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Research Article

A Controlled Clinical Study on the Role of *Nasya Karma* and *Shirodhara* in the Management of Migraine

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Abstract: Migraine (*Ardhavbhedaka*) is now recognized as a chronic illness, the second most common cause of headache, not simply as a headache. With advent of modern drugs, the pattern of disease has grossly changed, where the drugs only assuage the symptoms temporarily and the underlying pathology goes on progressively to worsen the condition. Therefore, the Ayurvedic therapeutics especially *Nasya karma* (Errhine therapy) and *Shirodhara* of *Panchakarma* (Five major bio-purificatory therapies) therapy has attracted considerable glamour for providing safe and effective remedies in the treatment of migraine. The study had been conducted on 33 patients of Migraine which were randomly divided in to three groups and were given treatment for 21 days and follow-up after 1 month. Out of the three groups, 11 patients were administered *Kumkumadi ghrita Nasya* 6 drops in each nostril, 12 patients of second group were administered *Dashmool shrita Ksheera Shirodhara*, and 10 patients of third group were administered Tab. Propranolol 40 mg bd and diclofenac 50 mg bd. During present trial it was observed that there was highly significant improvement in clinical manifestations of migraine after the therapy with *Nasya Karma*. So it is concluded that *Nasya karma* is completely or partially relieves the symptoms in Migraine.

Keywords: Migraine, Ardhavabhedaka, Nasya Karma, Shirodhara.

INTRODUCTION

Migraine is now recognized as a chronic illness, the second most common cause of headache, not simply as a headache. Worldwide, migraines affect nearly 15% or approximately one billion people. It is more common in women at 19% than men at 11% [1]. During adolescence migraines becomes more common among women [2] and this persists for the rest of the lifespan, being two times more common among elderly females than males [3]. The word migraine is derived from the Greek word hemicrania, meaning "half of the head" because the pain of migraine often occurs on one side. Pain also sometimes spreads to affect the entire head. The term "migraine" refers to a syndrome of vascular spasms of the cranial blood vessels. It is usually an episodic headache that is associated with certain features such as sensitivity to light, sound or movement; nausea and vomiting often accompany the headache [4].

In Ayurveda migraine is found to be identical to *Ardhavbhedaka* characterized by pain in half side of head. [5]. According to Charaka *Vata* either alone or in

combination with *Kapha*, seizes the one half of head and causes *Ativedana* (acute neuralgic pain) in the sides of the *Manya* (neck), *Bhroo* (eyebrow), *Shankha* (temple), *Karna* (ear), *Akshi* (eyes) or *Lalatardhe* (forehead of one side). This pain is very agonizing like that of churning rod (red hot needle). This disease is called *Ardhavabhedaka*. If the condition becomes aggravated, it may even impasse the functions of the *Nayana* (eye) and *Shrota* (ear) [6].

With advent of modern drugs, the pattern of disease has grossly changed, where the drugs only assuage the symptoms temporarily and the underlying pathology goes on progressively to worsen the condition. Though ample research is being carried out for alleviating the disease and new avenues are being explored for treating early stage of the disease. Therefore, the Ayurvedic therapeutics especially Nasya karma and Shirodhara of Panchakarma therapy has attracted considerable glamour for providing safe and effective remedies in the treatment of migraine. Kumkumadi ghrita Nasya [7] and Dashmool shrit ksheer shirodhara [8] were selected for the present

study which are mentioned in Ashtang Hridaya for treatment of *Ardhavabhedaka* on various scientific parameters to evolve a safe, effective, readily available and economic treatment protocol.

MATERIALS AND METHODS

Following materials and methods were adopted for conducting the present research project.

Selection of Cases/ Patients

The study was conducted on 33 clinical and pathological diagnosed patients of Migraine. The patients were selected from O.P.D. and I.P.D. of National Institute of Ayurveda, Jaipur and S.M.S. Medical College & Hospital, Jaipur.

Sampling Technique

In the present study 30 clinically diagnosed patients of *Ardhavabhedaka* (Migraine) were selected and randomly divided into three groups.

