

**A CLINICAL STUDY OF GUGGULU-APAMARGA KSHAR SUTRA IN THE
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ABSTRACT

Ayurveda, an ancient and unique part of Indian philosophy is really one of the great wonders of science. *Ayurveda* has been serving the mankind with its rich traditional resources to allay the suffering of the society and to reserve the health of the people. Surgical and para-surgical practices have been an inseparable part of *Ayurveda* which are mentioned in *Shalya Tantra*. In the present era ano-rectal disorders are increasing in number due to adaptation of sedentary life style and other factors. *Bhagandara* (Fistula in ano) is the second most common and notorious disease among all anorectal disorders. It is recurrent in nature due to lack of its complete cure in modern science, which makes it more and more difficult for treatment. It produces pain and inconvenience in routine life. It is a chronic purulent inflammatory disease, initially manifested by an abscess followed by continuous or intermittent discharge of pus through the track and leads to an unhealed condition. Improper care, hygiene and negligence leads to further aggravation of the disease. Now days, an appropriate answer for the management of *Bhagandara* is a unique specialized parasurgical procedure viz. '*Kshar Sutra therapy*' which is well accepted, WHO approved^[2] and without any complications. It has gained popularity due to its minimal invasive approach and complete cure of the disease. In the present research work *Guggulu-Apamarga Kshar Sutra* was prepared for the management of *Bhagandara*(Fistula-in-ano). 20 diagnosed case of *Bhagandara* were selected from OPD and IPD of P.G. Department of *Shalya Tantra*, Rishikul Campus, Uttarakhand Ayurveda University, Haridwar (U.K.) India. Considering all these factors, the present study was undertaken to assess the role of *Guggulu-Apamarga Kshar Sutra* in the management of *Bhagandara* (Fistula-in-ano). The results showed significant relief in subjective and objective parameters. Moreover, this therapy was well accepted by all patients and did not cause any hindrance in their daily routine work during period of management. No complications were observed in this clinical study with follow up period.

KEYWORDS: *Bhagandara*, Fistula in ano, *Guggulu-Apamarga Kshar Sutra*.**INTRODUCTION**

God has created the most complex and highly ordered arrangement of matter in the universe as human being and has bestowed the mankind with his best gifts like health, wealth, strength etc. Among them health is the factor of prime importance because wealth and other aspects of life enjoyed only with a good health. *Ayurveda* since time immemorial is one of such parameter showing the ideal way of living, having potency to provide a disease free, happy and long life.^[2]

Bhagandara can be co-related with Fistula-in-ano according to signs and symptoms, which are described in modern science. Due to sedentary life style of the patient, constipation is a very common in such people. So constipation, and other aggravating factors, gradually blocks the ducts of anal glands, promoting settling of

cryptoglandular infection resulting in ano-rectal abscess and ultimately Fistula-in-ano (*Bhagandara*). Such person passes continuous or on/off pus from peri-anal region or anus.

The aim of this case study was to understand the efficacy of *Guggulu-Apamarga Kshar Sutra* management in *Bhagandara* (Fistula-in-ano).

Personal clinical experiences, various research articles and modern texts were studied thoroughly and analyzed for proper understanding of the role of *Guggulu-Apamarga Kshar Sutra* in the management of *Bhagandara*. Hence this *Kshar Sutra* was chosen. *Guggulu* and *Apamarga* having property like *Vaata-kapha shamak*, *Lekhana*, *Vrana-ropana*, *Krimighna*^[3]

and also anti-inflammatory, antimicrobial, Analgesics, cytotoxic^[4] properties.

Surgical and para-surgical practices have been an inseparable part of *Ayurveda* which are mentioned in *Shalya Tantra*. So *Shalya Tantra* is the first and prime branch of *Ashtanga Ayurveda* which is rich in many aspects as described by *Acharya Sushruta*

अष्टास्वपि चायुर्वेदतन्त्रेष्वेतदेवाधिकममितम्, आशुक्रियाकरणात्,
यन्त्रशस्त्रक्षाराग्निप्रणिधानात्, सर्वतन्त्र सामान्याच्च ।^[6]

(सु.सू.१/२६)

Acharya Sushruta had done excellent work in the field of surgery, which are prior to time. *Sushruta Samhita* is the only authentic and most ancient classical text in surgical practices, describing detailed surgical and para-surgical techniques in context of *Chikitsa*, and some of them still have no comparison. Current surgical parlance has made enormous progress in branches like neurosurgery and microscopic surgery. Biomedical engineering is also advanced in diagnostic as well as management techniques. But certain diseases seem to mock the progress achieved. They demand innovative techniques for their management. Moreover with regards to anorectal and perianal surgery, *Acharya Sushruta* has expounded much and equal emphasis is given to surgical as well as para-surgical measures. From the beginning of life, human being suffered from various diseases and among them *Bhagandara* is one such grave and oldest^[7] disease, for which it has been included in *Ashta Mahagada*^[8] by *Sushruta*. *Ashta Mahagada* includes eight grave diseases-Viz. *Vatavyadhi*, *Prameha*, *Kushta*, *Mudha-Garbha*, *Arsha*, *Bhagandara*, *Ashmari* and *Udara-Roga*.

