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Clinical Efficacy of *Parnabeejadi* Rectal Suppository in the Management of *Parikartika* (Acute Fissure-In-Ano) – Randomized Controlled Clinical Trial

Supriya Kurane-Singh[1], Vivek Singh[2], S. D. Waghmare[3]

Abstract

Acute fissure-in-ano is a distressing and common anorectal condition characterized by painful defecation and rectal bleeding. Although several treatment modalities are available in conventional surgery, the search for an effective and safe remedy remains ongoing. This study aims to assess the efficacy of *Parnabeejadi* rectal suppository as compared to diclofenac rectal suppository in managing acute fissure-in-ano. It was an open-label randomized controlled clinical trial. A total of 30 patients were enrolled in each group, patients of Group A received *Parnabeejadi* rectal suppository whereas patients of Group B were treated with diclofenac rectal suppository per anum, twice a day for a period of 2 weeks. The parameters for assessment were pain in the anal region, measured using a Visual Analog Scale, burning sensation, and bleeding P/R. Both groups showed a highly significant reduction in pain and burning sensation after 2 weeks of treatment, whereas the *Parnabeejadi* group had a better effect on bleeding P/R compared to the diclofenac group ($P < 0.05$).

Keywords: Acute fissure-in-ano, *Parikartika, Parnabeeja, Parnabeejadi* suppository

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Background

Acute fissure-in-ano is a very common and painful anal condition. As the condition becomes chronic, it may be associated with the presence of hemorrhoids or a sentinel tag. The prevalence rate of fissure-in-ano is 15.62% (males – 76.20% and females – 23.80%). Almost 40% of patients who present with acute fissure progress to chronic fissure-in-ano.[1] Hence, to restrict the progress of the disease and the emergence of complications it should be treated early.

The disease *Parikartika* described in *Ayurveda* can be correlated with fissure-in-ano.[2-4] Sushruta has described features of *Parikartika* such as cutting or burning pain in the anus, penis, umbilical region, and neck of the urinary bladder with cessation of flatus.

A sedentary lifestyle, stressful life, irregular dietary habits, etc. have a key role in the occurrence of *Parikartika*. Excessive consumption of *Katu*, *Tikta*, *Lavana Rasa*, *Ushna Aahara,* and irregular timing of food and sleep are the precipitating factors. In the acute type of fissure-in-ano, there is a spasm in the anal musculature so that with each defecation there is pain. The burning sensation after defecation disturbs the daily activities of a person and due to tightness in the anal region, ulceration develops with the passage of stool.

The treatment protocol for fissure-in-ano depends on the type of the disease; e.g., in cases of acute variety with a short history of the problem, it can be treated on the conservative lines, which include oral pain-killing medication to be taken before anticipated bowel movement. A stool softener may be used to make the stool soft, weak bulk laxatives or cathartics are used. Soothing ointment, self-dilatation, etc. are also considered to be of sufficient usefulness.

Various forms of local treatments were studied in fissure-in-ano earlier such as ointment, matra basti, tail pichu, etc.,[5-7] which are found effective. In this study, an anal suppository form of local treatment is used as it is easy to self-administer and hassle-free.

[1]Department of Shalyatantra, Institute of Teaching and Research in Ayurveda, Jamnagar, Gujarat, India.

[2]Department of Rachana Sharir, Shree V. M. Mehta Institute of Ayurveda, Rajkot, Gujarat, India.

[3]Department of Shalyatantra, R.A. Podar (Ayu.) Medical College, Mumbai, Maharashtra, India.

Corresponding Author: Supriya Kurane-Singh. Department of Shalyatantra, Institute of Teaching and Research in Ayurveda, Jamnagar, Gujarat, India. E-mail: drsupriyakurane123@gmail.com

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Aims and Objectives

To evaluate and compare the efficacy of *Parnabeejadi* suppository and diclofenac suppository in the management of acute fissure-in-ano.

Methods

Trial Design

It was an open-label randomized controlled clinical trial.

Participants

Patient inclusion criteria were as follows:

(1) Diagnosed case of acute fissure-in-ano, (2) either gender was included in the study, (3) age: 18–50 years, (4) acute fissure during pregnancy and during the lactation period.

The exclusion criteria were as follows:

(1) Other anorectal conditions such as chronic fissure-in-ano, fistula-in-ano, internal or external piles, (2) Crohn's disease, (3) ulcerative colitis, (4) anal tuberculosis, (5) congenital anomalies of the anus, (6) acquired immunodeficiency syndrome, (7) syphilis, (8) diabetes.

The study was conducted at M.A. Podar Hospital, Worli, Mumbai. The study was approved by the Institutional Ethics Committee – Reference no. 5613 dated August 06, 2013, and done during the period of 2013–2015. The patients were selected from the outpatient department and inpatient department of Shalya Tantra at the same hospital.

