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Effects of Garlic extract (*Allium sativum*) in combination with Amlodipine in mild to moderate essential hypertensive patients: An Open randomized parallel group study

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ABSTRACT

Hypertension (HTN) is a major burning problem worldwide and nearly 1 billion individuals are affected. Moreover administration of current anti-hypertensive drugs is usually associated with severe side effects. Hence alternative therapies are necessitated. In traditional medicine garlic has been widely used to treat various diseases which also include hypertension. However, the effect of garlic preparations on HTN in combination with modern medicine has not studied. Hence, the present study is undertaken. As a part of the a part of the study 60 HTN subjects (mild to moderate essential hypertensive patients) were randomized and enrolled in to two groups of 30 subjects each, one as Amlodipine group (20 males and 10 females) and other as combination group (22 males and 8 females). 30 subjects were received either Amlodipine 5 mg OD (once in a day) or Amlodipine 5 mg plus garlic (8gm) OD for duration of eight weeks. Blood pressure (BP) was measured at baseline, weekly and at the end of 8 weeks. Results indicated statistically significant decrease in SBP (systolic blood pressure) in combination group as compared to Amlodipine group consistently from the week 6 to 8. Similarly, significant decrease was also observed in DBP (diastolic blood pressure) in combination group as compared to Amlodipine from week 3 to week 8. Combination of Amlodipine and garlic found to be more effective than Amlodipine alone in controlling blood pressure among essential hypertensive patients.

Keywords: Amlodipine, garlic, Systolic blood pressure, Diastolic blood pressure

INTRODUCTION

Hypertension (HTN) or High blood pressure also referred as arterial hypertension is a chronic medical condition in which the blood pressure is elevated in the arteries¹. The major risk factors include stroke, myocardial infarction, heart failure, aneurysms of the arteries, peripheral arterial disease and chronic kidney disease etc¹⁻². Hypertension leads to cardiovascular morbidity and mortality; affecting approximately 20%-50% of the world's adults. According to the estimates of year

2000 nearly 1 billion adults have been suffered with hypertension and it is predicted to increase to 1.56 billion by 2025²⁻³. Recent global statistics also revealed that it occupies fourth place in premature deaths in developed countries, where as seventh place in developing countries. In India its prevalence rate is higher in urban compared to rural areas and moreover prevalence pattern is comparable with that of USA^{3,5-6}. Hypertension has been classified into two types; one is essential hypertension and other as secondary hypertension. Majority of the cases up to 90-95% are categorized

as "essential hypertension" which means high blood pressure without specific underlying medical complications³. The left over cases will fall under the category of secondary hypertension, which is caused by medical complications that affect the kidneys, arteries, heart or endocrine system. Elevation or shift in the arterial blood pressure is associated with a shortened life expectancy. Controlling blood pressure by adapting suitable lifestyle and dietary habits could reduce the risk factor associated health complications. However, drug treatment is often necessary in people for whom lifestyle changes prove ineffective. Moreover administration of current anti-hypertensive drugs is usually associated with severe side effects¹⁻⁶.

At present, the practice of Medicinal plant/herbal medicine for treating various diseases rapidly progressing and is assumed to have no side effects⁷. The active agents present in these plant extracts have been shown to efficiently slow down the disease symptoms in a synergistic manner. The active ingredients present in these plants encompass polysaccharides, pigments, steroids, terpenoids, flavonoids and alkaloids⁷⁻¹⁰. The crude plant extracts and purified compounds from various medicinal plants have been demonstrated significant role in controlling various diseases⁷⁻¹⁰. In spite of numerous therapeutic effects of medicinal plants, its effect on hypertension has not been studied in detail. Moreover in recent times garlic has been employed in treating cardiovascular diseases⁵. Therefore, we are interested in screening and evaluating the efficacy of garlic preparations in hypertension patients.

