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A comparative clinical study on the effect of *Vibhitaki Ksharasutra* and *Apamarga Ksharasutra* in the management of *Bhagandara* (Fistula-In-Ano)

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ABSTRACT

Bhagandara (Fistula in Ano) at modern parlance is a common anorectal condition prevalent in the populations worldwide and its prevalence is second highest after *Arsha* (hemorrhoids). It is very common surgical condition necessitating safe treatment modality as open surgery may result anal incontinence in most of the time. Fistula- in- Ano is one such disease where ideal care delivery is still a challenge. It may be because of nature of disease, regional anatomy, hygiene, etc. *Kshara Sutra* is one of the chief modality in the treatment of *Bhagandara* in Ayurvedic science. Exploration of the new plants for the preparation of the *Kshara* as a better substitute for previously tried *Ksharasutras*. The *Apamarga Ksharasutra* is widely being practiced. When we go through the classics, we get reference regarding *Vibhitaki* grouped into *Kshara* dravyas. This *Vibhitaki* is not widely practiced. *Apamarga Kshara* is very effective but preparation of this *Apamarga Kshara* is not at all an easy process. It needs burning of lot of *Apamarga* plants, then process including boiling etc, and at the end we get very little quantity of final product. In the other hand *Vibhitaki*, as per reference, is also *Kshara*, cost effective and abundantly available as it is a huge plant will get adequate quantity of drug, hence this study is planned to evaluate the efficacy of *Vibhitaki Kshara Sutra* in the management of Fistula- in-Ano which is referred as *Bhagandara* in Ayurveda.

Key words: *Bhagandara, Fistula- In- Ano, Vibhitaki Ksharasutra, Apamarga Ksharasutra.*

INTRODUCTION

The Fistula in ano is difficult problem that surgeon have been struggling from centuries. Appropriate treatment is based on three central principles 1. control of sepsis 2. closure of the Fistula 3. maintenance of continence.

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The incident of Fistula in ano is 9/1,00,000 even though the current treatment modalities in Fistula like Fistulaectoy, fibrin glue, anal Fistula plug, LIFT[1] procedure, Bio LIFT, seton are being adopted, still patients are not getting satisfactory results.

The ideal treatment for an Anal Fistula should be associated with no recurrence rate, good safety margin and good quality of life.

The Ayurvedic management of anorectal disorders is becoming more popular especially in Fistula in ano aspect. *Apamarga Kshara* is being widely used in Fistula in ano management, it is need of hour to find a new drug which is having good qualities can be tried.[2] When we consider the properties of *Vibhitaki* like *Kashaya Rasa, Ushna Veerya, Madhura Vipaka, Ruksha* and *Laghu Gunas* is in favour with *Kshara* qualities. *Acharya Sushruta* has also explained to consider this plant in preparation of *Kshara*, as its

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having above mentioned qualities, it can be considerable for the preparation *Kshara Sootra.*[3]

In Ayurvedic classics, this disease has been described with the name of *Bhagandara*, which has more similar signs and symptoms with Anal Fistula.[4]

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 Sutras* were tried out in the department like *Arka Kshara Sutra, Apamarga Kshara Sutra, Vibhitiki Kshara Sutra* etc. Though each of the thread had good cutting rates and other preparation advantages they also had some disadvantages.[7]

Therefore in the present study, the *Vibhitaki Kshara* has been tried which is known for its *Kashaya Rasa, Rooksha, Laghuguna, Ushna Veerya, Madhura Vipaka* and *Lekhana, Rechana, Vranaropaka* properties[8] which are mentioned in *Dravyaguna Vignyana.*[8]

OBJECTIVE OF THE STUDY

A comparative clinical study on the effect of *Vibhitaki Ksharasutra* and *Apamarga Ksharasutra* in the management of *Bhagandara* (Fistula- In- Ano)

MATERIALS AND METHODS

The present study has been undertaken to analyze *Vibhitaki Kshara Sutra* and to compare it with *Apamarga Kshara Sutra* in the management of *Bhagandara* (Fistula- in- Ano).

Present study was an open clinical study in which 30 patients were selected on the basis of simple random sampling (SRS) procedure and divided in 2 equal groups. It was performed on the patients who attended the Outpatient and Inpatient Department of Shayla Tantra, S.J.G. Ayurvedic Medical College & Hospital, Gavimath Campus, Koppal- 583231, Karnatak

Group Design

- **Group I -** 15 Patients were treated with *Vibhitaki Ksharasutra.*
- **Group II -** 15 Patients were treated with *Apamarga Ksharasutra.*

Inclusion criteria

- Patients aged between 20- 50 years.
- Clinical signs and symptoms of all types of *Bhagandara*

Exclusion criteria

- HIV and HBsAg positive patients.
- Secondary Fistula due to Ulcerative colitis, Crohn's disease, Tuberculosis, Carcinoma of rectum.