- Group A- In this group 10 patients were registered for *Kumkumadi Ghrita Nasya Karma*.
- Group B In this group 10 patients were registered for Dashmoola-Shrita Ksheera Shirodhara Karma.
- Group C Control group of 10 patients were on allopathic regimen.

The patients were selected randomly irrespective of, sex, religion, education and occupation etc.

Duration of Trail: 21 days in each group **Nasya Dose:** 6 drops in each nostrils

Shirodara with duration: continuous pouring of 2 lt. *Dashmoola-Shrita Ksheera* for 45 min/day.

Follow up: Follow up was carried out for 1 month after the completion of treatment to see the long standing effect of the therapy.

Diagnostic Criteria's Adopted

- Age: 15 to 50 years.
- Patients presenting with signs and symptoms of Migraine described as per Ayurvedic texts and Modern texts were included in the study.
 For this purpose a special research proforma was prepared as per the Modern and Ayurvedic view.
- The diagnosis of the disease was done on the basis of clinical manifestations like recurrent

attacks of headache, mostly unilateral in nature, variable in intensity, frequency and duration with or without nausea, vomiting, photophobia, phonophobia and vertigo.

Inclusion Criteria

- Age between 15 to 50 years.
- Patients presenting with signs and symptoms of Migraine described as per Ayurvedic and modern science.

Exclusion Criteria

- Pregnant and lactating women.
- Patients suffering from major disease e. g. tuberculosis, cancer, diabetes mellitus, heart disease, hypertension etc.
- Ophthalmoplegic migraine.
- Complicated migraine.
- Secondary Headache caused by sinus headache, meningitis, brain tumour, encephalitis, cervical spondylitis, refractive error and increased intra ocular pressure.
- Patients using drugs for any other systemic illness.

Discontinuation criteria

- Aggravation of symptoms.
- Patients not willing to continue.

Selection of drug

The drug selected for the present study is in group A *Kumkumadi Ghrita* [7] 6 drops in each nostrils for *Nasya Karma* and in group B *Dashmool shrita Ksheera Shirodhara* [8] for *Shirodhara* and in group C Propranolol 40 mg bd and Diclofenac 50 mg bd for 21 days. The Ayurvedic drugs were prepared in the pharmacy, National Institute of Ayurveda, Jaipur and allopathy drugs were purchased from drug market.

Investigations Performed

Following investigations were advised-

- Blood for CBC, ESR
- Vision test

Criteria for Assessment Subjective Improvement

Improvement in the following subjective sign and symptoms are

Table 1: Scoring of Clinical Symptoms

Criteria	Symptoms Symptoms	Score				
Intensity of Headache	No Headache	0				
intensity of Headache	Mild headache which doesn't interrupt patient's regular activities.					
	Moderate headache which interrupt patient's activities & diverting his/her	2				
	concentration.	2				
	Severe headache in which patient is unable to perform his/her regular work.	3				
	Severe headache due to which patient prefers to be in bed/dark room.	4				
Painless interval	No reoccurrence of pain	0				
1 anness meet var	> 15 days					
	> 7 days - < 15 days					
	> 3 days - < 7 days	3				
	< 3 days	4				
Duration of Headache	Nil	0				
(hours/days)	1-6 hours/day	1				
(nours/ days)	7-12 hours/day					
	13-18 hours/day	3				
	•					
Nausea	18-24 hours/day No nausea	0				
Nausea						
	Occasionally	1				
	Moderate nausea, but does not disturb the routine work	2				
	Severe nausea, disturbing routine work	3				
Vomiting	Severe enough, small amount of fluid regurgitating from mouth No vomiting	0				
	Only if headache dose not subside	1				
	Vomiting 1-2 times	2				
	Voliting 1-2 times Vomiting 2-3 times	3				
	Forced to take medicine to stop vomiting	4				
Photophobia	No photophobia	0				
	Very mild photophobia	1				
	Photophobia on exposure to sun light/bright light	2				
	Photophobia on exposure to indoor light.	3				
DI 11'	Severe Photophobia in which patient unable to open the eye.	4				
Phonophobia	No phonophobia	0				
	Very mild phonophobia	1				
	Moderate phonophobia	2				
	Severe phonophobia	3				
¥7. 4*	Severe Phonophobia which force to take medicine	4				
Vertigo	Nil	0				
	Feeling of giddiness	1				
	Patient feels as if everything is revolving	2				
	Revolving signs + black outs	3				
T 7' 1 1' 4 1	Unconscious	4				
Visual disturbance	Nil	0				
	Mild	1				
	Moderate	2				
	Severe	3				
	Very severe	4				