Garlic (*Allium sativum*) belongs to the family Alliaceae. In traditional medicine it has been widely used to treat various human diseases and disorders resembling tumors, worms, bites, and other ailments⁵. It also used as a diet to increase physical and mental health. Moreover it is reported to inhibit the pathogenesis of cardiovascular disease, also to prevent various cancers and other chronic diseases associated with aging^{5, 11-13}. The garlic is mainly composed of fructose-containing carbohydrates, sulfur compounds, protein, fiber, and free amino acids¹⁴. It is also a rich source for saponins, Phenols, phosphorus, potassium, sulfur, zinc, followed by moderate levels of selenium and Vitamins A and C, and low levels of calcium, magnesium, sodium, iron, manganese, and B-complex vitamins¹⁵. Various garlic preparations have been investigated in various studies by several researchers include raw garlic, garlic powder

tablets, oil of steam-distilled garlic, oil of oil-macerated garlic, ether-extracted oil of garlic, and aged garlic extract etc¹¹⁻¹⁸. Recent studies also clearly demonstrated the application of garlic preparations in prevention and treatment of cardiovascular disease both in vitro and in vivo⁵. However, there is no concrete evidence to use garlic in combination with Amlodipine as a treatment modality for essential hypertensive patients. Thus, the present study is undertaken to evaluate garlic extract in combination with Amlodipine.

MATERIALS AND METHODS

Demographic data

Study subjects age and sex, height (cm), weight (kg), smoking, consuming alcohol, diabetics and duration of hypertension (months) was recorded. Blood pressure was measured as described³ using mercury sphygmomanometer with the patient in the sitting position. After 5 min of rest in the sitting position, BP was measured and the systolic and diastolic pressure was recorded.

Ethical Clearance

The Institutional Ethical Committee approved this open randomized parallel group study protocol. Informed consent was obtained from study participants. All the participants were in the age group between 20 to 65 years with sitting systolic blood pressure between 140-160 mm Hg and diastolic blood pressure between 90-99mm Hg. Patients were excluded, if the hypertension was secondary to hepatic, renal, cardiac or endocrine disorders, Pregnant or lactating. A total of 60 patients were enrolled in the study.

Preparation of garlic extracts and administration to the HTN patients

Fresh garlic cloves were collected from the local market. Peels were removed and fresh garlic were steamed at 60 °C for 20 minutes in water bath and crushed to create a fine paste. The prepared fresh garlic paste (8 g) was administered to the HTN patients. Thirty patients were administered either with Amlodipine 5 mg OD (once in a day) or Amlodipine 5 mg plus garlic (8gm) OD for duration of eight weeks. Blood pressure (BP), were measured at baseline, weekly and at the end of eight weeks. Demographic characteristics of the enrolled patients were also recorded. After the completion of the study, the patients were instructed to consult their physician for further management.

STATISTICAL ANALYSIS

The statistical analysis will be carried out with Graph pad prism software Version-5, USA. Categorical data will be presented as actual numbers and percentages. For normally distributed continuous data between group analyses was done by unpaired "t" test. Categorical variables will be analyzed with "Fischer's exact test". For statistical significance, a two tailed probability value of less than 0.05 will be considered.

RESULTS

The anti-hypertensive effects of some of the medicinal plants have been validated and others disproved. However, traditional knowledge needs to be coupled with modern medicine and more scientific research needs to be done to verify the effectiveness, and elucidate the safety profile of such herbal remedies for their antihypertensive potential^{5, 7, 19}. Therefore the present study is undertaken in an aim to screen the efficacy of garlic extract in combination with Amlodipine in HTN patients. In the present study, 60 HTN subjects (mild to moderate essential hypertensive patients) were selected and randomized enrolled in to two groups of 30 subjects each. One group named as Amlodipine group and other as combination group. There were 20 males and 10 females in the Amlodipine group and 22 males and 8 females in the Combination group.

