11. Diseases of the Digestive Syestem

Reference

Kim YM, Park YC, Jo JH, et al. Effect of herb medicine treatment for functional dyspepsia: a randomized placebo-controlled and compared standard treatment trial. *Daehan-Hanbang-Naegwa-Hakhoeji* (*Korean Journal of Oriental Internal Medicine*) 2010; 31(1): 1–13 (in Korean with English abstract).

1. Objectives

To evaluate the effectiveness of herb medicine (DA-9701) for functional dyspepsia.

2. Design

Randomized controlled trial (RCT).

3. Setting

One Oriental hospital (Daejeon Oriental Hospital), Republic of Korea.

4. Participants

Functional dyspepsia patients (n=42; male/female=9/33).

5. Intervention

Three times a day, one tablet each time, for 2 weeks.

Arm 1: Herb medicine (DA-9701) treatment group. Herb medicine is composed of Sinapis Semen (白芥子) 100 mg, Corydalidis Tuber (玄胡索) 200 mg, Pharbitidis Semen (牽牛子) 200 mg, microcrystalline cellulose, lactose, starch 100 mg, a yellowish brown colored rectangular tablet.

Arm 2: Standard drug (Mosapride) treatment group. Mosapride citrate 5 mg, a gray colored rectangular tablet.

Arm 3: Placebo control group. Microcrystalline cellulose, lactose, starch 600 mg, a gray colored rectangular tablet.

6. Main outcome measures

Nepean Dyspepsia Index (NDI), Functional Dyspepsia Quality of Life (QOL) score.

7. Main results

All treatments significantly improved functional dyspepsia symptoms evaluated by comparing the Nepean Dyspepdia index and functional dyspepsia QOL score before and after treatment within each group (DA-9701, $P<0.05$; Mosapride, $P<0.01$; placebo, $P<0.001$), but there were no statistically significant differences in these measures among the three groups.

8. Conclusions

Herb medicine (DA-9701) improves the symptoms and QOL of patients with functional dyspepsia.

9. Safety assessment in the article

Not mentioned.

10. Abstractor's comments

This randomized, controlled trial evaluated the effect of herb medicine (DA-9701) on functional dyspepsia. The herb medicine (DA-9701) treatment significantly improved NDI and QOL scores, but there were no significant differences in these scores between Arm 2 and Arm 3. Because of its limitations (single-blinded randomization, inappropriate inclusion and exclusion criteria, lack of an equivalence and non-inferiority trial design), this study should be considered a pilot study.

11. Abstractor and date

Kim JS, 12 July 2010.