Efficacy of Kshar Sutra (medicated seton) therapy in the management of Fistula-in-Ano

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Abstract

Background Fistulas in ano are common at any time of human life and difficult to manage. Aims To compare Kshar sutra (medicated seton) therapy with linen thread in the management of fistula in ano. Histopathologic study was undertaken to compare the pattern of excision of fistula. Settings and Design A nonblinded, noncrossover prospective randomised controlled study. Methods and Materials The technique involved passing a medicated seton through the fistulous tract. The concept of Kshar Sutra Therapy has been taken from ancient Ayurvedic classic “Sushruta Samhita”. Sixty patients with fistula in ano of cryptoglandular origin were selected and divided into two groups of thirty patients each. Group A was treated with Kshar sutra and the Group B with the surgical linen thread number 20. Statistical analysis used Student’s t-test (SPSS Version 7.5.1) was applied for statistical analysis. Results The healing occurred in all the patients treated either with Kshar Sutra or plain thread. The median healing time was 7 weeks for Kshar Sutra and 11 weeks with plain thread. Recurrence rate was only 3.33 percent (1 patient) with the Kshar Sutra and 13.33 percent (4 patients) with plain thread. Mild incontinence led to complete recovery during follow-up irrespective of whether treated with the plain thread or Kshar Sutra. Histopathologic study showed that the cutting and healing of the fistulous tract was not a mechanical effect of Kshar Sutra only but it was also due to anti-inflammatory and the chemical properties of the drugs. Conclusion The technique of Kshar Sutra therapy is appropriate for healing of the fistulous tract with minimal complications and insignificant rate of recurrence and incontinence.

KEYWORDS: fistula in ano; kshar sutra; recurrence; incontinence
INTRODUCTION

The purpose of this study was to assess the results of Kshar Sutra therapy (medicated seton) in the management of Fistula in ano in comparison to plain surgical linen thread.

Fistula-in-Ano, considered second to haemorrhoids in importance among all ano-rectal abnormalities, is prevalent all over the world and its incidence in a London hospital study was reported to be 10% of all in patients and 4% of all new out patients.[1] Similar study in India reported anal fistula to constitute 1.6% of all surgical admission.[2]

Surgical treatment of fistula in ano requires hospitalisation, regular post-operative care and is associated with a significant risk of recurrence (0.7 to 26.5%) and a high risk of impaired continence (5 to 40%).[3,4] To alleviate such miserable problems, surgeons have been craving for some alternative technique to treat these cases with minimal operative complications and failure.

In this study we have evaluated the efficacy of a unique parasurgical procedure in the management of fistula-in-ano, which included the application of medicated thread (Kshar sutra, derived from Sanskrit word- Kshara means, to cut; Sutra means thread) coated with herbal drugs and rendered alkaline.

MATERIALS AND METHODS

In the preparation of Kshar Sutra, (medicated thread) three herbal drugs had been taken namely-

1. Latex of Commiphera mukul (family-Burseraceae)
2. Alkaline powder (Kshar) of Achyranthes aspera (family- Amaranthaceae)
3. Powder of Curcuma longa (family-Asitaminacea)

Latex of C. mukul, oleoresin exudate was collected and put into absolute alcohol (200 gm in 500 ml). Latex, dissolved in alcohol after few days, was filtered through fine cloth and was taken as dirty yellow coloured sticky solution.

For alkaline powder (Kshar) of A. aspera, the whole plant was collected and allowed drying under shade. When completely dried, the plant was cut into pieces and burnt in iron vessel into ashes. The ashes were mixed with six times of water and allow the precipitate to settle down. Finally, the supernatant fluid was collected in a separate vessel. The residual ashes were again mixed with four times of water and the same procedure was repeated at least twice in order to take away all the alkaline material from ashes. The collected fluid was then filtered through double Wartman filter paper into clean glass container. Finally, alkaline powder was obtained from evaporation of filtered solution of ash prepared by incineration of A. aspera plant.
For the powder of *C. longa*, dried rhizomes of *C. longa* (turmeric) plant were cut into pieces, crushed in grinder, filtered through the fine cloth and was kept in a clean glass jar.

**Preparation of Kshar sutra**

For the preparation of thread, surgical linen thread gauge number 20 was manually coated eleven times with the latex of *C. mukul*, followed by seven coatings of the latex and the alkaline powder of *A. aspera* alternatively, and dried. In the final phase, three coatings of latex and powder of *C. longa* were given alternatively.

