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A COMPARATIVE STUDY ON THE EFFICACY OF GUGGULU BASED CHITRAKA KSHARASUTRA AND APAMARGA KSHARSUTRA IN THE MANAGEMENT OF BHAGANDARA

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ABSTRACT

Bhagandara is one among Ashtamahagada's mentioned in Sushruta samhita and is one of most common ailment pertaining to ano-rectal region. Management of Fistula-in-ano has become a challenge to Allopathic surgeon's, because of its complications like post-operative pain, wound management, recurrence and incontinence. In Ayurveda the effective treatment is Ksharasutra ligation. Snuhi based Apamarga Ksharasutra is standard one which is highly effective treatment in the management of Fistula-in-ano but, burning pain, local irritation during the course of therapy and difficulty in manufacturing process has limited in its uses. To overcome this lacuna present study has been carried out with guggulu based chitraka ksharsutra. Here 40 patients were randomly divided into two groups namely Group A with trial drug i.e.,*Guggulu based Chitraka Ksharasutra* and Group B with Control drug i.e, *Apamarga Ksharasutra* with 20 patients in each. Assessment was made on subjective (Pain, Discharge, Pruritis Ani) and objective (Length of the track, Unit Cutting Time UCT) parameters. Observations were made before the treatment and on every 7th day of the therapy until complete cutting of the track. Assessment of Pain, Discharge, Pruritis Ani, length of the track in Group A showed 97%, 100%, 100%, 100% improvement and in Group B 90%, 94%, 80%, 100% improvement respectively. Mean UCT of Group A was 11.47 days/cm and Group B was 10.95 days/cm. The study showed that the trial drug was as good as the standard drug in the treatment of *Bhagandara.*

KEYWORDS: *Bhagandara, Fistula-in-ano, Apamarga Ksharasutra, Guggulu based Chitraka Ksharasutra*

INTRODUCTION

Acharya Sushruta has included Bhagandara as one among the Ashtamahagadas[1]. It is one of the most common diseases pertaining to ano-rectal region. Detailed description about the Nidana, Samprapti, Laxana and Chikitsa is available in Sushrutha Samhitha (1500B.C) and Ashtanga Hridaya while, Charaka (1000 B.C.) has mentioned in shotha chikitsa adhyaya and advocated Kshara sutra and other remedies in the management of Bhagandara.

The literal meaning of Bhagandara is daarana which is splitting up/bursting up of pakwa pidaka in the bhaga, guda, basti pradesha results in the formation of a

communicating track, thus causing discomfort to the patient.

Bhagandara can be co-related with Fistula-in-ano mentioned in Allopathic medical science is considered second to haemorrhoids among all ano-rectal abnormalities[2]. According to a recent study approximately 10% of all patients and 4% of new patients were reported to suffer from this disease[3]. A study in India, reported that anal fistulae constitute 1.6% (Raghavaiah 1976) of all surgical admission. Prevalence rate of fistula-in-ano is 8.6 cases per 100,000 populations. The mean age of patients is 38.3 years[4].

As the wound is located in the anal region is more prone to get infected and results in delayed healing and unhealthy granulation tissue or fibrous tissue formed in the track hinders healing process. In addition to this, there will be severe post-operative pain which persists for many days. Moreover surgical treatment requires hospitalization, regular dressing and post-operative care for longer duration. To overcome such problems, surgical field is planning for some alternative techniques to treat these cases with minimal operative complications, recurrences and failure.

Ayurvedic line of treatment for Bhagandara includes medical, para-surgical and surgical management. Parasurgical management includes Kshara karma, Agni karma and Varti. The standard Ksharasutra as we see today was the result of the extensive research of Dr. P. J. Deshpande and his team, who finally standardized its preparation, preservation and application. Ksharasutra treatment, for the management of fistula-in-ano was a part of the "National Campaign on Ksharsutra Therapy for Ano-Rectal disorders"[5]. The advantages of this procedure are, it is cost effective, needs minimal hospitalization and has least adverse effects. The recurrence rate of Ksharasutra ligation is negligible (3-5%) with a success rate of 95%. Apamarga Ksharasutra is standardized one, effectively used. But pain and burning sensation during the treatment is a very often complaint by the patient.

Guggulu has laghu, ruksha, vishada, sukshma, sara gunas, ushna virya and having tridoshahara, lekhana properties. Guggulu is a safe and effective alternative to NSAID'S. As a pain relieving analgesic, Guggulu is an excellent alternative to non-steroidal-anti-inflammatory drugs (NSAID'S) in its ability to relieve pain in skin and other inflammations as well as promoting healing of the underlying cause[6].

Chitraka used for Kshara karma mentioned in Sushruta[7]. Chitraka has laghu, ruksha, teeksna gunas, ushna veerya, is vata kapha hara and best in gudashotha[8]. Kshara prepared using Chitraka have chedana, bhedana, lekhana, ksharana, kshanana, shodana and ropana properties.

