Original Article

Comparing Ksharasutra (Ayurvedic Seton) and open fistulotomy in the management of fistula-in-ano

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Abstract

Background: Most commonly practiced surgical "lay open" technique to treat fistula-in-ano (a common anorectal pathology) has high rate of recurrence and anal incontinence. Alternatively, a nonsurgical cost efficient treatment with Ksharasutra (cotton Seton coated with Ayurvedic medicines) has minimal complications. In our study, we have tried to compare these two techniques. **Materials and Methods:** A prospective randomized control study was designed involving patients referred to the Department of General Surgery in RG Kar Medical College, Kolkata, India, from January 2010 to September 2011. **Results:** Among 50 patients, 26 were in Ksharasutra and 24 were in fistulotomy group. 86% patients were male and 54% of the patients were in the fourth decade. About 74% fistulas are inter-sphincteric and 26% were of trans-sphincteric variety. Severe postoperative pain was more (7.7% vs. 25%) in fistulotomy group, while wound discharge was more associated with Ksharasutra group (15.3% vs. 8.3%). Wound scarring, bleeding, and infection rate were similar in both groups. Ksharasutra group took more time to heal (mean: 53 vs. 35.7 days, $P = 0.002$) despite reduced disruption to their routine work (2.7 vs. 15.5 days work off, $P < 0.001$). Interestingly, pain experienced was less in Ksharasutra group, there was no open wound in contrast to fistulotomy and it was significantly cost effective (Rupees 166 vs. 464). **Conclusion:** Treatment of fistula-in-ano with Ksharasutra is a simple with low complications and minimal cost.

Key words: Fistula-in-ano, fistulotomy, Ksharasutra, Seton

INTRODUCTION

Fistula-in-ano is one of the most common anorectal diseases in which the chronic granulating track runs from the anal canal or rectum to the perianal skin or perineum and is associated with considerable discomfort and morbidity to the patient. Various modalities such as open surgery in the form of fistulectomy or fistulotomy; Seton treatment (chemical or cutting); chemical destruction of the tract by corrosives; application of fibrin glue or fistula plug are advocated for management of fistula-in-ano.

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Surgical "lay open" technique, which is most widely practiced, has the problems of extensive surgery in-and-round the anal canal; prolonged hospitalization; high rate of recurrence and anal incontinence. Moreover, the initial recovery period is a bit discomfort to patients and patient usually loses few days work activities. Alternatively, application of chemical Seton named "Ksharasutra" (a medicated cotton thread coated with Ayurvedic medicines) [Figure 1] is mentioned in the ancient Indian literature and is still practiced in some centers in India.[1] Application and follow-up of Ksharasutra are very easy, require lesser hospital stay, lesser pain, have very low rate of complications and most importantly cost of therapy is minimal. Hence, in our study, we compared the treatment

Figure 1: Ksharasutra in a glass bottle

and outcome of fistula-in-ano between classical "lay open" technique and using Ksharasutra (chemical Seton).

MATERIALS AND METHODS

The study carried out at the Department of General Surgery in our Institution, from January 2010 to September 2011. The study was approved by the Institutional Ethics Committee and written consent was obtained from all participants during the study. A two digit random number table was used to select the treatment protocol for 50 patients selected from General Surgery outpatient department (OPD). A total of 26 patients was selected for the Ksharasutra (medicated Seton) group and 24 patients were selected for fistulotomy group. After completion of the study, all data were tabulated and analyzed with SPSS version 17 [IBM Corporation] and Epi info version 3.6.3.[CDC, Atlanta] software.

Inclusion criteria

Patient complaining perianal discharge (mucoid, stool-like) evaluated at outpatient department. OPD patients admitted after proper work up and subjected to intervention (fistulotomy or medicated Seton).

Exclusion criteria

Patients with severely compromised cardiopulmonary status, suffering from or having history of tuberculosis or Crohn's disease and those who are immunocompromised, having evidence of HIV infection, diabetes, and cancer therapies.

