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Effect of Allium Sativum (Garlic) Intake on Biochemical Parameters among Type I Hypertensive Clients – A Randomized Controlled Trials

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Abstract

Hypertension, commonly known as high blood pressure, is a prevalent ailment that is referred to as the silent killer." Hypertension is responsible for at least 45% of heart disease deaths and 51% of stroke deaths. The present study aims to assess the effectiveness of Allium sativum (Garlic) intake on biochemical parameters among Type-I hypertensive clients. A Quantitative approach with a true experimental pretest and post-test control group was adopted for the present study. 60 clients diagnosed with Type-I hypertension were recruited using the purposive sampling technique and were assigned to experimental and control groups. A self-structured questionnaire method was adopted to collect the demographic information. Followed by that, monitored blood pressure levels with the help of a manual sphygmomanometer and stethoscope, serum cholesterol before and after the intake of Allium sativum (Garlic) syrup. Following that, the treatment group received 100 gms of fresh garlic syrup three times daily, while the control group received a placebo along with the routine treatment. The results revealed that there was a significant difference identified in pre and post-test levels of blood pressure was calculated using a paired" test which was a statistically significant difference (P<0.005) concerning reduction in systolic and diastolic blood pressure. Hence, the findings of the present study concluded that oral supplementation of Allium sativum (Garlic) was found to be effective in reducing blood pressure and serum cholesterol among Type - hypertensive clients.

Keywords: Allium Sativum, Biochemical Parameter, Type -I Hypertensive Clients.

Introduction

Hypertension is one of the most common and serious health issues in both developed and underdeveloped countries. In total, 18-54% of the world's population is hypertensive. Hypertension and its direct effects are responsible for 12% of all deaths [1]. Twenty per cent of the general population should be

prepared to develop high blood pressure at some point in their lives. The aetiology of hypertension is unclear in 90% of instances, which is known as essential hypertension, damages the heart, kidneys, and central nervous system (atherosclerosis occurs in 30% of cases, while congestive heart failure, stroke, renal failure, and retinopathy occur in more than half of cases) [2, 3]. Lifestyle changes (diet, weight,

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and activity) are regarded as first-line treatment for prehypertensive individuals; however, pharmacological therapy should be undertaken in partial or non-responsive instances [4].

Hypertension is easily diagnosed and treated with appropriate medications. Unfavourable health outcomes associated with hypertension could be reduced through strategies such as early detection, treatment, and control by providing timely access to primary care providers to expedite the process, lowering the cost of medications for those in treatment through insurance coverage, cost sharing, and benefit designs, and finally supporting hypertension control by expanding workplace wellness and quality control measures [5, 6].

Plant foods, such as fruits, vegetables, and whole-grain cereals, are recommended in dietary guidelines developed by regulatory bodies and healthcare organisations. Interestingly, while being particularly rich sources of phytochemicals, notably polyphenols, recommendations for the plant-based consumption of beverages (excluding fruit juices) such as tea (Camilla sinensis) and tisanes (herbal teas) are lacking. There is a lot of evidence that dietary changes can help with inflammation and blood pressure control. Adherence to a healthy dietary pattern, such as the "Mediterranean" and "DASH" diets, which emphasise whole grains, legumes, vegetables, colourful fruit, fish, legumes, and olive oil, can, for example, lower blood pressure in hypertensive clients [7, 8, 9].

Garlic has been used as a medicinal plant, it contains bioactive chemicals such as allicin, S-allylcysteine (SAC), ajoene, diallyl disulfide, SAC sulfoxide, and S-methylcysteine sulfoxide, which contribute to its medicinal benefits. Garlic consumption has been linked to a lower risk of cardiovascular disease and cancer. Garlic has been demonstrated to improve insulin resistance and obesity, as well as fatty liver and liver functions like ALT and GGT [10]. Accordingly, this clinical trial was designed to assess the pretest level biochemical

parameter among type-I hypertensive clients in both the experimental and control group, to determine the effectiveness of Allium sativum (Garlic) on biochemical parameter among type-I hypertensive clients in the experimental group, to compare the post-test level of biochemical parameter among type-I hypertensive clients both in experimental and control group and to find out the association between the post-test level of biochemical parameter among type-I hypertensive clients with their demographic variables.

