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Research Article

THE EFFICACY OF *VIBHITHAKI KSHARASUTRA* IN THE MANAGEMENT OF *BHAGANDHARA* (FISTULA IN ANO) A CONTROLLED CLINICAL TRAIL

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ABSTRACT

Bhagandara (Fistula-In-Ano) is one of the *Astamahagadha* disease mentioned in *Susrutha Samhitha*, which is difficult to cure. Fistula-In-Ano is an abnormal communication between two epithelial-lined surfaces in the anorectal region. Various operative procedures (fistulectomy, etc.) often lead to complication ns like recurrence, incontinence of the anal sphincter, and other infections resulting from surgery. The *Kshara Sutra* is a parasurgical procedure that is found to be more effective in the management of fistulas in ano. The *Apamarga Ksharasutra* is widely used and is made up of *Apamarga Kshara, Snuhi Kshira* and *Haridra*. The preparation process for *Apamarga Kshara* can be difficult and time-consuming. If we turn to the classics, we find the reference to *Vibhithaki*, mentioned under *Kshara Dravys*, which are used to prepare *Ksharasutra*. *Vibhitaki* is cost-effective and easily available as it is a big tree. The properties of *Vibhitaki* are favourable to *Kshara* qualities The present clinical study deals with the efficacy of *Vibhitaki* and *Apamarga Kshara Sutras* in the management of *Bhagandara*.

INTRODUCTION

Fistula-in-Ano, also known as *Bhagandara* in Ayurveda, is a challenging surgical condition that has been a challenge for centuries. It is one among the *Astamahagadha*[1] (which is difficult to cure), described in *Susrutha Samhitha*. The word fistula is derived from the Latin word reed, pipe, or flute. It is an inflammatory tract which has an external opening (secondary opening) in the perianal skin and an internal opening (primary opening) in the anal canal or rectum[2]. This tract is linked by unhealthy granulation tissue and fibrous tissue. It usually caused by an anorectal abscess that bursts spontaneously, making it more susceptible to infection. The condition is difficult to cure and often leads to complications like recurrence and incontinence. Hippocrates, about 430 B.C., suggested the disease was caused by contusions and tubercles from rowing or horseback riding. He was the first person in the West to advocate the use of Seton (from the Latin seta a Bristle). The prevalence rate of fistula-in-ano is population is 9 cases per 100,000 people, with a male-to-female ratio of 1.8:1 and a recurrence rate of 30%–40%.

In Ayurvedic classics, *Kshara Karma* therapy was practiced and used for a long time with great success and negligible recurrences in the management of fistula-in-ano. *Susutha* mentioned *Ksharasutra* in *Nadivrana*[3]; *Chakradatt*[4] and *Rasatarangini*[5] indicated *Ksharasutra* made up of *Snuhi, Apamarga kshara,* and *Haridra* in their texts. In 20th century Prof. P.J. Deshpande, B.H.U, the pioneer in this field has revived the ancient para-surgical *(Ksharasutra)* techniques with the best results. Its preparation, standardization, preservation, application, etc are established after expensive investigations and trials.

The *Apamarga Ksharasutra* is widely practiced in India. As per Susrutha Samhita there is reference of *Vibhitaki* in *Kshara dravyas*[6]. The properties of *Vibhitaki* like *Kashaya Rasa, Ushna Virya, Madhura Vipaka, Ruksha, and Laghu Guna*[7] are favourable to qualities of *Kshara.* As per available Ayurveda texts. *Acharya Sushruta* has also explained that we should consider this plant in preparation for *Kshara*. *Vibhitaki*, according to the reference, is also *Kshara*, which is cost effective, and widely accessible because it is a large tree that yield a sufficient amount of drug, as compared

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to *Apamaraga*. The present clinical study deals with the efficacy of two different *Ksharasutras* namely; *Vibhitaki* and *Apamarga Kshara Sutras* in the management of *Bhagandara.*

AIMS AND OBJECTIVES

- To study the efficacy of *Vibhitaki Kshara Sutra* in the management of *Bhagandhara*.
- To study the role of standard *Apamarga Kshara* sutra in the management *Bhagandhara*.
- Comparative study of the efficacy of *Vibhithaki Ksharasutra* with standard *Apamarga Ksharasutra* in the management of *Bhagandhara.*

Selection Criteria

Inclusive criteria

- Subjects of irrespective of gender.
- Subjects with age ranging from 20 to 60 years.
- Low anal fistula.

