

Efficacy of *Palashadigudavarti* (Ayurvedic Anal Suppository) in comparison with Diclofenac Sodium Suppository in the management of *Parikartika* (Acute fissure in ano)

Research Article

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Abstract

Introduction: *Parikartika* is most common ano-rectal disorder. The text of *parikartika* is mentioned in *Samhitas*. In this disease there are symptoms such as bleeding per rectum, hard stools, burning sensation around anal region. In this trial, group A (n=30) included *Palashadigudavarti*, whereas group B included Diclofenac sodium suppository for administration over *Parikartika* (acute anal fissures). *Gandharva haritaki choorna* acts as laxative and helps to relieve constipation and sitz bath was given to both group as conservative management. Materials and method: Literary aspect of the study was collected from classical Ayurvedic and contemporary text and updated with recent medical journals, previous research work done on same topic. Observation and results: Assessment was done by the parameters such as pain, bleeding and itching as Subjective and healing as Objective Parameter. Results were obtained by statistical analysis. Discussion: In this research work *Palash*, *Goghrita* and *Beewax* as suppository base was used in the form of *varti* application (advanced anal Suppository) for managing Anal fissure. There is need of ayurvedic suppository easily available in market which will relieves anorectal symptoms instantly, because repeated use of diclofenac sodium have side effect to the body. In the present case series, it proved to be significant in managing Fissure in ano, it reduced pain, itching, bleeding and promoted healing. Conclusion: In the treatment of *Parikartika*, *Palashadigudavarti* was more effective than Diclofenac sodium suppository.

Key Words: *Parikartika*, fissure in ano, *Palashadigudavarti*, Diclofenac Sodium Suppository.

Introduction

In modern medicine, *Parikartika* is associated with fissure-in-ano, with cutting and searing pain at *Guda* (anal region), which is described as a result of some disorders or as an obstacle to some *Panchakarma* treatments. (1) It was not described in extensively in classical *Ayurvedic* texts such as *Bruhatrayi*. It is mostly discussed in those compendia's as a complication of *Virechana* and *Atisar*. (2) A fissure in ano is a crack or tear in the anal canal's muco-cutaneous junction. It produces acute discomfort during defecation with the passage of small amounts of blood, i.e. blood streaks. Fissure in ano primarily is of two types viz. Acute and chronic. Secondly it is caused due to other diseases. (3) Contributing factors include prolonged constipation, spasm of the internal sphincter, surgical disaster during haemorrhoids surgery and anal stenosis, which can lead to anal fissure. Secondary factors such as Crohn's

illness, Ulcerative colitis, Syphilis, HIV, Tuberculosis, and even pregnancy have all been blamed for the disease fissure-in-ano development Acute fissure in ano usually responds well to conservative treatment, but when it gets converted into chronic fissures which is generally associated with the tag it needs surgical intervention. Currently, treatment for anal fissures comprises laxatives, topical anesthetic agents, antibiotics, and painkillers. If this treatment fails, the patient is advised to undergo surgery, which has its own set of restrictions. As a result, despite numerous changes in conservative and surgical improvements, controlling anal fissures remains a difficulty even for skilled anorectal surgeons. (4)

Various research works has been conducted to evaluate efficacy of new medicaments to treat anal fissures in Ayurved. This study was also aim to evaluate a better alternative treatment for Anal fissures. In this research work *Palash*, *Goghrita* and *Beewax* as suppository base was used in the form of *varti* application (advanced anal Suppository) for managing Anal fissure. (5) *Palash* is a folklore medicine used by the tribal people for managing wound/ulcer. (6) *Palash* also act as analgesics, anti-inflammatory, anti-fungal activity and reduce itching . (7) Using this reference study was conducted.

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Aim and Objective of the Study

To rule out Efficacy of *Palashadigudavarti* in comparison with Diclofenac Sodium Suppository in the management of Acute Fissure in ano (*Parikartika*) and to standardize the ayurvedic suppository which will have instant relief with no side-effects and easily available in management of *parikartika* (Acute Fissure in ano).

