

Is Cable-Tie-Seton (Azami Seton) an Ideal Treatment for Complex Fistula-in-Ano? A Cohort Study

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Abstract

Background: Treating complex fistula in ano is a common anorectal surgical issue with countless complications. Effective treatment methods are required to minimize such complications.

Objective: To determine the outcomes (incontinence, recurrence, infection, bleeding) in patients who were treated with cable tie seton for complex FIA, in a tertiary care hospital.

Methods: This is a cohort study, which included patients who were treated for complex FIA, from 1st June 2014 to 31st March 2021. Data was retrieved from the HIMS department. Each patient was contacted and asked about incontinence and recurrence. Data were analyzed using SPSS version 21. Continuous variables were analyzed as mean \pm SD and the categorical variables are represented as proportions and percentages. Fisher's exact test was used for analyzing predictors of incontinence (co-morbidities, gender).

Results: No patient had bleeding or infection requiring readmission or re-exploration. None of the patients reported severe pain (defined as VAS 7 or above). All the patients were followed up for a minimum period of six months and none of them reported recurrence. Some of them reported having incontinence in the initial post-operative days of the procedure which resolved spontaneously except in one patient who had two fistulae (5.1%)

Conclusion: Cable tie seton is an effective treatment option for complex fistulae in ano, and demonstrates good outcomes.

Keywords: Rectal fistula, cable tie seton, complex fistula in ano, fistula in ano, perianal fistula.

INTRODUCTION

A fistula-in-ano (FIA) is considered an unnatural path or cavity lined with granulation tissue, starting from an opening inside the anal canal and leading its way out towards the perianal skin. A complex FIA can be defined by any one of the following criteria: 1) a fistula with more than one external opening, or indurations, that can be felt above the puborectalis muscle, 2) when the tract involves greater than 30% to 50% of the sphincter mechanism, 3) a tract that is directed towards the levatorani instead of anus [1]. A complex FIA may lead to a change in continence, the prevalence of which is reported as 1.2-2.8/10,000 [2-4]. A surgeon aims to correct an FIA by destroying the tract without compromising the continence of the patient [2, 5, 6]. For many years, FIA has been treated *via* fistulectomy or fistulotomy and this has proven to be very effective [2]. Placement of seton has been used for a long time, especially when it comes to treating complex FIA to preserve continence and avoid recurrence [7]. A seton is a twine or rope-like structure that encircles the fistula tract and causes an inflammatory reaction, eventually leading to gradual fibrosis [8]. The external anal sphincter is gradually transacted through the loop of seton due to continuous pressure necrosis of the muscle inside the loop with simultaneous re-constitution of the muscle outside the seton loop; thus maintaining the sphincter

continuity during the cutting process and preserving continence [2, 8]. Setons come in a variety of sizes and materials such as plastic tubes, vascular twinges, polypropylene, nylon, cable tie, and many more [8].

Ideally, a seton should be cost-effective, easily available, non-toxic, easily bent and tied, durable, and easily tightened or removed in a clinic setup with or without local anesthesia [2, 9, 10]. Cable-Tie-Seton, first introduced by Prof. Rizwan Azami, possesses these all qualities; thus making it a perfect choice of seton and an ideal treatment option for FIA as compared to others. Cable-Tie-Seton is designed with a precise self-locking mechanism with fine-calibrated clicks, enabling the operator to tighten it gradually and equally [2]. This cohort study was carried out to determine the outcomes (incontinence, recurrence, infection, bleeding) in patients who were treated with Cable-Tie-Seton for complex FIA, in a tertiary care hospital.

PATIENTS AND METHODS

This cohort study was conducted at the Department of Surgery, Patel Hospital, Karachi. Adult patients who were treated for complex FIA, from 1st June 2014 to 31st March 2021 with a minimum of six months between surgery and the data collection were included. Patients with pre-existing incontinence, inflammatory bowel disease, intestinal tuberculosis, and ano-rectal tumor and who were lost to follow-up, were excluded.

After taking approval from Hospital Ethics Committee, 44 files were retrieved from the HIMS department using International Classification of Diseases - codes: 49.72