Exclusive Criteria

- Concomitant ano-rectal conditions like ulcerative colitis, malignancy, Crohn's disease, multiple fistulas and high anal fistula.
- Pregnant subjects,
- Obstructive uropathies
- Other systemic diseases like uncontrolled diabetics, severe cardiac disease, chronic renal failure, chronic liver disease
- Secondary fistula due to ulcerative colitis, crohn's disease, tuberculosis, carcinoma of rectum.

MATERIALS AND METHODS

40 patients of *Bhagandara* will be randomly categorized into 2 groups, each comprising of 20 patients.

- **Group A:** Application of *Vibhithaki Ksharasutra* was put into test group in 20 diagnosed cases of fistula-in-ano.
- **Group B:** Application of *Apamarga Ksharasutra* was put into controlled group in 20 diagnosed cases of fistula-in-ano.

Required Materials

Lithotomy table*, Kshara* sutra in a sterile test tube, cotton, gauze, kidney tray, sponge holding forceps, syringes various sizes of probes, artery forceps, scissors, surgical blade, B.P handle proctoscope, anti-septic lotion, local anaesthetic drugs, suture material, Bourbar 2.0 lenin surgical tread, *Vibhithaki Kshara*, *Haridra, Snuhi Kshira.*

Preparation of *Vibhithaki Kshara*[8]

Kshara is prepared by burning *Panchangas* of *Vibhitaki* plant and ash is collected in vessel, then ash was mixed with 6 parts of water, then ash has to settle down, the supernatant water is collected and filtration was repeated for 21 times with clean cloth. The liquid was then evaporated slowly on a moderate constant flame. During evaporation process, the mixture has to stir time to time with a flat stirrer. By evaporating, a uniform fine clear white powder, *Kshara* was produced at the end of boiling. The alkaline *Kshara*, with a pH of 12, is stored in a glass bottle.

Preparation of *Vibhitaki Ksharasutra*

Barbour linen surgical thread no- 20 is fix to the *Ksharasutra* hangers*, Snuhi ksheera (Euphorbia neriifolia)* smeared on the thread with the gauze piece and dried in the *Ksharasuta* cabin, the same process is repeated for 11 days then pass the thread through *Vibhitaki Kshara* powder and which is allowed to dry, same process is repeated for 7 days, then pass the thread through *Haridra churna (Curcuma longa)* and allowed to dry, same process is repeated for 3 days. The thread is sterilized with UV light for 30 minutes per day. Then *Ksharasutra* is sealed in glass test tube.

Method

Procedure of Application of *Ksharasutra*

It includes *Purva karma, Pradhana karma* and *Paschat karma*.

Purva Karma

- Written informed consent of every patient was taken.
- Patient was kept nil by mouth six hours prior to procedure.
- Inj. Xylocaine 2% sensitivity test was done.
- Inj. Tetanus Toxoid was given.
- Part was prepared after local shaving.
- Soap water enema was given in the early morning on the day of surgery as preparative procedure for surgery.

Pradhana Karma

The patient should be in the lithotomy position with buttocks pulled down over the edge of the table.

