

**COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF  
PALASH KSHARSUTRA AND APAMARGA KSHARSUTRA IN THE  
MANAGEMENT OF KAPHAJ BHAGANDAR**

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**ABSTRACT:**

Fistula in ano is the very common disease in colo-proctology. The disease has high rate of recurrence and very difficult to manage. Due to long course of disease having pain and foul smelling discharge causing soakage of under garments patients felt a kind of social discomfort that affects the productivity of patients as well as social life of patients. Fistula in ano has resemblance to *Bhagandar* described in *ayurvedic* classias. In *Ayurveda Ksharsutra* therapy is excellent method for treatment of *Bhagandar*. *Ksharsutra* therapy is standardized and scientifically proved. In *Ayurveda Doshaghnatva* is the basic concept for management of diseases by various medicines. Every medicine has specific effect of specific *Dosh*. The problem for *Ksharsutra* therapy is that most of *Ayurvedic* surgeon used *Apamarga Ksharsutra* for all types of *Bhaganadar*, that creates the discomfort to the patients during therapy. So keeping this in mind this study was planned and taken specific *kaphaj Bhagandar* patients and treated with *Palash Ksharsutra*, having *kaphaghna* property. Total 60 patients divided in two groups and results were compared with *Apamarga Ksharsutra*. The results observed were very encouraging.

**Keyword:** *Bhagandar*, Fistula in ano, *Ksharsutra*, *Palash*.

**INTRODUCTION:** Fistula in ano is a chronic non healing communicating track between anal canal and external skin having unhealthy granulation tissue<sup>1</sup>. It is characterized by one or more small opening around anal orifice. In its simplest form, it is a single track with an external opening in the skin of perianal region, and internal opening in the modified skin or mucosa of anal canal or rectum. In *Ayurvedic* classic literature fistula in ano has resemblance to *Bhagandar*. *Acharya Sushruta* is the prime surgeon of *Ayurveda*. He wrote the first ever surgical text of *Ayurveda* known as *Sushrut Samhita*. *Sushrut* mentioned five types of *Bhagandar* according to *Doshik* predominance<sup>2</sup>. *Sushruta* well explained the management of all kind of *Bhagandar*<sup>3</sup>. There

are various technique for the management of fistula in ano in modern medical science. The conventional methods as Fistulotomy, Fistulectomy, seton placing<sup>4</sup> and some other advance technique as Ligation of Intersphincteric Fistula Track (LIFT)<sup>5</sup>, Fibrin glue, Advancement Flap<sup>6</sup>, Expanded adipose derived Stem Cells (ASCs)<sup>7</sup>, Vedio Assisted Anal Fistula Treatment (VAFT)<sup>8</sup>. In spite of having all these advance technique fistula in ano is still a challenge for the surgeons. *Ksharsutra* therapy is the gold standard technique for management of fistula in ano. *Ksharsutra* is basically a medicated thread having the coating of alkali material called *Kshara*. *Kshara* is prepared by using the ash of plant. Now days most of the *Ayurvedic* surgeon ignore the *Doshik* pre-

dominance of *Bhagandar* and treat all the *Bhagandar* similar way, using *Apamarga Ksharsutra*. *Apamarga Ksharsutra* is the well-established standard, mostly use by most of the *Ayurvedic* surgeons. In spite of having good results *Apamarga Ksharsutra* create some problems like severe burning sensation, delayed healing, inflammation at operative site and sometime sensitivity during the treatment of fistula in ano. On the basis of a study done by Dr. Sudeep Rath<sup>12</sup> et<sup>al</sup> in NIA Jaipur on the *Kshara* source plant, we prefer the treatment of particular *Bhagandar* with the use of particular plant having the *Doshaghnavta* properties for the involved *Dosh* so it is the need of hours that we should use some other *Ksharsutra* also keeping the *Doshik* predominance in mind. *Sushruta* mentioned various plants for the preparation of *kshara*. So keep in mind the pharmacological properties (*Doshaghnta*) of *Palash* plant the study was plan entitled “Comparative Study to Evaluate the Efficacy of *Palash Ksharsutra* in the Management of *Kaphaj Bhagandar*” the results were compared with standard *Apamarga Ksharsutra*.

