

Original Article

Garlic intake lowers fasting blood glucose: meta-analysis of randomized controlled trials

Li-qiong Hou MSc¹, Yun-hui Liu MSc², Yi-yi Zhang MSc²¹Department of Rheumatology, the First Hospital of Lanzhou University, China²Department of Endocrinology and Metabolism, West China Hospital of Sichuan University, China

Garlic is a common spicy flavouring agent also used for certain therapeutic purposes. Garlic's effects on blood glucose have been the subject of many clinical and animal studies, however, studies reporting hypoglycemic effects of garlic in humans are conflicting. A comprehensive literature search was conducted to identify relevant trials of garlic or garlic extracts on markers of glycemic control [fasting blood glucose (FBG), postprandial glucose (PPG), glycosylated haemoglobin (HbA1c)]. A meta-analysis of the effect of garlic intake on human was done to assess garlic's effectiveness in lowering glucose levels. Two reviewers extracted data from each of the identified studies. Seven eligible randomized controlled trials with 513 subjects were identified. Pooled analyses showed that garlic intake results in a statistically significant lowering in FBG [SMD=-1.67; 95% CI (-2.80, -0.55), $p=0.004$]. Our pooled analyses did not include PPG control and HbA1c outcomes. Because only 1 study included in the meta-analysis reported PPG variables and only 2 studies reported HbA1c variables. In conclusion, the current meta-analysis showed that the administration of garlic resulted in a significant reduction in FBG concentrations. More trials are needed to investigate the effectiveness of garlic on HbA1c and PPG.

Key Words: garlic, meta-analysis, glucose, randomized controlled trial, type 2 diabetes

INTRODUCTION

The number of individuals suffering from diabetes worldwide is predicted to reach 325 million by the year 2025 due to sedentary lifestyle, consumption of energy-rich diet, obesity, longer life span, etc.¹ It still remains a major public health problem and prevention of diabetes still lies in the realm of future. Plants have always been an exemplary source of drugs and many of the currently available drugs have been derived directly or indirectly from them. The herbal drugs are prescribed widely because of their effectiveness, fewer side effects and relatively low cost. A wide array of plant derived active principles have demonstrated activity consistent with their possible use in the treatment of diabetes mellitus.² Among all such agents, garlic has attracted the attention of modern medical science because of its widespread over-the-counter use.

Garlic (*Allium sativum*) is a rich source of bioactive compounds and is used in folk medicine for the treatment of various diseases. Garlic contains a variety of effective compounds, such as allicin, a sulfur-containing compound that exhibits antithrombotic, antioxidant, hypocholesterolemic, hypoglycemic, and hypotensive activities.³⁻⁵ Although the blood glucose lowering effect of different garlic preparations has been comprehensively reported in animal models of diabetes,⁶⁻⁹ studies reporting hypoglycemic effects of garlic in humans are conflicting. Some studies showed that garlic significantly improved glycemic control, whereas others observed no significant anti-hyperglycemic effect. As a result, the precise effect of garlison glucose metabolism has not been established to our knowledge. Therefore, we conducted a meta-analysis

of all published randomized controlled trials (RCTs) to quantitatively evaluate the effects of garlic on such glycemic control measurements such as fasting blood glucose (FBG), postprandial glucose (PPG), and glycated haemoglobin (HbA1c).

METHODS AND MATERIALS

Literature search

In an independent manner, we searched the electronic databases MEDLINE (1996 to December 2012), EMBASE (1998 to December 2012), the Cochrane Library, the Web of Science (1980 to December 2012), and reviews and reference lists of relevant articles using the text keywords "garlic", "*Allium sativum*", "allicin" and "organosulfur compounds", which were paired with the following word "glucose", "glycemic control", "OGTT", "HbA1c", "fructosamine", or "diabetes". Only those papers with clinical trials were selected. No limit was placed on language. In addition, the reference lists of the published papers on clinical trials, review articles and meta-analyses were hand-searched for other relevant studies. For unpublished and published trials which were

Corresponding Author: Li-qiong Hou, Department of Rheumatology, the First Hospital of Lanzhou University, No 1, Donggang Road, Chengguan District, Lanzhou 730000, Gansu Province, P.R. China.

