



Management of acute fissure in ano by *Pterocarpus santalinus* ointment (LA) and oral Phytotherapy

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ABSTRACT

Background: Anal fissure is defined as longitudinal tear in lower end of anal canal. In modern science, conservative treatment of acute fissure in Ano includes oral analgesic and laxative along with ointment having anesthetic & healing properties with varied prognosis. Similarly, surgical treatment such as lateral sphincterotomy, dorsal fissurectomy and anal advancement flap is practiced with underlying complications such as recurrence, incontinence is even more agonizing than actual pathology. According to Ayurveda *Parikartika* can be co-related with Fissure in ano. *Bhesaja chikitsa* is considered as first line of treatment and *deepan*, *pachan*, *anuloman* drugs are advocated along with local therapies such as *Basti* and *Guda Pichu* etc.

AIM: To evaluate the clinical efficacy of *Pterocarpus santalinus* ointment (locally) along with *Terminalia chebula* tablet (internally) in the management of *Parikartika* w.s.r. Acute Fissure- In-Ano.

Method: This is a single arm clinical interventional study. Total 50 patients of acute fissure in ano were selected for this study. Patients were treated with *Pterocarpus santalinus* ointment (locally) for 7 days along with *Terminalia chebula* tablet (orally) for 14 days. The parameters such as pain, per rectal bleeding, anal sphincter spasm, size of ulcer and Constipation were assessed before, during and after treatment.

Results: Before starting treatment on 1st day median value of pain and constipation was 3.00 and after completion of treatment it was gradually reduced to 0. Further, on 1st day median value of per rectal bleeding, anal sphincter spasm and size of ulcer was 2.00 and on 14th day median value 0 showed that the bleeding was completely stopped. Similarly, anal sphincter spasm was completely relieved and the size of ulcer also reduced to 0 i.e. healed on completion of treatment.

Conclusion: The prescribed combination therapeutic intervention proved effective in reducing symptoms of Acute fissure in Ano such as pain, p/r bleeding, anal sphincter spasm, size of ulcer and constipation.

KEYWORDS: Fissure-in-ano, *Parikartika*, *Pterocarpus santalinus*, *Terminalia chebula*

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INTRODUCTION

Fissure in Ano is an ulcer in the longitudinal axis of the lower part of the anal canal. (1) It is very common and painful condition. In males' fissures usually occur in the midline posteriorly (90%) and much less commonly anteriorly (10%). In females fissures on the midline posteriorly commoner than anteriorly (60:40). (2) The curvature of the sacrum and rectum, hard faecal matter while passing down causes a tear in the anal valve leading to posterior anal fissure. Anterior anal fissure is common in females due to lack of support to pelvic floor. Other causes of fissure in ano are haemorrhoidectomy, Crohn's disease, venereal disease, ulcerative colitis and tuberculosis. (3) Acute fissure in ano is characterised by severe anal pain associated with defecation, which usually resolves spontaneously after a variable time only to recur at the next evacuation, as well as the passage of fresh blood, normally noticed on the tissue after wiping. (4) Conservative treatment of Fissure in ano are includes laxatives, xylocaine surface anesthetic application, 2% nifedipine ointment, fiber rich diet, adequate fluid intake and sitz bath. Similarly, Surgical treatment includes lateral anal sphincterotomy, dorsal fissurectomy and anal advancement flap. (5)

According to Ayurveda *Parikartika* can be correlate with Fissure in ano. '*Parikartika*' has been mentioned as one of the complications of *Bastinetrayapad*, *Virechanavyapad*. (6,7) Acharya Charak and Kashyap has also described *Parikartika* as *bastivyapad* and complication of *Vatajaatisara*. (8,9) It is characterized by *Kartanavat* and *Cheanavatshoola* in *Guda*. (10) *Parikartika* is treated with internal palliative medicines and local applications formulated by using *Madhura*, *sheeta*, *snigdhadravayas*. Local therapies in the form of *Anuvasanabasti*, *Picchabasti*, *Madhura*, *Kashaya dravyasiddha basti*, *Tailapoorana*, *Lepa*, *Pichu dharana* given prime important in the management. (11) However, these treatment procedures have their own limitations and there is no common established conservative line of treatment for *Parikartika*.

AIM OF STUDY

To evaluate the efficacy of *Pterocarpus santalinus* ointment (locally) along with Tablet *Terminalia chebula* (internally) in the management of Acute Fissure in ano.

METHODOLOGY

Materials and Methods

The patients with acute fissure in ano were registered randomly from out-patients department Shalyatantra, D.Y Patil Ayurvedic hospital. Written informed consent was taken from all patients prior to embarking on the examination and treatment. Findings in each case were recorded over a follow-up of 14 days. A total number of 50 cases were selected irrespective of age, gender, occupation and religion. The study was approved by Institutional Ethics committee. This clinical trial also registered in CTRI and the number is CTRI/2022/05/042470. Drug authentication, antimicrobial test and standardization (HPTLC test) of *Pterocarpus santalinus* ointment were done.

