

**A CLINICAL STUDY TO ASSESS THE EFFECT OF HARIDRADI
OINTMENT AND SHAALA MALAHARA IN PARIKARTIKA (ACUTE
FISSURE IN ANO)**

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ABSTRACT

Parikartika or Fissure in ano is the most painful condition among the ano rectal disorders and the suffering is much greater in comparison to the size of the lesion. The present-day sedentary life style, intake of less fibrous and spicier food has led to an increase in the incidence of constipation in the population, thus leading to increased incidence of *Parikartika*. So, it is the need of the hour to find out an effective treatment for *Parikartika*, which brings about quick healing of the ulcer and also prevent the reoccurrence. It was a comparative clinical study with a pre and post design in 60 patients who were diagnosed with *Parikartika*, were assigned into 2 groups of 30 patients each randomly. After examination had given for group A with *Haridradi ointment* and group B with *Shaala malahara* for 14 days. The assessment criteria were noted before and after treatment and on followup. Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with Unpaired T test. The test shows that the treatment is significant in Group A when compared to Group B. Group A overall result is 82.58% and Group B overall result is 55.06%. Both the groups are having effect on reducing the symptoms statistically. Among the subjective and objective parameters, *Haridradi ointment* (Group A) showed better reduction 82.58%. *Shaala malahaara* (Group B) Showed reduction 55.06%. *Haridradi ointment* is having more effect on symptoms of *Parikartika* and shows long lasting result.

Keywords: *Parikartika, Haridradi ointment, Shaala malahaara, fissure in ano.*

INTRODUCTION: The word 'fissure' itself means 'a split or crack.' It's been described as an acute superficial breach in the anal canal's continuity. *Parikarthika* is a term used in Ayurvedic medicine to describe a situation in which the patient feels as if the anal canal is being sliced around with scissors.¹ The occurrence of fissure-in-ano is thought to be highly common in constipated patients, especially those who pass hard and dry stool, with a prevalence rate of 30–40% of overall ano-rectal complaints. In modern surgical treatments such as Lord's anal dilatation, fissurectomy, and sphincterotomy for anal

fissure are available but they have their own limitations like recurrence, incontinence, etc. Constipation with hard stool passage is the primary cause of fissure-in-ano,² although it can also be caused by a variety of disorders such as chronic amoebic dysentery, diverticulitis, irritable bowel syndrome, ulcerative colitis, and even after a hemorrhoidectomy or fistulectomy. Fissure-in-ano is most usually observed in young adults and after delivery in females at 6 o'clock, that is, midline posterior, lower part of the anal canal.³

Snehavasthi (oil enema therapy), *Avagaha Swedana* (medicated lukewarm water sitz bath), and *Lepanam* are the Ayurvedic treatments for fissure-in-ano (medicated ointments).⁴ Due to the existence of a painful longitudinal ulcer, *Parikartika* can be classified as *Sadya Vrana*. As a result, medication compositions with *Vranaropana* characteristics are more successful in treating *Parikartika*. *Saruja Shamana* (pain relief), *Vranasodhana* (wound cleansing), and *Vranaropana* (wound healing) are some of the qualities of *haridardi* ointment. Due to the fact that *Parikartika* is a *vata vikara*, *haridradi* ointment may be effective. Because the majority of the medications used in *haridradi* ointment are found in nature, such as *Tridosha shamaka*, *Vedana shamaka*, *Vranaropaka*, *Shotha hara*, and *Raktastamba*, local use of *haridradi* ointment is examined in this study. *Shaala malahara* was taken as controlled drug for the treatment of *Parikartika*, there is always a need for a cost-effective and patient-friendly procedure (Acute Fissure in ano). Given the shortcomings of various modern medical therapies, there is a need for an effective, safe, cost-efficient, and uncomplicated therapy. *Haridradi* ointment is one Ayurvedic remedy that can help with the above-mentioned deficiencies. As a result, this research is being undertaken to investigate the potential of *haridradi* ointment for local application as an effective, cost-effective, and short-term treatment for *Parikartika* (Acute Fissure-in-ano). In light of the foregoing, a comprehensive method to assessing the efficacy of *Haridradi* ointment⁵ and *Shaala malahara*⁶ in the treatment of *Parikartika* (Acute Fissure-in-ano) has been adopted. The current study's

findings will be analysed and compared to previous findings.

AIMS AND OBJECTIVES

1. To evaluate the efficacy of *haridradi* ointment in the management of *parikartika*. (Acute Fissure-in-ano)
2. To evaluate the efficacy of *Shaala malahara* in the management of *parikartika*. (Acute Fissure-in-ano)
3. To compare the effect of *haridradi* ointment and *Shaala malahara* in the management of *parikartika*. (Acute Fissure-in-ano)
4. To accept the cost effectiveness of *haridardi* ointment.

METHODOLOGY

METHOD OF COLLECTION OF DATA

Sample Size – 60 patients fulfilling the diagnostic and inclusion criteria of *Parikartika* (Acute Fissure-in-ano) for the study and randomly assigned into 2 equal groups *haridradi* ointment (Group A) *Shaala malahara* (Group B).

