



**A CLINICAL TRIAL OF “BEADED” KSHAR-SUTRA & “DOUBLE” KSHAR-SUTRA
TECHNIQUE IN THE CASES OF FISTULA IN ANO.**

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ABSTRACT

Kshar sutra therapy in cases of fistula in ano, despite a long medical history of credentials and conduct, still poses a challenge to medical fraternity in terms of finding satisfactory cure of disease. In this study, standard kshar sutra technique (SKST), a well known ayurvedic modality of treatment, has been compared with double kshar sutra technique (DKST) and beaded kshar sutra technique (BKST) for anal fistula. Forty five patients were selected randomly from OPD and IPD of department of ano-rectal surgery of Institute. All patients were randomly divided into three groups. Group (A) control group: 15 patients were treated with SKST; Group (B) control group: 15 patients were treated with DKST and Group (C) control group: 15 patients were treated with BKST. Same type of kshar sutra was used in all patients but technique used was different according to their group. Student's t-test was applied for statistical comparisons. Value were interpreted as mean \pm SD, p value < 0.05 was considered significant. Pain and burning sensation were found higher in group B and C, while the other symptoms like itching, duration of pain, discharge of pus were higher in group A. Double kshar sutra technique and beaded kshar sutra technique provide better, effective, safe and faster recovery in management of fistula in ano.

KEYWORDS: Fistula in ano, kshar sutra technique, bhagander.

INTRODUCTION

Bhagandara is a common ano-rectal disease. It can be co-related with fistula in ano. The first description of *kshar sutra* and its role in *bhagandar* comes from *Charka samhita* in the chapter of *shotha chikitsa*.^[1] "Father of Surgery", *Acharya Sushruta* mentioned it for the treatment of *Nadi Vrana* (sinus), *Bhagandara* (fistula-in-ano), *arbuda* (excision of small benign tumor) etc.^[2] It was *Chakrapani Dutta* who in late eleventh century emphasized in his book *Chakradatta*, the method of preparation with a clear-cut indication of its use in *bhagandar* (fistula-in-ano) and *arsha* (hemorrhoid).^[3] But because of brevity of preparation and inadequate explanation of procedure of application, it lost its popularity among *Ayurvedic* surgeons. Later on effort of Dr. P.J. Deshpande, brought back the usefulness of *Kshar sutra* for treatment of *nadi vrana* and *bhagandara*.^[4]

At present, treatment of fistula-in-ano with the help of *Kshar sutra* is very popular among *ayurvedic* as well as allopathic surgeons.^[5] Many of the surgeons are now establishing their specialized ano-rectal centers all over the India and providing the services related to the diseases of anal canal. Government sector is also very much concerned regarding encouragement of *kshar-sutra*

therapy. Now, it is well known, that *kshar sutra* treatment is recognized as non-recurrence therapy for fistula in ano. Lot of the researches has been done to improve the quality of *kshar sutra*.^[6] All of them are concerned with the coating material of drug by various means of *kshar* and latex. This study is not based upon the different type of coating material over thread; but it is a trial of two techniques "BEADED" *Kshar-sutra* & "DOUBLE" *Kshar-sutra* technique.

So many studies have already been carried out with variations in the *Kshara* and the latex. The most remarkable are *Guggulu Kshara sutra*, *Udumbara Kshara sutra*, *Gomutra Kshara sutra*, *Papaya tankana Ksharasutra*, *yava Kshara sutra*, *gritakumari Kshara sutra*, *aragvadhadi Kshara sutra* etc. The standard kshar sutra is prepared by repeated coatings of *snuhi ksheera* (latex of *Euphorbia nerrifolia* Linn), *apamarga kshar* (water extract of ashes of *Achyranthus aspera* Linn.) and *haridra* powder (*Curcuma longa* Linn.) over a surgical linen thread no. 20. This thread is spread lengthwise in hangers. Each thread on the hanger is then smeared with *snuhi* latex with the help of gauze piece soaked in the latex. This wet hanger is transferred in *kshar sutra* cabinet for drying and sterilization. *Kshar sutra* cabinet has a source of hot air with regulated temperature to dry

the thread and Ultra Violet light that is used for sterilization. Same process is repeated next day. Eleven such coatings with *snuhi ksheera* alone should be accomplished. The twelfth coating is done by first smearing the thread with *ksheera* and in wet conditioned thread is passed through the *apamarga kshar*. It is then again transferred into the cabinet for drying and sterilization. This process is repeated till seven coatings of *snuhi ksheer* and *apamarga kshar* is achieved. Final three coating are completed with *snuhi ksheera* and fine powder of turmeric in the same fashion. Thus twenty-one coatings over the thread are completed.