A pre-operative examination should be performed. Proper extensive shaving and painting of the peri-anal region should be performed. Peri-anal region was cleaned with antiseptic lotions and the operative area was draped with sterile cut sheets. Local anesthesia (Xylocaine 2%) was applied per anal after keeping the patient in lithotomy position. When the patient was assured, gloved lubricated index finger was gently introduced into the anal canal and a suitable metallic malleable probe was gentle passed with the help of other hand through the external opening of the fistula. The index finger inside the Anus guides the probe. The probe progressed towards the internal opening in the less resistant area. Forceful probing was avoided. After piercing the internal opening, the tip of the probe comes out through the anal canal. Then a suitable length of *Ksharasutra* was taken and threaded into the eye of the probe. Thereafter, the probe was pulled out through the anal orifice, to leave the thread in situ i.e. in the fistulous tract. The two ends of the thread were tied together

outside the anal canal. Complete haemostasis was checked, a sling soaked with betadine and xylocaine jelly is inserted into the anus and tight T bandage is applied. Daily antiseptic dressing is done after keeping *Jatyadi Taliapichu.*

Pascat Karma

The patient is advised to have sitz bath twice a day. Ambulation of the subjects is made as a routine to encourage all the subjects to remain as active as possible and to lead a normal life both physically and psychologically. All the patents are advised to take nutritious, easily digestible diet with rich of fiber. All the subjects are asked to report in the department for subsequent changes of *Ksharasutra*.

Progress and Follow Up

The progress of all the patients were noted for a period of 30 days at the interval of 7 days. The patients of both groups were followed up for every 2 or 3 days for 1 Months.

Assessment criteria

Subjective Parameters

- Pain
- Discharge

Objective Parameters

- C.H.T (Complete Healing Time)
- U.C.T (Unit Cutting Time)

Gradation of Parameters

A) Assessment of Pain

0 - No pain

1- Mild

2 - Moderate

3 - Severe

B) Assessment of Discharge

0 - No discharge or dry,

1 - Scanty occasional discharge and little wet dressing.

2 - Often discharge and with blood on dressing.

3 - Profuse, continuous discharge which needs frequent dressing.

C) Unit cutting time (U.C.T)

The effect of the treatment is determined by unit cutting time. This was defined to be total number of days taken to cut a unit length of the track.

U.C.T = Total number of days /Initial length of the track (in cm)

Assessment of unit cutting time is done every week while changing the thread.

D) Complete healing time (C.H.T)

It is the time taken for total healing of the ulcer made by the *Ksharasutra*. In comparison with the conventional surgery to the *Ksharasutra* treatment this parameter is established. Complete healing time is the total time taken for entire treatment. This is recorded in the subjects who are on the follow up regimen. They were asked to attend the OP on week up to thread falling.

OBSERVATIONS AND RESULTS

A. Subjective parameters

Table 1: Effect of *Vibhithaki Ksharasutra* Application in Fistula-in-Ano on Subjective Parameters in Group (A)

Parameters	N	Mean		M.D	% of Relief	S.D		't'	'df'	'p'
		BT	AT			BT	AT			
Pain	20	2.50	0,15	2.35	94%	0.51	0.37	17.899	19	<0.0001
Discharge	20	2.60	0.15	2.45	94.2%	0.50	0.37	15.6571	19	<0.0001

Pain: The Group A average pain before treatment is 2.50 and after treatment the pain has fallen to 0.15. When t test: Paired two samples for means is done the t value is 17.899 at P value <0.0001 level, which is highly significant

Discharge: The Group B average discharge before treatment is 2.60 and after treatment has fallen to 0.15. When t test: Paired two samples for means is done the t value is 15.964 at P value <0.0001 level, which is highly significant

Table 2: Effect of *Apamarga Ksharasutra* Application in Fistula-in-Ano on Subjective Parameters in Group (B)

Parameters	N	Mean		M.D	% of Relief	S.D		't'	'df'	'p'
		BT	AT			BT	AT			
Pain	20	2.40	0,20	2.20	91.6%	0.50	0.41	14.139	19	<0.0001
Discharge	20	2.5	0.2	2.30	92%	0.51	0.41	14.038	19	<0.0001

Pain: The Group A average pain is 2.40 and after treatment it has fallen to 0.20. When t test (paired two sample for means) is done the t value is 14.139 and at P value <0.0001 level, which shows highly significant.

