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A comparative clinical study of guggulu-apamarga kshar sutra & guggulu-arka kshar sutra in the management of bhagandara

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ABSTRACT

Ayurveda, an ancient and unique part of Indian philosophy is really one of the great wonders of science. Ayurveda is not merely a health science, but it also reflects the healthy life style. स्वस्थस्यस्वास्थ्यरक्षणमातुरास्यविकारप्रशमनंच I (च. सू. ३०/२६) is the first and foremost principle of Ayurveda.

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, lack of hygiene and negligence leads to further aggravation of the disease. Nowadays, management of Bhagandara with Kshar Sutra had proved as big revolution, it has gained popularity due to its minimal invasive approach and complete cure of the disease. It is the need of time to do further researches to get more efficient Kshar Sutra. In the present research work *Guggulu-Apamarga Kshar Sutra* and *Guggulu-Arka Kshar Sutra* were prepared for the management of Bhagandara. 40 diagnosed case of Bhagandara in two equal groups of 20 patients each of any age group were selected from OPD and IPD of P.G. Department of Shalya Tantra, Rishikul Campus, Uttarakhand Ayurveda University, Haridwar (U.K.) India. All the patients were selected in two groups and treated with respective Kshar Sutra. 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, Guggulu-Arka 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 can be enjoyed only with a good health. Throughout the chronology of civilization man has gone a step forward in putting the piece together but task of perfection is yet to be achieved. Being the master piece of nature, human has adopted several parameters to researches for betterment of nature as well as own. *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].

Ayurveda derives its origin from *Atharvaveda* [3] as a 'Science of life'⁴ and is also considered as fifth *Veda*⁵ itself. From ancient era to till today, *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*. So *Shalya Tantra* is the first and prime branch of *Ashtanga Ayurveda* which is rich in many aspects as described by *Acharya Sushruta*-
 v"VkLofi pk;qosZnrU=s'osrnsokf/kdefere~]
 vk"qkfdz;kdj.kkr~] ;U="kL={kkjkfXuizf.k/kkukr~]
 loZrU= lkekU;kPAA [6]
 (सु.सु.१/२६)

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*.

Bhagandara is a second most common ano-rectal disease after *Arsha*, progressively increasing in the society [9]. Among the few important causes are sedentary life style, irregular and inappropriate diet [10], prolonged sitting which leads to constipation, etc. These *Apathya Sevana* causes vitiation of *Tridosha* in the body and localization around one or two *Angula* area of *Guda Pradesha* leading to *Mamsa Shonita Pradushya* causing *Pidika*. This *Pidika*, when neglected, then in the due course of time it attains its *Pakva Avastha* and bursts leading to *Bhagandara* [11].

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The disease, *Bhagandara* closely resembles in clinical presentation with *Fistula-in-ano* described in modern science. Constipation, along with other aggravating factors increases the back pressure which leads to blockage of ducts of anal gland promoting settling of cryptoglandular infection resulting in ano-rectal abscess and ultimately *Fistula-in-ano* (*Bhagandara*). Only about 10% *Fistula-in-ano* (Non-cryptoglandular) occur without initial anal gland infection and common causes can be Crohn's disease, Ulcerative colitis, Tuberculosis, Traumatic, etc [12].

AIMS AND OBJECTIVE

The aims and objective of the study were

- To evaluate the effect of *Guggulu-Apamarga Kshar-Sutra* in *Bhagandara*.
- To evaluate the effect of *Guggulu-Arka Kshar-Sutra* in *Bhagandara*.
- To compare the effect of both these *Kshar Sutras* in the treatment of two different groups of patients of *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 two different groups, of each 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 patients 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 Haemorrhoids

Exclusion criteria

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

Selection of sample: Randomized sampling

Types of study- Single blind

Duration of study

All the cases were treated till respective *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(if required)
- ✓ Lipid profile(if required)
- ✓ Mantoux test(if required)

Urine: Routine and microscopic (if required)

Stool: Ova and cyst (if required)

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

PARAMETERS OF ASSESSMENT

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)

Objective parameters

Unit Cutting Time = $\frac{\text{Total No. of days taken to cut through the track}}{\text{Initial length of the Kshar Sutra in cm.}} = \text{days/cm}$

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

$p < 0.05$ - 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

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

OBSRVATION AND RESULT

Table no.1- (GROUP-A) *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 statistically 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.

