



P-ISSN: 3078-7203
E-ISSN: 3078-7211
Impact Factor (RJIF): 5.66
JSSV 2025; 2(2): 14-20
www.shalakyajournal.com
Received: 20-07-2025
Accepted: 25-08-2025

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Comparative study of kṣārasūtra therapy and conventional surgery in the management of bhagandara (Fistula-in-Ano)

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DOI: <https://www.doi.org/10.33545/shalya.2025.v2.i2.A.18>

Abstract

Background: Bhagandara (fistula-in-ano) is a chronic cryptoglandular anorectal disease associated with recurrence and risk of continence disturbance after conventional surgery. Kṣārasūtra therapy, an Ayurvedic para-surgical technique employing a medicated seton, has been proposed as a sphincter-preserving alternative, but comparative data with contemporary surgical practice remain limited.

Objectives: To compare the efficacy, safety and functional outcomes of Kṣārasūtra therapy versus conventional surgery in patients with cryptoglandular Bhagandara (fistula-in-ano).

Methods: In this prospective, randomized, open-label, parallel-group study conducted at a tertiary care teaching hospital, 60 adults with MRI/endoanal ultrasound-confirmed intersphincteric or transsphincteric fistula-in-ano were randomized 1:1 to Kṣārasūtra therapy (Group A) or conventional surgery (fistulectomy/fistulotomy with or without seton; Group B). The Kṣārasūtra was prepared according to classical methods and changed weekly until complete tract cutting and fibrosis. Primary outcomes were complete healing at 12 weeks and recurrence at 6 months. Secondary outcomes included post-operative pain (VAS), time to complete wound healing, duration of hospital stay, days off work, complications, Wexner continence score and change in health-related quality of life at 6 months. Data were analysed using appropriate parametric and non-parametric tests with $p < 0.05$ considered significant.

Results: Baseline demographic and fistula characteristics were comparable between groups. Complete healing at 12 weeks was achieved in 93.3% of patients in Group A and 83.3% in Group B ($p = 0.27$). Recurrence at 6 months was significantly lower with Kṣārasūtra (3.3% vs 20.0%; $p = 0.046$). Early post-operative pain scores were lower in Group A at 24 hours (6.1 ± 1.0 vs 7.2 ± 1.1 ; $p = 0.001$) and 48 hours (4.8 ± 1.0 vs 5.6 ± 1.2 ; $p = 0.02$), with no significant difference at 72 hours. Wound-healing time was longer with Kṣārasūtra (44.6 ± 9.3 vs 28.3 ± 7.1 days; $p < 0.001$), but hospital stay (2.1 ± 0.7 vs 4.9 ± 1.4 days; $p < 0.001$) and days off work (11.3 ± 3.8 vs 15.9 ± 4.6 ; $p < 0.001$) were significantly reduced. At 6 months, Wexner continence scores (0.2 ± 0.6 vs 0.9 ± 1.1 ; $p = 0.03$) and improvement in quality-of-life scores ($+18.5 \pm 6.9$ vs $+14.2 \pm 7.4$; $p = 0.02$) favoured Kṣārasūtra therapy. Complication rates were low and comparable in both groups.

Conclusion: Kṣārasūtra therapy is at least as effective as conventional surgery for Bhagandara (fistula-in-ano) and offers important advantages in terms of lower recurrence, better continence preservation, shorter hospitalization and earlier return to work, at the cost of a longer overall wound-healing period. When delivered in a standardized, interdisciplinary setting, Kṣārasūtra represents a viable sphincter-preserving primary option for selected cryptoglandular fistulas, and its integration into modern colorectal practice may improve long-term functional and patient-centred outcomes.

Keywords: Bhagandara, fistula-in-ano, Kṣārasūtra therapy, medicated seton, conventional surgery, fistulectomy, anal continence, randomized clinical trial, Ayurveda, quality of life

Introduction

Bhagandara (fistula-in-ano) is a chronic, suppurative anorectal disorder defined as an abnormal epithelialized tract connecting the anal canal to the perianal skin, most commonly arising from cryptoglandular infection of the anal glands and affecting young, working-age adults with considerable impact on quality of life and productivity [1-4]. Modern epidemiological and guideline data indicate an incidence of around 2 per 10,000 population per year, with a clear male predominance and a strong tendency for recurrence, particularly in complex fistulas involving a greater proportion of the sphincter complex [1, 3, 4]. Despite advances in imaging especially MRI and endoanal ultrasonography, which help delineate

