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Review

The effects of folate supplementation on lipid profiles among patients with metabolic diseases: A systematic review and *meta*-analysis of randomized controlled trials

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ABSTRACT

Background and objective: Although several studies have assessed the effect of folate supplementation on lipid profiles among patients with metabolic diseases, findings are inconsistent. This review of randomized controlled trials (RCTs) was conducted to summarize the evidence on the effects of folate supplementation on lipid profiles among patients with metabolic diseases.
Methods: Randomized-controlled trials (RCTs) published in PubMed, EMBASE, Web of Science and Cochrane Library databases up to until 20 August 2017 were searched. Two review authors independently assessed study eligibility, extracted data, and evaluated risk of bias of included studies. Heterogeneity was measured with a Q-test and with I_2 statistics. Data were pooled by using the fix or random-effect model based on the heterogeneity test results and expressed as standardized mean difference (SMD) with 95% confidence interval (CI).
Results: A total of thirteen randomized controlled trials were included. Folate supplementation did not affect systolic blood pressure (SMD −0.87; 95% CI, −1.83, 0.09) and diastolic blood pressure (SMD −0.59; 95% CI, −1.55, 0.37), and lipid profiles including triglycerides (SMD 0.10; 95% CI, −0.42, 0.63), total- (SMD 0.06; 95% CI, −0.31, 0.43), HDL- (SMD 0.04; 95% CI, −0.36, 0.44), VLDL- (SMD 0.08; 95% CI, −0.24, 0.41), and LDL-cholesterol (SMD −0.14; 95% CI, −0.55, 0.28).
Conclusions: Folate supplementation did not affect blood pressures and lipid profiles among patients with metabolic diseases. Additional prospective studies regarding the impact of folate supplementation on blood pressures and lipid profiles in patients with metabolic diseases are necessary.
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1. Introduction

People with metabolic diseases, type 2 diabetes mellitus (T2DM), cardiovascular disease (CVD) and polycystic ovary syndrome (PCOS) frequently have a comorbid dyslipidemia that increases risk of atherosclerosis and all-cause mortality [1–4]. In addition, subjects with diabetes mellitus have an approximately two-fold increased risk of CVD compared with subjects who do not have diabetes [5]. This dyslipidemia is characterized by increased concentrations of triglycerides and reduced concentrations of high-density lipoprotein cholesterol (HDL-cholesterol, while total cholesterol and low-density lipoprotein cholesterol (LDL-cholesterol) may be either normal or elevated [5],[6].

Correcting dyslipidemia decreases the risk of CVD and other metabolic complications for both patients with diabetes and those without. Several studies have explored the effects of improving the lipid profiles by using lipid-altering agents and evaluating the changes in incidence or risk of CVD and have included patients with diabetes in the study population [7,8]. These clinical trial data indicate that lowering total-, LDL-cholesterol and triglycerides as well as elevating HDL-cholesterol may be beneficial in reducing the risk of coronary heart disease (CHD). Previous studies have showed that low levels of folate, B12, and hyperhomocysteinemia were prevalent in people with T2DM [9] and CHD [10]. Recently, folate supplementation is suggested to control lipid profiles among patients with metabolic diseases. In a study by Vijayakumar et al. [11], it was observed that folate supplementation for 12 weeks among women with T2DM reduced serum homocysteine concentrations, increased serum folate and vitamin B_{12} concentrations, and lowered lipid profiles. Furthermore, a *meta*-analysis study demonstrated that folate intake was effective in the primary prevention of cerebrovascular events (CVCE) among patients with hypertension and hyperhomocysteinemia (HT/HHcy), as well as reducing the blood pressure and total homocysteine levels [12]. However, folate supplementation at a dosage of 5 mg/day for 4 weeks did not affect lipid profiles in familial hypercholesterolemia [13]. Such controversial findings complicate approaches to prescribe folate for these patients. Numerous RCTs have been conducted to assess whether folate supplementation has a causal effect on lipid profiles among subjects with metabolic diseases. We aimed to systematically review the current evidence on the effect of folate supplementation on lipid profiles in RCTs and to summarize the available findings in a *meta*-analysis, if possible.

2. Methods

2.1. Search strategy

Relevant studies were systematically searched from online databases PubMed, EMBASE, Web of Science and Cochrane Library databases up to 20 August 2017. Search terms included: patients [“diabetes” OR “type 2 diabetes mellitus (T2DM)" OR ‘type 1 diabetes mellitus (T1DM)" OR “non-alcoholic fatty liver disease (NAFLD)" OR “acute myocardial infarction (AMI)" OR “coronary artery disease (CAD)" OR ‘metabolic syndrome (MetS)" OR “polycystic ovary syndrome (PCOS)"]; intervention (“folate” OR “folic acid” AND ‘supplementation’ OR “intake’) and outcomes [‘systolic blood pressure (SBP)" OR “diastolic blood pressure (DBP)" OR “total-cholesterol” OR “triglycerides’ OR ‘LDL-cholesterol’ OR “HDL-cholesterol’ OR ‘VLDL-cholesterol’]. References cited in the selected studies were manually searched for additional relevant articles. Our search was restricted to studies published in the English language.

2.2. Selection criteria

The eligibility criteria were: human RCTs, patients with metabolic diseases, and administration and/or supplementation of folate or folic acid supplements. Studies that did not report mean changes of lipid profiles, along with standard deviation (SD) for the intervention and control groups, the abstracts of seminars without full text, case reports, and studies that did not obtain the minimum required score of quality assessment process were excluded.

2.3. Quality assessment

Data extraction and study quality assessment was conducted by three independent researchers (RT, MA, ZA)), according to Cochrane Collaboration Risk of Bias tool. The scale includes 3 domains related to quality of clinical trials: 1) random sequence generation description (0 = no description; 1 = inadequate description; 2 = adequate description); 2) blinding process (2 = double-blinding with adequate description; 1 = double-blinding with inadequate description; 0 = wrong usage of double-blinding), and 3), and withdrawal of patients (1 = the number and reasons of patients withdrawal described; 0 = otherwise). In the event of disagreement, resolved by discussion until consensus was reached.

2.4. Statistical methods

RevMan software (Cochrane Review Manager, version 5.2) and STATA version 12.0 (Stata Corp., College Station, TX) were used for data analyses. Heterogeneity was evaluated through the Cochran (Q) and I-squared tests (I_2). Given the existing heterogeneity between studies, when I_2 exceeds 50% or $P < .05$, the random-effect model was used; otherwise, the fixed-effect model was applied. Inverse variance method and Cohen statistics were used for estimation of standardized mean difference (SMD) and 95% CI for verifying the outcomes behavior of each study group (intervention/control). Sensitivity analyses also undertook in the trials one by one to evaluate the reliability of the pooled mean difference. In addition, the Cochrane Collaboration Risk of Bias tool was used to assess the methodological quality of the RCTs. Potential publication bias was assessed through visual inspection of funnel plots and quantitatively assessed using Egger’s tests.

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