



Research Article

A CLINICAL STUDY TO EVALUATE THE EFFECT OF “SHANKHPUSHPYADI YOGA” IN THE MANAGEMENT OF VYANBALVRIDDHI W.S.R. TO HYPERTENSION

Shilpi Singh^{1*}, Anjana Mishra², Y.K.Sharma³

¹P.G.Scholar, ²Reader, Dept. Kayachikitsa, Rajiv Gandhi Govt. Post Graduate Ayurvedic College, Paprola, H.P., India

³Principal cum Dean, Rajiv Gandhi Govt. Post Graduate Ayurvedic College, Paprola, H.P., India

ABSTRACT

Changing lifestyle is responsible for increase in number of people suffering from Hypertension, Stress, Diabetes mellitus, Obesity, Heart ailments and other Non Communicable diseases. Among these life-style disorders hypertension is an important public –health challenge worldwide. The disease Hypertension has no such clear cut reference in Ayurvedic texts. Eminent Ayurvedic scholar 'Vaidhya Brihaspati Dev Triguna Padam Vibhushan' correlated high blood pressure with *Vyana Bala Vridhi*. He postulated that increased *Vyana Bala* is responsible for increased Arterial pressure.

Present study was conducted to explore evidence based therapeutic potential of *Shankhpushpyadi Yoga* in the management of *Vyan Bal Vridhi* w.s.r. to Hypertension. The patients fulfilling the inclusion criteria and voluntarily willing for trial were registered from O.P.D. & I.P.D. Dept. of Kayachikitsa R.G.G.P.G.AYU Hospital, Paprola. The Clinical trial was approved by I.E.C. The trial formulation contains Hydroalcoholic extract of *Shankhpushpi* 150 mg, *Bhumyamlaki* 250 mg, *Punarnava* 200 mg, *Jatamansi* and *Sarpagandha* 100 mg each.

Clinical trial was of 45 days and total 30 patients were registered for the same. After 45days analysis revealed that out of 30 patients, 4 patients showed excellent improvement, 15 showed marked, 7 showed mild improvement and no improvement was noted in 2 patients. The mean systolic blood pressure before treatment was 148.71 mm of Hg which dropped to 140.14 mm of Hg at the end of 45 days therapy, with 5.28% reduction. The mean diastolic blood pressure before treatment was 95 mm of Hg which dropped to 87.142 mm of Hg at completion of trial with 8.27% reduction which was statistically significant. *Shankhpushpyadi* yoga proved to be an effective and safe remedy for patients of Hypertension.

KEYWORDS: *Shankhpushpyadi yoga*, *Vyan Balvridhi*, Hypertension.

INTRODUCTION

Hypertension is one of the preventable state of premature morbidity and mortality world-wide. The number of people living with Hypertension is predicted to be 1.56 billion world-wide by year 2025. Life style such as physical inactivity, Salt rich diet, Consumption of processed food, Alcohol use are factors responsible for the increased prevalence of the disease. Clear explanation of Hypertension is not found in Ayurvedic texts but diseases like *Paksahaghat*, *Mootraghata*, *Hridroga* are very well lained in texts which are common complications of hypertension. This proves the existence of hypertension in old days. But it seems that above said complications were not so common as are in present day practice, peaceful life style in ancient days may be the reason. In modern era, Anxiety, stress and strain are increasing and these factors are definitely influencing the pshyosomatic disorders including hypertension.

Different nomenclatures for hypertension have been adopted by Ayurvedic scholars like *Uccharaktachapa*, *Raktvrittavata*, *Sleshmavrittavyana*, *Siragatavata*, *Dhamni-paripuranaata* etc. Appropriate correlation is with '*Vyana Bala Vridhi*.'

Vyanavayu which has its presence in entire body is considered to play an important role in blood circulation. Eminent Ayurvedic scholar '*Vaidhya Brihaspati Devtriguna*

(Padam Vibhushan)' correlated high blood pressure with *Vyanabalavridhi*. He postulated that increased arterial pressure is the result of increased *Vyanabala*.

