

## AN OPEN LABELLED CLINICAL CONTROL STUDY TO EVALUATE THE EFFICACY OF VIDANGADI ARKA NASYA IN THE MANAGEMENT OF ARDHAVABHEDAKA (MIGRAINE WITHOUT AURA)

[Jeeva P<sup>1</sup>](#), [Veeravya R Hiremath<sup>2</sup>](#), [Shashikala K<sup>3</sup>](#), [Gururaj N<sup>4</sup>](#)

<sup>1</sup>P.G. Scholar, <sup>2</sup>Professor and HOD, <sup>3</sup>Associate Professor, <sup>4</sup>Assistant Professor;  
Dept. of Shalakyta Tantra, SJGAMC&H, Koppal, Karnataka, India

Corresponding Author: [jeeva13111@gmail.com](mailto:jeeva13111@gmail.com)

<https://doi.org/10.46607/iamj2608102020>

(Published online: October 2020)

### Open Access

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Article Received: 01/10/2020 - Peer Reviewed: 03/10/2020 - Accepted for Publication: 04/10/2020



## ABSTRACT

**Background and Objective:** *Ardhavabhedaka* (migraine without aura) is characterized by severe tearing, pricking and piercing pain in one half of the head and giddiness which develops suddenly after ten days or a fortnight. Based on signs and symptoms it may correlate with migraine characterized by half sided headache associated with nausea, vomiting, photophobia and phonophobia. The current line of management for migraine advocates the use of analgesics and antiemetics, vasoconstrictors, sumatriptan, topiramate, flunarizine, Propranolol. *Ayurveda* emphasizes various treatment modalities of *Ardhavabhedaka*, includes both *Shodhana* and *Shamana*. *Vidangadi avapeedana Nasya* and *Vidangadi arka* (distillate) *Nasya* have been mentioned for *ardhavabhedaka chikitsa*. *Arka* is the essence of the drug; possesses *laghu*, *ushna*, *kaphavatahara*, increased potency, more shelf life, easy absorption and act fast. **Materials and Methods:** 20 patients of Group A were treated with *Vidangadi Arka Nasya* and Group B 20 patients were treated with *Vidangadi Avapeedana Nasya* (each nostril 6 drops for 7 days). **Results:** The data of both the groups were collected according to the objective and subjective Parameters and analyzed using repeated measures of ANOVA, Bonferroni test, and Mann-Whitney U Test. The efficacy was statistically highly significant within the group at  $P < 0.001$  and statistically insignificant between the group at  $P > 0.05$  among all the parameters. **Interpretation and Conclusion:** Study can be concluded that patients treated with *Vidangadi Arka* and *Avapeedana Nasya* showed not much difference in the results statistically, clinically group A showed better results than group B.

**Keywords:** Ardhavabhedaka, Migraine without aura, Vidangadi Arka, Vidangadi Avapeedana, Nasya.

## INTRODUCTION

Ardhavabhedaka is a shiroroga caused by vitiation of tridosha characterized by severe tearing, pricking and piercing pain in one half of the head and giddiness which develops suddenly after ten days or a fortnight<sup>1</sup>. This can be correlated with Migraine.

Migraine is a chronic neurological disease characterized by recurrent, moderate to severe headaches often in association with autonomic nervous system symptoms. It constitutes

16% of the primary headache and affects 10-20% of the general population. It is three times more common in women than in men. It is underdiagnosed and undertreated, hence WHO ranks Migraine among the World's most disabling medical illness<sup>2</sup>.

Its management includes use of analgesics and antiemetics in acute attacks. If not responding, vasoconstrictor like ergot alkaloids are given. Sumatriptan has been used more successfully. Prophylaxis of migraine may be achieved by topiramate, flunarizine, Propranolol etc<sup>3</sup>.

Ardhavabhedaka chikitsa includes both Shodhana and Shamana. Vidangadi (avapeedana) nasya<sup>4</sup> and Vidangadi arka<sup>5</sup> (distillate) Nasya have been mentioned for Ardhavabhedaka chikitsa. Vidanga is kaphavatahara and ushna virya, Krishna tila is tridosha shamaka and ushna virya. Arka is the essence of the drug; and possesses laghu, ushna, kaphavatahara properties, increased potency, more shelf life, easy absorption, and act fastly<sup>6</sup>.

Hence, the present study was been taken up to evaluate the efficacy of vidangadi Arka Nasya and Vidangadi (Avapeedana) Nasya in the management of Ardhavabhedaka.