Methods and Materials

Study Design: A true experimental pretest post-test control group design was adopted to investigate the effectiveness of Allium sativum (Garlic) intake on the reduction of blood pressure and serum cholesterol (biochemical parameter) among type-I hypertensive clients. **Study Setting:** The study was conducted for 6 weeks from January 20th, 2023 till 4th March 2023 from the clients residing in the Thandalam area. Ethical Approval: After obtaining an ethical clearance from the Human Institutional Ethical Committee (HIEC) of Saveetha Institute of Medical and Technical Sciences and formal permission from the selected Village Administrative Officer, the study was conducted. Study Participants: 86 hypertensives were identified and screened consecutively at Saveetha Medical College and Hospital, Thandalam. Inclusion included clients with Stage I HT systolic BP (130-139mm Hg) & diastolic BP (80-89mmHg) according to the American Heart Association Category of BP, aged 35 - 64 years, both sexes, able to understand Tamil and English, willing to participate. Clients were excluded from the study pre-Hypertensive clients (systolic BP 120-129mm Hg & diastolic BP more than 80mmhg, Stage II HT (systolic BP 140-159mm Hg & diastolic BP (90-99mmHg) and systolic BP >160mm Hg & diastolic BP >100mm (according to American Heart Association Category of BP), history of alcohol abuse, liver diseases, diabetes mellitus, untreated hypothyroidism, mental diseases. kidney diseases, pregnancy, lactation, low blood pressure, who are in alternative system of medicine, garlic allergy, or unwillingness to participate. Finally, 60 clients were included in the study using a purposive sampling technique. Informed consent: The participants were informed about the risks and benefits of the study and were free to drop out at any time for any reason, a written informed consent was obtained from each one of them before conducting the current study. Randomization: A statistician generated randomization lists, and participants were assigned to study groups, the intervention group (garlic) or the placebo group with a trained person randomly assigning them. Assessment: On Day- 1: The demographic data and clinical information were collected using a self-structured questionnaire, followed

by, monitored blood pressure level with the help of manual sphygmomanometer stethoscope and laboratory staff for collecting fasting lipid profile before and after the administration of garlic syrup. Intervention: From Day 2: The treatment group received garlic syrup 50 ml (100 of fresh garlic & contains approximately 250-450 grams of allicin) three times daily 30 minutes after the meals, with the compromise of not modifying their eating habits, while the control group received a placebo along with the routine treatment. Outcome Assessment: On Day- 43: The study participants were reassessed the Systolic and Diastolic levels of BP by using the same sphygmomanometer and stethoscope, The Same laboratory staff for collecting fasting lipid profile, and the acquired data was compiled and analysed using statistical methods.

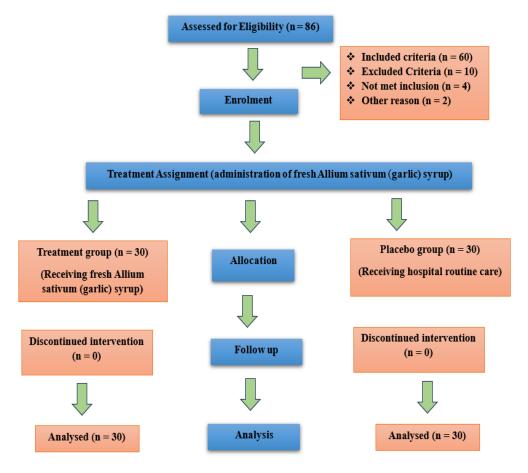


Figure 1. Consort Flow Chart Depicting the Steps Involved in the Sample Recruitment Process

