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A CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF INDIGENOUS DRUG FORMULATION IN ARDHAVABHEDAKA VIS-A-VIS MIGRAINE

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ABSTRACT

Background: *Ardhavabhedaka* is the disease afflicting *Shiras* (head) which is mentioned under *Dashapranayatana*. The disease was named because of its classical symptom of *Shoola* in half of the *Shiras*. *Ardhavbhedaka* is characterized *by Shastra arani nibhavat shoola* in half part of the Head and the areas like the nape of the neck, eyebrows, eyes, forehead, temporal region, and ears. The present study was undertaken to evaluate the efficacy of Indigenous formulation in *Ardhavbhedaka* vis-à-vis Migraine. **Objective:** To study the added efficacy of indigenous drug formulation in *Ardhavbhedaka* vis-àvis Migraine. **Methods:** Study design: A controlled clinical study with pre, mid and post-test design. **Intervention:** The interventions were as follows.

Group A – Control Group

- *Amrutadi taila nasya* for the first seven consecutive days in a dose of 8 drops in each nostril (*Ksheera, bala taila* was used for *Urdhvajatru* for massage)
- *Kamdugha rasa* – one tablet, thrice daily before food along with warm for 30 days

Group B – Test Group

- *Amrutadi taila nasya* for first seven consecutive days in a dose of 8 drops in each nostril (*ksheerabala taila* was used for *Urdhwajatru* for massage)

- *Kamdugha rasa* – one tablet, thrice daily before food along with warm water for 30 days
- *Anubhuta yoga (*Tablet form)- (Godanti *bhasma, Guduchi satva, Varatika bhasma, Jatiphala churna, Vibhitaki churna, Shankhapushpi churna-* are given *Bhavana* with *Bhringaraja swarasa*)– two tablets twice a day with warm water after food. (1 tablet= 500 mg) In this study, a total of three assessments of the subjects were done on 0day, 8th day, 16th day & 31st day. The results were analyzed statistically by using descriptive statistics, Contingency co-efficient test. In the study it was observed that the trial Group (Group B) showed clinically and statistically highly significant results; in reduction of severity of pain, duration of pain, Frequency of attack, Nausea, Vomiting, Photophobia, vertigo, and Phonophobia with a p-value 0.000; significant in the reduction of Tenderness with p-value 0.029; significant in the reduction of Confusional status with p-value 0.050.

On comparing the overall effect of the study, the trial group (Group B) showed better results than the control group (Group A). Hence, Indigenous drug formulation has a better role in the management of *Ardhavbhedaka*.

Keywords: *Ardhavbhedaka,* Migraine, *Nasya Karma.*

INTRODUCTION

Ardhavbhedaka is the disease afflicting shiras which is mentioned under *Dashapranayatanas*[1]. The disease is named because of its classical symptom of pain in half of the head[2]. *Ardhavbhedaka* is characterized by *Shastra arani nibhavat shoola* in half part of the Head and the areas like the nape of the neck, eyebrows, eyes, forehead, temporal region, and ears. The prime *Dosha* involved in *Ardhavabedaka* is *Vata dosha or Vata-Kapha dosha*[3] *(Tridoshas*[4]) Headache occurs periodically once in 15 days or once in a month or anytime and relieves by itself [5]. When it is severely aggravated it destroys Sensory functions like vision or hearing[6,7,8,9]. *Ardhavbhedaka* is similar to migraine, described in Western medical science. Migraine is a chronic neurological disease[10] characterized by recurrent, moderate to severe headache typically affecting one half of the head, is pulsating in nature and lasts from 4 to 72 hours. Associated symptoms may include nausea, vomiting, and sensitivity to light, sound, or smell. The pain is generally made worse by physical activity[11]. The management for migraine in western medical science includes Pharmacologic and non-pharmacological treatments which include NSAIDs, 5-HT1 agonists, dopamine antagonists and avoiding specific headache triggers, lifestyle, healthful diet, regular sleep patterns, and avoidance of acute changes in stress levels[12]. Frequent use of migraine medications like Ergotamine, opiates, analgesics, and triptans may cause medication-overuse headaches. Narcotics can lead to dependency, rebound headaches, and eventual loss of efficacy[13]. Classical textbooks of Ayurveda have explained various treatment modalities for *Ardhavbhedaka* such as *Nasya karma, Snehapana, Nadisweda, Bastikarma,* and *Agnikarma*[14]. Among which *Nasya karma* is appreciated for its superiority in treating *Shiroroga*[15]. Previous research works done on *Nasya karma* in the management of *Ardhavbhedaka* also gave encouraging results. In *Ardhavbhedaka* prime *Dosha* involved is *Vata dosha* associated with *Pitta and Kapha dosha*. These vitiated *Dosha* when it reaches *Shira,* in turn, vitiates *Rakta* and *Siras* resulting in the manifestation of *Shiroroga*[16]. Individual ingredients of *Amrutadi taila* possess *Tikta rasa Pradhana*. All ingredients are *Tridosha hara* mainly *Vata hara, Vedana sthapaka* and *Raktashodaka* property which is essential for *Samprapti vighatana* in *Ardhavbhedaka*. There are many formulations which are been traditionally used in *Ardhavbhedaka* for centuries by *Ayurvedic* clinicians. Drugs such as *Godanti bhasma, Varatika bhasma, Guduchi satwa, Jatiphala churna, Vibhitaki churna, Shankhapushpi churna and Bhringaraj*a are some of the individual drugs which are indicated and also being practically used by the clinicians.