Hypothesis

• **Null Hypothesis (H₀):** There is no significant difference observed in the comparative study between Efficacy of *Palashadigudavarti* and Diclofenac Sodium Suppository application in the management of *Parikartika* (Acute Fissure in ano).

Alternative Hypothesis

- **(H₁):** *Palashadigudavarti* is more efficacious than Diclofenac Sodium Suppository application in the management of *Parikartika* (Fissure in ano).
- **(H₂):** *Palashadigudavarti* is equally efficacious as Diclofenac Sodium Suppository application in the management of *Parikartika* (Fissure in ano).
- **(H₃):** *Palashadigudavarti* is less efficacious than Diclofenac Sodium Suppository application in the management of *Parikartika* (Fissure in ano).

Material and Methodology

Raw Material required for the study was taken by Rasashala of Mahatma Gandhi Ayurved College Hospital and Research Center, Salod Wardha, Maharashtra

Total 60 patients were selected from OPD and IPD of Mahatma Gandhi Ayurved College Hospital and Research Center, Wardha, Maharashtra.

The Study was open randomized control trial single blind parallel. The patients were selected by computerized simple random sampling method.

Approval for study was taken on 13/08/2020 from IEC committee of the Institute with Reference no. MGACHRC/IEC/August-2020/97. The Clinical trial was enrolled with CTRI No CTRI/2020/09/027734 on dated 03/09/2020.

Inclusion Criteria

Patients willing for the informed written consent as per Helsinki Declaration with age group of 20 years to 50 years. Following screening, clinical characteristics of Acute Fissure in ano were included. Patients of all genders, occupations, and socioeconomic backgrounds were included.

Exclusion Criteria

Patients with systemic illnesses such as diabetes, tuberculosis, HIV positive, HBsAg positive, Hepatitis B, known cases of cancer, Inflammatory bowel, diverticulitis, and chronic fissure in ano with 4th grade anal spasm

Study Design

Patients were allocated equally in two groups through Computer Generated Randomized table

method. Study Group A included 30 patients and Control Group B included 30 patients with treatment plan as shown in Table 2.

Statistical analysis

Statistical analysis was carried out using inferential and descriptive statistics such as the Chi square test, Student's paired and unpaired t test, and Graph pad Prism 6.0 version, with p0.05 regarded to be the level of significance.

Method of preparation

Palashadigudavarti was prepared as per *Varti kalpana* mentioned in *Bhaishhaya Ratnavali* by moulding method at Rasashala of Mahatma Gandhi Ayurved College Hospital and Research Center, Salod Wardha, Maharashtra.

Palashgudavarti preparation method

Firstly, the Part of *Kalka dravya* (paste of leaves) 4 parts of cow ghee and 16 parts of Drava (Water) were mixed together & heated by *Mandagni*. *Agni* used for *Sneha pak*: *Mridu* and *Madhyamagni* only. *Palash ghruta* was prepared. Vessel used for *Sneha pak* was stainless steel vessel. Bee wax was melted in vessel separately. Then the mixture of *Palash ghruta* were added and mixed thoroughly with the bee wax. The properly mixed *Churna* and base was then poured in the mould. The mould was kept for freezing in the refrigerator (Temperature- < 25 C). After half – one hr the mould was taken out from the refrigerator. suppositories were taken out from the mould and packed in the aluminium foil. The suppositories were then stored in the refrigerator.

Table 1: Contents of *Palashadigudavarti*

No	Drug	Botanical name	Part used	Proportion
1	Palash kalka	Butea Monosperma (Lam.)Taubert.	Bark	1
2	Palash Kwatha	Butea Monosperma (Lam.)Taubert.	Bark	4
3	Go Ghrita	-	-	4
4	Suppository Base (Bee wax)	-	-	1

