

Cholesterol lowering effect of Garlic (*Allium sativum*) in patients with hypercholesterolemia

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Abstract:

Background: Cardiovascular disease especially atherosclerotic coronary artery heart disease (CHD) are directly associated with increased total serum cholesterol levels and accounts for a large population of deaths and disability worldwide. The aim of the study was to reduce total blood cholesterol level with supplementation of garlic capsule.

Material and Methods: This was a prospective, randomized, single-blind, placebo controlled study conducted in the Department of Pharmacology, Sir Salimullah Medical College and Mitford Hospital, Dhaka. Eighty subjects with elevated total cholesterol level between 210mg/dl to 320mg/dl were enrolled. Two groups each comprising of forty subjects were given 10mg of garlic capsule and placebo capsule, respectively, daily for a total period of 12 weeks. Moreover, both groups were advised a regular diet and exercise routine. Systolic and diastolic blood pressure were measured and serum lipid profile of all subjects were estimated by enzymatic method. Follow-up was done on 6th week and 12th week after starting treatment. Statistical analysis was done by using paired sample t-test.

Results: In male subjects, serum cholesterol level showed significant reduction of 11% ($P < 0.001$) from mean baseline of 259.02mg/dl to 198.60mg/dl after 12 weeks. In female subjects, total serum cholesterol level reduction was 10% ($P < 0.001$) from mean baseline of 248.07mg/dl to 201.41mg/dl after 12 weeks of Garlic treatment. But there was no such significant changes ($P > 0.001$) in the placebo group among males neither females.

Conclusion: Garlic has an important role in total serum cholesterol reduction in most cases of significant hypercholesterolemia thereby reducing risk of atherosclerosis and cardiovascular heart diseases.

Key words: Garlic; Hypercholesterolemia; Cardiovascular disease.

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I. Introduction

Major causes of death and early disability are caused by atherosclerotic diseases. Hypercholesterolemia is one of the best known independent risk factor responsible for the pathology of atherosclerosis¹. Increased risk of cardiovascular disease, particularly coronary artery disease and atherosclerosis has strong association with elevated serum lipid levels^{2,3,4}. More than 224 million people in Asia have high cholesterol levels according to an Asian disease incidence and prevalence report released in 2013⁵. Hyperlipidemia is a major risk factor in the cardiovascular disease, one of the leading causes of mortality worldwide causing more than 80% of deaths in low and middle income countries⁶. Various factors might have cause dyslipidemia has increased due to rapid industrialization, change in life style pattern, work habit changes like technical advances lead to physical inactivity. Also rising affluence has modified the dietary pattern by increased consumption of fat reached diet, sugar and calories. Despite lifestyle modifications and pharmacological management of well-established risk factors, ischemic heart disease, stroke, and peripheral vascular disease remain known causes of mortality in developing countries. Increased serum cholesterol levels have been implicated as important risk factor for development of coronary artery disease⁷. Current practice is to prescribe lipid-lowering drugs such as statins all over the world with few patients experiencing adverse effects including myalgia, neuropathy, cognitive dysfunction, muscle weakness, and a possible risk of diabetes⁸.

Allium sativum, commonly known as Garlic is a herb with complex action. It has been widely used around the world with a history of human use of over 7000 years for culinary and medicinal purpose⁹. Garlic is a medicinal product and an important dietary component of food enhancing flavor and taste. It is still used as a cure for heart disease, headaches, and cancer. The allicin component obtained from garlic owns stronger bactericidal and fungicidal properties compared to other antibiotics. Daily intake of garlic is useful in fat

metabolism and lowering of blood cholesterol levels. Garlic increases high-density lipoprotein (HDL) (good cholesterol), which protects heart and blood vessels, and lowers Low-density lipoprotein (LDL) (bad cholesterol) along with triglycerides (TGs). Activity of the enzyme HMG CoA reductase involved in cholesterol synthesis is significantly reduced¹⁰. Another important property of garlic is stimulation of phagocytic function of macrophages and lymphocyte proliferation¹¹. Hypoglycemic, anticoagulant, antihypertensive, antioxidant, hepatoprotective, and immunomodulatory properties of garlic have been reported¹². There has been an increasing reorganization that certain natural substances of plant origin like garlic has become more widespread over the past few years driven undoubtedly may have fewer side effects and easily available and cheap with good efficacy¹³. The objective of this study was to assess the potent beneficial effect of garlic (*Allium sativum*) on total serum cholesterol level in patients with hypercholesterolemia.