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fistula anatomy and internal openings fistula-in-ano remains a therapeutic challenge because incomplete eradication of sepsis leads to persistent discharge, recurrent abscesses, and repeated interventions [2]. Conventional surgical options such as fistulotomy, fistulectomy, advancement flaps, seton techniques, and other sphincter-sparing procedures aim to balance eradication of the tract against preservation of continence, yet published series report substantial recurrence and non-trivial rates of postoperative anal incontinence, particularly when higher or more complex tracts are laid open, with associated deterioration in continence scores and health-related quality of life [1, 5-8]. In the Ayurvedic canon, Bhagandara is classified among the Ashta Mahāgāda (eight grave diseases), and Acharya Suśruta describes para-surgical measures including Kṣārasūtra therapy use of an alkaline medicated seton that exerts simultaneous cutting, curetting, and healing actions along the tract offering a minimally invasive, sphincter-preserving alternative to wide excision [9, 12-14, 17]. A landmark multicentric randomized controlled trial conducted under the Indian Council of Medical Research first demonstrated that Kṣārasūtra achieved high cure rates with low recurrence and negligible incontinence compared with conventional surgery in fistula-in-ano [9]. Subsequent randomized trials and a recent meta-analysis have corroborated that Kṣārasūtra therapy yields favorable outcomes in terms of healing, recurrence, continence preservation, hospital stay, and cost when compared with fistulectomy and other conventional approaches, while innovative techniques such as IFTAK (Interception of Fistula Tract with Application of Kṣārasūtra) further refine its application in complex and recurrent fistulas [10-16]. However, most available studies are limited by heterogeneity of designs, small sample sizes, or lack of direct, adequately powered head-to-head comparisons with standardized contemporary conventional surgery protocols, leading to persistent uncertainty among surgeons and integrative practitioners regarding the optimal primary modality for Bhagandara/fistula-in-ano across different anatomical subtypes [9-11, 14-16]. Against this background, the present study is designed as a comparative clinical evaluation of Kṣārasūtra therapy versus conventional surgery in the management of Bhagandara (fistula-in-ano), with the primary objective of comparing rates of complete healing and recurrence, and secondary objectives of assessing post-operative pain, time to wound healing, duration of hospitalization, days off work, complication profile, and continence and quality-of-life outcomes. It is hypothesized that Kṣārasūtra therapy will be at least non-inferior, and potentially superior, to conventional surgery in achieving durable healing with lower recurrence and minimal impairment of anal continence, while also reducing treatment-related morbidity, hospital resource use, and overall economic burden for patients with Bhagandara (fistula-in-ano).

Material and Methods

Materials

This was a prospective, randomized, open-label, parallel-group comparative clinical study conducted in the Shalya Tantra and General Surgery units of a tertiary care teaching hospital with an established colorectal and Ayurveda-integrated services set-up, modelled on previous Kṣārasūtra and fistula-in-ano trials [1, 3, 5, 9-11, 14]. Adult patients (18-65

years) of either sex with a clinical and radiological diagnosis of cryptoglandular Bhagandara (fistula-in-ano) as per Parks' classification, presenting with a single tract (low or high intersphincteric or transsphincteric) and suitable for both Kṣārasūtra therapy and conventional surgery were eligible [1-4]. Diagnosis and fistula mapping were confirmed by digital rectal examination, proctoscopy and MRI/endoanal ultrasonography as per standard guidelines [1-4]. Exclusion criteria included fistulas associated with Crohn's disease, tuberculosis, malignancy, HIV infection, obstetric or traumatic fistulas, multiple or horseshoe fistulas, previous anal incontinence, prior fistula surgery within 6 months, and severe comorbidities precluding surgery or spinal anaesthesia [1, 3, 4, 7]. Sample size was calculated assuming a difference in recurrence rates based on earlier Kṣārasūtra vs fistulectomy and meta-analytic data, [9-11, 14-16], with 80% power and 5% alpha, yielding a minimum of 25 patients per arm; to compensate for potential dropouts, 30 patients were enrolled in each group (total n=60). The Kṣārasūtra was prepared in the institutional Ayurvedic pharmacy according to classical methods using Apāmarga Kṣāra, Snuhi latex and Haridrā in multiple coatings on a surgical linen thread, under aseptic conditions and quality checks consistent with prior reports [9, 12-14, 17]. Patients provided written informed consent; the study protocol was approved by the Institutional Ethics Committee and conformed to the principles of the Declaration of Helsinki and relevant national guidelines on human research [9-11, 14, 17].