It is the expertise of surgeon that how skillfully he passes the *Kshar sutra* through fistula by probing. High anal fistula probing is done usually in spinal anesthesia, while low anal fistula may be handled under local application of 2% lignocaine gel. The first time placement of *kshar sutra* is quit difficult and is skill based. In next follow ups, *kshar sutra* is changed weekly on OPD basis.

Problems observed in traditional practice of *Kshar sutra*-(Why there is a need of modification in technique)

Generally, *kshar sutra* causes lot of discomfort to patient. Initially, after diagnosing the case, probing is performed and a *kshar sutra* or plain cotton thread is passed through the fistulous track. This is called primary threading. This thread is kept in tract for one week; patient is weekly called in OPD to change it. This procedure is called secondary threading. Secondary threading is necessary, because it is observed that the effect of coated drugs diminishes by time and cotton thread also become so weak, that it may disintegrate itself to shed off.

The standard *kshar sutra* is tied in track and gradually changed and tightened to produce the pressure effect to enhance cutting of track. During this process, after each secondary threading patient undergoes through the great pain and burning sensation. Most of the patients are scared on the day of their thread change. The presence of *kshar* (caustic) coated over thread is mainly responsible for burning sensation.

Generally after secondary threading, pus drains from the track due to capillary action of thread. Thread provides a drainage medium to pus and work as a drain. Patient is also educated to squeeze the collected pus in track and to rotate thread gently, so that the track must be clean and free from excess accumulation of debris. Hot Seitz bath and medicated oil application in track through catheter and syringe is also advised to patient. Medicated oil sticks to the thread due to adhesive forces between media and solvent. The applied oil (*jatyadi* or other) not only provide soothing effect to track but also it provide aseptic environment and less bacterial load.

During the course of normal standard *kshar sutra* technique, few problems were observed.

1. Thread can not be allowed to place for more than one week. As it is made up of cotton and it becomes disintegrate due to regular use of medicated oil and fomentation with Luke warm water. Thread also gets loose due to cutting effect of *kshar* in track and it needs regular tightening over one week interval. Degradation of cotton thread is also due to enzymatic lytic reaction of tissue fluid and inflammatory substances present in track.
2. Usually the drug coated over *kshar sutra* get dissolved and removed very soon due to regular Seitz bath and medicated oil application. As the drug is water soluble, it does not hold the thread for longer duration. The only force which binds the drug to thread is cohesive and adhesive force of *snuhi ksheer* and as soon as the *kshar* is dissolved, the turmeric and latex slowly get diluted in concentration.
3. Medicated oil, which is applied by patient in track to give antibacterial and antifungal medium, binds to thread due to surface tension of oil. The capillary action between thread and oil plays a very effective role in holding it for longer time. Present study is performed in order to establish an initiative to enhance those factors which can increase binding capacity.
4. After *kshar sutra* change, surgeon ties the knot tightly so that thread also works due to pressure effect along with the caustic effect of drug. The tightening of thread creates lot of problem to patient. Generally after *kshar sutra* change, patient suffers from burning sensation up to 24-36 hours or sometimes even more.
5. *Kshar sutra* is gradually tightened by surgeon, due to following reasons:
 - a) Track gets cut within one week so much that the thread becomes loose.
 - b) Cotton thread itself become so thin and disintegrate that it is liable to remove itself. So it is better to change the thread before it removes itself.

If once the thread remove itself, the surgeon go through the further probing and primary threading to continue the treatment. This condition is very difficult to manage both by patient and surgeon. Usually in these cases probing is generally done on OPD basis under very less anesthesia. Patient suffers a lot and goes through the higher agony. Such episodes demoralize the patient and decrease the faith of patient in therapy.

MATERIALS AND METHODS

Considering all above the points, two different and new techniques were adopted to sort out the problems related to traditional method.

