Efficacy of Shallaki Based Ksharasootra with Partial Fistulectomy in Bhagandara (Fistula-in-ano) – A Pilot Study

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INTRODUCTION

- In Ayurveda, Bhagandara is considered under eight grave diseases.
- Acharya Sushruta has mentioned that all types of Bhagandara are difficult to treat.
- It is also known for its significant risk of recurrence (0.7–26.5%) and a high risk of impaired continence (5–40%) in modern surgery.*
- In many of the cases, it reoccurs after surgical procedure like fistulectomy / fistulotomy.

PREVALENCE OF FISTULA-IN-ANO

- 8.6 cases per 1,00,000 Population.
- In Men: 12.3 cases per 1,00,000 Population.
- In Women: 5.6 cases per 1,00,000 Population.
- Male : Female = 1.8:1
- Mean age of Patient : 38.3 years

Acharya Sushruta mentioned that *Kshara* is the best among all Surgical and Para-surgical measures.

He had mentioned different types of *Kshara* and among all *Kshara*, *Apamarga Kshara* is generally used to prepare *Ksharasootra* which is widely used for the treatment of *Bhagandara*.

Now a days in some research institute different *Ksharasootra* are being tried like *Guggulu* based, *Udumbar ksheera* based, etc
Shallaki is a herb, used as medicine in India for the treatment of variety of diseases and its experimental study show anti inflammatory, anti fungal and analgesic activity.

Shallaki Niryas also easy to procure and preserve as compare to Snuhi Ksheera.
Shallaki Niryas based *Ksharasootra* is selected first time in this study (As per available records) to compare the effectiveness as well as to find out another alternative of Standarda *Apamarga* based *Ksharasootra*.

In this study the innovative *Shallaki Niryas* based *Ksharasootra* was used in fistula patients along with Partial Fistulectomy to minimize the duration of treatment.
MATERIALS & METHODS

• In this study total 15 patients of Bhagandara were selected from OPD & IPD of Shalya Tantra, IPGT & RA, Jamnagar, irrespective of sex, religion and occupation.

• Patients were treated with Partial Fistulectomy followed by Shallaki Niryas based Ksharasootra application in remaining part of the tract under spinal anaesthesia after considering required investigations and physical fitness.
**INCLUSION & EXCLUSION CRITERIA**

**INCLUSION**
- Age between 20 to 60 years
- Vātaja, Pittaja, Kaphaja, Vāta-Pittaja, Vāta-Kaphaja and Arśo Bhagandara (Kapha-Pittaja) (Piles fistula)
- Bhagandara with Parikartikā
- Fistula in ano with controlled TB, DM, Hypertension

**EXCLUSION**
- Age <20 or >60 years
- Sannipātaja and Āgantuja Bhagandara
- Fistula other than anorectal
- Fistula associated with uncontrolled TB, DM, Hypertension or Osteomyelitis, Venereal Disease, Pregnancy, Chronic or acute ulcerative colitis, Crohn’s disease
• Shallaki based *Ksharasootra* was prepared with *Shallaki Niryas* (*Boswellia serrata* Roxb), *Apamarga Kshara* (Ash of *Achyranthus aspera* Linn.) and *Haridra* powder (*Curcuma longa* Linn.) as per the guidelines of Ayurvedic Pharmacopeia of India (API). Here *Snuhi Ksheera* is replaced with *Shallaki Niryas*.

• *Shallaki* based *Ksharasootra* was prepared in the department of Shalya Tantra, IPGT & RA, Jamnagar.
• *Avagaha swedana* (hot sitz bath) with *Panchavalkala* decoction was advised for two times daily.

• Jatyadi oil 10ml per rectal twice in a day.

• Wound dressing with *Shatadhausta ghrita* was done daily.

• *Eranda Bhrishta Haritaki* powder 5gm with luke warm water at bed time.

