



ISSN 2456-3110

Vol 7 · Issue 6

July 2022

Journal of  
**Ayurveda and Integrated  
Medical Sciences**

*www.jaims.in*

**JAIMS**

An International Journal for Researches in Ayurveda and Allied Sciences



**Maharshi Charaka**  
Ayurveda

**Indexed**

## A randomized, controlled clinical study to evaluate the role of *Sarjarasa Apamarga Ksharasutra* in the management of *Bhagandara* w.s.r to fistula-in-ano

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### ABSTRACT

Fistula-in-ano is one of the most common ailments pertaining to ano-rectal region, is prevalent all over the world and its occurrence is 8.6 cases per 100,000 population.<sup>[1]</sup> The main cause known for fistula-in-ano is crypto glandular infection of anal crypts. In Ayurveda, according to similar clinical features the disease *Bhagandara* can be correlated with fistula in ano. Presently *Ksharasutra* therapy is found most approaching and attractive treatment modality among para-surgical procedures for fistula in ano. *Guggulu Apamarga Ksharasutra* which is widely used, having good binding nature and anti-inflammatory effect, But the main complaints reported by the patients are pain and discomfort during and after *Ksharasutra* procedure. So, instead of *Guggulu*, *Sarjarasa* was taken which is having binding property, *Vedanasthapaka*, *Vrana Ropana* and *Vrana Shodhana Guna*, for the *Ksharasutra* preparation.<sup>[2]</sup> A total of 30 subjects were taken, Trial group treated with *Sarjarasa Apamarga Ksharasutra* and control group treated with *Guggulu Apamarga Ksharasutra*. The study shows *Sarjarasa Apamarga Ksharasutra* had high efficacy in subjective parameters like pain and burning sensation compared to *Guggulu Apamarga Ksharasutra*. There were no complications like necrosis, stenosis, anal incontinence after application of *Sarjarasa Apamarga Ksharasutra*.

**Key words:** *Sarjarasa Apamarga Ksharasutra*, *Guggulu Apamarga Ksharasutra*, *Bhagandara*, *Fistula-in-ano*.

### INTRODUCTION

The word fistula is derived from a Latin word which means a reed, pipe or flute. An 'anal' fistula is defined as a track which communicates with the anal canal or rectum by means of an internal opening and usually is in continuity with one or more external openings in the perianal, perineal or ischio-rectal areas.<sup>[3]</sup> *Fistula-in-ano* is one of the most common ailments pertaining to ano-rectal region. The main cause known for *fistula-in-ano*

is crypto glandular infection of anal crypts. Mostly perianal abscesses and fistula in ano indicates the acute and chronic condition of same disease process of infective origin.<sup>[2]</sup>

In Ayurveda, according to similar clinical features the disease *Bhagandara* can be correlated with fistula in ano. *Acharya Sushruta* counted *Bhagandara* among the *Ashtamahagadas* which are difficult to cure. Fistulas are treated surgically, through a variety of different procedures depending on external and internal sphincter involvement includes Fistulotomy, Seton placement LIFT, Fibrin plug and Glue.<sup>[4]</sup>

*Acharya Sushruta* has also described different therapeutic measures for the management of *Bhagandara* as in terms of various oral medications, local applications, surgical procedures and para-surgical intervention. Presently *Ksharasutra* therapy is found most approaching and attractive treatment modality among para-surgical procedures for fistula in ano. It is standard treatment modality found in surgical practice for the management of fistula in ano, as the

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Submission Date: 11/05/2022 Accepted Date: 19/06/2022

#### Access this article online

Quick Response Code



Website: [www.jaims.in](http://www.jaims.in)

DOI: 10.21760/jaims.7.6.5

therapy has revolutionized the treatment of fistula in ano in terms of re-occurrence and incontinence.