- A) **DOUBLE *Kshar-sutra* technique (DKST):** At the time of secondary threading, two separate threads should be passed through previously placed single thread. Steps of this method are as follows:

1. Insert the whole length of new thread in old loop, just near the knot.
2. Tie a knot in mid length of thread.
3. Cut and hold the thread from proximal side.
4. Pull the old thread through rail –road technique, so that two threads come in track.
5. Cut the knot of new thread and tie them separately.

B) BEADED *Kshar-sutra* technique(BKST)

To make this type of *kshar sutra*, single simple knots were tied at regular gap of 1cm in standard thread along its whole length. This knotting mechanism gives thread a beaded appearance. Now it is ready to be used in the same manner like traditional secondary threading.

Hypothesis behind the above two methods

To understand the phenomena related to threads, we must understand the physics behind the capillary action and surface tension of fluids and overall mechanism.

Capillary action, or capillarity, is the ability of a liquid to flow in narrow spaces without the assistance of, and in opposition to external forces like gravity.^[7]

The effect can be seen in the drawing up of liquids between the hairs of a paint-brush, in a thin tube, in porous materials such as paper, in some non-porous materials such as liquefied carbon fiber, or in a cell.

It occurs because of inter-molecular attractive forces between the liquid and solid surrounding surfaces.

If the diameter of the tube is sufficiently small, then the combination of surface tension (which is caused by cohesion within the liquid) and adhesive forces between the liquid and container act to lift the liquid.

When a dry porous medium, such as a brick or a wick, is brought into contact with a liquid, it will start absorbing the liquid at a rate which decreases over time. For a bar of material with cross-sectional area A that is wetted on one end, the cumulative volume V of absorbed liquid after a time t is

$$V = A S \sqrt{t}$$

Where, S is the sorptivity of the medium, with dimensions $m/s^{1/2}$ or $mm/min^{1/2}$. The quantity

$$I = V/A$$

is called the cumulative liquid intake, with the dimension of length. Sorptivity is a relevant property of bar material, because it affects the amount of rising dampness. So, cumulative volume V of absorbed liquid is proportional to cross-sectional area A , as we increase the diameter of thread, absorption will be more. But, as we can't increase the thickness of *Kshar sutra*, so we should use DOUBLE *kshar sutra* or BEADED *kshar sutra*. It not only increases the total absorbed volume, but also provides added benefits.

Advantages of DOUBLE *Kshar-sutra* technique (DKST) and BEADED *Kshar-sutra* technique (BKST) over STANDARD *Kshar-sutra* technique (SKST):

DKSK

1. If one *kshar sutra* is damaged by itself, due to any cause, another one will always be there, so no further need of second time probing.
2. Proper drainage of tract.
3. Early cutting.
4. More availability of drug at a time inside the track, so half life of *kshar sutra* increases.
5. More holding time for the medicated oil at the time of dressing as capillary action is better for two threads.
6. No need to tie knot very tightly. Two loose *kshar sutra* in one track will provide better cutting effect than a single tight one.

BKSK

1. More cross sectional surface area is present at a particular interval.
2. It provides long holding of *kshar sutra* drug in the thread.
3. On each rotation of thread by patient, more cutting is produced in the track by multiple knots.
4. Initially, on first day, little pain occurs but as soon as the patient rotates it, cutting is faster.
5. No need to tie thread tightly. BEADED *kshar sutra* may be placed loosely, as it cuts the track not by pressure effect, but due to roughening and scrubbing action of their beads and long lasting presence of its *kshar aushadhi*.

Study design

- Randomized control trial
- Open trial

Selection of patient

Forty five patients were selected randomly from OPD and IPD of department of ano-rectal surgery, from February 2011 to March 2012. Patients who gave their informed consent were only chosen. Patients were explained regarding the purpose, procedure, possible danger etc.

Selected patients were examined thoroughly according to the IPD Performa of hospital.

Inclusion Criteria

1. Age between 18 to 75 years.
2. Diagnosed cases of fistula in ano.
3. Sound mental health.

Exclusion Criteria

1. Patient below 18 year and above 75 years.
2. Patient of fistula in ano also suffering from tuberculosis, diabetes mellitus, ulcerative colitis, Crohn's disease, CA rectum or anal canal, AIDS, Hepatitis B, or any other chronic systemic disease.

Grouping of patients

All selected patients were uniformly divided into 3 groups:

Group (A) (Control group): 15 patients were treated with Standard *kshar sutra* treatment (SKST).