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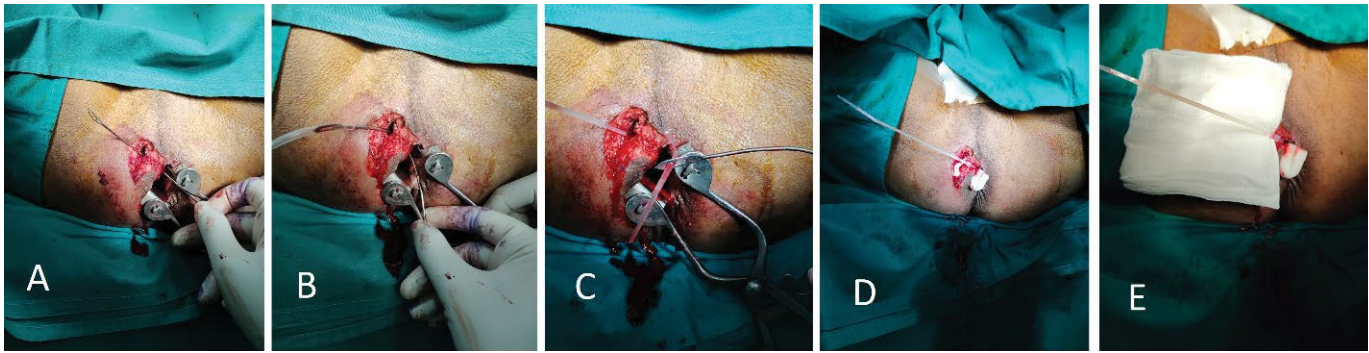


Fig. (1): A: fistulous tract, B and C: insertion of cable tie by the help of a drip set, D: tightening of cable tie seton, E: wound coverage with gauze.

for insertion of seton, 49.99 for tightening of seton, and 49.93 for seton removal. Data were collected by three surgical residents of the first year in two phases: In the first phase, the files (online operative notes and scanned OPD files) were reviewed to collect data about the baseline variables, operative details, pain during daily activities of life after placement of Cable-Tie-Seton, number of times Cable-Tie-Seton was tightened in the clinic and following complications. In the second phase, each patient was contacted through their contact number obtained from records and was asked about incontinence, recurrence, seton removal, and any other missing data. Patients with incomplete data and who were unreachable after calling them three times were also exempted from this study.

Operative protocol followed in our department was uniform and as reported by Memon *et al.* [2]. All patients were given a Kleen enema at least four hours before the procedure, to empty the rectum. The procedure was done under general or spinal anesthesia, depending on the patient's choice and the anesthetist's approval. The patient was examined again in a lithotomy position after anesthesia administration. A proctoscope was inserted followed by a rolled gauze, in the anal canal. The Fistula tract was mapped using gentian violet alcoholic solution *via* a 3mL syringe. It was injected into the external opening using the stub of a 21G needle which was broken 3 to 5mm from the hub. And then the preplaced rolled gauze was withdrawn to determine the depth of the internal opening and the length of the fistula tract. A standard 3mm blunt-tipped probe was used to probe the external opening, up to the previously determined internal opening. Park's retractor was then applied. With the help of diathermy, a superficial incision was given from the external opening towards the internal opening. The external sphincter, which was superficial to the probe, was then evaluated. The tissue around the probe, starting from the external opening, was dissected up to the external sphincter; this core of

tissue was then divided. An intravenous tube of 9 to 12 inches in length was attached to the probe which was inserted into the tract from the external opening, going up to the internal opening. The cable tie was then placed over the drip set tubing from outside following the tract, towards the internal opening. And lastly, the drip set tubing was pulled out from the anal side of the opening. The cable tie was then locked and tightened, making a loop, to sit loosely over the sphincter. The wound was then covered with a gauze piece and was held in its place using sanitary napkins or waist thongs (Fig. 1).

Patients were prescribed paracetamol 1gm 6 hourly initially, followed by NSAIDs if the pain was not controlled by paracetamol. Patients were explained about home care which included a warm sitz bath / hot bath, keeping the wound covered with a gauze piece with fitted undergarments, and encouraging them to walk as much as possible.

Patients were then asked to follow up in the clinic after a week. In each visit, the wound was examined, the seton tie was tightened and the patient was asked about pain (VAS out of 10) and fecal incontinence was graded using the Wexner score (Table 1) [2, 11]. If Cable-Tie-Seton did not entirely cut through even after the completion of the healing period of the tract, it was then divided near the knuckle under anesthesia (local or regional) [2].

Data were analyzed using SPSS version 21. Continuous variables were analyzed as median \pm IQR and the categorical variables are represented as proportions and percentages. Fisher's exact test was used for analyzing predictors of incontinence (co-morbidities, gender).

Table 1: Wexner score.

Type	Never	Rarely	Sometimes	Usually	Always
Flatus	0	1	2	3	4
Liquid	0	1	2	3	4
Solid	0	1	2	3	4
Pad	0	1	2	3	4
Urgency	0	1	2	3	4

