

A RANDOMIZED OPEN-LABELLED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF SNUHI KSHARASUTRA, MULAKA KSHARASUTRA, AND APAMARGA KSHARASUTRA IN THE MANAGEMENT OF BHAGANDARA W.S.R TO FISTULA-IN-ANO

Dr. Mohammad Ilyas*¹, Dr. Shivalingappa J Arakeri², Dr. Ashwini Hallad³

¹3rd year PG Scholar Department of Shalya Tantra.

²Professor Department of Shalya Tantra.

³Assistant Professor Department of Shalya Tantra.

Article Received on 15 Sept. 2026,
Article Revised on 05 Oct. 2026,
Article Published on 16 Oct. 2026,

<https://doi.org/10.5281/zenodo.23366877>

*Corresponding Author

Dr. Mohammad Ilyas

3rd year PG Scholar Department of
Shalya Tantra.



How to cite this Article: Dr. Mohammad Ilyas*, Dr. Shivalingappa J Arakeri, Dr. Ashwini Hallad. (2026). A Randomized Open-Labelled Comparative Clinical Study To Evaluate The Efficacy of Snuhi Ksharasutra, Mulaka Ksharasutra, and Apamarga Ksharasutra In The Management Of Bhagandara W.S.R To Fistula-In-Ano. World Journal of Pharmaceutical Research, 15(20), 336–348.

This work is licensed under Creative Commons Attribution 4.0 International license.

ABSTRACT

Fistula-in-Ano is a chronic infective condition of the anorectal region, most commonly resulting from cryptoglandular infection of the anal glands. It is characterized by an abnormal communication between two epithelial surfaces, forming a fistulous tract lined with unhealthy granulation tissue. In Ayurveda, Fistula-in-Ano can be correlated with Bhagandara, which is described extensively in the Ayurvedic classics and considered a *Krichchhrasadhya Vyadhi* (difficult-to-treat disease). Bhagandara is one of the most common disorders affecting the anorectal region, and its recurrent nature makes management particularly challenging. Ksharasutra therapy is a well-established Ayurvedic para-surgical procedure for the management of Bhagandara. In the present study, 45 patients of either sex diagnosed with Bhagandara were selected from the OPD and IPD of the Department of Shalya Tantra, Taranath

Government Ayurvedic Medical College and Hospital, Ballari. The patients were divided into three groups: Group A was treated with Snuhi Ksharasutra, Group B with Moolaka Ksharasutra, and Group C with Apamarga Ksharasutra. The treatment groups demonstrated significant results, suggesting the potential effectiveness of these Ksharasutra in the

management of Bhagandara.

KEYWORDS: Bhagandara, Fistula-in-ano, Ksharasutra.

1. INTRODUCTION

Bhagandara is a well-described disease in the Ayurvedic classics. Acharya Sushruta has included Bhagandara among the *Ashtamahagadas*^[1] (eight major diseases). It is one of the common disorders affecting the ano-rectal region. The earliest reference to Bhagandara is found in *Agnipurana*.^[2] A detailed description of its *Nidana* (etiology), *Samprapti* (pathogenesis), *Lakshana* (clinical features), and *Chikitsa* (management) is available in *Sushruta Samhita*^[3] and *Ashtanga Hridaya*, among the *Brihatrayees*. *Charaka*^[4] has also described Bhagandara in the context of *Shotha Chikitsa* and advocated Ksharasutra and other therapeutic measures for its management.

The literal meaning of Bhagandara is *darana*, meaning splitting or bursting. The bursting of a *Pakwa Pidaka* occurring in the regions of *Bhaga*, *Guda*, or *Basti Pradesh* may result in the formation of a communicating tract, causing considerable discomfort to the patient.^[5]

Fistula-in-Ano is a chronic condition characterized by an abnormal communication between the anal canal and the perianal skin. Its reported prevalence is approximately 8.6 cases per 100,000 population. The mean age of affected individuals is reported to be 38.3 years. The prevalence is higher in men, with approximately 12.3 cases per 100,000 population, compared with 5.6 cases per 100,000 population in women, resulting in a male-to-female ratio of approximately 1.8:1.^[6]

Various operative procedures, including fistulotomy, fistulectomy, and seton placement, are employed in the management of fistula-in-ano. Newer techniques such as fibrin glue or plug procedures and endoanal advancement flaps have also been introduced. However, recurrence, delayed healing, and the potential risk of sphincter injury continue to pose challenges in the management of fistula-in-ano. Consequently, newer and alternative treatment modalities continue to be explored.