OBSERVATIONS

For the clinical study, 33 clinically diagnosed and confirmed cases of Migraine were registered on the basis of a specially designed performa prepared for the purpose. Out of 33 patients, 3 patients discontinued the treatment. In group A, 11 patients were registered and 01 patients discontinued the treatment, in group B, 12 patients were registered and 02 discontinued the

treatment and in group C 10 patients were registered, and total 30 patients completed the treatment.

All the patient treated Nasya Karma with Kumkumadi Ghrita and Shirodhara dhara with Dashmoola Shrit Kshir were very well and no side or toxic effects in these trial were observed.

The observations made on the 33 patients of Ardhavbhedaka of this series showed that maximum number of patients were of age group of 21 - 30yrs (42.4%), Females (63.6%), Hindu (72.7%), Graduate and Higher Secondary passed (24.2%), Married (66.6%), House wives (39.4%), Student(36.3%), Middle class (90.9%), Urban habitat (75.6%), Vegetarian (60.6%). Majority of the patients had disturbed sleep (66.6%), Vata-pitta prakriti (51.5%), Rajas prakriti (72.7%), Madhyama Sara (84.8%), Madhyama Samhanana (72.7%), Madhyama Satmya (60.6%), Madhyama Satva (57.6%), Madhyama Pramana (81.8%), Madhyama Abhyavaharana Shakti (63.6%), Madhyam Jarana shakti (63.6%), followed by Madhyama Vyayama shakti (60.6%). The maximum nidanas (etiological factors) observed in patients were Anashana (63.6%), Ratrijagarana (60.6%), Chinta (57.6%), Vishamashana (51.5%) and Vega sandharana (42.4%). The chief complaints reported from the patients were Headache (Shirahshoola) (100%), Nausea (66.7%), Vomiting (60.6%), Photophobia (66.7%), Phonophobia (72.7%), vertigo (54.5%) and Visual disturbance (42.4%).

Maximum patients were having unilateral headache (90.9%), Throbbing type of headache (57.6%). Severe intensity of headache was seen in (66.7%) with chronicity of 2 years (39.4%). The duration 7-12 hours/day was seen in maximum (48.5%) with episode interval >3 days -<7 days in 39.4% of patients.

RESULTS

The clinical data presented here is based on the 30 patients of trial work.

Effect of therapy on chief complaints

In Group A (Wilcoxon matched-pairs test) (n=10) (Table 2)

The present study shows 68.75% relief in Intensity of pain (*shirhshool*) which was highly significant statistically (p =0.002), while 69.56% & 66.66% relief in episodic interval and duration of headache respectively was observed which was also highly significant statistically (p =0.002). The study also shows 68.86% relief in nausea which was

significant statistically (p = 0.0156) and 68.75% relief in vomiting which was also significant statistically (p =0.0313), 69.23% of improvement in both photophobia and phonophobia was observed which was statistically significant (p = 0.156) and highly significant (p= 0.078) respectively, whereas 71.42 relief was seen in both the symptom of visual disturbance and vertigo which was also non significant statistically (p= 0.125, p = 0.0625 respectively).

