



A CLINICAL STUDY ON THE EFFICACY OF VIBHITAKA KSHARSUTRA IN THE MANAGEMENT OF BHAGANDARA (FISTULA-IN-ANO) A PILOT STUDY

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ABSTRACT

Acharya Sushruta has mentioned that all types of *Bhagandara* (Fistula-in-Ano) are difficult to treat and in modern Surgery also it is known for its callous nature and recurrence. *Ksharasutra* Therapy is a time tested therapy for the treatment of this disease which requires a minimal set up and is a simple, safe and comparatively better choice. *Vibhitaka Ksharsutra* has been prepared and studied in this study. A total of 15 patients suffering from *Bhagandara* (Fistula-in-ano) were randomly selected and treated with *Vibhitaka Ksharsutra*. The duration of the Trial was three months from the day of intervention with a further follow up of two months. The data collected was statistically analyzed for the interpretation of results. *Vibhitaka Ksharsutra* was found effective in relieving symptoms of Itching and pus discharge with minimal post-operative complications and all the patients were completely relieved from the symptoms of the disease however one patient reported with the recurrence of symptoms one month after complete cutting and healing of the fistulous tract. *Vibhitaka Ksharsutra* can become a better alternative to *Apamarga Ksharsutra* in the treatment of *Bhagandara* (Fistula-in-ano).

KEYWORDS: *Bhagandara*, *Vibhitaka*, Fistula-in-ano.

INTRODUCTION

Bhagandara is one of the commonest diseases occurring in ano-rectal region which is difficult to treat because of its high recurrence rates. In *Ayurveda*, *Bhagandara* has been mentioned as one among *ashtamaharoga*^[1] (eight major diseases) because of its callous attitude. *Acharya Sushruta* has explained *nidana*, *samprapti*, *bheda*, *lakshana*, *upadrava* and *chikitsa*^[2,3] of *Bhagandara* in detail. *Bhagandara* can be compared to Fistula-in-ano in modern science on the basis of similarities in the symptomatology mentioned in *Ayurvedic* and modern text books. The Surgical operations of Fistulotomy and Fistulectomy adopted in modern surgery have high recurrence rate and subjects patients to a great discomfort and agony. *Ayurvedic Ksharsutra* therapy in the treatment of *Bhagandara* is a time tested modality which is safe, cost effective with low or no recurrence rate in the hands of an expert *Ayurvedic Surgeon*, which has been in practice since many centuries but the recent advancements in this therapy has made it more popular among the masses.

The *Ksharsutra* is routinely prepared with *Apamarga Kshara*, *Snuhi Ksheer* and *Haridra* as per standard procedure of 11 coatings of *Snuhi Ksheer*, 7 coatings of *Apamarga Kshara* and 3 coatings of *Haridra Churna* on

Barbour's thread no.20 as per specification. This type of *Ksharsutra* is called Standard *Apamarga Ksharsutra*. A lot of difficulties are arising in the preparation of this type of *Ksharsutra* because the *Apamarga* plant is a seasonal plant and the *Kshara* prepared cannot be preserved for longer periods of time. Secondly post-operative Pain and Burning sensation associated with *Apamarga Ksharsutra* application makes it unsuitable for sensitive patients. To overcome these problems, *Vibhitaka Ksharsutra* has been tried in this study in the light of references available in *Sushrut Samhita*.^[4]

AIMS AND OBJECTIVES

1. The main aim of this study is to evaluate the efficacy of *Vibhitaka Ksharsutra* in the management of *Bhagandara*.
2. To study the post-operative complications of *Vibhitaka Ksharsutra* in the management of *Bhagandara*.

MATERIALS AND METHODS

Sample Size: A total of 15 subjects were randomly selected for the trial, with ages ranging from 20 years to 60 years, irrespective of sex, religion, and socioeconomic status.

Source of Subjects: Out Patient and In Patient Department of P.G.Department of Shalya Tantra, National Institute of Ayurveda, Jaipur.

Inclusion Criteria

- Male or female between age 20 to 60 years and willing to give their written informed consent.
- No major systemic disease involved.
- Patients who have signs and symptoms of *Bhagandara* (Fistula-in-ano-in-ano).

Exclusion Criteria

- Male or female less than 20 years and greater than 60 years of age.
- Patient with known hypersensitivity to any of the components of the formulation.
- Secondary Fistula-in-ano.

Informed Consent

All the subjects selected for the study were fully informed about the nature of the disease, treatment and the possible post-operative complications. A written informed consent was taken from all the subjects before starting of the trial.

Diagnostic Criteria

- History
- Systemic Examination
- Local Examination
- Lab Investigations

Study Type: Interventional.

Study Design: Prospective, Randomized, Unicentric, Single Blind Trial.

Methods

15 subjects were randomly selected by lottery method.

Post-operative medication in all the patients

- Hot Sitz bath with ½ Tsf of Tankan until healing of the wound.
- Triphala Guggulu 2 Tabs BD for two weeks.
- Daily Antiseptic Dressing of the wound with Jatiyadi Tail until the complete healing of the wound.
- Triphala Churns 3g with Lukewarm water at bed time for two weeks.

