REVIEW ARTICLE

Evaluation of various Ayurvedic formulations for Migraine (Ardhavybhedak) – A review

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ABSTRACT:

Introduction: Migraine, is a primary headache disorder characterized by moderate to severe intensity recurrent headaches, starts at puberty and worsens during middle age. Approximately 15% of people are affected by the problem globally. **Aim:** To review clinical works carried out on Migraine. **Materials and Methods:** Clinical works carried out on Migraine from 1978 to 2018 at various departments of IPGT&RA, GAU, Jamnagar were compiled and analyzed as secondary data collection method. **Results:** In this article total of eight works, were included and reviewed, duration of which ranged from 7-60 days, almost all the Ayurvedic formulations i.e. different types of *Nasya* like *Pradhamana*, *Avapeeda* and *Sneha*; and some formulations like *Pathyadi Kwath*, *Sutsekhara Rasa*, *Laghu Sutsekhara Rasa*, etc. were given orally. **Conclusion:** Different Ayurvedic formulations used in different trials almost remained highly significant/significant on various subjective and objective criteria of the disease Migraine.

Keywords: Migraine, *Ardhavybhedak*, Ayurvedic formulations

INTRODUCTION:

Headache itself is a painful and disabling feature consisting of primary headache disorders, namely Migraine, Tension-type headache, and Cluster headache. Globally, it has been estimated that the prevalence of current headache disorder (symptomatic at least once within the last year) among adults is about 50%. Half to three quarters of adults aged

18–65 years in the world have had a headache in the last year and among those individuals, 30% or more have reported Migraine. It is more common in women, by a factor of about 2:1, because of hormonal influences. It is caused by the activation of a mechanism deep in the brain that leads to the release of pain-producing inflammatory substances around the nerves and blood vessels of the head.^[1]

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In the Global Burden of Disease Study, updated in 2013, Migraine is the sixth highest cause worldwide for **years lost due to disability (YLD)**. Considering disability level in living, headache disorders collectively had been second-highest as leading causes of non-fatal health loss for nearly three decades (1990-2017), whereas diabetes has emerged as the fourth.^[2] Therefore, people should enhance their mental health for peace of mind as it creates harmony all over the body.

In Ayurveda, some of migraine symptoms may be correlated with *Ardhavybhedak*. All the *Acharyas* have described more or less about it. Vitiation of *Vata* alone or in association with *Kapha*^[3] and vitiation of *Tridosha*^[4] causes *Ardhavybhedak* in which various types of pain might have been experienced i.e. excruciating pain in half of the head particularly in the sternomastoid region, eye-brows, temples, ears, eyes and forehead of that half side.^[5] The pain also might be of splitting, pricking and churning types.^[6] When the disease stage is aggravated eyes and ears may get damaged.^[7] For the treatment, various therapies have been described by different Acharyas. The treatment comprises for the elimination or pacification of *Doshas* which includes few cleansing processes like *Virechana* (purgative therapy), *Shirovirechana* [*Nasya*-nasal application of medicated oils (*Sneha Nasya*) or herbal decoction/ powder (*Avapeeda/ Pradhamana Nasya*)], *Basti*^[8] through which accumulation of *Dosha* get evacuated out of the body. *Lepa*^[9] (local application) with herbs is also described. *Shirobasti*^[10] (therapeutic retention of medicated oil over the scalp) has also been described in ancient texts which is also very beneficial in neurological disorders.^[11], ^[12] *Dahana* (cauterization), *Upanah* (poultice), *Nadisweda* (fomentation) and treatment as described in *Pratishyay* (coryza) and *Shiroroga* (head disorders) have also been mentioned.^[13]

Many times it happens that many formulations are available for a disease condition and at different times, their scientific trial has also been done but unless the various trials are compared and assessed, one cannot rationally choose the best treatment protocol under specific conditions. Taking into consideration the present work entitled "Evaluation of various Ayurvedic formulations for Migraine (*Ardhavybhedak*) – A review" is carried out with the following aim.

Aim: To review various clinical trials carried out on Migraine (*Ardhavybhedak*).

MATERIALS AND METHODS:

Clinical trials on Migraine carried out at various departments of IPGT & RA, Jamnagar from 1978 to 2018 were compiled

and analyzed. For that purpose, hard copies of the theses were availed from the central library as well as the Ayurvedic Research Database CD containing all PG theses from 2000 onwards were used. The trials included in this article are shown in **Table-1**. [14-34]

Inclusion Criteria:

- Clinical trials on Migraine (*Ardhavybhedak*) carried out in various departments of IPGT & RA, Gujarat Ayurved University, Jamnagar between 1978 and 2018.

