

## A clinical study to evaluate the effect of per-rectal instillation of Kaseesadi Taila in the management of Parikartika W.S.R. to Fissure-in-Ano

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### Abstract

**Background:** In today's world, a sedentary lifestyle, irregular diet, and stress often lead to digestive disturbances, resulting in various ano-rectal disorders, with fissure-in-ano being particularly troublesome. This condition affects health and daily functioning, and contemporary treatments often have limitations and side effects. *Ayurvedic* therapy, with its holistic approach, offers significant benefits. *Ayurvedic* treatments include *Bhesaja*, *Shashtra*, and *Kshara Karma*. Modern topical remedies are also available for wound healing, including Fissure-in-ano. This study focuses on *Kaseesadi Taila* functions like *Kshara*, shrinking and healing wounds without harming anal sphincters, and may be utilized for treating *Parikartika* as a standardized and accessible treatment modality.

**Aim and objective:** To evaluate the effect of per rectal instillation of *Kaseesadi Taila* in the management of *Parikartika* W.S.R. to Fissure-in-ano.

**Methodology:** Single arm open label clinical study was conducted to evaluate the effect of *Kaseesadi Taila* in *Parikartika* for 30 days

**Results:** There were statistically significant results seen in both subjective and objective parameters. The results were encouraging in terms healing.

**Interpretations:** *Kaseesadi Taila* has *Lekhana*, *Shodhana*, *Ropana* & *Raktasthambana* properties. It was observed that *Kaseesadi Taila* is good, safe, easily accessible, and effective treatment modality for *Parikartika*.

**Conclusion:** *Kaseesadi Taila* showed good efficacy in almost all the patients and emerge as an effective drug in treatment of *Parikartika*.

**Keywords:** Parikartika; Kaseesadi Taila; Fissure-in-ano; Shodhana; Ropana; Raktasthambana

### 1. Introduction

In contemporary world, sedentary lifestyle, change in diet and food timings, mental stress results in digestive disturbances which leads to various ano-rectal disorders. One of the most commonly troubling diseases is Fissure-in-ano with prevalence of around 1 in every 350 adults<sup>1</sup>. 95% of anal fissures in men are posterior, 5% are anterior. 80% of anal fissures in females are posterior, 20% are anterior<sup>2</sup>.

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An Anal Fissure is a longitudinal split in the anoderm of the distal anal canal<sup>3</sup>. Fissure occur most commonly in midline posteriorly (90%) and much less commonly anteriorly (10%)<sup>4</sup>. It typically causes severe intolerable pain which is similar to excruciating pain in *Parikartika* as mentioned by *Acharya Sushruta*<sup>5</sup>.

On the basis of *Lakshanas Parikartika* can be correlated with Fissure-in-ano. *Parikartika* is mentioned in *Bruhatrayees* as the complication of *Basti*<sup>6,7</sup> and *Virechana Karma*<sup>5,8,9</sup>. *Parikartika* literal meaning is "*Parikartanvat Vedana*" i.e., cutting type of pain around anal region<sup>10</sup>.

Modern treatment modalities include soothing ointments, bulk laxatives, surgeries like lateral internal sphincterotomy, V-Y advancement flap, are told, possibility of high recurrence, risk of incontinence, formation of fistula or abscesses are seen in some cases and are quite expensive.

According to classics, there are several treatment modalities like *Bhesaja*, *Shashtra*, *Kshara Karma*. Nowadays many topical remedies are available for local application of wound healing in market including Fissure-in-ano. In present study an effort is made to make a standard and easily accessible treatment.

In *Gadanigraha*, it is mentioned that *Kaseesadi Taila* works like a *Kshara* but does not affect the functions of the anal sphincters<sup>11</sup>. In *Rasatarangini*, external use of *Kaseesa* is considered to be *Sankochankarana param* i.e., it helps to reduce the size of wound and heals it<sup>12</sup>. *Kaseesa* also have *Vranashodhana*, *Vranaropana*, *Raktsthambana* properties<sup>13</sup>.

This research work was done to see the effect of *Kaseesadi Taila* in the management of *Parikartika*.

### *Aim and objective*

To evaluate the effect of per rectal instillation of *Kaseesadi Taila* in the management of *Parikartika* W.S.R. to Fissure-in-ano

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## 2. Material and methods

30 subjects were selected for the trial on the basis of inclusion criteria.