II. Material and Methods

This prospective, randomized, single-blind, placebo controlled study was conducted in the Department of Pharmacology and Therapeutics, Sir Salimullah Medical College and Mitford Hospital, Dhaka, Bangladesh, during the period of July 2017 to December 2017. Ethical approval was taken from the Institutional Ethics Committee (IEC) at Sir Salimullah Medical and Mitford Hospital, Bangladesh. A total number of eighty (48 males and 32 females) subjects were selected by purposive sampling technique.

Study Design: Prospective, randomized, single-blind, placebo controlled study.

Study Location: This was a tertiary care teaching hospital based study carried out in the Department of Pharmacology and Therapeutics, Sir Salimullah Medical College and Mitford Hospital, Dhaka, Bangladesh.

Study Duration: July 2017 to December 2017.

Sample size: 80 subjects.

Subjects and selection method: The subjects included were healthy volunteers with elevated total cholesterol level between 210mg/dl to 320mg/dl who attended the outpatient Department of Cardiology, Sir Salimullah Medical College and Mitford Hospital, Dhaka, Bangladesh. Subjects meeting the inclusion criteria of elevated cholesterol and willing to participate in study were enrolled. A structured questionnaire was filled up by each subject after giving a written consent for participation in this study. The subjects were divided into two groups each comprising of forty subjects. Both groups were also advised a regular diet and exercise routine.

Garlic group (N=40)- 10mg garlic capsule once daily for 12 weeks.

Placebo group (N=40)- placebo capsule once daily for 12 weeks..

Inclusion criteria:

1. Healthy volunteers with elevated cholesterol levels between 210mg/dl to 320mg/dl.
2. Either sex.
3. Age between 21 to 70 years.
4. No past history of cardiovascular events.

Exclusion criteria:

1. Cigarette smokers.
2. Hypertensive patients.
3. Diabetic patients.
4. Pregnant women.
5. Subjects taking lipid-lowering drugs (statins or fibrates).

Procedure methodology

A structured questionnaire was filled up by each subject after giving a written consent for participation in this study. Detailed history of the subjects was noted down through scrutiny of available medical records and a meticulous clinical examination. The questionnaire included particulars of subjects such as age, gender, height, weight, and personal habits like smoking, alcohol and drug history, presence of any disease like Diabetes, Hypertension, Cardiovascular disease, pregnancy (in females), among biochemical laboratory investigation total serum cholesterol was measured. Forty subjects were given Capsule Garlin 10mg (enteric coated liquid filled hard gelatin capsule with standardized garlic oil preparation containing 1.3% Allicin, the most active ingredient of garlic) daily for a total period of 12 weeks at bedtime. The remaining forty subjects were treated with placebo capsule once daily for the same duration. Follow-up was done on 6th week and 12th week after starting treatment. Clinical history, body weight, Body Mass Index (BMI) and blood pressure were reviewed. BMI was calculated as weight (in kilograms) divided by height (in meters squared). Blood pressure was recorded using an aneroid sphygmomanometer (Model: 500V, ALPK2, Tokyo, Japan) as the mean of two readings taken five minutes apart. On completion of 12 weeks treatment, blood samples were collected after ten hours of an overnight fast. Blood (10ml) was collected and centrifuged at 2500rpm to obtain serum, which was

stored for enzymatic colorimetric method. Estimation of total serum cholesterol was done by enzymatic method (CHOD-PAP) using reagents of Biocon® Germany by spectrophotometer.

Statistical analysis

Data was expressed as mean±SD. Statistical analysis was done by using SPSS version 21 (SPSS Inc., Chicago, IL). Paired sample t-test was used as test of significance and P value <0.001 was considered as significant.

III. Results

All subjects who participated in this study successfully completed the study with a co-operative attitude and bound to treatment nature. No adverse effects of these herbal drugs were reported during the follow-up visits or after completion of study.

Table no 1 displays the demographic characteristics of the subjects. Male subjects were 46(57.5%) and females were 34(42.5%). Mean age was 39.6 years.

Table no 1: Demographic features of both groups

Characteristics	Garlic group (n=40)	Placebo group (n=40)
Male	24	22
Female	16	18
Age (years) (Mean±SD)	44.75±9.55	34.63±6.92
Body Mass Index (BMI)	26.50±1.38	25.85±1.26

According to Table no 2, male population was 48(60%), whereas female population was 32(40%). Maximum number 22(45%) of male cases were in the age group of 41–50 years, whereas maximum number 10(31.25%) of female cases belonged to the age group of 31–40 years.