Inclusion criteria was having Patient of Acute Fissure in Ano, age group between 18-60 years and new cases who didn't receive any local treatment.

Exclusion criteria were having Chronic fissure-in-ano, secondary to ulcerative colitis, Crohn's disease etc. Patients with uncontrolled systemic disease as like as diabetes, hypertension, malignancies, HIV, HBsAG and VDRL positive, carcinoma of rectum and bleeding disorders were excluded from the study.

Withdrawal criteria were development of severe drug reactions, profuse bleeding or any other severe illness.

Trial drug and duration

Pterocarpus santalinus ointment (*Raktachandan malhar*) after defecation in morning & at night (locally) for seven days.

Tablet *Terminalia chebula* (*Terminalia chebula churna Vati*) 500mg 4 tablets at night with luke warm water (orally) for 14 days.

This clinical treatment period was of 14 days.

Dietary regimen: Dietary & Lifestyle modifications: Patients will be advised to reduce spices, coffee, tea, oily, cold beverages, constipating food such as *maida*, *pasta*, *potato*, white bread, non-vegetarian diet and to have sufficient dietary roughage like fruits, vegetables, whole meal bread along with plenty of water, daily butter milk after meals and avoid long-term travelling by roads and *Ratrijagaran*.

Diagnostic Criteria:

Laboratory investigations: CBC, Fasting blood sugar, post prandial blood sugar, BT, CT, LFT were carried out before start treatment.

Follow-up - Patients were called for follow-up from day 0, 1st, 3rd, 5th, 7th and 14th days.

ASSESSMENT CRITERIA:

For the therapeutic evaluation parameter such as Pain, Anal sphincter Spasm, size of Ulcer, P/R bleeding and constipation were assessed. [Table no. 1]

Observation and Result

In this present study maximum patient (68%) were having severe pain at anal region. The hard stool and straining provoke *Vata dosha* causes trauma to the anal mucosa resulting into pain.

Before starting treatment on 1st day median value of pain was 3.00 and after completion of treatment it was reduced gradually to 0.

Out of 50 patient 47 patients had per rectal bleeding, where as maximum patients were having moderate bleeding (50%) and 8% patients were having severe per rectal bleeding. On initial day before starting treatment median value of p/r bleeding is 2.00 and on 14th day median value 0 showed that the bleeding was completely stopped after their completion of treatment.

Out of 50 patient maximum numbers of patients were having anal sphincter spasm. After treatment 48 patients were cured and 2 patients got no improvement. On 1st day median value of anal sphincter spasm is 2.00 and after completion of treatment value was 0.

Further, maximum number of patients were having medium size of fissure (58%). On 1st day median value of size of ulcer is 2.00 and on 14th day median value 0 showed that the size of ulcer was completely healed on completion of treatment.

Furthermore, constipation is the cardinal symptoms of this disease. Maximum numbers of patients (60%) were having moderate constipation and 38% patient were having severe constipation. Before starting the intervention, on 1st day median value of constipation is 3.00 which is also gradually completely reduced to 0 after completion treatment.

The assessment of the results was made by adopting the standard method of scoring the sign and symptoms of Acute fissure in ano. [Table 2], [Fig 1,2]

DISCUSSION:

This clinical study was conducted to evaluate the efficacy of *Pterocarpus santalinus* ointment (locally) along with Tab *Terminalia chebula* (internally) in the management of Acute Fissure in ano. Amongst patients, the incidence of Acute fissure in ano was more in the age group of 18-30 years (42%), males (64%), serviceman (58%), mixed dietary habits (82%), *Vata-Pittaja* (54%) and persons having *Mandagni* (indigestion) and in the individuals indulging sedentary life style. Further, as the study was primarily aimed to access the efficacy of therapy on symptoms of fissure in ano, hence the demographic data can't help in drawing any such conclusion.

Pain which is the most evident and presenting symptom of fissure in ano. In this present study maximum patient (68%) were having severe pain at anal region, 50% patients were having moderate per rectal bleeding, 50% patients were having moderate anal sphincter spasm, and 60% patients were having moderate constipation.

The study revealed that on 1st day median value of pain and constipation was 3.00 and after completion of treatment it was gradually reduced to 0. Further, on 1st day median value of per rectal bleeding, anal sphincter spasm and size of ulcer was 2.00 and on 14th day median value 0 showed that the bleeding was completely stopped. Similarly, anal sphincter spasm was completely relieved and the size of ulcer also reduced to 0 i.e., healed on completion of treatment.

Thus, the prescribed combination therapeutic intervention proved effective in reducing symptoms of Acute fissure in Ano such as pain, p/r bleeding, anal sphincter spasm, size of ulcer and constipation.

