



## Randomized controlled clinical trial to study the efficacy of *Priyangvaadi Gana Siddha tail* in the management of *Parikartika* w.s.r. to fissure-in-ano-An Ayurvedic management protocol

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### ABSTRACT

Sushruta explained about Guda-Roga, i.e. Ano Rectal Disease in Shalya Tantra. It includes no. of disease out of them one is Parikartika," i.e. Fissure – in – Ano. 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. Priyangvaadi Gana siddha tail in the management of Parikartika. The present study is designed as a Randomized, single-blind parallel in which 60 patients will be enrolled. Priyangvaadi Gana Siddha Taila Pichu and Yastimadhu tail Pichu will be given for basti twice a day. Assessment will be done 0<sup>th</sup>, 7<sup>th</sup> day, 14<sup>th</sup> day, and 28<sup>th</sup> 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. The study is expecting the nonsurgical management of fissure in ano with respect to the impact of Priyangvaadi Gana Siddha tail pichu and Yastimadhu tail Pichu. The research is expecting to be a baseline and benchmark of the prospective studies in Acute Fissure in ano (*Parikartika*).

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### INTRODUCTION

Sushruta explained about Guda-Roga, i.e. Ano Rectal Disease in Shalya Tantra. It includes no. of disease out of them one is Parikartika," i.e. Fissure – in – Ano. ([Dilip et al., 2020](#)) Lifestyle diseases are mainly caused by improper work pattern, stressful life, improper diet intake and improper sleep habits. ([Steyn and Damasceno, 2006](#)) 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. ([Foxx-Orenstein et al., 2014](#)) Among all anorectal disorders, fissure in ano

is the most common disease. Fissure is a longitudinal ulcer in the lower end of the anal canal called fissure – in – Ano.

It is mostly due to constipation. (Shashidharan and Beauty, 2016) Anal Fissure is one of the major causes of pain in the anal region. Pruritus ani is associated with this disease. (Ansari, 2016) The fissure-in-ano can be of two types on the basis of clinical symptoms and durations of the disease 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. In males, anal fissure typically occurs in the midline posterior- 90 percent and 10 percent, much less frequently. Subsequently, a female fissure in ano is common on the anterior midline (60:40). (Jahny and Ashurst, 2020)

In modern medical science, parikartika can be compared with Fissure in ano (Sarkar, 2016). *Vamana-Virecana Vypada, Basti Karma vypada and Upadrava of Atisara, Grahani, Arśa, Udāvarta* are the causative factor of parikartika. In this regard. Pathogenesis of parikartika has been explained by acharya Sushruta (Srinivasa and Mamatha, 2020).

The word *Parikartika* means *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 (Pandey and Saxena, 2018). References about *Parikartika* are available from all *Bruhatrayi* and also mentioned in *Kashyap Samhita* and later authors of *Ayurveda*.

## METHODOLOGY

### Trial design

Randomized, single-blind parallel.

### Study setting

OPD of Department of Shalyatantra of Ayurveda College and Hospital. (Figure 1 and Figure 2).

### Inclusion Criteria

1. The patient having classical signs and symptoms of parikartika will be selected for the present clinical study.
2. Patients of age between 18 to 60 years.
3. Patient suffering from a fissure in ano without any complication.
4. Cooperative patient.

### Exclusion Criterion

1. Patients having Parikartika (Fissure-in-ano) secondary to Ulcerative colitis, Syphilis, Crohn's disease, Tuberculosis and Carcinoma of the rectum and anal canal.
2. Patients with infectious diseases like HIV/ Hbs Ag / HCV.
3. Patient with uncontrolled Diabetes and Hypertension.
4. Not willing to give consent.
5. Patients with Perianal abscess, rectal prolapsed and severe local sepsis.

### Criteria for discontinuing or modifying allocated interventions

If any complication arises during treatment case will be liable for rejection. The patient will be offered treatment free of cost till the disease subsided.

### Follow up period after treatment

28<sup>th</sup> day after treatment.

### Primary Objective

1. To study the efficacy of Priyangvaadi ganasid-dha tail Pichu in the management of Parikartika.
2. To study the efficacy of Priyangvaadi ganasid-dha tail Pichu in the management of Parikartika as compared to control drug yastimadu tail.

### Secondary Objective

1. To study the literature of parikartika in ayurvedic classics.
2. To study the fissure in ano in modern literature.
3. To study the concept of Pichu and Tail in detail according to Sharangadhar Samhita.
4. To study the classical literature regarding Priyangvaadi gana.

