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Research Article

EVALUATION OF AN AYURVEDIC FORMULATION IN THE MANAGEMENT OF ESSENTIAL HYPERTENSION IN ELDERLY PATIENTS

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ABSTRACT

Introduction: Hypertension is emerging as a pandemic in the society. Though a lot of potent antihypertensive drugs are available today but none of them is free from untoward effects. Especially the elderly population poorly tolerates these drugs.

Objective: This study was conducted to clinically evaluate the efficacy of an *Ayurvedic* formulation in the management of essential hypertension in elderly patients.

Materials and Methods: 45 patients of either sex of stage-I essential hypertension in the age group of 60-90 years were registered for the present study. Patients with stage-II hypertension, and secondary hypertension were excluded from study. Registered patients were randomly divided into two groups. In group-I patients were managed with *Tagar Churna*, *Gokshur Churna* and *Triphla Churna*. Group-II patients were managed with a standard calcium channel blocker drug Amlodipine. The duration of trial was 30 days.

Observations: After one month of therapy statistically highly significant reduction in systolic B.P., diastolic B.P. mean arterial B.P. and pulse pressure was observed in both groups. Pulse rate was statistically significantly reduced in group-I patients. Biochemical studies revealed a beneficial effect on serum lipid profile in group-I patients whereas in group-II patients it remained unchanged.

Conclusion: It is evident from results of the study that combination of *Tagar* and *Gokshura* along with *Triphala Churna* possess potent antihypertensive activity. Combination of trial herbs appear to be safe for elderly hypertensive patients when given in mentioned doses and duration as no untoward effect of therapy was observed during the study period.

KEYWORDS: Hypertension, Herbal drugs, *Tagar, Gokshur, Triphala*.

INTRODUCTION

India is labeled as global capital of hypertension due to the presence of maximum number of hypertensive patients in the country. Hypertension affects approximately one billion individuals worldwide. It is a multifactorial disease where age is also becoming an important predisposing factor. Hypertension is a major risk factor for the development of coronary artery disease, stroke, congestive heart failure and renal disorders[1]. Recent data from Framingham Heart Study suggest that individuals who are normotensive at the age of 55 have a ninety percent risk for developing hypertension[2]. In clinical trials, antihypertensive therapy has been associated with reduction in stroke incidence averaging 35-40 percent; myocardial infarction, 20-25 percent; and heart failure, more than 50 percent[3]. Recent clinical trials have demonstrated that effective blood pressure control can be achieved in most patients who are hypertensive. However, majority will require two or more antihypertensive drugs[4]. Currently, numbers of effective antihypertensive drugs are available. However, they are not free from side effects. Especially the elderly population poorly tolerates these drugs due to above said reasons. Beta blockers often cause fatigue, cold extremities, bradycardia and heart-failure. Similarly, angiotensin converting enzyme inhibitors may cause cough and rash[5] etc. Ideally, an antihypertensive drug should achieve optimum blood pressure control and improve patient's well being. Any treatment administered should be directed not only to control blood pressure, but

also prevent target organ damage, thereby preserving cardiac and renal functions which may also increase patient's life span[6-7]. Therefore based on these parameters we have tried to develop a safe anti hypertensive therapy with the help of an *Ayurvedic* herbal formulation.

Many herbs are described in *Ayurveda* which have diuretic, cardio protective and anti stress activities. Of these, *Gokshur* (*Tribulus terrestris L.*) and *Tagar* (*Valeriana wallichi DC.*) have been found to show potent antihypertensive activity in animals[8,10,11]. *Gokshur* is documented to have, antihypertensive[10], ACE inhibiter[11], anti dyslipidemic[12] and diuretic[13] properties.

Objectives of the Research work

To clinically evaluate the efficacy of *Gokshur* (*Tribulus terrestris* L.) and *Tagar* (*Valeriana wallichi DC.*) with *Triphla Churna* (powder) in the management of Essential Hypertension in Elderly patients.

