

A CLINICAL STUDY OF GUGGULU- SHIGRU KSHAR SUTRA IN BHAGANDARA (LOW LEVEL FISTULA)

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ABSTRACT

Among all the notorious diseases *Bhagandara* is one such ano-rectal disease which have callous nature. The pain, inconvenience and constant discomfort hinder the natural routine of an individual and create problems for them. A revolutionary treatment approach to this disease is *Kshar Sutra* therapy. But it is the need of time to make more efficient *Kshar Sutra* by doing further research on them. Therefore, a research work was performed in Gurukul Campus of UTTARAKHAND AYURVED UNIVERSITY Haridwar, entitled 'A clinical study of *Guggulu-Shigru Kshar Sutra* in the management of *Bhagandara* (Low level fistula)'. It is a single blind controlled study where 30 patients who fit in the inclusion criteria were randomly selected for the study. The *Guggulu-Shigru Kshar Sutra* was used to treat their anal fistulas and was changed on 7th day, 14th day, 21st day and so on till the end of the treatment. The present study has shown some very beneficial results in Unit Cutting Time (U.C.T.), pain, discharges, itching and burning sensation.

Keywords *Bhagandara*, Gurukul Campus, Low level fistula, *Guggulu-Shigru Kshar Sutra*, U.C.T.,

INTRODUCTION

Ayurveda is the oldest known traditional medical science which deals with the detailed aspects of human body from its normal functioning to the treatment of various disorders. Now a day a lot of research work had done in the field of *Ayurveda* to promote its standards. *Shalya Tantra*, which is one among *Ashtang Ayurveda*, got its origin from a divine soul *Acharya Sushruta*. *Acharya Sushruta* gave 4th position to *Bhagandara roga* among the *Astamahagadas*¹ (eight dreadful diseases) in his manuscript. *Bhagandara* is ancient disease which occurs in the ano-rectal region. Its classical feature is, firstly it occurs as *Pidika* around the *Guda* then it burst out and form *Bhagandara*. The modern correlation of *Bhagandara* is fistula-in-ano. Here fistula is the tract lined by granulation tissue which have one opening in the anal canal and other in the perianal skin. As *Ayurveda* has classified it as *Astamahagada* similarly in modern science this disorder is known for its high reoccurrence rate.

Fistulotomy and Fistulectomy are the two renowned surgical techniques for the treatment of anal fistula. But both these techniques have severe complications such as Incontinence due to sphincter muscle damage, rectal prolapse, fecal soiling, delayed healing of wound and subsequent high chance of reoccurrence. To overcome such complications *Ayurveda* is explored. *Acharya Sushruta* gave various treatment approaches for *Bhagandara*. One such technique is *Kshar Sutra*² which was later elaborated by *Acharya Chakradutta*. *Acharya Chakradutta* explained the methods of its preparation and its application over the *Bhagandara* patients. From a long period of time *Kshar Sutra* proven as the boon for the treatment of anal fistula. The principle of *Kshar Sutra* is to maintain adequate drainage of the tract as well excise the tract gradually. The *Kshar Sutra* dissolve the tough fibrous tissue and drains the pus thus facilitates the granulation tissue formation to heal.

Need of Study

Nobody can deny the fact that traditionally used *Kshar Sutra* is a boon for *Ayurvedic* surgeons for treating fistula patients. But certain inconveniences were observed during *Kshar Sutra* therapy and they are worth noting. The limited availability of *Apamarga* plant and highly

irritant characteristic of *Snuhi ksheer* makes this *Kshar Sutra* discomfort for patient. Also, it has been seen that *Apamarga Kshar Sutra* causes pain, burning sensation, inflammation and other discomforts to the patients. The *Apamarga* plant is only available in rainy season. All these factors collectively make it feel a need of new *Kshar* plant which is perineal and having less adverse effects without compromising the efficacy of *Kshar*. Therefore, in this study a new *Kshar* plant is taken into consideration i.e. *Shigru* and to lessen the complications caused by *Snuhi*, *Guggulu* extract is used.

