#### **Evidence Reports of Kampo Treatment**

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

# 14. Genitourinary Tract Disorders (including Climacteric Disorders)

#### Reference

Saruta T, Konishi K. Efficacy of Kampo medicines for renal diseases - with emphasis on saireito -\*. 21 Seiki no Iryo to Kampo (The 21st Century Medicine and Kampo) 1994: 157–65 (in Japanese).

## 1. Objectives

To evaluate the efficacy and safety of saireito (柴苓湯) for IgA nephropathy in adults.

## 2. Design

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

## 3. Setting

Department of Internal Medicine, Keio University School of Medicine and related facilities, Japan.

### 4. Participants

Forty-four patients with IgA nephropathy, aged  $\geq$  16 years.

#### 5. Intervention

Arm 1: saireito (柴苓湯) (manufacturer not specified) 3 g t.i.d. for 24 weeks (n=22).

Arm 2: dilazep hydrochloride 100 mg t.i.d. for 24 weeks (n=22).

#### 6. Main outcome measures

Urinary protein excretion, RBC count in urinary sediment, and creatinine clearance.

## 7. Main results

The mean urinary protein excretion for the analysis population of arm 1 (13 patients) was significantly decreased from  $2.1\pm0.4$  g/day at baseline to  $1.5\pm0.3$  g/day at 24 weeks after administration (P<0.01) but not for the analysis population of arm 2 (12 patients;  $2.2\pm0.7$  g/day at baseline and  $1.9\pm0.4$  g/day at 24 weeks). There were no significant changes in serum albumin concentration, cholesterol level, or creatinine clearance.

## 8. Conclusions

Saireito decreases urinary protein excretion in adult patients with IgA nephropathy.

# 9. From Kampo medicine perspective

None.

# 10. Safety assessment in the article

There were no adverse reactions in either arm.

## 11. Abstractor's comments

Although using sealed envelopes for allocation is likely to have compromised randomization, this study suggested that saireito decreases urinary protein excretion in adult patients with IgA nephropathy. A future randomized controlled trial should be performed with larger sample size and improved allocation.

#### 12. Abstractor and date

Okabe T, 25 August 2008, 1 June 2010, 31 December 2013.