AIMS AND OBJECTIVE

The aims and objective of the study were

- To evaluate the effect of *Guggulu-Apamarga Kshar-Sutra* in *Bhagandara*.
- To enhance the rate of healing.
- To decrease the intensity of pain, burning sensation and itching, so that the patient can do his routine works comfortably.
- To find out adverse reactions, if any, during the study period.

MATERIAL AND METHODS

The present clinical trial is designed in 20 patients of any age group on which blind and randomized study is taken over the patients, suffering from *Bhagandara* (Fistula in ano).

Selection of patients

Diagnosed cases of *Bhagandara* (Fistula-in-ano) were registered by simple random sampling method from OPD and IPD of the Dept. of *Shalya Tantra*, Rishikul

Ayurvedic College, Campus, hospital Haridwar, Uttarakhand Ayurved University, U.K., India.

Consent

The patient seeking the treatment for *Bhagandara* was selected. They are well informed about the treatment and a written informed 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 type with *Parikartika* (Fistula in ano with Fissure in ano)
- *Bhagandara* with *Niyantrita Madhumeha* (Fistula in ano with controlled Diabetes mellitus)
- *Bhagandara* with Haemorrhoid

Exclusion criteria

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

Ethical committee approval no. letter is UAU/R/C/IEC/2016-17/2

- **Selection of sample** - Randomized sampling.
- **Types of study** - Single blind.
- **Duration of study** - All the cases were treated till the *Kshar Sutra* gets 'cut through' the track, completely.
- **Follow up** - 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.

Investigation

Following investigations were done before starting any procedure:

Blood

- ✓ Hemoglobin
- ✓ T.L.C., D.L.C., ESR
- ✓ FBS and PPBS
- ✓ HIV, HBsAg, HCV
- ✓ LFT, KFT
- ✓ Lipid profile
- ✓ Mantoux test.

Urine: Routine and microscopic.

Stool: Ova and cyst.

Other investigations (if required)

- X Ray Chest P.A. view.
- ECG.
- Fistulogram.
- USG Abdomen and pelvis.
- Pus culture and sensitivity.
- Biopsy of the tissue of the track.

Parameter of assessment**1. Subjective Parameters**

- Pain
- Burning sensation
- Itching
- Discharge
- Inflammation.

Signs & symptoms found were graded on the basis of scoring system prepared for that by **Paul O. Madson & Peter**. These are as follows:

- ❖ No symptom 0
 - ❖ Mild symptoms +
 - ❖ Moderate symptoms ++
 - ❖ Severe symptoms +++
 - ❖ Very severe symptoms ++++
- (Disturbed daily routine of the patient)

2. Objective Parameters

Unit Cutting Time = Total No. of days taken to cut through the track = days/cm

OBSRVATION AND RESULTTable - *GUGGULU - APAMARGA KSHAR SUTRA***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	-2.14 ^a	0.001	100	H.S
Pain	3	0	-2.10 ^a	0.001	100	H.S
Discharge	3	0	-2.10 ^a	0.001	100	H.S
Burning Sensation	3	0	-2.16 ^a	0.001	100	H.S
Inflammation	3	0	-2.10 ^a	0.001	100	H.S

Assessment of subjective symptoms

In subjective assessment symptomatically the result was statically highly significant ($p < 0.001$) in lowering itching, pain, discharge, burning sensation and inflammation.

Effect of therapy on unit cutting time

- In analysis it shows that minimum U.C.T. 8.33 days/cm. in High anal and maximum U.C.T. 8.87 days/cm. was found in Low anal fistula-in-ano.
- Mean U.C.T. is 8.05 days/cm.

DISCUSSION

The purpose of the discussion is to interpret and describe the significance of your findings in light of what was already known about the research problems being investigated, and to explain any new understanding or

Initial length of the *Kshar Sutra* in cm.

- Time taken (in days) to cut one centimeter of the fistulous track with simultaneous healing is known as unit cutting time (UCT).

Statistical Analysis

❖ All information which are based on various parameter was gathered and statistical study was carried out in terms of mean (X), Standard Deviation (S.D.), Standard Error (S.E.), Paired t-Test (t-value) and finally result were incorporated in terms of probability (p) as:

- $p > 0.05$ - Insignificant
- $p < 0.05$ - Significant
- $p < 0.01$ and $p < 0.001$ - Highly significant.

