



COMPARATIVE CLINICAL STUDY OF KSHARASUTRA IN BHAGANDARA W.S.R. TO FISULA-IN-ANO

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ABSTRACT :

Sushruta has included *Bhagandara* in group of *Ashtamahagada*, means diseases difficult to treat. In modern surgical practice also fistula-in-ano is one of the complicated diseases due to its recurrence nature and fear of loss of continence. The clinical features of *Bhagandara* resembles with fistula-in-ano described in modern science. Ayurvedic para-surgical procedure *Ksharasutra* has been proved more effective treatment in fistula-in-ano, having minimum recurrence than modern treatment alternatives like Fistulectomy, Fistula plug, Fibrin glue, Video assessed anal fistula treatment (VAAFT), Ligation of intersphincteric fistula tract (LIFT) etc. The present research work was carried out to compare the efficacy of Indian Council of Medical Research (ICMR) approved *Apamarg Ksharasutra* and *Snuhi Haridra Ksharsutra* in *Bhagandara*. In this study 30 patients of fistula-in-ano were selected and randomly divided into two groups. In Group-A patients were treated with application of *Snuhi Haridra Ksharsutra* and in Group-B, *Apamarg Ksharasutra* was used. After *Ksharasutra* application patients were assessed for relief in symptoms like pain, discharge itching, swelling (subjective parameter) and unit cutting time (objective parameter). In both the study group, significant relief was observed in symptoms considered. The mean Unit Cutting time was 8.19 days/cm in group-A, whereas mean Unit Cutting time was 8.85 days/cm in group-B. The study revealed that conventional *Apamarg Ksharsutra* is better as compared to plain *Snuhi Haridra Ksharsutra* application in cases of *Bhagandara*.

Key words: Fistula-in-ano, Fistulectomy, *Bhagandara*, *Ksharsutra*

INTRODUCTION: Most scientific description about *Bhagandar* is found in Sushrut Samhita. Sushruta has included *Bhagandara* in group of *Ashtomahagada*, the disease difficult to treat. ^[1] ^[2] In spite of various treatment modalities available the recurrence rate of fistula is very high which a big challenge before the proctologists. ^[3] The prevalence rate of fistula-in-ano is 8.6 male cases and 12.3 female cases per one lack population where mean age of patient is 38.3 years. ^[4] Ayurvedic para-surgical procedure *Ksharasutra* has been proved more effective treatment in fistula-in-ano,

having minimum recurrence than modern treatment alternatives. It has been recently included in 25th edition of Bailey and Love's Short practice of Surgery. ^[5] The Indian Council of Medical Research (ICMR) has validated this therapy by conducting multicentric research trial and concluded that *Ksharasutra* is better than conventional surgery in fistula-in-ano. ^[6] *Ksharasutra* is routinely prepared with *Snuhi Ksheera*, *Haridra powder* and *Apamarga Kshara*. It is known as the conventional *Apamarga Ksharasutra*. It is a well proven device to treat fistula-in-ano and has been standardised by the CCRAS

,New Delhi and published details in API, Part 2, Volume 2, page 149. This conventional ICMR approved *Ksharasutra* is already proved significant for the management of *Bhagandara*. Further, when we refer the preparation methodology of *Ksharasutra* in Ayurvedic classical texts such as Sushrut Samhita, Bhaishajya Ratnavali and Ras Tarangini, use of *Apamarg Kshar* is not mentioned in *Ksharasutra* preparation and only smearing of *Snuhi Ksheer* with *Haridra powder* is advocated. Hence, this study has been planned with aim to compare the efficacy of ICMR's *Apamarg Ksharasutra* with *Snuhi Haridra Ksharasutra* in *Bhagandara*.

MATERIALS AND METHODS:

Selection of patients: Total 30 diagnosed cases of *Bhagandara* (Low Anal Fistula-in-ano) were registered from OPD and IPD of Shalya Tantra Department.

