14. Genitourinary Tract Disorders (including Climacteric Disorders)

Reference

Yoshikawa N, Ito H, Takekoshi Y, et al. Standard versus long-term prednisolone with sairei-to for initial therapy in childhood steroid-responsive nephrotic syndrome: A prospective controlled study. *Nihon Jinzo Gakkaishi* (*The Japanese Journal of Nephrology*) 1998; 40: 587-90 (in Japanese with English abstract). CENTRAL ID: CN-00158912, Pubmed ID: 9893457, Ichushi Web ID: 1999105890

1. Objectives

To evaluate the efficacy of initial steroid therapy with saireito (柴苓湯) for preventing relapse in childhood steroid-responsive nephrotic syndrome.

2. Design

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

3. Setting

Departments of Health Science of Kobe University School of Medicine, Department of Pediatrics of Hokkaido University, Department of Pediatrics of Keio University School of Medicine, and others (a total of 35 institutions), Japan.

4. Participants

Two hundred and twenty-one patients diagnosed with childhood-onset minimal change nephrotic syndrome based on clinical features, and not manifesting persistent hematuria, renal dysfunction, and hypertension at onset.

5. Intervention

Arm 1: prednisolone 2 mg/kg/day in three divided doses for 4 weeks followed by prednisolone 1.3 mg/kg every other day for 4 weeks (n=109).

Arm 2: prednisolone 2 mg/kg/day in three divided doses for 4 weeks followed by prednisolone 2 mg/kg every other day for 8 weeks, 1.5 mg/kg every other day for 2 weeks, 1 mg/kg every other day for 2 weeks, and 0.5 mg/kg every other day for 2 weeks (n=112).

Kanebo Saireito (柴苓湯) Extract Fine Granules were administered in doses of 2.7 g t.i.d. (in all patients weighing ≥40 kg), 2.7 g b.i.d. (in all patients weighing 20–40 kg), or 1.35 g b.i.d. (in all patients weighing ≤20 kg).

6. Main outcome measures

The rates of relapse and frequent relapse.

7. Main results

Eighty-eight of 109 patients in arm 1 and 83 of 112 in arm 2 with steroid-responsive nephrosis were followed for 2 years. There were no between-arm differences in the rate of relapse and rate of frequent relapse (70% *vs.* 65% and 21% *vs.* 24%, respectively).

8. Conclusions

The duration of the initial steroid therapy with saireito for childhood steroid-responsive nephrotic syndrome has no effect on relapse rate.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse effects included mild liver dysfunction in 1 patient treated with steroid for 8 weeks, and allergic cystitis in 1 patient treated with steroid for 18 weeks. Both effects were reversed with drug withdrawal.

11. Abstractor's comments

Although in Japan randomization by the RCT-envelope method tends not to be maintained, in the present study, the relapse rates did not differ between 8-week and 18-week treatments with steroid and saireito. As the authors mentioned, the rate of frequent relapse is lower in their study (21% in arm 1) than in other reports examining a short-term steroid treatment similar to that used in arm 1 (35–40%). Comparison with a treatment without saireito may be needed to confirm this observation. A randomized controlled trial using other methods of random allocation is also expected.

12. Abstractor and date

Okabe T, 25 August 2008, 1 June 2010.