J Ginseng Res xxx (2017) 1–8

Contents lists available at ScienceDirect

Journal of Ginseng Research

journal homepage: http://www.ginsengres.org

Research article

Efficacy and safety of *Panax ginseng* berry extract on glycemic control: A 12-wk randomized, double-blind, and placebo-controlled clinical trial

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ARTICLE INFO

Article history:
Received 23 March 2016
Received in Revised form
18 December 2016
Accepted 4 January 2017
Available online xxx

Keywords:
antihyperglycemic effects
clinical trial
glucose metabolism
oral glucose tolerance test
Panax ginseng berry

ABSTRACT

Background: Antihyperglycemic effects of *Panax ginseng* berry have never been explored in humans. The aims of this study were to assess the efficacy and safety of a 12-wk treatment with ginseng berry extract in participants with a fasting glucose level between 100 mg/dL and 140 mg/dL.
Methods: This study was a 12-wk, randomized, double-blind, placebo-controlled clinical trial. A total of 72 participants were randomly allocated to two groups of either ginseng berry extract or placebo, and 63 participants completed the study. The parameters related to glucose metabolism were assessed.
Results: Although the present study failed to show significant antihyperglycemic effects of ginseng berry extract on the parameters related to blood glucose and lipid metabolism in the total study population, it demonstrated that ginseng berry extract could significantly decrease serum concentration of fasting glucose by 3.7% ($p = 0.035$), postprandial glucose at 60 min during 75 g oral glucose tolerance test by 10.7% ($p = 0.006$), and the area under the curve for glucose by 7.7% ($p = 0.024$) in those with fasting glucose level of 110 mg/dL or higher, while the placebo group did not exhibit a statistically significant decrease. Safety profiles were not different between the two groups.
Conclusion: The present study suggests that ginseng berry extract has the potential to improve glucose metabolism in human, especially in those with fasting glucose level of 110 mg/dL or higher. For a more meaningful benefit, further research in people with higher blood glucose levels is required.
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1. Introduction

Diabetes mellitus is a serious metabolic disorder characterized by hyperglycemia and various life-threatening complications. Despite enormous preventive efforts, diabetes mellitus is one of the fastest growing chronic disorders across the world. In 2010, an estimated 285 million people worldwide suffered from diabetes mellitus, and the number of people with diabetes mellitus is expected to rise to 439 million or 7.7% of the global adult population aged 20–79 yr by 2030 [1]. According to the Korean National Health and Nutrition Examination Survey conducted in 2013, the prevalence of diabetes mellitus in Korea for adults over age 30 yr was estimated to be 11.0% [2].

Although no cure is yet available for diabetes mellitus, various pharmacologic agents have been developed and are being used to enable blood glucose control. However, the current pharmaceuticals for diabetes mellitus have a number of limitations, such as having adverse effects and high rates of failure in long-term glycemic control. This has led to research for alternative or complementary approaches, such as natural products or botanicals, which have some degree of efficacy and mostly are without the troublesome side effects associated with the conventional pharmacologic treatments. Furthermore, earlier intervention for glycemic control is being emphasized for prevention or delay of diabetes mellitus in the management of patients with prediabetes [3]. In this context, alternative approaches using natural products may provide

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http://dx.doi.org/10.1016/j.jgr.2017.01.003
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additional strategies for the early management of diabetes mellitus or prediabetes.

Ginseng is a slow-growing perennial herb that has been used as a traditional medicine for thousands of years in Asia. Ginseng has been reported to have various pharmacological properties, including anticancer, antiaging, anti-inflammatory, and antiallergy effects [4–7]. Ginseng has also received attention from medical researchers for its antihyperglycemic effects, which have been demonstrated by *in vitro* [8,9] and *in vivo* animal studies [10–19] and clinical trials [20–22]. Although both root and berry of ginseng were reported to possess antihyperglycemic effects, a recent *in vivo* study demonstrated that ginseng berry had more potent antihyperglycemic effects than its root when used at the same dosages [23]. Indeed, the ginseng berry has a distinct ginsenoside profile and contains significantly more ginsenosides than its root [23,24]. For this reason, the ginseng berry may exert more potent antihyperglycemic effects than its root. However, the antihyperglycemic effects of *Panax ginseng* berry have never been explored in humans. Therefore, the objective of the present study was to test the efficacy and safety of a 12-wk treatment with ginseng berry in participants with fasting glucose level between 100 mg/dL and 140 mg/dL, using a randomized, double-blind, placebo-controlled study design.