Table no.2 (GROUP-B) *GUGGULU-ARKA KSHAR SUTRA*

Table-2: 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	-2.10 ^a	0.001	100	H.S
Pain	3	0	-2.10 ^a	0.001	100	H.S
Discharge	3	0	-2.13 ^a	0.001	100	H.S
Burning Sensation	3	0	-2.10 ^a	0.001	100	H.S
Inflammation	3	0	-2.17 ^{ss} ^a	0.001	100	H.S

Assessment of subjective symptoms

In subjective assessment symptomatically the result was statistically 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. 9.1 days/cm. in High anal and maximum U.C.T. 9.0 days/cm. was found in Low anal fistula-in-ano. Mean U.C.T. is 7.58 days/cm.

DISCUSSION

Bhagandara 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, etc 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-Arka Kshar Sutra* has been chosen, to evaluate and to compare with *Guggulu-Apamarga Kshar Sutra* 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.

Arka (madaar)

Properties: *Kustaghna*, *Jantughna*, *Vrana shodhan*, *Shothahara* & *Vedana sthapana*

- ❖ It has Proceragenin and Terpenoids which act as Anti-bacterial agents.
- ❖ Saponins and Flavonoids which are act as potent Anti-Inflammatory agents.

Haridra

- ❖ 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-Arka Kshar Sutra* was selected to evaluate and compare with *Guggulu-Apamarga Kshar Sutra* in this present research work.

Probable Mode of action

- ❖ *Kshar Sutra* acts as cutting (*bhedhana*) as well as draining (*lekhana*) of the fistulous track. Various scientific studies suggest that due to effect of the drugs present in *Kshar Sutra* and mechanical pressure of thread itself, gradually cuts and heals the fistulous track simultaneously.
- ❖ *Kshar* being alkaline in nature, causes saponification of fat and forms alkaline proteinates which further causes liquefaction necrosis when applied over the tissue. Due to its caustic action, it destroys and removes unhealthy tissue and promotes healing of the fistulous track.
- ❖ Contents of *Kshar Sutra* like *Haridra* and *Guggulu* are helpful in healing of fistulous wound by virtue of their anti-inflammatory and wound healing properties.
- ❖ Mechanical action of *Kshar Sutra* along with necrotic effect of *Kshar* on unhealthy granulation tissue helps in gradual cutting of the track as well as formation of a healthy base for healing of the tissue, which leads to successful eradication of fistulous track.

CONCLUSION

- ❖ Conclusions drawn from present work are as follows: Group-A(*Guggulu-Apamarga Kshar Sutra*) and Group-B (*Guggulu-Arka Kshar*

Sutra) were 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.

- ❖ On inter-group comparison- Group A (*Gugguku-Apamarga Kshar Sutra*) and Group B (*Guggulu-Arka Kshar Sutra*) did not show significant difference between the groups on Pain, Burning Sensation, Itching, Discharge, Inflammation Size of track and Number of tracks.
- ❖ The overall effect obtained in Group-A (*Guggulu-Apamarga Kshar Sutra*) shows that all 20 patients cured completely.
- ❖ The overall effect obtained in Group-B (*Guggulu-Arka Kshar Sutra*) shows that all 20 patients cured completely.
- ❖ In Group-A: Smallest cured track was of 5 cm size and largest cured track was of 17 cm size.
- ❖ In Group-B: Smallest cured track was of 3 cm size and largest cured track was of 29 cm size. From the study, it can be concluded that-
- ❖ Group-A (*Guggulu-Apamarga Kshar Sutra*) and Group-B (*Guggulu-Arka Kshar Sutra*) both are effective in curing cured *Bhagandara* (Fistula in ano).
- ❖ But on the basis of overall effect of therapy it was found that *Guggulu-Apamarga Kshar Sutra* had little better result than *Guggulu-Arka Kshar Sutra* in Burning sensation, Inflammation, Pain and with better Unit Cutting Time (8.05 days/cm).
- ❖ *Guggulu-Arka Kshar Sutra* had better result than *Guggulu-Apamarga Kshar Sutra* in Itching, Discharge and with slight increase in Unit Cutting Time (8.28 days/cm).
- ❖ All patients completed the treatment of full duration without any complications like burning sensation etc. in post-operative period as well as follow up period in both groups.
- ❖ There is no any sign and symptoms of recurrence of disease in post-operative period as well as follow up period in both groups.
- ❖ Thus, both these *Kshar Sutra* can be successfully used to cure patients of *Bhagandara*(Fistula in ano).

