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A Randomized clinical trial on *Ardhavabhedaka*– Migraine and its *Ayurvedic* management

Research Article

Vaghela DB[1], Shweta Mata[2*], Dhiman KS[3], Manjusha R[4]

1. Assistant Professor, 2. Phd Scholar, 4. Professor & HOD
Department of Shalakya Tantra, IPGTRA, Gujarat Ayurved University, Jamnagar.
3. Director General, CCRAS, New delhi.

Abstract

Ardhavabhedaka defines *Ardha Mastak Vedana.* The word migraine is derived from the Greek word hemicranias, meaning "half of the head". Migraine is now recognized as a chronic illness, not simply a headache. Many medications have been tried and a lot are still in research work also, but modern drugs are not acceptable due to their drawbacks. In contrast to that *Ayurveda* has a variety of natural medication in the treatment of *Ardhavabhedaka*. It was planned to compare the result between *Laghu Sutashekhara Rasa* orally in Group A, *Brihat Dashamoola Taila Nasya* in Group B, placebo drug in Group C and *Go-ghrita Nasya* in Group D. The overall effect of therapy showed that in Group A 38% patients cured and 36% patients got marked improvement. In Group B 46.67% patients moderately improved and 35.55% patients marked improved. In Group C 90% patients unchanged. In Group D 48.89% patients moderately improved and 28.89% patients marked improved. No any adverse drug reaction was found during whole study. Total 150 patients were registered and from the results and observation which were received from this study it can be concluded that Group A is showing better results in *Ardhavabhedaka.*

Key Words: *Brihat Dashmoola Taila, Go-ghrita, Laghu Sutashekhara Rasa, Nasya*.

Introduction:

Headache has troubled mankind from dawn of civilization. Neurovascular headaches are the second most common primary headaches, which includes migraine(1). The term "migraine" refers to a syndrome of vascular spasms of the cranial blood vessels. Migraine is now recognized as a chronic illness, not simply a headache(2). Many medications have been tried and a lot are still in research work also, but modern drugs are not acceptable due to their drawbacks. All the medications, either the older one or the newly available one have a lot of side effects (GIT distress, etc). In contrast to that *Ayurveda* has a variety of natural medication in the treatment of various types of *Shiro-Roga*. Thus, here an attempt has been made to evaluate the efficacy of *Shamana Yoga – Laghu Sutashekhara Rasa* from *Rasa Tarangini*(3), which is having digestive, anti-oxidant, anti-inflammatory properties and *Vata-Kaphahara* quality of *Gairika*, *Shunthi* and Betel leaves. As a *Shodhana* therapy *Brihat Dashamoola Taila* from *Bhaisajya Ratnavali*(4), which is having *Vatahara* properties, has been selected in the present study. According to *Acharya Sushruta*(5), *Ardhavabhedaka* is best treated with *Ghrita* and it is effective in subsiding *Pittaja* and *Vataja* disorders; it improves *Dhatus* and is overall booster for improving *Ojas*.

So here the clinical study has been planned to find out the efficacy of *Brihat Dashamoola Taila* and *Go-ghrita* as *Nasya* and *Laghu Sutashekhara Rasa* as oral drug in comparison of placebo drug for the treatment of *Ardhavabhedaka*

*Corresponding Author:
Shweta Mata
PhD scholar,
Department of *Shalakya Tantra* ,
IPGT&RA, Gujarat Ayurved University,
Jamnagar -361008.
E-mail: shwetamatadr@gmail.com

Aims and objectives:

The present study was based on following aims and objects:

To study the etiopathogenesis of *Ardhavbhedaka* - Migraine from Ayurvedic and modern point of view.

To evaluate the efficacy of *Laghu Sutashekhara Rasa* (orally) and *Brihata Dashamoola Taila* (*Nasya*) in patients suffering from *Ardhavabhedaka* – Migraine.

Materials and methods:

For clinical study, patients attending O.P.D. & I.P.D. of Department of Shalakya, I.P.G.T. & R.A., hospital fulfilling the criteria for diagnosis were selected randomly, irrespective of their *Desha, Jati, Prakriti, Sattva* etc. Patients' written informed consent was taken before starting the treatment. The study was conducted in 150 subjects. CTRI reg. no. is 2015/07/009321. The study was approved by Institutional Ethics Committee (No.PGT/7/A/Ethics/2011-12/2687 dated on 23/08/2011).

