



# A Randomized Comparative Clinical Study To Evaluate The Efficacy Of Nimbapatra Taila Pichu Over Yashtimadhu Taila Pichu In The Management Of Parikartika With Special Reference To Acute Fissure In Ano

Dr. Ayesha Kaladgi <sup>1</sup>, Dr. Prasadshakti G Gannur <sup>2</sup>, Dr. Aneesur rehman Madni <sup>3</sup>

1. Final year PG Scholar

2. Professor & HOD

3. Associate Professor

Department of PG studies in Shalyatantra, BLDEA's AVS Ayurveda Mahavidyalaya  
Vijayapura. Karnataka.

## Abstract:

**Background:** Fissure in ano, a highly painful condition among ano rectal disorders, disproportionately affects individuals despite its relatively small lesion size. The prevailing sedentary lifestyle and diet lacking fibre, coupled with excessive spice consumption, have led to a surge in constipation and subsequently, an increased incidence of *Parikartika*. Given the rising prevalence, it is imperative to identify an effective treatment for *Parikartika* that facilitates rapid healing of the fissure and prevents recurrence.

**Objectives:** This study aimed to evaluate the efficacy of *Nimbapatra taila* and *Yashtimadhu taila pichu* in the treatment of *Parikartika* (Fissure in ano).

**Materials and Methods:** This comparative trial enrolled 44 patients of either sex, with clinical evidence of Fissure in ano. Patients were randomized into two groups of 22 each, designated as Group A and Group B. Patients in Group A received *Nimbapatra taila pichu* for 21 days, while those in Group B received *Yashtimadhu taila pichu* for 21 days.

**Results:** The treatment modalities of *Nimbapatra taila pichu* and *Yashtimadhu taila pichu* demonstrated equal efficacy in treating *Parikartika*. Both treatments showed highly significant effects on subjective parameters such as Pain, Burning sensation, Bleeding per Rectum as well as objective parameters like Sphincter spasm, Ulcer and Tenderness in anal region.

**Conclusion:** Clinically, both treatment groups exhibited significant improvement, with only marginal differences between them. Both groups showed significant results in all parameters, and statistical comparison revealed no significant difference between the two groups.

**Key words:** Fissure-in-ano; *Pichu*; *Parikartika*; *Nimbapatra taila*; *Yashtimadhu taila*.

## Introduction:

Ayurveda, often referred to as the 'knowledge of life', is an ancient system of medicine that remains highly relevant today due to its distinct approach to disease prevention and treatment. Ancient Ayurvedic texts offer a variety of therapeutic methods for managing various conditions.

*Parikartika*, a condition described by our Acharyas, is a complication of *virechana* and *basti*.<sup>1</sup> Acharya *Kashyapa* has also mentioned it as a condition commonly encountered in pregnant women (*garbhini*).<sup>2</sup> The symptoms of *parikartika* include *kartanavat shoola* (cutting pain) in the anus, *daha* (burning sensation) in the

anus, and *nabhi medhra basti shirasu sadaha parikartana* (severe pain in the umbilical region, anus and head).<sup>3</sup> These symptoms are often correlated with fissure in ano in modern medical terminology, characterized by cutting-type pain in the anus.

*Parikartika* is a common anorectal disorder encountered in our outpatient department, often causing severe pain that demands immediate relief. The adoption of a western lifestyle, consumption of low-fiber foods, and increased mental stress have contributed to the rising incidence and recurrence of this disease. These factors disrupt the digestive system's *jatharagni*, leading to various diseases. An anal fissure, also known as fissure-in-ano, is an elongated ulcer that occurs along the long axis of the anal canal.<sup>4</sup> Fissure-in-ano most commonly occurs in the midline posteriorly. The location of fissure-in-ano varies between genders. In males, 90% of cases occur in the midline posteriorly, while 10% occur anteriorly. In females, 60% of cases occur in the midline posteriorly, and 40% occur anteriorly.

