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Original Research Article

Role of seton versus conventional techniques in the management of anorectal fistulas

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ABSTRACT

Background: This study was conducted to compare the use of different setons with conventional management like fistulotomy and fistulectomy in terms of healing (after 1 and 3 months), recurrence and incontinence.
Methods: This was a retrospective non-randomized study conducted at JNMCH, Aligarh from January 2018 to June 2019. Patients included- patients (males and females) of age group 18-70 years, patients giving consent. Patients excluded- fistula secondary to- Crohn's disease, tuberculosis, malignancy, recurrent fistula, pregnant females, immuno-suppressed patients.
Results: After 1 month, 17 out of 24 patients (70.8%) of fistulotomy, 48 out of 68 patients (70.6%) of seton group and 21 out of 32 patients (65.6%) of fistulectomy group had their wounds healed (p=0.8693). After 3 months, 19 out of 24 (79.2%) patients of fistulotomy, 61 out of 68 (89.7%) of seton, and 24 out of 32 patients (75%) with fistulectomy had their wound healed (p=0.1374). Recurrence was observed in 5 out of 24 patients of fistulotomy, 10 out of 68 patients of seton use and 5 out of 32 patients with fistulectomy (p=0.7788). 6 out of 24 patients (25%) had incontinence after fistulotomy, 7 out of 68 (10.3%) of seton group and 8 out of 24 (25%) after fistulectomy (p=0.0944). Healing was higher in patients of non-cutting setons as compared to cutting seton (p=0.0252). After 3 months, no difference was observed (p=0.1245). Recurrence higher in cutting setons as compared to non-cutting setons (p=0.0187).
Conclusions: 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 a tract that connects the anal canal or rectum from deep inside upto the skin around the anus. It's primary opening is deep in the anal canal or rectum and the superficial openings, which may be multiple, are around the perianal skin.[1] It is one of the commonly encountered surgical problem worldwide with prevalence of 1.2 to 2.8/10000.[2] Hippocrates (460 BC) first wrote about anal fistulas and discussed its specific treatment, but the first description of a fistula in a patient was reported to have multinucleated giant cells is credited to Gabriel in 1921.[3,4]

Fistula-in-ano 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. 'cryptoglandular 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 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.[5]

In our study, we used cutting seton as well as seton created by cutting rubber gloves and evaluated it with our past experience in managing fistulas like fistulotomy and fistulectomy. The aim of the study was to know the role of both types of seton in the management of fistula- in-ano in terms of calculating the frequency of putting seton in patients of fistula- in- ano by comparing with patients in which seton is not placed, and evaluating the effectiveness of fistula healing when seton is placed by periodic follow up and calculating the recurrence rates and incontinence rates associated with seton use.

Classification

The classification of fistula-in-ano, as described by Parks et al.[6] is based on the location of its tract in relation to anal sphincter muscle i.e. inter-sphincteric, trans-sphincteric, supra-sphincteric, extra-sphincteric.

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.[7,8]

METHODS

This study was a retrospective non-randomized study conducted at Jawaharlal Nehru Medical College from January 2018 to June 2019.

Inclusion criteria

All patients (males and females) in the age group 18-70 years presented with primary fistula-in-ano. Patients giving consent for the procedure

Exclusion criteria

Fistula secondary to- Crohn's disease, tuberculosis, malignancy, recurrent fistula at presentation, pregnant females and immuno-suppressed patients.

Study design

It was a retrospective non-randomized study consisting of 124 patients between January 2018 to June 2019, who fulfilled the above selection criteria and were treated with appropriate fistula surgery, depending on the type of fistula. Patients were not required to give informed consent to participate in the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

Statistical analysis

Statistical analysis was done to compare both the groups by using SPSS 25® 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.

68 (54.8%) patients were placed in the group to be treated with seton placement in which 30 patients had a cutting seton placed through the fistulous tract and 38 patients had non-cutting seton made of rubber gloves placed through the fistulous opening. Remaining 56 (45.2%) patients were placed in another group to be treated by other means either with fistulotomy alone in 24 out of 56 patients or with fistulectomy done in 32 out of 56 patients (Table 1).

Table 1: Different types of operation performed.

Type of operation	No. of patients (n=124)
Fistulotomy	24
Cutting seton	30
Non-cutting seton	38
Fistulectomy	32

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(s) and its internal opening(s). 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 (Figure 1A). A seton of heavy, braided, nonabsorbable 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 (Figure 1B). 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 (Figure 2A and B). 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.