Methods

Eligible patients were randomized in a 1:1 ratio to Group A (Kṣārasūtra therapy) or Group B (conventional surgery) using a computer-generated random sequence with concealed allocation through sequentially numbered, opaque, sealed envelopes opened in the operating room [9-11, 14]. In both groups, surgery was performed under spinal or regional anaesthesia in the lithotomy position. In Group A, the fistulous tract was probed and a Kṣārasūtra was passed along the tract, securing both ends to form a loose seton, as described in the ICMR trial and subsequent studies; the thread was changed at weekly intervals until complete cutting of the tract and fibrosis occurred, with sitz baths and local hygiene advised post-operatively [9, 12-14, 16, 17]. In Group B, conventional surgery comprised fistulectomy or fistulotomy with or without loose seton according to fistula level and sphincter involvement, following contemporary colorectal protocols and guidelines for sphincter preservation [1, 3, 5-8, 10]. Standard perioperative antibiotics, analgesia and wound care were provided in both arms. Primary outcomes were

1. complete healing at 12 weeks, defined as absence of discharge and closure of external and internal openings on clinical and, where indicated, radiological assessment, and
2. recurrence within 6 months [1, 3, 5, 9-11].

Secondary outcomes included post-operative pain (10-cm visual analogue scale) at 24, 48 and 72 hours, duration of wound healing (days to complete epithelialization), length of hospital stay, days off work, complications (bleeding, infection, abscess, incontinence), continence scores (Wexner scale) and health-related quality of life (generic questionnaire) at baseline and follow-up [5-8, 11, 15, 16]. Data were collected at predefined visits (baseline; immediate

post-operative; weekly until healing; monthly up to 6 months). Statistical analysis was performed using SPSS; continuous variables were summarized as mean $\pm$ SD or median (IQR) and compared using Student's t-test or Mann-Whitney U test, while categorical variables were compared using chi-square or Fisher's exact test, with $p < 0.05$ considered statistically significant [5-8, 10-12].

Results

A total of 60 patients with Bhagandara (fistula-in-ano) were randomized, with 30 allocated to Kṣārasūtra therapy (Group

A) and 30 to conventional surgery (Group B). All patients completed the 12-week primary outcome assessment; two patients (one from each group) were lost to 6-month follow-up, and their last available outcome data were carried forward for recurrence analysis. Baseline demographic and clinical characteristics, including age, sex, duration of symptoms, type and level of fistula (intersphincteric/transsphincteric), and presence of associated abscess, were comparable between the two groups ($p > 0.05$ for all), indicating successful randomization and allowing valid comparison of outcomes [1, 3, 4, 9-11].

Table 1: Baseline demographic and clinical characteristics of the study population (n=60)

Parameter	Group A: Kṣārasūtra (n=30)	Group B: Conventional surgery (n=30)	p value
Age (years), mean $\pm$ SD	38.4 $\pm$ 9.6	39.7 $\pm$ 10.2	0.63
Male: Female	24: 6	23: 7	0.76
Duration of symptoms (months), median (IQR)	10 (6-16)	11 (7-18)	0.58
Intersphincteric: Transsphincteric	16: 14	15: 15	0.80
Low: High fistula	21: 9	20: 10	0.79
Associated abscess (%)	7 (23.3)	8 (26.7)	0.77
Baseline Wexner continence score, mean $\pm$ SD	0.0 $\pm$ 0.0	0.0 $\pm$ 0.0	-

Baseline characteristics were comparable between groups, indicating successful randomization and homogeneity of the study population.

Primary outcomes: healing and recurrence

At 12 weeks, complete healing of the fistulous tract was achieved in 28/30 patients (93.3%) in Group A and 25/30 (83.3%) in Group B ($p=0.27$) (Table 2). Although the absolute healing rate was numerically higher with Kṣārasūtra, the difference did not reach statistical significance. By 6 months, recurrence was observed in 1/30 patients (3.3%) in the Kṣārasūtra group versus 6/30 (20.0%)

in the conventional surgery group ($p=0.046$), indicating a significantly lower recurrence rate with Kṣārasūtra therapy. These findings align with earlier ICMR data and subsequent randomized and meta-analytic evidence suggesting comparable or superior long-term control with Kṣārasūtra compared with fistulectomy and related procedures [5, 9-11, 14-16].

