

## THE EFFICACY OF ASITA MUSHKAKA KSHARA SUTRA IN THE MANAGEMENT OF BHAGANDARA (FISTULA-IN-ANO) A CLINICAL CONTROLLED TRAIL

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### ABSTRACT

*Bhagandara* (Fistula-In-Ano) is classified as one of the *Ashtamahagada* diseases in *Sushruta Samhita*, recognized for its complexity and challenging prognosis. Fistula-in-Ano is characterized by an abnormal communication between two epithelial-lined surfaces in the anorectal region. Conventional surgical interventions, such as fistulectomy, are often associated with complications, including recurrence, anal sphincter incontinence, and postoperative infections. The *Kshara Sutra* technique, a parasurgical approach, has demonstrated greater efficacy in the management of Fistula-In-Ano. Among the various *Kshara Sutras*, *Apamarga Kshara Sutra* is widely utilized, composed of *Apamarga Kshara*, *Snuhi Kshira*, and *Haridra*. However, the preparation of *Apamarga Kshara* is labor-intensive and time-consuming. *Acharya Susuruta* also mention *Asita Mushkaka*

(*Elaeodendron glaucum*) as first choice of drugs and a potential *Kshara Dravya* for *Kshara Sutra* preparation. *Asita Mushkaka*, being a large and readily available tree, presents a cost-effective alternative with properties conducive to *Kshara* formulation. This study evaluates the clinical efficacy of *Asita Mushkaka* and *Apamarga Kshara Sutras* in the management of *Bhagandara*, offering insights into their therapeutic potential.

### INTRODUCTION

Fistula-in-Ano, referred to as *Bhagandara* in Ayurveda, is a complex surgical condition that has posed significant challenges for centuries. It is classified as one of the *Ashtamahagada*<sup>[1]</sup> (eight difficult-to-cure diseases) in *Sushruta Samhita*. The term *fistula* originates from the Latin word

meaning "reed," "pipe," or "flute." Fistula-in-Ano is characterized by an inflammatory tract with an external opening (secondary opening) on the perianal skin and an internal opening (primary opening) in the anal canal or rectum.<sup>[2]</sup> The tract is lined with unhealthy granulation and fibrous tissue, often resulting from an anorectal abscess that ruptures spontaneously, making it prone to recurrent infections. The condition is notoriously difficult to treat and frequently leads to complications such as recurrence and anal incontinence. Historically, Hippocrates (circa 430 BCE) attributed the development of this condition to contusions and tubercles caused by activities such as rowing and horseback riding. He was the first in Western medicine to recommend the Seton technique, derived from the Latin *seta* (meaning bristle), for managing fistula cases. Epidemiological studies indicate that the prevalence of Fistula-in-Ano is approximately 9 cases per 100,000 people, with a male-to-female ratio of 1.8:1. Despite advancements in treatment, the recurrence rate remains high, ranging between 30% and 40%.

In Ayurvedic literature, *Kshara Karma* therapy has been practiced for centuries with remarkable success and minimal recurrence in the management of Fistula-in-Ano. *Sushruta Samhita* mentions the use of *Kshara Sutra* in the treatment of *Nadivrand*<sup>[3]</sup> (sinus wounds), while texts such as *Chakradatta*<sup>[4]</sup> and *Rasatarangini*<sup>[5]</sup> describe *Kshara Sutra* composed of *Snuhi Ksheera*, *Apamarga Kshara*, and *Haridra*. In the 20th century, Prof. P.J. Deshpande of Banaras Hindu University (BHU) played a pivotal role in reviving and refining this ancient parasurgical technique. His contributions led to the scientific standardization, preservation, and application of *Kshara Sutra* therapy, following extensive research and clinical trials. These advancements have solidified *Kshara Sutra* as an effective and evidence-based treatment modality for Fistula-in-Ano.

