

A RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF JATIPHALADI VATI IN ARSHA WITH SPECIAL REFERENCE TO 1st AND 2nd DEGREE INTERNAL HAEMORRHOIDS.

Dr. Santosh S. Pathak^{*1}, Dr. Vinay R. Sonambekar², Dr. Pankaj P. Dixit³ and Dr. Bhausahab Suryavanshi⁴

¹Assistant Professor, Guide, Shalyatantra Department, A.S.S. Ayurved Mahavidyalaya Nashik, Maharashtra.

²HOD, Shalyatantra Department, A.S.S. Ayurved Mahavidyalaya Nashik, Maharashtra.

³Associate Professor, Shalyatantra Department, A.S.S. Ayurved Mahavidyalaya Nashik, Maharashtra.

⁴PG Scholar, Shalyatantra Department, A.S.S. Ayurved Mahavidyalaya Nashik, Maharashtra.

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***Corresponding Author: Dr. Santosh S. Pathak**

Assistant Professor, Guide, Shalyatantra Department, A.S.S. Ayurved Mahavidyalaya Nashik, Maharashtra.

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ABSTRACT

In Ayurveda, treatments for Arsha can be categorized into medicinal (Bhaishajyachikitsa) and surgical (Shalya Chikitsa) approaches. Among these, Vatikalpna, or herbal formulations, is of particular interest for research in medicinal treatment. One notable formulation is *Jatiphaladi Vati*, as described in the Bhaishajya Ratnavali. *Jatiphaladi Vati* has shown promising results in reducing the symptoms of Arsha due to its effective combination of ingredients. It is a non-invasive and patient-friendly alternative to surgical methods. During my research assignment, *Jatiphaladi Vati* was dispensed from the Shalyatantra OPD, demonstrating that its oral administration is highly convenient and effective for patient. Given the limited previous research in this area, the efficacy of *Jatiphaladi Vati* in treating Arsha is a subject of ongoing evaluation, highlighting its potential as a valuable treatment option.

KEYWORDS: Arsha, *Jatiphaladi Vati*, Ayurved.

INTRODUCTION

Ayurveda, the traditional system of medicine originating from ancient India, is dedicated to maintaining the health of the healthy and curing the diseased. Among its eight branches, Shalya Tantra (surgery) holds a crucial place. Acharya

Sushruta, a seminal figure in this field, is often referred to as the "Father of Surgery." His work, encapsulated in the Sushruta Samhita, forms the bedrock of many principles in modern surgical practice. In contemporary India, a rapidly industrializing society faces numerous health challenges. The competitive and stressful nature of modern life, coupled with irregular dietary habits and a predilection for fast, spicy foods, significantly impacts digestive health. This disruption often manifests in anorectal disorders, with Arsha (also known as hemorrhoids) being a prevalent condition. Arsha is categorized under the "Astumahagada" (eight great diseases) in Ayurveda due to its severe, persistent nature and involvement with vital points (Marma).

Arsha, in Ayurvedic terms, correlates with what modern science identifies as hemorrhoids—varicosities and dilations of the hemorrhoidal veins in the anal canal. The condition is known for its chronic and troublesome nature, often resisting treatment and causing significant discomfort.

In the Nidan Sthana of the Ashtanga Hridaya^[1], a classical Ayurvedic text, Acharya Vagbhata provides a detailed description of Arsha. According to Vagbhata, Arsha is a complex disorder that can be challenging to treat (dushchikitsy), tends to persist for a long duration (dirghakalanubandhi), and affects the crucial anatomical points (Marma) of the body.

अरिवत्प्राणीनो मांसकीलको विशसन्ति यत।

अर्शासि तस्मादुच्यते गुदमार्गविरोधतः ॥ अ.ह.नि.७/१

Arsha, a condition identified in Ayurveda, is likened to a muscular projection (Mans-keel) that troubles the patient like an enemy. This condition involves a structural derangement, primarily affecting the anal region. According to Ayurveda, Arsha results from the vitiation of the doshas—Vata, Pitta, and Kapha—that contaminate the tissues (twak, mansa, rakta, meda) and impair the function of Apana Vayu. This disturbance causes Mansa (muscle) growth at the anal opening, leading to Arsha.

