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Comparitive study of clinical effect of *Apamarga Kshara Sutra* prepared by 7 and 21 coatings in *Bhagandara*

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ABSTRACT

Background: *Bhagandara* is a 2nd highest prevalent disease among the anorectal diseases. It can be correlated to Fistula-In-Ano. For the management of fistula in ano various surgical, parasurgical and minimally invasive surgical procedures have been mentioned. But all these procedures carry a disadvantage of high rates of recurrence and also have a great chance of creation of serious complications like anal incontinence and anal stenosis. Hence the search for a newer, safer and scientific treatment for the management of this disease continues. **Objectives:** A new *Kshara Sutra* with fewer coatings has been tried to see if results are the same with an advantage of early and easy preparation. **Materials and Methods:** Total 30 patients were randomly selected in the study and divided into 2 groups fulfilling the inclusion criteria which were designed for the study. **Results:** Study showed significant results in reducing the discharge, pain, itching and burning sensation and induration within the group and insignificant result obtained between the groups statistically. **Conclusion:** The study revealed that *Kshara Sutra* prepared with 7 coating is more economical, easy to prepare and equally efficient in the management of *Bhagandara*.

Key words: *Fistula-In-Ano, Bhagandara, Kshara Sutra, Ano rectal diseases.*

INTRODUCTION

Fistula in ano^{[1],[2]} is prevalent all over the world and its incidence in a London hospital study was reported to be 10% of all in patients and 4% of all new out patients.^[3] Similar study in India reported anal fistula to constitute 1.6% of all surgical admission.^[4] The data of ano-rectal disorders collected from Shalya Tantra

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There are surgical, parasurgical and minimally invasive surgical procedures and seton therapy are in practice for treating Fistula-in-ano. The surgical measures are fraught with grave post-operative complications, such as anal incontinence and high rate of recurrence^[5] even after repeated operations in expert hands. To alleviate such problems in the management of *Bhagandara*,^[6] it was thought to find out some other technique of treatment. Acharya Sushruta has explained the *Chedana Karma* (excision) as one of the treatment in this regard. Other treatment modalities for *Bhagandara* (Fistula-In-Ano) like *Shodhana, Agnikarma, Kshara Karma, Varti, Lepa, Taila* and *Ksharasutra*^[7] are also mentioned in our various classics. *Kshara Sutra* is explained in *Nadiroga Chikitsa* in *Sushruta Samhita, Chakradutta*^[8] and *Rasatarangini*. Even though there are reference of *Kshara Sutra* but the exact method of preparation and the mode of actions are not elaborately explained in our classics.

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The preparation of *Kshara Sutra* and management of fistula by *Kshara Sutra* was not standardized and different experts have their own methods. Later the technique developed by Shalya Shalakya Department of BHU was considered as standard in preparataion of *Kshara Sutra*. Later on various *Kshara Dravyas* are used for different types of *Kshara Sutra*. It appears that caustic coating of *Kshara* over thread may make all the difference between plain thread and the *Kshara Sutra*. *Ksharasutra* therapy is now considered as one of the main treatment modality for *Bhagandara*. The Indian Council of Medical Research [ICMR] validated and CCRAS have standardized *Apamarga Ksharasutra* as an effective treatment^[9] modality in *Bhagandara* (Fistula-In-Ano). Eventhough there are lots of scientific study on various *Kshara Sutr*s, but there were no such study conducted on coatings of *Kshara Sutra*. In this study, 30 patients suffering from *Bhagandara* (Fistula-In-Ano) were selected and treated with *Kshara Sutra* of two different coatings and the results obtained are systematically recorded, tabulated and analyzed statistically.

MATERIALS AND METHODS

Source of data

A minimum of 30 patients diagnosed as *Bhagandara* (fistula-in-ano) were selected from OPD and IPD of S.D.M Ayurveda Hospital, Udupi.

Materials: The materials required for *Kshara Sutra* procedure are *Kshara Sutra*, artery forceps and scissor.

Method of collection of data

The patients attending the OPD and IPD of S.D.M Ayurveda Hospital, Udupi, diagnosed as *Bhagandara* (fistula-in-ano) and fulfilling the inclusion criteria were selected. Data was collected based on a detailed proforma designed for the study.

Inclusion criteria

Patients suffering from *Bhagandara* (fistula-in-ano) especially of low level type, Patients of either sex irrespective of age were selected.

Exclusion criteria

High level fistula-in-ano, Subjects with HIV and HBsAg positive patients, Patients suffering from uncontrolled diabetes and other systemic disorders, Fistulae developing secondary to diseases like tuberculosis, ulcerative colitis, crohn's disease, malignancy were excluded.

