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Erandamooladi Dhooma Nasya in Ardhavabhedaka (Migraine): A Single-Arm Pilot Feasibility Clinical Trial

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Abstract

Background: Migraine is a recurrent neurological disorder characterized by episodic headache attacks, often accompanied by nausea, sensitivity to light, and sensitivity to sound. In Ayurvedic literature, a comparable condition is described as *Ardhavabhedaka* (migraine). Nasya Karma is traditionally indicated for diseases of the head region, and Dhooma Nasya (medicated fume inhalation) is a specialized modality in which medicated smoke is administered through the nostrils.

Objective: To assess the feasibility, safety, and preliminary clinical outcomes of Erandamooladi Dhooma Nasya in patients suffering from Ardhavabhedaka (migraine).

Methods: A prospective single-arm pilot feasibility trial was conducted in ten patients diagnosed with migraine corresponding to Ardhavabhedaka. Erandamooladi Dhooma Nasya was administered once daily (3 puffs per nostril) before food for 7 consecutive days. Clinical outcomes were evaluated using the Visual Analogue Scale (VAS) for pain intensity and the Migraine Disability Assessment Scale (MIDAS). Assessments were performed at baseline, immediately after completion of therapy, and during two follow-up visits.

Results: All ten participants completed the treatment schedule and the scheduled follow-ups, indicating complete adherence and retention during the study period. A progressive reduction in headache intensity and migraine-related disability was observed following the intervention. The mean VAS score decreased from 5.6 at baseline to 3.2 after treatment and further reduced to 2.3 at the second follow-up. Similarly, the mean MIDAS score declined from 14.0 at baseline to 12.6 after treatment, reaching 10.7 at the final follow-up. Two participants experienced complete remission of symptoms, six demonstrated marked improvement, and two showed moderate improvement. No adverse events were reported during the treatment or follow-up period.

Conclusion: Erandamooladi Dhooma Nasya was feasible to administer and well tolerated in this pilot sample. The intervention showed encouraging trends toward improvement in migraine intensity and disability, supporting the need for larger controlled trials.

Introduction

Migraine is one of the most prevalent neurological disorders and is widely recognized as one of the major contributors to global disability [1]. It is usually characterized by recurrent attacks of moderate to severe headache which is mostly unilateral, and is often associated with nausea or vomiting, photophobia, and phonophobia [2]. In clinical practice it is seen that migraine often affects the individuals in their most productive years that is young adults and adults, which often results in their academic and occupational impairment.

Although acute and preventive therapies are available abundantly, many patients continue to experience incomplete relief or recurrence. In addition to this, long-term reliance on analgesics may predispose patients to medication-overuse headache and associated complications [3]. Therefore, there is continued interest in supportive, non-oral, and complementary therapeutic approaches to overcome this issue.

In Ayurveda, Ardhavabhedaka is specifically described as a condition involving episodic unilateral head pain of throbbing nature. The symptom pattern described in the classical texts resembles very closely to migraine which is defined in contemporary diagnostic criteria [2]. In Ayurveda, Nasya Karma is considered one of the most important Panchakarma interventions for disorders involving the head and neck region [4]. Among these, Dhooma Nasya is one of the subtypes of Nasya which is described as a specialized technique in which medicated smoke is administered through the nasal route, aiming to clear obstructions and pacify doshic imbalance affecting the head region [5].

Erandamooladi Dhooma Varti (Erandamooladi fume stick) is one such classical formulation which is mentioned in Charaka Samhita for treatment of Vata-Kaphaja Shirahshoola (Headache of Vata Kapha origin) [6]. However, despite being mentioned, its use and structured pilot evidence regarding feasibility and outcome trends is very limited for this procedure. Hence, the present pilot feasibility trial was conducted to explore whether Erandamooladi Dhooma Nasya can be administered safely and practically, and whether it demonstrates preliminary clinical benefit in migraine patients.

Objectives

Primary Objective

To assess and evaluate the preliminary effect of Erandamooladi Dhooma Nasya on headache intensity in patients of Ardhavabhedaka (migraine).

