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A COMPARATIVE STUDY OF EFFICACY OF BRIHAT DASHAMOOLA TAILA NASYA AND SHIRASHOOLADI VAJRA RASA IN THE MANAGEMENT OF ARDHA-VABHEDAKA

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INTRODUCTION

Now a day our lifestyle has drastically changed, and our growing needs have no end. Speed and accuracy have become the prime demands of the modern era. To cope with this situation everybody has to face a hectic, competitive, and stressful life. Due to this People are unable to pay attention to their physical and mental health. Irregular food habits, suppression of natural urges, improper sleep patterns, and less time for relaxation have become part of our life. As a result of that, incidences of many diseases mainly having psychosomatic origin are increasing. Migraine is one of such disorders, which can be compared with Ardhavabhedaka described in Ayurvedic texts. Ardhavabhedaka consists of two words, Ardha and Bhedaka. Ardha means half, halved, or forming

half and bhedaka means breaking into or through, piercing, or perforating. (1,2,3,4) There is a difference of opinion regarding the doshic predominance among acharyas. Sushruta considers it as tridoshaja. Charaka has explained it as either to be purely vataja or vatakaphaja. Vagbhata opines that only vata dosha is involved. He has dealt with Ardhvabheadaka after explaining vataja shiroroga. In Bhela Samhita, Madhava nidana, Yogaratnakara, and Bhavaprakasha it is considered as either purely vataja or vata kaphaja. Videha of Nimitantra opines it to be va-^(15,17,18, 21). Charaka, Sushruta, and takaphaja Vagbhata have described Shirorogas in general and Ardhavabhedaka as independent among the shirorogas. Constant exposure to dhooma, shareera, and

manasika ayasa constitute the main etiological factor for Ardhavabhedaka. In Ardhavabhedaka there will be severe pain in ardha shiras, manya, bhru, shankha, akshi, lalata, and bhrama. If Ardhavabhedaka is not treated properly it may lead to grievous complications like nayana and Shrotra vinasha etc.^(6,8,10,12,14) Migraine is a highly prevalent disorder, affecting about 5% of men, and 15% of women between the ages 25-55 years. Anger, excitement, irritation, consumption of chocolate, cheese and nuts, etc are the causes of common migraine (25,26). This disease seems to be very simple, but it seriously intervenes with the day-to-day life of a person. The majority of the drugs employed for this disease are almost limited to suppressing the symptoms. Repeated and long-term use of such drugs is found to cause serious side effects and tends to be habit-forming. Hence there is a need for an optimum effective therapy for either their total cure or for its decrease in the incidence of attacks, intensity, and duration, which will be of great relief to the patients. Keeping the same view in mind, this study with, nasya karma and abhyantara Shamanoushadhi were selected. As per the Ayurvedic classics, Nasya karma is supposed to be the first line of choice in all Urdhvajatrugata Vikaras. A medicine administered through the nose goes into Mastishka and expels out the vitiated doshas. So, considering this view Brihat Dashamoola taila⁽¹⁹⁾ was selected for nasya karma and abhyantara prayogartha shirasooladi vajra rasa (19) was selected. And the clinical study was conducted to evaluate the relative efficacy of these classical remedies in Ardhavabhedaka.

MATERIALS AND METHODS

AIMS AND OBJECTIVES: The present clinical study aims.

- To evaluate the efficacies of the two classical preparations –Brihat Dashamoola taila as a Nasya yoga and Shirashooladi Vajra rasa as Vati yoga in the management of Ardhavabhedaka.
- Observing the alleviations of clinical features in relation to age, sex, occupation, socio-economic status, chronicity of the disease condition, etio-logical factors, and food.

• At observing the follow-up recurrences.

METHODOLOGY

Source of data: The patients for the present study were selected on a random basis from the out-patient department of S.J.I.I.M. Bangalore.

Selection of drugs

The present study is to enumerate the efficiency of Nasya karma and Abhyantara shamanoushadhis in Ardhavabhedaka. The drugs were procured from Amrit Kesari Depot, Bangalore.

Organoleptic Characters and Physico - Chemical Analysis of The Yogas - were carried out at the Drug Testing laboratory, Government Central Pharmacy, Bangalore as per the pharmacopeial standards for Ayurvedic formulations, CCRAS, Delhi.

