

# CLINICAL EVALUATION OF EFFICACY OF PAPAYA –TANKAN KSHAR SUTRA IN MANAGEMENT OF BHAGANDARA W.S.R FISTULA IN ANO

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**Abstract—** Bhagandara<sup>1</sup> is one of the most common ano-rectal disease in field of Shalya tantra. It has been included in Astha Mahagada<sup>2</sup> by Acharya Sushruta, after surgery high recurrence rate is matter of great concern. An appropriate answer is a unique specialized parasurgical procedure Kshar Sutra Therapy<sup>3</sup> which is well accepted and without any complication. In the present research “Effect of Papaya-Tankan Kshar Sutra in the management of Bhagandara” has been evaluated. Total 40 patients were taken in one group and treated with Papaya- Tankan Kshar Sutra out of which 100% were Cured Completely without any complications. Result was observed on the basis of subjective (Pain, Burning sensation, Itching, Discharge and Inflammation) and objective parameters (Unit Cutting Time i.e. U.C.T.) and analysed statistically. The best response was seen in reduction of Burning Sensation and Pain after ligation by Papaya-Tankan Kshar Sutra. U.C.T. was also not high but in desired limits. Moreover, therapy did not caused any hindrance in their daily routine work during period of management. No complications were observed in this clinical study.

**Index terms-** Amrita Guggulu<sup>4</sup>, Bhagandara, Papaya-Tankan Kshar Sutra.

## I. INTRODUCTION

The word Fistula is Latin by origin, which means a reed, pipe or flute. A fistula-in-ano<sup>5</sup>, or anal fistula, is a track lined by granulation tissue, which connects deeply in the anal canal or rectum and superficially on the skin around the anus. In 19th century: Goodsall and Miles, Milligan and Morgan, Thompson, Lockhart-Mummery and Parks made substantial contribution in description and treatment of fistula-in-ano. Bhagandara is one of the most common ano-rectal disease in field of surgery. Bhagandara is one such grave disease, for which it has been included in Ashta Mahagada<sup>3</sup> by Sushruta. Ashta Mahagada includes eight dreadful diseases- Vatavyadhi, Prameha, Kushta, Mudha Garbha, Arsha, Bhagandara, Ashamari and Udara Roga. This shows the gravity of this

disease, Bhagandara can affect anyone. Present mechanical modern life style is pushing the rise of prevalent rate of this disease. Today Bhagandara can be correlated with Fistula in ano.

## II. THE PREVALANCE OF FISTULA IN ANO

According to a recent study conducted by Sainio P<sup>6</sup> on the prevalence rate of fistula in ano in a London based hospital is 8.6 cases per 1,00,000 population, in Men : 12.3 cases per 1,00,000 population, in Women : 5.6 cases per 1,00,000 population, Male : Female= 1.8 : 1, Mean age of patient : 38.3 year. 10% of all indoor patients and 4% of all outdoor patients reported to suffer from this disease. But inspite of the best possible efforts, the recurrence rate is very high i.e. 20-30 %. Kshar sutra therapy is possible way to treat fistula in ano. Today different modalities of Bhagandara management are - Fistulectomy, Non-medicated thread [Seton], Advancement flaps-Mucosal flap procedure, Fibrin glue, Anal fistula plug [AFP] repair, LIFT technique<sup>7</sup> [ligation of intersphincteric fistula tract], VAAFT Procedure [Video assisted anal fistula tract ligation], Radiofrequency ablation of fistula.

The surgical management of Bhagandara carries several problems and complications as severe pain for a long period during dressing. Operative raw site is the potential space for infection by faeces. Hospitalization and non-ambulatory life for a long period. In all these different procedures, the cure is often not certain and there is always a great possibility of recurrence of disease. In Sushruta samhita Acharya Sushruta, has described the treatment of Bhagandara through Chhedana<sup>8</sup> and Easana<sup>9</sup> karma which is included in ashtvidh shastra karma. Authentic reference regarding the preparation of Kshar Sutra is - Acharya Chakrapani in his treatise Chakra- Dutta described the method of preparation of Kshar Sutra along with its uses in Arsha & Bhagandara. First of all cotton thread is taken and it is dipped in turmeric powder mixed with snuhi latex again and again. Then this smeared sutra is ligated which

cures Arsha and Bhagandara by excision. The standard Apamarga Kshar Sutra is prepared by repeated 21 coatings of Snuhi ksheer, Apamarga kshar and Haridra choorn. Although the standard Apamarga Kshar Sutra is successfully used in the management of Bhagandara.

