

**Original Research Article****Modified Method of Ksharasuthra in the Surgical Management of High Anal, Multiple & Recurrent Fistulae-In-Ano**

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Dept of Gen Surgery, GIMSR**Abstract**

**Background:** Though open fistulectomy surgery has been practised for centuries to treat cases of fistulae in ano, new methods of managing the same with Ksharasutra, an ayurvedic seton<sup>9</sup> has been evolved in the recent times. But even this method has considerable per and post operative morbidity and poor patient satisfaction though the chances of recurrence are less. Hence still newer method is hereby discussed modifying the routine method of management with Ksharasutra with better patient acceptability.

**Material & Methods:** A prospective study of patients with fistulae in ano attending the private surgical clinics and the OPD of the working hospital from January 2017 to dec 2018. Study design; prospective study. Study setting; the present study is done at the research centre of GIMSR with due institutional permission and clearance.

**Results:** Among 100 patients 52 were of modified procedure group and 48 were of routine procedure group of management of fistulae in ano with Ksharasutra, the caustic thread of ayurvedic chemical preparation. 86 % were males and 54 % were in the 4<sup>th</sup> decade. 74 % fistulae are inter-sphincteric and 26 % were of trans-sphincteric variety. Relatively more severe post operative pain (7.7 % Vs 25 %) was reported in the routine group, and wound discharge was more associated with the routine group again ( 8.3% Vs 15.3% ) wound scarring, bleeding, infection were also relatively more common in the routine group. There is significant difference in the post operative pain which is least common in the modified group. Modified + Ksharasutra group takes less time to heal (mean 35.7 Vs 53 days, P = 0.002) and this group patients experience reduced disruption to their routine work and early return to the work front (2.7 Vs 15.5 days work off, P > 0.001). In both the groups of cases there is no open wound which was distressing in the open fistulaectomy patients in the past. Modified method is very cost effective and most patient acceptability & satisfaction. In both the groups recurrence is least.

**Conclusion:** The modified procedure is most suitable for multiple non tuberculosis fistulae in ano. In both the methods, Ksharasutra is used during procedure. The modified method of managing the case of fistulae in ano with Ksharasutra is simple, one stage procedure, less morbidity, short hospital stay, least pain, cost effective, early return to work and better patient satisfaction & acceptance.

**Keywords:** Fistulae in ano, modified, Ksharasutra.

## Introduction

**Historical background:** Sushruta is the father of Indian surgery, performed Ksharasutra method of surgically treating fistulae in the ancient times. It was referred to as “Bhagandara” in ayurvedic parlance. The modern method of this technique is popularised by Prof. Deshpande<sup>10</sup> PJ. Extensive work was done at Institute of Medical Sciences, Benaras Hindu University, Varanasi and later several ayurvedic centers and few allopathic surgical centers have been adopting this method of managing fistulae, haemorrhoids, sinuses with Ksharasutra. WHO has accepted this method. Even in a noted book like short practice of surgery by Bailey & Love, 26<sup>th</sup> edition there is reference to this method. Hence there is clearance to pursue this technique. Particularly in high anal, multiple non-TB, recurrent and posterior fistulae in ano the Ksharasutra technique is of immense value.

Method of surgery for FIA	% of recurrence
Lay open Method	36
Ksharasutra Method	8

Fistulae in ano is a very common ano rectal disease throughout the world moreso in developing countries. It starts as a perianal lymph node infected turning into abscess and granulating track develops from the perianal skin to internal anal canal or rectum. It discharges pus causing discomfort and morbidity. Surgery to remove the track completely is inadequate and so it is often recurrent due to its multi track nature and the intersphincteric and transsphincteric nature of course. The lay open operative technique has been routinely followed causing recurrence. Hence the management with Ksharasutra, an Ayurvedic seton (caustic chemical cautery) method has been evolved. The routine method of managing the case of fistulae in ano with Ksharasutra<sup>5</sup> has its own problems. Under spinal/local anaesthesia, the fistulae is passed through with a sleek malleable copper probe from exterior to the internal opening and the thread is tied out over the skin and at frequent intervals of one to two weeks it is again gradually tightened facilitating cut-open slowly over a period of time.

