STANDARDISATION OF SHALAPARNI (DESMODIUM GANGETICUM DC.) AND EVALUATION OF ITS ANTI-OXIDANT ACTIVITY WITH SPECIAL REFERENCE TO ARDHAVABHEDAKA (MIGRAINE)

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ABSTRACT

Ardhavabhedak (Migraine) is a common clinical problem characterized by episodic attacks of head pain and associated symptoms such as nausea, sensitivity to light, sound, or head movement. It is generally thought of as a headache problem, but it has become apparent inrecent years that many patients suffer symptoms from Migraine, which do not have severe headaches as a dominant symptom which is mainly due to oxidative stress. The number of people suffering with atypical forms of Migraine is unknown. Females are 3 times more likely to have Migraine than males. Although any personcan have Migraine at any age, Migraine is most common between ages 30 and 50. It isa common condition with a prevalence of 17.6% in females and 5.7% in males; however, this condition is under-treatedand under-diagnosed worldwide. Treatment of Migraine has not only medical but also serious economic and social implications. Thus, primary-care physicians should be well versed in the diagnosis and treatment of Migraine.

The objectives of the study were to standardize Shalaparni and to assess the effect of Shalaparni Kwatha and nasya alone, alongwith the Tab. Amitriptyline combined effect and Tab. Amitriptyline in the management of Ardhavabhedaka.

KEYWORDS: Ardhavabhedak, Shalaparni Kwatha, Amytryptyline, Migraine.

INTRODUCTION

Ardhavabhedak (Migraine) can be described as a complex multifactorial neurovascular brain disorder characterized by impaired information processing in the brain, as well as recurrent unilateral hemi-cranial pain occurring in attacks. The estimated prevalenceof migraine is from 12% to 16% of the population, higher in women than in men (3:1), and shows a tendency for familial occurrence. In the first decade of the 21stcentury, the possible lifetime incidence was estimated to be approximately 50% in women and approximately 20% in men. The speculated significant attention too xidative stress, understood as disturbances in the reactive oxygens pecies (ROS) production–degradationbalance. As such, this phenomenon is involved in the etiopathogenesis.of numerous diseases, such as atherosclerosis, reduced kidney function, or ischemic stroke. Shalaparni acts as rasayana**.** It possesses strong anti-oxidants like Flavanoids & Phenols. Antioxidants supplied with food prevent oxidative stress by inhibiting initiation, propagation, and the oxidative chain reaction itself. Other mechanism of action of antioxidants from food are, among others, the scavenging of free radicals, molecular oxygen quenching, and acting as reductants in oxidative reactions.

MATERIALS AND METHODOLOGY

Total 90 patients who fulfils the inclusion criteria of Ardhavabhedak was selected randomly from the patients attending Hospital OPD and IPD of Shri Shiva Yogeeshwar Rural Ayurvedic Medical College & Hospital, Inchal Dist. Belgaum as well as from various Screenings and Health Checkup Camps conducted by our college.

A) Inclusion Criteria
• Patients diagnosed on the basis of classical signs and symptoms of ardh¡vabh£daka (migraine) as described in ¡yurv£d¡.
• Patients with two or more attacks of Migraine (headache) lasting for 4-72 hours presenting with

a) at least two of the features viz

i) unilateral,

ii) Pulsating,

iii) Moderate to severe, and

b) at least one of the features viz

i) Nausea,

ii) Photophobia,

iii) Phonophobia

• Age: 18 – 65 years

• Sex: male and female both included

• Informed consent signed

B) Exclusion Criteria

• Headache other than Migraine.

• Classically diagnosed cases of Tension type headache, Cluster headache, Headache due to systemic infection, Drug induced headache

• Organic brain lesions

• Hypertension

• Systemic disorders

• Person undergoing treatment for any other serious illness

• Patients with severe systemic illness and immune-compromised persons.

• Pregnant and lactating women

C) Study Design: Total 90 patients were involved in the clinical trial, divided in three equal groups

Group A: 30 patients on Shalaparni kwatha paana & nasya

Group B: 30 patients on Shalaparni kwatha paana & nasya + Tab. Amitriptyline 10mg once a day

Group C: 30 patients on Tab. Amitriptyline 10mg once a day

STUDY CENTRE : Concerned Institute

TYPE OF STUDY : open labeled, parallel group

DURATION OF STUDY : 60 days.

DRUG SOURCE : college garden.

FORMULATION : Shalaparni kwatha.

ANUPANA : Warm water.

MODE OF ADMINISTRATION : oral & nasya.

