

Review Article

Clinical Efficacy of Ksharsutra Therapy in Fistula-in-Ano: A Prospective Observational Study from District Una, Himachal Pradesh

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Abstract

Background: Fistula-in-ano is a chronic anorectal condition with high recurrence rates and potential risk of sphincter injury following conventional surgery. Ayurveda describes Bhagandara extensively, and Ksharsutra therapy offers a minimally invasive, sphincter-preserving alternative. This study evaluates the clinical outcomes of Ksharsutra therapy in patients with fistula-in-ano. **Materials and Methods:** A prospective observational study was conducted at Jagat Hospital and Kshar Sutra Centre, District Una, Himachal Pradesh, India. Thirty-five patients aged 18–65 years with clinically confirmed fistula-in-ano were enrolled. Diagnosis was established through inspection, palpation, probing and proctoscopy. Ksharsutra was prepared using the standard ICMR-approved technique and applied on an outpatient basis. Weekly follow-up assessed thread changes, tract length and healing progress. Data were analyzed descriptively. **Results:** The study population was predominantly male (94.29%), with most patients aged 31–40 years (54.29%). A majority were married (74.29%) and engaged in labour or agricultural work (62.86%). Vegetarian diet was reported in 60%, and 62.86% had disease chronicity of less than one year. Vata–Pittaja prakriti (45.71%) and Vata–Pittaja disease patterns (40%) were most common. Anatomically, 51.43% had a single external opening, and 62.86% had tracts located more than two centimetres from the anal verge. The 5 o'clock position accounted for the highest number of openings (20%). Ksharsutra therapy achieved complete healing in 82.86% of patients, with no recurrence or incontinence. Mild, self-limiting discomfort occurred in 17.14% of patients. All procedures were outpatient-based, without hospitalization or anesthesia, and patients resumed routine activities immediately. **Conclusion:** Ksharsutra therapy is a safe, effective and convenient modality for fistula-in-ano, offering high cure rates, zero recurrence and preserved continence with minimal morbidity. Its outpatient feasibility makes it a valuable option in routine anorectal practice.

Keywords: Fistula-in-ano; Bhagandara; Ksharsutra; Ayurveda; Sphincter preservation; Apamarga kshara

Introduction:

Fistula-in-Ano (Bhagandara) is a chronic, debilitating ano-rectal disorder characterized by a tract lined with granulation tissue that connects the anal canal with the perianal skin. Globally, it remains a significant clinical challenge due to its recurrent nature, impact on quality of life, and the limitations associated with conventional surgical treatments. The condition commonly arises following anorectal abscess formation, with cryptoglandular infection being the predominant etiology. Despite advancements in modern colorectal surgery, recurrence rates after fistulotomy, fistulectomy, seton application, and flap procedures continue to range between 7–50%, particularly in complex and high fistulas. Moreover, risks such as sphincter injury, postoperative incontinence, prolonged wound healing, and hospitalization remain pertinent concerns.¹⁻⁷

Ayurveda, the ancient Indian system of medicine, has described Bhagandara in remarkable detail for more than 2,500 years. Acharya Suśruta – revered as the “Father of Surgery” – documented multiple types of Bhagandara in the Suśruta Saṃhitā, providing comprehensive guidelines for diagnosis, classification, prognosis, and management. Among the para-surgical modalities described, Kṣāra-Sūtra therapy (medicated caustic seton) stands out as a unique and sophisticated technique. The method combines chemical cauterization, debridement, incision, and sustained drug delivery through a specially prepared alkaline-coated thread, facilitating controlled cutting and simultaneous healing of the fistulous tract.⁷⁻¹⁰

Modern scientific validation of Kṣāra-Sūtra began in the late 20th century, with standardized preparation and procedural methodology established by the Department of Shalya Tantra, Institute of Medical

Sciences (I.M.S.), Banaras Hindu University (BHU) and endorsed by the Indian Council of Medical Research (ICMR). Numerous studies since then have demonstrated its effectiveness, reporting high cure rates (90–98%), minimal recurrence (0–2.5%), sphincter preservation, outpatient feasibility, and negligible postoperative complications. These advantages have resulted in growing global interest in Kṣāra-Sūtra as a safe, cost-effective, and sphincter-saving alternative to conventional surgical approaches.¹¹⁻¹⁵