Secondary Objectives

1. To observe safety and tolerability of Erandamooladi Dhooma Nasya (medicated fume inhalation).
2. To assess the feasibility of the intervention in terms of participant adherence, retention, and completion of the treatment protocol.
3. To assess changes in headache intensity using VAS.
4. To assess changes in migraine-related disability using MIDAS.

Materials and Methods

Intervention

For seven consecutive days, participants underwent a morning session of medicated inhalation (Dhooma Nasya) using Erandamooladi Dhoomavarti on an empty stomach. To ensure consistency and safety, each supervised session was standardized to three puffs per nostril.

Composition of the Medicated Fume Stick (Erandamooladi Dhoomavarti) [6]

The formulation used in this study consisted of equal parts of the following authenticated botanicals:

1. Erandamoola (Ricinus communis)
2. Chandana (Santalum album)
3. Aguru (Aquilaria agallocha)
4. Jatamansi (Nordostachys jatamansi)
5. Guggulu (Commiphora mukul)

All raw materials were verified and processed following standard pharmaceutical protocols.

Preparation of the Fume Stick (Dhoomavarti)

1. The ingredients were cleaned, dried, and ground into a fine powder (Churna). These powders were blended and processed with water to create a smooth paste (Kalka).
2. The medicated fume stick (Dhoomavarti) was then crafted using the following steps:
3. A hollow reed (Ikshika), roughly 24 cm long, was softened by soaking in water overnight.
4. A 16 × 16 cm cotton cloth was sanitized with hot water and dried.
5. Roughly 12 g of the herbal paste (Kalka) was spread evenly across the cloth.
6. The reed (Ikshika) was placed at the edge, and the cloth was rolled tightly around it to obtain a cylindrical stick.
7. The preparation was shade-dried until firm, after which the reed was removed to leave a hollow cylindrical fume stick (Dhoomavarti). [7]

Study Design

This was a prospective single-arm pilot feasibility trial. The present report represents findings from the intervention arm of a registered comparative clinical study. The comparator arm is not included in this manuscript and will be reported separately.

Study Setting

The study was carried out in the Department of Panchakarma, Parul Institute of Ayurveda and Research, Parul University, Vadodara, Gujarat, India.

Trial Registration

The parent clinical trial was registered in the Clinical Trials Registry–India under CTRI/2025/05/087105.

Ethical Considerations

Ethical approval was obtained prior to the recruitment. All participants had provided written informed consent. The study was conducted in accordance with ethical guidelines for research involving human participants [8].

Confidentiality Measures

Strict confidentiality was maintained. Participants were coded from P01 to P10. No identifiable information was included in the manuscript or analysis tables.

Eligibility Criteria

Inclusion Criteria

- ✓ The diagnosis was made based on the criteria of Ardhavabhedaka (Migraine).
- ✓ Patients between the age of 18yrs – 58 years who are *yogya* for *nasya* karma.
- ✓ Gender- Both
- ✓ Patients who come under the diagnostic criteria which is as follows-
  - ➢ Patients diagnosed based on the diagnostic criteria laid down by IHS (International Headache Society) for Migraine without Aura which is as follows:

A. At least five attacks fulfilling criteria from B-D

B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated)

C. Headache has at least two of the following four characteristics:

1. unilateral location
2. pulsating quality
3. moderate or severe pain intensity
4. aggravation by or causing avoidance of routine physical activity (eg, walking or climbing stairs)

D. During headache at least one of the following:

1. nausea and/or vomiting
2. photophobia and phonophobia

Exclusion Criteria

- ✓ Patients under other treatment modalities.
- ✓ Patients suffering from hypertension, COPD, and other systemic diseases.
- ✓ Patients suffering from other secondary headaches caused by meningitis, brain tumors, increased IOP, encephalitis, cervical spondylitis, referred pain, refractive error and glaucoma.
- ✓ Patients contraindicated for *nasya*.

Sample Size

Ten participants were included as per pilot trial feasibility principles. Pilot studies are primarily designed to test feasibility rather than to provide confirmatory evidence of efficacy [9].

Recruitment

Patients attending the Panchakarma OPD were screened. Eligible participants were enrolled consecutively.

Baseline Investigations

Routine hematological and biochemical investigations were conducted including CBC, ESR, RBS, and urine routine examination.