Figure 1: Prepared Suppository

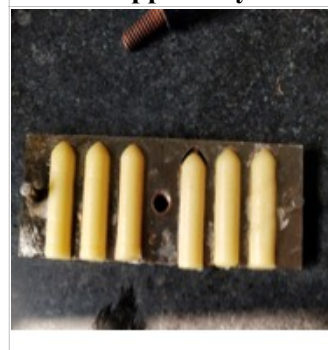


Figure 2: Suppository Packaging



Table 2: Treatment and Posology

	Sample Size	Intervention	Dose	Anupana	Route	Days
Study Group A	30	<i>Palashadigudavarti</i>	1 suppository Twice a day		Rectally	14 days
Control Group B	30	Diclofenac Sodium Suppository	1 suppository Twice a day	-	Rectally	14 days
Conservative Treatment		<i>Gandharva Haritaki Choorna</i>	7gm Once a day at night time	Lukewarm Water	Oral	1 month

Table 3: Methodology

Methods	
<i>Purva karma</i>	Selection of patients- symptomatic findings, relevant investigations and structured written consent <i>Palashadigudavarti</i> was prepared and stored in cool temperature. Raw materials were kept ready.
<i>Pradhan a Karma</i>	Under all aseptic precautions, cleaning and sterile draping done In study group <i>Palashadigudavarti</i> and in control group Diclofenac Sodium Suppository were gently pushed in the anal canal with help of finger. Antiseptic Dressing Done.
<i>Paschat Karma</i>	Lukewarm water Sitz Bath- Twice a day <i>Gandarva Haritaki Choorna</i> 7gm at night with lukewarm water Follow up on 7 th , 14 th , 28 th Day and assessment was done.

Assessment Criteria

Grading of Objective Parameters

1. Parikartika Healing (8) (Southampton Wound Grading System)

Table 2: Parikartika Healing

Grade	Explanation
Grade 0	Scar formation with complete healed
Grade I	Granulation tissue present with partial healing
Grade II	Wound without any associated symptoms (like Discharge or pus)
Grade III	Deep wound with associated symptoms (like Discharge or pus)

Grading of Subjective Parameters

Pain (9)

Table 3: Grading of Parameters

Grade	Pain	Bleeding per rectum	Itching (Pruritus Severity Scale)
Grade 0	No pain	Absent	No complaints of itching
Grade I	Mild pain	Very mild (Less Quantity)	Occasional itching.
Grade II	Tolerating pain relieved by analgesics	Mild	Frequent itching.
Grade III	Need oral analgesics SOS.	Severe (May require Blood Transfusion)	Continuous itching
Grade IV	Need oral analgesics regularly	Debilitating blood loss (Life Threatening)	

Observations and Results

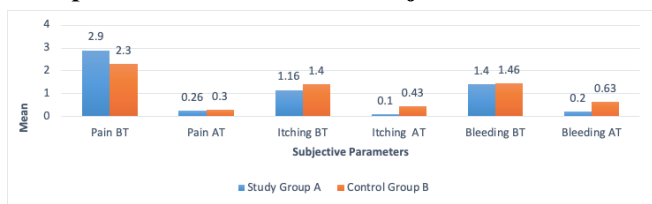
All the patients were examined before, during and after the intervention as per the case sheet format given in the annexure. Assessments were done on 0, 7th, 14th and 28th day, both subjective and objective criteria were recorded accordingly. The data recorded are presented under the Statistical method.

Overall Effect in both groups on Pain, Itching and Bleeding Parameters

Table 4: Overall Effect in Subjective Parameters

	Group	Mean Value Difference			p-Value	Significant
		Before Treatment	After Treatment	SD		
Pain	Study Group A	2.90	0.26	0.44	p= 0.0001	S
	Control Group B	2.30	0.30	0.46	p= 0.0001	S
Comparison of both groups (Mann Whitney U test) z= 0.28, p=0.77						
Itching	Study Group A	1.16	0.10	0.30	p= 0.0001	S
	Control Group B	1.40	0.43	0.50	p= 0.0001	S
Comparison of both groups (Mann Whitney U test) z= 2.78, p=0.005						
Bleeding	Study Group A	1.40	0.20	0.40	p= 0.0001	S
	Control Group B	1.46	0.63	0.66	p= 0.0001	S
Comparison of both groups (Mann Whitney U test) z=2.89, p=0.004						

Graph 1: Overall Effect in Subjective Parameters



In comparison of both groups in pain $z=0.28$, Itching $z=2.78$, Bleeding $z=2.89$. The p value is significant in pain, itching and bleeding parameter by using Mann Whitney test. Hence the intervention drug is having significant results in both group in this parameter.