Hence, the present study was undertaken to evaluate the efficacy of indigenous drug formulation, and *Amrutadi taila nasya, Kamadugha rasa* orally were tak-

en as a control in *Ardhavbhedaka.* Group A*: Amrutadi taila nasya* for the first seven consecutive days in a dose of 8 drops in each nostril (*Ksheerabala taila* was used for *Urdhwajatru* for Massage). *Kamadugha rasa* – one tablet, thrice daily before food along with warm water for 30 days. Group B: *Amrutadi taila nasya* for the first seven consecutive days in a dose of 8 drops in each nostril *(Ksheerabala taila* was used for *Urdhwajatru* for Massage). *Kamadugha rasa* – one tablet, thrice daily before food along with warm water for 30 days. *Anubhuta yoga* (Tabet form) - (*Godanti bhasma, Guduchi satva, Varatika bhasma, Jatiphala churna, Vibhitaki churna, Shankhapushpi churna*- are given *Bhavana* with *Bhringaraja swarasa*)– two tablets twice a day with warm water after food. (1 tablet= 500 mg). Duration of the intervention: 30 days.

The assessment was done on the following parameters: Severity of pain, duration of pain, Frequency of attack, and associated symptoms like Nausea, Vomiting, Photophobia, Vertigo, Tinnitus, Aura, Phonophobia, Numbness, Heaviness, Tenderness, Diarrhoea, and Confusional status. Data were collected on 0-day, 8th day (after completion of nasya karma), 16th day (mid-test assessment), 31st day (post-test assessment).

METHODOLOGY

MATERIALS

The Materials used in the study were:

1. *Ksheerabala taila*
2. *Amrutadi taila*
3. *Kamadugha rasa*
4. *Anubhuta yoga* (tablet form)

Source of Drugs and Method of preparation: *Amrutadi taila, Kamadugha rasa, Anubhuta yoga* (tablet form) specifically prepared as per the classics from NKCA Pharmacy Pvt Ltd., (a GMP certified unit), Krishna Raja Mohalla, Mysuru, were procured for study. *Ksheerabala taila* manufactured from Govt. Central Pharmacy, Bengaluru supplied to Govt. Ayurveda Medical College & Hospital, Mysuru and was procured for study.

METHODS: Objectives of the study: To study the added efficacy of indigenous drug formulation in *Ardhavbhedaka* vis-àvis migraine.

To study the efficacy of *Amrutadi taila nasya and Kamadugha rasa* in *Ardhavbhedaka* vis-à-vis migraine.

Source of the data: Patients of all Gender diagnosed to be suffering from *Ardhavbhedaka* were selected from the OPD, IPD of Government Ayurveda Medical & College Hospital, Mysuru.

Sample size and Sampling method: A total of 58 subjects irrespective of gender, socio-economic status, and religion, having the signs and symptoms of *Ardhavbhedaka* vis-à-vis Migraine fulfilling the inclusion criteria were registered for the study. The selected subject's detailed profile was prepared as per the detailed proforma designed for the same purpose, which incorporates relevant data like symptomatology, physical signs, laboratory investigation reports as well as assessment criteria after taking written informed consent of the subject. The proforma is affixed in the appendix. Incidental selection and Random sampling techniques were employed. Subjects were assigned into two groups viz., Group A (Control group) and Group B (Trial group).