In this context **PAPAYA- TANKAN KSHAR SUTRA** is selected for the management of Bhagandara along with Adjuvant therapy (ropan sanskar by Papaya pulp locally, Tab Amrita Guggulu orally & Ushnodaka Avagaha) to provide a new future of successful Kshar Sutra therapy.

### III. MATERIALS AND METHODS

#### A. Selection of Patients:

Diagnosed cases of Bhagandara (Fistula-in-ano) were registered by simple random sampling method from OPD and IPD of the Dept. Of Shalya Tantra of Rishikul Govt. P.G. Ayurvedic College and Hospital, Haridwar, Uttarakhand Ayurveda University, Harrawala, Dehradun, U.K., INDIA.

#### B. Inclusion Criteria:

fresh cases as well as recurrent cases of all type of bhagandara having clinical signs and symptom.

Age group between 10-70 years of either sex. ,Bhagandara of all type with Parikartika (Fistula in ano with fissure in ano) ,Bhagandara with Niyantrita Madhumeha (Fistula in ano with controlled diabetes), Bhagandara with Arsha(Fistula in ano with Haemorrhoids)

#### C. Exclusion Criteria:

HIV and HBs Ag positive patients, Secondary fistula due to Ulcerative colitis, Crohn's disease, Tuberculosis, Carcinoma of rectum.

#### D. DIAGNOSTIC CRITERIA:

Diagnosis was done on the basis of complaints of patient, past history, history of associated disease, inspection, palpation, digital examination, proctoscopy and required investigations as per specially designed proforma.

#### E. Chief complaints:

Majority of the patients had following complaints:

Pain in perianal area, Boil in perianal area , Discharge from perianal area, Bleeding per anum or from peri anal area, Itching.

#### F. INVESTIGATIONS:

Following investigations were done before starting any procedure:

**1.Routine hematological examinations** - Hemoglobin, T.L.C., D.L.C., ESR

**2. Biochemical parameter** - Fasting & postprandial blood sugar, HIV, HBsAg , VDRL.

**3.Urine:** Routine and microscopic

**4.Stool:** Ova and cysts

**Other investigations** (if required):

X Ray Chest, ECG, Fistulography Mantoux test, USG Abdomen and pelvis, RFT LFT, Lipid profile,

Pus culture and sensitivity, Biopsy of the tissue of the tract

### IV. APPLICATION OF KSHAR SUTRA

#### A. Poorva karma:

The application of Kshar Sutra was done under aseptic precaution and suitable anaesthesia.

Written informed consent taken, Patient was kept nil by mouth six hours prior to procedure, Inj. Xylocaine 2% sensitivity test was done , Soap water enema was given in the early morning on the day of surgery.

#### B. Pradhana Karma:

The patient was kept in lithotomy position, perianal region was cleaned with antiseptic lotions and Local anaesthesia (Xylocaine jelly 2%) was applied per anal & a suitable metallic malleable probe was gently passed with the help of other hand through the external opening of the fistula, probe was progressed towards the internal opening in the less resistant area. Forceful probing was avoided. After piercing the internal opening, the tip of the probe came out through the anal canal. Barber's thread no.20 was taken and threaded into the eye of the probe. Thereafter, the probe was pulled out through the anal orifice, to leave the thread in situ i.e. in the fistulous tract. The two ends of the thread were tied together outside the anal canal. Complete haemostasis was checked by inserting a plain lubricated gauze piece in the anal canal.

After this a gauze piece (surgical pad) soaked with ripe **Papaya pulp** was applied to the anal region and tied with the help of T-bandage and patient was shifted to the Shalya ward for post-operative management.

#### C. Paschaat Karma:

- ✓ **Ropan Sanskar with ripe Papaya pulp**
- ✓ **Amrita Guggulu** – 1 tab (500 mg) orally after food, twice daily.
- ✓ **Ushnodaka avagaha** twice in a day advised to patients.

### V. METHOD OF CHANGING KSHAR SUTRA

The Kshar Sutra was changed weekly after primary threading. It was done in lithotomy position, under aseptic precautions and under the effect of anaesthetic lubricant, a new Kshar Sutra of adequate length was taken and its one end was tied to the previous Kshar Sutra between the external opening and the knot. A clamp with artery forceps was made on the previous Kshar Sutra between its knot and anus. Then the previous Kshar Sutra was cut between its knot and the clamp. Holding the cut end of the previous Kshar Sutra with the applied artery forceps, it was taken out from tract through the internal opening and the new Kshar Sutra was introduced in the tract. Then the ends of newly applied Kshar Sutra were tied to each other, making the knot close to skin. The knot of the new Kshara Sutra was secured. Antiseptic dressing was applied. The measurement of the old thread was recorded in the folder proforma. The patients were advised to take rest for 5-10 min. and then allowed to go back for their routine work. This procedure was

repeated every week until cutting and complete healing of the track and finally cut through of the Kshar sutra automatically.

