

## A Comparative Study To Assess The Effectiveness Of Lycopus Virginicus 30c Versus Lycopus Virginicus Mother Tincture In The Management Of Essential Hypertension

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### Abstract

**Background:** Hypertension is a chronic, progressive condition that affects more than 1.28 billion adults globally and is among the leading causes of morbidity and mortality. There are two types of hypertensions- Essential or primary hypertension which constitutes about 90-95% cases and secondary hypertension which constitutes of remaining 10% cases of hypertension. The rising trend of essential hypertension in both urban and rural populations highlight the need for effective, safe, and holistic treatment approaches. In Homeopathy, there is a rare medicine named Lycopus Virginicus, known as "Bugleweed," has traditionally been used for cardiac irritability, anxiety, palpitations, and mild to moderate hypertension.

**Aim-** To assess the efficacy of Lycopus Virginicus 30C and Lycopus Virginicus mother tincture in the management of Essential hypertension, using Hypertension Symptom Score (HSS).

**Methodology:** A prospective randomized two-parallel-arm clinical study was conducted at Dr. Kuntal Homoeopathy Clinic, Bharatpur, Rajasthan for one year. A total of 100 patients with Stage 1 and Stage 2 Essential hypertension were enrolled and randomly allocated into two groups of 50 each: Group A: Received Lycopus Virginicus 30C and Group B: Received Lycopus Virginicus mother tincture. Blood pressure readings were recorded every 14 days over six months and Hypertension Symptom Score (HSS) before and after treatment. Data was statistically analyzed using paired t-test and independent t-test via SPSS software.

**Results:** A significant improvement was observed in HSS score in cases of Essential hypertension treatment with Lycopus Virginicus 30 (Group A) (M = 8.44, SD = 6.14) as compared to Lycopus Virginicus mother tincture (Group B) (M = 5.72, SD = 1.34). The mean difference between pre and post treatment HSS scores was 2.72(t-value- 3.06, p<0.05) indicating that the intervention in Group A was significantly more effective than in Group B.

**Conclusion:** This study concluded that Lycopus Virginicus 30C is beneficial in managing Essential hypertension producing significantly greater symptom improvement and blood pressure reduction as compared to mother tincture.

**Keywords:** Essential Hypertension; Lycopus Virginicus; Homoeopathy; 30C Potency; Mother Tincture; Hypertension Symptom Score (HSS)

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### Introduction:

Hypertension, a disease characterized by an increase in blood vessel pressure, affects over 20% of the global population and is associated with increased risk of cardiovascular disease events and mortality. It is often referred to as the "silent killer" as most people with hypertension do not exhibit symptoms. Hypertension can be classified into primary/Essential hypertension, which affects 90-95% of people and is asymptomatic, and secondary hypertension, which occurs in individuals with specific underlying causes, such as hormone imbalances or kidney dysfunction [1][2]. Over one billion adults globally suffer from hypertension, accounting for as much as 45% of the adult population with the condition [3][7]. Out of the 762 million people

in India who are 18 years of age or older, 234 million have hypertension.[8]

Essential hypertension, also known as primary hypertension, is a common cardiovascular condition characterized by persistent blood pressure elevation without a clear cause, mostly influenced by genetic predispositions, environmental factors and lifestyle choices. Risk factors include obesity, diabetes, high-salt diets, alcohol consumption, cigarette smoking, sedentary lifestyles, stress, family history of hypertension, age, gender, and race.[3]. Factors such as renal sodium processing, vascular tone regulation, sympathetic nervous system activity, endothelial dysfunction, oxidative stress, and inflammation contribute to

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Essential hypertension and cardiovascular disease risk.[5][6]

It is asymptomatic in the early stages but as the blood pressure increases symptoms like headache, palpitation, dizziness, tinnitus, shortness of breath, polyuria, sometimes chest pain.

Regular blood pressure monitoring is crucial for early detection and treatment of Essential hypertension. Both pharmaceutical and nonpharmacological methods are used to treat Essential hypertension, such as dietary adjustments, frequent exercise, controlling weight, reducing alcohol intake, and quitting smoking. Traditional pharmaceutical therapy, such as beta-blockers, ACE inhibitors, ARBs, calcium channel blockers, and thiazide diuretics, is used in treatment.[3]. However, these antihypertensive medications have unfavorable side effects.[9][10] So, there is a need to find a better treatment to control and manage Essential hypertension.