Fistula-in-Ano continues to be one of the Ashta-Mahāgāda (eight grave diseases) described in Ayurveda, signifying its chronicity and difficulty to cure. The multifactorial presentation—including varying tract lengths, external openings, chronic inflammation, and involvement of anorectal musculature—makes its management complex. In this context, Kṣāra-Sūtra offers a distinct therapeutic edge by ensuring gradual excision of the tract while promoting healthy granulation and preventing premature closure or abscess reformation.^{2,12,14,16}

The present clinical study evaluates the outcomes of Kṣāra-Sūtra therapy in clinically diagnosed cases of Bhagandara, with detailed demographic, lifestyle, anatomical, and treatment outcome assessments. A supplementary case series further validates its efficacy. By systematically analyzing both classical parameters (such as Prakṛti and disease chronicity) and modern clinical indicators (tract anatomy, healing rate, complications, recurrence), this study aims to contribute robust evidence to the growing literature supporting Kṣāra-Sūtra as an effective, safe, and globally relevant treatment modality for Fistula-in-Ano.

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Methodology

Study Design

This prospective observational clinical study was conducted to evaluate the therapeutic effectiveness of Ksharsutra therapy in patients diagnosed with fistula-in-ano (Bhagandara). A total of 35 patients meeting the diagnostic criteria were enrolled and followed systematically throughout the treatment period. Additional routinely treated cases at the centre were reviewed to enhance clinical validity. The study was carried out at Jagat Hospital and Kshar Sutra Centre, located in District Una, Himachal Pradesh, India.

Study Setting

The research was conducted in a specialized anorectal healthcare facility equipped with standard proctoscopic instruments, a dedicated Ksharsutra preparation unit, and an operational outpatient-based procedure room. The centre also had facilities for regular dressings, weekly follow-up, and maintenance of clinical records. Ksharsutra preparation, application, thread changes, and all postoperative care were performed at Jagat Hospital and Kshar Sutra Centre, Una, Himachal Pradesh.

Patient Selection

Patients between the ages of 18 and 65 years presenting with symptoms suggestive of fistula-in-ano were screened for the study. Inclusion criteria consisted of clinically confirmed fistula-in-ano with identifiable external openings and a demonstrable tract confirmed through probing or proctoscopy. Only patients willing to undergo Ksharsutra therapy and comply with regular weekly visits were included. Exclusion criteria comprised fistulas associated with Crohn’s disease, tuberculosis, malignancy, HIV infection, extensive horseshoe fistulas requiring major surgery, uncontrolled systemic illnesses, pregnant or lactating women, and patients unfit for minor anorectal procedures.

Diagnostic Evaluation

All patients underwent thorough clinical evaluation including inspection, palpation, and gentle probing to determine the number of external openings, the direction of the tract, the extent of induration, and the presence of discharge. Proctoscopic examination was routinely performed to identify internal openings and associated anorectal conditions. Additionally, Ayurvedic parameters such as patient prakriti, dosha predominance, chronicity, and nature of the tract were assessed in accordance with classical Ayurvedic diagnostic principles to provide a comprehensive clinical understanding.

Preparation of Ksharsutra

The Ksharsutra used in the study was prepared according to the standardized technique developed by the Department of Shalya Tantra,

Institute of Medical Sciences, Banaras Hindu University, and approved by the Indian Council of Medical Research. Preparation was carried out in the Ksharsutra preparation unit at Jagat Hospital and Kshar Sutra Centre, District Una, Himachal Pradesh. Barbour linen surgical thread (No. 20), Snuhi latex (*Euphorbia nerifolia*), Apamarga kshara (*Achyranthes aspera*), and Haridra powder (*Curcuma longa*) were used. Twenty-one coatings were applied in total: eleven coatings of Snuhi latex, seven coatings of Snuhi latex followed by Apamarga kshara, and the final three coatings of Snuhi latex followed by Haridra. After each coating, the threads were dried under controlled aseptic conditions in a Ksharsutra cabinet, sterilized, and stored for clinical use.

