



'A COMPARATIVE CLINICAL STUDY ON THE CUTTING AND HEALING EFFECT OF SNUHIDUGDHADI VARTHI AS KSHARASUTRA WITH STANDARD KSHARASUTRA IN BHAGANDARA'

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ABSTRACT

Bhagandara, one among the ashtamahagada, is a distressing disease occurring in the bhaga, guda and basti region and is described as can be treated with difficulty. Bhagandara can be correlated with the anorectal disease, Fistula-in-ano.

Various medical, surgical and para-surgical measures were described for treating bhagandara. Ksharasutra therapy has been found very effective in curing bhagandara. Apamarga ksharasutra is standardized and is widely used. It is logical to explore the possibility and feasibility of various drugs in the preparation of *ksharasutra*.

Snuhidugdhadi varthi mentioned in the textbook *Yogaratra samucchaya* was taken into consideration. Ingredients of Snuhidugdhadi varthi i.e. Snuhiksheera, arkaksheera and daruharidra choorna were collected and ksharasutra was prepared for comparing with Standard ksharasutra. Fifty subjects diagnosed with bhagandara were selected consecutively from IPD of Salyatantra Department of GAVC, Tripunithura and allocated randomly into trial and control groups. Trial group was treated with Snuhidugdhadi varthi as ksharasutra and control group with Apamarga ksharasutra.

From the statistical analysis done using Unpaired t test, it was found that, there is no significant difference in the cutting and healing effect of both groups.

KEYWORDS : Bhagandara, Fistula-in-ano, Snuhidugdhadi varthi as ksharasutra, Standard ksharasutra, Cutting and healing effect

INTRODUCTION:

The disease *Bhagandara* has been described in various Ayurvedic samhithas in detail. *Bhagandara* is considered as one among the *ashtamahagadas* by Acharya Susrutha. The word *bhagandara* means splitting up or bursting up of a *pakwa pitaka* in *bhaga, guda* and *bastipradhesha* resulting in the formation of a track¹.

By considering all the aspects of *Bhagandara* it can be correlated with the anorectal disease, Fistula-in-ano. It usually occurs in a pre-existing anorectal abscess which burst spontaneously. Low level anal fistula is common and can be treated easily by conventional lay open technique whereas high level anal fistulas are difficult to treat.

Operative procedures adopted for Fistula-in-ano are fistulectomy, fistulotomy and use of a seton. Newer methods like anal fistula fibrin plug, Endo anal flap, LIFT, Bio-LIFT, Expanded Adipose Derived Stem Cell therapy (ASCs), LAFT, VAAFT are also being used. Because of the lack of expected results and recurrence newer techniques have continuously been adopted for its effective management².

The causative factors, pathogenesis, premonitory symptoms, symptoms, management and post-operative care of *bhagandara* are mentioned by Acharya Susrutha³ in detail. In the context of swayadhu, Acharya Charaka opined that *bhagandara* is formed after the bursting out of a *bhagandara pitaka*⁴. Acharya Vagbhata has mentioned that the suppurated and burst open *pitaka* forms the *bhagandara* which discharges pus⁵.

According to Acharya Susrutha, all types of *Bhagandara* are difficult to treat and the two varieties which occur due to *tridosha* and *agantu* are incurable. Hence Acharya Susrutha, Vagbhata and Charaka mentioned various surgical, parasurgical techniques for the treatment of *bhagandara* apart from medical treatment.

Management of *bhagandara* is mentioned in two stages – management of *bhagandara pitaka* and *vrana*. *Ksharasutra* therapy has been found very effective remedy in case of *bhagandara*.

Acharya Susrutha detailed the application of *ksharasutra* in the context of *Nadivranachikitsa*⁶. Acharya Charaka also indicated *ksharasutra* for the cure of *bhagandara*.

Ksharasutra can be distinguished as a medicated seton. Mechanical action of the thread and the chemical action of drugs together helps in

the cutting, curetting, draining, and cleaning of the track simultaneously, which leads to healing of the *bhagandara*. *Ksharasutra* was standardized in the department of *Salya-Salakya* B.H.U Varanasi by Prof P J Deshpande, his research officer Dr S.R Gupta and his Coworkers⁷. Nowadays the standardized form of *ksharasutra* is widely practicing for the management of *Bhagandara*.

In medieval *Ayurvedic* texts like *Chakradutta, Rasatarangini* etc the preparation and application of *ksharasutra* has been told clearly. *Ksharasutra* therapy has worldwide acceptance and owes the credit of standing as a complete treatment procedure in curing *Bhagandara* without producing much complications when compared with modern surgical techniques⁸.