This method of changing the Kshara Sutra is known as **Rail-road method.**

**A. Duration of the treatment:**

All the cases were treated till the Kshara Sutra gets cut through the tract completely. Total duration of study was taken SIX MONTHS.

**Follow up period:**

Follow up was done once weekly for one month then monthly once for two months after the completion of treatment.

**B. ASSESSMENT CRITERIA**

- Subjective**
- Parameters Pain**
- Burning**
- sensation Itching**
- Discharge**
- Inflammation**

Sign & symptoms found were graded on the basis of scoring system prepared for that by **Paul O. Madson & Peter.** These are as follows-

❖ No symptom	0
❖ Mild symptoms	+
❖ Moderate	symptoms
++	
❖ Severe	symptoms
+++	
❖ Very severe symptoms with marks	
++++	

disturbance in daily routine of the patient.

**C. Objective parameters:**

**Unit Cutting Time = Total No. of days taken to cut through the tract**

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**Initial length of the Kshara sutra in cms**

➤ Time taken (in days) to cut one centimeter of the fistulous tract with simultaneous healing is known as unit cutting time (UCT).

**D. STATISTICAL DESIGN**

**Paired “t” – test of significance**

All information which are based on various parameter was gathered and statistical study was carried out in terms of mean (X), Standard Deviation (S.D.), Standard Error (S.E.), Paired t-Test (t-value) and finally result 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

**E. OBSERVATIONS<sup>10</sup>**

Total 40 patients were registered for this study; among them all 40 patients completed the full course of treatment. In this series of 40 patients of Bhagandara, the youngest patient was of 16 years and oldest patient was of 68 years. In analysis 25% female patient were found during study and rest 75% were male. Maximum cases i.e. 35 patients (87.5%) were found of Hindu religion, 3 patients (7.5%) of Muslim religion. Cases were analyzed in view of their habitat and out of the 40 cases of Bhagandara, 52.5% patients were reported from rural area, while 47.5% patients were belonging to the urban area. It was observed that the 55% patients were consuming Mixed diet whereas, 45% patients were on Vegetarian diet. In the present study nature of bowel habits were broadly classified into 4 groups.- The maximum numbers i.e. 21 patients (52.5%) were found with constipation, 10 patients (25%) have mucous discharge with feces, 8 patients (20%) with normal bowel habit were found and 1 patients (2.5%) with diarrhoeal bowel habit. Out of 40 cases, maximum numbers of patients i.e. 50% were reported under Parisravi Bhagandara,

32.5% were of Ushtra-greeva, 7.5% of Shambukavarta Bhagandara and 5% each were of Shataponaka and Unmargi Bhagandara. During diagnosis of 40 patients of Fistula-in-ano, the maximum 16 patients (40%) were observed under High anal type, 30% (12 patients) under Low anal, 22.5% (9 patients) under Sub mucous, 7.5% (3 patients) under Sub cutaneous group were observed and none case found in Pelvi - rectal group. Out of 40 patients, it was observed that 40% patients were afflicted from less than 1 year. 35% patients were suffering from 1-2 years of duration and 25% patients were suffering from more than 2 years. Out of 40 cases, 17.5% patients were reported having associated diseases. Among those 17.5% all patients were suffering from Hypertension only, none patients were found suffering from Diabetes mellitus, Tuberculosis, Ulcerative colitis. 10 Recurrent operated cases (25% patients) were further analyzed. Among all recurrent cases, 80% patients had undergone the operation only once, 20% patients were operated more than one times. Out of 40 cases external opening was found in upper half in 12 patients (30%) and in 28 patients (70%) it was found in lower half.

**Types of fistulous tract on probing**

**Table : Types of fistulous tract on probing; n=40**

Type of tract	No. of patients	Percentage
Straight	21	52.5%
Horse-shoe shaped	2	5%
Curved	17	42.5%
<b>Total</b>	<b>40</b>	<b>100%</b>

