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**CLINICAL COMPARATIVE STUDY ON THE EFFECT OF PAPAYA *KSHEERA*  
BASED *NIMBA KSHARASUTRA* AND STANDARD *APAMARGA KSHARASUTRA*  
IN *BHAGANDARA* (FISTULA-IN-ANO)**

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**ABSTRACT**

*Bhagandara* is considered as one among the *Mahagada* in *Sushruta Samhita*. *Kshara Sutra* Therapy is a Simple and safe parasurgical procedure, cost-effective and ambulatory, minimal recurrence rate, no surgical complications like incontinence, stenosis and stricture. *Snuhi Ksheera* based *Apamarga Ksharasutra* is proved effective treatment in the management of Fistula-in-ano. But, burning sensation, local irritation during the course of therapy and difficulty of manufacturing process has limited its use. To explore a better substitute of Standard *Apamarga Ksharasutra*, the

present study has been taken up to know the efficacy of Papaya *Ksheera* based *Nimba Kshara Sutra* in the management of *Bhagandhara*.

**Keywords:** Papaya *Ksheera*, *Snuhi*, *Apamarga*, *Ksharasutra*, *Bhagandara*, *Fistula in ano*

## INTRODUCTION:

The word fistula is derived from a Latin word a reed, pipe or flute. It implies a chronic granulating track connecting two epithelial-lined surfaces [1]. Fistula-in-ano is one of the most common ailments pertaining to ano-rectal region. This disease causes discomfort and pain to patient, which creates problems in routine work. In Ayurvedic classics, this disease has been described with the name of *Bhagandara* [2], which has more similar signs and symptoms with anal fistula. The *Kshara Sutra* therapy was practiced and used in since long with great success and without recurrences. The Standard *Kshara Sutra* is prepared by repeated coatings of *Snuhi Ksheera*, *Apamarga Kshara* and *Haridra*. Overcoming the causation of pain and burning sensation was a very important necessity because of which surgeons of *Ayurveda* came out with newer ideas. Thus it gave to many *Kshara Sutr*s were tried out in the department like *Arka Kshara Sutra*, *Madhu Kshara Sutra* [3], *Papaya Kshara Sutra* etc. Though each of the thread had good cutting rates and other preparation advantages they also had some disadvantages [4]. The idea

behind the present work is to find out the effectiveness of Papaya *Ksheera* based *Nimba Kshara Sutra* in the management of *Bhagandara* and find out such a treatment, which is economical, easily available, as well as minimize the problems of *Kshara Sutra* therapy.

## Objectives:

Evaluate and compare the efficacy of Papaya *Ksheera* based *Nimba Kshara Sutra* and Standard *Apamarga Kshara Sutra* in the management of *Bhagandara* (Fistula-in-ano).

## MATERIALS AND METHODS:

The efficacy of Papaya *Ksheera* based *Nimba Kshara Sutra* therapy has been studied in 40 cases which is divided into two groups i.e. Study group Papaya *Ksheera* based *Nimba Kshara Sutra* – Group A and treated group *Snuhi Ksheera* based *Apamarga Kshara Sutra* – Group B.

## Source of Data:-

The patients will be selected from the OPD and IPD department of Shalya Tantra of Shree Dharmasthala Manjunatheswara College of Ayurveda and Hospital, Hassan

## Groups Design:-

Minimum 40 Patients of *Bhagandara* will be randomly divided into the following two groups.

**Group A: Study group (20 Patients):-**

The patients of this group will be applied Papaya *Ksheera* based *Nimba Kshara Sutra*. The *Kshara Sutra* will be changed once in a week till a complete cutting of the tract.

**Group B: Standard group (20 Patients):-**

The patients of this group will be applied standard *Apamarga Kshara Sutra* as per Classical method. The *Kshara Sutra* will be changed once in a week till a complete cutting of the tract.

**Duration of the Treatment:-**

It will depend on the length of fistulous tract.

**Randomization Method:-**

It is Simple random sampling method

**Inclusion criteria**

- Clinical signs and symptoms of all types of *Bhagandara*

- Patients above the age of 18 years and below 60 years irrespective of caste, gender, religion and socio-economic status.

**Exclusion criteria:**

- Patients with secondary fistula due to Ulcerative colitis, Crohn's disease, Tuberculosis, Hidradenitis Suppurativa, Carcinoma of rectum & anal canal
- Patients with HIV and HbsAg positive patients
- Pregnancy and lactating women
- Patients with impaired cardiac, renal and hepatic function.

