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DOUBLE SETON IN THE MANAGEMENT OF COMPLEX ANAL FISTULAS: A NOVEL APPROACH

General Surgery				
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ABSTRACT

Aims & Objectives: To determine the surgical outcome in terms of fecal incontinence and recurrence rate, in patients with complex fistula in ano managed with a novel technique of dual seton at a tertiary care hospital.

Methods: This is a prospective case series of patients presenting with complex anal fistula, managed with double seton from January 2017 to January 2019.

Results: Twenty five patients were treated during the study period with the age (mean \pm standard deviation) of 40.04 \pm 8.36 years. In our study, we found 0% incontinence and 0% recurrence rate in 25 patients, treated with the new technique of double seton placement for complex anal fistulae. **Conclusion:** The double seton technique is a safe, low-cost, novel, precise, and a cost-effective option for the treatment of complex fistulae-in-ano with an excellent outcome, in regards of anal incontinence and recurrence.

KEYWORDS

Anal Incontinence(AI), Ligation Of The Intersphincteric Fistula Tract (LIFT), Video-Assisted Anal Fistula Treatment (VAAFT).

INTRODUCTION:

Fistula-in-ano is one of the commonly encountered surgical problems with prevalence of 1.2 to $2.8/10,000^{10}$. The classification of fistula-inano, 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 ^[2]. Low anal fistulas can be treated safely only by fistulotomy or fistulectomy, while the management of complex fistulas needs to balance the outcomes of cure and continence. There is a definite risk of sphincter muscle damage during fistulotomy in cases of high or complex fistulas, and this might lead to a significant risk of anal incontinence (AI) of varying degrees^[3,4]. The degree of incontinence depends on the amount of external

sphincter muscle damage, preexisting sphincter damage, and scarring of the anal canal.

Several alternative treatment strategies have been practiced in order to preserve the sphincter mechanism, including draining setons, cutting setons^[56,7], rectal mucosal or full-thickness advancement flaps^[8,8,10], rerouting^[11], two-stage seton fistulotomy^[12], coring out of fistulous tract, anal fistula plug^[13,14,15], ligation of the intersphincteric fistula tract (LIFT)^[16,17], primary fistulotomy with reconstruction of the sphincter mechanism [18], or fibrin glue [19], Video-assisted anal fistula treatment (VAAFT)^[20].

• Low versus High Anal Fistula:

- Fistulae are described according to the level at which they transgress the anal sphincters into "Low" or "High."
- Low Fistula:
- The internal orifice of the fistula begins below puborectalis
- The track passes through few or no sphincter muscle fibres and is relatively close to the skin
- E.g. superficial fistulas, low intersphincteric fistulas, and low trans-sphincteric fistulas
- These are relatively easy to manage (in the absence of complications or underlying conditions) and pose little threat to continence.

• High Fistula:

- The internal orifice begins above puborectalis
- A track that passes through or above a large amount of muscle; its route may be more complicated and further away from the skin
- E.g. high intersphincteric fistulas, high trans-sphincteric fistulas, suprasphincteric fistulas, and extrasphincteric fistulas
- Are much rarer than low fistulas, occurring in Crohn's disease, ulcerative colitis more rarely, or as a result of a foreign body
- Management of a high fistula is more complex than that of a low fistula^[3,4].

The oldest and theoretically the simplest technique is to use a seton, the well-known variations in modern surgical practice being cutting setons, drainage setons, and two-stage seton fistulotomy^[21]. A seton can be any type of foreign material inserted through a fistulous track. Although setons have been used since Egyptian times, Hippocrates first detailed a method of application in the anal fistula. He suggested the use of 'horsehair wrapped about a lint thread' and advanced through the fistula by means of a director made of tin. The ends of the horsehair thread were intermittently tied about the enclosed muscle until the flesh was eaten through^[21]. The word seton is derived from the Latin 'seta', meaning a bristle. Currently, many different materials have been used as setons, including silk, wire, elastic bands, Penrose drain, and nylon and plastic tubing^[22].

The seton works by several mechanisms:

- 1) It helps in draining pus and controlling sepsis prior to definitive treatment.
- It stimulates fibrosis and acts as a marker of the fistula tract for sphincter-sparing procedures such as fistula plug, fibrin glue and ligation of the intersphincteric fistula tract.
- The tight (cutting) seton promotes slow transection of the external sphincter muscle as a result of pressure necrosis with minimal separation of the cut ends^[5,6].

