

A Randomized Controlled Clinical Trial Comparing Koshataki Ksharasutra with Apamarga Ksharasutra in Bhagandara (Fistula in Ano) Management

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ABSTRACT

Bhagandara (Fistula in Ano) at modern parlance is a common anorectal condition prevalent in the populations worldwide and its prevalence is second highest after Arsha (hemorrhoids). *Kshara Sutra* (medicated thread) has been proved to be a big revolution in the treatment of fistula in ano. In the present clinical study, comparative study of *Koshataki* (Luffa acutangula) and *Apamarga* (Achyranthus aspera) *Ksharasutra* has been studied in the management of *Bhagandara*. Total 40 patients presenting with signs and symptoms of fistula-in-ano were registered of any age, sex etc. They were randomly divided into two groups - Group 'A': In this group total 20 patients of 'fistula in ano' were included and were treated by "*Koshataki Ksharasutra*". (Trial Group) Group 'B':- In this group total '20' patients of 'fistula in ano' were included and were treated by "*Apamarga Ksharasutra*". (Control Group) Assessment was done on objective parameters (Unit Cutting Time UCT, Induration, Tenderness) and subjective parameters (Pain, Itching, Discharge). After comparison of all above figures of signs & symptoms in group A and group B, we can conclude that the treatment used in Group A i.e. with *Koshataki Ksharasutra* is a good relief in treatment of *Bhagandara*.

Keywords: *Bhagandara, Fistula in ano, Koshataki Ksharasutra, Apamarga Ksharasutra*

1. INTRODUCTION

In Ayurveda certain diseases have been described as '*Mahagada*'. Keeping in mind the severity and troublesome behaviours, the *Fistula-in-ano* is one of them. Acharya Sushruta has mainly described surgical management of *Fistula-in-ano* (*Bhagandara*). He has described *Ksharasutra* treatment in *Nadivrana* and he added that *Bhagandara* can also be treated as *Nadivrana*. *Bhagandara* has described as *chhedya vyadhi* and it is included in *Astamahagada* by Acharya Sushruta.

In spite of many modifications in surgical procedures "*Fistula -in- ano*" still remains challenge even for the skilled surgeon. Also operative management has certain hazards like incontinence to stool, loss of gluteal cushion, post operative stenosis, rectal prolapse etc. To overcome such problem '*Ksharasutra*' treatment is the better treatment in the management of "*Fistula -in-ano*"

Bhagandara (*Fistula In Ano*): It is a disease of *Guda pradesh* (anal region). Sushruta defined it as a disease which causes splitting pain in vagina, anorectal region and urinary bladder with resultant discontinuity of these sites. He further added that when a boil called as *Pidika* suppurates and bursts open, it forms *Bhagandara*,¹

Bhagandara is included in eight *Mahagada* (big diseases) by Acharya Sushruta. Vagbhatta also mentioned it under eight *Mahagadas*, but added three other types as *Parikshepi*, *Riju* and *Arso Bhagandara*.²

Charaka gave a little description about *Bhagandara* in the chapter of *Shotha Chikitsa*.³

Fistula-in- Ano is a disease of ano-réctum and forms quite a large share of all the disease of this part of the body. It is characterized by single or multiple sinuses with purulent discharge in the perianal area. It becomes a notorious disease due to its anatomical situation. According to a recent study conducted on the prevalence of anal fistula in India by Indian Proctology Society in a defined population of some states, its incidence was approximately 17-20%; whereas in a London hospital, its incidence was approximately 10% of all the patients of anorectal disorders.⁴

Kshara Sutra: Generally in management of anorectal disorders, Sushruta (800 BC) described four folded line of approach as Bhaisaja chikitsa, *Kshara karma*, Agni karma and Shashtra karma. Among all these therapies *Kshara karma* has become very useful and recently modified method of treatment for selected Anorectal diseases mainly in *Bhagandara*

Now *Kshara Sutra* therapy has been accepted globally and has emerged as a gold standard treatment for fistula in ano.⁶

In this study *Koshataki Kshara Sutra* and *Apamarga Kshara Sutra* was used for evaluate the efficacy in fistula in ano. It is such a simple, safe and sure remedy for anal fistula and it is becoming universally acceptable day by day. The Indian Council of Medical Research (ICMR) has validated this unique and effective approach.⁷

2. MATERIALS AND METHODS

- Type of study: Prospective Single Blind Random Study.
- Ethical Clearance: Clearance from the Institutional Ethical Committee was taken
- Written Consent: An inform written consent of the patients was taken as the language best understood by them.
- Number of Patients: Total 40 patients presenting with signs and symptoms of fistula-in-ano were registered of any age, sex etc.
- Patients were randomly selected from the OPD & IPD of the Dept. of Shalya Tantra of RGES Ayurvedic Medical College, Hospital, Post Graduate Studies and Research Centre, Ron, Dist.-Gadag, Karnataka.They were randomly divided into two groups

Group 'A': In this group total 20 patients of 'fistula in ano' were included and were treated by "*Koshataki Ksharasutra*". (Trial Group)

Group 'B': In this group total '20' patients of 'fistula in ano' were included and were treated by "*Apamarga Ksharasutra*". (Control Group)

Inclusive Criteria:

- The patients are diagnosed as per classical texts.
- Patients will be selected between the age group of 16-70 yrs of either sex, irrespective of religion, occupation, economic status.
- Low anal fistula.