The development of Arsha is associated with Agnimandya (digestive impairment). Ayur vedic treatment for Arsha, known as Bhaishajyachikitsa, must address the following therapeutic action^[2]

अग्निसन्दीपनार्थं च रक्तसन्ग्रहाय च दोषाणाम् पचनार्थम् च परम् तिक्तैः उपचरेत् ॥ [च. वि. १४/१८३]

Agnisandipan (stimulation of digestive fire)

Agnidipaka (digestive enhancement)

Doshashamak (balancing of doshas)

Anuloma (normalizing bowel movement)

Tikta Rasatmaka (bitter-tasting, which aids in treatment)

Raktasangrahak (blood-regulating)

Doshapachaka (dosha-pacifying)

In Ayurveda, treatments for Arsha can be categorized into medicinal (Bhaishajyachikitsa) and surgical (Shalya Chikitsa) approaches. Among these, Vatikalpna, or herbal formulations, is of particular interest for research in medicinal treatment.

Acharya Charaka emphasizes conservative treatments, focusing on suitable dietary regimes and medications to improve Agni (digestive fire) through deepan (appetizer) and pachan (digestive) actions. Haemorrhoids, known as Arsha in Ayurveda, are a common anorectal disease affecting 50-60% of people at some point in their lives, with both males and females equally affected. The exact cause of hemorrhoids remains unclear, but they can be triggered by straining during bowel movements, chronic diarrhea or constipation, low fiber diet, and lack of exercise.

Regarding prevalence, Arsha affects a significant portion of the population. Studies indicate a prevalence rate of approximately 39.93%, with classification showing 72.89% for Grade 1 haemorrhoids, 18.42% for Grade 2, and 8.16% for other grades. Globally, the prevalence of haemorrhoids in the general population is estimated at **4.4%** (<https://www.news-medical.net>). In our day to day opd practice become across at least 4 to 5 patients suffering from the Arsha out of 10. The reason behind it is only the fast changing lifestyle. Haemorrhoids can be managed through conservative or surgical treatments. Conservative treatments typically include laxatives and symptomatic relief, whereas surgical options such as cryosurgery, dilatation, haemorrhoidectomy, stapling, rubber band ligation, and sclerotherapy are available but can be costly and associated with post-operative pain. In Ayurveda, treatment modalities for Arsha include.^[3,4,5]

चतुर्विधो अर्शसां साधनोपायः। तद्यथा भेषजं क्षारोऽग्नि शस्त्रमितिः ॥" [सु.चि ६/३]

Bhaishajyachikitsa (medicinal treatment)

Kshar Karma (chemical cauterization)

Agnikarma (thermal cauterization)

Shastra Karma (surgical technique)

AIM

- 1) To Evaluate the Clinical Efficacy of Jatiphaladi Vati in the Treatment of Arsha.

OBJECTIVES

- 1) To Study the Raktastambhaka Effect of Jatiphaladi Vati in the Treatment of Arsha.
- 2) To Study the Effect of Jatiphaladi Vati on Agnimandya. (Digestive Impairment)

MATERIALS & METHODS

Materials

1. Jatiphaladi Vati (**Trial Group**)
2. Tablet Pylonash (**Control Group**)
3. 40 patients **in each group**
4. Case Record Form
5. Patients Information Form
6. Informed Consent Document

Methods

Methodology for Literary Review

Compiled references from available Ayurvedic literature on Arsha.

Reviewed previous research and scholarly work on the subject.

Utilized this literary review to inform the clinical aspects of the study.

Methodology for Collection of Drugs

Drug Source

Obtained all drugs from authorized dealers who provided GMP-certified and purified churna.

Ensured that the drug preparation adhered to Standard Operating Procedures (SOP) under the Vati Kalpana of Bhaisahjya Kalpana.