**Study Design:** A single arm open label clinical study

**Table 1** intervention

Route of instillation	Per Rectal
Sample size	30
Medicine	Kaseesadi Taila
Dose	10 ml
Duration of drug intervention	7 days
Assessment was done on	0th ,7th ,14th, 30th days
Follow Up	14th and 30th days

### 2.1. Procedure

Per-rectal instillation of *Kaseesadi Taila* was done to each subject in the dose of 10ml, once a day for a period of 7 days.

### 2.2. Assessment parameters

As per the REALISE SCORE questionnaire<sup>14</sup>,

**2.3. Subjective parameters**

**Table 2** Gudagata vedana (pain) - vas scale

Grade	Pain
0	No pain(0)
1	Mild pain(1-3)
2	Moderate pain(4-6)
3	Severe pain(7-9)
4	Very Severe pain(10)

**Table 3** Gudagata daha (burning sensation after defecation)

Grade	Duration
0	Never
1	Less than 1 hour
2	More than 1 hour and less than or equals to 2 hours
3	More than 2 hours and less than or equals to 3 hours
4	More than 3 hours and less than or equals to 4 hours
5	More than 4 hours

**Table 4** Gudagata rakta srava (bleeding)

Grade	Bleeding
1	Never
2	Rarely, (less than or equals to 25% of defecations)
3	Sometimes, (more than 25% and less than or equals to 50% of defecations)
4	Often, (more than 50% and less than or equals to 75% of defecations)
5	Always, (more than 75% of defecations)

**2.4. Objective parameters**

**Table 5** Sphincter tonicity

Grade	Sphincter Tonicity
0	Normal
1	Hypotonicity
2	Hypertonicity

**Table 6** Size of fissure

Grade	Size
0	No Fissure
1	Small (1-5 mm)
2	Medium (6-10 mm)
3	Large (> 10 mm)

**Table 7** Site of fissure

Grade	Site
0	No fissure
1	Midline Anterior
2	Midline Posterior
3	Antero-posterior
4	Multiple

### 3. Observations and results

Data was collected, tabulated and analyzed. Friedman test and Wilcoxon sign rank test were applied within the groups to obtain the results.

**Table 8** Effect of treatment on *gudagata vedana* (pain)

PAIN	BT(N)	PERCENTAGE	AT(N)	PERCENTAGE
NO PAIN (0) GRADE 0	0	0.0%	28	93.33%
MILD (1-3) GRADE 1	0	0.0%	0	0.0
MODERATE (4-6) GRADE 2	16	53.3%	2	6.6%
SEVERE (7-9) GRADE 3	14	46.7%	0	0.0%
VERY SEVERE (10) GRADE 4	0	0.0%	0	0.0%

**Table 9** Effect of treatment on *gudagata daha* (burning sensation after defecation)

TIME	BT(N)	PERCENTAGE	AT(N)	PERCENTAGE
NEVER	0	0%	26	86.6%
<1 HR	7	23.3%	4	13.33%
>1 HR AND < OR = 2 HR	12	40.0%	0	0.0%
>2 HR AND < OR = 3 HR	4	13.3%	0	0%
>3 HR AND < OR = 4 HR	7	23.3%	0	0%
>4 HR	0	0.0%	0	0%

**Table 10** Effect of treatment on *gudagata rakta srava* (bleeding)

Gudagata raktasrava (bleeding)	Bt(n)	Percentage	At(n)	Percentage
Never	4	13.3%	28	93.33%
Rarely, (less than or equals to 25% of defecations)	6	20.0%	2	6.6%
Sometimes, (more than 25% and less than or equals to 50% of defecations)	8	26.7%	0	0%
Often, (more than 50% and less than or equals to 75% of defecations)	6	20.0	0	0%
Always, (more than 75% of defecations)	6	20.0	0	0%

**Table 11** Effect of treatment on sphincter tonicity

Sphincter tonicity	Bt(n)	Percentage	At(n)	Percentage
Normal	6	20.0%	28	93.33%
Hypotonicity	0	0.0%	1	3.3%
Hypertonicity	24	80.0%	1	3.3%

