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Viewpoint

Green tea catechins and cardiovascular disease risk factors: Should a health claim be made by the United States Food and Drug Administration?

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Green tea (*Camellia sinensis*) is an ancient beverage stemming from China, more recently gaining interest in Western societies due to its antioxidant capacity. Cardiovascular disease (CVD), a disease of the heart and blood vessels, is a result of increased lipid concentrations and blood pressure, responsible for numerous deaths worldwide. Green tea is highly enriched in catechins, which may be responsible for its proposed CVD prevention mechanism. The objective of this paper was to examine the scientific evidence pertaining to green tea and CVD risk and evaluate whether enough credible scientific evidence exists to support a health claim by the United States Food and Drug Administration (US FDA). Sixteen clinical studies have examined the effects of green tea on CVD risk factors however, following a critical evaluation of these studies, a health claim cannot be recommended due to the safety and metabolites of green tea, as well due to lack of high quality and properly designed studies.

Introduction

Green tea comes from the leaves of the *Camellia sinensis* plant with a long history stemming from China over 4000 years ago (Liao, Kao, & Hiipakka, 2001). Tea is the second most widely consumed beverage aside from water, worldwide; however, green tea has long been used as a crude medicine in Asian countries and has recently gained interest in Western societies due to its high antioxidant capacity (Liao *et al*., 2001), anti-inflammatory activity (Hirao *et al*., 2010), anti-microbial effects (Jigisha, Nishant, Navin, & Panka, 2012), and anti-carcinogenic effects (Yang, Lambert, & Sang, 2009). China stands as the number one producer and exporter of green tea worldwide (Food and Agriculture Organization, 2003). Green tea has numerous proposed health benefits including, but not limited to, anti-obesity, blood glucose control, anti-hypercholesterolemia and blood pressure improvements (Liao *et al*., 2001). The proposed health benefits can be attributed to the presence of catechin molecules, specifically, epigallocatechin-3-gallate (EGCG), the most biologically active ingredient in green tea (Liao *et al*., 2001).

Cardiovascular disease (CVD) affects the heart and blood vessels due to the buildup of plaque within the vessel walls through a process termed atherosclerosis (World Health Organization (WHO), 2013). CVD is a multifactorial disease that can be accelerated by behavioral factors such as smoking, obesity, an unhealthy diet, hyperlipidemia and hypertension (WHO, 2013). CVD is a rampant endemic worldwide, accounting for nearly 50% of non-communicable disease related deaths (WHO, 2013). Lipid concentrations, specifically low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), and blood pressure (BP) are believed to be surrogate risk factors in identifying the progression of CVD. With the number of mortalities per annum resulting from CVD estimated to reach 23.6 million people by 2030, it is crucial to identify novel therapeutic prevention

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remedies, such as green tea, to reduce the prevalence of CVD and the number of CVD mortalities (WHO, 2013).

Various epidemiological and animal studies have analyzed the effects of green tea on surrogate risk factors associated with CVD and demonstrated promising results (Frei & Higdon, 2003; Kukubo *et al*., 2013; Kuriyama *et al*., 2006; Mineharu *et al*., 2011). A qualified health claim petition on green tea and CVD submitted in 2006 was denied by the United States Food and Drug Administration (US FDA) as supportive scientific evidence was lacking (US FDA, 2006). Thus, it is of importance to reevaluate the evidence as to whether green tea catechins can provide a therapeutic remedy for CVD risk factors in humans and if a health claim within the US FDA framework should be passed. Therefore, the objective of this paper was to examine the scientific evidence pertaining to green tea and CVD risk within the past 10 years and evaluate whether enough credible scientific evidence exists to support a health claim by the US FDA.

