

Pilot Study on Partial Fistulectomy and *Shallaki* Based *Ksharasootra* in the Management of *Bhagandara* (Fistula-In-Ano)

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Abstract

Introduction: In Ayurveda, *Bhagandara* (Fistula-in-ano) is considered under the heading of *Ashtomahagada* (eight major diseases) due to its notorious nature. *Ksharasootra* is a medicated thread, indicated in ano-rectal disorders, particularly for management of *Bhagandara* (Fistula-in-ano). Now a days in some research institute different *Ksharasootra* are being tried like *Guggulu* based, *Udumbar ksheera* based, etc. In this study *Shallaki* based *Ksharasootra* was tried in the management of *Bhagandara*. It was prepared with *Shallaki Niryas* (*Boswellia serrata* Roxb), *Apamarga Kshara* (alkali of *Achyranthus aspera* Linn.) and *Haridra* powder (*Curcuma longa* Linn.) as per the guidelines of Ayurvedic Pharmacopeia of India (API). **Methodology:** 15 patients of *Bhagandara* were enrolled from OPD of *Shalya Tantra* and partial fistulectomy followed by *Shallaki Niryas* based *Ksharasootra* application in remaining part of the tract was done under spinal anaesthesia. From next day of surgery sitz bath with *Panchavalkala Kwatha*, dressing with *Shatadhauta Ghrita* and per rectal instillation of 10 ml *Jatyaditaila* was done daily. *Ksharasootra* was changed with a new one by rail-road technique on weekly interval. Length of thread as well as the condition of wound was noted to assess the unit cutting time (UCT) and healing till the complete healing of fistulous tract. **Result:** After 5 days of operation, healthy granulation tissue was seen in the fistulectomy wound. Average unit cutting time (UCT) of fistulous tract was 8.43 days / cm. complete cutting and healing of fistulous tract was observed within one and half month in 7 patients. In 3 patients time required for complete healing was 2 months while in 2 patients it was 4 months and in 3 patients it was 5 months. **Discussion:** Management of a long fistulous track by *Ksharasootra* is very tedious job. In this study fistulous tract was partially excised so early healing of fistulous tract was observed. *Shallaki* based *Ksharasootra* have shown less burning pain during the course of treatment.. The cutting and healing of fistulous tract was early as compare to simple *Ksharasootra* application. **Conclusion:** This pilot study demonstrated that early healing with mild pain by partial fistulectomy and *Shallaki* based *Ksharasootra* in management of *Bhagandara* (Fistula-in-ano).

Keywords: *Bhagandara*; Fistula-in-ano; *Ksharasootra*; Partial Fistulectomy; *Shallaki*.

Introduction

In Ayurveda, *Bhagandara* (Fistula-in-ano) is considered under the heading of eight major diseases (*Ashtomahagada*) due to its notorious nature [1]. *Pakva Avastha* of *Shoph* within the vicinity of two *Angula* of *Guda pradesha*, leads to *Darana* in *Bhaga*, *Guda* and *Vasti* then it is called as *Bhagandara* [2]. As per modern

science fistula in ano is a track lined by granulation tissue and communicating two epithelial lined surfaces which opens deeply in the anal canal or rectum and superficially on the skin around the anus [3]. Anal fistula is part of the spectrum of peri-anal sepsis. It is generally developed after crypto glandular infection and anorectal abscess [4]. Anal fistula causes various symptoms including pain, swelling, discharge, itching and social embarrassment [5]. In surgery fistulectomy, fistulotomy, new techniques like fibrin glue, fistula plug, Video Assisted Anal Fistula Treatment (VAAFT) and Ligation of Inter-sphincteric Fistula Tract (LIFT) are available with their own limitations [6]. Surgery for fistula has always put fear of recurrence and complications like incontinence in mind of patient. *Sushruta*, the father of surgery, described uses of *Kshara* (alkaline ash) *Bhagandara*

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(Fistula-in-ano) in in [7]. Later on *Chakrapani* and *Bhavamishra* detailed the preparation and application of *Ksharasootra* in *Bhagandara* (Fistula-in-ano) [8,9].

In this study, *Shallaki* based *Ksharasootra* was prepared as per API guidelines. *Snuhi* (latex of *Euphorbia nerifolia*) is replaced with *Shallaki* and rest of the ingredients and procedure was followed as per preparation of standard *Ksharasootra*. In this pilot study 15 patient of *Bhagandara* (Fistula-in ano) were enrolled and treated with Partial Fistulectomy along with *Shallaki* based *Ksharasootra* application.