Intervention

Participants were given Nasya with Erandamooladi Dhooma varti once daily in the morning before food for seven consecutive days. The dose was standardized at 3 puffs through each nostril. And all the sessions were conducted under supervision to ensure uniformity and safety. Participants were monitored daily for subjective comfort and classical signs of proper Dhooma Nasya response such as Shira Laghava, Mukha Shuddhi, Kantha Shuddhi, and Nasa Shuddhi.

During the treatment period, participants were advised to avoid known migraine triggers such as sleep deprivation, fasting, dehydration, and excessive sun exposure. Rescue analgesics were discouraged unless symptoms were severe.

Outcome Measures

Feasibility Outcomes

Feasibility was evaluated using recruitment completion, adherence to therapy, retention at follow-ups, and drop-out rate.

Clinical Outcomes

Headache intensity was measured using VAS. Migraine-related disability was measured using MIDAS.

Assessments were recorded at baseline, after completion of treatment (Day 7), and at two follow-up visits (On 14th day and 21st day).

Safety Assessment

All participants were observed for adverse effects such as burning sensation, nasal irritation, cough, epistaxis, dizziness, and respiratory discomfort.

Statistical Analysis

Considering the exploratory nature of the pilot study and the small sample size, the

data were analysed primarily using descriptive statistics. Continuous variables were expressed as mean and standard deviation (SD). Changes in VAS and MIDAS scores across assessment points were examined descriptively, and percentage improvement from baseline to final follow-up was calculated to understand the overall trend of clinical improvement.

Results

Participant Flow

All ten participants enrolled in the study completed the full course of treatment and follow-up visits. None of the participants discontinued the therapy.

- Enrolled: 10
- Completed intervention: 10
- Completed follow-ups: 10
- Dropouts: 0

Adherence and retention were 100%.

Baseline Characteristics

The trial included 8 female and 2 male participants whose age ranged between 22 and 29 years. The duration of migraine complaints ranged from 6 months to 10 years. All participants had a history of using analgesics for symptom control.

Clinical Outcomes

A gradual reduction in both VAS and MIDAS scores was observed following the intervention. The mean VAS score decreased from 5.6 at baseline to 3.2 after treatment and further declined to 2.3 at the second follow-up. Similarly, the mean MIDAS score reduced from 14.0 at baseline to 12.6 after treatment and reached 10.7 at the final follow-up visit. These findings indicate a consistent trend toward improvement in headache intensity and migraine-related disability during the treatment and follow-up period.

Additional Clinical Observations

During the course of the intervention, several participants reported noticeable reduction in the intensity of headache episodes. None of the participants required rescue analgesics during the treatment period. Some participants also reported improvement in the quality of sleep while undergoing the therapy. Although these observations were not assessed using standardized scales, they were consistently reported during daily monitoring and were considered clinically relevant supportive findings.

Individual Outcome Summary

MIDAS SCORE

Participant	MIDAS BT	MIDAS AT	MIDAS FU1	MIDAS FU2
P01	19	18	16	14
P02	11	9	8	7
P03	17	16	14	13
P04	10	9	8	6
P05	32	30	29	29
P06	8	7	7	6
P07	15	13	12	12
P08	9	8	8	7
P09	12	10	9	8
P10	7	6	6	5

VAS SCORE

Participant	VAS BT	VAS AT	VAS FU1	VAS FU2
P01	6	5	3	2
P02	4	3	3	2
P03	7	4	4	5
P04	3	1	1	0
P05	8	6	5	5
P06	7	6	4	3
P07	6	5	3	3
P08	6	0	0	0
P09	4	2	2	2
P10	5	0	0	1

Overall Clinical Improvement

Based on improvement grading, two participants achieved complete remission, six had marked improvement, and two had moderate improvement.

No participant was categorized as having no improvement.

Safety Outcomes

No adverse events were observed during therapy or during the follow-up periods. Participants tolerated the intervention well.

Discussion

This pilot feasibility trial suggests that Dhooma Nasya can be administered in patients with the complaint migraine without significant safety concerns. The absence of dropouts and the high adherence rate further indicates that the intervention is acceptable and practical in routine OPD clinical settings.

