



EVALUATION OF EFFICACY OF *KADALI, PALASHA, TANKANA*  
*KSHARASUTRA* IN *BHAGANDARA* VIZ FISTULA IN ANO- A  
CLINICAL STUDY

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ABSTRACT

*Bhagandara* is one among *mahagada* and for which only available promising treatment is *KsharaSutra*. Regularly *Apamarga KsharaSutra* is being used for the management of *Bhagandara* but because of certain drawbacks like non availability and irritation after application of *Snuhi* based *Apamarga Kshara Sutra*. The objective of the study was to reduce the complication like discomfort newer *KsharaSutra* were put to test which are prepared by *Guggulu* based *Kadali Kanda Kshara*, *Guggulu* based *Palasha Moola Kshara Sutra* and *Guggulu* based *Tankana Kshara Sutra*. Plain thread ligation was also done to understand the mechanical effect of *Sutra* in Cutting process. The comparative efficacy of these *KsharaSutra* was studied in 4 groups having 25 patients in each group diagnosed for *Bhagandara* and results were assessed for the post ligation complaints like pain and Discharge and Cutting Rate. The results were put to statistical analysis and results were validated. Overall results showed that the *Palasha moola Ksharasutra* showed better results in cutting the track and with low pain and Discharge among other *Kshara Sutra* and plain thread did not show any significant results. Average UCT was good in *Guggulu-Palashamoola Kshara Sutra* with rate of 10.49 days/cm. The conclusion drawn from the study was among four groups in the study Group A (*Guggulu-PalashamoolaKshara*) *Sutra* showed significant results in reducing discharge and controlling pain which was substantiated by statistical analysis. Statistically also it was seen that *Guggulu-PalashamoolaKshara* was significant with p value < 0.5.

**Keywords:** *Bhagandara, Fistula in ano, Guggulu based KsharaSutra, Unit cutting time*

**INTRODUCTION:** The word fistula is derived from a Latin word a reed, pipe or flute. It implies a chronic granulating track connecting two epithelial-lined surfaces. These surfaces may be continues or mucosal. The anal fistula is a single track with an external opening in the skin of peri-anal region and an internal opening in the modified skin or mucosa of anal canal or rectum. In Ayurvedic classics, this disease has been described with the name of *bhagandara*, which has more similar signs and symptoms with anal fistula. The severity of this disease was first realized by *Sushruta* (800-1000 B.C.)<sup>[1,2]</sup>, who

described it elaborately in his treatise. The *Kshara Sutra* therapy<sup>[3]</sup> was practiced and used in since long with great success and without recurrences. The Standard *kshara Sutra* is prepared by repeated coatings of *Snuhi ksheera*, *Apamarga kshara* and *Haridra*. But some of the problems are faced during the preparation and also in the course of *Kshara Sutra* therapy like Collection and preservation of *Snuhi ksheera*, *Kshara Sutra* produces much burning pain during primary and successive changes, Local irritant skin reactions occur during course of therapy, In spite of the good rates of cutting, severe

pain and burning sensation caused during the treatment with held many patients from accepting this treatment The most recent innovative thought was to use *Guggulu* in the preparation of *kshara Sutra* as *Guggulu* is inherited with the properties of *vranashodhana*, *vranaropana* and *lekhana*<sup>4</sup>.

Considering the above problems so, we are in need to find out such a drug which is easily available, preservable and equally effective. The idea behind the present work is to find out the effectiveness of *Guggulu based-kshara Sutra* in the management of *bhagandara* and find out such a treatment, which is economical, easily available, as well as minimize the problems of *Kshara Sutra therapy*. It is a comparative study of 4 groups in which 25 subjects were selected in each group to compare the efficacy of Group-A (*Guggulu based palasha kshara Sutra*), Group-B (*Guggulu based Kadali Kshara Sutra*), Group-C (*Guggulu based Tankana Kshara Sutra*) and Group-D (*Plain Sutra*) in clinically identified *Bhagandara* Patients.