Drug Review^[5,10]

GROUP A

Drug Name	Latin Name	Ras	Vipak	Virya	Guna	Part Use	Karma
1) Jatiphal	Myristica Fragrans	Tikta, Katu	Katu	Ushna	Laghu, Tikshna	Fruit	Vedanasthapana, Raktastambhak, Shothahar, Agnideepana, Vatanuloma
2) Lavang	Syzygium Aromaticum	Tikta, Katu	Katu	Shit	Laghu, Snighdha	Flower Bud	shoolprashman, Deepana, Vranshodhak, Vranropak
3) Pippali	Piper Longum	Katu	Madhur	Anushnashit	Laghu, Snighdha, Tikshna	Fruit	Arshoghna, Vatanulomak, Agnideepana Vatanulomak
4) Saindhav	Unique Chloride of Sodium	Lavan	Katu	Ushna	Laghu, Ruksha	Churna	Deepana, Pachana
5) Shunthi	Zingiber Officinalel	katu,	Madhur	Ushna	Laghu, Snigdh	Rhizome	Arshoghna, Shoolprashman
6) Dhaturbeej	Dhatura Metel	Tikta	Katu	Ushna	Laghu, Ruksha	Beej	Vedanasthapan, Kandughna, Shothahar
7) Hingul	Sulfuratum Hydrargyrum	Tikta, Katu	-	-	-	Bhasma	Yoagvahi, Rasayan,
8) Tankan	Sodium Pyro Borate	Katu	-	-	Ushna	Bhasma	Gnideepana Balya, Hrudy

GROUP B DRUG REVIEW OF TABLET PYLONASH AUSHADHI BHAVAN NASHIK.

Ingredients (Composition)

3.20 Table showing contents of tablet pylonash

1) Rason	100mg
2) Shunthi	100mg
3) Hingu	100mg
4) Nimb Beej	100mg
5) Shuddha Guggul	100mg

Method of Preparation of Jatiphaladi Vati

Preparation Process

Raw drug powders (Churna) in equal proportions:

Ingredients

Jatiphal (Myristica fragrans), Lavang (Syzygium aromaticum)

Pippali (Piper longum), Saindhav (rock salt)

Shunthi (Zingiber officinale), Sudha Dhaturbeej (seeds of Datura metel)

Sudha Hingul (sulfurated mercury), Tankan (sodium pyroborate)

Bhavana: Jambir Swaras

Mixing: All the ingredients were combined in powdered form (Churna) in equal proportions.

Tablet Formation: The mixture was processed using a machine to form tablets, with each tablet weighing approximately 500 mg.

Drying and Packaging: After tablet preparation, the tablets were dried and then packed in airtight containers to ensure preservation.

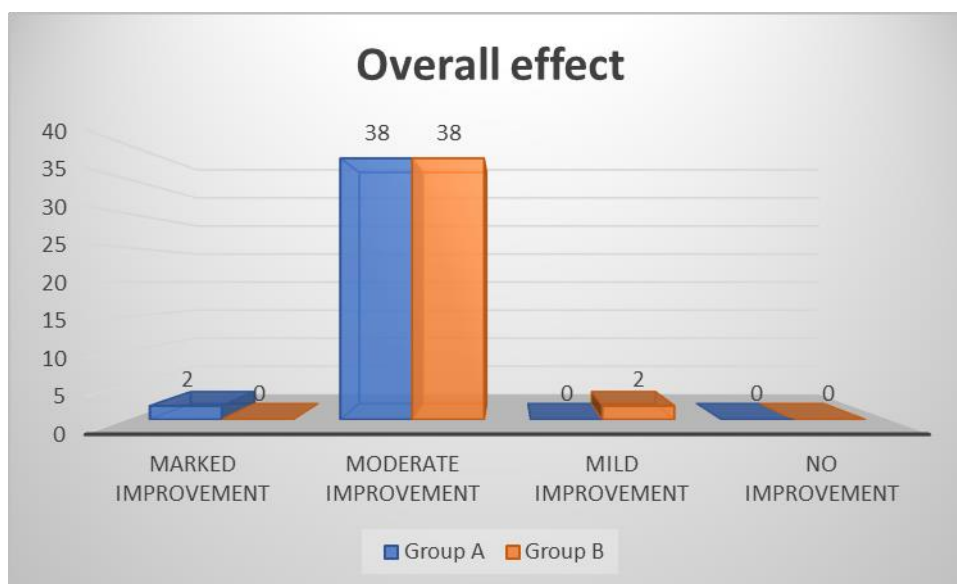
Quality Control: The preparation was conducted in the Rasashastra Bheshajya Kalpana Department under the supervision of experts. Samples were sent for physicochemical analysis to confirm quality and efficacy.

