WJPMR, 2026, 12(8), 268-273

Research Article

WORLD JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.wjpmr.com

Impact Factor: 7.555

ISSN (O): 2455-3301

ISSN (P): 3051-2557

Coden USA: WJPMBB

A RANDOMIZED OPEN LABELLED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF *MANJISHTHADI TAILA NASYA* AND *ANU TAILA NASYA* ALONG WITH *PATHYADI KWATH* IN THE MANAGEMENT OF *ARDHAVABHEDAKA* (MIGRAINE)"

Dr. Vaishali*[1], Dr. Manoj Kumar[2], Dr. Ashu[3]

*[1]P.G. Scholar, Department of *Shalakya Tantra*, Institute for Ayurved Studies and Research, Faculty of *Ayurved*, Kurukshetra, Haryana, 136119, India.

[2]Professor, Department of *Shalakya Tantra*, Institute for *Ayurved* Studies & Research, Kurukshetra, Haryana, 136119, India.

[3]Professor and Chairperson, Department of *Shalakya Tantra*, Institute for *Ayurved* Studies & Research, Kurukshetra, Haryana, 136119, India.

***Corresponding Author: Dr. Vaishali**

P.G. Scholar, Department of Shalakya Tantra, Institute for Ayurved Studies and Research, Faculty of Ayurved, Kurukshetra, Haryana, 136119, India.

DOI: https://doi.org/10.5281/zenodo.21698716

How to cite this Article: Dr. Vaishali*[1], Dr. Manoj Kumar[2], Dr. Ashu[3]. (2026). A Randomized Open Labelled Controlled Clinical Study To Evaluate The Efficacy of Manjishthadi Taila Nasya And Anu Taila Nasya Along With Pathyadi Kwath In The Management Of Ardhavabhedaka (Migraine)". World Journal of Pharmaceutical and Medical Research, 12(8), 268-273.

Article Received on 25/06/2026 **Article Revised on 15/07/2026** **Article Published on 01/08/2026**

ABSTRACT

Background: Ardhavabhedaka is one of the eleven Shirorogas described by Acharya Sushruta and is characterized by recurrent unilateral headache associated with severe pain. The clinical presentation closely resembles migraine, one of the most prevalent primary headache disorders worldwide. Migraine considerably affects the quality of life and is frequently associated with nausea, vomiting, photophobia, phonophobia and aura. Although several modern pharmacological therapies are available, long-term treatment is often associated with recurrence, adverse drug reactions and incomplete symptomatic relief. Ayurveda advocates Nasya Karma as the principal therapeutic intervention for diseases of Urdhwajatru, while Pathyadi Kwath is a classical formulation indicated for Shiroroga. Comparative evidence regarding the efficacy of Manjishthadi Taila Nasya and Anu Taila Nasya in migraine is limited, necessitating systematic clinical evaluation. **Objective:** To evaluate and compare the efficacy of Manjishthadi Taila Nasya and Anu Taila Nasya administered along with Pathyadi Kwath in the management of Ardhavabhedaka (Migraine). **Methods:** A randomized, open-labelled, controlled clinical trial will be conducted on 60 patients (30 in each group) diagnosed with Ardhavabhedaka (Migraine), aged 18–60 years. Participants will be randomly allocated into two equal groups using computer-generated randomization. Group A will receive Manjishthadi Taila Marsha Nasya along with Pathyadi Kwath, whereas Group B will receive Anu Taila Marsha Nasya along with Pathyadi Kwath for 35 days. Nasya Karma will be administered in three sittings of seven days each with an interval of seven days. Clinical assessment will be performed using subjective symptom scores, Visual Analogue Scale (VAS), and appropriate laboratory investigations. Data will be analysed using suitable statistical methods, considering $p < 0.05$ as statistically significant. **Expected Results:** Both treatment protocols are anticipated to reduce the severity, frequency and duration of migraine attacks, along with associated symptoms including nausea, vomiting, photophobia, phonophobia, vertigo and aura. Manjishthadi Taila Nasya is hypothesized to demonstrate comparatively superior therapeutic efficacy because of its Tridoshaghna, Vata-Kaphahara and Shiroshoolahara properties. **Conclusion:** The present study is expected to generate scientific evidence regarding the comparative efficacy of Manjishthadi Taila Nasya and Anu Taila Nasya as adjuncts to Pathyadi Kwath in the management of Ardhavabhedaka (Migraine). The findings may contribute to evidence-based Ayurvedic management of migraine and encourage wider clinical application of Nasya therapy.

