

EFFICACY OF BRAHMI YOGA IN VYANABALA VAISHAMYA (HYPERTENSION) -A CLINICAL STUDY

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Abstract

Hypertension is one of the major risk factors for cardio vascular mortality, which accounts for 20-50% of all deaths. Most of the allopathic drugs have minor side effects and since multiple drugs have to be taken for a longer period, non compliance is also a major problem. With an aim to evolve effective herbal preparation a compound namely 'Brahmi Yoga' was tried on 113 patients. Assessment was done according to changes in measurement of systolic and diastolic blood pressure as well as according to changes in severity of related symptoms like Headache, Dizziness, Irritability, Insomnia, Fatigue and Weakness. The analysis of results indicated statistically higher significant effect of the drug. The overall results, indicated Good response in 50 (44.2%), Fair response in 45(39.8%), Poor response in 17 (15.04%) and No response in 01(0.8%) case. It is suggested to make further study of this formulation in any extract form.

Introduction

Vyanabala Vaishamya (Hypertension) is not described directly as such

in Ayurvedic classics. Some Ayurvedic scholars take it as "Rakta-gata-vata" and some take as "Rakta-chapa". Hypertension is a condition with abnormally high blood pressure. According to WHO Experts Committee on Hypertension Control Meet in Geneva (1994), it is the commonest cardiovascular disorder, posing major public health challenge to society. It is one of the major risk factors for cardiovascular mortality, which accounts for 20-50% of all deaths.

India is a large, developing country with people of diversified culture and dietetic habits. Over the last decade, economic transaction in India has brought a vast variety of changes in lifestyle. With the increasing stress and strain of modern life, incidence of hypertension is increasing substantially. Salt intake, obesity, occupational stress, alcohol intake and smoking are the predisposing factors for development of Hypertension. Hypertension increases with age and is more common in blacks than in whites. In white population nearly 1/5th of the elder individuals have blood pressure > 160 mm Hg, while one half have Blood Pressure > 140/90 mm Hg.

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The incidence is still higher in the black population. The mortality rates for stroke and Coronary Heart Disease (CHD) the major complication of Hypertension, had declined by up to 60% over the past 3 decades, but have recently leveled off. The incidence of end-stage renal disease and heart failure, two other conditions on which Hypertension plays a major causative role, continues to rise.

A variety of drugs including Diuretics, ACE inhibitors, Calcium channel blockers, Vasodilators and antiadrenergic drugs are available for controlling hypertension. But they have their own side effects and contraindications. This results into their limited use. Moreover with a good understanding of patho-physiology, still etiology is unknown in 90-95% of the patients. To avoid/overcome a large number of minor side effects and relatively higher non-compliance rate, it clearly indicates the need of an Ayurvedic drug for non-specific hypertension with least side effects and cost effective.

The present study was aimed at evaluating the efficacy of a compound herbal preparation *Brahmi Yoga* (*Brahmi, Vacha, Jatamansi* and *Arjuna* powders in equal quantity), as an alternate approach of therapy.

Material and Methods

Place of study	Central Research Institute (Ayurveda), Bhubaneswar
Period of study	April, 2000 to March, 2006.

Normal	Systolic < 130 mm Hg	Diastolic < 85 mm Hg
High Normal	Systolic 130-139 mm Hg	Diastolic 85-89 mm Hg
Mild	Systolic 140-159 mm Hg	Diastolic 90-99 mm Hg
Moderate	Systolic 160-179 mm Hg	Diastolic 100-109 mm Hg
Severe	Systolic 180-209 mm Hg	Diastolic 110-119 mm Hg
Very Severe	Systolic > 210 mm Hg	Diastolic > 120 mm Hg

Inclusion criteria

1. Age above 35 years, up to 70 years.
2. Systolic B.P.>140 mm Hg / Diastolic B.P. >90 mm Hg.
3. No major complications of Hypertension.
4. Duration up to 10 years.
5. No retinal changes in fundoscopy.

