

## STANDARDIZATION AND CLINICAL EVALUATION OF *GUGGULU CHITRAKA KSHAR SUTRA* IN THE MANAGEMENT OF FISTULA-IN-ANO

Gond Pushpa<sup>1</sup> Rajeshwari<sup>1</sup> Ashok Kumar<sup>1</sup> Shringi M. K.<sup>1</sup> Jitendra Kumar<sup>2</sup>

<sup>1</sup>Dept. of Shalya Tantra, National Institute of Ayurveda, Jaipur, Rajasthan, India

<sup>2</sup>State Ayurvedic College, Lucknow, Uttar Pradesh, India

### ABSTRACT

*Bhagandar* (fistula-in-ano) is explained as one among the eight major diseases in *Ayurvedic* texts. This disease is recurrent in nature which makes it more difficult for treatment. So it produces inconvenience in routine life. *Kshar Sutra* has been proved as a big revolution in the treatment of fistula-in-ano. It is the need to do further researches to get more efficient *Kshar Sutra*. In the present research work *Guggulu Chitraka Kshar Sutra* has been taken for the study to standardise and evaluate its efficacy clinically. Fifteen patients of fistula-in-ano were selected from OPD/IPD of Shalya Tantra, National Institute of Ayurveda, Jaipur. The study revealed that the effect of *Guggulu Chitraka Kshar Sutra* was efficient in reducing itching, pus discharge, tenderness and burning sensation and the rate of Unit Cutting Time was satisfactory. Accordingly the study was performed and the result has been statistically interpreted.

**Keywords:** Fistula-in-ano, *Bhagandar*, *Guggulu Chitraka Kshar sutra*

### INTRODUCTION

*Ayurveda* deals with physical, mental as well as spiritual well being of an individual, thus covering all fields of human life. Among the various diseases *Ayurveda* has grouped eight of them that severely affect health, are often associated with troublesome complications and challenge to the medical science i.e. *Vatvyadhi*, *Prameha*, *Khustha*, *Arsha*, *Bhagandar*, *Ashmari*, *Mudagarbha*, and *Udar Roga* are those eight diseases which are difficult to cure by nature.<sup>1</sup>

In the present study attention is paid on the *Bhagandar*. According to *Sushruta Samhita*, this disease starts as *pidika* which suppurates and on bursting leads to *Bhagandar*. A very much similar condition is described in modern medical science as fistula-in-ano. A fistula-in-ano,

or anal fistula, is a chronic abnormal communication, usually lined to some degree by granulation tissue, which runs outward from the anorectal lumen (the internal opening) to an external opening on the skin of the perineum or buttock (rarely, in women, to the vagina).<sup>2</sup>

The introduction of *Kshar Sutra* into Fistulous tract gradually dissolves the fibrous tissues, drain the pus and enhance the granulation in the tract. With these numerous advantages of *Snuhi Apamarga Kshar Sutra* during the treatment, it creates discomfort like pain, burning sensation and inflammation etc. The essential component of this thread is *Snuhi* latex. A very little amount of latex can collect after incision of stem of *Snuhi* tree. While *Guggulu* is available throughout the year and its *Niryas* can obtain and preserve

easily than *Snuhi* latex. *Apamarga* is available in the beginning of year but *Chitraka* is available throughout the year. *Sushruta* has described procedure of making *pratisarniya Kshar*<sup>3</sup> in which there is presence of *Chitraka* with all 23 herbal plants<sup>4</sup> from this text; the idea came in mind to include *Chitraka Kshar* in place of *Apamarga Kshar* in making *Kshar sutra*. To make another choice of *Apamarga Kshar* and due to its good availability throughout year, *Chitraka Kshar* has been taken in making *Kshar sutra*.

## AIMS AND OBJECTIVES

- Standardization of *Guggulu Chitraka Kshar Sutra*
- To evaluate efficacy of *Guggulu Chitraka Kshar Sutra* in the management of fistula-in-ano

## MATERIALS AND METHODS

**Standardization:** Analytical study of *Kshar Sutra* was carried out at Amol Pharmaceuticals Private Ltd., an *Ayush* recommended Analytical Lab. at Sitapura, Jaipur, Rajasthan, India.

