1. Infections (including Viral Hepatitis)

Reference

Sato S, Ishikawa K, Chiba T. Efficacy of sho-saiko-to on chronic type B hepatitis. *Shokakika* (*Gastroenterology*) 1991; 15: 39–49 (in Japanese).

1. Objectives

To evaluate the efficacy of shosaikoto (小柴胡湯) in the treatment of chronic hepatitis B.

2. Design

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

3. Setting

Six university hospitals and 15 general hospitals, Japan.

4. Participants

Forty-four patients who met the following criteria: liver biopsy within a year of symptom onset, in principle; Hepatitis (H)Be antigen-positive; abnormal baseline glutamic-pyruvic transaminase (GPT) requiring treatment. However, those who received any immunostimulant agent such as antiviral agents (IFN, Ara-A, etc.) within 12 weeks of recruitment were excluded.

5. Intervention

Arm 1: TSUMURA Shosaikoto (小柴胡湯) Extract Granules at a dose of 7.5 g/day for 24 weeks (n=28).
Arm 2: common hepatoprotective agents (Proheparum, etc.) for 24 weeks (n=16).

6. Main outcome measures

HBe antigen/anti-HBe antibody and GPT were continuously monitored and rated on a 6-grade scale: seroconversion (SC), seronegative (SN), decreased antigen titer, unchanged antigen titer, increased antigen titer, and substantially worsened antigen titer.

7. Main results

Decrease in the HBe antigen titer was not significantly different between the two groups at Week 24. The anti-HBe antibody titer was significantly higher in arm 1 than in arm 2 at Weeks 4 ($P<0.05$) and 24 ($P<0.01$). GPT was not significantly different between the two groups at Week 24 or 48. A comparison of the percentage of patients with unchanged or higher HBe antigen titer and the percentage of patients with decreased HBe antigen titer between the two groups revealed a tendency for HBe antigen titer to decrease in arm 1 at Week 24 ($P<0.1$) but revealed no significant between-group difference at Week 48.

8. