No Effect of Garlic Extract Supplement on Serum Lipid Levels in Hypercholesterolemic Subjects

PRATANA SATITVIPAWEE, MPH*,
SAOWANIN INDRABHAKTI, MD***,
PANISA GETN-GERN, MSc****,
PETCH RAWDAREE, MD, MSc**,
TANAPORN RATANASUWAN, MD***,
CHUKIAT VIWATWONGKASEM, MSc*

Abstract

Objective : The authors assessed the effects of an enteric-coated Thai garlic extract tablet standardized for allicin-releasing potential on serum lipid levels in hypercholesterolemic subjects.

Subjects and Method : The authors performed a randomized, double-blind, placebo-controlled trial in 136 hypercholesterolemic subjects (cholesterol concentrations ≥ 5.2 mmol/L; mean age ± SD: 47.0 ± 6.6 yr). All subjects were given dietary advice to lower fat intake within 4 weeks and were advised to eat normally during the study period. The subjects were randomly assigned to receive an enteric-coated Thai garlic extract tablet once daily (standardized to 1.12% allicin or 5.6 mg/tablet), or placebo after the evening meal for 12 weeks. Seventy subjects (32.9% male; mean age ± SD and BMI of 47.0 ± 6.6 yr and 24.6 ± 3.3 kg/m^2) received the garlic extract treatment while 66 subjects (37.9% male, mean age ± SD and BMI of 47.0 ± 6.0 yr and 24.3 ± 3.4 kg/m^2) received placebo .

Results : There were no statistically significant changes in serum total cholesterol, triglycerides, low-density lipoprotein (LDL) cholesterol and high-density lipoprotein (HDL) cholesterol after the 12-week treatment as analyzed on repeated measures by analysis of variance. In addition, no changes in plasma glucose, liver and renal functions were found.

Conclusions : Treatment with an enteric garlic-coated Thai garlic extract and dietary advice did not produce any significant changes in lipid levels in subjects with hypercholesterolemia.

Key word : Allicin, Garlic Extract Supplement, Serum Lipids, Hypercholesterolemic Subjects

SATITVIPAWEE P, RAWDAREE P, INDRABHAKTI S, RATANASUWAN T, GETN-GERN P, VIWATWONGKASEM C
J Med Assoc Thai 2003; 86: 750-757

* Department of Biostatistics, Faculty of Public Health, Mahidol University, Bangkok 10400,
** Endocrinology Unit, Department of Medicine, Bangkok Metropolitan Administration Medical College and Vajira Hospital, Bangkok 10300,
*** Department of Medicine, Lerdsin Hospital, Bangkok 10500,
**** National Institute of Health, Department of Medical Sciences, Ministry of Public Health, Nonthaburi 11000, Thailand.

Cardiovascular diseases, especially coronary artery disease, remain the leading cause of premature death and disability among men and women in both industrialized and developing countries[1]. There is much evidence showing that the risks of coronary artery disease increase as blood cholesterol levels rise[2]. The relationship between death from heart disease and serum cholesterol levels is continuous, graded, and strong[3]. Numerous studies have shown that the clinical manifestations of heart disease, including myocardial infarction can be reduced by lowering cholesterol levels with a variety of lipid-lowering agents. The most effective class of these agents, the HMG-CoA reductase inhibitors, is very potent but produces side effects in a small proportion of patients and the cost of these drugs may also be of significant concern, especially in view of long-term therapy[4].

Garlic (*Allium sativum*), a readily available therapeutic agent devoid of adverse effects, has long been used because of its potential cardio-protective effect[5,6]. Several clinical trials have shown the hypocholesterolemic effects of standardized garlic powder or other forms to significantly lower serum cholesterol, triglycerides, and LDL-cholesterol levels while increase HDL-cholesterol levels[7,8]. However, garlic has also been reported in several other studies to be ineffective in lowering serum lipid levels[9,10]. Most clinical studies have focused mainly on measuring serum lipid changes induced by garlic, but little information is available using it as a single high dosage enteric-coated garlic supplement. The present study was thus conducted to evaluate an enteric-coated garlic extract tablet standardized for allicin releasing potential on lipid lowering effect in hypercholesterolemic subjects.

