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A comparative evaluation on efficacy of *Brihat Dashmoola Taila Snehapana* and *Brihat Dashmoola Taila Nasya* in the management of *Ardhavabhedaka* (Migraine)

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ABSTRACT

Migraine is a genetically influenced complex disorder characterized by episodes of moderate-to-severe headache, most often unilateral and generally associated with nausea and light and sound sensitivity. Around 15% of women and 6% of men experience migraines, the second most prevalent type of cerebral pain. The majority of those affected by the disease are in their prime age, or between the second and fifth decade, which has an impact on their professional and social lives and deteriorates their health. *Ardhavabhedaka* is technically comparable to migraine due to its paroxysmal nature and distinctive characteristic of a "half-sided headache". **Material and Methods:** In this study, eligible 64 patients were selected and randomly divided in two groups through computer generated randomization. *Brihat Dashmoola Taila Snehapana* was given in trial group and *Brihat Dashmoola Taila Nasya* was given in control group for 2 settings of 7 days with 7 days gap. The primary outcomes measured were percentage changes in chief complaints and associate complaint of *Ardhavabhedaka* in comparison to both groups. **Result:** Regarding effect of therapy on Chief complaints in trial group, 22.6% relief was found in severity of headache, 34.0% in duration of headache and 43.2% in frequency of headache. In control group, 32.8% relief was found in severity of headache, 32.8% in duration of headache and 45.4% in frequency of headache. **Conclusion:** The *Nasya Karma* is a better treatment option in the management of *Ardhavbhedaka* as compared to *Snehapana*. Although both the treatments are having statistically significant results.

Key words: *Ardhavabhedaka, Brihat Dashamoola Taila, Migraine, Nasya, Snehapana.*

INTRODUCTION

Migraine is a genetically influenced complex disorder characterized by episodes of moderate-to-severe headache, most often unilateral and generally associated with nausea and light and sound sensitivity. Around 15% of women and 6% of men experience migraines[1], the second most prevalent type of cerebral pain. The majority of those affected by the disease are in their prime age, or between the second and fifth decade, which has an impact on their professional and social lives and deteriorates their health. *Ardhavabhedaka* is technically comparable to migraine due to its paroxysmal nature and distinctive characteristic of a half-sided headache or *Ardha Mastaka Vedana.*[2] The pathogenesis of *Ardhavabhedaka* involves all three *Doshas*[3], with *Vata*[4] or *Vata-Kapha*[5] predominating according to *Acharya Sushrut* and *Acharya Charaka* respectively.

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AIM AND OBJECTIVES

Aim

To evaluate the efficacy of *Brihat Dashmoola Taila Snehapana* and *Brihat Dashmoola Taila Nasya* in the management of *Ardhavabhedaka*.

Objectives

1. To evaluate the efficacy of *Brihat Dashmoola Taila Snehapana* in the management of *Ardhavabhedaka.*

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2. To evaluate the efficacy of *Brihat Dashmoola Taila Nasya* in the management of *Ardhavabhedaka.*
3. To compare the efficacy of both the group in the management of *Ardhavabhedaka*

Materials and Methods

This study was approved by Institutional Ethical Committee (IEC) of Ch. Brahm Prakash Ayurved Charak Sansthan, Khera Dabar, Najafgarh, New Delhi vide IEC code IEC- CBP-IEC/2020/PK-04/MD/19 on 29/01/2022 and CTRI registration was also done (CTRI/2022/03/041061 on 14/03/2022). Patients were selected from the OPD and IPD of Panchakarma dept. of Ch. Brahm Prakash Ayurved Charak Sansthan, Khera Dabar, Najafgarh, New Delhi. Patients written informed consent was taken before starting the treatment. Patients were selected using, Simple random sampling method. The study was conducted on 64 subjects. The drug, *Brihat Dashmoola Taila*[6] was procured from the GMP certified pharmacy.

Criteria for inclusion

1. Age Control group between 20 to 50 years and having sign and symptom of *Ardhavabhedaka* (Migraine) According to Ayurvedic Classics.
2. Having recurrent attack of headache.
3. With or without nausea, vomiting, aura
4. The diagnosis of the disease was done on the basis of clinical manifestations like recurrent attacks of headache, mostly unilateral in site, variable in intensity, frequency and duration with or without nausea, vomiting, aura and other associated symptoms.

