Efficacy Of Vacha Pippali Taila Nasya And Pathyashadangam Kashaya In The Management Of Ardhavabhedaka (Migraine): A Pilot Clinical Study

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ABSTRACT

Background: Migraine is a prevalent neurological disorder with significant impact on daily productivity and quality of life. Many individuals experience over 50% reduction in work, academic, or household efficiency during attacks. The search for safe and effective alternatives has prompted exploration of traditional Ayurvedic interventions.

Objective: To evaluate the clinical efficacy of Vacha Pippali Taila Nasya in combination with Pathyashadangam Kashaya for the management of Ardhavabhedaka (migraine).

Methods: A total of 10 patients diagnosed with Ardhavabhedaka were enrolled from the OPD of Shalakya Tantra, SGT Ayurveda College and Hospital. Patients received Vacha Pippali Taila Nasya and Pathyashadangam Kashaya for 28 days, with follow-up assessments on days 15, 30, and 60. Outcome measures included HIT-6, MIDAS, and symptom severity scores. Statistical analysis was conducted using paired t-tests, Wilcoxon signed-rank tests, and Friedman tests, as appropriate.

Results: Significant improvements were observed in headache severity, nausea/vomiting, and photophobia/phonophobia scores ($p<0.05$). Mean HIT-6 and MIDAS scores showed reductions, though not statistically significant. No major adverse effects were reported.

Conclusion: The combination of Vacha Pippali Taila Nasya and Pathyashadangam Kashaya may offer a safe and beneficial approach for reducing migraine symptoms, warranting further investigation in larger controlled trials.

Keywords: Pathyashadangam Kashaya, Vacha Pippali Taila, Migraine, Ardhavabhedaka.

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Introduction

Headache is a universal ailment that affects individuals across all ages, ethnicities, and social groups, with women being disproportionately impacted. Some headaches, like migraines, can be profoundly debilitating, substantially diminishing an individual's quality of life and incurring major healthcare and economic costs. The International Headache Society (IHS) describes migraine not as a disease, but as a term representing a constellation of symptoms. Globally, migraine ranks as the third most prevalent health condition [1], with a worldwide prevalence of 14–15%, and contributes to 4.9% of global disability measured in years lived with disability (YLDs).[2]

In Ayurvedic medicine, migraine corresponds to *Ardhavabhedaka*, a subtype of *Shiroroga* (head disorders), characterized by episodic, one-sided headaches often accompanied by vertigo, nausea, sensitivity to light (photophobia), and sound (phonophobia).

Acharya Sushruta attributes the cause of *Ardhavabhedaka* to an imbalance in all three doshas—*Vata, Pitta,* and *Kapha[3]*. *Acharya Charaka* identifies *Vata* or *Vata-Kapha* as the main culprits[4], while *Acharya Vagbhata* emphasizes the predominance of *Vata dosha*.[5]

The condition was chosen for this clinical investigation due to its complex nature and diagnostic challenges, as it primarily relies on subjective symptomatology. Furthermore, there is currently no definitive cure for migraine in contemporary medicine.

Modern treatment strategies focus largely on symptom control and include:

- **Acute interventions:** Such as 5-HT1/5-HT1F agonists, CGRP receptor blockers, ergot alkaloids, NSAIDs, combination therapies, and antiemetics.
- **Preventive measures:** Including beta-blockers, antidepressants, calcium channel blockers, serotonin antagonists, CGRP inhibitors, and botulinum toxin.

However, prolonged or excessive use of these drugs may result in medication-overuse headaches and other side effects, such as gastrointestinal issues, dependency, withdrawal symptoms, and rebound headaches. These drugs are also unsuitable for patients with coexisting medical conditions, limiting their overall utility.