Methodology

15 patients of *Bhagandara* were enrolled from OPD of the dept. of *Shalya Tantra*, IPGT & RA, and admitted in *Shalya* ward for surgical intervention. The included patients were of fistula- in-ano long track with single branch or multiple branches. So in some of patients Trans Rectal Ultrasound was done to confirm the branch/tracts. *Bhagandara* (Fistula-in-ano) associated with conditions like uncontrolled tuberculosis, uncontrolled hypertension, uncontrolled diabetes mellitus, osteomyelitis, chronic or acute ulcerative colitis, crohn's disease were excluded. Carcinoma of ano-rectum & other malignancy, venereal diseases, HBsAg positive HIV positive cases and pregnant patients were excluded from the study. *Shallaki* based *Ksharasootra* was prepared in the department of *Shalya Tantra*, IPGT & RA, Jamnagar.

Pre-Operative

Written inform consent of patient was taken. Peri-anal part was prepared by doing necessary shaving. Proctolysis enema was given in early morning before operation. Injection T.T. 0.5cc IM and inj. Xylocaine sensitivity test was done.

Operative Procedure

In O.T., patient was kept in lithotomy position on O.T. table after giving spinal anaesthesia. Peri-anal area was painted with Betadine solution and sterile cut sheet was draped. Probing was done from external opening and internal opening was revealed at anal canal. The excision of the fistulous tract was done from external opening to the level of anal sphincter with help of electric cautery. After that *Shallaki* based *Ksharasootra* was applied in remaining part of the tract (Figure 1). After proper haemostasis wound was packed with betadine gauze and applied T-Bandage.

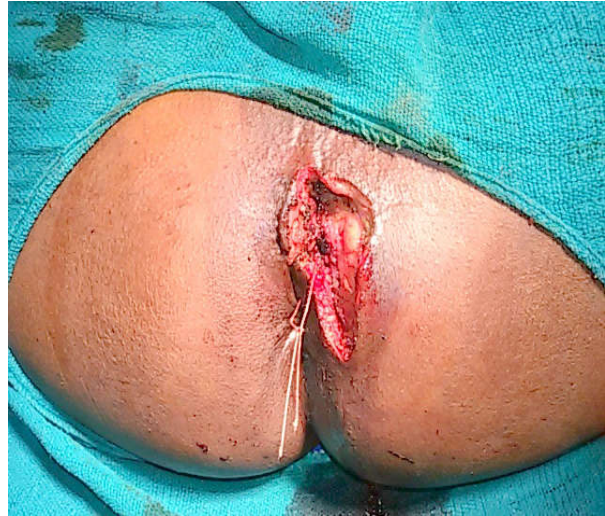


Fig. 1: Partial fistulectomy and Shallaki based Ksharasutra in situ.

Post-Operative

From next morning, patients were advised to Sitz bath with *Panchavalkala* decoction and then antiseptic dressing with *Shatadhauta ghrita* and *Matra Basti* with 10ml *Jatyadi Taila* was given was done daily. 5gm *Eranda Bhrishta Haritaki* (*Terminalia chebula*) powder with luke warm water at bed time was prescribed to relieve constipation. *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) and healing till the complete healing of fistulous tract (Figure 2, 3).



Fig. 2: Status of wound after one month



Fig. 3: Status of wound after one and half month

Duration of Therapy

The *Ksharasootra* application is one stage of operation but the total duration of treatment was different as the length of tract was varied from patient to patient. So therapy was continued till the fistulous tract got cut through with the *Ksharasootra*.



Fig. 4: Complete healed fistula wound after two month

Follow up

After cut through of the fistulous tract, patients were called for follow up examination at 7th, 15th days and one month (Figure 4).

Dietary Regimen

Diets like green vegetables, fruits, plenty of liquids were advised. Patient was advised not to consume non-vegetarian, spicy and oily food, junk foods, tobacco and alcohol. Patient was recommended to avoid long sitting and riding/travelling during the treatment and three month after healing of tract.

Criteria for Assessment

The relief in symptoms like pain, discharge, itching and swelling were assessed adopting the following scoring pattern/ gradation (Table 1).

