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Effectiveness Of Medicated Seton Placement in The Management of Fistula in Ano: A Prospective Study (Effectiveness Of 'Ksharasutra' in FIA Management – A Prospective Study)

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Abstract:
Back ground*: This case series analysis, where patients were included on accrual, assessed the effectiveness of Ksharasutra in treating fistula-in-ano due to cryptoglandular infection and the impact of MRI on its management.*
Methods*: Of 74 patients, 35 had simple fistulae and 39 had complex ones, all treated with Ksharasutra as a seton. MRI fistulogram proved valuable for diagnosing occult complex fistulae and guiding treatment.*
Results: *Simple fistulae achieved a 100% healing rate with no recurrence or faecal incontinence. For complex fistulae, tailored Ksharasutra applications resulted in a 100% cure rate in certain types (e.g., multiple, fistulae with multiple openings, recurrent, associated with abscesses or inter sphincteric space sepsis,) High fistulae-in-ano and those with undelineated internal openings saw a 50-55% healing rate without complications. Different methods of applying Ksharasutra and their usefulness are described.*
Conclusions: *Ksharasutra application is a simple and safe method of treatment with minimum morbidity for all types of fistulae-in-ano due to cryptoglandular infection.*
Keywords: *fistula in ano, Ksharasutra, medicated seton, complex fistula in ano, simple fistula in ano and MRI fistulogram*

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I. Introduction:

Managing fistula-in-ano (FIA) presents significant challenges due to prolonged recovery, high recurrence rates, and the risk of incontinence associated with traditional surgical approaches. Patients often face extended pain, limited daily activities, and anxiety, prompting the search for less invasive yet effective alternatives. *Ksharasutra therapy*, an ancient Indian technique [1], has emerged as a promising candidate. This prospective observational study aimed to evaluate the efficacy of Ksharasutra in treating FIA due to cryptoglandular infection by analysing its cure rates, complications, and recurrence rates. It also assessed the impact of integrating modern diagnostics like MRI, along with anaesthesia, antibiotics, and analgesics, on treatment outcomes.

II. Aims And Objectives:

1. To evaluate the efficacy of Kshara Sutra therapy in the management of Fistula in Ano (FIA) by analysing the treatment's cure rates, associated complications, and recurrence rates.
2. To determine the impact of integrating modern diagnostic technologies, such as MRI, in conjunction with the use of anaesthesia, antibiotics, and analgesics, on the outcomes of Kshara Sutra therapy for FIA.

III. Patients And Methods

Patients with perianal complaints were examined, and eligible individuals (meeting inclusion criteria) received detailed explanations of their diagnosis, Ksharasutra treatment (benefits/limitations), and alternative options before providing *written informed consent.*

- *Inclusion Criteria:* fistula-in-ano due to Cryptoglandular infection, or fistulas recurring after surgery performed approximately one year prior.
- *Exclusion Criteria:* Fistulas due to systemic diseases (TB, Crohn's, UC), anal/anorectal carcinoma, unwilling participants, recurrences from surgery within the last 12 months, or rectovaginal fistulas.

1. A total of 74 consecutive fistula-in-ano patients were treated exclusively with Ksharasutra between January 2024 and April 2025, in Malla Reddy hospital, attached to Malla Reddy institute of medical sciences Suraram, Hyderabad with follow-up periods ranging from 30 days to 16 months.

Demographics and Clinical Evaluation

The study population predominantly consisted of males (77.7%) aged 30-50 and females (60%) aged 40-50, highlighting the importance of treatment strategies that minimize lost workdays. All patients underwent a thorough three-tier clinical and physical examination. Key clinical findings recorded included the number, position, and distance of external and internal openings, the presence of associated anorectal diseases (like haemorrhoids or fissures), the palpability, length, and direction of the fistulous tract, and the type of discharge.

