10. Respiratory Diseases

Reference

Hamada H, Sekikawa K, Murakami I, et al. Effects of Hochuekkito combined with pulmonary rehabilitation in patients with COPD. *Experimental and Therapeutic Medicine* 2018; 16: 5236-42. CENTRAL ID: CN-01788887, Pubmed ID: 30542479, UMIN ID: UMIN000015092

1. Objectives

To investigate the efficacy and safety of adding hochuekkito（補中益気湯）to pulmonary rehabilitation for patients with chronic obstructive pulmonary disease (COPD).

2. Design

Randomized controlled trial (RCT).

3. Setting

One university and five hospitals, Japan.

4. Participants

Moderate to severe COPD (defined by forced expiratory volume in 1 sec/forced vital capacity [FEV1/FVC] <70% and FEV1% predicted to be >30% and <80%), predicted percent of ideal body weight (%IBW) less than 100%, clinically stable disease and able to participate in pulmonary rehabilitation (PR) for 12 weeks, 40 years or older; and smoking history of more than 10 pack-years. Patients were excluded if they had any of the following: i) undergone PR within 24 weeks preceding the study; ii) a diagnosis of other pulmonary diseases or alpha1-antitrypsin deficiency; iii) diagnosis of an acute exacerbation within 4 weeks preceding the study; iv) received pulmonary transplantation; v) received herbal medicine for any problem within 4 weeks preceding the study; vi) had newly received bronchodilators or inhaled or systemic corticosteroids within 2 weeks before the study; vii) a diagnosis of other severe diseases, such as malignant tumors, autoimmune disease, liver disease, renal disease, heart disease, hematologic disease, and metabolic disease; viii) engaged in another clinical trial within 4 weeks preceding the study; ix) signs of definite or possible pregnancy; or x) inability to participate in the present study as judged by the physician (n=35).

5. Intervention

Arm 1: TSUMURA Hochuekkito（補中益気湯）Extract Granules 2.5 g three times daily orally before or between meals and pulmonary rehabilitation for 12 weeks (n=18).

Arm 2: Pulmonary rehabilitation without Hochuekkito for 12 weeks (n=17).

6. Main outcome measures

The primary endpoint was the change in the 6-minute walk distance (6MWD). The secondary endpoints were change in body weight, % ideal body weight, body mass index (BMI), modified Medical Research Council (mMRC) dyspnea scale score, visual analog scale (VAS) score for dyspnea, VAS for fatigue, COPD assessment test (CAT) score, and the number of acute exacerbations.

7. Main results

The analysis was conducted on 33 patients (18 patients in the hochuekkito group and 15 patients in the control group), after exclusion of 2 patients because of withdrawal. In both groups, the 6MWD showed no changes. Body weight (P<0.05), % ideal body weight (P<0.05), mMRC dyspnea scale score (P<0.05), VAS scores for dyspnea and fatigue (P<0.05, P<0.05), and CAT score (P<0.005) significantly improved in Arm 1, but not in Arm 2. In Arm 2, one patient experienced pneumonia requiring hospitalization, and two patients experienced acute exacerbations of COPD. In Arm 1, no patients had such an experience.

8. Conclusions

The addition of hochuekkito to pulmonary rehabilitation improved body weight, dyspnea scores, and health-related quality of life scores in patients with COPD.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse effects were noted with the use of hochuekkito.

11. Abstractor's comments

This study was conducted on a small number of patients, and the 6-minute walk distance showed no significant difference contrary to the authors' hypothesis. However, this study is important in that the hochuekkito group showed significant improvement in the general condition of COPD patients. It is desired that larger studies will follow this pilot study.

12. Abstractor and date

Koike H, 4 November 2019.