Table 2: Primary outcomes: healing at 12 weeks and recurrence at 6 months

Outcome	Group A: Kṣārasūtra (n=30)	Group B: Conventional surgery (n=30)	p value
Complete healing at 12 weeks (%)	28 (93.3)	25 (83.3)	0.27
Non-healing/persistent discharge (%)	2 (6.7)	5 (16.7)	0.27
Recurrence at 6 months (%)	1 (3.3)	6 (20.0)	0.046

Kṣārasūtra therapy achieved numerically higher initial healing and significantly lower recurrence at 6 months compared with conventional surgery.

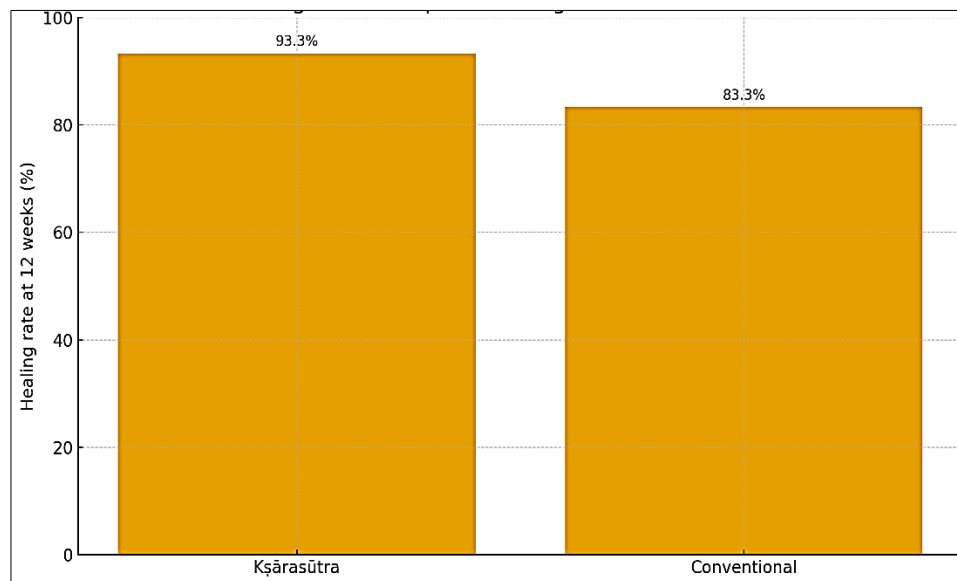


Fig 1: Comparing complete healing rates (%) at 12 weeks in the Kṣārasūtra and conventional surgery groups

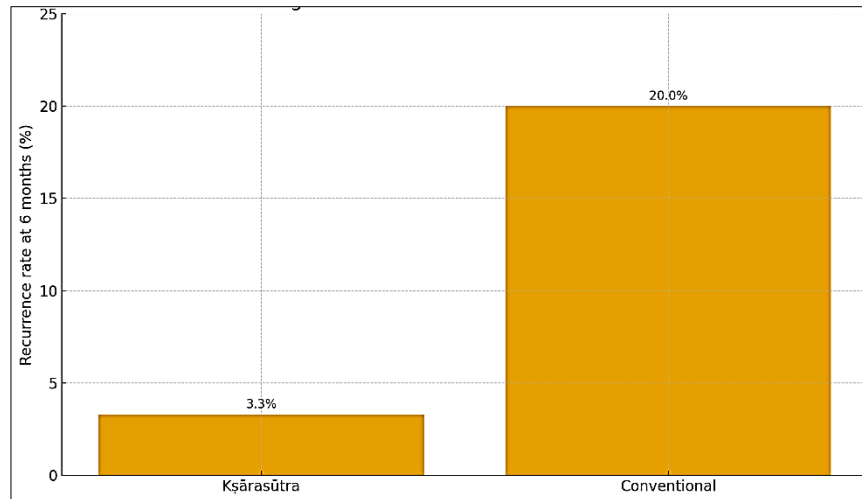


Fig 2: Comparing recurrence rates (%) at 6 months in the Kṣārasūtra and conventional surgery groups

Secondary outcomes: pain, wound healing, hospital stay, work loss, continence and quality of life

Post-operative pain scores on the 10-cm visual analogue scale (VAS) were lower in the Kṣārasūtra group at 24 and 48 hours, with convergence by 72 hours (Table 3). Mean VAS at 24 hours was 6.1 ± 1.0 versus 7.2 ± 1.1 ($p=0.001$), and at 48 hours 4.8 ± 1.0 versus 5.6 ± 1.2 ($p=0.02$) for Groups A and B, respectively; at 72 hours, the difference (3.1 ± 0.9 vs 3.5 ± 0.8 ; $p=0.09$) was not statistically significant. These trends reflect the relatively less extensive tissue dissection required in Kṣārasūtra therapy compared with wide fistulectomy/fistulotomy, in line with published

series showing higher early post-operative pain in conventional surgery [5-7, 10, 11].