Homeopathy is a system of medicine which is an art and science that focuses on the patient's health rather than the actual hypertension. Homeopathy is directed towards a vital force that reduces both the symptoms of elevated blood pressure and the patient's numerous distinctive symptoms after considering the patient's unusual indications and symptoms. [8][11] There are many homeopathic medicines present in our vast Materia medica which helps in management of hypertension. There is one more medicine Lycopus Virginicus which is also effective in controlling blood pressure. But there is limited research being done on this medicine.[12] Therefore, this study was conducted to assess the efficiency of Lycopus Virginicus in management of patients having Essential hypertension and as well to determine which potency is more effective 30C or Mother tincture.

**Aim:** To assess the efficacy of two distinct Lycopus Virginicus potencies in the control of Essential hypertension based on pre- and post-treatment blood pressure readings and HSS.

### **Objectives:**

1. To explore the symptomatology of homeopathic medicine - Lycopus Virginicus in cases of Essential hypertension.

2. To determine whether the Hypertension Symptom Score (HSS) was an effective tool for evaluating the severity of hypertension symptoms both prior to and following treatment.

3. To determine the underlying causes of Essential hypertension.

### **Hypothesis:**

**Null Hypothesis(H0)** – No difference was seen between Lycopus Virginicus 30 C and Lycopus Virginicus mother tincture in the management of cases of Essential hypertension.

**Alternate Hypothesis (H1)**- A significant difference was seen between Lycopus Virginicus 30 C and Lycopus Virginicus mother tincture in the management of cases of Essential hypertension.

### **Methodology:**

The prospective randomized two parallel arm study was conducted at OPD of Dr. Kuntal Homeopathy Clinic, Bharatpur, Rajasthan. The study was done for a period 12 months including 6 months for enrollment and 6 months for follow-up. The effective sample size for each group is 50, and the total sample size was 100.

**Allocation:** A patient who are fulfilling the eligibility criteria were enrolled. Simple random allocation using a computer-generated randomization table was done.

**Group A:** received Lycopus Virginicus 30C; 50 cases

**Group B:** received Lycopus Virginicus mother tincture; 50 cases

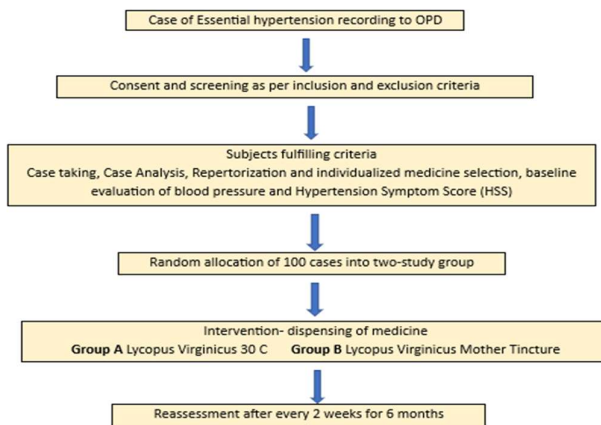
The study inclusion criteria consisted of patients with both men and women (18–65 years of age) and the patient diagnosed with Stage 1 and Stage 2 Essential hypertension according to JNC 7 Classification.

The exclusion criteria includes (1) the cases of secondary hypertension. (2) the cases who refused to give their consent. (3) the cases with systemic disorders (4) the patients suffering from isolated systolic hypertension (SBP $\geq$ 140mm Hg and/or DBP < 90 mm Hg). (5) the pregnant women and lactating mothers were also excluded from the study.

The withdrawal criteria: includes (1) the cases discontinuing treatment in between and cases without proper follow-up. (2) The cases requiring emergency treatment.

### **BRIEF OF STUDY PROCEDURES:**

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**Figure 1: Brief of study procedure**

## INTERVENTION- Dispensing of medicine

In Group A- Homoeopathic medicine Lycopus Virginicus 30C was given orally in globules size 10. The medicine was obtained from the good manufacturing Practices certified company. The dosage and repetition of medicine was given according to patient’s susceptibility and homoeopathic principles.