Exclusive Criteria:

- Patients with high anal /rectal fistula.
- Recurrent fistula-in-ano.
- Patients suffering from systemic diseases like- Diabetes Mellitus, Hypertension etc.
- Patients suffering from inflammatory diseases like-Ulcerative colitis & Crohn's disease.
- Patients suffering from infectious diseases like -HIV, Tuberculosis.

Observational Parameters:

Subjective Criteria

Vedana

Grade 0 No pain

Grade 1 Mild pain

Grade 2 Moderate pain

Grade 3 Severe pain

Kandu

Grade 0 No itching

Grade 1 Itching sometimes

Grade 2 Itching, interfering with function

Grade 3 Itching that disturbs the sleep and/ or demand treatment associated with skin patches.

Śrava

Grade 0 No discharge

Grade 1 Mild discharge

Grade 2 Moderate discharge

Grade 3 Profuse discharge

Objective criteria:

► Local tenderness

Grade 0 No tenderness

Grade 1 Mild

Grade 2 Moderate

Grade 3 Severe-patient denies touching.

► Induration:

Grade 0 Absent

Grade 1 Slight swelling without induration.

Grade 2 Swelling around wound margin with little area of induration.

Grade 3 Swelling with marked induration.

► Length of tract in cm

Unit cutting time = (Initial length of the tract - length of the tract remaining) / No of weeks taken

Statistical Analysis: As the sample size was small student's t test was applied to know significance of the parameters having quantitative data where as for qualitative data chi-square, or Wilcoxon signed rank or Mann Whitney test was applied as per requirements.

The level of significance was set at 5% (P=0.05).

P<0.05 was considered significant and P>0.05 was considered as statistically insignificant.

Preparation of Ksharasutra

Raw Materials Used To Prepare Koshataki 'Ksharasutra'

1. Surgical linen thread No.20.

2. *Snuhi ksheera*

3. *Koshataki Kshara*

4. *Haridra* Powder

Surgical linen thread: Barbour's surgical linen thread No.20 was used which is proved to be best by previous study for the preparation of K.S.

Snuhi ksheera: *Snuhi ksheera* (Latex of the plant 'Euphorbia nerifolia') was collected daily in a glass container by taking incision on selected part of the *Snuhi* mainly early in the morning

Koshataki Kshara: "*Koshataki Kshara*" was prepared in the department of '*Rasashastra*' under supervision of head of the department.

Koshataki whole plant is collected and cut into pieces after drying. *Koshataki* panchanga was burned to ash. Then the ash was dissolved in Six Times of water (1 Drona *Kshara*: 6 Times Water) and was kept stable for 10-12 hrs. Then clear supernatant portion was taken, filtered Twenty-One times with fine cloth, separated settled solid portion tested by litmus paper. It was found to be highly alkaline. Then again separated solid portion dissolved in water and supernatant filtered solution was obtained. This process repeated once again.

Then the obtained supernatant and filtered solution was evaporated and dried, anhydrous '*Koshataki Kshara*' was obtained.

Thus prepared *Kshara* was kept in the air tight glass bottles and used as requirement. *Haridra* Powder: Raw *Haridra* was collected from the market and *churna* were prepared and passed through the fine cloth. This powder was kept in the closed clean jar for use. '*Ksharasutra*' Preparation: *Ksharasutra* were prepared as per techniques developed by *Shalyatantra* Department,

Banaras Hindu University. Take a surgical linen thread No. 20 and bind in Aluminium frame. Then apply coatings of *Snuhi ksheera* and kept in a drying chamber. In this way 11 coatings in 11 days were completed. Then upto 12 to 18 days apply *Koshataki Kshara* per day. After *Koshataki Kshara* coatings upto 19 to 21 days *Haridra Churna* were applied.