Exclusion Criteria

- Trials conducted other than IPGT & RA.
- The clinical trials carried out after 2018/ ongoing clinical trials.

Observations:

Regarding assessment criteria:

As this article includes research works from 1978 to 2018, many assessments about the assessment criteria are found. In these trials different subjective and objective criteria have been assessed which are shown below.

1) Subjective Criteria

- Severity of Headache
- Duration of Headache
- Frequency of Headache
- Nausea
- Vomiting
- Vertigo
- Aura
- GIT associated symptoms i.e. Hyperchlorhydria

Headache with its severity, duration, frequency and nausea were assessed in all the trials. Vomiting was included as a subjective parameter from 1987 onwards. Vertigo was not assessed until 1997 than after it has been included as a subjective parameter in all the studies. Aura was considered as a subjective parameter from 2003 to 2018 (Study-4,5,6,7). Hyper-chlorhydria was assessed in the studies of 2008, 2015 and 2018 (Study-5,6,7).

2) Objective Criteria: MIDAS scale (It was assessed only in PhD work carried out in 2018 (Study-7))

Status of carried out works:

Total of 8 studies were carried out on migraine during the period. There number of enrolled patients increased gradually. Dr. JyotsanaRaval did not do statistical analysis hence it is not included in the table showing results. The number of patients (n) in each criterion before 2003 had not been mentioned whereas after 2003 the number of patients affected with the symptom is mentioned which is more scientific.

Regarding formulations used in carried out works:

As far as the formulations are concerned, *Nasya* (*Pradhamana*, *Avpeeda*, *Snehana*) as well as oral administration of classical formulation like *PathyadiKwath*, *UnmadharaChurna*, *LaghuSutsekhara Rasa* and *Anubhuta* (planned on the basis of experience) formulation like *MandukparnadiVati* as well as modern prophylaxis like Flunarizine had been used.

RESULTS:

The relief in subjective and objective criteria as well as the significance/effect of therapy of different trials are as mentioned in Table-2. Some of the highlights of the table are described below.

Study-1 (Dr. Aruna B. N.) showed the comparison of oral formulation (*PathyadiKwath*) and nasal administration of herbo-mineral liquid compound (*ManshiladiAvpeedaNasya*). In this trial, the nasal administration had shown better improvement as compared to oral administration.

Study-2 (Dr. Aruna Nimavat) was divided into three groups. It compared *Nasya* (with *JatamansyadiTaila*), *Shirobasti* (with *JatamansyadiTaila*) and combined effect of both. In this study, *Shirobasti* showed better results as compared to *Nasya* and combined therapy showed better results in all the subjective criteria as compared to other groups.

Study-3 (Dr. Kirti Raja) had shown first the comparison of *Nasya* (*DashmoolaTaila*) and oral formulation (*MandukparnadiVati*) alone; and *Nasya* with oral formulation. In this trial, combined therapy showed better improvement as compared to individual oral or nasal administration.

Study-4 (Dr. Suraj Shoor) also have same groups like Study-3. In this study oral formulation (*UnmadaharaChurna*) was taken in powder form and for *Nasya*, *DashmoolaGhrita* was chosen. In this study also the combined therapy of *Nasya* and oral formulation showed the better results compared to other groups.

Study-5 (Dr. Hemal Parekh) was the first study in which

herbo-mineral oral compound (*LaghuSutsekhara Rasa*) was introduced with a comparison of combined therapy of *Nasya* (*BrihadaDashmoolaTaila*) and herbo-mineral compound. In this study also combined therapy showed better improvement.

Study-6 and Study-7 (Dr. Shweta Mata) showed the comparison of Ayurvedic formulation and procedure i.e. *Nasya* (*BrihadaJivakadyaTaila* and *BrihadaDashmoolaTaila* accordingly) and herbo-mineral compound (*Sutsekhara Rasa* and *LaghuSutsekhara Rasa* accordingly) as a trial group with prophylaxes of contemporary medicine (Flunarizine) as a control group. The trial group found better result than modern prophylaxes. In the follow-up period, the recurrence of the Migraine was shown in the modern prophylaxes group while in the trial group it had not repeated in the follow-up period.

DISCUSSION:

As these articles include researches from 1978 to 2018, there is shown many assortments regarding sample size, methodology, statistical analysis, assessment criteria and their gradation, formulations, etc.

As it is well evident that the sample size affects the overall result as it helps to specify the estimates. In previous theses, few patients were registered in the trials. These might be because of less prevalence of the disease or due to unawareness of Ayurvedic treatment in Migraine condition. Also, the methodology was not as developed as of now. Although work has given satisfactory results in each trial, the gradation for subjective criteria was framed after 1997 and was letter evolved in a more scientific way.