In Group B Homoeopathic medicine Lycopus Virginicus mother tincture was given orally as 10 drops in 30 ml of distilled water, which was repeated 2 times in a day, morning and night. The drug was taken half an hour after food. All the patients were provided medicine bottles with droppers.

**CO- INTERVENTION** – Dietary and lifestyle advice for both groups.

**Key Modifications and Recommended Actions include:**

- **Physical Activity:** Engage in at least 2.5 hours of moderate activity weekly (e.g., brisk walking).
- **DASH Diet:**
  - Consume fruits, vegetables, low-fat dairy, whole grains, fish, lean poultry, and nuts.
  - Limit saturated, trans, and total fat intake.
  - Reduce sodium intake to  $\leq 100$  mmol/day (~2.4 g sodium or 6 g salt).

-Ensure adequate potassium intake ( $>90$  mmol or 3,500 mg/day).

- **Alcohol Consumption:** Limit to 2 drinks/day for men and 1 drink/day for women or lighter individuals.

**OUTCOME:** Every fourteen days, the systolic and diastolic blood pressure readings were recorded. Based on blood pressure - Changes in the systolic and/or diastolic blood pressure in a timeline of 6 months. The final blood pressure value was calculated by taking the average of two recorded blood pressure readings spaced at least one minute apart. The Hypertension Symptom Score (HSS) was used to compare Group A and Group B's symptom severity before and after treatment. The **percentage change from baseline** helps quantify improvement or worsening in HSS score after treatment. **DATA ANALYSIS:** The appropriate statistical test was used for the analysis of data using statistical software IBM SBSS 20.0.

**Paired t-test** was applied to ascertain the statistical results of the study of HSS score for pre and post treatment within the group.

**Independent t-test** was used for outcome measures and comparisons between two groups- Group A and Group B.

In this study sample size 100 was taken, degree of freedom ( $n_1+n_2 - 1$ ) is 99 and level of significance is  $\alpha= 0.05$ .

## OBSERVATIONS AND RESULT:

**Table 1: Baseline Demographic Characteristics of cases of Essential Hypertension in Group A and Group B**

Variables	Total cases (n=100)	Group A (n=50)	Group B (n=50)
<b>Gender</b>			
Female	32(32%)	18(36%)	14(28%)
Male	68(68%)	32(64%)	36(72%)
<b>Area of residence</b>			
Rural	41(41%)	21(42%)	20(40%)
Urban	59(59%)	29(58%)	30(60%)
<b>Socio-economic status</b>			
Upper	21(21%)	11(22%)	10(20%)
Middle	49(49%)	25(50%)	24(48%)
Lower	30(30%)	14(28%)	16(32%)

## Occupation

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Agricultural/Farmer	16(16%)	7(14%)	9(18%)
Industrial/Labor	25(25%)	12(24%)	13(26%)
Sedentary/ Desk work	22(22%)	12(24%)	10(20%)
Unemployed	15(15%)	7(14%)	8(16%)
Night duty workers	9(9%)	5(10%)	4(8%)
Businessman	13(13%)	7(14%)	6(12%)

**Marital Status**

Married	69(69%)	34(68%)	35(70%)
Unmarried	31(31%)	16(32%)	15(30%)

**Past history**

Tuberculosis	6(6%)	4(8%)	2(4%)
Piles	10(10%)	6(12%)	4(8%)
Jaundice	14(14%)	5(10%)	9(18%)
Cholecystectomy	5(5%)	3(6%)	2(4%)
Typhoid	13(13%)	8(16%)	5(10%)
Dengue	17(17%)	9(18%)	8(16%)
Urticaria	8(8%)	0(0%)	8(16%)
Renal Calculi	19(19%)	9(18%)	10(20%)
Tinea	8(8%)	6(12%)	2(4%)

