



RESEARCH ARTICLE

A COMPARATIVE CLINICAL STUDY OF GUGGULU APAMARGA KSHARA-SUTRA AND GUGGULU BIBHITAKI KSHARA-SUTRA IN BHAGANDARA

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ABSTRACT

Bhagandara is a common ano-rectal disorder which is also described as a *Mahagada* in Ayurved. It can be correlated with *Fistula-in-ano* in modern science. Different surgical treatments are available in modern science but they all have some complications and recurrence. *Kshara-sutra* is a unique minimal invasive para-surgical procedure of Ayurvedic science which cures *Bhagandara* without complications and recurrence. In the present research work, *Guggulu Apamarga Kshara-sutra* and *Guggulu Bibhitaki Kshara-sutra* were prepared for the management of *Bhagandara*. 34 diagnosed cases of *Bhagandara* in two equal groups of 17 patients each (on the basis of computer generated randomization number) were selected from OPD and IPD of P.G. Department of *Shalya Tantra*, Rishikul campus hospital, Haridwar (Uttarakhand, India). First group (group A) was treated with *Guggulu Apamarga Kshara-sutra* ligation and second group (group B) was treated with *Guggulu Bibhitaki Kshara-sutra* ligation. All 34 patients completed the study and got cured. No complications were observed in this clinical study during treatment as well as in follow up period. Whole research work was statistically analysed and conclusion was drawn out.

INTRODUCTION

Ayurved is the oldest traditional system of medicine. Its roots are present in the *Vedas* and are based on scientific validation of principles. According to *Acharya Sushruta*, among those eight branches, *Shalya Tantra* branch is superior to others because of its *Aashukari Chikitsa Prabhava*, utility of *Yantra*, *Shastra*, *Kshara*, *Agnikarma*, and similarity with all other *Tantras*. (Shastri, 2017a, p. 8) *Bhagandara* is described as a *Mahagada* in Ayurved. *Acharya Sushruta* described detailed description in *Nidana Sthana* and *Chikitsa Sthana* of *Sushruta Samhita*. In modern science, it can be correlated with *Fistula-in-ano*. Generally, it occurs as a consequence of cryptoglandular infection of anal gland and perianal abscess. There are many treatment modalities available for the management of *Fistula-in-ano* in Ayurvedic and allopathic science. In Ayurvedic science, *Fistula-in-ano* is managed by different procedures, i.e., *Kshara-sutra* therapy, *Kshara Varti*, *Chhedana Karma*, *Agnikarma*, etc. In allopathic science, it is managed by different surgical procedures, i.e., *Fistulotomy*, *Fistulectomy*, *Seton ligation*, *Fibrine glue*, *Mucosal advancement flaps*, *Ligation of intersphincteric fistula tract (LIFT)*, *Video assisted anal fistula treatment (VAAFT)*, *Anal fistula plug*, *Radiofrequency ablation*, etc. These modern surgical operative procedures have limited use due to high chances of recurrence and complications like incontinence. *Kshara-sutra* is a unique para-surgical procedure and novel drug delivery system to treat *Bhagandara* disease. In this procedure, a medicated alkaline thread is ligated to fistulous tract, which works mechanically, as well as

chemically to cut and heal fistulous tract. Research regarding *Kshara-sutra* was done by Late Prof. (Dr.) P. J. Deshpande sir (BHU) and his team. The standard technique for preparing *Kshara-sutra* was introduced by them. It cleared multicentric trials and was approved by the Indian Council of Medical Research (I.C.M.R.). (Murthy, 2012) *Kshara-sutra* is prepared by repeating 21 coatings of *Snuhi Ksheera* (11 coatings), *Apamarga Kshara* with *Snuhi Ksheera* (7 coatings), and *Haridra Choorna* with *Snuhi Ksheera* (3 coatings). This is the standard *Snuhi-Apamarga Kshara-sutra*. Although it often creates some difficulty during preparation and use of the *Kshara-sutra*. So, *Guggulu Nirayasa* was taken as the best alternative to *Snuhi Ksheera*. *Guggulu Bibhitaki Kshara-sutra* was prepared by same method by taking *Bibhitaki Kshara* in stand of *Apamarga Kshara*. In this present study, 34 diagnosed cases of *Bhagandara* in two equal groups of 17 patients each (on the basis of computer generated randomization number) were selected. First group (group A) was treated with *Guggulu Apamarga Kshara-sutra* ligation and second group (group B) was treated with *Guggulu Bibhitaki Kshara-sutra* ligation. They were assessed on the basis of subjective and objective parameters.

Aim and Objectives

- To evaluate the effect of *Guggulu Apamarga Kshara-sutra* in *Bhagandara*.
- To evaluate the effect of *Guggulu Bibhitaki Kshara-sutra* in *Bhagandara*.

