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A Clinical Study to Evaluate the Efficacy of *Varunadiksheeragrithanasyain Ardhavabhedaka* w.s.r Migraine

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ABSTRACT

Title: A Clinical study to evaluate the efficacy of *VarunadiksheeragrithaNasya* in *Ardhavabhedakaw.s.r* to Migraine.

Background and Object: *Ardhavabhedaka* is a type of *Shiroroga* with the cardinal feature of unilateral headache, which when left untreated may develop complications like blindness and deafness. This disease can be correlated to Migraine based on the clinical manifestations. *Varunadiksheeragritha* has been chosen as a trail drug which was administered in the form of nasya.

Materials and Method: 20 therapeutic participants of *Ardhavabhedaka*/Migraine were selected from the IPD and OPD of SDM Ayurveda hospital Udupi. Patients were subjected to *Nasya* as per the procedure mentioned in classics. *Sthanikaabhyanga* and *Swedana* were done as Poorvakarma, *Dhoomapana* and *Kavala* were performed as Paschat karma.

Results: Data was tabulated and analyzed by using Wilcoxon signed rank test, which showed moderate improvement in *Ardhavabhedaka*.

Conclusion: This clinical trial proved significant effect in *Ardhavabhedaka*/Migraine.

KEYWORDS

Nasyakarma, Ardhavabhedaka, Migraine, Varunadiksheeragritha



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INTRODUCTION

Today is the era of fast life and modernization. With such fast change the human beings are becoming victim of different life style diseases which are because of improper food habits along with stressful life. Such changes end with unfruitful struggle in life which can keep the person under depression because of unproductive activities due to ailments. Hence certain codes and conducts are explained in the texts which will help in preventing the onset of diseases as well to take care of those diseases which had already appeared in life time. Apart from prevention, there are certain curative measures which are explained in the classics under respective chapters which will be followed as guidelines for the treatment of disorders. One such disease which trouble human being physically, mentally and socially is the disease *Ardhavabhedaka* which is one of the *shiroroga* due to impaired life style and one such annoying disorder characterized by transient attack of pulsatile pain occurring once in three days, fifteen days or once in a month. This disease in its chronic stage may be devastating in terms of destruction of the functioning of eyes and ears resulting in blindness and deafness, respectively¹. Ayurveda postulates principles of

management of diseases which is to be adopted aptly at respective condition of the disease. Such principles of treatment are categorized in terms of purification, palliation and nourishing treatment. All the three modalities are to be implied in each and every disease. If judiciously applied along with the implementation of *nidanaparivarjana* then there will not be any recurrence of the disease. Since the disease takes its adhisthana in the *Shiras* and the disease is of lingering in nature, an ideal therapeutic approach through Panchakarma is mandatory to counteract the ill effects of the disease. Amongst panchakarma, *Nasya karma* is one such procedure which is considered as the means to reach the *Shiras* and is considered as the gate way to the *shiras*.²In this procedure, the medicaments which are instilled to the nostrils straightaway enters into the *shiras* via *srotas* and helps to eliminate, palliate or nourish the *dosha* depending on the drug used.

In *Ardhavabhedaka*, there will be severe pain in one half of the *shiras* i.e., *Manya*, *Bhru*, *Shankha*, *Karna*, *Akshi*, and *Lalata*. Pain will be similar to those produced by sharp objects like *shastra* and *arani*.³The episodic attack of *Ardhavabhedaka* occurs once in ten days, fifteen days or in a month. Such an interpretation of the disease *Ardhavabhedaka* in modern parlance is