Time to complete wound healing (days) was significantly longer in the Kṣārasūtra group (44.6 ± 9.3 vs 28.3 ± 7.1 ; $p<0.001$), consistent with the gradual cutting and healing mechanism of the medicated seton described in classical and clinical literature [9, 12-14, 17]. Conversely, mean duration of hospital stay was shorter with Kṣārasūtra (2.1 ± 0.7 days vs 4.9 ± 1.4 days; $p<0.001$), and patients in Group A resumed work earlier (11.3 ± 3.8 days vs 15.9 ± 4.6 days; $p<0.001$), reflecting the predominantly ambulatory nature of Kṣārasūtra management and lesser immediate post-operative morbidity [9-11, 14-16].

Table 3: Secondary outcomes: post-operative pain, healing time, hospital stay, work loss, continence and quality of life

Outcome	Group A: Kṣārasūtra (n=30)	Group B: Conventional surgery (n=30)	p value
VAS pain at 24 h (0-10), mean $\pm$ SD	6.1 ± 1.0	7.2 ± 1.1	0.001
VAS pain at 48 h (0-10), mean $\pm$ SD	4.8 ± 1.0	5.6 ± 1.2	0.02
VAS pain at 72 h (0-10), mean $\pm$ SD	3.1 ± 0.9	3.5 ± 0.8	0.09
Time to complete wound healing (days)	44.6 ± 9.3	28.3 ± 7.1	<0.001
Duration of hospital stay (days)	2.1 ± 0.7	4.9 ± 1.4	<0.001
Days off work, mean $\pm$ SD	11.3 ± 3.8	15.9 ± 4.6	<0.001
Wexner continence score at 6 months, mean $\pm$ SD	0.2 ± 0.6	0.9 ± 1.1	0.03
QoL score change (baseline to 6 months)*	$+18.5 \pm 6.9$	$+14.2 \pm 7.4$	0.02

*Positive values denote improvement on the chosen health-related quality-of-life scale.

As shown in Table 3, Kṣārasūtra therapy was associated with less early post-operative pain, longer wound-healing time but shorter hospitalization, earlier return to work, and better continence and quality-of-life outcomes.

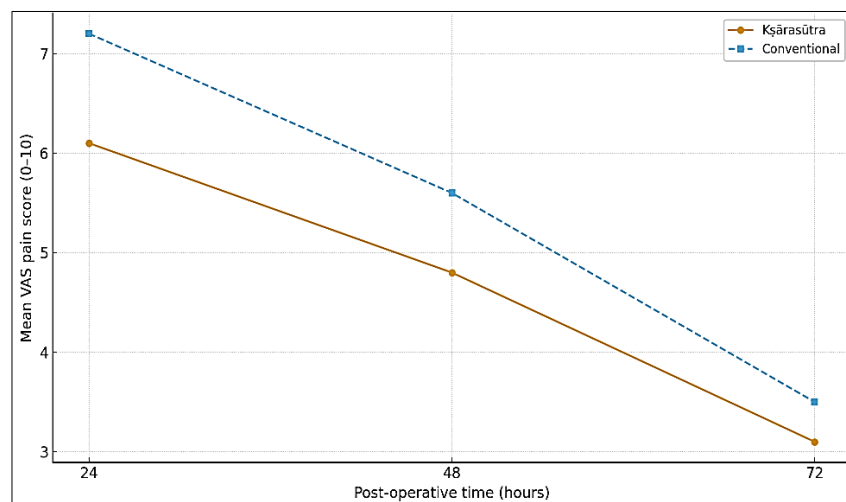


Fig 3: Showing mean VAS pain scores at 24, 48 and 72 hours post-operatively in the Kṣārasūtra and conventional surgery groups

