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A CLINICAL STUDY TO EVALUATE THE EFFECTIVENESS OF SARIBA MOOLA GRTHA INFILTRATION WITH GANDHARVAHASTHADI KASHAYA INTERNALLY IN FISSURE IN ANO

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ABSTRACT

Fissure-in-ano is very commonly encountered in current day to day practice. It comprises of 6-15% of anorectal disorders and the incidence is high in the age group 20 – 40 years. This disease is characterized by excruciating pain during and after defecation, bleeding per anum with burning sensation. Constipation is the major known cause of the disease which leads to friction and ulcer formation in the long axis of anal canal.

Fissure-in-ano is a medico- surgical condition. Medical management is said to be conservative and surgical intervention is the ultimate choice in the chronic ulcers. Medical treatment for acute fissure is oral analgesics, stool softeners, soothing ointment and self-dilatation on medical advice etc. Surgical management includes Fissure-in-ano is a medico-

surgical condition. Medical management is said to be conservative and surgical

intervention is the ultimate choice in the chronic ulcers. Medical treatment for acute fissure

is oral analgesics, stool softeners, soothing ointment and self-dilatation on medical advice

etc. Surgical management includes

Lord's dilatation, sphincterotomy, fissurectomy, anal advancement flap. To

overcome the complications of these expensive treatments and to evolve economical, safe

and alternative treatment modality through Ayurveda, this study was carried out. Hence

the study was an effort to find the effectiveness infiltration of Sariba Moola Grtha

mentioned in Vangasena Samhitha, Vrana Chikitsa Adhikara in fissure in ano along with

96ml Gandharvahasthadi Kashaya internally.

Key words - Fissure in ano; *Sariba Moola Grtha*; *Gandharvahasthadi Kashaya*

INTRODUCTION

Fissure-in-ano is a common ano rectal disorder, characterized by sharp and intense pain

during and following defecation. It results from a longitudinal tear in the distal part of the

anal canal, frequently precipitated by the passage of a constipated stool. The disorder is

more common in males and has a peak incidence in the second decade in females and the

third decade in males, although it may also occur in infancy and in old age. In 75 to 94 per

cent of cases the fissure is situated at the posterior anal margin. Anterior fissures are more

commonly encountered in women and may follow parturition or gynecological procedures

[1].

The ideal drug for this disease should have Vrana Shodhana Ropana properties and Vata

Pithaharatva. Sariba Moola Grtha mentioned in Vangasena Samhitha as Sarva Vrana

Vishodana [2].

Sariba (Hemidesmus indicus) is of Madura Tiktha Rasa, Guru Snigtha Guna, Sita Veerva

and Madura Vipaka and also Vata Pithahara and Daha Prasamana may help to subside

clinical features like pain, bleeding and burning sensation [3].

Grtha is Vāta Pitha Samaka, Madura, Sita and Ropana [4]. Due to its soothing effect, it forms

a thin layer over the wound and allows early epithelization and protects from invasion of

any microbes [5-6]. Grtha possessing the property Samskarasya Anuvarthana is best

suited as the vehicle for administration of the drug sariba in the study.

Apana Vaigunya is the cause for all Gudaja Vikaras. As Ayurveda promotes Nidana

Parivarjana, Anulomana line of treatment is ideal for Apana Vaigunya [7]. So

Gantharvahasthadi Kashaya[8] which have Agni Deepana, Vata Samana and Mala Shodana

properties when given with proper Anupanas (Guda and Saindhava) will be ideal for the

condition. So the present study is aimed towards finding an easily accessible economic

treatment for fissure in ano.

Fissure in ano is very common and distressing problem encountered in day to day practice.

It comprises of 6 – 15 % of ano-rectal disorders and is characterized by excruciating pain

during and after defecation, bleeding per anum due to spasm of anal sphincter. The method

of treating this pathology should preferably be the one that results in optimal clinical

outcome, less painful and patient friendly. Hence the present study was an effort to find an

effective remedy for ulcer healing using Sariba Moola Grtha.