Diagnostic criteria:

Criteria for inclusion: Age Control group between 16

to 60 years and having sign and symptom of *Ardhavabhedaka* (Migraine) according to *Ayurvedic* Classics as well as Modern science. The diagnosis of the disease shall be done on the basis of clinical manifestations like recurrent attacks of headache, mostly unilateral in site, variable in intensity, frequency and duration with or without nausea, vomiting, aura and GI tract symptoms.

Criteria for exclusion:

Sinusitis, hypertension, fever, Secondary headache caused by meningitis, tumour, encephalitis, cervical spondylitis and refractive errors. Patients using any other systemic drugs which may alter the results of study.

Grouping:

Group A: *Laghu Sutashekhara Rasa*: (*Rasa Tarangini Parishista*)
Dose - 500 mg Tablet thrice per day orally
Duration - 02 Months.

Group B: *Brihata Dashamoola Taila* for *Nasya* (*Bhaishajya Ratnavali* 65/94-98)
Dose- 6 - 8 drops in each nostril.
Duration- (02 Months) 4 sittings, each sitting of 7 days at the interval of 1 week.

Group C: Placebo Tablet prepared by wheat floor.
Dose - 500 mg Tablet thrice per day orally
Duration - 02 Months.

Group D: *Go-Ghrita Nasya*: (Su. U. 26/31-35)
Dose- 6- 8 drops in each nostril.
Duration- (02 Months) 4 sittings, each sitting of 7 days at the interval of 1 week.

Investigations:

Routine haematological, urine and blood sugar level analysis was carried out before treatment to rule out any disease. Digital PNS X-Ray, Ophthalmologic Fundus examination, Nasal endoscopy and CT-SCAN was done wherever required.

Scoring pattern:

Subjective symptoms

The improvement in patients was assessed on the basis of relief in the signs and symptoms of the disease. The details of the score adopted for the main signs and symptoms in this study are as follows:

Severity of Headache
- 0 = No headache.
- 1 = Mild headache, patient is aware only if he/she pay attention to it.
- 2 = Moderate headache, can ignore at times.
- 3 = Severe headache, can't ignore but he/she can do his/her usual activities.
- 4 = Excruciating headache, can't do anything.

Frequency of Headache: Assessed in term of (frequency in days)
- 0 = Nil
- 1 = ≥ 20 days
- 2 = 15 days
- 3 = 10 days
- 4 = ≤ 5 days

Duration of Headache: (Assessed in term of hours/day)
- 0 = Nil
- 1 = 1-3 hours/day
- 2 = 3-6 hours/day
- 3 = 6-12 hours/day
- 4 = More than 12 hours/day

Nausea:
- 0 = Nil
- 1 = Occasionally
- 2 = Moderate, but does not disturb the routine work
- 3 = Severe, disturbing routine work
- 4 = Severe enough, small amount of fluid regurgitating from Mouth

Vomiting:
- 0 = Nil
- 1 = Only if headache does not subside
- 2 = Vomiting 1-2 times
- 3 = Vomiting 2-3 times
- 4 = Forced to take medicine to stop vomiting

Vertigo:
- 0 = Nil
- 1 = Feeling of giddiness
- 2 = Patient feels as if everything is revolving
- 3 = Revolving signs + black outs
- 4 = Unconscious

Aura:
- 0 = Nil
- 1 = Lasts for 5 minutes.
- 2 = Lasts for 15 minutes
- 3 = Lasts for 30 minutes
- 4 = Lasts for 60 minutes

Gradation For Associated Symptoms:
- 0 = No symptoms
- 1 = Mild (can do his/her work)
- 2 = Moderate (forced to stop work)
- 3 = Severe (forced to take rest)
- 4 = Excruciating (force to take medicine)

Overall assessment:

The improvement was assessed on the basis of subjective symptoms and salivary tests (objective parameters).

