

# A pilot study on clinical efficacy of *Agnikarma* and *Pathyadi* decoction (an Ayurvedic formulation) in the management of *Ardhavabhedaka* (migraine)

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## Abstract

**Introduction:** *Ardhavabhedaka* described under *Shiroroga* (disease of the head in Ayurveda) occurs due to vitiation of *Tridosha* (all of three biological humors). The signs and symptoms of migraine can be correlated with *Ardhavabhedaka*. Looking to the agony caused during acute episode of migraine and unavailability of specific management and only symptomatic management in conventional medicine this study was conducted. *Agnikarma* is indicated in severe pain and *Pathyadi* decoction is indicated in the management of *Shiroroga*. **Aim and Objective:** The aim of this study was to evaluate the efficacy of *Agnikarma* and *Pathyadi* decoction in the management of *Ardhavabhedaka* (migraine). **Materials and Methods:** A total of 15 patients were selected from outpatient department of Ayurveda College. *Agnikarma* was done on affected temporal side of face, dot type for 1 time, once in a week followed by application of honey–Ghee. Along with this, *Pathyadi* decoction 40 ml twice a day for 30 days was also given. **Results:** Statistically highly significant relief ( $P < 0.001$ ) was noted in headache, photophobia and phonophobia and statistically significant ( $P < 0.05$ ) relief was noted in vomiting, nausea and vertigo. **Conclusion:** *Agnikarma* along with *Pathyadi* decoction can be considered as an effective line of treatment to manage *Ardhavabhedaka* (migraine).

**Keywords:** *Agnikarma*, *Ardhavabhedaka* (migraine), *Pathyadi* decoction

## Introduction

*Ardhavabhedaka* is one of the *Shiroroga* (disorder of head) which can be correlated with migraine having symptoms like paroxysmal unilateral (half cranial) headache sometime associated with vertigo, nausea, photophobia and phonophobia. As per *Acharya Sushruta* *Ardhavabhedaka* occur due to vitiation of *Tridosha* (*Vata – Pitta – Kapha*).<sup>[1]</sup> While *Acharya Charaka* had mentioned that vitiated *Vata/Vata - Kapha* are involved in manifestation of *Ardhavabhedaka*,<sup>[2]</sup> while *Acharya Vagbhatta* believed that *Ardhavabhedaka* occurs due to vitiated *Vata*.<sup>[3]</sup>

According to International headache society, migraine is the most common neurovascular headache and is a common disabling primary headache disorder. It is now recognized as a chronic illness, not simply as headache. Migraine headache often limited the degree to which headache sufferers could engage in regular activities.<sup>[4]</sup> In the global burden of disease

survey 2010, it was ranked as the third most prevalent disorder and 7<sup>th</sup> highest specific cause of disability worldwide.<sup>[5]</sup> The world health organization (WHO) ranks migraine among the world's most disabling medical illness. It is three times more common in women than men.

As per Ayurveda, 'pain can not occur without involvement of *Vata Dosha*'.<sup>[6]</sup> *Agnikarma* (local cauterization) having *Ushna* (hot), *Tikshna* (penetrating) property may pacify the aggravated *Vata Dosha* and thus, *Agnikarma* can be beneficial in *Ardhavabhedaka*. Furthermore, *Agnikarma* is easy and quick procedure to perform and also effective. Thus, *Agnikarma* has been selected as the choice of treatment procedure in this trial.

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*Pathyadi* decoction<sup>[7]</sup> is mentioned in *Sharangdhara Samhita*, especially in the management of *Shiroroga*. This decoction has ingredients having *Ushna Virya* (hot potency) and *Vata Shamaka* (*Vata* subsiding) property which can be beneficial in *Ardhavabhedaka* as this disease has dominancy of vitiation of *Vata* and *Kapha Dosha*, dominancy. Further it is also being widely practiced to manage *Shiroroga*.

### Aim and objectives

The aim of this study is to evaluate the efficacy of *Agnikarma* and *Pathyadi* decoction in the management of *Ardhavabhedaka* (migraine).

## Materials and Methods

### Patients

- In the present study, 15 patients fulfilling the criteria for diagnosis of *Ardhavabhedaka* (migraine) were selected from the outpatient department of Shalakyatantra Govt. Akhandanand Ayurveda college, Ahmedabad, Gujarat, India.

### Drug

*Pathyadi* decoction was procured from Government Ayurved Pharmacy, Rajpala, Gujarat, India.

The research protocol was approved by the Institutional ethics committee (Certi. No. 28; date: 25/06/2016) and registered in clinical trial registry of India vide CTRI/2017/01/007845. Informed consent from each enrolled patient was obtained before commencement of the treatment.