In this study, fissure in ano was taken as a Vrana or Guda Vidarana, 5ml Sariba Moola

Grtha infiltration given externally for Vrana Vishodana and Ropana was studied along with

Gandharvahasthadi Kashaya 96 ml internally twice daily used for Mala Shodana and Agni

Deepana.

This present research work entitled "A clinical study to evaluate the effectiveness of Sariba

Moola Grtha infiltration with Gandharvahasthadi Kashaya internally in Fissure in ano" was

carried out in P.N.N.M. Ayurveda Medical College and Hospital, Shoranur.

Aim of the study

To find an effective, safe, economic and alternative treatment protocol in the management

of fissure-in-ano.

Objectives of the study

- To evaluate the effectiveness of Sariba Moola Grtha infiltration with Gandharvahasthadi Kashaya internally in fissure in ano.
- To understand the disease entity fissure-in-ano in detail.

Methodology

The study was a single group study of pre and post-test design without control group. The study was undergone for 7 days continuously in 32 subjects in the age group 20 to 40 years satisfying the inclusion criteria, from the O.P.D and I.P.D of Shalyatantra department, P.N.N.M. Ayurveda Medical College & Hospital, Cheruthuruthy, Shoranur. The intervention was carried out in a well-equipped O.T after obtaining informed consent and positioning the subject left laterally. 5ml Sariba Moola Grtha was taken in 5ml sterile disposable syringe connected with red rubber catheter (No.4) and introduced to the anal canal at least 2 cm inside from the anal verge before completely voiding the medicine. The intervention was continued for 7 days regularly along with 96ml Gandharvarvahasthadi Kashaya twice daily was given internally. The parameters pain, burning sensation, bleeding and constipation were assessed on 0th and 7th day of intervention. Data were collected after grading the parameters and analysed statistically using paired T test.

Study design

A single group interventional study of pre and post test design.

Study setting

O.P.D. and I.P.D. of P.N.N.M. Ayurveda Medical College, Cheruthuruthy

Study Period

18 months

Study population

Patients diagnosed as fissure in ano by clinical symptoms and confirmed by physical examination in the age group 20 – 40 years irrespective of sex registered in O.P.D. and I.P.D. of P.N.N.M. Ayurveda Medical College, Cheruthuruthy.

Sample Size- 32

Sampling technique

Consecutive cases satisfying the inclusion criteria will be recruited until attaining the Sample size.

Inclusion criteria

- Subjects irrespective of gender.
- Between the ages group of 20 40 years.
- All subjects fulfilling assessment criteria and diagnosed as fissure-in-ano.

Exclusion criteria

- Fissure in ano associated with colon conditions like malignancy, ulcerative colitis.
- Patients with systemic disorders like diabetes, tuberculosis.

Diagnostic criteria

The patients were diagnosed on the basis of history, signs and symptoms and confirmed through physical examination of fissure in ano.

Withdrawal Criteria

- Unwillingness of participants to continue.
- Adverse effect of procedure.
- Un- controlled co-morbid condition.

Study Tool

- Clinical case Proforma
- Visual Analogue Scale

Study procedure

Preparation of the medicines

- Sariba Moola Kalka 500g
- Grtha 2L

• Water – 8L

Preparation Grtha as per Snehapāka Vidhi (1:4:16).

• The drug Sariba Moola was made into small pieces, washed and grinded well to

made fine paste.

• The Kalka is mixed with Grtha and Jala respectively and the mixture is heated in low

flame until Madhyamapaka

• The medicated Grtha is sieved through a cloth • Kept in air tight container after

cooling.

Pakam – Madhyamapaka

Intervention

Patient was made to lie down in left lateral position (Sim's position). Sariba Moola

Grthawas infiltrated using 5 ml syringe which is connected to sterile rubber catheter (No-

4). Catheter was inserted in to anal canal, at least 2 cm from the anal verge before

completely voiding the medicine. Patient was advised to lie down in supine position for 15

minutes. After that a sterile cotton pad was used as a temporary packing outside the anal

verge.

Duration - Once daily for 7 days.

