



“AN OPEN LABELLED CLINICAL STUDY TO EVALUATE THE EFFECT OF *TANKANA KSHARASUTRA* IN THE MANAGEMENT OF *BHAGANDARA* w.s.r. TO FISTULA-IN-ANO”

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ABSTRACT:

Acharya Sushruta considered *Bhagandara* as one among the *Asta mahagada*. *Bhagandara* is a disease of perianal region. It can be correlated with *Fistula-in-ano*. Recurrent nature of this disease which makes it more and more difficult for treatment. *Fistula in Ano* is a condition which has been recognized as a difficult surgical disease in all the ancient and modern medical sciences. *Ksharasutra* therapy is an established mode of treatment for dissolving the tough fibrous track which leads to development of healthy base for healing. No complications like incontinence for flatus, faeces and spread of infection were seen till date by *Ksharasutra* treatment.

KEYWORDS:

Bhagandara, Fistula-in-ano, Tankana Ksharasutra

INTRODUCTION:

Bhagandara is defined as a disease of perianal region, which causes tearing pain in *bhaga, guda and basti pradesha*. *Bhagandara* is correlated as *Fistula-in-ano*. Recurrent nature of this disease makes it more and more difficult for treatment. Since both fistulotomy and fistulectomy involved a long period of post operative dressings of the wound and consequently a prolonged hospitalization, there was a need on cutting short the duration of treatment. So fistulectomy with primary closure of the wound was attempted by skilled surgeons. . The problem

was excision of the hard fibrous tissue which was seated deeper in the ischioanal fossa or even higher above the levator ani muscles. The surgical knife obviously failed to achieve this object since an ambitious excision invariably result into division of anal sphincter and a complete permanent faecal incontinence. At this stage *Ksharasutra* came to the rescue of surgeons since a chemical fistulectomy rather than a surgical fistulectomy proved to be free from complications. *Ksharasutra* causes chemical debridement of fibrous track and dissolves it and also aids in healing from the base. Dr P J Deshpande (BHU) contributed the Standardization of *Ksharasutra* with 21 coatings and the reference is available in his work. This is a revolutionary management of fistula in ano. The gradual & sustained action of drugs resulted in debridement of debris followed by appearance of healthy granulation tissue. Thus it is effective in healing the deeper tissues also. In present days the management of fistula in ano is challenging and aimed to prevent sphincter damage and to prevent its recurrence. *Ksharasutra* technique is considered as one of the best treatment modality for *Bhagandara* or fistula in ano. So keeping on view of its importance the present study was selected, in this study 30 patients suffering from *Bhagandara*(fistula-in-ano) were selected and treated with *Tankana ksharasutra*. The results obtained are systematically recorded, tabulated and analysed statistically.

AIMS AND OBJECTIVES OF THE STUDY

1. To evaluate the effect of Tankana ksharasutra in the management of Bhagandara w.s.r. to Fistula-in-ano.
2. To prepare ksharasutra as explained in classics.
3. Conceptual and detailed study of Bhagandara and Fistula in Ano.

STUDY DESIGN:

It was an open labelled clinical study with pre-test and post-test design.

METHODOLOGY:

Present study was an open labeled clinical study with pre test and post test study design. 30 Patients diagnosed with *Bhagandara* were selected from the IPD and OPD of S.D.M. Ayurveda Hospital, Udupi.

30 patients were treated with *Tankana Kshara sutra*.

METHOD OF PREPARATION OF TANKANA KSHARASUTRA:

The technique of preparing *Tankana Ksharasutra* is similar to standard *Snuhi-Apamarga Ksharasutra* by the Department of Shalya Shalakyia, IMS, Banaras Hindu University, Varanasi. It was prepared by total of 21 coatings in which, 11 coatings of *Shuddha Guggulu* followed by, 7 coatings of *Tankana Kshara* and 3 coatings of *Haridra churna*.

For this purpose a surgical barbour linen thread of No. 20 was spread out lengthwise in *Ksharasutra* hangers. For each thread in the cabinet, 21 coatings was done.

Firstly, *Shodhita Guggulu* was smeared over the total length of the surgical barbour linen thread . Then it was kept in *ksharasutra* cabinet for 24hours to dry. Next day again this thread is smeared with *Shuddha Guggulu*. This process was repeated for next 10 coatings and dried daily. Thus it accounted for 11 coatings of *Shuddha Guggulu* over the thread.

