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A Comparative Clinical Study to Evaluate the Efficacy of Koshataki Ksharasutra in the Management of Bhagandara with Special Reference to Fistula-in-ano

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ABSTRACT

The disease *Bhagandara* is included among *Ashtamahagadas* by Acharya *Sushruta.* The disease Bhagandara can be correlated to Fistula-in-ano. Incidence of Fistula in India is 17-20% in a defined population of some states. It is the recurrence nature of Fistula which makes difficult for treatment. *Ksharasutra* is a proven Para-surgical procedure for the management of Fistula-in-ano. A randomized clinical comparative study was conducted on 40 patients of *Bhagandara* and they were divided in to two equal groups. Patients of Group A were treated with *Koshataki Ksharasutra* and Group B were treated with *Apamarga Ksharasutra.* Pharmacological properties of kshara prepared out of different drugs behave differently. Therefore it is logical to hypothesis that kshara made out of *Koshataki* which is having *Kapha-pittahara*[13] property may cause less incidence of burning because of its *Tikta rasa.* Crude extract of drug *Koshataki* (*LuffaAcutagula*) and its isolated compound possess broad antioxidants, antimicrobial, analgesic and anti-inflammatory property[14]. So the treatment modality will be better acceptable to the patient when compared to classical *Apamarga ksharasutra.* In the present study, the effect of treatment in both the groups showed statistically highly significant, and statistically Non-significant in between two groups. Overall results of treatment in Group A are 98.75% and in Group B it is 93.90%.

KEYWORDS: *Bhagandara, Ashtamahagadas, Ksharasutra, Fistula-in-ano*

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INTRODUCTION

Bhagandara literally means *Darana* of *Bhaga, Guda* and *Basti pradesha*[1] resulting in the formation of communicating tract which produces discomfort to the patient. *Acharyas* included *Bhagandara* as one among the *Ashtamahagadas*[2].

In this context the disease *Bhagandara* can be correlated to Fistula-in-ano. It is defined as an abnormal tract lined with unhealthy granulation tissue that connects a primary opening inside the anal canal to a secondary opening in the perianal skin; secondary opening may be multiple and can extend from same primary opening.

Incidence of Fistula-in-ano developing after Incision and drainage of an abscess ranges from 26 to 38%. One study showed that the prevalence of Fistula-in-ano is 8.6 cases per 1 lakh population. In men the prevalence rate is 12.3 cases and in women it is 5.6 cases per 1 lakh population. Male: Female ratio is 1.8:1 and the mean age is 38.3years[3].

Clinical presentation includes history of chronic discharge (of pus/serous/sero-sangeuinous), intermittent pain in anal region, pruritis ani and systemic infection if abscess gets infected.

Treatment depends on the location and involvement of anatomical structures, amount of anal sphincter

involved in the fistula and the underlying disease process. Traditional modalities of surgical treatment Fistulotomy and Fistulectomy have 40% of high risk of impaired continence. Up to 26.5 % recurrence rate, and 5.6% non-healing of the wound were reported after surgical treatment. Disadvantages of newer modalities are, Risk of viral transmission through autologous fibrin glues, Dislodgement of Fistula plug, involvement of longer techniques, expensive instrumentation. To overcome such problems, surgical field is planning for some alternative techniques to treat these cases with minimal operative complications, recurrence and failure.

Ayurveda line of management of *Bhagandara* includes Medical (*Rasaushadhis, Guggulukalpas, Ghrita, tailas*), para-surgical (*Kshara karma, Agni karma* and *Varti* insertion) and surgical modalities. In *Charaka samhita* there is direct reference of *Ksharasutra* in the management of *Bhagandara*[4]. In Sushruta Samhita, *Ksharasutra* treatment is mentioned in *NadivranaAdhikara*[5]which is widely adopted in treating the *Bhagandara* as well. Dr. PJ Deshpande and team standardized the method of preparation and application of *Ksharasutra.*

Apamarga ksharasutra is standardized and effectively used. But the burning sensation during treatment is often complained by patients. To overcome this there is a need for an alternative drug for preparation of *ksharasutra*. Pharmacological properties of kshara prepared out of different drugs behave differently. Therefore it is logical to hypothesis that kshara made out of *Koshataki* which is having *Kapha-pittahara*[6]property may cause less incidence of burning because of its *Tikta rasa.* Crude extract of drug *Koshataki* (*LuffaAcutagula*) and its isolated compound possess broadantioxidants, antimicrobial, analgesic and anti-inflammatory property. So the treatment modality may be better acceptable to the patient when compared to classical *Apamarga ksharasutra*.