Surgical techniques and steps

Patients were put in lithotomy position and site of external opening/s located. An endoscope view of proctodeum by proctoscope or anal speculum was performed in all cases to identify the internal opening (using methylene blue dye in some cases) and other associated lesion like hemorrhoids if present. All cases were operated under local/regional anesthesia.

Application of Ksharasutra

A long metallic malleable probe with an eye was introduced through the external opening and attempted to pass the tip of probe through the internal opening [Figure 2a]. Care was taken not to create false passage. The eye of the probe was threaded with Ksharasutra [Figure 2b] and probe was gently withdrawn, so the entire tract was threaded with medicated Ksharasutra. Following which the two ends of the thread were snugly tied using two knots outside the anal canal [Figure 2c].

In patients with multiple external openings, it was found that whenever internal opening is single, one tract is the side branch of the other tract and ultimately forms a single channel before opening into the anal canal. In these cases, close vicinity fistulotomy or laying open of the tract was done for the side branch up to the main tract, thereafter through the main tract with the help of a probe Ksharasutra was threaded. For multiple fistulas in different quadrants (far from one another by clock position), multiple Ksharasutra were applied.

Open fistulotomy

A long metallic malleable probe with an eye was used to probe the whole fistulous tract. The whole fistulous tract was then laid open. In cases of high fistula, track above the anorectal ring was curetted. Few patients bleed significantly during the procedure and needed suturing with absorbable suture.

In patients with multiple external openings, merging of the tracts with fistulotomy was done when they were nearby and preferably in the same quadrant. When external openings are located in different quadrants, fistulotomy of each tract was done individually.

Postprocedural care

In Ksharasutra-treated group, the thread was changed at 2 weeks interval and gradually tightened [Figure 3a]. A new Ksharasutra was applied by rail-road technique and the conditions of wound, discharge, pain, etc., were evaluated. Number of dressings changed per day gave an estimate of wound discharge and postoperative pain was evaluated by visual analog scale. The length of old thread was measured to know the length of cutting of fistulous tract. Gradually, the thread cuts out of the tract [Figure 3b] with a healed wound [Figure 3c].

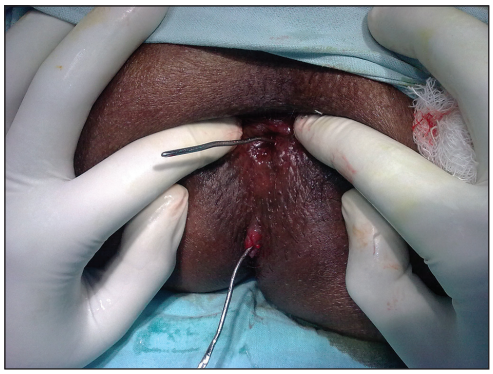

Figure 2a: A metallic malleable probe passed through a fistula tract

Figure 2b: Eye of the probe threaded with Ksharasutra

Figure 2c: Fistulous tract threaded and two knots snugly tied

Figure 3a: During first postprocedural visit after 2 weeks

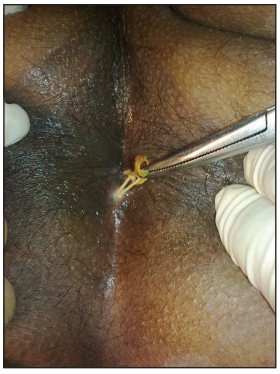

Figure 3b: After 4 weeks

Figure 3c: After completion of treatment procedure

RESULTS

Among the 50 patients, 13 (50%) patients in Ksharasutra group and 14 (58.34%) patients of fistulotomy group belong to 30-39 year of age. Most (86%) of the patients were males, however, with equal gender distributed in both the groups. Most of the external openings were located either antero-laterally (52%), that is, 10, 11, 1, and 2 o'clock position; or postero-lateral (36%), that is, 4, 5, 7, and 8 o'clock position. No patient was presented with anteriorly positioned fistula or fistula at 12 o'clock and majority of the patient had single external opening (88%). Furthest distance (between external opening and anal verge) was 7 cm and closest distance was 0.5 cm. Furthest distance (between internal opening and anal verge) was 4 cm and minimum distance was 1 cm. We observed 74% cases with inter-sphincteric fistula and 26% of trans-sphincteric fistula [Table 1].

