

## **A COMPARATIVE CLINICAL STUDY TO OBSERVE THE EFFICACY OF SHARKARA MISRITHA KSHEERA NASYA & SHARKARODAKA NASYA IN THE MANAGEMENT OF ARDHAVABHEDAKA (MIGRAINE)**

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### **ABSTRACT**

Shirah is considered as the 'Uttamanga' as it is the abode for Jnanendriyas and site of Prana. Shirashoola is one of the common manifestations of Shirah, which is experienced by almost everyone in their lifetime at some time or the other. Ardhavabhedaka is the disease producing piercing type of pain in the Ardha Shiras. The symptoms are very much similar in line with the Migraine headache. Nasya Karma eliminates the vitiated doshas from Shirah and rejuvenates the body, mind and alleviate pain. One of the modalities among Nasya Karma is Brihmana Nasya, indicated in Ardhavabhedaka, explicitly decreases the severity and provides nourishment. The objectives of the present study were undertaken to evaluate the efficacy of Sharkara Misritha Ksheera Nasya and Sharkarodaka Nasya in Ardhavabhedaka before and after treatment in the group and between the groups.40 patients were randomly assigned into 2 groups. Sharkara Misritha Ksheera Nasya was administered to Group A and Sharkarodaka Nasya for Group B. The dosage of Nasya was 16 bindus in both groups. In both groups subjective and objective parameters were assessed. Observations were made on the 1<sup>st</sup> day (before treatment) and 7<sup>th</sup>day (after treatment). Follow up: will be done on 14<sup>th</sup> & 21<sup>st</sup> day and results were tabulated and statistically analyzed. Significant results were obtained in relieving the symptoms of Ardhavabhedaka by the end of treatment period in both groups. Overall assessment showed marked, moderate and mild improvement in the patients. From the clinical study, it was evident that all patients responded to the treatment. Comparative analysis of the overall effect of the treatments in both the groups showed that the treatment is statistically significant in Group A when compared to Group B.

**Keywords**-Ardhavabhedaka, Migraine headache,Sharkara Misritha Ksheera Nasya & Sharkarodaka Nasva.

### **INTRODUCTION**

Ardhavabhedaka is one among the Shirorogas. According to Susrutacharya Shirashoola which is

present in the right or left halves of head, which is splitting, pricking or churning in nature and appearing in

intervals of either 15 or 10 days and without any known cause is called as Ardhavabhedaka<sup>1</sup>. Acharya Vagbhata says when it is greatly aggravated it destroys either the vision or hearing<sup>2</sup>. Ardhavabhedaka can be correlated with migraine.

The cardinal features of Ardhavabhedaka are piercing type of pain in the ArdhaShira affecting particularly neck, eye brows, temporal region, ear, eye and forehead suddenly after a fortnight or ten days. Based on the Nidanas and Lakshanas of Ardhavabhedaka.

Panchakarma therapy aims at cleansing the body from the root level from the vitiated doshas. Nasya is one of the Panchakarma procedures. The drug or medicated liquids like SnehaSwarasa etc. administered through the nostril is known as Nasya. This procedure purges and rejuvenates the tissue and organs of the head and neck.

Though many treatments are explained, Nasya plays an important role as a main line of treatment for Shirorogas. Nasya is one of the important procedures of classical Panchakarma therapy as Nasya is the gateway to the Shirah which is the Uttamanga and Nasya plays an important role as a main line of treatment in Urdwajatrugata Vikaras. Vagbhata opines that by proper Nasyakarma one can attain Ghanonnata Skanda and Griva. So no doubt that Ardhavabhedaka being one of the Urdvajatrugata Vikara can be easily dominated.