Exclusion criteria

1. Age < 35 years or > 70 years.
2. B.P. less than or equal to 140/90 mm Hg.
3. Malignant Hypertension.
4. C.V.A.
5. Renal Hypertension.
6. Retinal or systemic Hypertension.
7. Hypertensive complications.
8. Patients responding to salt restriction.
9. Patients with chronic infection and disorders in addition to Hypertension.

Drug, Dose and Duration of Treatment

The drug was supplied by a specific unit of Central Council for Research in Ayurveda and Siddha, and was given in the dose of 3 gms thrice daily with water for a period of 90 days.

Diagnosis and Assessment

Blood Pressure was measured in three different positions i.e. Sitting, Standing and lying down positions on the basis of following classification.

Clinical signs and symptoms of the patients i.e. *Shirahshula* (headache), *Bhrama* (Dizziness), *Kshubdhata* (Irritability), *Shrama* (Fatigue), *Anidra* (Insomnia) and *Dourbalya* (Weakness) were recorded as per their severity in three different grades as **Severe (+++)**, **Moderate (++)**, **Mild (+)** and **Nil (-)**. All these were recorded before treatment, after every 15 days and after completion of the trial.

Classification of Results

According to changes in blood pressure as well as subjective features the results were classified as follows.

1. Good Response

- a) Normalecy in the systolic and diastolic blood pressure as per criteria.
- b) Free from presenting symptoms.
- c) Improvement in general well being of the patients.

2. Fair Response

- a) Considerable reduction of blood pressure (systolic and diastolic).
- b) Improvement in clinical symptoms.
- c) No significant improvement in general well being of the patient.

3. Poor Response

When there is mild improvement in clinical symptoms and well being of the patient, but blood pressure remains unchanged.

4. No Response

No response in the symptoms and blood pressure remains unchanged or increased.

Observation & Results

Demographic data

A total number of 127 patients were included in the study but 113 out of them could complete the trial and remaining 14 were excluded. Out of 113 patients, 56 (49.5 %) were males while females predominated being 57 (50.4%). The high number of patients were in the age range of 41-50 years being 37 (32.7%) followed by 35 (30.9%) in the age range of 51-60 years, 27 (23.8 %) in the range of 61-70 years while only 14 (12.3%) were in the age range of 35-40 years (Table-I).

Table-I
The distribution of age and sex

Age in years	Male	Female	Total
35-40	07(6.1%)	07(6.1%)	14(12.3%)
41-50	17(15%)	20(17.6%)	37(32.7%)
51-60	17(15%)	18(15.9%)	35(30.9%)
61-70	15(13.2%)	12(10.6%)	27(23.8%)
Total	56(49.5%)	57(50.4%)	113(100%)

As regards chronicity, 98 (86.8%) patients approached us within 2 years of illness while 10 (8.8%) between 2-4 years and only 5 (4.9 %) between 4-6 years duration (Table-II).

Table -II
Duration of illness

Duration of illness	No. of patients
Upto 2 years	98(86.8%)
> 2 years upto 4 years	10 (8.8%)
>4 years upto 6 years	05 (4.9%)
>6 years upto 8 years	00(0%)
>8 years upto 10 years	00(0%)
Total	113 (100%)

The data on occupational status of the patients revealed highest number of housewives being 54 (47.7 %) followed by 24 (21.2 %) service holders, 14 (12.39%) labourers, 11 (9.73%) retired employees while others were of negligible numbers (Table-III).

Table -III
Occupation of the patient

Occupations	No. of patients
House-wife	54(47.7%)
Service	24(21.2%)
Retd. from Service	11(9.7%)
Business	05(4.4%)
Unemployed	02(1.73%)
Sedentary	03(2.6%)
Labourer	14(12.39%)
Total	113 (100%)

The per family per month income was above Rs 10,000/- in 46 (40.7%) cases while 35 (30.9%) had the income between Rs 5000/-10,000/- and 32 (28.3%) had the income up to Rs.5000/- only. Most of the patients i.e. 99(87.6%) had already taken allopathic treatment while only 6 (5.3 %) had taken Ayurvedic treatment also. 18(15.9%) patients had family history of hypertension while only 2 (1.7%) had such history of Diabetes mellitus.

