



Research Article

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OPEN CLINICAL TRIAL OF A POLY HERBAL COMPOUND M-SARPAGANDHA MISHRAN IN ESSENTIAL HYPERTENSION: A PILOT STUDY

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ABSTRACT

Hypertension is a condition in which the arteries have persistently elevated blood pressure. It is considered as the silent killer as most sufferers are asymptomatic. Essential or primary hypertension is considered as the leading contributory cause of death worldwide. Despite good access to care, admittance to lifestyle modification, and the presence of highly efficacious anti-hypertensive therapies, management of hypertension effectively has been a distant reality. Developing innovative and cost-effective solutions to improve hypertension diagnosis and control thus remains a key priority. The present study was conducted to evaluate the efficacy of polyherbal compound M-Sarpagandha Mishran in the management of Essential Hypertension. 41 patients of essential Hypertension (HT) under the age group of 18-70 years without any co-morbid illness, attending the OPD under National Campaign of All India Institute of Ayurveda, New Delhi, India were selected for the study. All patients were screened on the basis of JNC 7 criteria of HT and were administered M-Sarpagandha Mishran for 8 weeks. Blood pressure (BP) was monitored on subsequent follow up visits at 2, 4, 6, and 8 weeks. Change in Diastolic BP (DBP), Systolic BP (SBP) and Mean arterial BP (MBP) was analyzed statistically by paired Student's t-test. During the study, 11 patients dropped out and 30 patients were followed. Paired t test was applied using SPSS software to analyze the data. On first visit the mean SBP, DBP, and MBP was 158.53 + 2.471, 98.37 + 2.203 and 118.43 + 1.558 mm Hg, respectively. After 8 weeks of therapy there was a statistically significant fall in SBP (126.6 + 1.897), DBP (78.37+ 1.264) and MBP (84.43 + 1.268) in mmHg (P value <0.0001) M-Sarpagandha Mishran offers an efficacious and safe combination for the treatment of hypertension.

Keywords: Hypertension, Sarpagandha Mishran, Ayurveda

INTRODUCTION

Essential or primary hypertension is considered as one of the primary members of group of non-communicable diseases (NCD) and a major risk factor for cardiovascular diseases. It produces discernible effects on patients, either because of hypertension per se or through its complications (stroke, heart attack, ischemic heart disease, renal dysfunction and heart failure) which can produce premature death or permanent disability. It is estimated that more than fifty percent of deaths resulting from cardiovascular diseases globally is caused by hypertension. It is responsible for 9.4 million deaths and 7 per cent of disability adjusted life years in 2010¹. A study estimated that in 2001, it accounted for 10 per cent of global healthcare expenditure causing considerable economic repercussion to resource constrained health systems, particularly those in low and middle income countries². The challenges of managing hypertension (HT) and preventing the development of these latter outcomes are unlikely to concede; the global burden of hypertension is anticipated to increase by 60 % to affect approximately 1.6 billion adults worldwide by 2025.³ In India, hypertension is the foremost NCD risk and predicted to be responsible for nearly 10 per cent of all deaths⁴. Over the past three decades, there has been a considerable increase in prevalence of adult hypertension

from 5 per cent to between 20-40 per cent in urban areas and 12-17 per cent in rural areas^{5,6}. The number of hypertensive individuals is expected to nearly double from 118 million in 2000 to 213 million by 2025⁶. It is estimated that hypertension is accountable for about 16 per cent of ischemic heart disease, 21 percent of peripheral vascular disease, 24 percent of acute myocardial infarctions and 29 percent of strokes⁷. Thus effective hypertension prevention and control can have colossal impact on reducing the rising burden of cardiovascular disease (CVD). There are various modern drugs available as anti-hypertensive e.g. Beta blockers, ACE inhibitors, Calcium channel blockers, α blockers and diuretics but these drugs have side effects and most of these are not cost effective. Hence there is a dire need to search for potent safe and cost effective Ayurveda anti-hypertensive medicine. M-Sarpagandha Mishran which is a combination of herbal ingredients having normo-tensive properties as mentioned in classical Ayurveda texts is taken up for the present study. The product has been in use for many years and has shown normo-tensive effect, with no side effects observed so far.