found in the disease Migraine. Migraine is a common disabling condition mostly occurring in adult population and shows female predominance. Unilateral throbbing type with moderate to severe intensity headache is a common manifestation of the migraine though it may present with varied presentation. Migraine is the third most common disease in the world with an estimated global prevalence of 14.7 % (that is around 1 in 7 people). Chronic migraine affects approximately 2% of the world population and many medications have been designed to treat migraines. Depends on the frequency and severity of headache, pain relieving medications and preventing medications are used.⁴ The sufferer of migraine will not be satisfied by the conventional treatment modality since there is no effective remedy to counteract the disease Migraine in current system of medicine. The sufferer has to find an alternative remedial measure towards such ailment. But as per Ayurveda, the treatment modalities are emphasized not only to palliate the disease but even to help in eradication of the disease from its root only. In this regard, the *nasya* as a procedure had been selected by utilizing the drug *Varunadiksheeragritha* which is a formulation mentioned in *Ashtangahridaya* under *Shirorogadhikara* for the treatment of *Ardhavabhedaka*. Hence a planned

study was undertaken to prove the effect of *nasyakarma* in *Ardhavabhedaka* by utilising *Varunadiksheeragritha*

AIMS AND OBJECTIVES

To evaluate the efficacy of *Varunadiksheeragrithanasya* in *Ardhavabhedakaw. s. r* to Migraine.

MATERIALS AND METHODS

Ethical Committee Approval No 03_A009_77108

MATERIALS

The formulation selected for the study was *varunadiksheeragritha* (ref. *Ashtangahridaya*).

The medicine was prepared at *Vaidyaratnampharmacy, Thrissur, Kerala*.

SOURCES OF DATA

Patients were selected from the OPD and IPD of *Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi*.

METHOD OF COLLECTION OF DATA

Minimum of 20 patients of either gender were included for the clinical study. Patients were selected on the basis of history taking and clinical examination, detailed proforma was prepared by incorporating all the signs and symptoms of *Ardhavabhedaka/Migraine*.



DIAGNOSTIC CRITERIA:

- a) At least 5 attacks of migraine fulfilling the following criteria.
- b) Headache attacks lasting 4-72 hours if untreated or unsuccessfully treated.
- c) It must have at least one of the following symptoms
 - Pain in one side of the head
 - Pulsating or throbbing type of pain
 - Pain severe enough to impair daily activities
 - Pain intensified by exertion such as walking
- d) During attack one or more of the following symptoms may be present such as
 - Nausea or Vomiting
 - Photophobia or Phonophobia

INCLUSION CRITERIA

1. Patients of either gender between age group of 16 – 70 yrs were taken.
2. Patients presenting with the signs and symptoms of Ardhavabhedaka/migraine.
3. Patients who are fit for Nasya karma.

EXCLUSION CRITERIA

1. Severe depression or any Psychiatric illness.
2. Referred pain in one half of head due to disorders of ear, nose, tooth and neck.
3. Unilateral headache due to sinusitis, Hypertension

4. Cluster headache, Tension headache, Trigeminal neuralgia

5. All patients who are contraindicated for nasyakarma

STUDY DESIGN

20 patients of Ardhavabhedaka (Migraine) fulfilling the inclusion criteria were randomly selected and subjected to varunadiks sheeraghrithanasya to both the nostrils daily for a period of 7 days and evaluated even after 14 days of follow up study.

INTERVENTION:

- *Poorva karma – Sthanika Abhyanga* was performed with Murchitatilataila followed by bashpaswedana by using cloth dipped in hot water.

- *Pradhana karma – Nasyakarma* was performed with *Varnadiks sheeragritha*. The avaramatra of *nasya* dose was considered as 8 bindu (4 ml.) and was administered to each nostril.

- *Paschat karma* – Once the *samyaknastalakshana* appeared in the patient, as paschat karma, *dhoomapana* was administered with Haridrachoorna and *Kavalagrahais* done with lukewarm water.

STUDY DURATION: 7 Consecutive days.

FOLLOW UP PERIOD: 14 days after completion of course of the *Nasyakarma*.



TOTAL DURATION OF THE STUDY:

21 Days

ASSESSMENT CRITERIA

- Assessment was done on the basis of improvement in symptoms of Ardhavabhedhaka /Migraine.
- Patients were assessed with subjective parameters formulated for Ardhavabhedhaka w.s.r to Migraine before and after the treatment and during follow up period.