SUBJECTS AND METHOD

Subjects

Hypercholesterolemic subjects were recruited by means of poster advertisements and word of mouth. Subjects who were willing to participate in the study underwent a medical screening including physical examination and laboratory testing. The screening visit was performed 4 weeks before the baseline. To be eligible for inclusion, subjects had to have total cholesterol $\geq$ 5.2 mmol/L ($\geq$ 200 mg/dl); be 35-60 years old; have body mass index (BMI; in kg/m^2) $\leq$ 35; be healthy on the basis of physical examination, vital signs, medical history, clinical laboratory assessments; and be willing to give informed consent and comply with the study procedures. The exclusion criteria were those with a known secondary cause of hypercholesterolemia, unstable angina or myocardial infarction occurring within 2 months of entry into the study, diabetes mellitus, liver disease, renal disease, severe metabolic or endocrine disorders, pregnancy, taking any lipid-lowering and anti-hypertensive drugs within 4 weeks before the beginning of the study. The study protocol was approved by the institutional Ethics Committee Board at each of the participating study centers. All subjects received written and oral information regarding the trial and gave written consent. The demographic characteristics of these subjects are summarized in Table 1.

Study design

This was a randomized, double blind, placebo-controlled, 12-week parallel trial. At the point of recruitment, the subjects were advised to take food according to the dietary instructions specified by the National Cholesterol Education Program Step I diet and maintain their lifestyle throughout the study[11]. After 4 weeks of diet control (week 0 or baseline), subjects were randomly assigned in permuted blocks of four to receive either garlic extract tablets or identically prepared placebo tablets by members of the study team uninvolved in the recruitment (Fig. 1). Blinding of the garlic and placebo tablets were performed. A sealed box of garlic or placebo tablets that contained a 4-week supply (36 tablets/box) was given every four weeks. The garlic and placebo tablets were prepared by a private pharmacy in Thailand. Each garlic tablet contained 333 mg of garlic extract (equivalent to approximately 7 g fresh garlic) standardized to yield 5.6 mg allicin.

Physical examinations including body weight, height, pulse, blood pressure, and fasting blood collection were performed and the subjects were then instructed to return to the clinics in a fasting state at weeks 4, 8, and 12. At each clinic visit, the measurements of blood pressure (5 min seated at rest, mean of two readings), pulse and body weight were recorded, and a 12-14 h fasting blood sample was collected. Adverse events or intercurrent illnesses were recorded. After the subjects had taken the tablets for each 4-week period, the drug box was turned in, the remaining tablets were counted and recorded in order to assess the compliance with the treatment and a new box with a 4-week supply was dispensed.