The pathophysiology of migraine involves the activation of trigeminovascular leading to the release of inflammatory neuropeptides and altered pain processing mechanisms [10]. Intranasal drug delivery is recognized for its rapid absorption and its potential benefit in acute migraine management, as demonstrated by intranasal triptans [11]. In this context, Dhooma Nasya may offer a relevant therapeutic approach through nasal mucosal absorption of volatile constituents.

From the Ayurvedic viewpoint, Ardhavabhedaka is described as a Vata predominant disorder involving Shirah Pradesh. Nasya is considered a direct intervention for Urdhvajatrugata disorders, and Dhooma Nasya is traditionally described to clear Kapha obstruction and pacify vitiated Vata in the head region [4]. Improvement in associated symptoms such as nausea and photophobia observed in this trial further supports the potential systemic influence of this therapy. The therapeutic potential of this method likely stems from the transition of solid medicine into Dhuma (medicated fumes), which are characterized by Sookshma (subtle), Vyavayi (rapidly spreading), Ushna (heating), and Tikshna (penetrating) qualities. These inherent attributes may allow the active components to reach deep into the Srotas (channels) of the head. When ignited by Agni (fire), the formulation releases volatile constituents that are dispersed by Vayu (air). As a gaseous delivery system, it bypasses the digestive tract and directly reaches the nasal mucosa and upper respiratory passages, which may offer high bioavailability. The treatment appears to work through two complementary pathways: a local action where the Ushna (heating) and Tikshna (penetrating) nature of the smoke may help liquefy and clear Kapha and Vata (stagnant fluids or energy), and a systemic action where volatile compounds might be absorbed into the bloodstream via the nasal lining. Together, these combined actions may promote Srotoshodhana (clearing of

obstructed channels) and help restore Dosha Samya (physiological balance) in the Shirah Pradesh (head region), potentially addressing the Vata-Kapha vitiation (neuro-metabolic disruptions) associated with conditions like Ardhavabhedaka (migraine). [12][13]

The overall efficacy of the fume stick is likely supported by the individual properties of its constituent herbs. Erandamoola (Ricinus communis) possesses properties traditionally associated with Vatahara (calming the nervous system) and Shoolahara (relieving pain and inflammation), which may play a role in managing the hypersensitivity linked to vascular headaches. This is complemented by Chandana (Santalum album), which exhibits a Pittashamaka (cooling and stabilizing) effect that could potentially reduce heat-related irritation in the sensitive tissues of the head. Furthermore, the Sookshma (subtle and penetrating) nature of Aguru (Aquilaria agallocha) suggests it may act as a carrier, potentially helping other medicinal properties reach the finer Srotas (channels) of the upper body. Jatamansi (Nardostachys jatamansi) is known for Vedanasthapana (neuro-protective and pain-stabilizing) qualities, which may help soothe the nervous system and address neurological pain triggers. Finally, the Tikshna (penetrating) and Ushna (heating) properties of Guggulu (Commiphora mukul) are traditionally used for Srotoshodhana (clearing obstructions), which may be vital for breaking down Kapha (metabolic congestion) and assisting in the effective absorption of the entire formulation. [15]

Although the improvements in VAS and MIDAS are encouraging, this report represents only the intervention arm of a registered comparative trial. Therefore, the results should be interpreted as preliminary and cannot establish comparative efficacy. The primary value of the present pilot study lies in its feasibility confirmation and early outcome trends, which can guide future trial planning.

Limitations

This study has several limitations. The sample size was small and not statistically powered for efficacy conclusions. The single-arm nature of the present report does not allow comparison with control outcomes. Blinding was not feasible, and placebo effects cannot be excluded. Follow-up duration was limited, and longer follow-up is necessary to assess sustained migraine prevention.

Future Scope

A well-designed randomized controlled trial with adequate sample size and longer follow-up is recommended. Inclusion of headache frequency diaries,

HIT-6 scoring, quality-of-life scales, and analgesic requirement documentation would strengthen outcome assessment.

Conclusion

Erandamooladi Dhooma Nasya was feasible and safe in this pilot sample of migraine patients corresponding to Ardhavabhedaka. Preliminary results showed improvement in headache intensity and migraine-related disability. These findings support the planning of larger controlled trials to confirm efficacy.

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