Inclusion Criteria

Patients above the age of 16 yrs irrespective of sex, religion, occupation, socio- economic status.

Patients presenting symptoms like

- Piercing type of pain in half portion of the Shiras,
- Bhrama,
- Recurrence
- Ganda Shotha
- Netra avadeerana.

Exclusion Criteria

- Ardhavabhedaka due to systemic disease
- Ophthalmoplegic migraine
- Complicated migraine

Investigations: CBC with Hb%, LFT, RBS, Lipid Profile, Urine Routine, etc. were carried out before and after treatment.

Study design

- A course of Brihat dashamoola taila shodhana nasya, 4 to 6 drops for 7 days followed by a gap of 7 days. The procedure was conducted for 2 more courses similarly to Group A.
- A course of Shirashooladi vajra rasa 1T.I.D. for 42 days for Group B.

For this study, 40 patients were selected on a random basis, and Patients were grouped into two groups, Group A and Group B consisting of 20 patients each.

Preparatory measures for both groups: After a detailed clinical examination, the laboratory investi-

gations procedure was explained to the patients, and consent was obtained. One day before the actual treatment schedule, all the patients were subjected to mrudu virechana with Trivrut leha (the dose was fixed after koshta Nirnaya)

The method followed in Group A: Group A patients were administered Brihat Dashamoola Taila Nasya

Procedure

Poorva karma

The patient was made to lie down in a supine position on a table with the head in a lower position. Sthanika abhyanga with lukewarm Ksheerabala Taila. After abhyanga patient was subjected to swedana karma.

Pradhana karma: The patient was made to lie down on a table stretching his legs and arms comfortably. The head of the patient was slightly raised. The tip of the nostril was raised with the help of the thumb of the left and with the right hand, 6 drops of taila were instilled in each nostril. While instilling in each nostril, the other nostril should be closed. Then the patient was asked to inhale deeply the instilled medicine.

Paschat karma: The patient was asked to spit the oil which came into his mouth (throat). Then he was asked to do gargling with triphala kashaya.

The method followed in group B: In Group B, a Tablet of Shirashooladi Vajra Rasa was given to patient 1 T.I.D. after food with madhu anupana.

Instruction to the patients: Patients were asked to take a normal diet. They were instructed to use hot water for drinking and bathing. Patients were asked to avoid vega dharana, diwa swapna, drinking cold water, having cold water baths, exposure to smoke, dust, sunlight, and head bath during nasya karma.

Parameters for a clinical study

1. Ardha Shirashoola (unilateral headache)

Nil (0) – No pain

Mild (1) – Pain that is tolerable and does not cause any disturbance to carrying out day-to-day work