Results and Discussion

Demographic and Clinical Characteristics

In the treatment group, with regards to the demographic and clinical characteristics the type-I hypertensive clients, 25(41.7%) were between 25 - 35 years, 36(60%) were male, 37(61.7%) were Hindus, 19(31.7%) were daily wages, 24(40%) had family income of >5000 per month, 41(68.4%) were non-vegetarian, 41(68.4% had no previous history, 46(76.7%) had moderate BMI and 45(75%) had no lifestyle practice, 23(38.3%) had heavy physical activity, 25(41.6%) had signs of 23(38.3%) hypertension, had signs hypertension, 24(40%) had Antihypertensive 25(41.6%) had side effects Antihypertensives. In the placebo group, with regards to the demographic and clinical characteristics the type-I hypertensive clients38(30%) were aged between 45 - 54 years, 24(80%) were male 26(86.7%) were Hindus, 25(83.3%) were daily wages, 24(80%)

had family income of >10000. 45(75%) were non-vegetarian, 17 (56.7%) had no previous history, 16(53.3%) had another previous history, 46(76.7%) had moderate BMI and 21(70%) had no lifestyle practice. 25(41.7%) had heavy physical activity, 36(60%) had signs of hypertension, 37(61.7%) had signs of hypertension 41(68.4%) had Antihypertensive and 25(41.6%) had side effects of Antihypertensives.

Estimation of Pre and Post-Test Levels of Blood Pressure among Study Participants in Treatment and Placebo Group

In the pretest of the treatment group, 20(33.3%) had stage II and 10(16.6%) had stage I and in the post-test, 28(63.34%) had stage I and 2(3.33%) had normal. Whereas in the pretest of the placebo group, 30(50.07%) had prehypertension and in the post-test, 28(46.67%) had stage I hypertension and 2(3.33%) had normal.

Table 1. Estimation of Pre and Post-Test Levels of Blood Pressure among Study Participants in Treatment and
Placebo Group (N=60)

	Treatment Group				Placebo Group				
Blood	Il . CDL I D	Pre-test		Post Test		Pretest		Post Test	
Pressure	Level of Blood Pressure	F	%	F	%	F	%	F	%
Systolic Blood Pressure	Normal (<120)	0	0	2	3.33	0	0	2	3.33
	Pre-hypertension (120 to 139)	0	0	20	33.33	30	50.07	0	0
	Stage – I (140 – 159)	10	16.6	8	13.3	0	0	28	63.34
	Stage – II (≥160)	20	33.3	0	0	0	0	0	0
Diastolic Blood Pressure	Normal (<80)	0	0	1	1.67	0	0	2	3.33
	Pre-hypertension (80 to 89)	30	50.07	29	46.67	23	38.33	0	0
	Stage – I (90 – 99)	0	0	0	0	0	0	28	46.67
	Stage – II (≥100)	0	0	0	0	7	11.6	0	0

Davood Soleimani et al., (2021) conducted a randomised, double-blind, placebo-controlled experiment on 98 patients with NAFLD. The patients were given two pills of 400 mg of garlic or a placebo every day for 15 weeks. The garlic intervention significantly reduced systolic

blood pressure (SBP) (mean: -7.89; 95%CI: -11.39 to -4.39 mm Hg), diastolic blood pressure (DBP) (mean: -5.38; 95%CI: -7.77 to -3 mm Hg) and mean arterial pressure (MAP) (mean: -6; 95%CI: -8.4 to -3.6 mm Hg) [11].

Hence, the present study findings and other studies depict that garlic intake can be an effective medicine for decreasing blood pressure in people with stage 1 hypertension.

Effectiveness of Allium Sativum (Garlic) Syrup on Blood Pressure among Type-I Hypertensive Clients

The pretest mean score of systolic BP was 146.83 ± 12.65 and the post-test mean score was 125.46 ± 10.54 . The calculated paired' test value of t=10.992 was found to be statistically highly significant at p<0.001 level. The pretest mean

score of diastolic BP was 96.10±7.45 and the post-test mean score was 80.26±10.54. The calculated paired 't' test value of t=9.021 was found to be statistically highly significant at p<0.001 level. which clearly shows that there was a significant decrease in the level of blood pressure after the administration of Allium sativum (Garlic) syrup. This infers that; garlic juice was found to be effective in decreasing the level of blood pressure among type I hypertensive clients in the treatment group (Table 2 & Figure 2).