Diagnostic Imaging and Classification

MRI fistulograms were performed on all patients to precisely delineate the fistula tract, internal opening, and classification. Most external openings (66 patients) were near the anal verge. MRI confirmed various classifications:

- **Low trans-sphincteric:** 35 cases
- **Low inter-sphincteric:** 34 cases
- **High trans-sphincteric:** 1 case
- **High inter-sphincteric:** 1 case
- No supra-sphincteric/extra-sphincteric cases were observed.

Further observations revealed tract lengths ranging from 7 cm to 20 cm. Internal openings were not visualized in 9 patients, and 14 patients presented with abscesses. Eleven cases with multiple external openings showed branching, and two patients had multiple distinct FIAs.

Based on these findings, fistulas were categorized as:

- **Simple Fistulas:** Low trans-sphincteric or low inter-sphincteric with less than 30% sphincter involvement.
- **Complex Fistulas:** High trans-sphincteric/inter-sphincteric (more than 30% sphincter involvement), multiple openings/FIAs, associated abscesses, non-visualized internal openings, or supra/extra-sphincteric types.

The methylene blue test was found ineffective for non-visualized internal openings if MRI had already failed to detect them.

Ksharasutra Application: Procedure Details

Ksharasutra is a medicated thread coated with Snuhi latex, Apamarga Kshara (from Achyranthes aspera ash), and turmeric. Apamarga Kshara provides a mild corrosive, base-like action; Snuhi latex acts as a binder; and turmeric offers antiseptic benefits. This thread works by a dual mechanism: gradually cutting the fistula tract while promoting a mild inflammatory response that aids healing [1].

Preoperative and Surgical Steps

Patients underwent a health check-up, a 24-hour clear liquid diet, overnight fasting, and bowel preparation. The procedure was performed under *regional or general anaesthesia*. Prophylactic intravenous antibiotics were administered. *Identification of Internal Opening*

This is perhaps the most crucial step, as missing the internal opening or creating a false passage can lead to complications and treatment failure.

Methylene Blue and Hydrogen Peroxide Test (Dye Test):

To aid in the precise identification of the internal opening, the anal canal and the distal one-third of the rectum are gently packed with three-gauge pieces of surgical gauze.

A sterile mixture of methylene blue and hydrogen peroxide (prepared in a 1:10 ratio, typically 2-5 ml) is carefully injected into the fistulous tract via the external opening.

The packed gauze pieces are then slowly and systematically removed one by one from the anal and rectal canal. The presence of methylene blue staining on the gauze confirms the exact location of the internal opening.

Threading the Ksharasutra

Once the internal opening is identified, the next step is to accurately guide the medicated thread through the entire fistula tract.

1.Fistula Probe Introduction:

A malleable metallic fistula probe with one end blunt tip and other end with eyelet is chosen. Its blunt end is meticulously introduced into the external opening. The probe is gently and carefully advanced along the identified fistulous tract. The surgeon uses tactile feedback and their knowledge of anatomy (and often, the pre-operative MRI fistulogram) to navigate the twists and turns of the tract.

Emergence at Internal Opening: The goal is for the probe's tip to emerge from the identified internal opening within the anal canal. If the internal opening is very small or difficult to probe, the surgeon may aim for the *most probable site* indicated by the MRI, sometimes gently enlarging it slightly to allow the probe to pass.

Ksharasutra Preparation and Loading:

A sterile length of Ksharasutra, typically 20-30 cm long, is prepared.

One end of the Ksharasutra is carefully threaded through the eyelet at one end of the fistula probe. This is done with precision to ensure it securely attached to the probe.

Pulling Through the Tract:

With the Ksharasutra now attached to the probe, the surgeon gently grasps the emerged tip of the fistula probe (along with the threaded Ksharasutra) within the anal canal using an artery forceps.

The probe is then slowly and steadily pulled *out* through the anal opening, simultaneously drawing the entire length of the Ksharasutra along with it through the fistula tract. This "railroad" technique ensures the thread follows the exact path of the fistula.