#### AIMS & OBJECTIVES:

1. To evaluate the efficacy of *Palash Ksharsutra* in the Management of *Kaphaj Bhagandar*.
2. To assess the acceptability of *Palash Ksharsutra* in the Management of *Kaphaj Bhagandar*.
3. To compare the effect of *Palash Ksharsutra* with *Apamarga Ksharsutra* in the management of *kaphaj Bhagandar*.

#### MATERIALS AND METHODS:

##### Randomized trial

##### Sample size:

Total 60 patients (30 in each Group) of *Kaphaj Bhagandar* were registered for the

trial who fulfilling the all inclusion criteria and given informed consent.

**Study design:** 60 patients were randomly selected from the OPD and IPD of National Institute of *Ayurveda*, Jaipur from department of *Shalya Tantra* and divided in two Group A and B.

**Group A** 30 patients of *Bhagandar* were selected according to *Dosh (Kaphaj)* predominance and treated with *Apamarga Ksharsutra*.

**Group B** 30 patients of *Bhagandar* were selected according to *Dosh (Kaphaj)* predominance and 30 patients in this Group treated with *Palash Ksharsutra*.

**Source:** Subjects were selected from O.P.D. / I.P.D. at P.G. Department of *Shalya Tantra*, N.I.A., Jaipur

**Study type:** Interventional.

Materials required for the study:

1. Prepared *Palash Ksharsutra* from the *kshara* of *Palash panchang* ash with *Snuhi Ksheera* (latex) and *Haridra* powder.
2. Normal saline, cotton swabs, gauge pieces, pads, sterile surgical gloves, feeding tube, disposable syringes, adhesive tapes and artery forceps and other essential equipment/ instruments.

The method of *Ksharsutra* preparation includes 11 coatings of *Snuhi Ksheera* alone, 7 coating of *Snuhi Ksheera* and *Kshara* prepared by *Palash* and finally 3 coating of *Snuhi ksheer* and *Haridra* powder. Total 21 coatings were applied on every *Ksharsutra*. The prepared *Ksharsutra* were placed for sterilization in *Ksharsutra* chamber and the stored in glass test tubes for later use.

**Informed consent:** The study were explained clearly to the subjects and their signed, written informed consent were taken before starting the trial.

Study acquire the approval from Institutional Ethic committee N.I.A. Jaipur, ref. no IEC/ACA/2015/15 dated 21.05.2015

#### **Inclusion Criteria:**

1. Patients of *Vataj Bhagandar* from 20 - 65 years age Group, irrespective of sex and economic status.
2. Patients were ready to give written informed consent.

#### **Exclusion Criteria:**

1. Patients having *Vataj, Pittaj Sannipataj* and *Agantuj Bhagandar*.
2. High level fistula having internal opening in rectum or above anorectal ring.
3. *Bhagandar* with systemic involvement of disease like Diabetes Mellitus, Hypertension, AIDS, Hepatitis-B, Tuberculosis, Crohn's disease and Ulcerative colitis having morbid changes.

#### **Withdrawal Criteria**

1. Intolerance to therapy.
2. Unwillingness to continue with the study.
3. Patients with irregular follow-up. Development of any condition requiring any other specific management.

#### **Selection of Sample According to Ayurvedic Features of Disease**

##### **Features of Vataj Bhagandar**

1. *Arun varna pidika*
2. Small multiple openings
3. *Phenayukta shrav* (Continuous frothy discharge)
4. *Tadan, bhedan, chedan* and *Tod* kind of *ruja*

##### **Features of Pittaj Bhagandar**

1. *Rakta varna pidika*
2. *Chos (Dah)* type of *ruja*
3. *Durgandhit usna shrav* (Foul smelling warm discharge.)

##### **Features of Kaphaj Bhagandar (Group-A and B)**

1. *Sukla varna pidika*
2. *Kandu* (Itching)
3. *Pichhil shrav* (Thick discharge)
4. *Sthiram* ( hard swelling)

**Duration of clinical assessment and follow-up study:** Clinical assessments were done weekly after primary threading up to 8 weeks. All the Patients were assessed for the pain, discharge of pus, burning sensation, tenderness, itching, Length of tract, granulation tissue and unit cutting time every week. The overall assessment on subjective and objective parameters in all sub Groups of A and B were done after eight weeks. The patients were followed up every month for further six months.

