

Effects of garlic tablet (GARLET) in combination with telmisartan on high blood pressure

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ABSTRACT

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Hypertension (HTN) is a health problem worldwide affecting tens of millions of people. Giving modern antihypertensive alone is not enough to cure this disease. Garlic has been used to treat and cure various diseases, including high blood pressure (BP). This study aims to evaluate the effectiveness of administering telmisartan with garlic in reducing BP. In this study, 96 people with mild to moderate HTN were randomly selected and assigned to three groups consisting of 32 subjects; each participant in the garlic group received 400mg BD, the telmisartan group received 20mg OD, and the mixed group received 400 mg garlic BD and 20mg telmisartan OD for 8 wk of treatment. Blood pressure was measured at the beginning of each week, as well as on the closing day of the 8 wk. Combining telmisartan with garlic is more effective in reducing systolic blood pressure/SBP (113.0 ± 22.9 mmHg) compared to telmisartan (147.7 ± 4.6 mmHg; $p=0.015$) and diastolic blood pressure/DBP (71.0 ± 21.2 mmHg vs 90.75 ± 11.9 mmHg; $p=0.038$) during 8 wk of treatment in hypertensive patients. No significant side effects were identified during the treatment period. In conclusion, garlic, like other BP control pills, increases the effectiveness of chemical pills to lower SBP and DBP.

ABSTRAK

Hipertensi (HTN) merupakan masalah kesehatan di seluruh dunia yang mempengaruhi puluhan juta orang. Pemberian antihipertensi saja tidak cukup untuk menyembuhkan penyakit ini. Bawang putih telah digunakan untuk mengobati dan menyembuhkan berbagai penyakit, termasuk tekanan darah tinggi. Penelitian ini bertujuan untuk mengevaluasi efektivitas pemberian telmisartan dengan bawang putih dalam menurunkan tekanan darah. Dalam penelitian ini, 96 orang penderita HTN ringan hingga sedang dipilih secara acak dan dibagi menjadi tiga kelompok yang terdiri dari 32 subjek; setiap peserta dalam kelompok bawang putih menerima BD 400mg, kelompok telmisartan menerima OD 20mg, dan kelompok campuran menerima BD bawang putih 400 mg dan OD telmisartan 20mg selama 8 minggu pengobatan. Tekanan darah diukur pada awal setiap minggu, serta pada hari penutupan minggu ke-8. Kombinasi telmisartan dengan bawang putih lebih efektif menurunkan tekanan darah sistolik/SBP ($113,0 \pm 22,9$ mmHg) dibandingkan telmisartan ($147,7 \pm 4,6$ mmHg; $p=0,015$) dan tekanan darah/DBP diastolik ($71,0 \pm 21,2$ mmHg vs $90,75 \pm 11,9$ mmHg; $p=0,038$) selama 8 minggu pengobatan pada pasien hipertensi. Tidak ada efek samping signifikan yang diidentifikasi selama masa pengobatan. Kesimpulannya, bawang putih, seperti pil pengontrol tekanan darah lainnya, meningkatkan efektivitas pil kimia untuk menurunkan SBP dan DBP.

Keywords:

garlic;
telmisartan;
systolic blood pressure;
diastolic blood pressure;
hypertension

INTRODUCTION

Hypertension (HTN) is alternatively referred to as high or elevated blood pressure (BP). The vessels deliver blood from the heart to each location of the body. When blood is pumped by the heart, it presses on the walls of blood vessels, or arteries, creating BP. The heart pumps blood throughout the body with a force known as systolic pressure, represented by a greater number. Meanwhile, the resistance to blood flow in the blood arteries between heartbeats as blood circulates in the heart is known as the diastolic pressure (lower number).¹ High BP is one of most prevalent factors globally that brings about considerable risks of death and morbidity. High systolic blood pressure (SBP), poor diet, and cigarette use are the main risk factors for death and morbidity based on the latest findings from the Global Burden of Diseases (GBD).² Some of the fatal risk factors of high BP pointed out are stroke, coronary artery disease, failure of the heart, chronic renal illness, peripheral arterial disease, and arterial aneurysms.³⁻⁴

Morbidity and mortality rates are increasing along with the increase in the global elderly population caused by increasing vascular hypertension and the prevalence of systemic hypertension.⁵ According to the World Health Organization, there will be close to 1.6 billion adults worldwide by 2025 who have high BP and its related consequences, including cardiovascular diseases (CVD).²

A SBP of >140 mmHg and a diastolic blood pressure (DBP) of > 90 mmHg are signs of the complex condition known as HTN. However, adults who are assessed to be at the pre-HTN stage and who have a DBP of 80 to 89 mmHg and an SBP of 120 to 139 mmHg are at a higher risk of having high BP.^{4,6} Secondary HTN can be treated if the motivating causes are adequately identified. On the other

hand, 90% of all instances of identified cases are embodied by critical HTN.