Securing the Ksharasutra

The final step in the initial application is to secure the Ksharasutra, creating the seton that will gradually cut and heal the fistula.

Positioning the Ends:

After the probe is completely withdrawn, one end of the Ksharasutra will be at the external opening (on the skin) and the other end will be at the internal opening (within the anal canal), having passed through the entire fistula tract.

Tying the Knot:

Both ends of the Ksharasutra are then carefully tied together. The type of knot and its tightness are crucial and determined by the clinical situation:

Snug Tie (for slow cutting action): If the primary goal is to promote a strong cutting action (e.g., in a well-defined tract with minimal discharge), the knot is tied snugly. This applies continuous pressure to the tissue, causing ischemia and gradual necrosis, allowing the thread to slowly cut through.

Tight tie (for cutting action): knot tied tightly to cut the indurated tissues in recurrent fistula.

Loose Tie (primarily for drainage): If there's significant pus discharge or an associated abscess, a loose knot might initially be preferred to allow for better drainage and prevent accumulation of fluid, before tightening in subsequent follow-ups.

The knot is typically a secure surgical knot (e.g., a square knot or a modified sliding knot) that will hold the thread in place.

The total operating time for the procedure is meticulously recorded.

Postoperative Care and Follow-up

Immediate postoperative care included intravenous fluids. Patients received oral antibiotics, analgesics, and stool softeners for three days, along with sitz baths thrice daily. Pain was assessed using the VAS scale. Patients were discharged with instructions for follow-up every 10 days.

Ksharasutra replacement was performed every 7-10 days using the "railroad method," where a new thread was tied to the old one and pulled through the tract. The old Kshara Sutra is then cut off, and the new one is re-tied in a similar manner (snugly or loosely as required).

This process continued until the entire tract was cut and healed, typically spanning 6-8 weeks. A significant advantage is the *simultaneous cutting and healing,* preventing wide, unhealed wounds and allowing patients to perform routine tasks with minimal pain.

Treatment Protocols and Outcomes
The study developed tailored Ksharasutra application protocols based on fistula classification.

Simple Fistula-in-Ano (35 patients)
Defined as a single external opening, no abscess, and low inter-sphincteric or trans-sphincteric.
No Discharge (20 patients): Ksharasutra applied immediately as a *"cutting seton"*.
With Discharge (15 patients): Initial antibiotics for 5-7 days. If the fistula dried (12 patients), a cutting seton was applied. If purulent discharge persisted (3 patients), culture-guided antibiotics and a *"draining seton***"** were used until dry, then converted to a cutting seton.

This approach yielded a *100% healing rate* in simple fistulas with minimal hospital stays (24-48 hours). The treatment duration averaged 7-8 weeks, extending to 11-12 weeks for longer tracts. Patients typically resumed work within 3-5 days.

Complex Fistula-in-Ano (39 patients)
Defined as any fistula other than a simple one, encompassing a variety of presentations.

Abscess/Collection (14 patients)
MRI is necessary to diagnose the inter sphincteric abscesses.

Abscesses > 30 mL (4 patients): Incision and drainage, followed by a draining seton for 1-2 weeks, and systemic antibiotics. Once dry, converted to a cutting seton.

Collections < 30 mL (10 patients): Directly received a draining seton for 7-14 days. Converted to a cutting seton once dry. All 14 patients achieved complete healing within 10-12 weeks, with minimal downtime (6-7 lost workdays) and only temporary flatus incontinence.

Multiple Openings
Single Tract with Multiple Openings (11 patients): MRI identified the main tract, and a cutting seton was applied. Short branches (<2 cm) were laid open. Longer branches (>2 cm) received an additional Ksharasutra from the secondary opening to a newly created opening at the main tract junction ("T" shaped). All 11 patients achieved good healing without recurrence or permanent incontinence, returning to work within seven days. This avoided the extensive raw surface of laying open all tracts.