Aim and Objectives

Preparation of *Guggulu* based *Shigru Kshar Sutra*

1. To evaluate the efficacy of *Guggulu-Shigru Kshar-Sutra* Therapy in *Bhagandara (Low Level Fistula)*.
2. To evaluate the intensity of pain, burning sensation and itching, so that the patient can do his routine works comfortably.
3. To find the recurrence, if any, during the study period.
4. To enhance the rate of healing.

Materials and Methods

The present study was based on the clinical findings gathered during the study and it was randomized controlled trial.

Selection of Patients: A count of 30 patients were selected and carefully examined from the OPD/IPD of Gurukul Campus of Uttarakhand Ayurved University, Haridwar. The informed written consent were taken from them prior to the initiation of research work. The examination of the patients is carried out with the help of proforma and findings were recorded in it.

The Ethical clearance number is **Uttarakhand Ayurved University/GC/IEC/2020/4**.

Method of *Kshar Sutra* Therapy

- Pre-operative preparation
- Operative procedure *Kshar Sutra* ligation under suitable Anesthesia
- Post-operative measures
- *Kshar Sutra* Changing on 7th, 14th 21st& 28th days of follow up.

Inclusion criteria

- The patients having sign and symptoms of *Bhagandara* (low level anal fistula), were selected for present study.
- The patients of the age group 16-60 years were selected.
- Fresh as well recurrent cases were also registered for the research purpose.

Exclusion criteria

- HIV, HCV and HbSAg positive patients.
- Secondary fistula due to -
- Ulcerative colitis
- Crohn's disease
- Tuberculosis
- Carcinoma of rectum
- High level Fistula
- Piles, Fissure and any other ano-rectal disorder

- Others

All the 30 patients of *Bhagandara* were treated with *Guggulu* based *Shigru Kshar Sutra*.

Selection of Drug

The *Shigru* plant is used as a medicinal herb from a long period of time. *Shigru* poses *Kapha-Vaat Shamak*³ properties therefore it acts as anti-inflammatory and analgesic agent. The paste of the bark is used for healing wounds. The oil of *Shigru* seed were used in Osteo-arthritis. This plant is mentioned in *Kshar Dashak*⁴ by *Raj Nighantu*. But its *Kshar* efficacy is not being tested yet. Therefore, after going through from the previous research work done on the *Bhagandara* we decided to perform a research work on *Shigru Kshar* to give an alternative perennial plant for the *Kshar* formation instead of the seasonal plant (*Apamarga*).

In this study the Bark of *Shigru* plant is used for *Kshar* formation.

Investigations

Table 1: The blood and other radiological investigations were done as per requirements:

S. No	A. Laboratory investigations	
1.	Blood Investigations	Complete haemogram which includes Hb %, TLC, DLC, ESR, BT, CT, B. Sugar- fasting and pp, LFT, KFT, HIV, HbsAg, HCV, Any other (if required)
2.	Urine	Routine and Microscopic (if required)
3.	Pus	Culture and Sensitivity (if necessary)
4.	Stool	Ova, cyst & pus cells (if required)
B. Proctoscopy		
C. Radiological- MRI & Fistulogram (if necessary)		

Adjuvant Therapy

Avagaah sveda with *Sphatik bhasma* were instructed to the patients twice daily. In morning it was advised just after defecation and in second time in evening. The duration of *avagaah sveda* was 15 minutes.

Guggulu preparation (*Triphala Guggulu*⁵) was used as an internal medication, it had proven successful in preventing the secondary infections.

Matra basti of *Jatyadi tail*⁶ keeps the anal canal lubricated, reduces inflammation and prevents secondary infections.

Stool softener is also given to patients which was advised at bedtime so that there will not be pain by pulling of *Kshar Sutra* while defecating.

Period of Study

The treatment was variable because of the different length of fistulous tract in different patients. However, patients were instructed to have a weekly visit for changing *Kshar Sutra*. The changing *Kshar Sutra* is done till the complete cut through of the fistulous tract and gradual tightening of *Kshar Sutra* was also done. After completion of the study the patient is followed up for 3 months at the interval of 15 days.

