



Research Article

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *KUTAJ KSHAR SUTRA* USING IFTAK TECHNIQUE IN THE MANAGEMENT OF *BHAGANDARA* (COMPLEX FISTULA IN ANO)

Amit Kumar^{1*}, Rajesh Kumar Gupta²

¹PG Scholar, Dept. of Shalya Tantra, ²HOD & Professor, P.G. Dept. of Shalya Tantra, PGIA, DSRRAU, Jodhpur, India.

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ABSTRACT

Bhagandara (complex fistula-in-ano) is a challenging anorectal disorder with high recurrence rates and significant morbidity. Conventional surgical approaches often result in complications such as incontinence and delayed wound healing. Ayurveda offers a promising alternative through *Kshar Sutra* therapy, which is known for its minimal recurrence and effective fistula healing. *Kutaj (Holarrhena antidysenterica) Kshar Sutra* is a specialized medicated thread that has potent antimicrobial, anti-inflammatory, and wound-healing properties. **Objective:** This clinical study aims to evaluate the efficacy of *Kutaj Kshar Sutra* using the IFTak (Interception of Fistulous Tract and Application of *Kshar Sutra*) technique in the management of *Bhagandara* (complex fistula-in-ano). **Methodology:** A controlled clinical trial was conducted on patients diagnosed with complex fistula in ano. Participants were treated with the IFTak technique, wherein the fistulous tract was intercepted and *Kutaj Kshar Sutra* was applied. Patients were monitored for parameters such as pain relief, healing time, recurrence rate, and complications. **Results:** Preliminary findings suggest that the *Kutaj Kshar Sutra* with the IFTak technique leads to faster healing, reduced recurrence, and better postoperative outcomes compared to conventional surgical methods. The natural caustic and antibacterial properties of *Kutaj Kshar* enhance the healing process while minimizing tissue damage. **Conclusion:** The study highlights the effectiveness of *Kutaj Kshar Sutra* using the IFTak technique as a viable and safe alternative in the management of complex fistula in ano. It offers a minimally invasive, cost-effective, and recurrence-free approach with improved patient outcomes. Further large-scale studies are recommended to validate these findings.


INTRODUCTION

The oldest description of *Bhagandara* is found in *Sushruta Samhita* (1000-1500 BC). *Sushruta* classified *Bhagandara* as *mahagada* because it is difficult to treat and has a high risk of recurrence.^[1] Hippocrates (460-356 BC) mentioned that fistula in ano followed ano-rectal abscess and the required treatment is fistulectomy. Hippocrates treated it by the use of a linen aplinose ligature (seton) which was strained daily until fistulectomy was achieved. If this procedure was not successful, he advocated that fistula should be "cut down as far as it passes". Celsus in

Rome (53 BC-AD 7), Galen (AD 131-AD 200), Ambroise Pare (1510-1590), Percival Pott (1714-1788) have all suggested the use of ligatures or surgery for keeping open fistulous track.^[2]

It's a Latin term that means "reed," "pipe," or "flautist." Fistula can occur in any part of the body, but fistula in ano refers to a fistula that arises in the ano-rectal region. An anal fistula is a track that has one or more exterior openings in the perianal, perineal, or ischio-rectal areas and joins with the anal canal or rectum through an internal opening.^[3]

Bhagandara is made up of two words: *Bhaga* and *Darana*. *Bhaga* refers to the area between the anus and the genitalia, while *Daran* means to tear or demolish. As a result, *Bhagandara* is defined as shredding the anus, perineum, rectum, and pelvic regions. *Sushruta* explained.^[4]

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ते तु भगगुदंबस्त्रिदेशदाराणाच्च भगन्दरा इत्युच्यन्ते ।

अपक्वाः पिडकाः पक्वास्तु भगन्दराः ॥ सु० नि०- 4/4

He explained that in the region of perineum, anus, rectum and pelvis an inflammatory swelling situated is called *Pidika* until suppuration, after suppuration it converts in to *Bhagandara* which now a day is known as fistula in ano. *Bhagandara* has been regarded as one of the diseases of *Astamahagada* therefore it is *Krishsadhya* or *Asadhya*. Management of *Bhagandara* has been taken from *Shastiupkrama* which include 11 parts of *Poorvakarma*, *Pradhankarma* where main surgical procedure is included and *Paschatkarma*. Parasurgical procedures are taken into of consideration like - *Kshar karma* and *Agni karma* to treat *Bhagandara* if surgery is not possible and even after surgery.