DIAGNOSTIC CRITERIA

- Pain
- Steak of fresh blood
- Itching
- Constipation
- Sphincter spasm
- Ulcer

INCLUSION CRITERIA

- Age—Preferably 18 - 50years.
- Established cases of acute fissure in ano.

EXCLUSION CRITERIA

- Patients suffering from disorders like Tuberculosis, Malignant ulcers, Human Immunodeficiency Virus, Diabetic, Anaemic, Hepatitis B will be excluded
- Patient with chronic fissure in ano.

STUDY DESIGN

- Comparative clinical study with minimum 60 patients
- Patients were assigned into two groups consisting minimum of 30 patients each group fulfilling the inclusion criteria.

POSOLOGY

- **Group A** (*haridardi* ointment) - Patients of this group *haridardi* ointment were applied to the fissure with the finger under aseptic condition for 14 days.
- **Group B** (*Shaala malahara*) Patients of this group *Shaala malahara* were applied to the fissure with the finger under aseptic condition for 14 days.

INTERVENTION: Treatment procedure of *Matra Basti*.

Poorva Karma:

After the first defecation in the morning hours, diagnosed and selected Patients will be kept in lithotomy position. The perianal area will be cleaned under aseptic precaution with normal saline.

Pradhana Karma:

Haridradi ointment for Group A and *Shaala malahara* for Group B will be applied to the fissure with the finger under aseptic condition and patient will be asked to take rest for 2 minutes. This procedure will be carried out Twice a day for 14 days (two week).

Paschath Karma:

Patient will be instructed to maintain local hygiene. Patient will be instructed to have fibrous diet and warm milk. Eranda brishta haritaki 3 HS will administered in case of constipation.

STUDY DURATION:

- Study duration will be 14 days

- Readings will be observed on 1st day, 14th day, Follow up – 21st day.

ASSESSMENT CRITERIA

Group A – Patients were assessed before treatment and after treatment and on the day of follow up.

Group B – Patients were assessed before treatment and after treatment and on the day of follow up.

SUBJECTIVE PARAMETERS

- Pain
- Streak of fresh blood
- Itching
- constipation

OBJECTIVE PARAMETERS

- Assessment of sphincter spasm
- Ulcer

STASTICAL ANALYSIS

For the statistical analysis, the data obtained in both the groups were recorded, presented in tables, diagrams and graphs. The following statistical tests are used for assessment of parameters:

- Assessment of parameters within the group (after treatment and after follow up) – Wilcoxon sign rank test.

The corresponding p value was noted and obtained results were interpreted as follows:

- For p value > 0.05 – interpreted as no significant.
- For p value < 0.05 – interpreted as significant.

OBSERVATIONS AND RESULTS

The observations give a detail descriptive statistical analysis about all the 60 patients suffering from *Parikartika* according to their Age, Sex, Religion, Education, Socioeconomic status, Marital status, Occupation, *Ahara, Prakrithi*.

RESULTS

Statistical analysis of Subjective and Objective parameters

Table: 1 Comparative results of Signs and Symptoms of Group-A and Group-B.

Signs and Symptoms	Group A (Mean Score)	Group B (Mean Score)	S.E (±)	T Value	P Value
Pain	0.27	1.10	0.475	0.75	<0.05
Streak of Fresh Blood	0.03	0.60	0.047	0.31	<0.05
Itching	0	0.95	0.041	0.47	<0.05
Constipation	0.23	0.35	0.087	0.23	<0.05
Sphincter Spasm	0.27	0.70	0.029	0.44	<0.05
Ulcer	0.40	1.07	0.034	0.45	<0.05

Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with Unpaired T test. The test shows that the treatment is

significant in Group A when compared to Group B. Group A overall result is 82.58% and Group B overall result is 55.06%

Table: 2 Comparative results of Group A and Group B

Group A	Group B	Mean Difference	SE (±)	T Value	P value
82.58%	55.06%	2.36	1.03	1.65	<0.05

DISCUSSION

Discussion on Disease:

The condition *Parikartika* has been highlighted as a *vyapath* of *vamana* and *virechana karmas* by all *Acharyas*. The trauma caused to the *guda* due to improper administration of *basti*, or administration of *teekshna dravya* in *mridu koshta* causes *Parikartika*. The development of fissure due to trauma from the enema's nozzle is a common sequel even in the modern days. Considering the patients who reported for the present study, there was no history of recent use of any kind of enema by the patients.