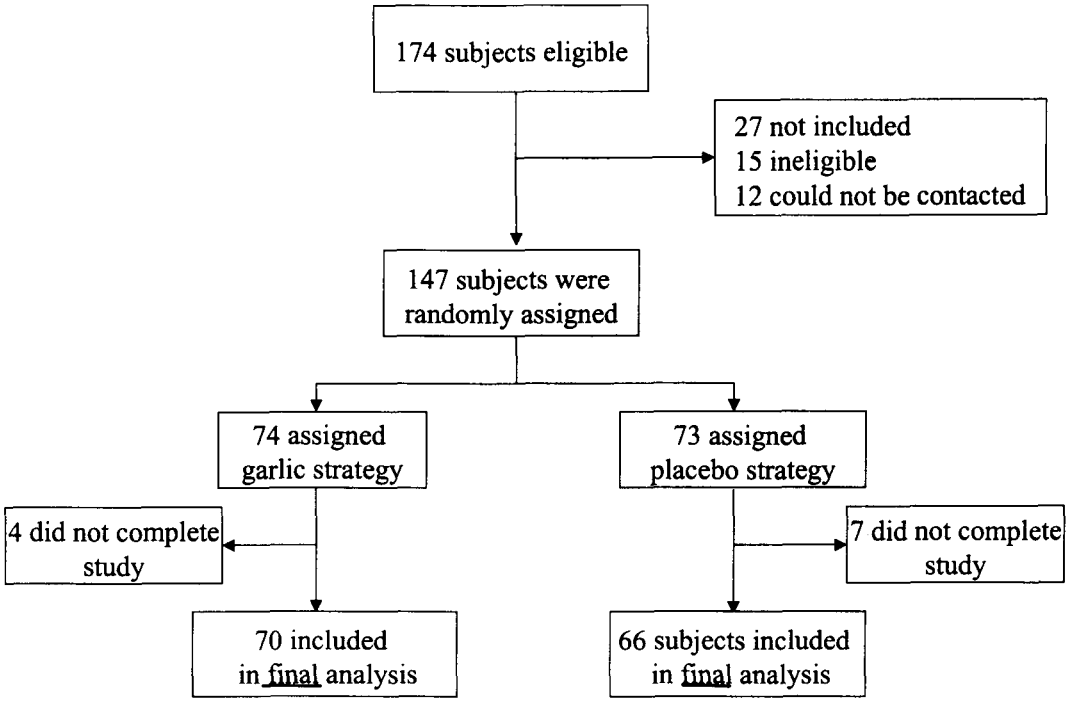

Fig. 1. Trial profile.

Laboratory analyses

After venous blood sample collection, plasma and serum were separated by centrifugation and lipid concentrations were determined immediately using an automated analyzer of Merck (Mega), Germany. The calibrator, control materials, and reagents were purchased from Merck, Germany, except for HDL-C the calibrator and of which reagents were purchased from Wako, Japan. Total serum cholesterol and triglycerides were measured by enzymatic methods[12,13]. HDL-cholesterol was measured enzymatically after binding of LDL, VLDL, and chylomicron with anti-human β-lipoprotein antibody[14]. The LDL-cholesterol was calculated from the Friedewald equation[15]. The internal quality control samples were included in every run. The intra- and inter-assay coefficients of variations of all lipid testing were less than 3 per cent. An external quality control was performed by participating in the External Quality Assessment Services (EQAS) program of Biorad Laboratories, USA. The per cent coefficient of variation values of total cholesterol, triglycerides, and HDL-cholesterol were 2.4, 3.9, and 3.3, respectively. Routine blood chemistry (glucose, renal/liver function test) and haematological (complete blood count) testing were also determined.

Statistical analyses

Statistical analyses were carried out by using the MINITAB statistical program for Windows (release 13; Minitab Inc, Philadelphia). All data were expressed as means ± SDs. Except for the levels of triglycerides, data were expressed as geometric means and its SDs because of its skewed distribution and transformed to logarithm for analysis. Differences between the two study groups were analyzed by the Pearson's chi-squared test and the Student's *t*-test, where appropriate. The main outcomes were the changes of serum lipid levels. Changes from baseline at 12 weeks were compared between the garlic and placebo groups with repeated measures by analysis of variance (ANOVA) with group and time interaction, group effect, time effect, and the baseline value as a covariate. All testing methods were two-sided, and p-value less than 0.05 was considered significant.

RESULTS

One hundred and forty-seven subjects were screened and included in the final study. A total of 136 subjects completed the 12-week study period. Eleven subjects withdrew after randomization. Of these, 4 were in the garlic group, and 7 were in the placebo group. Reasons reported for discontinuation included lack of interest (n = 5), time conflict (n = 5), and withdrawal by the investigator because of noncompliance (n = 1). Reports of side effects including belching, intestinal gas, constipation, and nausea were not different between the groups and did not cause withdrawal of subjects from the study. Baseline characteristics of the two groups were similar in terms of gender, age, weight, body mass index, lipid parameters, blood pressure, and plasma glucose (Table 1).

