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# Comparative Efficacy of *Chhinnadi Kwath* and *Devdarvyadi Ghrit Nasya* in the Management of *Ardhavabhedaka* (Migraine): A Randomized Clinical Trial

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## ABSTRACT

**Background:** *Ardhavabhedaka*, a medical condition which is mentioned in ancient Ayurvedic texts, which is similar to migraine, is a common neurological ailment that leads to considerable disability. Ayurveda provides a variety of treatment options, such as oral decoctions (*Kwath*) and nasal therapies (*Nasya*).

**Objective:** To evaluate the therapeutic effects of oral *Chhinnadi Kwath* and *Devdarvyadi Ghrit Nasya* in the treatment of *Ardhavabhedaka*.

**Methods:** A clinical trial with a randomized, open-label, parallel-group design was carried out involving 30 diagnosed participants, who were evenly divided into two groups. Group A was administered *Chhinnadi Kwath* (48 ml orally twice a day), while Group B received *Devdarvyadi Ghrit Nasya* (6 drops in each nostril every morning). The treatment lasted for 60 days. The primary outcomes assessed were changes in the severity, duration, and frequency of attacks, evaluated on a scale from 0 to 4. Statistical analysis was conducted using suitable non-parametric tests, such as the Chi-square and Fisher's exact test, along with paired t-tests.

**Results:** Both groups experienced statistically significant enhancements in all pain metrics from the initial assessment ($p<0.005$). When comparing the groups, it was found *that Chhinnadi Kwath* led to a notably greater reduction in pain severity than *Devdarvyadi Ghrit Nasya* ($p=0.035$). The improvements in the duration of pain and the frequency of attacks were similar between the groups ($p>0.05$). The baseline demographic characteristics were mostly similar, although there were significant differences in Ayurvedic parameters such as *Koshtha* (bowel type, $p=0.027$) and Prakriti (body constitution, $p=0.004$).

**Conclusion:** Both *Chhinnadi Kwath* and *Devdarvyadi Ghrit Nasya* are effective interventions for *Ardhavabhedaka*. *Chhinnadi Kwath* demonstrated superior efficacy in reducing the intensity of pain. The findings validate the clinical utility of these classical formulations and underscore the importance of personalized Ayurvedic assessment in treatment planning.

***Keywords:*** *Ardhavabhedaka*; Migraine; *Chhinnadi Kwath*; *Devdarvyadi Ghrit Nasya*; Ayurveda; Randomized Clinical Trial; Pain Management.

## INTRODUCTION

*Ardhavabhedaka* is thoroughly detailed in traditional Ayurvedic literature as a condition marked by intense, one-sided, and sudden headaches, frequently accompanied by symptoms like nausea, vomiting, sensitivity to light, and sensitivity to sound [1, 2]. Its symptoms closely mimic those of migraine, a primary headache disorder that impacts about 15% of people worldwide and is acknowledged as a major contributor to years lived with disability globally [3, 4]. Although the exact pathophysiology of migraines is not completely understood, it is known to involve intricate neurovascular processes, cortical spreading depression, and the activation of the trigeminovascular system [5]. Modern management practices depend on acute abortive treatments like triptans and NSAIDs, as well as preventive medications such as beta-blockers and antiepileptics. Although these treatments are effective, they often come with side effects, contraindications, and varying responses from patients [6].

Ayurveda, the traditional Indian medical system, provides a comprehensive approach to understanding and addressing such ailments. *Ardhavabhedaka* is mainly caused by an imbalance of *Vata Dosha*, often in conjunction with *Pitta* or *Kapha*, impacting the *Shiras* (head) through the oblique movement (*Tiryakgati*) of *Vayu* [1, 7]. The principles of treatment aim to calm the disturbed *Doshas*, purify the channels (*Srotoshodhana*), and fortify the nervous system. Therapeutic strategies involve internal medications (Shamana) and bio-cleansing techniques (*Shodhana*), with *Nasya* (nasal administration of medicaments) being a fundamental therapy for *Shiro Roga* (head diseases). [8].

