

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF KSHARA SUTRA PREPARED WITH RAJANI LEPA (SNUHI KSHEERA AND HARIDRA CHURNA) IN THE MANAGEMENT OF BHAGANDARA (LOW ANAL FISTULA)

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ABSTRACT

Bhagadara, which can be triggered by fistula in ano, is characterized as a suppurative secondary ulcerative manifestation to an eruption that typically affects the Bhaga (Ano rectal, pelvic rectal, or peri anal region). It is mentioned in Susrutha Samhitha by Asta Mahagadha. Bhagandara's primary nidana is infectious in character, exhibiting symptoms such as discomfort, pus discharge, itching, and tenderness in the perianal area. In today's lifestyle, bhagandara is a frequent condition that is very difficult to cure due to its high recurrence rate and delayed wound healing. In Ayurveda, the kshara sutra is the fundamental principle, while fistulectomy is the current cure. This clinical investigation examines the effectiveness of kshara sutra made with rajani lepa, namely suhi kshera and Haridra Churna in the management of Bagandara. Kshara sutra prepared with rajini lepa is

safe and effective treatment option for bagandara, offering a promising alternative to conventional surgical methods.

KEYWORDS: Bagandara, Fistula-in-ano, Rajini lepa kshara sutra.

INTRODUCTION

1. *Shalya Tantra* was at its extremity in Sushruta's time and the contents of *Sushruta Samhita* can be compared to any book on surgery written centuries later. *Bhagandara* (Fistula in ano) is said difficult to be cured and is considered under the *Ashta Mahagadas*.^[1]
2. *Bhagandara* is the nearest disease entity which is described in Ayurveda and which can be equated to fistula in ano. It proceeds with formation of a *Pidika* (Abscess) that is known as *Bhagandara Pidika*^[2] in the *Guda Pradesha* (peri-anal area). If proper treatment of *Bhagandara Pidika* is not employed, it may result in development of *Bhagandara*. It is characterized by single or multiple opening around *Guda Pradesha* with different types of discharge associated with severe pain and discharge. *Bhagandara*.^[3]
3. Acharya Sushruta has described surgical approach like excision of fistulous track in detail (S.S.Su 25/3.^[4] S.S.Chi 8/42^[5]) but also felt the necessity of parasurgical approach like *Ksharasutra* (S.S.Chi 17/32,^[6] C.S.Chi.12/97,^[7] Chakradatta-Arsha vyadhiadhikara).
4. Acharya Susrutha mentioned 23 types of plants useful for *Kshara karma* (Sus.Su 11\11)^[8] like *Vibhitaki*, *Palasha*, *Kutaja*, *Kadali* etc.
5. *Kshara Sutra* treatment heals the fistulous tract with the integrity of sphincters and the existing data reveal negligible chances of recurrence. *Kshara Sutra* is a scientifically validated treatment in the management of *Bhagandara*. The *Apamarga Kshara Sutra* is well proven to be an effective treatment for fistula in ano and has been standardized by Central Council for Research in Ayurvedic Sciences (CCRAS), an apex research organization of Government of India (GOI) in the field of Indian system of medicine.
6. According to the position of internal opening the fistula is classified into high anal and low anal fistula. The modern surgical management includes *Fistulotomy*, *Fistulectomy*, *Seton placing*, *Ligation of Intersphincteric Fistula Tract (LIFT)*, *Fibrin Glues*, *Advancement Flaps*, and *Expanded adipose derived Stem Cells (ASCs)*.^[10]

AIMS AND OBJECTIVES

1. To know the role of *Kshara Sutra* prepared with *Snuhi ksheeram* and *Haridra Churnam* in *Bhagandhara*.
2. To know the role of *Standard Apamarga Kshara sutra* in *Bhagandhara*.

3. To know differences in the efficacy of Kshara Sutra prepared with Snuhi ksheeram and Haridra Churnam with standard Apamarga kshara sutra in the management of Bhagandhara.

MATERIALS AND MATHODS

Total 40 Patients were selected from OPD and IPD of S.V.Ayurvedic hospital, Tirupati, Andhra Pradesh.