So this study is carried out to explore newer, efficacious procedures in the management of Ardhavabhedaka w.s.r to Migraine. Our Classics have given prime importance to Nasya Karma as an ideal therapy in treating Ardhavabhedaka. The therapy cleanses and opens the channels of head, thereby improving the process of oxygenation (prana), which has a direct influence on the functioning of brain. Therefore, this study is intended to evaluate the efficacy of Sharkara Misritha Ksheera Nasya and Sharkarodaka Nasya in Ardhavabhedaka<sup>3</sup>

### **Aims and Objectives**

1. To evaluate the efficacy of Sharkara Misritha Ksheera Nasya in the management of Ardhavabhedaka.
2. To evaluate the efficacy of Sharkarodaka Nasya in the management of Ardhavabhedaka.
3. To compare the efficacy of Sharkara Misritha Ksheera Nasya and Sharkarodaka Nasya in the management of Ardhavabhedaka<sup>3</sup>

### **MATERIAL AND METHODS**

#### **Source of Data:**

#### **Literary Source:**

All the Ayurvedic Samhitas, modern literatures, contemporary textbooks, medical journals and websites about disease and drug were reviewed and documented for the intended study.

#### **Sample Source:**

Diagnosed case of Ardhavabhedaka were selected from the OPD and IPD of Department of Panchakarma, Shri Shivayogeeshwar Rural Ayurvedic

Medical College and Hospital and Medical camps.

**Pharmaceutical Source:**

The formulation intended for the research work was prepared from the pharmacy of Shri Shivayogeeswar Rural Ayurvedic Medical College, and raw drugs from available sources.

**METHOD OF COLLECTION OF DATA**

**Study design** – Randomised comparative clinical study

**Sample size** – A minimum of 40 patients fulfilling the diagnostic and inclusion criteria of Ardhavabhedaka (Migraine), of either sex were selected randomly.

**Diagnostic criteria –**

- I. Signs and Symptoms of Ardhavabhedaka.
- II. Diagnostic Criteria for Migraine.
  - a. Repeated attacks of headache lasting 4-72 hrs in patients with following features:
    - Normal Physical Examination
    - No other reasonable cause for the headache
  - b. At least two of
    - Unilateral pain
    - Throbbing type of pain
    - Aggravation by movement
    - Moderate or severe intensity
- III. Plus at least one of
  - Nausea / Vomiting
  - Photophobia and Phonophobia.

**Inclusion Criteria –**

- Patients between the age group of 16 – 50 years of either sex.
- Patients who were fit for Nasya karma.

- Patients who were fulfilling the diagnostic criteria's will be selected randomly.

**Exclusion Criteria –**

- Age below 16 and above 50 years.
- Other types of Shirashoola such as Anantavata, Suryavartha, Pittaja Shirashoola, Kaphaja Shirashoola, Dustapratishyaya, Peenasa etc., were excluded.
- Referred pain in one half of the head due to disorders of eye, ear, nose, throat, teeth etc., were excluded.
- Patients with complicated Migraine, Ophthalmic Migraine, Hemiplegic Migraine, Retinal Migraine, Basilar artery Migraine etc., were excluded.
- Any other systemic disorders which interfere with the course of the treatment were excluded.

**PROCEDURE**

The whole procedure of Nasya is divided into 3 steps, Purva, Pradhana, and Paschat Karma. Patients were educated about the whole course of treatment. In Purva Karma Murchita Tila Taila Abhyanga was done to the Jatrurdhwa Pradesha of the patients followed by Sthanika Bashpa Swedana done by keeping the eyes protected. In Pradhana Karma the patient was made to lie in supine position with head slightly bend and legs raised. The procedure of Nasya Karma was carried out. 16 drops (6ml) of Sharkara Misritha Ksheera in one group and Sharkarodaka in other group were administered in each nostril keeping other closed. Patients were advised to inspire the medicine slowly. This procedure continued for 7



consecutive days. (In Paschat Karma The Jatrurdwa Pradesha was given gentle massage, and the patient was asked to spit the medicine along with doshas which had reached the throat. Haridra Varti for Dhumapana and Sukhoshnajala for Kavala had been done in order to remove the adhered kapha.

**ASSESSMENT CRITERIA**

**Subjective Parameters**

- Severity of Pain
- Duration of Pain
- Frequency of Pain
- Nausea
- Vomiting

**Objective Parameters**

Migraine Disability Assessment Score (MIDAS) Questionnaire.

**OBSERVATIONS AND RESULTS**

**RESULTS**

Analysis of treatment effects of Sharkara Misritha Ksheera Nasya in Group-A and Sharkarodaka Nasya in Group –B.