Compliance of subjects to the intervention assessed by tablet counting showed that mean compliance in the garlic and placebo groups was 82.6 per cent and 81.6 per cent, respectively. There were no significant differences in compliance between the two groups. The outcome results are shown in Table 2. There were no significant changes in serum total cholesterol, triglycerides, LDL-cholesterol, and HDL-cholesterol between the garlic group and placebo group. In addition, there were no changes in pulse rate, body weight, blood pressure, biochemical (glucose, renal, and liver function tests) and haematological testing that could be attributed to garlic and placebo treatment (data not shown).

DISCUSSION

Garlic's principal active ingredient appears to be allicin (diallyl thiosulphate) formed by catalytic reaction of enzyme alliinase (EC 4.4.1.4) on alliin (L-(+)-S-allylcysteine sulfoxide) when garlic cloves are crushed[16]. The alliin content of natural garlic may vary 10-fold and the quantity of released allicin can be influenced by specific extraction methods[17,18]. Garlic extract has been reported to reduce levels of serum lipids, diminish blood pressure, decrease plasma viscosity, inhibit platelet aggregation, increase fibrinolytic activity, and produce vasodilation. Therefore, garlic is claimed to have an antiatherosclerotic property[16,19]. Standardization of garlic product by using its potential for releasing allicin had been suggested to ensure the accuracy of dosage and effectiveness in long-term therapy[20].

The present study used a standardized garlic extract tablet at a high dosage of 5.6 mg allicin/once daily in assessing its effects on serum lipid levels. There were no significant differences in all lipid levels between the treatment groups after 12 weeks. The results were consistent with other studies that used similar study designs and reported no significant differences in lipid levels between groups receiving garlic and placebo. Four of five studies had diet control and used the same German garlic powder tablets (Kwai) at the same dosage of 1.8 mg allicin/three times daily[9,10,21,22] but one study used the American garlic powder tablet with lower dosage (1.5 mg allicin/

Table 1. Baseline characteristics of 136 subjects randomly allocated to garlic or placebo. The data were expressed as mean ± standard deviation.

Characteristics	Treatment groups		P-value
	Garlic (n = 70)	Placebo (n = 66)	
Gender (male/female)[a]	23/47	25/41	0.54
Age (years)[b]	47 ± 6.6	47 ± 6.0	0.78
Weight (kg)[b]	61 ± 9.9	61 ± 10.4	0.20
BMI (kg/m^2)[b]	24.6 ± 3.3	24.3 ± 3.4	0.63
Outcome measures (mmol/L)[b]			
Total cholesterol	6.65 ± 0.89	6.85 ± 0.83	0.17
Triglyceride +	1.19 ± 0.02	1.27 ± 0.02	0.49
LDL-Cholesterol	4.52 ± 0.86	4.63 ± 0.90	0.39
HDL-Cholesterol	1.5 ± 0.37	1.55 ± 0.26	0.49
Blood pressure (mm Hg)[b]			
Systolic	118 ± 13.0	118 ± 11.2	0.89
Diastolic	75 ± 9.3	76 ± 6.9	0.55
Plasma Glucose (mmol/L)[b]	5.33 ± 0.61	5.50 ± 0.64	0.17

+ geometric mean (standard deviation)
[a] $\chi 2$, [b] t-test for two independent samples

Table 2. Serum lipid levels at baseline and after 12 weeks' treatment with placebo and standardized garlic.[1]

Outcome measures (mmol/l)	Garlic group (n = 70)		Placebo group (n = 66)		P-value	
	Baseline	After treatment	Baseline	after treatment	Group x time interaction[3]	Group effect[3]
Total cholesterol[1]	6.65 ± 0.89	6.59 ± 0.93	6.85 ± 0.83	6.80 ± 0.90	0.583	0.981
Triglycerides2	1.19 ± 0.02	1.17 ± 0.02	1.27 ± 0.02	1.26 ± 0.02	0.469	0.217
LDL-Cholesterol[1]	4.52 ± 0.86	4.52 ± 0.77	4.63 ± 0.90	4.65 ± 0.83	0.328	0.768
HDL-Cholesterol[1]	1.50 ± 0.37	1.45 ± 0.28	1.55 ± 0.26	1.47 ± 0.26	0.396	0.463