The thread thus prepared was sterilized by ultra violet radiation and placed in a polythene bag, which was transferred to a glass tube containing silica gel as a desiccant, before sealing the tube. The pH of the thread was ensured to be about 9.75, while the length was about 25-28 cm.

**Patients**

Patients were selected randomly from all age groups of both sexes, different duration of signs and symptoms, from August 1999 to December 2001. During this period 87 patients were registered, out of them 60 patients with fistula of cryptoglandular origin had been selected for this study and divided into two groups of 30 patients each. Group A was treated with *Kshar sutra* and the Group B was treated with the plain surgical linen thread number 20.

All had a history of previous perianal suppuration drained spontaneously. Patients with fistula associated with inflammatory bowel disease, malignancy, tuberculosis and pelvic pathologies were not included.

**Application of Kshar sutra**

Before application of *Kshar sutra*, patients were advised to maintain proper local part preparation and general hygiene, to take mild laxatives for regularization of bowel. With proper bowel preparation, patient was placed in lithotomy position and after aseptic preparation of the part, probing was done under local anaesthesia.

Probe was passed into the external opening of fistula; gradually extended to the internal opening and before taking it out, a *Kshar sutra* was threaded into the eye of probe, present at tail end and then probe was taken out through anal orifice (Figure 1 & 2). The *Kshar sutra*, passed through the fistulous track, and tied snugly outside the anal orifice and left *in situ* (primary threading) (Figure 3). One week later, the old *Kshar sutra* was replaced by new one by railroad technique. After replacement of the *Kshar sutra*, the patient was advised to continue his normal routine work. The *Kshar sutra* was changed weekly till it fell out spontaneously.
Similar procedure was adopted for the patients of group B with the use of plain thread number 20. During this therapy, patients were advised to take regular stool softener and apply sitz bath to local area twice a day. Systemic anti-inflammatory analgesic agents were advised whenever required.

Tissue biopsy of approximately 2-3 mm size was taken with sharp knife from the bed of the fistula after 4 weeks, 6 weeks and 8 weeks of the treatment. Slides were stained with hematoxylin & eosin and were examined under light microscope with 250X magnification.

**Follow up**

Patients of both the groups were advised to visit ano-rectal clinic once in a month for first six months, bimonthly for next six months and then quarterly for next year to make thorough two-year follow-up.

**Statistical Analysis**

SPSS (Statistical Package for Social Sciences, Version 7.5.1 Standard Version. SPSS incorporated 1989-1996) was applied for statistical analysis. The results were presented as percentages, or means and standard deviations. Continuous data were analysed with Student's $t$-test.

**RESULTS**

Patient demographics were defined in table 1. In both the groups, the age of the patients ranged from 18 to 68 years and approximately 50 percent of them were in the age group of 30-50 years. Nearly 90 percent were males. All the 60 patients had a history of perianal abscess with spontaneous drainage. The duration of fistula varied from 1 month to 24 years in which nearly half (51 percent) of the patients had the disease from the past one to two years.

The anal fistulae were classified according to Parks et al \[5\] as follows: 12 (40 percent) in group A and 15 (50 percent) in group B intersphincteric; 10 (33.33 percent) in group A and 9 (30 percent) transsphincteric; 7 (23.34 percent) in group A and 3 (10 percent) in group B suprasphincteric and 1 (3.33 percent) in group A and 3 (10 percent) in group B extrasphincteric.

The distance of the external opening from the anal margin varied from 0.8 cm to 12 cm. The external opening was single in all the patients and most commonly, 23 patients (38 percent), located posteriorly between 5 o' clock to 7 o' clock position. The depth of the fistula is less than 3.0 cm in nearly half of the cases (51 percent); the shortest fistula measured 1.5 cm whereas longest one was of 11 cm. Internal opening could be negotiated in 54 (90 percent) patients whereas in 6 patients internal opening was created at a highest weak point of the anal canal.
The group statistics was given in table 2. The median healing time was 7 weeks for Kshar Sutra (group A) as compared to 11 weeks (p=0.001, df=58, 95% CI upper=1.33, lower=4.60) with plain thread (group B). It was calculated as the time taken by the Kshar sutra or plain thread to cut the fistulous tract in weeks.

The number of changing of the thread ranged from 4 to 9 with Kshar sutra as compared to 5 to 14 with the plain thread. The healing time was minimal in the age group of less than 30 years (4 weeks in group A and 6 weeks in group B), in the males (3 weeks in group A and 4 weeks in group B), in the intersphincteric type of fistulae (4 weeks in group A and 7 weeks in group B) and with the disease of less than one-year duration (2 weeks in group A and 4 weeks in group B).

