

Efficacy of Murivenna Tail Gudapurana and Yashtimadhu Ghrita Gudapurana in the Postoperative Pain Management of Haemorrhoids and Fissure in-ano: A Research Protocol for a Randomised Controlled Trial

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# **ABSTRACT**

**Introduction:** Lifestyle diseases resulting from sedentary work, stress, poor sleep, and unhealthy eating habits have led to an increase in anorectal disorders, such as anal fissures, fistulas, haemorrhoids, and abscesses. Haemorrhoids, which are dilated veins in the anal canal, are influenced by factors like prolonged sitting, straining, and pregnancy. Treatment options for haemorrhoids range from laxatives to surgical procedures. In Southern India, Murivenna Tail is commonly used for its anti-inflammatory and analgesic properties, aiding in wound healing and postoperative pain management.

**Need of the study:** Surgical procedures for fissure-in-ano, such as Lord's anal dilatation and lateral internal sphincterotomy, as well as haemorrhoid surgeries including various types of haemorrhoidectomy, can be extremely painful and typically require analgesics for pain management. However, traditional pain relief medications often come with side-effects, including diarrhoea, nausea, vomiting, skin rashes, headaches, mood swings, dependency, and overall dissatisfaction. Murivenna Tail, known for its anti-inflammatory and analgesic properties, presents a cost-effective and readily accessible alternative for managing postoperative pain following fissure and haemorrhoid surgeries. Preclinical studies have shown its potential to reduce inflammation, indicating it could serve as a viable alternative to conventional medications for postoperative pain relief.

**Aim:** To compare the efficacy of Murivenna Tail against Yashitimadhu Ghrita in managing postoperative pain associated with haemorrhoids and fissure-in-ano.

**Materials and Methods:** A randomised controlled trial will be conducted at the Mahatma Gandhi Ayurveda College, Hospital and Research Centre (MGACHRC) in Salod, Maharashtra, India, from January 2024 to June 2025. The study will include 72 participants who will provide written informed consent. They will be divided into four groups, with 18 subjects in each group. The treatments administered will be 20 mL of Murivenna Tila and Yashtimadhu Ghrita Gudapuarana, given twice a day for 14 days each. To assess the effectiveness of the four treatment groups Analysis of Variance (ANOVA) will be applied to compare mean scores if the data meet the criteria for normality and homogeneity of variance; otherwise, the Kruskal-Wallis test will be applied.

## Keywords: Analgesic properties, Anti-inflammatory, Haemorrhoidectomy, Postoperative pain, Traditional medicine

## INTRODUCTION

Lifestyle disorders are on the rise in today's world due to changing lifestyle factors, such as sedentary work patterns, increased stress, poor sleep habits, and low-quality diets. These unhealthy eating habits have contributed to a surge in anorectal diseases, referred to as *Gudavikar*. Anorectal conditions include fissures-in-ano, fistula-in-ano, haemorrhoids, and abscesses [1].

The prevalence of fissures-in-ano among patients with anorectal issues is approximately 18% [2]. The true prevalence of fistula-in-ano is not well documented. It is noted that around 50% of individuals over the age of 50 have haemorrhoids upon thorough examination [3].

Fissure-in-ano is a common and extremely painful condition affecting the anal region [4]. It presents as an ulcer along the longitudinal axis of the lower anal canal, characterised as a shallow, small, and painful lesion that typically ends at the dentate line. Fissures occur most commonly in the posterior midline (more frequently in males) but can also appear anteriorly (more common in females). About 95% of fissures in males are posterior, while 5% are anterior. In females, 80% of anal fissures are posterior, and 20% are anterior, with anterior anal fissures being more common in women [5]. Causes of fissuresin-ano include hard stools, diarrhea, increased sphincter tone, local ischaemia, trauma, and sexually transmitted diseases. They may also result from complications due to haemorrhoidectomy, Crohn's disease, ulcerative colitis, or tuberculosis. Haemorrhoids, also known as piles, are dilated veins in the subepithelial region of the anal canal, arising from the inferior rectal and superior medial veins. Their aetiology includes prolonged standing or sitting, which causes blood to flow against gravity, straining due to hard stools, congenital weakness of the veins, rectal carcinoma due to back pressure, portal hypertension, and pressures related to pregnancy, influenced by hormonal changes that relaxed vein muscles [6].