Following coatings have been given one by one to prepare the *Ksharasutra*-

Ingredients	No. of Coatings
<i>Snuhi ksheera</i>	11 coatings
<i>Snuhi ksheera</i> + <i>Koshataki Kshara</i>	07 coatings
<i>Snuhi ksheera</i> + <i>Haridra Churna</i>	03 coatings
	21 coatings

Raw Materials Used To Prepare *Apamarga 'Ksharasutra'*

1. Surgical linen thread No.20.
2. *Snuhi ksheera*
3. *Apamarga Kshara*
4. *Haridra* Powder

Ingredients

Standard *Ksharasutra* contains

Snuhi ksheera - 11 coatings

Snuhi ksheera + *Apamarga Kshara* = 07 coatings

Snuhi ksheera + *Haridra Churna* = 03 coatings

Total = 21 coatings

Application of *Kshara Sutra*

Pre-operative preparation

- Written informed consent was taken
- Part preparation was done
- Patient was kept nil orally for 6 hours
- Inj. Tetanus Toxoid, 0.5 ml, I/M was given
- Inj. Xylocaine sensitivity test was done
- Soap water enema was given twice, around 10 pm at previous day of operation and around 7 am on the day of operation.

Preparation of operation theatre and sterilization of instruments were done. Operative procedure The patient was kept in lithotomy position, perianal region was cleaned with *Triphalaa Kwatha* and draping was done after giving spinal anaesthesia. In some patients, local anesthesia was used. When the patient was assured, gloved index finger was gently introduced into the rectum and a suitable metallic probe was passed through the external opening of the fistula. The probe was forwarded along the path of least resistance to reach into the lumen of anal canal through the internal opening, guided by the index finger of the other hand inserted in to the rectum and the tip of probe was finally directed to come out of the anal orifice. In case of externally blind fistula, the tip of the probe was pushed to make the proximal opening in the anal orifice. Then a

suitable length of K.S. was taken and threaded into the eye of the probe. Thereafter, the probe was pulled out through the anal orifice, to leave the KS. in situ i.e. in the fistulous tract. The two ends of the K.S. were tied together with keeping the gap of index finger outside the anal canal. This procedure is termed as 'primary threading'. After this a gauze piece (surgical pad) soaked with Jati Kalpa Taila was applied, tied with the help of *Gophana Bhandra* (T-bandage).

Postoperative measures

- Patient was kept nil orally till complete waving off of the anesthetic effect is achieved i.e., maximum for 6 hours.
- I/V fluids were given as per the requirement.
- Suitable analgesic and antibiotics were administered as per the requirement.
- General management
- *Ushnodaka Avagaha* (Sitz Bath) with Sphatikadi Yoga thrice in a day.
- *Matra Basti* of *Jati Kalpa Taila*, 10 ml once daily (by anal route).
- *Triphala Guggulu* 2 tabs (1 g) orally, after food, twice daily, with warm water.
- *Gandhaka Rasayana* 2 tabs (500 mg) orally, twice daily after food with warm milk.

The aim of the present clinical study was to assess the effect of *Koshataki Ksharasutra* in *Bhagandara*. Sedentary habit, non-vegetarian diet played an important role in the treatment of post operative of *Bhagandara*. The results were assessed on the following basis and grades.

1. Good relief denotes complete reduction of post operative pain.
2. Moderate relief denotes considerable regression of post operative pain.
3. Mild relief denotes slight regression of post operative pain.
4. No relief

GOOD RELIFE >81%

MODERATE RELIEF 51%-80%

MILD RELIEF 21% -50%

NO RELIEF <20%

Table No. 1 Showing the Degree of Severity of Different Features Before and After

Clinical Features	B.T					A.T			
	Degree of Severity					Degree of Severity			
Grading	Total	G0	G1	G2	G3	G0	G1	G2	G3
Pain	20	0	0	10	10	17	3	0	0
Itching	20	0	0	11	9	16	4	0	0
Discharge	20	0	0	11	9	14	6	0	0
Tenderness	20	0	0	8	12	12	8	0	0
Induration	20	0	0	16	4	12	8	0	0
Length of Tract (cm)	20	0	0	12	8	11	9	0	0

B.T. = Before Treatment

A.T =After Treatment

BPR= Bleeding per Rectum

G = Degree of severity

G0= Normal

G1= Mild

G2= Moderate

G3= Severe

Table No.2: showing the Degree of Severity of Different features before and after:**Treatment in Group B (N=20)**

Clinical Features	B.T					A.T			
	Degree of Severity					Degree of Severity			
Grading	Total	G0	G1	G2	G3	G0	G1	G2	G3
Pain	20	0	0	7	30	10	10	0	0
Itching	20	0	0	8	12	10	10	0	0
Discharge	20	0	0	8	12	11	9	0	0
Tenderness	20	0	0	6	14	13	7	0	0
Induration	20	0	0	16	4	12	8	0	0
Length of Tract (cm)	20	0	0	10	10	12	8	0	0

Table No.3: Showing Statistical Analysis of different parameters in group A:

