



## Original Research Article

## Comparative study of seton v/s kshar-sutra in management of fistula-in-ano

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## Abstract

**Background:** Fistula-in-ano is a persistent pathological connection, lined with unhealthy granulation tissue, extending from the ano-rectum to the peri-anal skin, manifesting as an external orifice on the perineum or buttock. It is thought to originate from crypto-glandular factors, with the fistulous tract typically resulting from compromised drainage of anal glands. It frequently results in pain, edema, discharge, pruritus, and social shame. Setons have been utilized for the management of fistula-in-ano for centuries, primarily for high or difficult anal fistulas to prevent fecal incontinence and recurrence. Conversely, the widely recognized Kshara-sutra therapy is accessible for Bhagandara, exhibiting a minimal recurrence rate of 3.33%.

**Aims and Objectives:** To assess and compare the effectiveness of seton and kshar-sutra procedures in treatment of fistula in ano in a tertiary hospital

**Materials and Methods:** A randomized controlled study including 30 patients with anal fistula was conducted by the Department of General Surgery at Bhaskar Medical College for a duration of 18 months. Approval was obtained from the Institutional Ethical Committee prior to initiating the project.

**Results:** The demographic and clinical parameters were comparable between the groups. Kshar group had significantly lesser operating time [ $P < 0.001$ ], with lesser degree of pain [ $P < 0.05$ ] in the post operative period. The hospital stay [ $P < 0.001$ ], no. of days absent from work [ $P < 0.001$ ], and healing time [ $P < 0.05$ ] was also significantly lesser in Kshar Group.

**Conclusion:** Kshar-sutra procedures were significantly more effective than seton in treatment of fistula in ano.

**Keywords:** Fistula in ano, Seton, Kshar-sutra

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## 1. Introduction

Fistula-in-ano is a chronic abnormal communication, lined by unhealthy granulation tissue, runs from ano-rectum towards peri-anal skin presented as external opening on the perineum or buttock.<sup>1</sup> It is believed to be of crypto-glandular origin and most commonly fistulous tract is formed secondary to impaired drainage of anal glands.<sup>2</sup> It commonly produces pain, swelling, discharge, itching, social embarrassment etc.<sup>3</sup> In India anal fistula constitutes 1.6% of all surgical admissions with chances of recurrence 0.7 to 26.5% & incidence of anal incontinence 5 to 40%.<sup>4</sup> The principles of anal fistula surgery are to eliminate the fistula, prevent recurrence and preserve sphincter function.<sup>5</sup> Fistulectomy, fistulotomy and some new techniques like fibrin glue, fistula plug, Video Assisted Anal Fistula Treatment (VAAFT), Ligation of Inter-sphincteric Fistula Tract (LIFT) etc. are also available as treatment options with their own merits and demerits.<sup>6</sup> Surgery for fistula-in-ano may account for 5% of

the operative workload of a colorectal service.<sup>7</sup> The surgery itself thus constitutes only a small fraction of the work undertaken, but poorly performed surgery may result in considerable patient morbidity, including multiple re-operations and minor-to-major degrees of anal incontinence

Setons have been utilized for the management of fistula-in-ano for centuries, primarily for high or complex anal fistulas to prevent fecal incontinence and recurrence.<sup>8</sup> Conversely, the well-established Kshara-sutra therapy is effective for Bhagandara, exhibiting a minimal recurrence rate of 3.33%.<sup>9</sup> Sushruta documented the use of Kshara (plant ash, highly alkaline) in treating Bhagandara, while Charaka referenced Kshar-sutra.<sup>10</sup> Subsequently, Chakrapani and Bhavamishra provided comprehensive details on the preparation and application of Kshar-sutra for Bhagandara.<sup>11</sup> The application and follow-up of Kshar-sutra are straightforward, necessitating shorter hospital stays, resulting in reduced pain, presenting a very low complication rate, and,

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crucially, incurring minimal costs for therapy. This study was designed to compare treatment and patient outcomes between seton and kshar-sutra techniques for the management of fistula in ano.

## 2. Aim

To assess and compare the effectiveness of seton and kshar-sutra procedures in treatment of fistula in ano in a tertiary hospital

## 3. Objectives

1. To assess the effectiveness, hospital stay, post-operative pain, cost and other complications of kshar-sutra procedures in treatment of fistula in ano.
2. To assess the effectiveness, hospital stay, post-operative pain, cost and other complications between seton procedures in treatment of fistula in ano.
3. Compare the effectiveness, hospital stay, post-operative pain, cost and other complications of the two procedures in treatment of fistula in ano.