Out of 58 subjects registered, Group A consisted of 30 subjects and Group B with 28subjects. There were 6 dropouts, 4 in Group A and 2 in Group B, and the study was completed in 52 subjects with 26 subjects in each Group.

Inclusion Criteria

— Patients of all gender between the age group of 15-60yrs were selected.

 Patients with symptoms of *Ardhavbhedaka* vis-à-vis Migraine:

 Bheda, Toda, Shoola in Half *Shiras.*

 Occurrence of *Shirashoola- Pakshat, masat or Akasmat, Swayameva upashamyati.*

 Unilateral throbbing / Pulsating pain, paroxysmal associated with/ without nausea, vomiting, photophobia/ phonophobia.

 Both freshly detected and treated cases were selected.

Exclusion Criteria

 Patients having a history of severe head injury.

 Patients with complicated migraine, status migrainous, ophthalmic migraine, retinal migraine.

q Patients with co-morbidity of sinusitis, uncontrolled diabetes, and hypertension

 Referred pain in one half of the head due to disorder of eye, ear, nose, throat, and teeth.

 Pregnant and lactating women were excluded.

Diagnostic Criteria The diagnosis was made based on the criteria of migraine provided by the International Headache Society.

 At least 5 attacks in history.

 Headache attacks lasting 4-72 hours.

Headache has at least 2 of the following

1. Unilateral location.
2. Pulsating quality.
3. Moderate or severe pain intensity.
4. Aggravation by or causing avoidance of routine physical activity

(e.g., walking or climbing stairs).

 During headache at least one of the following

1. Nausea and/or vomiting
2. Photophobia and phonophobia

Not attributed to another disease

ASSESSMENT CRITERIA

Based on clinical grading of signs and symptoms:

1. Severity of pain

Intolerable pain	4
Disturbs the routine work	3
Do not disturb the routine work	2
Pain tolerable	1
No pain	0

2. Duration of pain

Over 24-72 hrs	4
12-24 hrs	3
4-12 hrs	2
Up to 4 hrs	1
No pain	0

3. Frequency of attack

Continuous / daily	4
0- 8th day	3
8-15th day	2
15th-30th day	1
No attacks	0

4. Associated symptoms

a) Nausea - Absent/Present
b) Vomiting - Absent/Present
c) Photophobia - Absent/Present
d) Vertigo - Absent/Present
e) Tinnitus - Absent/Present
f) Aura - Absent/Present
g) Phonophobia-Absent/Present
h) Numbness - Absent/Present
i) Heaviness - Absent/Present
j) Tenderness - Absent/Present
k) Diarrhea - Absent/Present
l)Confusional state Absent/Present

Assessment schedule: In this study, a total of three assessments of the subjects were done. Before starting the Intervention i.e., pre-test assessment was done on 0 day. The next assessment was done on 8th day i.e after completion of nasya karma. Mid-test assessment was done on the 16th day and post-test assessment i.e. After the completion of intervention was done on the 31stday.

STATISTICAL METHODS: The results were analyzed statistically by using descriptive statistics, Contingency coefficient test analysis using Service product for statistical solution (SPSS) for Windows software.

Investigations:

 As diagnosis is done based on symptoms explained for disease, no specific laboratory investigations are required.

 However necessary investigation was carried out in required cases to rule out other systemic diseases and complications

— Investigations for Exclusion purpose –All the subjects were evaluated for their physiological status in terms of pulse, respiration, body temperature, and pallor. To exclude other co-morbidity like sinusitis X-ray water's view was done.

 Haematological examination - Hb%, TC, DC, ESR, RA, FBS, PPBS; Urine examination – Sugar, Albumin, Micro, and other relevant investigations in

appropriate cases were done to rule out systemic disorders.

Research design: The present study was a controlled clinical trial with Pre, mid, and Post-test design.

Intervention: Group A.

 Amrutadi taila nasya for the first seven consecutive days in a dose of 8 drops in each nostril *(Ksheerabala taila* was used for *Urdhwajatru* for massage)

 Kamdugha rasa – one tablet, thrice daily before food along with warm water for 30 days

Group B

 Kamdugha rasa – one tablet, thrice daily before food along with warm water for 30 days

 Anubhuta yoga (Tablet form)- *(Godanti bhasma, Guduchi satva, Varatika bhasma, Jatiphala churna, Vibhitaki churna, Shankhapushpi churna-* are given *Bhavana* with *Bhringaraja swarasa*)– two tablets twice a day with warm water.