Assessment Criteria

Subjective criteria

1. *Kandu* (Itching): (Mild, Moderate, severe, & very severe)
2. *Ruja* (Pain): (Mild, Moderate, severe, & very severe)

3. *Srava* (Discharge): (Mild, Moderate, severe, & very severe)

4. *Daha* (Burning sensation): (Mild, Moderate, severe, & very severe)

Objective criteria

Total No. of days taken for cut through

$$\text{U.C.T.} = \frac{\text{Total No. of days taken for cut through}}{\text{Initial length of track in cms}} = \dots\dots\dots \text{Days/cm}$$

Table 2: Parameters for Assessment of Burning Sensation →

Explanation	Grade
No complaint	0
Negligible feeling of burning sensation for few minutes in a day	1
Tolerable burning sensation completely relived by hot sitz bath or local application of Oil	2
Tolerable but constant burning sensation slightly relived by hot sitz bath or local application of Oil	3
Unbearable burning sensation which makes the patient to seek medical help as soon as possible.	4

Table 3: Parameters for Itching Assessment→

Explanation	Grade
No complaint	0
Negligible Itching for few minutes in a day	1
Occasional sensation of itching with 4-6 hrs interval	2
Frequent sensation itching with 2-3 hrs interval	3
Continuous sensation of itching with 15-30 min interval	4

Table 4: Parameter for assessment of discharge→

Explanation	Grade
No sign of any discharge	0
Occasional appearance of discharge and patient use single cotton pad in 24 hrs	1
Frequent appearance of discharge and patient use 3-4 cotton pad in 24 hrs	2
Increased frequency of discharge and patient use 5-6 cotton pads in 24 hrs	3
Continuous discharge	4

Table 5: Parameters for Pain Assessment→

Explanation	Grade
No complaint of pain	0
Negligible/tolerable pain.	1—3
Localized tolerable pain completely relived by hot sitz bath	4—6
Intolerable pain, not relived by hot sitz bath relived by oral analgesic, no disturbance in sleep	7—8
Continuous and intolerable pain with sleep disturbance. Patient seek medical help as early as possible.	9—10

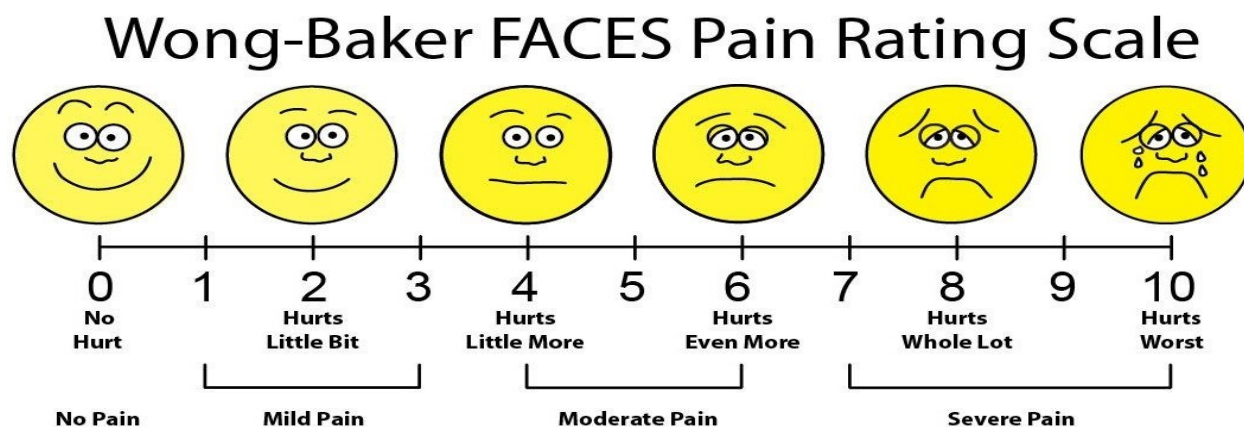


Table 6: Efficacy of *Kshar Sutra* Therapy

Efficacy of <i>Kshar Sutra</i> Therapy		
S. No.	Observation	Percentage
1.	No relief	0%
2.	Mild relief	1-25%
3.	Moderate relief	26-50%
4.	Significant relief	51-75%
5.	Excellent relief	76-100%

Statistical Analysis

The data which was collected from the above-mentioned parameters were statistically analyzed with the help of mean (X), standard deviation (S.D.), standard error (S.E.), parametric and non-parametric tests.