**EFFECT ON SEVERITY OF PAIN**

**Effects of Sharkara Misritha Ksheera Nasya (Group-A)**

**Table No.01. Effect of Group-A on Severity of Pain.**

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	Wilcoxon Z Value	p value
	BT			BT-AT					
Severity of Pain	3.20	AT	1.95	1.25	39.06	1.020	0.234	3.51	<0.05
		AF	1.60	1.60	50.00	1.095	0.251	3.62	<0.05

**Effect on Severity of Pain**

In this work of 20 patients studied in Ardhavabhedaka with Group-A Severity of Pain revealed are given in detail in Table No.01. Statistical analysis showed that the mean score which was 3.20 before the treatment was reduced to 1.95 after the treatment and after follow up it became 1.60 with 50% improvement and there is statistically significance. (P<0.05

Assessment of the condition were done on a detailed case proforma adopting standard scoring methods of subjective and objective parameters.

**OBSERVATION PERIOD**

- Initially on the first day before treatment.
- On the 7<sup>th</sup> day after treatment.

**Follow up** – In both groups follow up was done on 14<sup>th</sup> day, and 21<sup>th</sup> day.

**Statistical Method**

Average was found using mean and standard deviation. Pre-test and post-test data was compared using Wilcoxon test. Comparison of two groups was done using Mann Whitney U test.

**Effect of Sharkarodakanasya (Group-B)**

**Table.No.02. Effect of Group-B on Severity of Pain**

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	Wilcoxon Z Value	p value
	BT			BT-AT					
Severity of Pain	3.15	AT	2.15	1.00	31.75	0.725	0.166	3.51	<0.05
		AF	1.65	1.50	47.62	0.889	0.204	3.92	<0.05

**Effect on Severity of Pain**

In this work of 20 patients studied in Ardhavabhedaka with Group-B on Severity of Pain revealed are given in detail in Table No.02. Statistical analysis showed that the mean score which was 3.15 before the treatment was reduced to 2.15 after the treatment and after follow up it became 1.65 with 47.62% improvement and there is statistically significance. (P<0.05)

**EFFECT ON FREQUENCY OF PAIN**

**Table.No.03 Effect of Group-A**

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	Wilcoxon Z Value	p value
	BT			BT-AT					
Frequency of Pain	2.80	AT	1.60	1.20	42.86	1.196	0.274	3.18	<0.05
		AF	1.35	1.45	51.79	1.099	0.252	3.18	<0.05

**Effect on Frequency of Pain**

Magnitude of **Frequency of Pain** in patients of Ardhavabhedaka before and after the treatment was assessed and analyzed statistically. In patients registered in GROUP-A group showed significant improvement (P<0.05). The mean score which was 2.80 before treatment reduced to 1.60 after the treatment and after follow up it become 1.35 with 51.79% improvements. Further the particulars are detailed in table no 03.

**Effect of Sharkarodaka Nasya on Frequency of Pain**

**Table .No. 04 Effect of Group-B**

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	Wilcoxon Z Value	p value
	BT			BT-AT					
Frequency of Pain	2.55	AT	1.65	0.90	35.29	0.553	0.127	3.51	<0.05
		AF	1.35	1.20	47.06	0.523	0.120	3.82	<0.05

**Effect on Frequency of Pain**

Magnitude of **Frequency of Pain** in patients of Ardhavabhedaka before and after the treatment was assessed and analyzed statistically. In patients registered in

GROUP-B group showed statistically significant improvement ( $P < 0.05$ ). The mean score which was 2.55 before treatment reduced to 1.65 after the treatment and after follow up it become 1.35 with 47.06% improvements. Further the particulars are detailed in table no 04.

### EFFECT ON NAUSEA

#### Effect of Sharkara Misritha Ksheera Nasya on Nausea

**Table No. 05. Effect of Group-A**

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	Wilcoxon Z Value	p value
	BT			BT-AT					
Nausea	0.80	AT	0.65	0.15	18.75	0.366	0.084	2.00	>0.05
		AF	0.40	0.40	50.00	0.503	0.115	2.52	<0.05

Magnitude of **Nausea** in patients of Ardhavabhedaka before and after the treatment was assessed and analyzed statistically. In patients registered in GROUP-A group showed significant improvement ( $P < 0.05$ ). The mean score which was 0.80 before treatment reduced to 0.65 after the treatment and after follow up it become 0.40 with 50% improvement. Further the particulars are detailed in table no 05.

