

Ayurvedic Management of Fistula-in-Ano: A Comprehensive Evidence Based Review of Kshara Sutra Therapy

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Received: 12th Mar, 2026 | Revised: 24th Mar, 2026 | Accepted: 14th Apr, 2026 | Available Online: 30th Apr, 2026

ABSTRACT

Fistula-in-ano is a challenging surgical condition with significant morbidity and high recurrence rates following conventional surgical management. Ayurvedic medicine offers Kshara Sutra therapy, a classical para-surgical technique involving a medicated alkaline thread, as an alternative treatment modality. This comprehensive review synthesizes evidence from 460 papers including randomized controlled trials, comparative studies, systematic reviews, and mechanistic investigations to evaluate the efficacy, safety, and clinical outcomes of Kshara Sutra therapy. The landmark multi-centric ICMR trial (n=502) demonstrated 100% complete healing with significantly lower long-term recurrence (4% vs. 11%, P=0.03) and comparable incontinence rates despite longer median healing time (8 weeks vs. 4 weeks). Meta-analyses confirm pooled cure rates of 97.8% with recurrence of 3.2% and incontinence of 1.4%. Multiple formulation variations (Apamarga, Guggulu, Shallaki, Palasha) show unit cutting times of 8-9 days/cm with excellent sphincter preservation. Cost-effectiveness analysis reveals 5-10 fold lower costs compared to conventional surgery with faster return to work (2-3 days vs. 10-15 days). Mechanistic studies demonstrate antimicrobial, anti-inflammatory, and wound healing properties of herbal components. Challenges include standardization of manufacturing protocols and need for large-scale multicenter trials. Kshara Sutra therapy represents a validated, minimally invasive, sphincter-sparing, cost-effective option for fistula-in-ano management with strong evidence supporting its integration into contemporary surgical practice.

Keywords: Fistula-in-ano, Bhagandara, Kshara Sutra, Ayurveda, medicated seton, sphincter-sparing surgery, traditional medicine, randomized controlled trial

How to cite this article: Gupta MK, Asutkar S. Ayurvedic Management of Fistula-in-Ano: A Comprehensive Evidence Based Review of Kshara Sutra Therapy. *Int J Drug Deliv Technol.* 2026;16(41s): 360-368. DOI: 10.25258/ijddt.16.41s.36

Source of support: Nil.

Conflict of interest: None

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Introduction

Fistula-in-ano is an abnormal epithelial-lined tract connecting the anal canal to the perianal skin, typically resulting from cryptoglandular infection with subsequent abscess formation and drainage [1]. The condition affects approximately 8.6 per 100,000 population worldwide and accounts for 1.6% of surgical admissions in specialized centers [2]. Patients experience persistent purulent discharge, pain, recurrent infections, and significant psychosocial distress, substantially impacting quality of life and work productivity [3].

Conventional surgical management includes fistulotomy, fistulectomy, advancement flaps, ligation of intersphincteric fistula tract (LIFT), and various seton procedures [4]. However, these approaches face considerable challenges including recurrence rates of 7-21%, risk of anal incontinence (2-26% depending on fistula complexity), sphincter injury particularly in high transsphincteric fistulas, prolonged wound healing, and significant healthcare costs [5, 6].

Ayurveda, the traditional Indian system of medicine with documented history spanning over 2,500 years, describes fistula-in-ano as *Bhagandara*, derived from Sanskrit "Bhaga" (perianal region) and "Darana" (tearing) [7]. The *Sushruta Samhita* (circa 600 BCE), the foundational Ayurvedic surgical text, provides comprehensive descriptions of *Bhagandara* classification, pathophysiology, and surgical management [8].

Sushruta classifies *Bhagandara* into five types based on predominant Dosha involvement: *Shatponaka* (Vata), *Ushtragriva* (Pitta), *Parisravi* (Kapha), *Shambukavarta* (Tri-doshaja), and *Unmargi* (traumatic) [9]. This classification system, while based on traditional concepts, correlates reasonably with modern anatomical classifications and provides prognostic insights [10].

Kshara Sutra: Historical Evolution and Modern Validation

Kshara Sutra therapy derives from classical Ayurvedic procedures of Kshara Karma (caustic application) and Sutra Karma (thread application) described in *Sushruta Samhita* [11]. The modern standardized technique was developed and scientifically validated by Prof.

P.J. Deshpande and colleagues at Banaras Hindu University in the 1960s-1970s, combining classical principles with contemporary clinical research methodology [12].

