A Clinical Study of Badara Ghrita in the Management of Ardhavabhedaka w.s.r. to Migraine

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Abstract
Shira is considered as Uttamanga i.e. that where vital breath of living beings and also all the sense organs are located and which is supreme of all organs. In modern science, Ardhavbhedaka can be correlated with Migraine. The present study was conducted to evaluate the effect of Badaraadi Ghrita in the management of Ardhavabhedaka w.s.r to migraine. Total 20 patients were registered in a two groups out of them 18 patients completed the trial. The trial was conducted for 30 days and effects of drug was evaluated. The analysis based on subjective improvements reveals that 9 patients of Group - I, 4 patients were moderately improved while 5 patients were highly improved. In Group - II, 3 patients were moderately improved while 6 patients were highly improved. No adverse effect was seen during the trail and in the follow up as well. The study revealed that Badaraadi Ghrita plays a vital role in the management of Ardhavabhedaka w.s.r to Migraine.

Keywords: Ardhavabhedaka, Badaraadi Ghrita, Migraine

Introduction:-
The word Ardhavabhedaka has two components viz. Ardha and Avabhedaka. Ardha means half side, Ava suggest bad prognosis, Bhedaka means breaking through, perforating or bursting out type of pain. In this, pain affects half region of the head. Role of Agni-dusti, Manah-santapa, Rodana, Shoka, Bhaya etc. psychological factors have been emphasized in the etiopathogenesis of this condition. Ardhavabhedaka can be correlated with Migraine which is characterized mostly by the pain on one side of the head. It is associated with some features like nausea, vomiting, sensitivity to light, sound etc.

Migraine is the most common severe form of primary headache affecting the people of age group 16-65 and can cause significant disability. It is three times more common in women than in men. The world health organization (WHO) ranks migraine in its top 20 disabling conditions for women aged 15-44. This result in greater societal burden as the sufferer remains absent from the work. Generally, traditional medicine focus on pain relief, but the main objective of Ayurvedic diagnosis is to find the root cause and eliminate it through changes in life style (Dincharya), diet (Ahara) and keeping the Agni & Doshas in balance. Life style management like proper Diet and Sleep, Exercises, Yoga & Pranayam, following Ayurvedic Ritucharya, Ratricharya, Dincharya and Sadvritta etc. formulations like Ashwagandha, Pravalapishthi, Giloya satva, Pathyadi kwath, Shirah shuladi vajra rasa are effective. All Shiro-rogas are due to tridosha prakopa and chiefly due to Vata or Vata- Kapha. Thus, Ardhavabhedaka, a sadhya type of Shiro-roga can be best managed with ausadhis having Ushna, Snigdha, etc. Vatahara or Vata-Kaphahara properties. Badara Ghrita is having Vatanashaka, Kaphanashaka and Vedanaisthapaka i.e. pain relieving properties Hence, for present study Badara Ghrita having mainly Kaphavaata hara, properties have been selected. Also Ghrita efficacy is more as compared to other variety of Snehana dravyas.

Aims And Objectives:
- To explore the literature pertaining to Ardhavabhedaka in different Ayurvedic Samhitas and migraine in modern literatures.
- To compare the effect of Badar Ghrita Nasya and paana in the management of Ardhavabhedaka.
To assess the effect of Badar Ghritam Nasya and paana in the disease Ardhavabhedaka.
To develop cost effective Shalakya therapy in the management of Ardhavabhedaka.

Materials and Methods

Clinical study: Twenty patients with classical signs and symptoms of Ardhavabhedaka w.s.r to Migraine were selected randomly irrespective of creed and caste for the study from Shalakya Tantra OPD/IPD of R.G.G.P.G. Ayu. Hospital Paprola, IEC and Consent:- Approval from the Institutional Ethics Committee (IEC) was taken prior to begin with this study Ref. no. IEC/2015/1022 dated 16-06- 2015. Written and informed consent of the patients was taken before their registration for the study.

Criteria for Selection of Patient

Inclusion criteria
All the patients of both sex, age 16 to 65 years with typical history of migraine or hemicranias-Willinngness of the patients for the clinical trial, Episodic pain: once a week / twice week, Migraine with /without vomiting, Intensity – moderate to severe, Rhythm- continuous / intermittent, Hemicranial pain.

Exclusion Criteria
Patient not willing for trial, Childhood headache, Headache of ophthalmic origin, Menstrual headache, Headache due to cervical spondylosis, Head injury, Headache due to another case, Headache due to benign/malignant organic cause growth.

Investigations:
The following investigations were done only if found necessary Blood-Hb%, TLC, DLC, ESR, FBS, Lipid Profile. Urine- urine routine, Microscopic. MRI, CT Scan head.

