

# A clinical trial to see the Effectiveness of potentized homeopathic medicine *Lycopus virginica* 30c in patients of Primary Hypertension in the age group of 30-70 years

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**Abstract-** According to the World Health Organization (WHO), hypertension (HTN) is one of the most prevalent health problems in today's expanding population. Research indicates that only 5% of people have secondary hypertension and that 85–95% of people have essential hypertension. Nonetheless, homoeopathy is utilized as a substitute in these situations, namely HTN, and it produces excellent therapeutic outcomes in HTN instances. Although very little study has been done to support it, *Lycopus Virginica* lowers the blood pressure, reduce the rate of heart and increase the length of systole to a great degree. This is a heart remedy Indicated in pulse weak, Irregular, Intermittent, tremulous and rapid. The purpose of this study was to determine whether or not essential hypertension individuals' blood pressure can be lowered by the homoeopathic medication *Lycopus Virginica* 30C. This is a single arm, single blind, monocentric phase II clinical trial. A total of 40 individuals, both male and female, ranging in age from 30 to 70 years, were included in this investigation. Of them, 30 patients finished their follow-up and 10 patients were discontinued. The patient was seated when their blood pressure was taken. After 10–12 weeks of outpatient therapy, the blood pressure finally decreased. Significant drops in hypertension patients' blood pressure were seen both before and after treatment, and the patients' symptoms were also alleviated. *Lycopus virginica* 30C, a homoeopathic medication, significantly lowered blood pressure in critical hypertension patients.

**Keywords:** *Lycopus Virginica*, Homoeopathy, silent killer, hypertensive-sinogenic factors.

## INTRODUCTION:

In India, hypertension is a major public health concern that causes over 1.1 million fatalities a year. It is predicted to be responsible for 4.6% of all disability adjusted life years (DALYs) and 10.8% of all deaths in the nation. According to the World Health Statistics 2012, non-communicable diseases (NCDs) are predicted to have caused 36 million (63%) of the anticipated 57 million deaths worldwide in 2008. Heart problems account for the majority of NCD mortality.

illnesses (48%). Because hypertension is often asymptomatic, it is frequently referred to as the "silent killer." An "iceberg disease" is HTN. [1]

According to the WHO's 2017 guidelines, hypertension is defined as SBP of 140 mm Hg or greater and/or DBP of 90 mm Hg or greater at any level of BP in patients taking anti-hypertensive drugs in individuals 18 years of age and older who are not severely unwell. When hypertension has no discernible cause, it is referred to as Essential/Primary Hypertension. Eighty-five to ninety-five percent of hypertensive patients have essential or primary hypertension, which is primarily caused by psychological, genetic, and environmental causes (40–60%). Kidney disease is referred to as secondary hypertension, but only 5% of patients with hypertension have an underlying endocrine disease. [2,9,10,11]

. We shall refer to the factors that raise blood pressure as "hyperten-sinogenic factors." These factors include obesity (38%) and high salt (30%) intakes. Age, genetics, and a positive family history are additional risk factors for essential hypertension (40–60%). Men > women in terms of sex hormonal elements: elevated rennin, Blacks are more ethnically diverse than Whites. Neurotransmitters include dopamine, serotonin, acetylcholine, adrenaline, and reduced physical exercise, psychological stress, Increase consumption of coffee, saturated fat, and 31 percent of smokers. These are the main causes of risk for conditions affecting the heart, brain, kidneys, and peripheral arteries, which can be fatal if left untreated. [3,12]

**ACC/AHA 2017 Hypertension guidelines-**(13<sup>th</sup> November, 2017)

Classification of hypertension according to Joint national committee (JNC-8)

- Normal Hypertension - Systolic B.P. <120 mm Hg, and Diastolic B.P. < 80 mm Hg
- Elevated B.P. - Systolic B.P. 120-129 mm Hg and Diastolic B.P. < 80 mm Hg
- Stage 1- Systolic B.P. 120-139 mm Hg and Diastolic B.P. 80-89 mm Hg
- Stage 2 - Systolic B.P.  $\geq$  140 mm Hg, and Diastolic B.P.  $\geq$  90 mm Hg
- Hypertensive crisis- Systolic B.P.  $\geq$  180 mm Hg, and Diastolic B.P.  $\geq$  120 mm Hg

