



# A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF KSHUDRA SEVANTIKA TAILA PICHU (TRIDAX PROCUMBENS LINN.) AND DOORVADI TAILA PICHU IN THE MANAGEMENT OF PARIKARTIKA W.S.R TO FISSURE IN ANO

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## Introduction

The earliest reference about *Parikartika* is available from *Susruta samhita* (1000 B C). We get description about *Parikartika* in all Ayurvedic classics and later period authors of Ayurveda. The word *Parikartika* is mentioned in *Basti karma vyapath* and *Vamana-Virechana vyapath*<sup>1</sup>. Sushruta specifies that for *Virechana vyapath* it is *Gudaparikartika* and for *Vamana* it is *kantakshanana*, *Kashyapa* has described its type in the preview of *Garbini chikista*.<sup>2</sup> *Acharya Vagbhata* also explained *Parikartika* in the chapter *Atisaragrahani Nidana*.<sup>3</sup> An anal fissure is a longitudinal split in anoderm of the distal anal canal, which extends from the anal verge proximally towards but not beyond the dentate line<sup>4</sup>. It is characterized by severe pain during and after defecation is postponed, severe constipation, stools are hard, and there is drop of blood or streaks of fresh blood.<sup>5</sup> The incidence of fissure in ano is equal in both male and females and most often occur in adult aged 15-40. The commonest site of fissure in Ano is posterior midline or 6'o clock position. On the base of incidences anterior fissure are more common in women than in men and are often observed in the post parturition period<sup>6</sup>. Anal fissures can be acute or chronic based on the duration. Acute anal fissure is a deep tear in the lower anal skin with severe sphincter spasm. It presents with symptoms like severe pain, bleeding per anum and constipation. Chronic anal fissure-is characterized by deep tear in the lower anal skin with inflamed indurated margins, is having a skin tag which is edematous, acts like a guard this tag is known as Sentinel pile. Chronic fissure is less painful than acute one<sup>7</sup>

Fissure in ano is a medico-surgical condition. Medical managements said to be conservative and surgical intervention is the ultimate choice in the chronic ulcer. Medical treatment for acute fissure is oral pain killer, soothing ointment, stool softeners anal dilatation (using anal dilators) on medical advice etc. surgical management includes Lord's dilatation, sphincterotomy, fissurectomy and anal advancement flap<sup>8</sup>. Most of the methods of treatment are expensive and requires long stay in the hospitals. Acharyas have recommended the use of *Madhura*, *Sheeta*, *Snigdha dravyas* internally as well as locally in the form of application of *Picchabasti*, *Madhura Kashaya dravya siddha basti* and *anuvasanabasti* with *sneha* prepared with *Yashtimadhu* or *Ghritamanda*. From the available explanations in the Classics, we can infer that *Parikartika* is a *Vranalakshanayukta* and *shulapradhanagudavikara*.

Keeping in view the lacunas of different modern medical treatments and to prevent surgical intervention there is a need for an effective, safe, economical, simple and short term therapy. *Kshudrasevantika taila pichu* may be considered as effective treatment in *Ayurveda* which can overcome the above said lacunas. Hence this study is taken up to explore the possibilities of *Pichu dharana* as an effective, economical and short term treatment which is easily administered in OPD level also for Fissure-in-ano. To establish the significance effect of *Kshudrasevantika taila pichu* with *Doorvadi taila pichu* and its effect on *Parikartika* has also been taken up which later has already been established with 90 % of success rate from the previous studies

### Aims & objectives

1. To evaluate the efficacy of *kshudrasevantika taila pichu* in *Parikartika* w.s.r. to Fissure in ano.
2. To validate the efficacy of *Doorvadi Taila pichu* in *Parikartika* w.s.r. to Fissure in ano.
3. To compare the efficacy of *kshudrasevantika taila pichu* and *Doorvadi taila pichu* in *Parikartika* w.s.r. to Fissure in ano.

### Materials & methods

The study got approved by institutional ethics committee (no.360/2019-20,dated: july 30,2021) and trial was registered in clinical trial Registry of India(CTRI/2023/01/048884) Subjects visiting outpatient department of shalayatantra of BLDEA'S AVS Ayurveda Mahavidyalaya, hospital and research center, Vijayapur were thoroughly examined for clinical signs and symptoms of *Parikartika* along with necessary haematological and RVD investigations. Subjects were enrolled for the study considering the criteria of inclusion, exclusion and after getting the consent. The registered subjects were allocated into two groups, using the randomization.

*Kshudrasevantika taila pichu Dharana* in a day in trial group A and *Doorvadi taila pichu dharana* in trial group B For the age group of 18-60 years respectively. Patients of both A & B groups were advised to take 1tsf(5 gm) of *Triphala choorna* with luke warm water every night for 21 days, as a stool softener. After completion of the clinical trial, the patient were followed up for further 1 month.

