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Research paper

Effect of *Gundelia tournefortii* L. extract on lipid profile and TAC in patients with coronary artery disease: A double-blind randomized placebo controlled clinical trial

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ABSTRACT

Context: Gundelia tournefortii (GT) has been known to possess hypolipidemic and antioxidant activities.
Objective: This study was carried out to evaluate the effects of GT on total antioxidant capacity (TAC) and lipid profile in patients with coronary artery disease (CAD).
Materials and methods: A total of 38 angiographically confirmed CAD patients were enrolled in this randomized, double-blind, clinical trial. The subjects consumed *G. tournefortii* extract (GTE) or placebo for 8 consecutive weeks. Serum total cholesterol, triglyceride, high density lipoprotein-cholesterol (HDL-c), low density lipoprotein-cholesterol (LDL-c) and TAC were determined by conventional methods. In addition, dietary intake was recorded using 24-h recall method and converted into nutrients with software Nut4 version1.
Results: At the end of the study, the GTE group had recorded a significantly lower energy intake compared to the placebo group ($p = 0.04$). The BMI also significantly decreased in the GTE group by 3% (from $26.5 \pm 3.6\ kg/m^2$ at baseline to $25.9 \pm 3.6\ kg/m^2$ at the end of the trial). There was a significant reduction in total cholesterol level in the GTE group (151 ± 23.8 mg/dl at baseline to 131.1 ± 25.9 mg/dl at the end of the trial), however, its level increased slightly in the placebo group (133.5 ± 22 mg/dl at baseline to 141.4 ± 22.4 mg/dl at the end of the trial). The mean value of LDL-c level notably decreased in the GTE group from 86 ± 26 to 60.58 ± 29.9 mg/dl ($p = 0.001$). No significant differences were observed in the groups for HDL-c or triglyceride levels; however, TAC significantly changed in the two groups after the intervention.
Conclusion: The intervention resulted in a statistically significant difference in total cholesterol, LDL-c and BMI suggesting that GTE may be an appropriate adjunctive medicinal plant to help reduce the major risk factors of CAD.

1. Introduction

Coronary artery disease (CAD) is one of the major underlying global causes of death (Bundy et al., 2008; Galassi et al., 2006).

Approximately, 80% of CADs can be prevented through healthy life style and reducing associated risk factors (Mozaffarian et al., 2014). Consequently, nowadays, herbal medicine, one of the main therapeutic approaches of complementary and alternative medicine, has attracted considerable attention by individuals with CVD for its unique advantages in preventing and treating diseases (Craig, 1999; Keli et al., 1996; Tachjian et al., 2010; Xiong et al., 2014; Zhang and Wang, 2009). Many of the active phytochemicals in herbs, especially polyphenolic compounds, possess hypolipidemic, antioxidant and antiplatelet properties, that could improve the risk factors of CAD (Ahmad and Beg, 2013; Manich et al., 1996; Peluso, 2006; Quinones et al., 2013).

Gundelia tournefortii L. (GT) from the Asteraceae (Compositae) family, locally known as "Kangar" in Iran, is an edible spiny,

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thistle-like plant native to Iran, Turkey, Azerbaijan, Egypt, Cyprus, Jordan and other areas of Western Asia (Çoruh et al., 2007; Matthäus and Özcan, 2011). Common names of GT are Galgal, Tumbleweed, Tumble Thistle, Akkub or Akoub. In the Middle East, the stalk of the plant has been widely used in traditional medicine as a hepatoprotective and blood purifier as well as a potential remedy for diabetes, chest pain and heart stroke (Jamshidzadeh et al., 2005; Halabi et al., 2005; Hamdan and Afifi, 2004).

GT is rich in phenolic compounds, especially flavonoids, including caffeoylquinic acid derivatives (cynarin and chlorogenic acid), quercetin, gallic acid, and other components such as limonene, zingiberene and saponins which are responsible for the biological activity of the plant (Asadi-samani et al., 2013; Haghi et al., 2011; Wagner et al., 1984; Nakatani et al., 2000; Yamanaka et al., 1997). As potential antioxidants, the polyphenols of this plant may play a substantial role in the prevention of various pathological conditions, especially cardiovascular diseases and cancer (Asgary et al., 2009; Çoruh et al., 2007; Haghi et al., 2011; Halliwell, 1994). Some studies have suggested that the anti-atherosclerotic properties of GT are a result of its hypolipidemic, anticoagulant and antioxidant properties (Asgary et al., 2009; Hammadi and Salam, 2004). Furthermore, some animal studies have demonstrated that GT could modulate lipid profile. The suggestion is that it may decrease total cholesterol and low density lipoprotein-cholesterol (LDL-c) (Asgary et al., 2009; Azeez and Kheder, 2012). The plant has also displayed anti-inflammatory, analgesic and antioxidant effects in both in vitro and in vivo studies (Çoruh et al., 2007; Oryan et al., 2011). Some animal studies have also shown that GT may regulate appetite and energy intake thus conferring a possible anti-obesity effect (Azeez and Kheder, 2012; De Melo et al., 2010; Wagner et al., 1984).

To date, no clinical trials concerning the effects of *G. tournefortii* extract (GTE) in humans has been conducted. In view of the potential anti-atherosclerotic effects of GT, the present study was intended to investigate the possible effects of GTE consumption on lipid profile and total antioxidant capacity (TAC) in patients with CAD (Bunting et al., 1983).

2. Materials and methods

2.1. Preparation of the extract and placebo capsules

The aerial parts of GT (Fig. 1) were collected from mountainous areas around Urmia, West Azerbaijan Province, Iran in May 2013 and its identity was confirmed by a panel of expert botanists at the Botany Department, Tabriz University, Tabriz, Iran. The plant specimen with the necessary field records was prepared and stored in the herbarium at Tabriz University. Thereafter, 170 kg of the fresh plant was dried in a shaded and ventilated place at room temperature.

Dried plant material (aerial parts) were ground to a powder using a steel commercial blender. The powdered plant (9 Kg) was then macerated in 96% aqueous EtOH at room temperature for 72 h. The extract was filtered through filter paper (Whatman, No 1) and concentrated under a vacuum reduced pressure and low temperature (40 °C) on a rotary evaporator (Laborata 4000; Heidolph, Germany). The extract yield obtained from the powdered extract was 38 mg/g. The extract was frozen at −80 °C for one week. The whole freeze dried extract (350 gr) was then placed at room temperature and mixed with 350 gr of the excipient (microcrystalline cellulose and lactose). The whole extract powder (the mixture of extract and excipient) and placebo were filled into capsules with identical appearance using a hand-operated capsule-filling machine to preserve the double blind condition. Each GTE capsule contained 250 mg of hydroalcoholic extract, 200 mg microcrystalline cellulose, 50 mg lactose and 4 mg magnesium stearate. Whereas, the placebo capsules contained 450 mg microcrystalline cellulose, 50 mg lactose and 4 mg magnesium stearate.

2.2. Subjects

The study screened 60 potentially suitable individuals who were admitted to the heart hospital of Seyed-al-Shohada in Urmia, Iran and 45 men were enrolled. The inclusion criteria used were as

Fig. 1. *Gundelia tournefortii.*