[1] mean ± standard deviation
[2] geometric mean (standard deviation)
[3] repeated-measures ANOVA

three times daily)(23). However, considerable variability in outcomes existed between those studies. Jain et al reported a significant decrease of 6 per cent in total cholesterol and 11 per cent in LDL-cholesterol levels in moderately hypercholesterolemic adults after treatment with standardized garlic powder tablets (Kwai) for 12 weeks(7). Adler et al, using the same product and a similar design, also reported a significant decrease of 13 per cent in LDL-cholesterol levels relative to the placebo group(8). Moreover, Kannar et al used the Australian garlic powder tablets standardized to yield allicin potential at a dosage of 3.2 mg allicin/three times daily for 12 weeks and reported a significant 4.2 per cent reduction in total cholesterol and 6.6 per cent in LDL-cholesterol but significant differences in triglycerides and LDL/HDL ratio were not observed between the study groups(24). Most of those clinical trials used non-enteric coated garlic powder tablets. Only the study by Karnar et al who used enteric-coated tablets with high allicin producing garlic powder reported some positive findings. Hence, the subjects involved in the present negative clinical trials probably received considerably less allicin than those of Karnar's subjects. Other forms of garlic preparations used in other lipid-lowering trials included steam-distilled oil and aged garlic extract. Berthold et al used steam distilled oil garlic at a dosage of 10 mg/day for 12 weeks and reported no influence on serum lipid levels, cholesterol absorption or cholesterol synthesis(25). In addition, Steiner et al used a large dose of 7.2 g of aged garlic extract per day over a period of 4-6 months but reported a statistically significant 6.1 per cent and 4 per cent lowering of serum total and LDL-cholesterol, respectively (26). The mechanisms by which garlic may protect against cardiovascular disease are that the active ingredients of garlic, allicin and other sulfur compounds may act as HMG-CoA reductase inhibitors, reducing the production of cholesterol in the liver and may protect LDL against oxidations diminishing the plaque accumulations on the walls of arteries(27,28).

Some of the discrepancies reported in those studies can be explained by the heterogeneity that existed in terms of study design, subject characteristics, duration of treatment, forms of garlic preparation, dosage forms, study adherence, and others such as dietary control and physical activity. The present study has some strength over other studies. There was a system of random assignment during both selecting of the study population and giving drug treatment and there was a low dropout rate (11%). The garlic extract and placebo tablets were prepared according to the Good Manufacturing Practices (GMP). They were compliant with the United State Pharmacopeia guidelines in terms of dissolution and disintegration(29). With non-enteric coated products, stomach acids quickly destroy the allicin yielding potential of garlic by quickly destroying the enzyme alliinase. The tablets used in the present study were enteric-coated that can protect an active ingredient from inhibition in acidic condition and can dissolve in the intestinal tract. Moreover, they were also standardized. Therefore, the effectiveness of the allicin releasing potential could be ensured.

The clinic visit every 4 weeks promoted study adherence and allowed for multiple blood sampling and body weight documentation and the high study adherence suggested that garlic extract tablets were taken consistently.

The analysis of the outcome measures was performed with an optimal statistics and each study group had an adequate sample size. There was enough

statistical power to detect the difference in the order of the magnitude to test for different effects in a set of the study population. The inclusion of a placebo group in the study also supported the adequacy of the study for testing the hypothesis that garlic treatment lowers serum lipid levels. In addition, all lipid parameters were analyzed by a laboratory that followed the quality assurance system. Internal and external quality control was included in order to monitor the accuracy of the laboratory performance. The External Quality Assessment Program used by the laboratory was accredited by the Clinical Pathology Accreditation (CPA), UK.