**Table 1: Analytical Report of Chitraka Kshar**

Sl. No.	Test Parameter	Result
1	Loss on drying	13.03% w/w
2	pH	11.44
3	Sodium	10.76% w/w
4	Potassium	6.84% w/w
5	Total Alkalies as Carbonate	3.76% w/w

**Table 2: Analytical Report of Guggulu**

Sl. No.	Test Parameter	Result
1.	Guggulu Sterone	0.112% w/w

**Table 3: Analytical Report of Haridra Powder**

Sl. No.	Test Parameter	Result
1	Loss on drying	26.5% w/w
2	Sulphated ash	7.63% w/w
3	Curcuminoids	3.1% w/w
4	Hexane soluble extractive	3.23% w/w

**Table 4: Analytical Report of Guggulu Chitraka Kshar Sutra**

Sl. No.	Test Parameter	Result
1	Loss on drying (at 105°C)	7.70% w/w
2	pH	10.00
3	Length	30.4cm
4	Diameter	1.8mm
5	Total weight	0.5273g
6	Weight of coated material	0.45012g
7	Sulphate ash	27.05% w/w
8	Water soluble extractive	5.18% w/w
9	Sodium	4.53% w/w
10	Potassium	3.70% w/w
11	Total Alkalies as Carbonate	2.12% w/w
12	Curcuminoids	0.40% w/w
13	Hexane soluble extractive	5.91% w/w

**Clinical Study Design:** Randomized controlled Single blind clinical trial.

**Subjects:** The study was performed with 15 patients of low anal fistula.

**Selection of patients:** All the patients were randomly selected from the OPD of

Ano-rectal Unit, Dept. of Shalya Tantra, NIA, Jaipur and registered for the study.

**Inclusion criteria:** Age group of 20-60 yrs, irrespective to sex, economical status, educational status and marital status etc, all diagnosed cases of low anal fistula.

**Exclusion criteria:** Patients suffering from fistula-in-ano associated with any systemic disease were excluded from this study.

**Selection of Drug:** *Guggulu Chitraka Kshar sutra*

**Required material for *Guggulu Chitraka Kshar sutra*:** Barbour’s linen thread No.20, *Guggulu* Resin, Absolute Alcohol 99%, *Chitraka Kshar*, *Haridra* Powder, *Kshar Sutra* cabinet, *Kshar Sutra* hangers, Sterilized Test tube and Gauze piece.

**Table 5: Preparation of *Guggulu Chitraka Kshar Sutra***

<i>Guggulu chitraka Kshar sutra</i>	
Ingredients	No. of Coatings
<i>Guggulu</i> liquid*	11
<i>Guggulu</i> liquid + <i>Chitrak Kshar-sutra</i>	07
<i>Guggulu</i> liquid + <i>Haridra churna</i>	03
<b>Total coatings</b>	<b>21</b>

\* *Shuddha* semisolid form *Guggulu*, absolute alcohol was added to prepare syrupy consistency liquid

Lastly the prepared *Kshar Sutra* was kept in *Kshar Sutra* cabinet for 1 hr. under U.V. light radiation for sterilization and stored in sealed test tube.

**Pretreatment observation:** All the patients have been studied along with the registration by noting down their demographic profile including their age, sex, address, occupation, socioeconomic status, marital status, addiction, dietary habits etc. After preliminary registration, patients were subjected to detailed case history taking, physical, general and systemic examinations. In history and examination importance was given to ano-rectal examination.

**Investigations:**

Routine Haematological Examinations: Hb%, TLC, DLC, ESR, CT, BT, Blood

Sugar, Blood Urea, Serum Creatinine, Urine examination: Routine & Microscopic, Specific: Fistulogram, HBsAg, HIV, ECG, X-Ray: Chest P.A. view.