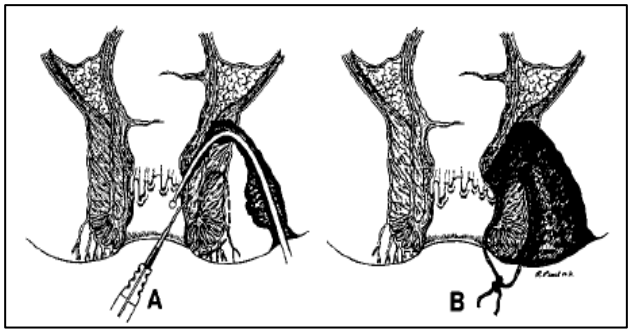

Figure 1: (A) The probe delineates the course of a high fistula. The internal sphincter and cephalad portion of the external sphincter are divided with the cautery along with the perianal skin. The remaining intact portion of the external sphincter is indicated by the dashed line. (B) A seton of heavy, braided, nonabsorbable suture is looped around the distal half of the intact external sphincter and tied loosely to mark the tract. When seton made of rubber gloves is used, the seton is tied tightly near the opening of the tract carefully and also to allow adequate drainage.

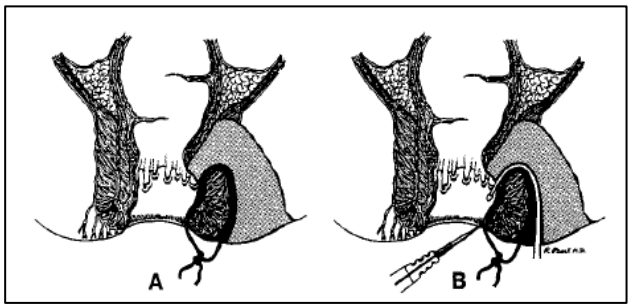

Figure 2: (A) After six to eight weeks, the proximal fistulotomy wound has healed, re-establishing the continuity of the anorectal ring (stippled areas). (B) A probe is placed through the remaining low fistula tract, and the distal portion of the external sphincter is divided with the cautery so that the seton is removed intact.

RESULTS

Out of 124 patients studied, 92 patients were males and 32 patients were females, with male to female ratio of 2.8:1.

66 patients out of 124 (53.2%) had a simple fistula, 32 (25.8%) had multiple fistulae and 26 (21%) had complex fistulae (Table 2a).

44 patients who had a simple fistula and 24 patients who had a complex fistula were selected and treated with seton placement (54.8%) in which cutting seton was placed in 30 patients and seton made of rubber glove was placed in 38 patients. Other patients who had either multiple or complex fistulae where treated with either fistulotomy or fistulectomy (Table 2b).

Table 2: Intra operative findings and procedures performed.

	No. of patients	Percentage %
Intra-operative findings		
Simple	66	53.2
Multiple	32	25.8
Complex	26	21.0
Procedure done		
Fistulectomy	24	19.4
Setons:		
I: Cutting seton	30	24.2
II: Non cutting seton	38	30.6
Fistulectomy	32	25.8

The mean time for the seton to cut through the sphincter and drop was 1 month. In 30 patients (44.1%), 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 3: Seton fell on its own after seton placement after 1 month.

Type of Seton	Seton Fell	No. of Patients (n=68)	Percentage %	P value
Cutting (n=30)	Yes	18	53.3	0.5435
	No	12	46.7	
Non-cutting (n=38)	Yes	20	68.4	
	No	18	31.6	

At the end of 1 month, 17 out of 24 patients (70.8%) who underwent fistulotomy had their wounds healed while in seton group, 48 out of 68 patients (70.6%) had their wounds healed. In fistulectomy group, 21 out of 32 patients (65.6%) had their wounds healed and the results were not found to be statistically significant (p=0.8693) (Table 4).

At the end of 3 months, 19 out of 24 (79.2%) patients had their wound healed who underwent fistulotomy, 61 out of 68 (89.7%) in patients of seton as the treatment modality, while with fistulectomy alone, complete wound healing was seen in 24 out of 32 patients (75%) but the results were not statistically significant (p=0.1374) (Table 4).

Recurrence was observed in 5 out of 24 patients of fistulotomy, 10 out of 68 patients of seton use and 5 out of 32 patients who underwent fistulectomy, but the results were comparable (p=0.7788) (Table 4).

Table 4: Association of outcomes according to the procedure.

