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Complementary and alternative medicinal effects of broccoli sprouts powder on *Helicobacter pylori* eradication rate in type 2 diabetic patients: A randomized clinical trial



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ABSTRACT

The effectiveness of high-sulforaphane broccoli sprouts powder, as both complementary and alternative treatment, was compared to the standard triple therapy on *Helicobacter pylori* eradication in type 2 diabetic patients. Eighty-six type 2 diabetic patients with positive *H. pylori* stool antigen test (HpSAG) were randomized to receive one of the three following regimens: (STT) standard triple therapy, (BSP) 6 g/d broccoli sprouts powder for 28 days, and combination of these as STT + BSP. *H. pylori* eradication rates were assessed both by HpSAG and the urea breath test (UBT). Fasting serum glucose, insulin, insulin resistance, pepsinogen (PG) I and II levels and PGI/II ratio were also assessed. The *H. pylori* eradication rates, as assessed by UBT and HpSAG, were 85.3% and 89.3% in STT, 36.0% and 56.0% in BSP, and 83.3% and 91.7% in STT + BSP groups, respectively. There were no significant differences in serum pepsinogen I, pepsinogen II and PGI/PGII ratio and glucose homeostasis parameters between the three groups. BSP regimen despite a considerable effect on *H. pylori* eradication could not compete with the standard triple therapy.

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Abbreviations: ANCOVA, analysis of covariance; BMI, body mass index; BP, blood pressure; BSP, broccoli sprouts powder; EDTA, ethylenediaminetetraacetic acid; ELISA, enzyme-linked immunosorbent assay; HOMA-IR, homeostatic model assessment of insulin resistance; HpSAG, *H. pylori* stool antigen test; PGI, pepsinogen I; PGII, pepsinogen II; PPIs, proton pump inhibitors; SFN, sulforaphane; STT, standard triple therapy; UBT, urea breath test; WC, waist circumference

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1. Introduction

Helicobacter pylori infection is now considered a health problem worldwide and it is estimated that more than half of the world's populations are infected with this gram-negative, microaerophilic bacterium (Go, 2002; Noto & Peek, 2012). In addition to the complications including gastritis, ulcer disease, atrophic gastritis and gastric cancer that *H. pylori* infection could impose on the gastrointestinal system, it may induce extra-gastric manifestations and metabolic disorders including systemic inflammation, oxidative stress, insulin resistance, hypertension and cardiovascular disease (Aydemir et al., 2005; Gunji et al., 2008; Martínez Torres & Martínez Gaensly, 2002; Naito & Yoshikawa, 2002; Polyzos, Kountouras, Zavos, & Deretzi, 2011a). Recent studies report a bilateral relation between *H. pylori* infection and type 2 diabetes; besides an increased susceptibility of diabetic patients to *H. pylori* infection, this infection is proposed as a major contributing factor for the developing insulin resistance and type 2 diabetes (Zhou, Zhang, Wu, & Zhang, 2013). Diabetic patients are also more resistant to common treatments of *H. pylori* infection and the risk of re-infection in these patients is higher than the non-diabetic subjects (Ojetti et al., 2011). Studies show that *H. pylori* eradication could improve the effectiveness of diabetes care and prevent the development of various diabetic complications (Luis et al., 2008; Rossi, Quadri, & Cavallo Perin, 2004). However, choosing the ideal treatment for optimal *H. pylori* eradication, with high efficacy, and low risk of recurrent and side effects has remained a major challenge (Gasparetto, Pescarin, & Guariso, 2012); meanwhile, complementary and alternative medicine also have something new to say in this regard. To avoid the adverse effects of common antibiotics, studies have focused on the use of natural antibacterial agents including plant extracts, functional foods, phytochemicals and bioactive nutraceuticals as new complementary or even, alternative approaches for *H. pylori* eradication and modulation of some related disorders including systemic inflammation, oxidative stress and insulin resistance (Keenan, Salm, Hampton, & Wallace, 2010; Keenan, Salm, Wallace, & Hampton, 2012; Lee, Shin, & Hahm, 2008).