Tel: +86-931-8625200; Fax: +86-931-8625200

Email: chuandazhaotieyun@163.com

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not exhaustively disclosed, an attempt was made (through email) to contact principal investigators in order to retrieve missing data. For all published trials, results reported in papers were used as the primary source of information, when available.

Eligibility criteria and study selection

Studies were eligible for inclusion if they met the following criteria: (1) randomized controlled trials (RCTs) on human subjects; (2) the subjects consumed garlic for at least 4 weeks, (3) the study was a parallel or crossover design, (4) the initial or endpoint values for fasting glucose or insulin or their difference and their SD or SE or 95% CI of each group were available, (5) the food intake control regimens of the experimental groups were consistent with that of the control groups.

Data extraction and quality assessment

Data extraction was independently conducted by two authors (LH and YZ). Any disagreements were resolved by consensus with the other author (YL). The following data were extracted from the eligible studies: name of the first author, year of publication, population information (age, ethnicity, sex, initial healthy status) sample size, type and dose of garlic, duration of the intervention, funding status and mean serum glucose levels, and the corresponding SD at the start and the end of intervention, were collected. For dose-range studies, only data arising from currently approved doses were extracted. In the absence of such data, the data for equivalent amounts of daily doses were used. If no approved dose was used, data for a dose having a maximal HbA1c-lowering efficacy were extracted. If a study had two or three comparisons (one monotherapy arm and one or two combination therapy arms), each comparison was treated separately. The randomized controlled trials were assessed for quality using the criteria based on the Cochrane Collaboration's tool for assessing risk of bias.¹⁰ The Jadad score was also introduced to evaluate the quality of the studies. Trials scored one point for each area addressed in the study design (randomization, blinding, concealment of allocation, reporting of withdrawals, and generation of random numbers), with a possible score of between 0 and 5 (highest level of quality).¹¹ Higher numbers represented better quality (Jadad score ≥ 4). One of the three authors (LH) assessed the quality of each trial, and the assessment was checked by another author (HL). Any disagreements were resolved by consensus between the authors.

Outcome measure

The outcomes of interest in this analysis were: (1) change from baseline in FBG; (2) change from baseline in PPG, and (3) change from baseline in HbA1c. For these outcomes 1-3, the weighted mean differences (WMDs) and associated precision for the change from baseline were calculated in each study.

Statistical analysis

All analyses were done with RevMan 5.0 and Stata version 10. The I^2 statistic was used to assess statistical heterogeneity. The Cochrane Handbook suggests that $I^2 > 50\%$ is considered representative of important statistical

heterogeneity. To identify the possible source of heterogeneity within these studies, a priori subgroup analysis and sensitivity analysis were performed according to the Cochrane Handbook for Systematic Reviews of Interventions. Subgroup analyses were conducted by comparing the summary results of studies grouped by duration, ethnicity, type of garlic, and baseline glucose concentration. In the sensitivity analysis, evaluation was performed both with and without studies that were identified as outliers, as suggested by Egger et al. A random-effect model was used in case of heterogeneity, a fixed-effect model in the absence of heterogeneity. Weighted mean differences (WMDs) and their 95% confidence intervals for each outcome relative to control were calculated for continuous variables. Studies were excluded from the meta-analysis if insufficient information was provided to enable standard error calculation.

RESULTS

Study selection

A total of 1029 studies were identified (Figure 1). After duplicate or irrelevant studies were excluded based on title, abstract, and inclusion criteria, 10 potentially relevant studies were retrieved for more detailed evaluation. Three studies were excluded due to them being non-randomized controlled trials. Thus, 7 studies¹²⁻¹⁸ were included in meta-analysis. (Figure 1 Search strategy flow chart).

