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Brief report

The effect of plant sterols or stanols on lipid parameters in patients with type 2 diabetes: A meta-analysis

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ABSTRACT

We performed a meta-analysis of five randomized, placebo-controlled trials to characterize the impact of plant sterols/stanols on plasma lipids in patients with type 2 diabetes. Upon meta-analysis, plant sterols/stanols significantly reduced total and LDL cholesterol, with a trend towards improvement in HDL. No beneficial effect on triglycerides was apparent.

1. Introduction

Plant sterols/stanols have been shown to alter serum lipid levels by decreasing intestinal cholesterol absorption by 26–36% [1]. A previous meta-analysis of randomized trials evaluated the ability of foods containing plant sterols/stanols to alter serum lipid levels [2]. The meta-analysis found that foods containing plant sterols/stanols were able to reduce LDL cholesterol by a mean of 6.7% at doses of 0.7–1.1 g/day and by as much as 11.3% at doses ≥2.5 g/day [2]. However, differences in the antihyperlipidemic response to these agents between patients with and without type 2 diabetes mellitus (DM) have been proposed [3].

Several clinical trials [3–7] have investigated the impact of plant sterols/stanols on plasma lipid concentrations in patients with DM but yielded conflicting results and had modest sample sizes. Therefore, we performed a meta-analysis of randomized controlled trials of plant sterols/stanols to better characterize their impact on plasma lipids in patients with DM.

2. Research design and methods

To be included in this meta-analysis, studies had to be randomized controlled trials evaluating the use of plant

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sterols/stanols in diabetic patients that reported efficacy data (suitable for calculation of change from baseline) on at least one of the following lipid endpoints: (1) total cholesterol, (2) LDL, (3) HDL, or (4) triglycerides. Both parallel and crossover trials were eligible for inclusion.

A systematic literature search of Medline, EMBASE, CINAHL, Web of Science, the Cochrane Library and the Natural Medicines Comprehensive Database was conducted from the earliest possible date through May 2008 [8]. We used the following Medical Subject Headings and text keywords: sterol, stanol, sitosterol, sitostanol, beta-sitosterol, beta-sitostanol, phytosterol, phytostanol, stanol ester, sterol ester in combination with lipids, cholesterol, hypercholesterolemia, hypercholesterolemic, hyperlipidemia, hyperlipidemic, low-density lipoproteins, high-density lipoproteins, LDL, HDL and triglycerides. For our MEDLINE search, we used the Cochrane Collaboration's Highly Sensitive Search Strategy sensitivity-maximizing version [8]. The McMaster University Health Information Research Unit search strategy was used for the EMBASE search [8]. This search was then limited to clinical trials in humans. A manual search of references from retrieved articles was also performed.

Through use of a standardized data abstraction tool, two reviewers (WLB, ELB), independently collected data, with disagreement resolved through discussion or by a third investigator (CIC). The following information was obtained from each trial: author identification, year of publication, study design, source of study funding, study population (including baseline lipid values), sample size, duration of patient follow-up, plant sterol and stanol dose and formulation utilized, use of concurrent dietary modification, and effect on lipid parameters (total cholesterol, LDL, HDL and triglycerides).

The mean change in lipid parameters from baseline was treated as a continuous variable and the weighted mean difference (WMD) and its 95% confidence interval was calculated as the difference between the mean in the sterol/stanol and placebo groups using a DerSimonian and Laird random-effects model [9]. For parallel trials, net changes in each of these study parameters were calculated as the difference (sterol/stanol minus placebo) of the changes (baseline minus follow-up) in the mean values (also referred to as the change score). For crossover trials, net changes were calculated as the mean difference in values at the end of the sterol/stanol and placebo periods. Because a beneficial effect can be seen after 3–4 weeks of treatment, no washout period was required for crossover trials [10]. Standard statistical methods were used to impute change scores, as suggested by Follman et al. [11]. Statistical heterogeneity was addressed using the I^2 Statistic. Visual inspection of funnel plots and Egger's weighted regression statistics were used to assess for the presence of publication bias. Statistics were performed using StatsDirect statistical software, version 2.4.6 (StatsDirect Ltd., Cheshire, England). A p-value <0.05 was considered statistically significant for all analyses.