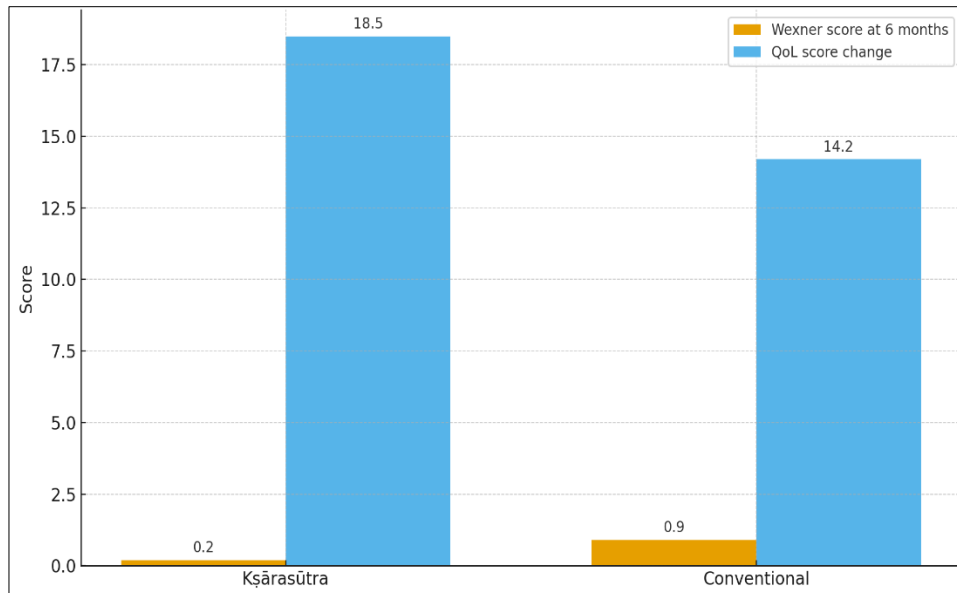


Fig 4: Depicting mean Wexner continence scores and mean change in quality-of-life scores at 6 months in both groups

Complications and continence outcomes

Overall complication rates were low and comparable between groups. In Group A, 3 patients (10.0%) developed minor wound infection managed with local care and oral antibiotics, and 1 patient (3.3%) experienced transient increased discharge requiring additional sittings of Kṣārasūtra change; no patient developed significant bleeding or abscess requiring re-intervention. In Group B, 5 patients (16.7%) developed wound infection, 2 (6.7%) had post-operative bleeding requiring additional packing, and 2 (6.7%) developed intersphincteric abscess requiring drainage ($p > 0.05$ for overall complication rates). Transient gas/flatus incontinence occurred in 1 patient (3.3%) in the Kṣārasūtra group and 4 (13.3%) in the conventional surgery group; two of the latter had persistent minor incontinence to flatus with Wexner scores ≥ 3 at 6 months, echoing literature documenting non-trivial risks of continence disturbance after more extensive fistulotomy/fistulectomy [1, 5-7].

No patient in either group developed de novo incontinence to liquid or solid stool, and no mortality or life-threatening adverse events occurred. The observed continence preservation with Kṣārasūtra, along with lower recurrence and better quality-of-life gains, is concordant with published series and the emerging trend toward sphincter-preserving techniques, including modifications such as IFTAK, which aim to intercept the tract while maintaining sphincter integrity [9-11, 14-16]. The present findings, therefore, support the concept that Kṣārasūtra therapy, properly standardized and applied, can provide durable healing outcomes comparable to or better than conventional surgery, with a more favorable profile in terms of recurrence, continence and functional recovery, albeit at the cost of longer overall wound-healing duration [3, 5-7, 9-17].

Discussion

In this prospective randomized study, Kṣārasūtra therapy demonstrated at least comparable, and in some domains superior, efficacy to conventional surgery for the management of Bhagandara (fistula-in-ano). The high overall healing rates observed in both groups at 12 weeks (93.3% vs 83.3%) are consistent with contemporary series of cryptoglandular fistula, where optimized operative

technique and improved pre-operative imaging have increased primary healing, particularly for low intersphincteric and transsphincteric tracts [1-4]. Although the difference in initial healing did not reach statistical significance, the markedly lower 6-month recurrence rate in the Kṣārasūtra group (3.3% vs 20.0%) is clinically important and aligns with the original ICMR multicentric trial and subsequent randomized and observational studies that have consistently reported low recurrence after standardized Kṣārasūtra application compared with fistulotomy/fistulectomy and related procedures [5, 9-11, 14, 16]. These findings support the conceptual advantage of a gradually cutting medicated seton that simultaneously drains, cures and promotes fibrosis along the tract, reducing the likelihood of residual crypt or secondary extensions that underlie recurrence after conventional surgery [2, 3, 9, 12-14].