The Ayurvedic management of Bhagandara includes medical, para-surgical, and surgical approaches. Para-surgical procedures include *Kshara Karma*, *Agni Karma*, *Varti*, and *Ksharasutra* therapy. The use of Ksharasutra was initially described in the context of *Nadi Vrana*, and a similar therapeutic principle was recommended for the management of

Bhagandara. The method of preparation of Ksharasutra was described subsequently by Chakrapanidatta.^[7]

The standard Ksharasutra currently in use is the result of extensive research and standardization carried out by Dr. P. J. Deshpande and his team. Their work contributed significantly to the standardization of its preparation^[8], preservation, and clinical application.

The mode of action of Ksharasutra^[9] can be understood through the combined mechanical and pharmacological effects of its constituents. The mechanical pressure exerted by the ligature facilitates gradual and controlled cutting of the fistulous tract. Simultaneously, the drugs incorporated into the Ksharasutra, such as *Ksheera*, *Kshara*, and *Haridra*, may contribute to continuous drainage, debridement, and progressive healing of the fistulous tract. Thus, Ksharasutra therapy acts through a combination of controlled cutting, drainage, and healing mechanisms.

"The ICMR has validated this and the Ksharasutra therapy is also under active consideration of the WHO for its globalization. This type of therapy is considered as a minimal invasive parasurgical measure at global level.^[10] Its inclusion in modern surgical literature^[11] further reflects its clinical relevance and growing acceptance as an alternative therapeutic approach.

Acharya Sushruta has enumerated 24 drugs as sources of *Kshara*.^[12] Among these, Apamarga Ksharasutra is widely standardized and commonly used in the management of Bhagandara. However, Apamarga is a seasonal plant, and patients may experience pain and burning sensation during treatment.

Snuhi is widely used in the preparation of *Kshara* and *Ksharasutra* because of its corrosive, antimicrobial, and wound-cleansing properties. It is also indicated in the management of *Bhagandara*, *Arsha*, *Gulma*, *Shotha*,^[13] and various skin disorders. *Mulaka*^[14] is particularly important in the preparation of *Kshara* due to its alkaline nature and therapeutic efficacy in anorectal disorders.

OBJECTIVES

- To know the Efficacy of Snuhi ksharasutra in the management Bhagandara (Fistula-in-ano).
- To know the Efficacy of Mulaka ksharasutra in the management of Bhagandara (Fistula-in-ano)

- To know the Efficacy of Apamarga ksharasutrain in the management of Bhagandara (Fistula-in-ano).
- To compare the efficacy of Snuhi ksharasutra and Mulaka ksharasutra with standard Apamarga ksharasutra in the management of Bhagandara (Fistula-in-ano).

2. MATERIALS AND METHODS

Source of data

45 patients of Bhagandara of either sex were selected from OPD and IPD, Department of Shalya Tantra, Taranath Govt. Ayurvedic Medical College and Hospital, Bellary.

Drug source

Drugs used for preparation of Snuhi Ksharasutra, Mulaka ksharasutra and Apamarga ksharasutra are.

Apamarga ksharasutra	Snuhi ksharasutra	Mulaka ksharasutra
<i>Snuhi ksheera</i>	<i>Snuhi ksheera</i>	<i>Snuhi ksheera</i>
<i>Apamarga kshara</i>	<i>Snuhi kshara</i>	<i>Mulaka kshara</i>
<i>Haridra churna</i>	<i>Haridra churna</i>	<i>Haridra churna</i>

Materials

- Surgical Linen thread No.20
- *Ksharasutra* cabinet

Drugs will be identified, collected as per classical techniques authenticated and certified by Department of *Dravya Guna*, TGAMC&H Ballari. Preparation of *Kshara* and *ksharasutra* will be carried out in the post graduate Department of Shalya Tantra of TGAMC& H Ballari.

Sampling technique

Total 45 Patients presenting with the clinical features of Fistula-in-ano were selected randomly, i.e, Group A, Group B and Group C.