Place of Study: The study was conducted as a part of post graduate thesis research work in P.G. department of Kayachikitsa of Rajiv Gandhi Govt. Post Graduate *Ayurvedic* College & Hospital Paprola, Himachal Pradesh in the year 2010.

Materials and Methods

The present study was open, single blind and double group in nature. The study was conducted on 45 patients of essential hypertension selected from OPD and IPD of associated hospital of Rajiv Gandhi Govt. Post Graduate *Ayurvedic* College, Paprola (H.P.). Patients of stage-I essential hypertension (JNC-7) in the age group of 60-90 years were registered irrespective of caste, sex, race and religion after obtaining their written informed consent. 5 patients did not turn up for follow up. They were considered dropped out from the study. Remaining 40 patients completed the trial.

Criteria of Diagnosis

Diagnosis was mainly based on readings of sphygmomanometer. With the help of sphygmomanometer, 3 consecutive readings of blood pressure in 3 different positions (sitting, standing and supine) on both arms were taken. Their mean value was calculated for each arm separately and the higher reading was utilized for diagnosing and categorizing the patients according to VII Joint National Committee on Detection, Education and Treatment of High Blood Pressure. To determine systolic and diastolic blood pressure the Kortokoff sound I and V were used.

Inclusion Criteria

1. Patients in age-group between 60-90 years.
2. Patients suffering from stage-I hypertension (Systolic Blood pressure 140–159 mmHg and diastolic blood pressure 90-99 mmHg) and isolated systolic hypertension (Systolic Blood pressure ≥140 mmHg and diastolic blood pressure <90 mmHg)

Exclusion Criteria

1. Stage II Hypertension i.e. Systolic B.P.>160 mmHg. and/ or Diastolic B.P.> 100 mmHg.
2. Secondary hypertension including endocrinal disorders, renal disease and hypertension associated with pregnancy.

Method of study: After registration patients were given the medicine and were followed up initially after 3 days and then after 10 days till completion of trial i.e., 30 days. The selected patients were divided into two groups.

Group-I (Trial group) Total 25 patients were registered in this group, out of them 5 patients discontinued the treatment and only 20 patients completed the trial. In this group hypertensive patients were treated with following drugs.

1. *Tagar Churna* (powder): 1gm BD with water.

2. *Gokshur Churna* (powder): 6gm BD with water.

3. *Triphla Churna* (powder): was given in the dose of 6gm at bed time with Luke warm water for 7 days in the beginning of trial along with other trial drugs.

Trial drugs were prepared in state *Ayurvedic* pharmacy Paprola, H.P. which is G.M.P. certified.

Gokshur (*Tribulus terrestris* L.) fruits were grinded to prepare fine powder. *Tagar* (*Valeriana wallichi* DC.) roots were also grinded to prepare fine powder. *Triphla Churna* was prepared by combining the powder of fruits of *Haritaki* (*Terminalia chebula* Retz.), *Vibhitak* (*Terminalia bellirica* Gaertn.) and *Amalaki* (*Emblica officinalis* Gaertn.) in equal quantity.

Group-II (Standard group): Total 20 patients were registered in this group and all the patients completed the trial. In this group patients were managed with a standard calcium channel blocker drug Amlodipine. It was given once a day schedule in a dose of 5 mg in the morning hours.

Investigations

Following investigations were carried out to rule out any other concomitant disease,

secondary hypertension and to see any untoward effect of the trial drugs both before and after the therapy.

Blood - Hb%, TLC, DLC, ESR, Blood Urea, S. Creatinine, FBS, Lipid profile (LDL, VLDL, HDL, S. Triglycerides, S. Cholestrol), S.G.O.T., S.G.P.T.

Urine- Routine and Microscopic, ECG, X-ray Chest, USG/IVP/X-ray KUB **-** if felt necessary.

Duration: The duration of trial was 30 days.