*Apamarga Kshara Sutra* is widely practiced in India for the management of *Bhagandara* (Fistula-in-Ano). *Sushruta Samhita* references *Asita Mushkaka* (*Elaeodendron glaucum*) as one of the *Kshara Dravyas*<sup>[6]</sup> (alkaline substances) used in *Kshara* preparation. The pharmacological properties of *Asita Mushkaka*, including *Katu-tikta Rasa* (pungent and bitter taste), *Ushna Virya* (hot potency), *Katu Vipaka* (pungent post-digestive effect), *Tikshna guna* (sharp), *Pacana and Bhedana karma*<sup>[7]</sup>, align well with the therapeutic attributes of *Kshara*. According to classical Ayurvedic texts, *Acharya Sushruta* emphasizes the importance of *Asita Mushkaka* by primarily using this drug for *Kshara* preparation. *Asita Mushkaka*, being a large and widely available tree, provides a cost-effective alternative to *Apamarga*, yielding a sufficient quantity of medicinal substance for *Kshara Sutra* formulation. The present clinical study evaluates and compares the efficacy of *Asita Mushkaka Kshara Sutra* and *Apamarga Kshara Sutra* in the management of *Bhagandara*, providing insights into their therapeutic

potential.

### AIMS AND OBJECTIVES

- To know the role of *Asita Mushkaka Kshara Sutra* (*Asita Mushkaka Kshara*, *Snuhi Kshira* and *Haridra Churna*) in *Bhagandara*.
- To know the role of Standard *Apamarga Kshara Sutra* (*Apamarga Kshara*, *Snuhi Kshira* and *Haridra Churna*) in *Bhagandara*.
- To know differences in the efficacy of *Asita Mushkaka Kshara Sutra* compared with standard *Apamarga Kshara Sutra* in the management of *Bhagandara*.

### SELECTION CRITERIA INCLUSIVE CRITERIA

- Subjects of irrespective of gender.
- Subjects with age ranging from 20 to 60 years.
- Low anal fistula.

### EXCLUSIVE CRITERIA

- Concomitant ano-rectal conditions like ulcerative colitis, malignancy, Crohn's disease, multiple fistulas and high anal fistula.
- Pregnant patients,
- Tuberculosis
- Obstructive uropathies
- Other systemic diseases like diabetics, hypertension, chronic renal failure, coronary artery disease

### MATERIALS AND METHODS

40 patients of *Bhagandara* will be randomly categorized into 2 groups, each comprising of 20 patients.

- Group A: Application of *Asita Mushkaka Kshara Sutra* was put into test group in 20 diagnosed cases of fistula-In-Ano.
- Group B: Application of *Apamarga Kshara Sutra* was put into controlled group in 20 diagnosed cases of fistula-In-Ano.

### REQUIRED MATERIALS

Lithotomy table, proctoscope, surgical blade, B.P. handle, various sizes of probes, artery forceps, scissors, and sponge-holding forceps, *Kshara Sutra* in a sterile test tube, cotton, gauze,

and a kidney tray, local anesthetic drugs, Bourbar 2.0 linen surgical thread, *Asita Mushkaka Kshara* (*Elaeodendron glaucum*), *Haridra* (*Curcuma longa*), and *Snuhi Kshira* (*Euphorbia nerifolia* latex).

### PREPARATION OF ASITA MUSHKAKA KSHARA

*Kshara* is prepared by burning the bark of the *Asita Mushkaka* plant, after which the ash is collected in a vessel. The ash is then mixed with four parts of water and allowed to settle. The supernatant liquid is carefully collected, and the filtration process is repeated 21 times using a clean cloth to ensure purity. The filtered liquid is then subjected to slow evaporation over a moderate and constant flame, on double boiler method with continuous stirring using a flat stirrer to maintain uniformity. As the evaporation progresses, a fine, clear white flakes are obtained at the bottom of the vessel, which is the final *Kshara*. This alkaline *Kshara*, with a pH of 10.8-13 is then stored in a glass bottle to maintain its potency and stability.