### Aim and Objectives

- To access the effect of **Vidangadi Arka Nasya** in the management of Ardhavabhedaka (Migraine without Aura).
- To access the effect of **Vidangadi Avapeedana Nasya** in the management of Ardhavabhedaka (Migraine without Aura).

- To compare the effect of **Vidangadi Arka Nasya** and **Vidangadi Avapeedana Nasya** in the management of Ardhavabhedaka (Migraine without Aura).

### Materials and Methods: -

This study was presented before IEC of SJGAMC KOPPAL and got clearance vide ref. No. HK/ICEC/2019-20/137/dt.19/09/2020 and it was registered in CTRI on 16/09/2019, vide reference No. CTRI/2019/09/021262.

**Source of data:** Shalakya tantra OPD, IPD and special camps of SJG Ayurvedic medical college and hospital Koppal

**Selection of patient:** 40 Patients diagnosed as Ardhavabhedaka (migraine without aura) were selected and randomly divided into two equal groups.

### Inclusion criteria:

- Patients having the cardinal features of Ardhavabhedaka (migraine without aura).
- Patients aged between 16-60 years irrespective of their gender.
- Patients fit for Nasya karma.

### Exclusion criteria:

- Patients having a history of head trauma and other types of headaches.
- Patients having any inflammatory diseases in nose, PNS, eyes and ears.
- Patients with other systemic disorders like hypertension, diabetes mellitus, etc.

### Sampling method:

Random sampling method.

### Assessment criteria:

The intensity of pain, duration of pain, frequency of attack & associated symptoms of Ardhavabhedaka w.s.r to migraine without aura were the parameters considered for the assessment of treatment.

**Ksheera Bala Taila:** Procured from Kottakal Arya Vaidya Sala Pharmacy, used for mukhaabyanga.

### Preparation of Vidangadi Arka:-

40 gms (each 20 gms) of Vidanga and Krishna tila made into a coarse powder form and later, 400 ml of cold water was poured and mixed up well. It was stored

in an airtight container for 12 hrs (previous day night of medicine preparation). Next day stored medicines were put into *arka yantra* (distillation apparatus), the distillation process started with 80° C heat, finally, 230 ml of arka was collected, after cooling arka was stored in an airtight container.

**Overall effect of therapy:**

- **Good response/Improvement** – More than 70% relief in objective and Subjective Parameters.
- **Moderate response/Improvement** –40-70% relief in objective and subjective Parameters.
- **Mild response/Improvement**– 20-45% relief in objective and subjective Parameters.
- **Poor response/Improvement** – less than 20% relief in objective and subjective Parameters.

**Group, dose and duration:**

Group	Intervention	Duration	Dosage
Group A	Vidangadi Arka Nasya	7 days	6 drops in each nostril/day
Group B	Vidangadi Avapeedana Nasya	7 Days.	6 drops in each nostril/day

**Follow-up of the treatment:** Patients were asked to attend the O.P.D. for 14 days after completion of therapy for the follow up.

**Statistical test:** The effect of the treatment was assessed statistically by using repeated measures of ANOVA, Bonferroni test, within the groups and Mann-Whitney ‘U’ Test between the groups. The results were interpreted at the level of P<0.001 as highly significant, P<0.05 or P<0.01 as significant, and P>0.01 as insignificant.

**Observation and Results:** In the present study, 50%patients belonged to the age group of ≤ 30 years, 85 % were females, 47. 5% patients were housewives, 62. 5% patients belonged to middle class. Maximum number of patients i.e., 57.5% were of *vata pradhana Prakriti*, 57.5% patients had *vishamagni*; 65% patients,

the condition has been triggered by *aharaja nidanas*; 75% triggered by *viharaja nidanas*; 85% triggered by *manasika nidanas*.

Maximum number of patients i.e., 100% patients were treated cases.

9 patients 22.5% had the Chronicity between 7-12 years, 15 patients 37.5% had a Chronicity between 4-6 years, 11 patients 27.5% had Chronicity ≤3 years, 5 patients 12.5 % had Chronicity >12 years; 97.5% had a gradual onset of the condition.

Maximum number of patients i.e., 100% were having half sided headache, followed by 70%patients were having nausea, 65% patients were having vomiting, 95% patients were having photophobia & 97.5% patients were having phonophobia.

