EFFECT OF VATA-ARKA KSHAR SUTRA IN THE MANAGEMENT OF BHAGANDARA

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Abstract
Bhagandara (Fistula in ano) is one of the most common and notorious disease among all anorectal disorders. It is a chronic purulent inflammatory condition usually affects perianal region, anal canal and rectum, initially manifested by an abscess followed by continuous or intermittent discharge of pus through the Fistulous tract and leads to an unhealed condition. Bhagandara is recurrent in nature which makes it more and more difficult for treatment. It produces pain and inconveniences in routine life. Improper care and negligence of the disease leads to further aggravation. Now days, management of Bhagandara with Kshar sutra has proved as big revolution, it gained popularity for its minimal invasive and complete cure of the disease. It is the need of time to do further researches to get more efficient kshar sutra. In the present research work Vata-Arka kshar sutra has been prepared for the management of Bhagandara.

Key Words: Bhagandara, Fistula in ano, Vata-Arka kshar sutra

INTRODUCTION
Bhagandara (Fistula in ano) is one of the oldest disease known to the medical science.1 History of medical literature available today very clearly speaks that the disease Fistula in ano affects more reputations of surgeons who deals with it. There is a proverb often used in medical world “The best way to take revenge of a surgeon is to refer him a patient of fistula in ano.” Acharya Sushruta included Bhagandara in Ashta Mahaganda2 (Eight grave diseases) which are very difficult to manage. Today many procedures are used by modern surgeons to manage fistula in ano but inspite of the best possible efforts, the recurrence rate is very high i.e. 20-30%,3 which is a big challenge in front of the medical world. But in Ayurveda a full-fledged management of Bhagandara by the KSHAR SUTRA Therapy has been mentioned since thousand years ago.4 Kshar sutra placed in the fistulous tract is capable of dissolving the tough fibrous tissue and unhealthy granulation tissue and ultimately draining it out creating a healthy base for healing. It’s gradual and sustained chemical action not only removes the debris from the Fistulous tract but also helps in encouraging fresh healthy granulation thereby inducing a long awaited healing pattern in the depth of tissue. So, in present modern era there is a great need to work on Fistula in ano. In fact, whole medical community seems to find a ray of hope in Ayurveda.

Need for Study
Acharya Sushruta has mentioned many drugs from which Kshar can be prepared.5 Among which Arka is one of the drug and no research work has been carried out in combination and with Vata Ksheer and to evaluate its effect in the management of Bhagandara. The standard Snuhi Apamarg kshar sutra is prepared by repeated 21 coatings of Snuhi Ksheer, Apamarg kshar and Haridra Churna.6 But Snuhi Ksheer is not available throughout the year and a particular session is indicated for its collection.7 During and after application of Snuhi Apamarg Kshar Sutra many patients do complain of moderate to severe burning type of pain. Considering the above problems, there is a need to find out such drug which is easily available throughout the year, is less irritant but equally effective.

Aims and Objectives
To evaluate the “Effect of VATA-ARKA Kshar Sutra in the management of Bhagandara” To observe the rate of cutting and healing. To decrease the intensity of pain, burning sensation and itching so that the patient can carry out his daily routine activities comfortably.

MATERIAL AND METHODS
The present clinical trial is designed as a single blind randomized study over the 40 patients suffering from Bhagandara. All the patients have been applied Vata-Arka Kshar Sutra as per classical method.
The Kshar Sutra was changed once in a week till the complete cutting of the tract. There after the patients were followed till complete healing of the track was achieved.

**Preparation of Vata-Arka Kshar Sutra**

The surgical linen thread No.20 was autoclaved and mounted on the hanger. A piece of folded gauze was taken, dipped in Vata Ksheer and the thread was smeared then hangers were placed in the Kshar Sutra cabinet for drying. The second smearing was given on next day only when the previous coating was dried. The threads were smeared 11 times in this manner.

The hanger was placed in the Kshar Sutra cabinet for drying after the each smearing. 12th coating onward was done with Fresh Vata Ksheer mixed with Arka Kshar. The thread was coated 7 times in this way, only when the previous coating got completely dried. The last 3 coatings were given with Vata Ksheer and Haridra Churn. This was done in the same way as the previous coating substituting Haridra churn in the place of Kshar. After finishing total 21 coatings on the threads, this prepared kshar Sutra were dried well in the cabinet and then packed in sterilized Borosilicate glass tube.