### Statistical analysis

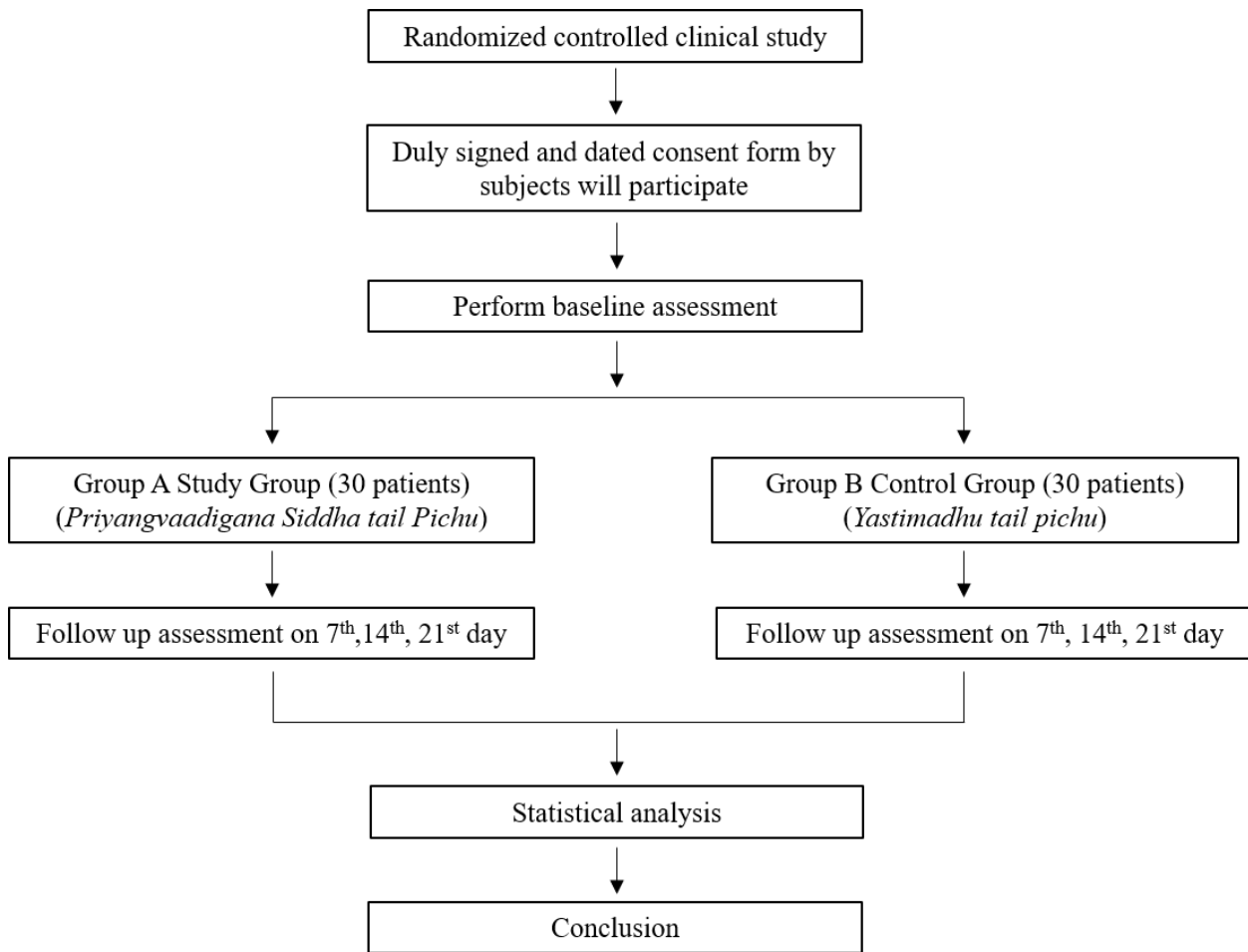
Wilcoxon rank-sum test.

### Time duration till following up

Follow up days is 0<sup>th</sup>, 7<sup>th</sup>, 14<sup>th</sup>, 28<sup>th</sup> days.

### Time schedule of enrolment, interventions

Diagnosed patients of Fissure in Ano will be enrolled in the present study after fulfilling the inclusion criteria.