In Ksharasutra group, maximum time duration needed for operation was 35 min and minimum time duration was 8 min. While, in fistulotomy group maximum and minimum time required was 40 and 15 min, respectively. Student's *t*-test showed that operating time was significantly less in Ksharasutra groups. Patients in Ksharasutra group experienced significantly ($P = 0.001$) less pain than fistulotomy patients. Amount of postoperative wound discharge was mild for both group and not statistically different ($P = 0.814$). In both the groups were given the

same antibiotics (i.e., ciprofloxacin + metronidazole) postoperatively, however lesser duration of antibiotic therapy was required in Ksharasutra group compared to fistulotomy.

Maximum of 48 h and minimum of 6 h hospital stay was required by patients treated with Ksharasutra. Whereas those patients who underwent fistulotomy maximum and minimum duration of hospital stay were 72 h and 24 h, respectively. Ksharasutra group had significant ($P < 0.001$) lesser duration of stay in the hospital.

The mean duration of healing was 53.00 ± 26.75 days in medicated Ksharasutra group. Whereas in fistulotomy group, mean duration of healing was 35.67 ± 9.17 days. Ksharasutra group required significantly ($P = 0.002$) more number of days for healing. However, in Ksharasutra group 19 out of 26 patients resumed their work the following day after the procedure. The maximum and minimum duration "off-work" was 8 and 26 days, respectively. Ksharasutra group had significantly ($P < 0.001$) few days "off-work" compared to fistulotomy group. Different postoperative complications were observed, scaring was the most common complication. Serious complication like recurrence was less in Ksharasutra groups [Table 2]. Expenditure was calculated for all patients excluding hospital bed charges and operation theater charges (as they are free in our Institution). Expenditure for Ksharasutra group was significantly cost effective than fistulotomy group (international normalized ratio 166 vs. 464).

Table 1: Clinical presentation of fistula-in-ano

Characteristics	Ksharasutra *n* = 26 (%)	Fistulotomy *n* = 24 (%)	*P*
Mean age			
Year	38.1 (±10.7)	36.7 (±9.3)	0.595*
Sex			
Male	22 (84.7)	21 (87.5)	1.0†
Female	4 (15.3)	3 (12.5)	
Site of external opening			
Antero lateral	11 (42.3)	7 (29.1)	0.489††
Postero lateral	12 (46.1)	14 (58.3)	
Lateral	4 (15.3)	4 (16.7)	
Posterior	4 (15.3)	1 (4.7)	
External opening			
Single	22 (84.6)	22 (91.7)	0.66†
Two	3 (11.5)	2 (8.3)	
Multiple	1 (3.9)	0	
Distance from anal verge (cm)			
To external opening	2.3 (±1.0)	2.5 (±1.4)	0.915*
To internal opening	2 (±0.7)	2.1 (±0.8)	0.707†
Type			
Inter-sphincteric	19 (73.1)	18 (75.1)	0.87††
Trans-sphincteric	7 (26.9)	6 (25.0)	

*Student *t*-test. †Fisher exact probability test (Fisher exact probability test applied as expected cell value in one of the above table was <5). ††Chi-square test