The study-on *Sharirik Prakriti* revealed maximum of 43 (38.05%) having *Vata-Pitta Prakriti* followed by *Vata-Kapha* in 31 (27.43%) cases, *Pitta-Kapha* in 21 (18.58%) cases while *Vatik* and *Kaphaj* each were 7 (6.19%) cases and only 4(3.54%) were of *Paitik prakriti*. Similarly the *Manasprakriti* of maximum 47 (41.59%) patients was *Rajotamas* followed by 26 (23.01%) *Rajasika*, 24(21.29%) *Satwa-Tamas*, 15(13.2%) *Satwa-Rajas* and only 1 (0.88%) was *Tamasik*.

The data related to personal history revealed maximum patients i.e. 107(94.6%) having stress while salt intake, constipation and obesity were also accounted for significant number of cases (Table-IV).

Table-IV
Data on personal history

Personal History	No. of patients
Smoking	15 (13.2%)
Obesity	21(18.5%)
Alcoholic	08 (7.0%)
Emotional Stress	107 (94.6%)
Salt intake	98 (86.7%)
Constipation	69 (61.0%)

According to severity of the Hypertension the systolic was mildly raised in 65 (57.5%) patients while moderate in 39 (44.0%) cases and severe in 9 (7.9%) cases the type of diastolic Hypertension was moderate in maximum of 74 (65-47) cases followed by 21 (18.5%) mild, 16(14.1%) severe and only 2 (0.7%) very severe (Table V).

Table -V
The clinical type of the
Hypertension.

Clinical Type	Systolic	Diastolic
Mild	65(57.5%)	21(18.5%)
Moderate	39 (44.0%)	74 (65.4%)
Severe	09 (7.9%)	16(14.1%)
Very Severe	00(0%)	02 (0.7%)
Total	113(100%)	113 (100%)

An observation on related sign/symptoms showed that dizziness was present in all 113 (100%) cases while headache was present in 111 (98.2%), Insomnia in 110 (97.3%), fatigue in 102 (90.2%) Irritability in 101 (89.3%) and weakness in 95 (84%) patients (Table-VI.)

Table -VI
The presentation of clinical signs/
symptoms

Clinical signs/ symptoms	No. of patients
<i>Shirashula</i> (Headache)	111(98.2%)
<i>Bhrama</i> (Dizziness)	113 (100%)
<i>Kshubdhata</i> (Irritation)	101(89.3%)

<i>Shrama</i>	102 (90.2%)
(Fatigue)	110(97.3%)
<i>Anidra</i>	
(Insomnia)	95(84%)
<i>Daurbalya</i>	
(Weakness)	01(0.88%)
Others (Pain, Numbness etc),	
Numbness etc.	

The level of Serum cholesterol which could be studied in 95 patients revealed maximum patients being 60 (63.15%) had between 151-200 mg% while 27 (28.4%) had between 201-250 mg% (Table-VII).

Table -VII
Level of Cholesterol

Level of Cholesterol in mg. %	No. of patients
150 or less	05 (05.26%)
151-200	60 (63.15%)
201-250	27 (28.42%)
Above 250	03 (03.15%)
Total	95 (100%)

Similarly the observation on serum triglyceride level in 101 patients revealed that maximum of 32 (31.68%) had triglyceride between 101-150 mg.% while in higher normal range (151-190 mg) 22 (21.78%) patients were there and above range 19 (18.81%) patients were there (Table-VIII).

Table-VIII
Triglyceride level

Triglyceride level in mg. %	No. of patients.
50 or less	01 (0.99%)
51 to 100	27 (26.73%)

101 to 150	32 (31.68%)
151 to 190	22 (21.78%)
Above 190	19 (18.81%)
Total	101 (100%)

Analysis of results

The data analysis used descriptive statistics and t-test for correlated samples both for systolic and diastolic blood pressure data. It was observed that the systolic blood pressure of the cohort declined after the treatment and the difference is highly significant statistically. ($t=20.48$, $p<0.001$ at 112 degree of freedom). Similarly the recorded decline in diastolic blood pressure is also highly significant. ($t=21.93$, $p<0.001$ at 112. df.) (Table IX).

