

**A COMPARATIVE STUDY IN THE MANAGEMENT OF FISTULA-IN-ANO BY
KSHARA- SUTRA AND MAKSHIKLAVANADI VARTI WITH ORAL USE OF
NAVKARSHIK GUGGULU****Dr. Ajay Kumar^{*1}, Dr. Om Prakash Dave² and Dr. Vishnu Dutt Sharma³**¹Department of Shalya Tantra, P. G Scholar, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, India.²Department of Shalya Tantra, H. O. D & Professor Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, India.³Department of Shalya Tantra, Assistant Professor, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, India.***Corresponding Author: Dr. Ajay Kumar**

Department of Shalya Tantra, P. G Scholar, Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur, India.

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ABSTRACT

Bhagandara (Fistula in Ano) at modern parlance 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 modalities in the treatment of Bhagandara in Ayurvedic science. Exploration of the new method for the management of Bhagandara is the need of the hour. To find out an effective alternative way of treatment Navkarshik Guggulu and Makshiklavanadi Varti was used in the present clinical evaluation. Total 30 cases of Bhagandara were divided randomly into 2 groups, having 15 patients in each group. In Group A, Apamarg Ksharsutra in Group B, Makshiklavanadi Varti and Navkarshik Guggulu were used. Assessment was done on objective (Unit Healing Time - UHT) and subjective parameters. Statistically significant difference was observed in the efficacy of treatment by subjective parameters like pain, discharge, etc. between the three parameters. It was found that Makshiklavanadi Varti and Navkarshik Guggulu showed lower UHT (7.10 days) while higher in Apamarg Ksharsutra (9.85 days). Thus Makshiklavanadi Varti and Navkarshik Guggulu can be used as a substitute for Apamarg Ksharsutra and can be employed in the recurrent fibrosed cases of Bhagandara.

KEYWORDS: Apamarg Ksharsutra, Bhagandara, fistula in ano, Makshiklavanadi Varti and Navkarshik Guggulu, Unit Healing Time.**INTRODUCTION**

Ayurveda is one of the most ancient medical sciences of the world. It describes the basis and applied aspect of life process, health, disease & management in terms of its own principles & approaches. Though, modern science has been developing advanced technology for the diagnosis and management of different disorders, still ancient system of medicine fulfill the health care needs of the vast majority of a population.

The word "Bhagandara" literally means 'Darana' around Guda, Yoni and Vasti. At first it presents as a Pidika around Guda and when it bursts out, it is called as "Bhagandara". There are various types of pain and if the condition is ignored there is discharge of Vata, Mutra, Purisha and Retas, Sushruta describes. Due to such a challenging condition with various complications, Sushruta has described it as an Ashta Mahagada. "It

resembles with the description of Fistula-in-ano as described in modern medical science.

Many techniques and researches have tried since a prolonged time to alleviate this ailment. Yet, till today, fistula-in-ano remained as a back-breaking job for the modern system of medicine. On the contrary, the ray of hope is moving from Ayurveda, for its excellence in combating the diseases.

In spite of the fact that the Ksharsutra, the excellent Ayurvedic remedy has earned an eminency as the first choice of treatment for fistula-in-ano, the further research on Ksharsutra is a command of time. Ayurveda is still now standing there, where it was thousands of years before, because of lack of proper research of its theory. No doubt, standard Ksharsutra is a best weapon against the enemy. Yet research on its management is a demanding fact in present situation. So I decided to take

Apamarga Ksharsutra and Navkarshik Guggulu with Makshiklavanadi Varti for my studies, so that the efficacy & the results can be compared.

AIMS AND OBJECTIVES

The aims and objectives of my thesis are-

1. To evaluate and assess the efficacy of the Apamarga Ksharsutra in Fistula-in-ano.
2. To evaluate the efficacy of the Makshiklavanadi Varti and Navkarshik Guggulu in Fistula-in-ano.
3. Comparison between the Apamarga Ksharsutra and the Makshiklavanadi Varti and Navkarshik Guggulu in Fistula-in-ano.

MATERIALS AND METHODS

1. **SAMPLE SIZE:** A total of 30 subjects were randomly selected for the trial, with irrespective of age, sex, religion, and socioeconomic status.
2. **SOURCE OF SUBJECTS:** All the patients were randomly selected from the I.P.D. and O.P.D. of Ano Rectal Unit, Dept of Shalya Tantra, D.S.R.R.A.U., Jodhpur
3. **INFORMED CONSENT:** All the subjects selected for the study were fully informed and explained about the nature of the disease, treatment and the possible post-operative complications. A written informed consent was taken from all the subjects before starting of the trial.

