

4. Metabolism and Endocrine Diseases

Reference

Azuma M, Motomiya M, Toyota T. Effects of Seishin-renshi-in (TJ-111) on blood sugar levels of patients with non-insulin-dependent diabetes mellitus. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine)* 1994; 45: 339-44 (in Japanese with English abstract). [CiNii](#)

1. Objectives

To evaluate the efficacy and safety of seishinrenshiin (清心蓮子飲) in the treatment of glucose tolerance.

2. Design

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

3. Setting

One university hospital and three community hospitals, Japan.

4. Participants

Eighteen patients with non-insulin-dependent diabetes mellitus.

5. Intervention

Arm 1: TSUMURA Seishinrenshiin (清心蓮子飲) Extract Granules 2.5 g t.i.d. for 2 weeks (n=12; male:female = 8:4).

Arm 2: no treatment (n=6; all males).

Patients were allowed to continue only an antidiabetic agent that had been taken at baseline.

6. Main outcome measures

Blood tests: HbA1, HbA1c, diurnal variation in blood glucose (once a week), fasting blood glucose (every other day), and other common blood tests.

Severity was classified into 3 grades based on HbA1 level. Efficacy was assessed in 5 grades based on blood glucose level.

Subjective symptoms: thirst, pollakiuria, pain in arms/legs, numbness in arms/legs, blurred vision, dizziness/orthostatic dizziness, heaviness of the head, and general malaise.

7. Main results

There was a significant difference between groups in glucose tolerance. In arm 1, four patients had improvement, four had mild improvement, and four had no improvement, while, in arm 2, no patient had improvement.

8. Conclusions

Seishinrenshiin is an effective and safe treatment for glucose tolerance.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No patient in the seishinrenshiin arm had adverse reactions. Although one in seishinrenshiin arm had increased dizziness, orthostatic dizziness, and heaviness of head (symptoms that had been observed before treatment), their direct association with seishinrenshiin was not clear. In addition, one had mild increase in total cholesterol and triglyceride, and another had mild increase in BUN and creatinine, but the association of these events with seishinrenshiin was uncertain.

11. Abstractor's comments

This meaningful article describes the efficacy and safety of seishinrenshiin in treating glucose tolerance. However, the problems of this study are the short duration of treatment as well as allocation bias, that is, all members of the no treatment group were male and there were between-group differences in diabetic history and treatment at baseline. So the reliability of the assessment should be considered. Recently, treatment of metabolic abnormalities such as metabolic syndrome has received attention. Further evaluation of the effectiveness of seishinrenshiin in improving glucose tolerance is expected.

12. Abstractor and date

Namiki T, 29 December 2008, 6 January 2010.