Most widely used is *Guggulu Apamarga Ksharasutra* which is having good binding nature and anti-inflammatory effect. But the main complaints reported by the patients are pain and discomfort during and after *Ksharasutra* procedure. Overcoming the causation of pain and burning sensation was a very important necessity because of which surgeons of Ayurveda came out with newer ideas. Thus, many more *Kshara Sutra* were tried out like, *Udumbara Kshara Sutra*, *Tankana Kshara Sutra*, *Yavakshara Sutra*, *Snuhi Swarasa Kshara Sutra*, *Ghrita Kumari Kshara Sutra*, *Aragvadhadi Sutra* etc. As "Necessity is the mother of invention", *Sarjarasa* which is having binding property, *Vedanasthapaka*, *Vrana Ropana* and *Vrana Shodhana Guna*, it is selected for the *Ksharasutra* preparation for the management of *Bhagandara*.

### AIM

To evaluate the role of *Sarjarasa Apamarga Ksharasutra* in the management of *Bhagandara* wsr to fistula in ano.

### OBJECTIVES OF THE STUDY

1. To evaluate the role of *Sarjarasa Apamarga Ksharasutra* in the management of fistula-in-ano.
2. To re-evaluate the role of *Guggulu Apamarga Ksharasutra* in the management of fistula-in-ano.
3. To compare the role of *Sarjarasa Apamarga Ksharasutra* with *Guggulu Apamarga Ksharasutra* in the management of fistula-in-ano.

### MATERIALS AND METHODS

The study design was open label, randomized controlled clinical study, in this study 30 patients who fulfilled the inclusion criteria were selected from OPD, IPD department of Shalya Tantra. They were divided into two groups Group A (N=15) and Group B (N=15). Group A being the control group and Group B being the trial group. IEC approval was taken before starting the trail, informed written consent of all patients was taken before the operative procedure. Duration of treatment was 4 weeks.

### Preparation of Sarjarasa Apamarga Ksharasutra

#### Materials Required

1. Thread (Barbour's linen no.20) [fig no: 1]
2. *Ksharasutra* cabinet [fig no: 2]
3. *Sarjarasa* [fig no:3]
4. *Apamarga Kshara* [fig no:4]
5. *Haridra* [fig no:5]
6. Surgical Spirit [fig no:1]



Figure 1

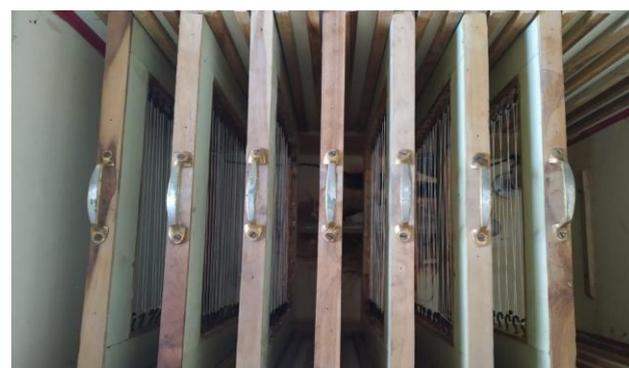


Figure 2



Figure 3



Figure 4



Figure 5

### Preparation

1. Barbour linen thread no:20 was tied in the hanger of the *Ksharasutra* cabinet. [fig no:6]
2. Followed by smearing the thread with *Sarjarasa* dissolved in surgical spirit uniformly and carefully all around the thread with the help of gauze piece. [fig no:7]
3. The hanger was placed in *Ksharasutra* cabinet after each coating for drying and sterilization (UV-RAYS) [fig no:8]
4. After 11 such coatings with *Sarjarasa*, on next day after 12th coat of *Sarjarasa*, it was passed through a heap of finely powdered *Apamarga Kshara* to obtain a uniform coating of the same. [fig no:9]
5. The process of *Kshara* coating was repeated for 7 times. The remaining 3 coatings with *Sarjarasa* dissolved in surgical spirit and fine powder of *Haridra* were done for making a total of 21 coatings. [fig no:10]

6. After complete drying of *Ksharasutras* under aseptic precautions the sutras were cut into required size and was packed in a sterile air tight container. [fig no:11]

