



Research Article

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EFFECT OF GUGGULU-KUTAJ KSHAR-SUTRA IN BHAGANDARA

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ABSTRACT

Ayurveda, the Indian medical science emphasizes on disease prevention than treatment. In present era busy and sedentary lifestyle along with mental stress and irregular diet schedule leads to one of the common diseases in ano-rectal region known as Bhagandara (Fistula-in-ano). 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. No specific surgical method or other medication has proven complete remedy to cure Fistula in ano. But in Ayurveda a full-fledged management by the Kshar Sutra Therapy has been mentioned. It has gained popularity due to its minimal invasive accessibility and overall cure of the disease. It is the requirement of time to do further researches to get more effect in Kshar Sutra. In the present research work Guggulu-Kutaj Kshar Sutra application was done for the management of Bhagandara. 20 diagnosed cases of Bhagandara were selected from OPD and IPD of P.G. Department of Shalya Tantra, Rishikul Campus, Uttarakhand Ayurveda University, Haridwar (U.K.) India. The results showed significant relief in subjective and objective parameters along with complete cure. Thus, it can be concluded that the preparation of Kutaj Kshar Sutra using Kutaj Kshar may open a new path in the treatment of Bhagandara as is evident by successful result. No complications were observed in this clinical study with follow up period.

Keywords: Bhagandara, Fistula in ano, Guggulu-Kutaj Kshar Sutra.

INTRODUCTION

In Ayurveda, it is mentioned that the causes of all disease are Apathya Sewan and treatment of all diseases is nidanparivarjan. Bhadandara is also caused by apathya sewan and it is very difficult to manage so Acharya Sushruta considered it under the ashtamahagadas (eight grave disorders)¹. Bhagandara is one of the most common diseases in ano-rectal region. Bhagandara closely harmonize in clinical presentation with Fistula-in-ano described in modern medical science. Cryptoglandular infection, the most common cause, results in ano-rectal abscess and ultimately leads to Fistula-in-ano (Bhagandara). Cryptoglandular infection is responsible for causing 90% of all anal fistulas. 10% Fistula-in-ano (Non-cryptoglandular) occur without initial anal gland infection and common causes can be Crohn's disease, Ulcerative colitis, Tuberculosis, Traumatic² etc. Many surgical management of Bhagandara (Fistula-in-ano) in modern science like Fistulotomy, Fistulectomy, Non-medicated thread (Seton), Fibrin glue, Advancement flaps- Mucosal flap procedure (Endorectal advancement flap, Anocutaneous advancement flap, Anal fistula plug [AFP] repair, LIFT technique [ligation of Intersphincteric Fistulous Track], VAAFT Procedure [Video Assisted Anal Fistula Treatment]³ etc. All these variants of Fistula-in-ano treatment seem to have limited scope due to high chance of recurrence and some of them complicates as incontinence⁴. Surgical treatment required regular dressing and post-operative care for long time duration and may not be affordable for common public. To overcome such problem some alternative technique should be required. But in Ayurveda

management of Bhagandara by the Kshar-Sutra is present in Charak Samhita in the chapter of Shoth Chikitsa which is first description of Kshar Sutra and its role in Bhagandara⁵. Acharya Sushruta mentioned Kshar Sutra for the treatment of Nadi Vran, Bhagandara, arbud⁶, later on in eleventh century Chakrapanidutt mentioned preparation of Kshar Sutra and its clear-cut indication in Arsh and Bhagandara in his book Chakradutt⁷. The Indian council of medical research (I.C.M.R.) has validated this unique and effective approach. Presently, Kshar Sutra management is also mentioned in international book of surgery, like Bailey's and Love, etc. Kshar Sutra treatment heals the fistulous tract with the integrity of sphincters and the existing data reveal negligible chance of recurrence. Kshar Sutra management is popular as non-recurrence treatment for Fistula-in-ano. Kshar and other herbs are applied to exhibit both mechanical and chemical effect which promote in cutting and healing of the Fistula track.