DOSE : Internally for oral- 40 ml twice a day Externally for Nasya- 2 drops once a day.

KALA : early morning and hours sleep for paana & nasya in morning.

FOLLOW UP : Every 15 days.

D) Diagnostic Criteria : Diagnosis was made on the basis of classical sign and symptoms mentioned in Ayurvedic text.

E) Criteria for Assessment: Assessment was done on the basis of scoring of cardinal sign, Scoring pattern was developed according to severity of symptoms and improvement was assessed accordingly.

a) Subjective Parameters

1) Manya shoola (Pain in neck)

No pain – 0

Occasionally present - 1

Often present with headache – 2

Always present with headache - 3

2) Bhru shoola

No pain – 0

Occasionally present - 1

Often present with headache – 2

Always present with headache-3

3) Shankha Vedana (temple pain)

No pain-0

No disturbance in routine work-1

Disturbance in routine work but relieved by rest or medication-2

Sever pain not responding to rest or medication-3

4) Karna Vedana (ear ache)

No ear ache-0

Mild-1

Moderate-2

Severe-3

5) Akshi Vedana (pain in eyes)

No pain-0

Mild -1

Moderate-2

Severe-3

6) Lalatardha vedana (unilateral headache)

No pain-0

No disturbance in routine work-1

Disturbance in routine work but relieved by rest or medication-2

Severe pain not responding to rest or medication-3

7) Shastra araniwat Vedana (pulsating pain)

No pulsating pain-0

No disturbance in routine work-1

Disturbance in routine work but relieved with rest or medication-2

Severe pain not responding to rest or medication-3

8) MIDAS score (Migraine Disability Assessment Scale)

Grade 1

Grade 2

Grade 3

b) Objective parameters

Enzyme study - Levels of MDA, SOD & GSH (For anti-oxidant study)

1. GSH - Normal range in serum: 25-38 mg/dl

2. MDA- Normal range in serum : 1.53-3.60 nmol/ml

3. SOD- Normal range in serum : 5.0-12.9 U/ml

OBSERVATION AND RESULT

The overall assessment of the treatment was done on the basis of relief in the main signs and symptoms of the disease as well as the general signs and symptoms of the disease. On the basis of subjective criteria and objective criteria assessment was done as following.

Table showing the Subjective Parameters Data of Group A.

	Manyashoola		Bhrushoola		Shankhavedana		KarnaVedana	
S.No	BT	AT	BT	AT	BT	AT	BT	AT
1	3	1	3	1	2	1	2	1
2	3	1	2	1	2	1	2	1
3	2	0	3	2	2	1	2	1
4	3	1	2	1	3	2	2	1
5	3	2	2	1	2	1	2	1
6	2	1	1	1	2	1	1	1
7	2	1	3	1	2	1	1	1
8	3	1	1	1	2	1	1	1
9	2	1	2	1	3	2	1	1
10	3	2	2	1	2	1	2	0
11	3	1	2	1	3	1	3	1
12	3	1	3	1	2	1	2	1
13	3	2	3	1	3	2	2	1
14	3	2	2	0	3	2	1	1
15	3	0	2	1	2	1	1	1
16	3	1	2	1	2	1	1	0
17	3	1	2	1	3	0	3	2
18	2	1	2	1	2	1	1	0
19	2	1	3	1	2	1	2	1
20	2	1	3	1	2	1	2	1
21	3	1	2	0	3	1	3	2
22	3	2	3	1	3	2	2	1
23	3	1	2	0	2	1	2	1
24	2	1	2	1	2	0	1	1
25	3	2	3	1	2	1	2	1
26	2	1	2	1	2	1	3	1
27	3	2	2	0	3	2	2	1
28	3	1	3	0	2	1	2	0
29	3	2	1	0	2	2	2	1
30	2	1	2	1	2	0	1	0

Table showing the Subjective Parameters Data of Group A.