In *Sushruta Samhita*, a conventional Ayurvedic literary work, the creator referred to explicit iatrogenic clinical circumstances, specifically *Parikartika* (cutting agony in the rectum) and *Gudakshata* (anal ulcer), which refers to difficulties emerging from an improperly administered enema therapy [7,8]. According to *Acharya Sushruta*, due to *Mandagni* (improper digestion), Fundamental Ayurvedic Principles get vitiated and travel up to *Gudavali* (two sphincters) through *Dhamani* (arteries) thereby, producing *Mansankuras* which is termed as Arsha (Haemorrhoid) [9].

For fissures-in-ano laxatives, local anaesthetic agents, and sitz bath is given as treatment. According to modern treatment of haemorrhoids non-surgical, para surgical and surgical are involved. Non-surgical methods include local anesthetic application, sitz baths, laxatives, and analgesics. Para-surgical methods include sclerotherapy, cryotherapy, and bandaging. Surgical methods involve open haemorrhoidectomy, closed haemorrhoidectomy, stapled haemorrhoidectomy, etc., [6].

*Murivenna* is an Ayurvedic oil used in the state of Kerala, India, for acute injuries like contusions, wounds, and fractures. It is applied externally through techniques such as *Abhyanga* (oleation), *Pichu* (Soaked Cotton pad), *and Katibasti* (Ayurvedic), and can also be used internally for *Snehapana* (Internal oleation) and administered rectally as *Basti* (Anal Infiltration) [10]. *Yashtimadhu ghrita* is a gheebased formulation with cold potency, known for its wound healing properties. It contains Glycyrrhizine, an anti-inflammatory saponin, and asparagine, an amino acid that acts as a natural painkiller [11].

Given the rise in fissure-in-ano cases and limited effective treatments, this study aims to compare the efficacy of Murivenna Tail and Yashtimadhu Ghrita in postoperative pain relief for haemorrhoids and fissures.

#### Study objectives

- To study efficacy of Murivenna Tail on postoperative pain of haemorrhoids and fissure-in-ano
- To study efficacy of Yashtimadhu Ghrita on postoperative pain of haemorrhoids and fissure-in-ano
- To compare the efficacy of Murivenna Tail and Yashtimadhu Ghrita on postoperative pain of haemorrhoids and fissure-in-ano

**Null Hypothesis (H0):** Murivenna Tail is less or equally effective than *Yashtimadhu Ghrita Gudapurana* in postoperative pain management of Haemorrhoids and fissures-in-ano.

Alternative Hypothesis (H1): *Murivenna Tail Gudapuran* is more effective than *Yashtimadhu Ghrita Gudapurana* in postoperative pain management of haemorrhoids and fissures-in-ano.

# **REVIEW OF LITERATURE**

The present research aimed to conclusively evaluate the effectiveness of Murivenna Tail and Yashtimadhu Ghrita in managing postoperative pain in patients with haemorrhoids and fissures, offering an assertive, safer, and more cost-effective alternative to modern analgesics, particularly for patients with controlled diabetes, immunocompromised conditions, and other co-morbidities.

In a study by Kizhakke Meladam PS et al., it was conclusively demonstrated that Ayurvedic approaches, including Murivenna oil infiltration, Triphala choorna, sitz baths, and fibre diets, effectively relieved symptoms and facilitated the healing of fissures in 15 cases, all without any reported adverse events. These robust findings underscore the undeniable potential of Ayurvedic methodologies in managing anorectal conditions, delivering substantial patient satisfaction and significantly reducing recurrence rates [12]. Similarly, a study by Sreerag MV and Dhule M unequivocally showcased the potency of Murivenna ointment in providing symptomatic relief for acute fissures-in-ano, coupled with its proven anti-inflammatory and wound healing properties [13].