Criteria for exclusion

1. Age group less than 20 and more than 50 yrs.
2. Patient suffering from any other types of Headaches.
3. Patient unfit for *Nasya Karma* as mentioned in *Ayurvedic reference books*.
4. Patient having history of Head Trauma.
5. Pregnant women and Lactating mothers.

Sample Size: 64

Grouping

Group A - Trial group

Brihat Dashmoola Taila Snehapana: *Snehapana* was given in the dose of 2 *Karsha*[7] (24ml) Morning on empty stomach when patient feels hungry with lukewarm water for two settings of 7 days with 7 days gap.

Group B - Control group

Brihat Dashmoola Taila Nasya: *Nasya* was done in the dose of 8 *Bindu*[8] in each nostril for 2 sittings of seven days with the interval of 7 days after each sitting.

Follow up - 28 days

Scoring pattern[9]

Subjective symptoms based on the reduction of disease signs and symptoms, the patient's improvement was evaluated. Following are specifics of the score used for the study's primary indications and symptoms based on the reduction of disease signs and symptoms, the patients' improvement was evaluated. Following are specifics of the score used for the study's primary indications and symptoms:

Severity of Pain	No Pain	0
	Pain Tolerable	1
	Do not disturb the routine work	2
	Disturb the routine work	3
	Intolerable pain	4
Frequency of Pain	No attack	0
	Once in 21-30 days	1
	Once in 11-20 days	2
	Once in 1-10 days	3
	Continues/ daily	4
Duration of	No pain	0

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Headache	1-3 hours/day	1
	3-6 hours/day	2
	6-12 hours/day	3
	More than 12 hours/day	4
Aura	Nil	0
	Lasts for 5 min	1
	Lasts for 15 min	2
	Lasts for 30 min	3
	Lasts for 60 min	4
Nausea	Nil	0
	occasionally	1
	moderate but does not disturb routine work	2
	severe, disturbing routine work	3
	severe enough, small amount fluid regurgitating from mouth	4
Vomiting	Nil	0
	Only if headache does not subside	1
	Vomiting 1-2 times	2
	Vomiting 2-3 times	3
	Forced to take medicine to stop vomiting	4
Vertigo	Nil	0
	Felling of giddiness	1
	Pt. feels as if everything is revolving	2
	Revolving signs +black outs	3
	unconscious	4
Gradation for associated Symptoms	No symptoms	0
	Mild (can do his/her work)	1
	Moderate (forced to stop work)	2
	Severe (forced to take rest)	3
	Excruciating (force to take medicine)	4

Overall assessment

The improvement was assessed on the basis of subjective symptoms.

Statistical estimation of results

The obtained data were analyzed statistically. The data were analyzed by ANOVA Test and independent T-test.

$P > 0.05$ = Insignificant

$P < 0.05$ and 0.01 = Significant

$P < 0.001$ = Highly significant

Observations and Results

In this clinical trial of *Ardhavabhedaka*, there are total 70 patients registered, and were randomly distributed into two groups i.e., Group A and Group B. Among them 32 patients were registered in Group A and 32 patients in Group B. 04 patients were drop out in Group A and 02 patients were drop out in Group B.

Observation

In the present study, one patient dropped out due to migration to other state. In present clinical trial, maximum number of patients, i.e., 47% patients belonged to age group of 21–30. 83% of patients were female, 50% were homemakers, 80% were Hindu, 73% were married, 37% of patients had education till graduation, 34% of patients were from middle class, 40% of patients were having moderate appetite, 66.67% patients were having regular defecation, 73% of patients having *Vata-Pitta Sharirika Prakriti* (physical constitution) and 53% of patients were having *Tamasika Manasa Prakriti* (psychological status).

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In the current study, it was discovered that the majority of patients (57%) engaged in *Vishamashana*, which is the practise of eating regardless of hunger or time, while 38% practised *Adhyashana*, which is the practise of eating before the previous meal has been digested, and 18% had a predominance of *Lavana Rasa* (salty) in their regular diet.

It was observed that intolerable pain was present at 0 day in 31.3% of the patients in *Snehapana* group and in the *Nasya* group 46.9% of the patients were having intolerable pain at day 0. Nearly 46.9% of the patients at 0 day in *Snehpana* group complained of daily pain episodes and In *Nasya* group daily episode of pain was present in 53.1% of the patients at 0 day. In the *Snehpana* group, 87.5% of the patients at day 0 were having pain for more than 12 hrs/day and pain for more than 12 hrs/day was observed in 6.3% of the patients at 0 day in *Nasya* group.