According to classics[9], Snuhi ksheera is used in the preparation of Ksharasutra. But Snuhi is not available throughout the year; the time of collection is in adana kala particularly in shishira ritu. Due to this fact, we should collect the ksheera in February-March. Hence as an alternative to Snuhi ksheera, Guggulu is used because as it is available in bulk, has binding properties, can be preserved and used for long duration.

Considering all these factors an attempt is made in this study to substitute Apamarga Kshara and Snuhi Ksheera by Chitraka Kshara and Guggulu niryasa respectively for the preparation of Ksharasutra used in the management of Bhagandara.

OBJECTIVES

-To evaluate the efficacy of Guggulu based Chitraka Ksharasutra in the management of Bhagandara.

-To evaluate the efficacy of Apamarga Ksharasutra in the management of Bhagandara.

-To evaluate the efficacy of Guggulu based Chitraka Ksharasutra in the management of Bhagandara by comparing the same with the efficacy of Apamarga Ksharasutra.

METHODOLOGY

The study was conducted at SJIIM Hospital Bengaluru. Patients suffering from classical features of Bhagandara were selected for the study from the OPD & IPD. It is the open clinical study where 40 patients suffering from Bhagandara were selected randomly and made each group of 20 patients.

Criteria for Selection of Cases:

Inclusion criteria:

Patients with clinical features of Fistula-in-ano namely pain, seropurulent, discharge from the tract and pruritis ani.

Patients with single fistulous tract.

Exclusion criteria:

Fistula-in-ano secondary to Tuberculosis, Chron's disease, Ulcerative colitis, Veneral diseases, HIV, Regional Ileitis, Intestinal & Pelvic Malignancies and associated with other systemic disorders which may come in the way of Ksharasutra treatment

Associated with other anorectal disorders which may come in the way of the treatment (Carcinoma rectum and anal canal, 3rd degree Haemmoroids or bleeding haemmoroids, acute fissure in ano, thrombosed sentinel pile)

Pregnancy.

Recurrent fistula in-ano after previous surgery.

Study Design

A total number of 40 patients of Bhagandara those fulfilling the above mentioned criteria were included for the study and were randomly allotted into two groups namely Group –A and Group –B with 20 patients each.

Group	Diagnosis	Treatment	Duration
A	Fistula-in-ano	*Guggulu based Chitraka Ksharasutra* application	Complete cutting of tract
B	Fistula-in-ano	*Apamarga Ksharasutra* application	Complete cutting of tract

Preparation of Guggulu based Chitraka Ksharasutra is as follows

Guggulu niryasa– 11 coatings

Guggulu niryasa +Chitraka Kshara – 7 coatings

Guggulu niryasa + Haridra churna – 3 coatings

This was prepared in the hospital using Barbour's thread number 20. One coating was applied each day and kept for drying in the Ksharasutra cabinet. A total of 21 days was needed to complete the preparation of the thread. After this the threads were cut in

2 sizes; Medium length- 25cm, small length- 16cm and packed in a sterile sealed pack after placing in the UV cabinet with a small pack of silica inside to absorb moisture. All these were then packed in air tight container and stored keeping it away from contact with any moisture.

Preparation of Apamarga Ksharasutra is as follows

Snuhi ksheera – 11 coatings

Snuhi ksheera+ Apamarga Kshara– 7 coatings

Snuhi ksheera + Haridra churna – 3 coatings

This was prepared in the hospital using Barbour's thread number 20. One coating was applied each day and kept for drying in the Ksharasutra cabinet. A total of 21 days was needed to complete the preparation of the thread. After this the threads were cut in 2 sizes;

Medium length-25cm, small length- 16cm and packed in a sterile sealed pack after placing in the UV cabinet with a small pack of silica inside to absorb moisture. All of these were then packed in air tight container and stored keeping it away from contact with any moisture.

Procedure:

For both the groups required materials were kept ready. Procedure was explained to the patient and informed consent was taken.

As a laxative, triphala churna+sonadi churna 1 tsf Hs was advised to the patients on the day prior to probing of` the fistulous tract.

Advised to come on 7th day for Ksharasutra threading.

Group A: For the patients in Group A, Guggulu based Chitraka Ksharasutra prepared as per standard methods under strict aseptic precautions was applied.