Aims and objectives

- To evaluate the effect of Guggulu-Kutaj Kshar-Sutra in Bhagandara.
- To enhance the rate of healing.

MATERIAL AND METHODS

The present clinical trial was designed in a group, on which randomized study was taken over the patients, suffering from Bhagandara (Fistula in ano). Under Sterile conditions our Rishikul Hospital Haridwar has Kshar-Sutra Lab in which

preparation of Kshar-Sutra is done under full aseptic precautions and Patient was examined under Local Anesthesia (Xylocaine jelly 2%) then Gentle probing was done under aseptic condition. Primary Threading was done with the help of Surgical linen Barbour thread no 20. After that Kshar Sutra was changed weekly after primary threading by Rail-road technique. This procedure was repeated every week until 'cut through' of the Kshar Sutra was achieved automatically.

Kshar Sutra is a medicated alkaline thread. Application of this thread in fistulous tract allows better wound drainage and simultaneously cutting and healing of the wound.

Method of preparation of Kshar Sutra

The technique of preparation of Guggulu-Kutaj Kshar Sutra was same as standardized by the Department of Shalya Tantra, IMS, Banaras Hindu University, Varanasi (U.P).

Guggulu-Kutaj Kshar Sutra was prepared by repeated 21 coatings in which 11 coatings were of Guggulu extract alone, 7 coatings of Guggulu extract with Kutaj Kshar, and 3 coatings of Haridrachurna with Guggulu extract were done. The prepared Guggulu-Kutaj Kshar Sutra was packed and sealed under aseptic precautions and stored in Formalin chamber in operation theatre, and ready for application in Bhagandara patients⁷.

Selection of Patients

Diagnosed twenty cases of Bhagandara (Fistula-in-ano) were registered by simple random sampling method from OPD and IPD of the Department of Shalya Tantra, Rishikul Ayurvedic college campus hospital, Haridwar, Uttarakhand Ayurved University, U.K., India. Ethical clearance no-uau/rc/ICE/2017-18/05

Consent

The patients seeking the treatment for Bhagandara were selected. They were well informed about the treatment and a written informed bilingual consent was obtained from the patient and close relative of the patient.

Inclusion Criteria

- Clinical signs and symptoms of all types of Bhagandara, fresh cases as well as previously operated*.
(*They were operated elsewhere by any other surgeon)
- Any age group of either sex.
- Bhagandara of all types with Parikartika (Fistula in ano with Fissure in ano)
- Bhagandara with Niyantrita Madhumeha (Fistula in ano with controlled Diabetes mellitus)
- Bhagandara with Haemorrhoids

Exclusion Criteria

- HIV, HCV and HBsAg positive patients.
- Secondary Fistula due to -
-Ulcerative colitis
-Crohn's disease
-Tuberculosis
-Carcinoma of rectum

Assessment Criteria

Subjective criteria

- Itching (Mild, Moderate, severe and very severe)
- Pain (Mild, Moderate, severe and very severe)
- Discharge (Mild, Moderate, severe and very severe)
- Burning sensation (Mild, Moderate, severe and very severe)
- Inflammation (Mild, Moderate, severe and very severe)

(Very severe +++++, Severe +++++, Moderate ++, Mild +, Absent -)

Objective criteria

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

Efficacy of Kshar Sutures in a group of patients was assessed on the basis of following signs and symptoms:

- Itching
- Pain
- Discharge
- Burning sensation
- Inflammation
- Unit cutting time (U.C.T.)