The present study was an attempt to explain hypertension on Ayurvedic *doshic* fundamentals to understand the pathogenesis of disease and evaluate the efficacy and safety of '*Shankhpushpyadi yoga*' in the management of *Vyanabalavridhi*.

Aims and objectives

- To analyze etiopathogenesis of '*Vyan Bal Vridhi*' with special reference to hypertension from modern and Ayurvedic point of view.
- To study the efficacy of '*Shankhpushpyadi yoga*' in the management of '*Vyan Bal Vridhi*'.
- To evaluate the safety of drug.

Plan of study

To fulfill the above mentioned aims and objectives, the research work has been planned in following way

i. Conceptual study

The available literature regarding *Vyan Bal Vridhi* and modern literature regarding hypertension and of component drugs of *Shankhpushpyadi* yoga has been collected from different Ayurvedic texts, Modern texts and

reputed Journals as well as from internet and retrospective studies done in various institutions.

ii. Clinical study

This is the main study of present research work. A sample of 30 patients was assessed during trial.

All patients were selected from OPD and IPD of Rajiv Gandhi Govt. Post Graduate Ayurvedic College and Hospital, Paprola, Himachal Pradesh.

Selection of patient

1. Diagnostic criteria

Diagnosis was mainly based on readings of mercurial sphygmomanometer. Three consecutive readings of blood pressure in 3 different positions (sitting, standing and supine) on both arms were taken. Their mean was calculated for each arm separately and the higher reading was considered for diagnosing and categorizing according to VII report of Joint National Committee on prevention, detection, evaluation and treatment of high blood pressure. In the JNC 7 guidelines, the 7 categories of blood pressure are defined in JNC 6 were simplified and reduced to 4 categories, which is as follows:

Table no 1: As per JNC 7

Category	Systolic pressure (mmHg)	Diastolic pressure (mmHg)
Normal	< 120	and < 80
Pre-hypertension	120 – 139	and / or 80 – 89
Stage 1 Hypertension	140 – 159	and / or 90 – 99
Stage 2 Hypertension	≥ 160	and/or ≥ 100

2. Inclusion criteria

a. Patients in the age group of 30-60 years of either sex.

Trial drug Shankhpushpyadi yoga

Table 2: The drug was prepared by Dr.Vasishth’s Ayuremedies

Sr. no.	Description	Yoga
1.	Formulation name	<i>Shankhpushpyadi yoga</i>
2.	Pharmaceutical form	Tablet
3.	Dose	1 tab
4.	Route of administration	Oral
5.	Frequency of administration	Thrice a day
6.	Duration of administration	6 weeks
7.	<i>Anupana</i>	Plain water
8.	Reference	<i>Vishista yoga</i>

5. Protocol of Research

a. Clearance of I.E.C. : The detailed synopsis of the study was submitted to I.E.C. and after getting clearance from committee this study has been undertaken.

b. Consent: Written and informed consent of every patient was taken before inclusion in the clinical trial.

c. Clinical History Proforma: The detailed clinical history with examination and investigations, including assessment of each patient under trial at each follow up was recorded on a proforma.

d. Method of study: In the present study total 35 hypertensive patients were screened, out of which 5 patients were found unfit for the trial according to

b. Patients suffering from stage I hypertension on the basis of recommendation of 7th Joint National Committee of Hypertension.

c. Patients willing for trial.

3. Exclusion criteria

a. Stage II hypertension i.e. Systolic blood pressure ≥160 mmHg, Diastolic blood pressure ≥ 100 mmHg.

b. Suffering from endocrinal disorder.

c. Associated with target organ damage.

d. Malignant hypertension.

e. Any other patient considered unfit for inclusion in trial after investigation.

f. Symptomatic patient with clinical evidence of heart failure.

g. Alcoholics and drug abusers.

h. Patient who have completed participation in any other clinical trial during past 6 months.

4. Investigations

Investigations were done at the time of enrollment and after the completion of drug treatment i.e. 45th day.

a. Hematology- Hb%, TLC, DLC, ESR, Blood Sugar.

b. Bio chemistry- B. Urea, S. Creatinine.

