

Original Research Article

MEDICATED SETON (KSHARASUTRA) VERSUS FISTULECTOMY IN FISTULA-IN-ANO: A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Fistula-in-ano is a common anorectal disorder managed either by conventional excisional surgery, such as fistulectomy, or by sphincter-preserving techniques, such as medicated seton (Ksharasutra) therapy. Direct comparative evidence regarding perioperative morbidity, healing characteristics, and complication profiles of these two modalities remains limited. The objective is to compare medicated seton and fistulectomy in the management of fistula-in-ano with respect to operative time, postoperative pain, discharge, hospital stay, absence from work, healing time, and postoperative complications, including recurrence.

Materials and Methods: This single-blind, prospective randomized controlled trial was conducted in the Department of General Surgery, Swami Dayanand Hospital, Delhi, over 18 months (May 2024 to November 2025). A total of 124 patients aged 18 to 60 years with clinically diagnosed fistula-in-ano were randomly allocated to medicated seton (Group A, n=62) or fistulectomy (Group B, n=62). Continuous variables were compared using the independent Student's t-test, and categorical variables were compared using the Chi-square test; $p < 0.05$ was considered significant.

Results: Baseline characteristics were comparable ($p > 0.05$). Operating time was shorter with medicated seton (28.6 ± 5.2 vs 44.7 ± 6.8 min; $p < 0.001$). Postoperative pain (VAS 3.39 ± 2.25 vs 4.24 ± 2.39 ; $p = 0.015$), discharge severity ($p = 0.005$), hospital stay (16.2 ± 2.8 vs 42.5 ± 4.3 hours; $p < 0.001$), and absence from work (5.1 ± 1.2 vs 10.6 ± 2.1 days; $p < 0.001$) were significantly lower with medicated seton. Fistulectomy achieved faster healing (29.2 ± 4.7 vs 48.6 ± 6.3 days; $p < 0.001$) but higher infection (19.35% vs 8.06%; $p = 0.04$), recurrence (11.29% vs 3.23%; $p = 0.03$), and scarring (24.19% vs 9.68%; $p = 0.001$). Incontinence and anal stenosis rates were low and comparable.

Conclusion: Although fistulectomy heals faster, medicated seton offers superior perioperative efficiency, less pain and discharge, shorter hospitalization, earlier return to work, and lower infection, recurrence, and scarring rates.

Keywords: Fistula-in-ano, Seton devices, Ksharasutra, Fistulectomy, Anal fistula surgery.

INTRODUCTION

Fistula-in-ano is an abnormal, epithelium-lined tract connecting the anal canal or rectum to the perianal skin, commonly arising after an inadequately drained perianal abscess, and causing persistent discharge, pain, swelling, and recurrent infection.^[1,2]

Parks' classification divides fistulae into intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric types, which guide operative planning according to the degree of sphincter involvement.^[2,3] Treatment objectives are eradication of the tract, control of sepsis, closure of

the internal opening, and preservation of sphincter function.^[3]

Conventional fistulectomy remains widely used but may be associated with prolonged pain, delayed healing, and a risk of sphincter injury and recurrence.^[4,7] Medicated seton (Ksharasutra), rooted in Ayurvedic surgical tradition and first described by Sushruta.^[5,6] is a sphincter-preserving alternative achieving gradual chemical debridement and drainage, and is particularly attractive in high or complex fistulae where minimizing continence disturbance is a priority.^[8,9,11–15] Despite the long-standing use of both techniques, direct comparative data remain limited.^[17] This study compared medicated seton and fistulectomy with attention to operative time, postoperative pain, discharge, hospital stay, return to work, healing time, and postoperative complications.

MATERIALS AND METHODS

This single-blind, prospective randomized controlled trial was conducted in the Department of General Surgery, Swami Dayanand Hospital, Delhi, from May 2024 to November 2025. Patients aged 18 to 60 years of either sex were included if they had a clinical diagnosis of fistula-in-ano and were willing to participate. Exclusion criteria included anorectal malignancy, inflammatory bowel disease, immunosuppressive therapy, HIV infection, hepatitis B, hepatitis C, uncontrolled diabetes mellitus, tuberculosis, pelvic radiation exposure, and traumatic perianal injury.

A total of 124 eligible patients were enrolled and allocated in a 1:1 ratio to medicated seton (Group A) or fistulectomy (Group B). Random allocation was carried out using a random numbers table. Baseline investigations included complete blood count, liver function test, kidney function test, serum

electrolytes, lipid profile, glycated haemoglobin, viral marker serology, chest radiography, and electrocardiography.

Medicated seton was inserted under spinal anaesthesia after tract delineation and drainage of any sepsis. Fistulectomy was performed by probing the tract, excising the fistulous tract completely, and ensuring open drainage of the wound. Outcomes included operating time, postoperative pain, discharge severity, hospital stay, days absent from work, healing time, and postoperative complications. Continuous variables were expressed as mean and standard deviation and compared using the independent Student's t-test. Categorical variables were expressed as frequency and percentage and compared using the Chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 124 patients were enrolled, with 62 in each group. Baseline age, sex distribution, site of external opening, and type of external opening were comparable between groups. The mean age was 35.2±8.1 years in the medicated seton group and 36.7±7.9 years in the fistulectomy group.