Aims and Objectives

To study the effect of polyherbal compound M-Sarpagandha Mishran in essential hypertension

MATERIALS AND METHODS

Study design

Present study was an open, single arm clinical trial. Patients attending O.P.D. under National Campaign of All India Institute of Ayurveda, New Delhi, India with essential hypertension were included in the study. A total of 41 patients of essential HT of age above 18 years and below 70 years, of either sex, satisfying the inclusion criteria were enrolled for the study. During the study, 11 patients dropped out and only 30 were followed till the end. Informed consent was taken from the patients before including them in the trial. All the patients were administered with trial drug M Sarpagandha Mishran 250mg twice a day, 30 minutes after light meals. The patients were registered and their data for demographic and clinical profile was maintained. The drug was given with follow ups every 2 weeks for duration of eight weeks. The study was conducted in OPD of AIIA under National Campaign Programme during the period Dec 2013 to May 2014 as per ICMR ethical guidelines for biomedical research.

Diagnostic Criteria

Patients were categorized according to the classification of hypertension as defined by 7th Joint National Committee Report (JNC 7 classification) and stage I and Stage II patients were considered for the study⁸. (Table 1 stages of HT according to JNC 7 classification)

Inclusion Criteria

- Willing to give written consent to participate in the study
- Age above 18 years and below 70 years of either sex.
- Diagnosed patients of essential hypertension of duration < one year with:
S.B.P > 140 mm Hg; and/or
D.B.P. > 90 mm Hg
- Patients with stable BP and with no significant change in their therapy over the last 4 weeks prior to entry into the study
- Controlled type 2 diabetic patients without complications and not on insulin.

Exclusion Criteria

- Age below 18 years and above 70 years
- Patient already receiving anti- hypertensive medicine.
- Complicated hypertensive cases e.g. nephropathy, left ventricular hypertrophy, heart block, congestive heart failure, coronary artery disease and retinopathy
- Asthmatic and COPD patients
- Accelerated and malignant hypertension.
- Patients on steroids, oral contraceptive pills, estrogen replacement therapy or NSAID group of drug, pregnancy.
- Patients on anti depressant therapy.
- Patients with other severe illness hepatic/renal failure.
- Secondary hypertension.

Assessment Criteria

Assessment was done on basis of systolic, diastolic and mean arterial blood pressure blood pressure level measured before and after the treatment.

Withdrawal of Subjects

Patients were withdrawn from the study on following grounds:

- Failure of subjects to adhere to protocol requirements.
- Subject consent withdrawal.
- Disease progression.
- Subject gets pregnant.

Lab Investigations

- Blood - Routine hematology investigation, lipid profile, blood urea, serum creatinine (if necessary and possible), CPK-MB (if necessary and possible).
- Urine - Routine and microscopic examination.
- ECG and X-ray (if necessary and possible).

These investigations were conducted to exclude any other underlying pathology.

Intervention

Patients were categorized according to JNC7 classification of hypertension and the patients with stage I and stage II HT were prescribed the trial drug, M-Sarpagandha Mishran 250 mg twice a day with lukewarm water. All the patients were motivated for diet and life style modifications (adequate exercise, salt restriction in diet, smoking cessation, avoidance of alcohol intake). All the patients attended the clinic at 2 weekly intervals at 2, 4, 6, and 8 weeks. Each time BP was measured by the same person to reduce the subjective error. BP measurements were taken uniformly after rest for at least 5 minutes and in sitting position in the right arm using same zero mercury sphygmomanometer on each visit. At each visit SBP, DBP and mean BP (MBP) were recorded. MBP was calculated as $DBP + PP/3$ (PP = Pulse Pressure). Results were statistically analyzed at the end of the study by paired Student's t- test.

Trial Drug and Posology

M- Sarpagandha Mishran was given to the subjects enrolled for the study.

Formulation of M- Sarpagandha Mishran (Table 2 Formulation of M- Sarpagandha Mishran)

Dose

M-Sarpagandha Mishran: 1 tab (250 mg) twice a day with water after light meals. The required amount of medicines was supplied by the Indian Medicines Pharmaceutical Corporation Limited (A Government of India Enterprise) Mohan - Dist. Almora (via-Ramnagar-244715), Uttarakhand, India after ensuring safety and batch to batch quality.