**Family History**

Tinea	10(10%)	6(12%)	4(8%)
Hypertension	21(21%)	10(20%)	11(22%)
Arthritis	4(4%)	1(2%)	3(6%)
Diabetes	16(16%)	8(16%)	8(16%)
Eczema	4(4%)	1(2%)	3(6%)
Migraine	3(3%)	2(4%)	1(2%)
Vitiligo	1(1%)	0(0%)	1(2%)
Asthma	8(8%)	3(6%)	5(10%)
Hypothyroidism	10(10%)	4(8%)	6(12%)
Cholelithiasis	7(7%)	5(10%)	2(4%)
Tuberculosis	5(5%)	4(8%)	1(2%)
Cancer	5(5%)	3(6%)	2(4%)
Kidney Disorders	6(6%)	3(6%)	3(6%)

**Table 2: Distribution of 100 cases of Essential hypertension according to” Age group”**

Sno.	Age group	Total (n=100)	Percentage
1.	18-27	5	5%
2.	28-37	15	15%
3.	38-47	21	21%
4.	48-57	29	29%
5.	58-67	30	30%
	<b>Total</b>	100	100%

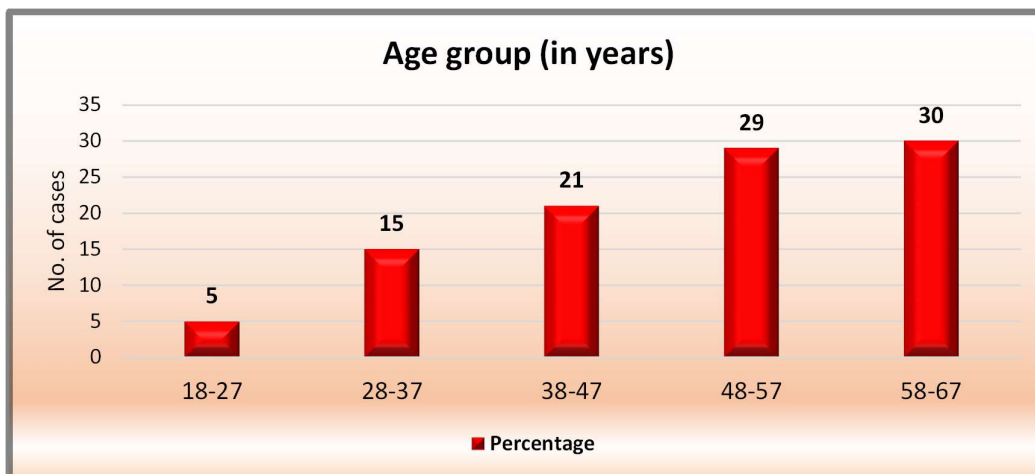


Chart 1: Distribution of 100 cases of Essential hypertension according to "Age group"

Table 3: Distribution of 100 cases of Essential hypertension according to "Causative factors"

S No.	Causative factors	Total(n=100)	Percentage
1.	Excessive salt intake/ Processed foods	13	13%
2.	Alcohol Consumption	6	6%
3.	Smoking	6	6%
4.	Obesity/Overweight (BMI>=25)	11	11%
5.	Physical inactivity	5	5%
6.	Work related stress	13	13%
7.	Family history (1°) of HTN/ CVD	15	15%
8.	Age Related	31	31%
	<b>Total</b>	100	100%

