

A CONTROLLED CLINICAL STUDY OF PARIBHADRAKA KSHARASUTRA IN THE MANAGEMENT OF BHAGANDARA

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ABSTRACT

Background: *Bhagandara* (Fistula in ano) is a common ano-rectal condition prevalent in *Shalya* speciality and its prevalence is second highest after *Arshas* (Haemorrhoids). On the basis of successful management of *Bhagandara* by *Ksharasutra*, exploration of new plants for the preparation of *Kshara* is the need of the hour. **Objectives:** To evaluate efficacy of *Paribhadra* *Ksharasutra* in comparison with standard *Apamarga* *Ksharasutra* in the management of *Bhagandara*. **Methodology:** 40 Patients of *Bhagandara* were randomly divided into two equal groups- Group S (control) was treated with *Apamarga* *Ksharasutra* and Group T (trial) was treated with *Paribhadrika* *Ksharasutra*. *Ksharasutra* for each group was applied on the day I of surgery and with the replacement of *Ksharasutra* in an interval of 7 days, it was retained till the cutting of tract. Follow up were done until the next 1 month after complete cutting of tract. **Results:** On the basis of assessment criteria and on overall results of treatment, both the *Ksharasutras* are having almost equal effect in the management of *Bhagandara*. Both Group S and Group T got 100% results in the symptoms like itching, discharge and induration. Also, there was statistically significant reduction in both the groups in the symptoms of pain and length of track. On comparison, there was no statistically significant differences between the groups. **Conclusion:** *Paribhadra* *Ksharasutra* can be considered to have almost equal result with that of *Apamarga* *Ksharasutra*. So, *Paribhadra* *Ksharasutra* can be used as an alternate of *Apamarga* *Ksharasutra*.

Keywords: Fistula- in- ano, *Bhagandara*, *Apamarga* *Ksharasutra*, *Paribhadra* *Ksharasutra*.

INTRODUCTION

“Health is wealth” is a common saying. Health in the sense powerful mind and body; without which our day to day activities are restricted. The disease manifests in the body as structural and functional impairment or in the mind as fluctuation in the emotional and intellectual activities. But certain diseases are notoriously affecting the body. In Ayurvedic classics, *Acharyas* have

mentioned such diseases as ‘*Ashtamahagada*’¹ under which *Bhagandara* is one among them.

A study conducted in India (Raghavaiah, 1976) regarding the incidence and epidemiology of Fistula- in- ano, reported that anal fistula constitutes 1.6% of all surgical admissions. The prevalence rate of fistula-in-ano is 8.6 cases per 100,000 population. The prevalence in men is

12.3 cases per 100,000 population, and in women 5.6 cases per 100,000 population. The male-to-female ratio is 1.8:1. The mean age of patients is 38.3 years.²

Fistula-in-ano is one of the most common anorectal diseases in which the chronic granulating track runs from the anal canal or rectum to the perianal skin or perineum and is associated with considerable discomfort and morbidity to the patient. The use of *Ksharasutra* for the treatment of *Bhagandara* (Fistula-in-ano) is discussed and explained in our classic texts of *Ayurveda*.

The ancient books of *Ayurveda* has described various extensive uses of *Ksharasutra* other than *Bhagandara* (Fistula-in-ano) likes *Arsas* and *Charmakeela*, which demand excision of overgrown tissues and also for non-healing chronic sinuses and ulcers where debridement is an important factor to induce healing. The *Ksharasutra* when introduced into the fistulous tract, dissolves the unhealthy granulation tissue and thus draining it out by creating a healthy base for healing. It not only removes the debris but also aids in promoting the fresh healthy granulation tissue formation.