Operative Procedure

All procedures were conducted on an outpatient basis without the need for spinal or general anesthesia. Local application of lignocaine jelly was used when required for patient comfort. After cleaning the perianal area, the fistulous tract was gently probed to ascertain its patency and direction. The prepared Ksharsutra was then passed along the tract using appropriate instruments and tied externally at the anal verge. The medicated thread facilitated gradual chemical cauterization, debridement, controlled cutting of the tract, and simultaneous healing from the base.

Postoperative Care and Follow-Up

Patients were advised to take warm sitz baths twice daily and to apply Jatyadi taila locally in case of irritation. Oral analgesics such as diclofenac sodium were prescribed when necessary. Patients were reviewed weekly at the same institution for removal and reinsertion of Ksharsutra, assessment of tract length, and monitoring of healing progression. The expected cutting-healing rate was approximately one centimeter per week. Treatment continued until the entire fistulous tract healed completely without discharge or residual openings.

Outcome Measures

The primary outcome measure was complete healing of the fistulous tract without recurrence. Secondary outcomes included duration of healing, number of thread replacements required, presence of pain or discomfort, postoperative complications if any, and preservation of anal continence.

Data Analysis

All collected data were systematically compiled and analyzed using descriptive statistical methods. Results were expressed as frequencies and percentages. Demographic characteristics, lifestyle factors, anatomical features, and treatment outcomes were presented in tabulated form. Due to the observational design and limited sample size, inferential statistical analysis was not applied.

RESULTS

The demographic distribution of the 35 patients included in the study demonstrated a clear male predominance, with 33 males (94.29%) and only 2 females (5.71%). The majority of patients belonged to the age group of 31–40 years, accounting for 54.29%, followed by 25.71% in the 41–50-year group, indicating that fistula-in-ano predominantly affects individuals in the most productive phase of life. With respect to marital status, 74.29% of the patients were married, while 20% were unmarried, and no patients were children; marital information was unavailable in 5.71% of cases. Occupational analysis revealed that the majority were engaged in labour or agricultural work (62.86%), followed by service employees (17.14%), businessmen (11.43%), homemakers (5.71%), and a small proportion of retired individuals (2.86%). Students were not represented in the study population. Overall, the demographic pattern suggests that physically active, working-age males constitute the largest affected group.

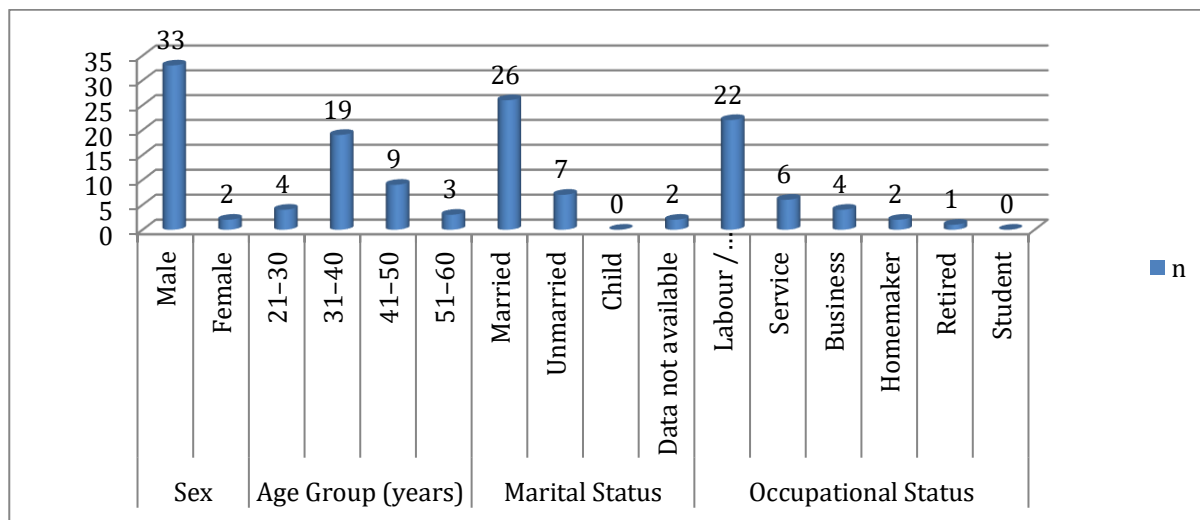


Figure-1: Demographic Profile of Fistula-in-Ano Patients (n = 35)