In contrast, Ayurveda offers a holistic approach through natural remedies targeting the root cause of illness. Ayurvedic texts attribute *Shiro-roga* to *Tridosha* imbalances, especially *Vata* and *Kapha*. As a severe variant of *Shiro-roga*, *Ardhavabhedaka* can be effectively managed using Ayurvedic formulations that are warming (*Ushna*), unctuous (*Snigdha*), and *Vata-Kapha pacifying*.

In this clinical study, two interventions were selected:

1. **Pathyashadangam Kashaya**, a decoction containing seven herbs—*Haritaki, Bibhitaki, Amalaki, Bhunimba, Haridra, Nimba*, and *Guduchi*.[6]
2. **Vacha Pippali Taila Nasya**, a nasal formulation composed of *Vacha, Pippali*, and *Til Taila*.[7]

Both preparations possess warming and *Vata-shamaka* properties, making them ideal for addressing the Vata-Kapha pathology in *Ardhavabhedaka*.

Aims and Objectives of the Study

Aim:

To assess the clinical efficacy of *Vacha Pippali Taila Nasya* in conjunction with *Pathyashadangam Kashaya* for the treatment of *Ardhavabhedaka*, with a particular focus on its correlation to migraine.

Objectives:

- To explore the etiopathogenesis of *Ardhavabhedaka* as explained in classical Ayurvedic literature.
- To evaluate the effectiveness of *Vacha Pippali Taila Nasya* and *Pathyashadangam Kashaya* in reducing the frequency, severity, and associated symptoms of *Ardhavabhedaka*.

Materials and Methods

Study Setting and Participant Selection

A total of 10 patients were randomly selected for this study based on specific diagnostic criteria. Participants were recruited from the outpatient department (OPD) of the Shalakya Tantra Department at SGT Ayurveda College and Hospital, Gurugram, including referred cases from other departments. Selection was made irrespective of gender, religion, caste, or race.

Inclusion Criteria

Patients aged between 15 to 50 years.

Presence of classical clinical features of *Ardhavabhedaka* (Migraine)[8], as detailed in both Ayurvedic and modern diagnostic frameworks (ICHD-3).

Exclusion Criteria

Patients presenting with secondary headaches arising from other medical conditions.

Individuals with systemic or metabolic illnesses or on medications likely to interfere with the treatment outcomes.

Patients unwilling to provide informed consent or continue participation.

Diagnostic Criteria

The diagnosis was made on following criteria of migraine.

• At least 5 episodes of headache, in past history fortnightly or at 10 days interval or random occurrence (Pakshahat (madrosis)– Dashahat– Aksmatprvartate)

• Headache episode lasting for 4–72 h

• Headache has at least 2 or 3 of the following four characteristics.

i. Unilateral location

ii. Pulsating quality

iii. Moderate or severe pain intensity

iv. Aggravation by or leading to avoidance of routine physical activity (e.g., walking or climbing stairs).

• During headache at least one of the following:

i. Nausea or vomiting

ii. Photophobia and or phonophobia.

Investigations

Routine blood tests and blood glucose levels were checked prior to treatment to exclude systemic pathologies.

Plasma cortisol levels were assessed both before and after therapy to gauge the body's physiological response.

Intervention Protocol

1. Pathyashadangam Kashaya

Dosage: 20 ml with half a glass of lukewarm water

Frequency: Twice daily (at 7:00 AM and 7:00 PM) before meals

Duration: 28 days

** Vaidyaratnam Pathyadi Shadangam Kashayam(Ref-Sharangdhar Samhita*) was taken for this.

2. Vacha Pippali Taila Nasya

Dosage: 6 drops in each nostril

- **Time of Administration:** 9:00 AM
- **Course Duration:** 28 days, delivered in two 7-day sessions with a 7-day gap between sessions

*Vacha pippali tail was prepared in SGT Ayurveda pharmacy.

Diagram 1. Pippali and Vacha

Diagram 2: Preparation of Vacha Pippali Tail

Follow-up

Participants were monitored at 15, 30, and 60 days after starting treatment to evaluate recurrence and assess long-term therapeutic effects.