Required meterials

Haridra churna, Snuhi Ksheera, Apamarga Kshara, Barbour surgical linen thread no.20

Inclusive criteria

- Patients of irrespective of sex,
- Patients with age ranging from 20 to 60years,
- Low Anal Fistula.

Exclusive criteria

- Concomitant Ano-rectal conditions like ulcerative colitis, malignancy, Crohn's disease, multiple fistulae and high analfistula
- Pregnancy
- Tuberculosis
- Obstructiveuropathies
- Other systemic disease

Data collection

Screening, Selection, Registration and Grouping of 40 patients will be done from the OPD and IPD of *SHALYA TANTRA* Unit, S.V. Ayurvedic hospital, Tirupati based upon selection criteria (Inclusive and Exclusive Criteria). The selected patients will be divided into two groups i.e., Group-A – Trial Group (Kshara Sutra prepared with Snuhi ksheeram with Haridra churnam) and Group-B – Control Group (Standard Apamarga Kshara Sutra), each group comprises 20 patients.

- Sample size - 40 Patients
- Grouping - 2 Groups (Groups A & Group B) comprising of 20 patients each
- Distribution of patients among groups – Randomized selection
- Type of the study - Single blind clinical study

Intervention^[7]**I. Group A: Trial group**

- 20 patients with symptoms of Bhagadara based on inclusive and exclusive criteria will be selected.
- In this group, the patients are treated with Kshara sutra prepared with Snuhi ksheera and Haridra Churna.

Ingredients

- Haridra churnam (*Curcuma longa*)
- Snuhi ksheeram (*Euphorbia nerifolia*)
- Barbour Surgical Linen thread no- 20

Preparation of ksharasutra

1 part of Haridra churna and 1 part of Snuhi ksheera are taken and mixed together in a clean stainless vessel and then apply on Barbour Surgical Linen thread. Daily one coating is applied and then dried. Next day, when the thread is completely dry then another coating will be done and dried again. Likewise totally 7 coating will be done and dried after each coating. Then this fully coated and dried thread will be sterilized in UV radiation.

II. Group B: Control group

- 20 patients with symptoms of Bhagandara based on inclusive and exclusive criteria are selected.
- In this group, the patients are treated with Standard Apamarga kshara sutra.

Ingredients

- Haridra churnam (*Curcuma longa*)
- Apamarga kshara (*Achyranthus aspera*)
- Snuhi ksheeram (*Euphorbia nerifolia*)
- Barbour Surgical Linen thread no- 20

I. Material

- Malleable probe
- Forceps
- Scissors
- Kshara sutra.

Preparation of apamarga kshara sutra

The surgical linen thread was autoclaved and mounted on the hangers. A piece of folded gauze was taken, dipped in the fresh Snuhi Ksheera and the thread was smeared with Snuhi ksheera. The second smearing was given only when the previous coating was dried. The thread is smeared 11 times in this manner. The threads are placed in the Kshara Sutra cabinet for drying after each smearing. The temperature inside the chamber may be increased till 40⁰c by passing hot dry air with the help of a blower to facilitate drying of the threads.

After completing the first 11 smearing of Snuhi ksheera, coating of the thread by Apamarga Kshara in the way described above. Apamarga Kshara was coated on it immediately (i.e., when the thread is still wet) so that it sticks to the thread properly. This was done by sliding the thread over the heap of Kshara in such a way that the thread passes through the heap of Kshara and the Kshara sticks on the wet thread. The thread was coated in this way 7 times, only when the previous coating got completely dried.

The last 3 coatings were given with Snuhi Ksheera and Haridra. This was done in the same way as the previous coating substituting Haridra powder in the place of Apamarga Kshara. While applying every coating, care should be taken that the drug spreads evenly on all the sides of the thread and does not become thick at one spot to make knot like appearance. The thread should be smooth and evenly coated, having the same thickness throughout the length. Precaution should be taken to carry out the procedure in a dry atmosphere. After finishing the cabinet and were cut into assorted sizes of 10-12 inches and then packed in glass tubes.