TYPES OF SETONS AND MECHANISM.

- Cutting Seton: The definition of cutting seton is any seton intended to cut through tissue, either by mechanical or chemical means. It works on the mechanism of the formation of fibrosis prevents retraction of the sphincter behind the advance of the seton.
- 2) Draining Seton: A draining seton is any seton which is placed loosely in the fistula tract that allows continuous drainage of fistulous abscess externally through out the course of treatment.
- 3) Combination of Draining and Cutting Seton: This can be achieved by two setons placed together, one keeping loose as a drainage seton and another tight seton as a cutting seton by intermittently tightening it. In some studies single seton has been used as both draining and cutting seton by keeping it loose(as a draining seton) and intermittent pulling to make it as cutting seton, this has been referred to as PULLING seton.^[23]
- **4) HYBRID SETON:** Is created by cutting a thin (2-3mm) circular stip from surgical gloves (No-8) including its thicker sleeve^[23].

In this study, we have evaluated our experience in managing Complex Anal Fistulas with a simple modification of the cutting and draining seton by replacing them with a the two seton placement method, comprising one draining and debridement seton and another one acting as a cutting seton, for all consecutive patients with a Complex Anal Fistulae in the outpatient clinic.

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METHODS

A prospective series of 25 consecutive patients with complex anal fistula managed by dual seton placement between January 2017 to January 2019, with a follow up of one year, were studied.

PATIENT SELECTION

- INCLUSION:
- Single tarct fistulas,
- Two fistulas with different tracts.

EXCLUSION:

- · Patients with fistulas secondary to inflammatory bowel disease
- Past or present malignancies
- Trauma
- Patients with a history of vaginal deliveries involving tears, episiotomies or forceps.
- Branched Fistulas

TECHNIQUE:

The procedures was performed in the operating room under spinal anaesthesia. The patient was examined in lithotomy position and tract was defined with dilute hydrogen peroxide which was injected from the external opening and internal opening was located under transparent operating proctoscope.

Fistula tract wass probed with a special malleable fistula probe which was delieverd through the internal opening into the anal canal and brouht out and thraeded into the button hole of fistula probe(**Image 1 & 2**).

A non-absorbable suture monofilament ethilon 3-0 (ethicon, edinburgh, uk) was used for this purpose and thread was pulled out with fistula probe. The same , maneuver was repeated to bring out second thread. A roders knot was made for each seton in which one seton was tightened while another one was left loose with multiple knots and long tail(**Image 3**).

The seton with the short tail which has been tied tightly, served as a cutting seton which was changed every week. The seton with the long tail will become the draining seton which will be moved by the patient after sitz bath daily producing microdebridement.

Repeated examinations were carried out once a week. at each visit, under local anaesthesia, two threads (ethilon 3-0) are pulled out in piggy back fashion using the long tailed seton. The previous two threads are removed and newly delievered two threads are applied, one tight as a cutting, and one loose as a draining & debriding. Same process was repeatedly weekly till seton comes out or it becomes very superficial and it was removed after dividing skin bridge.

TABLE 1 : WEXNER'S SCORE FOR FECAL INCONTINENCE. Type of incontinence Frequency

	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4



Image 1 and 2: Insertion Of Fistula Probe and delineating the fistulous tract.



Image 3: Placement Of Dual Seton.

FOLLOW UP

The data of previous anal operations, history of patient incontinence before and after seton treatment, wound healing, and recurrence of anal fistula was recorded. Patients were followed up for one year regularly, to detect any recurrence and any problems of faecal incontinence. A satisfactory score to the treatment was finally obtained from each patient at the end of the each follow up visit.

RESULTS:

This study was conducted on 25 patients, 15 males (60 %) and 10 females (40 %). None of the patients had any history of perianal surgery or fistula. All the patients were treated with double seton technique as described above. All the patients were followed up for a period of 12 months, at a weekly interval till the drop of seton and then at monthly intervals. No patient was lost during follow-up. All of the patients were discharged on the first or second postoperative day. None required readmission or needed analgesics after discharge. No infective complications or significant bleeding were noted.