Another study by Nair VV et al., definitively established the antiinflammatory activity of *Murivenna* in acute inflammation, while also suggesting its potential utility in chronic inflammation. The statistically significant effectiveness of *Murivenna* in acute inflammation compared to the control and standard groups underscores its robust therapeutic potential, attributed to the proven anti-inflammatory properties of its constituent ingredients [14].

Badwe Y et al., authoritatively reported that *Yashtimadhu Ghrita* was clinically as effective as lignocaine jelly in managing postoperative pain in patients with haemorrhoids and fissures-in-ano. The comparable

reduction in pain levels and anal spasm when comparing the effects of *Yashtimadhu Ghrita* with lignocaine jelly in postoperative patients with haemorrhoids and fissures-in-ano further validates its assertive efficacy [15]. A study by Patel JR and Dudhamai TS definitively revealed that both *Yashtimadhu Ghrita* and lignocaine-nifedipine ointment are equally potent in providing symptomatic relief in the management of *Parikartika* (acute fissure-in-ano) [16]. Another study decisively demonstrated the superior efficacy of *Yastimadhu Ghrita* over *Yashtimadhu* Hydrogel in *Parikartika* [11].

## MATERIALS AND METHODS

A randomised controlled trial will be conducted at the Mahatma Gandhi Ayurveda College, Hospital and Research Centre (MGACHRC) in Salod, Maharashtra, India, from January 2024 to June 2025. The Institutional Ethics Committee at DMIMS, Wardha, Maharashtra, India, with reference number MGACHRC/IEC/Sep-2023/, has granted ethical clearance for the study. The trial is registered in Clinical Trials Registry-India (CTRI) with Ref. No. CTRI/2023/12/060766. An informed written consent will be taken from the subjects before conducting the study.

# Inclusion criteria:

- 1. Patients aged between 20 years to 60 years.
- Diabetic patient within the given range of sugar level (fasting plasma glucose 100-125 mg/dL and two hour plasma glucose 140-199 mg/dL) [17].
- 3. Postoperative patients with clinical features of fissure-in-ano and haemorrhoids will be included after screening irrespective of sex, religion and socio-economic status.
- 4. Haemorrhoid Grade 3 and 4 [18].

## Exclusion criteria:

- 1. Patients who are suffering with carcinoma rectum.
- 2. Patients who have undergone LASER anorectal surgery.
- 3. Pregnant and lactating women.
- 4. Immuno-compromised patients such as those suffering from Human Immunodeficiency Virus, Hepatitis B and tuberculosis.
- 5. Patients who are known cases of anaemia, anorectal malignancy, Crohn's disease, or ulcerative colitis.

Sample size calculation: The sample size is determined based on the mean difference before and after treatment, considering the effect on pain relief, with an estimated standard deviation of 2 for Yashtimadhu Ghrita.

n1=n2=2
$$\frac{(Z_{\alpha}+Z_{\beta})^{2}\sigma^{2}}{(\delta)^{2}}$$

Z<sub>α</sub>=1.96

 $\alpha \text{=} \text{Type I}$  error at 5% at both sides two tailed

Z<sub>8</sub>=0.84=Power at 80%

Mean Pain Score before the treatment=3

Mean Pain Score after the treatment=0.96 [15].

Change in Pain score Mean difference  $(\delta)=2.04$ 

Estimating Standard Deviation=2

Sample size n1=n2=2 $\frac{(1.96+0.84)^2(2)^2}{(2.04)^2}$ =16 per group

Considering 10% drop out=2

Total sample size required=16+2=18 per group.

Total sample size required for 4 groups (N)=72

The trial will adhere to the CONSORT guidelines, and the patient allocation is illustrated in the CONSORT flow chart presented in [Table/Fig-1].

Patients will be equally allocated to four groups using a computergenerated randomised table method with the intervention, frequency and posology illustrated in [Table/Fig-2].



[Table/Fig-1]: CONSORT flow chart.