**Diagnostic criteria**

Subject was diagnosed on the basis of Ayurvedic classical signs and symptoms of Parikartika. Subjects were also examined on the basis of specially prepared proforma.

**Inclusion Criteria:**

Patients having classical features of Parikartika (acute fissure-in ano), patient of either sex aged between 18-70 years and patients who were willing and able to participate in the study.

**Exclusion Criteria:**

Fissure secondary to ulcerative colitis, tuberculosis, syphilis. Crohn's disease, inflammatory bowel disease and other systemic disease pertaining to colo-rectum were excluded from the study, Patient with chronic fissure in ano, ca of rectum, ca of anal canal, fistula in ano, hemorrhoids or any other ano-rectal diseases, Systemic disorder such as diabetes, tuberculosis, Patient suffering from conditions like HIV and HbsAg-positive patient.

**ASSESSMENT CRITERIA:** Effect of treatment was assessed on the basis of Changes in subjective and objective parameters before and after treatment.

No.	Subjective parameters	Objective parameters
1.	Pain	1.Tenderness
2.	Bleeding per anum	2.Sphincter spasm
3.	Burning sensation	3.Ulcer

**Statistical analysis**

The data obtained were entered in a Microsoft excel sheet, and statistical analysis was performed using statistical package for the social sciences (Version2.0).Results were presented as menu+SD,counts, percentage and Diagrams. Paired Data will be compared using ANOVA/Kruskal walli's test.  $P < 0.05$  was considered statistically significant.



Picture no.1 Before treatment

Picture no.2 After treatment

### Observations

A total 45 subjects were registered, with 5 being dropped out from the study, and total 40 subjects were being included in the study. Subjective were selected randomly and divided in two groups Group A and group B, each group contains 20 subjects.

The group A subjects given with Kshudrasevantika taila pichu and group B subjects given with Doorvadi taila pichu along with triphala gugulu 1tsf(5gm) every night as a stool softner. The parameter were noted before,during and after treatment. Maximum number of subjects were in the age group of 34-45years (in group A 35% in group B 85%), According to habitat in total 13 patients(32.5%) were from rural area and 27(67.5%) were from urban area. According to position of Parikartika among the 40 patients.35 (87.5%) patients had fisuure in 6'0 clock position, 5(12.5%) patients had fissure in 12'o clock position. Common site of fissure is The commonest site of fissure in Ano is posterior midline or 6'o clock position. On the base of incidences Anterior fissure are more common in women than in men and are often observed in the post parturition period.

### Results

On chief complaints Group B(Doorvadi taila pichu)provided significant results on Ulcer& Sphincter spasm. Group A(Kshudrasevantika taila pichu) showed significant results on the symptoms from table no. 1 and table no.2. overall response was better in Group B as compared to group A. Table no 3 shows the mean score of both the groups.

**Table no. 1: Comparison of the study parameters among the patients in Group A (within group Comparison)**

Parameter	Group A	Mean	Std. Dev	Std. Error Mean	t-value	df	P-value
Pain	BT	2.80	.410	.091	21.1	19	<0.0001 (S)
	AT	.10	.307	.068			
Bleeding	BT	1.75	.44	.099	17.6	19	<0.0001 (S)
	AT	.00	.000	.000			
Burning sensation	BT	2.50	.512	.114	17.9	19	<0.0001 (S)
	AT	.10	.307	.068			
Tenderness	BT	1.90	.718	.16	11.5	19	<0.0001 (S)
	AT	.100	.307	.068			
Ulcer	BT	1.00	.000	.000	19.0	19	<0.0001 (S)
	AT	.5500	.223	.050			
Sphincter spasm	BT	1.0000	20	.00000	3.94	19	0.001 (S)
	AT	.5500	20	.51042			

**Table no.2: Comparison of the study parameters among the patients in Group B (within Group comparison)**

Parameter	Group B	Mean	Std. Dev	Std. Error Mean	t-value	df	P-value
Pain	BT	2.7	.444	.099	21.1	19	<0.0001 (S)
	AT	.05	.221	.050			
Bleeding	BT	1.70	.470	.105	16.1	19	<0.0001 (S)
	AT	.00	.000	.000			
Burning	BT	2.50	.606	.135	15.9	19	<0.0001 (S)
	AT	.050	.223	.050			

Tenderness	BT	1.800	.410	.091	16.1	19	<0.0001 (S)
	AT	.1000	.307	.068			
Ulcer	BT	1.000	.22361	.05000	10.37	19	<0.0001 (S)
	AT	.1000	.30779	.06882			
Sphincter spasm	BT	1.0000	.00000	.00000	19.0	19	<0.0001 (S)
	AT	.0500	.22361	.05000			