SUBJECTIVE PARAMETERS:

- Severity of pain
- Duration of pain
- Frequency of pain
- Nausea
- Vomiting
- Phonophobia
- Photophobia
- Tinnitus
- Impaired concentration
- Burning sensation of head

ASSESSMENT CRITERIA FOR ARDHAVABHEDAKA/MIGRAINE

• SEVERITY OF PAIN

GRADE 3 = Unable to perform activities like walking

GRADE 1 = Does not disturbs the normal work

GRADE 0 = No pain

• DURATION OF PAIN

GRADE 3 = >12 hours

GRADE 2 = 6 to 12 hours /day

GRADE 1 = 4 to 6 hours /day

GRADE 0 = No pain

• FREQUENCY OF ATTACK

GRADE 3 = 1-5 days

GRADE 2 = 6-10 days

GRADE 1 = >10 days

GRADE 0 = Absent

• NAUSEA

GRADE 3 = Present and it disturbs the normal work

GRADE 2 = Present but does not disturbs the normal work

GRADE 1 = Occasionally

GRADE 0 = No nausea

• VOMITING

GRADE 3 = More than 6 episodes and forced to take medicine to stop vomiting

GRADE 2 = 2 to 5 episodes in 24 hours

GRADE 1 = 1-2 episodes

GRADE 0 = None

• PHOTOPHOBIA

GRADE 3 = Unable to resist dim light

GRADE 2 = Unable to resist normal light

GRADE 1 = Unable to resist bright light

GRADE 0 = No photophobia

• PHONOPHOBIA

GRADE 3 = Irresistant to low intensity sound

GRADE 2 = Unable to resist normal sounds

GRADE 1 = Unable to resist loud sounds

GRADE 0 = No phonophobia

• TINNITUS



GRADE 3 = Almost always heard and interferes with sleep and other daily activities.

GRADE 2 = Masked by environment sound and forgotten with activities

GRADE 1 = Heard in quite environment only

GRADE 0 = Tinnitus absent

• BURNING SENSATION OF HEAD

GRADE 3 = Severe which cannot be tolerated

GRADE 2 = Moderate which can be felt but can be tolerated

GRADE 1 = Mild which will be noticed only when the patient is sitting simply

GRADE 0 = Not present

• IMPAIRMENT OF CONCENTRATION

GRADE 3 = Unable to do the routine work

GRADE 2 = Unable to do the casual work

GRADE 1 = Able to do the casual works with utmost concentration only

GRADE 0 = Good concentration

CRITERIA FOR OVERALL ASSESSMENT OF RESULTS

The total effect of therapy was assessed in single groups:

- Cured -100 % relief in signs and symptoms
- Marked improvement – 76 % improvement in signs and symptoms

- Moderate improvement -51-75% improvement in signs and symptoms

- Mild improvement -26-50 % improvement in signs and symptoms

- Unchanged - < 25% reduction in signs and symptoms

STATISTICAL ANALYSIS

- For assessing the results software SPSS Version -20 was considered.

- It was a single group study with 20 patients and Wilcoxon on signing rank test was adopted here.

- Observation for 20 patients were taken and results was taken for 20 patients

OBSERVATIONS

In present study, 20 patients of Ardhavabhedaka (Migraine) were treated with Varunadiksheeragrithatailanasya karma for 7 days.

Total number of the patients registered for the study: 20

Number of patients completed the study: 20

Dropouts: Nil

Some of the observations are given in table 1 and 2.

Observations during nasya karma

During the *nasya karma* course, almos tall the patient hadmil dirritation in the nostril 2-3 hours then gradually reduced. On the second day onward, the intensity of the irritation were reduced.