So it is time consuming and the patient has to visit the surgeon 3 to 5 times for the same procedure over a period. Because it is tied over the skin, it is a painful procedure though not as much morbid as the lay open method. In some individuals among whom the pain threshold is less it is much more painful particularly at nights thereby necessitating the use of sedatives and high, frequent dose of analgesics giving scope for erosive gastritis and habit formation. The thread tightening facilitates cutting the track slowly but without morbidity. Hence a newer method got evolved at our level which is less cumbersome. This modified method is well tested by us in prospective randomised control study designed to apply over 100 patients over a period of 2 years from Jan 2017 to dec 2018. Hence in our study we compared the treatment and outcome of fistulae in ano surgical management between the routine method and our modified one though in both the methods the Ksharasutra is used as a seton and the results are compared.

## Material and Methods

The material for the study is collected from our case data file of our outside private surgical clinics at a coveted place in AP. The pooled data of 100 patients suffering from fistulae in ano from Jan 2017 to dec 2018. All the patients under study were thoroughly examined clinically, investigated with CT fistulogram, screened for high risk infections like HBsAg, HIV, HCV etc., apart from routine investigations. Counselling sessions were conducted to allay their fears and high risk consent is taken due to the recurrent nature of the disease due to its multi track inter/transsphincteric nature of the course of the disease. A two digit random number table was used to select the treatment protocol for 50 patients selected from general surgery clinic. A total of 26 patients were selected for the modified<sup>4</sup> method of Ksharasutra application and 24 patients were selected for routine method of application.

### Method of preparation and chemical composition of Ksharasutra

Ksharasutra is a medicated caustic thread works by erosion of the granulation and epithelium of the fistula track thereby promoting healing by fibrosis and closer of the lumen of the track. The chemical dissolves in the track and spreads to the rest of the branches of the main tract. It produces coagulative necrosis also. Cutting is not the main function of the caustic thread, unless it is mechanically tied tight at intervals and then it is painful.

Preparation<sup>3</sup>: It is prepared by serial coatings of certain plant product juices. Eleven coatings of snuhi latex (botanical name Euthorbia Nerifolia), seven coatings of apamarga kshara ( botanical name achyranthes aspara) mixed with snuhi latex and three coatings of curcuma longma ( botanical name harida churna ) mixed with snuhi latex. It will have Ph of 9.72. main caustic element is apamarga. **Mechanism of action:** With its caustic action it removes unhealthy tissue by seperating the debris and cleans the wound. Also facilitates drainage of pus the tract, currettes the track and promotes fibrosis. By histopathology early

necrosis (tissue coagulation) with active granulation is observed.

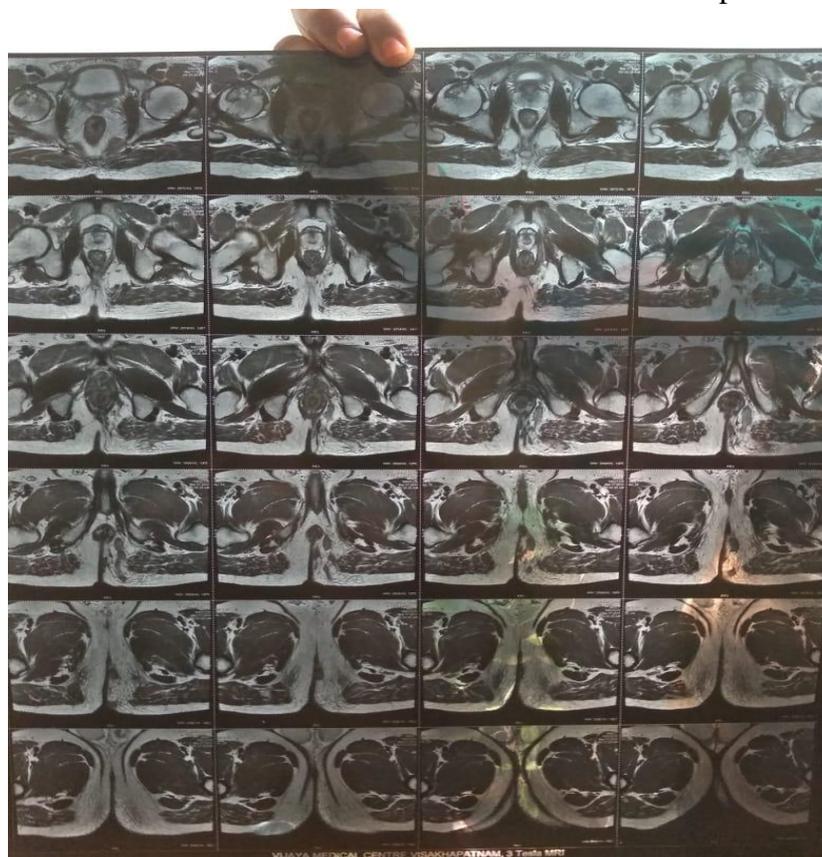
**Chemical Study:** Toyoma medical university of Japan, after chemical analysis found benzylingol, lingol, curcumin, euphal, antiquol, cyclo cucalcenol and 24 methelin cyclo artenol in Ksharasutra paste. These chemicals exhibit potent antimicrobial and antiinflammatory properties.