**Method of Application of Vata-Arka Kshar Sutra**

First of all, written informed consent of every patient was taken, then the patient was kept in lithotomy position, perianal region was cleaned with antiseptic lotions and the operative area was draped with sterile cut sheets. Local anesthesia (Xylocaine jelly 2%) was applied per anum. When the patient was assured, gloved lubricated index finger was gently introduced into the anal canal and a suitable metallic malleable probe was gently passed with the help of other hand through the external opening of the Fistula. The index finger inside the anus guided the probe. The probe was progressed towards the internal opening in the less resistant area. Forceful probing was not done at all. After passing the internal opening, the tip of the probe came out through the anal canal. Then a suitable length of sterile Vata-Arka Kshar Sutra was taken and threaded into the eye of the probe. Thereafter, the probe was gently pulled out through the anal orifice, to leave Kshar Sutra in situ i.e. in the fistulous tract. The two ends of Kshar Sutra were tied together outside the anal canal. Complete haemostasis was checked by inserting a plain lubricated gauze piece in the anal canal.

**Method of changing Vata-Arka Kshar Sutra**

The Kshar Sutra was changed weekly after primary threading. It was done in lithotomy position, under aseptic precautions and under the effect of anaesthetic lubricant. The anaesthetic lubricant (Xylocaine 2% gel) was applied in the tract through external opening as well as anal canal. When the anaesthetic effect was achieved, a new Vata-Arka Kshar Sutra of adequate length was taken and its one end was tied to the previous Kshar Sutra between the external opening and the knot. A clamp with artery forceps was made on the previous Kshar Sutra between its knot and anus. Then the previous Kshar Sutra was cut between its knot and the clamp. Holding the cut end of the previous Kshar Sutra with the applied artery forceps, it was taken out from tract through the internal opening and the new Kshar Sutra got introduced in the tract. Then the ends of newly applied Kshar Sutra were tied to each other, making the knot close to skin. The knot of the new Vata-Arka Kshar Sutra was secured. Antiseptic dressing was applied. The measurement of the previous Kshar Sutra was recorded in the folder proforma. This procedure was repeated every week until cutting and complete healing of the track and finally ‘cut through’ of the Kshar Sutra automatically. This method of changing the Kshar Sutra is known as Rail-road technique.**

**Inclusion Criteria**

- Clinical signs and symptoms of all types of Bhagandara; fresh cases as well as previously operated elsewhere.
- Any age group of either sex.
- Bhagandara of all type with Parikartika (Fistula in ano with Fissure in ano)
- Bhagandara with Niyamnitra Madhumeha (Fistula in ano with controlled Diabetes mellitus)
- Bhagandara with Haemorrhoid

**Exclusion Criteria**

- HIV, HCV and HBsAg positive patients.
- Secondary Fistula due to -
  -Ulcerative colitis
  -Crohn’s disease
  -Tuberculosis
  -Carcinoma of rectum

**Assessment Criteria**

**Subjective Parameters**

- Pain
- Burning sensation
- Itching
- Discharge
- Inflammation

Signs & symptoms found were graded on the basis of scoring system prepared for that by Paul O.
These are as follows-

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>No symptom</td>
<td>0</td>
</tr>
<tr>
<td>Mild symptoms</td>
<td>+</td>
</tr>
<tr>
<td>Moderate symptoms</td>
<td>++</td>
</tr>
<tr>
<td>Severe symptoms</td>
<td>+++</td>
</tr>
<tr>
<td>Very severe symptoms with marked disturbance in daily routine of the patient</td>
<td>++++</td>
</tr>
</tbody>
</table>

Objective parameters

Unit Cutting Time = Total No. of days taken to cut through the tract

Time taken (in days) to cut one centimeter of the fistulous tract with simultaneous healing is known as unit cutting time (UCT).

Duration of the treatment

All the cases were treated till the Vata-Arka Kshar Sutra gets ‘cut through’ the tract completely.