2.1 Demographic characteristics between Amlodipine and Combination groups

Monitoring demographic parameters allows early detection of problems in the particular population. Several studies have been demonstrated that the local population size is affected by local demographic parameters⁴. Therefore in the present study the demographic parameters has been assessed and compared between the Amlodipine group and Combination groups. The demographic parameters include Age, sex, weight (kg), height, smoking, consuming alcohol, diabetics and duration of hypertension (months) has been recorded (Table-1). The demographic parameters results between Amlodipine group and Combination group are age (49.17±7.73 vs. 50.77±8.97, p=0.46, weight (67.57±12.70 vs. 68.53±14.43, p=0.78) and Duration of hypertension (25.2±4.2 vs. 25.8±4.7 months, p= 0.63) respectively. These results clearly indicated that there is no significant difference observed among the demographic characteristics between Amlodipine and Combination groups. However, significant difference has been noticed between the

groups in the demographic parameter height (159.17±12.59 vs. 165.89±9.17 cm, p=0.02). Further, assessment of remaining parameters concluded that 20% of the patients in the Amlodipine group suffering with diabetes, 3% were current smokers and 13% were regular alcoholics respectively. Whereas in Combination group 10% of the patients were having diabetes, none were current smokers and 26% were regular alcoholics. On comparison we found that there was no significant difference between two groups as shown (Table 1).

2.2 Measure of Systemic Blood Pressure between Amlodipine and Combination group

Blood pressure (BP) is also referred as arterial blood pressure of the systemic circulation. It is the pressure exerted by circulating blood upon the walls of blood vessels. The blood pressure arises in the circulation due to the pumping action of the heart. Moreover the blood pressure varies between a maximum (systolic) and a minimum (diastolic) pressure during each heartbeat. The differences in blood pressure are accountable for blood flow from one region to another in the circulation. The measurement of blood pressure usually refers to the systemic arterial pressure measured at a person's upper arm and is a measure of the pressure in the brachial artery in the upper arm. In general person's blood pressure is usually indicated in terms either systolic pressure or diastolic pressure and is measured in millimeters of mercury (mmHg), for example 120/80¹¹. Hence, we assessed the Systemic blood pressure between Amlodipine and Combination groups. Initially these patients in respective groups were administered either with Amlodipine 5 mg OD or Amlodipine 5 mg plus garlic (8gm) OD for duration of eight weeks. Blood Pressure (BP), were measured at baseline, weekly and at the end of eight weeks. When we compared the levels of blood pressure at baseline, we found that patients in Amlodipine group exhibited low levels of SBP (systolic blood pressure) (151.7±8.91 mmHg Vs. 159.3±15.71 mmHg (P=0.02) as compared to combination group. Whereas, the levels in DBP (diastolic blood pressure) (85.3±7.1 mmHg vs. 81.8±10.8 mmHg (P=0.14) is almost similar in both the groups. After administration either with Amlodipine 5 mg OD or Amlodipine 5 mg plus garlic (8gm) OD in the subjects, we did not find significant difference in SBP (systolic blood pressure) between Amlodipine group vs. Combination group up to week 5. However, significant reduction in blood pressure levels has

been noticed from the week 6 onwards and sustained up to week 8. Whereas, the levels in DBP (diastolic blood pressure) was reduced drastically, which was observed much earlier starting from the week 3 and sustained up to week 8 as shown (Table 2, FIG-A and B). Thus, the results clearly specify statistically significant decrease in SBP and DBP in Combination group as compared to Amlodipine group (Table 2, FIG-A and B). Moreover the subjects who participated in the study showed good compliance and none of them developed side effects.