In Group B (Wilcoxon matched-pairs test) (n=10) (Table 3)

The present study shows 37.93% relief in intensity of pain (shirahshoola) which was highly significant statistically (p = 0.0039) and 41.1% relief in episodic interval which was significant statistically (p=0.0156), while 48% relief in duration of headache which was also significant statistically (p = 0.0156). The study also shows 41.66% relief in nausea & 33.33% relief in vomiting which were non significant statistically (p=0.0625) and significant statistically (p = 0.0313) respectively. 46.15% improvement in photophobia and 50% in phonophobia both were statically significant (p=0.0156) where as 45.45 % & 50% relief was observed in the symptom of visual disturbance & vertigo which were found non significant statistically (p=0.0625 & 0.125 respectively).

In Group C (Wilcoxon matched-pairs test) (n=10) (Table 4)

The present study shows 75.86% relief in intensity of pain (shirahshoola) which was highly significant statistically (p = 0.002) and 45% relief in episodic interval which was also highly significant statistically (p=0.0078), while 76% relief in duration of headache which was also highly significant statistically (p = 0.002). The study also shows 81.81% relief in nausea which was significant statistically (p = 0.0156) and 75% relief in vomiting which was highly significant statistically (p =0.0078), 75% improvement in photophobia and 80% in phonophobia which were statically significant (p=0.0156) and highly significant statistically (p=0.0039) respectively where as 80% & 75% relief was observed in the symptom of visual disterbence & vertigo which were found non significant statistically (p=0.0625).

Table 2: Effect of Kumkumadi ghrita Nasya in 10 patients of Migraine in group A

Symptoms	Mean Value		% relief	SD	SE ±	р	Remarks	
	BT	AT	D					
Intensity of pain	3.20	1.0	2.20	68.75%	0.78	0.24	0.002	HS
Episodic interval	2.3	0.7	1.6	69.56%	0.51	0.16	0.002	HS
Duration of Headeche	2.4	0.8	1.6	66.66%	0.51	0.16	0.002	HS
Nausea	2.28	0.71	1.57	68.86%	0.53	0.20	0.0156	S
Vomiting	1.6	0.5	1.1	68.75%	0.87	0.27	0.0313	S
Photophobia	1.9	0.6	1.3	69.23%	0.48	0.18	0.0156	S
Phonophobia	1.62	0.5	1.13	69.23%	0.35	0.13	0.0078	HS
Visual disturbance	1.75	0.50	1.25	71.42%	0.50	0.25	0.1250	NS
Vertigo	1.40	0.4	1.0	71.42%	0.44	0.20	0.0625	NS

Table 3: Effect of Kumkumadi ghrita Nasya in 10 patients of Migraine in group B

Symptoms	Mean Value		% relief	SD	SE ±	р	Remarks	
	BT	AT	D					
Intensity of pain	2.9	1.7	1.1	37.93%	0.56	0.17	0.0313	S
Episodic interval	1.7	1	0.7	41.17%	0.48	0.15	0.0156	S
Duration of Headache	2.5	1.3	1.2	48%	0.91	0.29	0.0156	S
Nausea	1.71	1	0.71	41.66%	0.48	0.18	0.0625	NS
Vomiting	1.5	1.0	0.5	33.33%	0.54	0.18	0.0313	S
Photophobia	1.62	0.9	0.8	46.15%	0.46	0.14	0.0156	S
Phonophobia	1.55	0.77	0.77	50%	0.44	0.16	0.0156	S
Visual disturbance	2.2	1.2	1.0	45.45%	0.44	0.20	0.0625	NS
Vertigo	1.6	0.8	0.8	50%	0.44	0.20	0.1250	NS

Table 4: Effect of Kumkumadi ghrita Nasya in 10 patients of Migraine in group C

Symptoms	Mean Value		% relief	SD	SE ±	р	Remarks	
	BT	AT	D					
Intensity of pain	2.9	0.50	2.2	75.86%	0.78	0.24	0.0020	HS
Episodic interval	2.0	1.1	0.9	45.0%	0.56	0.17	0.0078	HS
Duration of Headache	2.5	0.6	1.9	76%	0.73	0.23	0.0020	HS
Nausea	1.57	0.28	1.29	81.81%	0.48	0.18	0.0156	S
Vomiting	1.5	0.375	1.125	75%	0.64	0.22	0.0078	HS
Photophobia	1.71	0.42	1.28	75%	0.48	0.18	0.0156	S
Phonophobia	1.66	0.33	1.33	80%	0.5	0.16	0.0039	HS
Visual disturbance	2	0.4	1.6	80%	0.54	0.24	0.0625	NS
Vertigo	1.6	0.4	1.2	75%	0.44	0.2	0.0625	NS