#### MATERIAL AND METHODS:

Selection of patients

A total of 100 diagnosed cases of *Bhagandara* (fistula-in-ano) were registered from out-patient and in-patient departments of Shalyatantra of AyurvedaMahavidyalaya,Hubballi, irrespective of age, sex occupation and

religion and were divided in to 4 groups of 25 patients each..

#### Diagnostic criteria

The diagnosis was made on the basis of symptoms such as boil at peri-anal region, pus discharge and peri-anal pain. Per-anal examination findings revealing external opening and per-rectal digital examination confirming internal opening of fistula-in-ano.

#### Inclusion criteria

- Patients diagnosed as having anal fistula was included in the study.
- Patients of both sexes in between the age group of 20 and 60 years was included.
- Patients of fistula in ano with controlled systemic diseases like Diabetes mellitus and Hypertension are also included in the study.

#### Exclusion criteria

- Patients having multiple tracts was excluded.
- Fistulas secondary to Tubercular infection, Ulcerative colitis, and due to ano rectal malignancies will be excluded.
- Patients with H.I.V. and HBsAg Infection was excluded.
- Patients with systemic diseases like uncontrolled Diabetes and Hypertension was excluded.
- Female patients with pregnancy was excluded.

#### Materials

**Table.1 Ingredients and Preparation of KsharaSutra Materials Required**

Group A	Group B	Group C	Group D
Surgical linen Thread No 20.	Surgical linen Thread No 20.	Surgical linen Thread No 20.	Surgical linen Thread No 20.
<i>Shudda Guggulu</i>	<i>Shudda Guggulu</i>	<i>Shudda Guggulu</i>	
<i>Palasha Kshara</i>	<i>Kadali Kshara</i>	<i>ShuddaTankana</i>	
<i>Haridra choorna</i>	<i>Haridra choorna</i>	<i>Haridra choorna</i>	

Kshara Sutra cabinet	Kshara Sutra Cabinet	Kshara Sutra Cabinet	
<p><b>Method of preparation:</b></p> <ul style="list-style-type: none"> <li>• The <i>Shodita Guggulu</i> is dissolved in <i>triphala kwatha</i> and its lepa was done over the surgical linen thread which is tied to the hangers with cotton Gauze piece. Hangers was kept for drying in the <i>Kshara Sutra cabinet</i>. 7 coatings of <i>Guggulu</i> was applied and 5 coatings of <i>guggulu</i> with <i>Palasha Kshara</i> done and at last 1 layer <i>Guggulu</i> with <i>haridra</i> is applied uniformly.</li> <li>• Similarly 5coatings are done with <i>Kadali Kshara &amp; Shodita Guggulu</i>, <i>Tankana Kshara &amp; Shoditha Guggulu</i> and <i>KsharaSutras</i> was prepared.</li> <li>• The thread was again kept in the <i>kshara Sutra cabinet</i> and was exposed to ultraviolet light. After, sterilization the desired length was cut and packed in air tight polythene bags.</li> </ul>			
<p><b>Interventions.</b></p> <p>Method of <i>Kshara Sutra</i> Ligation:</p> <p><b>Pre-operative:</b></p> <ul style="list-style-type: none"> <li>• Injection Tetanus Toxoid 0.5ml i. m. was given.</li> <li>• Xylocaine test dose was given.</li> <li>• Consent was taken.</li> <li>• The preparation of the part was done by shaving part and washing with antiseptic lotion.</li> </ul> <p><b>Operative:</b></p> <ul style="list-style-type: none"> <li>• The patient is given Lithotomic position.</li> <li>• Local Anaesthesia is infiltrated.</li> <li>• Probing was done with malleable probe to assess length and direction of the tract guided by lubricated opposite finger in the anal canal. Care was taken not to create false passages.</li> <li>• <i>Kshara Sutra</i> was passed through the external opening and taken out through internal opening and anal canal with</li> </ul>		<p>the help of probe. Both the ends was tied neither too loose nor too tight.</p> <p><b>Post operative:</b></p> <ul style="list-style-type: none"> <li>• The patient was advised to take lukewarm <i>Avagaha sweda</i> of <i>Triphala kwatha</i> after one hour and Twice daily till the completion of the treatment.</li> </ul> <p><b>Method of changing <i>KsharaSutra</i> Changing the Thread (Rail – Road method):</b></p> <ul style="list-style-type: none"> <li>• The new <i>Sutra</i> is tied and the knot tightened against the knot of the thread in situ. The thread at the anal verge is clamped with forceps and cut in between the knot and forceps.</li> <li>• The forceps is slowly pulled. The new thread replaces the old Thread. The knot of the new thread is tied and confirmed. The measurement of the old thread is taken in cms. The patients was advised to take rest for the one hour and discharged. This method of changing thread is known Rail-road method the changing of thread was done on every seventh day. After the first change of thread the measurement of old thread is taken in cms. It is divided by 2, which gives the initial length of the tract.</li> </ul> <p><b>Follow up:</b> Follow up period was three months after the complete cut through of the track</p> <p><b>Assessment criteria Subjective criteria:</b></p> <p>a) The following clinical features was assessed before treatment, immediately after Ligation and on every seventh day till the completion of the treatment.</p> <ul style="list-style-type: none"> <li>• Pain in the anal region.</li> <li>• Pus discharge.</li> <li>• Constipation.</li> </ul> <p>Gradations of Clinical features Mc Gill’s Pain index score.</p> <ul style="list-style-type: none"> <li>• No Pain - 0</li> <li>• Mild Pain - 1</li> </ul>	

