A Randomized Clinical Trial on the Efficacy of *Siravedhana* and *Kumkumadi Ghrita Nasya* along with *Chandrakanta Rasa* Orally in *Ardhavabhedaka* w. s. r. to Migraine

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ABSTRACT:

Background: Migraine is a form of primary headache, manifested by the recurrent attacks of pulsating headache, mostly associated with nausea, vomiting, photophobia and phonophobia with or without an aura. It is the second most common cause of headache disorder affecting about 12%. In this females are most prone 15% and males are affecting about 6%. On the basis of the symptoms of *Ardhavabhedaka,* it can be correlated with Migraine.

Aim and objectives: To conduct a randomized clinical trial on *Kumkumadi Ghrita Nasya* and *Siravedhana* along with *Chandrakanta Rasa* in the management of *Ardhavbhedaka* w.s.r. to Migraine.

Material and method: Patients attending the O.P.D. and I.P.D. of N.I.A. having the signs and symptoms of *Ardhavbhedaka* (Migraine) were screened and the diagnosis was achieved on the basis of careful history taking and clinical examination. 30 clinically diagnosed patients of *Ardhavbhedaka* were registered for trial and they were divided randomly in two groups.

Result: Clinical data shows that in Group A effect of therapy on *Ardhavbhedhaka* is 74.91% and in Group B it is 63.93%; both the results are statistically highly significant at the level of $p < 0.001$.

Conclusion: It can be concluded that clinically *Siravedha, Kumkumadi Ghrita Nasya* and *Chandrakanta Rasa* combine work better to manage the *Ardhavabhedaka* (Migraine).

Key words: *Ardhavabhedaka*, Migraine, *Siravedha, Nasya*

INTRODUCTION

Our ancient sages defined important organs and emphasized the necessity of three essential organs, as the body's survival is dependent on them. *Shirah* is one of them, including both life and sense abilities.[1] A lot of description is given in Ayurveda to preserve wellbeing and control *Shirah's* ill state. Our ancient sages defined important organs and emphasized the necessity of three essential organs, as the body's survival is dependent on them. *Shirah* is one of them, including both life and sense abilities.[2] It is mentioned as *Tridoshaja* by *Sushruta*,[3] *Vata/Vata-kaphaj* by *Acharya Charaka*[4] and *Vataja* by *Vagbhatta*[5]

Different opinions are available regarding *Shiro-roga.* Among them especially *Charaka* and *Sushruta* have considered *Shiro-roga*, where *Shoola* is the main symptom. They have not taken *Kapalgata Vyadhi* like *Khalitya, Palitya* in consideration as *Shiro-roga*. All the *Acharyas* have mentioned different numbers of *Shiro-roga* but all of they have mentioned *Ardhavabhedaka* as one of them. In *Ardhavabhedaka, Ardhaparshwa Shirovedana, Pakshahat - Dashahat - Aksmat Vedna, Bheda-Todavat Vedana and Bhrama* are the common symptoms.[6] It is mentioned as *Tridoshaja* by *Acharya* Sushruta,[7] *Vata/Vata-kaphaj* by *Acharya Charaka*[8] and *Vataja* by *Acharya Vagbhatta*[9]

On the basis of the symptoms of *Ardhavabhedaka,* it can be correlated with Migraine. Migraine is a prevalent neurovascular sickness with a major influence on quality of life, according to the International Headache Society (I.H.S.). It is the second most prevalent cause of headache, and it has become a hard problem in the current scenario due to changes in lifestyle. It affects three times as many women as it does men. More than two-thirds of Migraine sufferers have never sought medical advice or have stopped doing so. It goes undiagnosed and untreated. The precise mechanism of migraine is yet unknown. As a result, the World Health Organization lists migraine as one of the world's most debilitating medical conditions. Migraine is increasingly considered a chronic illness rather than just a headache. The term "migraine" refers to a vascular spasm condition affecting the cranial blood vessels. Increased sensitivity to light and sound (Son photophobia), nausea, auras, difficulty speaking, and strong pain on one side of the head are all symptoms of a migraine episode.