METHOD OF PREPARATION

• Preparation of Apamarga kshara

- Collected *Apamarga (Panchanga)* will be cut into small pieces and dried under shade.
- Once they are completely dried the pieces will be burnt uniformly and completely until it becomes ash.
- This ash will be stored in a clean container after cooling, 6 parts of water will be added to ash, stirred well and kept undisturbed overnight.

- Next day it will be filtered through double layered muslin cloth for 21 times and lastly through whatmans filter paper and collected clear filtrate will be boiled over mild heat till it attains powdery form.
- The final product, a clear white powder collected and stored in an airtight container.
- **Preparation of Apamarga ksharasutra**
 - Surgical linen thread No. 20 will be tied throughout the length on *ksharasutra* hanger.
 - Freshly collected *Snuhi ksheera* will be smeared on thread equally throughout its length and it will be dried in Thermostatic cabinet. The same procedure will be repeated for 10 more days.
 - On 12th day thread will be smeared with *Snuhi ksheera* and then hanger will be passed through a heap of *Apamarga kshara*, and then dried in cabinet. Then same procedure will be repeated for 6 more days
 - On 19th day the thread will be smeared with *Snuhi ksheera* and will be passed through heap of fine *Haridra churna* and dried in cabinet. The same procedure will be repeated for 2 more days.
 - Lastly the prepared *ksharasutras* are kept in cabinet for till it becomes dry Under UV light radiation for sterilization. And then it will be packed in a sterile, airtight tubes with proper labeling.

<i>Snuhi ksheera</i>	11 coatings
<i>Apamarga kshara</i>	7 coatings
<i>Haridra churna</i>	3 coatings

- Preparation of *Snuhi* and *Mulaka kshara* is same as that of *Apamarga kshara*, instead of *Apamarga*, *Snuhi* and *Mulaka* was used.
- **Preparation of *Snuhi* and *Mulaka ksharasutra***
 - Preparation of *Snuhi* and *Mulaka ksharasutra* is same as that of *Apamarga ksharasutra*, instead of *Apamargakshara*, *Snuhi kshara* *Mulaka kshara* was used.

3. METHODOLOGY

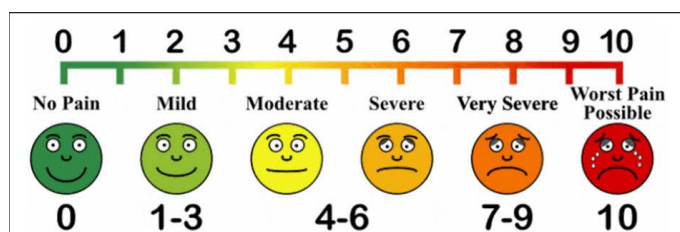
- Patient will be made to lie in lithotomy position. Probing is done to the fistulous track under all aseptic precautions and primary threading will be done using surgical linen thread No.20.
- On 7th day primary thread will be replaced using *ksharasutra* (In Group A- *Snuhi ksharasutra*, Group B-*Mulaka ksharasutra* and Group C-*Apamarg ksharasutra*) by

adopting Rail-Road Method. Later on every subsequent 7th day new ksharasutra will be changed until the Fistulous track is completely cut and healed.

- Patient is advised to attend his normal day today activities during the course of treatment.
- Observations are made before the treatment and on every 7th day of fresh application of ksharasutra.

- **Subjective parameters**

- **Pain**



Grade	Pain
0	No pain
1	Mild pain (1-3)
2	Moderate pain (4-6)
3	Severe pain (7-10)

- **Discharge**

- Do – No discharge
- D1 – Mild discharge (Wets 2×2 cm gauze piece per day)
- D2 – Moderate discharge (Wets 2×2 cm 2 gauze pieces per day)
- D3 – Severe discharge (Wets 2× 2 cm >2 gauze pieces per day)

- **Pruritus-ani**

- Po – Pruritus-Ani absent
- P1 – Pruritus-Ani present.

- **Objective criteria**

- Length of the tract is measured at every sitting in cm.

Length of the tract (In cms)	
0	L ₀
0.1-2	L1
2.1-4	L2
4.1-6	L3
6.1- 8	L4
8.1-10	L5

4. CLINICAL STUDY

Study Design: Open randomized clinical Comparative study.