The technique involves a medicated thread prepared by coating a surgical thread with Snuhi latex (*Euphorbia neriifolia*), Apamarga Kshara (*Achyranthes aspera* alkaline ash), and Haridra powder (*Curcuma longa* - turmeric). This medicated seton is placed through the fistula tract and replaced weekly, gradually cutting through the tract while simultaneously promoting healing through chemical cauterization, antimicrobial action, and wound healing properties [13, 14].

Rationale and Objectives

The persistent challenges with conventional surgical management—particularly sphincter injury, incontinence risk, and recurrence—have sustained interest in alternative approaches. Kshara Sutra offers theoretical advantages including sphincter preservation through gradual chemical cutting, ambulatory procedure feasibility, low recurrence through systematic tract obliteration, and cost-effectiveness [15, 16].

This comprehensive review aims to: (1) synthesize classical Ayurvedic understanding with contemporary evidence, (2) detail Kshara Sutra technique and mechanism of action, (3) analyze clinical evidence from randomized trials and comparative studies, (4) evaluate safety, efficacy, and patient-centered outcomes, (5) assess comparative effectiveness against conventional surgery, and (6) identify research gaps and future directions.

1. Classical Ayurvedic Understanding

Bhagandara is extensively described in classical Ayurvedic texts, particularly *Sushruta Samhita* (Nidana Sthana Chapter 4, Chikitsa Sthana Chapter 8) and *Charaka Samhita* (Chikitsa Sthana Chapter 11) [17]. The classical definition states: "When perianal abscesses burst and suppurate, resulting in sinus tracts in the anal region, groin, or genitals, these are termed *Bhagandara*" [8].

Sushruta's five-fold classification (Panchabhedam) based on Dosha predominance provides both diagnostic and prognostic framework [9]:

- Shatponaka (Vataja):** Thin discharge, minimal pain, hard edges, branching tracts - curable
- Ushtragriva (Pittaja):** Yellow discharge, burning pain, inflammation, foul odor - curable
- Parisravi (Kaphaja):** White thick discharge, itching, minimal pain - curable

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4. **Shambukavarta (Tridoshaja):** Mixed features, spiral tract, severe symptoms - manageable

5. **Unmargi (Agantuja):** Traumatic origin, irregular tract - prognosis depends on extent
This classification system correlates with modern understanding: low fistulas correspond to Vataja/Kaphaja types, high transsphincteric to Pittaja/Tridoshaja types, and complex horseshoe fistulas to Shambukavarta type [10].
Classical Ayurvedic etiology includes dietary factors (excessive dry, rough, incompatible foods), lifestyle factors (suppression of natural urges, excessive physical exertion, prolonged sitting on hard surfaces), and traumatic factors (perineal trauma, iatrogenic injury) [18]. The pathogenic sequence involves Dosha aggravation, impaired digestive fire (Agni Mandya), local tissue vitiation, abscess formation, rupture, and persistent tract formation [19]. This classical understanding parallels contemporary cryptoglandular theory [1].

2. Kshara Sutra Therapy: Technique and Mechanism

Pharmaceutical Preparation

Standard Apamarga Kshara Sutra preparation involves three primary ingredients [13, 20]:

1. **Snuhi Latex (*Euphorbia neriifolia*):** Binding medium with proteolytic enzymes and antimicrobial properties.
2. **Apamarga Kshara (*Achyranthes aspera*):** Primary caustic agent (pH 11-12) for chemical cutting; prepared by burning plant to ash, water filtration, and evaporation.
3. **Haridra Churna (*Curcuma longa*):** Antimicrobial, anti-inflammatory, wound healing agent.

Manufacturing Process

The standard protocol involves 21 coatings [21]:

- **First 11 coatings:** Snuhi latex only (establishes base)
 - **Next 7 coatings:** Snuhi latex + Apamarga Kshara (caustic action)
 - **Final 3 coatings:** Snuhi latex + Apamarga Kshara + Haridra powder
- Each coating is dried in shade, total preparation time 3-4 weeks, resulting in thread diameter 2-3 mm. Quality control parameters include uniform thickness, smooth surface, characteristic yellow-brown color, pH testing, and microbial sterility [22].

1.2. Mechanism of Action

Kshara Sutra acts through multiple synergistic mechanisms [23, 24]:

- **Chemical Cauterization:** Alkaline Kshara causes protein denaturation and tissue necrosis, providing gradual chemical cutting.
- **Mechanical Cutting:** Physical pressure and railroad technique (progressive tightening) enhance cutting.
- **Antimicrobial Action:** Alkaline pH, Snuhi antimicrobial compounds, and curcumin provide broad-spectrum activity against common fistula pathogens.
- **Anti-inflammatory Effect:** Curcumin inhibits NF- κ B pathway and pro-inflammatory cytokines.
- **Wound Healing Promotion:** Controlled debridement, granulation tissue stimulation, epithelialization from base upward.
- **Drug Delivery System:** Continuous release of active ingredients with weekly replacement.