Method of Study  After careful examination 20 patients of migraine will be selected from OPD/IPD of ENT unit of Shalakya Tantra. treated in two trial groups. Separate proforma will be prepared for complete assessment of patients.

STUDY DESIGN:
Selected patients were divided into 2 groups (10 patients in each group):-

- Group I  Badar Ghritam Nasya
- Group II  Badar Ghritam Nasya and Paana

1. Badar Ghrit (Nasya) – For Local Application
   ✓ Dose 6 drops every nostril
   ✓ Time Morning and Evening
   ✓ Duration 2 sittings of 7 days each with one week interval (Alternate week)

2. Badar Ghrit (Paana) – Orally
   ✓ Dose 12 gm twice a day (Orally).
   ✓ Anupana Sukhosna Gau Dugdha

Duration of Trial: - 30 days

Follow-up: Two follow ups at 10 days interval during treatment. one follow up one month after completion of trial.

Criteria for assessment of results: - Grading and scoring system was adopted for assessing each symptom before the commencement of trial and after completion of trial.

Statistical analysis:-
The information gathered regarding demographic data was given in percentage. The scoring of criteria’s of assessment was analysed statistically in terms of B.T. (before treatment), A.T. (after treatment), X (B.T. - A.T.), S.D. (Standard deviation), S.E. (Standard Error) and Paired ‘t’ test carried out at the level of p< 0.05 and p < 0.001.

Overall results were adjusted in terms of percentage relief obtained in symptoms.

- **Cured**– 100% relief in chief complaint and no reoccurrence during follow up study.
- **Markedly improved**– >75% relief in chief complaints was recorded as markedly improved.
- **Moderately improved**– 50%, <75% relief in chief complaints was considered moderately improved.
- **Mild improved**– >25%, < 50% relief in chief complaints was considered slightly improved.
- **Unchanged**– <25% relief in chief complaints was noticed as unchanged or unimproved.

Observation and Results:-

**Table 1: Effect of therapy on the Symptoms in Group-I and Group- II patients**

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Groups</th>
<th>N</th>
<th>Mean Score</th>
<th>S.D. (±)</th>
<th>S.E.</th>
<th>‘t’</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>BT</td>
<td>AT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intensity of Headache</td>
<td>I</td>
<td>9</td>
<td>3.667</td>
<td>1.111</td>
<td>0.726</td>
<td>0.242</td>
<td>10.553</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>9</td>
<td>3.444</td>
<td>1.000</td>
<td>0.527</td>
<td>0.176</td>
<td>13.914</td>
</tr>
<tr>
<td>Frequency of Headache</td>
<td>I</td>
<td>9</td>
<td>3.222</td>
<td>1.333</td>
<td>0.601</td>
<td>0.200</td>
<td>4.863</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>9</td>
<td>3.375</td>
<td>1.375</td>
<td>0.756</td>
<td>0.267</td>
<td>6.483</td>
</tr>
<tr>
<td>Duration of Headache</td>
<td>I</td>
<td>9</td>
<td>2.889</td>
<td>0.778</td>
<td>0.601</td>
<td>0.200</td>
<td>10.539</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>9</td>
<td>3.333</td>
<td>1.000</td>
<td>0.500</td>
<td>0.167</td>
<td>14.000</td>
</tr>
<tr>
<td>Nausea</td>
<td>I</td>
<td>9</td>
<td>3.333</td>
<td>1.556</td>
<td>0.441</td>
<td>0.147</td>
<td>4.962</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>9</td>
<td>3.667</td>
<td>1.667</td>
<td>0.707</td>
<td>0.236</td>
<td>6.483</td>
</tr>
<tr>
<td>Vomiting</td>
<td>I</td>
<td>9</td>
<td>3.667</td>
<td>1.556</td>
<td>0.601</td>
<td>0.200</td>
<td>10.539</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>9</td>
<td>3.111</td>
<td>1.222</td>
<td>0.601</td>
<td>0.200</td>
<td>9.430</td>
</tr>
<tr>
<td>Giddiness</td>
<td>I</td>
<td>9</td>
<td>3.111</td>
<td>1.444</td>
<td>0.500</td>
<td>0.167</td>
<td>6.658</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>8</td>
<td>2.778</td>
<td>1.222</td>
<td>0.527</td>
<td>0.176</td>
<td>4.454</td>
</tr>
</tbody>
</table>