- Discomforting- 2
- Distressing - 3
- Horrible - 4
- Excruciating - 5

**Constipation**

- Passes stools regularly without difficulty - 0
- Passes stools regularly with difficulty - 1
- Passes stools irregularly with difficulty - 2

**Pus Discharge**

- No Discharge - 0
- Mild Discharge - 1
- Moderate Discharge - 2
- Profuse Discharge - 3

**Objective Criteria:**

- 1. Unit cutting Time
- 2. Pus discharge

Total No. of days taken for complete cut through

• **Unit cutting Time** =  $\frac{\text{Total No. of days taken for complete cut through}}{\text{Initial Length of the Tract in cms.}}$  = \_\_days /cm

**Pus Discharge:** No. of cotton pads soaked in 24 hrs.

b) 1. Assessments of the clinical features after completion of the treatment was reviewed and results were categorized as.

- Complete relief -above 75%
- Moderate relief -50 - 75%
- Mild relief -25 – 50%
- No relief -0 – 25%

2. Comparative assessment of the *Palasha Kshara, Kadali Kshara, Tankana Kshara Sutra* and *Plain Sutra* was done on the basis of occurrence and relief of post Ligation pain and amount of discharge after Ligation in the corresponding groups. The average Unit cutting time taken in each groups was compared for the final assessment.

**STATISTICAL ANALYSIS**

The data obtained in the clinical study was subjected to statistical tests, such as Wilcoxon signed-rank test which was applied to subjective parameters; paired ‘t’-test to assess the result before and after treatment in individual groups; and unpaired ‘t’-test to compare the result between two groups for objective criteria.

**OBSERVATION:** In the present study it is seen that the incidence of *Bhagandara* is

more in age group more than 50 years followed by 30-39 years age group. Sex incidence shows that maximum patients were males (88 cases – 88%) and minimum were females (12cases – 25%) with ratio of 7:1. Maximum patients registered were from Hindu community and others was 12. It cannot be so concluded because the location of college is densely populated by Hindus. Out of 100 cases 28 patients were farmers, 24 patients were job holders and 22 patients from business class. Rest from labours, teachers, bankers, students, Homemakers in 9,5,3,3,8 respectively. Majority of the patients developed symptoms due to strenuous work, because they are exposed to many etiological factors of the disease like riding, sitting and in awkward position for long hours, strenuous exercise. Out of 100 patients in the study maximum patients (76) were vegetarian and few patients were (24) non vegetarian. Maximum patients (59) suffered from constipation, and 25 patients had regular bowels, and 16 patients had irregular bowel habits. Improper bowel habits may initiate the infection of crypto glandular infections Out of 100 patients 96 patients

presented with *parisravi* type and two patients with *ustragreeva* and 1 patient with *riju* and *parikshepi* type. In overall 100 patients, 23 patients had opening at 6 o'clock position, 20 patients had opening at 5 o'clock, 11 patients had opening at 11 and 1 o'clock. U.C.T in Group A is 10.49, in Group B is 12.81, in Group C is 14.05, and in Group D is 62.23.