Surgical Procedure

Pre-operative Assessment: Complete history, digital rectal examination, proctoscopy, MRI fistulography for complex cases, Parks classification [25].

Procedure Steps [26]:

4. Identification of external and internal openings.
5. Gentle probing with malleable fistula probe.
6. Threading Kshara Sutra through probe eye.
7. Probe withdrawal, pulling Kshara Sutra through tract.
8. Both ends tied outside anus with moderate tension.
9. Light dressing applied.

Post-operative Care: Weekly follow-up for railroad technique replacement, sitz baths twice daily, perianal hygiene, dietary modifications, prescribed oral medications [27].

Duration: Unit cutting time (UCT) typically 8-9 days per cm of tract; total treatment 6-8 weeks depending on tract length [28].

Formulation Variations

Multiple alternative formulations have been developed to address ingredient availability, patient tolerance, and optimization goals [29]:

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Alternative Kshara Sources:

- Palasha (*Butea monosperma*): Better availability, reduced burning sensation [30].
- Kadali (*Musa paradisiaca*): Readily available, cost-effective, mild caustic action [31].
- Tankana (Borax): Mineral-based, standardized composition, year-round availability [32].
- Gunja (*Abrus precatorius*), Koshataki (*Luffa acutangula*): Regional alternatives [33].

Modified Binding Agents:

- Guggulu (*Commiphora mukul*): Enhanced anti-inflammatory properties, better pain relief [34].
- Shallaki (*Boswellia serrata*): Potent anti-inflammatory (boswellic acids), faster cutting [35].
- Madhu (Honey): Natural antimicrobial, wound healing promotion [36].

Reduced-Coating Protocols: 15 or 18 coatings instead of 21 to reduce preparation time while maintaining efficacy [37].

2. Multi-Modal Treatment Approach

2.2. Integration with Herbal Medications

Ayurvedic management extends beyond surgical intervention to comprehensive multi-modal approach [38]: **Internal Medications:**

- *Triphala Guggulu*: Anti-inflammatory, wound healing, mild laxative (prevents constipation); dose 2-4 tablets twice daily [39].
- *Gandhak Rasayana*: Purified sulfur preparation with antimicrobial and blood purification properties [40].
- *Kaishor Guggulu*: Potent anti-inflammatory and analgesic effects [41].

Clinical Evidence: Randomized trials combining oral Triphala Guggulu with Kshara Sutra variants reported improved symptomatic relief and modest reductions in unit cutting time [35, 39].

2.3. External Applications and Wound Care

Topical Oils and Medicated Ghee:

- *Jatyadi Oil*: Potent wound healing, antimicrobial, anti-inflammatory; applied 2-3 times daily [42].
- *Karaveeradi Taila*: Wound healing, reduces discharge; used as oil instillation [43].
- *Karanjadi Ghrita*: Cooling effect, particularly for Pittaja type with burning sensation [44].

Wound Dressings: Honey dressing for antimicrobial action and moist wound environment; turmeric paste for anti-inflammatory effects [45].

2.4. Sitz Baths

- *Panchavalkala Decoction*: Bark of five trees (Vata, Udumbara, Ashvattha, Parisha, Plaksha) with astringent, wound healing, and antimicrobial properties [47].
- *Triphala Decoction*: Cleansing and wound healing properties [48].

2.5. Dietary and Lifestyle Modifications

- **Pathya (Beneficial):** Light easily digestible foods, adequate fiber, old rice, green gram, bitter gourd, pomegranate, cow ghee, adequate water [49].
- **Apathya (Contraindicated):** Heavy oily fried foods, excessive spicy/sour/salty foods, incompatible food combinations, alcohol, tobacco [50].
- **Lifestyle:** Regular bowel movements without straining, perianal hygiene, light exercise, adequate sleep, stress management, avoid prolonged sitting [51].

3. Clinical Evidence and Outcomes

3.2. Landmark Multicentric ICMR Trial

The definitive evidence comes from the multicentric randomized controlled trial conducted by the Indian Council of Medical Research [52].

- **Sample size:** Kshara Sutra n=265, Conventional surgery n=237
- **Design:** Proper randomization, long-term follow-up (up to 3 years)

Key Findings:

- Both treatments achieved 100% complete healing.
- Kshara Sutra showed significantly lower long-term recurrence (4% vs. 11%, P=0.03).
- Surgery provided faster healing (4 weeks vs. 8 weeks).
- Kshara Sutra offered ambulatory benefits and faster return to work.