Table No. 23: Showing study design.

Group		Diagnosis/Treatment	Duration
Group A	15	<i>Snuhi ksharasutra</i> ligation for <i>Bhagandara</i> (Fistula-In-Ano)	Till complete cutting and healing of Fistulous tract.
Group B	15	<i>Mulaka ksharasutra</i> ligation for <i>Bhagandara</i> (Fistula-In-Ano)	Till complete cutting and healing of Fistulous tract.
Group C	15	<i>Apamarga ksharasutra</i> ligation for <i>Bhagandara</i> (Fistula-In-Ano)	Till complete cutting and healing of Fistulous tract.

DIAGNOSTIC CRITERIA

- Clinical features of Fistula-In-Ano (Sero- purulent discharge, pain, Pruritus-ani).
- Fistula-In-Ano is confirmed by probing.

I. CRITERIA FOR ASSESSMENT

Assessment will be done before and after treatment as per parameters with pre and post test design.

- Unit Cutting Time (UCT) – It represents the number of days required to cut one cm of the track. This is calculated by dividing the total number of days taken by a Fistula to heal by the initial length of the track denoted as days/ cm.

$$\text{U.C. T} = \frac{\text{TOTAL NO. OF DAYS}}{\text{INITIAL LENGTH OF TRACK (THREAD)}}$$

II. Inclusion criteria

- Patients who have signed informed consent form.
- Age group of 16 to 70 years irrespective of Sex, religion, occupation.
- Patients with clinical features of Pain, Sero-purulent discharge from perianal skin.
- Patients with single low anal fistulous track.

III. Exclusion criteria

- Fistula-in-Ano secondary to Tuberculosis, Crohn's disease, Ulcerative colitis, HIV, Regional ileitis and Pelvic malignancy and associated with any other systemic disorders.
- Associated with other Ano-rectal disorders (Ca rectum and Anal canal, Haemorrhoids, Acute Fissure-in-Ano).
- High anal Fistula, Multiple Fistula-in-Ano.
- Pregnancy.

Note: The pathological conditions which are mentioned in the exclusion criteria will be ruled

out after considering the features and required investigations.

WITHDRAWAL CRITERIA

Patients can get withdraw from the trial at any time with the following reasons,

- Case may be having any health and safety issues.
- Personal reasons.
- Non-compliance.
- Loss to follow up.
- In case of Emergency.

IV. Treatment schedule

Group A	15	<i>Snuhi ksharasutra</i> ligation for <i>Bhagandara</i> (Fistula-In-Ano).
Group B	15	<i>Mulaka ksharasutra</i> ligation for <i>Bhagandara</i> (Fistula-In-Ano).
Group C	15	<i>Apamarga ksharasutra</i> ligation for <i>Bhagandara</i> (Fistula-In-Ano).

V. Investigations

- CBC
- RBS
- CT
- BT
- ESR
- HIV 1 & 2
- HBsAg
- TRUS (if necessary)
- MRI FISTULOGRAM (if necessary)

VI. INTERVENTION

- Total 45 patients of Fistula-in-ano will be selected and randomly assigned into Groups- Group A, Group B and Group C, each comprising of 15 Subjects.

Group-A	Ligation of <i>Snuhi ksharasutra</i> .
Group-B	Ligation of <i>Mulaka ksharasutra</i>
Group-C	Ligation of <i>Apamarga ksharasutra</i>

VII. Duration of the study

- Till the *ksharasutra* gets cut through the track completely.

VIII. Assessment

IX. Assessment will be made before the treatment and on every 7th subsequent day. A total duration of 30 days from the day of total cutting and healing fistulous track shall be fixed to observe the possibility of recurrence and the same shall be recorded in the proforma of case sheet. Length of the tract.