Subjective:

The assessment was done by adopting the following scoring pattern for subjective symptoms-

- Complete Remission: 100% relief in objective and subjective signs and symptoms.
- Marked improvement: 76 – 99% relief in objective and subjective signs and symptoms.
- Moderate improvement: 51 – 75% relief in

objective and subjective signs and symptoms.
- Mild improvement: 26 – 50% relief in objective and subjective signs and symptoms.
- Unchanged: Below 25% relief in objective and subjective signs and symptoms.

Statistical estimation of results:

The obtained data were analyzed statistically. The values were expressed as percentage of relief and Standard Error Mean. The data were analyzed by paired 't' test. Unpaired 't' test was applied for comparative study.

- P > 0.05 = Insignificant
- P < 0.05 and 0.01 = Significant
- P < 0.001 = Highly significant

Observations and Results

In this clinical trial of *Ardhavabhedaka*, a total number of 150 patients were registered and were randomly distributed into four groups. The general observations are shown in FIGURE NO. 1

Observation reveals that, regarding the chief complaints 100% patients were having *Shirah-Shoola* (headache), followed by *Hrillas* (nausea) and *Bhrama* (vertigo) 88% and 63.33% respectively, *Chhardi* (vomiting) 48%, and Aura 96.66%, which are identical to the textual *Lakshana* (symptoms) of *Ardhavabhedaka* and migraine.

Regarding the associated symptoms 77.33% patients were having Photophobia, 73.33% were having Supraorbital pain, 67.33% were having Ocular pain, 45.33% patients had blurring of vision, 27.33% had Lacrimation, 88.66% patients had sleep disturbance, 77.33% patients had Sleep disturbance, 37.33 patients had Stiffness of neck followed by other symptoms, which tally with textual *Lakshana* of *Ardhavabhedaka* and migraine.

Regarding the *Shirah-Shoola*, Maximum (72%) patients were having unilateral headache, that also particularly more in parietal and frontal region i.e., 88.00% and 74.00% respectively, nature of pain was *Tivra* (sharp) in 66.67% patients. Regarding the quality of headache, maximum patients (95.33%) were having *Shirogaurava* followed by others. The intensity of headache was Severe in 90.66% of patients. Maximum patients (36.66%) were having chronicity of >5 years. Maximum patients (88.66%) were having gradual onset of headache. The duration 3-6 hours per day of headache was seen maximum i.e., 62.66%. Regarding frequency, the episode at an interval of ≤ 5 days was seen maximum i.e., 51.33%. Maximum patients (84.66%) were found to be having continuous nature of headache. This shows that majority of the patients either have never consulted a doctor or have stopped doing so, which suggests the chronicity of disease. It was observed that patients rely on painkiller without any medical advice given by physician, in a hope to get rid of the headache quickly. But it was not going to stop the pathology. And the patients, who were taking anti-migraine drugs, were not responding. This results in chronic migraines i.e., rebound or transformed migraine headache.

The maximum *Nidanas* (etiological factors) observed in patients were *Amla Aahara* (85.33), *Lavana Aahara* (77.33%), *Samshana* (30.00%), *Adhyashna* (24.66), *Vishamashana* (17.33%), followed by *Ratrijagarana* 53.33% and *Diwaswapa* 71.00%. This shows faulty lifestyle, which is accepted by today's generation. Intake of junk food, taking food at any time, fasting habits of females, etc lead to *Agnimandhya* and *Tridosha Dushti*, which contributes chiefly in the pathogenesis of the disease. Also tyramine and other amines present in today's junk and sour-spicy food causes dilation of the nerves in the brain, resulting in a rush of blood. Similarly *Ratrijagarana* (53.33) and *Diwaswapa* (71.33) aggravate *Vata* and *Kapha Dosha* respectively. Also disturbed sleep was observed in maximum patients i.e., 90.00%. Disturbances such as sleep deprivation, too much sleep, poor quality of sleep and frequent awakening at night are associated with both migraine and tension headaches, whereas improved sleep habits helps in reducing the frequency of migraine headaches. Sleep also has been reported to shorten the duration of migraine headaches.

Environmental factors, like *Dhupa* (58.00%), *Dhuli* (36.66%), *Dhuma* (26.00%) causes the *Atiyoga* of *Indriyas* and serves as a triggering factor. Female's emotional nature, the responsibilities of the family were the cause of mental factors such as *Chinta* (88.66%), *Krodha* (64.00%) and *Shoka* (06.00%).