KEYWORDS: Ardhavabhedaka, Migraine, Nasya Karma, Manjishthadi Taila, Anu Taila, Pathyadi Kwath, Shiro Roga, Ayurveda.

INTRODUCTION

Our ancient sages have described three vital organs and have given prime significance to head i.e. *Shirah (Uttamanga*- the uppermost and chief part of the body)[1], as the actuality of body depends upon the vital organs.*Shirah* is that part of body where life along with sense faculties resides.[2] *Shalakya Tantra* also known as *Urdhwanga chikitsa* (treatment of disorders above the clavicle) deals with the diseases of *Shirah* and also its management. All *Shiroroga* occur due to vitiation of *Tridosha*. In *ayurvedic* textbooks, nearly all the *Acharya's* have mentioned *Ardhavbhedaka* in *Shiro-rogas. Acharya Sushruta* has mentioned 11 types of *Shiro-rogas* in *Uttar Tantra*,[3] and among them one is *Ardhavabhedaka* in which paroxysmal unilateral headache associated with vertigo and pain of varying intensity is seen.

This can be scientifically correlated with Migraine due to its cardinal feature "Half sided Headache". Migraine is a condition marked by recurrent moderate to severe headache with throbbing pain that usually last from hours to days. The term "Migraine" refers to a pattern of vascular spasms of the cranial blood vessels.

Symptoms of a Migraine attack may include heightened sensitivity to the light and sound (sonophotophobia), nausea, auras (loss of vision in one eye or tunnel vision), difficulty of speech and violent pain predominating on either side of the head.

Migraine is classified into two parts-with or without auras (seeing bright spots or stars). Common migraines are without auras. About 75% of migraines are the common type. Migraine with aura includes Visual, Retinal, Sensory, Motor, Speech and Language aura at least in two attacks. Aura symptoms are lasting from 5-60 minutes followed by headache.[4]

Headache is the most common problem experienced by the individuals. Around 40% of individuals worldwide are suffering from migraine. According to IHS (Indian Headache Society),[5] migraine constitutes 16% of the primary headache and affects about 10-20% of general population (about 15% male and 6% female are the sufferers of the migraine). About 80% of patients have migraine without aura and 15-20% have migraine with aura.[6] It is more common in women than in men (3:1) and family history is present in more than 60% of cases. Changing hormonal level also play a great role.[7]

Nasya is the complete treatment of *Shirogata vyadhi* because (***Nasa hi shirasho dwaram***)[8] According to *Acharya Sushruta[9] Ardhavabhedaka* is due to *Tridosha Prakopa* and primarily due to *Vata* or **Vata kapha**. *Acharya Charaka[10]* and *Madhav Nidana[11]* opines *Ardhavabhedaka* as *Vataja* or *Vata-Kaphaja*. Therefore, *Ardhavabhedaka*, a *Sadhya* type of *Shiro-roga* which can be best managed with *Ausadhis* (medicines) having *Ushna* (hotness), *Snigdha* (sliminess) and *Vatahara* or *Vata-kaphahara* properties.

Hence, to find out such unique phenomenon of *Ayurveda* and to solve the problem of sufferers of Migraine, *Ardhavabhedaka* (Migraine with and without aura) has been selected for the present study. *Pathyadi Kwath* is mentioned in *Bhavaprakash* for headache (*Shiroroga*).[12] The decoction has ingredients having *Ushana Virya* and *Vatashamak* properties, which may be useful in management of *Ardhavabhedaka*.