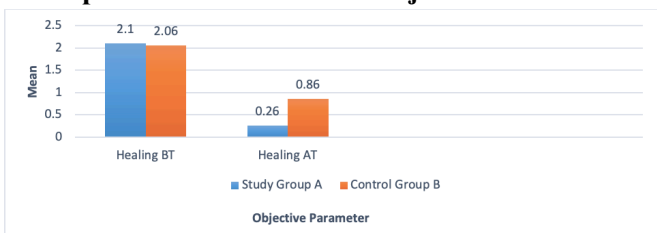
Overall Effect and Comparison of Treatment in both groups on Fissure Healing

Table 5: Overall Effect in Objective Parameter

Fissure Healing					
	Before	After	SD	p-Value	Signific
Study	2.10	0.26	0.44	p=	S
Control	2.06	0.86	0.34	p=	S

Comparison of both groups (Mann Whitney U test) $z=4.65$,

Graph 2: Overall Effect in Objective Parameter



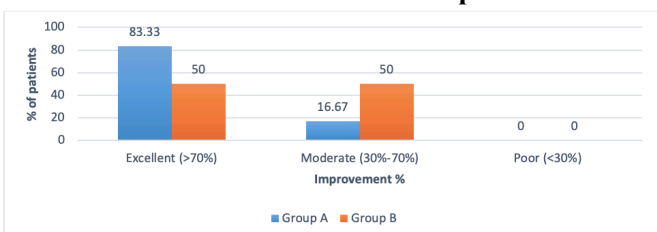
The mean value of Healing in Group A before treatment is 2.1 and Group B is 2.06. The mean value of Healing in Group A after treatment is 0.26 and in Group B is 0.86. The p value is significant in healing parameter by using Mann Whitney test. Hence the intervention drug is having significant results in both groups in this parameter.

Comparison of Percentage of relief after treatment in two Groups

Table 6: Comparison of Percentage of relief after treatment in two Groups

Relief criteria	Study Group A		Control Group B	
	Frequency	Percent	Frequency	Percent
Excellent (>70%)	25	83.33	15	50
Moderate (30%-70%)	5	16.67	15	50
Poor (<30%)	0	0	0	0
Total	30	100	30	100

Graph 3: Comparison of Percentage of relief after treatment in two Groups



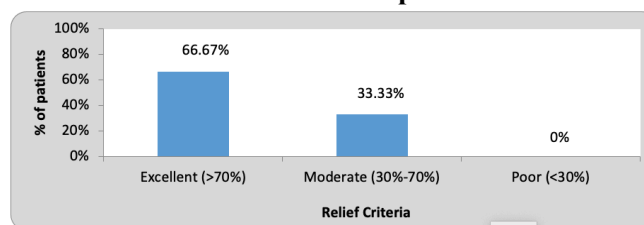
In Group A of percentage of excellent relief after treatment is 83.33%, moderate relief after treatment is 16.67% and in Group B of percentage of excellent relief after treatment is 50%, moderate relief after treatment is 50%. That means Group A is more efficacious than Group B in management of acute fissure in ano.

Comparison of Percentage of relief after treatment in total patients

Table 7: Comparison of Percentage of relief after treatment in total patients

Relief criteria	No. of	Percentage of
Excellent (>70%)	40	66.67
Moderate (30%-70%)	20	33.33
Poor (<30%)	0	0
Total	60	100

Graph 4: Comparison of Percentage of relief after treatment in total patients



Overall in 40 patients the relief of symptoms in acute fissure in ano was 66.67% and in 20 patients was 33.33%. That means treatment given in both groups was effective to reduce symptoms of acute fissure in ano.