Additional Information: Tablet Pylonash was sourced from Aushadhi Bhavan pharmacy in the market for comparative studies or use alongside Jatiphaladi Vati. This method follows the traditional guidelines outlined in the Sharangdhar Samhita and ensures a standardized approach to the preparation of Jatiphaladi Vati, adhering to quality control measures for safety and effectiveness.

TREATMENT DETAILS

PARAMETER	TRIAL GROUP A	CONTROLLED GROUP B
No of patients	40	40
Treated with	Jatiphaladi Vati	Tablet Pylonash
Dose	2 2 tablet of 500mg BD /Day	2 tablet 500mg BD /day
Frequency	Twice day	Twice day
Duration	28 days	28 days
Route of administration	Oral	Oral
Anupan	Koshna jala	Koshna jala
Kala	Before meal Apan kala	Before meal Apan kala

OBSERVATIONS



Upashaya	Group A		Group B	
	Frequency	Percentage	Frequency	Percentage
Uttam	2	5	0	0
Madhyam	38	95	38	95
Alpa	0	0	2	5
Anupashaya	0	0	0	0

Interpretation: Above table and graph reveal that, 5% patients in group A.

Uttam Upashaya, 95% showed Madhyam Upshaya. In group B, 0% patients showed Uttam Upashaya ,95% showed Madhyam Upshaya and 5% showed alpa Upshaya. No patient in both groups with Anupashaya.

So, it is clear that group A is more effective than group B.

DISCUSSION

1 Discussion on General observation of the patient

1. Disribution of patients

This research included a total of 80 patients. They were further divided into two equal groups, Group A and Group B.

2. Age

Above figure reveals that, in group A, 27.5% belongs to age group 41-50 yrs, followed by 25% from 31-40 and 51-60 yrs respectively. 17.5% from age group 21-30 yrs and only 5% from age group 61-70 yrs.

In group B, 32.5% belongs to age group 41-50 yrs, followed by 22.5% from 31-40 and 21-30 yrs respectively. 17.5% from age group 51-60 yrs and only 5% from age group 61-70 yrs

3. Gender

Above figure reveals that, in both groups male patients are more than female. In group A, 82.5% and in group B, 72.5% are male patients.

This suggested that males had a higher incidence rate of Arsha illness (60-70 percent).

4. Aahar

Above figure reveals that, in both groups maximum patients prefer mixed type of diet.

In group A, 92.5% and in group B, 87.5% patients prefer mixed diet and remaining are vegetarian.

5. Occupation

Above figure reveals that, in group A, 17.5 % patients are teacher, 12.5% doing private job, farmer, and student respectively. 10% are driver and in other profession respectively. 7.5% are housewives and 5% are retired.

In group B, 15% patients are housewives and student respectively, 10% are teacher and retired respectively, 7.5% are doing private job, 2.5% are farmer, doing majuri and having medical store respectively and 35% patients are in other profession.

6. Marital Status: Above figure reveals that, in Group A, 82.5% are married and in group B, 95% patients are married and 5% are unmarried.

7. Prakruti: In Group A, 45% patients with Vata-pitta prakruti, 42.5% with Vata-kapha, 10% with Pitta-kapha and 2.5% with Kapha-pitta prakruti.

In Group B, 52.5% patients with Vata-kapha and 47.5 with Vata-pitta prakruti.

8. Addiction: In Group A, 57.5% patients having addiction of tea or coffee. 20% having addiction of smoking 10% having addiction of alcohol. 7.5% having addiction of tobacco and 5% having addiction of mishri.

In Group B, 55% patients having addiction of tea or coffee. 20% having addiction of smoking 10% having addiction of tobacco and alcohol respectively. 5% having addiction of mishri.

DISCUSSION ON CLINICAL OBSERVATIONS

Gudgat Raktasrava (EFFECT ON BLEEDING)

GROUP “A”: All the 40 patients had complaints of bleeding occasional dripping, daily dripping etc. before treatment. After treatment All patients had relief from this complaints.

As p value < 0.05 , there is significant difference in grades of ‘Gudgat Raktstrav’ after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. In all patients it gets reduced, so the treatment is effective to reduce grades of ‘Gudgat Raktstrav’.