Criteria for Selection of the Patients

Exclusion Criteria

- Patients suffering from fistula-in-ano associated with following disease / criteria were excluded from study.
- Bhagandara present with Tuberculosis
- Diabetes Mellitus
- Hypertension
- Chronic Amoebiasis
- Urinary Tract Infections
- Osteomyelitis of Pelvic Bone / Femur
- Regional Ileitis
- Venereal Disease
- Any malignancies
- Chronic / Acute Ulcerative Colitis
- HIV & HBsAg Positive patient

Inclusion Criteria

1. Patients were selected randomly, irrespective to age, sex, economical status, educational status & marital status etc.
2. All diagnosed cases of fistula-in-ano other than exclusion criteria.

Trial Drug

1. **Makshiklavanadi Varti**
 - Honey
 - Saindhav Lavana

2. Navkarshik Guggulu

S. no.	Constituents	Latin name	Part used	Ratio
1.	Guggulu	Commiphora mukul	Extract	5 Part
2.	Haritaki	Terminalia chebula	Fruit	1 Part
3.	Vibhitaki	Terminalia bellirica	Fruit	1 Part
4.	Aamlaki	Embllica officinalis	Fruit	1 Part
5.	Pippali	Piper longum	Fruit	1 Part

3. Treatment Schedule

Grouping of Patient

All the 30 patients were divided in 2 groups.

Group A (Control Group)

15 patients were treated with standard Apamarg Ksharsutra.

Group B (Trial Group)

15 patients were treated with Makshiklavanadi Varti in fistula tract and oral use of Navkarshik Guggulu.

Duration of Trial: 2 month

Dose of Navkarshik Guggulu: 500 mg BD

Assessment Criteria

Through Modern Parameters

A. Subjective Criteria

1. Pain
2. Itching
3. Burning Sensation
4. Swelling
5. Discharge

B. Objective Criteria

1. U.H.T. (Unit Healing time)

Through Ayurvedic Parameters

• There are six status of healed Vrana mentioned by Acharya Sushruta.

- रुद्धवर्त्मनम्
- अग्रन्थिम्
- अशूनम्
- अरूजम्
- त्वकसवर्णम्
- समतलम्

Resembling this, an effort was made to mesearing the "Healing Status" of the Bhagandara through on Ayurvedic Parameters,

According to the presence of the above mentioned six parameters, the "Healing Status" was divided in the following categories.

- 1) Complete healing 6 / 6
- 2) Moderate healing 4-5 / 6
- 3) Mild healing 2-3 / 6.
- 4) No healing 0-1 / 6

Grading of Assessment Criteria

Subjective Criteria

It is based on feelings of patient. 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

Pain

Grade Explanations

- 0 No complain of pain
- 1 Negligible or tolerable pain, no need of medication
- 2 Tolerable pain, not relief by hot sitz bath, relived by oral analgesic
- 3 Continuous and intolerable pain with sleep disturbance

1. Itching

Grade Explanations

- 0 No complain of itching
- 1 Mild & Occasional itching, with 10 - 12 hours gap
- 2 Moderate & Frequent itching, with 4-6 hours gap
- 3 Severe & continuous intensification sensation

2. Burning Sensation

Grade Explanations

- 0 No complain of burning sensation
3. Occasionally tolerable burning sensation, relieved by oleation.
4. Constant tolerable burning sensation, slightly relived by local oleation.
5. Intolerable burning sensation makes the patient uncomfortable and makes the patient to rush for medical help.

6. Discharge: (Pus Discharge)

Grade Explanations

- 0 No discharge
- 1 Mild (if wound wets 1×1 cm gauze piece)
- 2 Moderate (if wound wets 2×2 cm gauze piece).
- 3 Severe (if wound wets more than 2 cm gauze piece)
- 4 Excruciating (Continuous & Profuse Discharge)

7. Swelling

Swelling was the analyzed on the localized area of swelling.

Grade Explanations

- 0 Swelling within 0.5-1 cm
- 1 Swelling within 1-2 cm
- 2 Swelling within 2-3 cm
- 3 Swelling within 3-4 cm
- 4 Swelling more than 4 cm

Objectives Criteria

The patients were assessed on the basis of relief and investigation.

4. UHT (Unit Healing Time)

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

U.H.T. = Total number of days (from the 1st day to complete healing of the tract / Initial length of fistula tract (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 21-30 yrs. Incidence of male patients was obtained higher 93.33% than female 06.66%. Incidence of fistula-in-ano in Hindu community was noticed higher with 90.00% in the present study. Most of the cases were from Labour class with 36.66%. The sedentary work was noted in 56.66% patients. Out of 30 cases 25 cases (83.33%) were married. Maximum patients were vegetarian 70.00%. Maximum cases 66.66% has given the history of irregular bowel. Higher incidence of the disease was observed in Vata-Kapha Prakriti (46.66%).

Clinical Observation

The maximum no. of cases were found within duration of 1-2 year with 50.00%. Positive family history was found in maximum 63.33%. Incidence of Bhagandara confirms that Parishravi type of Bhagandara was high 63.33% than other type. Out of 30 patients 14 patients (46.67 %) gave a history of itching type of pain. Also maximum patients complained mild type of pain 56.66% & moderate type of swelling 40.00%. Generally it was observed that the external opening may be single or multiple but the internal opening is usually single. In this study all the patient had single external opening with a single internal opening. In most of cases external opening was found in 5 o'clock position with a percentage of 26.66%.

