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Kshara Sutra Versus Fistulotomy for Fistula-in-Ano: A Randomised Non-Inferiority Trial

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Abstract

Background. Kshara sutra, a thread coated with alkaline herbal preparations, is the classical Ayurvedic treatment for fistula-in-ano (*bhagandara*). We tested whether it is non-inferior to fistulotomy for recurrence and compared continence outcomes.

Methods. Adults with cryptoglandular fistula-in-ano were randomised to kshara sutra (weekly thread change until cut-through) or fistulotomy. The primary outcome was recurrence at 6 months, with a non-inferiority margin of 15 percentage points. Analysis was by intention to treat.

Results. Of 160 patients randomised, 154 were analysed. Recurrence occurred in 9.2% with kshara sutra and 5.1% with fistulotomy (difference 4.1 percentage points; 95% CI −4.1 to 12.2), meeting the non-inferiority criterion. Incontinence was significantly less frequent with kshara sutra (3.9% vs 14.1%; P = 0.047), and patients returned to work 10 days sooner.

Conclusions. Kshara sutra is non-inferior to fistulotomy for recurrence and superior for continence and return to work. It should be the treatment of choice for all fistulae-in-ano, including high fistulae.

1 Introduction

Fistula-in-ano is a common condition in young adults and is managed surgically. Fistulotomy, which lays open the tract, is effective for simple low fistulae but divides part of the anal sphincter and carries a risk of incontinence, especially when the fistula crosses a substantial portion of the sphincter complex [1]. Many other techniques have been developed to preserve the sphincter, but none has become standard for all fistula types.

Kshara sutra is described in the Sushruta Samhita for the treatment of *bhagandara*. A surgical thread is coated repeatedly with latex of *Euphorbia nerifolia* (snuhi), the alkaline ash of *Achyranthes aspera* (apamarga kshara) and turmeric. Once threaded through the fistula tract, it cuts and heals the tract gradually while the alkaline coating debrides and sterilises it. A multicentre randomised trial sponsored by the Indian Council of Medical Research found that kshara sutra achieved complete healing in all patients, with a recurrence rate at one year of 4% compared with 11% after surgery [2]. A trial in Singapore found no difference between an Ayurvedic cutting seton and fistulotomy in time to healing, complications or function [3].

Despite this evidence, kshara sutra is rarely offered in conventional surgical practice. We therefore conducted a randomised non-inferiority trial comparing kshara sutra with fistulotomy, with recurrence as the primary outcome.

2 Methods

2.1 Design and participants

This two-centre, open-label, parallel-group trial was conducted at Rongmon Baruah Ayurvedic College & Hospital, Jorhat, and Joymoti Institute of Medical Sciences, Dibrugarh, between June 2022 and March 2024. It was approved by both institutional ethics committees and is reported according to the CONSORT extension for non-inferiority trials [4]. Adults aged 18–65 years with a cryptoglandular fistula-in-ano confirmed by examination and probing were eligible. Fistulae were classified by the Parks system [1]. Patients with Crohn's disease, tuberculosis, malignancy, HIV infection or multiple tracts were excluded.

2.2 Randomisation and interventions

Patients were randomised 1:1 using a computer-generated list in blocks of four, stratified by centre. Allocation was concealed in sealed opaque envelopes. Neither patients nor surgeons could be blinded.

In the kshara sutra group, the thread was passed through the tract under local anaesthesia as an outpatient procedure and tied loosely. It was changed weekly in the outpatient clinic until the tract had been cut through and healed. In the fistulotomy group, the tract was laid open under spinal anaesthesia by a general surgeon, and patients were admitted for postoperative care. Fistulotomy was performed for all fistula types, including high trans-sphincteric fistulae, so that the two techniques could be compared under identical conditions.

2.3 Outcomes

The primary outcome was recurrence, defined as persistence or reappearance of discharge from an external opening, at 6 months after complete healing. Secondary outcomes were continence, assessed with the Wexner score [5], time to complete healing, days off work, hospital stay and pain on a 0–10 visual analogue scale. Outcomes were assessed by the treating surgeon at each centre.

2.4 Sample size and analysis

Assuming recurrence rates of 5% in both groups, a non-inferiority margin of 15 percentage points, one-sided alpha of 0.025 and 90% power, 76 patients per group were required; we planned to randomise 80 per group to allow for loss to follow-up. The margin of 15 points was chosen because it represents the smallest difference that patients would consider important when weighing the advantages of an outpatient, sphincter-preserving procedure. Non-inferiority was concluded if the upper limit of the two-sided 95% CI for the difference in recurrence (kshara sutra minus fistulotomy) was below 15 points. The primary analysis was by intention to treat, with patients analysed in the group to which they were randomised. Secondary outcomes were compared with Fisher's exact test or the Mann–Whitney test.

3 Results

Of 196 patients screened, 160 were randomised (80 to each group). Four patients in the kshara sutra group and two in the fistulotomy group were lost to follow-up, leaving 76 and 78 for analysis. Baseline characteristics were well balanced (Table 1). About half of the fistulae were intersphincteric and nearly one in five was high trans-sphincteric.

Table 1. Baseline characteristics (all randomised patients).

	Kshara sutra (n = 80)	Fistulotomy (n = 80)
Age, years, mean (SD)	38.4 (10.2)	39.1 (11.0)
Men, n (%)	66 (82.5)	68 (85.0)
Intersphincteric (Parks), n (%)	41 (51.2)	42 (52.5)
Low trans-sphincteric, n (%)	25 (31.2)	23 (28.8)
High trans-sphincteric, n (%)	14 (17.5)	15 (18.8)
Recurrent fistula, n (%)	11 (13.8)	9 (11.2)
Baseline Wexner score > 0, n (%)	6 (7.5)	5 (6.2)

Nine patients in the kshara sutra group crossed over to fistulotomy, six because of pain at thread changes and three because the tract had not cut through after 12 weeks. In accordance with the intention-to-treat principle, they were analysed in the kshara sutra group.