Clinical Image of Patient in Group A (Palashadigudavarti Application)

Figure 3: Before Treatment Day 0 (2/09/21) **Figure 4: After Treatment Day 7 (9/09/21)**

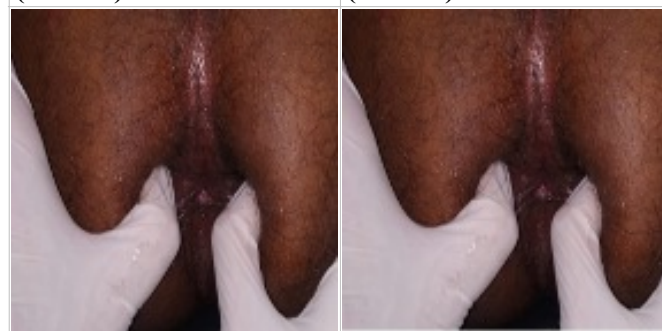


Figure 5: After Treatment Day 14 (16/09/21) **Figure 6: After Treatment Day 28 (23/09/21)**



Discussion

There is need of Ayurvedic suppository should be invented because as compare to diclofenac sodium suppository had side effects and cannot use for longer time. Hence standard ayurvedic suppository should easily available with instant relief from symptoms of anorectal problems. In the present research work 60 patients of *Parikartika* were selected as per inclusion and exclusion criteria. They were divided into two Groups randomly. Group A patients were subjected to *Palashadigudavarti* local application over *Parikartika* whereas Group B patients were subjected to Diclofenac Sodium Suppository local application over *Parikartika*. Assessment was done by Objective and Subjective Parameters before and after treatment using Statistical Analysis. Subjective Parameters includes Pain, Bleeding and Itching parameters and in Objective parameter includes Healing Scale.

Probable mode of action of *Palashadigudavarti*

Palashadigudavarti has *vranashodhana* and *ropana*, characteristics that can aid in the healing of a *Vrana* (ulcer). (12) Also it having analgesic property to relieve pain in anal region. (13) It's one of the ingredients is *Ghrta*, which has *Samskaranuvarti* (i.e. it improves the characteristics of the medication) and property of healing. (14) *Palashadigudavarti* is cost effective because to readily available components and a time-tested traditional composition.

As mentioned earlier *Palash* is a traditional medicine used by the tribal people in day to day medicines. We find its reference in Ayurvedic classics by many author. Pharmacological action of any drug depends on its chemical constituents and here there is no conjecture that owing to number of chemicals present in *Palash*, it works incredibly. It was found to be important in this case series for treating Acute Fissure in ano, since it decreased pain, itching, bleeding, and improved healing. It contains Butein which is anti-inflammatory, antipruritic, antioxidant, anticancer, antidiabetic, hypotensive and neuroprotective effect. (15) Also it contains ethanolic extract which is highly responsible for wound healing (16) and methanolic extract of the stem bark of *palash* showed analgesic and anti-inflammatory properties. (17) Medicarpin extract of *palash* had greater antifungal activity than the standard fungicide benlate against *cladosporium cladosporioides*. (18) *Palash* is effective in treating any ulcer, including anal fissures, and managing discomfort due to all these characteristics of its chemical constituents. While Diclofenac sodium suppository mainly act as anti-inflammatory and analgesic property. (19)

Discussion on Overall Effect and Comparison of Treatment in both groups:

In Study Group A of percentage of excellent relief after treatment is 83.33%, moderate relief after treatment is 16.67% and in Control Group B of percentage of excellent relief after treatment is 50%, moderate relief after treatment is 50%. The null

hypothesis is rejected and the alternative hypothesis is approved after taking into account all of the data, results, statistical analysis, and its interpretation in the current study. It is observed that *Palashgudavarti* application is more efficient than Diclofenac Sodium Suppository in the therapy of *Parikartika* (Acute fissure in ano).

Conclusion

Palashadigudavarti was more efficacious than Diclofenac Sodium Suppository in management of Acute fissure in ano. Diclofenac suppository acts only on pain but *Palashadigudavarti* acts on wound healing, analgesics, bleeding and itching. Ayurvedic suppository can be widely used as it is cost-effective, no side effects. It might replace various types of ointments, lotions, creams used in wound at anal region specially in fissure in ano.

Conflict of Interest: Nil

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