### Inclusion Criteria

Patient complaining perianal dischard (mucoid, stool-like) evaluated at our outpatient surgical OPD and 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 are excluded from the study. Pure anterior short straight low anal fistulae are excluded from the modified group of study as they can be safely managed with lay open method with minimum and acceptable morbidity.



**MRI Fistulogram:** Complex fistula in ano with internal opening at infra-levatoric 6 o'clock position communicating to the exterior by two tracts at left perianal 6 o'clock position.

#### **Surgical technique<sup>4</sup>**

After thorough pre operative evaluation and pre anaesthetic checkup and obtaining high risk consent from the patient the cases are shifted to the operation theatre. Patients are 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 haemorrhoids if present. All cases were operated under local/regional/spinal anaesthesia.

#### **Application of Ksharasutra<sup>5</sup>**

A long copper metallic malleable probe with an eye was introduced through the external opening and attempted to pass the tip of probe through the internal opening. Care was taken not to create false passage. The eye of the probe was threaded with Ksharasutra 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, one end of the thread could be passed through a subcutaneous tunnel perianally.

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 fistulectomy 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 in routine method. This is done when the anatomy of the side tract is identified clearly and it is sure that it is not high anal and not transsphincteric. For multiple fistulas in different quadrants (far from one another by clock position), multiple Ksharasutra were applied. The CT fistulogram is of great value to

identify the course of different tracts. The surgeon has to read the CT on his own apart from basing on the radiologist. Clear preparation of mind and thorough knowledge of the pathological anatomy of the fistulae is very essential for the successful outcome of the surgery.

Under modification, alternatively instead of malleable copper probe sinus forceps can be negotiated through the fistula track, through which thread can be passed in the furrow and the internal tip can be palpated with finger and the thread drawn out obviating the need to bend the probe and to bring it out through the lumen of anal canal which is cumbersome and may need maximum anal dilatation which may cause temporary incontinence leading to patient's anxiety.

#### **Postprocedure Method**

In the routine Ksharasutra-treated group, the thread was changed at two weeks interval and gradually tightened. 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 with a healed wound.

In the modified method of Ksharasutra it is one time application of the thread (seton) and there is no further course of tightening and cutting. No need to change the thread again and again. There is no role for cutting the tract by tightening the thread in this modified method. Hence it is very safe with the best patient acceptability with least morbidity and very early return to work, also cost effective. In this modified method the belief is that Ksharasutra works by caustic cautery & coagulation. The chemicals applied to the seton liberate in the main tract and seep & spread to the other branches connected to it. So cutting is only mechanical and has no real role. Due to cutting and dissection morbidity is more in open surgical method. The applied Ksharasutra thread through the tract and the subcutaneous tunnelling of it and

tide can be removed after 3 to 4 weeks observing the copious discharge time of stopping. No use of retaining the thread for a long time unremoved as it may result in sinus formation. Once the discharge stops the thread can be removed. All external openings have to be negotiated with separate threads and all of them come out through the internal opening as a single bunch of thread bundle.

### Results

Among the 100 patients, 48 (50 %) patients in Ksharasutra group and 52 (58.34 %) patients of modified group belong to 30 to 39 years of age. Most (86 %) of the patients were males. Most of the external openings were located either anterolaterally (52 %), that is, 10, 11, 1 and 2 o'clock position are posterolateral 36 %, that is, 4, 5, 7 and 8 o'clock position no patient was presented with anteriorly positioned fistula are fistula at 12 o'clock position and majority of the patients had multiple openings (88%) as the selection of patients were made like that. Farthest distance between external opening and anal verge was 7 cms and above and the length of anal canal is 4 cm often. And the farthest distance between the internal opening and anal verge was 4 cms and above. We observed 74 % of the cases are intersphincteric fistula and 26 % are 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 modified 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 ( $P = 0.001$ ) more pain than modified group 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, and in few cases an antibiotic covering the staph.aureus was also added.