Manjishthadi Taila and *Anu Taila* have the property of *Tridoshaghnta* and *Snigdha guna*. *Manjishthadi Taila* mentioned in *sahashrayogam* for *Shirosula*.[13] *Anu Taila[14] Nasya* cures all types of *Shirorogs.*

Modern drugs don't have satisfactory effect due to their many drawbacks like insomnia, dermatitis, dry mouth etc.

So *Manjishthadi Taila* and *Anu Taila* has been selected for *Nasya* therapy Along with this *Pathyadi Kwath* selected for internal administration which is recommended in *Ardhavabhedaka*. In *Ayurveda Nasya* therapy has been considered as one of most promising treatment for all the *Urdhawajatrugata Vikaras*.

Nasya Karma involves administration of herbal oil/drug/liquid into nostril which remove the blockages of the nasal pathways, relief mental stress. These effects of *Nasya* gives significants relief in disease associated with nose and head region such as *Ardhavabhedaka* (Migraine). Hence these drugs have been selected to evaluate their efficacy in *Ardhavabhedaka* w.s.r. to Migraine.

Previous *Ayurvedic* studies evaluating *Nasya* therapy in migraine have largely been limited by small sample sizes, single-arm designs and lack of comparative evaluation. Comparative clinical evidence regarding *Manjishthadi Taila Nasya* and *Anu Taila Nasya* administered along with *Pathyadi Kwath* remains insufficient.

Therefore, the present randomized controlled clinical study has been planned to compare the efficacy of these two *Nasya* formulations in the management of *Ardhavabhedaka (*Migraine) and to generate evidence supporting evidence-based *Ayurvedic* practice.

AIM AND OBJECTIVES

Aim

To compare the effect of *Manjishthadi Taila Nasya* and Anu Taila Nasya along with *Pathyadi Kwath* in the management of *Ardhavabhedaka* (Migraine).

Primary Objective

To Evaluate and Compare the efficacy of *Manjishthadi Taila nasya* and *Anu Taila Nasya* along with *Pathyadi*

kwath in the management of *Ardhavabhedaka* (Migraine).

Secondary Objective

1. To study the *Ardhavabhedaka* from various *ayurvedic* and modern texts.
2. To study the *Nasya* from various ayurvedic texts.

Research Question

Is there any difference between efficacy of *Manjishthadi Taila Nasya* and *Anu Taila Nasya* along with *Pathyadi Kwath* in the Management of *Ardhavabhedaka* (migraine)?

Hypothesis

Null Hypothesis (H_0)

There is no difference in the efficacy of *Manjishthadi Taila Nasya* and *Anu Taila Nasya* along with Pathyadi Kwath in the management of *Ardhavabhedaka* (migraine).

Alternate Hypothesis (H_1)

There is significant difference in efficacy of *Manjishthadi Taila Nasya* in comparison to *Anu Taila Nasya* along with *Pathyadi Kwath* in the management of *Ardhavabhedaka* (migraine).

MATERIAL AND METHODS

To fulfil the aim and objectives, the study plan is divided into two sections. Literary Review.

Clinical Study

Study Design

Type of trial-Interventional

- Study Design-Open Labelled Controlled Clinical study
- Health type- Patient diagnosed with *Ardhavabhedaka* (Migraine).
- Purpose-To evaluate the efficacy of *Manjishthadi Taila Nasya* in comparision with *Anu Taila nasya* along with *Pathyadi Kwath* in *Ardhavabhedaka* (Migraine).
- Masking/Blinding-Open labelled
- Method of Randomization-Computer based randomization
- No. of groups-2 • Sample Size-60(30 groups in each group)
- Allocation-Random allocation
- Phase of trial-Phase 2
- Estimated total duration of trial-1.5 years
- Statistical Tool-As adviced by statician.

