1. Infections (including Viral Hepatitis)

Reference

Hatakeyama S, Ueki J, Ishizuka M, et al. Comparative study of ursodeoxycholic acid and Shosaikoto as treatment for chronic liver diseases type C. *Yakuri to Chiryo* (*Japanese Pharmacology & Therapeutics*) 1994; 22: 3295-305 (in Japanese). Ichushi Web ID: 1995069962

1. Objectives

To evaluate the efficacy and safety of shosaikoto (小柴胡湯) for type C chronic liver diseases.

2. Design

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

3. Setting

One general hospital, Japan.

4. Participants

A total of 55 patients (27 with chronic hepatitis C [CH] and 28 with type C compensated liver cirrhosis [cLC]).

5. Intervention

Arm 1: treatment with ursodeoxycholic acid (UDCA) 200 mg t.i.d. for 6 months (n=26).
Arm 2: treatment with TSUMURA Shosaikoto (小柴胡湯) Extract Granules 2.5 g t.i.d. orally before meals for 6 months (n=29).

6. Main outcome measures

Liver functions and serum bile acid fractions.

7. Main results

Three UDCA-treated and 2 shosaikoto-treated patients withdrew from the study. The percent decrease in GOT and GPT at 6 months was significantly greater in arm 1 than in arm 2 for both CH and cLC patients. γ-GTP and γ-globulin also decreased significantly more in arm 1 than in arm 2. Albumin increased significantly more in arm 1 than in arm 2. The glycine-conjugated UDCA fraction increased significantly while the glycine-conjugated cholic acid (CA) and chenodeoxycholic acid (CDCA) fractions decreased significantly in arm 1. There were no variations in serum bile acid level in arm 2.

8. Conclusions

The efficacy of shosaikoto for type C chronic liver diseases is not clear, and UDCA is more effective than shosaikoto.

9. From Kampo medicine perspective

Not specifically mentioned. The authors commented that UDCA might be a better choice when *sho* (証, pattern) is not a consideration.

10. Safety assessment in the article

One UDCA-treated patient developed pruritus and withdrew from the study. Two shosaikoto-treated patients withdrew due to abnormally high levels of GPT.

11. Abstractor's comments

The authors of this study deserve praise for conducting an RCT using UDCA as a control. Longer-term follow-up and inclusion of virological examination results would enhance the clinical significance of this study.

12. Abstractor and date

Kogure T, 8 August 2008, 1 June 2010.