Table 1 Demographic observation:

PARAMETER	Observations in each parameter	Maximum number of patients	%
Age	21-30	10	50%
Gender	Female	15	75%
Marital status	Married	11	55%
Occupation	Students	8	40%
Religion	Hindu	13	65%

Table 2 Observation related to the disease

Symptoms	Maximum observation	Number of patients	%
Severity of pain	Present	20	100%
Duration of pain	Present	20	100%
Nausea	Present	18	80%
Vomiting	Present	13	65%
Photophobia	Present	7	35%
Phonophobia	Present	9	45%
Burning sensation of head	Present	7	35%
Tinnitus	Present	5	25%
Impairment of concentration	Present	20	100%
Frequency of attack	Present	19	95%

The symptoms like *indriyavishudh* in the form of increased functional ability of the *karmendriya* was observed in all the patient. *Vikaropashama* in the form of improvement in the symptoms of *Ardhavabhedaka* was noted in all the patients. Even though all the patient had delayed or disturbed sleep, in none of the patient complete *svapnasukha* was observed as *samyaklakshana*. But in some patients, the quality and quantity of the sleep was improved to some extent. *Urahshirolaghavata* is not observed in any

patient, because none of the patient had *gauravata* in these parts before *nasya*. No patient presented with *ati* or *heena yoga* of *nasya*.

RESULTS

In this study, *Varunadiksheeragrithanasya* was administered in 20 patients of *Ardhavabhedaka*/Migraine. The relevant data were collected before the treatment and patient were assessed on first day of treatment (BT), after the treatment (AT), and after follow up of 7 days (AF). The data collected and analyzed by using paired t test and statistical test was done using wilcoxon signed rank test.

After a course of the *Nasya karma*, the analysis of the patients revealed that there was statistically significant improvement observed in severity of pain, duration of pain, nausea, vomiting, photophobia, phonophobia, burning sensation of head, tinnitus, impairment of concentration and frequency of attack.

The different values are given in table 3.

DISCUSSION

Nasyakarma is one of the Panchakarma procedure, wherein drugs administered through nostrils will enter into the *shiras* and eliminates only morbid dosha out of the



body along with giving nourishment to the jathrudhwapradesha. *Nasya* is considered to

be the effective treatment modality for *urdhwajatrugata roga*.⁵

Table 3 Statistical analysis of observed results

Symptoms	BT		AT		AF		Ties	Total	Z Value	P Value
	MR	SR	MR	SR	MR	SR				
Severity of pain	10.00	190.0	6.00	66.0	10.50	210.0	1	20	-3.987	<.000
							9	20	-3.317	<.000
							0	20	-3.999	<.000
Duration of pain	10.50	210.0	6.50	78.00	10.50	210.0	0	20	-4.179	<.000
							8	20	-3.464	<.001
							0	20	-4.035	<.000
Nausea	9.50	171.00	3.50	21.00	7.00	91.00	0	18	-4.001	<.000
							7	13	-2.449	<.014
							0	13	-3.286	<.001
Vomiting	7.00	91.00	2.50	10.00	8.00	120.0	2	15	-3.358	<.001
							11	15	-2.000	<.046
							0	15	-3.573	<.000
Photophobia	4.00	28.00	4.00	28.00	4.50	36.00	1	8	-2.428	<.015
							1	8	-2.646	<.008
							0	8	-2.549	<.0.11
Phonophobia	5.00	45.00	3.50	21.0	5.50	55.00	2	11	-2.810	<.005
							5	11	-2.333	<.020
							1	11	-2.850	<.004
Burning sensation of head	4.00	28.00	3.50	21.00	4.50	36.00	2	9	-2.530	<.011
							3	9	-2.449	<.014
							1	9	-2.565	<.010
Tinnitus	3.00	15.00	1.50	3.00	3.00	15.00	0	5	-2.236	<.025
							3	5	-1.414	<.157
							0	5	-2.070	<.038
Impairment of concentration	10.50	210.0	10.50	210.0	10.00	190.00	0	20	-4.300	<.000
							0	20	-4.030	<.000
							1	20	-4.065	<.000
Frequency of attack	10.00	190.00	-	-	10.50	210.00	1	20	-4.065	<.000
							0	20	-4.028	<.000