Anupana: Water

Duration: 8 weeks

The patients were given medicine for 8 weeks and were assessed after every 2 weeks i.e., 4 times during the course of treatment to observe the extent of relief and side effects, if any. However during first week, patients were monitored twice to see any untoward change in blood pressure.

Diet

Patients were kept under normal diet with special restriction of excessive salt intake, deep fried, oily and spicy food. A copy of diet chart was given to each patient.

OBSERVATION AND RESULTS

In the present study, all the patients selected were in the age group of 18-70 years. Out of total enrolled subjects, 30 completed the study of which 08 (26.7 %) were male and 22 (73.3 %) were female (Table 3: Gender wise Distribution). The mean age of the patients was 50.73 ± 1.624 years with 70 % patients in the age group of 41-60 years of age (Table 4: Age wise Distribution). On first visit the mean SBP, DBP and MBP were 158.53 ± 2.471 , 98.37 ± 2.203 and 118.43 ± 1.558 mm Hg, respectively. Clinically significant improvement in BP was seen in each visit right from within 15 days of starting the therapy (Table 5 and 6: Changes in the severity of Systolic and diastolic BP after treatment). The Mean SBP was 142.00 ± 3.048 , 134.10 ± 3.048 , 127.53 ± 2.520 and 126.6 ± 1.897 mmHg at 15, 30, 45 and 60 days, respectively. The Mean DBP was 86.30 ± 2.016 , 82.33 ± 1.958 , 78.90 ± 1.612 and 78.37 ± 1.264 mmHg at 15, 30, 45 and 60 days, respectively. The Mean MBP was 104.97 ± 2.184 , 99.57 ± 2.215 , 95.17 ± 1.781 , 84.43 ± 1.268 mmHg at 15, 30, 45 and 60 days, respectively. (Table 7, Figure 1 and 2: Changes in blood pressure after 1st, 2nd, 3rd and 4th week of treatment). The change in mean SBP, DBP, and MBP before and after the treatment was analyzed by paired student t test and the result was found to be statistically significant (P value < 0.0001) (Table 8: Statistical analysis of improvement blood pressure after 60 days of treatment). The decrease in mean SBP, DBP and MBP was more in Stage II Hypertension as compared to Stage I Hypertension at all intervals of time. (Table 9: Showing change in BP according to stage of hypertension). The range of changes in systolic and diastolic BP, after the treatment is shown in Table 10 and 11.

DISCUSSION

Hypertension has emerged as a leading contributory cause of deaths among the group of non-communicable diseases worldwide and a major risk factor for cardiovascular diseases. It accounts for approximately 50 % of all strokes and ischemic cardiac events globally⁹. The risks for both of these outcomes increase progressively with incremental rise in both systolic and diastolic blood pressure above 115/75 mm Hg¹⁰. Similarly, progressive increase in pulse pressure (difference between systolic and diastolic blood pressures) is likewise associated with heightened cardiovascular risk¹¹. Despite advances in pharmacological therapy and well established goals of