Table 2. Effectiveness of Allium Sativum (Garlic) Syrup on Blood Pressure among Type-I Hypertensive Clients (N=60)

Variables	Test	Mean	SD	Paired 't' Test Value		
	Pretest	146.83	12.65	t = 10.992		
Systolic BP	Post Test	125.46	10.54	p = 0.0001 S***		
	Pretest	96.10	7.45	t = 9.021		
Diastolic BP	Post Test	80.26	10.54	p = 0.0001 S***		

***p<0.001, S - Significant

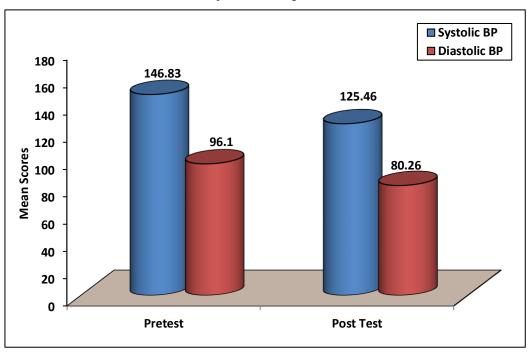


Figure 2. Effectiveness of Allium sativum (Garlic) Syrup on Level of Blood Pressure among Type-I Hypertensive Clients in the Treatment Group

The present study findings are consistent with the findings of the randomized, tripleblind, placebo-controlled parallel trial conducted by José C. E. Serrano., et al (2023) involving a Grade I hypertensive population tested the antihypertensive effects of an aged

black garlic extract with low doses of s-allyl-cysteine (SAC). Results showed a significant reduction in systolic and diastolic blood pressure, 1.8 mmHg (0.7 to 4.1 95% CI) and 1.5 mmHg (0.3 to 3.0 95% CI) with a dose of 0.25 mg/day for 12 weeks [14].

The results of the current study clearly stated that there are differences in the results of pre and post-test interventions consumption of garlic promotes nitric oxide (NO) activation, which leads to vasodilation by inhibiting the renin-angiotensin-aldosterone system (RAAS) and the synthesis of prostaglandins, hence angiotensin-converting inhibiting enzyme activity. Garlic's vasodilation mechanism is due to its high sulphur content, which is associated with the formation of hydrogen sulphides (H2S). H2S binds to and activates vascular ATP-sensitive potassium channels (kATP), causing hyperpolarization and eventual dilatation. Hence, the present study findings depict that garlic compounds

mechanical pathways contribute to blood pressure management among hypertensive clients [13].

Effectiveness of Allium Sativum (Garlic) Syrup on Serum Cholesterol Levels among Type-I Hypertensive Clients

The pretest mean score of total cholesterol was 251.01±8.17, and the post-test mean score was 193.28±30.44. The mean difference score was 57.73, with a statistically significant difference of 57.73. The mean difference score for LDL was 164.85±5.54, and the mean difference for HDL was 35.05±3.97. The mean difference for triglycerides was 432.23±9.85, and the mean difference for VLDL was 37.48±4.56. The study concluded that garlic was effective in decreasing these levels of total cholesterol, triglycerides, LDL, HDL, and VLDL among type-I hypertensive clients. (Table 3 & Figure 3).

Table 3. Effectiveness of Allium Sativum (Garlic) Syrup on Serum Cholesterol Levels Among Type-I Hypertensive Clients (N=60)

	Pretest		Post Test		Mean			
Parameters	Mean	S.D	Mean	S.D	Difference Score	Paired 't' test & p-value		
Total Cholesterol	251.01	8.17	193.28	30.44	57.73	t = 14.153 p=0.0001, S***		
LDL	164.85	5.54	123.23	7.95	41.62	t = 30.990 p=0.0001, S***		
HDL	35.05	3.97	58.46	6.08	23.41	t = 27.373 p=0.0001, S***		
Triglycerides	432.23	9.85	192.21	7.69	240.02	t = 167.959 p=0.0001, S***		
VLDL	37.48	4.56	17.56	8.26	19.92	t = 17.255 p=0.0001, S***		