Amongst the five varieties of *Nasya* explained by *Charaka*, *Varunadiksheeragrithanasya* can be included under *Snehanavariety* of *Navananasya*. As per *vagbhata*, it belongs to *Brimhana* variety of *nasya*. According to *Sushruta*, it is included under *snehana* variety of *nasya*. The importance of dosage has to be highlighted in the study, to know about the type of *nasya* which is dependent

on the dosage pattern. In this study 8 bindu is considered as the dosage of *nasya* which is considered to be the *avaramatra* of the *snehananasya* as told by *Sushruta*. Usually the dosage of *Nasya* is explained in terms of *bindupramana*. *Bindupramana* is assessed by dipping the *Pradeshinianguliparvadwaya* into the *Snehadravya* and the quantity of *sneha* falling entirely from the *Pradeshinianguli*



is considered as one bindu.⁶As discussed in the methodology, the standard of one bindupramana was considered as 0.5ml. Hence 8 bindumatra will be equal to 4ml. and that dose has been fixed to all the therapeutic participants in this study.

Ardhavabhedaka is one among the *shiroroga* where in there will be throbbing or pricking type of pain present in one half of the head. Nidana like *adhyashana*, *atimaitihuna*, *rajosevana*, *ratrijagarana*, *uchairbhasana*, *vegadharana*etc are considered as the aggravating factors of the disease.⁷*Ardhavabhedaka* can be understood in modern parlance as Migraine. In migraine there will be presence of unilateral pain in the head. Due to the nidana, there will be vitiation of *Vata*alone or *Vatakapha* which in turn vitiates the *raktadhatu* located in the *shiras*, and gets lodged in *Ardhashiras* leading to *Ardhavabhedaka*. According to *Acharya Charaka*, the involvement of dosha is *Vata* and *Kapha*.⁸ According to *AcharyaVagbhata*, it is *vatadosa*⁹ and *Acharya Sushruta* says that it is having *tridosha*involvement.¹⁰ The nidana explains the involvement of tridosha. By the suppression of natural urges, sleep during the day time, vigil during the night, intoxication, speaking aloud, exposure to frost and easterly wind, sexual indulgence, inhalation of undesirable smell, exposure to

dust, smoke, snowfall and sun, intake of heavy and sour food and rhizomes including tubers etc, in excessive quantity, excessive intake of cold water, injury to the head, presence of ama (a product of improper digestion and metabolisam) suppression of tears, advent of cloud, anxiety and adopting regimen contrary to those prescribed for the locality and season, doshas like vataetc gets aggravated resulting in the vitiation of raktadhatu in the *shiras*. This causes disease with various symptoms in the head.

The nidana factors like *aharaja* (*rukshaahara* and *adyashana*), *vihara* (*purvavatasevana*, *vegasandharana*, *atimaitihuna*), *manasika* (*krodha*, *shoka*, *bhaya*) and *agantuja* like any agata to the shira vitiates vata or associated with kapha enters the *siras* of *shiras*, vitiates the *raktadhatu*, invades the half portion of the head and leads to *Ardhavabhedhaka*.

Varunadiksheeragritha was selected for the study which is explained in the context of *shirorogadhikara* by *Vagbhata*.¹¹For the preparation of this ghritha, *Varunadiganadravya* are used.¹²Among the *varunadiganadravya* most of the drugs are having *tikta* and *kashaya* rasa, *laghu* and *rukshaguna*, *ushnavirya*, *katuvipaka* and has *kaphavatashamaka* properties. All *shirorog* as are due to *tridoshaprakopa* and chiefly due to *vata* or *vata-kaphaprakopa*.



Thus, *Ardhavabhedaka* is a *sadhya* type of *shiroroga* which can be managed with the drugs predominantly having *laghu*, *rukshaguna* and also possessing *vatahara* and *kaphavatahara* properties. *Ardhavabhedaka* is best treated with *gritha* because *gritha* is possessing the property of *pitta* and *vatahara* but according to *kaiyadevanighantuandraja nighantu*, it is *kaphahara* also. *Ghritha* is also having the properties like *indriyabalavridhikara*, *rasayana* and is indicated in *shiroroga*.