• Internal medicine - Gandarvahasthadi Kashaya 96 ml twice daily before food with

Saidhava and Guda (4 gm each) as Anupana for 7 days.

Treatment period -7 days.

Materials required

• Sterile gloves

• Sterile cotton pads

• 5 ml disposable syringe

• Sterile rubber catheter (No-4).

Sariba Moola Grtha



Follow up

On 14th day from the first day of intervention.

Assessment criteria

Assessment was done based on the following parameters before and after the treatment. The parameters were graded and results was evaluated and statistically analyzed.

Outcome variable

Subjective parameters

- Constipation
- Bleeding
- Burning Sensation
- Pain

Preparation of Sariba Moola Grtha

Observations

The general observations are as below in brief

❖ The maximum patients belonged to 35-40 years of age group (44%), females (65.6%), hindu religion (72%), married (87.5%), house wives (31%), non-

vegetarians (87%), spicy food preference (90.6%), irregular food intake (90.6%), economically middle class (84.4%), non-addicted (84.4%), constipated (96.9%), with stress (88%), with disturbed sleep (75%) and moderate nature of work (72%).

❖ The parameters assessed were pain, burning sensation, bleeding and constipation. It was observed that among 32 patients, severe pain (59%), grade 1 bleeding per rectum (40%), grade 1 burning sensation (53%) and constipation (91%).



Madhyama Paka



Sieved through cloth

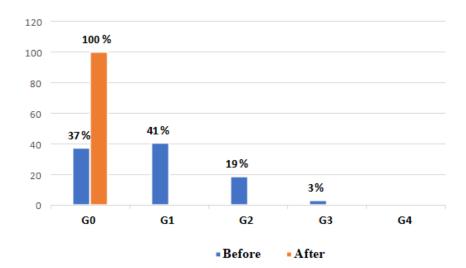


Sariba Moola Grtha

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Results

- The study was highly significant on assessment parameters like pain, bleeding, constipation and burning sensation.
- \clubsuit The results were statistically significant on pain (p<0.000l), the patients got remarkable relief from pain during the treatment. The treatment was very effective on pain and the t value with probability P = 0.001, is less than 0.05.
- ❖ During treatment, the burning sensation got decreased day by day. The treatment was highly significant with P=0.000001 by a mean difference 1.063, had initial mean of 1.22 before treatment and was decreased to 0.12.
- ❖ In this study, it was observed that all 32 patients had got complete relief in bleeding within 7 days. The initial mean of bleeding was 0.88 before treatment which was reduced to 0.00 after the treatment showing extremely significant result statistically (P = 0.00001). The patients had got 100% relief from Bleeding.
- ❖ The constipation was relieved within 7 days in all 32 patients. The treatment was highly effective and the report shows that highly significant impact with a mean difference 0.97 before treatment reduced to 0.03 after treatment with t value of probability P=0.00006.
- Overall, the treatment was highly significant in all 32 patients.



Among 32 patients, 41% of participants had bleeding with defecation, 19% of subjects with mild bleeding (0-5 drops), and 3% with moderately severe bleeding while after the treatment it was improved as no bleeding in all of the participants, i.e. All 32 participants (100%) had no bleeding after the treatment.

3. Effect on constipation before and after treatment

Participants by percentage change in constipation

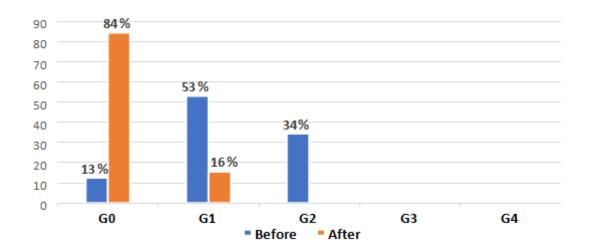
The above graph shows that 91% of subjects (31 patients) had constipation (hard stools daily) before treatment and was decreased to 3% after treatment. Only 6% of subjects had normal bowel before treatment and was increased to 97% after treatment. 3% of participants had severe constipation (once in 2 days) before treatment was reduced to 0% after treatment.