Inclusion criteria:

- Patients of age between 20-60 years
- Low anal fistula (with patent tract having primary opening below dentate line)
- Irrespective of Age, Sex, Occupation and Religion

Exclusion criteria:

- High anal Fistula and Complex fistula
- Horse shoe fistula
- Fistula-in-ano associated with one or more of the following conditions: Tuberculosis, Hypertension, Diabetes mellitus, Osteomyelitis of hip bones, Acute or chronic ulcerative colitis, Chrohn's disease, Ano-rectal and other Malignancy, Positive cases of Venereal diseases, HIV and HBsAg, Pregnancy, Fistula other than ano rectal fistula

INVESTIGATIONS: CBC, ESR, BSL- F & PP, Urine R/M, RFT, LFT, Lipid profile, HIV 1 & 2, HBsAg
Fistulogram, X- Ray Chest (P A view) & ECG for fitness purpose

Materials: Both in Group-A and B, 15 patients each of *Bhagandara* (fistula-in-ano) were enrolled and were randomly allotted. The common materials used for preparation of ICMR's conventional *Apamarg Ksharasutra* :

1. Barbour surgical linen thread no. 20 (Purchase from surgical store)
2. Specially prepared Alkaline Ash (*Kshar*) of *Apamarg* (*Achyranthes aspera*)
3. Dried *Haridra powder* (*Curcuma longa*)
4. Fresh latex of *Snuhi* (*Euphorbia nerifolia*)

Preparation Apamarg Ksharasutra:

The thread tied on specially designed hangers was smeared with latex of *Snuhi* for 11 times, followed by 7 coatings of wet *Snuhi-Ksheer* mixed with *Apamarga Kshar* and 3 coatings of *Snuhi Ksheer* and fine powder of *Haridra*. Thus, total 21 coatings were performed in specific order. For drying purpose, after smearing the threads, every time the hanger was placed in the specially designed 'Ksharasutra-cabinet' provided with UV radiation for sterilization. The pH was maintained between 8.5 to 9. The thread was kept 12 inch long & sealed in air tight glass tube. with aseptic precautions.

The materials used for preparation of *Snuhi Haridra Ksharasutra* :

1. Barbour surgical linen thread no. 20 (Purchase from surgical store)
2. Fresh latex of *Snuhi* (*Euphorbia nerifolia*)
3. Dried *Haridra powder* (*Curcuma longa*)

Preparation of Snuhi Haridra Ksharasutra:

Preparation methodology for Snuhi Haridra Ksharasutra was also same as above but, differed in coating order. The thread tied on specially designed hangers was smeared with latex of Snuhi for 7 times, followed by 7 coatings of wet Snuhi-Ksheer mixed with fine powder of Haridra .Thus, total 14 coatings were performed. Further, drying method by keeping it in Ksharasutra Cabinet after every coating etc. was same as above.

Methodology: Ksharasutra Application

Method: Patient was placed in Lithotomy position after standard pre-operative conduct. The Ksharasutra was inserted/applied into the fistulous tract under Spinal anaesthesia (Saddle block) with the help of a specially designed malleable metal probe following all aseptic precautions. Post operatively, patient was kept in head low position and nil by mouth for about six hours, followed by liquid and semi solid diet as per set protocol. Appropriate antibiotics (Tab.Mahacef-OZ -BD) and analgesic (Tab.Brufen-TDS)

Objective parameter:

Unit Cutting Time (UCT)

$$UCT = \frac{\text{Total number of days required for complete cutting of tract}}{\text{Initial length of thread (tract) in cm}} = \text{days/cm}$$

Subjective parameter:

Grade = 0	No Pain
Grade = 1	Mild Pain, can be tolerated without any medication
Grade = 2	Moderate Pain, requiring oral analgesics
Grade = 3	Severe Pain, not reliving with oral analgesics and required injection

Table 1: Showing Gradation for Pain

Grade = 0	No Discharge
Grade = 1	Mild Discharge (wets 1 × 1 cm gauze piece)
Grade = 2	Moderate Discharge (wets 2 × 2 cm gauze piece)
Grade = 3	Profuse Discharge (wets more than 2 × 2 cm gauze piece)

Table 2: Showing Gradation for Discharge

drugs were given for three consecutive post-operative days. Adjuvantly, patient was advised to start warm water Seitz bath with Panchavalkala Kwatha from the next day of procedure followed by sterile gauze dressing.

Duration of Therapy:The Ksharasutra was replaced with a newer Ksharasutra on every 7th day by 'Ride & Rail method' till the fistulous tract completely healed up. The total duration of treatment was different for each patient as the length of tract varied from patient to patient.