DISCUSSION

Hypertension (systolic blood pressure (SBP) \geq 140 mm Hg; diastolic blood pressure (DBP) \geq 90 mm Hg) is a biggest burning problem worldwide and nearly 1 billion individuals are affected¹¹. Recent guidelines specifies the importance of HTN and various treatment strategies, followed by preventive measures for the control and management of blood pressure, which also include pre-hypertensive individuals (SBP 120–139/DBP 80–89 mm Hg)^{5,11,19}. Primary management will depend on lifestyle modifications such as increased exercise, weight loss and dietary changes which could incorporate dietary supplementation. However, drug treatment is often necessary in people for whom lifestyle changes prove ineffective or insufficient. Moreover administration of current anti-hypertensive drugs is usually associated with severe side effects. Hence alternative therapies are necessitated. From few decades, about 75 to 80% of the world population relies on herbal medicines, for primary health care in developing countries, because of their better acceptability with human body and lesser side effects^{5, 11, 19}. Numerous investigations have been initiated around the globe into researching, screening and analyzing the local plants with hypotensive and anti-hypertensive therapeutic values. The anti-hypertensive effects of some of the medicinal plants have been validated and others disproved²⁰. However, traditional knowledge needs to be coupled with modern medicine and more scientific research needs to be done to verify the effectiveness, and elucidate the safety profile of such herbal remedies for their anti-hypertensive potential.

Garlic (*Allium sativum*) is one among the plants which is having anti-hypertensive properties. It is the common ingredient in our daily diet having a medicinal role^{5, 20}. Several studies demonstrated the effect of garlic on humans. These studies have

showed that it reduces cholesterol, inhibits platelet aggregation, reduces blood pressure, and increases antioxidant status. It acts as a anti-hypertensive and also exhibits cardio-protective effects, which include decrease in unstable angina, an increase in elastic property of blood vessels, and a decrease in peripheral arterial occlusive disease^{5, 11,20}. Even though the mechanism by which it lowers the blood pressure is known²¹, its impact in real life as well as its therapeutic role in the treatment of hypertension is still a matter for debate. However, the number of clinical trials on humans in combination with modern medicine is limited. Therefore, we assessed the effect of garlic in combination with modern medicine like Amlodipine.

Thus the present investigation is carried out in an aim to screen the efficacy of garlic extract in combination with Amlodipine in HTN patients. As a part of the study 60 HTN subjects (mild to moderate essential hypertensive patients) were randomized and enrolled in to two groups of 30 subjects each, one as Amlodipine group (20 males and 10 females) and other as Combination group (22 males and 8 females). Initially the demographic characteristics have been studied between Amlodipine and Combination groups. The parameters include age (49.17 \pm 7.73 vs. 50.77 \pm 8.97, p=0.46), weight (67.57 \pm 12.70 vs. 68.53 \pm 14.43, p=0.78) and duration of hypertension (25.2 \pm 4.2 vs. 25.8 \pm 4.7 months, p=0.63) has been assessed respectively (table-1). The results of demographic characteristics clearly indicated that no significant difference has been observed among the various parameters assessed among the two groups (Table 1). However, significant difference has been noticed between the groups in the demographic parameter height (159.17 \pm 12.59 vs. 165.89 \pm 9.17 cm, p=0.02).

Further the efficiency of garlic is tested in combination with Amlodipine as a treatment modality for essential hypertensive patients. Therefore, we further assessed the Systemic Blood Pressure between Amlodipine and Combination groups. Initially these patients in respective groups were administered either with Amlodipine 5 mg OD or Amlodipine 5 mg plus Garlic (8gm) OD for duration of eight weeks. Blood Pressure (BP), were measured at baseline, weekly and at the end of eight weeks. The results clearly revealed that the Amlodipine group exhibited low levels of SBP (systolic blood pressure) (151.7 \pm 8.91 mmHg Vs. 159.3 \pm 15.71 mmHg (P=0.02) as compared to combination group. whereas, the levels of DBP