4. Effect on burning sensation before and after treatment

Participants by percentage change in burning sensation

In this study Among the 32 participants, 53% of the subjects had burning sensation only during defecation before treatment and after treatment it was reduced to 16%. Also only 13 % of subjects were asymptomatic before treatment

and 84% (27 patients) got asymptomatic in burning sensation after the treatment.



The statistical analysis was conducted using SPSS software with the aid of paired T test. The results obtained were extremely significant on all assessment parameters with P value < 0.05. Thus the alternative hypothesis was accepted and null hypothesis was rejected.

Overall response of the treatment T-Test

One-Sample Statistics for change in pain, bleeding, constipation and burning sensation

	N	Mean	Std. Deviation	Std. Error Mean
Change in Pain	32	-4.2500	1.19137	.21061
Change in Bleeding	32	8750	.83280	.14722
Change in Constipation	32	9375	.35355	.06250
Change in Burning sensation	32	-1.0625	.56440	.09977

Discussion

In this study, the drug Sariba Moola Grtha has selected from Vrana Chikitsa context

mentioned in Vangasena Samhitha as the disease is a true ulcer in the anal canal. The

excruciating pain due an ulcer has to be considered primarily because it is the major

symptom of the disease. Wound healing with normal bowel movement is the ultimate aim

of the treatment. The treatment which promotes early epithelialisation and granulation

tissue formation can give better results.

It is mentioned that Sariba Moola Grtha is having Shodana and Ropana properties will

promotes healing of the ulcer. Once the *Vrana* became *Shodhita*, will results in *Ropana* thus

controls the pain and cures the disease.

The drug Sariba have Tikta Madura Rasa which is Vata Samaka, Snigdha Guna and Madura

Vipaka can alleviate Vata Kopa.

Grtha also have Vata Pitha Samana and Vrana Ropana properties which can initiate wound

healing by early epithilialization and prevents microbes. By Samskarasya Anuvarthana

property, Grtha can support and strengthen the Vata Samana property of Sariba. Thus it

controls *Vedana* in fissure in ano.

In Gandarvahasthadi Kashaya, the major ingredient is Gandarvahastha which is very good

Vata Samana Dravya and the synergic action of Usna and Sita Veerya drugs in this Yoga can

perform *Agni Vardana* and *Mala Anulomana*, which prevents further trauma in the *Vrana*.

The drug Sariba Moola Grtha is Vrana Shodana and Ropana which have significant effect on

ulcer healing. The Sariba is having Tikta Madura Rasa, Guru Snigdha Guna and Madura

Vipaka acts on Vrana and the response of treatment was strengthened by similar Rasadi

properties and Samskarasya Anuvarthana quality of Grtha.

The procedure infiltration is meant for applying the medicine in the ulcer without harming

the patient and hindering the healing process as it is a very painful disease.

All patients responded with significant results in reduction of pain, burning sensation, constipation and bleeding.

Conclusion

- Fissure in ano is a crack or longitudinal ulcer in the long axis of anoderm with excruciating pain during and few hours after defecation.
- The disease has the chief complaints of severe pain, bleeding and burning sensation associated with habitual constipation. So these symptoms are taken as assessment criteria for this study.
- As the disease Fissure in ano is a true ulcer in the anoderm, the formulation Sariba
 Moola Grtha mentioned in Vrana Chikitsa Adhikarana of Vangasena Samhitha taken
 in account. It is mentioned as Sarva Vrana Vishodana and promotes faster healing
 and cure of ulcer.
- Constipation along with digestive impairments is the major cause of the disease. So
 that for Agni Vardhana and Mala Shodana, the drug Gandharvahasthadi Kashaya
 internally was selected.
- In this study, among 32 patients, the 7 days treatment has got considerable effect on pain, bleeding, burning sensation and constipation to almost all of the patients. The combined effect of 5ml *Sariba Moola Grtha* infiltration per anum along with 96 ml *Gandharvahasthadi Kashaya* internally twice daily showed highly significant impact and stable results in the end of 14th day on follow up.

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