Study characteristics

The characteristics of the trials are shown in Table 1. The work of Zhang et al¹⁸ was separated into 2 trials (effects of garlic oil and garlic powder on glucose metabolism). The study by Sobeninet al¹⁷ reported 2 separately controlled trials, 1 was an intervention with garlic powder, and the other was an intervention with garlic powder plus sulfonylurea. The study by Rizwan¹³ was a dose-range study, only data for a dose having a maximal HbA1c-lowering efficacy were extracted. The study of Kumar¹⁵ was separated into 2 trials, 1 was intervened using garlic powder, and the other intervened using garlic powder plus metformin. All of the 7 included studies were parallel in design. Garlic powder (GP), mainly Kwaibrand with doses ranging from 600 to 900 mg/d, was the most utilized garlic product. One study used garlic oil (GO), two studies used garlic extract (GE), one study used garlic (spray dried method). Volunteers in all studies received dietary advice. Seven studies reported the effects on FBG levels, while two studies investigated the effects of garlic on HbA1c and only one study investigated the effects of garlic on PPG. Thus, a total of seven studies that involved 9 comparisons were identified for inclusion in the meta-analysis. The trials varied in size from 33 to 180 subjects. The study duration varied from 4 to 24 week (median: 12 week). Doses of garlic in the treatment group ranged from 600 to 1500 mg/d. A total of 393 subjects in 5 studies had elevated fasting glucose concentrations at baseline.^{12,13,15-17} Two studies were conducted in healthy adults,^{14,18} 3 studies were performed in whites and black subjects,^{14,17,18} and the remaining 4 trials were carried out in Asian countries.^{12,13,15,16} In all trials, investigators attempted to maintain the usual lifestyles of participants.

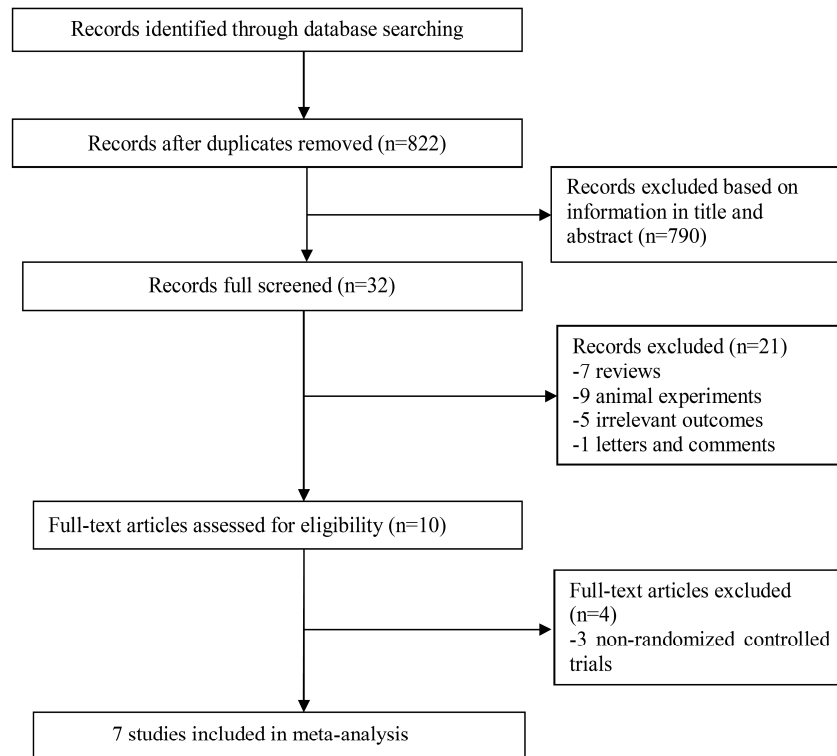


Figure 1. Search strategy flow chart.

