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## A Clinical Study of Interception of Fistulous Tract with Application of *Kshar Sutra* (IFTAK) Technique Using *Madhu Saindhav Aragwadhadi Kshar Sutra* in the Management of *Bhagandara* (Crypto Glandular Fistula).

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### ABSTRACT:

The humanity had been suffered from various diseases and among the many uncomfortable conditions from the onset of civilization. Fistula in ano one of the most important one. Its anatomical situation makes it difficult to treat. It is known as *Bhagandara* in Ayurvedic classics. The disease was widely prevalent and numerous techniques were tried for its management. However, none of them could provide solace to the suffering mankind. Though there has been a lot of advancement in the modern surgery in recent years and many surgical diseases are treated with less invasive procedure such as laparoscopic and robotic surgeries which has revolutionized the management of surgical diseases. But fistula in ano is still the disease with high recurrence rates in present time also. Ayurveda offers an effective, safe, less invasive treatment modality called *ksharsutra* therapy which have been in since many centuries practice). *Ksharsutra* therapy has many advantages like the tract is completely excised by *lekhan* and improved healing simultaneously so, there are least chances of recurrence, minimal scaring and no chance of anal incontinence but *Ksharsutra* cause certain discomfort such as long anxiety period, number of hospital visit, Discomfort and longer duration of treatment. The present study regarding interception of fistulous tract with application of *ksharsutra* (IFTAK) was done in the patient of usually horse shoe type fistula, supralelevator fistula, transsphincter fistula, extra sphincter, fistula in ano which showed great potential in the management of fistula in ano by reducing the duration of treatment with minimal post operative scar.

**Keywords:** *Bhagandara*; *Ksharsutra*; Fistula in Ano; IFTAK (Interception of Fistulous Tract with Application Of *ksharsutra*) Technique

### INTRODUCTION

A fistula is an abnormal connection between any two epithelial-lined surfaces. It is a Latin word that means of reed, pipe or flute. Fistula can occur in any part of the body but a fistula occurring in ano-rectal region is called

fistula in ano. An anal fistula is a track which communicates with the anal canal or rectum by an internal opening and usually has continuity with one or more external openings in the perianal, perineal or ischiorectal



areas. *Bhagandara* is made up of two words: *bhaga* and *darana*. *Bhaga* refers to the area between the anus and the genitalia, while *Daran* means to tear or demhe explained that in the region of perineum, anus, rectum and pelvis an inflammatory swelling situated is called *pidika* until suppuration, after suppuration it converts in to *Bhagandara* which now a day is known as fistula in ano.<sup>1</sup> *Bhagandara* has been regarded one of the diseases of *Astamahagada* therefore it is *grihastha* or *asadhya*. Management of *Bhagandara* has been taken from *shastiupkrama* which include 11 parts of *poorvakarma*, *Pradhan karma* where main surgical procedure is included and *panchakarma*. Para surgical procedures are taken into consideration like – *kshar karma* and *Agni karma* to treat *Bhagandara* if surgery is not possible & even after surgery. Now a days the principles of treatment of fistula in ano is changed after minimal assess of surgery as Fistulectomy may cause of several complication like incontinence, deformity and recurrence and also long period of treatment for wound healing. Para surgical procedure is effective up to the large extent and majority of cases are treated well but some of fistula are difficult to treat by surgery or Para surgical procedure. These fistulas in ano included usually horse shoe type fistula, supraleator, transsphincter, extra sphincter, or fistula related to specific lesson – TB, Malignancy and HIV cases. That’s why it was selected for this clinical study. Under these circumstances it was thought to select these cases to understand it well for diagnosis and management. Olish. As a result, *Bhagandara* is defined as shredding the anus, perineum, rectum, and pelvic regions). The application of *kshar sutra* is recommended in contest to *Nadi Vrana* as well as for *Bhagandara* also (*S.Ch.17/32*).<sup>2</sup> *Kshar Sutra* therapy has many advantages like the tract is completely excised by *lekhan* and improved healing simultaneously so, there are least chances of recurrence, minimal scaring and no chance of anal incontinence but *Kshar sutra* cause certain discomfort such as long anxiety period, number of hospital visit, Discomfort and longer duration of treatment. The present study regarding interception of fistulous tract with application of *kshar sutra* (*IFTAK*) is designed to reduce the duration of treatment with minimal post operative scar and problems related to conventional method.<sup>3</sup> In the studies about interception of fistulous tract with application of *Ksharasutra* (*IFTAK*) have found very effective as it reduces anxiety period and painful sitting of *kshar sutra* placement. This approach was found very effective for patient as well as for operating surgeon. Interception of fistulous tract with application of

