Efficacy of a Chinese Herbal Proprietary Medicine (Hemp Seed Pill) for Functional Constipation

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Abstract

Objectives: Functional constipation (FC) is a common clinical complaint. Despite a lack of consolidated evidence, Chinese herbal medicine (CHM) has become a popular alternative treatment for this condition. The aim of this study was to assess, with a rigidly designed study, the efficacy and safety of a CHM proprietary medicine, Hemp Seed Pill (HSP), in optimal dosage for treating FC.

Methods: This study comprised two parts: trial I, a dose determination study, and trial II, a placebo-controlled clinical study. In trial I, the optimal dosage of HSP was first determined from among three doses (2.5, 5.0, and 7.5 g b.i.d.). In trial II, a randomized double-blind study, the efficacy and safety of HSP for FC patients (Rome III criteria) in excessive syndrome as defined by traditional Chinese medicine (TCM) theory were compared with placebo. All participants in trials underwent a 2-week run-in, an 8-week treatment, and an 8-week follow-up. The primary end point was the responder rate for complete spontaneous bowel movement (CSBM) during treatment. Participants with a mean increase of CSBM $\geq$ 1/week compared with their baselines were defined as responders. Secondary outcome measures included responder rate during follow-up, individual and global symptom assessments, and reported adverse effects (AEs).

Results: The dose of 7.5 g b.i.d. showed better therapeutic effect than that of 2.5 and 5.0 g b.i.d. among 96 subjects (32 per arm) in trial I and was therefore selected for comparison with placebo in trial II. In trial II, 120 subjects were randomized into two arms (60 per arm). Responder rates for the HSP and placebo groups were 43.3 and 8.3 % during treatment and 30.0 and 15.0 % in the follow-up period, respectively ($P < 0.05$). Those in the HSP group showed benefit in terms of increased CSBM, relief in the severity of constipation and straining of evacuation, and effective reduction in the use of rescue therapy when compared with placebo. No serious AE was reported.

Conclusions: HSP (7.5 g b.i.d.) is safe and effective for alleviating FC for subjects in excessive syndrome. Optimal dose determination may be crucial for all CHM studies.