Discharge: The Group B before treatment average discharge is 2.50 and after treatment it has fallen to 0.20 when t test: paired two samples for means is done the t value is 14.038 at P value <0.0001 level, which is highly significant.

B. Objective Parameters

Table 3: Showing the effect of both methods on UTC in the subjects of Group A (*Vibhithaki Ksharasutra*) and Group B (*Apamarga Ksharasutra*)

Group	N	Mean	SD	M.D	S.E	't'	'df'	'p'
Group A	20	7.55	0.667	2.04	0.404	5.0278	19	<0.0001
Group B	20	9.59	1.680					

In present study, the complete healing time is taken for entire treatment. The overall average of Unit Cutting Time are **7.55 and 9.59** for A, B groups respectively, on applying of unpaired t test, t-value was 5.0278, and P-value is less than 0.0001 which means highly significant ,on analysis the data, it was found that found Group-A better than Group-B.

Table 4: Showing the effect of both methods on CHT in the subjects of Group A (*Vibhithaki Ksharasutra*) and Group B (*Apamarga Ksharasutra)*

Group	N	Mean	SD	M.D	S.E	't'	'df'	'p'
Group A	20	26.3	4.61	1.68	1.743	3,3267	19	<0.0020
Group B	20	32.15	6.29					

In present study, the average C.H.T of the individual groups score are 26.35 and 32.15 for A, B groups respectively, on applying of unpaired t test, t-value was 3.3267, and P-value is less than 0.0020 which means highly significant, on analysis the data Statistically it was found that found Test Group-A better than controlled Group-B.

Table 5: Comparison of Overall % of Relief Per Parameter of 2 Groups

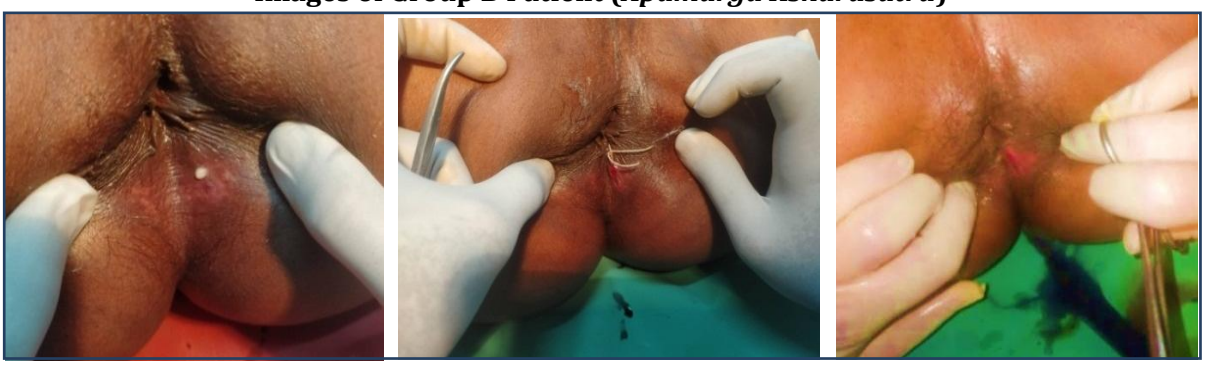
Parameters	Percentage % of Relief	
	Group A	Group B
Pain	94%	91.6%
Discharge	94.2%	92%

Group A (94%) is better in controlling pain than Group B (91.6%), in case of discharge Group A (94.2%) has better results in controlling discharge than Group B (92%).

Images of Group A Patient (*Vibhithaki Ksharasutra*)

Before Treatment **After Treatment**

Images of Group B Patient (*Apamarga Ksharasutra*)



Before Treatment **After Treatment**

DISCCUSION

In the present study total cases were divided into 40 cases into 2 groups. Group A (test), treated with *Vibhitaki Ksharasutra* and in Group B (controlled) treated with *Apamarga Ksharasutra*. 20 cases were included in each group, which were treated on parameters like pain, discharge, unit cutting time and complete healing time.