**Operative procedure:** At first the patient were kept in lithotomy position and perianal region was cleaned with antiseptic solution and draping was done after local anaesthesia infiltration. After assuming complete anaesthetic effect, lubricated gloved finger with Xylocaine jelly 2% was introduced into the anus. Then suitable selected probe was passed through the external opening of fistula. 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. Then suitable length of plain Barbour's thread was threaded into the eye of probe, thereafter the probe was pulled out through the anal orifice to leave behind the thread into fistulous track. The two ends of plain thread were tied together loosely outside anal canal. The area was cleaned and dressed with surgical pad and T- bandage was tied. Patient was shifted to postoperative ward.

**Changing of Ksharsutra :** On second postoperative day plain thread was replaced by *Palash* and *Apamarga Ksharsutra* accordingly after sensitivity test and

later on weekly threads was changed. For first week *Ksharsutra* was kept loose .For changing *Ksharsutra* , it was tied on previously applied thread towards outer end of knot .Then an artery forceps was applied at inner end to the same knot. Then the old thread was cut between the artery forceps and the knot. Pulling of artery forceps along with old thread ultimately replaced the old thread by new *Ksharsutra*. Then the two ends were tied and bandaging was done. The same procedure was followed for successive changes.

At each sitting of changing of *Ksharsutra* the length of track was measured and recorded on Performa.

**ASSESSMENT CRITERIA:**

**Subjective parameters:**

1. Itching

**Objective parameters:**

2. Pus Discharge
3. Granulation Tissue
4. Unit cutting time (U.C.T.)

**OBSERVATION AND RESULTS:**

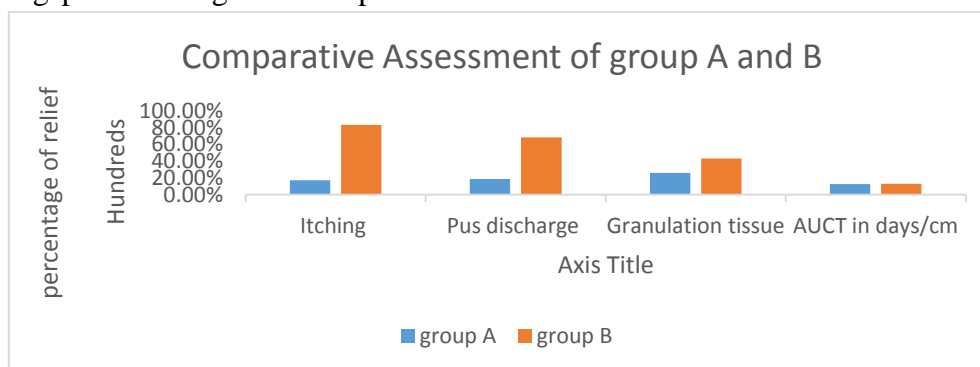
**Results of Intergroup Comparison**

**Table no. 1 Comparative Assessment of Group A and B**

S.N.	Parameter	% relief in Group A	%relief inGroup B	Mann-Whitney U-statistic	p-value	Remarks
1	Itching	17.2%	83.3%	25.0	0.0250	S
2	Pus discharge	18.5%	68.4%	30.0	0.0488	S
3	Granulation tissue	25.9%	43%	43.0	0.3014	NS
4	Average Unit cutting time	12.6 days/cm	12.9 days/cm	42.5	0.2982	NS

**Comparative Assessment of Group A and B:** After statistical analysis of inter Group comparison between Group A and B data, It was observed that When we compare itching, p-value= 0.0250 that shows so significant improvement in reducing itching in Group B. U value=25. When we compare pus discharge p-value= 0.0488 that shows significant improvement in reducing pus discharge in Group B. U

value=30. When we compare granulation tissue, p-value= 0.3014 that shows no significant improvement in formation of healthy granulation tissue in Group 3. U value=43.0 When we compare Average Unit cutting time p-value= 0.2982 that shows no significant difference in Average Unit cutting time in both Groups. U value=42.



Graph of comparative assessment of both Groups

**COMPARISON OF % RELIEF OF DIFFERENT PARAMETER IN BOTH**

**GROUP A AND B**

**Assessment of Itching :**In the assessment

of itching in both the Group it was found a significant improvement in Group B.

#### Assessment of pus discharge

In the assessment of pus discharge in both the Group it was found a significant improvement in Group B.

#### Assessment of Granulation tissue

In the assessment of itching in both the Group it was found no significant improvement seen in Group B.

#### Average unit cutting time

In the assessment of Average unit cutting time in both the Group, there is no significant difference in any trial Group.