Group (B) (Trial group): 15 patients were treated with DOUBLE *Kshar-sutra* technique (DKST)

Group (C) (trial group): 15 patients were treated with BEADED *Kshar-sutra* technique (BKST).

Formulation

Kshar sutras issued to hospital by govt. agency were taken for the study. Same type of *kshar sutras* was used in all patients but the technique used was different according to their groups.

Investigation

1. Blood investigation: Hb%, TLC, DLC, ESR, B. SUGAR fasting, BT, CT, HIV, HBSAg, B. UREA, S. CREATININE.
2. Chest x-ray PA view, ECG, (Fistulo-gram, MRI-perineum- if required to make diagnosis about level of fistula)

Adjuvant therapy

1. Hot Seitz bath with *tankan* or *sphatika bhasma*.
2. *Jatyadi* oil or *Prabhakar* oil for local application.

3. Laxative- *Swadista Virechan Churn*, *Triphala churna* or *panchsakar churna*.5 gm HS with Luke warm water.
4. Oral medicine- *Sapta vinshati guggulu* or *panch tikta ghrith guggulu*.2 BD, *Syrup Abhayarista* 4 tsf BD with equal amount of water.

Patients were instructed for follow ups in concerned Shalya OPD after seven days for changing of *kshar sutra*. The changing of *kshar sutra* was done in each group accordingly. The secondary threading was done until the whole length of fistulous tract was cut through. Final follow up period was for 4 weeks after the completion of treatment.

Assessment criteria

1. Pain
2. Duration of pain after *kshar sutra* change
3. Discharge of pus
4. Burning sensation
5. Itching
6. Unit cutting time

Physical properties of Kshar sutras

1. Dissolution of drug
2. Holding of *jatyadi* oil
3. Strength of thread



Figure: showing double kshar sutra technique (L) and Beaded kshar sutra technique (R).

RESULT**Comparative evaluation of TKST, BKST and DKST**

Symptom	Study group	Average Score	S.D.(±)	S.E.	t-value	p-value
1. Pain	Group-A	4.987	0.553	0.143	34.874	<0.01
	Group-B	5.653	0.537	0.139	40.669	<0.001
	Group-C	5.533	0.432	0.112	49.401	<0.001
2. Duration of pain	Group-A	3.407	0.493	0.127	26.827	<0.05
	Group-B	1.493	0.208	0.053	28.169	<0.02
	Group-C	2.366	0.385	0.099	23.898	<0.05
3. Discharge of pus	Group-A	1.92	0.237	0.061	31.475	<0.01
	Group-B	1.187	0.159	0.041	28.951	<0.02
	Group-C	1.227	0.166	0.043	28.534	<0.02
4. Burning sensation	Group-A	1.867	0.195	0.05	37.34	<0.001
	Group-B	2.08	0.166	0.043	48.372	<0.001
	Group-C	2.467	0.327	0.084	29.369	<0.01

5. Itching	Group-A	1.32	0.147	0.038	34.737	<0.01
	Group-B	1.093	0.103	0.027	40.481	<0.001
	Group-C	1.107	0.128	0.033	33.545	<0.01
6. Unit cutting time	Group-A	7.726	0.548	0.142	54.408	<0.001
	Group-B	6.423	0.307	0.079	81.304	<0.001
	Group-C	6.577	0.574	0.148	44.439	<0.001

- 1. Pain:** Pain score just after change of *kshar sutra*, evaluated by visual analogue score (VAS) was significantly higher in group B and C as compare to group A.
- 2. Duration of Pain after *kshar sutra* change:** This was found significantly higher in group A as compare to group B and C.
- 3. Discharge of pus:** Discharge of pus was observed significantly higher in group A as compare to group B and C.
- 4. Burning sensation:** Burning sensation just after *kshar sutra* was found higher in group B and C in initial hours.
- 5. Itching:** Itching was found significantly very less in group B and C as compare to A.
- 6. Unit cutting time:** Unit cutting time was calculated in all 3 groups. UCT was observed significantly less in group B and C as compare to A.