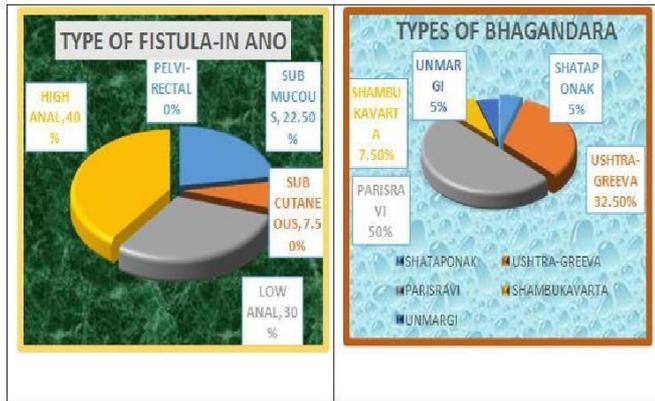


Table -Summarized result after completion of treatment

Parameter	% Relief	t-value	p-value	Statistical result
Pain	100	21.58	<0.001	HS
Burning sensation	100	22.80	<0.001	HS
Itching	100	21.10	<0.001	HS
Discharge	100	26.46	<0.001	HS
Inflammation	100	26.41	<0.001	HS

Table – Result of therapy

Result of therapy	No. of patients	Percentage
Arogya (Cured)	40	100%
Anarogya (Unchanged)	0	0%

In none case recurrence of the disease ever reported during study period.

**Overall result of U.C.T. on all 40 patients:**

Table: Effect on U.C.T.

S.N.	Name of the patients	Length of tract (in cm.)	Period of cut through (within month)	No. of days taken for cut through	U.C.T.(in days/cm)
1	Case no. 1	4 cm.	1	30	7.5
2	Case no. 2	6.5cm.	2	62	9.53
3	Case no. 3	5cm	2	46	9.2
4	Case no. 4	7.5cm.	2	62	8.26
5	Case no. 5	14cm.	>3	150	10.71
6	Case no. 6	15.5cm.	>3	155	10
7	Case no. 7	7.5cm.	2	65	8.66
8	Case no. 8	6cm.	2	59	9.83
9	Case no. 9	6cm.	2	58	9.66
10	Case no. 10	4cm.	1	20	5
11	Case no. 11	4cm.	1	29	7.25
12	Case no. 12	5cm.	2	43	8.6
13	Case no. 13	8cm.	2	41	5.12
14	Case no. 14	14cm.	>3	135	9.64
15	Case no. 15	6cm.	2	58	9.66
16	Case no. 16	7cm.	2	62	8.85
17	Case no. 17	6cm.	2	55	9.16
18	Case no. 18	7.5cm.	3	69	9.2
19	Case no. 19	8.5cm.	3	80	9.41
20	Case no. 20	8cm.	3	72	9
21	Case no. 21	8cm.	2	48	6
22	Case no. 22	12cm.	>3	98	8.16
23	Case no. 23	8cm.	3	78	9.75
24	Case no. 24	5.5cm.	2	53	9.63
25	Case no. 25	10cm.	3	70	7
26	Case no. 26	14cm.	>3	130	9.28
27	Case no. 27	14cm.	>3	135	9.64
28	Case no. 28	16cm.	>3	162	10.12
29	Case no. 29	9.5cm.	>3	91	9.57
30	Case no. 30	6.5cm.	2	54	8.30
31	Case no. 31	19cm.	>3	172	9.05
32	Case no. 32	8cm.	3	68	8.5
33	Case no. 33	6cm.	2	50	8.33
34	Case no. 34	5cm.	2	38	7.6
35	Case no. 35	11cm.	>3	116	10.54
36	Case no. 36	10.5cm.	3	90	8.57
37	Case no. 37	11cm.	>3	105	9.54
38	Case no. 38	20cm.	>3	178	8.90
39	Case no. 39	15cm.	>3	152	10.13
40	Case no. 40	14cm.	>3	145	10.35

F. Overall Effect of Therapy

The duration of the treatment was till the Papaya<sup>12</sup>-Tankan<sup>13</sup>Kshar Sutra gets cut through the tract completely. Total duration of study was taken upto maximum SIX MONTHS. In all the patients had complete cut through of the fistulous tract. The shortest duration of treatment was in a patient where the tract was 4 cm and 20 days were taken for the cut through of the tract. The longest duration of treatment was in a patient who had curved tracts and it took 178 days for the complete cut through of the 20 cm fistulous tract. 40 patients completed their follow up period and no patient was reported with recurrence. Neither recurrence nor any side effects were reported.

VI. DISCUSSION

The review of Ayurvedic literature, reveals that Bhagandara one among the Mahagadas<sup>2</sup>. It's inclusion in Mahagadas proves that it is difficult to cure. Acharya Sushruta has described Chhedana Karma, Kshar Karma, Kshar Sutra therapy and Agnikarma for the management of Bhagandara. Out of these, Kshar Sutra became more popular and proven therapy as a radical cure of Bhagandara with negligible rate of recurrence and complication in comparison to the contemporary methods like fistulectomy and fistulotomy.