**Table 12** Effect of treatment on size of fissure

Size of fissure	Bt(n)	Percentage	At(n)	Percentage
No fissure	0	0.0%	26	86.6%
Small (1-5 mm)	9	30.0%	4	13.3%
Medium (6-10 mm)	21	70.0%	0	0%
Large (> 10 mm)	0	0%	0	0%

**Table 13** Effect of treatment on site of fissure

Site of fissure	Bt(n)	Percentage	At(n)	Percentage
No fissure	0	0%	26	86.6%
Midline anterior	8	26.7%	2	6.6%
Midline posterior	10	33.3%	2	6.6%
Antero-posterior	12	40.0%	0	0%

**Table 14** Overall effect of treatment

Grading	Effect of treatment	No. Of patients
Grade 0	No Relief (0-25%)	0 Patient
Grade 1	Mild Relief (26-50%)	2(6.6%) Patients
Grade 2	Moderate Relief (51-75%)	2(6.6%) Patients
Grade 3	Marked relief & Cured (76-100%)	26(86.6%) Patients

Among 30 patients, 2(6.6%) patients had shown improvement in symptoms, 2(6.6%) patients cured from the disease but disease recurred during the course of study. 26(86.6%) patients had cured with no recurrence.

#### 4. Discussion

At the end of treatment, 26 patients showed good response where there was complete healing of fissure and relief from all associated symptoms. And 2 patients showed poor response towards treatment, whereas in 2 patients recurrence of fissure was observed.

The good response in patients may be due to the therapeutic action of *Kaseesadi Taila* and following *Pathya*. Poor responses and recurrence may be due chronicity of ulcer, fibrosis of ulcer and not following the *Pathya* properly.

The results analyzed statistically were significant & show quick action of *Kaseesadi Taila* with minimal recurrence.

#### 4.1. Effect on pain (*Gudagata Vedana*)

Painful defecation was found in all patients (100%) before treatment. 26 patients got relief after treatment. But 4 patients didn't get complete relief. This might be due to *Vranaropaka* (Wound healing), analgesic, anti-inflammatory and rubefacient properties of *Kaseesadi Taila*. It acts like *Kshara* (Alkali) & irritates the anal musculature, dilates the blood vessels leading the increase in blood circulation that promotes healing, thus relieves the intensity of the pain.

#### 4.2. Effect on bleeding (*Gudagata Raktasrava*)

Among the 30 subjects, 26 patients had bleeding. 24 subjects got relief from bleeding. This may be due to *Kshara* property of *Kaseesadi Taila* which leads to Hemostasis.

#### 4.3. Effect on burning sensation (*Gudagata Daha*)

Among the 30 patients, 23 patients had burning sensation. All patients got relief from burning sensation to some extent. *Kaseesadi Taila* by virtue of its action relaxes the anal musculature by *Snehana* (Oleation), increases blood circulation and enhances drainage of inflammatory markers thus relieves the burning sensation.

#### 4.4. Effect on Size of Fissure

Among the 30 patients, all patients had Fissure. 26 patients got relief from Fissure. This might be due to *Vranaropana* and *Vranasodhana* (wound debriding) properties of *Kaseesadi Taila*. *Kaseesa* also have a property of *Vranasankochkara Param* i.e., reduces the size of fissure and heals it. *Kaseesadi Taila* also increases blood circulation, which provides necessary environment for healing of Fissure.

#### 4.5. Effect on Sphincter tone

Among the 30 patients, 24 patients had Hypertonicity. 22 patients got relief from hypertonicity. This may be due to spasmolytic activities, and better lubrication of anal canal procured by *Kaseesadi Taila* which relaxes the sphincter of anal canal.

#### 4.6. Site of Fissure

Among the 30 patients, 12 patients had multiple fissures. 10 patients had Posterior fissure, 8 patients had anterior fissure. 26 patients got relief.

Reason for posterior location is explained as due to posterior angulation of anal canal, relative fixation of anal canal posteriorly, divergence of fibre of external sphincter muscle posteriorly. As the hard stool descends down, it first strikes the posterior median raphae and emerges out of anal orifice. Majority of anterior fissures were found in females in this study. Most of them were married and multiparous and gave a history of assisted labour with episiotomy. A probable explanation is that they developed fissure due to a damaged pelvic floor. The anterior wall of anal canal is less supported and over stretching of the wall during labour as well as on passing a hard column of stool is possible, leading to a tear.

