13. Diseases of the Musculoskeletal System and Connective Tissue

Reference

Kanai S. The effect of kami-kihi-to on the maintenance of bone mass in patients with osteoporosis. *Nihon Toyo Igaku Zasshi* (*Japanese Journal of Oriental Medicine*) 1998; 49: 59-66 (in Japanese with English abstract). CiNii

1. Objectives

To evaluate the effects of kamikihito (加味帰脾湯) on menopause index, bone mass, and anemia in postmenopausal women with osteoporosis.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Research Institute of Oriental Medicine, Kinki University, Japan.

4. Participants

Eighty-three women (aged 59–84 years) who visited the above institution, were diagnosed with osteoporosis according to the criteria for osteoporosis by the Ministry of Health and Welfare (currently the Ministry of Health, Labour, and Welfare), and had been followed for two years since 1993.

5. Intervention

Arm 1: oral administration of alfacalcidol (1 μg) once daily after breakfast and zaltoprofen 80 mg t.i.d. after meals.

Arm 2: oral administration of kamikihito (加味帰脾湯) (manufacturer, not specified) 2.5 g t.i.d. after meals and zaltoprofen 80 mg t.i.d. after meals.

Arm 3: oral administration of zaltoprofen 80 mg t.i.d. after meals.

All treatments were administered for 2 years.

6. Main outcome measures

Bone density measured by Computed X-ray Densitometry (CXD), cytometry, and efficacy based on Simplified Menopausal Index (SMI) score before treatment and at 1 and 2 years after the start of treatment.

7. Main results

As compared with bone mass in arm 1, bone mass in arm 2 and arm 3 increased significantly after 1 year of treatment ($P<0.05$). However, after 2 years, bone mass was further increased in arm 1, but remained stable in arm 2. Red blood cell and reticulocyte counts increased significantly after 1 year in arm 2 compared with arm 3 ($P<0.05$), but their increases were stabilized after 2 years. SMI decreased significantly after 1 year in arm 2, as compared with arms 1 and 3 ($P<0.05$). A weak but significant positive correlation between changes in bone mass and SMI was observed ($P<0.05$). In patients with increased bone mass and treated with kamikihito, compared with patients with decreased bone mass, SMI decreased and anemia improved.

8. Conclusions

Treatment of osteoporosis with kamikihito in women is clinically effective in increasing bone mass, as well as in improving anemia and decreasing SMI.

9. From Kampo medicine perspective

Kampo prescription was not based on *sho* (証, pattern). Kamikihito seemed to exert its effects by improving general physical status which resulted in increased energy in individual patients, and subsequent increase in bone density.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

Kamikihito has been conventionally prescribed for nonspecific climacteric symptoms or for improving anemia and its effects are also apparent in the present study. Its bone density-increasing effect appears to be about half of that of vitamin D. However, clinical application of kamikihito for osteoporosis in postmenopausal women is strongly expected. According to a number of osteoporosis-related studies, the effect of vitamin D varies greatly among individuals. It is currently understood that vitamin D preserves but does not increase bone mass. Therefore a multidrug approach with kamikihito would be more desirable for the therapy of osteoporosis. A case series study examining the combined therapy with western medicines is expected.

12. Abstractor and date

Ushiroyama T, 20 August 2008, 6 January 2010, 1 June 2010, 31 December 2013.