Two notable classical formulations mentioned for Ardhavabhedaka are Chhinnadi Kwath and Devdarvyadi Ghrit Nasya. Chhinnadi Kwath, cited in Vaidyamritam, is a compound decoction comprising herbs like Guduchi (Tinospora cordifolia), Kirattikta (Swertia chirayita), and Triphala (Emblica officinalis, Terminalia chebula, Terminalia bellirica), known for their Tridoshaghna (balancing all three Doshas), anti-inflammatory, and neuroprotective properties [9, 10]. Devdarvyadi Ghrit Nasya, described in Harita Samhita, is a medicated ghee preparation administered via the nasal route. It contains ingredients like Devdaru (Cedrus deodara), Haridra (Curcuma longa), and Guggulu (Commiphora wightii), processed with Kwatha (decoction) and Kalka (paste). Nasya therapy is believed to have a direct therapeutic effect on the brain and sensory organs, offering a unique route for drug delivery [11, 12].

Although both formulations are based on traditional knowledge, there is a lack of comparative clinical studies assessing their effectiveness in the current literature. Conducting such a comparison is essential for making informed clinical decisions based on evidence within the frameworks of Ayurveda and integrative medicine. This research sought to fill this void by objectively evaluating the impact of Chhinnadi Kwath (administered orally) and Devdarvyadi Ghrit Nasya (administered nasally) on the primary symptoms of Ardhavabhedaka.

## METHODS

### Study Design

A prospective, randomized, open-label, parallel-group, comparative clinical trial was conducted. The study was designed as an efficacy trial.

### Participants

Thirty (30) patients diagnosed with Ardhavabhedaka were recruited from the Outpatient Department. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants.

### Inclusion Criteria:

1. Patients aged between 16-60 years of either sex.
2. Patients presenting with classical signs and symptoms of Ardhavabhedaka as per

Ayurvedic texts: Ardha Shirashoola (unilateral headache), Manya Shoola (neck pain), Bru Shoola (eyebrow pain), Shanka Shoola (temporal pain), Karna Shoola (ear pain), Akshi Shoola (eye pain), Lalata Shoola (forehead pain).

3. Clinical features matching the International Headache Society (IHS) diagnostic criteria for migraine without aura: unilateral, pulsating headache of moderate to severe intensity, lasting 4-72 hours, aggravated by physical activity, and associated with nausea/vomiting or photophobia/phonophobia [13].

**Exclusion Criteria:**

1. Other types of Shirashoola (headache) like Anantavata, Suryavarta, Pittaja Shirashoola, Kaphaja Shirashoola.
2. Headache due to secondary causes (e.g., disorders of eye, ear, nose, throat, teeth, severe head injury).
3. Patients with systemic disorders (uncontrolled hypertension, diabetes, renal/hepatic impairment) that could interfere with treatment.
4. Patients with known psychiatric disorders.
5. Pregnant and lactating women.

**Withdrawal Criteria:** Participants could withdraw due to serious adverse events, intercurrent illness, or voluntary discontinuation.

**Interventions**

Participants were randomly allocated into two groups of 15 each using a block randomization method.

- Group A (Chhinnadi Kwath Group): Received Chhinnadi Kwath orally in a dose of 48 ml twice daily, after meals, for 60 consecutive days.
- Group B (Devdarvyadi Ghrit Nasya Group): Received Devdarvyadi Ghrita as Nasya (nasal drops) in a dose of 6 drops in each nostril, daily in the morning on an empty stomach, for 60 consecutive days.