It is mainly divided into two subtypes- Migraine without aura (common migraine) and Migraine accompanied by aura (classical migraine). Classic migraines account for 25% of migraine cases, and there is frequently a familial history of the disorder. Visual disturbances such as fortification, scotomata (blind spots within the field of vision), or visual field abnormalities may occur before the beginning of headache in classical migraine. Unusual tastes and aromas may also be present in the aura. The most common type of migraine is common migraine, which accounts for 75% of all instances.[10] As a result, there is a need to investigate an effective Migraine management strategy.

In *Ayurveda* headaches are known by *Shiroroga, Shirotapa, Shirahshula* according to *Sushruta Aacharya.* There are 11 type of S*hiroroga* according to *Acharya*

Sushruta and *Bhavprakasha* viz *Vattaja, Pittaja, Kaphaja, Tridoshaja, Raktaja, Krimijakshayaja, Sankhaka, Suryavritta, Anantvatta* and *Ardhavabhedaka* . *Ardhavabhedaka* seems to be most similar with Migraine headache. *Ardha* refers to something affecting only one side of the head and *Bhedavat* indicates that is splitting, pricking and piercing in nature. Therefore, *Ardhavbhedaka* means splitting, pricking and piercing pain affecting the half side of head at every fortnight or 10 days due to the vitiated *Doshas. Acharya Vagbhatta* has mentioned *Ardhaavbhedaka* under *Vataja Shiroroga*, when greatly aggravated it destroys the eyes (sight) and the ears (hearing). Western drug treatment options have multiple side effects and are largely unsuccessful in the managing Migraine headache.

In India, 15-20% of people suffer from migraine. The World Health Organization estimates the worldwide prevalence of current migraine to be 10% and the lifetime prevalence to be 14%. In the United States, more than 30 million people suffer from 1 or more migraine headaches per year. This corresponds to approximately 18% of females and 6% of males. Approximately 3000 migraine attacks per million persons worldwide occur every day. Migraine also has a strong genetic component.

AIM AND OBJECTIVES

Aim- To conduct a randomized clinical trial on *Kumkumadi Ghrita Nasya* and *Siravedhana* along with *Chandrakanta Rasa* in the management of *Ardhavbhedaka* w.s.r. to Migraine.

Objectives- To study and establish a conceptual correlation between *Ardhavbhedaka* and Migraine. To evaluate and compare the efficacy of trial drugs and procedures in *Ardhavbhedaka* (Migraine). To study the adverse effect of trial drugs or procedures if any.

MATERIAL AND METHOD

Source of data:

30 patients suffering from *Ardhavbhedaka* (Migraine) who fulfilled the inclusion criteria were selected and placed in two groups by simple randomization process from IPD & OPD of *Shalakya* Department of NIA, Jaipur (Raj.). Written consent of each patient was taken on prescribed proforma**.** The study was conducted under a strict protocol to prevent bias and to reduce the source of error in the study.

Criteria for selection of patients: Patients attending the O.P.D. and I.P.D. of N.I.A. having the signs and symptoms of *Ardhavbhedaka* (Migraine) were screened and the diagnosis was achieved on the basis of careful history taking and clinical examination.

a)   Inclusion Criteria

1. Patients willing to participate in this trial through written informed consent.
2. Patients between 16 to 60 years of age from either sex.
3. Patients presenting with symptoms of *Ardhavabhedaka,* described as per Ayurveda and modern science.

b)   Exclusion Criteria

1. Secondary headaches caused by meningitis, tumors, encephalitis, head and neck trauma, trigeminal neuralgia, cervical spondylitis, refractive errors, sinusitis and other disorders of cranium, neck, eyes, ears, nose, sinuses, teeth etc.
2. Patients with complicated Migraine like status migrainosus, hemiplegic migraine and having any chronic debilitating disease with other neurological pathology.
3. Pregnant and lactating women.
4. Patients suffering from any other major systemic disorders e.g. tuberculosis, cancer, heart disease etc.
5. Patients unfit for *Siravedhana* such as patients with hemorrhagic diseases (e.g. hemophilia), anemia, hypotension, severe allergic diathesis and on anticoagulant treatment.