## 4. Materials and Methods

A randomized controlled study including 30 patients with anal fistula was conducted by the Department of General Surgery at Bhaskar Medical College for a duration of 18 months. Approval was obtained from the Institutional Ethical Committee prior to initiating the project. The participants were apprised of the study's goal, methods, risks, and benefits. Informed and written consent was acquired from all subjects.

### 4.1. Inclusion criteria

All patients with low anal fistula

### 4.2. Exclusion criteria:

1. High anal fistula
2. Complicated fistulae
3. Multiple fistulae
4. Fistulas associated with other ano rectal conditions

The Institutional Ethical Committee approved the study. A comprehensive history and clinical examination were conducted in individuals presenting with anal fistula. The subsequent investigations were conducted:

1. Fistulogram
2. Pus culture and sensitivity

3. Proctoscopy
4. Routine blood investigations

A cohort of 30 individuals identified with anal fistula via fistulogram was included in the study following the acquisition of consent. They were randomly assigned into two equal groups. Fifteen participants were assigned to the Kshar-sutra (medicated Seton) group, while the remaining fifteen were allocated to the Seton group.

### 4.3. Procedure of Kshar-sutra:

Patients are positioned in lithotomy and the sites of external openings are identified under aseptic precautions. An endoscopic examination of the proctodeum using a proctoscope or anal speculum is conducted in all instances to locate the internal opening through the injection of methylene blue dye. All procedures are conducted under local anesthetic. The Kshar-sutra is applied by introducing a long, pliable metallic probe with an eye via the external aperture, aiming to slide the probe's tip through the interior opening. The probe's eye was threaded with Kshar-sutra, and the probe was carefully retracted, resulting in the entire tract being threaded with medicated Kshar-sutra. The two ends of the thread were secured with two knots external to the anal canal.

### 4.3. Data analysis

The data underwent statistical analysis using MS Excel and SPSS 23.0. Categorical variables were examined with the Chi-square test or Fisher's exact test. The disparity between the mean scores of the two groups under investigation was assessed utilizing an unpaired Student's t-test. A P value below 0.05 is deemed statistically significant.

## 5. Results

Among the study groups, there was no statistically significant difference between the clinical parameters. Both the groups were comparable. (**Table 1, Table 3**)

Table showing the operative and post operative parameters of study groups;

Among the study groups, Kshar group had significantly lesser operating time [ $P < 0.001$ ], with lesser degree of pain [ $P < 0.05$ ] in the post operative period. The hospital stay [ $P < 0.001$ ], no. of days absent from work [ $P < 0.001$ ], and healing time [ $P < 0.05$ ] was also significantly lesser in Kshar Group. (**Table 2**)

**Table 1:** Showing the clinical characteristics of study population

Parameter		Kshar Grou N=15(%)	Seton Group N=15 (%)	P Value
Age	(M±Sd)	34.33 ±4.92	34.40 ±7.71	> 0.05
Gender	(Male/Female)	(13/2)	(12/3)	> 0.05
Site Of External Opening	Anterolateral	5(33.3)	4(26.67)	> 0.05
	Posterolateral	7(46.67)	6(40)	
	Lateral Posterior	2(13.33)	3(20)	
	Posterior	1(6.67)	2(13.33)	
External Opening	Single	12(80)	13(86.67)	> 0.05
	Two	3(20)	2(13.33)	
Distance From Anal Verge(Cm)	To External Opening	2.46±0.40	2.23±0.63	>0.05
	To Internal Opening	2.55±0.57	2.05±0.45	>0.05
Type	Intersphincteric	10(66.67)	12(80)	>0.05
	Transsphincteric	5(33.33)	3(20)	

**Table 2:** Showing the operative and post-operative parameters of study groups

Parameter	Kshar Group N (%)	Seton Group N (%)	P Value
Mean Operating Time (Minutes) Mean (± Standard Deviation)	15.53±3.31	21.53±2.59	<0.001**
Pain			
No Pain	3(20)	0(0)	<0.05*
Mild	7(46.67)	3(20)	
Moderate	4(26.67)	7(46.67)	
Severe	1(6.67)	5(33.33)	
Discharge			
Mild	8(53.33)	4(26.67)	>0.05
Moderate	4(26.67)	6(40)	
Severe	3(20)	5(33.33)	
Post-Operative Stay (Hours)	28±4.07	37.8±5.95	<0.001**
Absent From Work (Days)	2.33±0.62	8.13±3.52	<0.001**
Healing Time (Days)	43.07±6.84	48.87±5.68	<0.05*