Changes in each parameter and overall changes from before treatment to after treatment

	Group	Changes from	% of change
Pain	Group A	Before treatment to after treatment	75.68
	Group B	Before treatment to after treatment	76.74
	Group C	Before treatment to after treatment	79.55
Discharge	Group A	Before treatment to after treatment	100.00
	Group B	Before treatment to after treatment	100.00
	Group C	Before treatment to after treatment	93.10
Pruritus-Ani	Group A	Before treatment to after treatment	87.50
	Group B	Before treatment to after treatment	100.00
	Group C	Before treatment to after treatment	80.00
Length	Group A	Before treatment to after treatment	100
	Group B	Before treatment to after treatment	100
	Group C	Before treatment to after treatment	100
Overall	Group A	Before treatment to after treatment	89.44
	Group B	Before treatment to after treatment	93.49
	Group C	Before treatment to after treatment	87.36

Result of Treatment in Group A



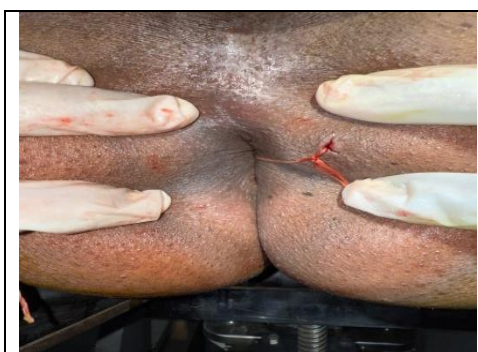
Fig. 9: Primary threading



Fig. 10: During Treatment



Fig. 11: After Treatment.

Result of Treatment in Group B**Fig. 12: Primary threading.****Fig. 13: During Treatment.****Fig. 14: Cut through.****Fig. 15: After Treatment.****Result of treatment in Group C****Fig.16: Primary threading.****Fig.17: During Treatment.****Fig.18: Cut through.****Fig.19: After Treatment.**

5. DISCUSSION

Probable mode of action of Ksharasutra on Bhagandara

- **Theory of chemical cauterization:** The Alkaline nature of kshara causes saponification of fat and formation of alkaline protinates which subsequently results in liquification necrosis when applied over the tissue.
- **Theory of antibacterial effect:** Microbicidal action of the drugs present in Ksharasutra destroys the infected anal glands, and promotes the cutting and healing.
- **Mere mechanical Cut and Open theory:** Moderately tight ligation of Ksharasutra in the tract allows close contact of the medicaments with the diseased tract. The traction and tension of the thread mechanically cut the tract and the medicinal coating over the thread heals the track.
- **Navel technique of local drug delivery:** Thread acts like a vehicle for the medicines to reach the targeted area (infected cryptal glands) and the multiple coatings over the thread renders a sort of sustained release effect of the medicines in the disease tract.

6. CONCLUSION

- Bhagandara is one of the Ashtamahagadas described in Ayurveda and can be correlated with Fistula-in-ano, a chronic inflammatory condition characterized by an abnormal tract connecting the anal canal to the perianal skin.
- The classical descriptions of Nidana, Purvarupa, Samprapti, classification, and management of Bhagandara mentioned in Ayurvedic texts closely resemble the etiopathogenesis and clinical presentation of Fistula-in-ano.
- Inclusion of Bhagandara under Ashtamahagada indicates its chronic nature, difficulty in management, and tendency for recurrence if not treated appropriately.
- The present study was conducted on 45 patients diagnosed with Bhagandara, who were randomly divided into three groups of 15 patients each. Group A was treated with Snuhi Ksharasutra, Group B with Mulaka Ksharasutra, and Group C with the standard Apamarga Ksharasutra.
- Maximum patients belonged to the age group of 26–35 years (35.5%), indicating a higher prevalence of Bhagandara during the active working age group.
- Male predominance (86.7%) was observed in the study, suggesting greater susceptibility among males.
- Most patients belonged to the middle socioeconomic class (66.7%), were married (82.2%), and consumed a mixed diet (91.1%).