After 11 coatings of *Shuddha Guggulu*, This procedure is repeated once in a day till 18th coating. That is for 12th coating, the thread was smeared with *Shuddha Guggulu* and in wet condition, passed through a heap of powdered *Tankana Kshara* then dried in cabinet. This process was repeated for next 6 coatings. Thus it accounts for 7 coatings of *Tankana Kshara*.

On 19th coating, the same thread was smeared with *Shodhita Guggulu*, in wet condition it was passed through a heap of *Haridra churna*, it was then dried in the cabinet. This process was repeated for 2 more consecutive coatings. Thus it accounted for 3 coatings of *Haridra Churna*. This is the standard method of preparation of *Tankana Ksharasutra*.

Thus thread each *Ksharasutra* has 11 coatings of *Shodhita Guggulu* , 7 coatings of *Tankana Kshara* and 3 coatings of *Haridra churna*. This processed thread is placed in the *ksharasutra* cabinet and sterilized under the ultra violet rays on it.

INCLUSION CRITERIA:

- Patients suffering with clinical signs and symptoms of *Bhagandara* and *Fistula-in-ano* were selected.

EXCLUSION CRITERIA:

- Patients suffering from systemic diseases like uncontrolled diabetes.
- Patients suffering from secondary fistula due to Carcinoma, Ulcerative colitis, Tuberculosis.
- Patients suffering from infectious diseases like HIV, Hepatitis-B.

- High anal fistula

PURVAKARMA :

- Consent of the patient was taken after explaining the procedure.
- Identification of External opening/s and Internal opening/s by Digital examination, Proctoscopy and with advanced diagnostic techniques if required.
- Position of the patient- patient should be made to lie down on a table and position as described for the operation of *Arshas* i.e., lithotomy.
- Primary threading was done.

PRADHANA KARMA:

- On the 7th day after primary threading, patient was treated on OPD basis with Tankana Ksharasutra.
- Patient was positioned to lithotomy.
- After inspection, the primary threading was removed and replaced with Tankana Ksharasutra.
- Ksharasutra was changed on every 7th day until the complete tract cut through was achieved.

PASCHAT KARMA:

Internal Medications :

1. Tab. Triphala Guggulu (450mg.) - 1TID(After food)
2. Tab. Gandhaka Rasayana (250mg.) – 1TID(After food)

External Medications :

1. Sitz bath with Panchavalkala Kashaya twice daily
2. Jathyadi taila 10ml per rectum at Bed time

Observation period:

- The patients were observed once on every 7th day till the fistulous track gets cut through.

Intervention period:

- Patient follow up was done on 14th day after the fistulous track cuts through.

Subjective Parameters:

- Pain
- Burning sensation
- Itching

Objective Parameters:

- Tenderness
- Discharge
- Visual Analogue Scale
- Unit cutting time(UCT) = $\frac{\text{Total no. of days taken for cut through}}{\text{Initial length of track in centimeter}}$

OBSERVATIONS AND RESULTS**EFFECT OF TREATMENT ON LENGTH OF THE TRACK (WILCOXON'S SIGNED RANK SUM TEST)**

Length of the track BT Mean	2.42
Length of the track AT 7 th day Mean	1.69
Length of the track AT 14 th day Mean	1.15
Length of the track AT 21 st day Mean	0.55
Length of the track AT 28 th day Mean	0.15
Length of the track AT 35 th day Mean	0.03
Length of the track AT 42 nd day Mean	0.00
Length of the track AT 14days follow up Mean	0.00

EFFECT OF TREATMENT ON UNIT CUTTING TIME(WILCOXON'S SIGNED RANK SUM TEST)

UCT AT 7 th day Mean	0.62
UCT AT 14 th day Mean	0.60
UCT AT 21 st day Mean	0.52
UCT AT 28 th day Mean	0.41
UCT AT 35 th day Mean	0.10
UCT AT 42 nd day Mean	0.01

EFFECT OF TREATMENT ON LENGTH OF THE TRACK (PAIRED T TEST)

