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A randomized controlled clinical study to evaluate the efficacy of *Nasya* with *Devadarvadi Ghrita* in the management of *Ardhavabhedaka*

Pooja S. Patil¹, Sudarshan A², Guruprasad³, Vidyashree⁴

¹Post Graduate Scholar, Department of Panchakarma, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Karnataka, India.

²Professor and HOD, Department of Panchakarma, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Karnataka, India.

³Professor, Department of Panchakarma, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Karnataka, India.

⁴Assistant Professor, Department of Panchakarma, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Karnataka, India.

ABSTRACT

Background: *Ardhavabhedaka* is one among the *Shirorogas* explained by our *Acharyas* in which *Shoola* is experienced in *Ardha Bhaga* of the *Shiras*. *Ardhavabhedaka* can be scientifically correlated with Migraine due to its cardinal features of Half sided headache. *Ardhavabhedaka* if not treated it can cause *Netra* and *Shotra Nasha*, hence an early treatment is essential. *Devadarvadi Ghrita Nasya* is indicated in *Ardhavabhedaka* by *Acharya Harita*, therefore, this study was conducted to access its efficacy. **Objective:** To compare the efficacy of *Devadarvadi ghrita Nasya* and *Shadbindu taila Nasya* in the management of *Ardhavabhedaka*. **Methodology:** In this single-blind study, 40 patients exhibiting classical features of *Ardhavabhedaka*, who met the inclusion criteria, were divided into two groups of 20 patients each for analysis. Group A was treated with *Devadarvadi Ghrita Nasya*, while Group B was treated with *Shadbindu Taila Nasya* for 7 days, followed by a follow-up assessment on the 14th day, after which statistical analysis was conducted. **Result:** Although there was no statistical significance observed, both the groups demonstrated clinical significance in reducing the frequency, duration, severity of headache and giddiness. **Conclusion:** *Devadarvadi Ghrita Nasya* showed better results than *Shadbindu Taila* in the management of *Ardhavabhedaka*.

Key words: *Ardhavabhedaka*, *Devadarvadi Ghrita*, *Nasya*, *Migraine*

INTRODUCTION

Ayurveda is a science of life which promotes positive health, prevents diseases, and helps in achieving long life. The main of the *Ayurveda* is to maintain health in healthy persons and to cure the diseases in diseased

person. *Shiras* is considered as *Uttamanga*,^[1] as it is the seat for *Panchagyanendriya*, it is one among the *Trimarma's* and it is one among *Dashapranayatanas*. In Ayurveda different *Acharyas* have mentioned different number of *Shirorogas* in which *Ardhavabhedaka* is one among them. *Ardhavabhedaka* as the name indicates it produces *Shoola* in half part of the head. As explained by *Acharya Charaka*, *Shastraarani Nibha Shoola* is experienced in *Manya*, *Bhru*, *Akshi*, *Karna*, *Shankha Pradesha* etc,^[2] this is mainly caused by *Vata dosha* or in association with *Kapha Dosha*,^[3] symptoms reoccur in the interval of 10 or 15 days without any relevant cause. *Ardhavabhedaka* can be correlated with Migraine, as both the disease showcases unilateral headache (*Ardhamastaka Vedana*). Migraine is a chronic neurological disease characterised by recurrent, moderate to severe headache typically affecting one half of the head, is pulsating in nature and

Address for correspondence:

Dr. Pooja S. Patil

Post Graduate Scholar, Department of Panchakarma, Muniyal Institute of Ayurveda Medical Sciences, Manipal, Karnataka, India.

E-mail: poojas5696@gmail.com

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lasts from 4 to 72 hours. Associated symptoms may include nausea, vomiting and sensitivity to light, sound, or smell. The pain is generally made worse by physical activity.^[4] Migraine is one of the common causes of recurrent headache. According to IHS, Migraine constitutes 16% of the primary headache and affects 10-20% of the general population. It is three times more common in women than men. *Ayurveda* classics has an elaborate description of the disease, including its treatment. *Acharya Charaka* has mentioned the treatment as intake of 4 types of *Sneha*, *Shirovirechana*, *Kayavirechana*, *Upanaha*, *Shirobasti*.^[5] *Nasya* or *Shirovirechana* is one of the *Panchakarma* procedure in which drugs or medicated liquids like *Sneha*, *Swarasa* etc. is administered through the nose. *Nasya* is especially described for the treatment of *Urdhwa Jatrugata Vikaras*.^[6] *Nasa* is said to be the door of the *Shiras*. Medicine administered through the nose, spreads into different parts of *Shiras* and helps in the evacuation of the *Doshas*, thereby pacifying the diseases. *Devadarvadi Ghrita* is one of the formulations mentioned in *Harita Samhita* and this is direct indicated for *Nasya* in *Ardhavabhedaka*.^[7] Hence keeping in view of all the above references and increasing incidence, a clinical study has been chosen to assess the efficacy of *Devadarvadi Ghrita Nasya* in the management of *Ardhavabhedaka*.

