 months</b>					
Yes	15 (83.33)	19 (79.17)	28 (93.33)	22 (78.57)	0.14
No	3 (16.67)	5 (20.83)	2 (6.67)	6 (21.43)	
<b>Recurrence</b>					
Yes	3 (16.67)	6 (25)	2 (6.67)	4 (14.29)	0.79
No	15 (83.33)	18 (75)	28 (93.33)	24 (85.71)	
<b>Incontinence</b>					
Yes	5 (27.78)	3 (12.5)	2 (6.67)	6 (21.43)	0.08
No	13 (72.22)	21 (87.5)	28 (93.33)	22 (78.57)	

5 out of 18 patients (27.78%) were observed as having incontinence who underwent fistulotomy alone, 5 out of 54 (9.26%) in patients of seton group and 6 out of 28 (21.43%) had incontinence in fistulectomy group but the results were statistically insignificant ( $p=0.08$ ) (Table 3).

**Table 4: Healing of fistulous tract**

Procedure	No. of patients	P value
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Healing of fistulous tract after 1 month		
Cutting setons	13	
Non-cutting setons	24	0.03
Healing of fistulous tract after 3 months		
Cutting setons	19	0.14
Non-cutting setons	28	
Recurrence of fistula		
Cutting setons	6	
Non-cutting setons	2	0.016
Incontinence		
Cutting setons	3	0.38
Non-cutting setons	2	

Healing of the fistulous tract was found to be higher in patients in whom the non-cutting setons made of rubber gloves was used as compared to cutting setons made of non-absorbable sutures ( $p=0.03$ ) (Table 4).

However, at the end of 3 months, no difference on healing was observed between setons made of rubbergloves and non-cutting setons of non-absorbable suture ( $p=0.14$ ) (Table 4).

Recurrence of fistula was found to be higher in cutting setons as compared to non-cutting setons ( $p=0.016$ ) (Table 4).

Incontinence rates was found to be similar in cutting setons and in non-cutting setons made of rubber gloves ( $p=0.38$ ) (Table 4)

## Discussion

The ano-perineal suppuration or sepsis arising from the glands of the anal crypts leads to fistula formation. It has a primary internal orifice in the anal canal, connecting fistulous tract, and an abscess and/or secondary external (perineal) orifice with purulent discharge. Surgery is the main curative treatment. Perineal abscess is treated by incision and drainage on emergency basis. The primary aim of treatment in perianal sepsis is to control infection without sacrificing anal continence. Second stage or the definitive treatment of the fistulous tract can wait.

A seton (derived from the Latin word seta, meaning bristle) has traditionally been described as a loop of strong, non-absorbable, braided suture or elastic material that is placed in high fistulous tracts to prevent complete disruption of the external anal sphincter muscle.<sup>25</sup> Setons are employed most commonly for less than 10 percent of fistulas that involve the puborectalis muscle, the division of which invariably results in faecal incontinence. Different types of setons are used for this purpose like silastic tube, silk, linen, braided silk, rubber band, braided polyester, vascular loop, polypropylene, nylon, cable tie, and so forth.<sup>25</sup> The reported incontinence and recurrence rate ranges from 0% to 62% and from 0% to 16% respectively, with different materials used as seton.<sup>25,26</sup>

Different seton materials has been used with different rates of recurrence and incontinence. But whatever the material is, recurrence and incontinence rate is mainly dependent on expertise and judgment of the surgeon.<sup>9</sup> Other factors that need to be considered during the selection of the seton are that it should be durable, cheap, nontoxic/nonallergic, technically easy to tie even in clinic setting, and allows to tight repeatedly without causing pain and without anaesthesia (local or general).<sup>27,28</sup>

Due to these properties, we selected cutting setons (non- absorbable sutures) and non-cutting setons made by cutting rubber gloves. The rubber seton was superior to cutting seton as it could be easily passed through the fistulous opening, and the surgeon could adequately tight

it without any need of further assistance or retraction. In cutting setons, the knot was applied by sliding the knot over the suture and so there was high risk of slippage and loosening of the knot. Hence, tightening is gradual and controlled by the use of rubber setons in comparison to cutting seton. After tightening, none of the patients had unbearable pain for more than few minutes; this is attributed to the precise and controlled tightening achieved by rubber seton as well as the fact that we did not tighten it until found loose. This controlled and gradual tightening decreased the incidence of incontinence and recurrence. None of the patients reported any difficulty in walking or carrying out routine activities.