Grading of assessment criteria

1. Pain

Grade	Explanation
0	No complain of pain
+	Negligible or tolerable pain. No need of any medicine
++	Localized tolerable pain, completely relieved by hot sitz bath
+++	Intolerable pain, not relieved by hot sitz bath, relieved by oral analgesic. No disturbance in sleep
++++	Continuous and intolerable pain with sleep disturbance. Patient seek medical help as early as possible

2. Burning sensation

Grade	Explanation
0	No complain of any burning sensation
+	Negligible feeling of burning sensation for few minutes in a day
++	Tolerable burning sensation completely relived by hot sitz bath or local oleation
+++	Tolerable but constant burning sensation slightly relieved by hot sitz bath or local oleation
++++	Unbearable burning sensation which makes the patient to seek feeling of medical help as soon as possible

3. Itching

Grade	Explanation
0	No complain of itching
+	Negligible itching for few minutes in a day
++	Occasional sensation of itching with 4-6 hours interval
+++	Frequent sensation of itching with 2-3 hours interval
++++	Continuous sensation of itching with 15-30 minutes interval

4. Discharge

Grade	Explanation
0	No sign of any discharge
+	Occasional appearance of discharge and patient uses single cotton pad in 24 hours
++	Frequent appearance of discharge and patient uses 3-4 cotton pads in 24 hours
+++	Increased frequency of discharge and patient uses 5-6 cotton pads in 24 hours
++++	Continuous discharge

Duration of the Study

It was depended on the length of fistulous tract till Kshar Sutra get “cut through” automatically.

5. Inflammation

Grade	Explanation
0	No sign of inflammation around external opening
+	Very little inflammation around external opening
++	Inflammation in 1 cm. diameter of external opening
+++	Inflammation in 2 cm. diameter of external opening
++++	Inflammation in more than 2 cm. diameter of external opening

Follow up study

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

For each follow-up visit, the patients were examined for any recurrence of disease or any associated lesion of the ano-rectal region.

RESULT

Table 1: Effect of therapy on Subjective criteria in 20 patients of Bhagandara

Symptoms	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Itching	3	0	-210.00	0.001	96.42	H.S
Pain	3	0	-210.00	0.001	98.24	H.S
Discharge	3	0	-190.00	0.001	95.31	H.S
Burning Sensation	2	0	-210.00	0.001	97.72	H.S
Inflammation	2	0	-210.00	0.001	100	H.S

Table 2: Overall result of U.C.T. on all 20 patients

S. N.	Name of the patients (Case no.)	Length of tract (in cm.)	No. of days taken for cut through	U.C.T. (in days/cm)
1	Case no. 1	9	94	10.44
2	Case no. 2	8	82	10.5
3	Case no. 3	7.5	42	5.6
4	Case no. 4	6.5	62	9.53
5	Case no. 5	5	41	8.2
6	Case no. 6	7	69	9.8
7	Case no. 7	12	109	9.08
8	Case no. 8	10.5	95	9.04
9	Case no. 9	7.5	62	8.26
10	Case no. 10	5.5	54	9.8
11	Case no. 11	9.5	83	8.73
12	Case no. 12	6.5	62	10.33
13	Case no. 13	15	119	7.93
14	Case no. 14	7.5	62	9.57
15	Case no. 15	13	112	8.61
16	Case no. 16	7	62	8.83
17	Case no. 17	11	125	11.36
18	Case no. 18	12	98	8.16
19	Case no. 19	10	85	8.5
20	Case no. 20	14	96	6.85

Effect of therapy on Unit Cutting Time

Table 3: U.C.T. according to types of Fistula-in-ano

Type of fistula-in-ano	U.C.T. (in days / cm.)
Sub-cutaneous	8.85
Low anal	9.31
High anal	8.10
Mean	8.75

- In analysis it shows that minimum U.C.T. 8.10 days/cm. in High anal and maximum U.C.T. 9.31 days/cm. was found in Low anal fistula-in-ano.
- Mean U.C.T. was 8.75 days/cm.

Table 4: U.C.T. according to types of Bhagandar

Type of Bhagandara	U.C.T. (in days / cm.)
Shataponaka Bhagandara	8.81
Ushtrageev Bhagandara	9.83
Parisravi Bhagandara	8.82
Shambukavarta Bhagandara	8.41
Unmargi Bhagandara	8.36
Mean	8.84

- The above analysis shows that minimum U.C.T. 8.36 day/cm. in Unmargi Bhagandara whereas maximum U.C.T. 9.83 days/cm. was found in Ushtrageev Bhagandara.
- Mean U.C.T. is 8.84 days/cm.