(diastolic blood pressure) (85.3 ± 7.1 mmHg vs. 81.8 ± 10.8 mmHg ($P=0.14$)) were almost similar in both the groups. During treatment process, no significant difference has been observed in SBP among the Amlodipine group vs. Combination groups up to week 5. However, significant reduction in blood Pressure has been noticed from the week 6 and continued up to week 8. Similarly, in case of DBP (diastolic blood pressure) significant reduction in blood pressure was observed much earlier starting from week 3 and sustained up to week 8 as shown (Table 2, FIG-A and B) Thus, the results clearly specify statistically significant decrease in SBP and DBP in Combination group as compared to Amlodipine group (Table 2, FIG-A and B). Moreover the subjects who participated in the study showed good compliance and none of them developed side effects. The above results clearly demonstrate garlic supplementation along with Amlodipine, in combination reduced systemic blood pressure more efficiently than Amlodipine alone in hypertensive patients. Earlier studies suggested that garlic induces reduction of blood pressure levels is might be due to hydrogen sulphide production and inherent active compound allicin, liberated from alliin with the help of the enzyme alliinase, which has angiotensin II inhibiting and vasodilating effects^{5, 11, 23-27}. Also, it stimulates production of nitric oxide (NO)²¹ and hydrogen sulphide which helps relax blood vessels²². Also, garlic indirectly decrease atherosclerosis by reduction of hyperlipidemia and hypertension and probably diabetes mellitus and prevents thrombus formation²⁸.

Moreover, supplementation of various preparation procedures of garlic plays a vital role in prompt reduction in blood pressure. In one study it has been showed that the garlic powder dosages of 600–900 mg per day, provides 3.6–5.4 mg of allicin²⁹ whereas, fresh garlic cloves (~2 g) resulted in 5–9 mg allicin³⁰. Thus, various garlic preparations cause variable reduction of blood pressure, e.g. aged garlic extract or heat treated garlic contain less allicin compound which may limit its hypotensive properties^{5, 11}. Therefore it is

advisable to use standardized garlic preparations^{11, 31}. Our study finding were similar to meta-analysis of 11 randomized, placebo-controlled studies, where hypertensive subjects (SBP ≥ 140 mmHg; DBP ≥ 90 mmHg) were treated with garlic powder 600 to 900 mg/day showed a mean decrease 8.4 mmHg in SBP and 7.3 mmHg in DBP. Interestingly, there was no significant reduction systemic blood pressure with garlic preparations in studies including normotensives¹¹. Similarly, Auer et al. showed reduction in supine DBP in the group receiving garlic treatment from 102 to 91 mm Hg after eight weeks ($p < 0.05$) and to 85 mmHg after 12 weeks ($p < 0.01$) as compared to placebo group³². Also, Morgan et al. have shown the effect of garlic preparations on systemic blood pressure were comparable to the hypotensive effects of commonly-prescribed anti-hypertensive drugs such as beta-blockers reduction of SBP by 5 mm Hg, angiotensin converting enzyme inhibitors (ACEI) SBP by 8 mm Hg³³ and angiotensin II type 1 receptor antagonists DBP by 10.3 mm Hg³⁴. However, studies on combination of garlic and Amlodipine are lacking and needs Larger-scale long term studies are required to know whether standardized garlic preparations along with Amlodipine could reduce blood pressure more than Amlodipine alone.

STUDY LIMITATIONS

In the present study, we observed combination therapy provided better improvement in systemic blood pressure as compared to Amlodipine alone. However, such an interpretation needs carefulness because the time at which they took the medication before each study day, concomitant medications, unknown co-morbid conditions could be the confounding factors. Larger-scale studies are required to confirm above stated results. Also, as garlic preparations are not subject to the same regulations as drugs, different garlic preparations may contain various active components hence varied effectiveness. As garlic was taken as a part of diet, the effect of cooked garlic may not be the same as the garlic preparations, as heating it could reduce its effectiveness.

