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A Clinical Study To Evaluate The Efficacy Of *Palasha Kshara Sutra* In The Management of *Bhagandara w.s.r. To Fistula In Ano.*

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ABSTRACT: -

Bhagandara is a common disease of ano-rectal area. According to Acharya Sushruta, '*bhagandara*' starts as deep-seated *pidika* (boil) surrounding the *guda* (anus) within two *angulas* perimeter, producing fever and pain. The signs & symptoms of *Bhagandara* closely resemble with the disease *Fistula-in-ano*. *Fistula-in-ano* is a communicating track lined by morbid granulation tissue linking two epithelial lined surfaces in the ano-rectal area. It is one of the most obnoxious condition for the patient and a challenge for the medical fraternity due to its peculiar site of occurrence. Conventional choice of treatment is ano-rectal surgery. Many complications viz itching, swelling, pain, recurrence, infection may occur following ano-rectal surgery. Whereas, Ayurvedic treatment i.e. *Ksharasutra therapy* is much more cost-effective and with least complications. The present study was conducted on 20 patients of *Bhagandara* to evaluate the effectiveness and suitability of *Palasha Ksharasutra* in the management of *Bhagandara* (fistula in ano). The therapy showed encouraging results in all the parameters of *Bhagandara* viz pus discharge, pain, healing time with no complications. It is more economical and readily available throughout the year.

Keywords: *Bhagandara*, *Fistula-in-ano*, *Palasha Kshara sutra*, unit cutting time, healing time.



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INTRODUCTION

In Ayurvedic classics Fistula in ano (*bhagandara*) is included among the *Ashta mahagada* i.e. eight very difficult to cure diseases^[1,2]. The word *Bhagandara* is made by conjunction of two words 'Bhaga' and 'Darana'. The term 'Bhaga' means all the structures around the *guda* (anus) including *yoni* (vagina) and *basti* (bladder). The second word *Darana* means tear of surface associated with pain. So, *Bhagandara* is a pathological condition which causes tear and pain in the ano-rectal canal, vagina or urinary bladder^[3].

Fistula-in-ano is a very unpleasant condition from the patient aspect and the sufferer is a victim of anxiety as well as social stigma. It is an ano-rectal disease, with one or many sinuses with purulent discharge in the peri-anal region. For its peculiar location i.e. ano-rectal region, the doctors face many problems for its proper treatment and management. The major challenge in combating this disease is the wound contamination and the consequent sepsis which results in its recurrence and hence it poses a constant threat to the surgeons and patients alike. The patient has to face all the discomforts caused by the surgery like wound infection, non-healing, painful post-operative dressings etc. Almost all the standard textbook of surgery describes the general principles of ano-rectal surgery primarily in relation to the management of fistula-in-ano. The inadequacy of various conventional surgical procedures is proved by the frequent changes and modifications in the ano-rectal surgery. From the point of its peculiar location, the disease presents many problems for proper management. Wound contamination and consequent sepsis is one of the major hurdles in combating the disease. The recurrence of the disease, therefore has posed a constant threat to the surgeons and patients alike. Ayurveda has put forward an alternative

choice of treatment for the patients suffering from ano-rectal diseases. In recent years the *Ksharasutra* therapy has become the most suitable treatment option for the patients of *Bhagandara*^[4,5]. The *Ksharasutra* therapy is a unique technique of drug delivery for healing the fistulous track. It is quite an effective, ambulatory and safe alternative treatment. The CCRAS and ICMR has also validated this unique and effective approach^[6,7]. The present study is an attempt to evaluate the efficacy of *Palasha Kshara sutra* in the management of *Bhagandara* with special reference to fistula-in-ano to explore a more economical, easily available treatment module with least side effects.

OBJECTIVES

To evaluate the efficacy and acceptability of *Palasha Ksharsutra* in the Management of *Bhagandara*.

CLINICAL STUDY

Trial type: Randomized trial

Sample size: Total 20 patients were registered fulfilling all the inclusion criteria.

Study design: The clinical study was planned on Palash-kshara sutra and a clinical trial was done in Dept. of P.G. Studies in Shalyatantra, Jammu Institute of Ayurveda and Research Hospital, Jammu. 20 patients of *Bhagandara* were randomly selected from the OPD and IPD of department of Shalya Tantra of J. I. A. R., Jammu and treated with Palash Ksharsutra.

Criteria for selection of patients

A. Inclusion criteria:

- a) Age group of 25-70 years.
- b) Patients of Both the sexes
- c) Operative recurrences
- d) Patients with signs and symptoms as documented in classics.