Selection of Patients: A total of 60 patients meeting the inclusion criteria were selected for the study from OPD & IPD of Department of *Shalakya Tantra*. These patients were randomised into two groups, each consisting of 30 patients.

Inclusion Criteria

- Age- 18-60 years
- Patients with sign and symptoms of *Ardhavabhedaka* (Migraine with or without aura) will be selected irrespective of Sex, Religion and Profession.
- Patients those are fit for *Nasya Karma* according to *Ayurveda* text.
- Patient willing to participate and able to provide signed informed consent.

Exclusion Criteria

- Age group < 18 years and >60 years.
- The patient having any systemic illness, like - Diabetes mellitus, Hypertension, Tuberculosis, Hypotension & fever etc.
- Patients suffering from head injury, and other type of headaches except migraine.
- Patients Contraindicated for *Nasya Karma*.
- Pregnant and lactating mothers.
- Secondary headache caused by sinusitis, meningitis, brain tumour, encephalitis, cervical spondylitis etc.
- Patients with alcohol, opioids other drug addiction and using any other systemic drugs which may alter the result of study.

Sources of Data

Literature Source: *Ayurvedic Samhitas* and *Ayurvedic* textbooks related to *Shiro-Rogas* and *Nasya karma* will be reviewed. Modern medical science texts, Research papers, Internet, Google scholar and Previous research work regarding this study will be screened for information regarding the subject.

Clinical Source: Daily OPD, IPD patients of Institute For Ayurved Studies & Research Hospital, Kurukshetra & patients diagnosed as *Ardhavabhedaka lakshanas* will be considered for the study after obtaining written informed consent.

Experimental Source: This was a human clinical study, no animal experimentation was conducted.

Plan of Study

The study will be conducted in two groups consisting of 60 patients (30 each) Duration of trial: 35 days.

GROUP -A (Trial Group)

- No of patients:- 30
- *Pathyadi Kwath Pana*:- 50ml twice a day Before Meal for 35 days.
- *Marsh Nasya* with *Manjishthadi Taila Nasya*.
- 3 Sittings of *Nasya* i.e., 7days each with an interval of 7 days in between.

GROUP- B (Control Group)

- No of patients :- 30
- Pathyadi Kwath Pana 50 ml twice a day Before Meal for 35 days.

- *Marsh Nasya* with *Anu Taila.*
- 3 Sittings of *Nasya* i.e., 7days each with an interval of 7 days in between.

***Kwath* Dose**
Matra: 2 *Pala* (Approx.96ml) ***Anupana* for *kwath***: Guda.
Marsh Nasya Matra: 8 Bindu in each nostril.[15]

Route and form of administration-Nasally in the form of *Marsh Nasya***.**
Kala- *Purvahna*
Follow up- Follow up of patient will be done on 15th, 35th day of the treatment.

Follow up on 15th, 30th day after treatment.

Assessment Criteria
- Scoring is given to each sign and symptom which is as follows-

A) *Subjective criteria*[16]
- The patients will be diagnosed on the basis of signs and symptoms given in Ayurvedic literature:
- *Ardha Shiro Shoola* (Unilateral Pain)
- *Bheda*, *Toda*, *Shoola* (Pulsating, throbbing type of pain)
- *Pakshaat, Akasmat* (Paroxysmal in nature)
- *Prakasha Asahishnut* (Photophobia)

1) *Intensity of Headache*

Grading	Clinical Severity Status
0	Normal (No headache)
1	Mild (Headache doesn't interrupt regular activities)
2	Moderate (Headache interrupts daily activities & diverts concentration)
3	Severe (Not able to perform regular work)

2) *Frequency of Headache*

Grading	Clinical Severity Status
0	Normal (Nil)
1	Mild (>15 days)
2	Moderate (>7 days - <15 days)
3	Severe (>3 days - <7 days)