Probable mode of action:

Mode of action of *Pterocarpus santalinus* ointment:

Pterocarpus santalinus ointment exhibits local effects. It heals the ulcers without causing strictures. *Pterocarpus santalinus* has a property of *Ropan* (healing), which helps in the granulation the wound, stabilizes endothelial lining, and prevents bleeding. (14) According to Ayurvedic text book *Pterocarpus santalinus* has properties like *varnya*, *Sothahara* (anti-inflammatory), *srotovishodhan* (channel detoxification), *vranashodhan* (cleaning wound), *vranaropan* (healing wound) and *Dahshamak* (burning sensation inhibitor). (12,13)

Mode of action of Tablet *Terminalia chebula*: Oral medication of Tablet *Terminalia chebula* having *Kasaya rasa* (Astringent taste) *Pradhan* but possess *Anuloman* property. The composition of its rest of the *rasa*, *ushna veerya* (hot in potency) and *Madhura vipaka* (sweet after digestion) helps in *malapachan* (digestion) and leads to easy evacuation of stools from bowel. Hence, *Terminalia chebula* was chosen for systemic management in the study. (14,15)

CONCLUSION

In this clinical study, patient with acute fissure in ano were treated with *Pterocarpus santalinus* ointment (locally) along with Tablet *Terminalia chebula* (orally). Application of *Pterocarpus santalinus* ointment proved user-friendly, ambulatory and cost-effective preparation. *Pterocarpus santalinus* has properties like *Vedanashamak* (Analgesic) & *Dahasamak* (burning sensation inhibitor). So, it was observed that pain -burning sensation and per rectal bleeding were relieved significantly (within 2-4 application), without any side effect by local application of *Pterocarpus santalinus* ointment. This therapeutic intervention proved efficacious in reducing symptoms of Acute Fissure in ano such as pain, burning sensation, p/r bleeding, anal sphincter spasm, size of ulcer and constipation on completion of treatment.

Declaration of patient consent

The authors certify that they have obtained patient consent for images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest - There are no conflicts of interest.

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Table 1: Showing the gradations of parameters for assessment.

PARAMETER	GRADATIONS	SCORE	
<i>Gudagatashoola</i> (pain)	No Pain	0	0
	Mild pain	1-3	+
	Moderate pain	4-6	++
	Severe pain	7-10	+++
<i>Gudagata Rakta Strava</i> (PR Bleeding)	NO Bleeding	0	0
	Mild (<5drops)	1-3	+
	Moderate(5-10)	4-6	++
	Severe(>10 drops)	7-10	+++
Anal Sphincter spasm	No spasm / Per rectal digital examination can be done without pain	0	0
	Per rectal digital examination can be done with mild pain	1	+
	Per rectal digital examination can be done with moderate pain	2	++
	Not allowing per rectal digital examination due to severe pain	3	+++
Size of Ulcer	No ulcer	0	0
	Wound size reduces to 75%	1	+
	Wound size reduces to 50%	2	++
	Baseline (actual size on Day 1)	3	+++
Constipation	Minimal or no effort to defecate	0	0
	Mild effort or straining required to defecate	1	+
	Moderate or straining required to defecate	2	++
	Unable to defecate despite maximum effort or straining	3	+++

Table 2: Shows overall statistical analysis of all parameters.

Parameters	Statistical Analysis	P. SANTALINUS OINTMENT						
		Day 0	Day 1	Day 3	Day 5	Day 7	Day 14	AT
PAIN	Median	3.00	3.00	2.00	1.00	0	0	0
	Range	0-3	0-3	0-3	0-1	0	0	0
	Total Score	130	130	84	52	19	4	4
	Sample size	50						
	P Value	P<0.01, Highly significant						
PR Bleeding	Median	2.00	2.00	1.00	0	0	0	0
	Range	2.00	0-3	0-1	0	0	0	0
	Total Score	78	78	37	14	3	2	2
	Sample size	50						
	P Value	(p<0.01).00, Highly significant						
Size of ulcer	Median	2.00	2.00	1.00	1	1	1	1.00
	Range	1-2	1-2	0-1	0-1	0-1	0-1	0-1
	Total Score	103	103	54	24	15	9	
	Sample size	50						
	P Value	P<0.0001, Highly significant						
Anal Sphincter Spasm	Median	2.00	2.00	1.00	0.00	0.00	0	1.00
	Range	1-2	1-2	0-1	0-1	0	0	0-1
	Total Score	119	119	78	47	12	2	2
	Sample size	50						
	P Value	(p<0.01) Highly significant						
Constipation	Median	3.00	3.00	2.00	1.00	0	0	1.00
	Range	1-3	1-3	1-2	1-1	0	0	0-1
	Total Score	132	132	84	45	13	8	8
	Sample size	50						
	P Value	(p<0.01), Highly significant						

Figure 1: Before treatment



Figure 2: After treatment