Aims and Objectives:

- To evaluate the efficacy of Koshataki Ksharasutra in the management of Bhagandara with special reference to Fistula-in-ano.
- To evaluate the efficacy of Apamarga Ksharasutra in the management of Bhagandara with special reference to Fistula-in-ano.
- To compare the efficacy of Koshataki ksharasutra and Apamarga ksharasutra in the management of Bhagandara with special reference to Fistula-in-ano.

Materials and Methods:

Source of Data:

Sample sources: A total of 40 patients presenting with the features of Fistula-in-ano mentioned in inclusion criteria approached to OPD and IPD Taranath Government Ayurveda Medical College and Hospital, Ballari were selected for the study. Andthey were randomly divided into two groups, each containing 20 patients.

Drug source: The identified raw drugs required for the study were collected and authenticated by the faculty of *Dravya Guna* department of TGAMC Ballari. *Kshara* preparation was done at *Rasa shastra* and *Bhaishajya kalpana* department of TGAMC Ballari.

Inclusion Criteria:

- Patients with clinical features of Fistula-in-ano (Discharge from perianal skin, Pain, Pruritis ani)
- Age group 16-70 years irrespective of Sex, Religion, Occupation, Duration of the symptoms.
- Patients with single low anal fistulous tract.
- Patients who were willing to participate in the study and have signed consent form.

Exclusion criteria:

- Fistula-in-ano secondary to Tuberculosis, Crohn's disease, Ulcerative colitis, HIV, Regional ileitis, Intestinal and pelvic malignancies and associated with any other systemic disorders.
- Associated with other ano-rectal disorders (Carcinoma of rectum, Haemorrhoids, Acute fissure in ano).
- Patients who are having multiple fistulous tract.
- High anal Fistula-in-ano.
- Pregnancy.

Investigations: Routine hematological, Biochemical and urine examinations were done to rule out the pathological conditions mentioned above. Transrectal ultrasonography.

Group	Diagnosis	Treatment	Duration
A	*Bhagandara*(Fistula-in-ano)	*Koshataki Ksharasutra*	Till complete cutting and healing of tract
B	*Bhagandara*(Fistula-in-ano)	*Apamarga Ksharasutra*	Till complete cutting and healing of tract.

Study Design: Randomized clinical comparative study

Methodology:

Poorva Karma*:*

- written Informed consent
- Part preparation was done.
- Inj. Xylocaine 2% - 0.2cc sensitivity test was done.
- Inj. T T 0.5ml (I/M) stat.
- Soap water enema at previous night of surgery and early morning on the day of surgery.

Pradhana Karma*:*

- Under all aseptic precautions, patients were made to lie in lithotomy position.
- Part was painted and draped. Patency of the fistulous tract was confirmed by pushing the Betadine + Hydrogen peroxide through external opening. Local anaesthesia (Inj. Xylocaine with adrenaline 2%) was infiltrated. A well lubricated suitable malleable probe was inserted through external opening and index finger was gently inserted into rectum.
- Probe was forwarded along the path of least resistance and was guided by the finger in anal canal to reach the internal opening.
- Its tip was finally directed to come out of anal orifice. Suitable length of surgical linen thread no 20 was threaded in to the eye of probe.
- Probe was taken out through anal orifice, by leaving the thread in fistulous tract.
- The two ends of the thread were then tied together with a moderate tightness outside the anal canal.

Paschat Karma:

- *UshnaJalaAvagaha* for 15 min twice daily.
- Internally Tab. *TriphalaGuggulu* (01 TID A/F), *Tab.GandhakaRasayana* (1 BD A/F), *Triphala Churna* (1 tsf HS B/F).