Table 1: Subjective parameters: Pain:

Grade = 0	No Pain
Grade = 1	Mild Pain, can be tolerated without any medication
Grade = 2	Moderate Pain, requiring oral analgesics
Grade = 3	Severe Pain, not reliving with oral analgesics and required injection
Discharge:	
Grade = 0	No Discharge
Grade = 1	Mild Discharge (wets 1 ×1 cm gauze piece)
Grade = 2	Moderate Discharge (wets 2×2 cm gauze piece)
Grade = 3	Profuse Discharge (wets more than 2×2 cm gauze piece)
Itching:	
Grade = 0	No Itching
Grade = 1	Negligible Itching with 10-12 hrs gap
Grade = 2	Occasional Itching with 4-6 hours gap
Grade = 3	Frequent Itching with 2-3 hours gap
Swelling:	
Grade = 0	No Swelling
Grade = 1	Swelling within 1 × 1 cm
Grade = 2	Swelling within 2 × 2cm
Grade = 3	Swelling within 3× 3 cm

Objective Parameter

Unit Cutting Time (UCT)

$$UCT = \frac{\text{Total number of days required for complete cutting of tract}}{\text{Initial length of thread (tract) in cm}} = \text{days/cm}$$

Overall Effects of Therapy

The overall effect was assessed on the basis of relief in signs and symptoms as follow.

- Complete remission: 91-100% relief
- Marked improvement: 76- 90 % relief
- Moderate improvement: 51- 75 % relief
- Mild improvement: 26- 50% relief
- Unchanged: <25% relief

Statistical Analysis

Wilcoxon signed Rank Test was applied to evaluate effect of therapy for subjective criteria.

Observations and Result

All the 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. Maximum external openings were found 26.66 % in 7 O'clock position. 20% external openings were found at 1 O'clock position while 13.33 % external openings were found at 4, 5, 8, 11 O'clock position and minimum 7% external opening was found at 6 O'clock position. All fistula were low anal type of fistula in which 60% were complete type of fistula-in-ano and 33 % blind external while 7%, blind internal type of fistula-in-ano. The relief in symptoms like pain, discharge and swelling was statistically found highly significant. The relief in itching in this group was found statistically insignificant (Table 2). The Unit Cutting Time (UCT) is considered as the objective parameter to assess the result. After every change of *Ksharasootra* the length of the thread was measured and recorded (Table 3).

Complete cutting and healing of fistulous tract was occurred within one and half month in 7 patients. In 3 patients time required for complete healing was 2 months while in 2 patients it was 4 months and in 3 patients it was 5 months. All patients cured completely and during follow up as per protocol after 1 month no any recurrence was noted by patient. Telephonic call was done to all patients after 6 months and there was no recurrence in any patient.

Table 2: Effect of Therapy

Symptom	Mean		Mean Diff	S.D	SEM	P	Significance
	B.T	A.T					
Pain	1.40±0.163	0.00±0.00	1.400	0.632	0.163	<0.001	HS
Discharge	1.33±0.159	0.00±0.00	1.333	0.617	0.159	<0.001	HS
Itching	0.40±0.190	0.00±0.00	0.400	0.736	0.190	0.125	IS
Swelling	1.20±0.144	0.06±0.06	1.133	0.516	0.133	<0.001	HS

Table 3: Unit cutting time (UCT) of 15 patients:

n=15	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
UCT	6.8	7	9.3	8.8	8.2	9.6	7	7	5.6	6	9.3	9.3	12.6	10.5	9.3	
n	Mean UCT (Days/cm)														S.D.	S.E.M
15	8.43														1.875	0.484

Discussion

Conventional *Apamarga Ksharasootra* is a proven device to treat *Bhagandara* (fistula-in-ano) and it has been standardised in Ayurvedic Pharmacopeia of India (API) [10]. An innovative *Shallaki Niryas* based *Ksharasootra* was used in fistula patients along with partial fistulectomy to minimize the duration of treatment. In cases of long, curved or multi-branches fistulous more time is required to cut the tract with plain *Ksharasootra*. So in this study partial fistulectomy along with *Ksharasootra* was found very useful because its take out long tract 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.

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 [11]. 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 [12].

In compare to *Snuhi Ksheera*, *Shallaki* is easily available in abundant quantity in the market, can preserve for long time. *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 conventional *Ksharasootra* which enhance cutting power. The applied *Kshara* on thread has anti-inflammatory and anti-microbial activity. Alkaline nature of *Kshara* cauterizes dead tissue and control local infection which facilitates cutting as well as healing [13]. The cutting is also assumed by mechanical pressure of tight *Ksharashootra*. *Haridra* has *Lekhaniya*, *Kushthaghna*, and *Vishaghna* properties which showed its anti-septic and anti-toxic activity [14]. *Haridra* diminishes reaction of caustics and make healthy environment for healing of wound.

Panchavalkal decoction has cleaning and wound healing properties so it helped to keep wound clean and promoted healing [15-16]. *Shatadhauta Ghrta* (clarified butter) is recognised for an excellent *Sneha Dravyas* due to its *Samskaranuvaratana* (as like element to increase the power of another drug) and *Yogvahi* (synergetic effect) properties [17]. *Jatyadi taila* is a good *Shodhana* and *Ropana* formulation recommended for the dressing of wounds [18]. It acts as a soothing agent for smooth evacuation of faeces as well as it takes care of partially excised wound of fistulous tract. *Erandbhrishtha haritaki* is *Mridu Virechaka* (Soft Laxative) and helps to relieve constipation.

