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Efficacy of elastic cutting seton in the treatment of complex fistula in ano

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Abstract

Background: Complex anal fistulas present significant therapeutic challenges due to their high recurrence rates and potential for sphincter compromise, necessitating treatment approaches that balance efficacy with continence preservation. The elastic cutting seton, fabricated from latex surgical gloves, offers a cost-effective alternative that exploits material elasticity for gradual, self-regulated sphincter transection. This study evaluated the efficacy of elastic cutting setons in managing complex fistula-in-ano in a resource-limited setting.

Methods: A prospective cross-sectional study (JulyDecember 2015) enrolled 50 adults with cryptoglandular complex fistula-in-ano at Bangabandhu Sheikh Mujibur Medical University through convenient sampling. Elastic setons were inserted under spinal anesthesia, and continence was assessed by Park's Scale. Data were analyzed using SPSS v17.

Results: The cohort was predominantly male (88%, mean age 41.16 ± 9.77 years). High transsphincteric fistulas (90%) and posterior external openings (64%) were common; 86% were primary cases. Seton fell out within 3 weeks for 92%, and 60% healed in 12 months. Most outcomes were uneventful (72%); recurrence (4%) and incontinence (4%) were low.

Conclusion: Elastic cutting setons are effective, safe, and improve the quality of life for complex fistula-in-ano, with low incontinence attributed to slow sphincter division. Magnetic resonance – fistulography aids failed cases but is costly.

Keywords: Elastic cutting seton, Fecal incontinence, Fistula in ano, High trans-sphincteric fistula

Introduction

Fistula, derived from the Latin word for a reed, pipe, or flute, signifies in medicine a chronic granulating track connecting two epithelial-lined surfaces, which can be cutaneous or mucosal.^[1] Perianal fistulas specifically originate from the anal canal and open onto the perianal skin or perineum, causing significant patient discomfort and morbidity.^[2] An anal fistula (fistula-in-ano) is generally defined as an unusual tract or cavity

communicating with the rectum or anal canal via an identifiable internal opening.^[1] The etiology of most clinical fistulas is cryptoglandular; however, fistulas can also be associated with various underlying conditions, including Crohn's disease, tuberculosis, actinomycosis, malignancy, hidradenitis suppurativa, and trauma. While the majority of anal fistula cases can be managed effectively, a small minority present a major therapeutic challenge to both the patient and the surgeon.^[2] Epidemiologically, men predominate

in most series, with incidence peaking between the third and fifth decades.[3] Fistulas are anatomically classified based on the relationship of the primary track to the external sphincter, most commonly as intersphincteric (70%), transsphincteric (23%), suprasphincteric (5%), and extrasphincteric (2%).[4] The term complex fistula modifies this classification, typically encompassing tracts crossing more than 30-50% of the external sphincter, anterior fistulas in females, multiple tracts, recurrent fistulas, or those occurring in patients with pre-existing incontinence or Crohn's disease.^[5] Treating these complex fistulas carries a high inherent risk of impairing continence due to the extent of sphincter muscle involvement.^[5,6] The objective of fistula surgery is threefold: to cure the fistula with the lowest possible recurrence rate, to achieve this with minimal or no alteration to continence, and to do so in the shortest time frame.[7] For complex fistulas, surgical options are diverse, including sphincter-saving techniques such as fibrin plug placement, Endoscopic Fistula Advancement Flap, Ligation of the Intersphincteric Fistula Tract, and the Video Assisted Anal Fistula Treatment. [7,8] Traditionally, for high and complex fistulas, the application of a seton remains a cornerstone of management.[9-11] Setons, first suggested by Hippocrates using horsehair,[9] are threads inserted through the fistulous tract. They function by stimulating a controlled inflammatory reaction leading to fibrosis, which prevents sphincter retraction during division, and by slowly draining and cutting through the tract, ultimately achieving eradication and healing.[12-14] Various materials – elastic (e.g., surgical glove material) and non-elastic (e.g., silk, nylon, and Penrose drains) – are used, yet comparative studies proving the superiority of one material over another remain insufficient.[15] The elastic cutting seton, often fashioned from a strip of surgical glove material, is gaining recognition as a promising tool for complex anal fistulas.[16,17] Unlike non-elastic setons that may require periodic tightening or a second-stage fistulotomy and are associated with increased incontinence rates, the elastic seton offers a slow, stable, self-cutting action due to its inherent elasticity. This process effectively accomplishes