Data quality

The study qualities of the selected trials were diverse: 2 trials^{17,18} were classified as high quality (Jadad score ≥ 4), and 5 trials¹²⁻¹⁶ were classified as low quality (Jadad score = 3 or 2). Allocation concealment was clearly adequate in 2 studies.^{17,18} No trials reported the generation of random numbers. All trials reported details of dropouts. (Table 2 Quality of included trials)

Glycemic control Change in FPG

As shown in Table 1, a total of 7 trials recruiting 390 subjects reported data on FBG concentrations. The I^2 values show high heterogeneity among the studies. To identify the possible source of heterogeneity within these studies, a priori subgroup analysis and sensitivity analysis were performed. Table 3 summarizes the results of I^2 test of heterogeneity among pooled studies in the subgroup analyses for all outcome measures. The I^2 values show high heterogeneity among the studies for all outcome measures. When sensitivity analyses were attempted by excluding outlier trials, moderate to high heterogeneity was observed among pooled studies. Therefore, the random-effect model was used as the pooling method. The results suggested that garlic significantly improved the FBG compared with the placebo [SMD = -1.67; 95% CI (-2.80, -0.55), $p=0.004$]. (Figure 2 Meta-analysis data and results). The results of the subgroup analyses are shown in Table 3. The effects of garlic on serum FBG level were more striking in studies with long-term garlic intervention. GP and aged garlic extract (AGE) were more effective in reducing serum FBG level. The effect of garlic on serum FBG was found to be greater in subjects with higher baseline subjects with basal hyperglycemia. Furthermore, the

effects of garlic on serum FBG were more striking in Asian subjects. We did not perform the subgroup comparisons based on the doses, because the active ingredients and bioavailability of garlic vary between different types of preparations (powder, oil, aged extract, raw). Furthermore, dosage of the active ingredient can also vary within one type, depending on brand and processing. So in the present meta-analysis, subgroup meta-analysis by dosage was not meaningful, as not all trials established or reported the dosage of active ingredients. Future trials on the effect of garlic on blood glucose should include information on the dosage of active ingredients of standardized garlic preparations for better comparison of trials.

Change in PPG

Only one study¹⁵ assessed the effect of garlic on the PPG. They found there was a significant reduction ($p < 0.01$) in PPG for garlic group after starting of treatment until the end of study.

Change in HbA1c

Only two studies^{13,15} reported the effect of garlic on the HbA1c, Kumar et al¹⁵ found that there was a nonsignificant difference ($p > 0.05$) in HbA1c between garlic and placebo, however, Rizwan¹³ found the garlic treated group had a significant reduction in HbA1c ($p < 0.005$) when compared with placebo.

DISCUSSION

The trials included in this systematic review enrolled male and female subjects, both healthy and with diabetes. Our meta-analysis showed that consumption of garlic significantly reduced FBG concentration.

Garlic may act on blood glucose through different

Table 1. Data extracted from included trials

Study	Study design	Sex (M/F) garlic/placebo	Ethnicity	Age garlic/placebo	Duration	Dose	Side effect
Jain, 1993	Parallel	(11/9)/(8/14)	White and black	Healthy subjects: 48±15/55±9	12 weeks	1. Garlic powder 300 mg tid 2. Placebo 300 mg tid	Yes
Sitprijja, 1987	Parallel	(6/11)/(5/11)	Asian	Patients with type 2 diabetes: 50.8±9.08/49.4±6.18	4 weeks	1. Garlic (spraydriedmethod) 350 mg bid 2. Placebo 350 mg bid	Yes
Zhang, 2001	Parallel	GO (12/13) GP (8/19)/(13/13)	White	Healthy subjects: GO 24±7 GP 26±8/29±9	11 weeks	1. Garlic oil 8.2 mg of allyl sulfide/d (2 capsules/d) 2. Garlic powder 7.8 mg allicin/d (2 capsules/d) 3. 2 placebo capsules/d	No
Sobenin, 2008	Parallel	(26/34)	White	Patients with type 2 diabetes: 48.2±2.6	4 weeks	1. Garlic powder tablets 300 mg bid 2. Placebo 300 mg bid 3. Sulfonylurea+ garlic powder tablets 300 mg bid 4. Sulfonylurea+ placebo 5. 300 mg bid	No
Rizwan, 2011a	Parallel	(17/13)/(16/14)	Asian	Patients with type 2 diabetes: 47±6.6/47±6.0	24 weeks	1. Tablet: garlic 300 mg thrice daily+ metformin 500 mg twice daily 2. Placebo: 300 mg thrice daily+ metformin 500 mg twice daily	No
Rizwan, 2011b	Parallel	(15/15)/(90/60)	Asian	Patients with type 2 diabetes: 40±5.04/45±4.58	24 weeks	1. Garlic tablets 300 mg/d 2. Garlic tablets 600 mg/d 3. Garlic tablets 900 mg/d 4. Garlic tablets 1200 mg/d 5. Garlic tablets 1500 mg/d 6. Metformin 500 mg twice daily 7. Placebo	No
Kumar, 2013	Parallel	30/30	Asian	Patients with type 2 diabetes: 52.8±11.0/53.8±12.2	12 weeks	1. Metformin 500 mg bid or tid 2. Tablet: garlic extract (one capsule bid) + metformin 500 mg twice daily	No