In the present study, from the traditional method of kshar sutra preparation, Snuhi ksheer has been replaced by **Papaya Pulp** and Apamarg kshar has been replaced by **Tankan kshar**. The advantages of Papaya pulp over Snuhi Ksheer can be enumerated as follows – **Papaine enzyme<sup>14</sup>** is main component. Some other chemical constituents of Papaya include:-Proteolytic enzymes Chymopapaine & Carpaine; Alkaloid like Carpaine, Pseudocarpaine & Carpinine; Vitamins like A, C & E; Minerals like Mg & Zn. Its action

**Debriding agent, Analgesic effect, Less- irritant, Anti-inflammatory, Anti itching effect, Anti-microbial and Anti-bacterial.** So considering these beneficial properties, Papaya was selected in place of Snuhi ksheer in this present research work for preparation of Kshar Sutra along with Tankan kshar and Haridra churna. Tankan works as local antiseptic. Local application on wound stops bleeding, due to its vasoconstriction action. Tankan does not absorb moisture so it dissolves very slowly so retained in fistulous tract for longer time. Haridra(Curcuma longa) exhibit potent anti-

inflammatory effects. The anti-inflammatory properties may be attributed to its ability to inhibit pro-inflammatory arachidonic acid as well as neutrophil function during inflammatory states. Curcumin may also be applied topically to animal skin to counteract inflammation and irritation associated with inflammatory skin conditions and allergies. **Anti-bacterial activity of C. longa (Haridra)** was found against both **Gram positive and Gram negative organism**. It is found beneficial in **reducing the Pruritus-ani** in Patients of Bhagandara in present study. There are several factors, which were observed in the Unit Cutting Time (U.C.T.) in this study as follows: U.C.T. was less (6.58 days/cm.) in sub cutaneous fistulae. In this category, Mean U.C.T. was found 8.35 days/cm. In relation to types of Bhagandara U.C.T. was less (8.27 days/cm.) in Parisravi Bhagandara. Mean U.C.T. was found 9.27 days/cm in this category. U.C.T. increases as length of fistulous tract and chronicity increases as U.C.T. was 7.52 days/cm. in tract having initial length within 5 cm. whereas it was 9.61 days/cm in tract of more than 10 cm. In this category, Mean U.C.T. was found 8.6 days/cm (according to length of fistulous tract) and 8.94 days/cm (according to chronicity).

On the basis of this entire discussion outcome turns out that, this Kshar Sutra is a unique and exclusive procedure for the management of Bhagandara in Ayurveda. It has brought revolution in the Indian system of surgery. Kshar Sutra ligation therapy in the management of Fistula-in-ano has proved boon for the humanity. It can very effectively Substitute the modern surgical procedures. Kshar Sutra acts by gradual chemical excision of the Bhagandara (fistula -in -ano) with simultaneous healing. It is economically low cost and less discomfort occurs. Other complications of the operation that mentioned priority has never been reported in Kshar Sutra therapy. No need of long duration hospitalization.

#### A. Overall effect of Papaya-Tankan Kshar Sutra therapy

Total 40 patients were treated in this present study out of which 100% were Cured Completely. None of the patients remained unchanged/ uncured in treatment group. In none case any sign and symptom of the recurrence & incontinence was ever found out during study period. No adverse reactions of any of the drugs were observed during the course of study.

### VII. CONCLUSION

In modern surgery the only form of treatment of fistula-in-ano that affords any reliable prospect of cure is operation. The surgeries of fistula-in-ano have an unenviable reputation for subsequent recurrences, faecal soiling, imperfect control of flatus, chronic wound healing, more hospitalization etc

The preparation of **Papaya - Tankan Kshar Sutra** may provide a new future of successful Kshar sutra therapy in the management of Bhagandara. In the present clinical study positive results were observed. The **Papaya - Tankan Kshar**

**Sutra and Adjuvant therapy of Papaya pulp** locally, **Amrita Guggulu** orally & **Ushnodaka Avagaha** possess properties of Vrana-Shodhan, Vrana-Ropan, Vednasthapan etc which helps in early healing. In statistical analysis **Papaya - Tankan Kshar Sutra** therapy showed **highly significant** results. This Kshar Sutra can be easily prepared. It is devoid of side effects like pain, irritation, post ligation burning sensation etc during treatment and no recurrence after treatment. Hence, it can be concluded that **Papaya - Tankan Kshar Sutra** can definitely be used very safely to cure patients suffering from Bhagandara (Fistula- in- ano).

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