#### Effect of Sharkarodaka Nasya on Nausea

**Table No. 06. Effect of Group-B**

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	Wilcoxon Z Value	p value
	BT			BT-AT					
Nausea	0.70	AT	0.25	0.45	64.29	0.510	0.117	2.66	<0.05
		AF	0.35	0.35	50.00	0.489	0.112	2.36	<0.05

Magnitude of **Nausea** in patients of Ardhavabhedaka before and after the treatment was assessed and analyzed statistically. In patients registered in GROUP-B group showed statistically significant improvement ( $P < 0.05$ ). The mean score which was 0.70 before treatment reduced to 0.25 after the treatment and after follow up it become 0.35 with 50% improvement. Further the particulars are detailed in table no 06.

### EFFECT ON VOMITING

#### Effect of Sharkara Misritha Ksheera Nasya on Vomiting

**Table No.07. Effect of Group-A**

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	Wilcoxon Z Value	p value
	BT			BT-AT					
Vomiting	0.40	AT	0.30	0.10	25.00	0.308	0.071	2.00	>0.05
		AF	0.10	0.30	75.00	0.470	0.108	2.20	<0.05



Magnitude of **Vomiting** in patients of Ardhavabhedaka before and after the treatment was assessed and analyzed statistically. In patients registered in GROUP-A group showed significant improvement ( $P < 0.05$ ). The mean score which was 0.40 before treatment reduced to 0.30 after the treatment and after follow up it become 0.10 with 75% improvement. Further the particulars are detailed in table no.07

**Effect of Sharkarodaka Nasya on Vomiting**

**Table No.08. Effect of Group-B**

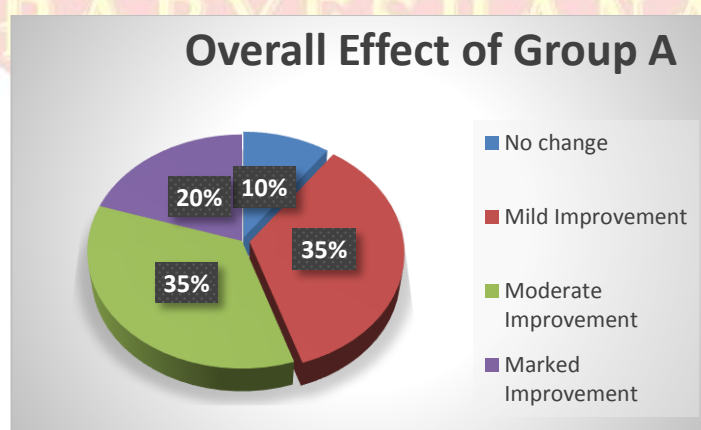
SYMPTOM	Mean score				%	S.D (±)	S.E (±)	Wilcoxon Z Value	p value
	BT			BT-AT					
Vomiting	0.50	AT	0.25	0.25	50.00	0.444	0.102	2.02	<0.05
		AF	0.35	0.15	30.00	0.366	0.084	2.02	<0.05

Magnitude of **Vomiting** in patients of **Ardhavabhedaka** before and after the treatment was assessed and analyzed statistically. In patients registered in GROUP-B group showed statistically significant improvement ( $P < 0.05$ ). The mean score which was 0.50 before treatment reduced to 0.25 after the treatment and after follow up it become 0.35 with 30% improvement. Further the particulars are detailed in table no 08.

