13. Diseases of the Musculoskeletal System and Connective Tissue

Reference

Matsuura M. Efficacy of saireito in the management of chronic rheumatoid arthritis (RA)*. *Modern Physician* 1994; 14: 403–8 (in Japanese). Ichushi Web ID: 1994187959

1. Objectives

To evaluate the efficacy of saireito (柴苓湯) in the management of chronic rheumatoid arthritis in a controlled trial using lobenzarit, a western medicine with the established efficacy, as control.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Six facilities including the Department for Rheumatic Diseases, Tokyo Metropolitan Fuchu General Hospital, Japan.

4. Participants

Forty-nine patients (12 males and 37 females) seen at the above facilities and diagnosed with chronic rheumatoid arthritis.

5. Intervention

Arm 1: TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d. before meals for 16 weeks (n=24).
Arm 2: lobenzarit 80 mg t.i.d. after meals for 16 weeks (n=25).

6. Main outcome measures

Clinical usefulness taking into account improvement in clinical symptoms and incidence of adverse drug reactions after 16 weeks of treatment.

7. Main results

Symptoms were improved in 7 of 18 patients (38.9%) and 3 of 20 patients (15.0%) receiving saireito and lobenzarit, respectively, although there was no significant difference between treatments. Clinical usefulness was noted in 7 of 18 patients (38.9%) and 4 of 21 patients (19.1%) receiving saireito and lobenzarit, respectively, showing that saireito was clinically useful in a significantly larger proportion of patients ($P<0.05$).

8. Conclusions

Saireito seems to be useful for the management of systemic symptoms of chronic rheumatoid arthritis, and is associated with comparable or higher global improvement and significantly fewer adverse drugs reactions compared with lobenzarit, a western medicine with established efficacy.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse reactions including laboratory abnormalities occurred in 13.0% and 36.0% of patients receiving saireito and lobenzarit, respectively. Adverse reactions to saireito included renal impairment (in 2 of 3 cases), and those to lobenzarit included gastrointestinal disorders (in 4 of 9 cases).

11. Abstractor's comments

The use of a positive control in this trial helped establish the clinical usefulness of saireito for chronic rheumatoid arthritis. However, no objective measures were used. Efficacy was based on global symptom improvement (measured by interview) and on development of adverse reactions. A prospective confirmatory study incorporating changes in biomarkers, imaging findings, and laboratory data is desired.

12. Abstractor and date

Ushiroyama T, 13 August 2008, 1 June 2010, 31 December 2013.