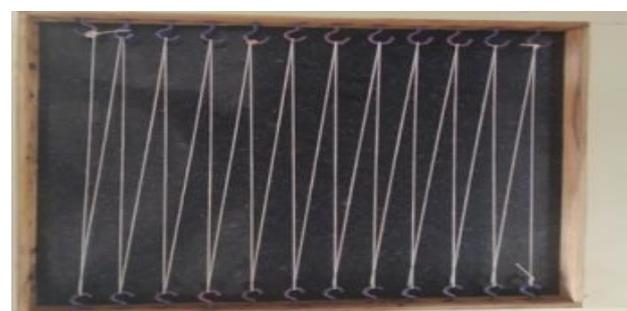


Figure 6



Figure 7

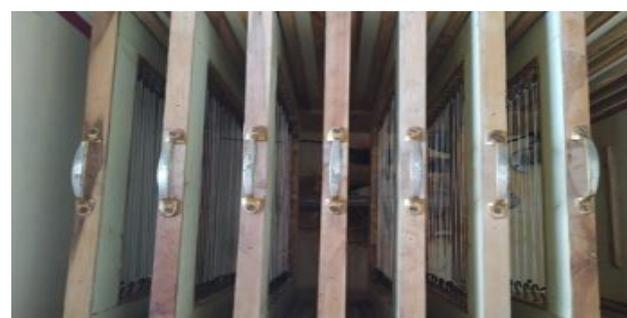


Figure 8

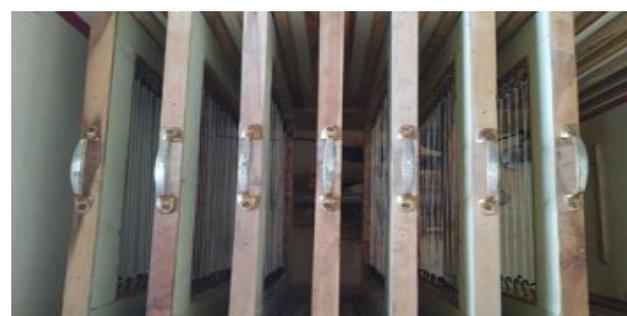


Figure 9



Figure 10



Figure 11

### Poorvakarma

- Written Informed consent was taken prior to the procedure.
- Xylocaine Sensitivity test and Tetanus Toxoid (IM) given prior to procedure.
- Perianal Part Preparation was done.
- Laxatives were given prior to procedure

### Pradhana Karma

#### Group A

Application of *Guggulu Apamarga Ksharasutra* under suitable anaesthesia the patient was taken into lithotomy position and cleaning and drapping done. The patient was assured and gloved finger was gently introduced into the rectum. Then a suitable probe was passed through the external opening of fistula. The tip of the probe was forwarded along the path of least resistance being guided by the finger in rectum to reach into the lumen of anal canal through the internal opening and its tip was finally directed to come out of anal orifice. Primary thread was taken and threaded

into the eye of probe, thereafter the probe was pulled out through the anal orifice to leave the thread behind in the fistulous track. The two ends of the thread were then tied together with a moderate tightness outside the anal canal. On every week ksharasutra changing was done.

#### Group B

Application of *Sarjarasa Apamarga Ksharasutra* Under suitable anaesthesia the patient was taken into lithotomy position and cleaning and drapping done. The patient was assured and gloved finger was gently introduced into the rectum. Then a suitable probe was passed through the external opening of fistula. The tip of the probe was forwarded along the path of least resistance being guided by the finger in rectum to reach into the lumen of anal canal through the internal opening and its tip was finally directed to come out of anal orifice. Primary thread was taken and threaded into the eye of probe, thereafter the probe was pulled out through the anal orifice to leave the thread behind in the fistulous track. The two ends of the thread were then tied together with a moderate tightness outside the anal canal. On every week ksharasutra changing was done.

### Paschat Karma

Patient were asked to do sitz bath twice daily from post operative day 1. Regular dressing was done.

### Ksharasutra change

In both the groups *Ksharasutra* was changed once in a week.

### Diagnostic Criteria

Subjects with classical symptoms of *Bhagandara* were selected for study such as *Pidaka* associated with *Ruk*, *Jwara*, *Kandu*, *Daha* and *Shopha* around Perianal region.