Multiple Distinct Fistulae (2 patients): Each tract received a dedicated cutting seton after ruling out systemic causes like tuberculosis. One patient healed, while the other was lost to follow-up.

Fig.1 two fistlae ext openings | Fig.2 two probes passed in two fistulae | Fig.3 two Ksharasutras applied | Fig.4 fistula tract cut through

c. Undelineated Internal Opening (9 patients)

MRI guided probe insertion from external opening to the anal/rectal lumen, followed by Kshara Sutra application as ‘cutting seton’.
Two cases identified as *high FIA* (internal opening above anorectal junction)

High Fistula-in-Ano (2 patients)

Ksharasutra was applied snugly for slow, synchronized cutting and healing, preserving sphincter integrity. One case healed completely another patient lost for follow up.

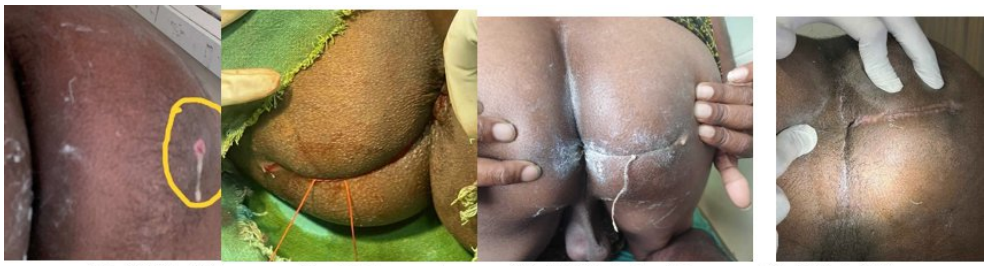

Fig.5 high FIA Fig.6 Ksharasutra Applied Fig.7 Fistula tract is healing. Fig.8 high FIA healed

Recurrent Fistula-in-Ano (1 patient)

One patient with a heavily scarred recurrent low trans-sphincteric fistula experienced more initial pain (7 days), pain after each Ksharasutra change (2 days), and a longer healing time (20 weeks) due to tissue induration, with 10 days of initial work loss and 2 days per change. Despite these challenges, Ksharasutra proved beneficial.

Simple Fistulas with Lengthy Tracts (>10 cm, 19 patients)

For tracts too long for a single Ksharasutra, a modified technique was used: A probe was passed through the tract. An incision was made on the middle of the tract over the probe, to create an opening. Two Ksharasutras were applied simultaneously to the distal and proximal segments. This reduced healing time, though these cases still took an additional 2-3 weeks compared to average.

Ksharasutra Tension

The tension of the Ksharasutra was adjusted based on tissue characteristics:
Soft Tissues (females, young patients <30): Applied snugly for controlled cutting.
Indurated Tissues (previous surgery, chronic infection): Applied tightly to cut through dense fibrotic tissue.
High FIA: Applied snugly for simultaneous cutting and healing to prevent strangulation.
Draining purpose: Applied loosely, like a drain, without tying.

IV. Results:

Postoperative Clinical Course and Therapeutic Outcomes

Table. 1. Postoperative Clinical Course

Fistula Classification	n	Treatment Duration (weeks)	Pain Duration (days)	Discharge Duration (days)	Work Resumption (days)	Transient Flatus Incontinence (3-5 days)	Incontinence for Faeces
Simple Fistula-in-Ano	27	7.0 SD 1	3.2 SD 0.4*	5.1 SD 1.2	3.0 SD 0.0	30/35	0
Simple fistula with long tract	8	11.0 SD 0.1	3.2 SD 0.4*	5.1 SD 1.2	5.0 SD 1.0	30/35	0
Complex Fistula (Abscess)	14	11.2 SD 0.8	4.0 SD 0.0*	14.0 SD 0.0	6.0 SD 1.0	14/14 (100%)	0
Single Tract, Multiple Openings	11	11.0 SD 0.0	3.8 SD 0.4	7.0 SD 0.0	6.0 SD 1.0	11/11 (100%)	0
Multiple Tracts	2	12.0 SD 0.0	4.5 SD 0.7	7.0 SD 0.0	7.0 SD 0.0	2/2 (100%)	0