HS: Highly Significant, S: Significant, NS: Non-Significant

Overall Effect of Therapy

The overall effect of therapy showed that in Group A, complete and moderate improvement was seen in 20% in each, 50% patients had marked improvement and 10% patients had mild improvement. In Group B, 20% patients had marked improvement, 50% patients had moderate improvement and 30% patients had mild improvement while in Group C, complete and moderate improvement was seen in 30% in each and 40% patients had marked improvement.

DISCUSSION

Regarding the response of the treatment on symptoms in the patients of Group A, treated with Nasya therapy, it was found that there was highly significant response in symptoms of Intensity of pain, interval, Duration of headache Episodic which may be because the drug Phonophobia administered through nose reaches the Shringataka Marma and spreads throughout Murdha, Netra, Shrotra and Kantha through their Siras (Shringataka Marma is a Sira Marma and formed by the Siras of Nasa, Akshi, Jivha and Shrotra). Thereby eliminates the morbid Dosha of Urdhwa Jatru and expels them from the Uttamanga and nutritive part of nasya is nourishes the shirah (head) [9] Tikta rasa and usna guna of Kumkuma(Crocus sativus) [10] have Sroto-shodhaka property, which helps in expelling the morbid doshas. Tikta rasa also shows its Shoshana Karma, more particularly Kleda Shoshana and Shlesma Prashamana properties [11] and significant response in symptoms of Nausea, Vomiting and Photophobia was found it may be because of Sheeta Virya present in Ghrita [12] and Sharkara [13] pacify the Pitta dosha which is responsible for nausea, vomiting & Photophobia.

In Group-B patients, treated with Shirodhara therapy, highly significant changes were found in non of the symptoms, only significant changes were found in Intensity of pain, Episodic interval, Duration of Vomiting, Photophobia, Phonophobia Headache, bscause of the continuos pouring of medicated milk in a relaxed and comfortable position has an effect, which can be near compared to the cardling of a mother to her child. This acts as an sedative and soothing effect to the brain and induces sleep. Also the medicated milk enters into the circulation acts as vatahar effects and imbalance of Prana, Udana and Vyana Vayu, Sadhaka Pitta and Tarpaka Kapha can produce stress and tension. Shirodhara re-establishes the functional integrity between these three subtypes of Dosha through its mechanical effect and dashmoola [14] has potent Tridoshaghna property specially Vat-kapha Shamaka property, which is the main culprit in Ardhavbhedaka. Thus over all it pacifies Vata, Vatakapha Dosha or Tridosha and Ardhavbhedaka being a Vata Pradhana Vyadhi (Vata-kapha(Ch.) Ttridoshaja (Su.)), there is every possibility of Samprapti Vighatana of Ardhavbhedaka Roga.

In Group C patients, treated with Propranolol and Diclofenac (Standard control group), statistically highly significant changes were found in maximum 5 symptoms out of 10 symptoms i.e. Intensity of pain,

Episodic interval, Duration of headache, Vomiting and Phonophobia and significant changes were found in Nausea, Photophobia. Diclofenac is directly indicated in the treatment of acute migraines and Propranolol(nonselective beta bloker) is indicated in Migraine prophylaxis.

CONCLUSION

It is concluded that *Kumkumadi Ghrita Nasya* was more effective in alleviating symptoms of *Ardhavabhedaka* (Migraine) than *Dashmool shrita ksheer Shirodhara*. Allopathic drugs were slightly more effective than *Kumkumadi Ghrita Nasya* except relief in episodic interval, Allopathic drugs were lesser effective than *Nasya*. Research showed long term sustained relief as evident from 30 Days follow up study. Prolongation of therapy may provide better results. No adverse effect of the trial drug was observed during the study.

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