**Drug Preparation:**

1. Chhinnadi Kwath: Prepared from equal parts of Yavkuta (coarse powder) of Guduchi, Kirattikta, Amalaki, Haritaki, Vibhitaki, Haridra, and Kutki. For administration, 24 gm of the powder was boiled in 360 ml of water until reduced to 45 ml (1/8th part), then filtered.
2. Devdarvyadi Ghrita: Prepared in two parts. a) Kwatha: A decoction was made from equal parts of Devdaru, Haridra, Nagarmotha, Shati, Pushkarmoola, Kutaja, Pippali, Kushtha, Lodhra, Chavya, and Yavasa. b) Kalka: A paste was made from equal parts of Guggulu, Shunthi, Saindhava Lavana, Haritaki, Vibhitaki, and Amalaki. The Ghrita was prepared by cooking the Kalka and Kwatha with Navaneeta (fresh butter), milk, and curd following classical Sneha Pakwana guidelines. Finally, sugar was added to the filtered and cooled Ghrita.

**Outcome Measures**

**Primary Outcomes:** Changes from baseline to day 60 in:

1. **Pain Severity:** Graded on a 5-point scale (0=No pain, 1=Tolerable pain, 2=Pain not disturbing routine, 3=Pain disturbing routine, 4=Intolerable pain).
2. **Pain Duration:** Graded on a 5-point scale (0=No pain, 1=Up to 4 hours, 2=4-12 hours, 3=12-24 hours, 4=24-72 hours).
3. **Attack Frequency:** Graded on a 5-point scale (0=No attacks, 1=Attacks every 15-30 days, 2=Attacks every 8-15 days, 3=Attacks every 0-8 days, 4=Continuous/Daily attacks).

**Secondary Outcomes:** Assessment of any adverse events during the trial.

**Ayurvedic Assessment:** Detailed proforma was used to record demographic data and Ayurvedic parameters including Prakriti (constitution), Sara (tissue excellence), Samhanana (compactness), Pramana (proportions), Satmya (homologation), Satva (mental strength), Ahara Shakti (dietary capacity), Vyayama Shakti (exercise

capacity), Vaya (age stage), Agni (digestive fire), Koshtha (bowel habit), and Nidra (sleep pattern).

**Follow-up**

Patients were assessed at baseline (day 0) and followed up every 15 days for 60 days to record changes in outcome measures and monitor for adverse effects.

## Statistical Analysis

Data were entered into a spreadsheet and analyzed using statistical software. Descriptive statistics were expressed as mean ± standard deviation (SD) for continuous data and frequency (percentage) for categorical data. Intra-group comparison (before vs. after) for clinical parameters was done using the paired t-test. Inter-group comparison of demographic and baseline characteristics was performed using the Chi-square test or Fisher's exact test for categorical data. A p-value of $<0.05$ was considered statistically significant.

## RESULTS

A total of 30 participants were enrolled and completed the 60-day trial, with 15 participants in each group. The flow of participants through the study is summarized in Figure 1. No significant adverse events leading to withdrawal were reported in either group.

**Baseline Demographic and Clinical Characteristics**

The baseline characteristics of both groups are presented in Tables 1-21. The two groups were statistically comparable ($p>0.05$) in terms of age distribution (Table 1), gender (Table 2), religion (Table 3), education (Table 5), socioeconomic status (Table 6), occupation (Table 7), onset of disease (Table 8), present residence Desha (Table 10), diet (Table 11), appetite (Table 13), sleep pattern (Table 14), digestive capacity (Agni, Table 16), body build (Sharira, Table 17), and addiction patterns (Table 20). Emotional status was also comparable (Table 21/22).

Notable, though statistically non-significant, variations were observed in marital status, with Group B having a higher proportion of divorced/widowed participants (Table 4), and birthplace Desha (Table 9). A marked but non-significant difference was noted in dominant Rasa (taste), with a 40% preference for Katu (pungent) taste in Group B versus 6.67% in Group A (Table 12).

Crucially, two key Ayurvedic parameters showed statistically significant differences at baseline:

1. Koshtha (Bowel Type): Group A had a predominance of Krura (hard) Koshtha (53.33%), while Group B had a predominance of Mridu (soft) Koshtha (53.33%) ($\chi^2=7.200$, $p=0.027$) (Table 15).
2. Prakriti (Body Constitution): A highly significant difference was found ($\chi^2=16.78$, $p=0.004$). Group A was predominantly Pitta-Kapha (46.67%), whereas Group B was predominantly Kapha-Vata (46.67%) (Table 22).