Vyadhi nimittaja nidanas

Acharya Sushruta has described *Parikartika* as a symptom of *Arsas*. Also, it is mentioned as a symptom in lots of conditions like *Jwara*, *Atisara*, *Bhagandara chikitsa*, *Garbhini Vyapada*, and *Grahani*. In *Kashyapa Samhita*, this disease has been described as a

complication in pregnant women, which is again a very good observation from the modern point of view and is also seen in everyday practice. Fissure-in-ano which is common in women after delivery is explained as due to trauma created by the fetal head during delivery. According to different surgery textbooks Fissure in ano is found secondary to various diseases like Ulcerative colitis, Crohn's disease, Syphilis and Tuberculosis, which once again confirms the *Vyadhi nimittaja nidana*. Nowadays the prevalence of the disease Fissure in ano is very high and this may be due to untimely food intake, intake of less fibre diet, sedentary work style, lack of proper exercises. Even though *Atisara* is one of the causes for *Parikartika*, in most of the patients there was no history either of Diarrhea or recent use of enema. On the contrary majority of the cases in this study suffered from habitual constipation and often passed

thick and hard column of stool. Reviews of modern literature suggest that constipation is the greatest contributing factor in the development of Fissure-in ano. Constipation leads to passage of hard stools which causes tear or ulceration in the anal mucosa leading to fissure. Fissure in ano causes severe pain during defecation, associated with spasm of the sphincter muscles again worsening the condition. Therefore, these symptoms described in the ancient books, are very much justified and correct. For the better understanding of the disease, we can derive at the following *Samprapti*. Chronic constipation, wherein passing of hard stools is present, causes *abhighata* to the *Guda* region, resulting in the condition called *Parikartika*. These ulcers may take a long time to heal because of constant irritation caused by hard stools. Acute superficial ulcers may heal in 2-3 weeks especially if motions are kept soft and constipation is avoided. The chances of recurrence of the Fissure are more, if proper bowel care is not taken. Spasm of the sphincter is considered one of the reasons responsible for the chronicity of the ulcer. Fissure may also develop secondary to surgical catastrophes where excess of skin is removed during operation for Hemorrhoids and Fistula in ano.

Discussion on Drug review:

Haridradi ointment

The drugs in *Haridradi* ointment are *Haridra*, *Koshataki*, *Sarshapa taila* and *Madhu chista*.

Haridra – It has *Kashaya rasa*, *Laghu Ruksha guna*, *Ushna veerya*, *Katu Vipaka* and *Vata kapha hara* and has *Varnya*, *Vranashodhana* and *Raktastambhaka* properties and thus heals the wound.

Koshataki – It has *tikta rasa*, *Ruksha*, *Laghu*, *Tikshna guna*, *Ushna veerya*, *katu Vipaka* and *kaphapittahara* and has *Varnya* and *Vranashodhana* properties and thus heals the wound.

Sarshapa taila – It has *Katu tikta rasa*, *Laghu Snigdha guna*, *Ushna veerya*, *katu Vipaka* and *kaphavatahara* and *Grahi*, *deepana*, *pachana*, and *lekhanam* properties.

Madhu chista -It has *Madhura khasaya rasa*, *Guru snigdha guna*, *Sheeta veerya*, *Katu vipaka*. It has *Vranaropana*, *Sandhanakara* and *Bhutagna* and thus heals the *vrana*.

When *haridradi* ointment applied before and after defecation helps in relieving pain, stops bleeding, relieves burning sensation and helps in relieving anal sphincter spasm by repeated application of *haridradi* ointment in turn helps in healing of ulcer also.

Shaala Malahara

The drugs in *Shaala Malahara* are *Shaala*, *Narikela*, and *Madhuchista*.

Shaala - It has *kashaya* and *madhura rasa*, *ruksha* and *laghu guna*, *sheeta veerya*, *katu Vipaka* and *tridoshahara* and has *Asra dagdharuk* and *Vranashodhana* properties and thus heals the wound.

Narikela - - It has *madhura rasa*, *guru* and *snigdha guna*, *sheeta veerya*, *madhura Vipaka* and *vatapittahara* and has *Raktapitta shamaka* and *Vranashodhana* properties and thus heals the wound.

Shaala Malahara is mentioned in *Bhaishajya kalpana*. It has *Sheeta Virya* and it act as *Vata* and *Pitta Dosha hara*. It is very effective in heals the wound.

DISCUSSION ON RESULTS:

Group A - In Overall effect of treatment in *parikartika*, out of 30 patients in this study, 25 patients (83%) were getting

Moderate and Marked improvement and 5 patients (17%) were getting Complete Remission. Group B - In Overall effect of Group B in *parikartika*, out of 30 patients in this study, 19 patients (64%) were getting Moderate and 10 patients (33%) were getting Marked improvement and 1 patient (3%) were getting Complete Remission. Overall effect of the treatment is 55.06%. Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with Unpaired T test. The test shows that the treatment is significant in Group A when compared to Group B. Group A overall result is 82.58% and Group B overall result is 55.06%.

CONCLUSION:

At the end of the study both the groups are having effect on reducing the symptoms statistically. Among the subjective and objective parameters, Group A showed better reduction 82.58%. Group B Showed reduction 55.06%. in Pain, Steak of fresh blood, Itching, Sphincter spasm, Ulcer. *Haridradi* ointment is having more effect on symptoms of *Parikartika* and shows long lasting result.

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