Fissure-in-ano can be classified into two types based on clinical symptoms: Acute Fissure-in-ano and Chronic Fissure-in-ano. Acute Fissures are typically managed conservatively with oral analgesics, stool softener, soothing ointments and self-dilation. In contrast, chronic fissures often require surgical intervention, such as: Lord's dilatation, Posterior fissurectomy, Lateral sphincterotomy, Excision of anal ulcers and Anal advancement flap.<sup>5</sup>

To address the limitation of existing treatments, an effective, safe, economical, simple, and short-term therapy for Fissure-in-ano is necessary. Ancient Ayurvedic texts recommend the use of *madhura* (sweet), *sheeta* (cooling), and *snigdha* (oily) substances internally, as well as through *picchabasti* (a type of medicated enema), and *madhura kashaya dravya siddha basti* (a type of medicated enema with sweet and astringent properties). Additionally, *anuvasana basti* (a type of medicated enema) with *sneha* (oily substances) such as *taila* (oil) and *ghrita* (ghee) prepared with *Yashtimadhu* (licorice).<sup>6</sup> *Pichu* is considered safe, ideal, convenient and cost effective. As the *pichu* remains in situ for a longer duration, better absorption and action of the drug can be achieved.

## Materials And Methods:

**Selection of Patients:** A total of 44 diagnosed subjects with clinical features of *Parikartika*, who met the inclusion criteria, were selected from the Outpatient and Inpatient department of Shalya Tantra, BLDEA'S AVS Ayurveda Mahavidyalaya, Hospital & Research centre, Vijayapura. The registered subjects were randomly allocated into two groups using a random sampling technique (lottery method).

**Ethical Approval:** This study was approved by the Institutional Ethical Committee (Reference letter no-346/2022-2023 dated 15/10/2022). Additionally, the study was registered in the Clinical Trial Register of India (Registration number: CTRI/2023/01/048749) prior to the commencement of the clinical trial.

**Diagnostic criteria:** Patients presenting with symptoms of *Parikartika*, characterized by, A longitudinal ulcer in the anal region, Pain in the anal region during and after defecation, Constipation, Bleeding per anum (stool streaked with blood), Burning sensation in the anal region.

**Inclusion criteria:** Patients fulfilling the diagnostic criteria for Acute Solitary Fissure were selected for the study, Patients of both sexes, aged 17 to 70 years, were eligible for participation.

**Exclusion criteria:** Patients with *Parikartika* (Acute fissure-in-ano) and any systemic disorders, such as tuberculosis, diabetes Mellitus, malignancies, HIV, HBsAg and HCV positivity, were excluded from the study, as these conditions may interfere with the study outcomes, Patients with *Parikartika* and other associated anorectal diseases such as, fistula, haemorrhoids etc were also excluded from the study.

**Laboratory investigations:** Haemoglobin (HB%) and Random Blood Sugar (RBS) were conducted.

**Preparation of Drugs:** *Nimba patra* was collected from Natural Resources, and *Yashtimadhu* was purchased from approved vendors. The authenticity of both herbs was verified by the faculty of Dravya Guna, BLDEA's AVS Ayurveda Mahavidyalaya, Hospital & Research Centre Vijayapura. *Tila taila* was purchased from the local market and authenticated by the pharmacy of Rasashastra & Bhaishajya kalpana BLDEA's AVS Ayurveda Mahavidyalaya, Hospital & research Centre, Vijayapura. Both *taila's* were prepared according to the classical method of *taila kalpana* in the pharmacy attached to the PG studies Department of Rasashastra and Bhaishajya kalpana, BLDEA's AVS Ayurveda Mahavidyalaya Hospital and Research Centre, Vijayapur.

**Methodology:** The present clinical study aimed to evaluate the efficacy of *Nimbapatra taila pichu* (Group A) and *Yashtimadhu taila pichu* (Group B), with the latter serving as the standard treatment based on previous studies demonstrated 80% efficacy.

### Intervention Of Drugs:

GROUP	TREATMENT	DURATION
GROUP A	<i>Nimbapatra taila pichu</i> should be applied once daily in the morning, immediately after defecation.	21 days
GROUP B	<i>Yashtimadhu taila pichu</i> should be applied once daily in the morning, immediately after defecation.	21 days

- All patients in Group A & Group B were advised to take 1 teaspoon (5 gm) of *Triphala choorna* with warm water every night for 7 days, as a stool softener.
- Patients in both groups were also instructed to follow a diet rich in fiber and low in spices, and to drink plenty of oral fluids.