Study design: It's a comparative clinical study with pre-test and post-test design.

Examination of the patient

Each case was thoroughly examined and investigated as per the detailed proforma designed for this present clinical study on *Bhagandara*. Each patient was examined under the following headings.

1. Complete History of the Patient
2. Systemic Examination
3. Local Examination
 - a. Inspection
 - b. Palpation
 - c. Digital Rectal Examination
 - d. Instrumentation- Proctoscopy, Probing

Investigations

Blood - Hb%, TC, DC,HIV, HBsAg, Fistulography. (if necessary)

Method of application *Kshara Sutra*

In this study the patients diagnosed with *Bhagandara* were divided into two groups with 15 subjects in each and subjected with *Apamarga Kshara Sutr*s prepared with 7 and 21 coatings respectively. *Kshara Sutra* is applied as per the standard method of application of *Kshara Sutra*.

Internal Medications

1. Triphala Guggulu 500 mg 1 TID
2. Gandhaka Rasayana 500 mg 1 TID

Duration of treatment

Changing of *Kshara Sutra* was done once in a week till there is healing of the track.

Observation period

The patients were observed once in a week during intervention period. Follow-up of the patient is done once in a week for 4 weeks after the intervention period. A special proforma was prepared and the efficacy of the *Kshara Sutra* was assessed based on the subjective and objective parameters.

Assessment Criteria

- Pain
- Burning sensation
- Itching
- Tenderness
- Discharge
- Induration
- Length of Track

Statistical Design

Paired 't' test of significance: All the informations based on various parameters are collected, tabulated and statistical study was carried out in terms of Mean (X), Standard deviation (S.D), Standard error (S.E), Paired and unpaired 't' test (t value) and results were incorporated in terms of Probability (p) as $P > 0.05$ - Insignificant, $P < 0.05$ - Significant, $P < 0.01$ and $P < 0.001$ - Highly Significant.

OBSERVATIONS AND RESULTS

Patients were observed for various following parameters and statistical results were listed below.

Table 1: Showing age wise distribution of 30 patients of Bhagandara

Incidence of age	Total
14-20 years	0
21-30 years	3
31-40 years	10
41-50 years	09

51-60 years	05
61-70 years	03
Total	30

Table 2: Showing sex wise wise distribution of 30 patients of Bhagandara

Gender	Total
Male	28
Female	2
Total	30

Table 3: Showing Dietary habit wise wise distribution of 30 patients of Bhagandara

Dietary habit	Total
Vegetarian	6
Non vegetarian	24
Total	30

Table 4: Showing Bowel habit wise wise distribution of 30 patients of Bhagandara

Bowel habit	Total
Regular	2
Irregular	17
Constipated	11
Total	30

Table 5: Showing Prakruti wise distribution of 30 patients of Bhagandara

Prakruti	Total
Vata Pitta	11
Vata Kapha	18

Pitta Kapha	1
Total	30

Table 6: Showing type of Fistula wise distribution of 30 patients of Bhagandara

Type of Fistual	Total
Intersphinteric	8
Trasnsphincteric	7
Subcutaneous	6
Submucous	9
Total	30

Table 7: Showing UCT acc. to gender in 30 patients of Bhagandara

Gender	Average UCT in days/cm	
	Group A	Group B
Male	8.3	7.5
Female	8.5	0

Unit Cutting Time (U.C.T.)

The Unit Cutting time means it is the time taken by the Kshara Sootra to cut one centimetre of fistulous track in days. This is an important parameter to assess the efficacy of the kshara sutra . This was calculated by using following formula.

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

Table 8: Showing UCT acc. to Nature of work in 30 patients of Bhagandara

Nature of work	Average UCT in days/cm	
	Group A	Group B
Sedentary	8.61	8.37

Moderate	7.9	7.0
Strenous	8.78	7.42

Table 9: Showing UCT acc. to dietary habit in 30 patients of Bhagandara

Dietary Habit	Average UCT in days/cm	
	Group A	Group B
Vegetarian	8.24	7.0
Non vegetarian	8.34	7.62

Table 10: Showing UCT acc. to type of Bhagandara in 30 patients.

Bhagandara Type	Average UCT in days/cm	
	Group A	Group B
Vataja	9.33	7.0
Pittaja	9.33	9.3
Kaphaja	7.58	7.25
Agantuja	0	7.44
Vata-Pittaja	8.16	6.5
Vata-Kaphaja	7.56	7.58

Table 11: Effect of treatment within the groups.