The pH of *Palasha Moola Kshara* is high than rest *Kshara* and  $K^+$  and  $Na^+$  salts are also high.

## Results

### Group-A GugguluPalashamoolaKshara Sutra

A Wilcoxon signed rank test showed that comparison of before treatment, 1<sup>st</sup> week, 2<sup>nd</sup> week, 3<sup>rd</sup> week, 4<sup>th</sup> week, 5<sup>th</sup> week, *Guggulu Palasha Kshara Sutra* over Discharge elicited a statistically significant change *bhagandara* at the time points of Before treatment and 1<sup>st</sup> week ( $z=-2.4490$ ,  $p=0.0140$ ), 2<sup>nd</sup> week ( $z=-4.5240$ ,  $p=0.0001$ ), 3<sup>rd</sup> week ( $z=-4.5810$ ,  $p=0.0001$ ), 4<sup>th</sup> week ( $z=-4.5860$ ,  $p=0.0001$ ), 5<sup>th</sup> week ( $z=-4.4930$ ,  $p=0.0001$ ). All showed statistically significant with p-value 0.0001.

### Group-B GugguluKadaliKshara Sutra

A Wilcoxon signed rank test showed that comparison of before treatment, 1<sup>st</sup> week, 2<sup>nd</sup> week, 3<sup>rd</sup> week, 4<sup>th</sup> week, 5<sup>th</sup> week, *Guggulu Kadali Kshara Sutra* over Discharge elicited a statistically significant change *bhagandara* at the time points of Before treatment and 2<sup>nd</sup> week ( $z=-4.4720$ ,  $p=0.0001$ ), 3<sup>rd</sup> week ( $z=-4.6130$ ,  $p=0.0001$ ), 4<sup>th</sup> week ( $z=-4.5070$ ,  $p=0.0001$ ), 5<sup>th</sup> week ( $z=-4.5260$ ,  $p=0.0001$ ). All showed statistically significant with p-value  $p<0.05$ .

### Group-C GugguluTankanaKshara Sutra

A Wilcoxon signed rank test showed that comparison of before treatment, 1<sup>st</sup> week, 2<sup>nd</sup> week, 3<sup>rd</sup> week, 4<sup>th</sup> week, 5<sup>th</sup> week, *Guggulu Palasha Kshara Sutra* over Discharge elicited a statistically significant change *bhagandara* at the time points of Before treatment and 1<sup>st</sup> week ( $z=-2.4490$ ,  $p=0.0140$ ), 2<sup>nd</sup> week ( $z=-4.5240$ ,  $p=0.0001$ ), 3<sup>rd</sup> week ( $z=-4.5810$ ,  $p=0.0001$ ), 4<sup>th</sup> week ( $z=-4.5860$ ,  $p=0.0001$ ), 5<sup>th</sup> week ( $z=-4.4930$ ,  $p=0.0001$ ). All showed statistically significant with p-value  $p<0.05$ .

### Group-D Plain Thread

A Wilcoxon signed rank test showed that comparison of before treatment, 1<sup>st</sup> week, 2<sup>nd</sup> week, 3<sup>rd</sup> week, 4<sup>th</sup> week, 5<sup>th</sup> week, *Plain Sutra* over Discharge elicited a statistically significant change *bhagandara* at the time points of Before treatment and 1<sup>st</sup> week ( $z=0.0000$ ,  $p=1.0000$ ), 2<sup>nd</sup> week ( $z=0.0000$ ,  $p=1.0000$ ), 3<sup>rd</sup> week ( $z=0.0000$ ,  $p=0.0001$ ), 4<sup>th</sup> week ( $z=-1.0000$ ,  $p=0.3170$ ), 5<sup>th</sup> week ( $z=-1.7320$ ,  $p=0.0830$ ). All showed statistically significant.