The observation of both groups has been made on different parameters of study like age group, gender, occupation, appetite, bowel habit, addictions, type of *Prakruti*, initial length of tract, chronicity of disease, different types of *Bhagandara*, recurrent cases after surgical operations, number of fistulous openings.

Discussion on Results

Pain: After treatment it is observed that the relief from pain is maximum in Group A (94%) when compared to Group B (92%). Decrease in the pain may be due to the fact that *Vibhithaki Ksharasutra* exerts maximum caustic effect (pH 11), by which there is relief from tightness of thread.

Discharge: It is observed that the relief from discharge is maximum in Group A (94%) when compared to Group B (92%). The drug *Vibhitaki* has *Kapha Pittahara* property, it may alleviate *Kapha* and *Slaishmika srava,* the drug is of *Kasaya Pradhana rasa* which said to be good for fast healing and also act as *Krimighna,* as discharge increased by infections. The *Laghu-Ruksha Gunas* helps in *Shoshana* of the discharge and *Sroto vishodanam.*

Complete Healing Time (C.H.T): After analysis of the data statically it was found that found Group A better than Group B.

Unit Cutting Time (U.C.T): After analysis of the data statically it was found the unit cutting time of Group A better than Group B. *Vibhataki* is *Kasaya rasa Pradhana* and the *Kshara* dosage form helps both fast cutting and simultaneous fast healing along with scraping of slough, drainage of pus and often discharge.

Probable Mode of Action

- Action of *Ksharasutra* is cutting through and laying the tract open, the medicinal property in *Ksharasutra* helps to heal the cut through tract. It is also removes debris and cleans the wound.
- When *Kshara* was prepared using *Vibhitaki*, it attains properties of *Kshara* like *Shodhana, Ropana, Soshana, Stambana, Lekhana and Krimighna*.
- By virtue of its *Kashaya Rasa, Vibhitaki* binds the wound margins, the *Ruksha Guna* of *Vibhitaki* helps in removal of slough there by drying up of the wound. The *Madhura Vipaka* of *Vibhitaki* helps in formation of healthy granulation tissue, which aids in fast healing. The *Krimighna Guna* of *Vibhitaki* prevents infection.
- The *Shothahara* property of *Vibhataki* is due to *Laghu Ruksha guna, Sthambhana karma* and for *Kasaya rasa Pradhana*. This peculiar quality of Test Drug has made this *Kshara* a unique thread for the best treatment of fistula in ano.

CONCLUSION

The present study entitled on "The efficacy of *Vibhithaki Ksharasutra* in the Management *Bhagandhara*" was proposed to evaluate the comparative action of *Vibhithaki Ksharasutra* and *Apamarga Ksharasutra* on fistula in ano. After a clinical observation and statistical evaluation, the following conclusions were made.

1. The undesired effects like irritation and sever pain especially in subjects treated with *Apamarga Ksharasutra* management were minimized by using *Vibhithaki Ksharasutra.*
2. *Vibhithaki Ksharasutra* has been found very effective in relieving symptoms like pain and discharge in fistula in ano.
3. *Vibhithaki Ksharasutra* helps in cutting, draining and healing of the fistulous track due its *Vranaropana, Vranasodhana* and *Lekhaniya* properties of the combination of drugs.
4. The antimicrobial action of *Haridra* and *Snuhi* controls infection.

On the basis of the results of this research work it can be said that the *Vibhithaki Ksharasutra* is effective in the management of fistula in ano in several aspects as compared to *Apamarga Ksharasutra* method, but to establish this fact and effect on recurrence of disease, further study of longer duration and on larger sample is required, probably double blind randomized studies may required to re-establish the facts.

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