The changes in severity of the symptoms were analyzed using Z-test and it was revealed that difference in all the clinical features were highly significant at $p<0.001$ after treatment.

The symptom of headache which was severe in 6 (5.3%) cases, moderate in 97 (85.8%) cases and mild in 8 (7%) cases reduced drastically and become nil in 80 (70.7%) cases (Table-X).

The changes in severity of dizziness was quite prominent as maximum patients having moderate or severe dizziness had mild or no dizziness after the treatment (Table XI)

Table-IX
Statistical analysis of changes in systolic and diastolic blood pressure

Sl. No.	Blood Pressure	No. of subject	Mean				SD	SE	t	P	Statistical Remarks
			BT	AT	D	Percentage of inhibitions					
01.	Systolic Pressure	113	157.50	129.57	27.93	17.73	±13.97	1.31	20.48	P<0.001	Highly significant.
02.	Diastolic Pressure	113	101.08	86.67	15.21	14.93	±7.10	0.67	21.93	P<0.001	Highly significant.

Table-X
Changes in severity of Headache.

Severity of headache	No. of patients	
	BT	AT
Severe	06(5.3%)	00(0%)
Moderate	97(85.8%)	05(4.4%)
Mild	08(7%)	28(24.7%)
Nil	02 (1.7%)	80(70.7%)
Total	113 (100%)	113 (100%)

Table-XI
Changes in severity of Dizziness

Severity of Dizziness	No. of patients	
	BT	AT
Severe	27(23.8%)	00(0%)
Moderate	82(72.5%)	06(5.3%)
Mild	04(3.5%)	45(39.8%)
Nil	00(0%)	62(54.8%)
Total	113 (100%)	113 (100%)

The changes in severity of irritability after treatment also grossly declined as maximum patients having moderate or mild severity got relief of the same (Table XII).

Table -XII
Changes in severity of Irritability

Severity of Irritability	No. of patients	
	BT	AT
Severe	03(2.6%)	00(0%)
Moderate	54(47.7%)	00(0%)
Mild	44(38.9%)	16(14.1%)
Nil	12(10.6%)	97(85.8%)
Total	113 (100%)	113 (100%)

The symptom of fatigue which was mild or moderate in maximum cases become nil in a significant number of cases (Table XIII).

Table-XIII
Changes in severity of Fatigue .

Severity of Fatigue	No. of patient	
	BT	AT
Severe	01(0.8%)	00(0%)
Moderate	39(39.5%)	00(0%)
Mild	62(50.8%)	17(15%)
Nil	11(9.7%)	96(84.9%)
Total	113 (100%)	113 (100%)

Insomnia, the predominant symptom which was severe in 26(23%), moderate in 77(68.1%) and mild in 7(6.1%) cases become nil in 77 (68.1%) and mild in 33 (29.2%) cases (Table XIV).

Table-XIV
Changes in severity of Insomnia

Severity of Insomnia	No. of patients	
	BT	AT
Severe	26(23%)	00 (0%)
Moderate	77(68.1%)	03(2.6%)
Mild	07(6.1%)	33(29.2%)
Nil	03(2.6%)	77(68.1%)
Total	113 (100%)	113 (100%)

The symptom of weakness which was mild or moderate in maximum cases got relieved in maximum number of cases (Table XV).

Table -XV
Changes in severity of Weakness

Severity of Weakness	No. of patients	
	BT	AT
Severe	01(0.8%)	00(0%)
Moderate	21(18.5%)	00(0%)
Mild	73(64.6%)	07(6.1%)
Nil	18(15.9%)	106(93.8%)
Total	113 (100%)	113 (100%)

On the basis of above analysis the overall results were classified as Good response in 50 (44.23%) cases, Fair response in 45(.39.83%) cases, Poor response in 17 (15.04%) cases No response in 1 (0.88%) cases (Table XVI).