GP: garlic powder; GO: garlic oil

Table 2. Quality of included trials

Study	Allocation concealment	Blinding	Randomization	Withdraw	Free of selective reporting	Generation of random number	Jadad score
Sitprija, 1987	Not clear	Yes Double blind	Yes	Yes	Yes	Not clear	3
Jain, 1993	Not clear	Yes Double blind	Yes	Yes	Yes	Not clear	3
Zhang, 2001	Yes	Yes Double blind	Yes	Yes	Yes	Not clear	4
Sobenin, 2008	Yes	Yes Double blind	Yes	Yes	Yes	Not clear	4
Rizwan, 2011a	Not clear	Yes Double blind	Yes	Yes	Yes	Not clear	3
Rizwan, 2011b	Not clear	Yes Singer blind	Yes	Yes	Yes	Not clear	3
Kumar, 2013	No	No Open-label	Yes	Yes	Yes	Not clear	2

Table 3. Pooled effects on fasting blood glucose by sensitivity analyses and subgroup analyses stratified by previously defined study characteristics

Variables	Sample size treatment/control	Number of comparison	Net change (95% CI)	p	I ² (%)
Subgroup analyses					
Duration					
<12 week (low median)	86/88	5	-0.81 (-1.87, 0.26)	0.14	90
≥12 week (high median)	107/109	4	-3.79 (-6.20,-1.39)	0.002	97
Ethnicity					
Non-Asian	89/94	5	-0.84 (-1.86, 0.19)	0.11	89
Asian	104/103	4	-4.05 (-6.52, -1.59)	0.001	97
Type of garlic					
GP	127/130	6	-3.38 (-5.26, -1.49)	0.004	96
GO	19/21	1	0.41 (-0.22, 1.03)	0.20	Not applicable
AGE	30/30	1	-0.77 (-1.30, -0.25)	0.004	Not applicable
Baseline glucose concentration					
Subjects with normal blood glucose concentration	59/64	3	0.13 (-0.23, 0.49)	0.47	0
Subjects with basal hyperglycemia	134/133	6	-3.38 (-5.19, -1.58)	0.0002	96