2. Materials and methods

2.1. Preparation of ginseng berry extract and HPLC analysis

Ginseng berry and placebo capsules were provided by Amorepacific Corporation (Gyeonggi, Korea). Freshly harvested 4-yr-old Korean ginseng berries (*P. ginseng* Meyer) cultivated in Chungbuk province of South Korea were used. The seeds were separated, and the pulp and juice dried in hot air. The dried ginseng berries were refluxed with 70% ethanol for 10 h. The extract was filtered and evaporated under vacuum at 45°C to obtain standardized Korean ginseng berry extract. The concentration of seven major ginsenosides in ginseng berry extract was analyzed by HPLC (Fig. 1) [25]. Total ginsenoside concentrations (% w/w) were 19.99%. Individual ginsenoside concentrations were 0.77%, 1.90%, 2.11%, 1.65%, 11.06%, 1.66%, and 0.84% for the ginsenosides Rb1, Rb2, Rc, Rd, Re, Rg1, and Rg2, respectively. The content of ginsenoside Re in standardized ginseng berry extract was maintained at 10%. Each 500-mg ginseng berry capsule contained 250 mg of standardized ginseng berry extract. The total treatment dose of ginseng berry extract was 1 g/d. Placebo capsules were identical in appearance and flavor to the ginseng berry capsules. During the trials, four capsules (2 capsules at a single time before breakfast and dinner) of ginseng berry extract or placebo were given daily for 12 wk.

2.2. Participants

The study participants were recruited from January 2014 to December 2014 in Dongguk University Ilsan Hospital (Koyang, Gyeonggi, Korea) via hospital and subway advertisement. After the screening test, participants with fasting blood glucose within a range of 100–140 mg/dL, whose age was between 20 yr and 75 yr, were enrolled in this study. Exclusion criteria included: lipid metabolism disorders; acute or chronic inflammatory disease; corticosteroid use within 4 wk of the study; acute cardiovascular disease such as heart failure, myocardial infarction, or stroke; an allergy or hypersensitivity to any of the ingredients in the test products; a history of disease that could interfere with the test products or impede their absorption, such as gastrointestinal diseases or gastrointestinal surgery; participation in other clinical trials within the previous 2 mo; renal disease such as acute/chronic renal failure or nephrotic syndrome; abnormal hepatic liver function; use of antipsychosis drug therapy within 2 mo of the study; a history of alcohol or substance abuse; pregnancy or breast feeding; and laboratory test results, medical, or psychological conditions that the researchers considered unsuitable for this study. In addition, participants taking glucose-lowering medications or insulin injections were excluded from this study. This study was carried out in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board of Dongguk University Ilsan Hospital (IRB No. 2013-81). A total of 72 participants were enrolled in this study and provided their written informed consent for the study after they were provided with a detailed description of the experimental procedures and informed that they could withdraw from the study at any time.

2.3. Study design

This study was designed as a single-center, randomized, double-blind, placebo-controlled clinical trial that lasted for 12 wk. Following the screening visit, at which inclusion and exclusion criteria were assessed, participants were randomly assigned to receive ginseng berry extract or placebo using a computerized method of random list generation. All participants, investigators, pharmacists and study personnel were blinded to treatment allocation. The enrolled participants were scheduled to visit three

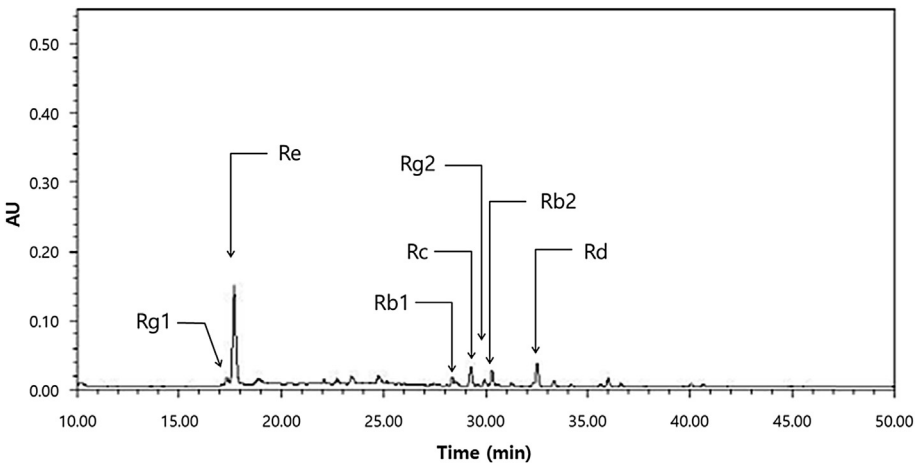

Fig. 1. HPLC of ginseng berry extract. AU, absorbance units.

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