#### 4.7. Discussion on probable mode of action of *Kaseesadi taila*

The probable mode of action of *Kaseesadi Taila* in the treatment of *Parikartika* (fissure-in-ano) can be elucidated through its multifaceted actions of cleansing, wound healing, infection prevention, inflammation reduction, and pain relief. By addressing both the symptoms and the underlying pathology of the fissure, it facilitates effective healing. *Kaseesadi Taila* alleviates pain and discomfort via its *Vata*-pacifying properties and also ensures smoother bowel movements, thereby preventing the aggravation of the condition. Below is an in-depth analysis:

##### 4.7.1. Cleansing (*Shodhana*) and Debridement (*Lekhana*) Action:

The ingredients *Kaseesa*, *Kushtha*, and *Chitraka* possess potent *Lekhana* (scraping) and *Shodhana* (cleansing) properties, which are instrumental in removing necrotic tissue, pus, and unhealthy granulation. This cleansing action is essential for preparing the fissure for healing, facilitating debris removal, and allowing for the regeneration of healthier tissue.

##### 4.7.2. Wound Healing (*Vranaropana*)

Components such as *Kaseesa*, *Manhashila*, and *Karvira* enhance *Vranaropana* (wound healing) by stimulating processes like neovascularization, epithelialization, and granulation. These processes are vital for accelerating the healing of the fissure through the formation of new blood vessels and granulation tissue.

*Tila Taila* as base provides moisture (*Snigdha Guna*) to the affected area, preventing excessive dryness and promoting rapid healing.

#### 4.7.3. Hemostasis (*Raktasthambana*):

*Kaseesa* and *Gomutra* exhibit *Raktasthambana* properties that effectively control bleeding in the fissured region. This haemostatic action is critical for managing minor bleeding associated with the fissure, thereby supporting the wound healing process.

#### 4.7.4. Anti-inflammatory (*Sothahara*) Effect

The formulation contains *Kaseesa*, *Sunthi*, and *Chitraka*, which demonstrate significant *Sothahara* properties. These ingredients work to reduce swelling, redness, and inflammation in the anal region, thereby alleviating discomfort associated with *Parikartika* and promoting healing.

*Sunthi* also plays a role in modulating vascular smooth muscle responses, further diminishing local inflammation.

#### 4.7.5. Antimicrobial (*Krumighna*) Action

Ingredients such as *Vidanga*, *Chitraka*, *Danti*, and *Kaseesa* exhibit *Krumighna* properties that are essential for preventing infections in the fissured area. This antimicrobial activity is crucial for maintaining a clean wound and avoiding complications like secondary infections.

Additionally, *Gomutra* contributes to the antimicrobial and antiseptic properties of the formulation, ensuring that the wound remains free from external bacterial contamination and fostering an environment conducive to healing.

#### 4.7.6. Pain Relief (*Vedananashaka*) and Vata-pacifying (*Vatahara*) Action

The formulation effectively pacifies *Vata Dosha*, a significant contributor to the pain and discomfort experienced in *Parikartika*. The *Ushna* and *Snigdha* properties of *Tila Taila* counteract *Vata Dushti*, alleviating pain and discomfort.

The *Vatahara* effect further enhances its *Vedananashaka Guna*, providing substantial relief from pain, reducing spasms, and easing discomfort associated with defecation.

#### 4.7.7. Facilitating Smooth Bowel Movements

The *Snighdha Guna* of *Tila Taila* serves as a lubricant for the anal canal, minimizing friction and preventing further injury during defecation. This lubricating effect is crucial for facilitating smoother bowel movements, thereby assisting in the management and prevention of exacerbation of anal fissures.

#### 4.7.8. Deep Tissue Penetration

The *Teekshana Guna* and *Ushna Virya* of majority ingredients ensure that the active constituents of *Kaseesadi Taila* penetrate deeply into the tissues, thereby enhancing its therapeutic effect and accelerating tissue regeneration and wound healing.

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## 5. Conclusion

Management of Fissure-in-ano by using *Kaseesadi Taila* was found to be effective in relieving pain, burning sensation, bleeding and healing of Fissure in ano. It lubricates the anal canal and provided easy evacuation of feces and thus promotes healing & relieving symptoms quickly and with minimal recurrence.

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## Compliance with ethical standards

### *Disclosure of conflict of interest*

There are no conflicts of interest.

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