Follow up period

- Follow up was done weekly once for one month then monthly once for two months after the completion of treatment.

For each follow-up visit, the patients were examined for any recurrence of disease or any associated lesion of the ano-rectal region.

Investigations

Following investigations were done before starting any procedure

Blood
- Hemoglobin, T.L.C, D.L.C, ESR
- FBS and PPBS
- HIV, HBsAg, HCV

Urine
- Routine and microscopic

Stool
- Ova and cyst

Other investigations (if required)

- X Ray Chest P.A. view
- ECG
- Fistulogram
- USG Abdomen and pelvis
- KFT
- LFT
- Pus culture and sensitivity
- Biopsy of the tissue of the tract

Observation & Results

- The study analysis revealed that the incidence of Bhagandara is commonly seen in age group of 25-50 years (32 cases - 80%) with peak incidence in the age group of 31-40 years (15 cases - 37.5%).
- The sex incidence shows that maximum patients were males (36 cases - 90%) and minimum were females (4 cases - 10%).
- In relation to religion, 33 cases (82.5%) were Hindus, 7 cases (17.5%) were Muslim. Analysis of socio-economic status of 40 cases of Bhagandara showed that the majority of the patients belonged to lower middle and middle class i.e. 47.5% and 35% respectively, whereas 17.5% patients were from poor section of the society and none of the patient were reported from high socio-economic status.
- Analysis of habitat of 40 cases of Bhagandara, 21 (52.5%) patients reported from urban area, while 19 (47.5%) patients were from rural area.
- In analysis 33 patients (i.e.82.5%) were found married during study and rest 7 (i.e. 17.5%) unmarried patients.
- Analysis of nature of work of 40 cases of Bhagandara showed that the majority of the patients 25 (62.5%) belonged to strenuous worker, 9 (22.5%) patients were found sedentary life style and 6 (15%) patients were moderate worker.
- In relation to nature of diet it was observed that the 57.5% patients were consuming mixed diet whereas, 42.5% patients were on Vegetarian diet.
- Incidence of occupational status revealed that maximum 37.5% patients were in Service and minimum 2.5% were retired.
- The maximum number of patients were found with KruraKoshtha (52.5%), 25% with MriduKoshtha, and 22.5% patients were reported of MadhyamKoshtha.
- The maximum numbers i.e. 25 patients (62.5%) were found with constipation, 12 patients (30%) were with normal bowel habit, 3 patients (7.5%) had mucus discharge with faeces.
- In analysis 42.5% patients were smokers, 42.5% patients were found non-addicted, 12.5% patients were alcoholic, and 2.5% patients was addicted by the habit of tobacco chewing.
- In present study none of the patient (00%) was found with family history of Bhagandara.
- This study revealed that 37.5% patients belonged to Vaat - pithajaPrakriti, 35% patients were of Pitta - kaphajaPrakriti and 27.5% patients belonged to vaat – Kaphaja Prakriti.
- Out of 40 cases, maximum numbers of patients i.e. 50% were reported under Parisravi Bhagandara, 27.5% were of Ushtra-greeva, 10% of Shambukavarta Bhagandara and 7.5% were of Unmargi and 5% were of Shataponaka Bhagandara.
During diagnosis of 40 patients of Fistula-in-ano, the maximum 22 patients (55%) were observed under Low anal type, 9 patients (22.5%) under High anal type, 9 patients (22.5%) under Sub cutaneous, none of the patient under Sub mucous group and in Pelvi -rectal group were observed.

Out of 40 patients, it was observed that 47.5% patients were afflicted from less than 1 year. 30% patients were suffering from 1-2 years duration and 22.5% patients were suffering from more than 2 years.

In analysis out of 40 cases, 7.5% patients were suffering from Diabetes mellitus.

In analysis of 40 patients of Bhagandara, 28 patients (70%) having no associated lesion 6 patients (15%) were found with external haemorrhoids, 4 patients (10%) were found with internal haemorrhoids and 2 patients (5%) were found associated with anal fissure.

In analysis 92.5% patients were reported fresh cases i.e. non-operated previously and 7.5% patients were reported as operated cases.