Observations and Results

Table 7: % age relief

Subjective Parameters	% relief
<i>Ruja</i> (Pain)	88.8 %
<i>Daha</i> (Burning Sensation)	78.21 %
<i>Srava</i> (Discharges)	91.34 %
<i>Kandu</i> (Itching)	83.15 %
Objective Parameters	
Unit Cutting Time	7.011 day/cm

Demographic Observation made during the study are as follows:

Table 8: Total number of patients

Registered	Discontinued	Completed
30	0	30

1. *Koshtha Lakshana* wise detailing of Patients:

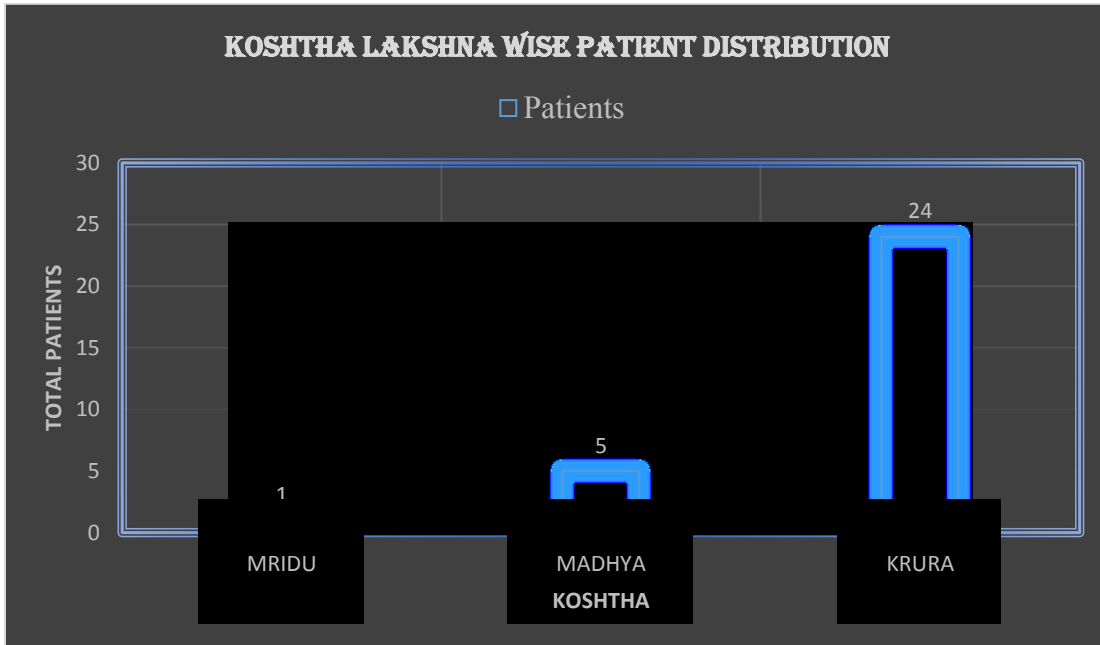


Table 9: Patients distribution according to their Koshtha

<i>Koshtha</i>	Number of Patients	Total patients	Percentage (%)
<i>Mridu</i>	1	30	3.3%
<i>Madhya</i>	5		16.6%
<i>Krura</i>	24		80%