Different *Ayurvedic* formulations and procedures like *Nasya* (nasal administration) i.e. *Sneha Nasya* (nasal administration with medicated oil/*Ghee*) and *AvpeedaNasya* (nasal administration with herbal/ herbo-mineral liquid), *Shirobasti* (therapeutic retention of medicated oil over the scalp) were used in different clinical trials reviewed in this article. As nostrils have been stated as the gateway of head, most of formulations are of nasal administration. The oral medicines have also shown good results in comparison to modern prophylaxes. Ultimately Ayurvedic formulations used in Migraine have proven to be beneficial. All the studies have accessed subjective criteria except the last study conducted in 2018 (Dr. Sweta Mata-PhD thesis) which has included MIDAS Scale as an objective criterion. There are two trails of comparison between Ayurvedic and contemporary medicine.

Both these studies show better results in the trial group which is of *Nasya* with oral medication.

Study-1(Dr. Aruna N.) showed better results in *Nasya* (with *ManashiladiAvpeeda*) group as compared to oral formulation (*PathyadiKwath*) as transmission of drug to the brain should be quick which was fulfilled by the *Nasya* procedure. Study-2 (Dr. ArunaNimavat) revealed the data that *Shirobasti* (therapeutic retention of medicated oil over the scalp) and *Nasya*(nasal administration) (with *JatamansyadiTaila*) alone had shown good results, but when they were given as a combined therapy, it had shown tremendous results. Study- 3 (Dr. Kirti Raja) revealed that the combined therapy(*DashmoolaTailaNasya*and*MandukaparnadiVati*) provided comparatively better relief in almost all the subjective criteria like severity, frequency and duration of headache and vomiting. Study-4 (Dr. Suraj Shoor) revealed that the combined group (*UnmadaharaChurna*and*DashmoolaGhritaNasya*) showed better results than individual use of formulations as it was a safe and effective procedure for stress and headache. In this dissertation work, *Manasika Bhava* had been considered as the main culprit for the disease and both the formulations in combination remained effective.Study-5 (Dr. Parekh Hemal) revealed that both *LaghuSutashekhara Rasa* and *BrihadadashamoolaTailaNasya*, if given alone, werehaving significant improvement in all the parameters like headache, nausea,vomiting and other associated symptoms of the disease *Ardhavabhedaka*.But when both *LaghuSutashekhara Rasa* and *BrihadadashamoolaTailaNasya*were given together in the combined group, it showed an augmented effect. Study-6,7 (Dr. Sweta Mata) both the studies revealed that Ayurvedic formulations (*Sutsekhara Rasa* and*LaghuSutsekhara Rasa*) and *Nasya* procedure (with *BrihadajivakadyaTaila* and *BrihadadashmoolaTaila*) remained effective when compared to Flunarizine. Both the oral formulation and nasal application of medicated oil pacified *Doshas*and normalize the condition. These effects have been seen in above trials due to systemic as well as local delivery of the drug which helped to cure the condition.

Overview of Procedures used in the trials reviewed in the article:

Most of the trials had included *Nasya* as a therapeutic procedure. As we know nasal administration of any medication gets into systemic circulation within 5 minutes as nasal mucosa is thin and well vascularized. If one wishes to deliver the drug to the brain it has to cross the blood-brain barrier (BBB) which is possible only with lipophilic material. [35] Thus, nasal administration of drug can act in two ways: 1) By

systemic circulation and 2) Direct pooling into the intracranial region. There are different medicated oil/ Ghee that have been described in Ayurveda which remains helpful in the treatment of *Ardhavbhedak* (Migraine) as the main pathology sites in the brain. Also, *Shirobasti* is being done with medicated oils but there is a future scope to know the effect on neurological disorders.

Total 259 patients were registered in different trails. Out of them, 214 patients were administered with Ayurvedic formulation and procedures. A total of 46 patients were treated exclusively with *Nasya* (nasal administration of medicated *Ghee*/oil/fine powder) procedure; *Nasya* with oral formulation (*Kwath*/*Vati*/*Churna*) had been given in 116 patients. Only oral formulation had been administered in 40 patients. We have seen that *Vati* had better results compared to *Churna* and *Kwath*. It may be because of palatability of the formulation and *Medhya* contents of *MandukaparnadiVati* as the paphthology recites in brain so *Medhya* drugs (brain tonics) might have affected well in the condition. *Shirobasti* had been administered in total of 6 patients and *Shirobasti* along with *Nasya* procedure had also been administered in 6 patients. This group showed the most significant result among all the carried out trials, as *Shirobasti* also affects the nervous tissue by vasodilatation and helps to get rid of the diseased condition.