Change of *Ksharasutra:*

- On 7th day primary thread was replaced with *Ksharasutra i*.e, in **Group A***koshataki ksharasutra*, **Group B** *Apamarga ksharasutra* by adopting Rail road method.
- At each sitting of *ksharasutra* changing, the length of the previous ksharasutra was measured and recorded. This gave an idea of the amount of remaining tissue to be cut through and time taken to cut through each centimeter.

Follow up- After 30days of complete cutting and healing of the tract.

Assessment criteria:

Pain

P0	No pain
P1	Mild pain (No need of Analgesics)
P2	Moderate pain (pain subsides after taking analgesics)
P3	Severe pain (persists even after taking Analgesics)

Pruritis ani

P0	Pruritis ani absent
P1	Pruritis ani present

Discharge - After screening the patients, 24 hours observation was done by providing 2x2cm gauze pieces of sufficient quantity to assess the discharge, and observations were noted.

D0	No discharge
D1	Mild discharge (wets 2x2cm 1 gauze piece)
D2	Moderate discharge (wets 2x2cm 2 gauze piece)
D3	Severe discharge (wets 2x2cm >2 gauze pieces)

Unit Cutting Time – It was calculated by dividing the total number of days taken by a fistulous tract to cut through by initial length of the tract.

UCT = Total Number of days taken for complete cut through Initial length of the tract.

Statistical Tests used for the assessment of Parameters:

The assessment parameters like pain, Discharge were subjected to **Wilcoxon signed rank** test to compare within the groups and **Mann Whitney U** test to compare the values between the groups. Assessment parameter Pruritis ani was subjected to **McNemar's test** to compare within the group and **Fisher's exact** test to compare the values between the groups .The assessment parameter Unit Cutting Time was subjected to mean and results were analyzed.

Observations:

Out of 40 patients, in **Group A** maximum patients were in the age group of 36-45 years. Where as in **Group B** maximum patients were in the age group of 26-35years and 36-45 years equally.In total 55% of Light workers (Businessman, Teacher, Shop keeper, LIC agent, Software worker, Bank employee, Driver, Principal, Press reporter)., 20% of moderate workers (Student, Sales man, Home maker, KEB employee, Filmmaker, Office worker)and 25% of heavy workers (Coolie, Factory employee, Agriculturist) took part in the present study. In total, 11 (27.5%) patients were having anterior Fistula-in-ano and 29 (72.5%) patients were having Posterior fistula-in-ano. Out of 40, 08 (20%) patients had no pain whereas 32 (80%) patients had mild pain (No need of Analgesics). In total, 21 (52.5%) patients had pruritis ani and it was absent in 19 (47.5%) patients.In total 25% patients had No discharge and 75% patients had mild discharge.

Table no .01-Unit cutting time wise distribution of patients.

	N No of Patients	
	Group-A	Group-B
Mean UCT (Days/cm)	15 17	14 47

In **Group A**mean UCT was 15.17 days/cm where as in**Group B** UCT was 14.47 days/cm.

Results:

Table no 02- Effect of treatment on Pain in Group A and Group B

PAIN	MEAN			%	S.D (+/-)	WSRT Value	Z - value	P-Value	R
	BT	AT	BT-AT						
GROUP A	0.85	0.00	0.85	100	0.366	-153.0	-4.123	<0.001	HS
GROUP B	0.75	0.05	0.70	93.33	0.47	-105.0	-3.742	<0.001	HS

Effect on pain was found statistically highly significant in Group A and Group B. (P-Value = <0.001)

Table no 03-Comparative effect of treatment on pain between Group A and Group B

PARAMETERS	BT-AT(MEDIAN)		Mann-Whitney Test		Remarks
	GROUP A	GROUP B	T-Value	P Value	
PAIN	1.000	1.000	440.0	0.270	**N.S**

There is no significant difference in between the groups statistically at BT-AT. (p value= 0.270)