**ASSESSMENT OF TOTAL EFFECT OF THERAPY**

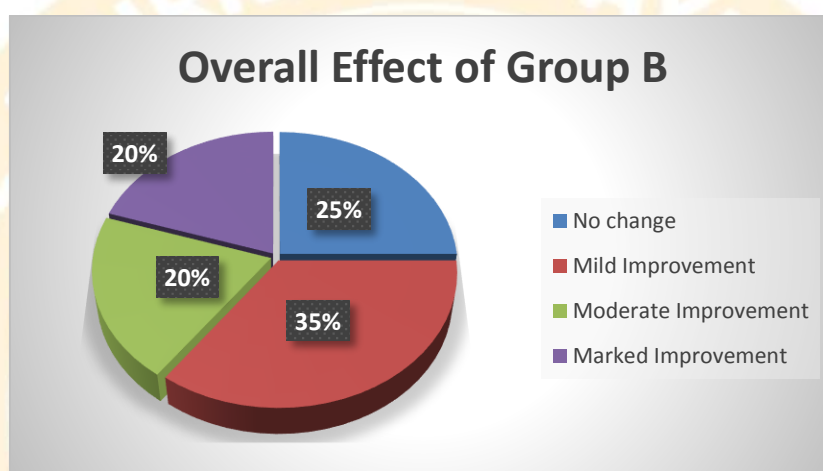
**Effect of Sharkara Misritha Ksheera Nasya in Group A**

EFFECT OF TREATMENT IN GROUP - A		
Class	Grading	No of patients
0-25%	No change	2
26%-50%	Mild Improvement	7
51% - 75%	Moderate Improvement	7
76% - 100%	Marked Improvement	4



**Result on Group- A**  
**ASSESSMENT OF TOTAL EFFECT OF THERAPY**  
**Effects of Sharkarodaka Nasya in (Group-B)**

<b>EFFECT OF TREATMENT IN GROUP - B</b>		
<b>Class</b>	<b>Grading</b>	<b>No of patients</b>
0-25%	No change	5
26%-50%	Mild Improvement	7
51% - 75%	Moderate Improvement	4
76% - 100%	Marked Improvement	4



**Result on Group -B**

**COMPARATIVE RESULTS**

The Mann Whitney U test was done to know significance difference between trial and standard groups by comparing the mean ranks of the score difference.

**Comparative results of Group-A and Group-B**

<b>Signs and Symptoms</b>	<b>Group A (Mean Score)</b>	<b>Group B (Mean Score)</b>	<b>Z-Value of Mann Whitney</b>	<b>U Value</b>	<b>P Value</b>
Severity of Pain	2.25	2.32	0.31	188.00	>0.05
Duration of Pain	1.70	1.97	1.33	150.00	>0.05
Frequency of Pain	1.92	1.85	0.09	196.00	>0.05
Nausea	0.62	0.43	1.51	143.50	>0.05
Vomiting	0.27	0.37	0.68	174.00	>0.05
Midas Grade	2.13	2.38	1.13	157.50	>0.05

**Severity of Pain:** Mann Whitney test indicated that there was no statistically significance difference between the severity of pain score difference of the Sharkara Misritha Ksheera Nasya group and Sharkarodaka Nasya group( Z = 0.31 , P > 0.05)

**Duration of Pain:** Mann Whitney test indicated that there was no statistically



significance difference between the duration of pain score difference of the Sharkara Misritha Ksheera Nasya group and Sharkarodaka Nasya group ( Z = 1.33, P > 0.05)

**Frequency of Pain:** Mann Whitney test indicated that there was no statistically significance difference between the frequency of pain score difference of the Sharkara Misritha Ksheera Nasya group and Sharkarodaka Nasya group ( Z = 0.09, P > 0.05)

**Nausea:** Mann Whitney test indicated that there was no statistically

Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with Mann Whitney test. The Statistical analysis shows that there is no significant result between the groups. The test shows that the treatment is statistically significant in both the Groups. Group A overall result is 53.98% and Group B overall result is 47.54%.

### **DISCUSSION**

Nasya has given a prime importance among all Chikitsas for Ardhavabhedaka. So here the present

Group A	Group B	Mean Difference	SE (±)	Z-Value of Mann Whitney	U Value	P value
53.98	47.54	6.44	7.74	1.06	160.00	>0.05

significance difference between the nausea score difference of the Sharkara Misritha Ksheera Nasya group and Sharkarodaka Nasya group ( Z = 1.51, P >0.05)

**Vomiting:** Mann Whitney test indicated that there was statistically no significance difference between the vomiting score difference of the Sharkara Misritha Ksheera Nasya group and Sharkarodaka Nasya ( Z = 0.68, P >0.05)

**Midas Grade:** Mann Whitney test indicated that there was no statistically significance difference between the Midas grade score difference of the Sharkara Misritha Ksheera Nasya group and Sharkarodaka Nasya group ( Z = 1.13, P > 0.05)

### **Overall Comparative results of Group A and Group B**

study is carried out to prove the comparative efficacy of SharkaraMisrithaKsheeraNasya and SharkarodakaNasya in the management of Ardhavabhedaka.