Procedure of Ksharasutra application:

Patient was made to lie in lithotomy position. Part prepared and painted with betadine and draped. The patency of the track was confirmed by infiltration of betadine using a 10 ml syringe through the external opening. A suitable malleable probe was passed through the external opening by lubricating it with lignocaine jelly. The tip of the probe was forwarded along the path of least resistance and was guided by the finger lubricated in lignocaine jellyin the anal canal to reach into its lumen. Then the tip was finally directed to come out of anal orifice through the internal opening in the anal canal. A suitable length of plain thread was taken and threaded into the eye of probe. Thereafter the probe was pulled out through the anal orifice, to leave the thread behind in the fistulous track. The two ends of the Plain thread were then tied together with a moderate tightness outside the anal canal. This procedure is called primary threading and on the seventh day Guggulu based Chitraka Ksharasutra application was done. Patient was advised to attend his normal duty during the treatment period.

Change of Guggulu based Chitraka Ksharasutra:

The Guggulu based Chitraka Ksharasutra is tied to the previously applied primary threading between external opening and outer end of the knot. Then an artery forceps is applied to the inner end of the same knot. Then the old thread is cut between the artery forceps and the knot. Pulling of the artery forceps along with the thread ultimately

replaces the old thread by Guggulu based Chitraka Ksharasutra. Then the two ends are tied snugly and a sterile pad dressing is done. This procedure is done by Railroad technique.

Follow up: Successive changes were done at weekly interval. The same procedure is followed for successive changes.

Observation: The observations made before the treatment and on fresh application of Ksharasutra were recorded in the proforma of the case sheet prepared for the study.

Duration: Till complete cutting of the tract.

Group B: For the patients in Group B, Apamarga Ksharasutra prepared as per standard methods under strict aseptic precautions was applied.

Procedure: Same as that of above, here instead of guggulu based chitrak ksharsutra, apamarga ksharsutra is used.

Change of ksharsutra: Same as that of above, here instead of guggulu based chitrak ksharsutra, apamarga ksharsutra is used.

Follow up: Successive changes were done at weekly interval. The same procedure is followed for successive changes.

Observation: The observations made before the treatment and on every day of fresh application of Ksharasutra were recorded in the proforma of the case sheet prepared for the study.

Duration: Till complete cutting of the tract.

Post Ksharasutra threading / Primary threading:

Patient was advised Sitz bath with luke warm water twice daily for 20 minutes.

Duration fixed for observing recurrence:

Duration of 60 days from the day of total cutting and healing of the fistulous tract was fixed to observe the possibility of recurrence and the same was recorded in the proforma of the case sheet prepared for the study

Assessment Criteria

a) Subjective

Pain

P0– no pain

P1 – mild pain (no need of analgesics)

P2– moderate pain (subsides with analgesics)

P3– severe pain (persists with analgesics)

Discharge

D0– No discharge

D1–Mild discharge (wets 2x 2 cm gauze piece/ day)

D2– Moderate discharge (wets 2 x 2cm 2 gauze piece/day)

D3– Severe discharge (wets 2 x 2cm >2 gauze piece/day)

Pruritis Ani

p0 – pruritis ani absent

p1– pruritis ani present

b) Objective

i) Length of the track measured at every sitting in cm.

ii) Unit Cuttting Time (U.C.T)

The Unit cutting time represents the number of days required to cut one cm of the track. This is calculated by dividing the total number of days taken by a fistula to heal by the initial length of the tract denoted as days/cm.

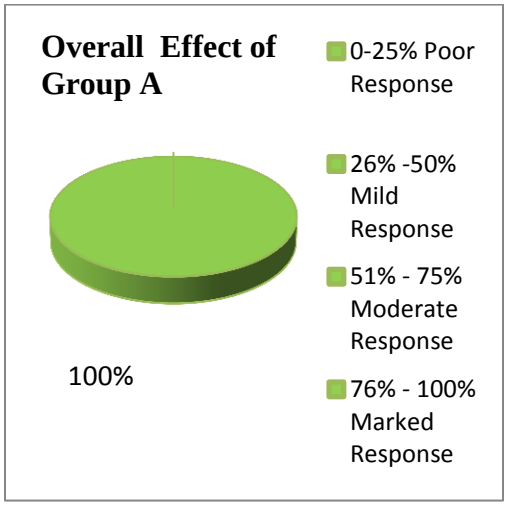
$$U.C.T = \frac{\text{Total number of days}}{\text{Initial length of Track (thread)}}$$

RESULT

Group A	Group B	Mean Difference	SE (±)	T value	P value
98	97.54	0.46	1.88	0.31	>0.05

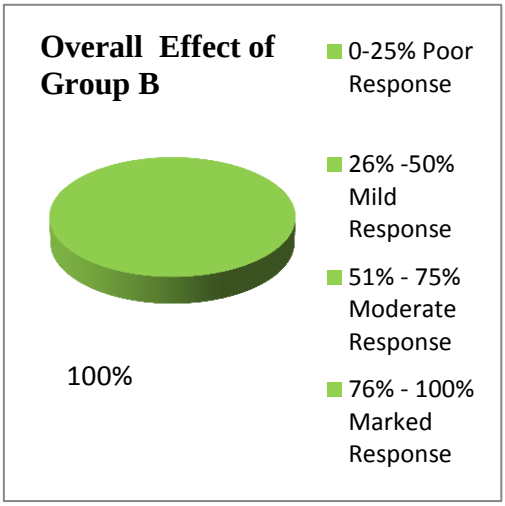
Result of group A:

The percentage of improvement in Group A on Pain is 97%, Discharge is 100%.,Pruritis Ani is 100% and Length of the track in Centimeter is 100%.