• *Ksharasootra* was changed with a new one by rail-road technique on weekly interval and the length of thread as well as the condition of wound was noted to assess the unit cutting time (UCT).
Informed written consent was taken.
The patient was kept NBM for 6 hours before the procedure.
The peri anal area was prepared by shaving.
Inj. Tetanus Toxoid 0.5ml IM was given.
Inj. Xylocaine sensitivity test intradermal was done.
Proctolysis enema was given in the early morning on the day of procedure.
Operative Procedure

- Low spinal anesthesia was given.
- In lithotomy position painting & draping was done.
- After cleaning and painting of the parts, Digital and Proctoscopic examinations were carried out.
- Then probing was done by lubricant probe.
- Partially tract was excised in wide tract or multi-branching tract.
- *Ksharasootra* was applied in fistulous tract.
POST-OPERATIVE PROCEDURE

On the day of operation:

- Observed all vital signs till the complete recovery take place.
- Patient was kept nil orally for 6 hours.
- I.V. fluids, appropriate analgesic and antibiotic has been prescribed for initial three days or as per the requirement.
Subjective criteria:-

- Pain
- Swelling
- Discharge
- Itching

Objective criteria:-

- Unit Cutting Time (U.C.T.)
  - = Total time taken to cut through the tract
  - Initial length of the *Ksharasootra*
  - = _____________ Days/cm
All patients were Male and from Hindu religion.

93.33% patients had Pidika in perianal region, 100% had complains of Srava, 86.66% of patients had complain of Vedna and only 26.66% patients had complain of Kandu.

Two patients having past history of surgery for Fistula-in-ano and 1 patient has history of hypertension. No any other illness were found in patients.
Position of external openings

- 1 O'clock: 20%
- 4 O'clock: 15%
- 5 O'clock: 15%
- 6 O'clock: 5%
- 7 O'clock: 25%
- 8 O'clock: 15%
- 11 O'clock: 10%

Series 1
All patients have low anal type of Fistula-in ano.
## RESULTS

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Mean±S.E.M</th>
<th>MEAN DIFF</th>
<th>S.D</th>
<th>SEM</th>
<th>P</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B.T</td>
<td>A.T</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>1.40±0.163</td>
<td>0.00±0.00</td>
<td>1.40</td>
<td>0.632</td>
<td>0.163</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge</td>
<td>1.33±0.159</td>
<td>0.00±0.00</td>
<td>1.33</td>
<td>0.617</td>
<td>0.159</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Itching</td>
<td>0.40±0.190</td>
<td>0.00±0.00</td>
<td>0.40</td>
<td>0.736</td>
<td>0.190</td>
<td>0.125</td>
</tr>
<tr>
<td>Swelling</td>
<td>1.20±0.144</td>
<td>0.06±0.06</td>
<td>1.13</td>
<td>0.516</td>
<td>0.133</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
RESULTS

UNIT CUTTING TIME

n = 15

Average UCT : 8.43 days/c.m.

Average UCT : -8.43 days/c.m.
<table>
<thead>
<tr>
<th>Required time for complete remission (Approx.)</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>One and half month</td>
<td>7 Patients</td>
</tr>
<tr>
<td>Two months</td>
<td>3 Patients</td>
</tr>
<tr>
<td>Four months</td>
<td>3 Patients</td>
</tr>
<tr>
<td>Five months</td>
<td>3 patients</td>
</tr>
</tbody>
</table>

All patients cured completely and during follow up as per protocol after 1 month no any recurrence was there. I have also made telephonic call to all patients after 6 month and there was not found any recurrence.
Discussion

• *Ksharasootra* application has been proven for effective and successful management of *Bhagandara*.

• The ICMR (Indian Council of Medical Research) has been studied *Ksharasootra* in fistula-in-ano and concluded better than conventional fistulectomy / fistulotomy with minimum recurrence rate.
The use of Shallaki has been reported in some chronic inflammatory diseases like rheumatoid arthritis, bronchial asthma, osteoarthritis, ulcerative colitis and Crohn's disease which also shows its anti-inflammatory and analgesic property.