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

The mean duration of healing was  $53.00 \pm 26.75$  days in Ksharasutra group. Whereas in modified group, mean duration of healing was  $35.67 \pm 9.17$  days. Ksharasutra group required significantly ( $P = 0.002$ ) more number of days for healing. However, in modified 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. Modified Ksharasutra group had significantly ( $P < 0.001$ ) few days "off-work" compared to Ksharasutra group. Different postoperative complications were observed, scarring was the most common complication. Serious complication like recurrence was less in both the Ksharasutra groups (Table – 2). Expenditure for modified Ksharasutra group was significantly cost effective than Ksharasutra group (international normalized ratio 166 Vs 464 ).

Characteristics	Ksharasutra n = 52 (%)	Modified Fistulotomy n = 48( % )	P
<b>Mean age</b>			
Year	38.1 (+/- 10.7 )	36.7 ( +/- 9.3 )	0.595*
<b>Sex</b>			
Male	22 ( 84.7 )	42( 87.5 )	1
Female	4 ( 15.3 )	6( 12.5 )	
<b>Site of external opening</b>			
Antero lateral	22( 42.3 )	14( 29.1 )	0.489
Postero lateral	24( 46.1 )	28( 58.3 )	
lateral	8( 15.3 )	8( 16.7 )	
Posterior	8( 15.3 )	2( 4.7 )	
<b>External opening</b>			
Single	44( 84.6 )	44( 91.7 )	0.66
Two	6( 11.5 )	4( 8.3 )	
Multiple	2 ( 3.9 )	0	
<b>Distance for anal verge ( cm )</b>			
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
<b>Type</b>			
Inter-sphincteric	38 ( 73.1 )	36( 75.1 )	0.87
Trans-sphincteric	14 ( 26.9 )	12( 25.0 )	

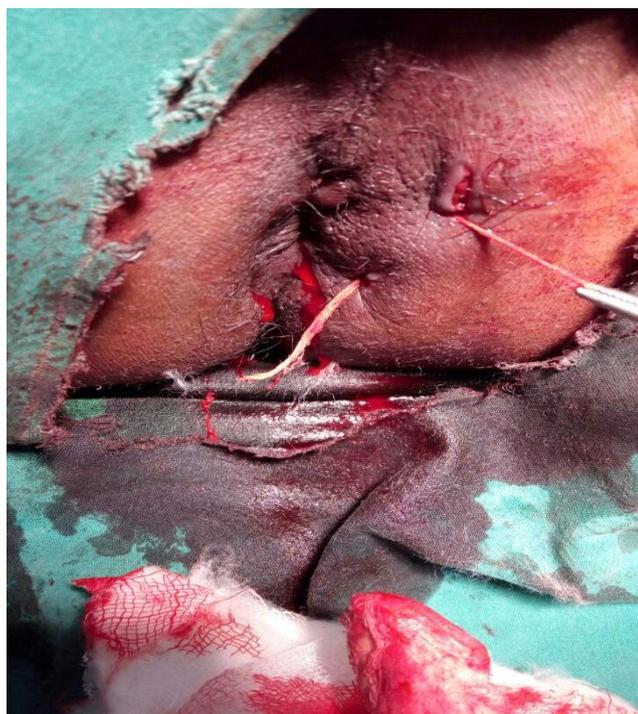
\*Student t = test. Fisher exact probability test (Fisher exact probability test applied as expected cell value in one of the above table was < 5). Chi-square test.

Characteristics	Ksharasutra n = 52 ( % )	Modified Fistulotomy n = 48 ( % )	P
<b>Operating time ( mean )</b>			
Minutes ( range )	14.8 ( +/- 7.6 )	25.8 ( +/- 14 )	<0.001*
<b>Pain</b>			
No pain	6( 11.6 )		0.001
Mild +	30( 57.7 )	10( 20.9 )	
Moderate ++	12( 23 )	26( 54.2 )	
Severe +++	4 ( 7.7 )	12( 25 )	
<b>Postoperative discharge</b>			
Mild	26(59)	20(41.7)	0.814
Moderate	18 (34.7)	24 (50)	
Severe	8(15.3)	4(8.3)	
<b>Hospital stay</b>			
Hours	24.2 (+/- 12.6 )	51 ( +/- 12.9 )	<0.001*
<b>Absent from work</b>			
Days	2.7 ( +/- 4.1 )	15.5 ( +/- 4.7 )	<0.001*
<b>Healing time</b>			
Days	53 (+/- 26.6 )	35.7 (+/- 9.1)	0.002*
<b>Complications</b>			
Bleeding	0	4 ( 8.3 )	0.005
Infection	1 ( 3.9 )	6( 12.5 )	
<b>Incontinence</b>			
Flatus	1 ( 3.9 )	48.3 )	
Faeces	0	2( 4.1 )	
Recurrence	1 ( 3.9 )	6( 12.5 )	
Scarring	3 ( 11.6 )	8( 16.7 )	
Anal Stenosis	1 ( 3.9 )	2( 4.1 )	