### Inclusion Criteria

- Subjects fulfilling diagnostic criteria of *Bhagandara* (fistula in ano)
- Age group between 21 - 60 years

**Exclusion Criteria**

1. Subjects who are Immuno-compromised anaemic, and diagnosed with non-cryptoglandular fistula.
2. Subjects with uncontrolled Diabetes Mellitus (PPBS more than 200mg/dl).
3. Subjects who are diagnosed with Crohn's disease, Bleeding disorders, Ulcerative colitis, Carcinoma of rectum.
4. Subjects who are pregnant and Lactating women

**Assessment Criteria****Subjective**

1. Assessment of pain
2. Assessment of burning sensation

**Objective**

1. Assessment of discharge
2. Unit cutting time calculation

**Pain was assessed by using VAS scale****Burning sensation were graded from 0-3<sup>[5]</sup>**

Grade 0 - No burning sensation

Grade 1 - Mild burning sensation

Grade 2 - Moderate burning sensation

Grade 3 - Severe Burning sensation.

**Discharge was graded from 0-3<sup>[5]</sup>**

Grade 0 : No discharge

Grade 1 : Mild discharge

Grade 2 : Moderate discharge

Grade 3 : Profuse discharge

**UCT - Unit Cutting Time Calculation<sup>[6]</sup>**

Total number of days required for complete cutting of tract / Initial length of the tract in cm.

**OBSERVATIONS**

Observation during preparation of *Sarjarasa Apamarga Ksharasutra*

- The powdered *Sarjarasa* was easily dissolved in surgical spirit.
- There was a slight yellowish tinge noticed in the thread after coating with *Sarjarasa*.
- There was sticking property noticed in the thread coated with *Sarjarasa* even after drying also.
- The repeated coating of *Kshara* and *Haridra* shows difficulty in spreading all across the *Sutra*.
- Mild loss of *Kshara* and *Haridra* was noted in each coating.
- Packing of the *Ksharasutra* without proper drying leads to wetness of *Sutra* due to left over moisture.
- Air tight packaging is needed for storage of *Ksharasutra*.

**Table 1: Assessment of Pain by Mann Whitney U test**

Pain	Group A		Group B		Total		Mann-Whitney U test		
	n	%	n	%	n	%	z	p	
A T	Nil	0	0	2	13.3	2	6.7	2.288	0.027
	Minimal	4	26.7	6	40	10	33.		
	Mild	1	6.7	7	46.7	1	56.7		
	Moderate	1	6.7	0	0	1	3.3		

**Table 2: Assessment of burning sensation by Mann Whitney U test**

Days of assessment	0 <sup>th</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	21 <sup>st</sup> day	28 <sup>th</sup> day	P value
Group A Control	2.8 ±0.11	2.8 ±0.11	2.87 ±0.09	2.47±0.13	1.60 ±0.13	p<0.03
Group B Trial	2.87	2.67±	2.20±0.11	1.47±0.17	1.07±0.15	

	0.0 9	0.1 3				
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**Table 3: Assessment of Discharge by Mann Whitney U test**

Assessment of discharge	0 <sup>th</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	21 <sup>st</sup> day	28 <sup>th</sup> day	P value
Group A	1.20 ± 0.11	1.67 ± 0.13	1.53 ± 0.13	1.40 ± 0.11	1.07 ± 0.15	No significant difference between the groups
Group B	1.60 ± 0.24	1.67 ± 0.13	1.53± 0.13	1.20 ± 0.14	0.80 ± 0.14	