**Overall Assessment of The Results**

**Table 1:** Showing the overall Results on Day-3 between Group A and Group B

Overall Response Day - 3				
Response	GROUP A		GROUP B	
	No. Of Subjects	%	No. Of Subjects	%
Un changed	0	0%	0	0%
Mild Response	4	20%	9	45%
Moderate Response	8	40%	8	40%
Marked Response	1	5%	2	10%
Complete Response	7	35%	1	5%
Total	20	100%	20	100%

**Table 2:** Showing the overall Results on FU 2 (Day-21) between Group A and Group B

Overall Response Day - 21				
Response	GROUP A		GROUP B	
	No. Of Subjects	%	No. Of Subjects	%
Un changed	0	0%	0	0%
Mild Response	0	0%	0	0%
Moderate Response	0	0%	2	10%
Marked Response	1	5%	4	20%
Complete Response	19	95%	14	70%
Total	20	100%	20	100%

**Table 3:** Showing Overall Result on Symptoms on Day 3 between Group A and Group B

Overall Result Day - 3				
Mean of Parameters	GROUP A		GROUP B	
	Mean	SD	Mean	SD
DURATION OF PAIN	0.75	0.786	1.25	0.716
FREQUENCY OF ATTACKS	1.80	1.508	2.85	0.671
INTENSITY OF HEADACHE	0.95	0.945	1.35	0.587
NAUSEA	0.00	0.000	0.25	0.444
VOMITING	0.00	0.000	0.25	0.444
PHOTOPHOBIA	0.20	0.410	0.40	0.503
PHONOPHOBIA	0.25	0.444	0.40	0.503

**Table 4:** Showing Overall Result on Symptoms on Day 21 (FU 2) between Group A and Group B

Overall Result Day - 21				
Mean of Parameters	GROUP A		GROUP B	
	Mean	SD	Mean	SD
DURATION OF PAIN	0.05	0.224	0.15	0.489
FREQUENCY OF ATTACKS	0.10	0.447	0.40	0.821
INTENSITY OF HEADACHE	0.05	0.224	0.15	0.366
NAUSEA	0.00	0.000	0.05	0.224
VOMITING	0.00	0.000	0.05	0.224
PHOTOPHOBIA	0.00	0.000	0.10	0.308
PHONOPHOBIA	0.00	0.000	0.10	0.308

**Result:**

**Overall effect of therapy:**

**The overall response on day 3**, in Group A out of 20 patients, 4 patients (20%) showed a mild response, 8 patients (40%) showed a moderate response, 1 patient (5%) showed a marked response and 7 patients (35%) showed complete response. While in Group B out of 20

patients 9 patients (45%) showed a mild response, 8 patients (40%) showed a moderate response, 2 patients (10%) showed a marked response, 1 patient (5%) showed complete response.

**The overall response after treatment day 8**, in Group A out of 20 patients, 0 patients (0%) showed a mild response, 2 patients (10%) showed a moderate response,

2 patients (10%) showed a marked response and 16 patients (80%) showed complete response. While in Group B out of 20 patients 1 patient (5%) showed a mild response, 5 patients (25%) showed a moderate response, 1 patient (5%) showed a marked response, 13 patients (65%) showed complete response.

**The overall response on day 14 (FU 1),** in Group A out of 20 patients, all 20 patients (100%) showed complete response. While in Group B out of 20 patients, 5 patients (25%) showed a marked response, 15 patients (75%) showed a complete response.

**The overall response on day 21 (FU2),** in Group A out of 20 patients, 1 patient (5%) showed a marked response and 19 patients (95%) showed a complete response. While in Group B out of 20 patients, 2 patients (10%) showed a moderate response, 4 patients (20%) showed a marked response, 14 patients (72%) showed complete response.

## DISCUSSION

**Discussion on selection of topic:-** Migraine is a chronic neurological disease; it constitutes 16% of the primary headache and affects% of the general population. Hence WHO ranks Migraine among the World's most disabling medical illness.

Even though a lot of research on migraine with different treatment modalities has been undergoing in the bio-medical world, a considerable number of the world population is suffering from this disease without satisfactory relief. This raises the need to explore an effective line of management for this disorder.

*Vidangadi avapeedana Nasya* and *Vidangadi arka* (distillate) *Nasya* have been mentioned for *ardhavabhedaka chikitsa*. *Arka* is the essence of the drug; possesses *laghu*, *ushna*, *kaphavatahara*, increased potency, more shelf life, easy absorption and act fastly in the management of *ardhavabhedaka*.