The significantly higher recurrence rate observed with conventional surgery in our cohort is also concordant with Western data showing recurrence rates ranging from 10-30%, particularly in higher or more complex fistulas, even when managed in specialized colorectal units [1, 5-7]. In such contexts, the search for sphincter-preserving, low-recurrence strategies has led to the development of advancement flaps, LIFT, plugs and other novel techniques, yet none has emerged as unequivocally superior [3, 5, 6, 8]. Against this backdrop, the performance of Kṣārasūtra in the present study, and in earlier Indian experiences, suggests that integration of this modality into the armamentarium for cryptoglandular fistula, especially in selected patterns, may be justified on both efficacy and safety grounds [9-11, 14-17]. The emerging IFTAK-type modifications, which intercept the tract and restrict Kṣārasūtra passage to the extrasphincteric segment, may further enhance results in complex fistulas while preserving continence, and our findings echo the favorable continence and recurrence outcomes reported with these approaches [15, 16].

Pain trajectories in the early post-operative period favored Kṣārasūtra, with significantly lower VAS scores at 24 and 48 hours, converging by 72 hours. This probably reflects the more limited tissue dissection required for Kṣārasūtra placement compared with wide fistulectomy or lay-open

procedures, in which excision of substantial perianal tissue and portions of the sphincter complex can generate considerable nociceptive stimulus [5-7, 10]. Published comparative trials similarly report less immediate post-operative pain, reduced need for parenteral analgesia, and better early mobility with Kṣārasūtra [9-11, 14]. At the same time, the significantly longer overall wound-healing time observed in the Kṣārasūtra group is consistent with the stepwise cutting and healing mechanism and has been repeatedly highlighted as a trade-off of this technique [9, 12-14, 17]. Importantly, this prolonged healing occurred predominantly in the ambulatory setting, with shorter hospitalization and earlier return to work in the Kṣārasūtra group, underscoring that the extended course did not translate into prolonged institutional stay or productivity loss. Similar patterns longer tract-cutting duration but shorter in-hospital stay and earlier resumption of routine activities have been reported by previous authors and are often considered acceptable by patients when explained pre-operatively [9-11, 14-16].

Continence preservation is arguably the most critical functional endpoint in fistula surgery, given the profound quality-of-life implications of even minor incontinence [5-7]. In our study, Wexner scores at 6 months were significantly better in the Kṣārasūtra group, with only one patient experiencing transient gas incontinence that resolved by follow-up, compared with four patients in the conventional surgery arm, two of whom had persistent minor flatus incontinence. Though the absolute numbers are small, this pattern mirrors larger series and systematic reviews, in which Kṣārasūtra has been associated with minimal or no clinically significant incontinence when properly applied, while conventional wide fistulotomy/fistulectomy carries an appreciable risk, particularly for high tracts [5-7, 9-11, 14-16]. The observed greater improvement in generic quality-of-life scores in the Kṣārasūtra group likely reflects the combined effect of lower recurrence, better continence, and earlier functional recovery, reinforcing prior evidence that functional and psychosocial outcomes must be weighed alongside crude healing rates when comparing techniques [5-7, 11, 15, 16].

The complication profile in both groups was acceptable and broadly comparable, with a non-significant trend toward more wound-related events in the conventional surgery arm. Our overall infection and abscess rates are in line with other contemporary fistula series and suggest that, under standardized peri-operative antibiotic and wound-care protocols, Kṣārasūtra is not associated with an excess of local sepsis despite the prolonged presence of a foreign body [1, 5-7, 9-11, 14]. Case reports and small series have occasionally raised concerns regarding local irritation or excessive fibrosis with Kṣārasūtra, [12, 13, 17] but such events were not prominent in our cohort, likely reflecting adherence to established preparation and application protocols from classical and ICMR guidelines [9, 12-14, 17].

The present study has several strengths. It uses a randomized design with concealed allocation, standardized inclusion and exclusion criteria based on widely accepted cryptoglandular fistula definitions and imaging confirmation, and clearly defined primary and secondary outcomes that allow comparison with international literature [1-4, 5, 9-11]. Both arms followed current best-practice peri-operative care, and follow-up to 6 months captured the majority of early recurrences documented in previous series

[1, 3, 5, 7, 9-11]. In addition, the incorporation of validated continence and quality-of-life instruments situates our findings within the growing emphasis on patient-centred outcomes in anorectal surgery [5-7, 11, 15, 16].