**Table 4: Assessment of UCT by Mann Whitney U test**

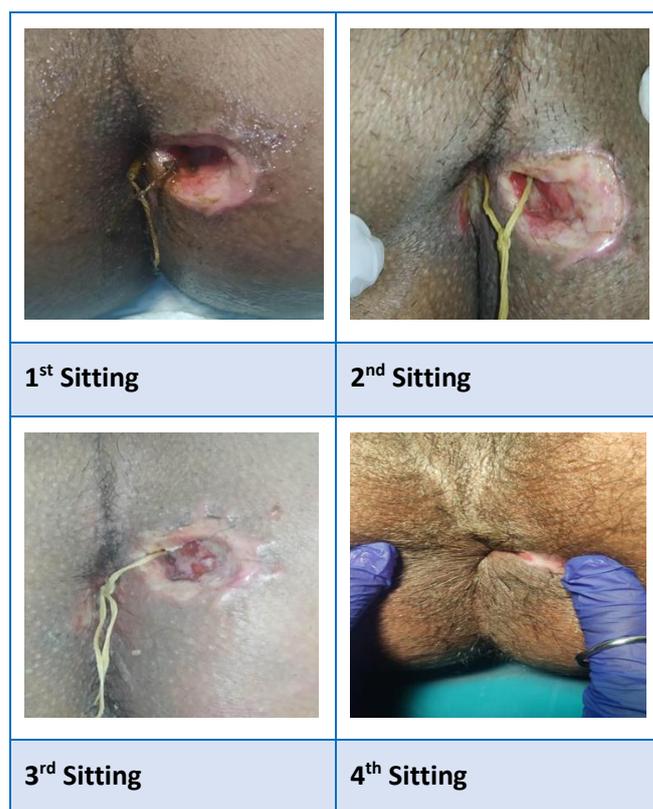
UCT	0 <sup>th</sup> day	7 <sup>th</sup> day	14 <sup>th</sup> day	21 <sup>st</sup> day	28 <sup>th</sup> day	P value
Group A	4.73 ± 0.32	4.49 ± 0.35	3.61± 0.36	2.50 ± 0.37	1.31 ± 0.36	No significant difference
Group B	5.07 ± 0.41	4.89 ± 0.42	4.03± 0.44	2.94 ± 0.43	1.77 ± 0.41	

There was a significant difference before and after the treatment between the groups with high clinical efficacy seen in Group B compared to Group A in respect to subjective parameters. Pain and burning sensation during and after treatment reduced in Group B compared to Group A.

**Trial Group**



**Control Group**



**LIMITATIONS**

While application of Sarjarasa on Sutra, faster drying was observed. Hence the following Kshara coating needed to do sooner. Otherwise, there is a chance of wastage of drug.

**DISCUSSION**

**Pain:** Vedanasthapana and Vranashodhana properties of Sarjarasa, possess reduced pain during the treatment.

**Burning Sensation:** As Sarjarasa having Kashaya, Tiktha rasa, and Seeta Veerya possess reduced burning sensation during the treatment.<sup>[7]</sup>

**Discharge:** Observation made on discharge showed majority of subjects had discharge during first 2 sittings, and it was reduced considerably.

**Unit Cutting Time:** UCT was considered to assess the efficacy of the *Ksharasutra* for healing of fistulous track. The average UCT obtained for *Sarjarasa Apamarga Ksharasutra* was 8.5 days and for *Guggulu Apamarga Ksharasutra* was 8.2 days. In this study, it was observed as UCT was greater in the patients above the age of 50 years, in both the groups and lesser in patients below 40 years. It was observed that as chronicity of the disease increases, there was a significant increase in the time required for the complete excision of the track.

Smaller tracks underwent excision faster, than those of longer tracks, when treated by *Kshara Sutra*.

## CONCLUSION

The study shows *Sarjarasa Apamarga Ksharasutra* statistically had high efficacy in subjective parameters compared to *Guggulu Apamarga Ksharasutra*. There were no complications like necrosis, stenosis, anal incontinence after application of *Sarjarasa Apamarga Ksharasutra*.

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**How to cite this article:** Anagha TS, KM Sweta, Dhyan Surendranath. A randomized, controlled clinical study to evaluate the role of Sarjarasa Apamarga Ksharasutra in the management of Bhagandara w.s.r to fistula-in-ano. J Ayurveda Integr Med Sci 2022;6:28-34. <http://dx.doi.org/10.21760/jaims.7.6.5>

**Source of Support:** Nil, **Conflict of Interest:** None declared.

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