*Ksharasutra* (*IFTAK*) is being practiced for treating complex and recurrent fistula in ano. In this technique proximal part of fistulas track is intercepted at the level of external sphincter along with the application of *kshar sutra* from site of interception to the infected crypt in anal canal. This is aimed at to eradicate the infected anal crypt with minimal damage to anal sphincter by using *Ksharasutra* (medicated seton). Use of *Ksharasutra* cause extensive fibrosis and favour proper healing which reduce the chance of recurrence.<sup>4</sup>

Hence it is advocated to carry out a clinical study of *interception of fistulous tract with application of Ksharasutra [IFTAK]* technique using *Madhu, saindhav Aragwadhadi Ksharasutra* in the management of “*Bhagandara*” (crypto glandular fistula).<sup>5</sup>

The objective of this study is to find out the efficacy of the *Madhu saindhav Aragwadhadi kshar sutra* with *IFTAK* in the management of cryptoglandular fistula as well as the adverse effect of *Madhu saindhav Aragwadhadi kshar sutra*.<sup>6</sup>

## METHODS

### Study design

Prospective study of randomized control trial with single blind test

### Study subjects

The study included 13 patients ranging in age from 18 to 60 years old, irrespective of gender or religious affiliation who met the inclusion and exclusion criteria from march 2022 to May 2022.

### Study setting

Patients were chosen at random from the IPD and OPD of the department of *Shalya tantra* Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University Jodhpur and registered for the study. All required general and routine examination and investigation were done.

### Study period

The patients were screened on the second to eighth week after each seven-day period for symptoms of a relapse of their sickness and any concomitant lesions in the ano-rectal region

**Ethical clearance no.** DSRRAU/UCA/IEC/19-20/286  
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### Inclusion criteria:

1. Blind fistula in ano.
2. Low anal fistula in ano
3. All type tract of Fistula in ano.
4. Recurrent fistula in ano.

### Exclusion criteria

1. *Bhagandara* present with tuberculosis
2. Hypertension.
3. Chronic Amoebias
4. Osteomyelitis of pelvic bone/femur.
5. Regional Ileitis
6. Any malignancies related with fistula in ano.
7. Chronic/acute ulcerative Colitis.
8. HIV & hbsag Positive patient.
9. Crohn's disease
10. Faecal Fistula & Uretero-Vaginal Fistula

### Withdrawal Criteria

The patients shown any allergic reaction with *Madhu saindhav Aragwadhadi kshar sutra* and non-cooperative patients will be remove from the study.

### Dietic Advice

*Laghu*, fibre rich meal, daliya, sooji, salad, butter, milk munakka, *patol parwal* etc.

### To Avoid

Bajara, spicy food, meda, curd, and oily food

### Assessment Criteria

#### Objective Parameters

1. U.C.T. (Unit Cutting Time):

Total No. Of Days Taken For Cut Through = ..... Days  
/centimetre

-----  
Initial Length of Track In Centimetre

#### Subjective Parameters

1. *Vedana* (Pain in perianal area)
  2. *Srava* (Pus discharge from perianal area)
  3. *Shotha* (Swelling)
  4. *Kandu* (Itching)
  5. An opening in perianal area.
- Assessment of sign and symptoms will be done pre & post trial on severity Grading scale. Table 1

### Table 1 As per visual analogue scale (VAS score 0-10) Statistical Analysis

All of the data was obtained, and statistical calculations in terms of mean score were performed. Prior to beginning therapy (BT), Following therapy (AT). Standard error (S.D. ), mean (x), and standard deviation (S.D.) (S.E.). The results were included in terms of probability (p) no. After a paired test (t value) was performed. (Table 2)

### Statistical Analysis:

The result was analysed by Wilcoxon rank test (p<0.05).

