

MASTER'S THESIS

Chinese herbal medicine for functional constipation

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Date of Award:
2009

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Chinese Herbal Medicine for Functional Constipation

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**A thesis submitted in partial fulfillment of the
requirements for the degree of**

Master of Philosophy

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Hong Kong Baptist University

September 2009

ABSTRACT

Background and aims: Constipation is a common gastrointestinal complaint in clinical practice, affecting an estimated up to 27% of general population. Many patients are disappointed in current conventional treatments and, therefore, seek help from complementary and alternative medicine (CAM). Traditional Chinese medicine (TCM) has thus become a popular choice. However, the efficacy and safety of available Chinese herbal medicine (CHM), including those for functional constipation (FC), are not well validated. In this project, the action of an ancient formula, MaZiRenWan (MZRW), on FC was investigated by conducting a randomized clinical controlled trial and the possible correlation between TCM Syndromes and Diseases of Western Medicine (WM) would be discussed.

Methods: First, the efficacy and safety of CHM for the treatment of FC was systematically reviewed by reading all currently available randomized controlled trials (RCTs) in new Cochrane approach. Second, a clinical trial was conducted to determine the optimal dosage of MZRW for the treatment of FC from three different dosages (2.5g bid, 5.0g bid or 7.5g bid). Third, the efficacy and safety of MZRW in optimal dose was determined in a randomized, double-blind, placebo controlled trial. Finally, the potential correlation between deficient and excessive constipation, and FC subtypes was determined on the basis of the results from colonic transit study and anorectal manometry.

Results: From the systematic review, CHM interventions or CHM combined treatments showed a benefit for the treatment of FC when compared with cisapride, PEG, mosapride,

phenolphthalein, itopride and bifidobacterium alone, but not when compared with massage. However, definite clinical recommendation could not be made from available RCTs on CHM with significant methodological flaws and lack of replicable validation. Secondly, in the dose determination study, the high dose (7.5g bid) of MZRW presented a better therapeutic effect but without significant increment of reported adverse effects than the recommendation dose (5.0g bid) and the low dose (2.5g bid). Third, in the efficacy and safety study, MZRW (7.5g bid) increased bowel movements, relieved the severity of constipation and straining of evacuation, and effectively reduced the use of rescue therapy when compared with placebo during treatment; however, further investigation was necessary to confirm its sustainable effects. In the pilot study about the correlation between TCM Syndromes with FC, patients with deficient constipation tended to have weaker voluntary contraction, to present with lower anal pressure during squeezing and lower intrarectal pressure together with a paradoxical increase in anal pressure during defecation. On the contrary, a relatively higher threshold volume for the urge to defecate and higher proportion to have slow colonic transit were noted for patients with excessive constipation.

Conclusion: MZRW (7.5g bid) is effective for the treatment of FC when compared with placebo, but the correlation between TCM Syndrome and WM Disease among FC patients is not well elucidated. The success of the present study suggests that the clinical trial protocol proposed here may be useful for other CHM. That is, first, doing a systematic review on a specific clinical question; then a dose determination study should be performed, followed by an RCT when studying the efficacy and safety of CHM intervention.

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