Assessment criteria

The clinical assessment of the patient were conducted before and after treatment and accordingly the effectiveness were evaluated as per the assessment criteria fixed. The subjective and objective parameters for assessment are as follows.

Subjective Parameters

Pain

G0	Absence of pain/no pain.
G1	Mild - Pain that can easily be ignored.
G2	Moderate - pain that cannot be ignored, interferes with function, and needs treatment from time to time.
G3	Severe - That is present most of the time demanding constant attention.

Discharge

Assessed by measuring the discharge by a pad of (3× 3) × 1 cm.

G0	No discharge
G1	Mild discharge - single pad is sufficient per day
G2	Moderate discharge - 2 to 3 pads are necessary per day
G3	Profuse discharge - more than three pads are necessary per day.

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Constipation

G0	No constipation
G1	Mild
G2	Moderate
G3	Severe

Objective Parameter

$$\text{U. C. T} = \frac{\text{Total no.of days taken to cut through the tract}}{\text{Initial length of tract in cms}}$$

OBSERVATIONS AND RESULTS

The efficacy of *Standard Apamarga Kshara Sutra* and *Vibhitaki Kshara Sutra* have been studied in 30 patients who attended OPD of Dept. of PG Studies in Shalyatantra, SJGAMC and Hospital. These patients divided into two groups. In control group *Apamarga Kshara Sutra* was applied, while in other group *Vibhitaki Kshara Sutra* was applied.

All 30 patients of *Bhagandara* have been analysied for age, sex, habitat, socio-economic status, type of *Bhagandara*, type of Fistula, chronicity of disease, position of external openings, length of the fistulous track, clinical findings, unit cutting time etc. were observed and noted.

The average U.C.T. of treated group (*Vibhitaki Kshara Sutra*) was calculated and compared with control group (*Apamarga Kshara Sutra*).

The process of healing was started with the cutting of the track during the course of treatment. However, the small area was still remained to heal completely at the end of total cut through which took 8 to 10 days in treated groups in complete closure of the wound whereas 10-12 days were taken for healing completely in control group.

Total average Unit cutting time

Finally total average U.C.T. of both control and treated group were evaluated and compared with control group. The analysis shows that average U.C.T. was 0.93 cm/week in treated group which is lesser in comparison to control group as 1.41 cm/week. (Table 1)

Assessment of pain, discharge, constipation in comparison to Group A and B.

It was observed that degrees of pain felt by the patients at the time of changing thread and subsequent change of *Vibhitaki Kshar Sutra* was significantly less in compared to *Apamarga Kshara Sutra.*

RESULTS

Table 1: Average Unit cutting time in cm/week in Control and Treated Groups

Groups	N	Mean (X̄)	Std. Deviation	Std. Error Mean
Group A	20	1.41	0.22	0.05
Group B	20	0.93	0.16	0.03

Table 2: Showing the effect on Pain, discharge, constipation in comparison Group A & B

After Treatment	Group A - Apamarga Ksharasutra				Group B - Vibhitaki Ksharasutra				t
	N	X̄	±S.D	±SE	N	X̄	±S.D	±SE	
Pain	20	1.50	0.51	0.11	20	0.85	0.49	0.11	4.10
Discharge	20	0.85	0.49	0.11	20	0.60	0.50	0.11	1.59
Constipation	20	0.30	0.47	0.11	20	0.20	0.52	0.12	0.64

Table 3: Showing the effect on 1st Follow-up.

Follow up 1	Group A - Apamarga Ksharasutra				Group B - Vibhitaki Ksharasutra				t
	N	X̄	±S.D.	±SE	N	X̄	±S.D.	±SE	
Pain	20	0.60	0.50	0.11	20	0.35	0.49	0.11	1.59
Discharg	2	0.3	0.4	0.1	2	0.2	0.5	0.1	0.3

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e	0	0	7	1	0	5	5	2	1
Constipation	20	0.20	0.52	0.12	20	0.15	0.37	0.08	0.35

Table 4: Showing the effect on 2nd Follow-up.

Follow up 2	Group A - Apamarga Ksharasutra				Group B - Vibhitaki Ksharasutra				t
	n	X̄	±S.D.	±SE	N	X̄	±S.D.	±SE	
Pain	20	0.10	0.31	0.07	20	0.15	0.37	0.08	-0.47
Discharge	20	0.05	0.22	0.05	20	0.05	0.22	0.05	0.00
Constipation	20	0.15	0.49	0.11	20	0.25	0.64	0.14	-0.56

DISCUSSION

In the present study total cases were divided into 30 cases into 2 groups. First group (Group A) as control group, second group (Group B) as treated group. In Group A, *Apamarga Kshara Sutra* was used and in Group B, *Vibhitaki Kshara Sutra* was used. 15 cases were included in each group, which were treated on the line of previous works and study carried out on various parameters including clinical findings and unit cutting time (in cm/week) to know the exact duration oftreatment.