Assessment of lifestyle-related and Ayurvedic constitutional variables showed that 60% of the patients followed a vegetarian diet, while 40% consumed a non-vegetarian diet. Chronicity analysis revealed that 62.86% of cases had a disease duration of less than one year, indicating a relatively early presentation,

whereas 25.71% reported a duration of 1–3 years, and 11.43% had chronic disease for more than three years. Evaluation of patient prakriti demonstrated that Vata–Pittaja constitution was most common (45.71%), followed by Vata–Kaphaja (31.43%) and Pitta–Kaphaja (22.86%). Similarly, disease prakriti assessment indicated a predominance of Vata–Pittaja type (40%), followed by Pitta–Kaphaja (28.57%), Vata–Kaphaja (20%), and a smaller proportion of Sannipataja cases (11.43%). These findings highlight the predominance of Vata-associated constitutional and disease patterns, which align with classical Ayurvedic descriptions of Bhagandara.

TABLE-1: Lifestyle and Clinical Constitution Profile (n = 35)

Variable	Category	n (%)
Diet Pattern	Vegetarian	21 (60.00%)
	Non-vegetarian	14 (40.00%)
Chronicity of Disease	< 1 year	22 (62.86%)
	1–3 years	9 (25.71%)
	> 3 years	4 (11.43%)
Patient Prakriti	Vata–Pittaja	16 (45.71%)
	Vata–Kaphaja	11 (31.43%)
	Pitta–Kaphaja	8 (22.86%)
Disease Prakriti	Vata–Pittaja	14 (40.00%)
	Vata–Kaphaja	7 (20.00%)
	Pitta–Kaphaja	10 (28.57%)
	Sannipataja	4 (11.43%)

Analysis of anatomical features showed that 51.43% of patients had a single external opening, while 31.43% had two openings, and 14.29% had three openings; only one patient (2.86%) had four external openings. The majority of fistulous tracts (62.86%) were located at a distance greater than two centimetres from the anal verge, whereas 37.14% were situated within two centimetres. Clockwise localization of external openings revealed that the 5 o'clock position was the most commonly affected site (20%), followed by the 2, 6, and 8 o'clock positions (each accounting for 11.43%). The 1, 3, 4, and 11 o'clock positions were each observed in 8.57% of patients, while the 7, 9, and 10 o'clock positions were less frequent at 2.86% each. No cases were reported at the 12 o'clock position. These anatomical distributions reflect typical posterior and posterolateral predominance commonly observed in cryptoglandular fistulas.

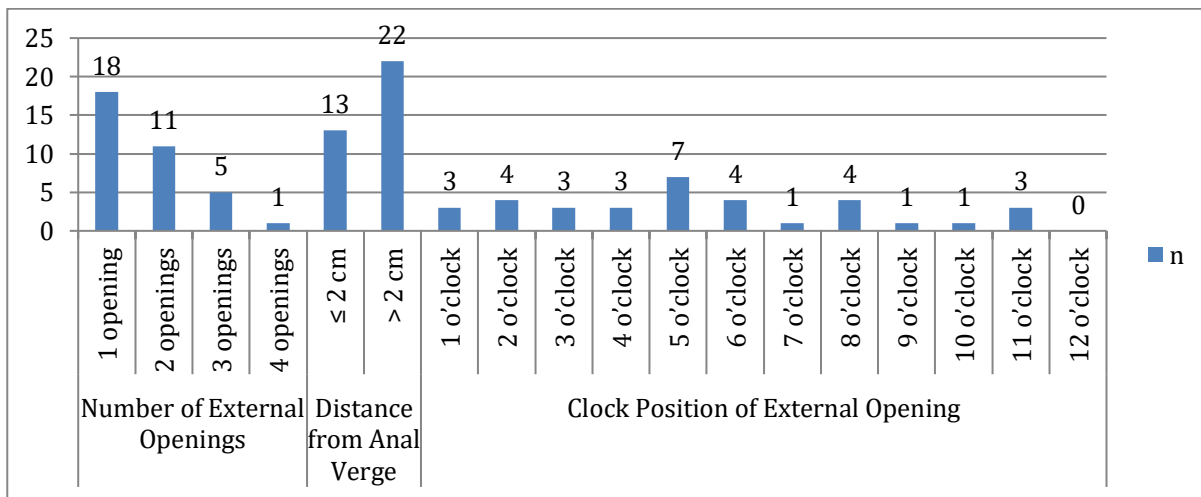


Figure-2: Anatomical Characteristics of Fistula Tracts (n = 35)