Follow up:During the Ksharasutra therapy, patient were called on every week for Ksharasutra changing viz. Day 0, Day 7, Day 14, Day 21, Day 28 and after cut through of the fistulous tract, patients were called for follow up assessment on 7th day, 15th day and after one month.

Criteria for assessment:The assessment was done on the basis of objective subjective parameters like relief in symptoms like pain, discharge, itching and swelling and UCT as an objective parameter.

Grade = 0	No Itching
Grade = 1	Negligible Itching with 10-12 hrs gap
Grade = 2	Occasional Itching with 4-6 hours gap
Grade = 3	Frequent Itching with 2-3 hours gap

Table 3: Showing Gradation for Itching

Grade = 0	No Swelling
Grade = 1	Swelling within 1 × 1 cm
Grade = 2	Swelling within 2 × 2cm
Grade = 3	Swelling within 3× 3 cm

Table 4: Showing Gradation for Swelling

Overall effects of therapy: The overall effect was assessed on the basis of relief in signs and symptoms as below:

- Complete remission:91-100% relief
- Marked improvement:76- 90 % relief
- Moderate improvement:51- 75 % relief
- Mild improvement: 26- 50% relief
- Unchanged: <25% relief

Observations:In the present study, majority of patients (47.62%) patients were observed in age group of 31 to 40 years suggesting that middle age group is more prone to suffer from fistula-in-ano. In surgical text books also it is mentioned that 3rd, 4th and 5th decades of life are most commonly affected with fistula-in-ano.^[7]

Furthermore, maximum patients were male (88.1%) which go hand in hand with a study conducted by Sainio P. et.al

concluded that the prevalence rate is double in males as compared to females.^[8] Similarly, maximum patients (54.76 %) belonged to *Vatakaphaja Prakriti* . The *Samprapti* of *Bhagandara* starts with the vitiation of *Vata Dosha* in all type of *Bhagandara* and it implies that respective of *Prakriti* is equally prone for the disease of *Bhagandara*.^[9] The position of external opening at posterior half was 57% while external opening at anterior half of anus was 43%. The anal glands are 4-8 in number and most of them are situated at posterior portion of anal canal.^[10] The curved fistulous tracts were noted in 61.90 % patients as external openings at posterior part of anus are curved tract which opens midline at 6 O'clock which supports the previous study report of Cirocco WC and Reilly JC.^[11]

Symptom	Mean		MEAN DIFF	S.D	SEM	P
	B.T	A.T				
Pain	1.18±0.084	0.00±0.00	1.182	0.395	0.084	<0.001
Discharge	1.09±0.091	0.00±0.00	1.091	0.426	0.091	<0.001
Itching	0.50±0.127	0.00±0.00	0.500	0.598	0.127	0.002
Swelling	0.09±0.063	0.046±0.05	0.046	0.213	0.046	1.000

Table-5: Showing Effect of Therapy in Group-A: n=15

Symptom	Mean		MEAN DIFF	S.D	SEM	P
	B.T	A.T				
Pain	1.60±0.112	0.00±0.00	1.600	0.503	0.112	<0.001
Discharge	1.40±0.112	0.00±0.00	1.400	0.503	0.112	<0.001
Itching	0.90±0.124	0.00±0.00	0.900	0.553	0.124	<0.001
Swelling	0.40±0.112	0.00±0.00	0.400	0.503	0.112	0.008

Table-6: Showing Effect of Therapy in Group-B: n=15

Group	Mean Unit cutting time
Group A	8.85days/cm
Group B	8.19 days/cm

Table-7: Showing Mean Unit cutting time: UCT in both Group

RESULTS: In group-A *Snuhi Haridra Ksharasutra* was applied and revealed significant relief in pain, discharge and itching, while insignificant relief in swelling. In group-B conventional *Apamarg Ksharasutra* was applied which showed the statistically significant relief in symptoms like pain, discharge, itching. The relief in swelling in this group was also found statistically significant.

In group-A, mean Unit Cutting time was 8.19 days/cm where *Snuhi Haridra Ksharasutra* was applied. In group-B, mean UCT was 8.85 days/cm in which *Apamarg Ksharasutra* was used.