POSTOPERATIVE PAIN Table No. 2: Postoperative Pain Score.

Postoperative Pain	Surgery				
	Postoperative Day 1	Postoperative Day 7			
Present (VAS > 2)	09	00			
Absent (VAS $<$ 2)	16	25			
Total	25	25			

In our study, Postoperative pain was managed according to the guidelines of French Anaesthesia Society. Pain was assessed using a Visual analogue scale (VAS)²⁴¹.

72% of the patients had no pain (VAS<2) on postoperative day 1, while 100% of the patients had no pain on postoperative day7.

BASELINE VARIABLES

Table No. 3: Baseline Variables. Characteristics Value 40.04 +/- 8.36 Age(In Years) Sex: Male 15 (60%) Female 20 (40%) Type Of Fistula: 06(24%) Low Transsphincteric 14(56%) High Transsphincteric Suprasphincteric 05(20%) OUTCOMES: Perfect Continence 25(100%) Recurrence(1 Year) 00

Using Wexner scoring fecal incontinence was assessed. None of the cases presented with major fecal incontinence. Only one patient developed transient gas incontinence, which was resolved within 2 weeks. None of the patients in our study had reoccurrence after follow up of one year.

Only one patient developed a new fistula at a distant site from the primary site in our study, which was also managed by double seton

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technique and it healed completely in 4 weeks.

DISCUSSION:

Our study introduces a New Double Seton-based technique in the treatment of complex perianal fistulas whose efficacy has been tried in 25 patients during an acceptable follow-up period.

Treatment of perianal fistula, especially complex fistulas, is always a compromise between recurrence and incontinence. In different studies, rate of incontinence after Seton fistulotomy varies from 0% to 70%. Overall rate of incontinence after Seton-based surgeries for perianal fistula varies between 5.6% and 25.2%^[57,21,22].

The traditional cutting Seton is associated with a high incidence of postoperative fecal incontinence^[5,6,7]. In our study, we found 0% incontinence and 0% recurrence rate in 25 patients treated with the new technique of double seton placement for complex anal fistulae. The data on continence was determined and validated by Wexner's score in all the patients with complete follow up, which includes incontinence of feces as well as flatus.

All the procedures were done by a single surgeon, eliminating the bias which could have occurred with multiple surgeons.

Previous studies using double seton have also been performed in which one is a cutting seton and one is a pulling seton, wherein the rate of incontinence is 6% and the rate of recurrence was found to be 9%.^[23]

The 0% incontinence and 0% reoccurrence in our study can be attributed to:

- (1) Nominal dissection as only external opening with small part of fistulous tract was excised for histopathological examination and rest of the tract was gently curreted with a small currete followed by flushing the tract with dilute hydrogen peroxide and betadiene followed by placement of dual seton.
- (2) The sphincter muscle complex is gradually cut through because of the direct compression effect of the cutting seton and "wearing through" the tissues because of the movements produced by walking, while the depth of the tissues have a chance of adhering to each other because of the fibrosis that has occurred. Such fibrosis does not allow distraction of the sphincter muscle and the resultant incontinence.
- (3) As the patient moves the draining seton daily, microdebridement is done which sloughs out the debris and provides a healthy granulation tissue along with draining of the abscess cavity preventing infective complications of seton.

Looking into the literature, a wide range of incontinence rates(12-54%) and rate of reoccurrence(10-57%) is reported after the use of seton placement by various procedures for the treatment of complex anal fistula[11-18]

This is because of the fact that in previous studies either a cutting seton $^{[5,6,7,19,23]}$ is placed or a draining seton $^{[4,8,22]}$ is placed.

Our study has combined both the modalities, as a result of which there is an excellent out come.

CONCLUSION:

The double seton technique is a novel, safe, splendid, ubiquitous, precise, and a very cost effective option for the treatment of complex fistulae-in-ano with an excellent outcome in regards of incontinence and recurrence.It does not carry the disadvantage of repeated anesthesia and visits to the operating theater and reduces the morbidity, inconvenience, and cost to the patient as seen in previous studies.

We, therefore, recommend it to treating complex fistulae-in-ano requiring the placement of a seton but the technique worths more investigation and we recommend more trials especially randomized controlled ones to demonstrate its efficacy.

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