**Table 3:** Showing the complications

Nature of complications		Kshar Group N (%)	Seton Group N (%)
Bleeding		0(0)	4(26.67)
Infection		1(6.67)	3(20)
Incontinence	Flatus	1(6.67)	2(13.33)
	Feces	0(0)	1(6.67)
Recurrence		1(6.67)	3(20)
Scarring		1(6.67)	2(13.33)
Anal Stenosis		0(0)	2(13.33)

## 6. Discussion

The present study was a randomized controlled study conducted to assess and compare the effectiveness of seton and kshar-sutra procedures of treatment of in 30 patients of fistula in ano in a tertiary hospital.

The findings of the study are discussed below;

The two study groups were comparable for age and gender, as the mean age and gender variances were not statistically significant.  $P > 0.05$ .<sup>12</sup> in their study examined

forty cases of anal fistula, noting that male patients constituted the predominant demographic (89.47%).<sup>13</sup> conducted a study including six patients (five males and one female) aged 20 to 60 years with Bhagandara, who were treated with Kshar-sutra. All patients had TRUS examination to ascertain the specifics of the fistulous tract and associated structures prior to the Kshar-sutra intervention, which was subsequently repeated at treatment completion. In the study conducted by.<sup>14</sup> among the 50 patients,<sup>13</sup> (50%) in the Kshar-sutra group and <sup>14</sup> (58.34%) in the fistulotomy group were aged 30-39 years. The majority (86%) of the patients were

male, although there was an equal gender distribution in both groups, consistent with the current study. In the study conducted by.<sup>15</sup> the mean age of patients was 38.40 years (SD  $\pm$  11.03). Among 63 patients, 56 (88.89%) were male and 7 (11.11%) were female, indicating that the age of fistula incidence in females was younger than in males. The fundamental demographic parameters of the two groups, when exami.

In the current investigation, within the Kshar group, the majority of patients, 10 (66.67%), exhibited intersphincteric type fistulae, whereas 5 (33.33%) presented with transsphincteric type fistulae. In the seton group, 12 patients (80%) exhibited intersphincteric type fistulae, while 5 patients (33.33%) displayed transsphincteric type fistulae. The comparative distribution of inter-sphincteric and transsphincteric types aligns with prior research.<sup>16-17</sup>

A multicentric randomized controlled clinical trial using Kshar-sutra in the treatment of fistula-in-ano, compared to traditional surgery, was conducted in Bombay, Chandigarh, New Delhi, and Wardha. Complete recovery was observed in all 265 patients in the Kshar-sutra cohort and all 237 patients in the surgical cohort. The median healing duration was significantly prolonged in the Kshar-sutra group (8 weeks) compared to the surgical group (4 weeks). In both sets, the healing duration was shortest for subcutaneous fistula and longest for high anal fistula. Patients in both cohorts were monitored for one year post-treatment completion, revealing recurrence rates of 4 percent in the Kshar-sutra cohort and 11 percent in the surgical cohort, indicating a statistically significant difference ( $P = 0.03$ ). Most patients treated with Kshar-sutra had transient local burning and heightened discharge from the fistulous orifice. Mild anal incontinence was noted in 8 individuals who underwent Kshar-sutra treatment and 13 patients who received surgical intervention. The experiment determined that the long-term results with Kshar-sutra surpass those of surgery, despite a prolonged initial healing period. Kshar-sutra provides an efficient, mobile, and secure alternative therapy for individuals with fistula-in-ano. It also represented an innovative medicine delivery method for illnesses such as anal fistula.