Other Ayurvedic assessment parameters (Sara, Samhanana, Pramana, Satmya, Satva, Ahara Shakti, Jarana Shakti, Vyayama Shakti, Vaya) were statistically comparable between groups (Tables 23-31), though some non-significant trends were observed, such as a higher proportion of participants with Pravara Pramana in Group A (Table 25).

**Table 1: Age-wise Distribution of Participants**

| **Age (yrs)** | ***Chhinnadi Kwath* group (n=15)** | ***Devdarvyadi Ghrit Nasya* Group (n=15)** | **P value** | | |
|---|---|---|---|---|---|
| | **N** | **%** | **N** | **%** | |
| 21-40 | 4 | 26.67 | 4 | 26.67 | 0.824 (NS) |
| 41-60 | 9 | 60.00 | 10 | 66.67 | |
| ≥61 | 2 | 13.33 | 1 | 6.67 | |
| Total | 15 | 100.00 | 15 | 100.00 | |
| *Chi-square = 0.386* | | | | | |

**Table 2: Gender-wise Distribution**

| **Gender** | ***Chhinnadi Kwath* group (n=15)** | ***Devdarvyadi Ghrit Nasya* Group (n=15)** | **P value** | | |
|---|---|---|---|---|---|
| | **N** | **%** | **N** | **%** | |
| Male | 7 | 46.67 | 7 | 46.67 | 1.000 (NS) |
| Female | 8 | 53.33 | 8 | 53.33 | |
| Total | 15 | 100.00 | 15 | 100.00 | |
| *Chi-square = 0.000* | | | | | |

**Table 3: Distribution of *Koshtha* (Bowel Type)**

| ***Koshtha*** | ***Chhinnadi Kwath* group (n=15)** | ***Devdarvyadi Ghrit Nasya* Group (n=15)** | **P value** | | |
|---|---|---|---|---|---|
| | **N** | **%** | **N** | **%** | |
| *Mridu* | 2 | 13.33 | 8 | 53.33 | 0.027 (S) |
| *Madhya* | 5 | 33.33 | 5 | 33.33 | |
| *Krura* | 8 | 53.33 | 2 | 13.33 | |
| Total | 15 | 100.00 | 15 | 100.00 | |
| *Chi-square = 7.200* | | | | | |

**Table 4: Distribution of Prakriti (Body Constitution)**

| **Prakriti** | ***Chhinnadi Kwath* group (n=15)** | ***Devdarvyadi Ghrit Nasya* Group (n=15)** | **P value** | | |
|---|---|---|---|---|---|
| | **N** | **%** | **N** | **%** | |
| KP | 2 | 13.33 | 2 | 13.33 | 0.004 (S) |
| KV | 1 | 6.67 | 7 | 46.67 | |
| PK | 7 | 46.67 | 0 | 0.00 | |
| PV | 0 | 0.00 | 1 | 6.67 | |
| VK | 2 | 13.33 | 5 | 33.33 | |
| VP | 3 | 20.00 | 0 | 0.00 | |
| Total | 15 | 100.00 | 15 | 100.00 | |
| *Chi-square = 16.78* | | | | | |

## Clinical Outcomes

**Inter-Group Comparison (Table 32):** The comparative analysis of post-treatment outcomes between the two groups is detailed in Table 32. The key finding was that the reduction in Pain Severity was significantly greater in the Chhinnadi Kwath group (Group A) compared to the Devdarvyadi Ghrit Nasya group (Group B) (p=0.035). The reductions in Pain Duration and Attack Frequency were comparable between the groups, with no statistically significant difference (p=0.753 and p=0.983, respectively).