	Akshi Vedana		Lalatardha Vedana		Shastra arnivat Vedana		MIDAS Score	
S.No	BT	AT	BT	AT	BT	AT	BT	AT
1	3	2	3	1	2	1	3	1
2	3	1	3	2	2	1	2	1
3	3	2	3	2	2	1	3	2
4	3	2	3	1	2	1	2	1
5	2	1	2	1	2	1	2	1
6	2	1	2	1	1	1	1	1
7	1	1	1	0	1	1	3	1
8	2	1	2	0	1	1	1	1
9	2	2	2	2	1	1	2	1

10	3	1	3	2	2	0	2	1
11	3	2	3	2	3	1	2	1
12	2	0	2	0	2	1	3	1
13	2	0	3	1	2	1	3	1
14	2	1	2	1	1	1	2	0
15	2	1	2	1	1	1	2	1
16	3	2	3	2	1	0	2	1
17	3	1	3	1	3	2	2	1
18	3	2	3	2	1	0	2	1
19	2	1	2	1	2	1	3	1
20	2	1	2	1	2	1	3	1
21	2	1	2	1	3	2	2	0
22	3	2	3	1	2	1	3	1
23	3	1	3	2	2	1	2	0
24	2	1	2	1	1	1	2	1
25	3	2	2	0	2	1	3	1
26	3	2	3	1	3	1	2	1
27	2	1	2	1	2	1	2	0
28	1	0	2	1	2	0	3	0
29	3	1	3	1	2	1	1	0
30	2	1	2	0	1	0	2	1

Table showing the Subjective Parameters Data of Group B.

	Manyashoola		Bhrushoola		Shankhavedana		KarnaVedana	
S.No	BT	AT	BT	AT	BT	AT	BT	AT
1	3	1	3	1	2	1	2	1
2	3	1	2	1	2	1	2	1
3	2	0	3	2	2	1	2	1
4	3	1	2	1	3	2	2	1
5	3	2	2	1	2	1	2	1
6	2	1	1	1	2	1	1	1
7	2	1	3	1	2	1	1	1
8	3	1	1	1	2	1	1	1
9	2	1	2	1	3	2	1	1
10	3	2	2	1	2	1	2	0
11	3	1	2	1	3	1	3	1
12	3	1	3	1	2	1	2	1
13	3	2	3	1	3	2	2	1
14	3	2	2	0	3	2	1	1
15	3	0	2	1	2	1	1	1
16	3	1	2	1	2	1	1	0
17	3	1	2	1	3	0	3	2
18	2	1	2	1	2	1	1	0
19	2	1	3	1	2	1	2	1
20	2	1	3	1	2	1	2	1
21	3	1	2	0	3	1	3	2
22	3	2	3	1	3	2	2	1
23	3	1	2	0	2	1	2	1

24	2	1	2	1	2	0	1	1
25	3	2	3	1	2	1	2	1
26	2	1	2	1	2	1	3	1
27	3	2	2	0	3	2	2	1
28	3	1	3	0	2	1	2	0
29	3	2	1	0	2	2	2	1
30	2	1	2	1	2	0	1	0

Table showing the Subjective Parameter Data of Group B.

	Akshi Vedana		Lalatardha Vedana		Shastraarnivat Vedana		MIDASScore	
S.No	BT	AT	BT	AT	BT	AT	BT	AT
1	3	2	3	1	2	1	3	1
2	3	1	3	2	2	1	2	1
3	3	2	3	2	2	1	3	2
4	3	2	3	1	2	1	2	1
5	2	1	2	1	2	1	2	1
6	2	1	2	1	1	1	1	1
7	1	1	1	0	1	1	3	1
8	2	1	2	0	1	1	1	1
9	2	2	2	2	1	1	2	1
10	3	1	3	2	2	0	2	1
11	3	2	3	2	3	1	2	1
12	2	0	2	0	2	1	3	1
13	2	0	3	1	2	1	3	1
14	2	1	2	1	1	1	2	0
15	2	1	2	1	1	1	2	1
16	3	2	3	2	1	0	2	1
17	3	1	3	1	3	2	2	1
18	3	2	3	2	1	0	2	1
19	2	1	2	1	2	1	3	1
20	2	1	2	1	2	1	3	1
21	2	1	2	1	3	2	2	0
22	3	2	3	1	2	1	3	1
23	3	1	3	2	2	1	2	0
24	2	1	2	1	1	1	2	1
25	3	2	2	0	2	1	3	1
26	3	2	3	1	3	1	2	1
27	2	1	2	1	2	1	2	0
28	1	0	2	1	2	0	3	0
29	3	1	3	1	2	1	1	0
30	2	1	2	0	1	0	2	1

Table showing the Subjective Parameters Data of Group C.