Fistula Classification	n	Treatment Duration (weeks)	Pain Duration (days)	Discharge Duration (days)	Work Resumption (days)	Transient Flatus Incontinence (3-5 days)	Incontinence for Faeces
Undelineated Internal Opening	9	11.5 SD 0.5	4.1 SD 0.3*	7.0 SD 0.0	6.5 SD 0.7	9/9 (100%)	0
High fistula in ano	2	18 SD 2	5 SD 1*	7.0 SD 0.0	7 SD 0.0	2/2	0
Recurrent fistula	1	20 SD 2	7 SD 2*	10 SD 0.0	10	1/1	0

*Pain duration includes days after each Kshara Sutra change.

Table.2. Therapeutic Outcomes at 12-Month Follow-Up

Fistula Classification	n	Complete Healing (%)	Mean Healing Time (weeks)	Lost to Follow-Up	Recurrence	Complications
Simple Fistula-in-Ano	35	35 (100)	6.0 SD 0.0	0	0	None
Complex Fistula (Abscess)	14	14 (100)	11.2 SD 0.8	0	0	None
Single Tract, Multiple Openings	11	11 (100)	11.0 SD 0.0	0	0	None
Multiple Tracts	2	1 (50)	12.0 SD 0.0	1	0	None
Undelineated Internal Opening	9	5 (55.6)	11.5 SD 0.5	4	0	None
High fistula in ano	2	2 (100)	19 SD 1	1	0	None
Recurrent fistula in ano	1	1 (100)	20	0	0	None

Overall, simple fistulas achieved a *100% healing rate,* while complex fistulas demonstrated an *82% healing rate*. Follow-up MRI at 6 months for high and recurrent FIAs showed no residual inflammation, only fibrosed tracts.

V. Discussion

This study systematically demonstrates Ksharasutra's efficacy across various fistula types, emphasizing the importance of precise categorization and tailored treatment protocols. Traditional surgical fistulotomy, though effective for simple cases, carries considerable risks of recurrence (0.7-26.5%) and continence impairment (5-40%) [2], often exacerbated by factors like branching or missed internal openings [3,4]. Accurate diagnosis, ideally with MRI, is crucial, as many complex fistulas (34%) are clinically undetected [5].

Ksharasutra, in contrast, offers a simpler day-care procedure with benefits such as less pain, no raw wound, minimal postoperative care, and quicker recovery with fewer lost workdays. The study's 100% healing rate in simple fistulas is attributed to:

Accurate diagnosis using MRI to exclude complex cases.

Ksharasutra application to dry fistulas to prevent infection spread.

Snug (not tight) application to ensure balanced simultaneous cutting and healing.

Ksharasutra's anti-inflammatory and chemical properties promote controlled tissue inflammation and fibrosis, aiding both cutting and healing [1]. Its unique composition makes it superior to conventional setons, showing better healing and shorter healing times.

Management of Complex Fistulas

Fistulas with Abscesses/Collections (14 patients):

Between 15-40% of fistulas are associated with an abscess or collection [6,7]. The American Society of Colon and Rectal Surgeons recommends incision and drainage, but drain placement has shown comparable efficacy [8,9]. In this study of 14 patients with chronic fistulas and communicating abscesses, all were treated with *Ksharasutra*. Four initially underwent incision and drainage, then received Ksharasutra as a draining seton. The other 10 directly received Ksharasutra as a draining seton for 1-2 weeks to ensure continuous drainage and maintain tract patency. Subsequently, the Ksharasutra was used as a cutting seton, leading to complete healing in all 14 patients within 10-12 weeks. Patients experienced minimal downtime (6-7 lost workdays) and only temporary flatus incontinence. the study highlights the critical need for *continuous drainage [10],* for inter sphincteric sepsis. For *fistulas with abscesses/collections*, continuous drainage achieved by Ksharasutra as a draining seton was critical. This contrasts with other treatments that often fail due to inadequate drainage [10,11.]

