

Original article

Safety and efficacy of a dietary supplement containing functional food ingredients for erectile dysfunction

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ABSTRACT

Purpose: Functional food ingredients are widely used for erectile dysfunction. We conducted 2 clinical studies to evaluate the safety and efficacy of a commercialized dietary supplement containing *Panax ginseng* C.A. Meyer extract, *Lepidium meyenii* root extract, yeast extract, egg white peptide, *Mucuna pruriens* extract, black ginger extract, polyphenol, L-arginine, L-carnitine, coenzyme Q₁₀, vitamin E, black pepper extract, and zinc.

Methods: In the first study, after providing informed consent, 15 healthy men (mean age, 35.3 ± 1.9 years) participated. A dietary supplement, EDiSON was administered for 8 weeks. Adverse events were recorded daily. In the second study, 14 men diagnosed with mild-to-moderate erectile dysfunction participated in an 8-week randomized, double-blind, placebo-controlled study. They were assigned to the dietary supplement group ($n = 8$) or the placebo group ($n = 6$). The primary outcome was the quality of life, as assessed by the International Index of Erectile Function-5 (IIEF-5) questionnaire.

Results: All patients completed the studies. In the first study, the intake of the dietary supplement was not associated with any adverse events. In the second study, the intake of the supplement was associated with significant improvement of the IIEF-5 score at 4 weeks and at 8 weeks of the trial, compared to the baseline.

Conclusion: Our initial findings support the safety of the EDiSON dietary supplement. The results from the randomized, double blind, placebo-controlled trial support the use of the EDiSON dietary supplement for the treatment of mild-to-moderate erectile dysfunction. This study was registered at <http://www.umin.ac.jp>, as UMIN000009405.

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1. Introduction

Sexual dysfunction and/or erectile dysfunction (ED) are major challenges for an individual's subjective well-being. In recent years, several studies report the benefits of functional food and herbal ingredients such as *Panax ginseng* C.A. Meyer and *Lepidium meyenii* in the treatment of ED [1,2].

Abbreviations: ED, erectile dysfunction; IIEF-5, International Index of Erectile Function-5.

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Panax ginseng C.A. Meyer is a commonly used herbal medicine that induces a variety of physiological and pharmacological effects [3]. It contains saponins called ginsenosides, which are the biologically active ingredients.

Lepidium meyenii (the maca plant) is an Andean plant in the brassica (i.e., mustard) family that has been used for centuries in the Andes as an adaptogenic plant to manage anemia, infertility, and female hormone balance [4]. The potential bioactive ingredients in maca include macaridine, macamides, macaene, gluosinolates, maca alkaloid, and maca nutrients.

Preliminary data show that ginseng and/or maca improves ED. An 8-week double-blind, placebo-controlled study showed that 143 patients with ED who received tissue-cultured mountain ginseng extract reported a significant improvement in the IIEF score [5]. A 12-week, double-blind, placebo-controlled, randomized trial

showed that men 21–56 years old who received maca reported improved sexual desire [6].

The polyamines and zinc have a role in promoting sperm motility, and they improve sperm parameters [7–9]. Oral supplementation of egg white peptide and L-arginine increases nitric oxide production [10–12]. *Mucuna pruriens* extract enhances sexual behavior and improves sperm parameters [13,14]. Black ginger extract improves ED by inhibiting phosphodiesterase type 5 [15]. Oral coenzyme Q₁₀ and L-carnitine supplementation improve sperm function [16,17]. ViNitrox, which contains grape and apple polyphenols, acts synergistically with L-arginine to increase the production of endothelium nitric oxide. Thus, ViNitrox has a vasodilating effect, thereby potentially contributing to improving or preventing ED. Vitamin E improves vascular endothelial function and may decrease the risk of vasculogenic ED [18]. Black pepper extract enhances the bioavailability of functional food ingredients [19]. The purpose of this study was to investigate the safety and efficacy of a commercialized dietary supplement for ED in Japanese individuals.

2. Methods

2.1. Study participants and study protocol

We conducted 2 clinical studies to evaluate the safety and efficacy of a dietary supplement containing *P. ginseng* C.A. Meyer extract, *L. meyenii* root extract, yeast extract (0.2% polyamine), egg white peptide, *M. pruriens* extract, black ginger extract, polyphenol (i.e., ViNitrox), L-arginine, L-carnitine, coenzyme Q₁₀, vitamin E (α -tocopherol), black pepper extract, and zinc.