Table 1: Primary Outcomes of ICMR Multicentric Trial [52]

Outcome	Kshara Sutra	Surgery	P-value
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Complete Healing	100% (265/265)	100% (237/237)	NS
Median Healing Time	8 weeks	4 weeks	<0.001
Recurrence Rate (1-yr)	4% (6/150)	11% (17/150)	0.03
Mild Incontinence	8 patients	13 patients	NS
Hospital Stay	Ambulatory (OPD)	3-5 days	<0.001

3.3. Additional Randomized Controlled Trials

RG Kar Medical College, Kolkata RCT [53]:

- Mean healing time: 53 days vs. 35.7 days (P=0.002)
- Days off work: 2.7 vs. 15.5 days (P<0.001)
- Post-operative pain (VAS day 1): 2.3 vs. 6.8 (P<0.001)
- Recurrence (6 months): 0% vs. 4.2%

IGIMS Patna Comparative Study [54]:

- Operating time: 16 min vs. 38 min (P=0.0021)
- Recurrence: 3.3% vs. 16.7% (P<0.05)
- Patient satisfaction: 96.7% vs. 80% (P<0.05)

3.4. Systematic Reviews and Meta-Analyses

A meta-analysis of Kshara Sutra efficacy and safety included 7 RCTs and >500 patients [56].

Table 2: Pooled Results from Meta-Analysis [56]

Outcome	Pooled Estimate	95% CI	Heterogeneity
Complete Cure Rate	97.8%	95.2-99.1%	Low ($I^2=12\%$)
Recurrence Rate	3.2%	1.8-5.1%	Low ($I^2=18\%$)
Anal Incontinence	1.4%	0.6-2.8%	Low ($I^2=8\%$)
Mean Healing Time	6.8 weeks	5.9-7.7 weeks	Moderate ($I^2=45\%$)

Conclusion: High cure rates, very low recurrence, and negligible incontinence risk.

4. Comparative Effectiveness

4.2. Efficacy Comparison

- **Complete Healing Rates:** 95-100% for

Kshara Sutra vs 90-100% for surgery.

- **Recurrence Rates:** Kshara Sutra recurrence is significantly lower (4% vs 11%, P=0.03) [52].

- **Healing Time:** Kshara Sutra takes 3-4 weeks longer, but is offset by ambulatory nature.

4.3. Sphincter Preservation and Continence

Mechanism: Gradual chemical cutting allows sphincter muscle fibers to adapt and re-orient, minimizing acute sphincter disruption [58].

Outcomes: Incontinence is 1.4% for Kshara Sutra [56] vs 2-26% for conventional surgery. This is a major advantage for high transsphincteric fistulas.

4.4. Cost-Effectiveness Analysis

- **Direct Costs:** Kshara Sutra is 5-10 times less expensive than surgery [53].

- **Indirect Costs:** Work loss is significantly reduced (2-3 days vs 10-15 days).

- **Healthcare System:** Reduced hospitalization, no operating room requirement, and suitability for resource-limited settings [60].

5. Mechanistic Studies

5.2. Antimicrobial Activity

In vitro studies show *Apamarga Kshara* has broad-spectrum activity due to alkaline pH [63]. Turmeric (Curcumin) disrupts membranes and inhibits bacterial enzymes [64], while Snuhi latex provides proteolytic enzymatic action on cell walls [65].

5.3. Anti-inflammatory Effects

Curcumin inhibits the NF- κ B pathway and COX-2 enzymes [66]. Guggulsterones in Guggulu inhibit inflammatory pathways and reduce edema [67]. Boswellic acids in Shallaki are potent 5-LOX inhibitors [68].

5.4. Wound Healing Properties

Curcumin promotes fibroblast proliferation and angiogenesis [69]. Honey maintains a moist wound environment and promotes granulation [70]. The alkaline environment stimulates granulation from the base upwards.

6. Challenges and Future Directions

6.2. Standardization Issues

Currently, preparation is predominantly manual, leading to batch-to-batch variability. Solutions include automated manufacturing pilot studies [72] and developing official pharmacopoeial standards.

6.3. Research Priorities

- **Immediate:** Consensus guidelines and

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large-scale multicenter RCTs (n=400-600).

- **Medium-term:** Mechanistic research and studies in complex fistulas (Crohn's).
- **Long-term:** Global dissemination and international trials.

7. Conclusion

This comprehensive evidence-based review establishes Kshara Sutra therapy as a validated, minimally invasive, sphincter-sparing treatment option. With complete healing rates of 97.8%, significantly lower recurrence rates (4% vs 11%), and 5-10 fold lower costs compared to conventional surgery, it is a compelling option. While healing time is longer, the preservation of continence and ambulatory nature provides superior patient-centered outcomes. Continued research and standardization will facilitate its integration into global surgical practice.

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