

MULTICENTRIC RANDOMIZED CONTROLLED TRIAL OF KSHAAR-SOOTRA (HERBAL MEDICATED THREAD) IN THE MANAGEMENT OF BHAGANDAR (FISTULA-IN-ANO)

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ABSTRACT

Introduction: The condition of complicated, recurrent and high anal fistula, although not a major surgical task; but always remains a nagging issue not only to the patients but to the surgeon as well. The present method of Kshaar Sootra treatment in anal fistula has been found efficacious and have been accepted by many countries in world. **Aims and Objectives:** To calculate the healing time of the fistulous track, to evaluate the recurrence rate of fistula, to assess side effects and complications and to estimate the time of hospitalization. **Materials and Methods:** Total 106 no. of patients were taken in two different groups. Group K: 55 patients-Trial group (received Kshaar Sootra treatment) Group S: 51 patients -Control group (received surgical treatment-i.e. fistulectomy). **Observations and statistical analysis-** all the observations are recorded in tabular form. Paired t-test & unpaired t-test are used to compare both the groups.

Results: from both groups show significant results, but long term outcome is better with 'K' group then 'S' group. Poor risk patients for anesthesia and surgery can also be subjected to Kshaar-Sootra treatment safely.

Keywords: Kshaar Sootra, fistulectomy, fistula-in-ano

INTRODUCTION:

As you know that the anal fistula is a notorious disease due to its anatomical situation and recurrence even with skilled surgeons. Its location and tendency to recur many a times brings discredit frustration to the surgical fraternity. The condition of complicated, recurrent and high fistula in ano, although not a major surgical task, but always remains a nagging issue not only to the patient but to the surgeon as well. The present method of *kshaar-Sootra* treatment

in anal fistula has been found efficacious and have been accepted by many countries in world.

Aims and Objectives: this research paper aimed to evaluate the following points.

- A) Healing time of the fistulous track.
- B) Recurrence rate of fitula.
- C) Side effects and complications.
- D) Time of Hospitalization.

Materials and Methods: The *Kshaar-Sootra* is prepared by smearing a surgical linen thread (gauge no. 20) with the fresh

latex of *euphorbia nerifolia* and a specially prepared alkaline powder (known as *kshaar*) from the plant of *achyranthes aspera* and turmeric powder from dried rhizomes of *curcuma longa*.

Method: The thread is manually coated first with the latex of *euphorbia nerifolia* for eleven times. Followed by seven coating of the latex and the ash of *achyranthes aspera* alternatively and dried it. In the final phase, three coatings of the latex and turmeric powder are given alternatively.

The thread thus prepared is sterilized by exposing to ultra violet radiation for few minutes and placed in a polythene bag. This is transferred to a glass tube containing silica gel. Before sending the tube the pH of the *kshaar-sootra* was ensured to be about 9.7, while the length was about 25cm. And the thread gauge numbering 14 to 17 thicknesses is accepted as the standard one. The whole processing of the thread is done inside a specially designed cabinet.

Patients: Patients attending the Ano-Rectal Clinic (ARC) were subjected to detailed clinical examination and only the following were considered eligible for inclusion in the study.

Inclusion criteria: Patients with evidence of anal fistula and willing to

- A) Be hospitalized for two to six week to undergo surgery.
- B) Report once a week for changing of thread.
- C) Report once in two months for one year for follow up after completion of treatment.

Exclusion criteria: Patients with Diabetes, Cardio-vascular disease, renal disease and cellulites to the ano rectal area were excluded from the study.

Methodology of treatment: *Kshaar Sootra* was inserted in the O.P.D., patient was placed in the lithotomic position and after aseptic preparation of part probing was done under local anesthesia. With specially designed probes the sterile silk thread was passed through carefully in the fistulous track; tied and left in situ (primary threading). A week later the silk thread was replaced by *kshaar sootra* by the railroading 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 *kshaar sootra*, 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 surgical treatment comprised fistulectomy in the subcutaneous and low anal types of fistula and excision of the track below the ano-rectal ring along with curetting of the upper track in case of high anal fistula. A malleable probe was passed through the track till it come out at the internal opening. Using the probe as a guide, the complete fistulous track along with adjuvant tissue was excised as a wedge and 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. The 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 complication. For the purpose of this study,

recurrence is defined as reappearance of the fistula at the same site at a different site, with in a period of 12 months.

The randomized controlled trial comprised 106 patients of fistulae in ano from three centers of Gujarat.

Clinical Study: Condition of Patients on Admission: In both the series (*kshaar sootra* series and Surgery Series) nearly 91% were males

Series	Male	Female	Total
K	49 (89%)	6 (11%)	55
S	47(92%)	4 (8%)	51

In both the series nearly 79% aged less than 35 yrs, while approximately 14% were aged between aged between 35 to 45 Years. The characteristics of anal fistula, on admission are summarized as follows

1). Duration of the Disease: (in Years)

Duration of the Disease (in Years)	Percentage of Patients	
	K Series n= 55	S Series n= 51
≤ one year	52	56
Between one to three year	28	23
≥ three year	20	21

52% of the patients in the K Series and 56 % patients in the S Series had the disease for at least one year.

