

A CLINICAL EVALUATION OF *SHIGRU YUKTA TRIPHALA GUGGULU* WITH STANDARD *KSHARA SUTRA* IN THE MANAGEMENT OF FISTULA-IN-ANO

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ABSTRACT

Bhagandara (Fistula in Ano) at modern era is a common anorectal condition prevalent in the populations worldwide and its prevalence is second highest after Arsha (hemorrhoids). Kshara Sutra (K.S.) is one of the chief modality in the treatment of Bhagandara in Ayurvedic science. Exploration of the new method for the management of Bhagandara is the need of the Time. To find out an effective alternative way of treatment shigru yukta triphala Guggulu and standard kshara sutra was used in the present clinical evaluation. Total 30 cases of Bhagandara were divided randomly into 3 groups, having 10 patients in each group. In Group A- triphala gugglu & standard Ksharsutra, in Group B-shigru Ghana vati & standard ksharasutra,

Group C- shigru yukta triphala gugglu & standard ksharasutra were used. Assessment was done on objective and subjective parameters. Statistically significant difference was observed in the efficacy of treatment by subjective parameters like pain, discharge, etc. between the Three parameter. It was found that shigru yukta triphala gugglu & standard kshara sutra showed higher unit cutting time (UCT) (7.1 days). thus shigru yukta triphala gugglu & standard ksharasutra can be used in bhagandara (fistula-in-ano).

KEYWORDS: standard Ksharsutra, Bhagandara, fistula in ano, shigru yukta triphala gugglu.

INTRODUCTION

Ayurveda deals with physical, mental as well as spiritual well being of an individual, thus covering all fields of human life. Our great ancestors, through their experience, logic, keen observation and power of wisdom explored the cause of various diseases and methods to cure them. 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, Bhagandra, Ashmari, Mudagarbha, and Udar roga are those eight diseases which are difficult to cure by nature.

Fistula in ano is a condition which has been recognized as difficult surgical diseases in all the ancient and modern medical sciences of the world. Recurrent nature of this disease makes it more and more difficult for treatment. Almost all the surgeons starting from *Sushruta* to Hippocrates and also down to the modern reputed surgeons of present time have realized the difficult course of this disease which offers for its surgical, medical, medico-surgical method of treatment. Because of its anatomical position and high recurrences it becomes a notorious disease in terms of cure rate. Treatment of fistula-in-ano is always a challenging situation for the surgeons and restlessness for the sufferer.

On the contrary the ray of hope is moving towards *Ayurveda*, for its Excellency in combining the disease. In spite of the fact that the *kshara- Sutra*, the excellent *Ayurveda* remedy has earned an eminency as the first choice of treatment for fistula-in-ano, the further research on *kshara sutra* is a demand of time. No doubt, standard *kshara- Sutra* is a best weapon against the fistula-in-ano.

AIMS AND OBJECTIVES

The objectives of the selected research work are as follows-

1. To evaluate the efficacy of the *Triphala guggulu* and *standard Kshara sutra* in *bhagandara*.
2. To evaluate the efficacy of the *Shigru Ghana vati* and *standard Kshara sutra* in *bhagandara*.
3. To evaluate the efficacy of the *Shigru yukta Triphala guggulu* and *standard Kshara sutra* in *bhagandara*.

MATERIALS AND METHODS

SELECTION OF CASES

1. **Source of patients:** All affected patient suffering from fistula in ano for present study will be screened out from O.P.D. and I.P.D. of University college of *Ayurved* Hospital, Dr. Sarvepalli Radhakrishanan Rajasthan Ayurved University Jodhpur.
2. **Age group:** patient between 20 to 70 years will be included in the study.
3. **Number of cases:** 30 patients will be screened out from above source.

CRITERIA FOR SELECTION OF THE PATIENTS

INCLUSION CRITERIA

All the patients between age group of 20-70 years.

- Single tract fistula in ano.
- Multiple tract fistula in ano.
- Recurrent fistula in ano.
- Blind fistula in ano.
- High anal fistula in ano.
- Low anal fistula in ano.
- Ir-respective of age, sex & occupation.

EXCLUSION CRITERIA

- *Bhagandara* present with tuberculosis.
- Diabetes Mellitus.
- Hypertension.
- Chronic Amoebiasis.
- Urinary tract infections.
- Osteomyelitis of pelvic bone/femur.
- Chronic / acute ulcerative Colitis.
- HIV & HBsAg Positive patients.

TRIAL DRUG**1) Shigru yukta triphala gugglu Guggulu**

S.NO.	Constituents	Latin name	Part used	Ratio
1.	Guggulu	<i>Commiphora mukul</i>	Extract	5 Part
2.	Haritaki	<i>Terminalia chebula</i>	Fruit	1 Part
3.	Vibhitaki	<i>Terminalia bellirica</i>	Fruit	1 Part
4.	Aamlaki	<i>Embllica officinalis</i>	Fruit	1 Part
5.	Shigru	<i>Moringa oleifera</i>	Fruit	1 Part

2) standard kshara sutra.