Although the underlying pathological processes are partially unclear, it is considered that lifestyle is one of several contributing variables. Luckily, most of these factors can be regulated to control the commonness of morbidity. Diet is thought to have a vital role in the emergence of HTN and associated illness, through a host of lifestyle variables. Age, gender, race, heredity, and genetic susceptibility are other extrinsic variables.⁷

Hydrogen sulfide (H₂S) was identified by Abe and Kimura as an endogenous gas transmitter in 1996. This discovery is regarded as a turning point for the emerging field of study that has had a substantial influence on physiopharmacology.⁸ In the previous 25 yr, H₂S has been proven as a fundamental compound for maintaining the equilibrium of various systems. The cardiovascular (CV) system is among the most substantial domains in which the function and importance of H₂S have been studied.⁹ Since various mechanisms of action, such as the activation of potassium channels like vascular potassium channel (Kv7) or ATP-sensitive potassium channel (KATP) and the inhibition of 5-phosphodiesterase (5-PDE) enzymes, are connected, the H₂S compound demonstrated that it was able to promote vasodilation.^{10,11} This observation opened the foundation for the investigation of exogenous H₂S-donors, or compounds that can release H₂S, to develop cutting-edge HTN treatment methods of garlic.¹²

This directed the researchers to the finding that sure natural molecules acquired from *Alliaceae* (i.e., garlic) and *Brassicaceae* (i.e., rocket or broccoli) botanical households suggest the profile of sluggish H₂S-donors (i.e., suggesting that they will display an H₂S-liberating profile extra analogous to that of the unhurried endogenous

manufacturing of this gasotransmitter). This belongs to the fact that the *Alliaceae* and *Brassicaceae* derivatives, whether or not they are natural extracts or pure molecules (polysulfides or isothiocyanates), might be incredibly successful in treating hypertension or pre-hypertension symptoms.⁹ Garlic (*Allium sativum*) has pharmacologically been used for thousands of years; with a thorough study of the benefits of garlic supplements and fresh garlic in preventing atherosclerosis and protecting the heart, however, little was previously known about and supported by research on its therapeutic and pharmacological features.¹³

Drugs that are used as renin-angiotensin converting enzyme inhibitors (ACEIs) are successfully used for the treatment of HTN at any age.¹⁴ The angiotensin-2 (AT-II) receptor antagonist telmisartan, which connects specifically to the angiotensin one (AT1) receptor, restrains the pro-hypertensive effects associated with AT-II, including sodium chloride preservation, vasoconstriction, vascular and cardiac muscle expansion, and pro-fibrotic characteristics in both the renal and cardiovascular systems.¹⁵ Telmisartan is licensed to treat cardiovascular conditions and systemic hypertension in humans.¹⁶

Many studies were conducted on the combined effect of garlic with BP-lowering drugs such as calcium channel blockers, beta-blockers, and ACEIs. Telmisartan is an angiotensin II receptor blocker (ARB) and it is a common drug that is used to treat high BP. However, until now no study conducted to evaluate the effect of combination telmisartan with garlic.

MATERIAL AND METHODS

Design of the research

The clinical trial was carried out

with 96 outpatient men with HTN (aged 40 to 80 yr) who were randomized and double-blinded. Prior to receiving various medications such as diuretics, ACEIs (angiotensin-converting enzyme inhibitors), beta/alpha-blockers, and other locally sourced herbal remedies that proved ineffective, the patients were all diagnosed with HTN. This study was conducted in the Department of Internal Diseases, Alami Curative Hospital. While conducting this study, we followed the 1975 Declaration of Helsinki Principles and the 1983 amendments. This study turned into permitted via the Institutional Ethical Committee, Department of Research of Medical School, Alberoni University.