METHODOLOGY

Research Question

Whether Snuhidugdhadi varthi as ksharasutra has more effect in cutting and healing of *Bhagandara* when compared to Standard ksharasutra in patients of age group 20-60 years.

AIM AND OBJECTIVE

AIM: To evaluate the cutting and healing effect of Snuhidugdhadi varthi as ksharasutra in *Bhagandara*.

OBJECTIVE:

1. To compare the cutting and healing effect of Snuhidugdhadi varthi as ksharasutra with Standard ksharasutra in *Bhagandara*.

HYPOTHESIS

A. Null Hypothesis: Snuhidugdhadi varthi as Ksharasutra has less or equal effect in cutting and healing of *Bhagandara* when compared to Standard Ksharasutra.

B. Alternate Hypothesis: Snuhidugdhadi varthi as Ksharasutra has more effect in cutting and healing of *Bhagandara* when compared to Standard Ksharasutra.

Study Population

50 patients with *Bhagandara*, 25 in each group in the age group of 20-60 years were selected according to inclusion and exclusion criteria from IPD Department of Salyatantra, Govt. Ayurveda College, Tripunithura, Ernakulam.

Sample Frame

A. Trial design: Comparative clinical study

B. Sample size: 50

C. Study setting: IPD Department of Salyatantra, Govt. Ayurveda College, Tripunithura, Ernakulam

D. Sampling procedure: Random lottery method

E. Selection and withdrawal of subjects:

a) Subject inclusion criteria

1. Low anal fistula patients were selected
2. Patients with age group of 20-60 years
3. Patients were selected irrespective of gender, caste, religion, and economic status
4. Patients with written consent

b) Subject exclusion criteria

1. Fistula secondary to systemic diseases.
2. Fistula in known cases of colorectal carcinoma.
3. Uncontrolled diabetes mellitus
4. Uncontrolled hypertension.

COLLECTION OF DATA

Primary Data: Interview and observation as per case proforma

Intervention:

a) Medicine used

- **Trial group :** Snuhidugdhadhi varthi as ksharasutra
- **Control group:** Standrad ksharasutra

b) Dosage form : Ksharasutra

c) Dose : According to the length of the track

d) Dosing schedule : Changing of ksharasutra was done on every 7th day

e) Vehicle : Not applicable

f) Route/mode of administration: Ano rectal region in the form of Ksharasutra

Treatment period including follow up:

Changing of ksharasutra was done on every 7th day.

Medication/treatment permitted and not permitted before and/or during the trial

- Gandharvahasthadi Kashayam 90ml bd before food
- Triphala choorna 10 gm with lukewarm water at bed time

Study tool

- i. Case proforma
- ii. Investigations
- iii. Anorectal examination

Assessment of efficacy

a) Efficacy parameters: Outcome variable

Objective parameters:

- Unit Cutting Time
- Healingtime

Statistical Analysis

OBJECTIVE CRITERIA:

Independent sample t test –Used to compare objective parameters between groups

The level of significance used: 5% significance

OBSERVATION AND RESULTS

1. Unit cutting time

Table 1 Unit cutting time

Unit Cutting Time	Mean	Std. Deviat	Mean Difference	t value	p value	Remark
Trial Group	8.788	1.662	-0.462	-0.687	0.496	NS
Control Group	9.250	2.924				

Independent Sample t Test, *Significant at 0.05 level

Here Independent sample t test was used to compare Unit cutting time between trial and control groups. Here the mean value of unit cutting time for trial group is 8.788 with standard deviation 1.662 and the mean value for control group is 9.250 with standard deviation 2.924. The calculated t value is -0.687 with p value > 0.05. So there is no significant difference in cutting time between trial and control groups.

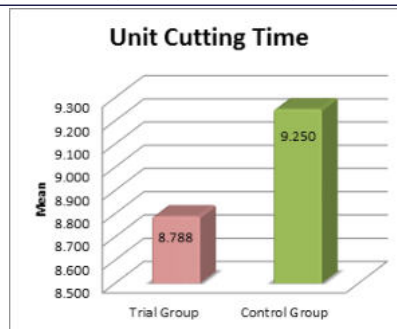


Fig 1

2. Healing time

Table 2 Healing time

Healing Time	Mean	Std. Deviation	Mean Difference	t value	p value	Remark
Trial Group	13.131	3.877	0.208	0.181	0.857	NS
Control Group	12.924	4.230				

Independent Sample t Test, *Significant at 0.05 level

Here Independent sample t test was used to compare healing time between trial and control groups. Here the mean value of healing time for trial group is 13.131 with standard deviation 3.887 and the mean value for control group is 12.924 with standard deviation 4.230. The calculated t value is 0.181 with p value > 0.05. So there is no significant difference in healing time between trial and control groups.