**Pharmacotherapy-** Initial therapy with beta-blockers reserved for specific conditions including ischemic heart disease and heart failure.[4]

**European Society of Hypertension 2023 (ESH) Guidelines-**

- **Hypertension definition >140/90 mmHg**

**1.Normal BP ranges (mmHg)-**

- Optimal BP- 120/80 mmHg
- Normal BP –Systolic B.P. <120-129 mm Hg, and Diastolic B.P. < 80-84 mm Hg
- High Normal- 130-139/80-89 mmHg

**2.Hypertensive BP ranges (mmHg)-**

- Hypertension Grade I- 140-159/90-99 mmHg
- Hypertension Grade II- 160-179/100-109 mmHg
- Hypertension Grade III- More than(>) or equal to 180/110 mmHg

**BP targets for treatment-**

- 18-64 years - <130/80 mmHg
- 65-79 years - <140/80\* mmHg
- More than 80 years- 140-150/< 80

**Pharmacotherapy-** beta blockers use as a first line therapy for hypertension. [16]

Despite plethora of anti-hypertensive medicines are available, only 17% to 27% of HTN patients reach optimal B.P. [5] Despite the fact that the current medical system offers a wide variety of medications for treating HTN, it is complicated by annoying side effects reaction. Reducing blood pressure to a normal range is the primary goal in reducing the complications associated with cardiovascular disease. [6]

The consequences of elevated B.P. comprise encephalopathy, hypertensive retinopathy, cardiomyopathy, CVAs or cardiac strokes, etc. Based on data from the World Health Organization, homoeopathy ranks as the second most beneficial medical system globally and holds great promise for lowering high blood pressure in the general population. The medicine selected for this study was not supported by clinical trials, which is a requirement for science. [7, 15] In this investigation *Lycopus Virginica* employed in its 30th potency, which is derived from plant. *Lycopus* lowers the blood pressure, reduces the rate of the heart and increases the length of systole to a great degree. [8,14]

**MATERIAL AND METHODS:-**

This is a single arm, single blind, randomized, monocentric, Phase 2 clinical research that looks at the effectiveness of *Lycopus virginica* 30C in treating primary hypertension in people between the ages of 30 to 70 years. Patients complained of having increased blood pressure at rest, with a systolic blood pressure of at least 130 mmHg or more and a diastolic blood pressure of at least 90 mmHg or more, for no apparent reason. All patients received medicine in the form of 30 size globules and at an oral dosage of 4 tablets x TDS, with no water allowed for at least 15 to 20 minutes. The medication was kept at the proper temperature and in accordance with Pharmacopoeia (HPI) regulations. Log and batch numbers were kept up to date. A total of 30 cases—both male and female—were chosen voluntarily to participate in the study based on symptoms of Primary hypertension inclusion and exclusion criteria. Patients with any co-morbidity, secondary organ damage from hypertension, any systemic illness and/or very high BP i.e. more than 150/100 mmHg was excluded from the study. Every case was monitored for roughly three months. First follow-up after 7 days; subsequent follow-ups within 15 days, or sooner if necessary. A case form was used to record the patient's medical history, physical examination, which included a systemic examination and vital signs. As per standard operating protocols, blood pressure measurements were obtained on the right arm using a manual sphygmomanometer while the patient was seated. Prior to participation in the research project all basic test like complete blood count, serum electrolytes, blood sugar level, lipid profile, renal function test, and a 12-lead electrocardiogram were performed. Systolic and diastolic blood pressures were the parameters used. All patients with

primary hypertension who do not have any significant systemic problems, regardless of gender, and who fall within the age range of 30 to 70 years old are considered for inclusion. Patient with a blood pressure below 100 diastolic and 140 systolic, the competence to comply with study procedures, give informed consent, and exercise legal authority. Patients with serious co-morbidities or those in need of immediate medical attention are excluded. Lack of written agreement from the patient, Poor communication skills, individuals with any kind of systemic disease, Patients with blood pressure readings greater than 150 systolic and 100 diastolic; those using sedative drugs; and those taking anti-hypertensive drugs on a regular basis.

