A Comparative Clinical Study on the Effect of Tankan Ksharasutra and Apamarga Kaharasutra in the Management of Bhagandara (Fistula in Ano)

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ABSTRACT

Fistula in Ano is very common surgical condition necessitating safe treatment modality as open surgery may result anal incontinence in most of the time. Fistula-in-Ano is one such disease where ideal care delivery is still a challenge. Though in this disease many ksharasutras are tried, Apamarga Ksharasutra is widely being practiced. When we go through the classics, we get reference regarding Tankana grouped into Kshara dravyas. This Tankana is not widely practiced. Apamarga Kshara is very effective but preparation of this Apamarga Kshara is not at all a easy process. It needs burning of lot of Apamarga plants, then process including boiling etc, and at the end we get very little quantity of final product. In the other hand Tankana, as per reference, is also Kshara, cost effective and abundantly available hence this study is planned to evaluate the efficacy of Tankana Ksharasutra in the management of Fistula in Ano which is referred as Bhagandara in Ayurveda.

Key words: Tankana Ksharasutra, Apamarga Ksharasutra, Fistula in Ano, Bhagandara.

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 cutaneous or mucosal. The anal fistula is a single track with an external opening in the skin of perianal 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. In Ayurvedic classics Bhagandara is considered as one of the Asta mahagada i.e., very difficult to cure. The importance of this disease was first realized by Sushruta (800-1000 B.C.), The Father of Indian Surgery, who described it elaborately in his treatise. Charaka (1000 B.C.) has given reference of Bhagandara in Shotha chikitsa chapter and has written very little on this disease. In Rigveda, Bhaga has been described among 12 Adityas. In Aitreya Brahmana, Bhaga means Fortune or Prosperity. Synonym to Indra, Vayu and Saptarishi Vijayarakshita and Srikantadutta had told that three structures namely Bhaga (Vagina), Basti (Urinary bladder) and Guda (Ano-rectal canal) are considered as Bhaga. Bhavamishra has mentioned Bhaga as the synonym for Yoni (vagina) and Mehana (Penis).

Similarly in Modern surgery the
use of ligation and some irritant chemicals like urithane and silver nitrate has been advised but most of the modern surgeons depend on operative treatment for this disease where they follow the radical excision of the track along with the removal of major portion of surrounding tissue. Their patients require hospitalization for a long period and suffer to a great extent by physical and economical loss. Finally it can be concluded that Bhagandara, is a pathological condition which causes tear and pain in the ano-rectal canal, vagina or urinary bladder. [5]

OBJECTIVES:
1) Collection of Apamarga plant is very difficult because it is a seasonal plant and time taking process.
2) Apamarga Kshara Sutra produces much burning pain during primary and successive changes.
3) Considering the above problems we are in need to find out such a drug which is easily available, less irritant and equally effective, among which Tankan is selected in the preparation of Kshara sutra. Tankan has katu rasa, rooksha, teeksna, usna guna, usna veerya, amla vipaka and lekhan, rechana and vranaopak properties. So Tankan is selected in place of Apamarga. [6-8]
4) Evaluation and observation of the effect of Tankan Kshara sutra on Bhagandara and to establish the time taken for execution of track in each group.

MATERIALS AND METHODS
The present study has been undertaken to analyze Tankana Ksharasutra and to compare it with Apamarga Ksharasutra in the management of Bhagandara (Fistula-in-Ano).

Present study was an open clinical study in which 40 patients were selected on the basis of simple random sampling (SRS) procedure & divided in 2 equal groups. It was performed on the patients who attended the outpatient and inpatient Department of Shalya Tantra, S.J.G. Ayurvedic Medical College & Hospital, Gavimath Campus, Koppal- 583231, Karnataka

Group I - 20 Patients were treated with TANKANA KSHARASUTRA.
Group II - 20 Patients were treated with APAMARGA KSHARASUTRA.

