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Original article

Effects of Korean red ginseng on cold- and heat-related symptoms and the autonomic nervous system

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Abstract

Introduction: Korean red ginseng (KRG) is known to alleviate psychological, aging-related, and gynecological problems. These problems are thought to be related to cold and heat imbalance or to autonomic dysfunction. However, few studies have addressed the effects of KRG by using a placebo-controlled study design. Therefore, the purpose of this study was to examine the effect of KRG on pathological cold and heat patterns and cardiovascular autonomic function (CAF) by using a randomized, double-blind, placebo-controlled design.

Methods: Ninety subjects were randomly assigned to the KRG group ($n = 44$) or the placebo group ($n = 46$). Subjects were asked to complete a cold–heat questionnaire (CHQ) and to undergo a heart rate variability (HRV) test, both before and 8 weeks after taking KRG or placebo capsules (6 g/day). Differences in changes in cold and heat subscale scores and HRV parameters between the 2 groups were examined using two-way repeated measures ANOVA.

Results: The cold subscale score decreased only in the KRG group, whereas the heat subscale score decreased in the KRG and placebo groups. Among the HRV parameters, high frequency (HF) decreased in the KRG group and low frequency (LF)/HF ratio, a sympathovagal balance indicator, increased. This indicated that KRG alleviated the severity of cold patterns and improved sympathovagal balance in a manner related to the relaxation of physical or mental tension.

Conclusions: KRG may alleviate the severity of cold patterns and improve sympathovagal balance.
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Keywords: Korean red ginseng; Cold–heat questionnaire; HRV; Randomized controlled trial

Introduction

Korean red ginseng (KRG) is the steamed root of *Panax ginseng*. Ginseng products are used as general tonics and adaptogens to help the body resist the adverse influences of a wide range of physical, chemical, and biological factors as well as to restore homeostasis [1,2]. These tonic and adaptogenic effects of ginseng are known to enhance physical performance and general vitality in healthy individuals, to increase the body's ability to fight stress, to support resistance to diseases by strengthening normal body functions, and to reduce the detrimental effects of aging [3,4]. Recently, more specific effects of KRG have emerged, such as its ability to improve climacteric syndrome [5], postmenopausal symptoms [6], sexual function, and general quality of life in women [7]. KRG is also beneficial in patients with xerostomia, especially in menopausal women [8]. These results indicate that KRG has the ability to alleviate psychological, aging-related, and gynecological problems.

Oriental medicine (OM) emphasizes the coordination of various parts of the human body as an organic whole. If this coordination breaks down, heat- or cold-related symptoms appear as a patient's chief complaint [9]. Some studies have reported that

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KRG regulated or improved symptoms of imbalance of cold and heat, including heartburn, flushing [6], and thirst [8]. These results show that KRG could be effective in both cold- and heat-related symptoms. However, research demonstrating such effects of KRG is scarce. Thus, the first purpose of our study was to examine whether KRG can improve cold- and heat-related symptoms.

Furthermore, it has been reported that pathological cold and heat patterns are related to autonomic nervous system (ANS) function in patients with gynecological problems, as estimated by heart rate variability (HRV) parameters [10]. Considering that KRG improved cold- and heat-related symptoms, which are in turn related to ANS function, it is plausible that the ANS will be involved in changes in pathological cold and heat patterns produced by KRG administration. Thus, the second purpose of our study was to examine the relationship between improvements in cold- and heat-related symptoms and HRV parameters. To examine the effect of KRG on pathological cold and heat patterns, and to examine the relationship between pathological cold and heat patterns and the ANS, we performed a randomized, double-blind, placebo-controlled trial using 133 subjects.