In this study, the efficacy of *Varunadikskeeragritha* was assessed in 20 patients diagnosed as *Ardhavabhedaka*/Migraine. *Nasyakarma* was performed for 7 days along with 7 days of follow up period. Hence the total study duration was considered as 14 days. Regarding *Varunadikskeeragrithanasya*, 3 patients had nasal block and burning sensation after the administration of the trial drug, which was for few minutes and for initial 3 days only. Two patients were complaining of headache in the first 2 days of *nasyakarma*, but it was observed that the type of headache was only heaviness and presence of frontal ache for half an hour. This may be due to *apathy sevana* like drinking cold water, head bath just after the *Nasyakarma*. In every patient we can't expect each and every symptom. Depending upon the severity and duration

of the disease *lakshanas* were observed. In this study *urolaghava* and *shirolaghava* were observed for every patients and rest of the symptoms observed after few days of *nasyakarma*. Some of the patients didn't get proper sleep during the *nasyakarma* on first 2 days then after 2 days it became normal. That may be due to some of the personal problems not because of *Nasyakarma*. Among the 20 patients 4 patients got 100% relief and further recurrence was not being observed even during the follow up period. The common observation observed during the *nasya karma* amongst 15 patients of trial group was heaviness of the head, head ache during first 2 days of *nasya*, then burning sensation was observed after the medicine was instilled into the nostrils for about 10 minutes.

In the present study, only few patients observed the symptoms like *Shiroarti*, *Akshiarti* and *Shankhatoda*. It was observed that the patients underwent *nasya* and they travelled after the *nasyakarma*, hence the same reason can be attributed to this symptom. As one of the *Astamahadoshavarjekarabhava* explains not to travel after the *nasya karma*, but since the patient had followed the same and hence the same reason can be attributed to that complaint. During the *nasyakarma* first 3 days tears came from the eyes and it is reduced from the 4th day onwards, it was



observed in only one patient. In the present study only few of the patients observed the features like *Shirashoonyata*, *Kaphapraseka* and *Aruchi*. It is observed that the patients didn't follow the diet during the *nasya karma*, so it was manifested.

CONCLUSION

Ardhavabhedaka is one among the *Shiroroga* which can be understood under the disease Migraine in modern parlance. Its symptoms are aggravating depending upon the nidana factors. *Nasya* is one of the important *Panchakarma* procedure for *urdhwajatrugataroga*. Throbbing type of pain on one or both sides of the head accompanied by nausea, vomiting, photophobia, phonophobia, tinnitus, impaired concentration, burning sensation of head are all considered to be the symptoms present in *Ardhavabhedaka*.

In the present study, some of the therapeutic participants were taking pain killers during the time of headache and some of them were not taking any sorts of medication. In the present study, the response was assessed after the treatment and after the follow up period. Totally for 14 days the vigilance on the patient was carried out and it is worth to be mentioned here that all the 20 patients were registered in this study responded to

the treatment very well. Symptomatic improvement has been observed in majority of the patients after *nasyakarma*. This shows the reduction in the severity of the disease in this study. *Vataandkapha* are the main dosh as involved in the pathogenesis producing the *Ardhavabhedaka*. Among the *varunadi* drugs most of the drugs were having *Kaphavataashamaka*. So this medicine was acting very quickly and this was found to be effective for every therapeutic participant in this study.

Amongst the symptoms of the *Ardhavabhedaka* presented in the study, Improvement showed for nausea, vomiting, photophobia, phonophobia, etc. Severity and duration of pain also reduced in this study.

With regard to the percentage of improvement in results and also the relief given by the treatment it could be concluded that *Varunadiksheeragritha* is effective in reducing the severity of the disease *Ardhavabhedaka*. It can be concluded that it is a safe and effective Ayurvedic management for *Ardhavabhedaka*. *Pathya* and *nidanaparivarjana* also plays an important role in the management of *Ardhavabhedaka*.



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