Therapeutic outcomes of Ksharsutra management demonstrated encouraging results. Out of 35 patients, 29 (82.86%) achieved complete cure during the study period, while 6 patients (17.14%) were still under treatment at the time of analysis. Notably, no recurrence was observed in any of the completed cases, yielding a recurrence rate of 0 percent. Mild, self-limiting pain or irritation was reported by 17.14% of patients, whereas the majority (82.86%) remained free from complications. Anal continence was preserved in all patients, and no cases of incontinence or sphincter injury were observed. These findings reinforce the safety and effectiveness of Ksharsutra therapy as a sphincter-saving modality for fistula-in-ano.

TABLE-2: Treatment Outcomes of Kshar Sutra Therapy (n = 35)

Variable	Category	n (%)
Treatment Status	Cured	29 (82.86%)
	Under Treatment	6 (17.14%)
Recurrence	Present	0 (0%)
	Absent	35 (100%)
Complications	Mild pain / irritation	6 (17.14%)
	No complications	29 (82.86%)
Continence Status	Preserved	35 (100%)
	Lost	0 (0%)

Procedure-related observations showed that Ksharsutra therapy was entirely outpatient-based, with no patient requiring hospitalization or general anesthesia. All 35 patients completed the procedure without the need for anesthetic intervention aside from occasional local lubrication for comfort. Return to routine daily activities was immediate for every patient, reflecting the minimally invasive nature of the therapy. The expected cutting-healing rate of approximately one centimetre per week was consistently observed throughout the follow-up period. Overall, the procedural indicators highlight the convenience, safety, and patient-friendly nature of Ksharsutra treatment, allowing uninterrupted routine activities while ensuring steady and reliable healing.

TABLE-3: Procedural & Recovery Indicators (n = 35)

Variable	Category	n (%)
Hospitalization Requirement	Required	0 (0%)
	Not Required	35 (100%)
Anesthesia Requirement	Required	0 (0%)
	Not Required	35 (100%)
Return to Routine Activity	Immediate	35 (100%)
	Delayed	0 (0%)

DISCUSSION

The present clinical study was undertaken to evaluate the efficacy, safety, and clinical applicability of Ksharsutra therapy in the management of fistula-in-ano. The findings demonstrate that Ksharsutra offers a highly effective, minimally invasive, and sphincter-preserving alternative to conventional surgical techniques. This is particularly relevant given the well-known challenges associated with fistula management, including high recurrence rates, risk of sphincter injury, postoperative morbidity, and requirement of hospitalization in contemporary surgical practice.

Demographic results indicated a strong male predominance, with most patients belonging to the 31–40-year age group. This pattern is consistent with global epidemiological trends where fistula-in-ano is more prevalent in young and middle-aged males engaged in physically active occupations. A similar observation has been reported in previous studies suggesting that strenuous physical activity, prolonged sitting, and sweat retention around the anal region may contribute to cryptoglandular infections that initiate fistula formation.^{6,9,12} The dominance of labour and agricultural workers in the present study supports this association. Additionally, the majority of patients reported a disease chronicity of less than one year, indicating relatively early health-seeking behaviour, possibly due to discomfort, discharge, and interference with daily work. From the Ayurvedic perspective, the predominance of Vata–Pittaja prakriti and Vata-dominated disease patterns correlates well with the classical descriptions in Sushruta Samhita, where Bhagandara is attributed primarily to vitiated Vata and its disruptive action on the anorectal region.^{2,17} Vata dominance is known to contribute to the formation of winding, multiple, or deeper tracts, and this aligns with the anatomical findings of multiple external openings and posterolateral tract orientation in several patients.