Green tea catechins

Green tea is one of the richest sources of polyphenols, specifically catechins, which represent 80–90% of the total flavonols (Velayutham, Babu, & Liu, 2008). Green tea contains the highest amount of antioxidant activity in comparison to other tea varieties due to the processing procedure. Fresh *C. sinensis* leaves are steamed and dried which inactivates the polyphenol oxidase enzyme to preserve the polyphenol content (Zaveri, 2006). Four main catechin molecules comprise the green tea composition; epicatechin, epigallocatechin, epicatechin gallate and epigallocatechin-3-gallate (EGCG) (Fig. 1) (Jochmann, Baumann, & Stangl, 2008). However, EGCG is the most active derivative in green tea and the most abundant accounting for 48–55% of total catechins (Stangl, Lorenz, & Stangl, 2005). One cup of green tea made with one tea bag contains around 150–200 mg/g catechins, including 90 mg EGCG (Basu & Lucas, 2007). Comparatively, absorption of green tea catechins is low due to metabolic and conjugative processes within the small intestine and colon during absorption (Stangl *et al*., 2005). Nakagawa, Okuda, and Miyazawa (1997) reported that 90 min following consumption, only 0.2–2% of the ingested amount of green tea catechins were found in the plasma. This may be associated with several metabolic modifications taking place during absorption, such as the formation of glucuronide conjugates and *O*-methylated catechins in the small intestine (Stangl *et al*., 2005), and phenolic acids and valerolactones, break down products of unabsorbed flavonoids by colonic microflora in the large intestine (Spencer, 2003). While these metabolites may contribute to the health effects of tea, either individually or collectively, they may also contribute to decreased absorption, thereby suppressing the biological actions of catechins, especially EGCG *per se,* in vivo.

It has been proposed that green tea catechins act through various mechanisms for the reduction of CVD risk factors. Such mechanisms include, antioxidant effects, endothelial function protection, lipid profile modification, anti-inflammatory, and anti-proliferative effects. The antioxidant nature of the polyphenol compounds is due to the ability of phenolic hydroxyl groups to scavenge reactive oxygen species. This antioxidant property of green tea polyphenols prevents oxidative modification to LDL-C, one of the crucial steps in the progression of atherosclerosis (Stangl *et al*.,

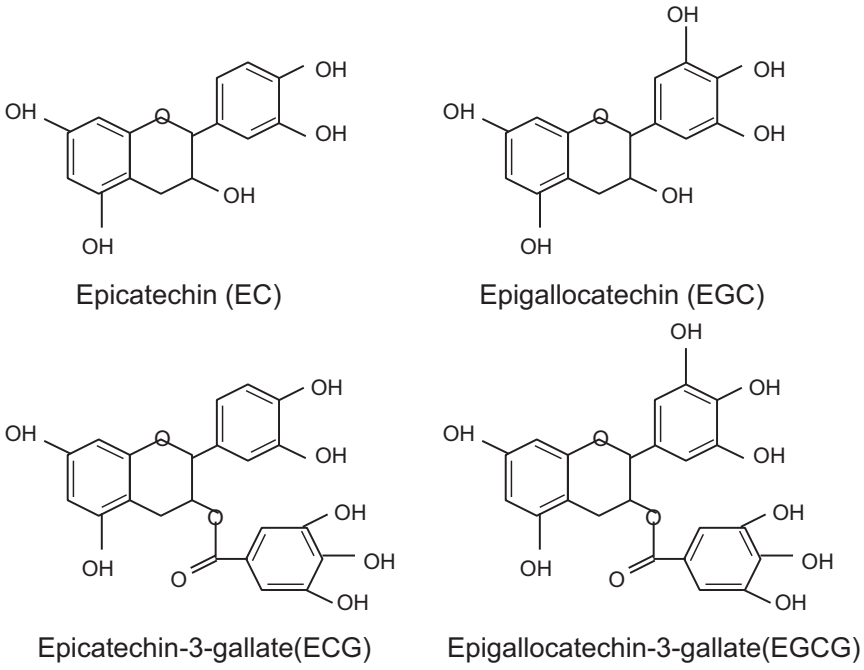

Fig. 1. Chemical structures of the major catechin molecules found in green tea.