MATERIALS AND METHODS

Study design: Single blind randomized controlled clinical study.

Methodology: 40 patients suffering from classical features of *Ardhavabhedaka* fulfilling the inclusion criteria were taken up for the study, from the OPD and IPD of *Panchakarma* and *Shalaky* department of our college hospital, and they were divided into two groups each comprising of 20 patients, Informed consent was obtained from eligible patients before the initiation of treatment. Approval was taken from the institutional committee (IEC/MIAMA/PK/02/22) prior to the patient's enrolment.

Preparation of medicine: After proper identification, the drugs were collected from local area and *Devadarvadi Ghrita* was prepared as per *Sneha Paka*

Vidhi in the department of *Rasashatra* and *Bhaisajya Kalpana* department of our college.

Table 1: Ingredients of Devadarvadi Ghrita

Name	Botanical name	Family	Part used	Quantity
<i>Devadaru</i>	<i>Cedrus deodara</i>	Pinaceae	Bark	1 part
<i>Rajani</i>	<i>Curcuma longa</i>	Zingiberaceae	Rhizome	1 part
<i>Shati</i>	<i>Hedychium spicatum</i>	Zingiberaceae	Rhizome	1 part
<i>Pushkaramola</i>	<i>Inula racemosa</i>	Asteraceae	Root	1 part
<i>Kutaja</i>	<i>Holarrhena antidysenterica</i>	Apocynaceae	Seeds	1 part
<i>Maghadi</i>	<i>Piper longum</i>	Piperaceae	Fruit	1 part
<i>Kushta</i>	<i>Saussuria lappa</i>	Asteraceae	Root	1 part
<i>Lodhra</i>	<i>Symplocos racemosa</i>	Symplocaceae	Bark	1 part
<i>Chavika</i>	<i>Piper chaba</i>	Piperaceae	Root	1 part
<i>Yavasa</i>	<i>Alhagi camelorum</i>	Fabaceae	Whole plant	1 part
<i>Musta</i>	<i>Cyperus rotundus</i>	Cyperaceae	Tubers	1 part
<i>Guggulu</i>	<i>Commiphora mukul</i>	Burseraceae	Resin	1/8 th part
<i>Shunti</i>	<i>Zingiber officinale</i>	Zingiberaceae	Rhizome	
<i>Haritaki</i>	<i>Terminalia chebula</i>	Combretaceae	Fruit	
<i>Vibhitaki</i>	<i>Terminalia bellerica</i>	Combretaceae	Fruit	
<i>Amalaki</i>	<i>Emblilca officinalis</i>	Combretaceae	Fruit	
<i>Saindhava</i>	-	-	-	

Go Ghrita	-	-	-	1 part
Go Ksheera	-	-	-	4 parts
Go Dhadi	-	-	-	4 parts
Khanda Sharkara	-	-	-	Q.S

Inclusion criteria

- Patients having the classical signs and symptoms of *Ardhavabhedaka*.
- Patients of either sex, irrespective of caste and religion.
- Patients aged between 18-60 years.
- Patients fit for *Nasya karma*.

Exclusion Criteria

- Diagnosed patients having *Shiroroga* other than *Ardhavabhedaka* like *Suryavarta* etc.
- Diagnosed patients with any inflammatory diseases of Nose, Ear, Eye.
- Diagnosed Patients having history of head trauma.
- Diagnosed Patients of Hypertension, cervical spondylitis, meningitis and refractive errors.
- Pregnant women and Lactating women.
- Patients who are unfit for *Nasya*.

Intervention

Group A was administered with *Devadarvadi Ghrita Nasya* and Group B was administered with *Shadbindu Taila Nasya*. Treatment duration was 7 days. Post treatment follow up was on 14th day. The dose for *Nasya* is 6 *Bindu* in each nostril.

Procedure of Nasya

Purva Karma: *Sthanika Abhyanga* and *Swedana* was done over *Urdhwajatra Pradesha*, then patient was made to line in supine position with head slightly extended.

Pradhana Karma: 6 *Bindu* of lukewarm medicine was instilled in both the nostrils.

Paschat Karma: *Dhoomapana* with *Haridra Dhooma Varti* followed by *Kavala* with *Sukoshna Jala* was done.

Assessment criteria: A detailed proforma was prepared for the assessment criteria and the data obtained was analysed statistically.

- No. of location of pain
- Frequency of headache
- Duration of headache
- Severity of headache
- Giddiness

Statistical Analysis

Data collection was followed by entry in Excel, and analysis was conducted using Graphpad InStat v3.0. Quantitative data were presented as mean and standard deviation, while qualitative data were shown as numbers and percentages. Normality was assessed with the Shapiro-Wilk test. Comparisons for quantitative data utilized unpaired T-test or Mann-Whitney U test, and qualitative data were analysed using the Chi-square test. A p-value of less than 0.05 was considered statistically significant.