Inclusion criteria in this study are male patients between ages 40 and 80 yr, who receive treatment of continuous ARB and are not assisted by other anti-hypertensive drugs. Criteria for exclusion in this study are patients with cancer, heart disease, failure Kidney, the inability to handle garlic or telmisartan, in the age range between 40 and 80 yr. In this investigation, the SBP for patients ranged from 160 to 190 mmHg, while DBP ranged from 90 to 115 mmHg. Patients fulfilling eligibility criteria (inclusion and exclusion criteria) were randomized into three treatment groups as follows: Group A: the patients were given low-dose monotherapy of telmisartan 20 mg, OD, for 8 wk (Getz Pharma Karachi, Pakistan). Group B: patients were given low-dose monotherapy of 400 mg of garlic tablet BD for 8 wk (Amin Pharmaceutical Co., Isfahan, Iran). Group C: patients were given a combination of telmisartan 20 mg OD and a 400 mg garlic tablet BD for 8 wk. Follow-up visits were performed after the time of inclusion of the participants, once every week, and at the end of the 8 wk. The randomization was carried out using a random number generator. All groups' treatment periods came to an end after 8 wk. The participants adopted a low-salt, low-fat

diet and adhered to the same dietary and behavioral recommendations.

Demographic information

Age, weight, height, and length of high BP were noted for the participants under study. When the patient was seated, a mercury sphygmomanometer was used to take their BP. The patient was given a five-minute rest before having their SBP and DBP checked and recorded.

Measurements of BP

Arterial BP was checked at the time of inclusion of the participants, once every week, and after the 8 wk. It was consistently measured in the left and right arms in the supine, sitting, and standing postures early in the morning. The results obtained from both the second and third readings were documented, and using the mean value of the 12 readings, an integral estimate of arterial BP was calculated.

Statistical Analysis

The data were analyzed using SPSS version 10.1.7 (SPSS, Chicago, IL, USA). Following a review of the variable distribution, within-group effect calculations were made using Wilcoxon statistics, and between-group comparisons were made using one-way Anova. Data were presented as means, standard error of the mean (SEM),

median for non-parametric data, and 95% confidence interval (CI) where applicable. Significance was determined at the 0.05 level of confidence.

RESULTS

A total of 96 participants involved in this study. Eight patients stopped taking study drugs throughout the treatment period: 2 in the garlic group owing to gastrointestinal discomforts, 3 in the telmisartan group, and 3 in the combination group (garlic + telmisartan) group for unidentified reasons. After the 8 wk therapy period, 88 individuals: 30 in the garlic group, 27 in the telmisartan group, and 31 in the combined group (garlic + telmisartan) were assessed.

Demographic indicators between telmisartan and combination groups

TABLE 1 listed the demographic data, which included height, weight, age, and the number of months that the elevated BP had persisted. The age (62.4±10.4 vs. 61.9±11 yr; p=0.9) and weight (76.2±9.9 vs. 76.7±1.7 kg; p=0.7) as well as height (163±26 vs. 166.4±18 cm; p=0.1) and duration of HTN (33.2±15 vs. 33.1±12 mo; p=0.16) are the demographic data that differentiate the telmisartan group from the combination group. The results unequivocally demonstrate that there were no discernible demographic differences between the combination group and the telmisartan group.

TABLE 1. Demographic of subjects (mean ±SD) between telmisartan and combination groups

Demographic of subjects	Telmisartan (n=32)	Combination (n=32)	p
Age (yr)	62.4±10.4	61.9±11	0.9
Weight (kg)	76.2±9.9	76.7±1.7	0.7
Height (cm)	163±26	166.4±18	0.1
Duration (mo)	33.2±15	33.1±12	0.16

Measuring systemic BP

Blood pressure is the pressure exerted by circulating blood on the walls of arterial blood vessels within the systemic circulatory system. Blood pressure refers to the force exerted by blood flow upon the blood vessel' inner walls. This pressure stems from the rhythmic contraction of the heart, which circulates the blood throughout the body's vascular system. Blood pressure has two components a maximum (systolic) and a minimum (diastolic) pressure throughout each cardiac cycle. Generally, a person's BP is usually indicated in terms of either SBP or DBP. It is quantified in units known as millimeters of mercury (mmHg), often illustrated, for instance, as 120/80.