Table no 2: Gender distribution in different age groups

Age group (in years)	No. of males (%)	No. of females (%)	Total (%)
21-30	4 (8.33%)	6 (18.6%)	10 (12.50%)
31-40	12 (25%)	10 (31.25%)	18 (22.50%)
41-50	22 (45%)	8 (25%)	32 (40%)
51-60	6 (12.50%)	6 (18.60%)	14 (17.5%)
61-70	4 (8.33%)	2(6.25%)	6 (7.50%)
Total	48 (60%)	32 (40%)	80 (100%)

Table no 3 indicates the majority 14(17.50%) and 12(15%) patients of either sex were within the range of total serum cholesterol 241–250 mg/dl and 251–260 mg/dl, respectively, followed by other groups.

Table no 3: Gender distribution in different total serum cholesterol level groups

Total serum cholesterol (mg/dl)	Total (100%)
211-220	4 (5%)
221-230	6 (7.50%)
231-240	6 (7.50%)
241-250	14 (17.50%)
251-260	12 (15%)
261-270	4 (5%)
271-280	10 (12.50%)
281-290	10 (12.50%)
291-300	8 (10%)
301-310	3 (3.75%)
311-320	3 (3.75%)
Total (n)	80 (100%)

There was a significant change (P<0.001) in Body Mass Index (BMI) in the garlic group after a 12 week treatment with garlic capsule compared to the placebo group as shown in table no 4.

Table no 4: Change in Body Mass Index (BMI) before and after treatment in both groups

Study groups	Body Mass Index (BMI) kg/m ²		P value
	Before treatment (0 week)	After treatment (12 th week)	
Garlic group (n=40)	26.50±1.38	24.78±0.87	<0.001*
Placebo group (n=40)	25.85±1.26	25.23±0.91	0.56 ^{ns}

* (significant); ns (non-significant)

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There were no significant changes ($P>0.001$) in blood pressure in both groups after a 12 week treatment with garlic capsule and placebo respectively as revealed in table no 5.

Table no 5: Change in blood pressure before and after treatment in both groups

Study groups	Systolic blood pressure (mm of Hg)		P value
	Before treatment (0 week)	After treatment (12 th week)	
Garlic group (n=40)	125.31±7.29 (110-140)	124.53±6.01 (110-140)	0.64 ^{ns}
Placebo group (n=40)	120±4.02 (110-140)	119±4.54 (110-140)	0.60 ^{ns}
	Diastolic blood pressure (mm of Hg)		
Garlic group (n=40)	79.69±4.39 (70-85)	79.38±5.20 (70-85)	0.80 ^{ns}
Placebo group (n=40)	77.81±3.07 (65-85)	77.19±4.00 (70-80)	0.56 ^{ns}

ns (non-significant)

Figure no 1 displays the changes in mean total serum cholesterol levels in both garlic and placebo groups during the entire study duration of 12 weeks. There was a remarkable reduction in the mean total serum cholesterol in the garlic group before and after treatment with garlic. But there was no such noticeable change in the placebo group during the same duration.

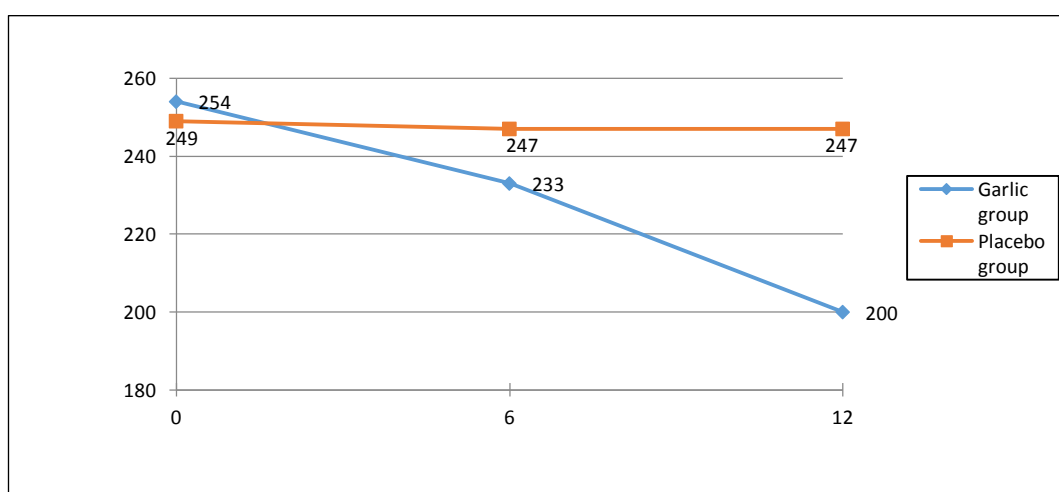


Figure no 1: Changes in the mean total serum cholesterol level in both groups during 12 week treatment