Table 5: U.C.T. according to position of external opening

Clockwise position	U.C.T. (in days/cm.)
1 'O' Clock	(No Case)
2 'O' Clock	8.83
3 'O' Clock	9.27
4 'O' Clock	7.93
5 'O' Clock	9.08
6 'O' Clock	8.54
7 'O' Clock	9.42
8 'O' Clock	8.61
9 'O' Clock	6.85
10 'O' Clock	(No Case)
11 'O' Clock	10.5
12 'O' Clock	8.16
Mean	8.71

- In analysis the study shows that minimum U.C.T. (i.e. 6.85 days/cm.) at 9 'O' clock and maximum U.C.T. (i.e. 9.42 days/cm.) was found at 7 'O' clock position.
- Mean U.C.T. was 8.71 days/cm.

Table-6: U.C.T. According to initial length of track

Initial length of tract (in cm.)	U.C.T. (in days/cm.)
0 – 5	8.2
5.1 – 10	9.09
> 10	8.71
Mean	8.66

- In analysis it is found that minimum U.C.T. 8.2 days/cm. in group of 0-5 cm. and it was maximum in group of 5.1 - 10 cm. i.e. 9.09 days/cm.
- Mean U.C.T. was 8.66 days/cm.

Table 7: U.C.T. according to Chronicity

Chronicity (in years)	U.C.T. (in days/cm.)
0 – 1	8.96
1 – 2	9.59
>2	8.33
Mean	8.96

- The above study shows that minimum U.C.T. was 8.33 days/cm. under the duration of more than two years, 9.59 days/cm. in 1-2 year while in 0-1 years it was 8.96 days/cm.
- Mean U.C.T. was 8.96 days/cm.

Table 8: U.C.T. according to surgery

Surgery	U.C.T. (in days/ cm.)
Operated	9.1
Non –operated	8.41
Mean	8.75

- In analysis table shows that U.C.T. was 9.1 days/cm. in operated cases and 8.41 days/cm in non-operated cases.
- Mean U.C.T. was 8.75 days/cm.

Table 9: U.C.T. according to tract of Fistula-in-ano

Type of tract	U.C.T. (in days/ cm.)
Horse shoe shaped	8.4
Curved	9
Straight	9.1
Mean	8.83

- The above table shows that minimum U.C.T. 8.4 days/cm. in horse shoe shaped track and maximum U.C.T. 9.1 days/cm. in straight track, U.C.T. in horse-shoe shaped track was 8.4 days/cm.
- Mean U.C.T. was 8.83 days/cm.

Table 10: U.C.T. according to surgery

Surgery	U.C.T. (in days/ cm.)
Operated	8.8
Non –operated	8.5
Mean	8.4

- In analysis table shows that U.C.T. was 8.8 days/cm. in operated cases and 8.5 days/cm in non-operated cases.
- Mean U.C.T. was 8.4 days/cm.

Table 11: U.C.T. according to tract of Fistula-in-ano

Type of tract	U.C.T. (in days/ cm.)
Horse shoe shaped	8.4
Curved	9.0
Straight	8.4
Mean	8.6

- The above table shows that minimum U.C.T. 8.4 days/cm. in horse shoe shaped track and straight track, maximum U.C.T. 9.0 days/cm. in curved track.
- Mean U.C.T. was 8.6 days/cm.

Table 12: Estimation of Overall Result in 20 Patients

Final result	Anarogya (unchanged)	Kinchit-arogya (improved)	Arogya (cured)
After 1 month	15	4	1
After 2 month	5	7	8
After 3 month	0	5	15
After completion of therapy	0	0	20

Table 13: Result of therapy

Result of therapy	No. of patients	Percentage
Arogya (Cured)	20	100%
Anarogya (Unchanged)	0	0%

Overall Effect of Therapy

- The duration of the treatment was till the *Guggulu-Kutaj Kshar Sutra* gets ‘cut through’ the track completely.
- In all the patients complete ‘cut through’ of the fistulous track was achieved.
- The shortest duration of treatment was in a patient where the track was 5 cm and 41 days were taken for the ‘cut through’ of the track.

