Chakramarda Ghrita & Go-Ghrita in the management of Parikartika (fissure in ano): An Ayurvedic management protocol for the treatment of fissure

Alok Kumar Diwedi*, Kiran Khandare

Department of Shalyatantra, Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Datta Meghe Institute of Medical Sciences, Wardha 442001, Maharashtra, India

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ABSTRACT

Anal Fissure is one of the significant causes of pain in the 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. The objective of the prospective study is to find the effectiveness of Chakramarda Ghrita & GoGhrita in the management of Parikartika. The present study is designed as a randomized, single-blind parallel in which 30 patients will be enrolled. Ghrita will be applied for local application twice a day. Assessment will be done 0th, 7th, 14th, and 28th day. 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 and tenderness. The study is expecting the non-surgical management of fissure in ano concerning the impact of Chakramarda Ghrita & GoGhrita. The research is expecting to be baseline and benchmark of the prospective studies in Parikartika.

INTRODUCTION

In the age of fast food, there is a shift in the habit of taking food and its timings as well as in the lifestyle that has become sedentary. Both of these causes produce a disturbance in the digestive system that leads to many diseases, including anorectal disorders such as piles, fissure, fistula, prolapsed etc. constitute a significant category.

Anal Fissure is one of the significant causes of pain in the anal region. The fissure-in-ano is categorized into two types depending on the clinical symptoms & durations of the disease; viz. Acute and Chronic (Villalba, 2007).

The two primary signs of this disorder are, bleeding and pain; pain is often unbearable. In long-standing instances, sentinel tag and haemorrhoids can be associated with this. Pruritus ani can be another symptom of this disorder (Murtagh Collection, 2020).

In males, anal fissure typically occurs in the midline posterior- 90 per cent and 10 per cent much less frequently. Subsequently, female fissures on the anterior midline are somewhat more common than before. (60:40) (Jonas and Scholefield, 2001).

In contemporary sciences, parikartika can be correlated with Fissure in Ano (Jadhav, 2017). Sources on Parikartika are available from all Bruhatrayi and corresponding writers of Ayurveda. Parikartika (fis-
sure in Ano) is a widespread condition.

The factors responsible for the causation of Parikartika can be found in various ayurvedic texts such as Vamana – Virecana Vypada, Basti Karma vypada and Upadrava of Atisara, Grahani, Arsa, Udāvart. In this regard, Acharya Sushruta stated the aetiopathogenesis of disease that if anyone is impaired, with Mrudukoshta (mild digestive power), Mandagni (poor appetite) in these circumstances, more intake of food has the quality of Rukshna (dry), Ushna (hot), Lavana (salty) etc.). A diet which is having such quality will vitiate Vata & Kapha & leads to Parikartika (Kulkarni, 2015).

The word Parikartika signifies Parikartana-vatvedana 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 cessation (Bhagat et al., 2015).

In Kashyap Samhita, in the chapter Garbhini Chikitsa, we receive doshik classification, Aetiology, symptomatology and treatment of Parikartika (Tiwari, 2008).

Acharya Charaka further mentioned fissure in ano is a Vataj Atisara complication (Rajan et al., 2020). Chakramarda has Anti-inflammatory activity, Antibacterial, Antifungal Scavenging Activity, Antilulcer, Anti-proliferative activity, Antioxidant activity (Choudhary and Gulia, 2011).

METHODOLOGY

Trial design
Randomized, single-blind, parallel study design.

Study setting
Diagnosed Patients will be selected from Shalyatantra OPD & IPD of MGACH and RC Wardha (Figure 1).

The protocol has been registered with CTRI (CTRI/2019/08/020827) and Institutional Ethical committee clearance (DMIMS/DU/IEC/2017-18/7255).

Inclusion Criteria
- Patients aged 20 years to 50yrs
- Patients who will have clinical characteristics of Acute Fissure in ano shall be identified after screening.

Exclusion Criterion
- Patients with chronic illnesses such as diabetes mellitus, tuberculosis, HIV positive, Hepatitis B.
- Known case of Cancer and Inflammatory bowel disease.
- Patients who will be suffering from the 4th-grade anal spasm.

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; the patient will be offered treatment free of cost till the disease subsided.

Follow up period after treatment
28th day after treatment.

Primary Outcomes
To evaluate the changes in the symptoms of fissure such as Pain, Bleeding, Itching.

Secondary Outcomes
To observe the changes in Healing

Statistical analysis
Wilcoxon rank-sum test.

Time duration till following up
Follow up days is 0th, 7th, 14th, 28th days (Figure 1).

Schedule of enrolment, interventions
Diagnosed patients of Fissure in Ano will be enrolled in the present study after fulfilling the inclusion criteria (Figure 2).

Interventions
Quantity sufficient will be taken for local application of Ghrita after Hot Sitz Bath twice a day during the treatment period. The participants will be divided into two groups (Table 1).

Recruitment
Patient will be recruited by single-arm study

Implementation
Principal invigilator will register the subject.

Data collection methods
Randomized

Assessment criteria
Subjective criteria
1. Pain - Vas Scale
2. Bleeding per Rectum - Truncated rectal score for rectal bleeding
3. Itching - Numerical Rating Scale
Figure 1: Flow diagram of the study procedure

Figure 2: Gantt Chart (Quarterly based)

Table 1: Two groups with 15 patients in each

<table>
<thead>
<tr>
<th>Group</th>
<th>Sample Size</th>
<th>Local Application of Ghrita</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>15</td>
<td>Chakramarda ghrita</td>
</tr>
<tr>
<td>Group B</td>
<td>15</td>
<td>Go-ghrita</td>
</tr>
</tbody>
</table>
Objective criteria

1. Parikartika healing - The Southampton wound scoring system
2. Tenderness - Soft tissue tenderness scale

Data management

Principal investigator will do coding of data.

Ethics and dissemination

Permission for research has been taken from the Institutional Ethical Committee ref no. DMIMS(DU)/IEC/2017-18/7255

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 a reputed journal.

Informed consent materials

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

DISCUSSION

In Ayurveda, Chakramarda is used for the treatment of Pama, Jwara, Kasa, Kandu, Dadru. Rasapanchak of Chakramarda is Rasa-Katu, Guna-Laghu, Ushna, Virya-Ushan, Vipaka-Katu, Karma-Vata-Kaphasamak (Choudhary and Gulia, 2011). It is known for Vranaropak properties. Fissure in ano is a longitudinal tear in the anoderm distal of the anal canal. In contemporary sciences, surgical treatment available for fissure in ano is sphincterotomy, lord's dilatation, fistulectomy, but these surgical procedure having adverse effects such as bleeding, infection, incontinence. To sort out this problem, we need treatment which is easily applicable and non-surgical.

CONCLUSION

Chakramarda has Anti-inflammatory activity, Antibacterial, Antifungal Scavenging Activity, Antilulcer, Anti-proliferative activity, Antioxidant activity. The predicted outcome of this analysis is that group A with intervention is a more effective intervention to group B. It is useful in subsiding the symptom of the fissure in ano 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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Conflict of Interest

The authors declare that they have no conflict of interest for this study.

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