Fifteen healthy men participated in the first study, after providing informed consent. They had a mean age of 35.3 ± 1.9 years. The dietary supplement was administered for 8 weeks. Adverse events were recorded daily. Blood pressure was measured daily, and body composition measurements were conducted with a bioelectric impedance analyzer.

In the second study, after providing informed consent, 14 men diagnosed with mild-to-moderate ED participated in an 8-week randomized, double-blind, placebo controlled study. They were assigned to the dietary supplement group ($n = 8$, mean age of 44.9 ± 3.8 years) or the placebo group ($n = 6$, mean age of 43.3 ± 5.5 years). The primary outcome was the quality of life (investigated by the International Index of Erectile Function-5 [IIEF-5] questionnaire), which was assessed at 0 weeks, 4 weeks, and 8 weeks of the trial. Adverse events were recorded daily. Blood pressure was measured and body composition measurements were conducted with a bioelectric impedance analyzer. Lab data were obtained for a comparison between the pre-intervention and post-intervention.

The treatment group ingested tablets of dietary supplements with their meals. The placebo group ingested placebo tablets without any active ingredients.

2.2. Study drug

A dietary supplement (EDiSON; DHC Corporation, Tokyo, Japan) was provided to the participants in tablet form. Six tablets contained 200 mg of *P. ginseng* C.A. Meyer extract, 250 mg *L. meyenii* root extract, 250 mg yeast extract (0.2% polyamine), 250 mg egg white peptide, 150 mg *M. pruriens* extract, 150 mg black ginger extract, 125 mg polyphenol (ViNitrox), 50 mg L-arginine, 50 mg L-carnitine fumarate, 30 mg coenzyme Q₁₀, 10 mg D- α -tocopherol, 10 mg black pepper extract, and 2.5 mg zinc. A placebo tablet was prepared without any active ingredients.

2.3. Statistical analysis

Values obtained after the 8-week supplementation period were compared to the baseline values by using the Wilcoxon *t* test. A *p* value of less than 0.05 was considered statistically significant.

3. Results

All 15 men completed the first study. The intake of the dietary supplement was not associated with any adverse events.

All 14 men completed the second study. The intake of the dietary supplement was associated with a significant improvement in the IIEF-5 score at 4 weeks and at 8 weeks of the trial, compared to the baseline. In the placebo group, there was no significant change during the 8-week study (Fig. 1).

The serum free testosterone level and the total testosterone level did not change in either group during the study (Fig. 2). One man in the dietary supplement group showed improvement in the IIEF-5 score and an increased level of serum free testosterone after the 8-week intervention (Fig. 3).

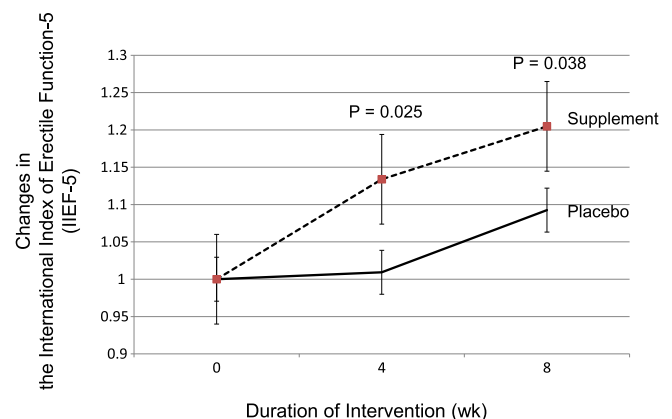
No adverse events were reported in either group. During the 8-week study, diagnostic serum examinations revealed no group differences for hepatic and renal functions or for metabolic measures such as serum albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, blood urea nitrogen, calcium, chloride, fasting blood glucose, potassium, sodium, total bilirubin, and total protein (data not shown).

4. Discussion

It is apparent that the pathogenesis of ED is most probably multifactorial. Factors to be considered as potential causes include peripheral atherosclerosis, neurogenic abnormalities, hormonal disturbances, mental/psychological disorders, and certain types of medications. Therefore, the treatment for ED needs to be initiated with an appropriate diagnosis of the underlying causes.

A variety of herbs, botanicals, and other functional foods have recently been widely used as ingredients in dietary supplements for treating ED or improving sexual function [1–4].

In this study, a commercialized dietary supplement containing several functional food ingredients was administered to patients



Footnote: Changes in the International Index of Erectile Function-5 (IIEF-5) scores in patients with mild to moderate erectile dysfunction. The *p* value in the graph represents the presupplementation to 4-week period or the presupplementation to 8-week period in the supplement group.

Fig. 1. Changes in the International Index of Erectile Function-5 scores.

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