Anatomical assessment revealed that most of the tracts were located more than two centimetres from the anal verge, with the 5 o'clock position being the most frequently affected. This reflects the well-established predisposition of posterior and posterolateral cryptoglandular infections leading to fistula formation. The observed anatomical distribution is consistent with the prevailing understanding of anal gland topography and the course of intersphincteric spaces described in modern surgical literature.^{5,12,16}

The therapeutic outcomes of Ksharsutra therapy in this study were highly favourable. A cure rate of 82.86 percent among the completed cases, with no recurrence observed, highlights its remarkable clinical value. The complete absence of recurrence aligns closely with earlier studies conducted at Banaras Hindu University and other institutes, reporting recurrence rates between 0 and 2.5 percent. The gradual cutting and healing mechanism of Ksharsutra, which ensures simultaneous tract excision and controlled healing from the base, may be responsible for eliminating residual infection pockets and preventing premature closure, thereby reducing recurrence.

Importantly, no patient in this study experienced incontinence or sphincter damage, which remains one of the major concerns with conventional fistulotomy or fistulectomy. The sphincter-preserving nature of Ksharsutra makes it particularly advantageous for complex, high, or recurrent fistulas where surgical excision carries a higher risk of functional impairment. The complete absence of hospitalization and general anesthesia requirements further strengthens the feasibility of Ksharsutra as a cost-effective and patient-friendly treatment option, allowing continuity of routine work throughout therapy.

Complications were minimal and limited to mild pain or irritation in a small percentage of patients. These symptoms were easily manageable with sitz baths, topical applications, and simple analgesics, reflecting the safety and tolerability of the procedure. The treatment is also uniquely suited for outpatient settings, making it accessible to rural and semi-urban populations such as those in District Una, Himachal Pradesh, where this study was conducted.

The results of the study also support the classical Ayurvedic rationale behind the use of Ksharsutra. Its composite action of chemical cauterization, antibacterial effect, debridement, and tissue regeneration aligns well with the modern concepts of tract sterilization, removal of unhealthy granulation, and prevention of dead space formation. The use of Snuhi latex, Apamarga kshara, and Haridra powder provides a combined alkaline, proteolytic, and wound-healing effect that promotes steady granulation and natural tract obliteration.

Overall, the results of this study affirm that Ksharsutra therapy is a highly effective, safe, and practical modality for managing fistula-in-ano. Its ability to ensure complete healing while preserving sphincter function, minimizing complications, and avoiding hospitalization makes it an attractive treatment option, especially in resource-limited settings. These findings underscore the relevance of traditional Ayurvedic parasurgical techniques in modern anorectal practice and warrant further multicentric research to consolidate its global therapeutic significance.

Strengths and Limitations

This study's strengths include the use of a standardized ICMR-approved Ksharsutra preparation method, uniform treatment protocol, and consistent weekly follow-up, ensuring reliability of the clinical outcomes. The real-world setting and detailed assessment of demographic, anatomical, and therapeutic variables add practical relevance, while the absence of recurrence and preserved continence underscore the effectiveness of the therapy. However, the study is limited by its moderate sample size, single-centre design, and lack of a comparative surgical control group. The follow-up duration was also limited, restricting evaluation of long-term recurrence. Larger multicentric studies with extended follow-up are needed to further validate these findings.

Conclusion

The present study demonstrates that Ksharsutra therapy is a highly effective, safe, and practical treatment modality for fistula-in-ano. The therapy achieved a high cure rate with no recurrence and complete preservation of anal continence, while also requiring neither hospitalization nor anesthesia. Its gradual cutting–healing action, minimal complications, and outpatient feasibility make it a valuable sphincter-saving alternative to conventional surgery. The demographic and anatomical patterns observed in the study align with both classical Ayurvedic descriptions and modern cryptoglandular understanding of fistula formation. Although limited by its single-centre design and moderate sample size, the findings strongly support the clinical utility of Ksharsutra, particularly in resource-limited settings. Further multicentric studies with larger populations and long-term follow-up are warranted to strengthen its global evidence base and establish its role in contemporary anorectal practice.

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