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# *Clinical Trial of Ksharsutra in The Management of Fistula in ANO*

***Dr. Deodatta Bhadlikar[1], Dr. Devyani Bhadlikar[2]***

*Principal/ Medical Director/ Professor[1], Professor[2]*

*Department of Shalya tantra[1], Department of Rasa Shastra & BK[2]*

*Rashtriya Ayurved College and Research Institute Hatnoor, Tehsil- Kannad, Dist. - Chhatrapati Sambhaji Nagar, Maharashtra[1], Sau Vandana Tasgaonkar Ayurved Mahavidyalaya Karjat, Dist.- Raigad, Maharashtra[2]*

***Email ID:*** *bhadlikar69@gmail.com[1], drdevyani.bhadlikar@gmail.com[2]*

## *ABSTRACT*

***Background:*** *Fistula-in-ano is a common anorectal condition with significant morbidity. Conventional surgery (fistulectomy/fistulotomy) often requires hospitalization, carries risks of recurrence (0.7–26.5%) and anal incontinence (5–40%), and involves painful postoperative care. Ksharsutra, an ancient Ayurvedic technique using a medicated thread (coated with Euphorbia neriifolia latex, Achyranthes aspera ash, and Curcuma longa), offers a non-surgical alternative.*

***Objective:*** *To compare the efficacy of Ksharsutra therapy versus conventional surgery in healing time, recurrence, and complications.*

***Methods:*** *Randomized controlled trial of 502 patients with fistula-in-ano. Patients were stratified by fistula type (subcutaneous, low anal, high anal) and randomized to Ksharsutra (n=265) or surgery (n=237). Ksharsutra was applied outpatient under local anesthesia and changed weekly until healing. Surgery involved fistulectomy or excision with secondary intention healing. Follow-up lasted one year post-healing.*

***Results:*** *Complete healing occurred in 100% of patients in both groups. Median healing time was longer with Ksharsutra (8 weeks) than surgery (4 weeks; $P<0.01$), though similar by 40 weeks (92% vs 98%). Recurrence at one year was significantly lower with Ksharsutra (4%) than surgery (11%). Mild anal*

*incontinence occurred in 5% (Ksharsutra, mostly transient) vs 9% (surgery, mostly permanent). Ksharsutra caused transient local burning and discharge; surgery caused postoperative pain requiring analgesics. No systemic side effects occurred with Ksharsutra.*

***Conclusion:*** *Despite slower initial healing, Ksharsutra provides better long-term outcomes with lower recurrence and incontinence rates. As an ambulatory, outpatient, cost-effective procedure requiring no hospitalization, it is a safe and effective alternative to surgery, especially for poor-risk patients.*

***KEYWORDS:*** *Fistula-in-ano, Ksharsutra, Ayurvedic treatment, Conventional surgery, Fistulectomy, Randomized controlled trial, Healing time, Recurrence rate, anal incontinence, Medicated thread, Euphorbia neriifolia, Achyranthes aspera, Curcuma longa, Ambulatory treatment, Outpatient procedure*

## INTRODUCTION

Fistula in ano is an age old, common condition prevalent all over the world. Considered second to haemorrhoids in importance amongst all anorectal conditions, its prevalence in study was reported to be 10 percent of patients and 4 perecnt of all new outpatients. A retrospective study from India reported anal fistula to constitute 1.6 percent of all surgical admission. However, a benign condition, fistula in ano leads to major physical, psychological and social problems due to the persistent discharge through the external opening. Most of the fistules develop after rupture of adequate drainage of pyogenic anorectal abseesses, which develop secondary to infection of the cryptic gland.

Surgical treatment demands familiarity of the surgeon with the anatomy of the anorectal region and with the pathogenesis of fistula in ano. The treatment usually comprises laying open or completely excising the fistulous track and then allow healing by secondary intention. This procedure requires hospitalisation and regular post-operative dressing which is often painful. Complete healing takes from a few weeks to months. The chances of recurrence (0.7 to 26.5%) and incidence of anal incontinence (5 to 40%) being rather high.

An alternative, non-operative ayurvedic technique known as Ksharsutra in the treatment of

fistula in ano. The method described by the ancient Indian surgeon Sushruta in his famous treatise, Sushruta Samhita (600 B.C) involves insertion, into the fistulous track, of a specially prepared medicated thread coated with herbal drugs, and rendered alkaline.

As per research on selected thrust areas of traditional medicine, with a new disease oriented approach and the role of ksharsutra in the management of fistula in ano was identified as one of the thrust areas selected. It was decided to evaluate the efficacy of Ksharsutra.