*Acharya Sushruta*³ and *Chakrapani*⁴ have mentioned the concept of management through *Kshara* and *Ksharasutra* which possess both cutting and healing properties. Now the *Ksharasutra* treatment has become standardized and popular. *Acharya Sushruta* in *Ksharapakavidhi Adhyaya* has mentioned 23 drugs for the preparation of *Kshara* and *Ksharasutra*⁵, the efficacy of all of them are not yet studied. *ParibhadraKa* is one among them having qualities like *Katu Tikta rasa*, *Laghuguna*, *Ushnaveerya*, *Katuvipaka*⁶ and in *Kshara* form even it attains the quality of *Chedana*, *Bhedana* and *Lekhana*. So, here a sincere attempt is made to evaluate the efficacy of *ParibhadraKa Ksharasutra* in comparison with the standard *Apamarga Ksharasutra* in the management of *Bhagandara*.

Materials and Method:

Sample source: 40 patients attending OPD and IPD, Alva's Ayurveda Medical college Hospital and Alvas health Centre, Moodbidri were selected and divided into two Group S and Group T.

Sample size: 40 patients diagnosed as *Bhagandara* were divided into two equal groups Group S and Group T for the study.

Study design: Controlled clinical study.

Selection Criteria:

Diagnostic Criteria:

The patients showing classical symptomatology of *Bhagandara* like

1. *Shoola* – Pain, tenderness
2. *Srava* – Discharge
3. *Shotha* – Swelling, induration
4. External opening in the peri-anal region.

Inclusion criteria:

- The patients having classical symptoms of *Bhagandara* was selected.
- Low anal fistula was selected.
- Patients was selected between the age group of 18 -70 yrs. of either gender, irrespective of religion, occupation, economic status.
- Controlled systemic illness like Hypertension and Diabetes Mellitus.

Exclusion criteria:

- Patients suffering secondary to inflammatory diseases like- Ulcerative colitis and Crohn's disease.
- Patients suffering from H.I.V., Tuberculosis and Ca. of rectum.
- Pregnant women.

Interventions:

In Group S and T

- Study period: Treatment period including observation period – 57 days.
- Assessment was done before treatment and on 8th, 15th, 22nd, 29th, 36th, 43rd, 50th and 57th day.
- Follow up was done on 75th and 90th day.

Procedure for Group S and Group T

Purva Karma

- Informed consent was taken from the patient.
- Established investigation report with patient.
- Part preparation was done.

Pradhana Karma

- Patient was made to lie down in Lithotomy position.
- Painting and draping were done.
- Local anaesthesia was given with Inj. Lignocaine 2%.

- Gloved finger was gently introduced into the anal canal after lubricating the finger with Lignocaine gel.
 - Then a suitable selected probe threaded with *Ksharasutra* (Group S- *Apamarga Ksharasutra* and Group T- *ParibhadraKa Ksharasutra*) 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 to reach into the lumen of anal canal through the internal opening and its tip was finally directed to come out of anal orifice.
 - Thereafter the probe was pulled out through the anal orifice, to leave the *Ksharasutra* behind in the fistulous track.
 - The two ends of the *Ksharasutra* was then tied together with a moderate tightness outside the anal canal.
 - The *Ksharasutra* was changed and fresh one was tied in an interval of one week until the tract cuts completely.
 - Dressing was done under aseptic precautions until the complete healing of the wound is attained.
- Paschat Karma**
- Sitz bath with lukewarm water was given for 10-15 minutes twice a day.
 - Antibiotics and Analgesic drug were given as per requirement.

Assessment Criteria

Effect of treatment was assessed on the basis of gradation of both subjective and objective parameters before and after treatment.

Subjective Criteria

1. Pain
2. Discharge
3. Itching

Objective Criteria:

1. Length of tract (in cm)
2. Induration

RESULTS:

The research study was done in 40 patients of *Bhagandara* in 2 equal groups

Parameters used pain, discharge, itching, length of tract and induration. Statistical methods used were:

- Average was found using mean and standard deviation.
- Mann-Whitney U test was used to compare within the groups.
- Fishers F test was performed for comparing the effectiveness of treatment between Group- S and Group-T.