GP: garlic powde; GO: garlic oil; AGE: garlicaged extract

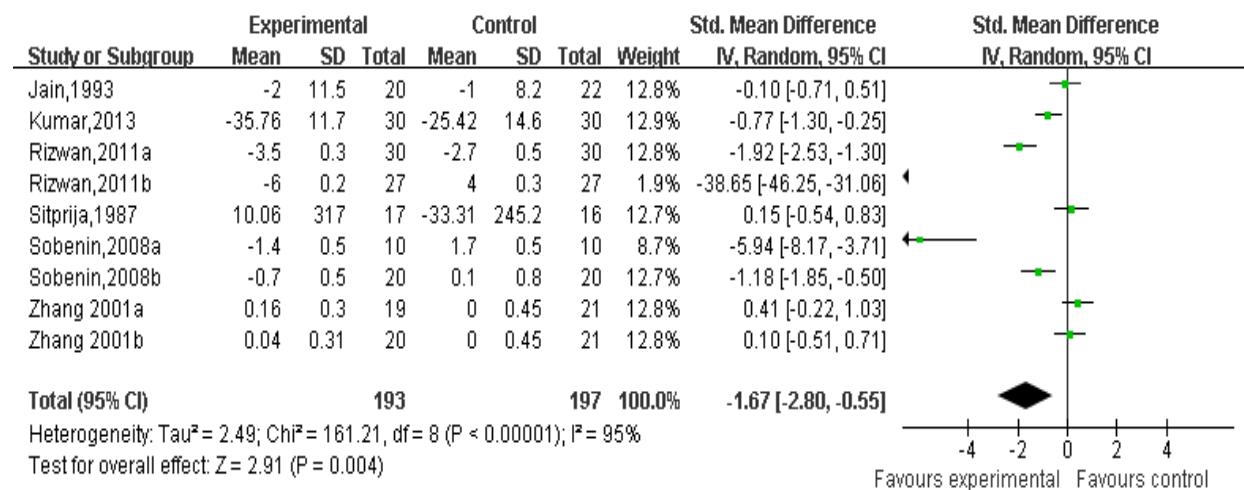


Figure 2. Comparison of change in FPG in the garlic and the placebo groups.

mechanisms, such as (1) it may increase secretion of endogenous insulin; (2) enhance of insulin sensitivity and insulin-like activity;^{8,19} (3) improvement in oxidative stress;²⁰ (4) enhancement of beta cells in the pancreas by activating regeneration of these cells;²¹ and (5) the fibre of the plant may also interfere with carbohydrate absorption, thereby affecting blood glucose.²²

Although, as noted, there have been several recent reports assessing garlic's effect on FBG, several factors have led us to revisit the issue of garlic effects on blood glucose. One is the glucose levels of participants at baseline and the severity of diabetes. In the 1970s, Jain et al^{23,24} investigated the hypoglycemic effects of garlic juice or extracts of garlic on OGT in normal and in alloxan-DM rabbits. All of the garlic preparations used improved OGT in both normal and diabetic animals and decreased FBG in diabetic models. Similar studies were conducted by Mathew and Augusti,^{25,26} however, they found that allicin had no effect on FBG in normal rats but lowered FBG and improved OGT in rats with mild, but not severe, DM induced by alloxan. Mathew and August suggested that the lack of effectiveness of garlic in lowering FBG concentrations in normal animals could be explained by the ability of these animals to maintain normal blood sugar homeostasis. However, the lack of effectiveness of garlic in lowering abnormally high FBG concentrations in diabetes is thought to have resulted because the residue β -cell mass in the model used was too low to provide high enough basal insulin concentrations to show improvements in glucose clearance at a first-order rate.

The type of garlic used as well as its preparation in these studies is of significance, because different types of garlic preparations have different chemicals. Indeed, The chemicals present in a garlic product are largely dependent on the processing conditions, such as temperature, the duration of preparation, and the extraction solvents used.²⁷ As a dietary supplement, garlic is available as dehydrated GP, AGE, garlic oil (steam-distilled), garlic essential oil (etherextracted) and garlic oil macerate, with each having a markedly different set of compounds. GP is the most commonly used garlic product. The active substances of GP are believed to be remarkably similar to those found in raw, whole garlic cloves, and GP is composed of alliin and a small amount of lipid-soluble ingredients.^{28,29} Another two commonly used products, GO and AGE, have very different compositions. GO only contains lipid-soluble compounds, mainly diallyl sulfide (DAS), diallyl disulfide (DADS), and diallyl trisulfide (DATS) without water-soluble compounds and allicin. Garlic macerate oil contains allicin-decomposed compounds including ajoene and dithiols. Storing sliced raw garlic in 15-20% ethanol for 20 months, which causes a considerable loss of allicin and an increase of some newer compounds such as S-allylcysteine (SAC), produces AGE.³⁰ It has been reported that the hypoglycemic effect of garlic has been attributed to their sulfur-containing compounds. But the truly active component (s) of garlic accounting for the hypoglycemic effects are still unclear. In the 1970s, Jain and coworkers^{23,24} found a short-term treatment with allicin significantly reduced the blood sugar levels of the diabetic rabbits and the effect of the allicin was comparable with that of tolbutamide. The studies by