- To compare the effect of both these *Kshara-sutra* in the treatment of two different groups of patients of *Bhagandara*.
- To enhance the rate of healing.

MATERIALS AND METHOD

The present clinical trial was designed for two groups of patients which were randomly selected on the basis of a computer generated random number. Patients of respective groups received the same treatment i.e. one group *Guggulu Apamarga Kshara-sutra* ligation and another group *Guggulu Bibhitaki Kshara-sutra* ligation for the management of *Bhagandara*. These *Kshara-sutra* were prepared in our *Kshara-sutra* lab under full aseptic precautions at Deptt. of Shalya Tantra, Rishikul Campus, Haridwar. Patients were examined under local anesthesia (xylocaine jelly 2% and xylocaine spray 10%) for diagnosis of *Bhagandara*. Gentle probing was done under aseptic precautions to trace out direction and nature of tract. Primary threading was done with the help of sterile surgical linen Barbour's thread no. 20. After primary threading, *Kshara-sutra* was changed weekly by the rail-road technique until it gets cut-through spontaneously.

Method of Preparation of Kshara-Sutra: The technique for preparation of *Kshara-sutra* standardized by the Department of *Shalya Tantra*, IMS, Banaras Hindu University, Varanasi was followed. *Guggulu Apamarga Kshara-sutra* was prepared by repeating 21 coatings, of which 11 coatings were of *Shuddha Guggulu Niryas* alone, 7 coatings of *Guggulu Niryas* with *Apamarga Kshara*, and 3 coatings of *Guggulu Niryas* with *Haridra Choorna*. *Guggulu Bibhitaki Kshara-sutra* was prepared by repeating 21 coatings, of which 11 coatings were of *Shuddha Guggulu Niryas* alone, 7 coatings of *Guggulu Niryas* with *Bibhitaki Kshara*, and 3 coatings of *Guggulu Niryas* with *Haridra Choorna*. The prepared *Kshara-sutra* were packed and sealed under aseptic precautions and stored in a formalin chamber in operation theatre.

Selection of Patients: Diagnosed 34 cases of *Bhagandara* were registered and divided in two groups randomly by computer generated randomization numbers from OPD and IPD of the Department of *Shalya Tantra*, Rishikul Ayurvedic College Campus Hospital, Uttarakhand Ayurved University, Uttarakhand, India.

Consent: All 34 patients were well informed about the treatment and written informed bilingual consent was obtained from the patient and a close relative of patient.

Inclusion Criteria

- Clinical signs and symptoms of all types of *Bhagandara*.

Exclusion Criteria

- Known Patient with Malignancy of Anus, Rectum and Prostate.
- HIV, HCV and HBsAg positive patients
- 'Covid-19' positive patients
- Secondary Fistula due to known -
 1. Crohn's disease
 2. Ulcerative colitis
 3. Tuberculosis, etc.

Blood Investigations

- Haemoglobin (Hb%)
- Total Leukocyte Count (T.L.C.)
- Differential Leukocyte Count (D.L.C.)
- Erythrocyte sedimentation rate (ESR)
- Bleeding Time (BT)
- Clotting Time (CT)
- Fasting Blood Sugar (FBS)
- Post Prandial Blood Sugar (PPBS)
- Liver Function Test (LFT)

- Kidney Function Test (KFT)
- Viral markers :- Human Immunodeficiency Virus (HIV)
- Hepatitis C Virus (HCV)
- Hepatitis B surface antigen (HBsAg)

Assessment Criteria: Before and after treatment, clinical examination of patient was conducted and then effectiveness of drug was evaluated. The subjective and objective parameters for assessment are as follows:

Subjective Parameters

- Pain
- Burning sensation
- Itching
- Pus discharge

Signs and symptoms found were graded on the basis of the following scoring system:

- No symptom 0
- Mild symptoms +
- Moderate symptoms ++
- Severe symptoms +++
- Very severe symptoms ++++ (Disturbed daily routine of the patient)

Objective Parameter:

Unit Cutting Time = $\frac{\text{Total No. of days taken to cut through the track}}{\text{Initial length of the Kshara-sutra in cm}}$

Time taken (in days) to cut one centimeter of the fistulous track with simultaneous healing is known as unit cutting time (UCT).