Out of 259 patients, data of 244 patients had been analysed statistically. Out of which, 199 patients were treated with Ayurvedic modalities and the rest were treated with Flunarizine. From 199 patients treated with Ayurvedic formulations, 48 patients (24.12%) got cured, 96 patients (48.24%) got marked improvement, 36 patients (18.09%) got moderate improvement, 18 patients (9.05%) got mild improvement and 01 patient (0.5%) remained unchanged. Patients who had taken Flunarizine, out of 45 patients, 13 patients (28.89%) got cured, 22 patients (48.89%) got marked improvement, 07 patients (15.56%) got moderate improvement, 03 patients (6.67%) got mild improvement.

Thus we can say that Ayurvedic formulations not only give a better cure to a greater extent but also give promising results to enhance the quality of life of patients with Migraine.

CONCLUSION:

Being a *Shiroroga*, migraine should be treated by giving importance to *Uttamanga*. Again, *Nasya* is a therapeutic procedure, which is carried out through the *ShirasoDwaaram*-an open access to the head. As per the documented data in this article, Study-2 (Dr. ArunaNimavat), revealed combined procedure of *Nasya* and *Shirobasti* with *JatamansyadiTaila*.

There was showed an excellent output in comparison to other modalities. During the dissertation work it was carried out on small sample size of 6 patients only. We recommend it to be carried out on large sample size to make out a definite outcome in aid of both science and community.

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able 1: No. of trials carried out in between 1978 and 2018 with its details

Sr. No.	Name of Scholar (with Dpt. & year)	No. of treated pts.	Gp.	Drug and posology	Dose	Duration
1.	Dr. Jyotsna H. Raval ^[13] (KC-1978)	15	Single group	<i>PradhamanaNasya</i> with <i>Swas-kutharaRasa</i> ^[14] *	500mg	7 days
2.	Dr. Aruna B. N. ^[15] (KC-1987)	7	Gp.-A	<i>ManhashiladiAvapeedaNasya</i> ^[16]	8 drops in each nostril	8 days
		6	Gp.-B	Oral administration – <i>Pathyad-iKwath</i> ^[17]	30 ml twice a day	30 days
3.	Dr. ArunaNimavat ^[18] (P(KC-1997)	10	Gp.-A	<i>JatamansyadiTailaNasya</i> (after routine diet)	16 drops in each nostril	3 weeks with gap of 1 day after each week
		6	Gp.-B	<i>Shirobasti</i> ^[19] with <i>Jatamansyadi-Taila</i> (empty stomach)	1 st day-20 mins 2 nd day-25 mins 3 rd day onwards -30 mins	20 days
		6	Gp.-C	<i>JatamansyadiTailaNasya</i> & <i>Shi-robasti</i>	First <i>Nasya</i> then after <i>Shirobasti</i>	6 weeks
4.	Dr. Kirti P. Raja ^[20] (PK-1999)	6	Gp.-A	<i>DashmoolaTailaNasya</i> ^[21]	16 drops in each nostril	43 days (2 sit-tings of 18 days with a gap of 7 days)
		6	Gp.-B	<i>MandukparnadiVati</i> [#]	4 gm thrice a day	45 days
		6	Gp.-C	<i>DashmoolaTailaNasya</i> <i>MandukparnadiVati</i>	As per Gp.-A As per Gp.-B	15 days+ 30days (Total 45 days)

5.	Dr. SurajShoor ^[22] (KC-2003)	8	Gp.-A	<i>UnmadaharaChurna</i> ^[23]	3 gm thrice a day with milk/ ghee as <i>Anupana</i>	2 months
		8	Gp.-B	<i>DashmoolaGhritaNasya</i> ^[24]	16 drops in each nostril	2 months (4 sittings of 7 days each with a gap of 7 days)
		8	Gp.-C	<i>UnmadaharaChurna&DashmoolaGhritaNasya</i>	As per Gp-A and Gp-B	2 months
6.	Dr. Parekh Hemal ^[25] (Shalaky-2008)	20	Gp.-A	<i>LaghuSutsekhar Rasa</i> ^[26]	500 mg tab twice a day	45 days
		17	Gp.-B	<i>LaghuSutsekhar Rasa</i>	500 mg tab twice a day	3 sittings of 7 days each with 1 week gap (<i>Nasya</i>)
				<i>BrihadaDashmoolaTailaNasya</i> ^[27]	4-8 drops in each nostril	
7.	Dr. Shweta Mata ^[28] (Shalaky-2015)	15	Gp.-A	<i>BrihadaJeevakdhyaTailaNasya</i> ^[29]	6 drops in each nostril	45 days (2 sittings of 7 days each with 15 days gap)
				<i>SutsekharRasa</i> ^[30] with <i>Draksha-JalaAnupana</i>	250 mg tab twice a day	
		15	Gp.-B	Flunarizine (10 mg)	1 tab at night	45 days
8.	Dr. Shweta Mata ^[31] (PhD thesis-Shalaky-2018)	70	Gp.-A	<i>BrihadaDashmoolaTailaNasya</i> ^[32]	6-8 drops in each nostril	60 days (4 sittings of 7 days each with 1 week gap)
				<i>LaghuSutsekhar Rasa</i> ^[33]	500 mg tab thrice a day	60 days
		30	Gp.-B	Flunarizine (10 mg)	1 tab at night	60 days