Among all recurrent cases, 66.67% patients had undergone the operation only once, 33.33% patients were operated more than one times.

Out of 40 patients, for maximum cases i.e. 39 cases (97.5%) primary threading was done under local anaesthesia, whereas 01 case (2.5%) was conducted under spinal anaesthesia.

Note – Only Xylocaine jelly was used as local anaesthesia

in 37 cases and infiltration by injectable local anaesthesia was used in 2 cases.

Analysis of 40 cases was done in terms of number of external fistulous openings. 31 cases (77.5%) were having single external fistulous opening, while 08 cases (20%) were having two openings and 01 case (2.5%) had more than three openings.

Analysis shows that commonest site of external fistulous opening was at 7 ‘O’ clock position (18.86%), and minimum were found at 4 ‘O’ clock & 12 ‘O’ clock position. i.e. 1.88% each.

Out of 40 cases external opening was found in 26 patients (65%) it was found in lower half, in 11 patients (27.5%) it was found in upper half and in 3 patients (7.5%) it was found in both upper and lower half position.

The maximum cases i.e. 25 cases (62.5%) were having initial length of the thread, (changed for the first time) between 5.10 to 10 cm, 9 cases (22.5%) were having initial length in the range of >10 cm and 6 cases (15%) in the range of 0 to 5cm.

Maximum number of cases i.e. 20 cases (50%) were recorded having curved tract, 16 cases (40%) were recorded having straight tract and 4 cases (10%) were noted having horse-shoe shaped tract.

In analysis of Pain table shows 19 patients (47.5%) were found in grade-3, 12 patient (30%) were found in grade-4, 8 patients (20%) were found in grade-2, 1 patient (2.5%) was found in grade-1 and whereas no case was found in grade-0 before treatment in analysis of symptom Pain.

14 cases (35%) were recorded having grade-3, 11 cases (27.5%) were recorded in grade-2, 8 cases (20%) were recorded in grade-4, 7 cases (17.5%) were recorded in grade-1 and whereas no case was found in grade-0 before treatment in analysis of symptom Burning sensation.

In analysis maximum number of cases i.e. 17 cases (42.5%) were recorded having grade-2, 13 cases (32.5%) were recorded in grade-4, 5 cases (12.5%) were recorded in grade-3, 5 cases (12.5%) in grade-1 whereas no case was found in grade-0 before treatment in analysis of symptom Itching.

Maximum number of cases i.e. 16 cases (40%) were recorded having grade-2; 13 cases (32.5%) were recorded in grade-3, 7 cases (17.5%) were recorded in grade-4 & 3 cases (10%) were recorded in grade-1 whereas no case was found in grade-0 before treatment in analysis of symptom Discharge.

In analysis of Inflammation before treatment table shows 17 patients (42.5%) each were found in grade-3 & grade 4, 6 patients (15%) were found in grade-2 and no patients were recorded in grade-0 and grade 1 before treatment in analysis of symptom Inflammation.

Effect of therapy on subjective parameter Effect on ‘Pain’

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Mean B.T.</th>
<th>X</th>
<th>% relief</th>
<th>S.D.</th>
<th>S.E.</th>
<th>t-value</th>
<th>p-value</th>
<th>Statistical Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 1 month</td>
<td>3.05</td>
<td>1.75</td>
<td>1.27</td>
<td>41.64</td>
<td>0.69</td>
<td>0.10</td>
<td>11.59</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>After 2 month</td>
<td>3.05</td>
<td>0.90</td>
<td>2.10</td>
<td>68.85</td>
<td>0.83</td>
<td>0.13</td>
<td>15.94</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>After 3 month</td>
<td>3.05</td>
<td>0.32</td>
<td>2.75</td>
<td>89.34</td>
<td>0.96</td>
<td>0.15</td>
<td>17.80</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>After completion</td>
<td>3.05</td>
<td>0.00</td>
<td>3.05</td>
<td>100.00</td>
<td>0.78</td>
<td>0.12</td>
<td>24.67</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

The initial mean score of Pain observed was 3.05, which was brought down to 1.75 after 1 month,
Effect on ‘Discharge’

The mean score of Discharge was 2.55 before treatment which was regressed to 1.57 after 1 month, 0.80 after 2 months, 0.25 after 3 months and 0 after completion of treatment giving 100% relief in symptom.