Sheela et al³¹⁻³³ showed S-allylcysteine sulfoxide (SACS, a sulfur-containing amino acid of garlic and precursor of allicin), had a hypoglycemic effect similar to that of glibenclamide and also increased blood insulin concentrations. Saravanan³⁴ also showed the antihyperglycemic effect of SAC was compared with glyclazide, a well-known antihyperglycemic drug. Liu et al³⁴ showed DATS is a functional component for the hypoglycemic effect of garlic but not DADS. However, in accordance with previous studies, it is difficult to definitively conclude which constituents derived from the garlic are responsible for its hypoglycemic effects, because the inconsistent results of these studies are complicated by the different animal models used in the studies. Different garlic preparations have variable effectiveness on blood glucose. Therefore it is advisable to use standard garlic preparations in future trials.

Previous data indicate that the measurement of HbA1c is a reliable method for assessing long-term glycemic control.³⁵ Although a favourable change in fasting glucose concentration was observed in the current meta-analysis, we did not decide on the effect on HbA1c. Thus, the effects of garlic on long-term glycemic control need to be explored in the future.

The present systematic review has several advantages. First, this is the first systematic review that has examined the effects of garlic supplementation on glucose levels in humans. The strengths of the study also include the analysis of only randomized, controlled clinical trials and the objective assessment of trial quality. Although we believe that the current meta-analysis provides useful information, some potential limitations should be addressed.

This meta analysis only includes 7 RCTs (may be underpowered), the sample size is small and unpublished RCTs were not included, and these factors may cause bias. Furthermore, our pooled analyses did not include postprandial glycemic control and HbA1c outcomes because only 1 study included in the meta analysis have reported postprandial variables and only 2 studies have reported HbA1c variables. More trials are needed to investigate the effectiveness of garlic on HbA1c and postprandial glycemic control. Third, the quality of the studies included in our meta-analysis varied from low to high. Meanwhile, the study durations were short (from 3 week to 6 month). Therefore, more high-quality and long term (years) randomized studies are needed in the future.

In conclusion, the current meta-analysis showed that the administration of garlic resulted in a significant reduction in FBG concentrations.

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AUTHOR DISCLOSURES

The authors declare that there is no conflict of interest.

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Original Article

Garlic intake lowers fasting blood glucose: meta-analysis of randomized controlled trials

Li-qiong Hou MSc¹, Yun-hui Liu MSc², Yi-yi Zhang MSc²

¹Department of Rheumatology, the First Hospital of Lanzhou University, China

²Department of Endocrinology and Metabolism, West China Hospital of Sichuan University, China

大蒜摄入可降低空腹血糖：随机对照研究的meta分析

大蒜是一种常见的辛辣调味剂，也可用于某些疾病的治疗。目前已有关于大蒜对血糖影响的临床和动物研究。但各研究结论存在争议。本研究通过meta分析探讨大蒜对人体血糖的影响。全面检索相关数据库，对符合纳入标准的随机对照研究，由两位评审员按Cochrane系统评价方法独立进行资料提取、质量评价并交叉核对后进行meta分析。共纳入7篇随机对照试验文章，合计513人。Meta分析结果显示：与安慰剂对照组相比，大蒜摄入组空腹血糖水平显著降低[SMD=-1.67；95% CI (-2.80, -0.55)， $p=0.004$]。由于纳入的研究中仅有1个研究提供了餐后血糖相关数据，2个研究提供糖化血红蛋白相关数据，故本研究未对餐后血糖和糖化血红蛋白进行meta分析。总之，本研究结果提示大蒜摄入可以降低空腹血糖水平。仍需更多研究探讨大蒜对糖化血红蛋白及餐后血糖的影响。

关键词：大蒜、meta分析、血糖、随机对照研究、2型糖尿病