### DISCUSSION:

#### Discussion on assessment parameters

**Itching:** Patients of Group A felt 17.2% relief in Itching while patients of Group B felt 83.3% relief in Itching. So we see that maximum percentage of relief in the Itching at disease site was observed in Group B. These results are due to the properties of plant having that carry forward to the *Ksharsutra* also, that properties helps in reducing itching. As we know the itching occur due to the involvement of *kapha Dosh*. As per our classical literature *Palash* plant has *Rasa Katu, Tikta and Kashaya, Vipaka –Katu, Veerya–Ushna and Kaphapittahara*. With the virtue of these properties *Palash* has worked on *kapha Dosh* leading to the reduction of itching in the patients.

**Pus discharge:** Patients of Group A felt 18.5% relief in Pus discharge while patients of Group B felt 68.4 % relief in Pus discharge. The above data shows that in B Group there were significant improvement in % of relief in pus discharge was observed rest other Group patients there were no significant improvement was observed. The reason behind that may be *rasa, guna, virya* and *vipaka* of *Palash* plant. *Palash*

also have the *Lekhana, bhedana* and *krimighna* property that helps in early leaning of dead tissue so that pus reduces significantly.

**Granulation tissue:** Patients of Group A felt 25.9% relief in granulation tissue while patients of Group B felt 43 % relief in granulation tissue. The above data shows there is no significant improvement in the percentage of relief in granulation tissue formation.

**Average Unit Cutting Time:** Patients of Group A had average unit cutting time 12.6 days/cm, while patients of Group B had average unit cutting time 12.9 days/cm. Above data shows that there is no significant changes were observed in the average unit cutting time of both the Groups. This is may be due to that the cutting of fistulous track was depends on the mechanical pressure applied by thread on the tissue. Because the thread was tied almost equally in all the patients that's why there were no significant change in the average cutting time was observed.

**The overall assessment of therapy:** The overall effect of therapy in both the trial and control Group. The significant improvement in different parameters has been observed in trial Group. In case of itching *Palash Ksharsutra* have shown the significant results however *Apamarga Ksharsutra* have no significant effect. In case of pus discharge only *Palash Ksharsutra* have shown the significant results In case of granulation tissue *Palash Ksharsutra* have no significant improvement in. On comparing the unit cutting time of both trial and control Group no significant difference has been observed.

**Probable mode of action of trial drugs**  
The trial drug of the study was *Palash*. Results shows that *Palash* has significant re-

sults in reducing, itching and pus discharge in the patients of *Kaphaj Bhagandar*. As per *Ayurvedic* literature *Palash* has *Katu*, *Tikta*, and *Kashaya Rasa*, *Katu Vipak*, *Ushna Virya* and *Lekhan Abhedana* and *krimighna* property. By virtue of above mentioned all these properties *Palash* effectively pacified the vitiated *Kapha Dosh*a and works on the sign and symptoms produced by vitiated *Kapha*. That is why we found the significant effect of *Palash Ksharsutra* in the management of *Kaphaj Bhagandar*. On phytochemical study it was found that *Palash* has Antimicrobial, Antifungal activity, Antitumor activity, Wound healing and Anti helminthic activity. Due to these properties *Palash* work very well on the wound healing. It reduces itching and pus discharge because of having antimicrobial and anthelmintic property.

#### CONCLUSION:

- In overall assessment Group B patients shows more percentage of relief than Group A.
- Itching and pus discharge is the prominent feature of *Kaphaj Bhagandar*.
- *Palash Ksharsutra* is having significant effect on reducing itching and pus discharge in the patients of *Kaphaj Bhagandar*.
- There is no significant difference in average unit cutting time of *Apamarga* and *Palash Ksharsutra*.
- Patients treated with *Apamarga Ksharsutra* felt more postoperative discomfort during treatment than *Palash*.
- The duration of treatment is almost equal in both the Group but discomfort during treatment is less in Group B patients.

- The trial drug *Palash* has good acceptability by the patients of *Kaphaj Bhagandar*.
- Patients with *Kaphaj Bhagandar* should be treated with *Palash Ksharsutra*.
- *Palash* is the good option for the treatment of *Bhagandar*.
- *Haridra* is used for preparation of *Ksharsutra* provides faster wound closure or healing effect.
- No recurrence of case was found in six months of follow-up study.
- There were no side effects found during the complete trial.

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**Some pictures of trial**



BEFORE TREATMENT



DURING TREATMENT



AFTER TREATMENT



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