OBSERVATIONS

The study revealed that the highest incidence occurred in the 18-30 age group, comprising 40% of cases, followed by 35% in the 31-40 age group across both groups. Notably, most patients were female (67.5%), primarily consisting of housewives and students. Additionally, 40% of cases exhibited a chronicity of 6 months to 1 year.

RESULTS

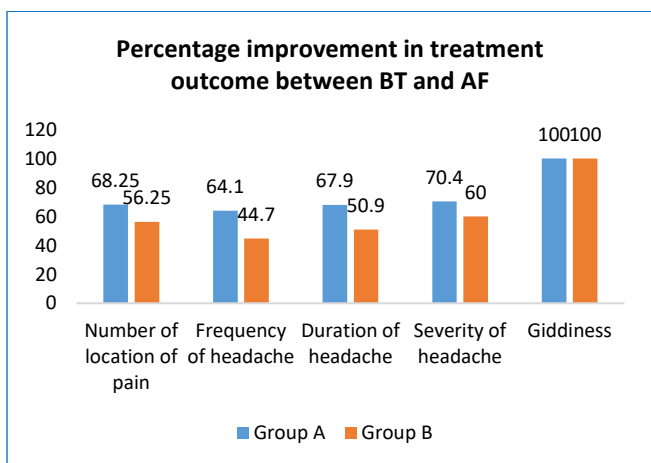
Table 2: Percentage change in treatment outcomes between before treatment, after treatment and at follow-up.

Group A	BT	AT	AF	P - value (Repeated measures ANOVA)
Number of locations of pain	3.15 ± 0.7	1.15 ± 0.9	1 ± 1	<0.01

Frequency of headache	1.95 ± 1.1	0.9 ± 0.5	0.7 ± 0.5	<0.01
Duration of headache	2.65 ± 1.1	1.05 ± 0.7	0.85 ± 0.7	<0.01
Severity of headache	2.7 ± 0.9	1.1 ± 0.7	0.8 ± 0.4	<0.01
Giddiness	0.1 ± 0.3	0	0	<0.01

Table 3: Percentage change in treatment outcomes between before treatment, after treatment and at follow-up.

Group B	BT	AT	AF	P- value (Repeated measures ANOVA)
Number of locations of pain	3.2 ± 0.7	1.5 ± 0.7	1.4 ± 0.8	<0.01
Frequency of headache	1.9 ± 1.04	1.1 ± 0.5	1.05 ± 0.6	<0.01
Duration of headache	2.55 ± 0.9	1.3 ± 0.7	1.25 ± 0.7	<0.01
Severity of headache	3 ± 0.7	1.3 ± 0.6	1.2 ± 0.7	<0.01
Giddiness	0.05 ± 0.2	0	0	<0.01



Graph 1: Percentage improvement in the treatment outcome between Before treatment and at follow up.

DISCUSSION

The disease *Ardhavabhedaka* is one among the 11 types of *Shirorogas* considered by our *Acharyas*. The causes of *Ardhavabhedaka* are excessive intake of *Ruksha Padarthas*, *Adhyashana*, *Purva Vata Sevana*, *Atimathuna* (excessive coitus), *Vegadharna* (suppressing of natural urges), *Atishrama* (excessive work) in which pain is appreciable in one half of the *Shiras*, *Shanka*, *Bru*, *Lalata*, and in *Karna Pradesha*. The attacks of *Ardhavabhedaka* will be once in three days, once in fifteen days and once in a month as per classics. Migraine is a syndrome of episodic recurrent headaches, more often unilateral, which is associated with nausea, vomiting, photophobia or phonophobia. It is more common in women than in men and a family history is present in more than 60% of cases. Approximately 80% of patients with migraine have migraine without aura and 15-20% has migraine with aura. By the above-explained definition we can correlate the disease *Ardhavabhedaka* with Migraine explained in western system of medicine.

Effect of treatment on number of locations of pain

Group A showed a 63.5% reduction after treatment and 68.25% reduction at follow up, while Group B had a 53.8% reduction after Treatment and at follow up 56.25% reduction.

Effect of treatment on frequency of Headache

Group A saw a 53.8% decrease after the treatment and 64.1% decrease at follow up while compared to Group B had 42.1% after treatment and 44.7% at follow up.

Effect of treatment on duration of Headache

Group A showed a 60.4% reduction after treatment and 67.9% reduction at follow up while compared to group B had 49.1% reduction after treatment and 50.9% reduction at follow up.

Effect of treatment of severity of Headache

Group A showed 59.2% decrease after treatment and 70.4% decrease at follow up while Group B had 56.7% decrease after treatment and 60% decrease at follow up.