At first it presents as *Pidika* around *Guda* and when it bursts out, it is called as *Bhagandara*. It can be correlated with fistula in ano as described in western medical science. Fistula in ano is a tract lined by granulation tissue which opens deeply in the anal canal or rectum and superficially on the skin around the anus.^[5]

Now a days the principles of treatment of fistula in ano is changed after minimal assess of surgery as Fistulectomy may cause of several complications like incontinence, deformity and recurrence and also it needs long period of treatment for wound healing. Parasurgical procedure is effective up to the large extent and majority of cases are treated well but some of fistula are difficult to treat by surgery or Parasurgical procedure. These fistulas in ano included usually horse shoe type fistula, supralelevator, transsphincter, extrasphincter. That's why it was selected for this clinical study. Under these circumstances it was thought to select these cases to understand it as well as for diagnosis and management. *Sushruta* described 5 types of *Bhagandara* namely *Shataponaka*, *ustragriva*, *parisravi*, *Shambukavarta* and *Unmargi*. Out of these first three *Bhagandara* are *Kastshadhya* (difficult to treat) rest of two *Shambukavarta* and *Unmargi* has been regarded as *Asadhya* (incurable). The application of *Kshar sutra* is recommended in contest of *Nadi Vrana* as well as for *Bhagandara* also (S.Ch. 17/32).^[6]

Kshar Sutra therapy has many advantages like the tract is completely excised by *Lekhan* and improve healing simultaneously. so, there are least chances of recurrence, minimal scarring and no chance of anal incontinence but *Kshar sutra* cause certain discomfort such as long anxiety period, number of hospital visit, discomfort and longer duration of treatment. The present study regarding interception of fistulous tract with application of *Kshar sutra* (IFTAK)^[7] is designed

to reduce the duration of treatment with minimal post-operative scar and problems related to conventional method. In the studies about interception of fistulous tract with application of *Kshara sutra* (IFTAK) have found very effective as it reduces anxiety period and painful sitting *Kshar sutra* placement. This approach was found very effective for patient as well as for operating surgeon.

For treating difficult and recurrent fistulas in ano, the Interception of Fistulous Tract with Application of *Kshara sutra* (IFTAK) method has been used. To create an inexpensive, readily available, and sanitary *Ksharasutra*.

MATERIALS AND METHODS

Study Design

To avoid bias and limit study error, the study followed a stringent process.

1. Randomized control trial: patients were assigned to one of two groups based on a simple random sampling process. Every unit of the population has an equal chance of being chosen, a technique known as unfettered random sampling.
2. Single-Blind Test: The patients had no idea what type of *Ksharsutra* they were wearing.
3. Ethics approval: the study was approved by the institutional ethical committee of DSRRAU, jodhpur, with letter no. DSRRAU/PGIA/IEC/21-22/479 prior to the initiation of the clinical experiment on *Bhagandara* patients (fistula in ano).
4. Participants: the study included 13 patients ranging in age from 18 to 60 years old, irrespective of gender or religious affiliation.
5. Patients were chosen at random from the IPD and OPD of the department of Shalya tantra, DSRRAU, Jodhpur, and registered for the study.
6. Under the guidance of the pharmacy in-charge, the *Ksharsutra* was manufactured in the *Ksharsutra* lab at the *Shalya tantra* UCA DSRRAU Jodhpur. Some of the basic ingredients came from the market, while others came from fresh plants.
7. On dated, 21/11/2023 the preparation of the *Kutaj Ksharsutra*^[8] began and was completed in 53 days. The pharmacist issued a job card with a unique number.

Drug required for the preparation of *Ksharsutra*:

1. *Kutaj kshar*
2. *Gugglu*
3. *Haridra*
4. Surgical Linen thread number 20
5. *Ksharsutra* hanger and cabinet
6. Sterilized test tube

7. Gauze piece
8. Gloves

Criteria for Selection of the Patients

Inclusion Criteria

1. Blind fistula in ano.
2. Low anal fistula in ano.
3. All type tract of complex fistula in ano.
4. Recurrent fistula in ano.
5. Complex fistula in ano.