Table no 04-Effect of treatment on Discharge in Group A and Group B

Discharge	MEAN			%	S.D (+/-)	WSRT Value	Z - value	P-Value	R
	BT	AT	BT-AT						
GROUP A	0.85	0.00	0.85	100	0.36	-153.0	-4.123	<0.001	HS
GROUP B	0.65	0.05	0.600	92.3	0.503	-78.0	-3.464	<0.001	HS

Effect on Discharge was found statistically highly significant in Group and Group B. (P-Value = <0.001)

Table no 05-Comparative effect of treatment on Discharge between Group A and Group B

PARAMETERS	BT-AT(MEDIAN)		Mann-Whitney Test		Remarks
	GROUP A	GROUP B	T-Value	P Value	
DISCHARGE	1.000	1.00	460.0	0.083	**N.S**

There is no significant difference in between the groups statistically at BT-AT. (p value= 0.083)

Table no 06- Effect of treatment on Pruritis ani in Group A and Group B

PRURITIS ANI	BT	%	AT	%	p value	Remarks
GROUP A	09	45	01	95	0.008	HS
GROUP B	12	60	02	90	0.002	HS

Effect on pain was found statistically highly significant in Group A. (P-Value = <0.001)

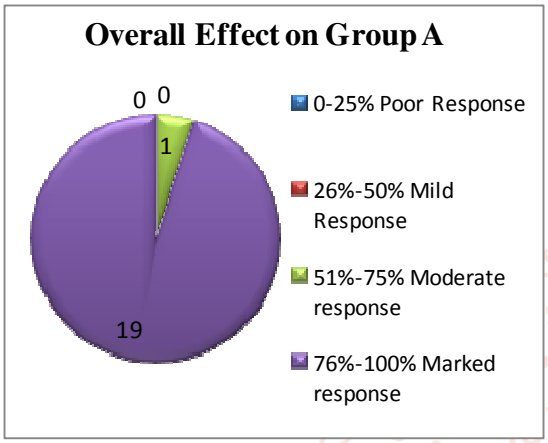
Table no 07- Comparative effect of treatment on pruritis ani between Group A and Group B

PARAMETER	TEST VALUE	DEGREE OF FREEDOM (d.f)	p-VALUE	REMARKS
PRURITIS ANI	0.833	1	0.650	N.S

There is no significant difference in between the groups statistically (p value= 0.650)

Table no 08- Overall effect of treatment on Group A& Group B

Effect of Treatment			
Class	Grading	No of patients in Group A	No of patients in Group B
0-25%	Poor Response	0	0
26%-50%	Mild Response	0	0
51%-75%	Moderate Response	1	4
76%-100%	Marked Response	19	16



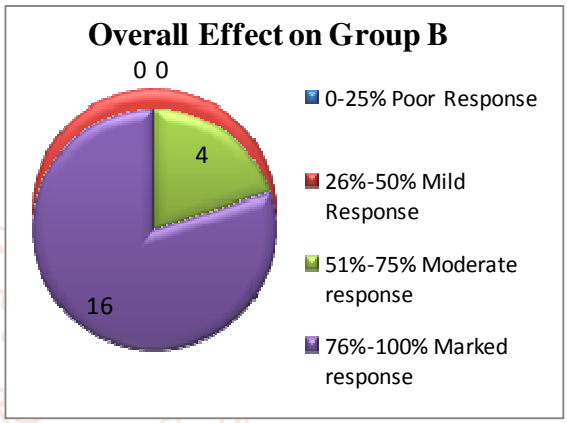


Chart 01-Overall effect on Group A **Chart 02-Overall effect on Group B**

Results of treatment in Group A:

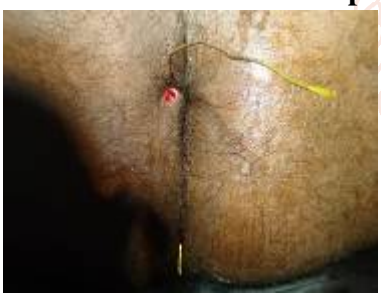


Fig 01: Before treatment

Fig 02: During Treatment

Fig 03: After treatment

Results of treatment in Group B:

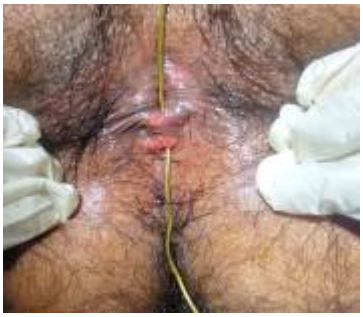


Fig 04: Before treatment

Fig 05: During treatment

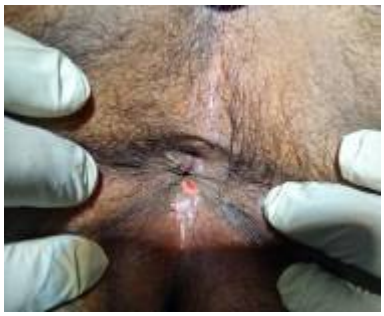


Fig 06:After treatment

Discussion:

*Acharya Sushruta*being a surgeon has gone in detail regarding the disease. *Nidana* of *Bhagandara*mentioned in different classicsultimately results in *Vataprakopa (Apanavata*) which is the prime dosha responsible for the formation of *Bhagandara pidaka.Acharya.* Modern authors also recognized the same etiological factors for the formation of Perianal abscess. *Sushrutas'* Concept of *Bhagandara pidaka* clearly shows that he had an idea regarding the occurrence of fistulous abscess.

In present study, Out of 40 patients in the present study, 92.5% patients were Male and 7.5% patients were female. This observation may probably due to, in Indian society females hang back to visit hospitals and express any complaints pertaining to ano-rectal region. In comparison to females, men will be exposing more to the *Nidanas*like excessive traveling on vehicles, *Ativyayama* and *kathinasana* this may be the reason Bhagandara is commonly seen in Men. In relation to previous history, 85% patients had Perianal abscess and 15% patients had history of infected fissure bed. Incidence of Fistula-in-ano developed after Incision and Drainage of perianal abscess ranges from 26-38%. *Arsho Bhagandara* type can be correlated to Fistulas arising as a result of infected fissure bed.

In present study, greater number of patientsi.e, 65% had chronicity of 1-6months. 20% of the patients had chronicity of 7-12 months. 7.5% of the patients had chronicity of 19-24 months. The abscess represents the acute inflammatory event, whereas the fistula is representative of the chronic process. Probably due to negligence, lack of awareness about the disease and intervening period of apparent healing, patients postpone to visit hospitals.

Patients of both the Groups experienced pain during and after application of *Ksharasutra*, but Patients of Group A had quick relief from pain. It may be because of Analgesic, anti-inflammatory property of *Koshataki*. *Teekshnata* of *Kshara* and *Vata dosha* are responsible for pain.*Haridra* and *Snuhi ksheera* which are used in *ksharasutra* preparation are having *Ushnaveerya* and *Kapha-vatahara* property.

During first 2-3 sittings the increase in the amount of discharge was observed. This may be because of liquification necrosis of unhealthy granulation tissue by the alkaline nature of *Kshara*. Along with reduction in the tract length, the discharge also got reduced. The presence of *ksharasutra* in the fistulous tract doesn't allow closing from either ends and there will be continuous discharge, this helps to wash off all the unhealthy granulation tissue from the tract and help in quick healing.

On comparing between the groups, average number of days to cut 1cm of fistulous tract in Group A was 15.17 days, in Group B it was 14.47 days. Hence result on Unit Cutting Time Group B was better than Group A. Combination of Snuhi ksheera, Kshara and Haridra, Multiple coatings of these drugs over the thread causes gradual and continuous cutting and curettage of the fistulous tract. Ksharasutra which is tied and left there for 7 days increases the tissue contact period, which in turn increases cutting and healing of Tract.

