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Research Article

EFFECT OF *NAVAJIVANA RASA* WITH *PATHYASHADANGAM KASHAYA GHANASATWA* IN CLASSICAL MIGRAINE - AN OPEN LABEL SINGLE ARM PILOT STUDY

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ABSTRACT

Migraine is the second most common cause of primary headache and as per GBD 2015; migraine was ranked third highest cause of disability worldwide. Migraine with aura is an episodic headache associated with certain features such as sensitivity to light, sound or movement; nausea, vomiting and various fully reversible neurological symptoms. The aim of study was to assess the effect of *Navajivana rasa* with *Pathyashadangam kashaya ghanasatwa* in Classical Migraine. The formulations were combined and made into a dispensable form of hard gelatin capsules. Selected participants were given with two 500mg capsules twice daily after food for 2 months and were observed during 1 month of follow up. Symptomatic features were assessed before treatment, after 2 months of medication & after follow up. The MIDAS score for the assessment of disability was assessed before and after 3 months of study period. The results showed that, the study drug was effective in relieving the sign & symptoms of classical migraine and in improving the quality of life.

INTRODUCTION

Ayurveda, the science of life deals with a holistic approach to health and personalized medicine. It is one of the oldest medical systems which comprise thousands of medical concepts and hypothesis. Now, an evidence based research is highly needed and essential for the global recognition and acceptance of Ayurveda. The validation of Ayurvedic drugs with reverse pharmacology refers to a scientific approach to develop a new drug candidate or formulation from already known facts in traditional medicines through sound preclinical and clinical researches. In this work, two formulations mentioned in Ayurvedic classics were combined to prepare a new therapeutic drug and its effectiveness in classical migraine was tested and validated.

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Here, *Navajivana rasa*[1] mentioned in *Rasatarangini* & *ghanasatwa* of *Pathyashadangam kashaya*[2] mentioned in *Sarangadhara samhita* were selected as the components of intervention.

Migraine has a global prevalence of 14.7 & India has more than 1.2 billion people affected with the same. Despite such high prevalence, migraine continues to be an under diagnosed and under treated disease, which reduces the familial, social and recreational activities. So the study on its prevention and cure is of very important. There are wide range of treatment options aimed at relieving the migraine symptoms and its prevention. Among them, analgesics and vasodilators are common in use now a day, but none of them will give complete cure to the condition. Analgesics are found to be an easiest way to manage painful headaches but in long term, a number of problems such as drug resistance, drug dependency and gastro intestinal irritations may develop to force and stop the drug. So, a safe therapeutic management which benefits the patients could be ideal. The major focus of this work is to identify a new combination and develop a new, patient friendly treatment option in order to prevent and cure the sign & symptoms of Classical migraine.

OBJECTIVES

1. Clinically evaluate the effect of *Navajivana rasa* with *Pathyashadangam kashaya ghanasatwa* in Classical migraine.
2. Evaluate the improvement in extend of disability.

METHODOLOGY

Preparation of drug

The therapeutic drug was made of two formulations - *Navajivana rasa* and *Pathyashadangam kashaya ghanasatwa*. *Navajivana rasa* was prepared by *Ardraka swarasa bhavana* of *Rasasindoora, Loha bhasma, Sodhita Kupilu choorna* and *Trikatu choorna*, each taken in equal quantity. *Pathyashadangam kashaya ghanasatwa* or the dried solid contents was prepared out of *Kashaya* which was made of ingredients like *Haritaki, Vibhitaki, Amalaki, Bhunimba, Haridra, Nimba* and *Guduchi* in the classical method explained in *Sarangadhara samhita*[3].

To prepare the therapeutic drug, *Navajivana rasa* and *Pathyashadangam kashaya ghanasatwa* were combined in 1:15 ratio and encapsulated to 500mg hard gelatin capsules. 125mg *Navajivana rasa* and 1.875g *Pathyashadangam kashaya ghanasatwa* (equivalent to 48ml of *Kashaya*) were required to prepare a single day dose of 2g (4 capsules). The prepared capsules were packed in small, airtight plastic containers for dispensing.

Navajivana rasa

Pathyashadangam kashaya ghanasatwa

Homogenization

Final product

Clinical Study

Patients of both sex aged between 20-60 years presenting with sign & symptoms of classical migraine were diagnosed as per the ICHD criteria[4] from OPD of *Rasasastra & Bhaishajya Kalpana*, Govt. Ayurveda College, Thiruvananthapuram. The patients who are pregnant or lactating women and those who having migraine without aura, sinusitis, trigeminal neuralgia, tension headache and uncontrolled hypertension were excluded from the study. The institutional ethical committee clearance was received from IRB and informed consent was taken prior to the intervention. The selected participants were given with the study drug of 500mg hard gelatin capsules and advised to take two capsules, twice daily, after food for a period of 60 days. The period of medication was continued by 30 days of follow up. Instructions were given to the patients regarding the contents of study drug and the precautions to be taken while administering the drug. After 60 days, the effect of the study drugs was assessed by analyzing the changes in the outcome variables like intensity of pain, frequency of pain, duration of pain and symptom aura. They were observed for 30 more days without the medication and the changes in outcome variables were noted again. The MIDAS[5] or extend of disability was assessed before and after completion of 3 months. The collected data were subjected to statistical analysis using non-parametric Wilcoxon's signed rank test and the effectiveness of treatment was analyzed.