Lipid profile- S.Cholesterol, S. Triglycerides LDL, VLDL, HDL.

c. Urine - Routine and Microscopic examination

d. ECG

e. USG- (if required)

f. Chest X-ray - (if required)

GROUP

The study was done in single trial group. It was open trial with voluntary participation of subjects.

exclusion criteria, 30 patients were registered for the trial and they took treatment for duration of 45 days and 28 patients completed all follow ups for entire trial duration as per protocol. The patients were selected from OPD and IPD of Rajiv Gandhi Govt.P.G.Ayurvedic Hospital, Paprola, irrespective of caste, sex, race, religion, etc. The diagnosis was made according to Blood Pressure values following JNC VII report 2004. Blood pressure was recorded with the help of mercurial Sphygmomanometer.

After enrollment in the trial, patients were given drugs and they were thoroughly assessed after every 15 days till completion of trial i.e. on 45th day.

Criteria for Assessment			
1. On the basis of Cardinal Sign		Palpitations hampers routine work	: 2
a) By noting the alteration in Systolic and Diastolic Blood Pressure, before and after treatment.		Continuous palpitations	: 3
b) On the basis of effect on Pulse pressure and Pulse Rate.		j) Krodha (Anger)	
		No anger	: 0
		Anger on & off	: 1
		Always in anger	: 2
		Always in anger which hamper routine work	: 3
2. On the basis of gradation of symptoms as:		k) Smriti Hrasa (Impaired memory)	
a) Siroruja (Headache)	Score	No impairment of memory	: 0
No headache	: 0	Recent memory impairment	: 1
Occasional headache but patient able to do casual work	: 1	Delayed memory loss	: 2
Continuous headache which hampers routine work	: 2	Marked impairment of memory	: 3
Patient unable to do routine work	: 3		
b) Samtapa (Burning sensation)		3. Effect of drug Therapy on various bio-chemical parameters is also a criteria for assessment.	
No burning	: 0	4. The total effect of therapy was assessed by determining the reduction of Blood Pressure.	
occasional burning	: 1	Overall effect of therapy on Blood Pressure:	
Burning on & off throughout the day	: 2	Assessment Criteria	
continuous burning	: 3	• Excellent improvement -Reduction in B.P. from stage- I to normotensive range with >2 grade improvement in 8 symptoms.	
c) Pada-Daha (Burning feet)		• Marked improvement -Reduction in B.P. from stage-I to pre-hypertensive range with >2 grade improvement in 6 symptoms.	
No burning	: 0	• Mild improvement - Some reduction in B.P. but still in Stage-I with >2 grade improvement in 4 symptoms.	
occasional burning	: 1	• No improvement -Neither reduction in B.P nor any symptomatic improvement.	
Burning on & off 2	: 2	Statistical methods	
continuous burning	: 3	Clinical symptoms, Subjective parameters and Laboratory parameters were subjected to analysis using IBM SPSS Statistics software. The results are expressed in terms of mean, standard deviation and standard error.	
d) Krishta (Tiredness)		P < 0.001 - Highly significant	
No tiredness	: 0	P < 0.05 - Significant	
Mild tiredness	: 1	P > 0.05 - Insignificant	
Tiredness on & off	: 2	Observations	
Unable to do routine work	: 3	In the present study total 35 patients were screened, out of which 5 patients were found unfit for the trial according to exclusion criteria, 30 patients were registered for the trial and 28 took treatment for duration of 45 days and completed all follow ups for entire trial duration as per protocol and 2 patients did not turn up for follow up.	
e) Aruchi (Loss of taste)		Out of 30 patients of Hypertension, maximum number of patients i.e. 46.66% registered were between the age group of 41-50 years followed by 36.66% patients were between 51-60 years and 16.66% were in 31-40 age group.	
Normal desire of food	: 0	Maximum patients registered for present trial were educated i.e. 16 patients (53 %). Maximum hypertensive patients i.e. 10 (33.33%) had the occupation related with desk work followed by housewives and field work with physical labour each 08 (26.66%) and rest of the patients i.e. 4 (13.33%) were doing field work.	
Eating timely without much desire	: 1		
Food intake only after long intervals	: 2		
No food intake at all	: 3		
f) Bhrama (Giddiness)			
No Giddiness	: 0		
Occasional but patient able to do usual work	: 1		
Continuous giddiness which hampers routine work	: 2		
Patient is unable to do any work	: 3		
g) Klama (Easy fatigability)			
No Klama	: 0		
Continuous Klama but able to do usual work	: 1		
Continuous Klama hampers routine work	: 2		
Unable to do any work	: 3		
h) Visual disturbances			
No visual disturbances	: 0		
Mild blurring of vision	: 1		
Blurring of vision hampers routine work	: 2		
Unable to do any work	: 3		
i) Hridayrava (Palpitations)			
No palpitations	: 0		
Occasional palpitations	: 1		

