

Comparative Study of *Palashgudavarti* and Diclofenac Sodium Suppository in the Management of Acute Fissure in Ano (Parikartika)-An Ayurvedic Management Protocol

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Abstract

Background - Anal Fissure is one of the major causes for pain at anal region. The two primary signs of this disease are pain and bleeding, and pain is often unbearable. In males anal fissure typically occurs in the midline posterior- 90 %, and 10 % midline anterior. Subsequently, female fissures on the midline anteriorly are significantly more frequent than posteriorly (60:40). In contemporary sciences *Parikartika* can be correlated with Fissure in Ano. **Objective**- The objective of the prospective study is to find the efficacy of *Palashgudavarti* & Diclofenac Sodium Suppository in the management of Acute Fissure in ano(*Parikartika*). **Material & Method**: The present study is designed as a Randomized single blind parallel in which 60 patients will be enrolled. Varti will be applied for local application once a day. Assessment will be done 0th, 7th day, 14th day, and 28th day. **Results**: The changes are expected to be observed in subjective parameters such as pain bleeding per rectum with itching as well as with objective parameters such as *Parikartika* Healing. **Conclusion**: The study is expecting the nonsurgical management of fissure in ano with respect to the impact of *Palashgudavarti* & Diclofenac Sodium Suppository. The research is expecting to be baseline and benchmark of the prospective studies in Acute Fissure in ano (*Parikartika*).

Keywords: *Parikartika, fissure in ano, Palashgudavarti*

Introduction

Lifestyle disorders are one of the most common condition seen in society. Lifestyle diseases are mainly caused by improper work pattern, stressful life, improper diet intake and improper sleep habits. These causative factors produce indigestion which leads to various lifestyle disorders specially anorectal disorders like piles, fissure in ano, fistula in ano etc. constitute a significant group. Among all anorectal disorders, fissure in ano is the most common disease. Anal Fissure is one of the major causes for pain at anal region The fissure-in-ano

is categorized into two types depending on the clinical symptoms & durations of the disease that is Acute and Chronic fissure in ano. The two primary signs of this disorder are, bleeding and pain; pain is often unbearable. In chronic conditions, sentinel tag and haemorrhoids can be associated with this. Pruritus ani can be present sometimes with this disorder¹. In males anal fissure typically occurs in the midline posterior- 90 percent and 10 percent much less frequently. Subsequently, female fissures on the anterior midline are somewhat more common than before. (60:40)².

Parikartika can be correlated with Fissure in ano in modern medical sciences. There are different causative factors of *Parikartika* such as *Vamana-Virecana Vypada, Basti Karma vypada and Upadrava of Atisara, Grahani, Arśa, Udāvarta*³. In this regard *Acharya Sushruta* explained the pathogenesis of disease⁴

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The word *Parikartika* means *Parikartanavatvedana* around *guda* i.e. cutting type of pain. *Parikartika* also has symptoms such as pain in the penis, anus, neck of the urinary bladder and umbilical region with flatus cessation⁵ References about *Parikartika* are available from all *Bruhatrayi* and also mentioned in *kashyap samhita* and later authors of *Ayurveda*⁶.

Methodology

Trial design: Randomized single blind parallel.

Study setting: Diagnosed Patients will be selected from *Shalyatantra* OPD & IPD of M.G.A.C.H. and R.C. Wardha.

Figure 1 Flow diagram of the study procedure

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Inclusion Criteria:

-Patients willing for the consent

-Patients with age group of 20 yrs to 50 yrs

-Patients with clinical features of Acute Fissure in ano will be included after screening.

-Patients irrespective of gender, occupation and economic status will be included

Exclusion Criterion:

-Patients suffering with systemic disorders like Diabetes mellitus, Tuberculosis, HIV Positive, and

Hepatitis B.

-Known cases of Malignancy, Crohn's disease, Ulcerative colitis will be excluded.

-Chronic patient with 4th grade anal spasm will be excluded.

Criteria for discontinuing or modifying allocated interventions: Patients will be withdrawal from intervention if any harmful incidence, signs of drug allergy or any problem will occur; patient will be offered treatment free of cost till the disease subsided.

Follow up period after treatment: 28th day after treatment.

Primary Outcomes: Changes in the symptoms of Fissure such as Pain, Bleeding, Itching.

Secondary Outcomes: To observe the changes Healing

Statistical analysis: Wilcoxon rank sum test.

Time duration till follow up: Follow up days is 0th, 7th, 14th, 28th days.

Time schedule of enrolment, interventions: Diagnosed patients of Fissure in Ano will be enrolled in the present study after fulfilling the inclusion criteria.

Interventions- One *Varti* of 2gm will be taken for local application after Hot Sitz Bath once a day during the treatment period.

Groups - Two groups with 30 patients in each.

Group	Sample Size	Local Application of Ghrita
Group A	30	Palashgudavarti
Group B	30	Diclofenac Sodium Suppository

Recruitment: Patient will be recruited by single arm study

Implementation: Principal invigilator will register subject.

Data collection methods: Randomized

Assessment criteria:

a) Subjective criteria

1. **Pain - Vas Scale**
2. **Bleeding per Rectum** –Truncated rectal score for rectal bleeding
3. **Itching** – Numerical Rating Scale

b) Objective criteria

1. **Parikartika healing** – Southampton wound scoring system

Data management: Principal investigator will do coding of data.

Ethics and dissemination: Permission for research has been taken from Institutional Ethical Committee ref no. IEC No: MGACHRC/IEC/August-2020/97

Consent or assent: Written informed consent will be obtained from the patient.

Dissemination policy: For future research results will be disseminated and research will be published in reputed journal

Informed consent materials: All the research related document and consent form will be given to the patients.

Figure no. 1 Gantt Chart (Quarterly based)

Scholar/Investigator	Dr. Shubham Biswas					
Title	“Efficacy of Palashgudavarti in comparision with Diclofenac Sodium Suppository in the management of Acute Fissure in ano (Parikartika)”					
Steps	Q1	Q2	Q3	Q4	Q5	Q6
Enrolment of Patients		█	█	█		
Drug Collection and preparation	█					
Data Collection		█	█	█		
Writing thesis parts up to Methods		█	█	█		
Data Analysis			█	█		
Writing rest of thesis					█	
Submission						█

Discussion

In *Ayurveda*, *palash* is used for the treatment of *vrana*, *gulma*, *bhagnasandhana*, *grahani*, *arsha*, *gudaroga*⁷. *Rasapanchak* of *Chakramarda* is *Rasa-Katu*, *tikta*, *kashaya*, *Virya-Ushan*, *Vipaka-Katu*, *Karma -Vata-Kaphahara*⁸. *Palash* has anti-inflammatory activity, analgesic, antifungal activity and anti-ulcer activity⁹ It is known for *Vranaropak* properties. Fissure

in ano is longitudinal tear in the anoderm distal of anal canal. In contemporary sciences surgical treatment available for fissure in ano are sphincterotomy, lord’s dilatation, fissurectomy, but these surgical procedures having adverse effects such as bleeding, infection, incontinence¹⁰. To sort out these problem we need treatment which is easily applicable and non surgical

Expected result and conclusion

Palash has anti-inflammatory activity, analgesic, antifungal activity and anti-ulcer activity. The predicted outcome of this analysis is that group A with intervention is more effective intervention to group B. It is effective in subsiding the symptom of *parikartika* such as pain & bleeding per rectum, itching. Patients who take all follow-up after treatment will have less chance of symptom reoccurrence.

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