

To study & compare the efficacy of *Amyl nitrosum* & *Rauwolfia serpentina* mother tincture in cases of hypertension

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Abstract

Background: Widely increasing prevalence of hypertension is a new herald for upcoming non-communicable lifestyle disorders like cardiovascular diseases. Newer incidences of freshly occurring cases in youth will be the big catastrophic strategy for upcoming years in medical and pharmaceutical world. Ever increasing cost of treatment in conventional medicine brings enormous burden over economy and budget. Offering few options to the treatment and management; alternative and complementary system of medicine found some good maladies to put forward the efficacious and safe replacement or application in conjunction to modern medicine to give better quality of life.¹

Aims: To evaluate the efficacy of *Amyl nitrosum* & *Rauwolfia serpentina* mother tincture in cases of hypertension.

Settings and Design: The study was designed to compare the effect of *Amyl nitrosum* and *Rauwolfia serpentina* in hypertensive cases.

Material and Methods: It was a randomized non-blind open study wherein total 30 subjects were selected for the study.

Results: At the end of study significant reduction in blood pressure from baseline was seen with minimal adverse events. Both the treatments were generally well tolerated. Minimum and maximum reduction in systolic and diastolic pressure was well achieved by *Rauwolfia serpentina*.

Keywords: hypertension, non-communicable lifestyle disorders, complementary & alternative medicine, homoeopathy, randomized non-blind open study, systolic and diastolic blood pressure

Introduction

Approximately 1 billion people worldwide have high blood pressure, and this number is expected to increase to 1.56 billion people by the year 2025. Hypertension is prevalent in developing as well as in developed countries. Prolonged uncontrolled or inadequate treatment of hypertension is a major risk factor for the occurrence of heart attack, cerebrovascular accidents, renal failure and other cardiovascular diseases. In India community surveys have documented that between three and six decades, prevalence of hypertension has increased by about 30 times among urban dwellers and by about 10 times among the rural inhabitants. That translates to about 1 out of every 4 adults being afflicted with hypertension^[1,2].

Patients with high blood pressure wonder if there is one particular medication option that is better than the others. Adequate control of high blood pressure depends on a wide variety of patient specific factors

Antihypertensive drugs work in different ways to lower BP. Some drugs lower BP by removing extra fluid and salt from the body (e.g. diuretics). Others lower BP by slowing down the heartbeat (e.g. beta-blockers) or by relaxing, widening or preventing the narrowing of blood vessels (e.g., angiotensin-converting enzyme [ACE] inhibitors, calcium channel blockers [CCBs]). A review has described the main homoeopathic medicines whose centre of action includes the heart, especially medicines commonly used in mother tincture form for Hypertension. Homeopathic mother tinctures like *Rauwolfia serpentina* Linn, and *Amyl nitrosum*, have established clinically better quality of antihypertensive potential^[3].

Singular effect of administration of both agents in clinical

hypertension is already proved but analysis was not compared for replacement over one another in choice of treatment.³

In this study effect of *Amyl nitrosum* has been compared to that of *Rauwolfia serpentina* in hypertensive patients.

Aims & objectives

Aim

This particular study was aimed at comparing the efficacy of *Rauwolfia serpentina* & *Amyl nitrosum* Mother Tincture in treating cases of Hypertension.

Objective

Primary objective: To evaluate and document the evidence-based efficacy and safety of the study drugs in lowering BP.

Secondary objectives^[3]

- To assess the efficacy of the study drugs in relieving symptoms associated with Hypertension.
- To assess the efficacy of the study drugs in improving quality-of-life (QOL) in hypertensive subjects.
- To assess the improvement or changes, if any, in necessary investigations performed at the beginning and end of study especially Lipid profile & echocardiograms.

Material and Methods

Study Design: The duration of the study was 6 months.

Subjects with Prehypertension or Hypertension without target organ damage attending the author's OPD were included in the study.

A total of 30 subjects were screened and included in the study.

Informed consent was obtained from each study subject. The study drugs were dispensed in 30 ml bottle pack duly labeled as per the Drug Authority requirements from a renowned Homoeopathic Pharmacy. It was a randomized non-blind open study.

Inclusion Criteria ^[4]

- Adults of both sexes aged 25-75 years.
- Newly diagnosed or subjects with Prehypertension (diastolic BP [DBP] 80-89 mmHg and systolic BP [SBP] 120-139 mmHg) of less than one year duration.
- Patients with stage 1 (SBP >140 and <160 and DBP >90 and <100 mmHg) Hypertension.
- Patients with Stage 2 (SBP >160 and DBP >100 mmHg) Hypertension.
- All subjects will be subjected to a washout period of two weeks.
- Written informed consent for the use of the study drugs as stand-alone treatment and necessary investigations.

Exclusion Criteria ^[4]

- Known Secondary Hypertension target organ damage
- Body mass index (BMI) >35 kg/m².
- Pregnant and lactating women.
- Poorly-controlled Hypertension and/or complications.
- Diabetes.
- Abnormal lab screening: Hemoglobin (Hb) < 75% of lower limit, Serum Cholesterol > 300 mg/dl. Abnormal resting ECG.
- Pre-existing chronic debilitating illness.
- Subjects on hormonal contraceptives, Steroids or Nonsteroidal Anti-inflammatory Drugs (NSAIDs).