### PREPARATION OF ASITA MUSHKAKA KSHARA SUTRA<sup>[8]</sup>

Barbour linen surgical thread No. 20 is fixed onto the *Kshara Sutra* hangers for preparation. The thread is first smeared with *Snuhi Kshira* (*Euphorbia nerifolia* latex) using a gauze piece and then dried in the *Kshara Sutra* cabin. This process is repeated for 11 days to ensure uniform coating. Following this, the thread is smeared with *Asita Mushkaka Kshara* and *Snuhi Kshira* and allowed to dry, with the process being repeated for 7 days to enhance its alkaline properties. Subsequently, the thread is coated with *Haridra Churna* (*Curcuma longa* powder) and *Snuhi Kshira*, dried and repeated for 3 days. Once the coating process is complete, the *Kshara Sutra* is sterilized using UV light for 30 minutes per day to maintain aseptic conditions. Finally, the prepared *Kshara Sutra* is sealed in a glass test tube for storage and clinical use.

### METHOD

Procedure of Application of *Kshara sutra*. This includes *Purva karma*, *Pradhana karma* and *Paschat karma*.

#### *Purva Karma*

- Written informed consent of every patient was taken.
- Patient was kept nil by mouth six hours prior to procedure.
- Inj. Xylocaine 2% sensitivity test was done.
- Inj. Tetanus Toxoid was given.

- Part was prepared after local shaving.
- Soap water enema was given in the early morning on the day of surgery as preparative procedure for surgery.

### ***Pradhana Karma***

The patient is positioned in the lithotomy position, ensuring that the buttocks are pulled down over the edge of the table. A pre-operative examination is conducted, followed by extensive shaving and antiseptic painting of the perianal region. The area is then draped with sterile cut sheets to maintain aseptic conditions.

After positioning, local anaesthesia (2% Xylocaine) is administered per-anally. Once the patient is assured and comfortable, a gloved, lubricated index finger is gently introduced into the anal canal. Using the other hand, a suitable metallic malleable probe is carefully passed through the external opening of the fistula. The index finger inside the anus guides the probe, ensuring it progresses along the least resistant area to reach the internal opening. Forceful probing is strictly avoided to prevent unnecessary trauma.

Once the probe pierces through the internal opening, its tip emerges through the anal canal. A suitable length of *Kshara Sutra* is then threaded into the eye of the probe, and the probe is carefully withdrawn, leaving the *Kshara Sutra* in situ within the fistulous tract. The two ends of the thread are securely tied together outside the anal canal.

After ensuring complete haemostasis, a sling soaked in betadine and xylocaine jelly is inserted into the anus, and a tight T-bandage is applied. Daily antiseptic dressing is performed, with the application of *Jatyadi Taila Pichu* to promote healing and reduce discomfort.

### ***Pascat Karma***

The patient is advised to take a sitz bath twice daily to maintain local hygiene and promote healing. Early ambulation is encouraged to ensure that the patient remains as active as possible, aiding both physical recovery and psychological well-being. A nutritious, easily digestible, and fiber-rich diet is recommended to prevent constipation and facilitate smooth bowel movements. Patients are instructed to report to the department for regular follow-ups and subsequent changes of the *Kshara Sutra* once in 7 days, ensuring continuous monitoring and optimal management of the condition.

***Progress and follow up***

After the fistulous tract is laid open, it is managed as a regular wound, following standard wound care protocols. Patients are advised to visit the department at 15-day intervals for thorough follow-up and monitoring and prevent recurrence.

***ASSESSMENT CRITERIA*****Subjective Parameters**

- Pain
- Discharge
- Itching

***Objective Parameters***

- C.H.T (Complete Healing Time)
- U.C.T (Unit Cutting Time)
- Tenderness

***Gradation of Parameters*****A) Assessment of Pain**

- 0 – No pain
- 1 – Mild - Nagging, annoying, but doesn't interfere with most daily activities
- 2 – Moderate - Interferes significantly with daily activities
- 3 – Severe - Disabling; unable to perform daily activities

**B) Assessment of Discharge**

- 0 - No discharge (Wound tissues dry)
- 1 - Mild discharge (Wound tissues moist, drainage involves 25% of dressing)
- 2 - Moderate discharge (Wound tissues saturated, drainage involves 25%-75% of wound dressing)
- 3 – Large discharge (wound tissues bathed in fluid, drainage involves 75% of dressing)

**C) Assessment of Itching sensation**

- 0 - No pain
- 1 - Mild - Nagging, annoying, but doesn't interfere with most daily activities
- 2 - Moderate - Interferes significantly with daily activities
- 3 - Severe - Disabling; unable to perform daily activities

**Objective parameters****A) Unit cutting time (U.C.T)**

The effect of the treatment is determined by unit cutting time. This was defined to be total number of days taken to cut a unit length of the track.