Median healing time was greater with the distance of fistula from the anal margin (2 weeks in group A and 4 weeks in group B with distance of less than 2 cm whereas 9 weeks in group A and 14 weeks in group B with distance of more than 5 cm).

Recurrence rate over four-year follow up was only 3.33 percent (1 patient) with the Kshar sutra therapy as compared to 13.33 percent (4 patients) with plain thread.

Mild incontinence like staining of underclothing and difficulty in holding gas were present in 2 (3.33 percent) patients of suprasphincteric fistulae, treated with Kshar Sutra and in 4 (6.66 percent) patients (3 patient of suprasphincteric and 1 patient of extrasphincteric fistulae) treated with plain thread but these were transient and get corrected after a period of 3-4 weeks.

Histopathologic study showed early debridement of necrosed tissue, significant reduction in inflammatory components, early fibroblastic proliferation, proper collagen laying and vascular proliferation in the wound treated with Kshar Sutra (group A) (Figure 4 & 5).

**DISCUSSION**

The management of fistula in ano in an effective manner has always been a challenge to the surgeons world over. The conventional operative treatment of low fistula in ano is to lay open or completely excise the fistulous track and allow healing by open granulation. In high anal fistulae, complete excision is not possible and the operative procedure has had to be modified to consist of partial excision along with the use of a seton to achieve cure.\[6,7\]

Fistula in ano is known to be predominantly a disease of middle-aged men. In the present study also, males predominates with a ratio of 9:1 as compared to 7:1, 9:1, 12:1 in other Indian studies.\[2,8,9\] The age distribution of patients was also similar to that reported by others.\[10,11\] The incidence of various types of fistulae also corresponded with those reported by others.\[10,12-15\]
In earlier studies, healing occurred in almost all the patients treated with *Kshar Sutra*. The healing rate was slower with plain thread as compared to *Kshar Sutra*. The median healing time was 7 weeks for *Kshar Sutra* as compared to 11 weeks with plain thread. This could be due to the fact that plain thread exerted only mechanical cutting effect whereas *Kshar Sutra* not only cut the track but also debride the fistula through its herbal ingredients effectively. Earlier studies of *Kshar Sutra* therapy have reported median healing time from 8 weeks to 12 weeks. A wide variation in healing time following surgery has been reported, from 4 to 26 weeks in low anal fistula and 8 to 52 weeks in high anal fistula.

In the present study, healing occurred in all the patients treated with either *Kshar Sutra* or plain thread whereas earlier studies have reported some patients failed to heal. In other studies on surgical treatment of anal fistula, 0.3 to 5.6 percent patients failed to heal following surgery and most of the patients who failed to heal had either high anal fistula or associated disease.

Recurrence rate over two-year follow up was only 3.33 percent (1 patient) with the *Kshar Sutra* therapy as compared to 13.33 percent (4 patients) with plain thread. This showed *Kshar Sutra* has got unique healing properties attributed to its herbal ingredients apart from mechanical cutting. Earlier studies reported 2 to 4 percent recurrence rate with the *Kshar Sutra* therapy.

Various seton therapies of fistula in ano are known to have a recurrence rate ranging from 2 to 4 percent, most of the recurrences (77 to 82 percent) being reported within one year. Surgical treatment of fistula in ano also reported 0.7 to 26.5 percent recurrence rate. High anal fistulae have been reported to be associated with higher incidence of recurrence though this was not observed with *Kshar Sutra* therapy. We have also not encountered recurrence problem with high anal fistulae.

Mild incontinence like staining of underclothing and difficulty in holding gas were present with some patients but these were transient and usually related to the stage of cutting through the anal sphincters by the tread, which subsequently led to complete recovery, during follow up irrespective of whether treated with the plain thread or *Kshar Sutra*.

Previous studies of *Kshar Sutra* therapy and wire seton therapy found almost no case of incontinence in their series. Surgical treatment caused high incidence of incontinence particularly with high anal and complicated fistulae that increased linearly with estimated amount of external sphincter divided during surgical treatment.