RESULTS**Intergroup Comparison
Comparison in UHT of Group A and Group B**

Sr. No. of Patient	U.H.T. of Group A	U.H.T. of Group B
1	9.64	6.50
2	8.75	6.52
3	10.00	7.20
4	11.11	6.66
5	9.28	6.00
6	10.35	6.00
7	10.41	8.75
8	8.9	7.07
9	9.00	6.25
10	9.21	8.88
11	9.28	6.66
12	11.87	7.50
13	9.06	7.33
14	9.65	6.52
15	11.25	7.40
Average Unit Healing Time=	9.85	7.10

Healing status according to Ayurvedic parameters

Healing Status	Number of Patients			
	Group – A		Group – B	
Complete Healing	11	73.33%	11	73.3%3
Moderate Healing	2	13.33%	3	20%
Mild Healing	2	13.33%	1	6.67%
No Healing	0	-	0	-

Intergroup Comparison of Subjective Parameters

Sr. No.	Assessment Criteria	% Group A	% Group B	U Value	P Value	Result
1.	Pain	80.02%	96.90%	64.500	0.0349	S.
2.	Itching	86.46%	88.87%	98.500	0.5470	N.S.
3.	Burning sensation	73.53%	92.30%	61.00	0.0253	S.
4.	Swelling	86.36%	90.68%	109.00	0.8954	N.S
5.	Pus Discharge	87.47%	91.82%	67.500	0.0489	S.

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 B. The predictable cause may be the 'Kapha Vata Shamak' property of Guggulu (S.S.) and Pippali. Again Pippali has anti allergic effect. Vrana Shodhanm and Ropanam properties of Madhu plays a key role because after proper drainage a clean fistula tract does not cause itching sensation.

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, Pippali and Madhu possesses the Shlesma- Hara qualities, thus reducing Kandu (Itching).

Effect on Burning Sensation

By the effect of Snigdha, Picchila Guna of Guggulu, is able to dissolve the burning sensation in group-B. Burning sensation is caused due to Inflammation may be by the release of Histamine. Anti-inflammatory effect of Guggulu, Anti-histaminic effect of Honey and Anti-allergic effect of Pippali may be suppressing release of Histamine, thus relieving Burning sensation.

Effect on Swelling

The better result of Trial drug is due to the fact that swelling is due to Kapha, Pippali, Madhu, and Guggulu have Kapha Shamak effect due to Katu Rasa and Laghu teekshna guna of Pippali & Ushna Virya, Katu Vipaka, and Ruksha Guna of Madhu, and Tikta ,Katu Rasa, Laghu, Ruksha, Tikshna, Vishda Guna, Ushna Virya and Katu Vipaka of Guggulu.

Effect on Pus Discharge

The better result of Group-B is due to the specific property of Madhu. Madhu has Vrana Shodhana, Sandhanam, and Prasadhana Guna. 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.

The reason for which pus discharge increased in the initial stage of treatment is due to the Chhedan, and Lekhan properties of Madhu, 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).

Another condition for continuous pus discharge is that in most of times, pus discharge is caused by microbial infestation in the fistulous track. Guggulu, Haritaki and Pippali have antibacterial as well as antifungal properties.

Overall Effect of the Therapy

In measuring the effect of overall therapy it has seen that:

- Group B has provided a better result in U.H.T 7.10 days/cm (7days/cm) in comparison to Group A (9.85 days/cm).
- Group B provided a better relief in Pain (96.90%), Burning sensation (92.30%), Itching (88.87%) Swelling (90.68%) & Discharge (91.82%) in comparison to Group A.
- By intergroup comparison, it is seen that, Pain, Burning sensation and Discharge showed significant result and Swelling & Itching showed non-significant result but according to percentage pain, itching, burning sensation, swelling & discharge showed significant results.

It is seen that application of Makshiklavanadi Varti and Navkarshik Guggulu provides better result in pain, burning sensation, itching, discharge & swelling than Apamarga Kshar-Sutra. By studying the overall effect, it can be concluded that trial Group-B showed markedly good results.

CONCLUSION

- On observing the overall effect of therapy Makshiklavanadi Varti with Navkarshik Guggulu were found to be more effective in relieving symptoms like pain, itching, burning sensation, swelling and pus discharge.
- On assessment parameter Makshiklavanadi Varti with Navkarshik Guggulu has been shown significant result in the form of percentage.
- There is negligible tissue loss and no structural damage.
- Post ligation complications like hypertrophied scar etc are not seen.
- Easily available and cost effective.
- Makshiklavanadi Varti with Navkarshik Guggulu should be used in combating this disease with further more research work.

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