We evaluated the SBP among telmisartan and combination groups. At first, these individuals undergoing treatment telmisartan 20 mg OD or telmisartan 20 mg plus garlic 400mg BD for 8 wk. The measurement of BP was initially taken, subsequently weekly, and finally after the completion of 8 wk. When the BP were compared after 8 wk of treatment, it was discovered that the group receiving combined treatment demonstrated reduced SBP levels (median:102.5 vs 150.0 mmHg; $p=0.015$) in contrast to the telmisartan group. However, the level of DBP in the telmisartan group was $(90.75\pm 11.9$

vs 71.0 ± 21.2 mmHg; $p=0.038$) in the combination group.

The significant differences were also shown in SBP among the garlic group (176.6 ± 2.6 mmHg) vs telmisartan group (148.7 ± 4.6 mmHg) vs the combination group (113 ± 29.9 mmHg) and DBP in telmisartan (90.7 ± 11.9 mmHg) vs combination group (71 ± 21.2 mmHg) as shown (FIGURE 1A and B). As compared with post treatment either with telmisartan 20mg OD or telmisartan 20mg plus garlic 400mg BID in the study participants, there was no notable variance in the SBP when comparing the telmisartan group with the combination group up to the 5 wk. However, a substantial decline in BP measurements started to be evident from the 6 wk and continued steadily until the 8 wk. On the other hand, the DBP levels experienced a significantly steep decrease, a trend which was noticeable much earlier, commencing from the 3rd wk and maintaining until the 8th wk. In contrast, the degree of DBP was reduced drastically, which was observed much earlier and maintained continuity from week 3 until week 8. Thus, the results specify a statistically significant decrease in SBP and DBP in the combination group as compared to the telmisartan group (FIGURE 1A and B). Also, the individuals who participated in this study showed good compliance, and none of them developed side effects.

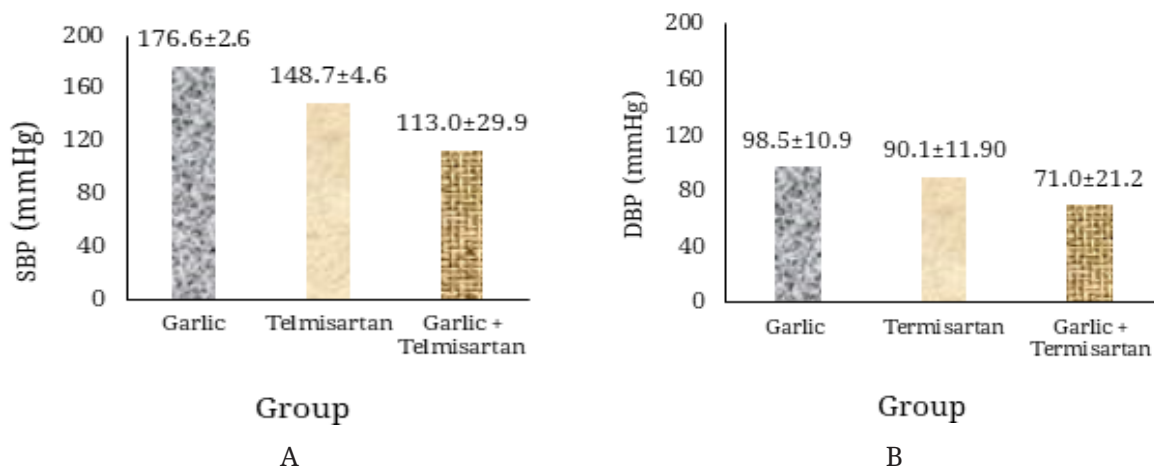


FIGURE 1. The mean of SBP (A) and DBP (B) in the garlic group, telmisartan group and combination group after the 8 wk treatment.

DISCUSSION

Hypertension, characterized by a SBP of 140 mm Hg or higher and a DBP of 90 mm Hg or above, is a pressing global issue affecting nearly a billion people. Current guidelines underscore the significance of treating hypertension and outline various methodologies, including preventive measures for regulating and managing BP levels. These guidelines also address individuals with pre-hypertension (SBP 120-139/DBP 80-89 mm Hg).¹⁷

The primary approach to managing hypertension hinges on lifestyle alterations like increased physical activity, weight reduction, and dietary modifications, potentially including dietary supplementation. Nevertheless, in cases where lifestyle adjustments fail to yield results or are insufficient, medication becomes a necessary course of action. These alternative therapies are necessitated.