2. Type of Bhagandara wise patients:

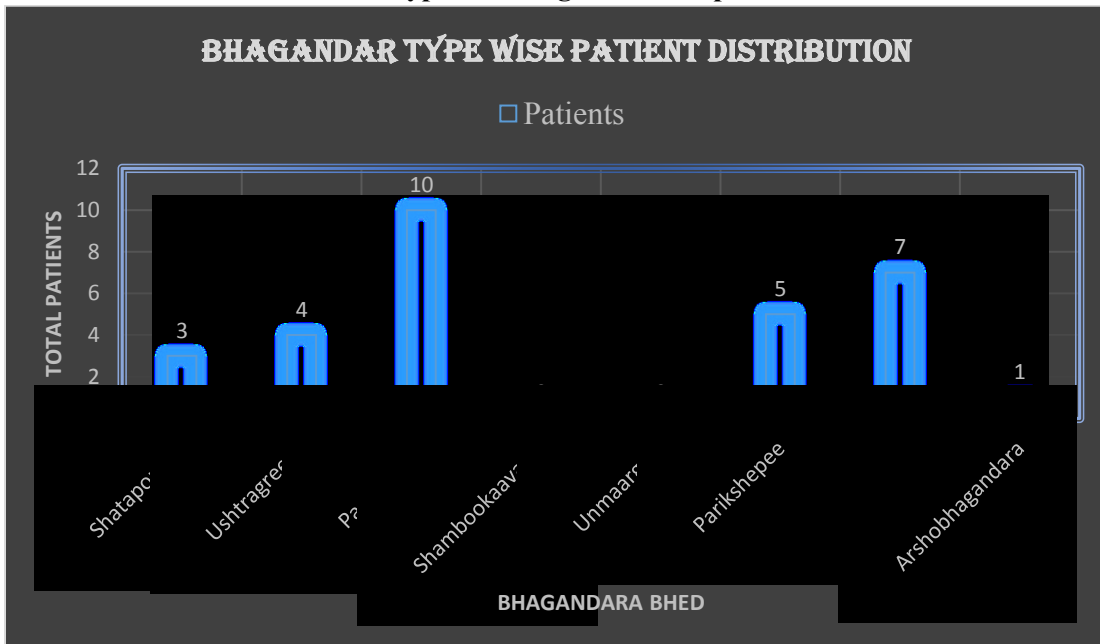


Table 10: Patients distribution according to the *Bhagandara Bheda*

Type of <i>Bhagandara</i>	Number of Patients	Total Patients	Percentage (%)
<i>Shataponaka (Vaataja)</i>	3	30	10 %
<i>Ushtragreeva (Pittaja)</i>	4		13.3%
<i>Parisraavee (Kaphaja)</i>	10		33.3%
<i>Shambookaavarta (Sannipaataja)</i>	0		0
<i>Unmaargee (Aagantuja)</i>	0		0
<i>Parikshepee (Vaatapittaja)</i>	5		16.7%
<i>Riju (Vaatakaphaja)</i>	7		23.3%
<i>Arshobhagandara (Kaphapittaja)</i>	1		3.3%