Exclusion Criteria

1. *Bhagandara* present with tuberculosis.
2. Regional Ileitis
3. Any malignancies related with fistula in ano.
4. Chronic/acute ulcerative colitis.
5. HIV & HBsAg positive patient.
6. Crohn's disease
7. Faecal fistula and uretero-vaginal fistula
8. Non-complex fistula in ano

Method of Study

Prior to the start of therapy in the selected patients and drugs, the following general information about the patients, the medicine, and the disease were gathered.

1. Diagnosis
2. Investigations
3. Treatment schedule
4. Duration of study
5. Criteria for assessment

Diagnostic criteria

Diagnosis will be made upon history of patient, the general system and local examination from Ayurvedic and modern view.

History of the patient

Complete history of the patient should be taken to rule out of the associated diseases as diabetes, tuberculosis, urinary, cardiac and neurological disease presenting complaints like, pain onset, duration, discharge and bowel habit.

Personal history, dietic habits, family history, occupation, history of previous treatment particularly previous surgery, type of operation, number of operations, should be taken.

Systemic examination

Different systems like digestive, cardiovascular, respiratory, nervous and genito-urinary system should be examined. If any organ was found diseased than the specific investigations related to diseased organ should be done and confirmed to treat first.

Local examination

A. Inspection

Patient should be in lithotomy position first. The skin condition near fistula like color of perineal region, indurations, discharging sinuses, inflammation of external openings, number of sinuses, clockwise position, number of sinuses, previous operated scars, discoloration of adjacent area were ruled out.

B. Palpation

Local temperature, tenderness, indurations, fluctuation, consistency of pus, fistulous track and its direction etc, should be done.

C. Digital Rectal Examination (DRE)

By digital examination, tenderness, any fissure, malignancy, indurated dimple, any cavity, thrombotic pile, tone of sphincter, internal openings with their positions and prostate in males were figured out.

Instrumentation

a. Probing

Soft, malleable, curved probes were carefully introduced through the external opening to find out that the track was complete or not, extent of the track, Position of the internal opening, direction of the track, relation of the fistulous track with levator muscles with the sphincter muscles, branching of the track.

b. Proctoscopy

Proctoscopy should be done to make sure for any growth or ulcer, presence or absence of pile masses, location of internal opening, condition of rectal mucosa etc.

c. Sigmoidoscopy

Sigmoidoscopy may be done to differentiate between rectal and anal canal opening, examination of the rectal mucosa, an underlying proctocolitis etc.

Laboratory Investigations

1. Blood for

- CBC
- BT/CT
- ESR
- Random blood sugar
- HIV, HBsAg

2. **Stool for:** Routine, microscopic (if necessary) stool for ova, cyst and occult blood.

3. **Urine for:** Routine, microscopic

4. **Pus for:** Culture and sensitivity (if necessary)

5. **Radiological:** Fistulogram is a medical term for a procedure that involves (if necessary). The purpose of a fistulogram was to determine the tract's exact path and place. In cases with intestinal discomfort or recurring fistula-in-ano, a barium enema is

indicated. To rule out pulmonary tuberculosis, a chest x-ray is needed.

- 6. Others:** Other tests were performed on suspected patients suspected of having a tubercular somewhere in the body as Mantoux test, sputum for acid fast bacilli, and other pulmonary tuberculosis tests were among them.

Treatment Schedule

Ksharsutra application

Required Equipment and Instruments

1. Lithotomy table
2. Spot light
3. Dressing trolley
4. Instruments box
5. *Nadi Svedana Yantra*
6. *Ushnodaka Awagaha Yantra*

Instruments box

Lithotomy table

(2) Spot light

(3) Dressing trolley

This trolley contains following instruments and materials

Drums

Instruments tray

Scissors, proctoscopes of various size etc.

Tray containing tubes of *Kutaj kshar Sutra*.

Different containers of *Kshar Varti*, *Kshar Pichu*, *Kshar Powder*, *Kshar Jala*.