In the study by Pearl et al, 116 patients were evaluated for the role of setons in fistulas.<sup>29</sup> Setons were employed as part of a staged fistulotomy in 65 patients (56%) to identify and promote fibrosis around a complex anorectal fistula. Other indications for seton placement were anteriorly situated high trans-sphincteric fistulas in 24 women (21%) and 3 patients with massive anorectal sepsis (2.5%). In addition, setons were used to preclude premature skin closure and promote controlled long-term fistula drainage in 21 patients with severe anorectal Crohn's disease (18%) and in three patients with AIDS (2.5%). In our study, 54 patients out of 100 (54%) had a simple fistula, 25 (25%) had multiple fistulae and 21 (21%) had complex fistulae. 54 patients who had a simple fistula and 25 patients who had a complex fistula were selected and treated with seton placement (54%) in which cutting seton was placed in 24 patients and seton made of rubber glove was placed in 30 patients.

In our study at the end of 1 month, 14 out of 18 patients (77.78%) who underwent fistulotomy had their wounds healed while in seton group, 37 out of 54 patients (68.52%) had their wounds healed. In fistulectomy group, 20 out of 28 patients (71.43%) had their wounds healed and the results were not found to be statistically significant ( $p=0.82$ ). At the end of 3 months, 15 out of 18 (83.33%) patients had their wound healed who underwent fistulotomy, 47 out of 54 (87.04%) in patients of seton as the treatment modality, while with fistulectomy alone, complete wound healing was seen in 20 out of 28 patients (71.43%) but the results were not statistically significant ( $p=0.14$ ).

In this study, there were 15 cases of recurrence with overall recurrence rate of 15%. However, 8 cases of recurrence out of 54 patients was seen in patients in whom seton placement was done with 6 out of 24 (25%) seen in patients with cutting seton and 2 out of 30 (6.67%) in patients in whom non-cutting seton made of rubber gloves were used with rate of recurrence more with the cutting setons as compared to the non-cutting setons ( $p=0.016$ ). The recurrence rate varied with the type of fistula i.e. simple or complex, but there was no statistically significant relation between the type of surgical treatment and recurrence ( $p=0.79$ ). The difficult target is the complex fistula, that is, those fistulas with any of these characteristics: primary track crossing 30-50% of the external sphincter (high trans-sphincteric, supra-sphincteric, and extra-sphincteric), anterior track in a female, multiple tracks.

In the study by Eitan et al the recurrence rate of the fistula or suppuration was reported as 19.5% in cases of trans-sphincteric fistulae.<sup>30</sup> Factors associated with recurrence included type and extension of the fistula, lack of identification or lateral location of the internal fistulous opening, previous fistula surgery and the surgeon experience

In Poon et al study (135 patients), there was recurrence in 13.3% of patients operated by fistulectomy compared to the present study in which there were 25% (8 out of 32) recurrence rate in patients operated by fistulectomy.<sup>31</sup>

Other techniques for treatment of fistulas includes fibrin glue, ligation of inter-sphincteric fistula tract (LIFT) and collagen plug. Metanalysis of trials on fibrin glue did not report any statistically significant difference over other techniques for recurrence or incontinence;

moreover, it is too expensive to be used in a low-income country- the cost of fibrin glue equals the cost of entire day care procedure of seton placement.<sup>32</sup> Early experience of LIFT is also promising and sounds good alternative; however, besides a steep learning curve, it needs technical expertise especially for complex fistulae.<sup>33</sup>

Ritchie et al have concluded that there is no relationship between incontinence and the frequency of tightening, type of seton, or classification of fistula.<sup>25</sup> Hence, we further reinforce the importance of surgeon's experience and the use of a seton having additive qualities as stated above.

### Conclusion

The present study concluded that the Setons are safe, low-cost, less invasive, precise, and cost-effective option for treating simple and complex fistula-in-ano.

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