## RESULT

### ( Shown in Table number 3)

13 patients were selected for the clinical study. (n=13)

The mean of pain significantly (p value<.001) reduced from  $2 \pm 19.61$  to  $0.154 \pm .1042$ . With percentage relief of 92.3%. Calculated value of t >table value of t so result was significant, in statistical analysis all 13 cases are having significant pain relief with p <.001. It may be due to *Ksharana* and *tikshan gun* of *kshara*.

The mean of itching significantly (p value<.001) reduced from  $0.4615 \pm .1831$ . To  $0.077 \pm .0769$  with percentage relief of 83.33%. Calculated value of t >table value of t so result was significant, in statistical analysis all 13 cases are having significant relief in itching with p <.001. It may be due to *kaphahara* property of *Aragwadhadi gana*. *Kandughna* effect is mentioned in *sushrut Samhita* of *Aragwadhadi gana*.

The mean of swelling significantly (p value<.001) reduced from  $1.615 \pm .1804$  to  $0.154 \pm .1042$  percentage relief of 90.52%. Calculated value of t >table value of t so result was significant. In statistical analysis all 13 cases are having significant relief in swelling with p <.001. *Shothaghna guna* of *Aragwadhadi gana* is also mentioned in *sushrut Samhita*.

The mean of pus discharge significantly (p value<.001) reduced from  $2.538 \pm .1831$ . To  $0.077 \pm .076$ . With percentage relief of 97%. Calculated value of t >table value of t so result was significant. In statistical analysis all 13 cases are having significant relief in pus discharge with p <.001. Significant relief in pus discharge may be due to anti-inflammatory effect of *Madhu saindhava Aragwadhadi kshar*. According to *Ayurveda* it may be due to *kaphahara guna* of *Aragwadhadi gana*. *Aragwadhadi gana* mitigates *slesma(kapha)* according to *aacharya*

*sushrut*. *Vran shodhan* quality of *Aragwadhadi gana* is also mentioned in *sushrut Samhita*.

UCT is recorded in various age group of patients; it was found minimum UCT 9.27 was in lower age less than 25yrs. & maximum UCT 9.9 in elder patients.

#### Assessment Of Result:

For the purpose of grading the results, some grade points were assigned based on the severity of various signs and symptoms. The following factors will be used to determine the outcome of the clinical evaluation:

Pain, swelling, discharge, discomfort, itching, and burning feeling are all cardinal signs and symptoms that must not be avoided.

1. Maximum improvement: 75 to 95 percent with the above cardinal signs and symptoms improve.
2. Moderate improvement: A 50% to 70% improvement has been seen in the aforesaid cardinal sign and symptoms.
3. Mild improvement: Improvement of the mentioned cardinal sign and symptoms by 25% to 49%.
4. No improvement: the above-mentioned cardinal sign and symptoms have improved by less than 25%..

#### DISCUSSION

*Bhagandara* is a condition that starts as an inflammatory swelling and progresses to an abscess between the anal canal and skin, eventually resulting in the formation of a continuously draining track. Anal glands are the main source of infection, which are located at the sub epithelial layer of anal canal<sup>7</sup>.

1. In this study 23% patients were of age group <25 years, 61.53% patients were of age group 25-50 years, 15.38 % patients were of age group >50 years.
2. Out of 13 cases, 12 patients were male and 01 were female patients. The ratio of male and female are 12:1. This analysis shows males are more prone to *Bhagandara* than female.
3. Out of 13 cases patients (84.61%) did not have Ano-rectal diseases. 01 patients (07.69%) suffered with piles and 01 patient (07.69) from Fissure & Sentinel Tag.
4. The anal region was divided into two halves anterior & posterior. Analysis shows that external opening of the fistula was maximum in posterior half (69.23%) while (30.76%) in anterior half.
5. Majority of the cases were of the Intersphincteric variety (61.53%), whereas the minimum cases were of the Extrasphincteric variety (15.38%).