### Procedure for Guda-pichu:

<b>Pre-Procedure Preparation (Pooorva Karma)</b>	The entire procedure was explained to the patient, and informed consent was obtained. All necessary materials were prepared. The patient was advised to take a 15-minutes sitz bath with luke warm water.
<b>Main Procedure (Pradhana Karma)</b>	The patient was asked to assume a comfortable lithotomy position on the examination table. The perianal region was cleaned with warm water. Under aseptic conditions, an autoclaved sterile <i>pichu</i> was dipped in <i>Nimbapatra taila</i> or <i>Yashtimadhu taila</i> and inserted into the anal region using artery forceps.
<b>Post- Procedure Care (Paschat Karma)</b>	A bandage was applied, and the patient was instructed to keep the <i>pichu</i> in place for 3 hours.

Assessments for both Group A and Group B were conducted on the following days:

1. Baseline assessment: Before treatment (Day 0),
2. Mid- treatment assessments: During treatment (Day 8 and Day 15) ,
3. Post-treatment assessment: After treatment (Day 22).

The treatment period spanned 21 days, followed by a 1-month follow-up period to monitor outcomes.

**Table No:1- Subjective and Objective parameters**

NO.	SUBJECTIVE	OBJECTIVE
1.	Pain	Tenderness
2.	Burning sensation	Ulcer
3.	Bleeding per anum	Sphincter spasm

**Table No:2-Gradation of symptoms**

Grade	0	1	2	3	4
<b>Pain</b>	VAS 0	VAS 1-3	VAS 4-6	VAS 7--10	
<b>Burning sensation</b>	No burning sensation	Present during defecation	Present up to 30 min after defecation	Present more than 30 min after defecation	
<b>Bleeding per rectum</b>	No bleeding	Blood streaks on faecal matter	Bleeding during defecation	Bleeding during and after defecation	
<b>Tenderness</b>	No tenderness	The patient says the area is tender	Patient winces due to pain	Patient winces and withdraws the affected part	Patient doesn't allow touching the affected part
<b>Ulcer</b>	Absent	Present			
<b>Sphincter spasm</b>	Normal tonicity	Hyper tonicity			

**Observations:** The study population consisted of 63.6% patients aged 20-35 years, 61.36% females, 63.63% hindus, 63.63% from the middle class, 65.90% married, 61.36% vegetarian, 2.72% with vata-pitta prakruti, 72.72% with fissure at the 6'o clock position, 77.27% from urban areas, 27.27% housewives.

**Results:** The results of both groups were analyzed statistically in relation to the assessment criteria for *parikartika* (Acute fissure in ano). The findings were: **Pain**- 96.03% significant improvement in Group A and 92.1% in Group B. **Bleeding**-100% significant improvement in Group A and Group B. **Burning Sensation**- 96.2% significant improvement in Group A and 90.7% in Group B. **Tenderness**-94.9% significant improvement in Group A and 88.3% in Group B. **Ulcer**- 91% significant improvement in Group A and 81% in Group B. **Sphincter spasm**- 91% significant improvement in Group A and 81% in Group B.

**Table No:3- Effect of treatment in Group-A (Nimbapatra taila pichu):**

Parameter	Period	Mean		Diff	SD	SE	z-value	P-value
		BT	AT					
<b>Pain</b>	8 <sup>th</sup>	2.27	1.41	0.86	0.35	0.05	<b>11.53</b>	<b>&lt;0.0001(HS)</b>
	15 <sup>th</sup>	2.27	0.63	1.63	0.49	0.10	<b>15.58</b>	<b>&lt;0.0001(HS)</b>
	AT	2.27	0.09	2.18	0.39	0.08	<b>25.91</b>	<b>&lt;0.0001(HS)</b>
<b>Bleeding</b>	8 <sup>th</sup>	0.95	0.41	0.54	0.51	0.11	<b>5.02</b>	<b>&lt;0.0001(HS)</b>
	15 <sup>th</sup>	0.95	0.00	0.95	0.65	0.13	<b>6.85</b>	<b>&lt;0.0001(HS)</b>
	AT	0.95	0.00	0.95	0.65	0.13	<b>6.85</b>	<b>&lt;0.0001(HS)</b>
<b>Burning Sensation</b>	8 <sup>th</sup>	2.36	1.50	0.86	0.46	0.09	<b>8.66</b>	<b>&lt;0.0001(HS)</b>
	15 <sup>th</sup>	2.36	0.72	1.63	0.49	0.10	<b>15.5</b>	<b>&lt;0.0001(HS)</b>
	AT	2.36	0.09	2.27	0.45	0.09	<b>23.4</b>	<b>&lt;0.0001(HS)</b>
<b>Tenderness</b>	8 <sup>th</sup>	1.77	1.22	0.54	0.51	0.11	<b>5.0</b>	<b>&lt;0.0001(HS)</b>