**Table no. 3 Mean score of parameters before treatment and after treatment in group A & group B**

Mean score	Group-A		Group-B	
	BT	AT	BT	AT
<b>Pain</b>	2.80	.10	2.7	.05
<b>Bleeding</b>	1.75	.00	1.70	.00
<b>Burning sensation</b>	2.50	.10	2.50	.050
<b>Tenderness</b>	1.90	.100	1.800	.1000
<b>Ulcer</b>	1.00	.5500	1.000	.1000
<b>Sphincter spasm</b>	1.0000	.5500	1.0000	.0500

## Discussion

The incidence of fissure in ano is around one in 350 Adults and this disease is ranked third among the anorectal diseases after constipation and Hemorrhoids. As per modern science intake of non-fibrous food will leads to hardening of stools and cause Fissure-in-ano Anal fissure can be acute or chronic based on the duration. Acute anal fissure is a deep tear in the lower anal canal with severe sphincter spasm. It present with severe pain, bleeding per anum and constipation.

Fissure in ano is a medico- surgical condition. Medical management said to be conservative and surgical intervention is the ultimate choice in the chronic fissure. Medical treatment for acute fissure is oral pain killer, stool softeners, soothing ointment, self anal dilation on medical advice etc. Due to more side effect of pain relieving medicines (NSAIDS),steroids and surgical procedure, Research Scholars are focusing towards finding alternatives medicines to get better results in treating the disease.

In the present study, out of 40 patients, Maximum 24 patients( 60%) were in between age group of 34-45 years. This is probably because of irregular food habits, and nature of work coming in way of evacuation of urges. This co-relates with the incidence that the occurrence of fissure is more in mid age.so this may be the

cause of Parikartika. Among 40 patients, 30% of patients were vegetarian and 70% were of mixed diet. People with mixed dietary habits were more susceptible as the diet is usually spicy, fried, less fibers and rich starch food leads to *vataprakopa*, *agnimandya* and *vibandha* in this study..

Among 40 patients 23 patients(57.5%) were of *vata Pitta prakruti* This indicates that the dominance of *vata* and *Pitta* in the individual constitution may have a role in developing *Parikartika* .Among 40 patients, 87.5% patients had posterior fissure and 12.5% had anterior fissures. commonest site for fissure is posterior fissure due to anatomical arrangement of anal canal.

Significant improvement was found in Pain, bleeding, ulcer,tenderness, Burning sensation in both the groups may be because of *Stambhana & Raktashodhaka*, *Dahaprasamana vrana ropaka vishaghna*, *shothahara*, *Raktashodhaka* and *rakta stambhana* Properties of both group drugs helps in relieving symptoms of Parikartika.

*Kshudrasevantika taila pichu* believed to act by ‘pacifying’ the three vitiated doshas. i.e *vata pitta kapha* by multiple actions attributes to its *kashaya*(astringent) *rasa*, *amla* and *tikta uparasa*, *guru*(heaviness) and *snigdha*(unctuousness) *Guna*, *sheeta*(cold) *virya*.

*Kashaya rasa* provides *lekhana*(scraping) that helps in desloughing, preparing the wound for healing. This way, *kshudrasevantika* serves as an excellent wound healer under its *sodhana*(purification), *Ropana*(healing) and *Sandhana*(union) actions Various researches on *kshudrasevantika* (*tridax procumbens*) shows that it has *vrana ropaka*, antiseptic, insecticidal, and parasitocidal properties.

Most of the ingredients of *Doorvadi taila* are having *Madhura*, *kashaya*, *tikta*.(*rasa*) *sita*(*virya*) *Madhura vipaka* it has also *tridoshahara*, *kaphapittashamaka guna*.

*Kashaya rasa*: It does *shoshana & vranaropana*. *Tikta rasa*: It does *twak-mamsa sthreekarana & lekhana* *Stambhana & Raktashodhaka* properties hence check bleeding & discharge.this properties are likely to clear the pathogenesis of Parikartika and thus may arrest the progression of the disease.

## Conclusion

This study showed that both *pichu dharana* provided improvement in parameters like Pain,bleeding, burning sensation, tenderness, sphincter spasm, Ulcer. The effect of the treatment in both the groups has shown highly significant results (P value <0.001) in parameters like pain, bleeding, burning sensation, tenderness, ulcer & sphincter spasm.But *Doorvadi taila pichu* has shown comparatively better results on size of fissure & sphincter spasm than *kshudrasevantika taila pichu* The procedures in both the methods were same, i.e. *Pichu Dharana* which was simple, economical, free from side effects and did not require hospitalization and it could be carried out at OPD level itself. No untoward effect of the treatment was noted during the course of treatment and follow up.

## References

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