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Meta-analyses

Black tea consumption and serum cholesterol concentration: Systematic review and meta-analysis of randomized controlled trials

Yimin Zhao, Sailimuhan Asimi, Kejian Wu, Jusheng Zheng, Duo Li*

Department of Food Science and Nutrition, Zhejiang University, Hangzhou, People's Republic of China

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SUMMARY

Background & aims: The results of randomized controlled trials in relation to the effect of regular black tea consumption on serum cholesterol concentration were inconsistent. We aimed to investigate and quantify the effect of black tea consumption on serum concentrations of total, LDL and HDL cholesterol.
Methods: We systematically searched and identified relevant literatures in PubMed, Scopus and the Cochrane Library. Inclusion and exclusion of studies, data extraction, quality assessment and meta-analysis were conducted according to the PRISMA statement.
Results: Ten eligible studies with 411 participants were identified in the present meta-analysis. No significant heterogeneity was found between studies. Consumption of black tea significantly reduced LDL cholesterol concentration (−4.64 mg/dL; 95% CI: −8.99, −0.30 mg/dL; $P = 0.036$). No remarkable change was detected in total cholesterol (−2.04 mg/dL; 95% CI: −6.43, 2.35 mg/dL; $P = 0.363$) or HDL cholesterol (−1.15 mg/dL; 95% CI: −3.04, 0.75 mg/dL; $P = 0.236$). Subgroup analysis showed that the lowering effect on LDL cholesterol was more effective in subjects with higher cardiovascular risk.
Conclusions: Black tea consumption significantly lowered serum concentration of LDL cholesterol, especially in subjects with higher cardiovascular risk. Black tea intake did not impose obvious effect on serum concentrations of total and HDL cholesterol.

1. Introduction

Tea is one of the most popular drink in the world with about 80% being consumed as black tea [1], thus tiny effect on individual health caused by tea arouses wide concern and could have an enormous influence on public health [2]. Tea is produced from *Camellia sinensis*, it can be classified into three major types according to the level of the fermentation process: unfermented green tea, partially fermented Oolong tea and fully fermented black tea [3]. As a rich dietary source of flavonoids, black tea has potential beneficial health effects on human body. Previous meta-analyses of observational studies suggested that high black tea intake was associated with reduced risk of type 2 diabetes and stroke [4,5]. Randomized controlled trial showed that black tea intervention can improve flow-mediated dilation which indicated a cardiovascular protective effect of black tea [6].

Hypercholesterolemia is closely correlated with risk of cardiovascular diseases, such as atherosclerosis and coronary artery disease [7]. Modification of serum cholesterol profile remains an important method for cardiovascular disease prevention and it was estimated that for every 1% reduction in total cholesterol concentration, the risk of cardiovascular diseases decreased by an average of 2% and 1 mg/dL reduction of LDL cholesterol concentration can reduce coronary artery disease risk by 1% [8,9]. To date, the results from randomized clinical trials concerning the effect of black tea on serum cholesterol concentration remained inconsistent. Therefore, the objective of this study was to systematically review and quantify the randomized controlled trials regarding the effect of black tea consumption on serum cholesterol concentration.

2. Methods

This systematic review and meta-analysis has followed the recommendations of the PRISMA statement [10].

2.1. Study selection and eligibility criteria

We conducted a systematic search for publications before November 2013 using the databases of PubMed (http://www.ncbi.nlm.nih.gov/pubmed), Scopus (http://www.scopus.com) and the

* Corresponding author. Department of Food Science and Nutrition, Zhejiang University, 866 Yuhangtang Road, Hangzhou 310058, People's Republic of China. Tel./fax: +86 571 88982024.
E-mail address: duoli@zju.edu.cn (D. Li).

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Cochrane Library (http://www.thecochranelibrary.com). We used the text words: tea, black tea and *Camellia sinensis*, paired with the following words: blood lipid, blood cholesterol, low density lipoprotein cholesterol and high density lipoprotein cholesterol. All searches were restricted in English-language publications. An additional manual search was conducted using reference lists from original research papers, previous meta-analysis and review articles. To be included, a study must meet all the following criteria: (1) conducted in adults; (2) randomized controlled trials of either parallel or crossover design; (3) used black tea as the only active treatment intervention; (4) provided available data to calculate the difference between baseline and endpoint for cholesterol measures including total cholesterol, LDL cholesterol and HDL cholesterol; (5) with an intervention duration ≥2 weeks and a sample size ≥10. Besides, a study will be excluded if it employed pregnant or severely ill participants.