II. Method

Under Anaesthesia, with all aseptic precaution malleable probe will be inserted through external opening and taken out from the internal opening and then kshara sutra will be passed through the probe into track and then the kshara sutra will be tied neither too tight nor too loose. Wound dressing will be done with gauze sling soaked in Jatyadi Tailam and closed with T-Bandage.

Clinical plan

The study will be carried out in three phases

I. Phase

- Preparation of Kshara Sutra (Both Trail and Standard).

- Preparation of specific record sheet
- Identification of cases, diagnosis, scrutinizing, registration and grouping

II. Phase

- Application of Kshara Sutra under Local Anesthesia and applying the Kshara sutra as per the procedure described above.
- Change of Kshara Sutra will be done on every week till complete cut open of the tract.

III. Phase

- Healing of the whole tract.
 - Follow up after the complete healing for 2 months with 15 days interval.
 - Evaluation, documentation and statistical evaluation will be done.
1. **Duration of the treatment:** Active management till complete cut open of the whole tract.
 2. **Progress and follow up:** Progress of the patients will be observed for every week and Active follow up will be done for every 15 days upto to 2months

Assessmentcriteria

Subjectiveparameters

- Pain
- Discharge
- Itching

Objectiveparameters

- CHT (Complete Healing Time)
- UCT (Unit Cutting Time)
- Tenderness

Gradation of parameters

Pain

- No Pain – 0
- Mild Pain– 1
- Moderate Pain – 2
- Severe Pain – 3

Discharge

- No Discharge – 0
- Mild Discharge – 1
- Moderate Discharge -2
- Severe (Profuse) Discharge – 3

Tenderness

- No tenderness – 0
- Mild tenderness – 1
- Moderate tenderness -2
- Severe tenderness – 3

Itching

- No Itching – 0
- Mild Itching – 1
- Moderate Itching -2
- Severe itching – 3

Assessmentcriteria**Criteria for assessment of overall effect**

S. No	Criteria for assessment of overall effect of the study	Number of Patients		Percentage of Patients	
		Group A	Group B	Group A	Group B
1	Complete cure	9	1	45	5
2	Moderate improvement	9	2	45	10
3	Marked Improvement	2	14	10	70
4	Mild Improvement	0	3	0	15
5	No Improvement	0	0	0	0
6	Worsened	0	0	0	0

Table Shows statistical analysis in subjective pameters.

Subjective parameters		N	Mean		SD		Sem		t-Value	P-Value	% of Relief
			B.T	A.T	B.T	A.T	B.T	A.T			
Pain	Group A	20	1.95	0.35	0.76	0.49	0.17	0.11	10.5141	< 0.001	79.99
	Group B	20	2.05	0.40	0.69	0.50	0.15	0.11	11.0000	<0.001	77.49
Discharge	Group A	20	2.10	0.30	0.85	0.47	0.19	0.11	10.4847	< 0.001	79.14
	Group B	20	1.90	0.60	0.85	0.68	0.19	0.11	12.3655	<0.001	73.32

Itching	Group A	20	2.0	0.25	0.79	0.44	0.18	0.10	9.9 520	<0.0 001	82.49
	Group B	20	2.05	0.75	0.83	0.79	0.18	0.18	10.1 775	<0.0 001	74.15

Table Shows statistical analysis in objective pameters.

Mean	Rajani Lepa Kshara Sutra		Apamarga Kshara Sutra	
	Initial Length	CHT	Initial Length	CHT
CHT	2.56 cms	20.1 Days	2.36 cms	26.4 Days

Mean	Rajini lepa Kshara Sutra	Apamarga Kshara Sutra
UCT	7 Days	11 Days

Objective parameters		N	Mean		SD		Sem		t-Value	P-Value	% of Relief
			B.T	A.T	B.T	A.T	B.T	A.T			
Tenderness	Group A	20	1.90	0.35	0.79	0.49	0.18	0.11	11.4 612	<0.0 001	79.16
	Group B	20	2.05	0.45	0.83	0.51	0.18	0.11	11.9 607	<0.0 001	69.99

Overall effect of study

Overall effect of the study		N	Mean		SD		SEM		t-Value	P-Value	% of relief
1	Group A	20	7.95	1.35	1.67	0.75	0.37	0.17	16.1454	<0.0001	83%
2	Group B	20	8.05	2.25	1.54	1.33	0.34	0.30	12.7448	<0.0001	72%
3	Total	20	6.60	5.80	1.50	0.83	0.34	0.19	2.0840	<0.0439	

Table Shows Comparison of percentage relief of all 2 Groups.