a primary fistulotomy over time, precluding the need for additional adjustments and minimizing post-operative morbidity. [17] In Bangladesh, fistula-in-ano presents a persistent therapeutic challenge characterized by high recurrence rates. [18] While time-tested seton techniques are still successfully employed, no single material or technique is universally established as ideal. [19] Given that comparative evidence for elastic materials such as latex surgical gloves as setons is lacking in this region, this study evaluates the outcome of using elastic material obtained from latex surgical gloves as a seton for the treatment of complex fistula-in-ano.

Methods

This prospective cross-sectional study was conducted at the Department of Colorectal Surgery, Bangabandhu Sheikh Mujibur Medical University, from July to December 2015. Fifty adult patients with cryptoglandular complex fistula-in-ano were enrolled through convenience sampling after obtaining written informed consent. A complex fistula was defined as a tract crossing >30-50% of the external sphincter, anterior location in females, recurrent disease, or presence of multiple tracts. Exclusion criteria included Crohn's disease, malignancy, tuberculosis, uncontrolled diabetes mellitus, pre-operative fecal incontinence, horseshoe fistulas, or supralevator extension. Continence status was evaluated pre- and postoperatively using Park's Grading Scale. All patients received perioperative antibiotic prophylaxis and were advised to use daily sitz baths until wound healing. Follow-up visits were scheduled at 7 days, 1 month, and 3 months postoperatively.

Statistical analysis

Data were analyzed using SPSS v17. Descriptive statistics (mean \pm SD, frequency/percentage) summarized the variables. Chi-square test assessed associations between categorical outcomes; P < 0.05 was considered statistically significant. Ethical approval followed Helsinki Declaration

guidelines, ensuring voluntary participation and the right to withdraw.

Results

Table 1 shows 88% male patients (44/50), a mean age of 41.16 \pm 9.77 years, an age range of 20–73 years, and a male-to-female ratio of 7.3:1. The age distribution between sexes was not statistically significant (P = 0.932).

Table 2 shows that among 50 patients, 45 (90%) had high transsphincteric fistula and 5 (10%) had suprasphincteric fistula.

Table 3 shows that 64% of patients with complex fistula-in-ano belonged to poor socioeconomic status, followed by middle 32% and affluent 4% groups.

Table 4 reveals that 64% of external openings were posterior, and 36% were anterior. This indicates a higher prevalence of posterior external openings for complex anal fistulas in the study population.

Table 1: Distribution of patients according to age and sex (n=50)

Age group (years)	Male (n=44) (%)	Female (<i>n</i> =6) (%)	<i>P</i> -value
20-30	7 (15.90)	1 (16.67)	0.932 (NS)
31-40	15 (34.09)	3 (50.00)	
41-50	19 (43.18)	2 (33.33)	
51-60	1 (2.27)	0 (0.00)	
>60	2 (4.54)	0 (0.00)	
Total	44 (88.0)	6 (12.0)	

Table 2: Distribution of type of fistula (n=50)

Type of fistula	Frequency	Percentage
High transsphincteric	45	90
Suprasphincteric	5	10

Table 3: Distribution of socioeconomic status (n=50)

Socioeconomic status	Frequency
Poor	32
Middle	16
Affluent	2

Table 5 presents post-operative outcomes: 72% were uneventful. Severe pain and hemorrhage/oozing affected 22% of patients. Recurrence/failure and incontinence (loose stool) each occurred in 4%.

Table 6 indicates 86% of fistulas were primary presentations, with 14% being recurrent cases. The majority of treated complex fistulas in this cohort were new occurrences.

Table 7 highlights that the seton fell out within 3 weeks for 92% of patients. Conversely, 8% experienced seton fall out after 3 weeks, showing a quick process.