Table 2: Preoperative and postoperative findings

Characteristics	Ksharasutra *n* = 26 (%)	Fistulotomy *n* = 24 (%)	*P*
Operating time (mean)			
Minutes (range)	14.8 (±7.6)	25.8 (±14)	<0.001*
Pain			
No pain	3 (11.6)		0.001‡
Mild +	15 (57.7)	5 (20.9)	
Moderate ++	6 (23)	13 (15.1)	
Severe +++	2 (7.7)	6 (25)	
Postoperative discharge			
Mild	13 (59)	10 (41.7)	0.814‡
Moderate	9 (34.7)	12 (50)	
Severe	4 (15.3)	2 (8.3)	
Hospital stay			
Hours	24.2 (±12.6)	51 (±12.9)	<0.001*
Absent from work			
Days	2.7 (±4.1)	15.5 (±4.7)	<0.001*
Healing time			
Days	53 (±26.6)	35.7 (±9.1)	0.002*
Complications			
Bleeding	0	2 (8.3)	0.005††
Infection	1 (3.9)	3 (12.5)	
Incontinence			
Flatus	1 (3.9)	2 (8.3)	
Faeces	0	1 (4.1)	
Recurrence	1 (3.9)	3 (12.5)	
Scaring	3 (11.6)	4 (16.7)	
Anal stenosis	1 (3.9)	1 (4.1)	

*Student *t*-test, ††Chi-square test, ‡Kruskal–Wallis test

DISCUSSION

Use of "chemical" Seton (Ksharasutra) for treatment of fistula-in-ano is reported in ancient Indian texts.[2] Such stenos are made from plant extracts impregnated in layers onto a cotton thread using latex. The Kshara (caustics)[3] applied on the thread are antiinflammatory, anti-slough agents and in addition, have chemical curetting properties.[1] The Ksharasutra remains in direct contact of the tract and, therefore, it physically and chemically curettes out the tract and sloughs out the epithelial lining, thereby allowing the fistulous tract to collapse and heal. Several modifications of this procedure are also reported.[4,5]

The classical "lay open" technique for management of fistula in ano practiced currently,[6] involves laying open the fistula tract in entirety. Nevertheless, there are several modifications of this procedure.[7] Despite best efforts, the problems of recurrence and anal incontinence are high in the classical "lay open" method.

In our study, 54% of the patients were in the fourth decade and there was significant male predominance with a ratio of 6:1, which is consistent with other studies in India[1,7-9] and worldwide.[10,11] The relative distribution of inter-sphincteric and trans-sphincteric variety is also consistent with previous studies.[10,12]

Although Ksharasutra can be performed without use of anesthesia,[13] however, during our study and by others[14] it was

difficult to apply Ksharasutra without sedation, hence opted for regional (spinal or caudal) anesthesia during the procedure. Early postoperative pain was observed in both group; and it was found to be less in Ksharasutra group, however, some studies have reported higher pain with this approach.[15]

As Ksharasutra is a multistaged procedure,[1] patients need to come hospital every week, hence, the duration of treatment in the Ksharasutra group was significantly longer than fistulotomy group. Despite this the number of days, "off work" was less in case of Ksharasutra because the pain was less and there was no open wound in contrast to fistulotomy. Hence, patients following Ksharasutra procedure were able to join their work from the next day of the procedure and it didn't affect their normal activities.

Recurrences are common after fistulotomy with some reporting 8.47% of recurrence.[16] However, we observed 12.5% recurrence which may be due to relative smaller sample size in our study. The recurrence rate was only 3.8% in Ksharasutra group, which is consistent with previous reports.[1,17]

Incontinence after fistulotomy is a very distressful problem both to patient and surgeon.[18,19] For fistulae that traverse longer distances of sphincter, such as high trans-sphincteric or more proximal, fistulotomy conveys high rates of postoperative incontinence and alternative surgical treatments are necessary. For these "complex" fistulae, cutting Setons are used to slowly divide fistulous tissue tracts on the leading edge of the Seton while allowing healing to occur on the trailing edge thereby preserving sphincter continuity and preserving sphincter function. In our study, only three case of minor incontinence was seen, and there was one case of major incontinence found in fistulotomy group.

We concluded that treatment of fistula-in-ano by Ksharasutra is simple, easy, and safe. The chances of recurrence and anal incontinence are very low and most importantly, the cost of the treatment is very low. As it is an "ambulatory treatment" patient can join in their work very early. Hence, the application of Ksharasutra is a better option not only because it is cost effective but also due to lesser postoperative complications.

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