Moderate (2)	_	Pain that is tolerable but
	causes	s discomfort while doing day-
	to-day	work.
Severe (3)	_	Agonizing constant pain
which keeps th	e patient	t isolated.
2. Vega (recur	rence)	
Nil (0)	-	absent
Mild (1)	-	once a month
Moderate (2)	-	once in 15 days
Severe (3)	-	once a week
3) Bhrama		
Nil (0)	-	absent
Mild (1)	-	not cause any disturbance to
carry out day-t	o-day w	ork.
Moderate (2)	-	causes discomfort while
doing day-to-d	ay work	
Severe (3)	-	completely bedridden be-
cause of severe	discom	fort
4) Ganda shot	ha	
Nil (0)	_	absent
Mild (1)	_	swelling over the forehead
Moderate (2)	_	swelling over the forehead
and cheek		
Severe (3)	-	swelling of half of the face
5) Netra avad	onnono	
/	eerana	
Nil (0)	-	absent
	- -	absent Pain that is tolerable and
Nil (0) Mild (1)	-	
Nil (0) Mild (1)	-	Pain that is tolerable and
Nil (0) Mild (1) does not cause day work. Moderate (2)	- - any dis	Pain that is tolerable and sturbance to carry out day-to- Pain that is tolerable but
Nil (0) Mild (1) does not cause day work. Moderate (2)	- - any dis	Pain that is tolerable and sturbance to carry out day-to-
Nil (0) Mild (1) does not cause day work. Moderate (2) causes discomf	- - any dis	Pain that is tolerable and sturbance to carry out day-to- Pain that is tolerable but e doing day-to-day work.
Nil (0) Mild (1) does not cause day work. Moderate (2) causes discomf Severe (3) which keeps th	- - - fort whil - e patient	Pain that is tolerable and sturbance to carry out day-to- Pain that is tolerable but e doing day-to-day work. Agonising constant pain t isolated.
Nil (0) Mild (1) does not cause day work. Moderate (2) causes discomf Severe (3) which keeps th 6. Doppler st	- any dis - fort whil - e patient	Pain that is tolerable and sturbance to carry out day-to- Pain that is tolerable but e doing day-to-day work. Agonising constant pain t isolated. the present study both right
Nil (0) Mild (1) does not cause day work. Moderate (2) causes discomf Severe (3) which keeps th 6. Doppler st and left superf	- any dis - fort whil - e patient tudy for ficial ter	Pain that is tolerable and sturbance to carry out day-to- Pain that is tolerable but e doing day-to-day work. Agonising constant pain t isolated. the present study both right nporal arteries were selected.
Nil (0) Mild (1) does not cause day work. Moderate (2) causes discomf Severe (3) which keeps th 6. Doppler st and left superf	- any dis - fort whil - e patient tudy for ficial ter	Pain that is tolerable and sturbance to carry out day-to- Pain that is tolerable but e doing day-to-day work. Agonising constant pain t isolated. the present study both right

time of Shirashoola, before starting the treatment. In this, systolic and diastolic velocities were recorded as also the ratio between systolic and diastolic velocity.

Criteria for assessment of treatment

In the present clinical trial, the duration of the study, including treatment and follow up was for a period of 3 months. Treatment was given for a period of 6

weeks. Therefore, for assessment of results, patients were asked about the intensity of Shirashoola, its duration, and frequency, 6 weeks before treatment and 6 weeks after the treatment.

1. Ardha Shirashoola

The pattern of change in ardha Shirashoola with the treatment was considered for assessment of the result.

- The total disappearance of shoola after the treatment was considered a good result.
- Any change in the degree of shoola after the treatment was considered a fair result.
- No change in the degree of shoola after the treatment was considered a poor result.
- **2. Vega** (Frequency of attacks)

Reduction in the frequency of attacks with the treatment was considered for the assessment of results.

- A reduction in the frequency of attacks above 75% after the treatment was considered a good result.
- A reduction in the frequency of attack to more than 25% and less than 75% was considered a fair result.
- A reduction in the frequency of attack by up to 25% after the treatment was considered a poor response.

3. Bhrama

The pattern of change in Bhrama with the treatment was considered for assessment of the result.

- The total disappearance of Bhrama after the treatment was considered a good result.
- Any change in the degree of Bhrama after the treatment was considered a fair result.
- No change in the degree of Bhrama after the treatment was considered a poor result.

4. Ganda shotha

Reduction in the Ganda shotha with the treatment was considered for the assessment of results.

- A reduction in the Ganda shotha above 75% after the treatment was considered a good result.
- Reduction in the Ganda shotha to more than 25% and less than 75% was considered a fair result.
- A reduction in the Ganda shotha up to 25% after

the treatment was considered a poor response.

5. Netra avadeerana

The pattern of change in Netra avadeerana with the treatment was considered for assessment of the result.

- The total disappearance of Netra avadeerana after the treatment was considered a good result.
- Any change in the degree of Netra avadeerana after the treatment was considered a fair result.
- No change in the degree of Netra avadeerana after the treatment was considered a poor result.

6. Doppler study: After the treatment, again Doppler study of both the right and left superficial temporal arteries were done and the velocities (ie., systolic and diastolic) were noted.

OBSERVATIONS: Were recorded on the 1^{st} , 14^{th} , 28^{th} , and 42^{nd} days of the treatment course for subjective parameters, while objective parameters were recorded on the 1^{st} and 42^{nd} days of the course.