Broccoli sprouts and its bioactive component, sulforaphane (SFN; 1-isothiocyanate-4-methylsulphanylbutane), have recently been considered as interesting functional food and natural agent for treatment of *H. pylori* infection. Studies show that SFN has potent bactericidal properties against extra- and intracellular *H. pylori* and even antibiotic-resistant strains, as well as modulatory effects on gastritis and inflammation related status (Fahey et al., 2002; Haristoy, Angioi-Duprez, Duprez, & Lozniewski, 2003; Yanaka et al., 2009). Unfortunately, since these results were only obtained from *in vitro*- or some limited preliminary human studies; so it is not clear whether broccoli sprouts or SFN could compete with the common standard therapies for *H. pylori* eradication. The optimal dose and duration of the treatment with SFN also has not yet been determined.

Previously, we reported several favorable effects of broccoli sprouts in type 2 diabetic patients and introduced it as a useful supplement for management of diabetes and its complications

(Bahadoran et al., 2011; Bahadoran, Mirmiran, & Azizi, 2013; Bahadoran et al., 2012; Mirmiran, Bahadoran, Hosseinpanah, Keyzad, & Azizi, 2012). In this clinical trial we aim to investigate and compare the effects of both the complementary and alternative treatment using high SFN-broccoli sprouts powder to those of standard triple therapy (omeprazole + clarithromycin + amoxicillin) on the eradication of *H. pylori*, and also improvement of gastric inflammation and insulin resistance in type 2 diabetic patients.

2. Methods

2.1. Subjects and study design

This randomized clinical trial was conducted between April 2012 to January 2013. Men and women, aged 25–60 years, with a clinical diagnosis of type 2 diabetes for at least 1 year were recruited from the Iran Diabetes Society and the endocrine clinic of Taleghani Medical Center. The purpose, eligibility recruitments and protocol of the study were explained for the patients. Three hundred and sixty-two type 2 diabetic patients were assessed for eligibility, and potential participants were deemed ineligible if they had been treated in the past for *H. pylori*, consumed PPIs, H₂ receptor antagonists, bismuth compounds or antibiotics during the previous 4 weeks, had previous gastric surgery, had severe illness, gestation or lactation and if they used estrogen, vitamin K-antagonists or antioxidant supplements.

Informed written consents were obtained from all participants. Ethics approval for the trial was obtained from ethical committee of the Research Institute for Endocrine Sciences of the Shahid Beheshti University of Medical Sciences. The trial was registered with the following identification: IRCT 201111081640N6. The results are reported according to Consolidated Standards of Reporting Trials guidelines 2010.

2.2. Baseline *H. pylori* detection, randomization, and intervention

Stool samples were collected from all eligible patients ($n = 191$) for detection of *H. pylori* infection by stool antigen test (HpSag). Of 108 *H. pylori* positive patients, 86 patients were randomly allocated in equal proportions, to one of the three treatment groups: (A) STT ($n = 33$), standard triple therapy of omeprazole 20 mg, clarithromycin 500 mg, amoxicillin 1000 mg, twice a day for 14 days; (B) BSP ($n = 28$), 6 g/d broccoli sprouts powder for 28 days; (C) STT + BSP ($n = 25$), standard triple therapy for 14 days plus 6 g/d broccoli sprouts powder for 28 days. The *H. pylori* positive patients had no severe gastrointestinal complications and did not require to urgent classic treatment for the infection. After the intervention, all the patients in the BSP groups who remained *H. pylori* positive received standard triple therapy.

The investigator and participants were blinded to group allocation. Randomization was performed by stratification for HpSag levels, with the use of sealed envelopes for group allocation. Broccoli sprouts powder, was purchased from the Cyvex Nutrition Company (Irvine, CA, USA) and packaged. It

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