Parameters	Group A % relief	Group B % relief
Pain	79.99 %	77.49 %
Discharge	79.14 %	73.32 %
Itching	82.49 %	74.15 %
Tendeness	79.16 %	69.99 %

DISCUSSION

Bhagandara, a condition characterized by suppurative ulceration in the anorectal region, poses significant challenges in modern medicine due to its high recurrence rate and delayed wound healing. The current treatment options, including fistulectomy, often fail to address the underlying causes of the condition, leading to unsatisfactory outcomes. In contrast, the Ayurvedic approach, which emphasizes the use of Kshara Sutra, offers a promising alternative.

Our study demonstrates the efficacy and safety of Kshara Sutra prepared with Rajani Lepa in the management of Bhagandara. The significant improvement in symptoms and wound healing, along with the absence of major complications, suggests that this treatment modality can be a valuable addition to the existing armamentarium against Bhagandara.

The advantages of Kshara Sutra prepared with Rajani Lepa include its ability to promote drainage, reduce inflammation, and enhance wound healing. The antimicrobial and anti-inflammatory properties of the herbal ingredients used in Rajani Lepa likely contribute to its efficacy in managing the infective component of Bhagandara.

CONCLUSION

To conclude, that the treatment of Fistula-in-ano by Rajani lepa Kshara sutra is a simple, easy, and safe. The chances of recurrence and anal incontinence are very low and most importantly, the cost of the treatment is very low. As it is an ambulatory treatment subject can join to their work very early. Hence, the application of Rajani lepa kshara sutra is a better option than kshara sutra not only because it is cost effective, easy for application but also due to lesser postoperative complications. The healing of bhagandhara without scar and restoring the free anal passage is a major advantage of this method. It can avoid the surgery or can postpone the need of surgery. This will be a treatment of choice in patients whom surgery cannot be taken off or those who are not fit to go for surgery.



Group A



Group B

REFERENCE

1. Murthy Srikantha K. R. *Susrutha Samhitha* Reprint Edition, Varanasi, Chowkhamba Orientalia, 2017; 4: I, 1-6.
2. Murthy Srikantha K. R. *Susrutha Samhitha*, Reprint Edition, Varanasi, Chowkhamba Orientalia, 2017; 4: I, 1-7.
3. Murthy Srikantha K. R. *Susrutha Samhitha*, Reprint Edition, Varanasi, Chowkhamba Orientalia, 2017; 4: I, 1-11.
4. Murthy Srikantha K. R. *Susrutha Samhitha*, Reprint Edition, Varanasi, Chowkhamba Orientalia, 2017; 182: 1, 25-3.
5. Murthy Srikantha K. R. *Susrutha Samhitha*, Reprint Edition, Varanasi, Chowkhamba Orientalia, 2017; 100: I, 8-42.
6. Murthy Srikantha K. R. *Susrutha Samhitha*, Reprint Edition, Varanasi, Chowkhamba Orientalia, 2017; 168: I, 7-32.
7. Sharma R. K, Dash Bhagwan. *Caraka Samhitha* Reprint Edition, Varanasi, Chowkhamba Sanskrit Series Office, 2022; 515: III, 12-97.
8. Murthy Srikantha K. R. *Susrutha Samhitha*, Reprint Edition, Varanasi, Chowkhamba Orientalia, 2017; 65: I, 11-11.
9. Angadi ravindra *Rasa sastra*, Reprint Edition, Varanasi Chowkhamba Surbharti Prakashan, 2023; 343: 24, 527-530.
10. Bailey & Love's *Short Practice of Surgery*, Edited by Norman S.Williams, Christopher J.K.Bulstrode, P.Ronan o'connell, 26th edition, Edward Arnold pub Ltd, London, 2013; 26: 72-1215.