### Pain in all four groups at different point of time.

A Kruskal-wallis H test showed that there was a statistically significant difference in Pain scores at different time points between the different treatment groups,  $p=0.0001$ , with a mean rank Pain score of 38.2 for Group A, 49.0 for Group-B, 49.6 for Group-C and 65.2 for Group-D at the end of 5<sup>th</sup> week of treatment, whereas comparison between BT and 1<sup>st</sup> week treatment there was a statistically significant in Pain score between treatments  $p=0.0001$  with mean rank discharge score of 65.6 for Group A, 78.4 for Group B, 30 for Group C, 28.00 for

Group D. It also revealed the statistically significant difference in Pain score at time point of Before treatment and 5<sup>th</sup> week,  $p=0.0001$ , with a mean rank score of 56.3 for Group A, 49.1 for Group B, 60.4 for Group C, and 36.2 for Group-D.

#### **Group-A Guggulu Palashamoola Kshara Sutra**

A Wilcoxon signed rank test showed that comparison of before treatment, 1<sup>st</sup> week, 2<sup>nd</sup> week, 3<sup>rd</sup> week, 4<sup>th</sup> week, 5<sup>th</sup> week, *Guggulu Palasha Kshara Sutra* over Pain elicited a statistically significant change in *bhagandara* at the time points of Before treatment and 1<sup>st</sup> week ( $z=-4.3590$ ,  $p=0.00001$ ), 2<sup>nd</sup> week ( $z=-4.6250$ ,  $p=0.0001$ ), 3<sup>rd</sup> week ( $z=-4.5900$ ,  $p=0.0001$ ), 4<sup>th</sup> week ( $z=-4.6250$ ,  $p=0.0001$ ), 5<sup>th</sup> week ( $z=-4.5620$ ,  $p=0.0001$ ). All showed statistically significant with p-value 0.0001.

#### **Group –B Guggulu Kadali Kshara Sutra**

A Wilcoxon signed rank test showed that comparison of before treatment, 1<sup>st</sup> week, 2<sup>nd</sup> week, 3<sup>rd</sup> week, 4<sup>th</sup> week, 5<sup>th</sup> week, *Guggulu Kadali Kshara Sutra* over Pain elicited a statistically significant change in *bhagandara* at the time points of Before treatment and 1<sup>st</sup> week ( $z=-4.9140$ ,  $p=0.00001$ ), 2<sup>nd</sup> week ( $z=-4.5560$ ,  $p=0.0001$ ), 3<sup>rd</sup> week ( $z=-4.5000$ ,  $p=0.0001$ ), 4<sup>th</sup> week ( $z=-4.4490$ ,  $p=0.0001$ ), 5<sup>th</sup> week ( $z=-4.4790$ ,  $p=0.0001$ ). All showed statistically significant with p-value 0.0001.

#### **Group-C Guggulu Tankana Kshara Sutra**

A Wilcoxon signed rank test showed that comparison of before treatment, 1<sup>st</sup> week, 2<sup>nd</sup> week, 3<sup>rd</sup> week, 4<sup>th</sup> week, 5<sup>th</sup> week, *Guggulu Tankana Kshara Sutra* over Pain elicited a statistically significant change in *bhagandara* at the time points of Before

treatment and 2<sup>nd</sup> week ( $z=-4.9140$ ,  $p=0.00001$ ), 3<sup>rd</sup> week ( $z=-4.8380$ ,  $p=0.0001$ ), 4<sup>th</sup> week ( $z=-4.4760$ ,  $p=0.0001$ ), 5<sup>th</sup> week ( $z=-4.4760$ ,  $p=0.0001$ ). All showed statistically significant with p-value 0.0001.