2). Type of Fistula:

Type of Fistula	Percentage of Patients	
	K Series n= 55	S Series n= 51
Sub cutaneous	23	25
Low Anal	65	62
High Anal	12	13

The type of fistula was sub cutaneous in 23 % of the K Series and 25 % in the S Series, Low Anal in 65 % and 62 % and High Anal in 12 5 and 13 5 respectively.

3). Distance from anal Margin: (in Cm)

Distance from anal Margin (in Cm)	Percentage of Patients	
	K Series n= 55	S Series n= 51
≤ 5	78	82
Between 5 to 7 cm	18	12
≥ 7	4	6

Less than 5 Cm distance from anal margin was 78% in K Series, Between 5 to 7 Cm in 18% in K Series and 82 % in S Series, Between 5 to 7 Cm in 18% and 12 % and more than 7 cm. in 4 % and 6 % respectively. So, in short the *kshaar sootra* patients and the surgery patients were broadly similar on admission to the clinical trial in all respect.

Results: Speed of Healing of the fistulous track:

Time	Percentage of patients with Healing
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(in Weeks)	K Series	S Series
By 12 weeks	63	81
By 24 weeks	78	92
By 36 weeks	89	98
By 48 weeks	97	100
By 52 weeks	100	100

Healing took place in all the patients. However, the healing was relatively slow in patients treated with *kshaar sootra*.

The Proportion with Healing by 12 Week was 63 % in K Series, as compared to 81 % in the S Series, it is significant difference.

By 48 Weeks, the significant difference come down to fairly similar, i.e. 97% in K Series and 100 % in S Series.

Complication: In *kshaar sootra* series

- Almost all the patients complained of local burning sensation especially after the first time changing of *kshaar sootra*. This was for only few minutes and rarely required any analgesics or other medications.
- In the most of the patients, Discharge tendency was noted from the fistulous track requiring the pad.
- In the follow up period of one year mild type of anal incontinence was observed. (i.e. incontinence to flatus or occasionally to liquid faces.)

In Surgery Series

- All the patients had post-operative pain lasting for a few days and requiring heavy analgesic and other medicaments.
- Anal Incontinence occurred.
- Discharge tendency and Heavy type of medical dressing required.
- Hospital stay following surgery varies from 5 days to 13 days.
- Recurrent perianal abscess and incomplete rectal prolapse were observed in surgical patients.

Recurrence rates of anal fistula in KSHAAR SOOTRA and surgery series: Among the 106 Patients who completed treatment, 7 patients failed to attend follow up schedule. Remaining 99 patients completed one year follow up, among these recurrence rate was 4% in 52 patients treated with *kshaar sootra* as compared to 13 % in surgery series.

The recurrence rate was not influenced by the type of fistula n either series.

Previous surgery	<i>kshaar sootra</i>			Surgery		
	Patients followed no.	Patients with recurrence		Patients followed no.	Patients with recurrence	
		No.	%		No.	%
Done	16	1	6	11	3	27
Not Done	36	1	3	36	3	8
Total	52	2	4	47	6	13

Previous anal surgeries also not affect the recurrence rate of *kshaar sootra* series. The proportions with recurrence being 6 % and 3% in those with and without previous sur-

gery. On the other hand, in the patients subjected to surgery, there was an appreciable and significant difference. The proportions

being 27 and 8 percent in those with and without previous surgery respectively.

DISCUSSION:

In the present study most of the patients were

+ Males (87%) , + 35 years of Age (80%)

+ Low anal fistula (64%)

1. In the present study healing occurred in both the series, the healing rates were slower with *kshaar sootra* as compare to surgery. This could be due to a slow cauterization of the track by *kshaar sootra*, through its herbal ingredients.
2. *kshaar sootra* treatment does not require hospitalization where as the average hospital stay following surgery varies from 5 days to 13 days.
3. Patients treated with *kshaar sootra* could continue with their normal routine work and the presence of thread did not bother them.
4. Recurrence rate over one year follow up was 4% in the K Series, as compared to 13 % in the surgery series.
5. High Anal Fistula has been reported to be associated with higher incidence of recurrence.
6. Low recurrence of fistula treated with KSHAAR SOOTRA has been because of better drainage, slow and gradual cutting with simultaneous healing and also complete destruction of the cryptic glands by the caustic action of the thread.
7. Mild anal incontinence was observed due to the stage of 'cutting through' the anal sphincters by the thread, which subsequently led to complete recovery during, follow up.

CONCLUSION:

On the basis of the result of this multi centric randomized clinical trial, it is concluded that,

1. Long term outcome is better with *kshaar sootra* then with the surgery, even Healing may take longer.
2. *kshaar sootra* technique can be used in OPD under local Anesthesia.
3. Patients are ambulatory throughout the period of treatment in *kshaar sootra* treatment.
4. In *kshaar sootra* treatment there is no need to do regular dressing.
5. No systemic side effects were encountered with *kshaar sootra*.
6. Poor risk patients for anesthesia and surgery can also be subjected to *kshaar sootra* treatment safely.
7. As no Hospitalization required *kshaar sootra* can be more effective then surgery.
8. Disadvantage of *kshaar sootra* include the necessity for weekly hospital visits for changing thread, apart from local burning sensation and increased discharge.
9. Despite *kshaar sootra* technique offers an effective ambulatory and safe alternative treatment for patients with anal fistula.

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