B. Exclusion criteria:

- a) Stool incontinence post-surgery.

- b) Secondary fistula as complication of other diseases viz Crohn's disease, Rectal carcinoma, Ulcerative colitis etc.
- c) Tuberculosis of the hip joint or spine as the prognosis is not good.
- d) Pregnancy.

Materials Required:

Palash Ksharasutra, Normal saline, cotton swabs, gauge pieces, pads, sterile surgical gloves, feeding tube, disposable syringes, adhesive tapes and artery forceps etc.

Selection of Drug

Acharaya Sushruta in *Sutrastana Ksharapakavidi Adhyaya* has mentioned 24 drugs which can be used for the preparation of *Kshara*, among them, we selected *Palasha* for the preparation of *Ksharasutra*, as *Palasha* is

freely available allover and is inherited with the properties of *Krimigna*, *Vranahara* and *Gudarogajith*.

Method of preparation of *Ksharasutra*:

The method of preparation of *Palash Ksharasutra* was same as standard *Ksharasutra* except the drug which has been replaced by *Plasha Ksharasutra*. The method includes 11 coatings of *Snuhi Ksheera* alone, 7 coating of *Snuhi Ksheera* and *Kshara* prepared by *Palasha* and finally 3 coating of *Snuhi Ksheera* and *Haridra* powder. Total 21 coatings were applied on every *Ksharasutra*. The prepared *Ksharasutra* were placed for sterilization in *Ksharasutra* chamber and stored in glass test tubes for later use



Figure 1: Preparation of *Palasha Ksharasutra*

Preoperative procedure:

After selection the patients were undergone through following course of action.

- a. Investigations Routine hematological, biochemical, urine and stool examinations were done to rule out the pathological conditions mentioned above.
- b. A written consent was taken from the patients before the procedure.

Operative procedure:

The patients were kept in lithotomic position and the perianal region was cleaned with *Triphala Kwatha* and draping was done after local anesthesia infiltration. After assuring the patient, lubricated indexed finger gloved with Xylocaine 2% jelly was introduced into the

anus. Then external opening of the fistula was probed by passing suitable selected probe. The tip of the probe was guided by the tip of finger in anal canal and its tip was finally directed to come out through the internal opening in anal canal. The *Ksharasutra* was then negotiated into the eye of the probe. The probe was pulled out of the anal orifice leaving the *Ksharasutra* into fistulous track. Both the ends of the *Ksharasutra* were tied together loosely outside anal canal. Lastly, a gauze piece soaked in *Jatyadi Taila* was applied and T bandaging was done. The Patient was shifted to postoperative ward. The *Ksharasutra* threading procedure has been shown in figure 2

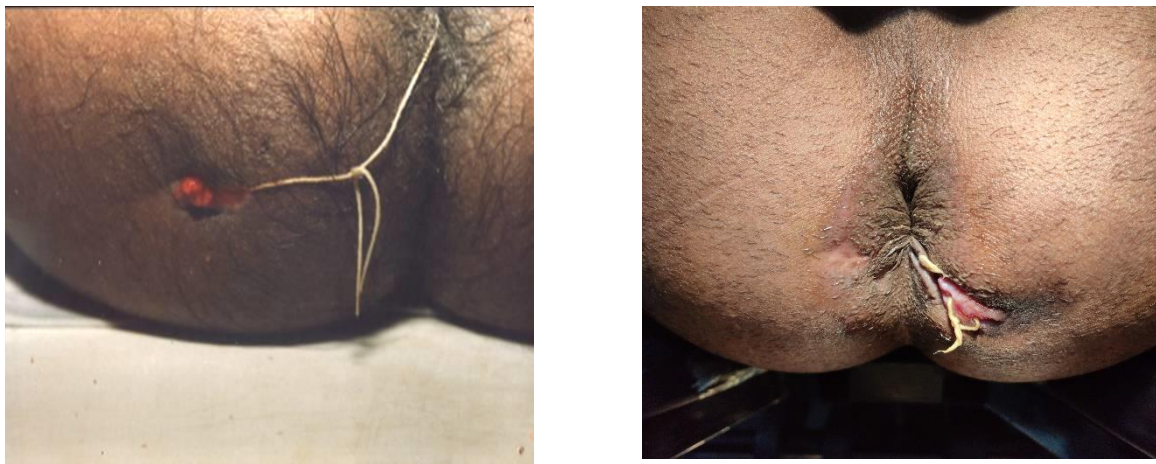


Figure 2: Showing application of Ksharasutra in patients of Bhagandara

Duration of treatment:

The Ksharasutra was changed by rail road technique^[8] every 8th day, the length of the track was measured at each sitting and recorded on a Performa. The principle behind changing the Ksharasutra after 7 days can be explained hypothetically that Shareera is composed of Sapta dhatus and it takes 24 hours for cutting each Dhatu. The procedure was continued till the track cut through completely.