## MATERIALS AND METHODS

The trial aimed to evaluete the efficacy of Ksharsutra. The Ayurvedic medicated thread in comparison with surgery, on

**(i)** The healing of the fistulous track

**(ii)** Reccurrence of fistula, after complete healing.

### Preparation and Supply of Ksharsutra

The Ksharsutra (medicated thread) were prepared according to the standar method. The Ksharsutra was prepared by smearing a surgical linen thread (guage no. 20) with the fresh latex of Snuhi or Euphorbia nenifolia (a cactus plant) and a specially prepared alkaline powder (known as kshara) from the plant Achyranthes aspera (Apaamarga) and turmeric powder from the dried rhizomes of Curcuma fonga (turmeric, Haridra).

The processing of the thread is done inside a specially designed cabinet for drying the threads. The thread is manually coated first with the latex of F.neriifolia cleven times, followed by seven coatings of the latex and the ash (Kshaara) of A.aspera alternatively and dried. In the final - phase, three coatings of the ‘latex and turmeric powder are given alternatively. The thread thus prepared is sterilised by exposing to ultra violet radiation for 15 min in the cabinct and placed in a polythene bag which is transferred to a glass tube containing silica gel as the dessicant, before scaling the tube. The pH of the Kshaarasutra was ensured to be about 9.75, while the length was about 25 cm.

Each batch of Ksharsutra prepared with subjected to quality control, in terms of pH. Tensile strength and other physico-chemical parameters.

**Patients:** Each patient attending the OPDs are subjected to detailed clinical examination and only the following were considered eligible for inclusion in the randomized clinical trial. Patients with evidence of anal fistula and willing to (i) be hospitalised for 2 to 6 wk to undergo surgery; (ii) report once a week for change of thread Ksharsutra and (iii) report once in two months for one year for follow up, after the completion of treatment. Patients with diabetes, cardiovascular disease, renal disease and cellulitis adjacent to the anorectal area were excluded from the randomized controlled study. These patients were, however, treated with Ksharsutra and followed up under the 'non-randomized group', along with those patients who refused surgery or insisted on being treated with Ksharsutra.

After obtaining informed consent, the patients found eligible for the controlled study were randomly allocated to Ksharsutra or surgery groups by sealed envelope method after stratification by the type of fustula, as per Miligan and Morgan's clasification modified by Goligher as subcutaneous, low anal and high anal and based on whether the track was single or multiple.

**Treatment:** Ksharsutra was inserted in the outpatients department itself. The patient was placed in the lithotomy position and after aseptic preparation of the part, probing was done under local anesthesia with specially designed probes . After probing a sterile silk thread was passed through the fistulous track, tied and left n situ primary threading. A week later the silk thread was replaced by Ksharsutra by the rail track technique and tied snugly outside the anal orifice. The initial length of fistulous track was recorded by measuring the length of the silk thread. After insertion of Ksharsutra the patient was sent home and advised to continue his normal routine work. The thread was changed at weekly intervals till the thread fell out spontaneously and the track healed.

The surfical treatment comprised fistulectomy in the subcutaneous and low anal types of fistulae and excision of the track below the anorectal ring along with curetting of the upper track, in case of high anal fistulae. A malleable probe was passed through the track until it came out at the internal opening. Using the probe as a guide, the complete fistulous track along with adjacent tissue was excised as a wedge and the raw area was packed. Post operatively, the patient was advised regular aseptic dressing with loose packing to allow the wound to heal from the apex. Then time required for the wound to heal completely was recorded for each

patient. After healing by either of the treatment schedules, all the patients were asked to report once in two months for a period of one year for physical examination for any complications. The randomized controlled trial comprised 502 patients of fistula-in-ano. The pooled results based on 265 patients randomised to Ksharsutra treatment and 237 to surgery are presented here.

## RESULTS

**Condition of patients on admission:** In both the Ksharsutra and surgery series, nearly 90 per cent were males and nearly 30 percent aged under 3 yr while approximately 40 per cent were aged 30-44 yr. Patients constituted 38 per cent of the Ksharsutra and 28 per cent of the surgery the corresponding proportions being 36 and 38 percent.

The characteristics of anal fistula, on admission, are summarised in Table. nearly 50 percent of patients in the Ksharsutra and 44 percent in surgery had the disease for atleast one year, and about a fourth of the patients in each had previous anal surgery. The type of fistula was subcutaneous in 29 percent of the Ksharsutra and 26 per cent of the survery, low anal in 56 and 61 percent and high anal in 15 and 14 percent, respectively. The two were also similar with respect to other characteristics such as the depth and shape of the fistula, distance from the anal margin and the location of the fistulous opening. In short, the Ksharsutra patients and the Surgery patients were broadly similar on admission to the clinical trial, in all respect.