ORGANOLEPTIC CHARACTERS: Brihat Dashamoola Taila:

- > Appearance: Light Orange Red coloured oil
- Odour: The odour of Sesume oil appreciated

Shirashooladi vajra rasa:

- Appearance: Circular-shaped biconvex Tablets of Blackish colour
- > Consistency: Solid
- ➢ Odour: Pleasant
- ➢ Taste: Saline

PHYSICOCHEMICAL ANALYSIS Brihat Dashamoola Taila:

Loss on drying at 110° :	0.23819	% w/w
Weight/ml:	0.9251% w/w	
Acid value:	3.8287	
Saponification value	:	194.1596
Refractive index at 40c	:	1.4581
Ester value:	190.3309	

Shirashooladi vajra rasa:

Uniformity: I	Passes the test
Disintegration Time:	20 minutes
Identification:	Answers to the test for Iron

Answers to the test

Total Ash: 15.54% w/w Acid Insoluble Ash:

10.125% w/w

for Mercury

Answers to the test

for Sulpher

CLINICAL OBSERVATIONS

TABLE 03: Incidence of Severity of Lakshana in Trial Groups (Before Treatment)

SI.	SI. LAKSHANAS		Severe		Moderate		Mild		Nil		
NO		Gr.A	Gr.B	Gr.A	Gr.B	Gr.A	Gr.B	Gr.A	Gr.B	Gr.A	Gr.B
1	Ardha Shirashoola	13	12	7	4	0	4	0	0	20	20
2	Vega	13	12	7	5	0	3	0	0	20	20
3	Bhrama	13	11	7	5	0	4	0	0	20	20
4	Ganda shotha	12	10	6	4	2	6	0	0	20	20
5	Netra avadeerana	12	11	5	4	3	5	0	0	20	20

TABLE 04: CHANGES ON THE 42nd DAY OF STUDY IN TRIAL GROUPS

SI.	SI. LAKSHANAS	Severe	Severe		Moderate		Mild		Nil		Total	
NO		Gr.A	Gr.B	Gr.A	Gr.B	Gr.A	Gr.B	Gr.A	Gr.B	Gr.A	Gr.B	
1	Ardha Shirashoola	6	7	4	5	1	5	9	3	11	17	
2	Vega	6	10	4	5	4	3	6	2	14	18	
3	Bhrama	5	7	6	4	2	5	7	4	13	16	
4	Ganda shotha	5	7	4	5	4	6	7	2	13	18	
5	Netra avadeerana	5	6	3	4	3	5	9	5	11	15	

TABLE 05: Assessment of Effect of Brihat Dashamoola Taila Nasya in Group-A After Treatment

Sl.no	Sl.no Lakshanas			Difference	Percentage	SE	Т	Р
		BT	AT	in Mean				
1	Ardha Shirashoola	2.65	1.35	1.3	49.05%	0.32077	4.05272	0.000121
2	Vega	2.65	1.5	1.15	43.39%	0.29713	3.87028	0.000207
3	Bhrama	2.65	1.45	1.2	45.28%	0.29691	4.04157	0.000125
4	Ganda shotha	2.5	1.35	1.15	46%	0.31435	3.65834	0.000383
5	Netra avadeerana	2.45	1.2	1.25	51.02%	0.32907	3.49465	0.000612

TABLE 06: Assessment of Effect of Shirashooladi Vajra Rasa in Group-B After Treatment

Sl.no	Lakshanas	Mean		Difference	Percentage	SE	Т	Р
		BT	AT	in Mean				
1	Ardha Shirashoola	2.4	1.8	0.6	25%	0.307794	1.949359	0.058662
2	Vega	2.45	2.15	0.3	12.24%	0.287914	1.041976	0.304007
3	Bhrama	2.35	1.7	0.65	27.65%	0.319333	2.035492	0.048819
4	Ganda shotha	2.2	1.85	0.35	15.90%	0.306723	1.141095	0.260971
5	Netra avadeerana	2.3	1.55	0.75	32.60%	0.329074	2.279125	0.028364

TABLE 07: Comparison of the Effect of Treatment in Both the Groups

Sl.no.	Lakshanas	Group	А	%	Of	Group B mean	%	Of	The	difference
		means		relief	f		relief		in %	of relief