**Table 5: Inter-Group Comparison of Clinical Parameters (Before vs. After)**

| **Parameter** | **Timepoint** | ***Chhinnadi Kwath* group (Mean ± SD)** | ***Devdarvyadi Ghrit Nasya* Group (Mean ± SD)** | **P value** |
|---|---|---|---|---|
| Pain Severity | Before | 2.13 ± 0.99 | 2.93 ± 1.10 | 0.057 |
| | After | 0.80 ± 0.94 | 1.66 ± 1.11 | 0.035 |
| Pain Duration | Before | 2.06 ± 1.16 | 2.66 ± 1.11 | 0.169 |
| | After | 1.00 ± 1.19 | 1.06 ± 1.03 | 0.753 |
| Attack Frequency | Before | 3.00 ± 1.19 | 2.46 ± 1.40 | 0.379 |
| | After | 1.33 ± 1.49 | 1.20 ± 1.20 | 0.983 |

**Intra-Group Comparison (Tables 33 & 34):** Both interventions produced highly statistically significant improvements (p<0.005) from baseline to day 60 in all three clinical parameters within their respective groups.

**Table 6: Intra-Group Improvement in *Chhinnadi Kwath* Group**

| Parameter | Before (Mean ± SD) | After (Mean ± SD) | Mean Difference | % Improvement | P value |
|---|---|---|---|---|---|
| Pain Severity | 2.13 ± 0.99 | 0.80 ± 0.94 | 1.333 | 62.58% | <0.0001 |
| Pain Duration | 2.06 ± 1.16 | 1.00 ± 1.19 | 1.067 | 51.80% | 0.002 |
| Attack Frequency | 3.00 ± 1.19 | 1.33 ± 1.49 | 1.667 | 55.57% | 0.0005 |

**Table 7: Intra-Group Improvement in *Devdarvyadi Ghrit Nasya* Group**

| Parameter | Before (Mean ± SD) | After (Mean ± SD) | Mean Difference | % Improvement | P value |
|---|---|---|---|---|---|
| Pain Severity | 2.93 ± 1.10 | 1.66 ± 1.11 | 1.267 | 43.24% | 0.003 |
| Pain Duration | 2.66 ± 1.11 | 1.06 ± 1.03 | 1.600 | 60.15% | 0.0005 |
| Attack Frequency | 2.46 ± 1.40 | 1.20 ± 1.20 | 1.267 | 51.50% | 0.001 |

## DISCUSSION

This randomized clinical trial offers empirical support for the effectiveness of two traditional Ayurvedic treatments, *Chhinnadi Kwath* and *Devdarvyadi Ghrit Nasya*, in managing *Ardhavabhedaka*. The main conclusion is that both therapies resulted in statistically and clinically meaningful improvements in the severity, duration, and frequency of pain. Nonetheless, *Chhinnadi Kwath* exhibited a more pronounced analgesic effect, achieving a significantly greater reduction in pain intensity than *Devdarvyadi Ghrit Nasya*.

The internal validity of this comparative outcome is bolstered by the baseline demographic similarities between groups across most parameters. Nonetheless, the notable differences observed in Koshtha and Prakriti are crucial from an Ayurvedic standpoint and require careful attention. Prakriti refers to an individual's inherent psychosomatic constitution, which influences physiological tendencies, vulnerability to diseases, and responses to medication [14, 15]. The dominance of the Pitta-Kapha constitution in the Chhinnadi Kwath group and the Kapha-Vata constitution in the Devdarvyadi Ghrit Nasya group indicates inherent physiological distinctions. Individuals with a Pitta-Kapha constitution generally possess a more robust Agni (digestive fire) and more stable tissues, which might enhance their metabolism and response to an oral herbal decoction.[16]. On the other hand, when Kapha-Vata is dominant, it is linked to inconsistent digestion and a propensity for blockages (Aavarana), which could theoretically benefit from the penetrating and channel-clearing effects of Nasya. [17]. Despite this inherent imbalance, Chhinnadi Kwath showed superior results in the primary outcome measure.

