

**14. Genitourinary Tract Disorders (including Climacteric Disorders)****References**

Toba K. Role in host defense mechanisms and effect on prognosis of urinary tract infections in elderly subjects: A trial of a Chinese drug formulation. *Taisha (Metabolism and Disease)* 1992; 29 suppl: 350–4 (in Japanese).

**Toba K. Role in host defense mechanisms and effect on the prognosis of urinary tract infections in elderly subjects: A trial of a Chinese drug formulation\*. *Dai 8 Kai Tokyo Naika Kampo Kenkyukai Koen Naiyo Shu (Proceedings of the 8th Meeting of the Tokyo Society for Internal Kampo Medicine)* 1993; 8: 31–42 (in Japanese).**

**1. Objectives**

To evaluate the efficacy of shosaikoto (小柴胡湯) for improving immunity in the elderly.

**2. Design**

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

**3. Setting**

One university hospital (Department of Geriatric Medicine, Faculty of Medicine, University of Tokyo), Japan.

**4. Participants**

Seventeen outpatients without urinary tract infection and 14 inpatients with urinary tract infection.

**5. Intervention**

Arm 1: shosaikoto (小柴胡湯) (manufacturer not specified) for at least 3 months, outpatients without urinary tract infection (n=9).

Arm 2: no administration, outpatients without urinary tract infection (n=8).

Arm 3: shosaikoto (小柴胡湯) (manufacturer not specified) for at least 3 months, inpatients with urinary tract infection (n=10).

Arm 4: no administration, inpatients with urinary tract infection (n=4).

**6. Main outcome measures**

Neutrophil function, lymphocyte function, nutritional index, and infection index.

**7. Main results**

In arm 1, significant increases from baseline were noted in neutrophil superoxide generation at 1 month post-dose ( $P<0.05$ ), complement at 3 months post-dose ( $P<0.01$ ), [3H]-thymidine incorporation of phytohemagglutinin (PHA)-induced lymphocytes at 3 months post-dose ( $P<0.01$ ), interleukin-2 production ( $P<0.05$ ), serum  $\gamma$ -globulin, IgA ( $P<0.01$ ), and IgG ( $P<0.05$ ). In arm 3, none of the following variables were increased from baseline after shosaikoto administration: neutrophil superoxide generation, complement, [3H]-thymidine incorporation of PHA-induced lymphocytes, interleukin-2 production, and  $\gamma$ -globulin, and the urinary bacterial culture findings were similar before and after shosaikoto administration. In arm 1 and arm 2, none of the nutritional indices (serum total protein, albumin, cholinesterase, total cholesterol) were significantly increased.

**8. Conclusions**

Shosaikoto partially improves immunity in elderly individuals without urinary tract infection.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

There were no adverse reactions.

**11. Abstractor's comments**

Although using sealed envelopes for allocation is likely to have compromised randomization, this study concluded that shosaikoto partially improves immunity in elderly subjects without urinary tract infection but not in those with urinary tract infection. It was also suggested that shosaikoto does not improve nutritional status. As pointed out by the author, inpatients with urinary tract infection have poor nutritional status (i.e., decreased serum albumin), which is unresponsive to shosaikoto treatment. This may be an indication for *hozai* (補劑, formulations with tonic effects) using the *zuisho* (隨証, based on pattern) approach.

**12. Abstractor and date**

Okabe T, 26 August 2008, 1 June 2010, 31 December 2013.