3. Blood Diseases including Anaemia

Reference

Akase T, Akase T, Onodera S, et al. A comparative study of the usefulness of tokishakuyakusan and an oral iron preparation in the treatment of hypochromic anemia in cases of uterine myoma. *Yakugaku Zasshi* (*Journal of the Pharmaceutical Society of Japan*) 2003; 123: 817-24. CENTRAL ID: CN-00457950, Pubmed ID: 14513774, Ichushi Web ID: 2004068366 J-STAGE

1. Objectives

To evaluate the efficacy and safety of tokishakuyakusan (当帰芍薬散) for hypochromic anemia in patients with uterine myoma.

2. Design

Randomized controlled trial (RCT).

3. Setting

A university hospital (Outpatient Department of Obstetrics and Gynecology, Kitasato University Hospital), Japan.

4. Participants

Twenty-three patients having hypochromic anemia associated with uterine myoma visiting the above institution between August 1999 and the end of January 2000. Mean age: 45.4±1.99 years in the tokishakuyakusan group; 42.9 ± 1.68 years in the oral iron preparation group. Range of blood hemoglobin concentration: 8 – 12 g/dL.

5. Intervention

Arm 1: oral administration of a sachet of TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules (2.5 g) t.i.d. (before meals) for 3 months.

Arm 2: oral administration of a tablet containing sodium ferrous citrate (50 mg) q.d or b.i.d. (after meals) for 3 months.

6. Main outcome measures

Laboratory: hematology (RBC, hemoglobin, hematocrit, etc.), blood chemistry (serum iron, ferritin concentration, etc.), blood coagulation function (PT, APTT), evaluated at baseline, and 4 and 8 weeks.after dosing. Improvement in subjective symptoms, including pallor, dizziness on standing up, and dizziness/vertigo, evaluated on a 5-point scale at baseline, and 4 and 8 weeks after dosing. Adverse drug reactions (ADRs): incidences of heartburn, nausea/vomiting, diarrhea, etc. during 8-week administration.

7. Main results

Although there was no between-group difference in blood profile, subjective symptoms such as cold, pallor, spoon nail, and dizziness/vertigo were significantly improved with tokishakuyakusan (P<0.05). In particular, cold was improved significantly efficiently in the tokishakuyakusan group (score at 8 weeks: 0.3±0.2 for tokishakuyakusan, 2.0±0.6 for oral iron; P<0.05). ADRs occurred in 80% of patients receiving the oral iron preparation (heartburn and nausea noted with the highest incidences of 46.7% each) but in no patients receiving tokishakuyakusan.

8. Conclusions

Three-month treatment with tokishakuyakusan is more effective in improving subjective symptoms and is safer than an oral iron preparation for mild to moderate anemia in women with uterine myoma.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

ADRs occurred in none of 10 patients receiving tokishakuyakusan, while in 12 (80%) of 15 patients receiving the oral iron preparation.

11. Abstractor's comments

If clinicians designed a noninvasive antianemic treatment plan for the present study population, i.e., patients with anemia (defined as blood hemoglobin concentration, 8–12 g/dL) and uterine myoma, the oral iron preparation would be the treatment of choice. However, in the present study, tokishakuyakusan had higher efficacy for subjective symptom improvement. In addition, tokishakuyakusan was clinically more efficacious and safer (i.e., had no ADRs). However, since tokishakuyakusan (unlike the oral iron preparation) did not improve the blood profile, a combination of these drugs might be more efficacious. A new research protocol to investigate the efficacy of Kampo formulations combined with oral iron to reduce the severity of anemia is expected in the future.

12. Abstractor and date

Ushiroyama T, 1 April 2008, 1 June 2010, 31 December 2013.