### Statistical Analysis:

[Table-1] Statistical analysis of Systolic and Diastolic blood pressure before and after treatment.

Observation	N	Mean SD	±SEM	MIN	MAX	Median	'P' Value	Mean of difference	
SBP BEFORE TREATMENT	30	139.1 2.080	± 0.37	130	140	140	<0.0001	SBP before and after Rx	DBP before and after Rx
SBP AFTER TREATMENT	30	130.1 5.040	± 0.92	120	140	130		8.800	9.867
DBP BEFORE TREATMENT	30	94.93 3.956	± 0.72	94	100	94			
DBP AFTER TREATMENT	30	85.07 4.354	± 0.79	84	94	84			

(P Value <0.0001 =Considered to be statistically highly significant.)

### RESULTS:

Total 40 patients (n=40) were chosen based on age groups ranging from 30 to 70 years. Out of which 10 patients were dropped out from the study. According to the distribution by sex, 24 were male (60%) and 16 were female (40%). Lycopodium virginica 30c was prescribed to each patient. The Prior to therapy, the mean SBP was 139.1, the mean SBP was 130.1, the mean DBP was 94.93, and the mean DBP was 85.07. Thus, P is less than 0.0001, considered to be statistically significant.

### DISCUSSION:

One of the most prevalent lifestyle diseases that affect people all over the world is hypertension. Ninety-five percent of people have essential hypertension, which can cause problems and raise the death rate if left untreated. The main goal of the current study was to determine how well the homeopathic medication Lycopodium Virginica 30C works in treating cases of essential hypertension in people aged 30 to 70. Many studies on hypertension have been conducted in the context of the homeopathic system; nevertheless, the homeopathic remedy Lycopodium virginica has received very little attention. As a result, Lycopodium Virginica 30c was chosen as the sole cure for this investigation.

It acts on the cardiovascular system, lowering blood pressure and having a hypotensive impact. Forty cases of critical hypertensive patients, aged 30 to 70 years, both male and female, were chosen for this investigation. The trial was finished by 30 patients. Following appropriate case taking, they received therapy with Lycopodium virginica 30C for 12-15 weeks. The change in B.P. levels before and after the treatment was assessed, and the results demonstrated a beneficial effect on the hypertensive state of the study sample's patients. The findings of the statistical analysis utilizing the student paired "t" test, which show that the pretreatment and post treatment blood pressure values are clearly different, illustrated this effect. It demonstrates the potential of Lycopodium virginica 30C in the management of hypertension. The age-wise distribution was computed by deducting the average. Mean age of the patients is calculated as 50 year. The majority of the patients belonged to the 60-69 age range. This implies that the development of essential hypertension is more likely to occur in older adults. The percentage distribution of cases by gender was also computed, and the results showed that, out of 40 cases, 24 were male (60%) and 16 were female (40%). This suggests that the prevalence of hypertension is higher in men than in women. The findings of this study suggest that patients with essential hypertension may benefit greatly from the homeopathic remedy Lycopodium virginica 30C. It can be used as a substitute public health strategy to lower the high prevalence of hypertension that exists globally.

**CONCLUSION:**

Hypertension is a prevalent and pervasive lifestyle condition that primarily affects adults and the elderly. Thirty patients have finished this research study. The outcome shows that blood pressure decreased in those who were essential hypertensive. *Lycopus virginica* 30C has been shown to be safe and effective in the treatment of essential hypertension, resulting in an early, persistent, and considerable drop in blood pressure. As a result, *Lycopus virginica* is a wise option when it comes to treating essential hypertensive individuals specifically to control blood pressure. Given the modest sample size, more research with a larger sample size and a longer study period should be conducted in the future. More research using randomized placebo control groups can be a more valuable source of evidence supporting *Lycopus virginica* 30C's efficacy in treating critical hypertension.

**Conflict Of Interest**

There was no point of conflict of interest between the authors.

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