	15 <sup>th</sup>	1.77	0.54	1.22	0.61	0.13	<b>9.41</b>	<0.0001(HS)
	AT	1.77	0.09	1.68	0.56	0.12	<b>13.8</b>	<0.0001(HS)
<b>Ulcer</b>	8 <sup>th</sup>	1.00	1.00	0.0	0.0	0.0	---	---
	15 <sup>th</sup>	1.00	0.63	0.36	0.49	0.10	<b>3.46</b>	0.002(S)
	AT	1.00	0.09	0.91	0.29	0.06	<b>14.4</b>	<0.0001(HS)
<b>Sphincter spasm</b>	8 <sup>th</sup>	1.00	1.00	0.0	0.0	0.0	---	---
	15 <sup>th</sup>	1.00	0.63	0.36	0.49	0.10	<b>3.46</b>	0.002(S)
	AT	1.00	0.09	0.91	0.29	0.06	<b>14.4</b>	<0.0001(HS)

Table No:4- Effect of treatment in Group-B (*Yashtimadhu taila pichu*):

Parameter	Period	Mean		Diff	SD	SE	t-value	P-value
		BT	AT					
<b>Pain</b>	8 <sup>th</sup>	2.41	1.45	0.95	0.21	0.04	<b>19.5</b>	<0.0001(HS)
	15 <sup>th</sup>	2.41	0.54	1.86	0.35	0.07	<b>23.4</b>	<0.0001(HS)
	AT	2.41	0.18	2.22	0.42	0.09	<b>23.2</b>	<0.0001(HS)
<b>Bleeding</b>	8 <sup>th</sup>	1.22	0.54	0.68	0.47	0.10	<b>6.71</b>	<0.0001(HS)
	15 <sup>th</sup>	1.22	0.04	1.18	0.66	0.14	<b>8.34</b>	<0.0001(HS)
	AT	1.22	0.00	1.22	0.68	0.14	<b>8.4</b>	<0.0001(HS)
<b>Burning Sensation</b>	8 <sup>th</sup>	1.95	1.45	0.50	0.51	0.11	<b>4.58</b>	<0.0001(HS)
	15 <sup>th</sup>	1.95	0.54	1.41	0.59	0.12	<b>10.9</b>	<0.0001(HS)
	AT	1.95	0.18	1.77	0.52	0.11	<b>15.7</b>	<0.0001(HS)
<b>Tenderness</b>	8 <sup>th</sup>	1.54	1.22	0.31	0.47	0.10	<b>3.13</b>	0.005(S)
	15 <sup>th</sup>	1.54	0.54	1.00	0.61	0.13	<b>7.59</b>	<0.0001(HS)
	AT	1.54	0.18	1.36	0.58	0.12	<b>11.0</b>	<0.0001(HS)
<b>Ulcer</b>	8 <sup>th</sup>	1.00	1.00	0.00	0.00	0.00	--	---
	15 <sup>th</sup>	1.00	0.54	0.45	0.50	0.11	<b>4.18</b>	
	AT	1.00	0.18	0.81	0.39	0.08	<b>9.72</b>	
<b>Sphincter Spasm</b>	8 <sup>th</sup>	1.00	1.00	0.00	0.00	0.00	--	---
	15 <sup>th</sup>	1.00	0.54	0.45	0.51	0.10	<b>4.18</b>	<0.0001(HS)
	AT	1.00	0.18	0.81	0.39	0.08	<b>9.7</b>	<0.0001(HS)

**Discussion:** The incidence of anorectal disorders is steadily increasing in modern society, largely attributed to sedentary lifestyles, irregular eating habits, prolonged sitting, and psychological factors like anxiety and depression. These factors can disturb the digestive system, or *Jatharagni*, leading to conditions like *Vibandha* (constipation) and its associated symptoms. Common anorectal disorders such as hemorrhoids, fistula-in-ano, and fissure-in-ano are frequently encountered in outpatient departments. Even mild cases can cause significant discomfort because of the dense nerve endings in the perianal region, which makes it one of the most pain-sensitive areas of the body.