Humans have relied on herbal medicines for decades, for curative purposes. In numerous nations, certain substances are more easily accepted by the human body, resulting in fewer adverse reactions. Garlic, scientifically known as *A. sativum*, is a prime example of such substance, renowned for its anti-hypertensive properties. This common dietary component also plays a significant medicinal role.¹⁸ Multiple scientific investigations have underscored the beneficial impact of garlic on human health. These researches reveal that garlic can lower cholesterol levels, deter platelet clumping, decrease BP, and bolster antioxidant status. It functions as an effective anti-hypertensive agent and also exhibits cardio-protective benefits, these protective effects include reduction of unstable chest pain, improvement of blood vessel elasticity, and reduction of disorders triggered by blockage of peripheral arteries.

Nevertheless, there is a scarcity of

clinical trials investigating the combined effects of garlic with contemporary medicine on humans. In carrying out this study, the study found that the garlic tablet combined with telmisartan significantly decreases BP, both (SBO and DBP). This result is the same as previous studies. Telmisartan is a well-known drug for the treatment of high BP, and its effects in reducing BP have been proven in numerous studies, was generally similar in efficacy to enalapril, more effective than submaximal dosages of losartan, and better tolerated than linsopriole.¹⁹ Researchers and clinicians are interested in combining garlic with antihypertensive drugs like amlodipine, diuretics, and they reached satisfying results. This result is analogous to those of the other studies that have shown the hypotensive properties of the products containing garlic.^{8,20-22} Thus, this study is carried out to screen the effectiveness of garlic extract in plus telmisartan in patients with high BP.

Blood pressure was measured at baseline, weekly, and at the end of eight weeks. The results revealed that the telmisartan group exhibited low levels of SBP (median:102.5mmHg vs median: 150.0mmHg; p=0.015) as compared to the combination group; whereas, the level of DBP in the telmisartan group was (90.7±11.9 mmHg vs 71.0±21.2 mmHg; p=0.038) in the combination group. Thus, the results specify a statistically significant decrease in SBP and DBP in the combination group as compared to the telmisartan group (FIGURE 1A and B). The result obtained is similar to the study conducted by Satyanand *et al.* in 2013 on the effect of the combination of amlodipine (5 mg) once a day and garlic (8 mg) once a day.²³ Furthermore, the participants involved in the research exhibited robust health, with no instances of side effects. The data we obtained demonstrates that the combination of garlic supplements and telmisartan more effectively

lowers systemic BP compared to when telmisartan is utilized independently in patients with hypertension.

Past scientific research has posited that the BP lowering effect of garlic may be attributed to the production of hydrogen sulfide and the inherent active component, allicin, which is released from alliin with the assistance of the enzyme alliinase, known for its inhibiting effects on angiotensin II and its capacity for vasodilation.^{24,25} In a prior study, the daily dosage of garlic powder, ranging from 600-900 mg, delivered 3.6-5.4 mg of allicin; conversely, fresh garlic cloves (approximately 2 g) resulted in an allicin yield of 5-9 mg. Hence, different garlic preparations lead to varying degrees of BP reduction, for instance, aged garlic extract or heat-treated garlic contains a lesser amount of the allicin compound, potentially restricting its BP lowering abilities.²⁶

The conclusions drawn from this research bear resemblance to the collective analysis of numerous randomized, placebo-controlled investigations, these studies treated hypertensive individuals (with a SBP of at least 140 mmHg and a DBP of at least 90 mmHg) with a daily dosage of 400 mg of garlic powder showed a mean decrease of 9.5 mmHg in SBP and 8.5 mmHg in DBP. Interestingly, there was no significant reduction in SBP with garlic preparations in studies including normotensives. Similarly, Auer *et al.* showed a reduction in supine DBP in the group receiving garlic treatment from 102 to 91 mm Hg after 8 wk ($p < 0.01$) as compared to the placebo group.²¹ In another study, Morgan *et al.* research has indicated that the impact of garlic supplements on overall BP is akin to the decrease in SBP by 5 mm Hg, as seen with beta-blocker usage. Similarly, it also matches the 8 mm Hg SBP reduction observed with ACEIs.²⁷ Additionally, it is comparable to a 10.3 mm Hg decrease in DBP associated with angiotensin II type 1 receptor antagonists.²⁸

CONCLUSION

This study indicates that telmisartan with garlic worked better than telmisartan alone to manage SBP and DBP. We suggest adding garlic in addition to other BP-lowering medications. However, more research is needed to confirm the effectiveness of garlic added to traditional anti-hypertension medicines.

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