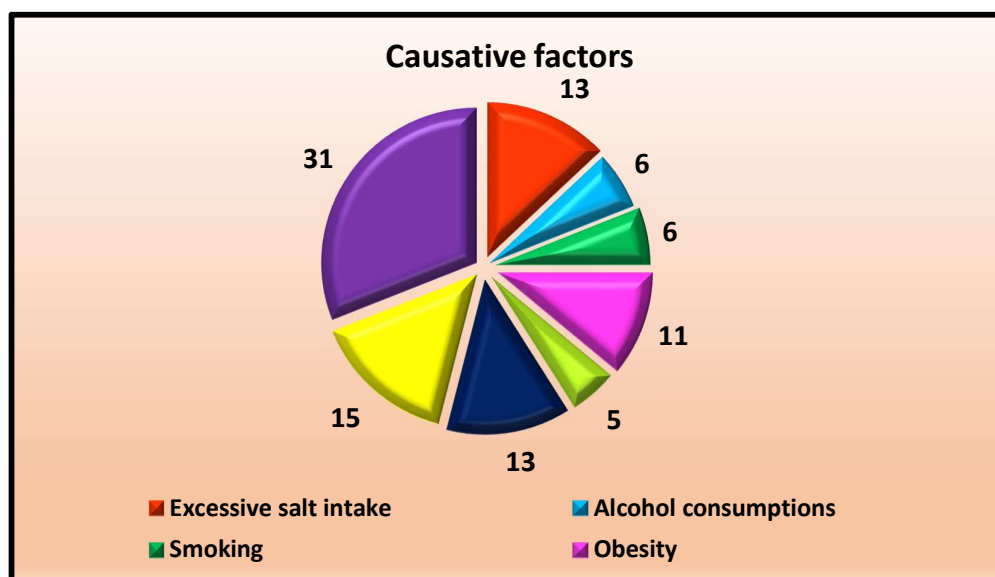


Chart 2: Distribution of 100 cases of Essential hypertension according to "Causative factors"

Table 4: Statistical Analysis- Paired sample t-test of both groups

Group (N=50)	A	Before	After	Group (N=50)	B	Before	After
Mean		29.66	21.22	Mean		31.18	25.46
S.D.		3.97	4.08	S.D.		2.42	1.97
SEM		0.56	0.58	SEM		0.34	0.28

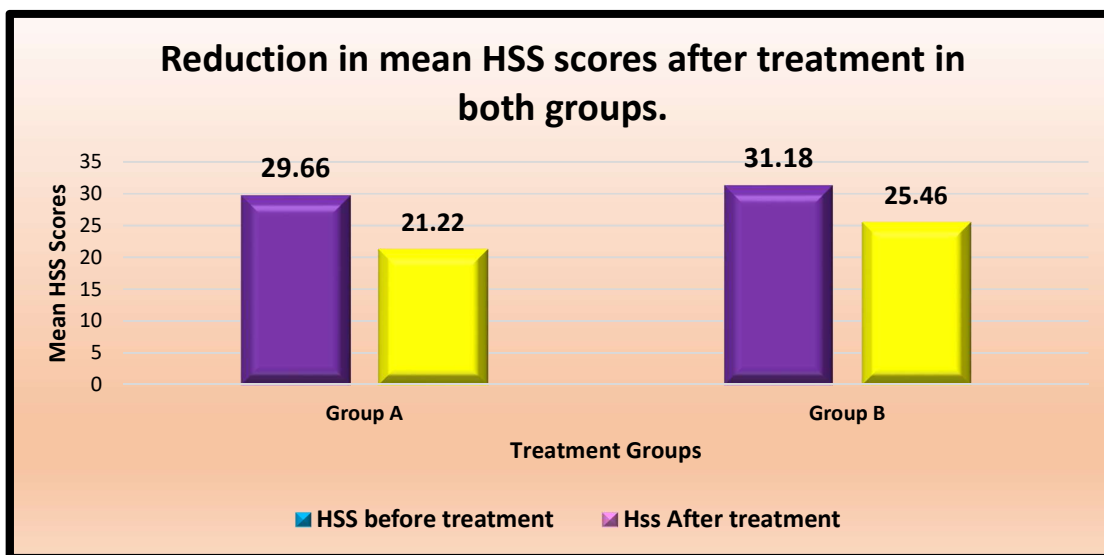
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t-value	9.73	t-value	30.17
df	49	df	49
Mean Paired difference	8.44		5.72