In recent years, *Parikartika* (fissure-in-ano) has become a noteworthy issue. While it isn't directly referenced in ancient Ayurvedic texts, *Arshas* (hemorrhoids) is mentioned as an anorectal condition. It is unclear whether the ancient scholars were aware of *Parikartika* but chose not to mention it or simply didn't recognize it as a distinct entity. However, some descriptions suggest it could be related to complications arising from treatments like *Virechana*, *Basti Karma*, and pregnancy-related issues, as well as conditions like *Atisara* (diarrhea) and *Jwara* (fever).

Interestingly, *Parikartika* is not formally categorized as a separate disease in Ayurvedic literature. Its relatively low incidence in ancient times may have been due to the people's adherence to *dinacharya* (daily routines), *ritucharya* (seasonal routines), and dietary principles, which may have minimized its occurrence and made it less noticeable to the ancient scholars. Various treatment approaches for *Parikartika* have been practiced, including *Deepana* (digestive stimulant), *Pachana* (digestion), *Vatanulomana* (regulation of *Vata dosha*), and local applications like *taila* (oils), as well as dietary changes. In this study, *Guda Pichu* (local application of medicated cotton) was chosen due to its effectiveness in promoting ulcer healing. Along with medication, dietary modifications play a crucial role in managing this condition. A fiber-rich diet that includes green leafy vegetables and fruits can help prevent constipation, while sufficient fluid intake helps soften stools. Regular physical activity is also essential, along with avoiding prolonged sitting or long-distance driving. A sitz bath with warm water can help relax the sphincter muscles and alleviate pain.

#### Probable Mode Of Action Of Drug:

**Nimba (Azadirachta indica):** *Nimba* possesses several properties that contribute to its therapeutic effects: *Tikta-kashaya rasa*-Helps in balancing *pitta* and *kapha doshas*, *Laghu guna*- Exhibits *lekhana* (scraping), *ropana* (healing) and *sheeghra paki* (quick action) properties. *Sheeta veerya*- Provides a cooling effect. *Kapha-pitta shamaka*-Balances *kapha* and *pitta doshas*. *Dahaprashamana*- Relieves burning sensation, *Vrana shodhana*-Cleanses wounds, *Vrana ropana*- Promotes wound healing, *Vedana sthapana*-Relieves pain. The active ingredients in neem leaves, such as nimbidin and sodium nimbidate, possess anti-inflammatory, anti-bacterial, anti-fungal and anti-viral properties that aid in wound healing.<sup>7</sup>

**Yashtimadhu (Glycyrrhiza glabra):** *Yashtimadhu* exhibits several properties that contribute to its therapeutic effects: *Madhura rasa*-Balances *Vata*, *Pitta* and *kapha doshas*, *Guru, snigdha guna*: Provides a soothing and calming effect, *Sheeta veerya*- offers a cooling effect, *Madhura vipaka*- Balances *pitta dosha*, *Tridoshahara*-Balances all three *doshas*, *Daha shamaka*-Relieves burning sensation, *Vedana sthapaka*-Relieves pain, *vrana shodhana*- cleanses wounds and *vrana ropana*-Promotes wound healing.<sup>8</sup>

**Tila taila (Sesame Oil):** *Tila taila* serves as a base oil for preparing *Nimbapatra taila* & *Yashtimadhu taila*. Its properties include: *Ushna veerya*- Provides a warming effect, *vyavayi, vishada, sukshma, tikshna, guru, vikasi, lekhana, sara gunas* exhibits various properties that aid in wound healing and pain relief.<sup>9</sup> *Tila taila* helps in reaching minute channels due to its *sukshma, vyavayi, and vikasi gunas*, reducing pain and inflammation.

**Triphala churna :** *Triphala churna* exhibits the following properties: *kashaya -tikta rasa*-Balances *pitta* and *kapha doshas*, *Laghu, rooksha, teekshna gunas*- Exhibits *lekhana, ropana* and *sheeghra paki* properties, *Mrudu virechaka* property-Facilitates easy passage of stool and *Vrana ropana* property-Promotes wound healing. *Triphala churna*, when given with warm water at bedtime, aids in easy stool passage and wound healing due to its *mrudu virechaka* and *vrana ropana* properties.