MATERIALS
The kshara sutra care unit contains following equipments.
1) Lithotomy table
2) Shadowless light
3) Kshara sutra dressing trolley with following:
   - Drums containing sterile cotton, gauze piece etc
   - Instruments tray having
   - Various sizes of probes
   - Artery forceps
   - Scissors
   - Surgical blade
   - Scalpel
   - Plain forceps
4) Sterile gloves
5) Kshara sutra tray containing kshara sutra tubes
6) Sterilizer
7) Local anesthetic drugs i.e. Xylocaine 2% Jelly
8) Bottles of antiseptic lotion etc
9) Disposable syringes
10) Inj. Xylocaine 2%

PREPARATION OF TANKANA KSHARA SUTRA
A. Materials required for preparation of kshara sutra
   1. Thread(Barbour’s linen no.20)
   2. Kshara sutra cabinet
   3. Tankana kshara(BOREX)
   4. Snuhi (Latex of Euphorbia nerrifolia)
   5. Haridra (Curcuma longa powder)

Tankana Shodhana:
Tankana should be taken in khalva yantra and powdered. Then it should be taken in iron pan and bharjana to be done on mandagni. Bharjana should be continued upto subsiding of hissing sounds, allow for swanga sheeta and store in airtight
Method of preparation of Tankana kshara sutra

Surgical Barbour’s thread No.20 was tied through length on hanger. The freshly collected Snuhiksheer was smeared on thread equally throughout its length and hanger was dried in cabinet. The process repeated for 11 days, on 12\textsuperscript{th} day again, the thread was smeared with Snuhiksheer and then hanger is passed through heap of fine powder of Tankana kshara, and then dried it in cabinet. The same procedure was repeated for 7 days. On 19\textsuperscript{th} day the thread was smeared with Snuhi ksheer and passed through heap of fine powder of Haridra churna and dried in cabinet. The procedure was repeated for 3 days. Last the prepared ksharsutra was kept in ksharsutra cabinet for 1 hr. under U.V. light radiation for sterilization.lastly sealed in glass tube to avoid atmosphere absorption as it is hygroscopic in nature.

Method of preparation of Apamarga kshara sutra: It is done in same method as of preparation of tankan kshara

\textbf{METHODS:} 40 patients of Fistula in ano were selected after being diagnosed and screened by the inclusion & exclusion criteria. Detailed findings were recorded in a specially designed case proforma to analyze the demographic values and the efficacy of Tankan ksharasutra on each individual sign & symptom.

\textbf{Inclusion criteria:}

Criteria for the selection of patient were based on the following.
1. Patients aged between 20- 50
2. Clinical signs and symptoms of all types of Bhagandara

\textbf{Exclusion Criteria:}

Exclusion criteria were based on the following
1. HIV and HBsAg positive patients.
2. Secondary fistula due to
   a. Ulcerative colitis
   b. Crohn’s disease
   c. Tuberculosis
   d. Carcinoma of rectum

\textbf{POORVA KARMA:} Administration of mild laxatives for regularization of bowels, Written Consent, Proper local part preparation, Inj.xylocaine 2\%.0.2cc test dose, Administration of inj.Tetanus toxoid.

\textbf{PRADHANA KARMA}

Group- 1: Application of Tankana-kshara sutra
Group 2: Application of the Apamarga-kshara sutr

\textbf{PASCHAT KARMA}

After Application of Tankana Kshara sutra:-
1. Patients were asked to have sitz bath daily twice from 2\textsuperscript{nd} day onwards.
2. To attend hospital for regular dressing and weekly change of thread.
3. To take leafy vegetables, fruits, buttermilk etc., diet which would be nutritious easily digestible to develop the general condition of the patient and to avoid constipation.
4. To avoid non vegetarian foods and spicy foods.

\textbf{ASSESSMENT CRITERIA}

The clinical assessment of the patient were conducted before & after treatment and accordingly the effectiveness were evaluated as per the assessment criteria fixed. The subjective and objective parameters for assessment are as follows.

\textbf{SUBJECTIVE PARAMETERS:}

\textbf{Pain:} -

Assessed by pain
G\textsubscript{0} – 0 -Absence of pain/no pain.
G\textsubscript{1} –Mild – Pain that can easily be ignored.
G\textsubscript{2} –Moderate – pain that cannot be ignored, interferes with function, and needs treatment from time to time.
G\textsubscript{3} –Severe – That is present most of the time demanding constant attention.

\textbf{Discharge:} -

Assessed by measuring the discharge by a pad of (3x 3) x 1 cm.
G\textsubscript{0} – No discharge
G\textsubscript{1} – mild discharge – single pad is sufficient per day
G\textsubscript{2} - moderate discharge – 2 to 3 pads are necessary per day
G\textsubscript{3} - Profuse discharge – more than three pads are necessary per day.
**Constipation:**
- **G₀** – No constipation
- **G₁** – mild
- **G₂** – moderate
- **G₃** – severe

**OBJECTIVE PARAMETER**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Grade Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>G₃</td>
<td>3</td>
</tr>
<tr>
<td>G₂</td>
<td>2</td>
</tr>
<tr>
<td>G₁</td>
<td>1</td>
</tr>
<tr>
<td>G₀</td>
<td>0</td>
</tr>
</tbody>
</table>

Clinical assessment of result: - Will be as per the following criteria.