Dietary and Lifestyle Guidelines

Patients were instructed to adhere to *Pathya-Apathya* (appropriate diet and lifestyle regimen) based on Ayurvedic principles related to *Ardhavabhedaka* and its treatment protocol.

Assessment of Therapy

Assessment Tools Used

- **HIT-6** (Headache Impact Test)
- **MIDAS** (Migraine Disability Assessment Score)
- **Multidimensional Grading and Scoring System**

Subjective Assessment Criteria

Symptom severity was recorded both before and after treatment using a standardized grading system, focusing on the following clinical features:

- Headache
- Nausea/Vomiting
- Photophobia and Phonophobia
- Vertigo

Each symptom was graded on a 5-point scale, considering intensity, frequency, and impact on daily function. Follow-up assessments were performed at 15, 30, and 60 days post-treatment to monitor for any recurrence or long-term improvements.

Symptom Grading Table (Simplified)

Symptoms	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
Headache	No head ache.	Mild Head ache, Patient notice this only if he/she pay attention to it.	Moderate Head ache, Patient can ignore at times.	Severe Head ache, Patient can,t ignore but can do daily activities	Severe Headache, Patient can ,t ignore and can't do daily activities
Nausea or vomiting	No symptoms	Mild (Person can do work)	Moderate (Forced to stop work)	Severe (Forced to take rest)	Excruciating (Forced to take medicine)
photophobia & phonophobia	No symptoms	Mild (can do his/her work)	Moderate (Forced to stop work)	Severe (Forced to take rest)	Excruciating (Forced to take medicine)
Vertigo	No symptoms	Mild (can do his/her work)	Moderate (Forced to stop work)	Severe (Forced to take rest)	Excruciating (Forced to take medicine)

Assessment of overall effect of therapy

Overall effect of therapy was assessed in terms of complete remission if 100% improvement in symptoms and no recurrences during the follow-up period was observed. When improvement in symptoms was between 75% and 100%, it was considered as marked improvement and as moderate improvement when the improvement in symptoms was between 50% and 75%. Mild improvement when the improvement in the symptoms was between 25% and 50%. Changes up to 25% were taken as no change.

Statistical analysis

Data were analyzed on an intention-to-treat basis (n=10). For continuous outcomes (HIT-6, MIDAS), normality of paired differences (Shapiro–Wilk) determined use of paired t-tests for normally distributed data or Wilcoxon signed-rank tests otherwise. Ordinal symptom grades (0–4 for Headache, Nausea/Vomiting, Photophobia/Phonophobia, Vertigo) were compared pre–post (Baseline vs Post-treatment Day 28) using Wilcoxon signed-rank tests, and longitudinal change across Baseline, Post-treatment Day 28, and Follow-ups on Day 15/30/60 was evaluated with Friedman tests. Effect sizes were reported as Cohen's d (paired) for parametric tests, rank-biserial r for Wilcoxon tests, and Kendall's W for Friedman tests. Two-sided α=0.05. For HIT-6 and MIDAS, bias-corrected bootstrap 95% CIs (5,000 resamples) were calculated for mean change.

Results

Primary scales

- **HIT-6:** Baseline 62.30 ± 4.85 vs Post D28 59.10 ± 6.47; Wilcoxon signed-rank (r), mean change 3.20 (95% CI 0.78 to 5.64), p=0.098, effect size r=0.643; mean % improvement 5.5%.
- **MIDAS:** Baseline 8.30 ± 12.57 vs Post D28 6.50 ± 9.71; Wilcoxon signed-rank (r), mean change 1.80 (95% CI −1.15 to 4.75), p=0.301, effect size r=0.405; mean % improvement 12.5%.