	Manyashoola		Bhru shoola		Shankhavedana		KarnaVedana	
S.No	BT	AT	BT	AT	BT	AT	BT	AT
1	3	1	2	0	2	0	2	0
2	3	1	2	0	2	0	2	0

3	3	1	2	0	2	0	2	0
4	3	0	2	0	2	0	2	0
5	3	0	2	0	2	0	2	0
6	2	0	1	0	2	0	1	0
7	2	0	2	0	2	0	1	0
8	2	0	1	0	2	0	1	0
9	3	0	2	0	3	1	1	0
10	3	0	2	0	1	0	1	0
11	3	1	2	1	2	0	2	0
12	3	0	3	1	1	0	2	0
13	3	1	3	0	3	1	2	0
14	3	0	2	0	3	1	1	0
15	3	0	2	0	2	0	1	0
16	3	0	2	0	2	0	1	0
17	3	0	2	0	3	0	3	1
18	2	0	2	0	2	0	1	0
19	2	0	3	0	2	0	2	0
20	2	0	3	0	2	0	2	0
21	3	0	1	0	1	0	3	1
22	3	0	3	1	3	0	1	0
23	3	1	1	0	2	0	2	0
24	3	0	2	0	2	0	1	0
25	3	1	2	0	1	0	2	0
26	3	0	2	0	2	0	1	0
27	3	0	2	0	3	0	2	0
28	3	0	3	0	2	0	1	0
29	3	0	1	0	2	1	2	0
30	2	0	2	0	2	0	1	0

Table showing the Subjective Parameters Data of Group C.

S.No	AkshiVedana		Lalatardha Vedana		Shastra arnivat Vedana		MIDAS Score	
	BT	AT	BT	AT	BT	AT	BT	AT
1	3	1	3	1	2	0	2	0
2	3	1	3	1	2	0	2	0
3	3	1	3	1	2	0	2	0
4	3	0	3	0	2	0	2	0
5	2	0	2	0	2	0	2	0
6	2	0	2	0	1	0	1	0
7	1	0	1	0	1	0	2	0
8	1	0	1	0	1	0	1	0
9	2	1	2	1	1	0	2	0
10	3	1	3	1	1	0	2	0
11	3	1	3	1	2	0	2	1
12	2	0	2	0	2	0	3	1
13	1	0	1	0	2	0	3	0
14	2	0	2	0	1	0	2	0
15	2	0	2	0	1	0	2	0

16	3	0	3	0	1	0	2	0
17	3	0	3	0	3	1	2	0
18	3	0	3	0	1	0	2	0
19	2	0	2	0	2	0	3	0
20	2	0	2	0	2	0	3	0
21	2	0	2	0	3	1	1	0
22	3	0	3	0	1	0	3	1
23	3	0	3	0	2	0	1	0
24	2	0	2	0	1	0	2	0
25	3	1	3	1	2	0	2	0
26	3	1	3	1	1	0	2	0
27	2	0	2	0	2	0	2	0
28	1	0	1	0	1	0	3	0
29	3	1	3	1	2	0	1	0
30	2	0	2	0	1	0	2	0

DISCUSSION

Discussion was done from the data available, Samhitas and Texts. The patients will be assessed on different parameters to obtain the effect of therapy. All the signs and symptoms was assessed on 30th day. The result and observation after follow up and after completion of study are mentioned earlier and was discussed as follows.

1. General discussion

2. Clinical parameters

3. Effect of therapy

4. Probable mode of action

5. Further scope of study

CONCLUSION

1. There is no reference regarding Shalaparni during in any of the Vedic literatures but the named "ANSHUMATI" is mention in Atharvaveda.

2. Shalaparni is considered as Desmodium gangeticum DC.(API Part 1 Vol.3), Shalaparni is comes under list of rare drugs. Now a days few Desmodium species, which are having morphologically similar characters are using on the name of Shalaparni.

3. Flavonoid, Steroid and Alkaloids are present in all five *Desmodium* species, while Tannins are not present in all five *Desmodium* species.

4. TLC profile shows very similar when developed with concept of Alkaloid.

5. Physicochemical parameters are within the range of Quality control parameters adopted by API for churna drug.

6. The clinical features of Ardhavabhedaka are closely related to Migraine. Oxidative stress parameters in migraine patients confirm the involvement of oxidative stress in the pathogenesis of migraine.

7. Therefore, with respect to migraine treatment (as well with as without aura), increasingly more attention is paid to antioxidants, particularly those with anti-oxidative properties.

8. Shalaparni has anti- oxidant properties as it is categorized under the Rasayana Drugs

9. The Antioxidants and Flavanoids & Alkaloids present in the drug has significant effect on the enzymes which produces the Oxidative stress hence causing the Migraine.

10. Hence, Among the 03 Groups the Group A is having highly significant effect cause the Shalaparni reduces the Oxidative stressby Anti-Oxidant property

11. Further for better results the drug needs to be trialed on the Larger samples with extensive clinical study.

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