Criteria for Assessment

Assessment of the effects of therapy was done on the basis of various objective and subjective parameters. However the change in systolic, diastolic and mean blood pressure was the main criteria. Signs and symptoms were graded according to severity.

Objective parameters: By noting down the alteration in blood pressure, pulse pressure, mean arterial pressure and pulse rate

Table: Gradation of subjective parameters

Subjective parameters	Gradation	Score
Shira shoola (Headache)	No Headache	0
	Mild - able to do daily work	1
	Moderate - hampers routine work	2
	Severe - unable to any work	3
Bhrama (Giddiness)	No Giddiness	0
	Mild - able to do daily work	1
	Moderate - hampers routine work	2
	Severe - unable to any work	3
Hridadrava (Palpitation)	No palpitation	0
	Occasional palpitation	1
	Palpitation which hampers routine work	2
	Continuous palpitation	3
Shwasa (Breathlessness)	No dyspnoea on exertion	0
	Mild dyspnoea on exertion	1
	Moderate dyspnoea on little exertion	2
	Severe dyspnoea with/without little exertion	3

Data Collection and Statistical Analysis: Data generated from clinical study was collected and analyzed statistically. The improvement in the status of patient was assessed on the grades of various variables compared between pre-trial and post-trial values in terms of percentage (based on mathematical mean and its difference) and the student 't' tests was applied wherever it was felt necessary by using degree of freedom value. The results were interpreted at the level of $p<0.001$ as highly significant, $p<0.01$ as moderately significant, $p<0.05$ as significant and $p>0.05$ as insignificant.

Results

Table 1: Showing statistical analysis of Objective parameters in both groups

Variable in mm Hg	Group-I							Group – II						
	Mean Score		% Change	SD	SE ±	t	P	Mean Score		% Change	SD	SE ±	t	P
	BT	AT						BT	AT					
Systolic BP	148.40	132.00	11.05	05.83	01.30	12.50	<0.001	150.00	125.50	16.30	07.81	01.74	14.02	<0.001
Diastolic BP	87.50	84.50	03.42	03.74	00.83	09.40	<0.001	91.40	82.70	09.51	03.62	00.80	11.30	<0.001
Mean Arterial Pressure	111.46	100.30	10.01	03.51	0.78	14.21	<0.001	110.80	97.03	12.42	02.71	0.60	22.72	<0.001
Pulse Pressure	60.90	47.50	22.00	07.55	01.83	05.80	<0.001	58.60	42.80	26.96	06.80	01.50	10.45	<0.001
Pulse Rate	85.10	79.40	06.69	02.92	00.65	08.72	<0.001	79.90	82.90	03.75	02.38	00.53	05.63	<0.001

Table 2: Showing statistical analysis of Subjective parameters in both groups

Subjective parameters	Group-I							Group – II						
	Mean Score		% Change	SD	SE ±	t	P	Mean Score		% Change	SD	SE ±	t	P
	BT	AT						BT	AT					
Headache	0.80	00.15	81.25	00.67	0.14	04.31	<0.001	02.00	00.88	56.23	00.35	00.13	09.00	<0.001
Giddiness	02.00	01.00	50.00	00.87	00.29	03.46	<0.01	02.00	00.67	66.27	00.82	00.33	04.00	<0.01
Palpitation	00.90	00.45	50.00	00.60	00.13	03.31	<0.001	0.98	0.56	43.18	0.49	0.07	5.68	<0.001
Breathlessness	02.00	00.89	55.56	00.60	00.20	05.51	<0.001	01.45	00.81	37.54	00.52	00.15	03.46	<0.01