Result of Group B

The percentage of improvement in Group B on Pain is 90%, Discharge is 94%.,Pruritis Ani is 80% and Length of the track in Centimeter is 100%.



Comparative results of Group A and Group B

Group A overall result is 98% and Group B overall result is 97.54%.

DISCUSSION

Kshara Sutra therapy is the most accepted and scientifically validated procedure worldwide for the treatment of Fistula-in-ano. The existing data on *Kshara Sutra* reveals very negligible chances of recurrence by this modality of treatment. The *Apamarga Kshara Sutra* is well proven to be an effective treatment for Fistula-in-ano and has been standardized by the Central Council of Research in Ayurveda and Siddha, an apex research organization of Government of India in the field of Indian system of medicine. Acharya Susruta has included Bhagandara in Ashtamahagada, as it is difficult to treat. However, a lot of work has been done in this perspective in the modern surgery including the lay open technique, fistulectomy, advancement flap treatment, seton etc. Inspite of availability of these methods of management of fistula it still remains challenge.

Selection of the drug:

Although the Snuhi ksheera and Apamarga kshara are used in the preparation of Ksharasutra and used successfully with almost negligible recurrence but, during the course of Ksharasutra treatment complications like burning pain, local irritation, discharge persists because of tikshna guna of Snuhi ksheera. So to reduce the post adverse effects of Ksharasutra and also non availability of Snuhi ksheera throughout the year. Guggulu is used which is having binding property, vedanasthapana, lekhana, vrana shodhana and ropana, properties and it is available in bulk. Chitraka also mentioned in Ksharapaaka vidhi adhyaya and it is best in Gudashotha

and Kshara prepared using Chitraka have chedana, bhedana, lekhana, ksharana, kshanana, shodana and ropana properties . In this regard, instead of Snuhi ksheeara and Apamarga kshara, Guggulu and Chitraka kshara respectively are used in this study.

The principle behind changing the *Ksharasutra* after 7 days is:

The *Kshara* will take some time to be absorbed and produce the ksharana effect. It takes seven days to be absorbed layer by layer into each of the tissue, cutting and healing are the simultaneous process in Ksharasutra treatment, approximately 1cm of the track is going to cut and heal in 1 week of treatment. So thread is going to become loose after 1 week due to which have no longer cutting effect and tensile strength of the thread is also going to be reduced after 1 week.

The probable mode of action of *Guggulu based Chitraka Ksharasutra*

As the Bhagandara is Vata-kapha pradhana tridoshaja vyadhi and the Guggulu which is having NSAID and Anti-bacterial properties, lekhana, vrana shodhana and ropana properties counteract the pain, discharge and pruritis ani easily within short duration and ensures for healthy granulation tissue to develop as well and cuts the track completely because of gudashothahara, chedana, bhedana, kharana, kshanana properties of Chitraka Kshara in similar to standard Snuhi based Apamarga Ksharasutra.

CONCLUSION

Guggulu based Chitraka Ksharasutra was found to be as effective as *Apamarga Ksharasutra* in the management of *Bhagandara* (Fistula-in-ano).

Group A overall result is 98% and Group B overall result is 97.54%. Hence both groups showed excellent/marked response.

The average unit cutting time of *Guggulu based Chitraka Ksharasutra* was 11.47 days/cm. This is almost same cutting time as of *Apmarga Kshara Sutra,* which is *10.95* days/cm.

It was observed that irrespective of the *Ksharasutra* used, the unit cutting time was delayed in chronic cases, with more of fibrosed tissue.

After cut through, complete healing was observed at an average of 4 days.

The trial drug *Guggulu based Chitraka Ksharasutra* showed promising results almost as good as *Apamarga Ksharasutra*, and hence may be used as a substitute at times when the availability of *Snuhi ksheera and Apamarga* may be a problem.

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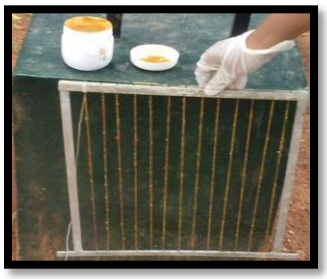
KSHARASUTRA PREPARATION

Guggulu based Chitraka Ksharasutra



Apamarga Ksharasutra

PROCEDURE OF KSHARASUTRA APPLICATION