Study Duration: 3 months from the date of intervention. The patients were followed up on weekly basis for *Ksharsutra* change in the OPD of P.G.Department of Shalya Tantra N.I.A. Jaipur

Follow-UP: 2 months from the day of complete healing of the wound.

Assessment Criteria

The assessment was done on the basis of following parameters according to Proforma.

A. Primary Outcome Measures

❖ Subjective parameters

- Itching
- Pus Discharge

❖ Objective parameters

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

❖ Post- Operative Complications

- Pain (VAS Score 0-10)
- Burning Sensation.
- Infection
- Recurrence
- Incontinence

B. Secondary Outcome Measures

- Wound Healing Time
- Recovery Time
- Result of *Ksharsutra* Therapy

OBSERVATION AND RESULT

Table No. 1: Effect of *Vibhitaka Ksharsutra* Therapy

S.N.	Parameter	B.T. mean	A.T. Mean	Diff. mean	S.D.	S.E	p-value	% relief	Remarks
1	Itching	2.33	0.20	2.13	0.74	0.19	<0.0001	91.4	E.S.
2	Discharge	2.93	0.20	2.73	0.79	0.20	<0.0001	93.17	E.S.
3	Average UCT	8.98 Days							

Table No. 2: Evaluation of Post-operative complications.

S.No	Post-operative Complication	Pts %		Remarks
1.	Mean of Post-operative Pain (VAS)	2.50	-	-
2.	Burning sensation	2	13.33 %	-
3.	Infection	1	6.66 %	Managed conservatively.
4.	Recurrence	1	6.66 %	-

Table No. 3: Evaluation of Secondary Outcome Measures.

S.N.	Parameter	Group-A
1	Mean Operative Time	30 Min
	Mean Hospital Stay Period in Days	4.66
3	Mean Recovery Period in Days	67.13
4	Mean Wound Healing Time in Days	30.53

DISCUSSION

In the present clinical study, among 15 patients, the incidence of *Bhagandara* was more (50 %) in the age group of 31-40 years and there were 90 % male patients and 10% female patients. The majority of patients enrolled belonged to rural areas, MIG, had Mandaagni, Vegetarian with Pitta-Kapha predominance. Majority of the Patients belonged to Parisravi type of *Bhagandar*. These observations cannot be interpreted because of small sample size in this study.

The Average Unit Cutting Time (UCT) of *Vibhitaka Ksharsutra* was observed as 8.98 days/ cm.

In the present study of 15 patients, *Vibhitaka Ksharsutra* has shown better results in relieving the symptoms of:

- Itching.
- Pus Discharge.

There were least or no Post-Operative complications such as:

- Early Post-operative Pain.
- Late Post-operative Pain.
- Post Procedure Burning Sensation.

Secondary Outcome Measures: The *Vibhitaka Ksharsutra* has shown better performance in the following secondary outcome Measures.

- Mean Hospital Stay Period.
- Mean Recovery Period.
- Mean Wound Healing Time.

Vibhitak Ksharsutra has better tolerability and acceptability and is cost effective and is easily available throughout the year and has a long shelf life.

CONCLUSION

- *Vibhitaka Ksharsutra* has shown better results in Kapha dominated *Bhagandara* such as Parisravi *Bhagandara*.
- UCT of *Vibhitak Ksharsutra* was calculated as 8.98 days/CM.
- The Post-operative Pain and Burning sensation observed was very less rather negligible.
- The Mean Hospital Stay Period, the Mean recovery period, the Mean wound Healing Period was remarkably low.
- *Vibhitak Ksharsutra* has better tolerability and acceptability and is cost effective and is easily

available throughout the year and has a long shelf life.

- *Vibhitaka Ksharsutra* can become a better alternative to conventional *Apamarga Ksharsutra*.

REFERENCES

1. Shashtri A.D., Sushrut Samhita in Ayurveda Tatva Sandipika, chaukhamba Sanskrit sansthan, sutra sthanam chapter 33/4: Page-126.
2. Susruta Samhita, Text with English translation, Dalhana's commentary along with critical notes, Edited and translated by Priya.Vrat.Sharma, Vol.II, published by Chaukhambha Viswabharati, Oriental Publishers and Distributors K-37/109, Gopal Mandir lane Varanasi, Chapter IV/ 1-8: Page-32-35.
3. Susruta Samhita Chikitsa Sthana, Text with English translation, Dalhana's commentary along with critical notes, Edited and translated by Priya.Vrat.Sharma, Vol.II, published by Chaukhambha Viswabharati, Oriental Publishers and Distributors K-37/109, Gopal Mandir lane Varanasi, Chapter VIII/ V-4: Page-349.
4. Sushrut Samhita with Ayurveda Tatva Sandeepika commentary by Dr Ambika Dataa Shaastry, Chaukhamba Sanskrit Sansthan Varanasi reprint reprint edition, 2007 Sootra Sthana Chapter 11, verse 12.