3. Type of fistula in ano wise patient distribution:

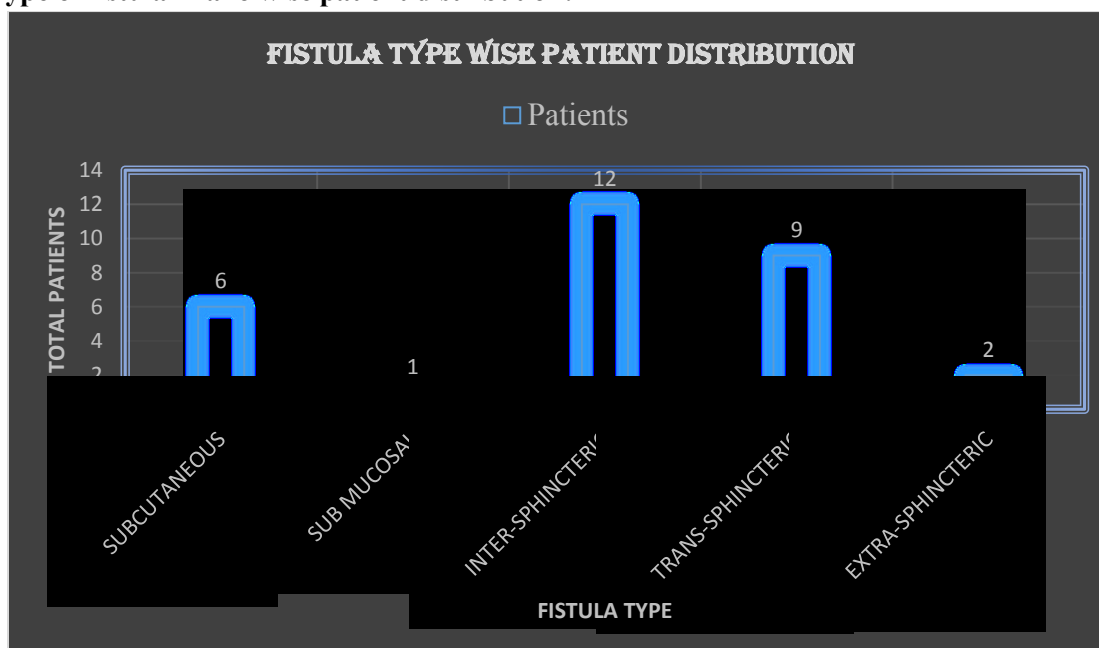


Table 11: Patients distribution according to the type of fistula

Type of fistula	Number of Patients	Total Patients	Percentage (%)
Subcutaneous	6	30	20%
Sub mucosal	1		3.3%
Inter-sphincteric	12		40%
Trans-sphincteric	9		30%
Extra-sphincteric	2		6.67%

DISCUSSION

The results were obtained from the assessment criteria which was recorded before and after treatment.

Ruja (Pain): It was observed that after the completion of the therapy the pain management was 88.8%. This reveals that *Guggulu-Shigru Kshar Sutra* have a good therapeutic effect in pain management while excising

the fistulous tract. This effect of *Shigru Kshar* is due to the *Vata Shamak* property of *Shigru* plant. This property makes it act as an anti-inflammatory and analgesic agent.

Kandu (Itching): It was observed that after the completion of the therapy the Itching was relieved about 83.15%. According to *Ayurvedic* text the *Kapha Dosha*

is mainly responsible for *Kandu* (itching) and *Shigru* have *Kapha Doshaghna* property in it. Thus, the relief over the itching was also seen in maximum number of patients.

Daha (Burning Sensation): It was observed that after the completion of the therapy the burning sensation was relieved about 78.21%. Burning sensation is less in comparison to the traditionally used *Kshar Sutra*. As in this *Kshar Sutra* we have replaced irritant *Snuhi* with *Guggulu* extract as a binding agent. Also, *Guggulu* poses some properties like *Krimighna*⁷ analgesic and anti-inflammatory, which make it more suitable choice over the *Snuhi*. Also, the *Kapha-Vatahara* property of *Shigru* lessen the sufferings of patients.

Srava (Discharges): The *srava* was last parameter of this study and statistically it had also shown marked improvement which is about 91.34 %. This was possible due to *Krimighna* property of both *Shigru* and *Guggulu*. *Krimighna* property of *Kshar Sutra* lessens the pus discharge and also inhibits the growth of secondary infectious agents. Also, *Shigru* have *vraha shodhana* property which debrides the necrosed tissue of fistulous tract and promotes the healthy granulation tissue formation.

Unit Cutting Time (U.C.T): Unit cutting time was an important objective parameter of this study which decide whether the patient got cured or not. The average U.C.T. of *Guggulu-Shigru Kshar Sutra* comes out 7.01 days/cm. This U.C.T. is a good rate of excising fistulous tract with minimal sufferings of the patients.

CONCLUSION

The observations and results obtained from the study justifies that *Guggulu* based *Shigru Kshar Sutra* is a better alternative approach of traditional *Kshar Sutra* due to more acceptability, easily available and better wound healing property after cutting through of fistula. From the above discussion it can be concluded that *Guggulu-Shigru Kshar Sutra* is effective in both excising the fistulous tract and decreasing the suffering of the patients.

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