**Conclusion:** The treatment outcomes in both groups demonstrated statistically highly significant results (P-value <0.001) for subjective parameters such as pain relief, Reduction in burning sensation and Decrease in bleeding per rectum, similarly, significant improvements were observed in objective parameters, including ulcer healing, Reduction in sphincter spasm and Decrease in tenderness. These findings indicate that both treatments were highly effective. However, *Nimbapatra taila pichu* demonstrated superior results compared to *Yasthimadhu taila pichu*, suggesting its potential as a more effective treatment option for *Parikartika* (Fissure-in-ano).

### References:

1. Sushruta, Sushruta Samhita with the commentaries, NibandhaSamgrahaCommentary of Dalhanacharya edited by VaidyaJadavjiTrikamji and Narayana Ram Kavyatirth Chaukhambha. Varanasi: Orientalia; Reprint edition 2009, Chikitsa sthana, Chapter 34, verse 16, pp 824, Pg 524.
2. Kashyapa samhita or vrddhajivakiya tantra Khila sthana with English translation and commentary, Edited by prof.P.V.Tewari,Choukhambha visvabharati Varanasi,reprint-2020, Chp-10. Pg-565.
3. Maharashi Sushruta,Sushruta Samhita Chikitsa Sthana,Edited with Ayurveda- tattva-sandipika Hindi commentary by Kaviraj Ambikadutta Shastri,Vol-1,Ed- Reprint-2017,Choukambha Sanskrit Sansthan Varanasi.,Chp-34/16 pg-187.
4. Williams NS, et all. Bailey and Love"s short practice of surgery.26th ed. Newyork: CRC press; 2013.pp 1517.
5. Das somen. A Concise Textbook of Surgery. 4th ed. Calcutta: Dr. S. Das; Reprint 2002. pp. 1324.
6. Maharashi Sushruta,Sushruta Samhita Chikitsa Sthana,Edited with Ayurveda-tattva-sandipika Hindi commentary by Kaviraj Ambikadutta Shastri,Vol-1,Ed- Reprint-2017,Choukambha Sanskrit Sansthan Varanasi.,Chp-34/16 pg-187.
7. J.L.N. Sastry and Tanuja M.Nesari A Text Book Of Dravyaguna Vijnana,Vol II First Edition 2018,Chaukhambha Orientalia Varanasi Chp.66 pg-212.
8. J.L.N.Shastry. Illustrated DravyagunaVijnana.Varanasi: ChaukambhaOrientalia; 2nd ed. 2005. Vol.2.pg no-152-155.
9. Bhavaprakasha of bhavamishra English translation by Prof.K.R.Srikantha Murthy Publisher; Chowkhambha krishnadas academy Varanasi 2011 Vol 1 pgno-475





**Fig no: 1- Nimba patra**



**Fig no:2- Yashtimadhu mula**



**Fig no:3- Preparation of Nimbapatra taila**



**Fig no:4- Preparation of Yashtimadhu taila**



**Fig no:5- Prepared Nimbapatra taila**



**Fig no:6- Prepared Yashtimadhu taila**

- IMAGES OF GROUP -A AND GROUP-B BT & AT



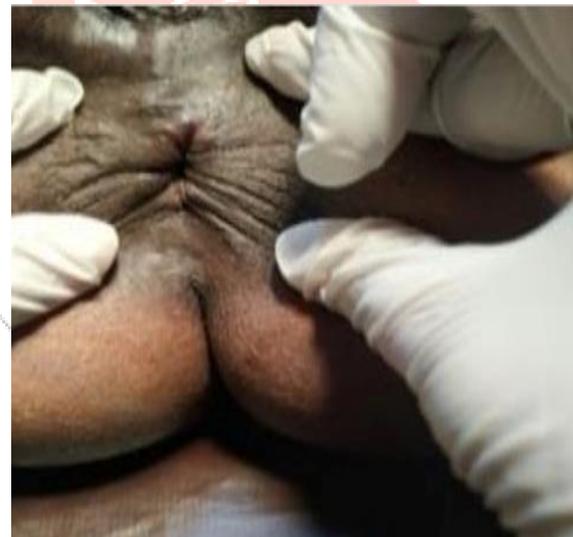
**Fig No:7- Pre-treatment image of fissure in ano showing ulceration.**



**Fig No:8- Post-treatment image after 21 days of *Nimbapatra taila pichu* therapy, showing healed ulceration.**



**Fig No:9- Pre-treatment image of fissure in ano showing ulceration.**



**Fig No:10-Post-treatment image after 21 days of *Yashtimadhu taila pichu* therapy, showing healed ulceration.**