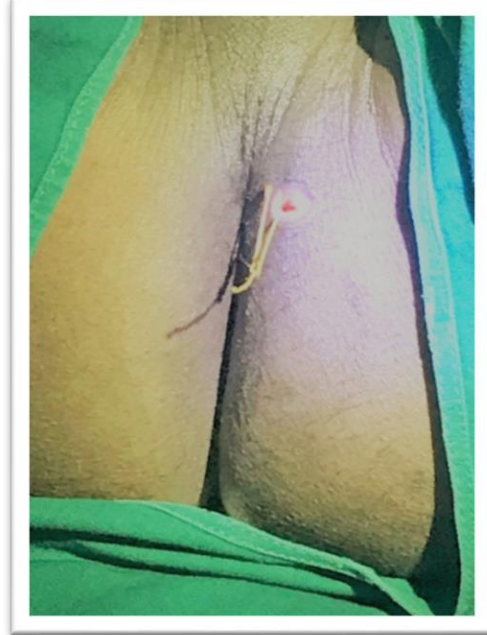
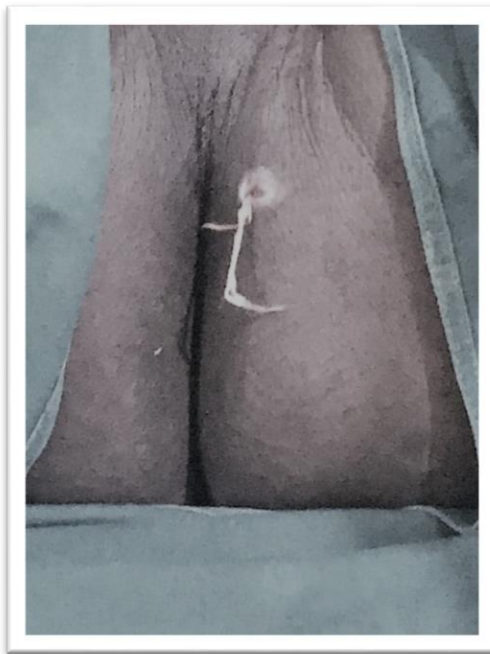
Parameters	Mean sq. cm	N	Std. deviation	Std. Error Mean	Mean difference in sq. cm	%	T	P value	Interpretation
Length of the track BT	2.42	30	0.84	0.15	0.73	30.16	13.94	0.00	Very Significant
Length of the track 7 th day	1.69	30	0.78	0.14	0.73	43.19	13.94	0.00	Very Significant
Length of the track BT	2.42	30	0.84	0.15	0.73	30.16	13.94	0.00	Very Significant
Length of the track 14 th day	1.15	30	0.75	0.13	1.27	110.4	15.49	0.00	Very Significant
Length of the track BT	2.42	30	0.84	0.15	0.73	30.16	13.94	0.00	Very Significant
Length of the track 21 st day	0.55	30	0.54	0.098	1.87	3.4	20.96	0.00	Very Significant
Length of the track BT	2.42	30	0.84	0.15	0.73	30.16	13.94	0.00	Very Significant
Length of the track 28 th day	0.15	30	0.32	0.059	2.27	15.13	17.54	0.00	Very Significant
Length of the track BT	2.42	30	0.84	0.15	0.73	30.16	13.94	0.00	Very Significant
Length of the track 35 th day	0.03	30	0.12	0.023	2.39	79.66	16.44	0.00	Very Significant
Length of the track	2.42	30	0.84	0.15	0.73	30.16	13.94	0.00	Very Significant

BT									
Length of the track 42 nd day	0.00	30	0.00	0.00	2.42	0	15.76	0.00	Very Significant
Length of the track BT	2.42	30	0.84	0.15	0.73	30.16	13.94	0.00	Very Significant
Length of the track after 14 days f/up	0.00	30	0.00	0.00	2.42	0	15.76	0.00	Very Significant

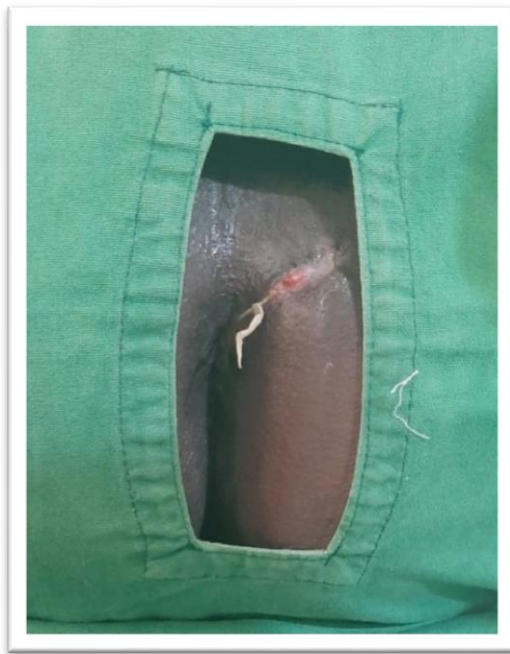
EFFECT OF TREATMENT ON UNIT CUTTING TIME (PAIRED T TSET)