All information on various parameters was gathered and statistical study was carried out in terms of median (X), standard deviation (S.D.), standard error (S.E.). Wilcoxon's signed rank test was applied on subjective parameters; Paired t test was applied on Biochemical parameters. And finally result was incorporated in terms of probability (p) as:

- $P > 0.05$ Insignificant
- $P < 0.01$ & < 0.05 Significant
- $P < 0.001$ highly significant.

insights about the problem after you have taken the findings into consideration.

It has been recognized as a difficult surgical disease in all the ancient and modern medical sciences from management point of view. The recurrent nature of this disease makes it more and more difficult for treatment. It has been categorized as a surgical condition and almost all the surgeons starting from *Sushruta* (about 1500 B.C – India) to Hippocrates (450 B.C – Greece) and also down to the modern reputed surgeons of present times have realized the difficult course in its management and struggled hard to combat the disease with many surgical & Para surgical methods of treatment. This is one condition for which so many types of surgical, Para surgical and medical applications have emerged.

In modern era, much advancement has come into existence, in the field of surgery, so also in the treatment of fistula in ano viz. fistulotomy, fistulectomy, LIFT, VAAFT, Radio frequency ablation & anal fistula plugs, etc¹⁹⁷ are also being practiced. All the advancements were started to overcome the problems of the earlier methods. But, still there are problems persistent in the treatment. Out of the many complications and problems of the Fistula management, the recurrence and sphincter damage are of great importance.

Kshar Sutra has emerged as an effective tool to replace the regular surgical and Para surgical procedures in the management of *Bhagandara* with negligible rate of recurrence and complication in comparison to the contemporary methods like fistulectomy, fistulotomy and many more. But not a single method is safer and better than *Kshar Sutra* management.

Discussion on Selection of the drug and their probable mode of action

There were some problems in preparation of conventional *Snuhi-Apamarga Kshar Sutra*. For example, *Snuhi Ksheer* is difficult to procure from the market as well as from the local area. *Snuhi Ksheer* requires a specific season and time for collection. It is not available readily and it is difficult to collect also. During *Kshar Sutra* therapy patients suffers some discomfort due to presence of *Snuhi Ksheer* like pain, burning sensation, inflammation and itching. So, there was a need for search of the alternate *Kshar Sutra* which may play a better role like *Snuhi-Apamarga Kshar Sutra*.

In present study *Guggulu* extract was used in place of *Snuhi Ksheer* due to its good binding capacity, *Vedna-Shamaka*, *Shothahara*, and *Dahprashaman*, properties which are the main requirements for *Kshar Sutra* therapy. Therefore, in the present study, *Guggulu-Apamarga Kshar Sutra* was chosen, which is standardized by Faculty of *Ayurveda* (I.M.S. B.H.U).

Guggulu (Guggul)

Properties: *Vedna-Shamaka*, *Vrana-Shodhana*, *Vrana-Ropaka*, *Rakta-shodhaka*, *Shothahara*, *Dahprashaman*, *Krimighna*.

- ❖ Its **oleoresin fraction** possessed significant **Anti-inflammatory activity**.
- ❖ It shows the inhibitory action against both gram positive and gram negative bacteria. It has very good analgesic and anti-obesity property.

Apamarga

Properties: *Vedna-Sthapana*, *Vrana-Ropana*, *Rakta-Shodhaka*, *Shothahara*, *Dahprashaman*

- ❖ It has Oleanolic acid which acts as Anti-Viral, Anti-Diabetic agents, Saponins which act as potent Anti-inflammatory agent.

Haridra

Properties

- ❖ The volatile oils and **Curcumin** of *Curcuma longa* exhibit potent anti-inflammatory effects.
- ❖ The anti-inflammatory properties may be attributed to its ability to inhibit pro-inflammatory **Arachidonic acid** as well as neutrophil function during inflammatory states.
- ❖ Anti-bacterial activity of *C. longa* (*Haridra*) was found against both **Gram positive and Gram negative organism**. It is found beneficial in reducing the itching and inflammation in Patients of *Bhagandara* in present study.
- ❖ So due to these beneficial properties, ***Guggulu-Apamarga Kshar Sutra*** was selected to evaluate in this present research work.

CONCLUSION

After vivid churning of discussion, automatically emerged essence is called conclusion. "Conclusions" drawn from present work are as follows:

- ❖ ***Guggulu-Apamarga Kshar Sutra*** was found to have very significant effect on Pain, Burning sensation, Itching, Discharge, Inflammation, Size of track and Number of tracks with good unit cutting time.
- ❖ The overall effect obtained by ***Guggulu-Apamarga Kshar Sutra*** shows that all 20 patients cured completely.
- ❖ Smallest cured track was of 5 cm size and largest cured track was of 17 cm size.

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