Effect on pain: In both the methods pain score remains the same. Mean pain score at the base level was 2.95 in both the groups. Even on 8th day it remains same (2.85). Later we could see the small differences between the groups but statistically not significant. At 57th day, the mean pain score of Group-S came to 0.13 with percentage decrease of 96.6% and in Group-T, it was 0.1 with percentage difference of 94.9%. But still this difference between the groups was not statistically significant ($p=0.681$). But the decrease from 1st day to 57th day is statistically very highly significant in both the groups ($p<0.001$). In *Apamarga*, it was 96.6% whereas in *ParibhadraKa* the reduction was 94.9% and the difference was not statistically significant between the groups $p=0.681$.

Effect on discharge: In discharge, almost all the values from 1st day to 57th day remains the same in both the groups. In Group-S, the mean discharge score is 2.45 and the same was in Group-T also. Even on the 8th day it reduces to 2.0 in both the groups. But on 15th day, the mean discharge score on Group-S was 1.45 whereas in Group-T was 1.4. On 22nd day, the mean discharge score was 1.05 and 1.1 respectively in Group-S and Group-T. But, later in both the groups the mean discharge score remained the same, and finally on 57th day the mean discharge score in both the groups were 0. There was no statistical significance between these two groups at any interval of time by applying students. But at each group, the percentage difference from 1st day to 57th day was 100% and it was found to be statistically significant through the period in both the groups ($p<0.001$).

Effect on itching: The mean itching score at the time of admission i.e. on 1st day was 2.1 in Group-S and 2.05 in Group-T. When we compare the mean score between the groups by using Mann Whitney U Test it was found that there was no significance difference between the

two groups. On 8th day, the mean itching score reduces to 1.65 at Group-S and Group-T. The reduction was same till 22nd day. On 29th day the mean itching score of Group-S was 0.35 and that of Group-T came to 0.4 and the difference between the two groups was not found to be significant even when we apply Mann Whitney U test. Here the reduction came to 100% on 43rd day itself at both the groups. The reduction from 1st day to 43rd day was found to be significant in both the groups by applying ANOVA.

Effect on length of tract: The mean length of tract was 6.340 in Group-S group on 1st day and 6.325 in Group-T group. And the difference between these two groups were not significant by using Mann Whitney U test ($p=0.935$). Similarly mean was taken at all the time interval. It was reducing in both the groups and the percentage difference from 1st day to 57th day in Group-S group was 92% whereas, in Group-T group the percentage reduction was 90.7 %. The reduction at different time intervals was found to be statistically significant in both the groups ($p<0.001$). But while comparing between the groups the percentage difference of Group-S and Group-T was not statistically significant U.C.T is 9.3 days/cm in standard group compared to 8.5 days/cm in trial group. On comparison, there was no statistically significant differences between the groups.

Effect on induration: We could see that there was not much difference between the groups. But the reduction of mean score is significant. As the mean score at 1st day was 0.6 in Group S and 0.45 in Group T, and it reduced to 0.55 at 8th day in Group S and 0.5 in Group T. The percentage reduction at both the groups was 100% at 29th day itself. The reduction was found to be significant ($p<0.001$) in both the groups. But comparison between the two groups was not significant at any time interval.

DISCUSSION

Trial group got 100% results in the symptoms like itching, discharge and induration. Also, there was statistically significant reduction in both the groups in the symptoms of pain and unit cutting of tract.

Probable Mode of Action of Ksharasutra:

Ksheera used in the preparation of *Ksharasutra* produces debridement of tissues by the presence of proteolytic enzymes present in it which act in acid media only. The moment the *Kshara* is added to it, the proteolytic action ceases since the *Kshara* is highly alkaline. But because of its alkalinity, it overpowers the action of *Ksheera* thereby, there will be quick debridement due to high concentration of *Kshara*. The *Haridra churna* added to it possess antiseptic property and anti-histamine property. The presence of *Ksharasutra* in the fistulous tract does not allow the cavity to close down from either ends and there is a continuous drainage of pus along the *Ksharasutra* itself.