Table-XVI

Results	No. of patients
Good response	50(44.23%)
Fair response	45(39.83%)
Poor response	17 (15.04%)
No response	01 (0.88%)
Total	113(100%)

Discussion

The study on 113 patients of hypertension revealed that females have also been more victim to this disease, rather out numbered the males. The age range of 41-50 years and 51-60 years have become more prone to this disease indicating stress and strain of the life facing more during this period. Maximum patients had the inclination to undergo Ayurvedic treatment within 2 years of illness indicating unsatisfactory response and side effects of other medicines and prognosis of the disease being *Yapya* or maintainable. Surprisingly housewives have out numbered other professionals followed by service-holders and retired employees. The disease seems to prevail more in higher income group. About 87.6% had already taken allopathic treatment and 15.9% patients had family history of this disease. The people of *Vata-Pitta Prakriti* and *Rajo-Tamas Prakriti* have been more vulnerable to this disease. Obviously 94.6% patients had emotional stress.

The systolic was mildly raised in maximum (57.5%) cases while diastolic was moderately raised in maximum (65.4%) cases. Insomnia, headache and dizziness were prominent symptoms of the disease while irritability, fatigue and weakness were also found in significant number of cases. Considering the normal range of serum cholesterol in Indians being 150-200 mg% maximum patients had within this limit while triglyceride was above the range in 18.81% cases in higher normal range in 21.78% cases.

The statistical analysis of the results pertaining to measurement of blood pressure and related subjective features like dizziness, insomnia, headache, irritability, fatigue and weakness showed the effect as highly significant. The overall results were Good response in maximum of 44.23% cases and Fair response in 39.83% cases while 16.4% cases had Poor response and only 0.8% i.e. 1 case had No response.

Out of 4 drugs present in this formulation *Jatamansi* (*Nardostachys jatamansi* DC) is known for its tranquilizing and sedative effect and *Vacha* (*Acorus calamus* linn.) is known for its effect on CNS. *Brahmi* (*Bacopa monnieri* Linn.) is having antihypertensive effect. *Arjun* (*Terminalia arjuna* W & A) is a cardiac tonic and has effect on CVS. Combination of such drugs may have synergistic role to regulate both CNS and CVS, thereby controlling the blood pressure and related symptoms.

Conclusion

Since Hypertension has no radical cure, to keep it under control is important. Since patient has to take the drug for a longer period rather in many cases life long, any drug to be selected should have least or no side effect. More

over the drug should be easily available and cost effective. This drugs seems to be effective, but in powder form it may not be palatable to all, may not retain potency for long period and will be of problem for preservation. So any other pharmaceutical form like tablets/capsules with their extracts may be considered for future study.

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सारांश

व्यानबल वैषम्य में ब्राह्मीयोग की कार्मकता—एक आतुरीय अध्ययन

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हृदय जन्य मृत्यु के कारणों में से व्यानबल वैषम्य एक प्रमुख कारण है जो कि कुल मृत्यु संख्या के 20–50 प्रतिशत माना जाता है। एलोपैथिक औषधियों में ज्यादातर पाश्वर्प्रभावयुक्त होते हैं तथा एकाधिक औषधियों को लम्बी अवधि तक सेवन करने के कारण औषधियों को नियमित रूप से ग्रहण न करना भी एक प्रमुख समस्या है। वनौषधियों से प्रस्तुत एक प्रभावी योग उद्भावन करने के उद्देश्य से ब्राह्मीयोग का 113 रोगियों पर आतुरीय अध्ययन किया गया। सिस्टोलिक डायेस्टोलिक रक्तचाप के साथ सम्बन्धित लक्षणों की तीव्रता में परिवर्तन के आधार पर औषधयोग के प्रभाव का आकलन किया गया। परिसांख्यिकी दृष्टि से यह योग अत्यन्त प्रभावी पाया गया। सामूहिक परिणाम 50 (44.23%) रोगियों में बेहतर, 45 (39.8%) रोगियों में अच्छा तथा 17 (15.04%) रोगियों में कम पाया गया जबकि केवल 01 (0.88%) रोगी में कोई प्रभाव नहीं मिला। इस योग के प्रभाव को देखते हुए यह प्रस्ताव किया जाता है कि इस योग को किसी सत्त्व रूप में प्रयोग के लिए अध्ययन किया जाये।