Follow-up period

Patient was called for Follow-up once after every 30 days for 3 months after the completion of treatment. The patients were examine for recurrence of the disease or any associated problem of the ano-rectal area.

Assessment criteria:

Subjective parameters:

- a) Pain
- b) Discharge
- c) Swelling
- d) Itching

These parameters were assessed by scoring patterns.

Objective parameters:

Unit cutting time (U.C.T.)

OBSERVATION AND RESULTS

The description of Bhagandara Pidika clearly shows that Acharyas had an exact idea regarding the occurrence of a fistulous abscess and also knew that not all abscesses in this region lead to fistula in ano^[9]. In the present study total 20 cases were taken. Palash Ksharasutra (Snuhi Ksheera, Palash Kshara and Haridra Churna) was used in 20 cases who were treated on the line of previous works^[10]. The observations were made based on several parameters of study like age, chronicity, types of prakriti, types of Bhagandara, recurrence of cases post-surgery, number of fistulous openings and quadrants. Clinical findings like pain, discharge, discharge, unit cutting time, healing time etc. were observed during primary and successive application of Ksharasutra. The severity of pain, discharge and unit cutting time (in days/cm), healing time, wound healing etc. were analyzed statistically. The statistical analysis revealed that the treated 20 cases showed significant results in pain and discharge. The analysis further revealed that the average unit cutting time was 8.48 days/cm. The overall effect of therapy showed significant improvement in different parameters

Table 1: Showing Average unit cutting time in relation to Initial length of track

Initial length of tracks in cms	Average unit cutting time in days/cm
1-5	8.86
6-10	8.28
11-15	8.30
15-20	-
Total	8.48

Table 2: Showing the effect on Unit cutting time (UCT) in patients of *Bhagandara* undergoing *Palasha Ksharasutra* therapy

	Mean	S.D.	S.E.	t	df	'p' Value	Inference
UCT	8.48	0.88	0.200	42.95	19	<0.001	Highly significant

Table 3: Showing the effect of *Palasha Ksharasutra* therapy on various parameters of *Bhagandara Roga*

Parameter	Mean		Mean Dif.	S.D.	S.E.	t	df	'p' Value	Inference	% relief
	BT	AT								
Pain	2.05	1.45	0.6	0.600	0.13	4.49	19	<0.001	Highly significant	29.26%
Discharge	2.0	0.4	1.60	0.60	0.13	11.96	19	<0.001	Highly significant	80%
Healing time	1.45	0.75	0.70	0.470	0.11	6.66	19	<0.001	Highly significant	48%
Wound Healing	1.0	0	0.80	0.366	0.818	14.19	19	<0.001	Highly significant	100%

DISCUSSION

The trial drug *Palasha* showed significant results in reducing pain and pus discharge in the patients of *Bhagandara*. As per Ayurvedic

literature, *Palash has Katu, Tikta, Kashaya Rasa, Katu Vipak and Ushna Virya*. It possesses *Lekhana, Bhedana and krimighna* properties^[11]. By virtue of above-mentioned

properties *Palasha* effectively pacifies the vitiated *Kapha* and *vata Dosha* and hence alleviates their sign and symptoms respectively^[12]. The phytochemical studies have confirmed that Palash reduces inflammation, itching and pus discharge because of its Antimicrobial and Wound healing activity as it contains butrin, Isobutrin, Butin, Plasitrin and butein^[13]. It also has an astringent action which aids in wound healing. Further studies have revealed that the bark of palash possess anti helminthic property because of ethanolic and aqueous extracts .

CONCLUSION

Collection problems were trespassed as the collection process of *Palasha* is much easy as palash is widely and easily available throughout the year. The *Palasha Ksharasutra* is economical and has minimal problems while preparation and application of *Ksharasutra*. Wound healing after cut through was good. No recurrences of cases were reported during the follow up. So, it can be concluded in the present study that *Palasha Ksharasutra* is cost effective and having good efficacy in the treatment of fistula in ano and can be used as another standard *Ksharasutra*.

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