#### **Group D Plain Thread**

A Wilcoxon signed rank test showed that comparison of before treatment, 1<sup>st</sup> week, 2<sup>nd</sup> week, 3<sup>rd</sup> week, 4<sup>th</sup> week, 5<sup>th</sup> week, Plain Thread over Pain elicited a statistically significant change in *bhagandara* at the time points of Before treatment and 2<sup>nd</sup> week ( $z=-4.1230$ ,  $p=0.0001$ ), 3<sup>rd</sup> week ( $z=-4.5620$ ,  $p=0.0001$ ), 4<sup>th</sup> week ( $z=-4.4490$ ,  $p=0.0001$ ), 5<sup>th</sup> week ( $z=-4.4740$ ,  $p=0.0001$ ). All showed statistically significant with p-value 0.0001.

#### **Effectiveness of Palashamoola Kshara Sutra**

*Guggulu based Palashamoola Kshara Sutra* has shown effective in *bhagandara*. The MIC and MIB study also proved the drug effect and analytical study viz pH value, concentration of Na<sup>+</sup> and K<sup>+</sup> salts LoD, Sulphated Ash, also substantiate the effectiveness of *Palashamoola Kshara*. Clinically the average UCT is also very less (10.49 days/cm) and the discharge and pain scores are also statistically significant.

#### **Effectiveness of Kadalimoola Kshara Sutra**

*Guggulu based Kadalimoola Kshara* was also significant in the treatment of *Bhagandara* but effect was delayed. The MIC and MIB study also proved its efficacy in all 4 different strains in bit higher concentration. Analytical study viz pH value, concentration of Na<sup>+</sup> and K<sup>+</sup> salts LoD, Sulphated Ash, also contributed in inferring the results.

Clinically the average UCT was 12.81 and the discharge and pain scores are also statistically significant in 2<sup>nd</sup> week onwards.

#### **Effectiveness of TankanaKshara Sutra**

*Guggulu based Tankanakshara Sutra* was also significant but comparatively delayed then *Palashamoola* and *Kadalimoola Kshara Sutra* group. Analytically also its pH value, concentration of Na<sup>+</sup> also substantiate the delayed effect of *TankanaKshara*. Clinically the average UCT is also very less (14.05 days/ cm) and the discharge and pain scores are also statistically significant at 4<sup>th</sup> week of the study.

#### **Effectiveness of Plain thread**

Plain thread showed in significant results compared to all above. The effect is very slow and duration of treatment. The average UCT is also high (62.23days / cm). pH is also 9.23 and with high Na<sup>+</sup> salt and no K<sup>+</sup> salt. MIB and MIC study was also effective in higher dilutions.

**DISCUSSION:** From the results of the study it was observed that *guggulu* based *ksharasutra* is best alternative for *snuhi* based *Ksharasutra*. *Guggulu palasha kshara sutra* has shown best performance in cut through of fistula track. The unit cutting time is much lower than other *kshara sutra*. The pH of the *palasha kshara* was also high (10.20). Statistically also group A i.e, *guggulu based palasha Kshara sutra* is best among other group. Other parameters like , pain, discharge has also shown significant improvement. The only setback with *guggulu* based *ksharasutra* is its hardness during administration, but once applied after getting enough moist the applied thread becomes soft and is not painful. The

cutting and healing is better appreciated in Group A than in other groups.

**CONCLUSION:** *KsharaSutra* is the most beneficial therapy in *Bhagandara* viz *Fistula* in ano. The *Guggulu based Kshara Sutra* had posed difficulty during changing the thread because of its tough and sturdy nature but after the day of change the patient compliance was good. Over all Pain, discomfort is minimal in *Guggulu Palashamoola KsharaSutra*. Average UCT was good in *Guggulu-PalashamoolaKshara Sutra* with rate of 10.49 days/cm. Among four groups in the study Group A (*PalashamoolaKshara Sutra*) showed significant results in reducing discharge and controlling pain which was substantiated by statistical analysis.

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