RESULTS

Table 1: Effect of Treatment on Intensity of Pain

Intensity of pain	**Before treatment**	**After treatment**	**After Follow up**
Degrees			
0	0 (0.0%)	3 (18.8%)	3 (18.8%)
1	0 (0.0%)	7 (43.8%)	7 (43.8%)
2	6 (37.5%)	6 (37.5%)	6 (37.5%)
3	10 (62.5%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	0(0.0%)	0 (0.0%)
Stage	**BT-AT**	**AT-AF**	**BT-AT**
Z	3.493	0.000	3.493
P value	0.000**	1.000NS	0.000**

****: Significant (P<0.01); NS: Not significant (P>0.05)**

Before treatment, 37.5% of the patients felt a pain having intensity of degree 2, and the remaining 62.5% had suffered from pain having an intensity of degree 3. After treatment, 18.8% patients had no headache and 43.8% had only a pain intensity of grade 1. Percentage of patients had a pain with 2nd degree intensity was 37.5% and no patients were suffered from degree 3rd and 4th. The percentages of patients having varying degree of pain intensity after treatment was maintained during follow up period. Statistical test shows the intervention have highly significant effect on intensity of pain (Z = 3.493, P<0.01).

Table 2: Effect of Treatment on Frequency of Headache

Frequency of headache	**Before treatment**	**After treatment**	**After Follow up**
Degrees			
0	0(0.0%)	3(18.8%)	3(18.8%)
1	1(6.3%)	8(50.0%)	8(50.0%)
2	7(43.8%)	5(31.3%)	4(25.0%)
3	7(43.8%)	0(0.0%)	1(6.3%)
4	1(6.3%)	0(0.0%)	0(0.0%)
Stage	**BT-AT**	**AT-AF**	**BT-AT**
Z	3.640	1.000	3.666
P value	0.000**	0.317NS	0.000**

****: Significant (P<0.01); NS: Not significant (P>0.05)**

Before treatment 6.3% of the patients felt a headache having frequency of degree 1. The percentage of patients having the frequency 2 and 3 were 43.8% each and the remaining 6.3% had suffered from the frequency of degree 4. After treatment, 18.8% of patients had completely recovered from headache frequency. Percentage of patients in degree 1 & 2 were 50% and 31.3% respectively and no patients were suffered from the frequency of degree 3 & 4. After follow up, the frequency of patients in degree 0 & 1 remained same in comparison to after treatment. The frequency of patients in degree 2 & 3 became 25% & 6.3% respectively after follow up. Statistical test shows the intervention have highly significant effect on frequency of headache (Z = 3.640, P<0.01).

Table 3: Effect of Treatment on Duration of Headache

Duration of headache	**Before treatment**	**After treatment**	**After Follow up**
Degrees			
0	0 (0.0%)	3 (18.8%)	3 (18.8%)
1	0 (0.0%)	8 (50.0%)	8 (50.0%)
2	9 (56.3%)	4 (25.0%)	3 (18.8%)
3	3 (18.8%)	1 (6.3%)	2 (12.5%)
4	4 (25.0%)	0 (0.0%)	0 (0.0%)
Stage	**BT-AT**	**AT- AF**	**BT-AF**
Z	3.493	1.000	3.372
P value	0.000**	0.317NS	0.001**

****: Significant (P<0.01); NS: Not significant (P>0.05)**

Before treatment, 56.3% of the patients felt a headache having duration of degree 2. The percentage of patients having the duration of headache of degree 3 and 4 were 18.8% and 25.0% respectively. After treatment, 18.8% of patients had recovered completely. Patients having duration of headache in degree 1, 2 and 3 were 50.0%, 25% and 6.3% respectively and no patients had headache duration of degree 4. After follow up, patients of grade 2 & 3 became 18.8% and 12.5% respectively. Patients of having duration of headache in all other degrees remained the same. Statistical test shows the intervention have highly significant effect on duration of headache (Z = 3.493, P<0.01).

Table 4: Effect of treatment on MIDAS

MIDAS	**Before treatment**	**After Follow up**
Degrees		
1	5(31.3%)	14(87.5%)
2	9(56.3%)	2(12.5%)
3	2(12.5%)	0(0.0%)
4	0(0.0%)	0(0.0%)
Stage	**BT-AF**	
Z	3.317	
P value	0.001**	

****: Significant (P<0.01)**

Before treatment, no patients were present in 4th degree MIDAS while 56.3%, 31.3% and 12.5% of the patients were included in MIDAS of degree 2, 1 and 3 respectively. After treatment, all patients suffered from 3rd degree MIDAS were recovered and patients in 1st & 2nd degree MIDAS were 87.5% and 12.5 respectively. Statistical test shows the intervention have highly significant effect on MIDAS (Z = 3.317, P<0.01).