REFERENCES

- [1]. Acharya Charak, Charak Samhita:Vidyotini Hindi Commentary; Edited by Dr. Gorakha Nath Chaturvedi and Pt. Kasinatha Sastri ; Chaukhambha Bharati Academy, Varanasi, Edition; Reprint; Viman Sthaana-8/37, 2008, 752
- [2]. Acharya Charak, Charak Samhita:Vidyotini Hindi Commentary; Edited by Dr. Gorakha Nath Chaturvedi and Pt. Kasinatha Sastri ; Chaukhambha Bharati Academy, Varanasi, Edition; Reprint Sutra Sthaana-30/23, 2008, 586
- [3]. Acharya Sushruta, Sushruta Samhita;Ayurveda - Tattva - Sandipika Hindi commentary; Edited by Kaviraja Ambikadutta Shastri; Chaukhambha Sanskrit Sansthan, Varanasi, Edition; Reprint; Sutra Sthaana- 1/ 6, 2010, 5
- [4]. Acharya Charak, Charak Samhita:Vidyotini Hindi Commentary; Edited by Dr. Gorakha Nath Chaturvedi and Pt. Kasinatha Sastri ; Chaukhambha Bharati Academy, Varanasi, Edition; Reprint;Sutra Sthaana-30/23, 2008, 586
- [5]. Acharya Kashyap, Kashyap Samhita
- [6]. Acharya Sushruta, Sushruta Samhita;Ayurveda - Tattva - Sandipika Hindi commentary; Edited by Kaviraja Ambikadutta Shastri; Chaukhambha Sanskrit Sansthan, Varanasi, Edition; Reprint; Sutra Sthaana- 1/ 26, 2010, 163
- [7]. www.iamj.in Harshithakumari, Rasmi Johnson Bhagandara-Multiple Fistula in ano Management by Ksharsutra ISSN :23205091
- [8]. Acharya Sushruta, Sushruta Samhita;Ayurveda - Tattva - Sandipika Hindi commentary; Edited by Kaviraja Ambikadutta Shastri; Chaukhambha Sanskrit Sansthan, Varanasi, Edition: Reprint;Nidan Sthaana- 33/4-5, 2010, 163
- [9]. www.iamj.in Harshithakumari, Rasmi Johnson Bhagandara-Multiple Fistula in ano Management by Ksharsutra ISSN :23205091
- [10]. Acharya Sushruta, Sushruta Samhita;Ayurveda - Tattva - Sandipika Hindi commentary; Edited by Kaviraja Ambikadutta Shastri; Chaukhambha Sanskrit Sansthan, Varanasi, Edition: Reprint; Nidan Sthaana- 4/6, 2010, 317
- [11]. Acharya Sushruta, Sushruta Samhita;Ayurveda - Tattva - Sandipika Hindi commentary; Edited by Kaviraja Ambikadutta Shastri; Chaukhambha Sanskrit Sansthan, Varanasi, Edition: Reprint; Nidan Sthaana- 4/11, 2010, 318
- [12]. SRB's MANUAL OF SURGERY by Sriram Bhat M Jaypee Brothers Medical Publishers (P) Ltd New Delhi 110002, India RECTUM and ANAL CANAL 4(25), 1055.