Table1: Demographic characteristics between Amlodipine and Combination group

Demographic Parameters	Amlodipine N=30	Combination N=30	P Value
Age	49.17 \pm 7.73	50.77 \pm 8.97	0.46
Sex (M/F)	20/10	22/8	0.77
Height (Cm)	159.17 \pm 12.59	165.89 \pm 9.17	0.02

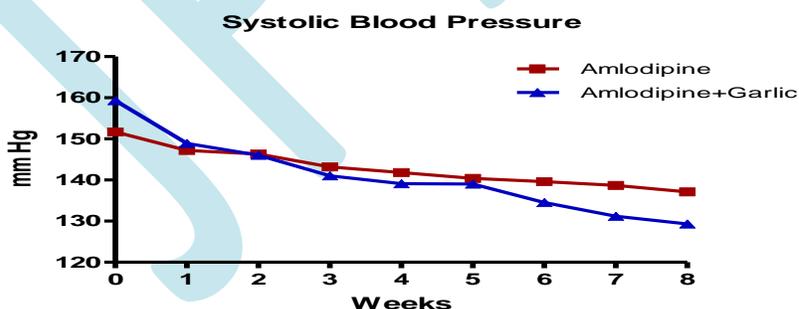
Weight (Kg)	67.57±12.70	68.53±14.43	0.78
Smoking	1	0	1
Alcohol	4	8	0.33
Diabetics	6	3	0.47
Duration of Hypertension (months)	25.2±4.2	25.8±4.7	0.63

Table 2: Measure of Systemic Blood Pressure between Amlodipine and Combination group

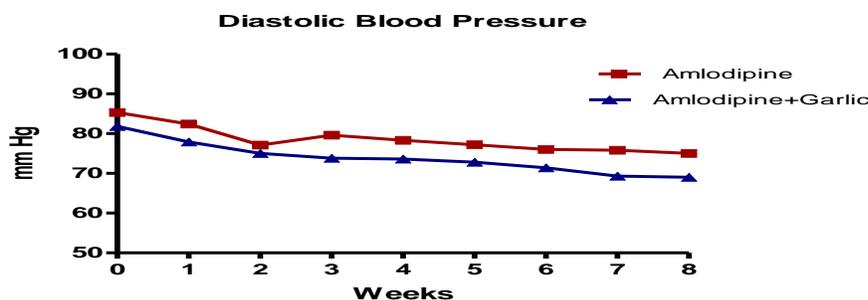
Weeks	Amlodipine	Combination	P Value	Amlodipine	Combination	P Value
Systolic Blood Pressure (mmHg)			Diastolic Blood Pressure (mmHg)			
Baseline	151.7±8.9	159.3±15.7	0.024	85.3±7.1	81.8±10.8	0.14
1	147.2±9.6	148.9±12.5	0.541	82.4±7.6	77.9±7.9	0.03
2	146.3±9.5	146.0±12.6	0.927	77.1±16.1	75.0±7.9	0.52
3	143.2±9.3	141.0±11.3	0.407	79.6±7.8	73.8±6.8	0.00
4	141.8±8.7	139.1±9.2	0.248	78.3±7.1	73.6±6.8	0.01
5	140.4±9.2	139.0±9.5	0.546	77.2±6.7	72.8±6.7	0.01
6	139.6±7.7	134.5±10.0	0.030	76.0±6.2	71.4±7.2	0.01
7	138.7±7.9	131.2±8.6	0.001	75.8±5.5	69.3±6.6	0.00
8	137.1±8.8	129.3±9.0	0.001	75.0±5.5	69.0±7.5	0.00

Blood pressure levels among the patients (n=60, each group=30) were assessed after administration of either with Amlodipine 5 mg OD or Amlodipine 5 mg plus Garlic (8gm) OD. Fig-A represents the levels of SBP (systolic blood pressure) in Amlodipine group and combination group up to week 8. Fig-B represents the levels of DBP (diastolic blood pressure) in Amlodipine group and combination group up to week 8.

1.FIG-A



2.FIG-B



CONCLUSION

Combination of Amlodipine and garlic found to be more effective than Amlodipine alone in controlling blood pressure among essential hypertensive patients. Hence we recommend Garlic as an add-on to standard care in treating hypertensive patients. However Larger-scale long term studies are required know whether standardized garlic preparations could provide a safe alternative or complementary treatment option for hypertension in clinical practice to confirm above stated results.

CONFLICT OF INTEREST: No conflict of interest.

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