**Diagnostic criteria:**

- Diagnosis was made on the basis of *Samanya Lakshanas* of *Bhagandara*
- Pain and boil in perianal region
- Discharge from perianal region

**Preparation of Papaya *Ksheera* based *Nimba Ksharasutra***

**Table 1: pH of different drugs in *Apamarga Ksharasutra* and Papaya *Ksheera* based *Nimba Ksharasutra***

S. No	Drugs	pH
01	<i>Apamarga Ksharasutra</i>	9.7
	<i>Snuhi Ksheera</i>	5.5
	<i>Apamarga Kshara</i>	9.6
	<i>Haridra</i>	6.6
02	Papaya <i>Ksheera</i> based <i>Nimba Ksharasutra</i>	9.9
	<i>Papaya Ksheera</i>	5.9
	<i>Nimba Kshara</i>	9.8
	<i>Haridra</i>	6.6



Fig 1: Papaya Kshelera



Fig 2: Nimba



Fig 3: Haridra Choorna



Fig 4: Coating process of Ksharasutra



Fig 5: Ksharasutra cabinet



Fig 6: Storage of Ksharasutra

**ASSESSMENT CRITERIA:**

1. Unit Cutting Time =  $\frac{\text{Total No. of days taken for cut through}}{\text{Initial length of track in cms}}$   
= days/cm

- 2. Pain
- 3. Discharge
- 4. Granulation tissue
- 5. Size of the wound

**Grading:**

**2) Pain**

Grade 0- No pain

Grade 1- Mild

Grade 2- Moderate

Grade 3- Severe

**3) Discharge**

Grade 0- Absent

Grade 1- Present

**4) Granulation Tissue**

Grade 0- Healthy

Grade 1- Moderate

Grade 2- Hyper granulation

Grade 3- Granulation absent

**5) Size of the wound**

Grade 0- Healed

Grade 1- 0.5-1cm

Grade 2- 1-2cm

Grade 3- 2-3cm

**Application of Papaya Ksheera based Nimba Kshara Sutra**

The patient is kept in proper lithotomy position and perianal region was cleaned with antiseptic lotions and draped. Patient is reassured and gloved finger was gently introduced into the rectum. Then a probe was

passed through the external opening of fistula. The tip of the probe was forwarded along the path of least resistance and was guided by the finger in rectum to reach into the lumen of anal canal through the internal opening and its tip was finally directed to come out of anal orifice. Then a suitable length of *Kshara Sutra* was taken and threaded into the eye of probe. There after the probe was pulled out through the anal orifice, to leave the thread behind in the fistulous track. The two ends of the thread were then tied together with a moderate tightness outside the anal canal.

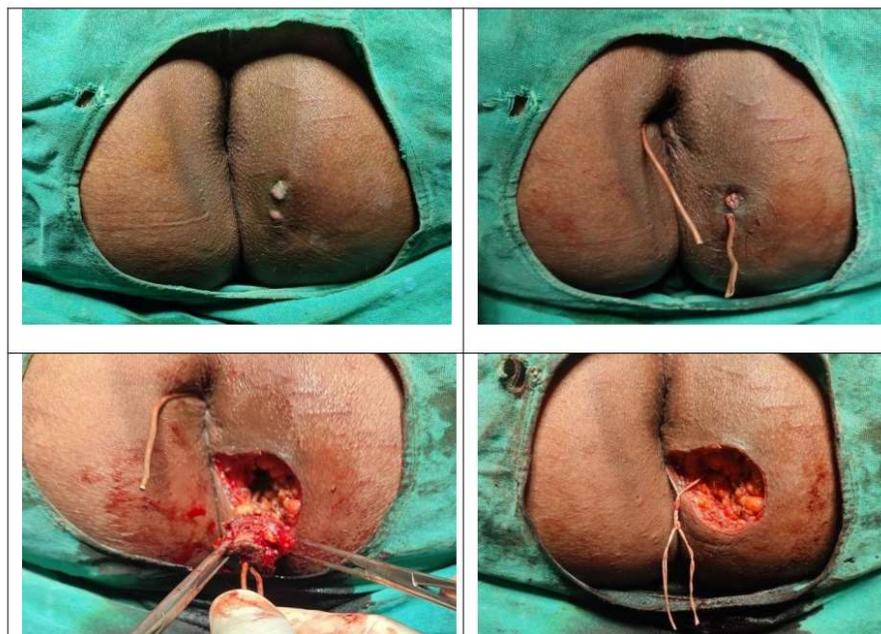


Figure 7: Method of application of Ksharasutra

Application of Papaya Ksheera based Changing of Ksharasutra	Probing from external opening to internal opening
Partial fistulectomy done to remove fibrosed tissue	Application of Ksharasutra