Maximum registered patients i.e. 73.33% in the present study had habit of taking mixed diet. 71% had disturbed sleep. The study also reveals affect that 16.66% were addicted to alcohol. 25 (83.33%) patients were suffering from moderate emotional stress and 16.66 were suffering from average stress. The data on the *Deha Prakriti* of 24 patients reveals the fact that 80% of the patients were of *Vata- Pittaja Prakriti*.

The mean systolic blood pressure before treatment was 148.71 mm of Hg which dropped to 140.14 mm of Hg at end of 45 days therapy, with 5.28% reduction. Reduction in systolic blood pressure was quiet gradual and steady over the treatment duration of 45 days. Similarly the mean diastolic blood pressure before treatment was 95 mm of Hg which dropped to 87.142 mm of Hg at completion of trial with 8.27% reduction. The reduction in both systolic and diastolic blood pressure at the end of 45 days of therapy was found statistically highly significant ($p < 0.001$). The mean of pulse rate before treatment was 73.85/min which increased to 73.21/min at end of therapy.

Results

The complaint of *Siruruja* before treatment was having mean score 0.714 which is reduced to 0.28 after treatment giving relief of 54.10 % and highly significant value of ‘t’ 9.625 ($p < 0.01$). *Samtapa* (Burning sensation) had a mean score of 0.714 before treatment which come down to 0.28 after treatment showing 60% relief and highly significant ‘t’ value 4.22 ($p < 0.01$). *Padadaha* (Burning sensation of feet) was having mean score 0.642 which is reduced to 0.321 after treatment giving relief of 50% and highly significant value of ‘t’ 3.313 ($p < 0.01$). *Krishta* (Tiredness) shows mean score value 1.035 which reduced to 0.50 after treatment with 51.6% relief and ‘t’ score 5.578 which is highly significant ($p < 0.01$). *Aruchi* (Loss of appetite) was having mean score 0.5 which is reduced to 0.25 after treatment giving relief of 50% and highly significant value of ‘t’ 3.012 ($p < 0.01$). *Hridayrava* (Palpitations) shows an improvement of 53% and highly significant ‘t’ value 7.73 ($p < 0.01$). In *Krodha* (anger), there was 81% relief, mean score before trial was 0.714 which dropped to 0.357 after trial with significant ‘t’ value 3.88 ($p < 0.01$).

Table 3: Effect of therapy on Systolic Blood Pressure in 28 patients of Hypertension

Systolic B.P at		Mean	Mean difference (A-B)	% variation	S.E±	P
A	B					
Day 0	Day15	146.07	2.64	1.77	0.42	<0.001
148.71	Day30	144.35	4.36	2.93	0.48	<0.001
	Day45	140.14	8.57	5.76	0.76	<0.001

Table 4: Effect of therapy on Diastolic Blood Pressure in 28 patients of Hypertension

Diastolic B.P at		Mean A B	Mean Difference (A-B)	% variation	S.E±	P
A	B					
Day0	Day15	91.86	3.14	3.30	0.51	<0.001
95.0	Day30	90.38	4.62	4.8	0.65	<0.001
	Day45	87.142	7.85	8.26	0.77	<0.001