**Table 2: Effect of therapy on the Symptoms in Inter Group Comparison**

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Group I</th>
<th>Group II</th>
<th>% D</th>
<th>S.D. (±)</th>
<th>S.E.</th>
<th>‘t’</th>
<th>P</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensity of Headache</td>
<td>9</td>
<td>9</td>
<td>1.26</td>
<td>0.673</td>
<td>0.317</td>
<td>0.353</td>
<td>&gt;0.05</td>
<td>Insignificant</td>
</tr>
<tr>
<td>Frequency of Headache</td>
<td>9</td>
<td>9</td>
<td>0.62</td>
<td>0.722</td>
<td>0.351</td>
<td>0.316</td>
<td>&gt;0.05</td>
<td>Insignificant</td>
</tr>
<tr>
<td>Duration of Headache</td>
<td>9</td>
<td>9</td>
<td>3.08</td>
<td>0.587</td>
<td>0.276</td>
<td>0.804</td>
<td>&gt;0.05</td>
<td>Insignificant</td>
</tr>
<tr>
<td>Nausea</td>
<td>9</td>
<td>9</td>
<td>1.2</td>
<td>0.625</td>
<td>0.294</td>
<td>0.755</td>
<td>&gt;0.05</td>
<td>Insignificant</td>
</tr>
<tr>
<td>Vomiting</td>
<td>9</td>
<td>9</td>
<td>3.15</td>
<td>0.406</td>
<td>0.191</td>
<td>1.162</td>
<td>&gt;0.05</td>
<td>Insignificant</td>
</tr>
<tr>
<td>Giddiness</td>
<td>9</td>
<td>8</td>
<td>2.43</td>
<td>0.545</td>
<td>0.257</td>
<td>0.432</td>
<td>&gt;0.05</td>
<td>Insignificant</td>
</tr>
</tbody>
</table>

**1.EFFECT OF THE THERAPY ON INTENSITY OF HEADACHE:**
The mean score of Intensity of Headache came down in both the groups. In Group- I, mean score before treatment was 3.667, which came down to 1.111 at end of the therapy with percentage relief of 69.7%. Statistically it was highly significant at p<0.001 after completion of therapy.
Similarly, mean score of Intensity of Headache in Group- II was 3.444, which came down to 1.000 at end of the therapy with percentage relief of 70.96%. Statistically it was highly significant at p<0.001 after completion of therapy.

Inter group comparison shows that there was no significant difference in the effect of therapy on Intensity of Headache in both the groups (p>0.05).

2.EFFECT OF THE THERAPY ON FREQUENCY OF HEADACHE:
The mean score of Frequency of Headache came down in both the groups. In Group- I, mean score before treatment was 3.222, which came down to 1.333 at end of the therapy with percentage relief of 58.63%. Statistically it was significant at p<0.01 after completion of therapy.

Similarly, mean score of Frequency of Headache in Group- II was 3.375, which came down to 1.375 at end of the therapy with percentage relief of 59.25%. Statistically it was highly significant at p<0.001 after completion of therapy.

Inter group comparison shows that there was no significant difference in the effect of therapy on Frequency of Headache in both the groups (p>0.05).

3.EFFECT OF THE THERAPY ON DURATION OF HEADACHE:
The mean score of Duration of Headache came down in both the groups. In Group- I, mean score before treatment was 2.889, which came down to 0.778 at end of the therapy with percentage relief of 73.07%. Statistically it was highly significant at p<0.001 after completion of therapy.

Similarly, mean score of Duration of Headache in Group- II was 2.1, which came down to 1.2 at end of the therapy with percentage relief of 42.85%. Statistically it was highly significant at p<0.001 after completion of therapy.

Inter group comparison shows that there was no significant difference in the effect of therapy on Duration of Headache in both the groups (p>0.05).

4.EFFECT OF THE THERAPY ON NAUSEA:
The mean score of Nausea came down in both the groups. In Group- I, mean score before treatment was 3.333, which came down to 1.556 at end of the therapy with percentage relief of 53.34%. Statistically it was significant at p<0.01 after completion of therapy.

Similarly, mean score of Nausea in Group- II was 3.667, which came down to 1.667 at end of the therapy with percentage relief of 54.54%. Statistically it was highly significant at p<0.001 after completion of therapy.

Inter group comparison shows that there was no significant difference in the effect of therapy on Nausea in both the groups (p>0.05).

5.EFFECT OF THE THERAPY ON VOMITING:
The mean score of Vomiting came down in both the groups. In Group- I, mean score before treatment was 3.667, which came down to 1.556 at end of the therapy with percentage relief of 57.57%. Statistically it was highly significant at p<0.001 after completion of therapy.

Similarly, mean score of Vomiting in Group- II was 3.111, which came down to 1.222 at end of the therapy with percentage relief of 60.72%. Statistically it was highly significant at p<0.001 after completion of therapy.