Investigations

 Investigations will be carried out before and after the treatment as shown in Table no. 1

METHOD
Site/s of study: NIA Hospital, Jaipur.
Health condition / Problem studied: *Ardhavbhedaka* / Migraine.
Study Design: A Open labeled, parallel, Randomized, comparative clinical study.
Method of generating randomization sequence: Computer generated.
Method of allocation concealment: SNOSE (sequentially numbered opaque sealed envelope)
Blinding / masking: Open labelled.
Primary outcome/s: Decrease in intensity and recurrence of *Ardhavbhedaka*/Migraine**. Secondary outcomes–**

Changes in clinical features of *Ardhavbhedaka*/Migraine and improvement in vision.
Sample population: All headache patients were reported to *Shalakya Tantra* department OPD and IPD.

Phase of trial: 2nd
Target sample size: 15 patients in each group.
Duration of Study: For group A 21 days and for group B 14 days.
Ethical Clearance: Clinical study was started after getting clearance from Institutional Ethics Committee (No. IEC/ACA /2019/1-66 dated 28/05/2019) and study was also registered under CTRI (CTRI/2020/07/026557.)

Grouping:

30 clinically diagnosed patients of *Ardhavbhedaka* (Migraine) were registered fortrail and they were divided randomly in two group:
Group I: 15 patients of *Ardhavbhedaka* (Migraine) were administered with *Kumkumadi   Ghrita Nasya* and *Chandrakanta Rasa* orally.
Group II: 15 patients of *Ardhavbhedaka* (Migraine) were administered *Siravadhan* and *Chandrakanta Rasa* orally.

Doses and Duration of trial:

1.   *Kumkumadi Ghrita:* Dose – 8-10 drops
Mode of administration – Nasal route
Duration - *Marsha Nasya* for 7 days with 7 days gap in between two sittings
2.   *Chandrakanta Rasa:* Dose -1 tablet of 125mg twice a day with honey Mode ofAdministration –oral.
 Duration -21days

3.   *Siravedha*

Method – Patient has been given oleation and sudation before venesection for internal *Snehana* medicated Ghee like *Tikta Ghrita, Mahatikta Ghrita* were indicated. A light diet mainly liquid like *Yavagu* given to the patient. Patient was sit facing the sun on a seat with his legs flexed elbows put on knee joint and hands with close fists place on carotid region. *Siravedha* on right or left temporal area just above the eye brows preferably on affected side of head.

Duration – once a week for two sitting.

Follow up:
Followed up was done at regular intervals of 15 days for a

period of 45days afterthe completion of clinical trial.

Assessment Criteria

For assessment of the efficacy of the trial therapy, following parameters were adopted-

1. Subjective parameters: Migraine associated disability will be assessed by MIDAS (Migraine DisabilityAssessment) questionnaire, Intensity of pain - by Visual Analogue Scale (VAS), Duration of pain, Frequency of attack.

2. Associated symptoms- nausea, vomiting, photophobia, vertigo, tinnitus, aura, transient loss/ blurring of vision, phonophobia, nasal discharge, sleep disturbance, stiffness of neck.

Statistical analysis of the result

The results having P value less than <0.05 were considered as statistically significant inthis study.

Criteria for assessment of overall effect

Overall effect of the therapy was assessed in terms of complete improvement, marked improvement, and improvement unchanged by adopting the criteria shown in table 2

OBSERVATIONS

15 patients were registered in Group A & 15 in Group B and all the 30 patients completed thetreatment and none of the patients were dropout.

Maximum number of patients i.e. 40 % belong to age group 21-30 years, followed by 23.33 % patients belong to 41-50 years, 20 % belong to 31-40 years, 13 % belong to16-20 years and only 3.33 % of patients belonged to 51-60 years. 50 % of the patients were male and 50 % female.

It was found that 40% of patients were from student category, 26.66 % were from service man, 16.66% were businessman, 10% were from house work and lastly 3.33% patients were labors and 3.33 % were from others group.