All Acharyas invariably accept the involvement of Vatadosha in the Samprapti of Ardhavabhedaka. This is justified by the cardinal feature, pain. Charaka has opined that dosha involved are Vata and Kapha, Susrutha as Tridoshaja; Dalhana as VataPittaja and Vagbhata attributes Vatadosha.

The invariable involvement of Rakta as a dushya in Shiroroga is mentioned by Charaka. He has included Shiro-Ruk in ShonitajaRoga. Moreover, it has been clearly stated by Charaka that the vitiated doshas after reaching Shirah vitiates Rakta in that Sthana to produce Shiroroga. Thus Rakta is the main Dushya in Ardhavabhedaka. As

Raktadhatu is involved, the Srotas which carries the dhatu is also vitiated. The Stana involved is Dakshina or VamaArdhashira. So Pitta is also a major dosha involved as Rakta is Dushita. Thus it can be considered as Tridoshaja.

The role of Vata probably represents a spreading front of excitation followed by depression (kapha) of activity of cortical cells. The headache is caused by an in coordinated circulatory response resulting in a sequence of vasoconstriction and vasodilatation of extra cranial vessels and a non-specific effect of intracranial metabolic disturbance. This explains the role of Rakta along with Vata in the manifestation of Ardhavabhedaka(Migraine)

Present study reveals that 65% were males and 35% were females out of 40 patients. Hence this re-establish the fact that incidence of migraine is more in males than in females which can be due to more strenuous work, Exertion and outfield work in males.

**Mode Of Action Of Sharkara Misritha Ksheera Nasya**-Ingredients -Sharkara, Go Ksheera; Sharkara is having Madhura Rasa ,Guna- Guru Sheeta, Veerya-Sita, Vipaka- Madhura, and Vatapitta Hara property. Go Ksheera is having Madhura Rasa, Guna- Snigdha, Veerya-Sita, Vipaka- Madhura and Tridoshahara property. This property of Sharkara and Go ksheera helps in relieving the symptoms of Ardhavabhedaka.

It acts as Brimhana, Balya, Jivaniya, Rasayana, Dahaprasamana. The

pharmacological actions of Sharkara Misritha Ksheera proves that it has CNS depressants, anti-inflammatory, analgesic, anti-emetic, antioxidant, anti-pyretic, antibacterial, hypotensive properties and Goksheera which supports the production of Serotonin. Due to these properties the medicine prevents recurrent pain and reduces inflammatory process. Thus Sharkara Misritha Ksheera helps in alleviation of cardinal symptoms of Ardhavabhedaka (migraine).

#### **Mode of Action Of Sharkarodaka Nasya**

Sharkara is having Madhura Rasa, Guna- Guru, Sheeta, Veerya-Sita, Vipaka- Madhura, and Vatapitta Hara property. Udaka- It is Jeevana, Tarpana, Hrudya, Hlaadana, Buddhiprabhodana, Tanu, without clear manifestation of any Rasa, Mrishta, Sita in Veerya, Laghu and helps in relieving the symptoms of Ardhavabhedaka.

It is anti-inflammatory, analgesic, hypotensive, anti-pyretic properties. Due to these properties the medicine prevents recurrent infections and reduces inflammatory process. It is also having the ability to alleviate the irritation particularly of mucous membrane of the nasal cavities.

#### **CONCLUSION**

From the above study it can be concluded that there is significant effect of both Sharkara Misritha Ksheera Nasya and Sharkarodaka Nasya in Ardhavabhedaka.. That is to say both the treatments may be accepted in treating patients with

Ardhavabhedaka..to reduce both signs and symptoms successfully.

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