**Periodical observation:** Patients were instructed to visit ano-rectal unit once in a week for changing *Kshar sutra*. The changing of *Kshar sutra* was done with gradual tightening of *Kshar sutra* until the whole length of fistulous tract was cut through.

**Assessment criteria through modern parameters**

**Subjective criteria:** Pain, Itching and Burning sensation

**Objective criteria:** Tenderness, Discharge and U.C.T.

**OBSERVATION AND RESULTS**

**Table 6: Average U.C.T**

No. of Patients	Average U.C.T ( Days/cm)
15	8.20

**Table 7: Weekly Relief in Pain**

DURATION	MEAN SCORE		RELIEF %	S.D.	S.E	W	P
	B.T.	A.T.					
1 <sup>st</sup> week	1.8667	1.2667	32.25	0.5936	0.1533	54	0.0342
2 <sup>nd</sup> week	1.8667	1.2000	35.48	0.5606	0.1447	41	0.0371
3 <sup>rd</sup> week	1.8667	1.1333	39.24	0.8338	0.2153	50	0.0244
4 <sup>th</sup> week	1.8667	0.5333	71.50	0.5164	0.133	91	0.0002
5 <sup>th</sup> week	1.8667	0.4667	75.26	0.5164	0.1333	91	0.0002
6 <sup>th</sup> week	1.8667	0.1333	93.01	0.3519	0.09085	120	<0.0001

**Table 8: Weekly Relief in Itching**

DURATION	MEAN SCORE		RELIEF %	S.D.	S.E	W	P
	BT	AT					
1 <sup>st</sup> week	2.067	1.733	16.01	0.5936	0.1533	25	0.1641
2 <sup>nd</sup> week	2.067	1.533	25.72	0.8338	0.2153	36	0.0078
3 <sup>rd</sup> week	2.067	0.8667	58.25	0.5164	0.1333	91	0.0002
4 <sup>th</sup> week	2.067	0.6667	67.96	0.488	0.126	91	0.0002
5 <sup>th</sup> week	2.067	0.3333	83.98	0.488	0.126	120	<0.0001
6 <sup>th</sup> week	2.067	0.1333	93.68	0.3519	0.09085	120	<0.0001

**Table 9: Weekly Relief in Discharge**

DURATION	MEAN SCORE		RELIEF %	S.D.	S.E	W	P
	BT	AT					
1 <sup>st</sup> week	1.733	1.267	27.16	0.5936	0.1533	36	0.123
2 <sup>nd</sup> week	1.733	1.267	27.16	0.5936	0.1533	29	0.0977
3 <sup>rd</sup> week	1.733	1.133	34.68	0.8338	0.2153	39	0.0488
4 <sup>th</sup> week	1.733	0.6	65.31	0.5071	0.1309	66	0.001
5 <sup>th</sup> week	1.733	0.4667	73.41	0.5164	0.1333	91	0.0002
6 <sup>th</sup> week	1.733	0.1333	92.48	0.3519	0.09085	120	<0.0001

**Table 10: Weekly Relief in Burning sensation**

DURATION	MEAN SCORE		RELIEF %	S.D.	S.E	W	P
	BT	AT					
1 <sup>st</sup> week	2.2	1.667	24.54	0.488	0.126	44	0.0537
2 <sup>nd</sup> week	2.2	1.467	33.63	0.5164	0.1333	47	0.0137
3 <sup>rd</sup> week	2.2	1	54.54	0.5345	0.138	45	0.0039
4 <sup>th</sup> week	2.2	0.5333	76.36	0.5164	0.1333	91	0.0002
5 <sup>th</sup> week	2.2	0.2667	88.18	0.4577	0.1182	91	0.0002
6 <sup>th</sup> week	2.2	0.1333	94.09	0.3519	0.09085	105	0.0001