***p<0.001, S – Significant

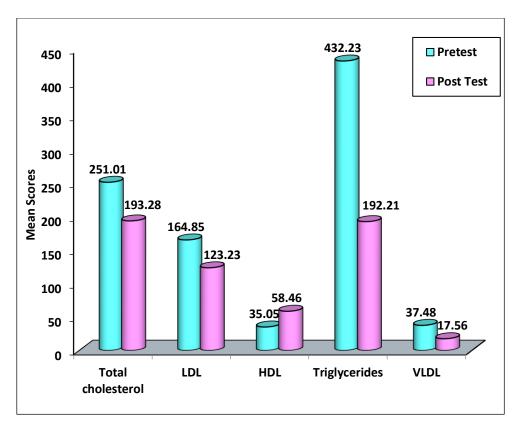


Figure 3. Effectiveness of Pretest and Post-Test Level of Total Cholesterol, LDL, HDL, Triglycerides and VLDL Among Type-I Hypertensive Clients in Treatment Group

The present study findings are supported by a double-blinded randomised control trial conducted by Abbas Ali Sangouni et al., (2023) to assess the effectiveness of garlic supplementation in treating non-alcoholic fatty liver disease. For 12 weeks, 90 patients were randomly randomised to receive either a garlic powder supplement or a placebo. The therapy had significantly lower serum group concentrations of total cholesterol (P = 0.009), triglycerides (P < 0.001), high-density lipoprotein cholesterol (P < 0.001), and lowdensity lipoprotein cholesterol (P = 0.01). The results revealed a considerable reduction in hepatic steatosis, liver enzymes, and lipid profile [11].

Roya Zadhoush et al., (2021) investigated a study on 80 women with PCOS and found that garlic supplementation significantly reduced serum total cholesterol, serum triglyceride levels systolic blood pressure and LDL-C levels compared to the control group. Results showed that no significant difference was observed

between the two groups in HDL-C and diastolic blood pressure levels. The study suggests that garlic supplementation might be effective in improving lipid markers, but further research is needed to confirm these findings [12].

Hence, the present study findings and other studies depict that garlic extract reduces the total cholesterol level among hypertensive clients.

Association between the Post-Test Level of Blood Pressure and Serum Cholesterol among Type-I Hypertensive Clients with their Selected Demographic Variables in the Treatment Group

The demographic variables age (2=17.854, p=0.001) and physical activity (2=13.742, p=0.031) revealed a statistically significant association with post-test systolic blood pressure $(p\le0.001)$. Physical activity (2=10.620, p=0.008) was significantly associated with post-test diastolic blood pressure (p<0.05). The remaining demographic characteristics did not have a significant

association with post-test systolic and diastolic blood pressure levels in clients with type 1 hypertension. The chi-square test independence is used to determine the relationship between post-test cholesterol levels and demographic variables like age, gender, religion, diet, education, or income. A p-value of 0.05 or less is statistically significant, indicating a less than probability of a coincidental relationship. All factors have a significant p-value at the 0.05 level, except religion.

Limitations

The researcher was unable to generalise the study findings due to the small sample size of 60 type-I hypertensive clients. The study only included type-I hypertensive who lived in a certain area. Another constraint is the choice of Tiruvallur location for data collecting. Only type-I hypertensive clients' cognitive and clinical data were considered. Due to a lack of literature, the current study has just a few supportive studies on the Indian population.

Conclusion

In conclusion, our current experiment demonstrates that garlic supplementation can be effective in lowering blood pressure, serum

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cholesterol levels, and the risk of cardiovascular illnesses in hypertensive patients.

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Authors Contribution

Sridevi. B developed the study concept and design, Vidhya collected the clinical data, Kavitha. M statistical analysis and interpretation of data, Sridevi. B study supervision, critical revision of the manuscript for the intellectual content and drafting of the manuscript. All authors read and approved the final manuscript.

Conflict of Interest and Funding Support

The authors for the current project have no financial investment are not investors in any of the health sectors related to the project and have not received any consultation payments. They did not have any patents linked to the project. The authors have no personal or professional contact with any of the healthcare organisations.

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