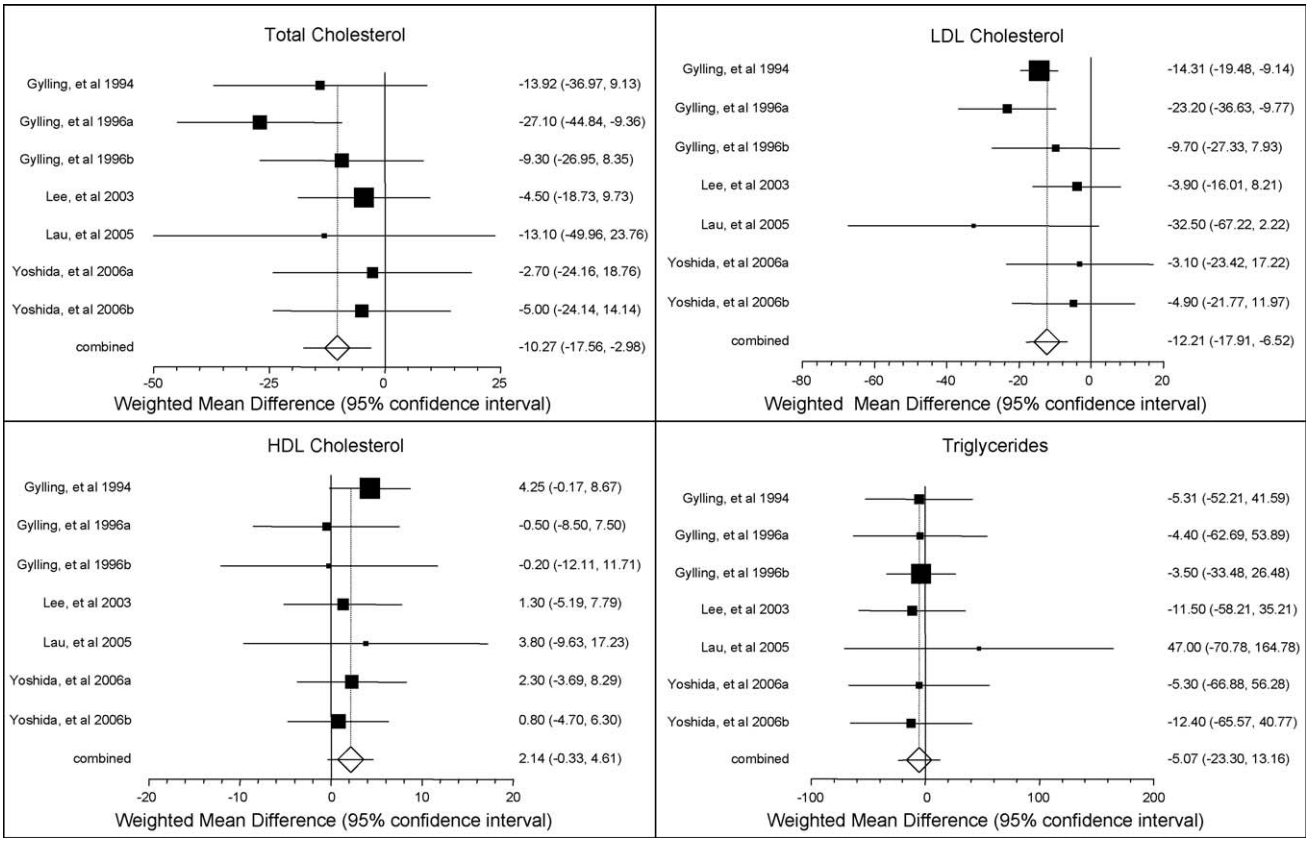

Fig. 1 – Results of meta-analysis of randomized controlled trials evaluating plant sterols/stanols. All results are reported in mg/dL as weighted mean differences with 95% confidence intervals using a random-effects model.