Sign and Symptoms	Mean		Relief %	S.D	S.E	T	P
	BT	AT					
Pain	2.50	0.15	94	0.48	0.11	21.47	<0.001
Itching	2.45	0.20	91.83	0.55	0.12	18.29	<0.001
Discharge	2.45	0.30	87.75	0.48	0.10	19.64	<0.001
Tenderness	2.60	0.40	84.69	0.52	0.11	18.80	<0.001
Induration	2.20	0.40	88.63	0.61	0.13	13.07	<0.001
Length of Tract	2.40	0.45	81.25	0.75	0.16	11.48	<0.001

Table No.4: Showing Statistical Analysis of different Parameters in Group B:

Sign and Symptoms	Mean		Relief %	S.D	S.E	T	P
	BT	AT					
Pain	2.65	0.50	81.13	0.58	0.13	16.37	<0.001
Itching	2.60	0.50	80.76	0.55	0.12	16.99	<0.001
Discharge	2.60	0.45	82.69	0.58	0.13	16.37	<0.001
Tenderness	2.70	0.35	87.03	0.58	0.13	17.89	<0.001
Induration	2.70	0.35	81.81	0.52	0.11	15.38	<0.001
Length of Tract	2.50	0.40	84	0.71	0.16	13.07	<0.001

Table No.5: Showing Overall Clinical Assessment of Therapy:

Result	Group A (A .T)	Group B (B.T)
Good Relief > 81 %	8	6
Moderate relief 51- 80%	9	8
Mild Relief 21- 50%	3	5
No relief < 20%	0	1

Discussion: Earlier studies have proved that 'Kshara Sutra' has action of Excision (Chedana)Scraping (Lekhana)Draining (Visravana), Debridement (Shodhana, Healing (Ropana)and bacteriostatic etc. It might be due to the , action and (pacifies all the three bio-humors) The of fistula-in-ano by Setons is the contribution of Hippocrates (460-356 BC)but the idea of the setons is derived from the *Kshara Sutrawhich* is being used for treating the disease *Bhagandara* ever since the period of Sushruta.¹⁰

Discussion on Adjuvant drugs: The adjuvant drugs were to achieve better outcome of the surgical . The properties are Rasa- Tikta, Guna- Tikshna Laghu Ruksha, Ushna Virya, Vipaka Katu and in the Karma property. These properties are helpfull in treating it reduce the pain,discharge and itching. on results: There are several factors, which affect the Unit Cutting Time (UCT) as follows:

U.C.T. is less in sub mucosal, subcutaneous and low anal fistulae. U.C.T. is high in cases of fibroses / tough scar tissue which generally after the previous done for fistulae in ano and in cases of high rectal fistulae, fistulae with abscess and trans-sphincteric fistulae. Presence of infection and delays the Unit Cutting Tune. When the UCT of both groups were , the UCT of *Ksharasutra* was lower to standard group i.e7 days. Apart from this, abscess was formed at the 2nd week in 2 patients of this group. The patients of this group also of burning sensation in the post period and successive change of the thread for few hours.

Koshataki Ksharasutra (Group-A) Good effect in *Bhagandara* in reducing the pain scores as compared to the standard group whereas *Apamarga Ksharasutra* (Group-B) reduced the pain scores effectively.

► *Koshataki Ksharasutra* (Group-A) produced not much discharge in the post operative period compared to the *Apamarga Ksharasutra* (Group-B).

► The average healing time after cut through of the *Ksharasutra* was 8.66 days in the groups A. *Apamarga Ksharasutra* (Group-B) shows a comparatively higher UCT of 9.76 days without producing any complications like burning sensation in post operative period. Though *Kshara* is *Tridoshoghna* and due to *Visheshakriyaavacharanat* the *Koshataki Ksharasutra* can also be used in *Pittaja Prakriti* patients effectively.

► Overall assessment of the therapy: After comparison of all above figures of signs & symptoms in Trial and Control groups, we can conclude that the treatment used in control group i.e. treatment of *Bhagandara* (Fistula-in-ano) by *Apamarga Ksharasutra* is less effective as compared to the treatment of Trial group with *Koshataki Ksharasutra*

3. CONCLUSION

After a clinical observation and statistical evaluation the following conclusion were drawn. The incidence of fistula in ano was observed in age group of 41 to 50 due to unhygienic maintenance. *Koshataki Kshara Sutra* has been found very effective in relieving symptoms i.e reduces pain, swelling. Complication necrosisstenosisanal incontinence *Ksharasutra*. Management with *Apanarga Ksharasutra* shows superiority than *Koshataki Ksharasutra*. The and tension tying and continuous granulation tissue causes healing *Koshataki Haridra* encourage the healing new granulation tissue formation base well maintain continuous aseptic condition of tract.

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