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		BT	AT		BT	AT		
1	Ardha Shirashoola	2.65	1.35	49.05%	2.4	1.85	22.91%	26.14%
2	Vega	2.65	1.5	43.39%	2.45	2.15	12.34%	31.15%
3	Bhrama	2.65	1.45	45.28%	2.35	1.8	23.40%	21.88%
4	Ganda shotha	2.5	1.35	46%	2.2	1.85	26.08%	30.1%
5	Netra avadeerana	2.45	1.2	51.02%	2.3	1.7	22.72%	24.94%

TABLE 08: Group-A: Case No. 1: Female Patient – 23 years (Spectral values are as follows)

	Before Tre	Before Treatment		tment	S/D Ratio		
	V1	V2	V3	V4	Ι	II	
Right Central Carotid	57.50	16.70	44.86	14.18	3.46	3.16	
Left Central Carotid	54.40	15.60	94.38	28.14	3.42	3.24	
Right Internal Carotid	64.80	22.40	36.56	12.20	2.82	3.12	
Left Internal Carotid	82.30	32.80	44.30	14.60	2.54	3.00	
Right Temporal	45.46	16.40	41.78	13.80	2.72	3.04	
Left Temporal	87.06	20.76	54.36	14.80	4.14	3.16	

TABLE 09: Group-B: Case No. 2: Female Patient – 34 years (Spectral values are as follows)

	Before Tre	Before Treatment		tment	S/D Ratio		
	V1	V2	V3	V4	Ι	II	
Right Central Carotid	77.64	24.14	67.64	20.34	1.08	3.36	
Left Central Carotid	65.28	21.22	60.68	15.65	3.07	3.84	
Right Internal Carotid	57.09	24.28	48.18	12.68	2.46	3.78	
Left Internal Carotid	63.80	24.30	43.24	16.42	2.68	2.51	
Right Temporal	72.56	22.36	91.50	20.16	3.40	4.54	
Left Temporal	71.52	20.24	65.54	15.46	3.42	4.08	

DISCUSSION

Ardhavabheadaka is a disease of Urdhvajatru specially the shiras which has a peculiar nature to be studied. In Ardhavabhedaka there will be severe pain in ardha shiras, manya, bhru, shankha akshi and in lalata pradesha, associated with bhrama, prakashasahishnuta and shabdasahishnuta. If it is not treated properly it leads to grievous complications like navana vinasha, sroto vinasha, etc. There is a difference of opinion regarding the doshic predominance among acharyas. Sushruta considers it as tridoshaja. Charaka has explained it as either to be purely vataja or vatakaphaja. Vagbhata opines that only vata dosha is involved. He has dealt with Ardhvabheadaka after explaining vataja shiroroga. In Bhela Samhita, Madhava nidana, Yogaratnakara, and Bhavaprakasha it is considered as either purely vataja or vata kaphaja. Thus, with this in mind 40

patients were selected randomly and divided into 2 groups. Group-A cases were treated with Brihat Dashamoola taila nasya and Group-B were treated with Shirashooladi vajra rasa internally (1 T.I.D.). The observation reveals that Ardhavabhedaka is more common in the age group of 26-35 years, followed by the age group of 36-45 years. This is because these individuals have to face both physical and mental strains. In clinical groups, based on sex, the incidence in females was observed to be high i.e., 60% in Group-A and 70% in Group-B. This is because female takes more stress and tension when compared to male. In clinical groups, on the basis of the study the incidence was observed to be high inhouse wives in Group-A i.e., 10 (50%), and in students in Group-B i.e.,7 (35%). This is because of mental as well as physical strain and untimely food habits. It was observed that the chronicity range was from 1 year to 25 years. A maximum number of patients had chronicity of 6-10 years in Group-A i.e., 10(50%) and in Group-B incidence of chronicity was more in 2-5 years i.e., 7 (35%). Among the patients selected for the study, the majority of patients were having mixed food habits. In clinical groups, on the basis of site of pain, the incidence was high in the frontotemporal region i.e., in Group-A, 16 (80%) in number, and in Group-B, 15 (75%) in number. Among 20 patients in Group-A, 7 patients (36%) showed a good response and among 20 patients in Group-B, 3 patients (16 %) showed a good response after the treatment. The response obtained after 42 days of treatment and 3-month follow-up study reveals that the mode of response to classical drugs used in clinical groups was very good in treating Ardhavabhedaka.

