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 Kshara Sutra. Regularly Apamarga Kshara Sutra 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 Kshara Sutra 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 Kshara Sutra 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: Bhaghandara, Fistula in ano, Guggulu based Kshara Sutra, 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 continuous 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.) [1,2], who described it elaborately in his treatise. The Kshara Sutra therapy [3] 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, 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 4. 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 Ayurveda Mahavidyalaya, Hubballi, irrespective of age, sex occupation and religion and were divided in to 4 groups of 25 patients each.

Diagnosis 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 be 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>
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<tr>
<th>Group A</th>
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<th>Group C</th>
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<td>Palasha Kshara</td>
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**Method of preparation:**
- The *Shodita Guggulu* is dissolved in *triphala kwatha* 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 *Kshara Sutra* cabinet. 7 coatings of *Guggulu* was applied and 5 coatings of *guggulu* with *Palasha Kshara* done and at last 1 layer *Guggulu* with haridra is applied uniformly.
- Similarly 5coatings are done with *Kadali Kshara & Shodita Guggulu, Tankana Kshara & Shoditha Guggulu* and *Kshara Sutras* was prepared.
- The thread was again kept in the *kshara Sutra* cabinet and was exposed to ultraviolet light. After sterilization the desired length was cut and packed in air tight polythene bags.

**Interventions.**

**Method of Kshara Sutra Ligation:**

**Pre-operative:**
- Injection Tetanus Toxoid 0.5ml i. m. was given.
- Xylocaine test dose was given.
- Consent was taken.
- The preparation of the part was done by shaving part and washing with antiseptic lotion.

**Operative:**
- The patient is given Lithotomic position.
- Local Anaesthesia is infiltrated.
- 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.
- *Kshara Sutra* was passed through the external opening and taken out through internal opening and anal canal with the help of probe. Both the ends was tied neither too loose nor too tight.

**Post operative:**
- The patient was advised to take lukewarm *Avagaha sweda* of *Triphala kwatha* after one hour and Twice daily till the completion of the treatment.

**Method of changing KsharaSutra Changing the Thread (Rail – Road method):**
- The new *Sutra* 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.
- 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.

**Follow up:** Follow up period was three months after the complete cut through of the track

**Assessment criteria Subjective criteria:**

a) The following clinical features was assessed before treatment, immediately after Ligation and on every seventh day till the completion of the treatment.
- Pain in the anal region.
- Pus discharge.
- Constipation.

**Gradations of Clinical features**

Mc Gill’s Pain index score.
- No Pain - 0
- Mild Pain - 1
• 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

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

**Pus Discharge**

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

**Objective Criteria:**

1. Unit cutting Time
2. Pus discharge

**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 (12 cases – 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 o clock position. 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 then 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, 1st week, 2nd week, 3rd week, 4th week, 5th week, Guggulu Palasha Kshara Sutra over Discharge elicited a statistically significant change bhagandara at the time points of Before treatment and 1st week (z=-2.4490, p=0.0140), 2nd week (z=-4.5240, p=0.0001), 3rd week (z=-4.5810, p=0.0001), 4th week (z=-4.5860, p=0.0001), 5th week (z=-4.4930, p=0.0001). All showed statistically significant with p-value <0.05.

Group-B GugguluKadaliKshara Sutra

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

Group-C GugguluTankanaKshara Sutra

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

Group-D Plain Thread

A Wilcoxon signed rank test showed that comparison of before treatment, 1st week, 2nd week, 3rd week, 4th week, 5th week, Plain Sutra over Discharge elicited a statistically in significant change bhagandara at the time points of Before treatment and 1st week (z=-0.0000, p=1.0000), 2nd week (z=-0.0000, p=1.0000), 3rd week (z=-0.000, p=0.0001), 4th week (z=-1.0000, p=0.3170), 5th week (z=-1.7320, p=0.0830). All showed statistically in 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 5th week of treatment, whereas comparison between BT and 1st 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 5th 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, 1st week, 2nd week, 3rd week, 4th week, 5th week, Guggulu Palasha Kshara Sutra over Pain elicited a statistically significant change in bhagandara at the time points of Before treatment and 1st week (z=-4.3590, p=0.00001), 2nd week (z=-4.6250, p=0.00001), 3rd week (z=-4.5900, p=0.00001), 4th week (z=-4.6250, p=0.00001), 5th week (z=-4.5620, p=0.00001). 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, 1st week, 2nd week, 3rd week, 4th week, 5th week, Guggulu Kadali Kshara Sutra over Pain elicited a statistically significant change in bhagandara at the time points of Before treatment and 1st week (z=-4.9140, p=0.00001), 2nd week (z=-4.8380, p=0.00001), 3rd week (z=-4.4760, p=0.00001), 4th week (z=-4.4760, p=0.00001). 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, 1st week, 2nd week, 3rd week, 4th week, 5th week, Guggulu Tankana Kshara Sutra over Pain elicited a statistically significant change in bhagandara at the time points of Before treatment and 2nd week (z=-4.9140, p=0.00001), 3rd week (z=-4.8380, p=0.00001), 4th week (z=-4.4760, p=0.00001). 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+ and K+ salts LoD, Sulphated Ash, also substantiate the effectiveness of Palashamoola Kshara. Clinically the average UCT is also very less (10.49days/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+ and K+ 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 2nd 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+ 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 4th 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 (62.23 days/cm). pH is also 9.23 and with high Na+ salt and no K+ 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 Kshara Sutra. Average UCT was good in Guggulu-Palashamoola Kshara Sutra with rate of 10.49 days/cm. Among four groups in the study Group A (Palashamoola Kshara) Sutra showed significant results in reducing discharge and controlling pain which was substantiated by statistical analysis.

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