Table 5: Effect of therapy on Pulse Pressure in 28 patients of Hypertension

Pulse Pressure at		Mean	Mean difference (A-B)	% variation	S.E±	P
A	B					
Day0	Day15	53.68	0.03	0.00	0.514	P>0.05
53.71	Day30	53.59	0.12	0.22	0.75	P>0.05
	Day45	52.78	0.93	1.73	1.1549	P>0.05

Table 6: Effect of therapy on Mean Arterial Pressure in 28 patients of Hypertension

Mean Arterial Pressure At		Mean Score	Mean difference (A-B)	% variation	S.E	P
A	B					
Day0	Day15	110.14	2.86	2.53	0.429	<0.001
113	Day30	108.5	4.5	3.98	0.47	<0.001
	Day45	105.225	7.77	6.8	0.775	<0.001

Table 7: Effect of therapy on Pulse Rate in 28 patients of Hypertension

Pulse Rate at	Mean Score		% variation	S.D±	S.E±	t	P
	BT (Day 0)	AT (Day 45)					
		73.85	73.21	0.86	2.740	0.5178	1.5160

Table 8: Effect of therapy on Hematological values in 28 patients of Hypertension

Variables	Mean Score		% variation	SD±	SE±	t	P
	BT	AT					
	0 DAY	45DAY					
Hb (gm %)	11.789	11.971	1.54	1.6931	0.3199	0.5689	>0.05
F.B.S mg/dl	90.107	86.28	4.26	13.611	2.5731	1.596	>0.05
B.Urea mg/dl	27.55	27.52	0.10	11.527	2.179	0.6060	>0.05

S.Creatinine mg/dl	0.79	0.89	0.13	0.4323	0.081	0.740	>0.05
S.Cholesterol	194.53	156.36	19.62	35.90	6.786	3.065	<0.05
HDL	58.03	51.57	11.132	15.083	2.851	2.792	<0.05
LDL	100.36	83.57	16.72	31.505	5.95	1.776	<0.05
VLDL	33.25	29.78	10.43	14.88	2.81	1.436	<0.05
Triglycerides	156.39	152.28	2.62	47.43	8.96	1.28	>0.05

Table 9: Effect of therapy on Clinical features in 28 patients of Hypertension

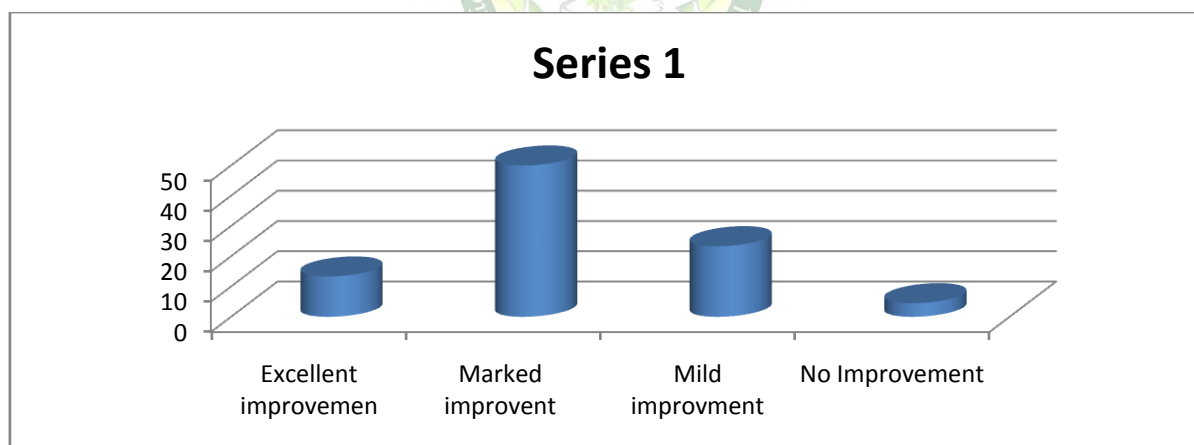
Sign and symptoms	Mean score		%age relief	SD±	SE±	T	P
	BT	AT					
<i>Siroruja</i>	1.46	0.67	54.10	0.4236	0.080	9.625	<.01
<i>Samtapa</i>	0.714	0.28	60	0.497	0.093	4.22	<.01
<i>Padadaha</i>	0.642	0.321	3.313	0.460	0.086	3.313	<.01
<i>Krishta</i>	1.035	0.50	51.6	0.507	0.095	5.578	<.01
<i>Aruchi</i>	0.5	0.25	50	0.440	0.083	3.012	<.01
<i>Bhrama</i>	0.75	0.462	38	0.475	0.089	3.606	<.01
<i>Klama</i>	1.5	0.67	55.3	0.356	0.067	12.791	<.01
<i>Krodha</i>	0.714	0.357	81	0.487	0.092	3.88	<.01
<i>Hridrava</i>	1.535	0.714	53	0.518	0.097	7.73	<.01