### **Change of Papaya Ksheera based Nimba Kshara Sutra**

All patients were instructed to take sitz bath before changing the thread. The Papaya Ksheera based Nimba Kshara Sutra was changed at weekly interval. The thread is tied to the previously applied Papaya Ksheera based Nimba Kshara Sutra in position towards outer end of the knot. Then an artery forceps is applied inner end to the same knot. Then the old thread is cut between the artery forceps and the knot. Pulling of the artery forceps along with the thread ultimately replaces the old thread by Papaya Ksheera based Nimba Kshara Sutra. Then the two ends are ligated and bandaging was done. This procedure is done by Railroad technique. The same procedure is followed for successive changes of Papaya Ksheera based Nimba Kshara Sutra at weekly interval.

### **Follow-up**

All the patients were instructed to visit OPD once in a week on the same day of previous week Ksharasutra change till the complete cut through of the fistulous tract

### **Observations and result**

The efficacy of Papaya Ksheera based Nimba Kshara Sutra and Apamarga Kshara Sutra have been studied in 40 patients of Fistula-in-

ano, divided into two groups, Study group (Group A) - Papaya Ksheera based Nimba Kshara Sutra and Control group (Group B) – Apamarga Kshara Sutra were applied.

All 40 patients of fistula-in-ano have been analysed for age, sex, occupation, habitat, nature of diet, addictions, Doshic Prakriti, bowel habits, type of Bhagandara, type of fistula-in-ano, position of the external openings, length of fistulous track and recurrent cases.

The length of the Papaya Ksheera based Nimba Kshara Sutra was measured after each change and was noted in every case. After few days of therapy, this Sutra comes out with the knot intact. This stage is known as Cut Through. The Average Unit Cutting Time (U.C.T.) of treated group (Papaya Ksheera based Nimba Kshara Sutra) was calculated and compared with control group (Apamarga Kshara Sutra).

During the course of treatment, the process of cutting and healing worked simultaneously. However, the small area was still remained to heal completely at the end of total cut through which took 2-3 weeks in control groups in complete closure of the wound and whereas 1-2 weeks was taken for healing completely in study group.

**Table 2: Average Unit cutting time Study and Control Groups**

Group	Average U.C.T.
Study group (Group A)	11.1
Control group (Group B)	9.3

**Table 3: Status showing the effect on U.C.T in therapy groups**

	Mean	S.D.	S.E	t	df	'p' Value	Inference
Group A	11.16	2.45912	0.54988	2.96	38	.005	Highly Significance
Group B	9.39	1.02218	0.22857	2.96	25.37	.006	Highly Significance

**Table 4: Status showing the pain criteria in study and control groups**

Treatment	Group A			Treatment	Group B		
	Mean	Mean difference	%		Mean	Mean difference	%
BT	5.53	4.15	75.04	BT	5.58	4.15	74.37
AT	1.38			AT	1.43		

**Table 5: Status showing the discharge criteria in between study and control groups**

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Mann-Whitney U	200.00	200.00	140.00	190.00	130.00	200.00
Wilcoxon W	410.00	410.00	350.00	400.00	340.00	410.00
Z value	.000	.000	-2.623	-.316	-2.876	.000
P value	1.000	1.000	.009	.752	.004	1.000
Significance	NS	NS	S	NS	HS	NS

**Table 6: Status showing the granulation tissue criteria in study and control groups**

Treatment	Group A			Treatment	Group B		
	Mean	Mean difference	%		Mean	Mean difference	%
BT	6.00	4.27	71.16	BT	5.93	3.9	65.76
AT	1.73			AT	2.03		

**Table 7: Status of wound healing in therapy groups after 7 days of cut through**

Treatment	Group A			Treatment	Group B		
	Mean	Mean difference	%		Mean	Mean difference	%
BT	5.60	3.62	64.64	BT	5.68	3.6	63.38
7 Days	1.98			7 Days	2.08		