Conclusion

This pilot study demonstrated the utility of partial fistulectomy and *Shallaki* based *Ksharasootra* in management of *Bhagandara* (Fistula-in-ano) with minimum pain and early healing of fistulous tract.

References

1. Shastri A, Editor, (12th ed.). Commentary Ayurved Tatva Sandipika on Sushruta Samhita of Sushruta Sootra Sthana; Ksharapakavidhi: Chapter 33, Verse 4. Varanasi: Chowkhambha Sanskrit Sansthan, 2001.p.63.
2. Sushruta Samhita; Dalhana, Nidanastana4/3.in: Jadavji Trikamji editor. Varanasi: Chaukhambha Surabharati Prakashana, 2008.p.280.

3. Williams NS, Bulstrode CJK, O'Connell PR Editors. Bailey & Love's Short practice of Surgery. The Anus and Anal canal. 26th ed. Boca Raton: CRC Press Taylor & Francis Group; 2013.p.1259.
4. Goligher J, Duthie H, Nixon H. Surgery of the Anus Rectum and colon. Fistula-in-ano. 5th ed. Delhi: A.I.T.B.S Publishers & distributors; 2002.p.178.
5. Jain SK, Kaza RCM, Pahwa M, Bansal S. Role of cyanoacrylate in the management of low fistula in ano: a prospective study. International Journal of Colorectal Disease. 2008; 23(4):355-58.
6. Johnson EK, Gaw JU, Armstrong DN. Efficacy of anal fistula plug vs. fibrin glue in closure of anorectal fistulas. Dis Colon Rectum. 2006; 49(3):371-76.
7. Shastri A, Editor, (12th ed.). Commentary Ayurved Tatva Sandipika on Sushruta Samhita of Sushruta Sootra Sthana; Ksharapakavidhi: Chapter 11, Verse 7. Varanasi: Chowkhambha Sanskrit Sansthan, 2001; 46.
8. Sharma PV, Editor, (1th ed.). Chakradatta of Chakrapani, Arshachikitsa; Chapter 5, Verse 148. Varanasi: Chowkhambha Sanskrit sanssthan, 2007.p.87.
9. Mishra BS, Editor, (11th ed.). Commentary Vidyotini on Bhavprakash of Bhavmishra: Madhya Khanda; Arshachikitsa: Chapter 5, Verse 144. Varanasi: Chowkhambha Sanskrit Bhavan 2007.p.66.
10. Unanimously, Ayurvedic Pharmacopia of India. Part-II. Ksharsootra (Medicated thread): Chapter- 51. 1st ed. Delhi: Published by AYUSH, Govt. of India 2001; II: 209-213.
11. Bhava-prakasha, Karpooradivarga -51, 2006, Ganga Sahaya Pande and Krishna Chandra Chuneekar, Chaukhamba Bharati Academy, Varanasi, 2001.p. 212.
12. Bhaisajya Ratnavali, 61/139-142. In.Govinddassen K, editor. Varanasi: Chaukhambha surbharati prakashan; 2011.p.965.
13. Londonkar M, Reddy VC and Abhay Ku. Potential Antibacterial and Antifungal Activity of *Achyranthesaspera* L. Recent Research in Science and Technology. 2011; 3(4):53-7.
14. Shastri SN, Editor, Commentary Vidyotini on Charaka Samhita of Charaka: Sootra Sthana; shadvirechanashtashritiya; Chapter 4, Verse 9,11 Varanasi: Chowkhamba Bharati Academy, 2009.p.82-83.
15. Khadkutkar DK, Kanthi VG. A Brief Review of Research Studies Conducted on *Panchavalkal*. Indian Journal of Ancient Medicine and Yoga, 2015; 8(2): 87-93.
16. Meena RK, Dudhamal TS, Gupta SK, Mahanta VD. Wound healing potential of Pañcavalkala formulations in a post-fistulectomy wound. Ancient Sci Life. 2015; 35(1):18-21.
17. Tripathi B, Editor, Commentary Charak-Chandrika on Charaka Samhita of Charaka and Dradhbala: Sootra Sthana; Sneha-adhyaya: Chapter 13, Verse 13 Varanasi: Chowkhamba Sanskrit sanssthan, 2009.p.264.
18. Dudhamal TS, Bhuyan C, Baghel MS. Wound healing effect of JatyadiTaila in the cases of chronic fissure-in-ano treated with Ksharasutra. AYU 2012; 34(5):22.