 Amrutadi taila nasya for first seven consecutive days in a dose of 8 drops in each nostril (*ksheerabala taila* was used for *Urdhwajatru* for massage)

after food. (1 tablet= 500 mg)

 Duration of the intervention: 30 days.

RESULT: The study hypothesized that Group B (Trial Group) intervention will be more effective than Group A (Control Group) intervention in the management of *Ardhavbhedaka* vis-à-vis Migraine. The data were collected from the subjects based on the scoring given to each of the symptoms as mentioned in the assessment criteria. It was collected on 0 days (Pre-test), 8th day (after *Nasya karma*), 16th day (mid-test), and on 31 st day(post-test). The results were analyzed statistically and assessed. The statistical analyses of the results were done using descriptive statistics, Contingency co-efficient test analysis using Service product for statistical solution (SPSS) for Windows software.

To evaluate the result, the following parameters were taken into consideration:

1. Severity of pain: In this study, the contingency co-efficient value revealed that Group B (CC=0.746) is showing better results than Group A (CC=0.704) for a reduction in Severity of pain.

Table 1: Showing the Distribution & Results on Severity of Pain

Groups			Severity of pain					Total
			No pain	Pain tolerable	Do not disturb the routine work	Disturbs the routine work	Intolerable pain	
Group A	Sessions	0 Day		0	0	5	21	26
				0.00%	0.00%	19.20%	80.80%	100.00%
		8th Day	0	0	5	21	0	26
			0.00%	0.00%	19.20%	80.80%	0.00%	100.00%
		16th Day	0	6	18	2	0	26
			0.00%	23.10%	69.20%	7.70%	0.00%	100.00%
		31st Day	3	12	11	0	0	26
			11.50%	46.20%	42.30%	0.00%	0.00%	100.00%
	Total		3	18	34	28	21	104
			2.90%	17.30%	32.70%	26.90%	20.20%	100.00%
Group B	Sessions	0 Day	0	0	0	6	20	26
			0.00%	0.00%	0.00%	23.10%	76.90%	100.00%
		8th Day	1	1	12	12	0	26
			3.80%	3.80%	46.20%	46.20%	0.00%	100.00%
		16t	2	17	7	0	0	26

		h Day	7.70%	65.40%	26.90%	0.00%	0.00%	100.00%
		31st Day	18	8	0	0	0	26
			69.20%	30.80%	0.00%	0.00%	0.00%	100.00%
	Total		21	26	19	18	20	104
			20.20%	25.00%	18.30%	17.30%	19.20%	100.00%
Total	Sessions	0 Day	0	0	0	11	41	52
			0.00%	0.00%	0.00%	21.20%	78.80%	100.00%
		8th Day	1	1	17	33	0	52
			1.90%	1.90%	32.70%	63.50%	0.00%	100.00%
		16th Day	2	23	25	2	0	52
			3.80%	44.20%	48.10%	3.80%	0.00%	100.00%
		31st Day	21	20	11	0	0	52
			40.40%	38.50%	21.20%	0.00%	0.00%	100.00%
	Total		24	44	53	46	41	208
			11.50%	21.20%	25.50%	22.10%	19.70%	100.00%

2. Duration of Pain: In this study, the contingency coefficient value revealed that Group A (CC=0.747) is showing better results than Group B (CC=0.733) for a reduction in Duration of pain.

Table 2: Showing the Distribution & Results on Duration of Pain

Group			Duration of pain					Total
			No pain	Up to 4 hours	4-12 hours	12-24 Hours	Over 24-72 Hours	
Group A	Sessions	0 Day	0	0	0	4	22	26
			0.00%	0.00%	0.00%	15.40%	84.60%	100.00%
		8th Day	0	0	4	22	0	26
			0.00%	0.00%	15.40%	84.60%	0.00%	100.00%
		16th Day	0	6	19	1	0	26
			0.00%	23.10%	73.10%	3.80%	0.00%	100.00%
		31st Day	3	14	9	0	0	26
			11.50%	53.80%	34.60%	0.00%	0.00%	100.00%
	Total		3	20	32	27	22	104
			2.90%	19.20%	30.80%	26.00%	21.20%	100.00%
Group B	Sessions	0 Day	0	0	1	6	19	26
			0.00%	0.00%	3.80%	23.10%	73.10%	100.00%
		8th Day	1	1	14	10	0	26
			3.80%	3.80%	53.80%	38.50%	0.00%	100.00%
		16th Day	2	17	7	0	0	26
			7.70%	65.40%	26.90%	0.00%	0.00%	100.00%
		31st Day	18	8	0	0	0	26
			69.20%	30.80%	0.00%	0.00%	0.00%	100.00%
			21	26	22	16	19	104