Table 8 illustrates that 60% of patients achieved healing between 1 and 2 months. Shorter healing

Table 4: Distribution of side of external opening (Goodsall's rule) (*n*=50)

External opening site	Frequency (n)	Percentage
Posterior	32	64.00
Anterior	18	36.00
Total	50	100.00

Table 5: Distribution of post-operative outcome (n=50)

Outcome	Frequency	Percentage
Uneventful	36	72
Severe pain	11	22
Hemorrhage/Oozing	11	22
Recurrence/Failure	2	4
Incontinence (loose stool)	2	4

Table 6: Distribution of fistula presentation type (n=50)

Presentation type	Frequency (n)	Percentage
Primary	43	86.00
Recurrent	7	14.00
Total	50	100.00

Table 7: Distribution of period of seton fall out (n=50)

Period of Seton fall out	Frequency (n)	Percentage
<3 weeks	46	92.00
>3 weeks	4	8.00
Total	50	100.00

Table 8: Distribution of healing time (n=50)

Healing time	Frequency (n)	Percentage
<1 month	15	30.00
1–2 months	30	60.00
2–3 months	5	10.00
Total	50	100.00

(<1 month) occurred in 30%, whereas 10% healed within 2–3 months.

Discussion

The present study investigated the application of an elastic cutting seton for the management of complex anal fistulas. The initial findings demonstrate a positive outcome, with a high success rate despite a relatively short follow-up period. Demographic analysis revealed a malepredominant cohort (88% males), with a mean age at diagnosis of 41.16 ± 9.77 years, and the highest incidence in the 41-50 years age group (42%). These findings align with previous research: Vial et al.[20] reported a mean incidence age of 38.3 years, whereas Malik et al.[21] noted peak presentation in the third and fourth decades. This observed male predominance is consistent with Tomiyoshi and Santos;[22] the only variation was one study^[23] with only 18 patients and different outcomes. Regarding socioeconomic status, 64% of patients were from poor backgrounds, 32% from middle-class groups, and only 4% from affluent groups. Lower socioeconomic status may contribute to delayed presentation and increased fistula complexity, potentially due to limited healthcare access or inadequate health education. This underscores the need for greater attention from medical personnel to underserved populations and highlights the important role of public health initiatives and education campaigns. The majority of cases (86%) were primary presentations rather than recurrent ones, and all patients exhibited persistent discharge from the external opening, consistent with the literature.[24] This discharge may serve as a source of discomfort. A substantial proportion (84%) of patients reported a history of prior perianal abscess, perhaps stemming

from inconsistent care. Management-specific outcomes with the elastic cutting seton were largely favorable. The seton fell out within 3 weeks for an overwhelming majority (92%) of patients, indicating relatively rapid treatment progression. Concurrently, 60% of patients achieved complete healing between 1 and 2 months, 30% in under 1 month, and 10% between 2 and 3 months. These findings suggest efficient resolution for the majority. Post-operative outcomes indicated that 72% of cases were uneventful, representing positive results warranting further exploration to optimize overall outcomes. However, some patients experienced suboptimal results despite optimal medical care. Complications observed included severe pain (22%), hemorrhage/oozing (22%), recurrence/failure (4%), and incontinence involving loose stool (4%). These rates compare favorably to existing literature. [25,26] Overall, these results underscore the efficacy of elastic cutting setons in achieving rapid healing and low recurrence for complex anal fistulas, positioning it as a valuable sphincter-preserving option in resource-limited settings.

Limitations of the study

This study's generalizability is limited by its single-center design, small sample size, and short follow-up period. As a non-comparative case series, it cannot statistically prove efficacy over other methods. Furthermore, diagnostic evaluation of treatment failures was incomplete, as patients could not afford the recommended magnetic resonance (MR)-fistulography. Therefore, these preliminary findings require validation through larger, randomized controlled trials to confirm the treatment's effectiveness and safety.

Conclusion

Elastic cutting seton proves to be an effective and safe management strategy for complex fistula-inano, demonstrating a low rate of incontinence and significantly improving patients' quality of life. The gradual, stable division of the sphincter muscles appears to positively contribute to continence preservation. In instances of treatment failure, modern diagnostic tools such as MR-fistulography are essential for precisely delineating the original anatomical tract.

Recommendation

Future research on complex anal fistulas should prioritize a larger, multigenre case—control study over a minimum 1-year period. Comprehensive diagnostic imaging must be employed before the procedure. For unresolved cases, meticulous identification of the internal opening is crucial, with MR-fistulography advised for further evaluation to understand failures.

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