### Diagnostic criteria

- The diagnosis was made on following criteria of migraine.
  - At least 5 episode of headache, in past history fortnightly or at 10 days interval or random occurrence (*Pakshahat (madrosis)–Dashahat–Akmatprvartate*)
  - Headache episode lasting for 4–72 h
  - Headache has at least 2 or 3 of the following four characteristics.
    - Unilateral location
    - Pulsating quality
    - Moderate or severe pain intensity
    - Aggravation by or leading to avoidance of routine physical activity (e.g., walking or climbing stairs).
  - During headache at least one of the following:
    - Nausea or vomiting
    - Photophobia and or phonophobia.

### Inclusion criteria

Patients fulfilling the diagnostic criteria of either sex having age between 16 to 70 years and willing to participate and provide consent were included.

### Exclusion criteria

- Patients not eligible for *Agnikarma* as per Ayurvedic texts
- Referred pain in one half of the head due to disorder of eye, ear, nose, throat, teeth etc.
- Patients having migraine other than Migraine without Aura

- Patients suffering from diabetes, tuberculosis, hypertension, malignancy, any other general debilitating health condition, needing surgical intervention (polyp etc.) or patients who were on any other medications which may interfere with trial treatment.

### Examinations

- Vitals examination – Pulse, temperature, blood pressure, respiration and general examination of eye, ear, nose, throat, head and oral cavity was done before initiating the treatment.
- Investigations were carried out before treatment like routine hematological tests complete blood count (CBC), bleeding time (BT), clotting time (CT).

### Treatment trial

All the patients ( $n = 15$ ) were administered treatment trial as follow.

*Agnikarma*.<sup>[8]</sup>

Equipment: *Panchdhatu Shalaka* [made up of *Tamra* (copper), *Loha* (iron), *Yashada* (zinc), *Rajata* (silver), *Vanga* (lead)] [Figure 1]

- Schedule: 4 schedules at the interval of 7 days
- Type: *Bindu* (Dot type) (1 time) (dimension – 2–3 mm) [Figure 2]
- Time: Morning (after breakfast)
- Site:<sup>[9]</sup> *Bhru–Lalat–Shankha Pradesha* (Temporal area of the face of affected side) [Figure 2]
- Precautions: Patients were asked to have light meal before *Agnikarma*.
- Pre–procedure: Before *Agnikarma*, site was cleaned with warm water swab to avoid any possibility of infection. *Agnikarma Shalaka* was heated on gas stove till red hot. Mixture of Honey – *Ghrita* in unequal quantity was kept ready.
- Procedure: Patient was asked to lie in lateral side, affected side facing upward. Most tender point was elicited and marked on temporal side of face. With red hot *Shalaka*, a small dot type burn (diameter 2–3 mm), till *Twaka Dagdha* (superficial burn) was done



Figure 1: *Agnikarma Shalaka* (instrument used for *Agnikarma*)



**Figure 2:** *Agnikarma*: Site of performing of *Agnikarma*

- Post-Procedure: immediately after burn, mixture of honey (1 ml)– *Ghrita* (2 ml) (unequal quantity) was applied to that site
- Instructions: After *Agnikarma*, patients were instructed to avoid washing that part for 24 hours to avoid any infection. After *Agnikarma*, all the patients were asked to apply mixture of honey – *Ghrita* 2 times a day for next 7 days for better wound healing effect.
- *Pathyadi* decoction<sup>[6]</sup> was given in the dose<sup>[10]</sup> of 40 ml, [Table 1]. Time of intake was 2 times/day, morning and evening (empty stomach) for 30days (along with *Agnikarma*).

Preparation<sup>[11]</sup> for *Pathyadi* decoction to this patient was given 20 gms of coarse powder of *Pathyadi* decoction and instructed to soak that powder overnight in 320 ml of water. Next morning, patient was instructed to boil that mixture till quantity was reduced to 40ml. then it should be filtered and drink while it is luke warm.

### Assessment criteria

- Symptoms of *Ardhavabhedaka* were given gradations as per the severity
- Headache was graded according to HIT-6 [Headache impact test– 6] (annexure 1)
- Results were assessed before and after the treatment on the basis of change in the grade.

### Assessment of overall effect of therapy

- Overall effect of therapy was assessed in terms of complete remission if 100% improvement in symptoms and no recurrences during the follow-up period was observed. When improvement in symptoms was between 75% and 100%, it was considered as marked improvement and as moderate improvement when the improvement in symptoms was between 50% and 75%. Mild improvement when the improvement in the symptoms was between 25% and 50%. Changes up to 25% were taken as no change.