1. *Shuni Ksheera*
2. *ApamargKshara*
3. *Haridra churna*
4. Linen (barber's) thread no 20.

TREATMENT SCHEDULE**GROUPING OF PATIENTS**

For clinical trial 30 patients will be grouped in three group-

Group-A- *Triphala guggulu and standard Kshara sutra.*

Group-B- *Shigru Ghana vati and standard Kshara sutra.*

Group-C- *Shigru yukta Triphala guggulu and standard Kshara sutra.*

Duration of Trial: 2 month.

Dose of shigru yukta triphala Guggulu: 500-500 mg BD.

ASSESSMENT CRITERIA

Efficacy of *shigru yukta triphala gugglu & Snuhi Apamarga Ksharsutra* was assessed on the basis of subjective and objective criteria.

A. Assessment criteria through modern parameters

- **Subjective criteria**

- ✓ Pain
- ✓ Itching
- ✓ Burning sensation

- **Objective criteria**

- ✓ Tenderness

- ✓ Discharge
- ✓ U.C.T.

Grading of Assessment criteria

- **Subjective**

It is based on feeling of patients. So researcher has to depend on his patient for assessment. It is known as simple verbal scale. In this particular research work, subjective criteria are as follows.

1. PAIN: ON VAS (Vas Analog Scale) starting from mild to severe as per with VAS:

Grade	Explanations
0	: ABSENCE OF PAIN
1	: 1- 3 Mark on scale mild pain that can be easily ignored
2	: 4- 6 Mark on scale moderate pain that cannot be ignored interfere with function and needs the treatment from time to time.
3	: 7-10 Marks on the scale –severe-that is present most of the time demanding constant attention.

2. Burning sensation

Grade	Explanations
0	: No complain of burning sensation
1	: Negligible burning sensation
2	: Occasional tolerable burning sensation, relieved by oleation.
3	: Constant and tolerable burning sensation slightly, relived by local oleation

3. Itching

Grade	Explanations
0	: No complain of itching
1	: Negligible itching, with 10-12 hours gap
2	: Occasional itching, with 4-6 hours gap
3	: Frequent itching, with 2-3 hours gap

Objective Criteria

The patients were assessed on the basis of relief of symptom and Investigation.

4. Discharge

Grade	Explanations
0	: No discharge.
1	: If discharge wets one pad of 4x4 cms gauze.
2	: If discharge wets 2 pads of 4x4 cms gauze piece.
3	: If discharge wets more than two pads of 4x4 cms gauze piece.

5. Tenderness

Grade	Explanations
0	: No tenderness
1	: Tenderness on firm pressure
2	: Tenderness on gentle pressure
3	: Patient denies touch.

6: UCT (Unit Cutting Time)

The initial length, as well as the length of *Ksharsutra* at each successive sitting has been measured and recorded. The gradual shortening of thread at the following sitting evidently corresponds to the cutting of tissue, which provides an idea of the progress of a particular case. This has been termed as unit cutting time (U.C.T.). Unit cutting time may be calculated as follows.

$$\text{U.C.T.} = \frac{\text{Total number of days (from the 1}^{\text{st}} \text{ day to cut through the thread)}}{\text{Initial length of } Ksharsutra \text{ (in cm)}}$$

Statistical Analysis

All information which are based on various parameters were gathered and statistical calculation were carried out in terms of mean (x), standard deviation (S.D.), standard error (S.E.), Paired test (t value) and finally results were incorporated in term of probability (p) no.

$P \geq 0.50$ Insignificant

$P \leq 0.020$ Moderately Significant

$p \leq 0.010$ Significant

$p \leq 0.001$ Highly Significant

OBSERVATION

On observation it was found that maximum number of patients 30.00% were between the age group 20-30 yrs. Incidence of male patients was obtained higher 90.00% than female 10.00%.

Incidence of fistula-in-ano in Hindu community was noticed higher with 96.66% in the present study. Most of the cases were from service class with 40%. The sedentary work was noted in 63.33% patients. Out of 30 cases 24 cases (80.00%) were married. Maximum patients were vegetarian 50.00%. Maximum cases 66.67% has given the history of irregular bowel. Higher incidence of the disease was observed in Vata-Kapha Prakriti (63.33%).