This suggests that the drug showed great effectiveness in *Gudgat Raktasrava* (Bleeding per rectum)

GROUP “B”- All the 40 patients had complaints of bleeding occasional dripping, daily dripping etc. before treatment.

As p value < 0.05 , there is significant difference in grades of ‘Gudgat Raktstrav’ after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. In all patients it gets reduced, so the treatment is effective to reduce grades of ‘Gudgat Raktstrav’.

Comparison between GROUP A and GROUP B

Mean rank of ‘Gudgat Raktstrav’ is less in group A than that of group B and as p value < 0.05 , there is significant difference between both groups. So, group A is more effective than group B to reduce grades of ‘Gudgat Raktstrav’.

EFFECT ON CONSTIPATION (MALAVASHTAMBHA)

GROUP “A”- Among 40 patients, all patients had complaints of constipation. After treatment there was almost all patients who had relief from complaints of Constipation.

As p value < 0.05 , there is significant difference in grades of ‘Malavstambha’ after treatment. For ‘Malavstambha’ grades changing negative to positive to become normal. So, Positive rank indicates it reduces after treatment. Ties indicate it remains same. In all patients it gets reduced, so the treatment is effective to increase grades of ‘Malavstambha’.

Group “B”

Among 40 patients, all patients had complaints of constipation. After treatment there was almost 70-80 percent patients who had relief from complaints of Constipation.

As p value < 0.05 , there is significant difference in grades of ‘Malavstambha’ after treatment. For ‘Malavstambha’ grades changing negative to positive to become normal. So, Positive rank indicates it reduces after treatment. Ties indicate it remains same. In almost all patients it gets reduced, so the treatment is effective to increase grades of ‘Malavstambha’.

Comparison between GROUP A and GROUP B

In 'Malavstambha', grades are increasing to become normal. Here, mean rank of 'Malavstambha' is more in group A than that of group B and as p value < 0.05 , there is significant difference between both groups. So, group A is more effective than group B to increase grades of 'Malavstambha'.

EFFECT ON ANAL ICHING (GUDA-KANDU)

GROUP "A"- Among 40 patients, all patients had complaint of anal guda kandu (itching). After treatment there was no any patients who had complaint of *Guda-kandu*.

As p value < 0.05 , there is significant difference in grades of 'Gud Kandu' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. In all patients it gets reduced, so the treatment is effective to reduce grades of 'Gud Kandu'.

GROUP "B"- Among 40 patients, all patients had complaint of anal itching. After treatment there was almost 70-80 percent patients who had relief from complaints of guda kandu.

As p value < 0.05 , there is significant difference in grades of 'Gud Kandu' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. In all patients it gets reduced, so the treatment is effective to reduce grades of 'Gud Kandu'.

Comparison between GROUP A and GROUP B-

Mean rank of 'Gud Kandu' is less in group A than that of group B and as p value < 0.05 , there is significant difference between both groups. So, group A is more effective than group B to reduce grades of 'Gud Kandu'.

EFFECT ON DEGREE OF HAEMORRHOID

GROUP A- Out of 40 patients all patient had 1st and 2nd degree haemorrhoid while.

After treatment there was Almost all patients who had relief from reduction of pile mass.

As p value < 0.05 , there is significant difference in grades of 'Degree of piles' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. In almost all patients it gets reduced, so the treatment is effective to reduce grades of 'Degree of piles'.

Group B- Out of 40 patients all patient had 1st and 2nd degree haemorrhoid while

After treatment there was most of patients who had relief from reduction of pile mass.

As p value < 0.05 , there is significant difference in grades of 'Degree of piles' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. In maximum patients it gets reduced, so the treatment is effective to reduce grades of 'Degree of piles'.

Comparison between GROUP A and GROUP B

Mean rank of 'Degree of piles' is less in group A than that of group B and as p value < 0.05 , there is significant difference between both groups. So, group A is more effective than group B to reduce grades of 'Degree of piles'.

EFFECT ON PAIN (GUDA-SHOOLA)

GROUP A- Among 40 patients, all patients had complaints of pain in ano. After treatment almost all patients had relief from complaints of pain.