**U.C.T** = Total number of days /Initial length of the track (in cm)

Assessment of unit cutting time is done every week while changing the thread.

**B) Complete healing time (C.H.T)**

It is the time taken for total healing of the ulcer made by the *Kshara Sutra*. In comparison with the conventional surgery to the *Kshara Sutra* treatment this parameter is established.

Complete healing time is the total time taken for entire treatment. This is recorded in the patients who are on the follow up regimen. They were asked to attend the OP on week up to thread falling.

**C) Tenderness**

- 0 – No tenderness (Perfectly normal)
- 1 – Mild tenderness (Mild discomfort to touch)
- 2 – Moderate tenderness (Discomfort with movement)
- 3 – Sever tenderness (Significant discomfort at rest)

**OBSERVATIONS AND RESULTS****Subjective parameters**

**Table No.1: Effect of Asita Mushkaka kshara Sutra application in Fistula-in-Ano on subjective parameters in Test group(A).**

PARAMETERS	N	Mean		M.D	% OF RELIEF	S.D		S.E	‘t’	‘df’	‘p’
		BT	AT			BT	AT				
PAIN	20	2.50	0.10	2.40	96%	0.51	0.31	0.152	15.7711	19	<0.0001
DISCHARGE	20	1.95	0.00	1.95	100%	0.76	0	0.170	11.4873	19	<0.0001
ITCHING	20	1.35	0.00	1.35	100%	0.75	0	0.167	8.1021	19	<0.0001

**Pain:** The Group A average pain before treatment is 2.50 and after treatment the pain has fallen to 0.10. When t test: Paired two samples for means is done the t value is 15.7711 at P value <0.0001 level, which shows statistically extremely significant.

**Discharge:** The Group A average discharge before treatment is 1.95 and after treatment has fallen to 0.00. When t test: Paired two samples for means is done the t value is 11.4873 at P value <0.0001 level, which shows statistically extremely significant.



**Itching:** The Group A average discharge before treatment is 1.35 and after treatment has fallen to 0.00. When t test: Paired two samples for means is done the t value is 8.1021 at P value <0.0001 level, which shows statistically extremely significant.

**Table No.2: Effect of Apamarga Kshara Sutra application in Fistula-in-Ano on subjective parameters in Controlled group(B).**

PARAMETERS	N	Mean		M.D	% OF RELIEF	S.D		S.E	't'	'df'	'p'
		BT	AT			BT	AT				
PAIN	20	2.55	0.15	2.40	94%	0.51	0.37	0.152	15.7711	19	<0.0001
DISCHARGE	20	2.01	0.00	2.01	100%	0.72	0.00	0.161	13.0767	19	<0.0001
ITCHING	20	1.45	0.00	1.45	100%	0.51	0.00	0.114	12.7045	19	<0.0001

**Pain:** The Group B average pain before treatment is 2.55 and after treatment the pain has fallen to 0.15. When t test: Paired two samples for means is done the t value is 15.7711 at P value <0.0001 level, which shows statistically extremely significant.

**Discharge:** The Group B average discharge before treatment is 2.01 and after treatment has fallen to 0.00. When t test: Paired two samples for means is done the t value is 13.0767 at P value <0.0001 level, which shows statistically extremely significant.

**Itching:** The Group B average discharge before treatment is 1.45 and after treatment has fallen to 0.00. When t test: Paired two samples for means is done the t value is 12.7045 at P value <0.0001 level, which shows statistically extremely significant.