Tray containing sterile syringe and plain rubber catheter.

Bottles of *Jatyadi tail* and antiseptic lotions.

Sterile lubricant container

Table 1

1.	<i>Vakra Eshani</i> (curved probe with eyelet)	3 assorted sizes
2.	<i>Vakra Eshani-Ara Shastra Mukhaakriti</i> (curved probe with notch)	3 assorted sizes
3.	<i>Eshani</i> (malleable straight probe)	3 assorted sizes
4.	<i>Eshani</i> (non-malleable straight probe)	3 assorted sizes
5.	<i>Sootra-Niyojini Shalaka</i> (thread carrier)	2 assorted sizes
6.	<i>Darvikriti Shalaka</i> (scooped <i>Kshar</i> applicator)	2 assorted sizes
7.	Artery forceps (straight and curved)	3 pair
8.	Scissors (straight)	1 pair
9.	Pile holding forceps	2 pair
10.	Proctoscopes of various sizes	2 pair
11.	<i>Kshar Sutra</i> tube	2 pair

Nadi Sweda Yantra

It consists of steam chamber containing a regulator, rubber tube and steam blower. This is very useful to provide the local steam fomentation in all the inflammatory and painful conditions of the ano-rectal region during the course of treatment.

Ushnodaka Awagaha Yantra

Prior to employing the *Kutajaadi Ksharsutra*, it is used to reduce the pain and inflammation and healthy granulation tissue is also encouraged to grow.

Pre-Operative

Before using the *Kutajksharsutra*, the following requirements should be followed. The patient was

admitted one day before the surgery. Mild laxatives were given to help the bowel become more regular.

Patients were instructed to keep proper local part preparation and general cleanliness in mind. Preventing local inflammation, indurations, infection, itching, and other symptoms with appropriate medications. Tetanus toxoid is a toxin that is used to treat tetanus was given. The patient's consent was obtained in his or her own language for primary threading under local anesthetic. Hairs in the perianal area were cleansed 4 to 6 hours before surgery.

Operative procedure (Application of *Ksharsutra*) Surgical Thread



The patient is kept in the proper lithotomy posture. The perianal region is treated with antiseptic lotions. The patient is to relax his thigh and anal sphincters. The sphincters are further relaxed by giving heat fomentation to the area using a *Nadi Sweda Yantra*. A gloved finger was thereafter gently placed into the rectum after assuring the patient. A suitable probe was then placed via the external fistula hole to determine the direction of the fistulous tract. A small vertical incision was made to intercept the fistulous tract at six o'clock roughly 1.0cm away from the anal verge. Then, normal saline was poured through an outside aperture and released from the spot where it had been intercepted in order to confirm the precision of IFTAK. A metallic probe was introduced through the window and taken out from internal opening through anus then *Kutaj Ksharsutra* inserted into the tract and packed it with a *Jatyadi tail* or an antiseptic dressing. The next day the patient was told to start hot sitz baths and to wear a *Jatyadi tail* taking daily. The initial

threading was done under general anesthesia in patients of high anal fistula.

Post-operative Measures

- The patient was kept nil orally until the anesthetic effect had completely won off, which could take up to 6 hours.
- I/V fluids were provided as needed.
- Appropriate analgesics and antibiotics were given as needed.
- All of the patients were directed to take a warm sitz bath.
- Patients were advised to take *Jatyadi Taila Basti* (4-5ml) at bedtime to clear the vowel.
- The track was cleaned with ark, iodine water, eusol, normal saline, and *Gomutra*.
- Patients were instructed to eat a regular, high-fiber diet.
- Patients were discouraged from engaging in physical activity and ambulation.

Change of Ksharsutra

Changing the Thread (Rail - Road Method)

By using the rail-road system, the *Ksharsutra* was changed every seventh day with a fresh thread.

Duration of the treatment

8 weeks (2 months) including follow up.

Follow up period

The patients were screened on the second to eighth week after each seven-day period for symptoms of a relapse of their sickness and any concomitant lesions in the ano-rectal region.

General management

Ushnodaka awagaha with *Panchvalkal kwath* thrice in a day.

Triphala Guggulu-2 tabs twice daily after food.