* To avoid irritation, local application of *Goghritain* nasal mucosa after *PradhamanaNasya*.

Anubhuta Yoga which contains *Mandukparni*, *Sankhpushpi*, *Jyotishmati* and *Pippalimula* 3-3 parts and *Godanti* 1 part.

S_i S_j – Statistical Significance

Scholar Name	Formulation	N	Severity of Headache		Duration of Headache		Frequency of Headache		Nausea		Vomiting		Vertigo		Aura		Hyper-chlorhydria		MIDAS Scale	
			Relief (%)	S _i S _j	Relief (%)	S _i S _j	Relief (%)	S _i S _j	Relief (%)	S _i S _j	Relief (%)	S _i S _j	Relief (%)	S _i S _j	Relief (%)	S _i S _j	Relief (%)	S _i S _j	Relief (%)	S _i S _j
Dr. Aruna B. N.	<i>Manhashiladi.vypeeda</i>	7	90.9	HS	97.58	S			83.72	IS	100	S								
	<i>Pathyadi Kwath</i>	6	42.27	S	56.3	IS			75	S	80.24	S								
Dr. Aruna Nimavat	<i>Jatamansyadi Taila Nasya</i>	10	66.66	HS	55	S	58.62	HS	94.44	HS	100	IS	100	IS						
	<i>Jatamansyadi Taila Shirobasti</i>	6	82.33	HS	68.66	S	69.87	S	91.5	HS	100	S	100	IS						
	<i>Jatamansyadi Taila Nasya & Shirobasti</i>	6	94.44	HS	92.53	S	93.33	HS	92.7	S	100	S	100	IS						
Dr. Kirti Raja	<i>Dashmoola Taila Nasya</i>	6	65.16	S	83.78	S	68.75	S	92	HS	87.5	S	62.5	S						
	<i>Mandukaparnadi Vati</i>	6	71.42	S	77.41	S	69.87	S	75	HS	90	HS	90	HS						
	Combine	6	84.2	HS	84.47	S	71.5	S	83.33	S	90	HS	80	HS						
Dr. Suraj Shoor	<i>Unmadhara Churna</i>	8	66.66	HS	70.13	HS	64.1	S	63.63	S	63	HS	68.35	S	50	HS				
	<i>Dashmoola Chhrita Nasya</i>	8	75	HS	71	HS	57	HS	73	S	82	S	55	S	81	S				
	Combine	8	86	HS	87	HS	85	HS	87	S	88	S	78	HS	87	HS				
Dr. Hemal Parekh	<i>Laghu Susekhara Rasa</i>	20	73.44	HS	59.09	HS	61.11	HS	90	HS	89.29	HS	78.57	HS	76.92	S	95.45	HS		
	<i>Laghu Susekhara Rasa + Brihadadaivakadya Taila Nasya</i>	17	85	HS	72.73	HS	75	HS	94.44	HS	92.31	HS	90	HS	81.25	HS	96.55	HS		
	<i>Brihadadaivakadya Taila Nasya + Susekhara Rasa</i>	15	81.03	HS	73.47	HS	78.86	HS	95.12	HS	82.76	HS	100	S	100	HS	92.85	HS		
Dr. Shweta Mata	Flunarizine Tablet	15	66.66	HS	63.41	HS	61.11	HS	78.57	HS	95.45	HS	73.33	S	55.55	S	35.29	S		
	<i>Brihadadaivakadya Taila Nasya + Susekhara Rasa</i>	70	83.21	HS	82.53	HS	82.06	HS	95.43	HS	100	HS	97.56	HS	93.75	HS	96.96	HS	64.14	HS
Dr. Shweta Mata	Flunarizine Tablet	30	83.02	HS	82.61	HS	82.29	HS	89.47	HS	92.86	S	89.47	HS	90	S	29.41	IS	48.04	HS