Table 5: Effect of treatment on aura

Aura	**Before treatment**	**After treatment**	**After Follow up**
Degrees			
0	0(0.0%)	3(18.8%)	3(18.8%)
1	11(68.8%)	10(62.5%)	10(62.5%)
2	5(31.3%)	3(18.8%)	3(18.8%)
3	0(0.0%)	0(0.0%)	0(0.0%)
Stage	**BT-AT**	**AT-AF**	**BT-AF**
Z	2.236	0.000	2.236
P value	0.025*	1.000NS	0.025*

***: Significant (P<0.05); NS: Not significant (P>0.05)**

Before treatment, 68.8% of the patients experienced aura of degree 1 and the remaining 31.3% had experienced aura of degree 2. After treatment, patients with of aura of degree 0, 1 and 2 became 18.8%, 62.5% and 18.8% respectively. After follow up period, the percentages of patients with different degrees of aura remained same as that of after treatment. Statistical analysis shows, significant effect on conditions of aura, (Z = 2.236, P<0.05).

DISCUSSION

Migraine is a common neurological disorder causing huge suffering both for the individual and society. The pain often begins as a dull ache and grows into throbbing pain, which may shift from one side of head to the other. In classical migraine, headache is associated with symptoms such as nausea, vomiting, fatigue, dizziness, and other neurological symptoms like sensitivity to light, sound and smell. The recurrence and nature of pain often results in considerable disability and a decrease in patient's quality of life.

Here, both the formulations combined are specifically indicated in *Ardhavabheaka* or the Ayurvedic correlation of migraine disorders. As *Navajivana rasa* it is a herbo mineral preparation, faster action and quicker assimilation of drug will be attained in smaller doses itself[6]. On addition of *Pathyashadangam kashaya ghanasatwa* as an *Anupana*, it might boost up the therapeutic effectiveness of drug as mentioned in *Rasatarangini*[7], "*Sahapana anupanabhyam bheshajam paribrimhayet, Yena rogaharasaktirbhavet gunavati sada*". The longer shelf life, easy preservation and a patient friendly dosage form in hard gelatin capsules could also made the people convenient to take medicines even in their stressful busy life. Among the ingredients of *Navajivana rasa* majority of drugs are having *Ushna virya, Vata kaphahara* properties and *Rasasindoora* have *Tridoshahara*[8] property. *Parada* and *Gandhaka* are having *Rasayana* property and drugs like *Parada, Loha, Pippali* and *Sundi* have *Vrishya* property. So, this might help in improving the immunity and strength of body and there by limits the manifestation of disease. *Gandhaka, Pippali, Maricha* and *Sundi* have *Deepana, Pachana* properties, *Kupilu* is *Grahi* and *Loha* have *Jadara gadanut* property. It will help to prevent *Rasa*

dhatu dushti and there by the vitiation of *Rakta dhatu*. By having *Vedanahara* or analgesic property, *Rasasindoora*[9] and *Kupilu*[10] will helps to reduce the intensity of headache in migraine. Due to *Yogavahi* property, it carries drugs to the required site and catalyses the action of other drugs and provide better therapeutic efficacy. It is also mentioned in the quotation of formulation that, it can be advised in conditions of *Manasika sramodbhuta avasada* or fatigue resulting from mental stress and have *Rakta janana, Bala janana* and *Nadibalakara* properties. There by it may promote proper blood flow to the brain and reduce the neurological symptoms associated with migraine including aura.

Among the ingredients of *Pathyashadangam kashaya ghanasatwa*, *Vibhitaki, Bhunimba* and *Haridra* are found to be *Kapha pittahara* and *Haritaki, Amalaki* and *Gudoochi* are *Tridoshahara* and *Rasayana* in nature. From the indications mentioned in the formulation like *Bhru sankha karna soola, Sooryavarta, Sankhaka, Dantapata, Dantasoola, Naktandhya, Netra patala, Netra sukla, Chakshupeeda,* including *Ardhavabhedhaka*[11] it can be understood that the formulation have a high affinity towards the area above shoulder and could be very much useful in *Urdhwajatrugata rogas*. So in combination, the study drug might have a *Tridoshahara* property and the cumulative action could be helpful in prevention of migraine headaches and provide a good quality of life.

CONCLUSION

- *Navajivana rasa* with *Pathyashadangam kashaya ghanasatwa* was found to be effective in relieving the intensity of headache, frequency of headache, duration of headache in classical migraine (P<0.01).
- The quality of life of migraine patients was found to be significantly better after administration of study drug (P<0.01).
- Significant changes were seen in the symptom aura (P<0.05)

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