			20.20%	25.00%	21.20%	15.40%	18.30%	100.00%
Total	Sessions	0 Day	0	0	1	10	41	52
			0.00%	0.00%	1.90%	19.20%	78.80%	100.00%
		8th Day	1	1	18	32	0	52
			1.90%	1.90%	34.60%	61.50%	0.00%	100.00%
		16th Day	2	23	26	1	0	52
			3.80%	44.20%	50.00%	1.90%	0.00%	100.00%
		31st Day	21	22	9	0	0	52
			40.40%	42.30%	17.30%	0.00%	0.00%	100.00%
	Total		24	46	54	43	41	208
			11.50%	22.10%	26.00%	20.70%	19.70%	100.00%

3. Frequency of attack: In this study, the contingency coefficient value revealed that Group B (CC=0.720) is showing better results than Group A (CC=0.685) for a reduction in Frequency of attack.

Table 3: Showing the Distribution & Results on Frequency of Attack

Group			Frequency Of Attack					Total
			No attacks	15th - 30th day	8-15th day	0- 8th day	Continuous / Daily	
Group A	Sessions	0 Day	0	1	0	7	18	26
			0.00%	3.80%	0.00%	26.90%	69.20%	100.00%
		8th Day	1	0	7	18	0	26
			3.80%	0.00%	26.90%	69.20%	0.00%	100.00%
		16th Day	1	19	6	0	0	26
			3.80%	73.10%	23.10%	0.00%	0.00%	100.00%
		31st Day	4	22	0	0	0	26
			15.40%	84.60%	0.00%	0.00%	0.00%	100.00%
	Total		6	42	13	25	18	104
			5.80%	40.40%	12.50%	24.00%	17.30%	100.00%
Group B	Sessions	0 Day	0	0	1	9	16	26
			0.00%	0.00%	3.80%	34.60%	61.50%	100.00%
		8th Day	1	0	8	17	0	26
			3.80%	0.00%	30.80%	65.40%	0.00%	100.00%
		16th Day	2	14	10	0	0	26
			7.70%	53.80%	38.50%	0.00%	0.00%	100.00%
		31st Day	18	8	0	0	0	26
			69.20%	30.80%	0.00%	0.00%	0.00%	100.00%
	Total		21	22	19	26	16	104
			20.20%	21.20%	18.30%	25.00%	15.40%	100.00%
		0 Day	0	1	1	16	34	52
			0.00%	1.90%	1.90%	30.80%	65.40%	100.00%

Total	Sessions	8th Day	2	0	15	35	0	52
			3.80%	0.00%	28.80%	67.30%	0.00%	100.00%
		16th Day	3	33	16	0	0	52
			5.80%	63.50%	30.80%	0.00%	0.00%	100.00%
		31st Day	22	30	0	0	0	52
			42.30%	57.70%	0.00%	0.00%	0.00%	100.00%
	Total		27	64	32	51	34	208
			13.00%	30.80%	15.40%	24.50%	16.30%	100.00%

Associated symptoms:

1. **Nausea:** it's included in vomiting
2. **Vomiting**: In this study, the contingency coefficient value revealed that Group B (CC=0.743) is showing better results than Group A (CC=0.612) for Vomiting.
3. **Photophobia:** In this study, the contingency coefficient value revealed that Group B (CC=0.698) is showing better results than Group A (CC=0.552) for Photophobia.
4. **Vertigo:** The results obtained regarding reduction in Vertigo showed a highly significant result in Group A with a p-value of 0.000 and significant in Group B with a p-value of 0.000.
5. **Tinnitus:** The results obtained regarding the reduction in Tinnitus showed a non-significant result in both the groups with a p-value of 0.387 in Group A and 0.564 in Group B.
6. **Aura:** The results obtained regarding the reduction in Aura showed a non-significant result in both the groups with a p-value of 0.259 in Group A and 0.167 in Group B.
7. **Phonophobia:** In this study, the contingency coefficient value revealed that Group B (CC=0.580) is showing better results than Group A (CC=0.472) for Phonophobia.
8. **Numbness:** In Group A among 26 subjects, Numbness was present in 2(7.7%) subjects and absent in 24(92.3%) subjects in the pre-test assessment.
9. **Heaviness**: None of the subjects reported this symptom in either of the group.
10. **Tenderness:** The results obtained regarding reduction in Tenderness showed a significant result in Group B with a p-value of 0.029 and non-significant in Group A with a p-value of 0.051.
11. **Diarrhoea:** The results obtained regarding reduction in Diarrhoea showed non-significant results in both the groups with a p-value of 0.387.
12. **Confusional status:** The result regarding reduction in Confusional status showed non-significant results in Group A with a p-value of 0.247 and significant results in Group B with a p-value of 0.050.