Table 2: Primary scales

Outcome	n	Baseline (meanÂ± SD)	Post D28 (meanÂ± SD)	Mean change (95% CI)	Test	p-value	Effect size	Mean % improvement
HIT6	10	54.80 Â± 1.75	54.80 Â± 1.75	0.00 (0.00 to 0.00)	Paired t-test	NA	NA	5.5 %
MIDAS	10	43.60 Â± 8.83	43.60 Â± 8.83	0.00 (0.00 to 0.00)	Paired t-test	NA	NA	12.5 %

Effect of therapy on signs & symptoms (0–4)

- Headache: median [IQR] Baseline 3.00 [3.00–4.00] → Post D28 2.00 [2.00–2.00]; Wilcoxon p=0.005, r=0.800.
- Nausea/Vomiting: 1.00 [0.00–1.00] → 0.00 [0.00–1.00]; p=0.034, r=0.674.
- Photophobia/Phonophobia: 2.00 [2.00–3.00] → 1.50 [1.00–2.00]; p=0.011, r=0.800.
- Vertigo: 0.00 [0.00–0.75] → 0.00 [0.00–0.00]; p=0.157, r=0.000.

Table 3: Results in signs & symptoms

Outcome	n	Baseline median [IQR]	Post D28 median [IQR]	Median Î”	Wilcoxon p	Effect size r
Headache	10	3.50 [3.00â€“4.00]	2.00 [2.00â€“2.75]	1	0.005	0.889
Nausea_Vomiting	10	1.00 [0.25â€“1.75]	0.00 [0.00â€“1.00]	0.5	0.034	0.671
Photophobia_Phonophobia	10	2.00 [2.00â€“3.00]	1.50 [1.00â€“2.00]	1	0.011	0.8
Vertigo	10	0.00 [0.00â€“0.75]	0.00 [0.00â€“0.00]	0	0.157	0

Follow-up (repeated measures across Baseline → Post D28 → FU Day 15 → FU Day 30 → FU Day 60)

- Headache: Friedman $\chi^2(4)=36.16$, p<0.001, Kendall's W=0.90.
- Nausea/Vomiting: $\chi^2(4)=21.36$, p<0.001, W=0.53.
- Photophobia/Phonophobia: $\chi^2(4)=35.65$, p<0.001, W=0.89.
- Vertigo: $\chi^2(4)=10.34$, p=0.035, W=0.26.

Table 4: Results in Follow ups

Outcome	Timepoints	Friedman (df)	Kendalls W	p-value
Headache	Baseline â†' PostTx D28 â†' FU D15 â†' FU D30 â†' FU D60	36.16 (4)	0.9	<0.001

Nausea_Vomiting	Baseline â†' PostTx D28 â†' FU D15 â†' FU D30 â†' FU D60	21.36 (4)	0.53	< 0.001
Photophobia_Phonophobia	Baseline â†' PostTx D28 â†' FU D15 â†' FU D30 â†' FU D60	35.65 (4)	0.89	< 0.001
Vertigo	Baseline â†' PostTx D28 â†' FU D15 â†' FU D30 â†' FU D60	10.34 (4)	0.26	0.035

Overall effect of therapy

Composite symptom score was the sum of the four symptom grades (range 0–16). Overall effect categories (based on % improvement from Baseline to Post D28) were:

- Marked (50–74%): 4 (40.0%)
- Moderate (25–49%): 3 (30.0%)
- Mild (>0–24%): 3 (30.0%)
- Complete (≥75%): 0 (0.0%)
- No Response (≤0%): 0 (0.0%)

Discussion

Ardhavabhedaka, an Ayurvedic classification of *Shiro-roga* (head disorders), is extensively described by classical scholars and bears a close symptomatic resemblance to migraine, primarily due to its characteristic unilateral headache. Commentator Chakrapani refers to it as *Ardha Mastaka Vedana*—pain restricted to one half of the head—with a paroxysmal nature mirroring the episodic attacks seen in migraines.

As per Ayurvedic understanding, the pathogenesis of *Ardhavabhedaka* involves all three doshas, with a predominance of *Vata* or *Vata-Kapha*. Though not fatal, the condition can significantly reduce quality of life and may lead to complications such as visual or auditory disturbances if not treated effectively.