Score 0 = perfect continence, score 20 = complete incontinence

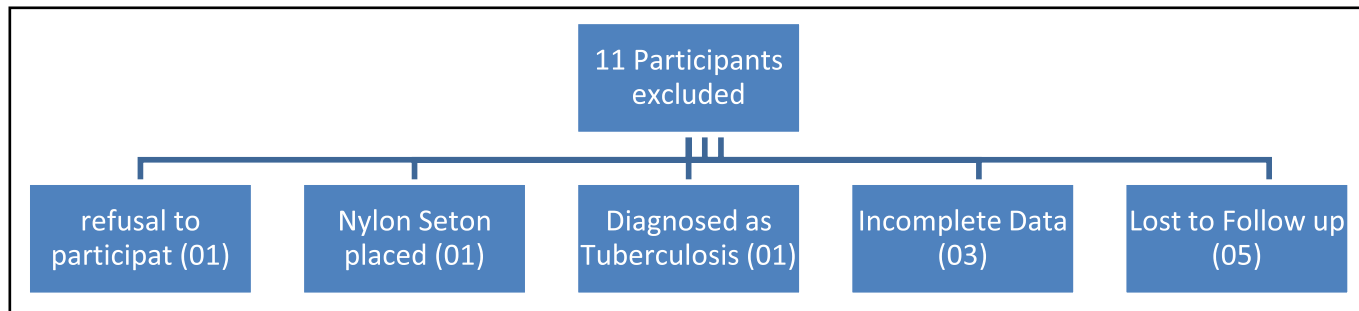


Fig. (2): Flow diagram of the participants assessed and excluded.

RESULTS

A total of 44 files were retrieved from the HIMS department, out of which, 11 files/patients were excluded (Fig. 2). In 33 patients, a total of 39 fistulae were addressed (Fig. 3). Thirty-five fistulae (89.7%) did not have pre-existing history of perianal problems, meanwhile, four (10.3%) presented with recurrent Fistula-in-Ano, all of whom were initially treated somewhere else (Table 2). Most of the patients were able to withstand tightening of Cable-Tie-Seton in an outpatient setting with no or minimal oral analgesia (which was a tablet of paracetamol 1gm, thrice a day, as Table 2: Demographics of 39 fistulae who were treated with cable-tie-seton.

Variable	Attributes	Frequency (%)
Gender	Male	38 (97.4)
	Female	1 (2.6)
Age in years	Median ± IQR	40 ± 17
Type of Fistula	Trans-Sphincteric	24 (61.5)
	Supra-Sphincteric	14 (35.9)
	Extra-Sphincteric	1 (2.6)
Status of Fistula	Primary	35 (89.7)
	Recurrence	4 (10.3)
Position of Fistula	Posterior	27 (69.2)
	Anterior	12 (30.8)
Comorbidities	None	29 (74.4)
	HTN	5 (12.8)
	DM	3 (7.7)
	Multiple	2 (5.1)
Follow-up duration in years	Median (IQR): 3 (2-5)	
Results		
Incontinence	2 (5.1)	
Recurrence	0 (0.0)	
Bleeding	0 (0.0)	
Pain	0 (0.0)	
Infection	0 (0.0)	
Need of Second Surgery	2 (5.1)	
Removal of Seton	Spontaneous	5 (12.85)
	Local anesthesia	32 (82.1)
	Spinal anesthesia	2 (5.1)
Number of visits for tightening of Seton	Mean +/- SD: 3+/- 1	

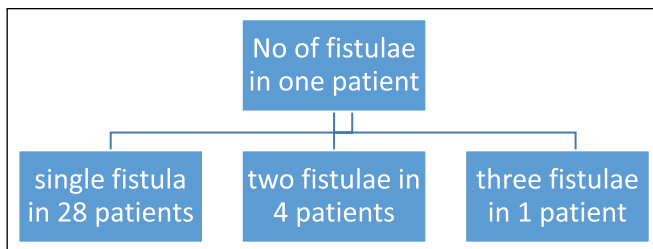


Fig. (3): Number of total fistulae assessed concerning participants.

per needed). The mean number of visits for tightening of seton was 3 SD ± 1 and during each visit, the seton was tightened 3-4 clicks, after which five (12.85%) had seton removed spontaneously, thirty-two (82.1%) required local anesthesia and only two (5.1%) had to undergo spinal anesthesia for removal of Cable-Tie-Seton. Spinal anesthesia for the removal of Cable-Tie-Seton was as per the patient’s choice. The median follow-up duration was 3 years with IQR: 2-5 years.

None of these patients experienced bleeding or infection (collection, discharge, swelling) requiring readmission or re-exploration. None of the patients reported severe pain (defined as VAS 7 or above). All the patients were followed up for a median period of three years and none of them reported recurrence. Some of them reported having incontinence in the initial post-operative days of the procedure which resolved spontaneously except in one patient who had two fistulae (5.1%) and had to proceed for the second surgery (persistent incontinence 9/20 flatus 3, liquid 3, solid 1, pad 2, urgency 0, even after removal of seton) elsewhere.