Group	Sample size	Intervention	Frequency	Dose	Duration
A	18	Yashtimadhu Ghrita Gudapurana (fissure-in-ano)	Gudapurana Twice a day after Sitz Bath	20 mL	14 days
в	18	Murivenna Tail Gudapurana (fissure-in-ano)	Gudapurana Twice a day after Sitz Bath	20 mL	14 days
С	18	Yashtimadhu Ghrita Gudapurana (Haemorrhoids)	Gudapurana Twice a day after Sitz Bath	20 mL	14 days
D	18	Murivenna Tail Gudapurana Haemorrhoids)	Gudapurana Twice a day after Sitz Bath	20 mL	14 days
[Table/Fig-2]: Intervention given in each group with posology.					

The ingredients for the Murivenna tail will be sourced locally and prepared in the MGACH & RC Pharmacy according to the guidelines provided in the Ayurvedic Formulary of India [19].

## Preparation Methodology

Decoction process: The herbs are boiled in water to extract their medicinal properties;

Oil infusion: Subsequently, the herbal decoction is combined with coconut oil and heated until the oil effectively absorbs the therapeutic compounds of the herbs;

Filtration process: The resultant mixture is then filtered to eliminate any solid particles, ensuring a smooth and refined oil.

Storage: The formulated Murivenna oil will be stored in airtight containers to preserve its efficacy and prevent any contamination [Table/Fig-3a] [10].

The Yashtimadhu Ghrita will be prepared following the instructions from the Ashtanga Hridayam [20]. The herbs are washed, dried, and then coarsely powdered. Yastimadhu and Nagabala are boiled with water until the volume is reduced to one-quarter. The decoction is then filtered. A paste is prepared using papaya, pippali, and Vamsi. Ghee is heated until it produces fumes, after which milk, the and the paste are added. The mixture is cooked until fully prepared [Table/Fig-3b].

#### Standard Operating Procedure (Validated)

All procedures will be performed under aseptic conditions while the patient is in the lithotomy position.



**[Table/Fig-3]:** Prepared formulations of Murivenna Tail Gudapurana (a) and Yashtimadhu Ghrita Gudapurana (b).

Using a gloved hand and proper lubrication, 20 mL of *Murivenna Tail* and *Yashtimadhu Ghrita* will be administered into the anal canal with a 20 mL disposable syringe and a sterile rubber catheter (No. 9). The patient will be instructed to take deep breaths during the administration.

After the administration of *Gudapurana*, the patient will lie in a supine position. Following this, they will be advised to sit up and rest [15].

#### Primary outcome:

Subjective pain assessment: The Visual Analogue Scale (VAS) will be employed as a tool to systematically evaluate pain levels in participants at four key time points: 7 days, 14 days, 21 days, and 28 days. This assessment will be conducted across all four groups involved in the study, allowing for a comprehensive comparison of pain experiences over time. The VAS is a reliable and validated measure that enables participants to indicate their pain intensity on a continuum, providing nuanced data for analysis [21].

**Secondary outcomes:** Anal sphincter muscle spasm will be assessed using the criteria illustrated in [Table/Fig-4] [15].

Grade	Symptoms		
0	Normal (1 finger can pass)		
1	Finger can be passed with severe pain		
Ш	No finger can be passed		
[Table/Fig-4]: Anal sphincter muscle spasm.			

## **STATISTICAL ANALYSIS**

The Statistical Package for Social Sciences (SPSS 27.0) Statistical Software will be used for Statistical analysis. To compare the mean scores across the four groups, ANOVA will be applied, provided the data meets the assumptions of normality and homogeneity of variances. If these assumptions are not satisfied, the Kruskal-Wallis test will be utilised instead. If significant differences are found through ANOVA, further investigation will be conducted using post-hoc tests like Tukey's Honestly Significant Difference (HSD). Similarly, if the Kruskal-Wallis test yields significant results, pairwise comparisons with corrections, such as Dunn's test with Bonferroni adjustment, will follow. A p-value of less than 0.05 will be considered statistically significant.

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