2.2. Data extraction and quality assessment

Data were extracted independently by two researchers and any discrepancy was resolved via discussion. Study characteristics were extracted including author, country, study design, intervention duration, sample size, population information, type of intervention and control, diet change. In each trial, the means and SDs of cholesterol measures at baseline and endpoint in both intervention and control groups were extracted. For studies that had multiple time points for the same participants, only the last endpoint was used for analysis. If a study adopted different intervention protocols, intervention group which met the inclusion criteria was used. Extracted data were converted to conventional units and for cholesterol 1 mmol/L was converted to 38.6 mg/dL. When SD was not reported directly, we calculated them from SEM and 95% CI using the following equations according to the Cochrane handbook for systematic reviews of interventions [11]:

$$SD = SEM \times \sqrt{n} \quad (1)$$

And

$$SD = \sqrt{n} \times (upperlimit - lowerlimit) \div 3.92 \quad (2)$$

Chang-from-baseline SD was estimated using the equation listed:

$$SD_{change} = \sqrt{SD_{baseline}^2 + SD_{final}^2 - 2 \times R \times SD_{baseline}^2 \times SD_{final}^2} \quad (3)$$

The R is the correlation coefficient. To be conservative, a minimum correlation coefficient of 0.5 was used.

Quality assessment was conducted in duplicate independently and quality characteristics included the following items: randomization, random sequence generation, allocation concealment, blinding of both participants and researchers, description of dropouts. The Jadad score was adopted to assess the quality of each study and trials scored one point for each area addressed [12]. Trials with Jadad score ≥4 were classified as high quality. Discrepancy was resolved through discussion until a consensus was reached.

2.3. Data synthesis and analysis

Statistical analysis was performed using Stata/SE 12.0 for Windows (StataCorp, College Station, TX, USA). Heterogeneity among trials was assessed by I^2 statistic and Cochrane Q test. We suggested there was no significant heterogeneity among trials when I^2 <50%. Both fixed-effect model and random-effect model were employed to calculate the pooled effect and corresponding 95% CI for each cholesterol measure [13]. The fixed-effects model was used when there was no obvious heterogeneity among trials, otherwise the random-effects model developed by DerSimonian and Laird was adopted to calculate the pooled effect [13]. Possible publication bias was examined by Begg's test [14], a $P < 0.1$ indicated potential publication bias may exist. Trim and fill method was used to correct potential publication bias and corresponding filled funnel plot was also presented for visual inspection of publication bias [15].

To explore the source of heterogeneity, we carried out a series of predesigned subgroup analyses. Subgroup analyses were implemented by comparing trials stratified by study and population characteristics including healthy status of subjects, duration, study design, daily flavonoids intake from black tea, type of intervention and control. Furthermore, we also conducted additional sensitivity analyses to test if the results were steady [10].

3. Results

3.1. Results of the study selection

The PRISMA flow diagram is shown in Fig. 1. Finally we identified ten studies that met the inclusion criteria [16–25]. Total of 597 potentially relevant titles and abstracts were identified from searches on PubMed, Scopus and the Cochrane Library together with other reference sources. After ruling out animal studies and those irrelevant to the aim of this meta-analysis, 27 articles were retrieved as full text and assessed for inclusion. We excluded studies with a duration shorter than two weeks [6] or with a small sample size less than 10 [26]. Furthermore two studies were excluded because black tea was used as a part of multicomponent supplement in intervention group [27,28]. Three articles were ruled out because they used Pu'er tea as intervention treatment [29–31]. Pu'er tea is a sort of wet-fermented tea despite it was called Chinese black tea in these studies. Another ten studies were excluded due to a lack of sufficient detail for inclusion or a cross-sectional design.

3.2. Study characteristics

The characteristics of all the included studies are listed in Table 1. The research of Bahorun et al. [16] was separated into 2 trials (effects on males and females respectively). Therefore, 11 trials involved 411 adult participants were included in this meta-analysis. Six trials from 5 studies were conducted in healthy people [16,17,21,23,25] while the other five trials were performed in subjects with higher cardiovascular risk such as prediabetes or hypercholesterolemia [18–20,22,24]. The sample size ranged from 15 to 77 with a median of 31. Six trials lasted for 4 weeks [17,19–21,23,25], four trials lasted longer than 10 weeks [16,22,24] and the average duration was up to 8 weeks. Only two trials were conducted in East Asian countries [21,24] and the rest were mostly performed in America or Europe. Black tea extract capsule was used in two trials [22,24] and the remaining adopted black tea beverages as the intervention treatment. Controlled background diet was adopted only in one trial [18]. Eight trials used parallel design [16,20–25] and the rest 3 trials adopted crossover design [17–19].

3.3. Quality assessment

Allocation concealment was adequate in two studies [19,22]. Three studies adopted appropriate method (e.g. using statistical software) to generate random sequence [16,19,22]. Double-blind design was employed only in two studies [18,24]. The statement and description of dropouts were reported in all of the included studies. Therefore, two studies were ranked as high quality [19,22] and the rest were low quality studies.