Wrong food and Sunlight were observed as maximum triggering factor i.e., 95.33% and 88.66% respectively. Bright lights and other high intensity visual stimuli can cause headaches in healthy subjects as well as patients with migraine headaches, but migraine patients seem to have a lower than normal threshold for light-induced pain. Sunlight, television and flashing lights all have been reported to precipitate migraine headaches.

Noise & air pollution was observed in 82.00%. Emotional (68.66%) and physical stress (74.66%) also acts as triggering factor. This may lead to *Dhatukshaya* and vitiation of *Vata Dosha.* Journey (74.66%) served as triggering factor because it also leads to vitiation of *Vata Dosha*. Fasting habits (60.66%) served as triggering factor because it possibly may precipitate migraine headaches by causing the release of stress-related hormones and lowering blood sugar.

Effect of therapies on signs & symptoms

Regarding effect of therapy on Chief complaints, group A showed significant results. Statistically highly significant (<0.001) improvement in severity (84.61%), duration (76.92%) and frequency (86.20%) of headache was obtained. Regarding effect of therapy on Chief complaints in group B statistically significant (<0.01) improvement in severity (77%) and highly significant (<0.001) improvement in frequency (75%) of headache. There was statistically insignificant improvement in severity (13%), duration (14%) and frequency (18%) of headache in group C. There was statistically significant (P<0.01) improvement in severity (75%) and frequency (70%) of headache in group D. TABLE NO. 1, 2, 3, 4.

Effect of therapy on other chief complaints showed that in group A reduction of Nausea (*Hrillas*) 87.50% is statistically highly significant (P<0.001).Reduction of Vomiting (*Chhardi*) 89.28% is statistically highly significant (P<0.001).Reduction of Vertigo (*Bharma*) 84.37% is statistically highly significant (p<0.001). Reduction of Aura 81.81% is statistically significant (p<0.01). Reduction of Nausea (*Hrillas*) 66.66% is statistically significant (P<0.01).Reduction of Vomiting (*Chhardi*) 76% is statistically highly significant (P<0.001).Reduction of Vertigo (*Bharma*) 66% is statistically significant (p<0.01) in group B. All the complaints are statistically insignificant at the level of P>0.10 and P>0.05 in group C. There was statistically significant (P<0.01) improvement in severity (75%) and frequency (70%) of headache in group D. TABLE NO. 5, 6, 7, 8.

Total effect of therapy:

The overall effect of therapy showed that in Group A 38% patients cured and 36% patients got marked improvement. In Group B 46.67% patients moderately improved and 35.55% patients marked improved. In Group C 90% patients unchanged. In Group D 48.89% patients moderately improved and 28.89% patients marked improved. FIGURE NO. 2

The pharmacodynamics of the drug depends on its physiochemical properties, which include *Rasa*, *Guna*, *Virya*, *Vipaka*, *Prabhava*, etc. The mode of action of the therapy can be inferred through the relief best owed by the therapy on the exhibited symptomatology.

Chikitsa is the elimination of *Samprapti*-Pathogenesis(6). Thus the therapy selected should provide positive effect on that particular disease, presumably by acting through the alleviation of *Samprapti* which is the resultant of various deranged humours and their interactions.

Probable mode of action of *Laghu Sutashekhara Rasa*:

Action at Doshic level:

The *Snigdha Guna* (28.57%), *Madhura Vipaka* (66.67%), *Madhura Rasa* (20%) and *Ushna Virya* (66.67%) present in *Laghu Sutashekhara Rasa* tablet pacify the *Vata Dosha*.

Ruksha Guna (14.29%), *Kashaya Rasa* (20%), *Madhura Rasa* (20%) and *Tikta Rasa* (20%), *Madhura Vipaka* (66.67%) and *Sheeta Virya* (33.33%) pacify the *Pitta Dosha*.

Laghu Guna (14.29%), *Tikshna Guna* (14.29%), *Ruksha Guna* (14.29%), *Katu Rasa* (40%), *Tikta Rasa* (20%), *Kashaya Rasa* (20%), *Katu Vipaka* (33.33%) and *Ushna Virya* (66.67%) pacify the *Kapha Dosha*.