Probable Mode Of Action Of ParibhadraKa Ksharasutra

ParibhadraKa is a drug having qualities like *Katu Tikta rasa*, *Laghu guna*, *Ushna veerya*, *Katu vipaka* and in *Kshara* form even it attains the quality of *Chedana*, *Bhedana* and *Lekhana*. Here, *ParibhadraKa* almost possess the same qualities of *Apamarga*. Because of the *Ushna Virya*, it possesses the property of alleviating the *Kapha* and *Vata*. In the *Kshara* form, due to the extra qualities of *Lekhana* it helps in eradicating *Dushitha Mamsa* and enhances healing. The *ParibhadraKa Ksharasutra* is having almost similar effect with the standard *Apamarga Ksharasutra*. So, *ParibhadraKa Ksharasutra* can be used as an alternative for *Apamarga Ksharasutra* in the management of *Bhagandara*.

CONCLUSION

The *Ksharasutra* slowly and gradually cuts through the fistulous tract from apex to the periphery. The *Ksharasutra* remains in direct contact of the tract and therefore, it chemically cures out the tract and sloughs out the epithelial lining, thereby allowing the fistulous tract to collapse and heal. There is an ideal simultaneous cutting and healing of the tract and no pocket of pus is allowed to stay back. The *Kshara* (Caustics) applied on the thread are anti-inflammatory, anti-slough agents and in addition, have property of chemical curetting. In the clinical study, the trial group showed significant result in all the attributes of *Bhagandara* i.e., *ParibhadraKa Ksharasutra* is having almost similar

effect with the standard *Apamarga Ksharasutra*. So, *ParibhadraKa Ksharasutra* can be used as an alternative for *Apamarga Ksharasutra* in the management of *Bhagandara*. Thus, *ParibhadraKa Ksharasutra* is having significant effect in the management of *Bhagandara* is accepted.

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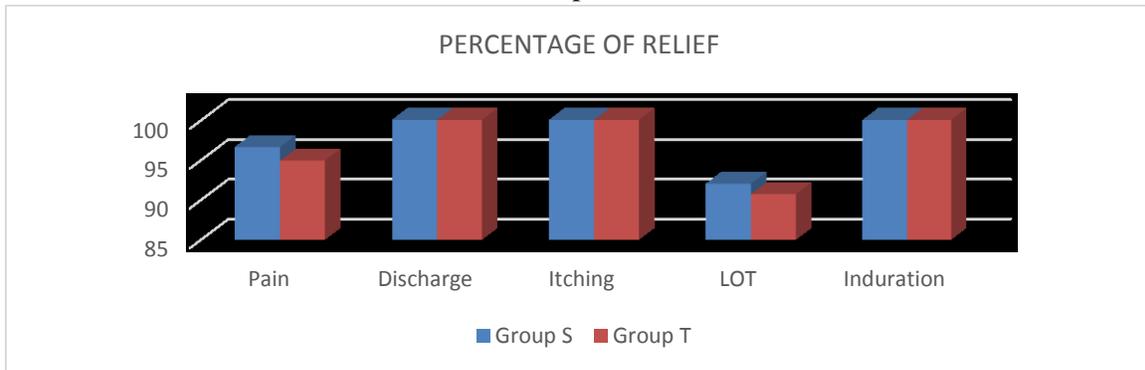
Table 1: Comparative effect of treatment between two groups

Symptoms	BT- AT mean		Difference of mean	Standard deviation		Z value	P value
	Group S	Group T		Group S	Group T		
Pain	2.85	2.80	0.05	0.366	0.308	0	<0.001
Discharge	2.45	2.45	0.00	0.308	0.308	0	<0.001
Itching	2.10	2.05	0.05	0.410	0.410	0	<0.001
Length of tract	5.835	5.735	0.10	0.590	0.943	0.685	<0,001
Induration	0.60	0.503	0.097	0.50	0.366	0	<0.001

Table 2: Comparative percentage of relief between Group S and Group T

Symptoms	Mean difference		Percentage relief	
	Group S	Group T	Group S	Group T
Pain	2.85	2.80	96.6%	94.9%
Discharge	2.45	2.45	100%	100%
Itching	2.10	2.05	100%	100%
Length of tact	5.835	5.735	92%	90.7%
Induration	0.60	0.503	100%	100%

Graph 1:



Source of Support: Nil

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