Maximum number of patient's i.e 63.33 % had good appetite, 33.3 % of patients had moderateappetite and lastly 3.33% patient had poor appetite.

Most of the patients i.e 53.33 had irregular bowel habits, while 46 % ofpatients had regular bowel habits. Most of the patient's i.e 96.66 % had normal micturition and 3.33% had Polyuria.

Most of the patients i.e. 53.33 had no addiction, while 33.33% patient were addicted to alcohol,followed by 20 %

patients were addicted to smoking, followed by 16.66 % patients were addicted to tobacco and rest of the patients were addicted to other .

53% had *Vata- Pitta Prakriti*, followed by36.66% of patients had *Vata- Kapha Prakriti* and 10% had *Pitta- Kapha Prakriti*. 56.66 % had *Rajasika Prakriti*, followed by 43.33 % of patients had *Tamasika Prakriti* and none of the patients have *Satvika Prakriti*.

The data of *Nidana* reveals that *Aharaj nidana,* was found in *Adhyashana* 76.66% of case, *Atisheetaambupan* was found in 73% of patients, excess of*Amla- lavana sevana* in 70% of patients, *Vishamashan*a was found in 43.33 % of patients, *Madya sevana* was found in 33.33 % of patients. None of the patient was *Samashan*a & *Anashana.* Regarding *Viharaja Nidana*, *Ratrijagarana* was found as a maximum *Nidana i*n 86.66% of patients followed by *Dhup sevanain* in 50% of patients, *Vega sandharana* in 43.33 %, *Ayasa* in 36.66 % of patients and *Diwaswapna* in 6.66 % of patients. Regarding *Manasika Nidana Chinta* and *Krodha* were found to be a chief *Nidana* in 63.66 % patients, followed by S*hoka* in 20 % of patients and *Bhaya* in 13.33 %.

Sunlight was major trigger factor responsible for *Ardhavabhedhaka* (100%) followed by Lack of sleep (83.3%), noise pollution (80%), physical exertion (70%), hunger (60%), hyperacidity (53.33%), emotional stress (40%), menstrual cycle (30%) fast food/spicy food/ chocolates/ fermented eatable (16.66%) and only Cold – cold breeze / AC/ colddrinks/ ice creams (6.66%). The major alleviating factor responsible for *Ardhavabhedaka* was Sleep (93.3%) followed by *Yoga Pranayama* (86.66%), followed by head massage (80%), relaxation (73.33%), followed by Medicine (66.66%) and cold food /weather (40%). maximum patients of *Ardhavabhedhaka* were having refractiveerrors (56.66%) and43.33% were not having any refractive errors.

Maximum patients i.e. 66.66 % had belonged to gradual onset while 33.33 % of patients hadsudden onset of headache. Maximum 66.33 % patients were having less than1 year of chronicity, followed by 16.66 % patients were having chronicity of more than 5 year, than 13.33 % patients were having 2 year chronicity, than 6.66 % were having chronicity of 5 year. 56.66% patients were having unilateral headache,followed by 43.33% having bilateral headache. Maximum patients i.e. 83.33 % were suffering from headache in eveningfollowed by noon (63.33%), morning (23.33) and night (16.66%). 53.33% patients were suffering from headache for 13 hours in a day

followed by >7 hours duration was seen in 20 % patients and < 1 hours & 4-7 hours in 13.33% patients each respectively. It was observed that maximum patients 43.33% were having episode of migraine once in7 days, 23 % patients were found having once in 15 day ,13.33 patients having episode daily and 13.33% patients having episode alternate and lastly 6.66 % patients having episode once in 3 day. Regarding the severity of the headache , it was observed that maximum patients i.e. 53.33% patients were having moderate type of pain followed by 30% patients had sever type of pain followed by 16.66% patients were having very sever type of pain and none of the patients had mild type of pain

RESULT

All the results were calculated by using In Stat Graph Pad Prism 8 software. For intra-group comparison; "Wilcoxon matched-pairs signed ranks test" for non-parametric data and "Paired-t test" for parametric data was used and the results calculated in each group. For calculating the inter-group comparison, "Mann-Whitney Test" for non-parametric data &"unpaired-t test" for parametric data was used and the results calculated. Interpretation of result was done as: Non-significant (NS) p > 0.05, Significant (S) p < 0.05, Very Significant (VS) p< 0.001, Extremely significant (ES) p < 0.0001.