Outcome	Fistulotomy (n=24)	Seton (n=68)		Fistulectomy (n=32)	P value
		Cutting (n=30)	Non-cutting (n=38)		
	N (%)	N (%)	N (%)	N (%)	
Healing at 1 month					
Yes	17 (70.8)	17 (56.7)	31 (81.6)	21 (65.6)	0.8693
No	7 (29.2)	13 (43.3)	7 (18.4)	11 (34.4)	
Healing after 3 months					
Yes	19 (79.2)	25 (83.3)	36 (94.7)	24 (75)	0.1374
No	5 (20.8)	5 (16.7)	2 (5.3)	8 (25)	
Recurrence					
Yes	5 (20.8)	8 (26.3)	2 (5.2)	5 (15.6)	0.7788
No	19 (79.2)	22 (73.3)	36 (94.7)	27 (84.4)	
Incontinence					
Yes	6 (25)	5 (16.7)	2 (5.2)	8 (25)	0.0944
No	18 (75)	25 (83.3)	36 (94.7)	24 (75)	

6 out of 24 patients (25%) were observed as having incontinence who underwent fistulotomy alone, 7 out of 68 (10.3%) in patients of seton group and 8 out of 24 (25%) had incontinence in fistulectomy group but the results were statistically insignificant (p=0.0944) (Table 4).

Table 5: Healing of fistulous tract.

Procedure	No. of patients	P value
Healing of fistulous tract after 1 month		
Cutting setons	17	0.0252
Non-cutting setons	31	
Healing of fistulous tract after 3 months		
Cutting setons	25	0.1245
Non-cutting setons	36	
Recurrence of fistula		
Cutting setons	8	0.0187
Non-cutting setons	2	
Incontinence		
Cutting setons	2	0.4212
Non-cutting setons	1	

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=0.0252) (Table 5).

However, at the end of 3 months, no difference on healing was observed between setons made of rubber gloves and non-cutting setons of non-absorbable suture (p=0.1245) (Table 5).

Recurrence of fistula was found to be higher in cutting setons as compared to non-cutting setons (p=0.0187) (Table 5).

Incontinence rates was found to be similar in cutting setons and in non-cutting setons made of rubber gloves (p=0.4212) (Table 5).

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, nonabsorbable, braided suture or elastic material that is placed in high fistulous tracts to prevent complete disruption of the external anal sphincter muscle.[9] 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 (Figure 1 and 2). 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.[9] The reported incontinence and recurrence rate ranges from 0% to 62% and from 0% to 16% respectively, with different materials used as seton.[9,10]

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.[9] 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).[11,12]

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.[13] 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, out of 124 patients, 68 patients (44 patients with simple and 24 with complex fistulas) had undergone seton placement in which 30 out of 68 (44.1%) had a cutting seton placed and 38 out of 68 (55.9%) had a non-cutting seton made of rubber gloves. Rest of the patients underwent sphincter cutting procedures namely- fistulotomy or fistulectomy.

Complete healing was seen in 69.4% of the patients at 1 month and 83.9% of the patients at 3 months. In patients who had seton, complete healing was observed in 38.7% at 1 month and 49.2% at 3 months with healing of rubber seton was found to be better than the cutting seton (p=0.0252) at 1 month but comparable (p=0.1245) at 3 months.

In this study, there were 20 cases of recurrence with overall recurrence rate of 16.1%. However, 10 cases of recurrence out of 68 patients was seen in patients in whom seton placement was done with 8 out of 30 (26.3%) seen in patients with cutting seton and 2 out of 38 (5.2%) 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=0.0187). 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=0.7788). 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.[14] 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.[15]

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.[16] 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.[17]

Ritchie et al have concluded that there is no relationship between incontinence and the frequency of tightening, type of seton, or classification of fistula.[9] Hence, we further reinforce the importance of surgeon's experience and the use of a seton having additive qualities as stated above.

CONCLUSION

Setons are safe, low-cost, ubiquitous, pragmatic, precise, and a cost-effective option for the treatment of simple and complex fistulae-in-ano. It does not carry the disadvantage of repeated anaesthesia and visits to the operating theatre and reduces the morbidity, inconvenience, and cost of the patient. Non-cutting seton is better than the cutting seton owing to its better healing and low recurrence rates. There was improvement in the quality of life in all the patients in whom seton was placed. Patient were able to perform their normal day to day activities soon after the procedure and also without any inconvenience.

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