However, the present study was also subject to some limitations. Garlic intake from food sources was not controlled during the study. Subjects were asked only to take a lower fat diet and did not have to abstain completely from fresh garlic in their food. This approach made the results more generalizable although differences in daily outside-study garlic intake between the study groups could have confounded the results. Dietary stabilization also became a crucial factor in assessing the lipid lowering effect of the garlic treatment under investigation. In the present study, the authors only gave dietary advice and documented body weight but diet compliance and stability were not assessed. However, Isaacsohn et al included dietary stability in their studies by measuring the Food Record Rating (FRR) scores and also reported no effects of garlic in hypercholesterolemic patients[9]. Finally, the present study focused on a garlic extract tablet at a definite dose in a specified population over a time period of 12 weeks and its effect on serum lipids. Additional controlled, higher dosage, bioavailability and longer-time period studies are necessary to clarify the exact roles of garlic on serum lipids and other risk factors, such as blood pressure or blood coagulation in preventing coronary heart disease.

ACKNOWLEDGEMENTS

This study was funded by a grant from the Department of Medical Services, Ministry of Public Health (MOPH). The authors wish to thank Dr. Chaisri Supornsilaphachai, Chief of Life Styles and Social Risk Control Group, the Bureau of Non-Communicable Disease, Departmrnt of Disease Control, MOPH, for kindly providing the grant and her help in the scientific criticism and discussion. We also wish to thank Dr. Pathom Sawanpanyalert, Director of National Institute of Health, Department of Medical Sciences, MOPH. and his staff for their partial laboratory support and discussion. Finally, special thanks to all who volunteered to be participants.

(Received for publication on March 18, 2003)

REFERENCES

1. The World Health Report 2002. Reducing risks, promoting healthy life. Geneva: World Health Organization; 2002: 47-98.
2. Verschuren WMM, Jacobs DR, Bloemberg BPM, et al. Serum total cholesterol and long-term coronary heart disease mortality in different cultures: Twenty five-year follow-up of the seven countries study. JAMA 1995; 274: 131-6.
3. Stamler JD, Wentworth D, Neaton JD. Is relationship between serum cholesterol and risk of premature death from coronary heart disease continuous and graded ? Findings in 356,222 primary screens of the Multiple Risk Factor Intervention Trial (MRFIT). JAMA 1986; 256: 2823-8.
4. Schaefer EJ, McNamara JR. Overview of the diagnostic and treatment of lipid disorders. In: Rifai N, Warnick GR. Dominiczak MH, ed. Handbook of lipoprotein Testing: AACC Press; 1997: 25-47.
5. Rahman K, Billington D. Dietary supplementation with aged garlic extract inhibits ADP-induced platelet aggregation in humans. J Nutr 2000; 130: 2662-5.
6. Neil A, Silagy C. Garlic: Its cardio-protective properties. Curr Opin Lipidol 1994: 5: 6-10.
7. Jain AK, Vargas R, Gotzkowsky S, McMahon FG. Can garlic reduce levels of serum lipids ? A controlled clinical study. Am J Med 1993; 94: 632-5.
8. Adler AJ, Holub BJ. Effect of garlic and fish oil supplementation on serum lipid and lipoprotein concentrations in hypercholesterolemic men. Am J Clin Nutr 1997; 65: 445-50.
9. Isaacsohn JL, Moser M, Stein EA, et al. Garlic powder and plasma lipids and lipoproteins. A multicenter, randomized, placebo-controlled trial. Arch Intern Med 1998; 158: 1189-94.