However, certain limitations must be acknowledged. First, the sample size, though adequately powered to detect differences in recurrence at 6 months, remains modest and may not capture rarer complications or long-term functional sequelae; recurrence beyond 6-12 months, particularly in more complex tracts, remains a pertinent concern [1, 3, 5, 7]. Second, our study was conducted in a single tertiary Ayurvedic-integrated centre with considerable experience in Kṣārasūtra, which may limit generalizability to settings without similar expertise or infrastructure; outcomes with Kṣārasūtra are likely operator-dependent, as suggested by variability across published series [9-11, 14-17]. Third, although MRI/endoanal ultrasound was used for pre-operative mapping, routine post-healing imaging was not performed in all cases, so subclinical residual tracts cannot be fully excluded. Finally, we did not formally compare cost-effectiveness; prior work suggests that shorter hospitalization and fewer re-interventions may offset the prolonged ambulatory follow-up associated with Kṣārasūtra, but this requires dedicated economic analyses [8-11, 14-16].

Despite these limitations, the findings add to the body of evidence supporting Kṣārasūtra as a viable, sphincter-preserving alternative to conventional surgery for selected cases of cryptoglandular fistula-in-ano. In low and mid transsphincteric or intersphincteric tracts, particularly in younger patients for whom continence preservation and avoidance of re-intervention are paramount, Kṣārasūtra may reasonably be offered as a first-line option, provided appropriate patient counselling regarding the longer tract-cutting time and the need for regular thread changes [1, 3, 5-7, 9-11, 14-17]. Future multicentric trials with larger samples, longer follow-up, detailed cost-utility evaluations and head-to-head comparisons of classical Kṣārasūtra with newer IFTAK and other hybrid techniques will be valuable in refining patient selection and optimizing protocols. Integration of Ayurvedic para-surgical modalities within evidence-based colorectal care pathways, as exemplified by this study, may help bridge traditional and modern paradigms to achieve outcomes that are not only anatomically successful but also functionally and economically sustainable for patients with Bhagandara (fistula-in-ano) [3, 5-7, 9-17].

Conclusion

This randomized comparative study demonstrates that Kṣārasūtra therapy is a safe, effective and functionally favourable alternative to conventional surgery in the management of Bhagandara (fistula-in-ano), with high primary healing rates, significantly lower recurrence at six months, better continence preservation, shorter hospital stay and earlier return to work, despite a longer overall wound-healing duration. These findings reinforce the concept that, in appropriately selected cases, a gradually cutting, medicated seton can achieve durable eradication of the fistulous tract while minimizing sphincter trauma and protecting long-term anorectal function. From a practical standpoint, the results support several concrete recommendations for clinicians and health systems. First, Kṣārasūtra therapy should be considered a first-line or co-primary option for low and mid intersphincteric and transsphincteric cryptoglandular fistulas, particularly in

younger, working-age patients and in those who place a high premium on continence preservation and avoidance of repeat surgery. Second, colorectal and Shalya Tantra units should collaborate to establish structured Kṣārasūtra services that include standardized preparation of the medicated thread, strict aseptic technique, clear protocols for weekly thread changes and consistent documentation of tract progression, thereby reducing variability in outcomes and facilitating audit. Third, pre-operative counselling must explicitly address the trade-off between the shorter wound-healing period but higher recurrence and incontinence risk associated with some conventional procedures versus the longer, ambulatory course of Kṣārasūtra with lower recurrence and better functional outcomes; shared decision-making tools and patient information leaflets can help align expectations and improve adherence to follow-up. Fourth, for complex or high fistulas, or in recurrent disease after prior surgery, the study's findings should encourage the judicious integration of Kṣārasūtra, including staged or modified approaches such as intercepting only the extrasphincteric segment, into multimodal treatment plans rather than defaulting to extensive sphincter-dividing surgery. Fifth, hospital administrators and policymakers should recognize the potential system-level benefits of Kṣārasūtra reduced bed occupancy, lower need for re-interventions and improved productivity due to earlier return to work and support training programmes, interdisciplinary clinics and inclusion of this modality in clinical pathways and insurance packages. Finally, the favourable outcomes observed here should stimulate further multicentric research that extends follow-up, refines case selection (for example, by integrating imaging-based risk stratification), and rigorously compares classical Kṣārasūtra with newer sphincter-preserving techniques, including combinations with modern imaging and minimally invasive methods. In summary, this study indicates that when delivered within a standardized, ethically governed and patient-centred framework, Kṣārasūtra therapy can meaningfully reduce recurrence and functional morbidity in Bhagandara, and the practical steps outlined above provide a roadmap for clinicians, institutions and health systems seeking to translate these findings into routine, high-quality care.

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