### Statistical analysis

Obtained data of before and after treatment was analyzed statistically with Wilcoxon signed rank test by using Sigma

**Table 1: Ingredient of *Pathyadi* decoction**

No.	Drug name	Latin name	Part used	Proportion
1	<i>Pathya</i>	<i>Terminalia chebula</i> Retz.	Fruit	1 part
2	<i>Aksha</i>	<i>Terminalia bellirica</i> Roxb.	Fruit	1 part
3	<i>Dhatri</i>	<i>Embelica officinalis</i> Gaertn.	Fruit	1 part
4	<i>Bhunimba</i>	<i>Andrographis paniculata</i> Burm.	Whole plant	1 part
5	<i>Nisha</i>	<i>Curcuma longa</i> Linn.	Tuber	1 part
6	<i>Nimba</i>	<i>Azadiracta indica</i> Linn.	Stem bark	1 part
7	<i>Amruta</i>	<i>Tinospora cardifolia</i> (willd.)	Stem	1 part

Stat, Ver-3.5 (2007), by Systat Software Inc., San Jose, California.

### Observation

In the present study, one patient dropped out due to migration to other state. In present clinical trial, maximum number of patients, i.e. 66.67% patients belonged to age group of 31–40. 60% of patients were female, 46.67% were homemakers, 80% were Hindu, 93.33% were married, 20% of patients had education till graduation, 60% of patients were from middle class, 40% of patients were having moderate appetite, 66.67% patients were having regular defecation, 53% of patients having *Vata-Pitta Sharirika Prakriti* (physical constitution) and 53% of patients were having *Tamasika Manasa Prakriti* (psychological status).

In the present study, upon observing the etiological factors of *Ardhavabhedaka*, it was found that maximum number of patients were having *Vishamashana* (taking food irrespective of time/hunger) that is, 47%; while 33% of patients were doing *Adhyashana* (having food before digestion of previous meal) and 20% of patients had dominancy of *Lavana Rasa* (salty) in the regular food.

By further analysis, it was observed that 100% of patients had headache, 60% of patients had nausea, 46.67% of patients had vomiting, 20% had vertigo, 86.67% of the patients complained of photophobia and 93.33% of patients had phonophobia.

### Results

- The present trial drugs provided highly significant ( $P < 0.001$ ) result in headache, nausea, vomiting, vertigo and photophobia [Table 2]. No any complication of the procedure or adverse drug reaction was found during this trial.

### Effect of therapy on sign and symptoms

In headache, 72.22% relief was found which was statistically highly significant at the level of  $P < 0.001$ . In *Hrillasa* (nausea), 100% relief was found and the result was statistically significant at the level of  $P = 0.004$ . In *Chhardi* (vomiting),



**Table 2: Effect of therapy**

Symptoms	n	Mean score		Mean difference	Percentage relief	W	P	Significance
		BT (%)	AT					
Headache	14	3.86	1.07	2.79	72.22	105	<0.001	HS
Nausea	9	1	0	1	100	45	0.004	S
Vomiting	7	1	0	1	100	28	0.016	S
Vertigo	3	1	0	1	100	28	0.016	S
Phonophobia	13	1	0	1	100	91	<0.001	HS
Photophobia	12	1	0	1	100	78	<0.001	HS

BT: Before treatment, AT: After treatment, S: Significant, HS: Highly significant, n: sample size

100% relief was found, the result was statistically significant at the level of  $P < 0.016$ . In *Bhrama* (vertigo), 100% relief was found, which was statistically significant at the level of  $P < 0.016$ . In *Shabda Asahishnuta* (phonophobia), 100% relief was found, which was statistically highly significant at the level of  $P < 0.01$ . In *Prakasha Asahishnuta* (photophobia), 100% relief was found, which was statistically highly significant at the level of  $P < 0.01$ .

### Overall effect of therapy

- On analyzing overall effect of therapy; maximum number of patients had marked improvement, that is, 11 (78.6%); 2 (14.3%) patient had complete remission while 1 (7.14%) patient had moderate improvement [Table 3].

### Discussion

In present study *Shirah-Shoola* (headache) was taken as chief complaint and 100% patients had headache. Along with headache there were associated complaints like nausea, vomiting, vertigo, phonophobia and photophobia.

Among these nausea and vomiting indicated vitiation of *Rasavaha Srotasa* in manifestation of *Ardhavabhedaka*. While *Bhrama* is one of the features of vitiated *Vata* and *Pitta Dosha*. photophobia and phonophobia is not specified as symptoms in *Ardhavabhedaka*, but is the progressive stage of disease, loss of vision and hearing impairment (*Nayana* and *Shravana Vinashyet*) may be present as complication. Hence, photophobia and phonophobia may be considered as systemic manifestations of the disease.