Most of the *Dravyas* like *Guggulu*, *Devadaru*, *Haridra*, *Shati* and *Pushkaramoola* present in *Devadarvadi Ghrita* are having *Vedanasthapana* and *Shoolahara* property making them effective in alleviating *Shirashoola*. The frequency, duration, and severity of headache are significantly reduced owing to the *Vatahara* properties of the *Dravyas* present in *Devadarvadi Ghrita*. These ingredients help to balance the aggravated *Vata Dosha*, which is often the root cause of *Ardhavabhedaka*. *Ghrita* as a *Medhya*, calms the mind, reduce stress and promote sleep thereby easing headache.

Effect of treatment on Giddiness

In the present study 3 patients out of 40 presented with giddiness, all of them got complete relief (100% relief in the symptom.) The *Pitta - Shamaka Dravyas* presents in *Devadarvadi Ghrita*, such as *Yavasa*, *Lodhra*, *Amalaki*, *Godugdha*, *Go-Ghrita*, effectively help to reduce Giddiness by balancing excess *Pitta Dosha* in the body.

Probable mode of action of Devadarvadi Ghrita Nasya in Ardhavabhedaka

Effect on Dosha

- *Devadarvadi Ghrita* contains *Tridosahara* properties, making it highly effective in balancing all the *Tridoshas - Vata, Pitta* and *Kapha* and maintaining their equilibrium.
- *Ghrita* and *Godugdha* due to its *Madhuara Rasa* and *Sheeta Veerya* effectively helps in pacifying vitiated *Vata* and *Pitta Doshas*.

Effect on Dushya

Devadaru and *Haridra* possessing *Raktaprasadaka* property that may normalise vitiated *Rakta Dhatu*.

Effect on Srotas

Saindhava Lavana effectively promotes the *Kapha Vilayana* and *Kapha Chedana* of accumulated *Kapha Dosha*, thereby clearing *Srotorodha*.

Teekshna Guna of drugs present in *Devadarvadi Ghrita* such as *Shati*, *Pushkaramoola*, *Shunti Kushta*, enables the formulation to deeply penetrate the *Sookshma Srotas*, thereby it expels the vitiated *Doshas*.

Mode of Action of Nasya Karma

Acharya Charaka, while explaining the indication for *Nasya* in *Siddhithana*, has emphasized that the *Nasya* drug usually acts through absorption by the *Shringataka Marma*. After absorption of the drug, it acts on the diseases of *Urdhwajatra* and the *Doshas* are expelled from the *Shira Pradesha*. The absorption of the drugs is carried out in three media they are, through blood circulation, through pooling into the venous sinuses of the brain via the inferior ophthalmic veins, passes the BBB and gets absorbed into CSF. Besides the small emissary veins entering the brain's cavernous sinuses, a pair of venous branches from the *alae nasi* drains into the facial vein. These ophthalmic veins, however, also drain into the cavernous sinuses, and both the facial and ophthalmic veins lack valves. This increases the likelihood of blood flow from the facial vein to the cavernous sinus when the head is lowered. The nasal cavity directly opens into the frontal, maxillary, and sphenoidal sinuses, with a continuous epithelial lining throughout. Temporary retention of the drug in the nasopharynx and suction can cause the drug to enter these air sinuses, which are richly supplied with blood vessels leading to the brain and meninges through natural openings in the bones. This pathway therefore enhances drug transport. Drugs administered here reach the paranasal sinuses where the ophthalmic and other veins are dispersed. The sphenoidal sinuses are close to intracranial structures, suggesting an as-yet-undetected route between the air and cavernous sinuses. The mention of *Shringataka* here appears reasonable, as *Marsha Nasya* therapy helps clear vitiated *Vata* and *Kapha Doshas* and can aid in treating *Ardhavabhedaka*.

CONCLUSION

Based on concepts, analysis and clinical observations made in this study, the following conclusions are drawn; *Ardhavabhedaka* is a *Shoola Pradhana Vyadhi* characterised by feeling of severe pain like *Shastra Arani Nibha* in half part of the head involving *Manya*, *Bhru*, *Shankha*, *Karna*, *Akshi* and *Lalata*. Currently, the incidence of *Ardhavabhedaka* is notably high, largely driven by the rise in stress and disrupted sleep patterns

prevalent in modern life. *Nasya Karma* is given prime importance in the management of *Shiroroga*. Since *Nasya Dravya* due to its *Tridosahara* properties, helps in balancing *Tridosha* leading to its significant effectiveness in treatment. In relieving Frequency, duration, Severity of Headache and Giddiness both the group showed significant results. *Devadarvadi Ghrita Nasya* is more effective than *Shadbindu Taila Nasya* in the management of *Ardhavabhedaka*.

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