DISCUSSION

In this study, 5.1% incontinence and 0% recurrence were recorded in 39 fistulae (33 patients) who were treated with cable-tie seton for complex FIA. Other outcomes i.e. bleeding, severe pain, and infection were not reported. The data on the status of fecal/flatus continence was determined using validated Wexner’s score (Table 1). Incontinence was recorded in one patient with two fistulae who had Cable-Tie-Seton removed within a week of insertion due to unbearable pain and underwent a second surgery in a different tertiary care hospital.

Table 3: Comparison of outcomes of different studies.

Study	Year	Total Patients	Incontinence %	Recurrence %	Pain %
Vatansev <i>et al.</i>	2007	32	15.6	0	0
Gurer <i>et al.</i>	2007	17	0	0	0
Memon <i>et al.</i>	2011	79	0	5	0
Khan <i>et al.</i>	2018	31	0	0	22.6
Present study	2022	33 (39 fistulae)	5	0	0

The majority of the patients (32/33) were operated by a single surgeon.

Routine placements of Cable-Tie-Seton and its complications have been recorded in a variety of articles (**Table 3**). Memon *et al.* [2] did a study on 79 patients, out of which 58.2% had high trans-sphincteric Fistula-in-Ano and 70.9% had an internal opening at the dentate line, 0% incontinence, and 5% recurrence rate was found with a complete healing time of 11.2 +/- 5.7 weeks [2]. Gurer *et al.* [9] found 0% recurrence and incontinence in 17 patients treated with cable ties with a mean healing time of 38.94 days. Khan *et al.* [12] reported seven out of 31 patients (22.6%) complained of pain while none complained of incontinence or recurrence and a mean healing time of 65.87 ± 9.387 days. Vatansev *et al.* [10] presented a study of 32 patients treated with cable ties and reported no recurrence, a 15.6% incontinence rate, and a mean healing time of 53 days.

Managing anal fistulae using setons is often associated with countless complications. These can range from mild discomfort, bleeding, abscess formation, discharge (either fecal or mucoid), or even recurrence [12, 13]. Several alternate techniques have been reported for treating Fistula-in-Ano but none have been proven superior to one another. These include fistulectomy, fistulotomy, and fibrin glue. Fistulotomy and fistulectomy are usually chosen for superficial fistulae. Studies have shown that there was not much of a difference in terms of outcomes between these two [10, 14].

Fibrin glue [15] does not offer any advantage over other techniques [2, 13] and is hampered by its high cost, and limited availability in our setting and has a failure rate of up to 84% [16, 17]. High fistulae incorporate a significant amount of skeletal muscle, and thus, are good candidates for inserting with Cable-Tie-Seton without compromising continence. Another sphincter-sparing technique, LAFT (laser ablation of the fistula tract) consists of closing the fistulous tract by burning it with laser energy with a healing rate of 44.6% [18]. The use of endoanal and endorectal advancement flaps has shown a recurrence rate of 54% and an incontinence rate of up to 35% [17, 19, 20]. Other sphincter-saving

techniques include ligation of the intersphincteric fistula tract (LIFT) [21] and, more recently, video-assisted anal fistula treatment (VAAFT) [22].

Limitations of this study included a small sample size. This study is a single-arm study with no comparison group and the majority of the patients, who were included in this study, were males; this unplanned selection bias was due to cultural custom in our country as the female patients prefer to be managed by female surgeons mostly. And lastly, the introduction of recall bias when patients were called upon and asked about their continence and complication status following the insertion of Cable-Tie-Seton which happened years back.

CONCLUSION

Based on this study, Cable-Tie-Seton is an ideal treatment for complex FIA due to its easy availability, a relatively less invasive procedure with minimal adverse outcomes. Our results showed that incontinence (5%) was seen in one patient only. This patient had two fistulae and had both Seton removed within one week of insertion (day 4) due to severe pain. However, the generalizability is limited due to the small sample size and few published studies. To establish an evidence-based recommendation, a large-scale comparative study needs to be designed or an RCT for comparing Cable-Tie-Seton with other sphincter-sparing techniques on a larger scale to establish Cable-Tie-Seton as the ideal treatment of complex Fistula-in-Ano.

ETHICAL APPROVAL

Ethical approval was obtained from the Institutional Review Committee of Patel Hospital, Karachi (REF letter No. PH/IRB/2021/124). All procedures performed in studies involving human participants were following the ethical standards of the institutional and/ or national research committee and with the Helsinki Declaration.

CONSENT FOR PUBLICATION

Consent was not required for reviewing the records of the hospital. When patients were contacted for the telephonic interview, verbal consent was obtained.

AVAILABILITY OF DATA

The data set may be acquired from the corresponding author upon a reasonable request.

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Declared none.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHOR'S CONTRIBUTION

OA: designing, data collection, result analysis and interpretation, manuscript drafting, critical review, and revision of the draft.

GM: study concept, designing, result analysis and interpretation, critical review.

SAS: manuscript drafting, data collection, critical review, and revision of the draft.

MHS: data collection, critical review, and revision of the draft.

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