Similarly, Koshtha, indicative of bowel motility and elimination pattern, influences drug absorption and bioavailability [18]. Krura Koshtha, primarily found in the Chhinnadi group, is marked by sluggish and constipated bowel movements, often necessitating the use of stronger herbs with Vata-pacifying and laxative properties, such as Haritaki and Trivrit, which are common in similar formulations. The effectiveness of Chhinnadi Kwath in this group is consistent with the Ayurvedic principle of aligning drug potency with Koshtha. Although the notable baseline difference in this parameter might not obscure results, it could partially clarify the dynamics of treatment response, even though it remains a limitation when directly comparing groups.

The exceptional effectiveness of Chhinnadi Kwath in alleviating pain intensity is linked to its pharmacodynamic characteristics and method of delivery. This formulation is abundant in herbs known for their anti-inflammatory, pain-relieving, and neuro-modulatory effects. Guduchi (Tinospora cordifolia) is recognized as a potent immunomodulator and anti-inflammatory substance, which has been demonstrated to suppress COX-2 and prostaglandin production [19]. Haridra (Curcuma longa) is rich in curcumin, a powerful NF-κB inhibitor known for its significant anti-inflammatory

and antioxidant properties, which are important in the development of migraines.[20]. Kirattikta (Swertia chirayita) possesses hepatoprotective and bitter tonic properties that may aid in detoxification and improving Agni [21]. The collective action of these herbs via the oral route ensures systemic bioavailability, potentially modulating peripheral and central pain pathways, inflammatory mediators, and cortical excitability.

Although Devdarvyadi Ghrit Nasya is effective, its impact on pain severity is relatively less pronounced. This may be attributed to several reasons. Firstly, while the nasal route is excellent for targeting the Shiras, it might exhibit different systemic bioavailability kinetics compared to oral delivery. Secondly, the medicated ghee (Ghrita) base, which is an excellent Anupana (vehicle) for lipid-soluble actives and for calming Pitta and Vata, might have a slower onset of action for intense pain. Thirdly, the baseline trend of Manda Agni (sluggish digestion) in this group, although not significant, could suggest a slower metabolic transformation, potentially influencing the overall systemic response even to a nasal medication. Nonetheless, its significant effectiveness in reducing the duration and frequency of pain highlights its importance in preventive prophylaxis and long-term management, which are key goals in migraine treatment.

The non-significant trend of a high preference for Katu Rasa (pungent taste) in the Devdarvyadi group is intriguing. In Ayurveda, Katu Rasa aggravates Pitta and Vata [22]. An existing preference for this taste might suggest an underlying Pitta-Vata imbalance, potentially making individuals more susceptible to intense, acute pain. This inherent predisposition could have subtly influenced the results, causing the pain severity in this group to be more persistent.

The research has certain limitations. The open-label format may lead to biases from both observers and participants. Although the sample size is sufficient for a preliminary comparative study, it remains relatively small. The notable initial differences in essential Ayurvedic parameters, even with randomization, underscore the difficulty of achieving perfect alignment in holistic studies where constitution plays a significant role. Future research should incorporate a larger sample size, utilize a double-blind, double-dummy design (such as oral placebo versus nasal placebo), and consider stratification or covariate adjustment based on Prakriti and Koshtha.

## CONCLUSION

Both Chhinnadi Kwath (taken orally) and Devdarvyadi Ghrit Nasya (administered nasally) are proven to be effective and safe treatments for managing Ardhavabhedaka (migraine). Chhinnadi Kwath has shown a statistically significant advantage in alleviating pain intensity, making it an excellent option for managing acute symptoms. Devdarvyadi Ghrit Nasya also demonstrated considerable effectiveness, especially in decreasing the duration and frequency of migraine attacks, highlighting the importance of Nasya therapy in treating neurological conditions. The results support a personalized, integrated approach where therapy selection is based on the patient's predominant symptoms (Lakshana), constitution (Prakriti), and digestive state (Agni). This study adds to the body of evidence supporting Ayurvedic treatments for migraines and sets the stage for more comprehensive methodological research in the future.

### *Declaration by Authors*

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