treatment as given by JNC7 and JNC8 recommendations, the morbidity and mortality of those afflicted with hypertension not only continues to remain high but also on an increasing trend globally. Main reasons are raising stress levels, faulty lifestyle, poor patient compliance and adverse effects of conventional antihypertensive drugs¹². Developing innovative and cost-effective solutions to improve hypertension diagnosis and control thus remains a key priority¹³. While selecting patients for the present trial, it was observed that most of the patients were in the age group of 41-60 years (70 %). Studies have indicated advancing age as one of the major risk factors for developing essential HT¹⁴. However due to increasing stress and lifestyle changes, cardiac problems are increasing in middle and younger age group also. The trial drug M-Sarpagandha Mishran is a polyherbal formulation which has been formulated taking into consideration the drawbacks of conventional antihypertensive medications. It contains seven ingredients, selected for their peculiar qualities which may help in regulating blood pressure. Sarpagandha (*Rauwolfia serpentina* Benthex Kurz.) is one of the main ingredients. Studies have shown Sarpagandha to have anti-adrenergic and antidepressant property and it is a well proven antihypertensive¹⁵⁻¹⁷. Shankhpushpi (*Convolvulus pluricaulis* Choisy) is a medhya rasayan, which controls the production of stress hormones. Its ethanolic extract has been found to reduce cholesterol, triglycerides, and phospholipids. Being an antioxidant also, its use in cardiovascular diseases (CVD), such as hypertension is known. Its stress lowering effect adds to its antihypertensive action¹⁸. Jatamansi (*Nardostachys jatamansi* DC) is another herb, oily extract of which has been found to have antioxidant, anti ischemic and anti arrhythmic potential. It also increases high density lipoprotein levels, which are protective lipids¹⁹. A few studies have also mentioned its anxiolytic action¹⁸. Rasayana property of Shankhpushpi, Brahmi, Guduchi and Punarnava check degenerative changes in affected organ (as arteriosclerosis in vessels) due to pathological changes and also provide nourishment at cellular level. Punarnava is a well known diuretic. Medhya property of Shankhpushpi, Brahmi, and Guduchi calms the mind and maintain equilibrium of autonomous nervous system which acts on vasomotor center which creates vasodilatation and may be helpful to decrease the blood pressure²⁰. Thus the synergistic action of all these is resulting in a high efficacy and high potency normotensive remedy "M- Sarpagandha Mishran." Treatment with M- Sarpagandha Mishran has produced an early, sustained and significant fall in BP. Normotensive effect of the drug in terms of SBP and DBP was observed in all the patients. Age or gender did not significantly affect the responsiveness to study drug. During analysis it was observed that normotensive effect of the drug in terms of SBP and DBP was observed in all the patients. Nearly 10-40 mmHg falls in systolic BP was observed in more than half of the trial subjects (53.33 %) patients and 11-30 mmHg fall of diastolic BP was observed in 73 % patients. The benefit was seen more in stage II patients than in stage I patients as revealed in Table 9. Two among the trial subjects were cases of isolated systolic hypertension in which diastolic BP was within normal

range. After treatment it was observed that their systolic BP came down but there was no change in diastolic BP. This observation compels us to believe that the medicine is essentially normotensive which helps in regulating BP without lowering it to the undesired levels.

Table 1: Stages of HT according to JNC 7 classification

Category	Blood Pressure mm Hg.	
	Systolic	Diastolic
Normal*	<120	< 80
Pre hypertension	120-139	80-89
Hypertension	> 140	> 90
Hypertension:		
Stage-1	140-159 or	90-99
Stage-2	≥160	≥100

Table 2: Formulation of M- Sarpagandha Mishran

Name of the ingredient	Botanical name	Part used	Each 250 mg tab contains
Sarpagandha	<i>Rauwolfia serpentina</i> Benthex Kurz.	Roots	39 mgm
Jatamansi	<i>Nardostachys jatamansi</i> DC	Roots	39 mgm
Vacha	<i>Acorus calamus</i> Linn.	Root and tubers	39 mgm
Punarnava	<i>Boerhavia diffusa</i> Linn.	whole plant	39 mgm
Brahmi	<i>Bacopa monierie</i> (Linn.) Pennel	whole plant	39 mgm
Shankpushpi	<i>Convolvulus pluricaulis</i> Chois	whole plant	39 mgm
Guduchi Extract	<i>Tinospora cordifolia</i> Willd Miers ex Hook f. and Thoms	Extract (for trituration)	
Sarpagandha Extract	<i>Rauwolfia serpentina</i> Benthex Kurz.	Extract (for trituration)	

Table 3: Gender wise distribution of patients (N = 30)

Gender	Number of patients	%
Male	08	26.70
Female	22	73.30

Table 4: Age wise distribution of patients (N = 30)

Age group (in years)	No. of patients	Percentage (%)
18-30	00	00.00
31-40	06	20.00
41-50	11	36.67
51-60	10	33.33
61-70	03	10.00

Table 5: Changes in the severity of systolic BP after treatment (N = 30)

Severity grade	BT		AT1		AT2		AT3		AT4	
	N	%	n	%	n	%	n	%	N	%
Normal	00	0.00	01	3.3	04	13.3	06	20.0	06	20.00
High Normal/ Pre HT	01	3.3	008	26.7	13	43.3	15	50.0	22	73.30
Stage 1 HT	13	43.3	16	53.3	10	33.3	09	30.0	02	06.70
Stage 2 HT	16	53.3	5	16.7	03	10.0	00	00.0	00	00.00