CLINICAL OBSERVATION

The maximum no. of cases were found within duration of 1-3 year with 43.33%. Positive family history was found in 20%. Incidence of Bhagandara confirms that Parishravi type of Bhagandara was high 56.66% than other type. Out of 30 patients 9 patients (30%) gave a history of itching type of pain. Also maximum patients complained moderate type of pain 56.67% & moderate type of tenderness 43.33%. Generally it was observed that the external opening may be single or multiple but the internal opening is usually single. In this study 70.00% of the cases had single external opening whereas 30% of the cases had double external opening with a single internal opening. In most of cases external opening was found in 5 o'clock position with a percentage of 30.00%, followed by 6 o'clock and 8 o'clock with 16.67% & 13.33% in each. No opening was noticed in 8 and 10 o'clock position. This is because of anal gland which is numerous in the posterior half of anal canal.

RESULTS

Comparison in U.C.T of Group A and Group B, Group C.

Sr. No. of Patient	U.C.T.of Group A	U.C.T of Group B	U.C.T of Group C
1	7.33	10.00	8.75
2	8.00	7.69	7.69
3	7.14	7.33	7.33
4	7.61	8.07	8.07
5	7.20	7.81	7.81
6	7.67	10.00	10.00
7	7.50	8.00	8.00
8	6.67	9.44	9.44
9	6.92	8.69	8.69
10	6.45	7.64	7.64
Average U.C.T	7.2	8.4	7.1

% Relief Group A, Group B, & Group C .

Symptoms	Group A		Group B		Group C	
	%	P value	%	P value	%	P value
Pain	87.5%	<0.001	76.92%	<0.01	92.59%	<0.001
Itching	96.00%	<0.001	88.46%	<0.01	92.00%	<0.001
Burning sensation	92.59%	<0.001	88.00%	<0.001	88.46%	<0.01
Tenderness	84.00%	<0.01	81.48%	<0.001	92.59%	<0.001
Discharge	84.61%	<0.01	88.88%	<0.001	92.85%	<0.001

DISCUSSION**EFFECT ON PAIN**

This most probable cause behind the significant result of trial drug in relief of pain is due to Vedanasthapaka Guna of Guggulu and Madakari effect of Vibhitaki acts as a systemic analgesic. Anti-inflammatory effect of Guggulu (Kirtikar and Basu) controls the inflammatory process & we all know less inflammation, less histamine on the site and less pain. Pain is due to Vata, Charak has mentioned Guggulu as best Vatahara in (Ch.su.3/4,7).

EFFECT ON ITCHING

This reveals that percentage of relief in Itching was higher in Group A. The predictable cause may be the 'Kapha Vata shamak' property of Guggulu (S.S.) and triphala. (Mentioned In Bhava Prakash Nighantu Vol-1, Page No.141, 71st Shloka no). 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 triphalalpossesses katu rasa and ushna, tikshna Guna, thus reducing Kandu (Itching).

EFFECT ON BURNING SENSATION

The cause behind it is, due to the effect of ushna virya of snuhi Ksheer, it causes irritation and burning sensation in the fistulous wound, whereas by the effect of snigdha, picchila guna of Guggulu, is able to dissolve the burning sensation in group-A (Ckd 39/12). Burning sensation is caused due to Inflammation may be by the release of Histamine. Anti inflammatory effect of Guggulu(According to Kantha D. Arunachalam et all) may be suppressing release of Histamine, thus relieving Burning sensation. (Kirtikar and Basu 1933, Chopra et al 1956).

EFFECT ON TENDERNESS

The better result in Group C of shigru yukta triphala gugglu is due to the fact that tenderness is due to kapha; Guggulu & shigru has kapha shamak effect due to katu rasa of shigru & katu

& tikta rasa of guggulu, lagu guna, ushna virya and katu vipaka of both. Sothghana (Ckd46/26), (39/12), Anti inflammatory, Analgesic property (Kirtikar and Basu1933, Chopra et al 1956) reduces tenderness. shothaghna (mentioned in bhava prakash nighantu vol-1, page no.141, 71st shloka no.) Anti inflammatory effect ofshigru.

EFFECT ON DISCHARGE

The better result of Group-C is due to the specific property of of shigru isvrana shodhan, which causes sodhan of the matured vrana. By the sodhan 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 (chakradatta 44/68).

The reason for which pus discharge increased in the initial stage of treatment is due to the chhedan, bhedan and lekhanproperties of kshar, which breaks down the pus pockets of micro abscesses, remained in the diseased track. Accordingly increase the amount of pus discharge. As it turns to heal up, the discharges get diminished (S.S.38/7).

CONCLUSION

- Goodsall's rule is always appropriate for different type of fistula-in-ano.
- On observing the overall effect of therapy *Shigru yukta triphala gugglu* was found to be more effective in relieving symptoms like pain, tenderness and pus discharge.
- Though U.C.T of *Shigru yukta triphala gugglu* is slightly higher, but in assessment parameter *Shigru yukta triphala gugglu* has been shown good result in the form of percentage.
- Post ligation complications like hypertrophied scar etc are not seen.
- Easily available and cost effective.
- *Shigru yukta triphala gugglu* should be used in combating this disease with further more research work.

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