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Mean B.T. A.T. X</th>
<th>% relief</th>
<th>S.D.</th>
<th>S.E.</th>
<th>t-value value</th>
<th>Statistical Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 1 month</td>
<td>2.55 1.52 1.02</td>
<td>40.19 0.86 0.13</td>
<td>7.51 &lt;</td>
<td>0.001</td>
<td>HS</td>
<td></td>
</tr>
<tr>
<td>After 2 month</td>
<td>2.55 0.82 1.78</td>
<td>69.95 0.88 0.14</td>
<td>12.73 &lt;</td>
<td>0.001</td>
<td>HS</td>
<td></td>
</tr>
<tr>
<td>After 3 month</td>
<td>2.55 0.35 2.20</td>
<td>86.27 0.95 0.15</td>
<td>14.57 &lt;</td>
<td>0.001</td>
<td>HS</td>
<td></td>
</tr>
<tr>
<td>After completion</td>
<td>2.55 0.0 2.55 100</td>
<td>0.92 0.14 17.40 &lt;</td>
<td>0.001</td>
<td>HS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This result shows statistically highly significant at p < 0.001.

Effect on ‘Burning sensation’

Subjective parameter Itching found as mean score before treatment was 2.65 which became down to 1.57 after 1 month, 1.27 after 2 month, 0.47 after 3 month and 0 after completion of treatment giving 100% relief.

The result shows that treatment was statistically highly significant at p < 0.001.

Effect on ‘Itching’

Effect on ‘Discharge’

In analysis it is found that minimum U.C.T. 8.61 days/cm. in group of 5.10-10 cm. and it was maximum in group of > 10 cm. i.e. 9.97 days/cm.

Mean U.C.T. is 9.30 days/cm.

Effect on ‘Unit Cutting Time’

Effect on ‘Inflammation’

This result shows statistically highly significant at p < 0.001.
DISCUSSION

In this study, which consists of 40 patients in single group, Vata-Arka Kshar Sutra was ligated on 40 cases, which were treated after proper examination and investigations. The observations were made on different parameters of study like age group, sex incidence, chronicity of disease, different Prakriti of patients, different types of Bhagandara, recurrent cases after surgical operations, number of fistulous openings and clock wise position.

A special proforma was prepared to assess the effects of Vata-Arka Kshar Sutra. Total six criteria were analyzed statistically to know the effects of Vata-Arka Kshar Sutra. Those were Unit Cutting Time (UCT), Pain, Burning sensation, Discharge, Itching and Inflammation. Unit Cutting time was measured in days/cm. Pain, Burning sensation, Discharge, Itching and Inflammation were measured in 5 grades each, from grade 0 to 4.

• The mean U.C.T. of overall 40 patients is 8.97 days/cm.
• Presence of infection and inflammation delays the Unit Cutting Time.
• U.C.T. was high in cases of fibrosis / tough scar tissue which were generally created after the previous operation.
• U.C.T. was more (10.12 days/cm.) in the cases of fibrosis and recurrent cases of fistula as the tough scar of the previous operation is likely to offer resistance in the process of cutting and delay the process of healing as well.
• All patients completed treatment duration without complains of any complications like irritation, post ligation burning sensation etc. in post-operative period.

Overall Effect of Vata-Arka Kshar Sutra therapy

➢ Total 40 patients were treated in this present study out of which 100% were Cured Completely.
➢ None of the patients remained unchanged/ uncured in treatment group.
➢ In none case, any sign and symptom of the recurrence & incontinence was ever found out during study period or follow up.
➢ No adverse reaction of any drugs/procedure was observed during the course of study and post treatment follow up.

CONCLUSION

Kshar Sutra in ano rectal disorders has shown miraculous results and now it’s a Precious gem in the crown of Shalya Tantra. We have no earlier reference regarding utility of Vata Ksheer and Arka Kshar in preparation of kshar sutra. Thus it can be concluded that Vata – Arka Kshar Sutra can be advised for successful treatment in patients of Bhagandara.

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