DISCUSSION

In this study parameters like the severity of pain, duration of pain, frequency of attack and associated symptoms like nausea, vomiting, photophobia, vertigo, phonophobia showed statistically highly significant results with a p-value o f 0.000 in both the groups. It is due to property of *Amrutadi taila* in the form of *Nasya* and *Kamadugha rasa* orally acted as, *Vedana stapaka*, *Srotoshodhaka*, *Rakta prasadaka and Pitta-Vata pradhana Tridosha prashamana* activity. But it was observed that reduction in these parameters was sustained for a longer duration in Group B (trail group). It is probably because of added effect of drugs used in indigenous formulation, i.e., *Godanti bhasma* and *Varatika bhasma* – which chiefly contain calcium and magnesium in small quantities. Calcium also controls the excitability of nerves and muscles. Researchers suggest that decreased magnesium play an important role in Migraine headache, hence magnesium supplementation may reduce the incidence of vascular disease. It also affects serotonin receptors and a variety of other migraine-related receptors and neurotransmitters.

Jatiphala churna- has anti-inflammatory and analgesic property and acts on Dopaminergic and serotonin pathways which is chiefly involved in Migraine. *Shankhapushp*i acts as a psychostimulant, tranquillizer, and neuroprotective. *Bhringaraja* – is traditionally used in folk culture as a remedy against pain and inflammation. The research study also concluded that Eclipta alba extract (fresh leaves juice) has a similar effect in alleviating pain. Thus, the action of all these drugs in combination with *Amrutadi taila nasya and Kamadugha rasa* contributed to *Samprapti vighatana* of *Ardhavbhedaka* vis-à-vis Migraine. The other parameters like tinnitus, aura, numbness, tenderness, diarrhoea and Confusional status showed insignificant results. This is because of the unequal distribution of subjects between the groups presenting with these symptoms.

CONCLUSION

Based on concepts, analysis, and clinical observations made in this study, the following conclusions were drawn. *Ardhavbhedaka* is a *shoola pradhana vyadhi* characterized by the feeling of severe pain like *Arani kantakavat* in half part of the head *involving manya, Bhru, shakha, karna, akshi* and *Lalita.* The *Dushyas* such *as Rasa, Rakta* and *Srothas* such as *Vata vaha* and *Raktavaha*, play an important role in the pathology of the disease *Ardhavbhedaka*. *Ardhavbhedaka* as a clinical condition is similar to Migraine described in western medical science. *Amrutadi taila* explained in Sahara yoga is a formulation advised for the management of *Shiroroga* and some of the individual drugs which are indicated and also being practically used in *Shiroroga* were made in tablet form. Also, the *Rasa, Guna, Veerya, Vipaka*, and *Doshaghnata* of individual ingredients and the formulation as a whole were analyzed and hypotheses that it is having *Vedana stapaka, Rakta prasadaka, Pitta-Vata pradhana Tridoshahara* property which is mainly required in the *samprapti vighatana* of the disease *Ardhavbhedaka*. So, this formulation was selected as a trial in the present study. This is a controlled clinical study, conducted on 52 subjects with 26 subjects in each group. In the study it was observed that the trial Group (Group B) showed clinically and statistically highly significant results; in reduction of severity of pain, duration of pain, Frequency of attack, Nausea, Vomiting, Photophobia, vertigo, and Phonophobia with a p-value of 0.000; significant in the reduction of Tenderness with a p-value of 0.029; significant in the reduction of Confusional status with a p-value of 0.050. The control group (Group A) showed the clinically and statistically highly significant results in a reduction of severity of pain, duration of pain, Frequency of attack, Nausea, Vomiting, Photophobia, vertigo, and Phonophobia with a p-value of 0.000; showed the non-significant result in a reduction of Tinnitus (0.387), Aura (0.073), Diarrhoea (0.387), Tenderness (0.051) and Confusional status (0.247).

On comparing the overall effect of the study, the trial group (Group B) showed better results than the control group (Group A). Hence, Indigenous drug formulation has a better role in the management of *Ardhavbhedaka*.

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