 Group A: Extremely significant result was obtained in Subjective parameters like intensity, duration, frequency of headache and MIDAS. In associated complaints, extremely significant results were reported in Nausea, vomiting, *Bhrama*, photophobia, panophobia, while significant results were achieved in tinnitus and transient loss of vision. No significant result was seen in Aura and sleep disturbances.

Group B: Extremely significant result was obtained in parameters like intensity, duration, frequency of headache and MIDAS. In associated complaints, extremely significant results were reported in Nausea, vomiting, *Bhrama*, photophobia, phanophobia, while significant results were achieved in tinnitus, sleep disturbances, and transient loss of vision. No significant result was seen in Aura and nasal discharge.

Comparative effect of both the groups: In subjective parameters, statistically significant changes have been assessed in intensity of Headache, while no significant results have been assessed in duration of headache and frequency of headache and in MIDAS. In associate complaints: Statistically extremely significant changes

have been assessed in Nausea & vomiting while no significant result reported in other associated complaints.

DISCUSSION

Kumkumadi Ghrita Nasya in Group A, *Siravedhana* in Group B and *Chandrakanta Rasa* in both groups aided in reducing the chief and associated complaints of *Ardhavabhedaka*. The following are the details of their probable mode of action:

Chandrakanta Rasa: Rasa Panchaka of *Chandrakanta Rasa* showed the predominance of *Ushna Virya, Madhura Vipaka, Tikta* and *Kashaya Rasa*, *Laghu* and *Ruksha Guna*. *Tikta Rasa* has *Aruchi-nashaka, Deepana,* and *Pachana* properties that contribute in increasing the *Jatharagni* and thus pacifying the *Aama Dosha. Kashaya Rasa* is *Sanshamana* and *Shleshma Rakta Pitta shamaka*. As a result, it is beneficial in both *Kapha* and *Rakta Dushti*, which are the underlying causes of *Ardhavabhedaka. Ushna Veerya* has *Pachana*, and *Vata-Kapha shamaka* property. It improves both local and overall metabolism. As a result, it will correct *Dhatu Poshana Krama.* In addition decreases the *Sheeta Guna* of *Vata* and *Kapha Dosha* and thus helps in relieving the pain.

In terms of *Doshaghnata,* the majority of the contents (71.42%) of *Chandrakanta Rasa* have a *Tridosha Shamaka* effect, which aids in balancing the *Vata Dosha*, as wellas *Pitta* and *Kapha*, and thus alleviating migraine pain. *Chandrakanta Rasa* contains drugs such as *Rasasindura (Parada+Gandhak), Abharak Bhasma, Tamra Bhasma, Lauha Bhasma,* which have *RaktaShodhana* and *Rakta Prasadana* properties that can help to normalize the vitiated *Rakta Dhatu. Vednasthapana, Shothahara, Nadi Tantra Balya, Medhya,* and *Rasayana Karma* of the contents, may prove beneficial in breaking the pathogenesis of migraine. *Vata Anulomaka* property of *Haritaki, Bhibhitaki*, *Aamalaki* normalizes the *Vimarggami Vayu* and helps in reducing the intensity of pain.

The contents of *Chandrakanta Rasa* have proven anti-inflammatory, antioxidant, anti-stress, analgesic, and anti-nociceptive activities which may help in reducing the pain of migraine.