The observation of *Vibhitaki Kshara Sutra* has been made on different parameters of study like age group, sex, indicence, chronicity of disease, different types of *Bhagandara*, recurrent cases after surgical operations and number of fistulous openings.

The study analysis revealed that the incidence of *Bhagandara* is commonly seen in age group of 31- 40 years (15 cases - 37%) with peak incidence. The sex incidence shows that maximum patients were males (31 cases - 77%) and minimum were females (9 cases - 23%). Hill (Jr) (1967) Charles C Thomas (1975) have reported Abscess and Fistula occur more commonly in men than women by ratio of 2:1. The probable reason is obviously males are more exposed to etiological factors of *Bhagandara* in comparison to females. Other reason may be in our society females are more reluctant to express any diseases pertaining to ano-rectal region. In relation to religion, 40 cases were analyzed. 39 cases (97%) were hindus, 1 cases (3%) were muslim. In relation to socio-economic status 10 cases (25%) belonged to lower class, whereas 25 cases (62%) belonged to middle class and 5 cases (13%) belonged to upper middle socio-economic status. In relation to the nature of work 11 cases (27%) were of sedentary work, 17 patients (43%) were of moderate and 12 cases (30%) were of strenuous work. Majority of the patients developed symptoms due to moderate work, because they are exposed to many aetiological factors of the disease like riding, sitting and in awkward position for long hours. In relation to nature of diet more patients were found in non-vegetarian (78%), because *Asthishalya* is one of the aetiological factors for *Bhagandara* and it has been residual diet with more protein content which delays digestion causing constipation. The analysis shows that 38% of patients had reported constipation.

According to clinical symptomatology, it was seen that there were maximum 24 cases (60%) reported as *Ustragreeva Bhagandara,* were 16 cases (40%) *Parisravi Bhagandara*. No cases were found in *Parikshepi, Unmargi* and *Shambukavarta Bhagandara.*

The maximum 47% patients were suffering from trans-sphincteric fistula, 25% in inter-sphincteric fistula, 20% in suprasphinteric, 5% in subcutaneous and 3% in extrasphinteric fistula. The maximum number of cases (100%) was reported with duration of illness less than 6 months, were no cases noted more than 6 months. In the present study 100% patients were reported as fresh ones (non-operated cases) where as no patients were operated for Fistula previously. Out of 30 cases, maximum (100%) were having single external openings and no patient noted with multiple external openings. It was noticed that commonest position of external opening of Fistula at

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6 and 7"O clock position, while least number of tracks open at 3, 11, 12"O clock position.

On probing in the present, 72.5% cases were of complete track, 13% cases were Radial Fistulas, 10% cases curved Fistula and 10% cases were Blind internal.

Clinical findings like pain, discharge and constipation etc. were observed during primary and successive application of medicated thread in control and thread groups. The severity of pain and discharge after cut through were analyzed and was less in treated group as compared to control group.

Unit cutting time

The unit cutting time was analyzed on various parameters like age, sex, *Prakriti*, type of *Bhagandara*, type of Fistula, etc. There are several factors, which modifies the Unit Cutting Time as follows:

1. U.C.T. is less in subcutaneous and low anal Fistulas.
2. U.C.T. is high in cases of high rectal Fistula, Fistula with abscess and transsphincteric Fistula.
3. Presence of infection and inflammation delays the unit cutting time.

The analysis shows that average U.C.T. was 0.93 cm/week in treated group which is lesser in comparison to control group as 1.41 cm/week.

The advantages of *Vibhitaki Kshara Sutra* over *Apamarga Kshara Sutra* can be enumerated as follows:

Easy availability

Vibhitaki is a very common drug, which is cost effective and abundantly available in all parts of the country. Where *Apamarga Kshara* is not at all an easy process. It needs burning of lot of *Apamarga* plants, then process including boiling etc., and at the end we get very little quantity of final product seasonal plant.

Less Pain and burning sensation: *Vibhitaki* has *Katu, Rooksha, Teekshna* and *Ushna* properties. So in treated group there were less pain and burning sensation found in comparison to control group and after cut through the wound healing was same in the treated group compared to in control group.

CONCLUSION

Patients treated with *Vibhitaki Kshara Sutra* experienced less pain and burning sensation in comparison to control group. After cut through the wound healing was same in the treated group compared to control group. The present study found to be encouraging as the patients treated with *Vibhitaki Kshara Sutra* reported minimum discomfort as compared to the group who have been treated with *Apamarga Kshara Sutra.* The cutting time is longer in *Vibhitaki Kshara Sutra* group but patients did not feel much discomfort when compared to other group. So this can be best utilized in patients who can't tolerate pain and burning sensation. The availability of *Vibhitaki* is easy, so *Vibhitaki Kshara Sutra* can be easily prepared. Further studies can show new vista in the management of Fistula-in-ano in general and *Vibhitaki Kshara Sutra* in particular.

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