Cure – 100% free from cardinal signs and symptoms, these are pain, swelling, discharge, itching, local tenderness, length of tract etc.

Max. Improvement – 75% to 99% improvement of the above mentioned cardinal signs and symptoms.

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Max. Improvement – 75% to 99% improvement of the above mentioned cardinal signs and symptoms.

**STUDY DESIGN:** According to the procedure stated above 40 patients with low anal fistula were selected for the study by random sampling technique method.

Group design:
- Before treatment group1 vs Before treatment group1
- Before treatment group2 vs Before treatment group2 Will be assessed
- After treatment group1 vs After treatment group2 will be compared

**A/T : Showing the effect on Pain, discharge, constipation in comparison Group A & B**

<table>
<thead>
<tr>
<th>After Treatment</th>
<th>GROUP A APAMARGA KSHARASUTRA</th>
<th>GROUP B TANKANAKSHARA</th>
<th>t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Mean ± S.D. ±SE</td>
<td>n</td>
<td>Mean ± S.D. ±SE</td>
<td></td>
</tr>
<tr>
<td>PAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>1.50 ± 0.51 ±0.11</td>
<td>20</td>
<td>0.85 ± 0.49 ±0.11</td>
<td>4.10</td>
</tr>
<tr>
<td>DISCHARGE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>0.85 ± 0.49 ±0.11</td>
<td>20</td>
<td>0.60 ± 0.50 ±0.11</td>
<td>1.59</td>
</tr>
<tr>
<td>CONSTIPATION</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>0.30 ± 0.47 ±0.11</td>
<td>20</td>
<td>0.20 ± 0.52 ±0.12</td>
<td>0.64</td>
</tr>
</tbody>
</table>

1) **PAIN :-** It was observed after treatment that degrees of pain felt by the patients in Tankan kshar Sutra was significantly less in compared to Apamarga Kshara Sutra

2) **DISCHARGE & CONSTIPATION:** Based on mean it was observed after treatment there is no significant difference in discharge & constipation in controlled and treated group.

(Follow up 1)

**Showing the effect on Pain, discharge, constipation in comparison Group A & B**

<table>
<thead>
<tr>
<th>Follow up 1</th>
<th>GROUP A APAMARGA KSHARASUTRA</th>
<th>GROUP B TANKANAKSHARA</th>
<th>T value</th>
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</tr>
</thead>
<tbody>
<tr>
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<td>n</td>
<td>Mean ± S.D. ±SE</td>
<td></td>
</tr>
<tr>
<td>PAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>0.60 ± 0.50 ±0.11</td>
<td>20</td>
<td>0.35 ± 0.49 ±0.11</td>
<td>1.59</td>
</tr>
<tr>
<td>DISCHARGE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>0.30 ± 0.47 ±0.11</td>
<td>20</td>
<td>0.25 ± 0.35 ±0.12</td>
<td>0.31</td>
</tr>
<tr>
<td>CONSTIPATION</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>0.20 ± 0.52 ±0.12</td>
<td>20</td>
<td>0.15 ± 0.37 ±0.08</td>
<td>0.35</td>
</tr>
</tbody>
</table>
• PAIN, DISCHARGE & CONSTIPATION: - Based on mean it was observed after treatment there is no significant difference in pain, discharge & constipation in controlled and treated group.

(Follow up 2)

Showing the effect on Pain, discharge, constipation in comparison Group A & B

<table>
<thead>
<tr>
<th>Follow up 2</th>
<th>Group A: Apamarga Ksharasutra</th>
<th>Group B: Tankan Kshara</th>
<th>t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>Mean ± S.D. ± SE</td>
<td>n</td>
<td>Mean ± S.D ± SE</td>
<td></td>
</tr>
<tr>
<td>PAIN</td>
<td>20 0.10 ± 0.31 ± 0.07</td>
<td>20 0.15 ± 0.37 ± 0.08</td>
<td>-0.47</td>
<td>0.01</td>
</tr>
<tr>
<td>DISCHARGE</td>
<td>20 0.05 ± 0.22 ± 0.05</td>
<td>20 0.05 ± 0.22 ± 0.05</td>
<td>0.00</td>
<td>0.05</td>
</tr>
<tr>
<td>CONSTIPATION</td>
<td>20 0.15 ± 0.49 ± 0.11</td>
<td>20 0.25 ± 0.64 ± 0.14</td>
<td>-0.56</td>
<td>0.01</td>
</tr>
</tbody>
</table>

• PAIN, DISCHARGE & CONSTIPATION: - Based on mean it was observed after treatment there is no significant difference in pain, discharge & constipation in controlled and treated group.