In this study, all the patients completed the treatment and cured completely. There was no Adverse Drug reaction (ADR) reported during the course of study. No recurrence was observed in any patient during follow up. Overall, both the groups showed good results in the management of fistula in ano with complete cure. However, in view of UCT (unit cutting time), Group- B proved better than group-A.

DISCUSSION: Conventional *Apamarga Ksharasutra* is a proven device to treat *Bhagandara* (fistula-in-ano). Its efficacy is

well known and that was standardised by Ayurvedic Pharmacopeia of India (API). The main objective of this study was to compare the results of conventional *Apamarg Ksharasutra* with *Snuhi Haridra Ksharasutra*.

In group-A, *Snuhi Haridra Ksharasutra* (which did not content corrosive *Kshar* coating) was applied, lead to persistent drainage of pus, itching and gradual cutting of the tract and statistically significant relief was observed. Furthermore, regarding inflammation of the tract or periphery; as the *Ksharasutra* has *Chedhan* (excision), *Bhedan* (incision) and *Lekhan* (Scraping) properties so, there is continuous tissue inflammation due to tissue reaction. So, till complete cut through of the fistulous tract the inflammation was noticed and hence statistically the result was insignificant. This inflammation was of mild nature or grade-1 which did not hamper the daily routine life of patients.

In both Groups (group A & group-B), symptoms such as pain, discharge, itching and swelling were relieved. However, pus drainage and discomfort was more in

Group B (compare to Group A), may be due to *Kshar* coating.

It was found that in group-A in 10 patients UCT was more than 10days/cm while in group-B only in 2 patients UCT was more than 10days/cm. This shows that Group A had less UCT.

It can be said that due to *Apamarg Ksharsutra* the total duration was minimized due to early cutting and healing of tract. Hence the patients of group-B showed better results as compared to patients of group-A. This difference in result might be due to additional coating of *Apamarg Kshar* having alkaline nature which does chemical cauterization which results in early cutting and healing. Overall both the groups showed good results in treatment of *Bhagandara* with complete cure without any complication. Moreover, on the prospects of relief in complaints and reducing the Unit Cutting Time group- B (ICMR'S *Apamarg Ksharasutra*) is better than group-A (plain *Snuhi Haridra Ksharasutra* application).

Probable mode of *Ksharasutra* action: The effect of *Ksharasutra* has the combined effect of all ingredients and found effective in cutting and healing of the fistulous tract without damaging the sphincters. This can be explained by a simple demonstration: If we give pressure to wire on ice block it passes through it but doesn't divide the ice. Similarly, after application of *Ksharsutra* in fistulous tract, it gradually divides the fibres of sphincter involved (with simultaneous repair), thus, passes through it smoothly without dissecting it completely at a time, hence, incontinence is avoided. Further, *Ksharsutra* helps in debridement and lysis of abnormal tissues, destroys residual anal gland epithelium (due to *Kshar*), produces a running sore to pus, has anti bacterial &

anti inflammatory effect (*Haridra* and *Snuhi*) and promotes simultaneous cutting & healing of Sphincters. In the nut shell, it can be said that the *Ksharasutra* acts by gradual chemical excision of the *Bhagandara* (fistula - in-ano) with simultaneous healing of tract as observed in this study.

CONCLUSION: *Ksharasutra* is minimal invasive para-surgical procedure and the first choice for treating the cases of fistula-in-ano as it requires a minimal setup, minimal equipments and instruments. Moreover, the best benefit to the patient is that patient remains ambulatory during the whole course of treatment. This study proved that both the groups A & B were effective in treating *Bhagandara* with complete cure but, on the prospects faster relief in complaints and reducing the Unit Cutting Time (UCT), Group- B (*Apamarg Ksharasutra*) was better than Group-A (*Snuhi Haridra Ksharasutra*). The adjuvant Seitz bath with *Panchavalka Kwatha* advocated during post operative, possesses anti microbial action and helped for proper hygiene at perianal region. ^[12]

There was no Adverse Drug reaction (ADR) reported during the course of study and follow up period. No recurrence was observed in any patient during follow up of one month after complete cut through the fistulous tract. Hence, study can be concluded that conventional *Apamarg Ksharsutra* is better as compared to plain *Snuhi Haridra Ksharasutra* application in cases of *Bhagandara* (Fistula-in-ano).

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