- History of perianal abscess was present in 77.8% of patients; supporting the fact that fistula-in-ano commonly develops as a sequel of anorectal abscess.
- Posterior external opening (66.7%) and intersphincteric fistula (57.8%) were the most commonly observed varieties in the present study.
- All three Ksharasutra groups produced statistically highly significant improvement ($p < 0.001$) in the major clinical parameters such as pain and discharge.
- Reduction in pain was observed as 75.68% in Group A, 76.74% in Group B, and 79.55% in Group C, demonstrating excellent symptomatic relief in all groups.
- Reduction in discharge was 100% in Group A, 100% in Group B, and 93.10% in Group C, indicating effective wound cleansing and healing properties of all three Ksharasutras.
- Intergroup comparison revealed no statistically significant difference among the three groups in pain, discharge, and other assessment parameters, indicating comparable therapeutic efficacy.
- Snuhi Ksharasutra and Mulaka Ksharasutra demonstrated clinical efficacy comparable to the standard Apamarga Ksharasutra in the management of Bhagandara.
- Patients tolerated the procedures well, and no significant adverse effects or complications were observed during the treatment period.
- The study validates the classical Ayurvedic principle that Ksharasutra therapy remains one of the most effective para-surgical modalities for the management of Bhagandara.
- Based on the observations and results, the study hypothesis is accepted.

LIST OF REFERENCES

1. Sushruta samhita. (Nimbandhasangraha commentary of Dalhanacharya and Nyaya panjika commentary of Jadavjitrikamji. Gayadasa), Edited by Chaukambasanskritasamsthana, Varanasi. Sutrasthana, Chapter, 2013; 33: 4-144.
 2. Maharshi Vedavyasa, Agni purana, Edited by Acharya Baladeva Upadhyaya; Cowkamba Sanskrit series office, Varanasi, Chapter, 1996; 283,23,286: 60-61, 298, 14-15, 563, 417.
 3. Sushruta. Sushruta samhita. (Nimbandhasangraha commentary of Dalhanacharya and Nyaya panjika commentary of Jadavjitrikamji. Gayadasa), Edited by Chaukamba sanskrita samsthana, Varanasi. Nidanasthana, chapter, 2013; 4: 3-280.
 4. Charaka. Charaka samhita. (Ayurveda Dipika commentary of Chakrapani data), Edited by Jadavji Trikamji. Chaukamba Sanskrit samsthana, Varanasi Chikitsasthana, Chapter, 2013; 12.
- Verse, 97-490.

- Verse, 96-490.
- 5. Somen Das. A concise textbook of Surgery. Edited by Dr. S. Das, 9: 1071.
- 6. <https://emedicine.medscape.com>article>
- 7. Chakrapanidatta. Chakradatta. Edited by Brahmashankar Mishra. Chaukambasanskritseries office. Varanasi, 2012. • Chapter, 05: 147-61. • Chapter, 45: 10-11, 360.
- 8. SK Sharma, KR Sharma, Kulwantsingh. Ksharasutra therapy in Fistula-in-ano and other Ano rectal disorders. Rashtriya Ayurveda Vidyapeeth. New delhi, 48-59.
- 9. <https://www.easyayurveda.com2017/03/19/mode-of-action-of-kshara-sutra/amp>.
- 10. Pib.Nic.in/newsite/erelease.apex? relid 09/03/2014.
- 11. Bailey and Loves'. Short practice of surgery. Edited by, Norman S Williams, P Ronan O'connel, Andrew W Mc Caskie. CRC Press, Chapter, 2018; 74: 1367.
- 12. Sushruta. Sushruta samhita. (Nimbandhasangraha commentary of Dalhanacharya and Nyaya panjika commentary of Gayadasa), Edited by Jadavjitrikamji. Chaukambasanskritasamsthana, Varanasi. Sutrasthana, Chapter, 2013; 11.
- Verse no, 11, 46
- Verse no, 03, 45.
- Verse no, 04, 45.
- Verse no, 6, 46.
- Verse no, 11, 12, 13: 46-47.
- Verse no, 5, 45.
- Verse no, 5, 16, 45-48.
- Verse no, 17, 48.
- Verse no, 10. 46 (Dalhana commentary)
- Verse no, 07, 8-46.
- Verse no, 9, 28. 46, 50.
- Verse no, 18, 19-49.
- Verse no, 26, 50.
- Verse no, 39, 50.
- 13. Acharya Priyavat Sharma-Kaiyadeva Nighantu, Edited by Guru Prasad Sharma.(Hindi commentatary). Reprint edition; Chaukamba Sanskrit samsthana, Varanasi, 2013.
- 14. BhavaprakasaNigantu (Indian Materia Medica) of Sri Bhavamishra forwarded by Prof.K.CChunekar (English commentatary by Prof. D.S Lucas. Reprint edition; Chaukamba Sanskrit Samsthana, Varanasi, 2017.