Grading of Assessment Criteria

Grading of Assessment criteria on Pain

Table 1. Grading of Assessment criteria on Pain

Grade	Explanation
0	No complain of pain
+ (+1)	Negligible or tolerable pain. No need of any medicine
++ (+2)	Localized tolerable pain, completely relieved by hot sitz bath
+++ (+3)	Intolerable pain, not relieved by hot sitz bath, relieved by oral analgesic. No disturbance in sleep
++++ (+4)	Continuous and intolerable pain with sleep disturbance. Patient seek medical help as early as possible

Grading of Assessment criteria on Burning sensation

Table 2. Grading of Assessment criteria on Burning sensation

Grade	Explanation
0	No complain of any burning sensation
+ (+1)	Negligible feeling of burning sensation for few minutes in a day
++ (+2)	Tolerable burning sensation completely relieved by hot sitz bath or local oleation
+++ (+3)	Tolerable but constant burning sensation slightly relieved by hot sitz bath or local oleation
++++ (+4)	Unbearable burning sensation which makes the patient to seek feeling of medical help as soon as possible

Grading of Assessment criteria on Itching

Table 3. Grading of Assessment criteria on Itching

Grade	Explanation
0	No complain of itching
+ (+1)	Negligible itching for few minutes in a day
++ (+2)	Occasional sensation of itching with 4-6 hrs interval
+++ (+3)	Frequent sensation of itching with 2-3 hrs interval
++++ (+4)	Continuous sensation of itching with 15-30 minutes interval

Grading of Assessment criteria on Pus discharge

Table 4. Grading of Assessment criteria on Pus discharge

Grade	Explanation
0	No sign of any discharge
+(+1)	Occasional appearance of discharge and patient uses single cotton pad in 24 hrs.
++(+2)	Frequent appearance of discharge and patient uses 3-4 cotton pads in 24 hrs.
+++(+3)	Increased frequency of discharge and patient uses 5-6 cotton pads in 24 hrs.
++++(+4)	Continuous discharge

Duration of the Study: It was based on the length of the fistula tract until the *Kshara-sutra* gets 'cut through' spontaneously.

Follow up Study: Follow up was done weekly once for one month, then monthly once for two months after the completion of treatment. For each follow-up visit, the patients were examined for any recurrence of disease or any associated lesion of the ano-rectal region.

Statistical Observation: In the present study 34 patients were selected and randomly (as per randomization chart generated by computer) divided into two equal groups. Appropriate statistical technique was adopted for data analysis. The information was gathered on the basis of various subjective and objective parameters, and analyzed in term of mean, median, standard deviation and standard error. Wilcoxon signed rank test and paired "t" test was carried out for intra group comparison. Mann-Whitney test and unpaired "t" test was carried out for inter-group comparison.

OBSERVATIONS AND RESULT

Table 5. Effect of Therapy on Subjective Criteria in 17 patients of Group – A (Guggulu Apamarga Kshara-sutra)

Symptoms	Median		Wilcoxon signed rank W	Z-Value	P-Value	% Effect	Result
	BT	AT					
Pain	3	0	-153.000	-3.99	<0.001	100%	HS
Burning Sensation	2	0	-153.000	-3.70	<0.001	100%	HS
Itching	2	0	-153.000	-3.68	<0.001	100%	HS
Pus Discharge	3	0	-153.000	-3.72	<0.001	100%	HS

Table 6. Effect of Therapy on Subjective Criteria in 17 patients of Group – B (Guggulu Bibhitaki Kshara-sutra)

Symptoms	Median		Wilcoxon signed rank W	Z-Value	P-Value	% Effect	Result
	BT	AT					
Pain	3	0	-153.000	-3.76	<0.001	100%	HS
Burning Sensation	2	0	-153.000	-3.70	<0.001	100%	HS
Itching	3	0	-153.000	-3.73	<0.001	100%	HS
Pus discharge	3	0	-153.000	-3.70	<0.001	100%	HS

Assessment of Subjective symptoms in Group – A: In subjective assessment symptomatically the result was statistically highly significant ($p < 0.001$) in reducing pain, burning sensation, itching and pus discharge.

Effect of therapy on Unit cutting time (U.C.T.) in Group – A: In analysis it shows that the minimum U.C.T. 2.00 days/cm in Sub-mucous and maximum U.C.T. 12.09 days/cm was found in High-anal Fistula-in-ano. Mean U.C.T. of all 17 patients was 9.00 days/cm.

Assessment of Subjective symptoms in Group – B: In subjective assessment symptomatically the result was statistically highly significant ($p < 0.001$) in reducing pain, burning sensation, itching and pus discharge.

Effect of therapy on Unit cutting time (U.C.T.) in Group – B: In analysis it shows minimum U.C.T. (8.27 days/cm) in Low-anal, and maximum U.C.T. (13.23 days/cm) was found in High-anal Fistula-in-ano. Mean U.C.T. of all 17 patients was 8.85 days/cm.

DISCUSSION

Bhagandara has been recognized as a *Mahagada* in Ayurved science due to its difficult management and recurrent nature. In all Ayurvedic texts it is considered as *Shastra Sadhya Vyadhi*. Various *Acharya* described surgical and para-surgical methods to treat *Bhagandara*. In allopathic science various surgical procedures viz. Fistulectomy, fistulotomy, LIFT, VAAFT, Radio frequency ablation, anal fistula plug repair etc. (Gustafsson, 2007) are being practiced. But all these modern procedures still have complications like recurrence and anal sphincter damage. *Kshara-sutra* is the unique para-surgical procedure of Ayurved which works more effectively than other surgical methods. It cures the *Bhagandara* disease without recurrence and complications.