***Table 1: Characteristics of the anal fistula on admission***

| Characteristics | % of Patients | |
|---|---|---|
| | **Ksharsutra n = 265** | **Surgery n = 237** |
| **Duration of disease (yr)** | | |
| <1 | 49 | 56 |
| 1 – 2 | 33 | 21 |
| ≥3 | 17 | 23 |
| **Type of fistula** | | |
| Subcutaneous | 29 | 26 |
| Low Anal | 56 | 61 |

| | | |
|---|---|---|
| High Anal | 15 | 14 |
| **Depth of Fistula (cm)** | | |
| <3 | 53 | 62 |
| 3 – 4 | 34 | 31 |
| ≥5 | 13 | 8 |
| **Shape of fistula** | | |
| Radial | 26 | 16 |
| Curved | 45 | 41 |
| Straight | 28 | 38 |
| Others | 1 | 4 |
| **Distance from anal margin (cm)** | | |
| <3 | 63 | 70 |
| 3 – 4 | 29 | 26 |
| ≥5 | 8 | 4 |
| **Location of the fistulous opening :** | | |
| Towards rectum | 77 | 75 |
| Towards anal canal | 18 | 17 |
| Others | 5 | 8 |

**Speed of healing of the fistulous track:** Healing took place in all 265 patients subject to Ksharsutra and also in all 237 patients subject to surgery. However, the healing was relatively slow in-patient treated with Ksharsutra. Thus, the proportion with healing by 12 week was 68 per cent in the Ksharsutra as compared to 89 percent in the surgery. (Table-2) a significance difference ($P < 0.01$). By 40 week the proportions became farily similar, i.e. 92 and 98 per cent respectively. The median healing time was 8.0 week in Ksharsutra series and 4.0 week in the surgery series) $P<0.01$).

In both the speed of healing varied appreciably with the type of anal fistula ($P<0.01$). Thus in the Ksharsutra the median healing time was 5.0 week in subcutaneous type, 8.0 week inlow anal type and 15.0 week in high anal type of fistula. The corresponding figures in the Surgery also showed a similar trend but were constitenly lower viz. 2.0, 4.5 and 8.0 week respectively. The difference in median healing time between the Ksharsutra and the surgery varied with the

type of fistula, being 3.0 wk in subcutaneous type, 3.5 wk in low analy type and 7.0 wk inhigh anal type.

***Table 2: Speed of healing of anal fistula in Ksharsutra and surgery.***

| Time | Percentage of patients with healing | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | All types | | Subcutaneous | | Low anal | | High Anal | |
| | K | S | K | S | K | S | K | S |
| By 12 wk | 68 | 89 | 88 | 95 | 67 | 88 | 33 | 78 |
| By 26 wk | 86 | 97 | 97 | 97 | 85 | 97 | 64 | 97 |
| By 40 wk | 92 | 98 | 97 | 98 | 91 | 98 | 85 | 100 |
| By 52 wk | 95 | 98 | 100 | 98 | 94 | 99 | 87 | 100 |
| After 52 wk | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| Total number of patients | 265 | 237 | 77 | 61 | 147 | 144 | 39 | 32 |
| Median healing time (wk) | 8.0 | 4.0 | 5.0 | 2.0 | 8.0 | 4.5 | 15.0 | 8.0 |

**Side effects and complications**: With Kshara sutra treatment, almost all the patiens complained of local burning sensation expecially after the first insertion this lasted usually for a few minutes and was rarely of a severe nature requiring mediation. Increased discharge from the fistulous opening was observed in the first few days in most of the patients, required the use of a pad. During one year, follow up anal incontinence was observed in eight patients (5%) treated with Kshara sutra and this was mostly of mild type and six of them recovered sphineter control. Recurrent parienal absesses were seen in five paients and incomplete prolapse of rectum in two patients.

With surgical treatment, all the patients had post operative pain lasting for few days and requiring analgesies. During the follow up, anal incontinence, mostly of mild type, occurred in 13 patients (9%), four of whom recovered sphineter control. Recurrent perianal abscess and incomplete rectal prolapse were observed in five and two patients resepctively.

## DISCUSSION

Fistula in ano is known to be predominantly a disease of men and of middle age. In the present study also, most of the patients were males. Single track being found in 90 percent and low anal fistula in 59 percent in this study.

Healing occurred in all the patients treated with either Kshara sutra or surgery. In the present study, the healing rate was slower with Kshara sutra as compared to surgery. Thus, the proportions with healing by 12 wk were 68 and 89 percent, but became 92 and 98 percent by 40 wk. The median healing time was 8 wk for Kshara sutra as compared to 4 wk with surgery. This could be due to a slow cauterisation of the track by Kshara sutra, through its herbal ingredients. The median healing time was least for subcutaneous fistula and maximum for high anal fistula. A wide variation in healing time following surgery has been reported from 4 to 26 wk in low anal fistula and 8 to 52 wk in high anal fistula. A healing rate of 74 percent is reported in uncomplicated fistula. Within 12 wk of surgery. In the present study, the median healing time following surgery, was 2.0 wk for subcutaneous, 4.5 wk for low anal and 8.0 wk for high anal fistula.