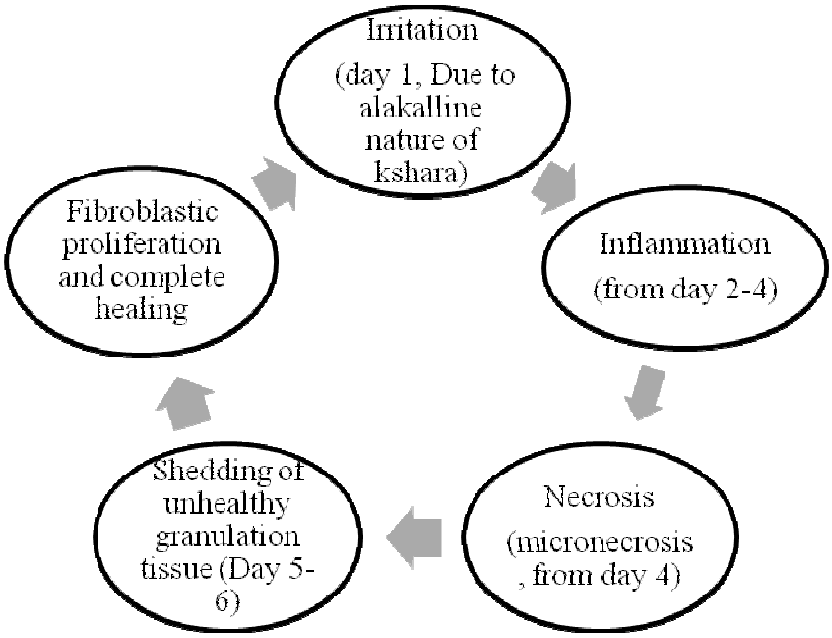
On completion of the study, in both the groups highly significant results are seen in all the parameters and statistically not much significant difference were observed in almost all parameters, reason for this may be the most of the properties such as Vedanasthapana, Shothahara, vranashodhana, vranaropanaare common in both Koshataki ksharasutra and Apamarga ksharasutra. But overall effect of Koshataki ksharasutra was better in most of the parameters i.e, on pain, discharge, pruritis ani.

Probable mode of Action of Ksharasutra:

- **Theory of Chemical cauterization**: The Alkaline nature of *kshara c*auses saponification of fat and formation of alkaline protinates which subsequently results in liquification necrosis when applied over the tissue.
- **Theory of Antibacterial effect:**Microbicidal action of the drugs present in *Ksharasutra* destroys the infected anal glands, and promotes the cutting and healing.
- **Mere mechanical cut and open theory:** Moderately tight ligation of *Ksharasutra* in the tract allows close contact of the medicaments with the diseased tract. The traction and tension of the thread mechanically cuts the tract and the medicinal coating over the thread heals the track.
- **Novel technique of local drug delivery:** Thread acts like a vehicle for the medicines to reach the targeted area (infected cryptal glands) and the multiple coatings over the thread renders a sort of sustained release effect of the medicines in the diseased tract.

Ksharasutra treatment for Bhagandara is known for its simultaneous cutting and healing property. Histo-pathological studies over the effect of Ksharasutra showed, the fibroblastic proliferation and laying down of the collagen is seen too early. And capillary formation is also found in second and third week.

Stages of effects of Ksharasutra:



By 7th day Ksharasutra loses all its' coatings and moderately tied ksharasutra becomes loose, due to which the cutting effect will be reduced. This may be the rationality behind changing ksharasutra after 7 days.

Conclusion:

- Inclusion of Bhagandara among *Ashtamahagadas* (8 grave disease) shows it is difficult to cure.
- The effects of treatment in both the groups have shown statistically highly significant results (p value <0.001) in all assessment parameters. The effects of treatment in between the groups have shown statistically Non-significant.
- The percentage of improvement in Group A on pain is 100%, on pruritis ani is 95%, on Discharge is 100% and on length of the tract is 100%.
- The percentage of improvement in Group B on pain is 93.33%, on pruritis ani is 90%, on Discharge is 92.3% and on length of the tract is 100%.
- Mean UCT in Group A is 15.17days/cm and in Group B 14.47 days/cm.
- Overall results of treatment in Group A are 98.75% and in Group B it is 93.90%.

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