BT: Before treatment, AT1: After 15 days of treatment, AT2: After 30 days of treatment, AT3: After 45 days of treatment, AT4: After 60 days of treatment, N: Number of patients

Table 6: Changes in the severity of diastolic BP after treatment (N = 30)

Severity grade	BT		AT1		AT2		AT3		AT4	
	N	%	n	%	n	%	n	%	N	%
Normal	1	3.3	6	20.0	7	23.3	8	26.7	11	36.70
High Normal/ Pre HT	1	3.3	9	30.0	12	40.0	16	53.3	17	56.70
Stage 1 HT	10	33.3	8	26.7	8	26.7	6	20.0	2	06.70
Stage 2 HT	18	60.0	7	23.3	3	10.0	00	00.0	00	00.00

BT: Before treatment, AT1: After 15 days of treatment, AT2: After 30 days of treatment, AT3: After 45 days of treatment, AT4: After 60 days of treatment, N: Number of patients

Table 7: Changes in Blood Pressure After 1st, 2nd, 3rd And 4th Week of Treatment

	N	BT	AT1	AT2	AT3	AT4
Systolic Blood Pressure (SBP)	30	158.53 + 2.471	142.00 + 3.048	134.10 + 3.048	127.53 + 2.520	126.6 + 1.897
Diastolic Blood Pressure (DBP)	30	98.37 + 2.203	86.30 + 2.016	82.33 + 1.958	78.90 + 1.612	78.37 + 1.264
Mean Arterial Blood Pressure (MBP)	30	118.43 + 1.558	104.97 + 2.184	99.57 + 2.215	95.17 + 1.781	84.43 + 1.268

BT: Before treatment, AT1: After 15 days of treatment, AT2: After 30 days of treatment, AT3: After 45 days of treatment, AT4: After 60 days of treatment, N: Number of patients

Table 8: Statistical analysis of improvement in blood pressure after 60 days of treatment

Observations	Mean			S.D.	S.E.	t	p
	B.T.	A.T.	Diff.				
Systolic B.P.	158.53	126.60	31.933	14.215	2.595	12.304	< 0.001
Diastolic B.P.	98.37	78.37	20.00	11.280	2.059	09.711	< 0.001
Mean Arterial B.P.	118.43	94.43	24.00	8.808	1.608	14.924	< 0.001

Table 9: Change in BP according to Stage of Hypertension

	Stage	AT1	AT2	AT3	AT4
Systolic Blood Pressure (SBP)	Stage I	-14.71 + 3.219	-19.86 + 3.944	-25.71 + 3.338	-23.00 + 2.639
	Stage II	-18.12 + 4.082	-28.43 + 4.483	-35.62 + 3.323	-39.75 + 2.703
Diastolic Blood Pressure (DBP)	Stage I	-10.17 + 2.111	-11.75 + 1.880	-12.59 + 1.930	-14.42 + 1.435
	Stage II	-13.33 + 2.322	-18.89 + 2.698	-24.06 + 2.273	-23.72 + 1.550

BT: Before treatment, AT1: After 15 days of treatment, AT2: After 30 days of treatment, AT3: After 45 days of treatment, AT4: After 60 days of treatment, N: Number of patients

Table 10: Range of change in systolic BP, after the treatment (N = 30)

S. No.	Change in Systolic BP (mmHg)	No. of patients	Percentage (%)
1.	5-10	04	13.33
2.	11-20	05	16.67
3.	21-30	07	23.33
4.	31-40	08	26.67
5.	41-50	04	13.33
6.	51-60	02	06.67

Table 11: Range of Change in Diastolic BP, After the Treatment (N = 30)

S. No.	Change in Diastolic BP (mmHg)	No. of patients	Percentage (%)
1.	0-10	06	20.00
2.	11-20	14	46.67
3.	21-30	08	26.67
4.	31-40	01	03.33
5.	41-50	00	00.00
6.	51-60	00	00.00
7.	61-70	01	03.33

CONCLUSION

M-Sarpagandha Mishran along with the diet and lifestyle modification is a safe and efficacious remedy for the management of all grades of essential hypertension in all age groups with no apparent adverse effects observed so far.

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