6. It was evaluated that majority of the fistulous tracks (76.92 %) were complete. 01 patient (07.69%) was from the group of the blind internal and The tracks were blind external in 02 patients (15.38%).
7. Majority of the cases were of the low anal variety (84.61%), rest of the patients (15.38%) had a high anal fistula in ano.
8. *Madhu saindhav Aragwadhadi Kshar sutra* has very important property like-*kushthaghan*, *shothhar*, *vranashodhak*, and *vranaropak*.<sup>7</sup> It reduces accumulation of pus within the track by allowing continuous drainage and causes the cauterization of the crypto glandular origin of the fistula due to its *chhedan*, *lekhan*, *bhedan*, & *tikshan guna* property. It penetrates deeply and bring out the unhealthy granulation tissue which is the most important cause of fistula (more than 90% of cases of fistula in ano are due to crypto glandular infections).

#### CONCLUSION

The purpose of this research is to lay down the efficacy and relevance of the *Aragwadhadi kshar Sutra* to treat the *Bhagandara* based on the clinical statistical data presented above, the following conclusions are drawn. In this clinical trial, there was a significant reduction in the symptoms of irritation, inflammation, and local reactions. It was found that *Aragwadhadi Kshar sutra* have better wound healing due to *Vrana Ropan* and *Vrana shodhan* property of *Aragwadhadi gan*. Pathogens did not multiply and invade the cavity due to alkaline PH of *kshar*. During the last 1.5 months of follow-up, no new instances were reported. In this clinical trial, not only the average unit cutting time was reduced, but also the discomfort and burning feeling.

*Madhu saindhav Aragwadhadi Kshar Sutra* is a better alternative because it has better wound healing properties after being cut through.

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**Diagrammatic Representation of IFTEK Procedure with Time**



**Before Procedure**



**During Procedure**



**After Procedure 7<sup>th</sup> Day**



**After procedure 14<sup>th</sup> day**



**After Procedure 21<sup>th</sup> day**



**After Procedure 28<sup>th</sup> day**

**Table 1 As per visual analogue scale (VAS score 0-10)**

Sr no.	<i>Vedana</i> (Pain)	Grading
1.	No pain	0
2.	Mild pain	1
3.	Moderate to Severe Pain	2
4.	Very severe pain	3
2. <i>Srava</i> (Pus discharge)		
Sr no.	<i>Srava</i> (Pus discharge)	Grading
1	No discharge	0
2	Mild (if wound wets 1×1 cm gauze piece	1
3	Moderate (if wound wets 2×2 cm gauze piece	2
4	Severe (if wound wets more than 2 cm gauze piece	3
3. <i>Shotha</i> (swelling)		
Sr no.	<i>Shotha</i> (swelling)	Grading
1.	Swelling within 0.5-1 cm	0
2.	Swelling within 1-2 cm	1
3.	Swelling within 2-3 cm	2
4.	Swelling within 3-4 cm	3
4. <i>kandu</i> (itching)		
Sr no.	<i>Kandu</i> (Itching)	Grading
1.	No itching	0
2.	Mild itching	1
3.	Moderate itching	2
4.	Severe and continuous itching	3
5. Thread length(cm)		
Sr no.	Thread length(cm)	Grading
1.	<3	0
2.	3-4	1
3.	4-5	2
4.	>5	3
6. Unit Cutting Time		
Sr no.	Unit Cutting Time	Grading
1.	<15 days	0
2.	15-30 days	1
3.	30-45 days	2
4.	>45 days	3

**Table 2 Shows STATISTICAL ANALYSIS**

P	≥	0.05	Not Significant (NS)
P	≤	0.05	Not Quite Significant
P	≤	0.01	Significant (S)
P	≤	0.001	Extremely Significant (ES)

**Table 3 Shows RESULT**

SYMPTOM	NO. OF PATIENTS	MEAN		DIFFERENCE	% OF CHANGE	SD	SE	P	R
		BT	AT						
PAIN	13	2	0.154	1.846	92.3	0.5547	0.154	0.0002	CES
ITCHING	13	0.4615	0.077	0.3846	83.33	0.5064	0.14	0.0625	CNS
SWELLING	13	1.615	0.154	1.462	90.52	0.5189	0.144	0.0002	CES
PUS DISCHARGE	13	2.538	0.077	2.462	97	0.6602	0.183	0.0002	CES