10. Simons LA. Balasubramaniam S, Konigsmark M, Parfitt A, Simons J, Peters W. On the effect of garlic on plasma lipids and lipoproteins in mild hypercholesterolemia. Atherosclerosis 1995; 113: 219-25.
11. The Expert Panel. Report of the National Cholesterol Education Program on detection, evaluation and treatment of high blood cholesterol in adults. Arch Intern Med 1988; 148: 36-69.
12. Allain CC, Poon LS, Chan CS, Richmond W, Fu PC. Enzymatic determination of total serum cholesterol. Clin Chem 1974; 20: 470-5.
13. Sampson EJ, Demer LM, Kreig AF. Faster enzymatic procedure for serum triglycerides. Clin Chem 1975; 21: 1983-5.
14. Hino K, Nakamura M, Nakanishi K, Manabe M. A new method for the homogeneous assay of serum HDL-cholesterol. Clin Chem 1996; 42: S298.
15. Friedewald W, Levy R, Fredrickson D. Estimation of the concentration of low-density lipoprotein cholesterol in plasma, with use of the preparative ultracentrifuge. Clin Chem 1972; 18: 499-502.
16. Lawson LD. The composition and chemistry of garlic cloves and processed garlic. In : Koch HP, Lawson LD eds. Garlic: The science and therapeutic application of *Allium sativum* L. and related species, 2nd ed. Baltimore: Williams and Wilkins; 1996: 37-107.
17. Kleijnen J, Knipschild P, Riet GT. Garlic, onions and cardiovascular risk factors. A review of the evidence from human experiments with emphasis on commercially available preparations. Br J Clin Pharmac 1989; 28: 535-44.
18. Aye RD. Garlic preparations and processing. Cardiology in Practice 1989; 10 (Symposium suppl): 7-8.
19. Koscielny J, Klubendorf D, Latza R, et al. The antiatherosclerotic effect of *Allium sativum*. Atherosclerosis 1999; 144: 237-49.
20. Muller B. Analytical methods for standardization of fresh garlic and garlic powder preparations. Deutsche Apotheker Zeitung 1991: 131 (Suppl 24): 8-10.
21. Superko HR, Krauss RM. Garlic powder, effect on plasma lipids, postprandial lipemia, low-density lipoprotein particle size, high-density lipoprotein subclass distribution and lipoprotein (a). J Am Coll Cardiol 2000; 35: 321-6.
22. Neil HA, Silagy CA, Lancaster T, et al. Garlic powder in the treatment of moderate hyperlipidaemia : A controlled trial and meta-analysis. J R Coll Physicians Lond 1996; 30: 329-34.
23. Gardner CD, Chatterjee LM, Carlson JJ. The effect of a garlic preparation on plasma lipid levels in moderately hypercholesterolemic adults. Atherosclerosis 2001; 154: 213-20.
24. Kannar D, Wattanapenpaiboon N, Savige GS, Wahlqvist ML. Hypocholesterolemic effect of an enteric-coated garlic supplement. J Am Coll Nutri 2001; 20: 225-31.
25. Berthold HK, Sudhop T, Von Bergmann K. Effect of a garlic oil preparation on serum lipoproteins and cholesterol metabolism: A randomized controlled trial. JAMA 1998; 279: 1900-2.
26. Steiner M, Khan AH, Holbert D, Lin RIS. A double-blind crossover study in moderately hypercholesterolemic men that compared the effect of aged garlic extract and placebo administration on blood lipids. Am J Clin Nutr 1996; 64: 866-70.
27. Lau BHS. Suppression of LDL oxidation by garlic. J Nutr 2001; 131: 985s-8s.
28. Yeh YY, Yeh SM. Garlic reduces plasma lipids by inhibiting hepatic cholesterol and triacylglycerol synthesis. Lipids 1994; 29: 189-93.
29. "United States Pharmacopeia 24". Rockville: The United States Pharmacopeial Convention Inc, 2000: 1944-7.

การเสริมกระเทียมสกัดไม่มีผลต่อระดับไขมันในเลือดในผู้มีโคเลสเตอรอลสูง

ปรารถนา สถิตย์วิภาวี, สม, เพชร รอดอารีย์, พบ, วทม**, เสาวนินทร์ อินทรภักดี, พบ***, ธนพร รัตนสุวรรณ, พบ***, พนิตสา เกตุเงิน, วทม****, ชูเกียรติ วิวัฒน์วงศ์เกษม, วทม**

วัตถุประสงค์ : เพื่อศึกษาประสิทธิผลของกระเทียมสกัดมาตรฐานชนิดเม็ดที่มี allicin สูงต่อระดับไขมันในผู้มีโคเลสเตอรอลสูง