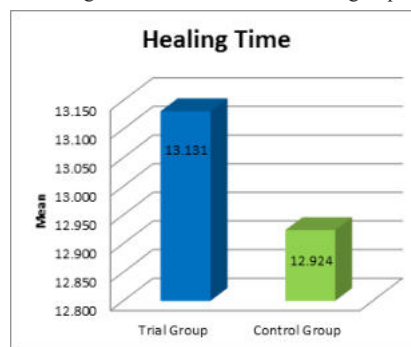


Fig 2

DISCUSSION ON MODE OF ACTION OF DRUG

The effectiveness of various ksharasutras like darvi ksharasutra, udumbara ksharasutra, gunja ksharasutra etc. were done previously and none of them proved to be more effective than standard ksharasutra.

The main ingredient of standard ksharasutra is apamarga kshara having properties of chedana, bhedana, ksharana, sthambhana, sodhana and ropana. Ksharasutra removes unhealthy fibrous tissue and debris from the track of fistula and promotes the formation of healthy granulation tissue. Kshara is tridoshahara, hence facilitates wound healing. Kshara acts through pachana and darana properties.

Along with sodhana, kshara helps in ropana or healing of wound. Soshana action of kshara helps in drying up and absorption of mucous discharge and promotes granulation tissue formation. Sthambhana property helps in wound contraction and promotes healing.

Vilayana property leads to liquification and dissolving of localized unhealthy tissues. Lekhana action helps to remove unhealthy growth of tissues. Tikshna guna helps to remove the fibrosed tissues. Thus kshara helps in wound healing through various processes by its own gunas.

Snuhidugdhadhi varthi as ksharasutra is prepared using snuiksheera, arkaksheera and daruharidra choorna. Euphol and Neriifolin are the main chemical constituents found in snuiksheera and are responsible for the proteolytic activity. Latex of snuhi also possess anti inflammatory and wound healing activity.

The *snuhiksheera* has *ksharana* property which also helps to remove slough from the fistula track. The antiseptic property of *snuhiksheera* also helps to arrest secondary infection.

Arkaksheera is having *snigdha, thiktha gunas* and is proven for anti microbial, anti inflammatory and wound healing activities. *Arkaksheera* (the latex of *Calotropis gigantea*) significantly promotes the collagen which helps in wound healing. *Daruharidra* is known for its *vranaropana* action. Aqueous and alcoholic extracts were used to prepare ointments and it helps to achieve faster healing of the wound.

From the statistical analysis, it is clear that, there is no significant difference in the outcome variables such Unit Cutting Time and Healing Time of both groups.

Snuhidugdhadi varthi as *ksharasura* has equal effect in cutting and healing of *bhagandara* when compared to standard *ksharasutra*.

CONCLUSION

Bhagandara, described in Ayurvedic samhithas, can be correlated with Fistula-in-ano. As per various studies surgical methods for treating Fistula-in-ano is associated with various post-operative complications and recurrence.

In Ayurveda various medical, surgical, parasurgical measures were described for treating *bhagandara*. *Ksharasutra* therapy is widely accepted and standardized for better cure of *bhagandara*. In the present study fifty subjects were consecutively selected and randomly allocated into two groups. Trial group was treated with *Snuhidugdhadi varthi* as *ksharasutra* and control group with *Standard Apamarga ksharasutra*.

Objective of the study was to compare the cutting and healing effect of *Snuhidugdhadi varthi* as *ksharasutra* and *Standard Apamarga ksharasutra*. As per statistical analysis done, there is no significant difference in the cutting and healing time between trial and control groups.

Therefore, the alternate hypothesis is rejected and null hypothesis is accepted i.e. *Snuhidugdhadi varthi* as *ksharasutra* has equal effect in cutting and healing of *bhagandara* when compared with *Standard ksharasutra*.

Limitations Of Study

- Limited period of follow-up. To understand the condition of the subjects of trial group, long term follow-up is necessary.
- The study drug was applied only for 25 subjects. To conclude that the *ksharasutra* made up of *snuhidugdhadi varthi* yoga is a better *ksharasutra*, more randomized clinical trials have to be carried out.

Suggestions For Further Study

- Long term effect of study drug should be observed by applying in a large population and for a longer follow-up period
- Healing time should be studied with the aid of histo-pathological and chemical analysis

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