Assessme nt parameter s	Grou p	Mean value			Paired 't' test	
		BT	AT	Diff. in Mean s	t	p
Pain	Group A	2.06	0.33	1.73	9.55	0.000
	Group B	2.46	0.533	1.92	8.42	0.000

Burning sensation	Group A	1.46	0.2	1.26	6.11	0.000
	Group B	1.4	0.2	1.2	4.30	0.001
Itching	Group A	1.26	0.4	0.86	6.46	0.000
	Group B	1.53	0.4	1.13	5.25	0.000
Tenderness	Group A	1.26	0.00	1.26	8.23	0.000
	Group B	1.86	0.133	1.72	9.43	0.000
Discharge	Group A	1.8	0.06	1.74	14.74	0.000
	Group B	2.2	0.133	2.06	17.5	0.000
Induration	Group A	0.933	0.00	0.933	9.52	0.000
	Group B	1.06	0.2	0.856	0.535	0.000
Length of track	Group A	1.06	0.000	1.06	16.06	0.000
	Group B	1.46	0.06	1.4	8.58	0.000

Table 12: Effect of treatment between the groups

Factors	Group	Mean value	Diff. in Mean	t	p
Pain	Group A	1.73	0.19	0.688	>0.05
	Group B	1.92			
Burning sensation	Group A	1.26	0.06	0.182	>0.05
	Group B	1.2			
Itching	Group A	0.86	0.27	1.12	>0.05
	Group B	1.13			
Tenderness	Group A	1.263	0.46	2.03	>0.05
	Group B	1.72			
Discharge	Group A	1.74	0.32	2.02	>0.05
	Group B	2.06			

Induration	Group A	0.933	0.073	0.448	>0.05
	Group B	0.86			
Length of track	Group A	1.06	0.34	2.03	>0.05
	Group B	1.4			

DISCUSSION

Apamarga Kshara Sutra contains *Apamarga* which has qualities like *Katu, Tikta Rasa, Laghu, Ruksha, Tikshna Gunas, Ushna Veerya, Katu Vipaka*. These properties of the drugs create an unfavourable condition for the progression of the disease. As it contain *Apamarga Kshara* which has *Shodhana* and *Ropana* properties and facilitates the *Vilayana* of the *Pooya* there by helps in the cleansing of the track. *Apamarga* drug has properties like *Shothahara, Vedanasthapana, Twakadhoshahara, Vrana Shodhana, Kushthaghna, and Kandughna*^[10] which helps to reduce the symptoms like itching, swelling, pain and burning sensation. All these properties of plant is helpful for wound healing.^[11] The mode of action of *Kshara Sutra* in the management of *Bhagandara* is as follows - By the application of *Kshara Sutra* it does cutting layer by layer and there is continuous drainage of fistulous track which helps in healing. The medicaments which are used to prepare the thread will dissolve the fistulous tissue of the track (Debridement by the *Ksharana* process) and stimulate the healthy granulation tissue for healing.

CONCLUSION

There are lots of study conducted on 21 coating *Kshara Sutra* where as only very few studies were carried on 7 coating *Kshara Sutra*. The aim of present study was to come out with a *Kshara Sutra* which is simple, economical, easily prepared, preserved and equally effective in the management of *Bhagandara*. Based on the above clinical statistical data the following conclusions can be drawn. Both the groups of *Kshara Sutra* have shown statistically highly significant result within the group. But between the groups statistically insignificant results were found. Collection of *Snuhi Ksheera* is a very strenuous and

time consuming process; instead of 21 coating 7 coating *Kshara Sutra* can be used as it requires less coatings of *Snuhi Ksheera*. *Kshara Sutra* prepared with 7 coating is found to be cost effective and can be prepared early in 7 days with less raw material. In case of 21 coated *Kshara Sutra* the tolerance capacity by the patient was less and procedure causes more pain where as these can be minimized with 7 coated *Kshara Sutra* which was evident in this study. Overall cutting through and healing is similar and satisfactory in both the groups. *Kshara Sutra* ligation in *Bhagandara* has given a very good result in healing of track without any recurrence in this study. None of the patients developed with fecal in continence and there were no complications of the therapy were observed in both the groups.

When we see the different studies which were undertaken in this regard, there were no specific scientific study has been carried out in reducing the number of coatings of *Kshara Sutra*. Hence this study can contribute to reduce the burden of difficulty in the preparation of *Kshara Sutra* and also it can be practiced in various centres of proctology. From this study it can be concluded that *Kshara Sutra* prepared with 7 coating is more patient acceptable, economical, easy to prepare and equally efficient in the management of *Bhagandara*.

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