#### Objective Parameters

**Table No.3: Showing the effect of both methods on TENDERNESS in the subjects of Test group (*Asita Mushkaka Kshara Sutra*) and controlled group (*Apamarga Kshara Sutra*).**

GROUP	N	Mean		M.D	% OF RELIEF	S.D		S.E	't'	'df'	'p'
		BT	AT			BT	AT				
TEST GROUP	20	2.05	0.00	2.05	100%	0.76	0.00	0.170	12.0764	19	<0.0001
CONTROLLED GROUP	20	1.75	0.00	1.75	100%	0.72	0.00	0.160	10.9252	19	<0.0001

**Table No.4: Showing the effect of both methods on UCT in the subjects of Test group (*Asita Mushkaka Kshara Sutra*) and controlled group (*Apamarga Kshara Sutra*).**

GROUP	N	MEAN	SD	M.D	S.E	't'	'df'	'p'
TEST GROUP	20	5.1685	1.3751	3.5615	0.377	9.4503	38	<0.0001
CONTROLLED GROUP	20	8.7300	0.9745					



The overall average Unit Cutting Time (U.C.T.) was 5.1685 days for Group A and 8.7300 days for Group B. Statistical analysis using the unpaired t-test yielded a t-value of 9.4503 and a P-value of <0.0001, indicating a highly significant difference between the two groups. Based on this statistical evaluation, it was concluded that Group A demonstrated superior efficacy compared to Group B, with a significantly faster healing process.

**Table No.5: Showing the effect of both methods on CHT in the subjects of *Test group* (Asita Mushkaka Kshara Sutra) and *controlled group* (Apamarga Ksharasutra).**

GROUP	N	MEAN	SD	M.D	S.E	't'	'df'	'p'
TEST GROUP	20	40.30	18.76	15.90	4.720	3.3687	38	<0.0017
Controlled Group	20	56.20	9.67					

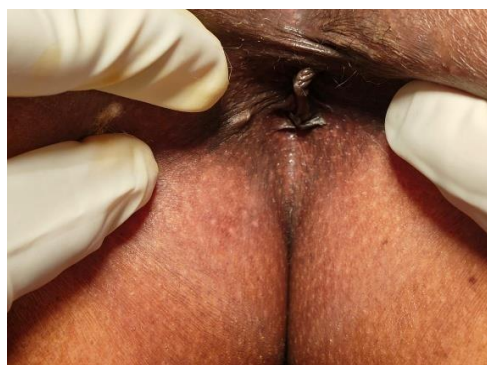
In the present study, the average Complete Healing Time (C.H.T.) for the individual groups was 40.30 days for Group A and 56.20 days for Group B. Statistical analysis using the unpaired t-test yielded a t-value of 3.3687 and a P-value of <0.0017, indicating a highly significant difference between the two groups. Based on this statistical evaluation, it was concluded that the Test Group showed better results compared to the Control Group.

**Table No. 6: Comparison of Overall % Of Relief Per Parameter of 2 Groups.**

PARAMETERS	PERCENTAGE % OF RELIEF	
	Test Group(A)	Control group(B)
PAIN	96%	94%
ITCHING	100%	100%
DISCHARGE	100%	100%
TENDERNESS	100%	100%

Group A (96%) is better in controlling pain than Group B (94%), the other parametric values of Discharge, Itching and Tenderness show similar results.

**Images of Group A Patient (Asita Mushkaka Kshara Sutra)**



**Figure 1 Before treatment**



**Figure 2 After the application of Kshara Sutra**



**Figure 3** After complete cut through of tract



**Figure 4** completely healed Bhagandara.

## DISCUSSION

In the present study, a total of 40 cases were divided into two groups, with 20 cases in each group. Group A (test group) was treated with *Asita Mushkaka Kshara Sutra*, while Group B (control group) received *Apamarga Kshara Sutra*. The treatment outcomes were evaluated based on key clinical parameters, including pain, discharge, itching, tenderness, unit cutting time, and complete healing time. Observations were systematically recorded for both groups, considering various demographic and clinical factors such as age group, gender, occupation, appetite, bowel habits, addictions, and *Prakruti* (body constitution).

Additionally, disease-specific factors such as the chronicity of the disease, different types of *Bhagandara*, were also analyzed to assess the overall effectiveness of the treatment methods.

## DISCUSSION ON RESULTS

### *Pain*

In the Group A, average pain reduced from 2.50 to 0.1 (96%), and in the Group B from 2.55 to 0.15 (94%). The reduction in pain may be attributed to the strong caustic action of *Asita Mushkaka Kshara Sutra* (pH 10.8–13), which likely alleviates thread tightness.