12 Identified forty cases of anal fistula in their investigation. The duration of the condition ranged from 3 months to 3 years. The majority of cases reported pain, drainage, and edema in the perianal area. Twenty percent of the fistulae were subcutaneous, 10% were submucous, 45% were intermuscular, 17.5% were anorectal, and 7.5% were of the high-level variety. The initial use of Kshar Sutra was straightforward in most instances, however others encountered challenges. All cases demonstrated successful application of Kshar Sutra in the fistulous tract. Subsequent application of Kshar Sutra was devoid of pain in 85.0% of cases.<sup>12</sup>

The research conducted by Nema et al.<sup>13</sup> reported an average Unit Cutting Time and healing (UCTH) of 7.86 days/cm. During the weekly evaluation, all patients exhibited significant alleviation of swelling, discomfort, discharge, and itching symptoms. Each weekly assessment throughout the Kshar-sutra shift revealed robust granulation, epithelization, and wound contraction. All patients received TRUS examination during the post-treatment period, and all six patients were found to have either normal findings or the presence of residual healthy scar tissue or fibrous tissue in lieu of the fistulous tract.

### 6.1. Lack of employment

In the current study, the Kshar group exhibited a considerably lower mean absence from work of 2.33 days, whereas the seton group demonstrated a mean absence of 8.13 days. In the research conducted by Dutta G. In the Kshar-sutra group, 19 out of 26 patients returned to work the day after the treatment, as reported by Dutta et al.<sup>14</sup> The greatest and minimum durations of "off-work" were 8 and 26 days, respectively. The Kshar-sutra group experienced considerably fewer days "off-work" compared to the fistulotomy group ( $P < 0.001$ ). The Kshar-sutra is a multi-stage surgery, necessitating patients to visit the hospital weekly; hence, the treatment period for the Kshar-sutra group was much longer than that of the fistulotomy group. Notwithstanding this, the duration of "off work" was reduced in the case of Kshar-sutra due to diminished pain and the absence of an open wound, in contrast to fistulotomy. Consequently, patients who underwent the Kshar-sutra technique were able to resume work the day following the surgery, and it did not impede their regular activities. Consequently, the average days of absence from work in the Kshar group in this study, as well as in previous comparable investigations, is much lower than that of the alternative modalities.

In their study, Reddy et al.<sup>18</sup> noted that most patients undergoing fistulectomy, particularly those working, were required to refrain from work until the wound had healed. The extended recovery duration and loss of workdays were intolerable to many patients. Surgery, particularly in instances of severe anal fistulae, exacerbates the patient's suffering rather than alleviating it.

Deshpande PJ et al.<sup>19-20</sup> reported cure rates of 96.5% and 96% in several investigations, however Faujdar H.S et al.<sup>12</sup> observed a cure rate of 95.0% in their study. Early postoperative discomfort was noted in both groups; however, the Kshar-sutra group exhibited reduced pain in this study, despite several studies indicating increased pain with this method.<sup>21</sup>

In contrast to the aforementioned studies and the current findings, a prospective randomized trial conducted by Ho et al.<sup>10</sup> comparing ayurvedic cutting seton and fistulotomy for low fistula in ano concluded that the chemical seton was more

painful than conventional fistulotomy, with no differences observed in wound healing duration, complications, or functional outcomes.

Recurrences frequently occur following fistulotomy, with some studies indicating a recurrence rate of 8.47%. Faujdar H.S et al.<sup>12</sup> observed that ninety-five percent of cases had complete resolution, while five percent experienced recurrence after therapy with Kshar Sutra.

Deshpande et al.<sup>22</sup> reported a recurrence rate of 3.5% (7 instances out of 200) following standard treatment of fistula, based on a follow-up period of 2 to 9 years. Kronborg<sup>23</sup> reported that the recurrence rates after fistulectomy and fistulotomy were 9.52% and 12.5%, respectively, after a 12-month follow-up period.

The study by Nema et al.<sup>13</sup> reported no recurrences in any patient over the 12-month follow-up period. The medication was deemed safe and well tolerated by all patients.

In their study, Soliman F et al.<sup>24</sup> observed that six patients (7.4%) experienced recurrence, comprising three 'real' recurrences (3.7%) and three 'de novo' fistulae (3.7%).

## 7. Conclusion

Kshar-sutra procedures demonstrated markedly more efficacy than seton in the treatment of anal fistula, particularly for simplicity, ease of application, and average operating time. Kshar-sutra treatments were correlated with reduced rates of complications such as pain, discharge recurrence, and anal incontinence, as well as decreased absenteeism from work and treatment costs. Kshar-sutra treatments shown superior efficacy compared to seton in the therapy of anal fistula.

## 8. Funding Source

None.

## 9. Conflicts of Interest

None.

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