As p value < 0.05 , there is significant difference in grades of 'Gudshool' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. In almost all patients it gets reduced, so the treatment is effective to reduce grades of 'Gudshool'.

GROUP B - Among 40 patients, all patients had complaints of pain in ano. After treatment most of the patients had relief from complaints of pain.

As p value < 0.05 , there is significant difference in grades of 'Gudshool' after treatment. Negative rank indicates it reduces after treatment. Ties indicate it remains same. In almost all patients it gets reduced, so the treatment is effective to reduce grades of 'Gudshool'.

Comparison between GROUP A and GROUP B

Mean rank of 'Gudshool' is less in group A than that of group B and as p value < 0.05 , there is significant difference between both groups. So, group A is more effective than group B to reduce grades of 'Gudshool'.

Discussion on Total Effect of Therapy: analysis of therapeutic outcomes in the two groups reveals significant differences in efficacy and patient responses.

Group A vs. Group B**Efficacy Overview****Group A**

5% of patients showed uttam upashaya.

95% of patients showed madhyam upshaya.

Group B

0% showed uttam Upshaya.

95% showed madhyam Upshaya, and 5% showed alpa Upashaya.

From this data, it is evident that Group A demonstrates superior effectiveness compared to Group B, particularly in the percentage of patients achieving marked improvement.

Treatment Modalities**Study Group A**

Uttam Upashaya (Optimal Treatment): 5% of patients received this treatment.

Madhyam Upashaya (Moderate Treatment): 95% received this.

Alpa Upashaya (Minimal Treatment): 0% received this.

Anupashaya (No Treatment): 0%.

Control Group B

Uttam Upashaya: 0% of patients received this treatment.

Madhyam Upashaya: 95% of patients.

Alpa Upashaya: 5%.

Anupashaya: 0%.

The higher percentage of patients in Group A receiving moderate treatment (Uttam Upashaya) likely contributed to the improved outcomes observed in this group. In contrast, while Group B also had a substantial number of patients on optimal treatment, the overall response was less favorable.

Discussion Regarding Probable Mode of Action of Drug

Actions of Ingredients in Jatiphaladi Vati

1. Jatiphal (*Myristica fragrans*)

Sthamhan: Coagulant properties, helps reduce bleeding.

Shoolprashmana: Relieves pain.

Shothhar: Reduces swelling.

Deepan: Acts as an appetizer.

Vatauloman: Balances vata dosha.

2. Lavang (*Syzygium aromaticum*)

Shoolprashmana: Alleviates pain.

Agideepana: Stimulates digestion.

Pachana: Aids in digestion.

Sthambhan: Helps to control bleeding.

3. Pippali (*Piper longum*)

Arshoghna: Anti-hemorrhoidal effects.

Shoolprashmana: Reduces pain.

Deepan: Enhances appetite.

Vatauloman: Promotes normal bowel function.\

4. Saindhav (Rock Salt)

Agideepana: Improves digestion.

Pachana: Aids digestion.

Ruchya: Enhances flavor and palatability.

Hridya: Beneficial for the heart.

Vrishya: Acts as an aphrodisiac.

Tridoshamak: Balances all three doshas.

5. Shunthi (*Zingiber officinale*)

Arshoghna: Reduces hemorrhoidal symptoms.

Deepana: Stimulates digestion.

Vatanuloman: Alleviates vata-related issues.

Pachana: Aids digestion.

6. Dhaturbeej (*Cuscuta reflexa*)

Shoolprashmana: Alleviates pain.

Shothhar: Reduces swelling.

7. Hingul (Resin of *Ferula* species)

Known for its carminative and anti-inflammatory properties, aiding digestion and reducing discomfort.

8. Tankan (Borax)

Acts as an antiseptic and hemostatic, beneficial in reducing inflammation and promoting healing.

CONCLUSIONS

Jatiphaladi Vati is an effective and low-cost oral medication for Arsha (1st and 2nd degree hemorrhoids), and its use is well-supported by Ayurvedic principles.

Recommendations: While the study duration was short, Jatiphaladi Vati can be administered intermittently until complete resolution of hemorrhoids is achieved.

Further research with a larger patient cohort is encouraged to validate these findings and strengthen clinical recommendations.

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