Table 3: Showing statistical analysis of objective/lab parameters in both groups

Variable	Group-I							Group – II						
	Mean Score		% Change	SD	SE ±	t	P	Mean Score		% Change	SD	SE ±	t	P
	BT	AT						BT	AT					
Hb%	11.43	11.58	01.30	00.48	00.10	0.09	>0.05	11.14	11.34	01.75	00.39	00.10	00.08	>0.05
TLC	8075	7595	05.94	893	199.7	02.43	<0.05	7856.3	7837	00.24	379.8	84.90	10.73	<0.001
ESR	10.25	8.95	12.68	04.28	00.95	01.35	>0.05	12.06	07.94	34.16	03.72	00.83	04.43	<0.001
Polymorphs	55.19	59.39	07.60	09.41	01.69	02.48	<0.05	56.79	59.84	05.37	06.08	01.39	02.19	<0.05
Lymphocytes	38.48	34.09	11.40	08.10	01.61	02.71	<0.05	36.63	34.15	06.87	05.95	01.37	01.85	>0.05
Monocytes	02.87	02.81	02.09	00.77	00.17	00.46	>0.05	02.95	03.10	05.36	00.96	00.22	00.72	>0.05
Eosinophils	02.69	01.38	48.69	01.09	00.25	05.18	<0.001	01.86	01.10	40.80	00.77	00.20	03.80	<0.01
F.B.S.	83.81	82.53	01.53	01.37	00.30	03.74	<0.01	82.00	79.40	03.17	10.11	02.26	01.88	>0.05
B. Urea	26.65	25.90	02.81	03.99	00.89	00.84	>0.05	26.73	23.38	12.53	03.23	00.72	04.14	<0.01
S.Creatinine	00.73	00.69	05.47	00.17	00.03	00.70	>0.05	00.60	00.55	08.30	00.04	00.08	05.28	<0.01
SGOT	27.35	17.71	35.24	6.22	1.66	5.79	<0.01	29.00	33.85	16.72	3.43	0.91	5.28	<0.01
SGPT	27.36	19.71	27.96	3.81	1.01	7.49	<0.01	27.86	30.57	09.72	4.71	1.25	2.15	>0.05
S. Cholesterol	237.20	223.35	05.87	14.24	03.87	3.66	<0.01	226.91	216.0	04.80	21.91	04.90	03.80	>0.05
S. Triglyceride	187.17	173.42	07.37	18.80	05.07	2.71	<0.05	164.02	158.9	03.09	15.61	03.49	05.00	>0.05
HDL	037.41	39.20	04.78	02.60	00.68	2.56	<0.05	37.13	37.46	0.88	1.53	0.23	1.35	>0.05
LDL	159.99	153.35	04.15	15.28	04.09	2.07	<0.05	155.67	150.2	03.51	15.08	03.37	07.70	>0.05
VLDL	39.08	37.88	03.07	08.14	02.17	0.73	>0.05	37.80	37.47	0.87	1.43	0.21	1.57	>0.05

Table 4: Showing comparison of effect of therapies between two groups

Group-I V/s Group-II Comparison	Mean Difference	t	P
Systolic Blood Pressure	5.25	3.76	<0.01
Diastolic Blood Pressure	6.09	5.08	<0.001
Mean Arterial Pressure	02.41	02.90	<0.01
Pulse Pressure	04.96	03.17	<0.01
Pulse Rate	02.74	07.37	<0.001
Headache	25.02	02.90	<0.01
Giddiness	16.27	01.95	>0.05
Palpitation	05.56	03.20	<0.01
Breathlessness	40.96	05.41	<0.01