Table no 6 revealed that total serum cholesterol level in males decreased significantly ($P<0.001$) from 259.02mg/dl at baseline to 198.60mg/dl and in females ($P<0.001$) from 248.07mg/dl at baseline to 201.41mg/dl after 12 weeks of treatment. But there was no such significant changes ($P>0.001$) in the placebo group among males neither females.

Table no 6: Gender distribution showing the effect of garlic on total serum cholesterol level

Study group	Gender	Mean total serum cholesterol [mean±SD (mg/dl)]		P value
		Before treatment	After treatment	
Garlic group (n=40)	Male (24)	259.02±16.75	198.60±23.41	<0.001 [*]
	Female (16)	248.07±27.55	201.41±36.45	<0.001 [*]
Placebo group (n=40)	Male (22)	254.23±14.95	252.04±16.45	>0.001 ^{ns}
	Female (18)	244.37±16.25	242.25±16.25	>0.001 ^{ns}

* (significant); ns (non-significant)

IV. Discussion

The present study was undertaken to establish the efficacy of garlic in reducing total serum cholesterol level in patients with hypercholesterolemia. Eighty healthy volunteers with elevated total serum cholesterol level in the range of 210 to 320mg/dl were selected and approximately 10mg capsule garlic and similar placebo was given respectively, for a total duration of 12 weeks.

Baseline serum cholesterol was obtained before the initiation of treatment and again evaluated on 6th week and 12th week respectively. At the end of the study, total serum cholesterol level reduced by 11% ($P<0.001$) from mean 259±16.75mg/dl at baseline to 198.60±23.41mg/dl in males, whereas in females it

reduced by 10% ($P < 0.001$) from 248 ± 13.66 mg/dl to 201 ± 36.45 mg/dl after 12 weeks of treatment, which was comparable with the placebo group.

This finding was analogous with the work of Ashraf R et al, where a significant reduction of 12.03% in total serum cholesterol was observed in the garlic treated group after a 12 week study when compared with the placebo controlled group.¹⁴

A meta-analytic study that included 39 primary trials of the effect of garlic preparations on total, LDL, HDL cholesterol and TGs, interpreted garlic to be effective in reducing total cholesterol 17 ± 6 mg/dl, LDL cholesterol by 9 ± 6 mg/dl in individuals with elevated cholesterol levels (> 200 mg/dl), provided garlic usage for more than 2 months in diet. Clinical relevance is associated if there is an 8% reduction in total serum cholesterol leading to a 38% reduction in risk of cardiovascular events at 50 years of age¹⁵. Similar studies were done by Tohidi and Rahbani's trial¹⁶ (9% decrease of total cholesterol), Steiner et. al.¹⁷ (6.1% of total cholesterol), Alder and Holub's work¹⁸ (11.5% of total cholesterol). All studies showed positive lipid-lowering effects of garlic on total serum cholesterol level.

In animal experimental studies, garlic extracts have been shown to reduce plasma lipid and cholesterol in rats^{19,20}. Moreover, a number of interventional studies have similarly shown that garlic and garlic preparations significantly reduced plasma lipids, especially total cholesterol and LDL cholesterol in humans^{21,22,23}.

This study of garlic to reduce hypercholesterolemia showed a significant reduction in total cholesterol levels. The best available evidence supports the use of garlic as one modality to reduce cholesterol levels in patients with raised levels. One of the limitations was the failure to include HDL, LDL, and TG values which could have revealed more precise results. As we mainly focused on total cholesterol levels, other parameters were not included. More studies including these parameters would be helpful.

V. Conclusion

Garlic has a significant role in reduction of serum cholesterol level in most cases of hypercholesterolemia. When patients have mild elevation of lipid levels or are intolerant to conventional medications, garlic therapy may provide a safe and effective alternative to standard drug therapy. However, this is a preliminary study evaluating a small number of cases. More elaborate studies among a large population are required to substantiate the uses of garlic in different medical conditions.

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