Shallaki having non-irritant, strong binding property and reduces the unnecessary labour and time required in preparing of Ksharasootra.
• Shallaki based Ksharasootra was appeared tougher as compared to Standard Apamarga Ksharasootra. So more toughness of Ksharasootra which enhance cutting power.

• Even after that Shallaki based Ksharasootra have shown less burning pain as compare to Snuhi based Ksharasootra due to anti-inflammatory and less irritant property of Shallaki.
• Boswellic Acids decrease the pro-inflammatory 5-lipoxygenase products including leukotriene B4 (LTB-4) levels. As a result, the inflammation response is dampened, thus allowing for quicker healing.

• Boswellic acid also helps in getting rid of foul odour and eliminating any pest in the surroundings which made wound healing faster.
• The applied Kshara on thread acts as anti-inflammatory and anti-microbial activity. Alkaline nature of Kshara slough out unhealthy tissue and facilitates Shodhana and Ropana (cutting as well as healing).

• The cutting is also assumed by mechanical pressure of tight Ksharasootra.

• Haridra having Lekhaniya, Kushthaghna, and Vishaghna properties which shows its anti-septic and anti-toxic activity. It diminishes reaction of caustics and make healthy environs for healing of wound.
• Partial Fistulectomy along with *Ksharasootra* was very useful because its take out long and multi-branches of fistula with fibrosed part of tract which reduced duration of treatment. So excision of fibrosed part of fistula ultimately decreased UCT.

• Partial fistulectomy with fistulous wound helps to drainage of pus from remaining tract and healed early.

• *Panchavalkal* decoction has cleaning and wound healing properties so it helped to kept wound clean and promoted healing.
• *Ghrita* (Clarified butter) is known for an excellent *Sneha Dravyas* due to its *Samskaranuvartana* (as like catalyst to increase the potency of another drug) and *Yogvahi* (synergetic effect) properties.

• *Ghrita* has been well emphasised for its wound healing activity due to presence of *Vitamin - A* which accelerates tissue healing process, epithelialization and skin texture improvement.

• *Jatyaditaila* is a good *Shodhana* and *Ropana* formulation recommended for the dressing of wounds. It acts as a soothing agent for smooth evacuation of faeces as well as it takes care of partially excised wound of fistulous tract.
**SHALLAKI BASED KŚĀRA-SŪTRA - MODE OF ACTION**

**Shallaki Niryas**
- Kaşāya, Tikta Rasa, Rukṣa Laghu Guṇa, Uṣṇa Vīrya
- Vraṇaśodhana, Klēdaśoṣaṇa, Śothahara

**Apāmārga Kṣāra**
- Laghu, Rukṣaguṇa Kaşāya, Kaṭu, Uṣṇa Kaṭu Vipāka
- Chedana, Bhedana, Lekhana, Ropaṇa Tridoṣaghana

**Haridrā powder**
- Laghu, Rukṣaguṇa Kaṭu Tikta Rasa, Uṣṇa Vīrya, Kaṭu Vipāka
- Rakta Śodhaka, Śothahara, Vraṇa Ropaka, Kṛmighna

*Kśāra-Sūtra* exert pressure inside the tract for cutting and debriding of all necrotic tissue, epithelial lining, fibrous tissue and facilitate for free drainage of pus and inhibit growing of pathogens which enhance to healing.

So *Kśāra-Sūtra* acts by gradual chemical excision of the Bhagandara (fistula-in-ano) with simultaneous healing.
CONCLUSION

• This pilot study demonstrated the utility of Partial Fistulectomy with Shallaki based Ksharasootra in management of Bhagandara (Fistula-in-ano) in which have a lesser irritation, lesser amount of pain and less time is required to heal fistulous tract completely.

• There was no Adverse Drug Reaction (ADR) reported during the course of study and follow up period.

• No Recurrence was observed in any patient during follow up.
Case no. 1
Case no. 2