Assessment Criteria

1. U.C.T. (Unit Cutting Time)

Total no. of days taken for cut through = Days/centimeter

Initial length of track in centimeter

2. Pain

3. Discharge

Assessment Parameters

Subjective Parameters

1. *Vedana* (pain in perianal area)

2. *Srava* (pus discharge from perianal area)

3. *Shotha* (swelling)

4. *Kandu* (itching)

5. An opening in perianal area.

Assessment of sign and symptoms will be done pre and post-trial on severity grading scale.

Table 1: Vedana (Pain): As per visual analogue scale (VAS score 0-10)

S.No.	Vedana (Pain)	Grading
1.	No pain	0
2.	Mild	1-3
3.	Moderate to severe pain	4-6
4.	Very severe pain	7-9
5.	Worst pain possible	10

Table 2: Srava (Pus discharge)

S.No.	Srava (Pus discharge)	Grading
1.	No discharge	0
2.	Mild (if wound wets 1×1 cm gauze piece)	1
3.	Moderate (if wound wets 2×2 cm gauze piece)	2
4.	Severe (if wound wets more than 2 cm gauze piece)	3

Table 3: Shotha (Swelling)

S.No.	Shotha (Swelling)	Grading
1.	Swelling within 0.5-1 cm	0
2.	Swelling within 1-2 cm	1
3.	Swelling within 2-3 cm	2
4.	Swelling within 3-4 cm	3

Table 4: Kandu (Itching)

S.No.	Kandu (Itching)	Grading
1.	No itching	0
2.	Mild and occasional itching	1
3.	Moderate and frequent itching	2
4.	Severe and continuous itching	3

Table 5: Thread length (cm) of anal fistulous tract

S.No.	Thread length (cm)	Grading
1.	<3	0
2.	3-4	1
3.	4-5	2
4.	>5	3

Table 6: Unit Cutting Time of fistulous tract

S.No.	Unit Cutting Time	Grading
1.	<15 days	0
2.	15-30 days	1
3.	30-45 days	2
4.	>45 days	3

Table 7: Pain

Follow up	Pain			p value
	Mean ± SD	Mean difference from Baseline	% of improvement	
Baseline treatment	7.76±0.72	-	-	-
1 st week	5.73±0.90	2.033	26.20	<0.0001
2 nd week	4.33±0.71	3.44	44.33	<0.0001
3 rd week	3.16±0.46	4.60	59.28	<0.0001
4 th week	1.83±0.64	5.933	76.46	<0.0001

Table 8: Swelling

Follow up	Swelling			p value
	Mean ± SD	Mean difference from Baseline	% of improvement	
Baseline treatment	3.00±0.00	-	-	-
1 st week	2.3±0.46	0.700	23.33	<0.0001
2 nd week	1.66±0.47	1.333	44.43	<0.0001
3 rd week	1.56±0.50	1.433	47.77	<0.0001
4 th week	0.76±0.43	2.233	74.43	<0.0001

Table 9: Discharge

Follow up	Discharge			p value
	Mean ± SD	Mean difference from Baseline	% of improvement	
Baseline treatment	2.83±0.37	-	-	-
1 st week	2.16±0.37	0.666	23.53	<0.0001

2 nd week	1.6±0.49	1.233	43.57	<0.0001
3 rd week	1.53±0.50	1.300	45.94	<0.0001
4 th week	0.83±0.37	2.00	70.67	<0.0001

Table 10: Itching

Follow up	Itching			p value
	Mean ± SD	Mean difference from Baseline	% of improvement	
Baseline treatment	3.00±0.00	-	-	-
1 st week	2.3±0.46	0.700	23.33	<0.0001
2 nd week	1.73±0.44	1.267	42.23	<0.0001
3 rd week	1.6±0.49	1.400	46.67	<0.0001
4 th week	0.8±0.40	2.200	73.33	<0.0001

Table 11: Thread Length

Follow up	Thread Length			p value
	Mean ± SD	Mean difference from Baseline	% of improvement	
Baseline treatment	2.93±0.25	-	-	-
1 st week	2.2±0.40	0.733	25.02	<0.0001
2 nd week	1.73±0.44	1.200	40.96	<0.0001
3 rd week	1.6±0.49	1.333	45.49	<0.0001
4 th week	0.76±0.43	2.167	73.96	<0.0001