**Table 8: Status of wound healing in therapy groups after 15 days of cut through**

Treatment	Group A			Treatment	Group B		
	Mean	Mean difference	%		Mean	Mean difference	%
BT	5.60	4.12	73.57	BT	5.68	4.33	76.23
15 Days	1.48			15 Days	1.35		

**DISCUSSION**

Average unit cutting time in Study Group A is 11.1cm and Control Group B is 9.3cm. Both study group and control groups are equally effective in reducing pain in *Bhagandara*. Pain felt by the patients at the time of changing Papaya based *Nimba Kshara Sutra* was very less in compared to *Apamarga Kshara Sutra*, 75.04% patients complained less degree of pain in Group A compared to 74.37 patients in Group B. Status of discharge in comparison with Group A and B, there

was no much Mean difference in both the groups, only 3<sup>rd</sup> and 5<sup>th</sup> week there was significant difference. Group A is equivalent to Group B in criteria of reduction of discharge. Assessment of granulation tissue Group A was more effective 71.16% than of Group B 65.76%. Status of wound healing in both groups after 7 days of cut through is 63.38% of cases in Group B as compared to 64.64% of cases in Group A, hence both of the groups are significantly effective in wound healing.



**Figure 8: Case report – 1 Application of Papaya Ksheera based Nimba Ksharasutra**

Application of Papaya Ksheera based Nimba Ksharasutra	Changing of Ksharasutra on 3rd week
Patient came for follow up 1 week after cut through of Ksharasutra	



**Figure 9: Case report-2 Application of standard Apamarga Ksharasutra**

Application of Standard Apamarga Ksharasutra	Patient came for follow up after cut through of Ksharasutra
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**Probable mode of action:**

**Papaya Ksheera** is having *Vranaghna*, *Vedanasthapana*, *Krimighna* properties and acts as anti-inflammatory, anti-microbial agent to counteract the pain, discharge and pruritis and within short duration. Papaya *Ksheera* acts as enzymatic tissue debriding agent, which helps in removal of fibrosed and unhealthy granulation tissue. It enhances collagen synthesis, thus improving healthy granulation tissue, wound contraction and complete healing [5].

**Nimba Kshara** (*Azadirachta indica*) has *Kushtagna*, *Krimighna*, *Pitta Kaphahara Karma*. In *Kshara* form it attains *Bhedana*, *Lekhana* and *Chedana* properties. Chemical constituent Nimbidin having antifungal, antimicrobial, antiviral, antidiabetic and antihelmintic action [6]. *Nimba* having properties; *Kashaya Tikta Rasa*, *Laghu Rooksha Guna*, *Katu Vipaka*, and *Sheeta Veerya*. [7] *Dhanwantari Nighatu* emphasizes *Shothahara* and *Vedanashamaka* properties of *Nimba*. [8]. *Nimba* is easily available easy to prepare and cost effective and *Kshara*.

**CONCLUSION:**

The aim of present study is to find out the efficacy of Papaya *Ksheera* based *Nimba Kshara Sutra* in the management of *Bhagandara*. Based on the clinical

statistical data, it may be concluded as follows:

- Pain, burning sensation, irritation, inflammation, hyper granulation and local reactions was minimal in study group as compared to control group.
  - There was faster healing of wound after cut through in treated group than control group.
  - Total average of UCT was less in control group 9.3 days/cm in comparison with treatment group 11.1 days/cm. there is statistically no significant difference of UCT between the groups.
  - Papaya *Ksheera* based *Nimba Kshara Sutra* is easy to prepare in comparison to *Apamarga Ksharasutra*.
  - Out of 40 cases treated, no recurrence has been reported after 6 months of follow up.
- So, Papaya *Ksheera* based *Nimba Kshara Sutra* can be considered as a better alternative in place of Standard *Apamarga Kshara Sutra*. Although UCT time is more than the Standard one but it has more acceptability, easily available, convenient in preparation, less burning sensation and irritation felt by patients, better in reduction of pain and discharge, better in improvement of granulation tissue and requires minimal hospital stay.

**Informed Consent:** All patients provided informed consent for the publication of this study.

**Ethics:** The study was conducted adhering to all clinically ethical principles and recommended by institutional ethical committee (IEC), SDMCAH, Hassan. IEC No: SDM/IEC/93/2021

**CTRI No:** CTRI/2023/02/049502

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