Globally, migraine is a major cause of chronic, recurrent headaches and affects more than 20% of women and over 10% of men. Conventional management of chronic migraine typically includes:

- **Lifestyle adjustments and trigger avoidance**
- **Acute symptom control during attacks**
- **Preventive therapy to reduce the frequency and intensity of episodes**

Although lifestyle management can provide relief, the majority of patients with chronic migraine require pharmacological or procedural interventions. However, such modern treatments often carry adverse effects, risk of dependency, contraindications in co-morbid conditions, and limited long-term applicability. In contrast, Ayurveda provides a comprehensive and individualized approach, targeting the root imbalance of doshas while simultaneously offering preventive and curative measures.

Therapeutic Rationale of Pathyashadangam Kashaya

According to *Sharangadhara Samhita*, *Pathyashadangam Kashaya* acts as a vasodilator, nervine tonic, and tranquilizer. It is traditionally used in conditions like tremors, convulsions, wasting disorders, mental health issues, gynecological problems, and most notably, head-related ailments such as migraine and cluster headaches.

The decoction contains a combination of seven powerful herbs which are *Haritaki* (*Terminalia chebula*), *Bibhitaki* (*Terminalia bellirica*), *Amalaki* (*Emblica officinalis*), *Bhunimba* (*Andrographis paniculata*), *Haridra* (*Curcuma longa*), *Nimba* (*Azadirachta indica*), *Guduchi* (*Tinospora cordifolia*) Phytochemical analyses have shown that this formulation contains alkaloids, flavonoids, sterols, triterpenoids, saponins, glycosides, and *andrographolide*—a well-known anti-inflammatory and neuroprotective compound.

Scientific Evidence Supporting Key Ingredients

- **Triphala (Haritaki, Bibhitaki, Amalaki):** Known to balance *Vata* and *Kapha*, Triphala has demonstrated immune-boosting properties, especially enhancing neutrophil activity under stress-induced immunosuppression.[9]
- **Bhunimba (Andrographis paniculata):** Exhibits anti-hyperalgesic effects in experimental models of sensory hypersensitivity, a common feature in migraines. It may reduce migraine-related pain by inhibiting pro-inflammatory responses in pain-processing areas of the brain.
- **Haridra (Curcuma longa):** Curcumin, its active component, has shown potent antioxidant and anti-nociceptive effects. It may reduce oxidative stress and pain sensitivity, thereby contributing to migraine prevention.[11]
- **Guduchi (Tinospora cordifolia):** Recognized for its analgesic properties and actions like *Raktaprasadana* (blood purification) and *Dipana* (digestive stimulation), Guduchi helps in detoxification by correcting *Ama* (metabolic toxins), a known aggravating factor for doshic imbalance.[12]

Vacha and Pippali (in Taila form):

- **Vacha (Acorus calamus):** Traditionally used in neurological and psychological disorders, it exhibits anxiolytic, neuroprotective, and anti-inflammatory properties.[13]
- **Pippali (Piper longum):** Known for its bio-enhancing and anti-inflammatory effects, Pippali supports improved absorption and effectiveness of co-administered drugs, and helps pacify *Vata* and *Kapha*.

Conclusion of Discussion

The clinical observations and pharmacological insights suggest that *Pathyashadangam Kashaya* and *Vacha Pippali Taila Nasya* offer a holistic and effective solution for managing *Ardhavabhedaka* (Migraine). The intervention works through multiple mechanisms:

- Pacification of *Vata* and *Kapha* doshas
- Reduction of inflammation and pain sensitivity
- Correction of digestive imbalances (*Agni*) and metabolic toxins (*Ama*)
- Stabilization of neurovascular functions

This integrative and natural treatment approach, with minimal side effects, emerges as a promising alternative or complementary strategy to conventional migraine therapy, especially for patients with chronic conditions or sensitivity to modern medications.

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