Action at Panchabhautika level:

Vayu (40%) and *Agni* (20%) *Mahabhoota* are present maximum in *Laghu Sutashekhara Rasa* compound drug. *Vayu* due to its *Chalatva* works as a media in *Urdhavaga Pravriti* and its *Laghutava* enhances the function of *Agni Mahabhoota*. Thus *Deepana – Pachana Karma* is also seen at *Bhautika* level.

Prithvi (20%), *Jala* (10%) and *Akasha* (10%) provide nourishment at *Bhautika* level due to their *Balya*, *Snehana* and *Mardavakara Karma* respectively.

The compound drug is thus having *Shothahara*, *Vedanasthapana*, *Deepana*, *Pachana*, *Sheeta prashamana* and *Tridosha Shamaka Karma*.

Probable mode of action of Brihat Dashmoola Taila Nasya:

Action at Doshic level:

The *Snigdha Guna* (11.29%), *Guru Guna* (9.68%), *Madhura Vipaka* (33.33%), *Madhura Rasa* (18.37%), *Lavana Rasa* (4.08%) and *Ushna Virya* (85.18%) present in *Brihat Dashamoola Taila* pacify the *Vata Dosha*.

Ruksha Guna (27.42%), *Kashaya Rasa* (14.29%), *Madhura Rasa* (18.37%) and *Tikta Rasa* (28.57%), *Madhura Vipaka* (33.33%) and *Sheeta Virya* (3.70%) pacify the *Pitta Dosha*.

Laghu Guna (35.48%), *Tikshna Guna* (12.90%), *Ruksha Guna* (27.42%), *Katu Rasa* (34.69%), *Tikta Rasa* (28.57%), *Kashaya Rasa* (14.29%), *Katu Vipaka* (66.67%) and *Ushna Virya* (85.18%) pacify the *Kapha Dosha*.

Action at Panchabhautika level:

Vayu (38.78%) and *Agni* (19.39%) *Mahabhoota* are present maximum in *Brihat Dasahmoola Taila*. *Vayu* due to its *Chalatva* works as a media in *Urdhavaga Pravriti* and its *Laghutava* enhances the function of *Agni Mahabhoota*. Thus *Deepana – Pachana Karma* is also seen at *Bhautika* level.

Jala (9.18%) *Mahabhoota* has *Kledana* and *Bandhana Karma*, which acts as a binding agent and *Akasha* (14.29%) *Mahabhoota* provides proper space for the process.

Prithvi (18.37%) *Mahabhoota* is having *Sanghataka* and *Adhogamana Karma*. Hence it takes back the already expelled morbid *Dosha*s with an aim to remove them from the micro-channels.

Most of the contents in *Brihat Dashmoola Taila* are having *Shothahara*, *Vedanasthapana*, *Deepana*, *Pachana* and *Tridosha Shamaka Karma*.

Probable mode of action of *Go-Ghrita Nasya*:

Ghrita is supreme in *Jangama Sneha* and is *Balavardhaka*, *Ojovardhaka*, *Vayasthapana*, *Agni Deepana* and *Dhatuposhaka*. By virtue of its *Sanskaranuvartana* property, it attains the properties of ingredients without losing its own. According to *Acharya Charaka, Ghrita* is effective in subsiding *Pittaja* and *Vataja* disorders; it improves *Dhatus* and is overall booster for improving *Ojas*(7). *Ghrita* having *Balya*, *Brimhana*, *Rasayana* and *Medhya* effect which can be explained by two ways. Digestion, absorption and delivery to the target organ are made easy when any drug is processed with *Ghrita* due to its lipophilic action. Anti-oxidant effect of *Go-Ghrita* is due to its Vitamin A and Vitamin E content(8).