Fistulas with Multiple Openings and Multiple Fistulae-in-Ano

Accurate preoperative diagnosis, ideally with MRI, is vital for both these complex fistula types. All cases in this study were classified as low trans sphincteric or inter sphincteric.

Fistulas with multiple openings, precise MRI mapping allowed for a targeted approach where a cutting seton was applied to the main tract, and branches were either laid open or received an additional Ksharasutra. This method avoided extensive raw surfaces and prolonged recovery

Multiple Fistulae-in-Ano

Often associated with systemic conditions (like tuberculosis or Crohn's), these cases were only included if systemic causes were ruled out. A dedicated *Ksharasutra* was applied to each individual tract. In this study's limited experience (two patients), one healed, and the other was lost to follow-up.

Fistulas with Undelineated Internal Openings

Identifying the internal opening of an anal fistula can be challenging in 10-25% of cases, even with advanced imaging like MRI[25]. An unlocated opening significantly increases *recurrence risk (up to 22 times higher) [12].*

In this study, for 9 simple and 2 high fistulas where the internal opening wasn't clear, *MRI was crucial* for meticulously mapping the fistula tract's length, direction, and distance to the mucosal surface. Additionally, the distance from the anal verge to the mucosal termination point of the tract was accurately measured and recorded. This detailed mapping guided the careful insertion of a fistula probe, enabling Ksharasutra application.

Ksharasutra achieved a 55% healing rate in LOW fistulas (5 out of 9 patients) and 50% in high fistulas (1 out of 2 patients) with undelineated internal openings, *without complications* like incontinence. This highlights a key advantage of Ksharasutra: it doesn't require forceful, potentially damaging, identification of the internal opening, which can lead to false passages and recurrence in other procedures. *Close collaboration with radiology is essential* for these complex cases.

Recurrent fistulas are challenging due to anatomical distortion and dense scar tissue from prior surgeries, making it difficult to assess sphincter involvement and increasing the risk of faecal incontinence. In these cases, a cutting seton is considered safer, and Ksharasutra is the preferred material.

While these cases involved more pain and longer healing times, the method successfully addressed the complexities without incontinence.

The modified technique for *simple fistulas with lengthy tracts* demonstrated that using two Ksharasutras simultaneously could reduce overall healing time.

Associated Conditions

The study successfully managed associated conditions like symptomatic haemorrhoids and chronic anal fissures concurrently with Ksharasutra application without complications or faecal incontinence.

VI. Conclusion:

In conclusion, *Ksharasutra application is a simple, effective treatment for fistula-in-ano that significantly minimizes work disruption compared to surgical procedures.* Its anti-inflammatory properties make it superior to other seton types. This study effectively demonstrated the efficacy of various Ksharasutra application methods tailored to different fistula types, showing excellent outcomes in simple fistulas (100% healing, no recurrence, no faecal incontinence) and varying but generally high healing rates (55-100%) in complex types without recurrence or incontinence. *MRI is crucial for accurate diagnosis and guiding treatment for complex*

cases. Anaesthesia, antibiotics, and analgesics serve as valuable adjuncts, enhancing patient comfort and recovery.

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Figures Legends

Figure 1: Two fistulae in ano openings are seen
Figure 2: Two probes passed through the two fistulae tracts
Figure 3: Two Ksharasutras passed through fistulae tracts
Figure 4: Fistulae tracts are cut through
Figure 5: high fistula in ano, external opening seen 10cm from anal opening
Figure 6: Ksharasutra applied.
Figure 7: fistulous tract was cutting through and simultaneously healing. Ksharasutra in place
Figure 8: Fistula healed well.