Kumkumaadi Ghrita Naysa: *Acharya Vagbhata* mentions *Kumkumadi Ghrita* in the context of *Shiroroga Chikitsa*. Systemically conducted *Nasya Karma* heals practically all *Urdhvajatrugata Rogas* (illnesses).[11] *Snehana Nasya* with medicated *Ghrita* has been chosen to soothe the *Tridosha*, namely *Vata Dosha* due to its *Snehana Guna* and *Pitta* due

to its *Sheeta Veerya*. *Kumkuma*, the main element in *Kumkumadi Ghrita*, functions as *Srotoshodhaka* because it contains *Tikta* and *Katu Rasa*,[12] which aid in the expulsion of morbid *Doshas*, as well as qualities like *Kleda Shoshana* and *Shleshma Prashamana* due to *Tikta Rasa*.[13] Other constituents in *Kumkumadi Ghrita* include *Ghrita*[14] and *Sharkara*,[15] both of which include *Sheeta Veerya* and so help to balance the *Pitta Dosha*, which is responsible for nausea, vomiting, and photophobia. *Tridosha Shamana* is a property of Medicated *Ghee*, according to *Acharyas*.[16] As a result of its *Tridosha Shamaka* feature, *Kumkumadi Ghrita Nasya* can bring relief in *Ardhavabhedaka*, and *Nasya* is the closest root to alleviate head disorders.[17]

Siravedhana Karma: *Siravedhana* comes under *Ashastrakrita* type of *Raktamokshana* (bloodletting) that is suggested for all *Dosha Prakopa* but is especially beneficial for *Rakta* vitiated by *Pitta Dosha*. In *Ardhavabhedaka*, *Rakta* is the main *Dushya* which is vitiated by all the three *Doshas*. During the trial, it was noticed that *Siravedhana* had a very quick effect on pain. Patients with severe and acute pain of migraine experienced complete pain relief immediately following *Siravedhana Karma*.

Siravedhana proved beneficial in reducing the intensity of pain due to its ability to remove the *Ashuddha* or *Dushita Rakta* along with the vitiated *Doshas*. According to *Acharya Vagbhatta*, the mechanism of action of *Siravedhana* is similar to how a swan drinks milk and leaves water from a mixture of milk and water. The therapeutic action of *Siravedhana* is based on the blood removed by the venous suction action. This removal of vitiated *Rakta* results in *Srotoshodhana*, which leads to *Anulomana* of obstructed and aggravated *Vata*, and that, might be the cause of significant pain relief. Relief in migraine by *Siravedhana* may be attributed to which is the cause of the onset of a migraine attack.

CONCLUSION

Ardhavabhedaka, described in *Ayurveda* can be nearly correlated with Migraine especially Migraine without Aura. *Siravedha* gives instant relief but reoccurrence chances is more, but *Kumkumadi Ghrita Nasy*a works better and reoccurrence chances is less. *Kumkumadi Ghrita* effectively works on associated symptoms like *Hrillas, Chhardi, Bhrama, Shabdaasahishnuta, and Prakash Asahishnuta*. Hence, it can be concluded that clinically *Siravedha, Kumkumadi Ghrita Nasya* and *Chandrakanta*

Rasa combine work better to manage the *Ardhavabhedaka* (Migraine). Though, clinically combine therapy (Group A) works better to manage *Ardhavabhedaka,* statistically there is no significant difference in the effect of both the groups.

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Table 1 Shows Investigations

Group A	Group B
C.B.C, ESR, RBS, LFT, RFT, Routine Eye checkup, Vision test by Snellens chart and refraction, IOP	C.B.C, ESR, RBS, LFT, RFT, Routine Eye checkup, Vision test by Snellens chart and refraction, IOP, CT, BT, HIV Hbs Ag, X-ray PNS

TABLE 2: CRITERIA FOR ASSESSMENT OF OVERALL EFFECT.

Complete remission	100% relief in Chief complaints with no moderate improvement, mildrecurrence during follow up study have been considered as complete remission.
Marked improvement	76 - 99% improvement in chief complaints has been recorded asmarked improvement.
Moderate improvement	51 - 75% improvement in chief complaints has been recorded asmoderate improvement.
Mild improvement	26 - 50% improvement in chief complaints has been considered as mild improvement.
Unchanged	Less than 25% reduction in chief complaints or recurrence of the symptoms to thesimilar extent of severity