In the present study, in Headache, 72.22% ( $P < 0.001$ ) relief and 100% relief in nausea, vomiting, vertigo, phonophobia and photophobia was found. Three patients (21.43%) had the recurrence of headache at the end of the course but severity, duration and frequency were decreased significantly. All these patients had to take analgesic medicine before treatment but after treatment none of the patients had to take analgesics for the same.

### Probable mode of action of Agni Karma

Heat is often used to relieve pain in many diseases, however, the exact mode of its action and mechanism is not clearly understood.

According to Ayurveda, *Agni* has *Ushna Guna*. This *Ushna Guna* gets transferred to *Twaka* (skin) by *Agnikarma*. This

**Table 3: Overall effect of therapy**

Effect of therapies	Number of patient	Percentage
Complete remission	2	14.3
Markedly improved	11	78.6
Moderately improved	1	7.14
Mild improvement	0	0
No change	0	0

*Guna* normalises *Vata* and *Kapha*. This might have helped to reduce *Shira – Shoola* in *Ardhavabhedaka*.

The local thermos therapy may increase tissue metabolism and toxins. Heat may stimulate lateral spinothalamic tract which leads stimulation of descending pain inhibitory fibers which release endogenous opioid peptide which binds with opioid receptors at substantia gelatinosa rolandi which inhibit release of P-substance (Presynaptic inhibition) and blockage of transmission of pain sensation occur.<sup>[12]</sup>

Heat has also been claimed to act as a counter irritant. It has been suggested that such responses might be explained on the basis of the pain gate control theory. In this theory, it is believed that nociceptor fibers residing in the superficial skin get stimulated by heat. These fast-acting fibers after activating, close the gate for slow-acting fibers for chronic pain.<sup>[13]</sup>

### Probable mode of action of Pathyadi decoction

This formulation is a multidrug combination and is indicated specially in *Shiroroga* in *Shrangdhara Samhita*.<sup>[6]</sup> It contains 67% *Dravya* with *Ushna Virya* (hot potency) and *Madhura Vipaka* (sweet post digestion effect) 43% drugs are *Tridoshaghna* (all three *Dosha* pacification). So by all virtues cited above, it normalizes the vitiated *Vata-Kapha Dosha*. In addition, *Pathyadi* decoction contains drugs such as *Guduchi* [*Tinospora cordifolia* (willd.)], *Nimba* [*Azadiracta indica* Linn.], and *Haridra* [*Curcuma longa* Linn.] possessing *Raktaprasadaka* (blood purifier) property that may normalize vitiated *Rakta Dhatu* (oxygen carrying capacity of blood). Drugs such as *Guduchi* [*Tinospora cordifolia* (willd.)] and *Amalaki* [*Embelica officinalis* Gaertn.] have *Dipana* (appetizing) property. These drugs will normalize *Ama* (by product toxins after digestion), as *Ama* get decreased it may subside *Ajirna* (Indigestion).

It is reported that most of the drugs of *Pathyadi* decoction also possess analgesic, anti-inflammatory, a nervine tonic property which might have helped to reduce pain.

## Conclusion

*Agnikarma* and *Pathyadi* decoction provided significant relief in the symptoms of *Ardhavabhedaka* (migraine). *Agnikarma* has provided significant relief in pain, whereas, *Pathyadi* decoction may have acted on systemic symptoms such as nausea, vomiting and vertigo.

Thus *Agnikarma* and *Pathyadi* decoction therapy are effective in the management of *Ardhavebhedaka* (migraine). Further research work on *Agnikarma* as pain management should be done on large sample size.

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## Conflicts of interest

There are no conflicts of interest.

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O.D.D/I.P.D.

DATE:

**HIT-6™ Headache Impact Test**

(To complete, please circle one answer for each question.)

1. When you have headaches, how often is the pain severe?



Never

rarely

sometimes

very often

always

2. How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?



Never

rarely

sometimes

very often

always

3. When you have a headache, how often do you wish you could lie down?



Never

rarely

sometimes

very often

always

4. In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?



Never

rarely

sometimes

very often

always

5. In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?



Never

rarely

sometimes

very often

always

6. In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?



Never

rarely

sometimes

very often

always






COLUMN 1

COLUMN 2

COLUMN 3

COLUMN 4

COLUMN 5

6 points each

8 points each

10 Points each

11 Points each

13 Points each