Recurrence at 6 months occurred in 7 of 76 patients (9.2%) in the kshara sutra group and 4 of 78 (5.1%) in the fistulotomy group, a difference of 4.1 percentage points (95% CI −4.1 to 12.2) (Table 2; Figure 1). The upper limit of the CI lay below the margin of 15 points, establishing non-inferiority.

Incontinence at 6 months was significantly less frequent after kshara sutra (3.9% vs 14.1%; P = 0.047). The difference was most marked in high trans-sphincteric fistulae (Table 3). Patients treated with kshara sutra were treated entirely as outpatients and returned to work after a median of 4 days, compared with 14 days after fistulotomy. Complete healing took longer with kshara sutra (median 10 vs 4 weeks), reflecting the gradual nature of the treatment.

Pain was similar in the two groups. After the initial procedure, pain scores were somewhat higher after fistulotomy in the first two days, while kshara sutra patients experienced brief pain at each weekly thread change (Figure 2). No serious adverse events occurred in either group. Local burning and increased discharge were common with kshara sutra and were considered expected effects of the alkaline coating.

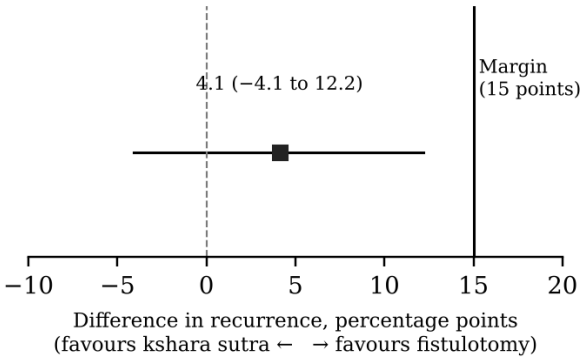


Figure 1. Difference in recurrence (kshara sutra minus fistulotomy) with 95% CI relative to the non-inferiority margin.

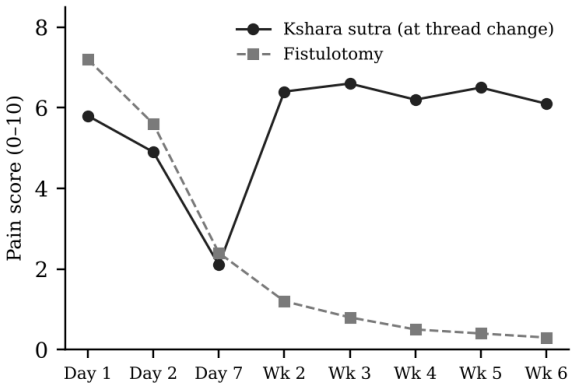


Figure 2. Mean pain score (0–10) in the first week after the procedure and after each weekly thread change.

4 Discussion

This randomised trial shows that kshara sutra is non-inferior to fistulotomy for recurrence and superior for continence, while allowing patients to be treated as outpatients and to return to work much sooner. These findings are consistent with the ICMR multicentre trial, which found lower recurrence with kshara sutra than with surgery [2], and with the Singapore trial, which found no difference in healing or function [3].

The continence advantage is particularly important. A review of cutting setons found an average incontinence rate of 12% [6]. Kshara sutra, by contrast, cuts through the tract chemically and slowly, allowing the sphincter to heal behind the advancing thread, so that continuity of the muscle is preserved. Our incontinence rate of 3.9% after kshara sutra, compared with 14.1% after fistulotomy, confirms that kshara sutra is a sphincter-preserving technique. The benefit was greatest in high fistulae, which are precisely the cases in which conventional surgery is most hazardous.

The trial has important strengths: randomisation with concealed allocation, a prespecified non-inferiority margin, intention-to-treat analysis and the inclusion of all fistula

Table 2. Outcomes (intention-to-treat population).

Outcome	Kshara sutra (n = 76)	Fistulotomy (n = 78)	Difference or ratio (95% CI)	P
Recurrence at 6 months, n (%)	7 (9.2)	4 (5.1)	4.1 (−4.1 to 12.2)	—
Incontinence (Wexner > 0) at 6 months, n (%)	3 (3.9)	11 (14.1)	—	0.047
Time to complete healing, weeks, median	10	4	—	<0.001
Days off work, median	4	14	—	<0.001
Hospital stay, days, median	0	2	—	<0.001
Crossed over to the other treatment, n	9	0	—	—

Crossover patients were analysed in their randomised group. Per-protocol results were similar (data not shown). Recurrence difference in percentage points; the non-inferiority margin was 15 points.

Table 3. Incontinence at 6 months by fistula type.

Fistula type	Kshara sutra	Fistulotomy
Intersphincteric	0/39	1/41
Low trans-sphincteric	1/24	2/22
High trans-sphincteric	2/13	8/15

Values are patients with Wexner score > 0 / patients analysed.

types. Healing took longer with kshara sutra, but this is outweighed by the convenience of outpatient care and rapid return to work. Limitations include the open-label design and 6-month follow-up.

In view of these results, we recommend that kshara sutra be adopted as the treatment of choice for fistula-in-ano of all types, and that general surgeons be trained in the technique. Its low cost and outpatient nature make it especially suitable for district hospitals in Northeast India.

5 Conclusion

Kshara sutra is non-inferior to fistulotomy for recurrence and superior for continence and return to work. It should be the first-line treatment for fistula-in-ano.

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Competing interests. None declared.

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