**Table 11: Weekly Relief in Tenderness**

DURATION	MEAN SCORE		RELIEF %	S.D.	S.E	W	P
	BT	AT					
1 <sup>st</sup> week	1.8	1.33	25.00	0.488	0.126	28	0.0547
2 <sup>nd</sup> week	1.8	1	44.44	0.7559	0.1952	58	0.021
3 <sup>rd</sup> week	1.8	0.8	55.55	0.6761	0.1746	45	0.0039
4 <sup>th</sup> week	1.8	0.33	81.66	0.488	0.126	78	0.0005
5 <sup>th</sup> week	1.8	0.26	85.22	0.4577	0.1182	120	<0.0001
6 <sup>th</sup> week	1.8	0.06	96.66	0.2582	0.06667	120	<0.0001

**Follow up:** There was no evidence of recurrence and complications were found in follow up period of 30-60 days. All the patients were instructed to visit the O.P.D. once in 15 days after the completion of treatment.

## DISCUSSION

### Discussion on clinical observation of patients

The probable cause behind the significant result of *Guggulu Kshar Sutra* in relief of pain is due to *snigdha, picchila guna* of *Guggulu*, *Guggulu* acts as local analgesic and anti inflammatory<sup>5</sup>. Pain is

due to *vata*, *Charak* has mentioned *guggulu* as best *vata hara*.<sup>6</sup>

The predictable cause may be the '*Kapha Vata shamak*' property of *Guggulu*<sup>7</sup> and *Chitrak*<sup>8</sup>. Again according to *Ayurveda*, itching (*Kandu*) is a property of *kapha*, so any drug which will contain the *kaphahara* property will definitely play a key role to dwindle the symptom. *Guggulu* possesses the *shlesma hara* quality due to *katu, tikta rasa* and *Chitrak* possesses *katu rasa* and *ushna, tikshna Guna*, thus reducing *Kandu* (Itching).

The cause behind efficient result in burning sensation by the effect of *snigdha, picchila guna* of *Guggulu*, is able to dissolve the burning sensation<sup>9</sup>. Burning sensation is caused due to Inflammation may be by the release of Histamine. Anti inflammatory effect of *Guggulu* and *Chitrak*<sup>10</sup> may be suppressing release of Histamine, thus relieving Burning sensation<sup>5</sup>. The tenderness is due to *kapha*; *Guggulu* and *Chitraka* have *kapha shamak* effect due to *katu rasa*. *Katu* and *tikta rasa* of *guggulu, lagu guna, ushna virya* and *katu vipaka* of both, *Sothghana*<sup>11</sup>, Anti inflammatory, Analgesic property<sup>5</sup> reduces tenderness.

The specific property of *Chitrak* is *vrana shodhan*, which causes *sodhan* of the matured *vrana*. By the *shodhan* quality it sloughs away the debridement of necrosed tissue from the fistulous track, thus it helps in formation of healthy granulation tissue. Consequently it reduces the pus discharge<sup>12</sup>.

The reason for which pus discharge increased in the initial stage of treatment is due to the *chedan, bhedan* and *lekhan* properties of *kshara*, which breaks down the pus pockets of micro abscesses, remained in the diseased tracks; accordingly increase the amount of pus discharge. As it turns to heal up, the discharges get diminished<sup>12</sup>.

Another condition for continuous pus discharge is that in most of times, pus discharge is caused by microbial infestation in the fistulous track. *Chitraka* is sharp and has antibacterial as well as antifungal properties<sup>13</sup> due to presence of plumbagin in it, thus pus discharge is reduced<sup>8, 14</sup>.

## CONCLUSION

The study revealed that preparing *Guggulu Chitraka Kshar Sutra* is easy and cost effective and the effect of the

prepared *Guggulu Chitraka Kshar Sutra* was efficient in reducing itching, pus discharge, tenderness and burning sensation and the rate of Unit Cutting Time was also satisfactory.

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**CORRESPONDING AUTHOR**

Dr. Pushpa Gond  
PG Scholar of Shalya Tantra  
National Institute of Ayurveda  
Amer Road, Jaipur – 302002  
Rajasthan, India  
Email: drpushpagond@gmail.com

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