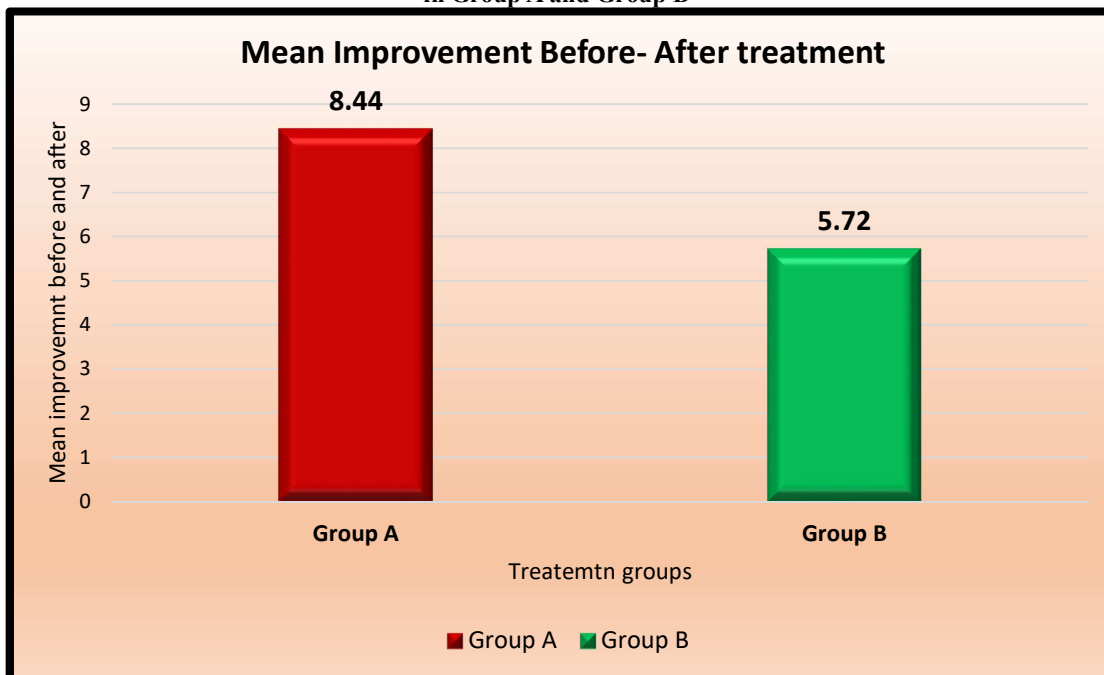
(S.D.- Standard Deviation; SEM- Standard error mean; df- degree of freedom)

**Table 5: Group A and B statistics**

	Group	N	Mean	Std. Deviation	Std. Error Mean
Difference	1	50	8.44	6.14	0.87
	2	50	5.72	1.34	0.19



**Chart 3: Distribution of 100 cases of Essential hypertension according to “HSS Score before and after treatment in Group A and Group B”**



**Chart 4: Distribution of 100 cases of Essential hypertension according to “Mean improvement before and after treatment in Group A and Group B”**

**Table 6: Statistical Analysis- Independent Sample t-test of both groups**

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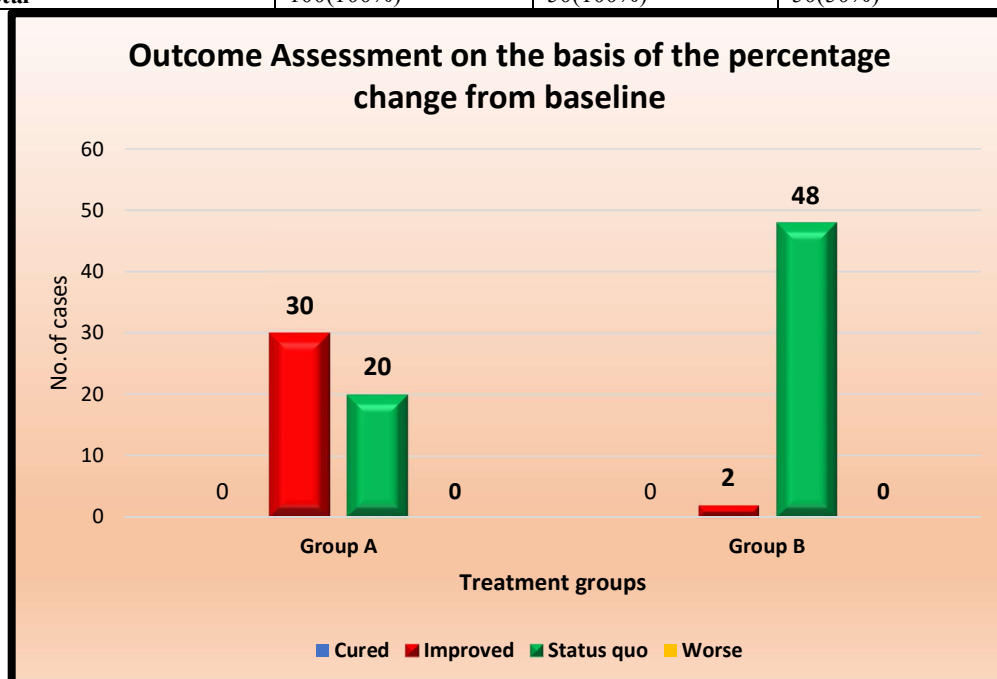
	Levene's Test For Equality of Variances		T-Test for Equality of Means						
	F	Sig.	t	df	Sig.(2-tailed)	Mean difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
<b>Difference Equal Variances Assumed</b>	52.19	0.000	3.06	98.00	.003	2.72	.89	.96	4.48
<b>Equal Variances Not assumed</b>			3.06	53.67	.003	2.72	.89	.94	4.50