Both groups had significant outcomes when it came to the therapy's impact on the chief complaints. The trial group Group A saw a statistically highly significant (<0.001) improvement in headache severity (22.6%), duration (34.0%), and frequency (43.2%), while Group B saw a statistically highly significant (<0.001) improvement in headache severity (32.8%), duration (32.8%), and frequency (45.4%). It was observed that complaint of nausea changed significantly in both the groups as revealed by within group analysis (p-value <0.001). Mean score for nausea in *Snehpana* group was 1.63 at day 0 which reduced to 0.41 at day 28th (% change = 74.8%). While, in *Nasya* group at day 0 mean score was 1.72, which decreased to 0.59 at day 28th (% change = 65.6%). It was observed that in both the groups, within group analysis showed statistically significant difference in Vomiting score at day 28th as compared to day 0 (p-value <0.001). Mean score for vomiting at day 0 in *Snehpana* group was 1.63 which decreased to 0.34 at day 28th (% change = 79.1%). In *Nasya* group mean score at day 0 was 1.72 which reduced to 0.44 at day 28th (% change = 74.4%). At day 21st, between group analysis revealed significant difference between both groups (p-value = 0.039). Between group analysis revealed significant difference between both the groups at day 21st in vertigo score (p-value =0.002). Mean change in *Snehpana* group from day 0 to day 28th was (1.22, % change = 88.4%) as compared to 1.46 in *Nasya* group (% change = 91.8%). It was observed that both the groups differ significantly at day 21st in grading of associated symptoms score (p-value = 0.019). Mean change in *Snehpana* group was 1.44 (% change = 56.9%) as compared to 1.47 in *Nasya* group (% change = 59.5%).

Assessment of effect of *Brihat Dashmoola Taila Snehapana* in Group-A

SN	*Lakshana*	Mean		%	S.D.	p-value (within group)	p-value (between group)
		B.T	A.T				
1.	Severity of pain	3.31	2.56	22.6	0.504	<0.001(*)	0.074
2.	Frequency of pain	3.47	1.97	43.2	0.595	<0.001(*)	0.659
3.	Duration of headache	3.88	2.56	34.0	0.504	<0.001(*)	1.000
4.	Aura	0.84	0.72	-	0.457	0.065	0.055
5.	Nausea	1.63	0.41	74.8	0.499	<0.001(*)	0.138
6.	Vomiting	1.63	.34	79.1	0.483	<0.001(*)	0.450
7.	Vertigo	1.38	.16	88.4	0.369	<0.001(*)	0.724
8.	Gradation for associated symptoms	2.53	1.09	56.9	0.641	<0.001(*)	0.608

Assessment of effect of *Brihat Dashmoola Taila Nasya* in Group-B

SN	Lakshana	Mean		%	S.D.	p-value (within group)	p-value (between group)
		B.T	A.T				
1.	Severity of pain	3.44	2.31	32.8	0.592	<0.001(*)	0.074
2.	Frequency of pain	3.50	1.91	45.4	0.530	<0.001(*)	0.659

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3.	Duration of headache	3.81	2.56	32.8	0.716	<0.001(*)	1.000
4.	Aura	1.00	0.44	-	0.669	<0.001(*)	0.055
5.	Nausea	1.72	0.59	65.6	0.499	<0.001(*)	0.138
6.	Vomiting	1.72	0.44	74.4	0.504	<0.001(*)	0.450
7.	Vertigo	1.59	0.13	91.8	0.336	<0.001(*)	0.724
8.	Gradation for associated symptoms	2.47	1.0	59.5	0.803	<0.001(*)	0.608