3). *Duration of Headache (hours/day)*

Grading	Clinical Severity Status
0	Normal (Nil)
1	Mild (1-8 hours/day)
2	Moderate (9-16 hours/day)
3	Severe (17-24 hours/day)

4). *Nausea*

Grading	Clinical Severity Status
0	Normal (No nausea)
1	Mild (Occasionally)
2	Moderate (Nausea but does not disturb routine work)
3	Severe (Disturbing routine work)

5). *Vomiting*

Grading	Clinical Severity Status
0	Normal (No vomiting)
1	Mild (Only if headache doesn't subside)
2	Moderate (Vomiting 1-2 times)
3	Severe (Vomiting 2-3 times)

6). *Photophobia*

Grading	Clinical Severity Status
0	Normal (Nil)
1	Mild (Very mild)
2	Moderate (On exposure to sunlight/bright light)
3	Severe (On exposure to indoor light)

7). *Phonophobia*

Grading	Clinical Severity Status
0	Normal (Nil)
1	Mild (Very mild)
2	Moderate (Moderate phonophobia)
3	Severe (Severe Phonophobia)

8). *Vertigo*

Grading	Clinical Severity Status
0	Normal (Nil)
1	Mild (Feeling of giddiness)
2	Moderate (Patient feels as if everything is revolving)
3	Severe (Revolving signs + black outs)

9). *Aura*

Grading	Clinical Severity Status
0	Normal (Nil)
1	Mild (Lasts for 10 minutes)
2	Moderate (Lasts for 30 minutes)
3	Severe (Lasts for 60 minutes)

B) *Objective Parameters*

1. **Visual Analogue Scale (VAS)** Pain severity was observed on a standard 0-10 Visual Analogue Scale to measure subjective pain intensity pre- and post-intervention.

Investigative Parameters (if any)

- **Laboratory Investigations:** Complete Blood Count (CBC), Erythrocyte Sedimentation Rate (ESR), and Urine Routine/Microscopic (R/M) examinations will be performed.
- **Ophthalmological Examination:** Visual Acuity, Intraocular Pressure (IOP), and Fundoscopy checks will be recorded.
- **Radiological Examination:** X-ray of Paranasal Sinuses (PNS) were carried out in doubtful diagnostic cases.

Outcomes Primary

1. Significant improvement in intensity, frequency, duration of headache.
2. Reduction in scoring pattern of sign and symptoms of *Ardhavabhedaka*(Migraine) along with nausea, vomiting, photophobia, phonophobia and aura.

Secondary

1. Improvement in mental & physical well being of patient.

Sample Size

The observation and result will be analyzed and presented on the basis of respective and applicable statistical tests.

Sample Size Calculation

Sample Size at 90% Power

Sample size is calculated on the basis of expected cured % with trial drugs using the formula:

P1 = 1.00 (100%) the proportion of migraine before applying the trial drug

Where p2 = 0.0884 (8.84%) the proportion of migraine after applying the trial drug (equal to the approx prevalence in general population)

(Ref : Kulkarni, Girish & Rao, Girish & Gururaj, G & Kumaraswamy, Subbakrishna & Steiner, Timothy & Stovner, Lars. (2014). EHMTI-0333. The prevalence and burden of migraine in india: results of a population-based study in Karnataka state. The Journal of Headache and Pain. 15. B18-B18. 10.1186/1129-2377-15-S1-B18.)

e = 0.95(p1 – p2), the proportion difference considered to be clinically significant Type I error, α=5%

Type II error β=10% for detecting results with power of study 90% The sample size is n = 30 each group.

Ethical clearance & CTRI Registration

The Institutional Ethical Committee granted Ethical approval before the commencement of the study (SKAU/Acad/2024/11627). The clinical Trial was registered with the clinical Trial Registry of India under registration number (CTRI/2025/03/083175).