Randomization

A computer-generated randomization table was used for randomization.

Sixty patients matching with inclusion criteria were randomly assigned into Group A – 30 (experimental group) and Group B – 30 (control group).

Intervention

- Group A: *Parnabeejadi* rectal suppository – Two times a day
- Group B: Diclofenac rectal suppository – Two times a day.

Duration of Treatment

Two weeks.

Follow Up

Four weeks.

Common treatment for both groups:

Gandharva Haritaki Churna (*Eranda Bhrishta Haritaki*) at bedtime was given as a laxative to both groups and a sitz bath with warm water was advised twice a day to maintain hygiene at the anal region.

Trial Drug

The *Parnabeejadi* suppository was made in Rasashastra Department of R.A. Podar Ayu. Medical College, Mumbai.

Method of Preparation

Parnabeeja and *Erandamoola* siddha *ghrita* were prepared using the standard method of preparation of *ghrita* as stated in *Sharangadhara samhita*, then it was converted into suppository using a mold with bee wax as a base and adding *Shuddha Gairik* to it.[8,9]

Parameters for Assessment

1. Pain in the anal region
2. Burning sensation after defecation
3. P/R bleeding.

A. Assessment of pain in the anal region

The Visual Analog Scale was used to assess the severity of pain (Table 1).

B. Assessment of local burning sensation

0 – No burning sensation
1 – Mild= Up to ½ h after defecation
2 – Moderate = Up to 2 h after defecation
3 – Severe = More than 2 h after defecation

C. Assessment of P/R bleeding

0 – No bleeding PR
1 – Streak of blood with stool
2 – 1–2 drops of blood
3 – more than 2 drops of blood.

Statistical Methods

The effect of intervention on parameters before and after treatment was assessed by the Wilcoxon Signed Rank test and to compare between two groups Mann–Whitney Test was used.

Results

Demographic Data and Clinical Characteristics

The maximum number of patients in the study belonged to the age group 21–30 years (31 patients), followed by patients of the age group 31–40 years (17 patients). The number of female patients was found to be more in this study (males – 23 and females – 37). In this study, the patients of Vata-pittaja, Vata-Kaphaja, and Kapha-Vataj prakruti were found to be more prone to this disease (Table 2). Posterior fissure was observed in more proportion in both the groups (Group A – 46.66% and Group B – 53.33%) (Table 3).

Effect of Interventions on Parameters of Assessment

A statistically significant effect ($P < 0.0001$) was noted in a burning sensation in either group (Tables 4 and 5) and in comparison between the two groups non-significant difference ($P > 0.05$) was observed (Table 6). In this trial, the statistically significant effect ($P < 0.0001$) was noted in pain relief in either group (Tables 4 and 5), and in comparison between the two groups non-significant difference ($P > 0.05$) was observed (Table 6). In bleeding P/R, *Parnabeejadi* suppository (Group A) showed a highly significant effect ($P < 0.0001$), whereas in Group B, it was

Table 1: Visual Analog Scale

0	*1 2*	*3 4*	*5 6*	*7 8*	*9 10*
No Nil	Mild Mild	Discomfort Moderate	Distress	Horrible Severe	Excruciating

Table 2: Prakruti-wise distribution

Prakruti	*Experimental*		*Control*	
	No. of Patients	*%*	*No. of patients*	*%*
VP	5	16.66	8	26.66
VK	8	26.66	4	13.33
PV	5	16.66	6	20
PK	3	10	4	13.33
KV	6	20	8	26.66
KP	3	10	0	0

Table 3: Distribution according to position of fissure

Position	*Group A*		*Group B*		*Total*	
	No	*%*	*No.*	*%*	*No*	*%*
Anterior	8	26.60	5	16.66	13	21.66
Posterior	14	46.66	16	53.33	30	50
Both	6	20	8	26.60	14	23.33
Other	2	6	1	3.33	3	5

Table 4: Experimental group

Symptoms	*Mean*	*SD*	*SE*	*W*	*N*	*Value of Z*	*P*	*Results*
Burning sensation								
BT	1.43	0.81	0.14	351	30	3.60	<0.0001	Highly significant
AT	0.36	0.49	0.08					
DIFF	1.07	0.32	0.06					
Pain								
BT	2.8	1.6	0.30	435	30	4.47	<0.0001	Highly significant
AT	0.73	0.90	0.16					
DIFF	2.07	0.7	0.14					
Bleeding P/R								
BT	1.06	0.69	0.12	300	30	3.08	<0.0001	Highly significant
AT	0.16	0.37	0.06					
DIFF	0.9	0.32	0.06					