DISCUSSION

Following *Vatika Shirahshoola*, *Ardhavabhedaka* is discovered to be the most prevalent complaint in *Shiroroga*. Paroxysmal, unilateral headache that can be rather severe is a defining feature of the illness *Ardhavabhedaka*. The pathogenesis of *Ardhavabhedaka* involves all three *Doshas*, with *Vata* or *Vata-Kapha* predominating coupled with *Rakta Dushya*. Even while the illness might not be fatal, improper management could result in vision or hearing loss.[10] Due to its paroxysmal character and distinctive trait of a half-sided headache, which commentator *Chakrapani* also refers to as a *Ardha Mastaka Vedana*, *Ardhavabhedaka* can be scientifically linked to migraine. Additionally, there are signs of *Pitta Dosha* involvement, such as giddiness, nausea, and vomiting, which can be described as follows. When *Pitta* and *Prana Vata* combine, sensations such as nausea and burning are experienced.[11] *Murcha*, *Daha*, *Bhrama*, and *Klama* are the outcomes of *Udana Vayu* and *Pitta.*[12] *Bhrama* is a sign of *Rajoguna* and *Pitta-Vata Dosha* involvement[13], according to the condition *Ardhavabhedaka* can be identified as a *Vatika* or *Vata-Kaphaja* disorder after researching its aetiology and symptoms. The first *Doshas* for *Ardhavabhedaka* may be preliminary *Vata* alone or in combination with *Kapha*, but given the nature of the illness, it may quickly take on the appearance of *Sannipatika*.

In this clinical trial Administration of *Snehapana* as well as *Nasya* showed significant results in the management of *Ardhavbhedaka* (Migraine) independently but when both the groups are compared, the results were statistically significant only in three parameters i.e., Vomiting, vertigo and Associated symptoms.

Group A was found better than Group B in reducing Vomiting, Vertigo and other associated Symptoms parameter on the 21th day.

Both the groups were shown significant relief in reducing nausea parameter.

In Group A Aura was found insignificant (p value- 0.065) when compared with Group B (p value- 0.001*).

Average relief in Parameters of *Ardhavbhedaka* (Migraine) found more in *Nasya karma* (58.5%) than *Snehapana* (51.85%).

Probable mode of action of *Brihat Dashamoola Taila*

There are various modalities for the alleviation of *Shirahshoola*. *Acharya Charaka* mentioned "चतुःस्नेहोत्तमा मात्रा शिरःकायविरेचनम्"[14] as treatment modality of *Ardhavabhedaka. Brihat Dashmoola Taila* mentioned in *Bhaishjya Ratnavali* as *Abhyanga, Pana* and *Nasya* in *Shirorogadhikara* chapter with special indication to *Ardhavabhedaka*. In the present study *Brihat Dashmoola Taila* used as *Snehapana* and *Nasya* for treatment of *Ardhavabhedaka.*

Among the 10 *Dravyas* of *Dashmoola 5 Dravyas (50%)* have *Vata-Kapha Shamak* property, *4 Dravyas (40%)* have *Tridosaghna* property and *1 Dravya (10%)* has *Vata-Pitta Shamak* property. It means, in *Dashmoola* all *Dravyas (100%)* have *Vata Shamak* property and *9 Dravyas (90%)* have *Vata- Kapha Shamak* property. Therefore, it will be a potent *Vata Dosha Shamak, Vata-Kapha Shamak* and *Tridoshaghna* compound. Thus, over all it pacifies *Vata, Vata-kapha Dosha* or *Tridosha* and *Ardhavbhedaka* being a *Vata Pradhana Vyadhi (Vata- kapha-Ch.* or *Tridoshaja Su.),* there is every possibility of *Samprapti Vighatana* of *Ardhavbhedaka Roga.*

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Ushna Virya, Katu Rasa and *Tikta Rasa* have *Deepana-Pachana Karma*, which causes *Amapachana* and thus provides proper metabolism and ultimately balances the *Agni.*

Ushna Virya has *Deepana - Pachana, Virechana, Vilayana* property, which softens and liquefies the morbid doshas which are ultimately expelled out due to *Virechaka Karma*. *Laghu Guna* and *Tikshna Guna* have *Sroto-Shodhaka* property, which helps in expelling the morbid doshas. These *Guna* also have the property of *Urdhavabhaga-doshaharatva*, which breaks the *Samprapti* at *Prasaravastha*, where *Vata* alone or *Kapha* along with *Vata* causes *Urdhavaga Pravriti* of vitiated *Doshas*.

Also in a clinical study, the effect of *Dashamoola* in the management of sensory and motor disorders pertaining to sympathetic and parasympathetic outflow amongst the patients presenting with primary neurological disorders.

Conclusion

The *Nasya Karma* is a better treatment option in the management of *Ardhavbhedaka* as compared to *Snehapana*. Although both the treatments are having statistically significant results.

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