*Kshar Sutra* treatment is an outpatient procedure and can be done in a minor operation theatre. It does not require hospitalisation, whereas
the average hospital stay following surgery varies from 3 to 16 days.\textsuperscript{[10,14]} Patients can resume their job on the same day and are not left with a large perineal wound and its associated morbidity. The presence of \textit{Kshar Sutra} did not bother them as was also demonstrated by earlier studies.\textsuperscript{[9,16]} Contrary to that, the mean duration of absence from work in surgically treated patients has been reported to be 49 days.\textsuperscript{[10]}

The \textit{Kshar Sutra} therapy in fistula \textit{in ano} of cryptoglandular origin, evaluated in this study is having many advantages with minimal complications and thus can be considered as preferable method of treatment for the following reasons—

1. It is technically easy, safe, simple and does not require any special paraphernalia. It can be carried out in the outpatient department, as most of the cases do not require any anaesthesia also, it is considered as cost-effective treatment as compared to others.
2. It does not require hospitalisation and patients could continue with their normal routine work, thus patient’s social, psychological and economic status is not disturbed during the treatment.
3. Impaired continence is transient and related to the stage of ‘cutting through’ the anal sphincters by the \textit{Kshar Sutra}, which subsequently lead to complete recovery, during follow-up.
4. The rate of recurrence after the treatment is negligible as compared to its various other seton and surgical management.
5. It is an ideal management for the patients of old age or having respiratory or cardiovascular diseases and or otherwise unfit for surgery.
6. No systemic side effects are encountered with \textit{Kshar Sutra} therapy, although transient infection, local burning sensation, mild pain, itching and slight indurations are observed, which rarely need medication.
7. Post-operative tissue damage and scarring are minimal.

The \textit{Kshar Sutra} therapy, a unique method of drug delivery, most appropriate for healing the fistulous track offers an effective, ambulatory and safe alternative treatment in patients with fistula \textit{in ano}.

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http://services.bepress.com/wjcs/vol2/iss1/art6
REFERENCES
Table 1: Patient demographics on admission

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Number of patients (percent)</th>
<th>Group A (Kshar Sutra) (n = 30)</th>
<th>Group B (Plain Thread) (n = 30)</th>
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<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 20</td>
<td>3 (10)</td>
<td>2 (6.66)</td>
<td></td>
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<tr>
<td>20-30</td>
<td>6 (20)</td>
<td>6 (20)</td>
<td></td>
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<tr>
<td>30-40</td>
<td>8 (26.66)</td>
<td>10 (33.33)</td>
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<tr>
<td>40-50</td>
<td>7 (23.34)</td>
<td>8 (26.66)</td>
<td></td>
</tr>
<tr>
<td>&gt;50</td>
<td>6 (20)</td>
<td>4 (13.33)</td>
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</tr>
<tr>
<td><strong>Mean (SD)</strong></td>
<td>37.8 (13.6)</td>
<td>37.8 (12.9)</td>
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</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>26 (86.66)</td>
<td>27 (90)</td>
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</tr>
<tr>
<td>Female</td>
<td>4 (13.33)</td>
<td>3 (10)</td>
<td></td>
</tr>
<tr>
<td><strong>Duration of disease (years)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1</td>
<td>10 (33.33)</td>
<td>8 (26.66)</td>
<td></td>
</tr>
<tr>
<td>1-2</td>
<td>16 (53.33)</td>
<td>15 (50)</td>
<td></td>
</tr>
<tr>
<td>≥3</td>
<td>4 (13.33)</td>
<td>7 (23.34)</td>
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<tr>
<td><strong>Mean (SD)</strong></td>
<td>2.14 (3.12)</td>
<td>2.34 (4.32)</td>
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<td><strong>Type of fistula</strong></td>
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</tr>
<tr>
<td>Intersphincteric</td>
<td>12 (40)</td>
<td>15 (50)</td>
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<tr>
<td>Transssphincteric</td>
<td>10 (33.33)</td>
<td>9 (30)</td>
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<tr>
<td>Suprasphincteric</td>
<td>7 (23.34)</td>
<td>3 (10)</td>
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<tr>
<td>Extrasphincteric</td>
<td>1 (3.33)</td>
<td>3 (10)</td>
<td></td>
</tr>
<tr>
<td><strong>Distance of external opening from anal margin (cm)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>&lt;2</td>
<td>19 (63.33)</td>
<td>20 (66.66)</td>
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</tr>
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<tr>
<td>≥5</td>
<td>5 (16.66)</td>
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<tr>
<td><strong>Depth of fistula (cm)</strong></td>
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<td>&lt; 3</td>
<td>16 (53.33)</td>
<td>15 (50)</td>
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<td>8 (26.66)</td>
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<td>≥ 5</td>
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Table 2: Group Statistics

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<th>Group</th>
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<th>Standard Deviation</th>
<th>Standard Error Mean</th>
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<td>Group A</td>
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<tr>
<td>Group B</td>
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<td>8.86</td>
<td>3.65</td>
<td>0.67</td>
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