Table 5: Control group

Symptoms	*Mean*	*SD*	*SE*	*W*	*N*	*Value of Z*	*P*	*Results*
Burning sensation								
BT	1.56	0.85	0.15	190	30	1.95	<0.0001	Highly significant
AT	0.70	0.65	0.11					
DIFF	1.07	0.32	0.06					
Pain								
BT	2.8	1.3	0.24	465	30	4.78	<0.0001	Highly significant
AT	0.56	0.67	0.12					
DIFF	2.24	0.63	0.12					
Bleeding P/R								
BT	0.93	0.69	0.12	66	30	0.67	<0.001	Significant
AT	0.56	0.67	0.12					
DIFF	0.37	0.02	0.00					

Table 6: Comparative efficacy of both groups: Mann–Whitney U test

Symptoms		*U*	*U*[1]	*R1*	*R2*	*Z*	*P*	*Result*
Burning sensation	Bt-At	387	512	977	852	0.89	>0.05	Not significant
Pain	Bt-At	445	455	910	920	−0.36	>0.05	Not significant
Bleeding P/R	Bt-At	238	661	1126	703	4.038	0.0016	Significant

also statistically significant ($P < 0.001$) (Tables 4 and 5). The results of the Mann–Whitney test were significant ($Z = 4.038$, $P \leq 0.001$). In comparison between the two groups, a significant difference ($P \leq 0.001$) was observed (Table 6).

Discussion

Fissure-in-ano and an ulcer elsewhere in the body are different as concerned with healing as in the former case there is constant contamination of the wound by feces and its frequent friction with mucosa, also often there is a spasm of sphincter muscles. These factors keep fissures away from normal healing. For the treatment of acute fissure-in-ano, it is better to give locally acting remedies to avoid systemic side effects and for early results.

Suppository is feasible to use as a drug delivery system. There is direct access to the site of action and trans-mucosal absorption is faster.

Diclofenac has anti-inflammatory, antipyretic, and analgesic action, and inhibits prostaglandin synthesis by inhibition of cyclo-oxygenase.[10] Diclofenac suppository is commonly used as an analgesic in painful anal conditions including fissure-in-ano. It has certain contra-indications such as active gastrointestinal bleeding, renal and cardiac insufficiency, hypersensitivity, etc. In this study, it was found effective in relieving pain and burning sensation in anal region.

Parnabeeja (*Bryophyllum pinnatum*) has *Kashay Rasa*, *Madhur Vipaka*, *Shita Virya*, *Vata-Pitta Shamak*, *Vranashodhan,* and *Vranaropana* properties.[11] It has anti-inflammatory and analgesic properties.[12] Gairik has *Madhur Rasa* and *Madhur Vipaka*, *Snigdha*, *Rakta-Pitta Shamak*, *Daha-Kandu Shamana*, *Vranaropana*, and *Vishanashak* properties.[13] Ghee as a base for suppository or ointment acts as a carrier for delivering herbal medicine to deeper tissues.[14] It has *Vata-Pitta Shamak* and *Vranaropaka* properties. It facilitates wound healing with early epithelialization.

Parnabeejadi rectal suppository was found equally effective as diclofenac suppository in managing pain and burning sensation at anal region and was better effective in bleeding per rectum because of its *Rakta Stambhaka* and *Vranaropaka* property. With *Parnabeejadi* suppository lubrication of anal canal takes place which further soothes the next episode of defecation, also it does not cause soiling of clothes as it occurs with local application of any ointment or jelly.

A maximum number of patients in the study belonged to the age group 21–30 years, followed by patients in the age group 31–40 years. This shows that the disease acute fissure-in-ano is more common in middle-aged people. This could be because of improper dietary habits, sedentary lifestyle, and the nature of work coming in the way of evacuation of urges. All of the patients reported constipation as a preceding history. The low fiber content in diet and sedentary lifestyle could be the reason for that, mild laxative like *Gandharva Haritaki Churna* at bedtime was found effective for preventing hard stools. Sitz bath with lukewarm water twice a day improves local blood circulation and helps to relieve the spasm.

Conclusion

Parnabeejadi suppository and diclofenac suppository both are equally effective in reducing pain and burning sensation in acute fissure-in-ano, whereas *Parnabeejadi* suppository is slightly better in bleeding per rectum.

Scope for Further Studies

This study was carried out on a limited number of patients; a larger study is needed for future huge database statistical study. Therefore, we may conclude that with this sample study which shows a positive result, a large-scale study can also be undertaken in the future. There is scope for study regarding anorectal mucosal absorption and systemic effects of *Parnabeejadi* suppository. Testing of suppositories, such as melting range test, liquefaction or softening time test, breaking test, dissolution test, etc., should be done in the standard pharmacological laboratory.

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