Inter group comparison shows that there was no significant difference in the effect of therapy on Vomiting in both the groups (p>0.05).

6.EFFECT OF THE THERAPY ON GIDDINESS:
The mean score of Giddiness came down in both the groups. In Group- I, mean score before treatment was 3.111, which came down to 1.444 at end of the therapy with percentage relief of 63.58%. Statistically it was highly significant at p<0.001 after completion of therapy.

Similarly, mean score of Giddiness in Group- II was 2.778, which came down to 1.222 at end of the therapy with percentage relief of 56.01%. Statistically it was significant at p<0.01 after completion of therapy.

Inter group comparison shows that there was no significant difference in the effect of therapy on Giddiness in both the groups (p>0.05).
Table 3: Overall effect of the therapy in 18 patients

<table>
<thead>
<tr>
<th>Overall Effect</th>
<th>Group- I</th>
<th>Group- II</th>
<th>Overall Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Patients</td>
<td>%age</td>
<td>No. of Patients</td>
</tr>
<tr>
<td>No Improvement</td>
<td>0</td>
<td>0 %</td>
<td>0</td>
</tr>
<tr>
<td>Mild Improvement</td>
<td>0</td>
<td>0 %</td>
<td>0</td>
</tr>
<tr>
<td>Moderate Improvement</td>
<td>4</td>
<td>44.4 %</td>
<td>3</td>
</tr>
<tr>
<td>Highly Improvement</td>
<td>5</td>
<td>55.6 %</td>
<td>6</td>
</tr>
<tr>
<td>Complete Remission</td>
<td>0</td>
<td>0 %</td>
<td>0</td>
</tr>
</tbody>
</table>

Among the 9 patients of Group- I, 4 patients were moderately improved while 5 patients were highly improved. In Group- II, 3 patients were moderately improved while 6 patients were highly improved.

DISCUSSION

Almost all the Acharayas have mentioned Ardhavabhedaka in Shiro-roga. Acharaya Sushruta has mentioned 11 types of Shiro-roga in Uttar Tantra. Among them, one of them is Ardhavabhedaka in which paroxysmal unilateral headache associated with vertigo and pain of varying intensity is seen. Ardhavabhedaka can be scientifically correlated with Migraine due to its cardinal feature “half sided headache”

Maximum Nidanas show the predominance of Vata dosha. Vata gets provoked by addiction to dry articles or excess of diet or eating on a loaded stomach. The quantity of food to be taken depends upon the power of digestion. Though even light food article, if taken in excessive quantity can produce Agnimandhya resulting in Amarasas formation which obstructs the channels and aggravates all the three doshas. The other factor exposure to eastern wind leads to constriction of blood vessels due to Sheeta Guna of Vata causing headache. Similarly suppression of natural urges obstructs the movements of Vata. Excessive sexual indulgence produces degeneration of Dhatus in reverse order. Also the various types of pain like Toda, Bheda, etc are suggestive of “Vishama” nature of Vata dosha.

The prevalence rate of the disease in India is 16-20% and the disease greatly affects the quality of life. Research indicates that migraine also increases the risk for other types of heart problems. Also the diagnosis is based only on the history narrated by patient, which is verifiable. Moreover, it has been reported that most migraines are not treated according to any expert recommendations or accepted evidence. Also WHO has ranked Migraine among the world’s most disabling medical illness. The scope for prevention of the disease in modern science is not satisfactory. Hence, an attempt has been made to study the complete aspect of disease and to find the best possible way for the betterment of mankind.

CONCLUSION

In the present research work; a detailed study of ingredients of Badara Ghrita was done in different classical literatures, modern literature and on internet. Ardhavabhedaka and Migraine was also studied in different literatures. The clinical study was done on 20 patients to observe the effect of Badara Ghrita in the management of Ardhavabhedaka w.r.t. to Migraine. The effect of therapy has been described in the Clinical Study part of the Dissertation.

On the basis of facts, observations and results, it could be concluded that:
- Continuous and drastic change in the lifestyle in the modern era is the root cause for the life style disorders like Migraine.
- In both Ayurveda and modern management, primary prevention (Nidanaprivarjanam) strategy has been given priority.
- Migraine mentioned in Modern Medicine closely resembles with Ardhavabhedaka.
The patients were strictly advised to follow the restrictions regarding food, food habits and life style. *Manya* (neck), *Bhru* (eyebrow), *Shankha* (Temporal region), *Karna* (ear), *Akshi* (eye) and *Lalata* (fore head) are the prime sites of headache in *Ardhavabhedaka*. Particularly in *Ardhavabhedaka* involvement of *Prana Vayu* is of much importance.

**References:**