Conclusion:

Patients from 31-40 yrs of age group, females, housewives, married and middle class people were more

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prone to Migraine. Migraine sufferers had gradual onset with severe intensity and unilateral episodic pain with continuous rhythm. Triggering factors described in modern texts are the *Nidanas* mentioned by our ancient *Acharyas*. *Laghu Sutashekhara Rasa* is more effective than *Brihat Dashamoola Taila Nasya* and *Go Ghrita Nasya*. *Laghu Sutashekhara Rasa* is having significant improvement on all the parameters like *Shirahshoola*, *Hrillas*, *Chhardi* and on other associated symptoms of the disease *Ardhavabhedaka.*

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FIGURE NO. 1: GENERAL OBSERVATIONS (n=150):

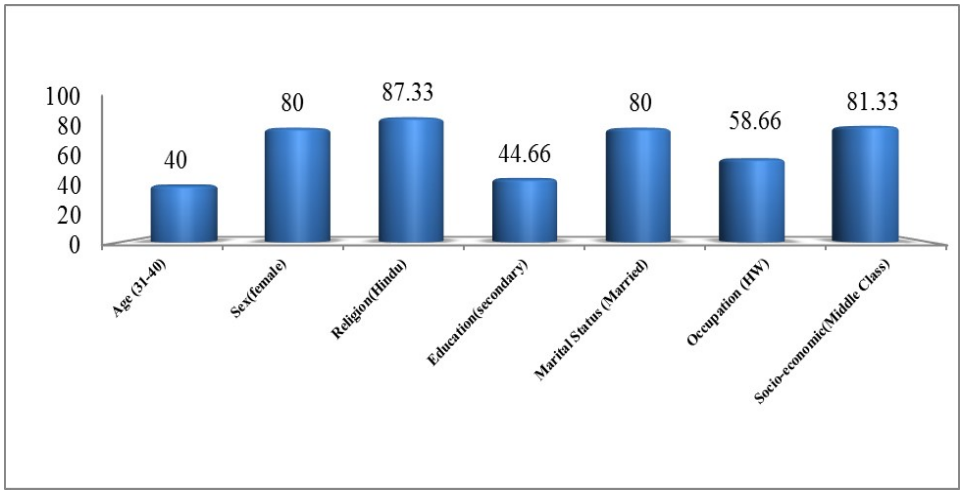

FIGURE NO. 2: OVERALL EFFECT OF THERAPY:

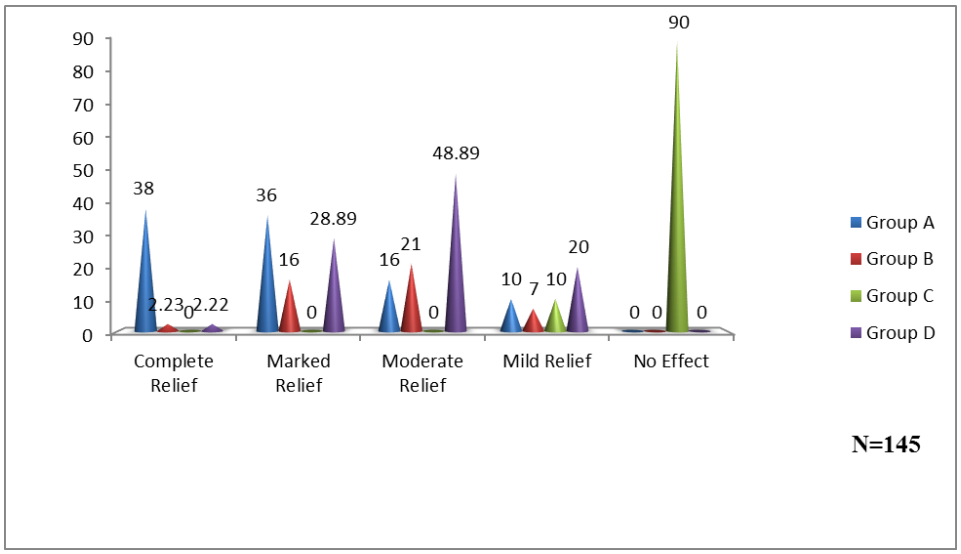

TABLE – 01: EFFECT ON HEADACHE (CHIEF COMPLAINT) IN 50 PATIENTS OF ARDHAVABHEDAKA IN GROUP A.

Headache	Mean		% of relief	S.D. ±	S.E. ±	T	P
	B.T.	A.T.					
Severity	02.60	0.4	84.61	0.141	0.044	4.90	<0.001
Duration	01.30	0.3	76.92	0.091	0.028	3.46	<0.01
Frequency	02.90	0.4	86.20	0.117	0.037	6.70	<0.001

TABLE – 02: EFFECT ON HEADACHE (CHIEF COMPLAINT) IN 45 PATIENTS OF ARDHAVABHEDAKA IN GROUP B.