Mode of Action of Brihat Dashamoola Taila Nasya

Vriddha Vagbhata was the first who narrated the mode of drug action by nasya karma. The medicine administered will reach the sringataka Srotos and spread to the siras of the eye, ear, throat, etc, and the head (Murdha). The majority of ingredients of Brihat Dashamoola taila have vatakapha hara and sroto shodhaka, shoola prashamana karaka properties, and also thridoshaharatva in general. Regarding the mechanism of action of nasya karma, the hypothesis is that it acts both at local and general levels, by direct contact with nerve terminals and uptake of drugs by the nasal mucosa. It is currently known in the literature that the trigeminal nerve, through its trigemino vascular system is deeply involved in the genesis and maintenance of pain in headache syndromes. The nasal mucosa which comes in contact with drugs applied directly involved in nasya therapy is supplied with both the ophthalmic as well as maxillary branches of the trigeminal nerve. Direct counter irritation or stimulation to these nerve terminals could cause changes in the trigeminal ganglion itself. The result of these hypothetic changes could lead to the alleviation of pain. The ptergopalatine ganglion could also be involved in the local effects of nasya. This ganglion lies on the anterior wall of the pterygopalatine fossa right below the maxillary nerve and it is easily accessible through the nasal cavity. The pterygopalatine ganglion has sensory, parasympathetic, and sympathetic fibres from the carotid plexus. Direct stimuli to these sympathetic fibres could cause changes in the carotid vascular motility, helping to alleviate the symptoms of headaches.

Mode of Action of Shirashooladi vajra rasa

Another group was administered Shirashooladi vajra rasa internally. The purpose was to observe, which drug brings down the symptoms faster in acute attacks, and also as a prophylaxis. The ingredients of Shirashooladi vajra rasa have the property of kapha vata shamana. The Yoga shirashooladi vajra rasa contains many ingredients which are not only vatashamaka, and kaphahara but also nadi balya in its nature. Sukshma and teekshna property help to reach even to the minute srotas and does shodhana, due to laghu and rukshata helps to remove avarana, and the drugs mainly are shothahara and shoolahara which helps to alleviate the shoola which is the chief complaint of the study. Yoga contains vidanga which is krimihara, nadi balyakara, Shirovirechana, and rakta shodhaka and its main Amayika prayoga is in nadi dourbalya, because of all the above overall properties of yoga are chosen for the clinical trial. The study revealed that the response in reduction of severity of shoola was promising in group-A compared to that of group-B. Pathyahara and vihar play an important role in the prevention and control of Ardhavabhedaka. In Group-A, in 6 patients the response was good, in 7 patients the response was moderate, and 5 patients showed a mild response. In Group-B, in 6 patients the response was good, in 7 patients the response was moderate, and 5 patients showed a mild response. The analysis of the results of the trial confirms that Brihat Dashamoola taila nasya is very effective than Shirashooladi vajra rasa which was given internally.

CONCLUSION

The above study can conclude that guda plays a vital part in the excretory process of the human body. It helps in the excretion of mala and apan vavu or excretory products of our body. Along with these functions, it has significant surgical importance in the human body. Its structural relevance should be kept in mind while performing any surgical or parasurgical procedures. Otherwise, it can be a lifethreatening condition. This study has shown that the disease Ardhavabhedaka is more common in the age group of 26-35 years and also females are affected more. Common etiology being vegadharana, divaswapna, manastapat, adhyasana, consumption of chocolate, cheese, nuts like ground nuts, and cashew nuts have precipitated and aggrevated the headache attack. This has to be avoided in order to prevent the onset of headache attacks.

In a clinical trial conducted on 40 patients i.e, 20 patients in group-A, and 20 in Group B. Group-A advocated Brihat Dashamoola taila nasya proved to be beneficial in reducing the intensity of headache attacks and frequency of headache attacks compared to that of Group-B.

Nidana parivarjana is very much necessary to control the severity of the disease as well as in avoiding the disease's due course.

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