### *Discharge*

In the Group A, average discharge reduced from 1.95 to 0.00 (100%). Similarly, in the Control Group, discharge decreased from 2.10 to 0.00 (100%). The analysis shows a marked and statistically significant reduction in discharge in both groups. *Slaishmika Srava* (mucous discharge), a classical sign of *Kapha* vitiation, is effectively managed by *Asita Mushkaka* due to its *Kapha-Pittahara* and *Shothahara* properties. Its *Katu-Tikta Rasa* and *Krimighna* (antimicrobial) actions contribute to faster healing and reduction of infection-induced discharge.

***Itching***

In the Group A, average itching sensation reduced from 1.35 to 0.00 (100%). In Group B, it decreased from 1.45 to 0.00(100%). Both groups showed a statistically significant reduction in itching sensation. Itching (*Kandu*) is a classical symptom of Kapha vitiation. *Asita Mushkaka*, possessing *Kapha-Pittahara* and *Kandughna* properties, effectively pacifies *Kapha* and alleviates itching.

***Tenderness***

In the Group A, average tenderness decreased from 2.05 to 0.00(100%). In Group B, it reduced from 1.75 to 0.00(100%). Both groups showed a statistically significant reduction in tenderness.

***Complete Healing Time (C.H.T)***

The average CHT was 40.30 days in the Group A and 56.20 days in the Group B. Statistically, the Test Group showed faster healing compared to the Control Group.

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

UCT was 5.1685 days in the Test Group and 8.7300 days in the Control Group. This suggests the Test Group achieved faster tract cutting than the Control Group. *Asita Mushkaka*, having *Katu-Tikta* Rasa and endowed with *Pachana* and *Bhedana* properties, enhances the potency of its *Kshara*, enabling rapid cutting and simultaneous healing. This distinctive property makes it an effective and unique *Kshara Sutra* in the management of *Bhagandara* (Fistula-in- Ano).

**PROBABLE MODE OF ACTION**

- *Asita Mushkaka Kshara*, with its *Katu Rasa*, accelerates the corrosion of *Mamsa*, leading to faster cutting and healing of *Vrana*, while reducing itching and killing germs.
- Its *Tikta Rasa* acts as a germicide, reduces itching, and promotes the firmness of skin and muscles, aiding tissue regeneration.
- The *Tikshna Guna* ensures deep penetration with strong potency and quick action, resulting in a lower UCT in the Test Group.
- The *Krimighna Guna* prevents wound infections, while its *Kandughna* property pacifies itching through *Kaphagna* and *Kandugna* effects.
- The *Pacana*, *Bhedana*, and *Shothahara* properties contribute to both rapid cutting and fast healing, making *Asita Mushkaka* a unique and effective treatment for *Fistula-in-Ano*.

## CONCLUSION

The present study titled "To Study the Efficacy of Asita Mushkaka Kshara Sutra in the Management of Bhagandara (Fistula-in-Ano)" aimed to compare the effects of *Asita Mushkaka Kshara Sutra* and *Apamarga Kshara Sutra* on Fistula-in-Ano. Based on clinical observations and statistical analysis, the following conclusions were drawn:

1. *Asita Mushkaka Kshara Sutra* significantly minimized undesired effects like irritation and severe pain compared to the traditional *Kshara Sutra*.
2. It was found highly effective in relieving symptoms such as pain, swelling, itching, and discharge in Fistula-in-Ano.
3. The combination of *Pacana*, *Bhedana*, *Vranaropana*, *Vranasodhana*, and *Lekhaniya* properties of *Asita Mushkaka Kshara Sutra* facilitated efficient cutting, draining, and healing of the fistulous tract with minimal scarring.
4. The antimicrobial properties of *Haridra* and *Snuhi* effectively control infections.

Based on the results of this study, *Asita Mushkaka Kshara Sutra* proves to be more effective in managing Fistula-in-Ano compared to the *Apamarga Kshara Sutra*. However, to confirm these findings and examine the effect on disease recurrence, further research with a longer duration and larger sample size is recommended. Double-blind randomized studies would be essential to revalidate the outcomes.

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