DISCUSSION

The Kshara Sutra therapy was practiced and used more than six decades with great success and practically with almost negligible recurrence in the management of Bhagandara. But some of the problems that we are facing during Collection of Apamarga plant is very difficult because it is a seasonal plant, not available in a single place and time taking process and produces much burning sensation and pain during primary and successive changes. So the present study has been done to propose the efficacy in the field of preparation of Kshara Sutra. Therefore in the present study, the Tankan Kshara has been tried which is known for its katu rasa, rooksha, teekshna, usna Guna and
Lekhana, Rechana, Vranaropaka properties. So, the method of preparation of Tankan Kshara Sutra is same as standard Apamarga Kshara Sutra technique practiced in our department. On the basis of successful management of Fistula-in-ano by Kshara Sutra it has become an accepted technique worldwide since it has been tried at many surgical centers now.

In the present study total cases were divides into 40 cases into 2 groups. First group (Group A) as control group, second group (Group B) as treated group. In Group A, Apamarga Kshara Sutra (Snuhi ksheera, Apamarga Kshara and Haridra churna) were used and in Group B, Tankan Kshara Sutra (Snuhi ksheera, Tankan Kshara and Haridra churna) was used. 20 cases were included in each group, which were treated on the line of previous works and study carried out on various parameters including clinical findings and unit cutting time (in cm/week) to know the exact duration of treatment. The observation of Tankan Kshara Sutra have been made on different parameters of study like age group, sex, indcidence, chronicity of disease, different types of Bhagandara, recurrent cases after surgical operations, number of fistulous openings. The maximum 47% patients were suffering from transspincteric fistula, 25% in interspincteric fistula, 20% in supraspincteric, 5% in subcutaneous and, 3% in extraspincteric fistula. The maximum number of cases (100%) was reported with duration of illness less than 6 month, were no cases noted more than 6 month. In the present study 100% patients were reported as fresh ones (non-operated cases) whereas no patients were operated for fistula previously. Out of 40 cases, maximum 40 (100%) were having single external openings and no patient noted with multiple external openings. It was noticed that commonest position of external opening of fistula at 6 and 7'O clock position, while least number of tracks open at 3, 11, 12'O clock position. Less Pain and Burning sensation: Tankan has Katu, Rooksha, Teekshna, and Ushna properties. So in treated group there were less pain and burning sensation found in comparison to control group and after cut through the wound healing was same in the treated group compared to in control group.

TANKAN KSHARA SUTRA’S MECHANISM OF ACTION:
The mode of action of Kshara Sutra therapy in the management of Bhagandara is as follows:
1. By application of Tankan Kshara Sutra, it does cutting (by tension due to tying) layer by layer and there is continuous drainage of fistulous track which helps in healing.
2. The medicaments which are used to prepare the thread will dissolute the fistulous tissue of the track (Debridement by the Ksharana process) and Tankan stimulate the healthy granulation tissue for healing.
4. Important factor is it maintains continuous aseptic condition of the track.
5. It not only cuts the tissue, but also does continuous drainage of the wound, which enables to lay the track open.

CONCLUSION
Tankan has Katu, Rooksha, Teekshna, and Ushna properties. Patients treated with Tankana Ksharasutra experienced less pain and burning sensation in comparison to control group. After cut through the wound healing was same in the treated group compared to control group. The present study found to be encouraging as the patients treated with tankana ksharasutra reported minimum discomfort as compared to the group who have been treated with Apamarga ksharasutra. The cutting time is longer in Tankanksharasutra group but patients did not feel much discomfort when compared to other group. So this can be best utilized in patients who can’t tolerate pain & burning sensation. The
availability of Tankana is easy, so Tankana ksharasutra can be easily prepared. Further studies can show new vista in the management of Fistula in ano in general and tankana ksharasutra in particular.

REFERENCES


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