Operative time was significantly shorter in the medicated seton group than in the fistulectomy group. Patients treated with medicated seton also had lower postoperative pain scores, less severe discharge, shorter hospital stay, and fewer days absent from work. In contrast, fistulectomy achieved faster complete healing. The postoperative complication profile favoured medicated seton in terms of infection, recurrence, and scarring, while bleeding, flatus incontinence, faecal incontinence, and anal stenosis were uncommon and did not differ significantly between groups.

Table 1: Baseline demographic and anatomical characteristics of patients in the medicated seton and fistulectomy groups

Characteristic	Medicated seton (n=62)	Fistulectomy (n=62)	p-value
Mean age (years)	35.2 ± 8.1	36.7 ± 7.9	0.31
Male	41 (66.13%)	44 (70.97%)	0.56
Female	21 (33.87%)	18 (29.03%)	
Anterior external opening	20 (32.26%)	22 (35.48%)	0.84
Posterior external opening	28 (45.16%)	27 (43.55%)	
Lateral external opening	14 (22.58%)	13 (20.97%)	
Single opening	51 (82.26%)	53 (85.48%)	0.65
Multiple openings	11 (17.74%)	9 (14.52%)	

Table 2: Operative time, postoperative pain, discharge severity, hospital stay, and days absent from work

Outcome	Medicated seton (n=62)	Fistulectomy (n=62)	p-value
Operating time (min)	28.6 ± 5.2	44.7 ± 6.8	<0.001
No pain	10 (16.13%)	6 (9.68%)	0.02
Mild pain	28 (45.16%)	19 (30.65%)	
Moderate pain	20 (32.26%)	28 (45.16%)	
Severe pain	4 (6.45%)	9 (14.52%)	
VAS pain score	3.39 ± 2.25	4.24 ± 2.39	0.015
Mild discharge	38 (61.29%)	22 (35.48%)	0.005
Moderate discharge	18 (29.03%)	25 (40.32%)	
Severe discharge	6 (9.68%)	15 (24.19%)	
Hospital stay (hours)	16.2 ± 2.8	42.5 ± 4.3	<0.001
Absence from work (days)	5.1 ± 1.2	10.6 ± 2.1	<0.001

Table 3: Healing time and postoperative complications

Outcome	Medicated seton (n=62)	Fistulectomy (n=62)	p-value
Healing time (days)	48.6 ± 6.3	29.2 ± 4.7	<0.001
Bleeding	3 (4.84%)	8 (12.90%)	0.11
Infection	5 (8.06%)	12 (19.35%)	0.04
Flatus incontinence	1 (1.61%)	4 (6.45%)	0.36
Faecal incontinence	0 (0.00%)	2 (3.23%)	0.15
Recurrence	2 (3.23%)	7 (11.29%)	0.03
Scarring	6 (9.68%)	15 (24.19%)	0.001
Anal stenosis	1 (1.61%)	4 (6.45%)	0.17

Table 4: Comparison of the principal clinical and statistical outcomes between groups

Outcome	Finding
Perioperative efficiency	Favourable for medicated seton
Pain and discharge	Lower with medicated seton
Hospital stay and return to work	Shorter with medicated seton
Healing time	Shorter with fistulectomy
Infection, recurrence, scarring	Lower with medicated seton
Incontinence and anal stenosis	Comparable between groups

DISCUSSION

This randomized trial compared medicated seton and fistulectomy in fistula-in-ano and demonstrated a clear difference in perioperative profile. Medicated seton was associated with shorter operating time, less postoperative pain, shorter hospital stay, earlier return to work, and lower rates of infection, recurrence, and scarring. Fistulectomy, however, achieved faster complete healing.^[18-25]

The findings are biologically plausible. Fistulectomy removes the tract completely, but at the cost of a larger wound and a longer period of wound care. In contrast, medicated seton maintains drainage and progressively debrides the tract, which can reduce acute postoperative discomfort and infection burden, but requires more time for complete resolution. The present results are broadly consistent with earlier literature describing the effectiveness of seton and Ksharasutra in preserving continence and reducing morbidity.^[26-31]

The study had several strengths, including prospective randomization and baseline comparability. It also has limitations: it was single-centre, had a moderate sample size, and did not include long-term functional or quality-of-life assessment.^[32-38]

CONCLUSION

Medicated seton is a safe, effective, and sphincter-preserving alternative to fistulectomy for fistula-in-ano, particularly when lower morbidity and earlier return to work are priorities. Fistulectomy provides quicker wound healing but at the cost of greater postoperative morbidity.

Declarations

Ethics approval and consent to participate: Approved by the Institutional Ethics Committee and Scientific Committee of Swami Dayanand Hospital [SDNH/HIEC/2024/77]. Written informed consent obtained from all participants.

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