The analysis in table 6 revealed a statistically significant difference in mean difference HSS scores between the two groups,  $t = 3.06$  at  $df=53.67$ ,  $p = 0.003$  with 95% CI= 0.94 to 4.50. When  $p=0.003 < 0.05$  and CI does not cross 0 confirms the significance, so there is a real

difference not by chance. Since the between-group comparison was statistically significant ( $p < 0.05$ ), the null hypothesis ( $H_0$ ) is rejected, and the alternate hypothesis ( $H_1$ ) is accepted

**Table 7: Distribution of 100 cases of Essential hypertension according to “Outcome assessment on the basis of the percentage change in HSS from baseline before and after treatment in Group A and Group B”**

Outcome assessment	Total(n=100)	Group A	Group B
<b>Cured</b>	0(0%)	0(0%)	0(0%)
<b>Improved</b>	32(32%)	30(60%)	2(4%)
<b>Status Quo</b>	68(68%)	20(40%)	48(96%)
<b>Worse</b>	0(0%)	0(0%)	0(0%)
<b>Total</b>	100(100%)	50(100%)	50(50%)



**Chart 5: Distribution of 100 cases of Essential hypertension according to “Outcome assessment on the basis of the percentage change from baseline before and after treatment in Group A and Group B”**

**Discussion:**

In this present study, total 100 cases were selected by random allocation sampling methods and reviewed. The

cases were randomly allocated to two treatment groups:

- 
- 1. **Group A – Lycopus Virginicus 30- 50 cases.**

## 2. Group B – Lycopos Virginicus mother tincture-50 cases

A discussion on the interpretations derived from the study has been given below: -

- 1. Age Incidence:** - In this study (table 2, Chart1), it was observed that the maximum incidence of Essential hypertension was seen in the age group of 58-67 years with 30 cases; it is followed by age group 48-57 years with 29 cases, followed by age group 38-47 years with 21 cases. The observation is similar to a study that states that the highest prevalence of Essential hypertension was found in the age group above 50 years. [13]
- 2. Gender:** - It was seen in table 1, that cases of were higher in males than in females [Female 32(32%) and males 68(68%)] in both the groups which similar with findings from other studies which shows Essential hypertension was more common in males than in females.[14][15]
- 3. Area of residence:** - In table 1, the most cases of Essential hypertension were found in urban areas 59 (59%), with rural areas accounting for 41 (41%). Urban areas in India have greater prevalence of Essential hypertension due to lifestyle changes, sedentary work conditions, and increasing intake of processed foods and in rural areas increase due to changing lifestyles and limited access to healthcare.[15]
- 4. Socio-economic status:** - The majority of patients in the study as in table 1 were from the middle-income group with 49 (49%) of cases, the lower-income group accounts for 30 (30%) cases and the high-income group with 21 (21%) cases. The observation was consistent with research that found that low- and middle-income nations account for roughly two-thirds of Essential hypertension cases because people with lesser education, poorer income, and unemployment were more likely to acquire high blood pressure and less likely to have it treated. [17]
- 5. Occupation:** - In table 1 The majority of patients in the study were from industrial/labor employment accounting for around 25 (25%), followed by those with sedentary or desk jobs 22 (22%), 16 (16%) from agricultural work environments, 15 (15%) who were unemployed, 13 (13%) who were businessmen, and 9 (9%) who were night duty workers. This finding is consistent with earlier research. Occupational determinants of Essential hypertension include elevated job stress which demands lifestyle behaviors such as physical inactivity, smoking, and alcohol consumption. [18].
- 6. Marital Status:** - In this study (table 1) it was found that cases who were married i.e. 69 (69%) cases were more affected than unmarried 31 (31%) ones.[19]
- 7. Family History:** - The study revealed that out of 100 cases of Essential hypertension, 21 (21%) cases had a family history of hypertension, 16 (16%) cases had diabetes, and 10 (10%) cases had a family history of hypothyroidism or tinea. This study supported the idea that family history and genetic factors play a