ตัวอย่างและวิธีการ : การศึกษาแบบ randomized, double-blind, placebo-controlled ในคนที่มีระดับโคเลสเตอรอลรวมเท่ากับหรือมากกว่า 5.2 มิลลิโมล/ลิตร จำนวน 136 คน (ชาย 48 คน, หญิง 88 คน) มีอายุเฉลี่ย 47.0 $\pm$ 6.6 ปี ทุกคนได้รับคำแนะนำให้รับประทานอาหารไขมันต่ำ เป็นเวลา 4 สัปดาห์ และไม่ให้เปลี่ยนพฤติกรรมการรับประทานอาหารในช่วงการศึกษา และสุ่มให้ได้รับกระเทียมสกัดของไทยชนิดเม็ดแบบเคลือบให้ละลายในลำไส้ที่มีสารออกฤทธิ์อัลลิซิน 1.12 เปอร์เซนต์ หรือ 5.6 มิลลิกรัม/เม็ด หรือยาหลอกในขนาดวันละ 1 เม็ด หลังอาหารเย็นเป็นเวลา 12 สัปดาห์ กลุ่มที่ได้รับกระเทียมสกัดมีจำนวน 70 คน (ชาย 32.9 เปอร์เซ็นต์ มีอายุเฉลี่ยและดัชนีมวลกายเท่ากับ 47.0 $\pm$ 6.6 ปี และ 24.6 $\pm$ 3.3 กก/ม^2) และ 66 คนได้รับยาหลอก (ชาย 37.9 เปอร์เซ็นต์ มีอายุเฉลี่ยและดัชนีมวลกายเท่ากับ 47.0 $\pm$ 6.0 ปี และ 24.3 $\pm$ 3.4 กก/ม^2)

ผลการศึกษา : ระดับโคเลสเตอรอลรวม ไตรกลีเซอไรด์ แอลดีแอล-โคเลสเตอรอล และเอชดีแอล-โคเลสเตอรอลในเลือดของกลุ่มอาสาสมัครที่ได้รับกระเทียมเม็ดเป็นเวลา 12 สัปดาห์ ไม่แตกต่างจากกลุ่มอาสาสมัครที่ได้รับยาหลอก นอกจากนี้ ยังไม่มีความแตกต่างของระดับกลูโคสในเลือดและหน้าที่การทำงานของตับและไตในกลุ่มศึกษา

สรุป : การเสริมด้วยกระเทียมสกัดของไทยแบบเคลือบให้ละลายในลำไส้ ร่วมกับการควบคุมอาหาร ไม่มีผลต่อการเปลี่ยนแปลงระดับไขมันในเลือดในผู้มีระดับโคเลสเตอรอลสูง

คำสำคัญ : อัลลิซิน, ผลิตภัณฑ์กระเทียมสกัด, ระดับไขมัน, ผู้มีโคเลสเตอรอลสูง

ปรารถนา สถิตย์วิภาวี, เพชร รอดอารีย์, เสาวนินทร์ อินทรภักดี, ธนพร รัตนสุวรรณ, พนิตสา เกตุเงิน, ชูเกียรติ วิวัฒน์วงศ์เกษม
จดหมายเหตุทางแพทย์ ฯ 2546; 86: 750-757

* ภาควิชาชีวสถิติ, คณะสาธารณสุขศาสตร์, มหาวิทยาลัยมหิดล, กรุงเทพ ฯ 10400
** หน่วยต่อมไร้ท่อ, ภาควิชาอายุรศาสตร์, วิทยาลัยแพทย์ศาสตร์ กรุงเทพมหานครและวชิรพยาบาล, กรุงเทพ ฯ 10300
*** หน่วยอายุรศาสตร์, โรงพยาบาลเลิดสิน, กรุงเทพ ฯ 10500
**** สถาบันวิจัยวิทยาศาสตร์สาธารณสุข, กรมวิทยาศาสตร์การแพทย์, กระทรวงสาธารณสุข, นนทบุรี 11000