The longest duration of treatment was in a patient who had single curved track and it took 125 days for the complete ‘cut through’ of the 11 cm fistulous track.

DISCUSSION

Acharya Sushruta has described numerous diseases and their management. Fistula-in-ano was recognized as disease known as

Bhagandara since the time of Acharya Sushruta and since then it was included among the list of Ashtamahagada (eight grave disease)⁹. Then also, it was difficult to treat. In modern science no satisfactory answer was obtained regarding about the management of Bhagandara (Fistula-in-ano). In the whole scenario, it was Prof. P.J. Deshpandey at Banaras Hindu University, Department of Shalya Tantra, who took the lead after pristine Acharya for exploring the technique, brought back the usefulness of Kshar Sutra for Nadivrana and Bhagandara and improved and standardized it with the help of modern science and technology and certified that the Kshar Sutra management is a safe, effective and unhazardous method of treatment in Fistula-in-ano¹⁰.

Ayurveda; it has brought revolution in the Indian system of surgery. Kshar Sutra ligation therapy in the management of Bhagandara (Fistula-in-ano) has proved boon for the humanity. Kshar Sutra acts by gradual chemical excision of the Bhagandara (Fistula-in-ano) with simultaneous healing. It is economically

low cost and with minimal discomfort. Early ambulation of patient even after the procedure is possible as it is a kind of minimal invasive procedure. There is no need of hospitalization in maximum number of cases. Damage of sphincter and soft tissues in anal region does not occur. Other complications of the modern surgical procedures have not been reported in Guggulu-Kutaj Kshar Sutra therapy.

Majority of the patients belonged to age of 25 to 50 years. In present era, the middle-aged people are doing more travelling and due to their various duties in factories, in construction sites, in warehouse, etc., they work in uncomfortable places and conditions in routine or occasionally, due to hectic lifestyle. Hence, the incidences of Bhagandara are more in the middle-aged men.

In the present study 95% males and 05% females were suffering from Bhagandara. The present study showed that female is also prone for disease Bhagandara due to modern lifestyle. Females are also doing work in offices, factories etc. in unfavorable posture and time. They could not spend more time for local hygiene.

Result was observed on the basis of subjective parameters (Pain, burning sensation, Itching, Discharge and Inflammation) and objective parameters (Unit Cutting Time i.e. U.C.T.).

All 20 patients got cured completely. In observation, Pain got cured in 98.30% of patients with highly significant result. On assessment of subjective parameters, all 20 patients got cured completely and Pain was subsided in all patients. Thus, in observation, Pain got cured in 98.24% of patients with highly significant statistically; the best response was seen in parameter of Itching, Burning sensation and Inflammation.

Thus, in observation, Pain, Itching, Discharge, burning sensation, Inflammation got cured in 100% of patients with highly significant result statistically. The mean U.C.T. of overall 20 patients of Guggulu-Kutaj Kshar Sutra are 8.85 days/cm.

CONCLUSION

In modern surgery so many forms of treatment for Bhagandara (Fistula-in-ano) shows its limitations and complications. Not a single treatment is spanning for Bhagandara (Fistula-in-ano) till today. In modern science people are still looking for new modalities for Fistula-in-ano but there is no answer regarding its complications such as frequent recurrences, faecal soiling and imperfect control of flatus, chronic wound healing, long hospitalization etc. Kshar Sutra management is popular as non-recurrence treatment for Fistula-in-ano. Kshar and other herbs is applied to exhibit both, mechanical and chemical effect which

promote in cutting and healing of the Fistula track. There is a reference available regarding utility of Kutaj twak in the management of Bhagandara but we have no reference regarding use of Kutaj Kshar. The Preparation of Kshar Sutra using Kutaj Kshar may open a new path in the treatment of Bhagandara as is evident by successful result.

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