Headache	Mean		% of relief	S.D.	S.E.	T	P
	B.T.	A.T.					
Severity	2.2	0.5	77.27	0.153	0.048	3.51	<0.01
Duration	1.0	0.5	50.00	0.052	0.016	3.00	<0.05
Frequency	2.8	0.6	78.87	0.141	0.044	4.90	<0.001

Table – 03*:* EFFECT ON HEADACHE (CHIEF COMPLAINT) IN 10 PATIENTS OF *ARDHAVABHEDAKA* IN GROUP C.

Headache	Mean Score		%	S.D. ±	S.E. ±	't'	P
	B.T.	A.T.					
Severity	2.2	1.9	13.63	0.048	0.015	1.96	>0.05
Duration	2.1	1.8	14.28	0.042	0.013	1.55	>0.10
Frequency	2.2	1.8	18.18	0.069	0.022	1.80	>0.10

TABLE – 04*:* EFFECT ON HEADACHE IN 45 PATIENTS OF *ARDHAVABHEDAKA* IN GROUP D

Headache	Mean Score		%	S.D. ±	S.E. ±	't'	P
	B.T.	A.T.					
Severity	1.6	0.4	75.00	0.091	0.029	4.12	<0.01
Duration	1.2	0.7	41.66	0.052	0.016	3.00	<0.05
Frequency	2.0	0.6	70.00	0.102	0.032	4.33	<0.01

TABLE – 05: EFFECT ON OTHER CHIEF COMPLAINTS IN 50 PATIENTS IN GROUP A.

Symptoms	Mean		% of relief	S.D. ±	S.E. ±	T	P
	B.T.	A.T.					
Hrillas (Nausea)	2.4	0.3	87.50	0.087	0.027	7.58	<0.001
Chhardi (Vomiting)	2.8	0.3	89.28	0.117	0.037	6.70	<0.001
Bhrama (Vertigo)	3.2	0.5	84.37	0.170	0.053	5.01	<0.001
Purvabhasa (Aura)	2.2	0.4	81.81	0.125	0.039	4.54	<0.01

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TABLE – 06: EFFECT ON OTHER CHIEF COMPLAINTS IN 15 PATIENTS OF ARDHAVABHEDAKA IN GROUP B.

Symptoms	Mean		% of relief	S.D.	S.E.	T	P
	B.T.	A.T.					
Hrillas (Nausea)	2.4	0.8	66.66	0.119	0.037	4.22	<0.01
Chhardi (Vomiting)	2.5	0.6	76.00	0.104	0.033	5.72	<0.001
Bhrama (Vertigo)	1.9	0.6	68.00	0.127	0.040	3.22	<0.01
Purvabhasa (Aura)	0.5	0.2	60.00	0.048	0.015	1.96	>0.05

Table – 07: EFFECT ON CHIEF COMPLAINTS IN 10 PATIENTS OF ARDHAVABHEDAKA IN GROUP C.

Chief Complaints	Mean Score		%	S.D. ±	S.E. ±	't'	P
	B.T.	A.T.					
Hrillas (Nausea)	1.8	1.6	11.11	0.042	0.013	1.50	>0.10
Chhardi (Vomiting)	1.2	1.0	16.66	0.025	0.008	2.44	>0.05
Bhrama (Vertigo)	1.6	1.4	12.50	0.034	0.011	1.80	>0.10
Purvabhasa (Aura)	1.4	1.1	21.42	0.042	0.013	2.25	>0.05

Table – 08: EFFECT OF GROUP D DRUG ON CHIEF COMPLAINTS IN 45 PATIENTS OF ARDHAVABHEDAKA

Chief Complaints	Mean Score		%	S.D. ±	S.E. ±	't'	P
	B.T.	A.T.					
Hrillas (Nausea)	2.1	0.8	66.66	0.124	0.039	3.56	<0.01
Chhardi (Vomiting)	2.0	0.6	70.00	0.102	0.032	4.33	<0.01
Bhrama (Vertigo)	1.2	0.5	58.00	0.094	0.030	2.33	<0.05
Purvabhasa (Aura)	0.5	0.3	40.00	0.042	0.013	1.50	>0.10

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