Discussion on Selection of the Drug: The traditional *Snuhi Apamarga Kshara-sutra* is associated with significant difficulty during collection of *Snuhi*, preparation and treatment. *Snuhi Ksheera* is generally collected in the morning and during the cold seasons. It coagulates rapidly and can't be stored. It often creates local irritative symptoms and severe pain after application in the fistulous tract. Hence, there was a need to find an alternate *Kshara-sutra* that performed similar actions to the *Snuhi Apamarga Kshara-sutra*. After much research, *Guggulu Niriyasa* was found to be a best alternative substance to *Snuhi Ksheera*. In the present study, *Suddha Guggulu Niriyasa* was used in place of *Snuhi Ksheera*. It has good binding capacity, *Vedana-hara*, *Shotha-hara*, and *Daha-prashamana* properties. (Sharma, 2012a, pp. 54–58) It also has local medicinal properties for wound healing. (Shah et al., 2012) *Bibhitaki* fruit also has antimicrobial, antiparasitic, analgesic, anti-inflammatory, and wound-healing properties. There is no study carried out earlier regarding the management of *Bhagandara* disease for *Guggulu Bibhitaki Kshara-sutra*.

Therefore, in the present study, *Guggulu Bibhitaki Kshara-sutra* (Trial group) has been chosen to evaluate and compare with *Guggulu Apamarga Kshara-sutra* (Standard group).

DISCUSSION ON OBTAINED RESULT

Kshara-sutra performs cutting as well as healing action of the fistulous tract. It works by mechanical action of thread as well as chemical action of *Kshara* simultaneously. *Kshara* debrides unhealthy tissue from fistulous tract due to its *Ksharana* and *Kshanana* property. (Shastri, 2017b, pp. 45–50) Patients of both groups cured completely. Both groups has highly significant result in all four subjective parameters but the best response in subjective parameters was seen in the parameter of pain in group-A (*Guggulu Apamarga Kshara-sutra*); and the parameter of burning sensation, itching and pus discharge in group-B (*Guggulu Bibhitaki Kshara-sutra*). Both *Kshara-sutra* have *Guggulu* and *Haridra* as a common drug constitute but *Guggulu Apamarga Kshara-sutra* give better result in reducing pain which is due to *Ushna Virya*, *Kapha Vata-hara* effect, Saponins and sterols present in *Apamarga*. *Guggulu Bibhitaki Kshara-sutra* give better

result in reducing burning sensation, itching and pus discharge which is due to *Kashaya Rasa, Ruksha Guna, Ushna Virya, Madhura Vipaka, Kapha-Pitta Shamaka* effect, *Krimighna* action and Tannins (gallic acid, ellagic acid, and chebulagic acid) present in *Bibhitaki*. (Chunekar, 2020a, pp. 9–10) *Guggulu Bibhitaki Kshara-sutra* (Mean U.C.T. – 8.85 days/cm) has better result than *Guggulu Apamarga Kshara-sutra* (Mean U.C.T. – 9.00 days/cm).

CONCLUSION

- Conclusion drawn from present work are as follows: Group-A (*Guggulu Apamarga Kshara-sutra*) and Group-B(*Guggulu Bibhitaki Kshara-sutra*) were found to have very significant effect in reducing pain, burning sensation, itching, pus discharge; and good unit cutting time.
- On inter-group comparison – Group-A and Group-B shows non-significant difference in parameter of pain, burning sensation, and itching; and shows significant difference in parameter of pus discharge.
- The overall effect obtained in Group-A and Group-B shows that all 17 patients in each group cured completely.
- In Group-A: Smallest curved tract was of 6 cm size and largest curved tract was of 14 cm size.
- In Group-B: Smallest curved tract was of 6 cm size and largest curved tract was of 16 cm size.
- Group-A (*Guggulu Apamarga Kshara-sutra*) and Group-B (*Guggulu Bibhitaki Kshara-sutra*) both are effective in curing *Bhagandara* (Fistula-in-ano).
- On the basis of overall effect of therapy it was found that *Guggulu Apamarga Kshara-sutra* had little better result than *Guggulu Bibhitaki Kshara-sutra* in parameter of pain.

- *Guggulu Bibhitaki Kshara-sutra* has better result than *Guggulu Apamarga Kshara-sutra* in parameters of burning sensation, itching, pus discharge and unit cutting time.
- All patients completed the treatment of full duration without any complications in post operative period as well as follow up period in both groups.
- Thus, both these *Kshara-sutra* can be successfully used to cure patients of *Bhagandara* (Fistula-in-ano) disease.

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