Overall effect of therapy

Depending upon relief in blood pressure after 45 days of treatment, the response of the drugs was evaluated as per criteria mentioned in the chapter of the clinical study of this thesis. The patients were categorized into four groups i.e. excellent improvement, marked improvement, mild improvement and no improvement. So overall effect of therapies on 28 patients of Hypertension is as follows:

Table 10: Overall effect of therapy

S.No.	Overall effect of therapy	No. of cases	Percentage
1	Excellent improvement	04	13.33
2	Marked improvement	15	50
3	Mild improvement	07	23.33
4	No improvement	02	06.66



CONCLUSIONS

The following conclusion can be drawn from the present study:

- Out of 30 patients of Hypertension, maximum number of patients i.e. 46.66% were registered between the age group of 41-50 years followed by 36.66% patients between the age group 51-60 years and 16.66% were in 31-40 age group, hence total 83.32% hypertensive registered patients were in the age group of 40-60 years.
- All Registered patients were Hindu. This may be attributed to the fact that the area of study was Hindu predominant.
- Majority belong to rural area. It may be due to the geographical location of the hospital in rural area of Himachal Pradesh
- Majority of registered patients were of *Vata-Pittajaprakriti* (80%) followed by *Pitta-Kaphaja* (16.66%). As the Hypertension was generally noted in middle and senile age, it can be said that the disease is mainly related to *Vata* and *Pitta* dominance *Prakriti*, because the susceptibility of body towards *Dosha* dominancy changes according to the age.
- Maximum patients were taking Mixed diet (73.33%). 60% patients were doing moderate kind of physical exercise and majority of patients i.e. 60% were without having any addiction.

- Maximum hypertensive patients i.e. 10 (33.33%) were engaged in desk work followed by housewives. The increased incidence among patients working in Govt. or private job may be due to the stress and tensions of work and sedentary life style. The incidence among housewives may be due to the day to day tensions especially education of children and family work load.
 - The mean systolic blood pressure before treatment was 148.71 mm of Hg which dropped to 140.14 mm of Hg at end of 45 days therapy, with 5.28% reduction. The mean diastolic blood pressure before treatment was 95 mm of Hg which dropped to 87.142 mm of Hg at completion of trial with 8.27% reduction.
 - Effect of therapy on Routine baseline Hematological and biochemical investigations including Hb gm%, TLC, DLC, ESR FBS, B.Urea, S.Creatinine, Lipid Profile revealed that these investigations were within normal limits before, during and after the therapy and were not much affected by the therapy.
 - Hypertension has probably become the fastest emerging, public health problem in the recent time and India is also facing the same situation.
 - On clinical evaluation the trial drug *Shankhpushpyadi* yoga proved to be an effective and safe remedy for patients of hypertension.
 - No major untoward effect of therapy was observed during the entire trial period. Therefore it can be concluded that *Shankhpushpyadi yoga* may prove a dependable, cost effective and safe remedy for the management of stage I essential hypertension.
- The present study was conducted on small patient sample. Further study is required on larger patient sample establishing the effectiveness of the drug.
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***Address for correspondence**

Dr Shilpi Singh
P.G. Scholar,
Dept. Kayachikitsa,
R.G.G. P.G.Ayu. College,
Paprola, H.P., India
Email: singhshilpi731@gmail.com