Methods

Subjects and data collection

From September 2007 to May 2008, 133 volunteers were enrolled in this study. All measurements and interviews were conducted at the Kyung Hee University Hospital in Gangdong, Seoul, Korea. Before starting the study, subjects were asked to fill out a cold and heat questionnaire (CHQ) [11], and were required to score greater than 18 on the cold subscale or the heat subscale for inclusion in the study. Since KRG is one of the most popular health-promoting herbs in Korea for both healthy and ill people, we only enrolled volunteers who were not affected by a specific disease. Because a score of 15 on the CHQ indicates no effect by either cold or heat, only subjects who had a score of over 18 were included to measure the susceptibility to either cold- or heat-related symptoms. It is known that cold and heat are not mutually exclusive and that they can occur in one patient at the same time. Therefore, we included subjects who had cold or heat scores of over 18, as well as subjects who had both cold and heat scores of over 18.

Exclusion criteria included heart disease, as indicated by self-reported arrhythmia, hypertension, or ischemic heart disease, which can affect HRV reports. Further exclusion criteria included pneumonia, infections with fevers, upper respiratory infection or urinary tract infection, abnormal thyroid function, and mental illness, which can affect cold- and heat-related symptoms. From the 133 volunteers who satisfied the inclusion criteria, 34 subjects (25.6%; 19 women [14.3%] and 15 men [11.3%]) were excluded based on the criteria mentioned above, and 9 subjects dropped out during the study because of personal reasons. Therefore, 90 volunteers completed this study. The study protocol was approved by the Institutional Review Board of Kyung Hee University under protocol number KHNMC-OH-IRB 2007-007. Informed consent was obtained from all subjects prior to the study.

Study design and assessment

Fig. 1 depicts the entire process of the study. This randomized, double-blind, placebo-controlled, parallel-group trial was designed to investigate the effects of KRG on changes in cold- and heat-related symptoms, and HRV parameters. At the first visit, the CHQ was provided and the HRV test was conducted. Using a random number generator, subjects were assigned randomly to the KRG or placebo groups in blocks of 4, which received either 6 g of KRG (Korean Red Ginseng Powder Capsule®; Korea Ginseng Corporation, Daejeon, Korea) or placebo (a capsule containing cornstarch powder with KRG flavoring), respectively, every day for 8 weeks. A voucher specimen was deposited with the Korea Ginseng Corporation (Seoul, Korea). The randomization list was kept by an independent pharmacist responsible for the KRG distribution until the end of the study. The subjects were given a diary, which they were asked to fill in twice per day after taking KRG or placebo.

Eight weeks after the subjects were given the prescription, the CHQ questionnaire scores and HRV parameters were reassessed. During each visit, the diaries were checked and the remaining capsules were counted. Compliance was estimated as a percentage of the number of capsules actually taken vs. the number of capsules that should have been taken.

Questionnaire measurement

In this study, each person was asked to complete the 15-item cold and heat questionnaire (CHQ) to estimate his or her severity of cold- or heat-related symptoms. The CHQ consisted of eight cold-related symptom items and seven heat-related symptom items [12,13]. The first CHQ was taken before the administration of KRG or placebo capsules, and the second CHQ was taken 8 weeks after administration of KRG or placebo capsules. Each item was rated on a 7-degree scale: 1 = disagree very strongly; 2 = disagree strongly; 3 = disagree; 4 = neither agree nor disagree; 5 = agree; 6 = agree strongly; and 7 = agree very strongly. Each subject was asked to fill out this questionnaire before the treatment and after the treatment (Table 1).

HRV recordings

Each subject was seated in a comfortable chair in a quiet room and asked to relax for 10 min. After the relaxation period, 3 clip-type electrocardiogram (ECG) leads of an SA-3000P HRV analyzer (Medicore Co., Seoul, Korea) were attached to the patient's wrists and left ankle. The SA-3000P HRV analyzer detects ECG signals at a sampling rate of 500 Hz, and automatically calculates the time-domain, frequency-domain, and nonlinear parameters based on the 5-min R-R interval. In this study, frequency-domain parameters were included, which were LF (0.04–0.15 Hz), HF (0.15–0.4 Hz), and the ratio of LF

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