\*Student t-test, chi-square test, Kruskal-wallis test

**Table 3 : Compare and Contrast Between Different Methods of Fistula Surgery<sup>7</sup>**

Item	Lay open surgical procedure	Routine Ksharasutra Technique	Modified Ksharasutra Method
Type of anal fistula	Low anal	High, multiple, posterior, recurrent fistulae	High, multiple, posterior, recurrent fistulae
Anaesthesia	Deep plane general/spinal	Regional/Pudendal in females	Local/regional
Thread knots	Nil	Over peri anal skin	Subcutaneous passage and outside knotting
Thread tightening	Nil	at intervals	Not
Multiple threads for multiple fistulae	Nil	Rarely	Often
Cutting with Thread	Nil	Necessary	Not necessary
Wound	Deep open wound	Small open wound rarely	Nil open wound
Pain	Severe P.O. pain	Moderate P.O. pain	Minimal P.O. pain
Time needed for surgery	Longer	Moderate	Short
Hospital stay	20 - 30 days	2 - 3 days	day care
Post operative recovery	Slow	fast	very fast
Convalescence	Poor	Good	Very Good
Sinus formation	Often	rarely	Nil
recurrence	34%	8 - 12 %	< 8 %
Anal incontinence	Possible	rare	never
Patient acceptability	Discouraging	Watchful	encouraging
Psychological problems	Depressed	rare	Mood evation
Consumer disputes	often	rare	almost never



Per operative photograph showing two separate Ksharasutra applied through separate external fistulae in ano.



Subcutaneous passage of the other end of the thread to tie it at the entry point avoiding transcuteaneous passage to tie - P.O. photograph in the ward.

**Discussion**

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 and worldwide. The relative distribution of inter-sphincteric and trans-sphincteric variety is also consistent with previous studies.

Although Ksharasutra can be performed without use of anaesthesia, however, during our study and by other it was difficult to apply Ksharasutra without sedation, hence opted for regional (spinal or caudal) an anaesthesia during the procedure. Early postoperative pain was observed in both the groups; and it was found to be less in modified Ksharasutra group, however, some studies have reported higher pain with this routine Ksharasutra technique.

As routine Ksharasutra is a multistage procedure, patients need to come to the hospital every week, hence, the duration of treatment in the routine Ksharasutra group was significantly longer than modified group. And the number of days, “ off work “ was less in case of modified Ksharasutra group because the pain was less and there was no open wound at all in contrast to routine one. 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 as it is a day care procedure.

Recurrences are common after fistulotomy with some reporting 8.47% of recurrence. However, we observed 12.5 % recurrence which may be due to relative smaller sample size<sup>6</sup> in our study. Here, the commendable work done by Prof. Deshpande PJ with 400 cases<sup>8</sup> published in Indian J of surgery, Vol : 37, in the year 1975 about ambulatory treatment of FIA with Ksharasutra is of great value. Yet our study, though of small sample size of 50 cases also throws some light particularly about the safe and uneventful outcome of the patients as it is a modified method. The recurrence rate was only 3.8 % in Ksharasutra group, which is consistent with previous reports.

Incontinence after fistulotomy is a very distressful problem both to patient and surgeon. 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, curetting setons are used to slowly collapsed fistulous tissue tracts to occur on the trailing edge thereby preserving sphincter continuity and preserving sphincter function. In our study, only three case of temporary and very minor incontinence was seen, and there was no case of major incontinence found in fistulotomy group.

### Conclusion

We concluded that treatment of fistule-in-ano by modified Ksharasutra method is very simple, easy, and safe. The changes of recurrence and anal incontinence are almost nil 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 modified Ksharasutra is a better option not only because it is cost effective but also due to lesser postoperative complications.

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**Conflict of Interest:** Nil

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