Parameters	Mean sq. cm	N	Std. deviation	Std. Error Mean	Mean difference in sq. cm	%	T	P value	Interpretation
UCT AT 7 th day	0.62	30	0.22	0.04	0.02	3.22	0.39	0.69	Non Significant
UCT AT 14 th day	0.60	30	0.16	0.03	0.02	3.33	0.39	0.69	Non Significant
UCT AT 7 th day	0.62	30	0.22	0.04	0.02	3.22	0.39	0.69	Non significant
UCT AT 21 st day	0.52	30	0.28	0.05	0.10	0.19	1.85	0.07	Non Significant
UCT AT 7 th day	0.62	30	0.22	0.04	0.02	3.22	0.39	0.69	Non Significant
UCT AT 28 th day	0.41	30	0.37	0.06	0.21	51.21	2.92	0.00	Very Significant
UCT AT 7 th day	0.62	30	0.22	0.04	0.02	3.22	0.39	0.69	Non Significant
UCT AT	0.10	30	0.24	0.04	0.52	5.2	9.09	0.00	Very

35 th day									Significant
UCT AT	0.62	30	0.22	0.04	0.02	3.22	0.39	0.69	Non
7 th day									Significant
UCT AT	0.016	30	0.09	0.01	0.61	3812.5	14.5	0.00	Very
42 nd day									Significant



**PRIMARY THREADING APPLICATION OF KSHARA SUTRA
ON 7TH DAY AFTER PRIMARY
THREADING**

**DURING TRACK CUT THROUGH****AFTER COMPLETE TRACK CUT****THROUGH****DISCUSSION ON RESULTS –**

Statistical analysis with different parameters on effect of *Tankana ksharasutra* before treatment and after treatment with 30 patients of *Bhagandara* are as follows:

Pain – Statistical analysis revealed that mean score of pain was 2.30 before treatment and it has reduced to 0.00 after treatment and this change is statistically highly significant with p value < 0.00 .

Burning Sensation – Statistical analysis revealed that mean score of burning sensation was 2.10 before treatment and it has reduced to 0.00 after treatment and this change is statistically highly significant with $p < 0.00$.

Itching – Statistical analysis revealed that mean score of itching was 2.28 before treatment and it has reduced to 0.00 after treatment and this change is statistically highly significant with $p < 0.00$.

Tenderness – Statistical analysis revealed that mean score of tenderness was 2.30 before treatment and it has reduced to 0.00 after treatment and this change is statistically highly significant with $p < 0.00$.

Discharge – Statistical analysis revealed that mean score of discharge was 1.27 before treatment and it has reduced to 0.00 after treatment and this change is statistically highly significant with $p < 0.00$.

Length of the track - Statistical analysis revealed that mean score of length of tract was 2.42 before treatment and it has reduced to 0.00 after treatment and this change is statistically very significant with $p < 0.00$.

Unit cutting time - Statistical analysis revealed that mean score of UCT was 0.62 on 7th day after treatment and it has reduced to 0.01 on 42nd day after treatment and this change is statistically very significant with $p < 0.00$.

Complications : No complications of the therapy were observed during the study.

Patients did not feel more burning sensation and pain during the application of *ksharasutra*. It was tolerable. This *ksharasutra* can be used for patients who can not tolerate burning sensation and pain. No recurrence was noticed after 14days follow up. Partial fistulotomy was adopted in few cases & then treated with *Tankana ksharasutra*. *Guggulu* coatings helped to overcome bead formation while coating & *Tankana* application was done in fine powdered form. Hence *Tankana* also did not cause any beads in this regard. This therapy was found successful in treating *Bhagandara* upto a track length of 4cm.

Discussion on mode of action

- 1) By the application of *ksharasutra* it does cutting layer by layer and there is continuous drainage of fistulous tract which helps in healing.
- 2) The medicaments which are used to prepare the thread will dissolve slough of the fistulous tract and stimulate the healthy granulation tissue for healing.
- 3) *Ksharasutra* maintains the aseptic condition of the fistula track.
- 4) Healing of fistula track relieves the symptoms i.e., Pain, itching, burning sensation, tenderness & discharge gradually.

CONCLUSION:

Tankana ksharasutra was found to be effective in treating *Bhagandara* & the results were highly significant. Since the clinical study was conducted on a limited number of patients it may not be claimed as final, more detailed study may be conducted in this regard to establish the efficacy of *Tankana ksharasutra*.

In present study there was no adverse drug reaction or any post treatment complications reported during the course of study and follow up period. No recurrence was observed in any patient during follow up of 14days after complete cut through of the fistulous tract. Hence *Tankana ksharasutra* was found safe & effective in the management of *Bhagandara* w.s.r. Fistula-in-ano.

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