Among the total 45 registered patients, 40 patients i.e. 20 patients in group-I and 20 patients in group-II completed the trial successfully. In both groups the effect of therapy showed statistically highly significant reduction in systolic blood pressure, diastolic blood pressure, pulse pressure and mean blood pressure (P<0.001). *Ayurvedic* herbal formulations and Amlodipine reduced (P<0.001) systolic, diastolic, pulse pressure and mean blood pressure in a similar manner. Inter group comparison showed significant difference between two therapies in reduction of systolic, diastolic, pulse pressure and mean blood pressure (P<0.01) (Table 4). Amlodipine reduced systolic, diastolic, pulse pressure and mean blood pressure to the greater extent than *Ayurvedic* formulation. Pulse rate was increased significantly (P<0.001) by Amlodipine, whereas trial drugs caused statistically highly significant reduction in pulse rate (P<0.001). However pulse rate remained within normal range in both groups both before and after the therapy (Table 1). In both groups the effects of therapy on the subjective parameters was highly significant and the intergroup comparison showed that therapy in group-I had statistically significant advantage over therapy used in group-II on headache, palpitation, and breathlessness (Table No. 4). Most of the base line hematological and biochemical parameters remained within normal

limits before and after the therapy in both the groups. Serum cholesterol and other components of lipid profile were significantly ($p<0.01$) reduced whereas serum HDL was significantly increased after the treatment in trial group-I (Table No. 3). In group-II no effect on serum lipid profile was observed after the therapy.

DISCUSSION

Increasing rate of hypertension is the major risk factors for cardiovascular mortality. Hypertension can be controlled in almost all the patients with the currently available drugs. However, none of the currently available antihypertensive drugs are free from side effects. Recent clinical trials have demonstrated that majority of hypertensive patients require two or more antihypertensive drugs for optimum blood pressure control. Due to multiple drug therapy the annoying side effects are further augmented, leading to decreased compliance in a symptomatic patient. The present trial is an attempt to develop an ideal herbal antihypertensive formulation which is safe for long term use.

In this study the antihypertensive therapies in both the groups showed statistically highly significant effect in reduction of systolic blood pressure, diastolic blood pressure, mean arterial pressure and pulse pressure. In terms of subjective parameters, trial herbal drugs showed statistically highly significant effect and it also showed statistically significant advantage over control group drug in all subjective symptoms except in giddiness in which the intergroup comparison showed statistically insignificant difference (Table No. 4). The trial drug also showed significant advantage over control group drug in improvement of lipid profile (Table No. 3). During the course of treatment all the patients reported a feeling of well being and no untoward effects were observed.

Hypertension accelerates the development of atherosclerosis, especially when combined with other risk factors like dyslipidemia. After the treatment the drug formulation significantly ($P<0.001$) lowered serum cholesterol level (Table No. 3). It was further observed that patients treated with herbal drugs formulation developed a sense of well being, increased physical and mental fitness after the course of therapy. No side effect was reported during or after the therapy. The possible action of drug formulation could be a result of reduced peripheral resistance, diuretic, decreased sympathetic tone and A.C.E. inhibiter activities[8,10,11,13]. One of the trial drug *Gokshur* is documented to have beneficial effect on dyslipidemia[12]. Further studies to understand the detailed mechanism of action of trial drugs are warranted.

CONCLUSIONS

On the basis of results obtained, it is clear that trial herbal drugs possess statistically significant antihypertensive activity though it is lesser than Amlodipin with no observed side effects. Thus it can be concluded that *Tagar Churna* and *Gokshur Churna* along with *Triphla Churna* could be used effectively in the management of essential hypertension. Furthermore, it may prove more useful in managing the hypertensive patients having concomitant dyslipidemia as the trial drug also possess significant hypolipidemic activities. More studies are required for thorough assessment of antihypertensive potential of trial drug.

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Abbreviations

B.P.	:	Blood Pressure
TLC	:	Total Leucocyte Count
DLC	:	Differential Leucocyte Count
ESR	:	Erythrocyte Sedimentation Rate
Hb	:	Haemoglobin
ECG	:	Electro cardio gram
gm	:	gram
mg	:	Milligram
mm Hg	:	Millimeter of mercury
SEM	:	Standard Error of Mean
SD	:	Standard deviation
BT	:	Before Treatment
AT	:	After Treatment

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TRIAL DRUGS PICTURES

Tagar Churna

Gokshura Churna

Triphala Churna