**Figure 1: Flow diagram of the study procedure**

|                                    |   |           |           |           |           |           |
|------------------------------------|---|-----------|-----------|-----------|-----------|-----------|
| <b>Scholar/ Investigator</b>       | Dr. Alok Kumar Diwedi   |           |           |           |           |           |
| <b>Title</b>                       | Randomized controlled clinical trial to study the efficacy of Priyangvaadi Gana Siddha tail in the management of Parikartika w.s.r. to fissure-in-ano |           |           |           |           |           |
| <b>Steps</b>                       | <b>Q1</b>   | <b>Q2</b> | <b>Q3</b> | <b>Q4</b> | <b>Q5</b> | <b>Q6</b> |
| Enrolment of Patients              |   |           |           |           |           |           |
| Data Collection                    |   |           |           |           |           |           |
| Writing thesis parts up to Methods |   |           |           |           |           |           |
| Data Analysis                      |   |           |           |           |           |           |
| Writing the rest of the thesis     |   |           |           |           |           |           |
| Submission                         |   |           |           |           |           |           |

**Figure 2: Gantt Chart (Quarterly based)**

**Table 1: Method of intervention**

| Groups                  | Experimental Group   | Control Group  |
|-------------------------|--|--|
| No. of Subject          | 30   | 30   |
| Drug                    | <i>Priyangvaadi gana siddha Tail Pichu</i>                         | <i>Yastimadhu Tail Pichu</i>                                       |
| Dose                    | External application for <i>tail Pichu</i> twice a day             | External application for <i>tail Pichu</i> twice a day             |
| Duration                | 21 days  | 21 days  |
| Route of administration | Local for 15 days  | Local for 15 days  |
| Follow up               | On the 7 <sup>th</sup> , 14 <sup>th</sup> , 21 <sup>st</sup> days. | On the 7 <sup>th</sup> , 14 <sup>th</sup> , 21 <sup>st</sup> days. |

**Table 2: Sample size and the local application of Ghrita**

| Group   | Sample Size | Local Application of Ghrita               |
|---------|-------------|---|
| Group A | 30          | <i>Priyangvaadigana Siddha tail Pichu</i> |
| Group B | 30          | <i>Yastimadhu tail pichu</i>              |

**Interventions**

The method of intervention is explained in Table 1

**Groups**

Two groups with 30 patients in each Table 2

**Recruitment**

Patient will be recruited by a single-arm study

**Implementation**

Principal invigilator will register the subject.

**Data collection methods**

Randomized

**Assessment criteria**

1. *Kartanavat Vedana*
2. *Daha* (Burning Pain)
3. *Rakta Srava* (Bleeding per rectum)
4. *Kandu*(Itching in the anus)

**Assessment of pain**

*Kartanavat Vedana*

0 Absent

1 Few hours after defecation

2 Continuous

3 As the suffer himself expresses the pain in his own terms, so this is graded, starting from mild to severe on par.

**Bleeding per rectum**

0 Absent

1 Bleeding with stool strip

2 Bleeding and required flush in a latrine

3 Massive bleeding

**Itching in anus**

0 No itching

1 Itching only when defecation

2 Itching after defecation

3 Itching occasionally during the whole day.

4 Frequent itching during the whole day

**Daha (Burning Pain)**

0 Absent-No Burning

1 Mild- rare Burning in the morning or at the start of defecation

2 Moderate- tolerable burning at starting & during defecation

3 Severe-burning, which is not tolerated at starting and prolonged for a long time.

**Healing of fissure**

Southampton wound scoring system.

**Data management**

Principal investigator will do the coding of data.

**Ethics and dissemination**

Permission for research has been taken from the Institutional Ethical Committee

### 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

According to Sushruta, Priyangvaadi gana has Vranasodaka and vranaropak properties. (Varshney and Dhyani, 2015) Most of drug in Priyangvaadi gana is kashay rasatmak and kashay rasa is Ropak and Raktastambhak in property. Regarding Parikartika management, previous work has been done, including YashtimadvadiGhruta, Pichha, Basti, VataharanTaila, Basti NirgundyadiMalhar, DashmuladiKwath. But it has been observed Priyangvaadi gana Siddha tail has not been yet used. Hence Priyangvaadi gana Siddha tail is taken for the present study.

## CONCLUSION

*Priyangvaadi taila* has haemostatic activity, analgesic, wound healing activity. The predicted outcome of this analysis is that group A with intervention is a 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.

### Conflict of Interest

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

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