Criteria for Improvement ^[3]

The outcome measures were the changes in the systolic and/or diastolic blood pressure at a timeline of three months and six months.

The effect size was considered as the lowering of systolic and diastolic BP by a minimum of 15 mm and 6 mm Hg, respectively.

Thus, cases where this lowering in systolic and diastolic BP was observed were ascribed as ‘improved’ and the rest as ‘not improved’.

The study end-point was lowering of BP following intervention.

The primary safety end-point was any adverse event during the study.

The stopping guidelines were, a marked deterioration of health condition and/or constant increase in BP among subjects in either group, constant progress of disease with appearance of complications, and adverse events (if any).

Investigations ^[3]

The hypertensive status of the study population was initially confirmed by taking the average of the measured blood pressure twice on two separate occasions in two contralateral arms in a supine position during rest, using a mercury sphygmomanometer of standard cuff size, throughout the study. Every case was subjected to detailed screening by a specified eligibility criteria followed by recruitment in the study. After recruitment, all were subjected to baseline assessments. The pre-entry and post-intervention laboratory investigations performed were as follows: Blood for routine investigation (haemoglobin%, White Blood Cells (WBC)/WBC total count (TC) and differential count (DC), Erythrocyte Sedimentation Rate (ESR) first hour, fasting and postprandial sugar, urea, creatinine, total cholesterol, High Density Lipoprotein cholesterol/ HDLc, Low Density Lipoprotein cholesterol/ LDLc, Very Low Density Lipoprotein cholesterol/VLDLc and triglyceride), urine analysis (albumin, blood, WBC or pus cells).

Drug Dose Protocol

Each subject was given 20 drops of the study drug diluted with 30 ml water thrice-daily. Patients who were intolerant to the study drug were instructed to start with 10 drops of the study drug diluted with 30 ml water twice-daily and increase the dose gradually to 15 and then 20 drops.

Follow-up

The subjects were clinically assessed every week and their BP readings were recorded. Investigations were done at baseline and after every 1 month of treatment or completion of the study period. During the six-month study, all data was measured and analyzed at entry, after three months, and after six months of the study by the outcome assessor.

Diet & Regimen ^[4]

All the participants were given additional instructions regarding the diet (DASH diet; i.e., Dietary Approach to Stop Hypertension) and regimen, keeping in mind their socioeconomic status and level of education. The usual measures include avoiding tobacco and alcohol, restricting salt and saturated fat in the daily diet, increasing fruit and fibre content in the diet, and encouragement to undertake more physical activity. These additional measures were advised to all the participants to minimize bias.

Observation & Analysis

Data was extracted from the reports directly and independently. Pre-designed proforma was used by the investigator. All these were compiled at the end; data was extracted and analyzed.

Table 1

Characteristics		Drugs	
		<i>Amyl nitrosum</i>	<i>Rauwolfia serpentina</i>
Number of patients		12	18
Age		45-60	45-60
Gender	Male	07	12
	Female	05	06
	Family history of hypertension in	09	12
Diagnosis of study	Mild	08	14
	Moderate	03	03

	Severe	01	01
Medical history	Hyperlipidemia	10	13
	Diabetes mellitus	07	07
Social history	Smoking	04	07
	Alcoholism	03	02
	Rich food	09	10
	Stress	06	13
	Menopause	03	04

Statistical analysis

Table 2

Parameter	Drug	Diagnosis	Reviews			
			Baseline	First review	Second review	Third review
Blood pressure (in mmHg)	<i>Amyl nitrosum</i>	Mild	140±0.67/90±1.38	136±0.47/86±0.40*	124±0.47/78±0.30*	110±1.90/70±0.33*
		Moderate	158±0.65/100±0.1.20	150±0.64/96±0.45	142±0.36/88±0.1.09*	130±0.45/80±0.48*
		Severe	180±0.23/110±0.33	172±0.43/104±0.43	160±0.43/90±0.54*	152±0.33/86±0.67*
	<i>Rauwolfia serpentina</i>	Mild	138±0.32/90±0.43	130±0.56/82±0.25*	116±0.48/76±0.28*	100±0.35/60±0.27*
		Moderate	160±0.36/94±0.47	152±0.37/86±0.87*	140±1.67/78±0.57*	118±0.29/70±0.12*
		Severe	190±1.95/116±1.26	176±1.95/100±0.25*	168±1.38/86±1.96*	158±1.09/80±0.98*

*p < 0.001. When compared with baseline figures (ANOVA)

Discussion

In this study, blood pressure was reduced significantly with both the medicines. However maximum efficacy is seen in *Rauwolfia serpentina*.

This shows that as compared to conventional hypertensive medicines, homeopathic mother tinctures were also found useful in hypertensive cases.

Along with prevalence of hypertension significant background characteristics like hyperlipidemia and diabetes mellitus were also seen as emerging risk factors. Not only lifestyle mutations but also social factors such as smoking, alcohol, stress etc. were found contributed to the disease prognosis.

Lifestyle modification may add as an additional boon along with homeopathic medicine in treatment of hypertension.

Summary & Conclusion

In this study, blood pressure was reduced significantly with both the medicines. However maximum efficacy is seen in *Rauwolfia serpentina*.

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