OBSERVATIONS AND RESULTS

The results were evaluated based on the predefined assessment criteria and statistically analysed for significance.

DISCUSSION

The obtained results will be discussed on the basis of *Ayurvedic* concept and modern parameters.

REFERENCES

1. Dr. Babita Rani, A Clinical study to evaluate the effect of Pathyadi Kwatha and Anu Taila Nasya in

the Manegement of Ardhavbhedaka w.s.r Migraine.
2. Shastri Kashinath, Chaturvedi Gorakhnath Charak Samhita Vidyotini, Varansi: Chaukhamba Bharti Academy; 2016 Siddhi Sathana 9 Verse no 04.
3. Shastri Ambikadutta. Sushruta Samhita, Varansi; Chaukhamba Sansthana 2018 Uttara Tantra 25 Verse no. 04
4. Harrison's Principles of Internal Medicine. Jameson JL, Fauci AS, Kasper DL, Hauser SL, Longo DL, Loscalzo J, editors. *Harrison's Principles of Internal Medicine*. 21st ed. New York: McGraw Hill; 2022.
5. International Journal of Trend in Scientific Research and Development (IJTSRD) Volume: 3|issue:3|mar-apr 2019 Available online: www.ijtsrd.com e-ISSN: 2456-6470.
6. Headache Classification Committee of the International Headache Society (IHS), The International Classification of Headache Disorders, 3rd edition ICHD3.
7. Prevalence burden and risk factors of migraine a community based study for eastern india, Biman K ray, Neelanjna paul, Avijit Hajra, sujata das etc., 2017; 65(6): 1280-1288.
8. Atrideva Kaviraja, Astangahardayam, Vidyotini hindi commentary, Varansi; Chaukhamba Prakasan 2018, Sutra Sathana 20 Verse no 01.
9. Shastri Ambikadutta. Sushruta Samhita, Varansi; Chaukhamba Sansthana 2018 Uttara Tantra 25 Verse no. 15.
10. Shastri Kashinath, Chaturvedi Gorakhnath Charak Samhita Vidyotini, Varansi: Chaukhamba Bharti Academy 2016, Chikitsa Sathana 9 Verse no 04.
11. Acharya Madhava, Madhava Nidana, Madhukosha Vyakha: Yadunandana Upashyaya, Varansi:Chaukhamba Prakashan, 2009; II: Adhayaya, 60, 463.
12. Pandit Shri Lalchandra Vaidya, Sarvangsundari Hindi Tika, Bhavprakash Third Edition, Shirorogadhikar, 54, 400.
13. R.Vidyanath & K.Nishteswar Sahasrayogam Second Edition 2008 Chowkhamba Sanskrit Series Office, Varanasi.
14. Shastri Kashinath, Chaturvedi Gorakhnath Charak Samhita Vidyotini, Varansi: Chaukhamba Bharti Academy, 2015, Sutra Sathana 5.
15. Sreeja.V.S & Vikram kumar: Standaridization of Nasya Dose by Bindu Pramana with Karpasatyadi Taila. International Ayurvedic Medical Journal 2021, 1200-1204. http://www.iamj.in/posts/2021/images/upload/1200-1204.pdf
16. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*, Jan. 2018; 38(1): 1-211.

BIBLIOGRAPHY

- AFI Textbook of Medicine
- *Ashtanga Hridayam*
- *Ashtanga Sangrah*
- *Bhavprakash*
- *Charaka Samhita*
- *Dravyaguna Vijnana* by P.V. Sharma
- Diseases of Ear, Nose and Throat by PL Dhingra
- Davidson's Principles and Practice of Medicine
- Harrison's Principles of Internal Medicine
- *Sushruta Samhita*
- *Sahasra Yogam*
- *Sarangdhara Samhita*
- Text book of Physiology by Sumbulingam
- Text Book of Anatomy by B.D. Chaurasiya
- Various National and International Journals
- *Yogaratnakar*