DISCUSSION

The debridement of this chronic fibrous tissue is particularly crucial in fistula in ano because it prevents the track walls from collapsing and healing. *Ksharsutra* has *Ksharana* and *Kshanana* properties (S. Su 11/4). Previous research has demonstrated that *Ksharsutra* has proteolytic activity. *Kutaj Ksharsutra* assists in the degradation of the fistulous track's (thick fibrous wall) debridement of chronic inflammatory and fibrous tissue occurs as the fibrous fistulous track degrades, resulting in complete healing of fistulas by debridement and continuous draining with the support of a patent external opening due to the *Ksharsutra* have an essential function in lowering pain, inflammation, microbial contamination, and wound healing, and thus play a crucial part in properly dealing with the condition.

Kutaj Ksharsutra breaks of pus pocket of micro abscess that result pus discharge is reduced due to its *Chhedan*, *Lekhan* and *Bhedana* property. Most of time accumulation of pus causes pain. If pus discharge drains out pain is also subsided. *Ushnavirya* of *Kutaj Ksharsutra* also help in reducing pain by vat shaman. Itching is diminished due to its *Kandughna* property that comes from *Katu tikt ras* and *Ushana virya* of *Kutaj Ksharsutra* anti-oxidative property of honey enhances the healing process whereas salt double the cutting

potency of *Ksharsutra*. Thus, the *Kutaj Ksharsutra* is capable of totally excising the fistulous track because proper wound healing prevents recurrence while also avoiding problems such as fissure and incontinence.

Merits of *Kutaj ksharsutra* Therapy

Kutaj ksharsutra has very important property like- *Kushthaghan*, *Shothhar*, *Vranashodhak*, and *Vranaropak*. It reduces accumulation of pus within the track by allowing continuous drainage and causes the cauterization of the crypto glandular origin of the fistula due to its *Chhedan*, *Lekhan*, *Bhedan*, and *Tikshna guna* property. It penetrates deeply and brings out the unhealthy granulation tissue which is the most important cause of fistula (more than 90% of cases of fistula in ano are due to crypto glandular infections).

It penetrates even small channels of fistula and drain them properly it is main cause of high recurrence rate of fistula. It is done by *Shodhan karma*. Use of *Kutaj Ksharsutra* has been already proved in *Dushta Vrana* that it minimized inflammatory components. *Kutaj Ksharsutra* has *Vrana Ropana twakdoshahar*, *Pachan*, *Vilayan*. This property improves cell energy level; promote cell division, production of healthy granulation tissue. Ultimately the combine effect helps in healing of the tract and cutting the fistulous track

along with sphincter muscle by *Ksharsutra* and *Ksharsutra* function.

CONCLUSION

The purpose of this research is to lay down the efficacy and relevance of the *Kutaj Ksharsutra* to treat the *Bhagandara* based on the clinical statistical data presented above, the following conclusions are drawn: In this clinical trial, there was a significant reduction in the symptoms of irritation, inflammation, and local reactions.

It was found that *Kutaj ksharsutra* have better wound healing due to *Vrana Ropan* and *Vrana shodhan* property of *Kutajaadi gana*. Pathogens did not multiply and invade the cavity due to alkaline pH of *Ksharsutra*. During the last 1.5 months of follow-up, no new instances were reported.

In this clinical trial, not only the average unit cutting time was reduced, but also the discomfort and burning feeling. *Kutaj Kshar Sutra* is a better alternative because it has better wound healing properties after being cut through.

As a result, the study found that IFTAK is safe, effective, and sophisticated approaches that reduces post-operative time and improves mild post-further research work.

This clinical study could include only 30 patients and it could have been on a greater number of patients to understand the detail pathology of complex fistula in ano therefore further study is required. During the last 1.5 months of follow-up, no new instances were documented.

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*Address for correspondence

Dr. Amit Kumar

PG Scholar

P.G. Dept. of Shalya Tantra, PGIA, DSRRAU, Jodhpur, India.

Email:

amitkumar007887@gmail.com

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