Physical properties of Kshar sutras

a. Dissolution of drug

Drug dissolution was compared in above three variants of *kshar sutra*. 3 types of *kshar sutras* were stick on filter paper and gradually dipped in beaker filled with plain water till the drug disappeared in any one of sample. After removal from water samples were dried in air. Further, samples were dipped in soap solution for one minute. Soap solution turns the color of turmeric into red. The comparative presence of turmeric was observed by the relative strength of red color over thread.

Turmeric was found in more concentration over BEADED *kshar sutra*, after that over DOUBLE *kshar sutra* and least on Standard *kshar sutra*.

b. Holding of jatyadi oil

Holding of jatyadi oil was compared in 3 variants of *kshar sutra*. 3 types of *kshar sutra* equally soaked in jatyadi oil were stick on filter paper and dipped five times in beaker filled with plain water. After removal from water, samples were dried in air. Dried samples were kept in between the two filter papers and hot iron was done over it. Comparative presence of oil in threads appeared on filter paper as oil spot.

Highest presence of oil was noticed on BEADED *kshar sutra*, after that over DOUBLE *kshar sutra* and least on Standard *kshar sutra*.

c. Strength of thread

Strength of thread was evaluated by comparative disintegration of thread by dipping 3 variants in phenol. Fastest disintegration was observed in Standard *kshar sutra*, after that in BEADED *kshar sutra* and slowest in DOUBLE *kshar sutra*.

DISCUSSION

Fistula in ano was recognized as a disease known as *bhagandar* since the time of *Acharya Sushruta* about 1200 BC.^[2] Since then it was included among the list of deadly diseases called as *mahagada*.^[8] Then also it was difficult to be treated. In modern science too it was not a cakewalk. In the whole scenario it was Prof. P. J. *Deshpande* who discovered the *kshar sutra* thread for the management of fistula in ano.^[4] Now it is an established gold standard treatment for anal fistula cases. Lot of researches and clinical trails has been done in regard to *kshar sutra*.^[9] The present study was not only focused on running methods of *kshar sutra* therapy but also an introduction of two new techniques and their clinical study. It is clear from the statistical data that double *kshar sutra* technique and beaded *kshar sutra* technique are superior techniques than the traditional one. It was observed that burning sensation and pain was higher in above two groups as compared to control group. It was just because of the more cross sectional area of thread inside the track. Initially the patients were worried about this pain and burning sensation but later on the benefits and faster recovery were observed in such cases. Use of local anesthetic agents and judicious use of analgesic drugs can further reduce the above mentioned complaints. In the clinical trail it was clear that the two adopted methods were better than the traditional ones.

As we go in details of capillary physics we can see that the availability of absorbent is more in case of thick fiber as compared to thin. If we increase the number of *kshar sutra* in track as we used in case of double *kshar sutra* technique it increases the surface area and cross sectional area to absorb and adsorb the drug. Ultimately the half life of double *kshar sutra* is more than the single. In the mean time it comes in mind that how many *kshar sutras* can be used in track. It was observed that use of more than two *kshar sutra* does not allow the physical movement of thread in track. It hampers the mobility of thread and blocks the passage of pus and exudates from track. But the use of two threads in track allows better and smooth mobility and provides good drainage medium. Besides this it also provides the longer holding of medicated oil inside the track which enhances the anti microbial activity of whole therapy. Drugs coated over

the thread are more present over it and doubles the action.

Beaded *kshar sutra* was also found significantly better than the traditional one. There are many beads or knots present on thread and as they move in track they work as a plunger inside the track. Patients were educated to rotate the thread the thread in track at the time of fomentation. Initially it was very difficult for the patients but after few days of therapy, they become habitual and feeling better than the tight traditional thread. Usually the diameter of knot is about double the diameter of thread. Drug is also trapped inside the knots which allow the slow release of drug for longer periods, Better cleaning of track was possible with the single rotation of thread by the patients. Knots also provide better holding of medicated oil. The best advantage of this technique is that there is no need to tie thread tightly at secondary threading. Loose beaded thread is sufficient to cut the track unless the patient is educated to rotate it at the time of fomentation. In both the techniques better patient acceptability was observed and cure rate was clinically and statistically found better.

CONCLUSION

On the basis of findings and observations obtained after completion of work, it can be concluded that the above two new variants of *kshar sutra* provide better, effective, safe and faster recovery in management of fistula in ano. Different techniques can also be used at different stages of therapy in combination or alone as per the requirement. Further need of research in above two variant in different paradigm is also obligatory.

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