**Discussion on procedure:** The administration of medicines through the nose is called *nasya*<sup>7</sup>. *Nasa* being the gateway for *Shira*, the drug administered through nostrils, absorbed through *Shringataka marma*, *ghrana*, *Netra*, *Asya*, *shrotra* through the minute channels (*srotas*), reach the upper region and eliminates the morbid

*doshas* from the *Uttamanga*<sup>8</sup>. Therein Group A, *Vidangadi Arka nasya* and in Group B, *Vidangadi Avapeedana nasya*.

**Discussion related to Drug:** Therein Group A, *Vidangadi Arka nasya* and in Group B, *Vidangadi Avapeedana nasya* were used for this study. Ingredients of *vidangadi arka* and *vidangadi avapeedana nasya* are *Vidanga* and *Krishna tila*.

**Ksheera Bala Taila**<sup>9</sup>: Containing *ksheera*, *Bala* and *tila taila*, having the quality of *vata-pitta prashamana*, *vedanasthapaka*, *snehana* and *dhatu poshana*, anti-inflammatory.

**Vidanga**<sup>10</sup>: It is *katukashaya rasa*; *laghu*, *ruksha*, *tikshna*, and *Sara guna*; *ushna virya*; *katu vipaka* and *kaphavatahara*, best *krimighna*, *vishagna*, and *deepana*, indicated in *Krimi*, *Udara*, *Adhmana*, *Sula*, *Kushta*. By its *kashaya rasa*, it does *pitta shamana* and by *ushna* and *katu*, it does *vatakapha shamana*. Hence, it carries *tridoshahara* property. By its *shulahara* property it is very much useful in neuralgia and headaches.

**Krishna Tila**<sup>11</sup>: It is *madhura rasa*; *guru* and *Snigdha guna*; *ushna virya*; *madhura vipaka* and *tridoshahara*, best *Vatahara*, *Tvacya*, *Balya*, *Keshya*, *Shukrala*, indicated in *Vataroga*, *Grahani*, *Agnimandya*, *Yoniroga*. By its *madhura rasa*, it does *pitta shamana* and by *ushna virya*, it does *vatakaphashamana*. Hence, it carries *tridoshahara* property. Hence, the *Vidangadi Arka Nasya* has been administered in *Ardhavabhedaka*.

### Mode of Action of Vidangadi Arka Nasya

*Snehana / Swedana*



*Dosha vilayana*



*Nasya dravya removing sroto-rodha*



Reaches *shringataka marma*

- *Vidanga* is *kaphavatahara* and *ushna virya*
- *Krishna tila* is *tridosha shamaka* and *ushna virya*
- *Arka* is the essence of the drug; and possesses *laghu*, *ushna*, *kaphavatahara* properties, increased potency, more shelf life, easy absorption and acts fastly in the Management of *ardhavabhedaka*.

The analysis report of *Vidangadi arka* showed properties of *vidanga*, *krishna tila*, volatile oil and steroid were present in *vidangadi arka*, so it was more effective in the management of migraine.

## CONCLUSION

*Tila* is more effective in pain management as well as *ardhavabhedaka* caused due to hormonal disturbances. Analyzing the observations and result obtained from Group A and Group B, it can be concluded that the patients of this study in *both the group* showed the better result. There was not much difference in the result statistically.

The analysis report of *Vidangadi arka* showed properties of *Vidanga*, *Krishna Tila*, volatile oil and steroid were present in *vidangadi arka*, so it was more effective in the management of pain and absence of recurrence of disease. Hence to conclude the study, group A (*Vidangadi Arka Nasya*) showed clinically better results compared to group B (*Vidangadi Avapeedana Nasya*).

## Recommendations for Further Study:

- Study on the effect of *Nasya* with para surgical procedures (*sira vyadhana*).
- The study can be conducted for a longer duration to see the recurrence of attacks.
- The present study can be done in a large sample size.

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Source of Support: Nil

Conflict of Interest: None Declared

How to cite this URL: Jeeva P et al: A Clinical Research On Open Labelled Clinical Control Study To Evaluate The Efficacy Of Vidangadi Arka Nasya In The Management Of Ardhavabhedaka (Migraine Without Aura). International Ayurvedic Medical Journal {online} 2020 {cited October, 2020} Available from: [http://www.iamj.in/posts/images/upload/4742\\_4747.pdf](http://www.iamj.in/posts/images/upload/4742_4747.pdf)