Kshara sutra treatment does not require hspitalisation, whereas the average hospital stay following surgery varies from 3 to 16 days. Patients treated with Kshara sutra could continue with their normal routine work.

Recurrence rate over one year follow up was 4 percent in the Kshara sutra group, as compared to 11 percent in the surgery group and this rate was not affected by the type of fistula. Previous anal surgery, however, adversely affected the recurrence rate in surgically treated patients but not in those treated with Kshara sutra.

Surgical treatment of anal fistula is known to have a recurrence rate ranging from 0.7 to 26.5 per cent, most of the recurrences (77-82%) being reported within one year. High anal fistulae have been reported to be associated with higher incidence of recurrence, though this was not observed in the present study. High recurrence after surgery is mainly due to incomplete laying open/ excision of track and faster union of skin edges. Slow and gradual cutting with simultaneous healing and complete destruction of the cryptic gland by the caustic action of the thread. Recent advances in surgical techniques and the advantage of anal manometry have also

led to a reduced rate of recurrence with surgery.

Mild anal incontinence was observed in patients treated with Kshara sutra as also in those treated surgically. In the Kshara sutra, the incontinence was temporary and perhaps related to the stage of cutting through the anal sphincters by the thread, which subsequently led to complete recovery, during follow up. High Risk of postoperative incontinence known to be associated with high anal and complicated fistulae may be attributed to factors like surgical trauma to the anal sphincters, sensory nerve damage and excessive loss of anal skin. In most cases, the damage is permanent, as also observed in 9 of the 13 patients in our series. A lower incidence (3%) of anal incontinence has been reported with the recent use of mucosal advancement technique following fistulectomy.

Based on the results of this Kshara sutra randomized clinical trial, it is concluded that the long-term outcome is better with than with surgery, even though the initial healing may take longer. Similar results with respect to healing and recurrence were obtained with Kshara sutra treatment in another series of 269 patients who were ineligible for the randomized control study including those who refused surgery.

Kshara sutra technique can be used in the outpatient department under local anesthesia. Patients are ambulatory thorughout the period of treatment and do not need regular dressings. The method is also more acceptable than surgery to most patients as it avoids any invasive surgical intervention. No systemic side effects were encountered with Kshara sutra, although transient local effects like slight burning and discomfort were observed. These local effects can be attributed to the caustic nature of the latex and the ash (Kshara) used in the thread. Another advantage of the technique is that poor risk patient for anesthesia and surgery can also be subjected to Kshara sutra treatment safetly. As no hospitalization is required, Kshara sutra can be more cost effective than surgery and therefore, more suitable. This advantages of Kshara sutra has also been emphasized by others. Disadvantages of Kshara sutra include the necessity for weekly hospital visits for changing the thread, apart from local burning sensation and increased discharge. Despite these, Kshara sutra technique offers an effective, ambulatory and safe, alternative treatment for patients with anal fistula.

The mechanism of action of Kshara sutra in healing the fistula track has not yet been clearly

elucidated. Among the three ingredients of the thread, the latex of E.nerifolia is well known in Ayurveda for its wound healing property. Whereas Acharanthes aspera Kshara (ash) is considered necessary for ensuring the aklanine medium, without which the thread is not at all effective. Curcuma longa or turmeric powder is used as the last coasting on the thread of aid in (i) minimizing the severe local reaction due to the caustic action of the other two herbal ingredients and also
(ii) for its known anti inflamatory and anti-infective efficacy. Anti-inflammatory, anti bacerial and anti-leprosy actions of Achyranthes aspera have been reported and there are a number of reports on Curcuma longa and its active constituent curcumin to demonstrate anti-inflammatory and anti-bacterial activities.

In the case of Kshara sutra it appears that the combination of the three herbal ingredients, through the medium of the thread achieves the desired results,. The techniques of Kshara sutra therefore constitues not only a unique drug formulation but also a novel method of drug delivery, most appripriate for healing the fistulous track.

Recently the results of preliminary chemical analysis of the thread used in Kshara sutra have been reported. In depth chemical studies on the finished thread as well as the individual ingrediднts of Kshara sutra. The results of these studies will be reported separetely. Studies are also under way to determine variation in clinical efficacy and physio chemical characteristics of different batches of thread manufactured under strict quality control.

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