major role in the development of Essential hypertension.[17]

- 8. Causative factors:** - Out of 100 cases (Table3, Chart 2), it was found that 31 (31%) of cases of Essential hypertension were related to age, 15 (15%) cases had a family history of hypertension or cardiovascular disease, 13 (13%) cases had work-related stress and excessive intake of salt and processed foods, 11 (11%) cases had hypertension due to being overweight or obese, 6 (6%) cases had it due to smoking and alcohol use, and 5 (5%) cases had it due to no physical activity[22]
  - 9. Changes in mean HSS scores and Mean improvement before and after treatment:** -In Table 4 and 5, Chart 3 ad 4 shows Group A (Lycopos Virginicus 30), the mean HSS score was  $29.66 \pm 3.97$  (mean  $\pm$  SD) before treatment, and it reduced to  $21.22 \pm 4.08$  (mean  $\pm$  SD) after treatment, while in Group B (Lycopos Virginicus mother tincture), the mean HSS score was  $31.18 \pm 2.042$  (mean  $\pm$  SD) before treatment and reduced to  $25.46 \pm 1.97$  (mean  $\pm$  SD) after treatment. The mean improvement before and after treatment is higher in Group A (mean difference= 8.44) compared to Group B (mean difference= 5.72). This indicates more improvement in Group A as compared to Group B.
  - 10. Statistical Analysis:** -A statistically significant difference in mean scores was found using the independent samples t-test ( $t = 3.06$ ,  $p = 0.003$ ), with a mean difference of 2.72 (95% CI: 0.94–4.50) in Table 4 and table 6. Since the between-group comparison was statistically significant ( $p < 0.05$ ), the null hypothesis ( $H_0$ ) is rejected, and the alternate hypothesis ( $H_1$ ) is accepted.
  - 11. Result obtained:** - In table 7 and chart 5, the outcome assessment revealed distinct differences between the two groups. In Group A, a substantial proportion of patients demonstrated improvement 30 (60%), whereas only 2 (4%) of patients in Group B showed similar improvement. Notably, the majority of Group B participants 48 (96%) remained in the status quo category, in contrast to 20 (40%) in Group A. None of the patients in either group were categorized as cured or worsened. These findings suggest that the intervention administered in Group A i.e. Lycopos Virginicus 30 was associated with a markedly greater clinical benefit compared to Group B i.e. Lycopos Virginicus mother tincture.
- Conclusion:** This study compares and assesses the therapeutic efficiency of Lycopos Virginicus in the conditions of management of Essential hypertension and symptoms like palpitation, vertigo, headache, shortness of breath, and many more. The Hypertension Symptom Score (HSS) was an effective tool for evaluating the severity of hypertension symptoms both prior to and following treatment. This study also compares the efficacy of

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two potencies of Lycopus Virginicus—30c and mother tincture. From the result, it is clearly seen that Lycopus Virginicus 30c is more effective in the reduction of blood pressure. This study also helps in finding the causative factors for the development of Essential hypertension, like age, family history or genetic susceptibility, smoking, alcohol, work stress, etc.

**Further Scope:** There is a need to focus on conducting studies with larger sample sizes across different demographic populations to improve results. The follow-up period and the study duration should also be extended for improving the clinical evidence of the use of Lycopus Virginicus in Essential hypertension and their long-term outcome assessment. Further studies also should focus on exploring other potencies of Lycopus Virginicus such as 6c, 200c, and 1M.

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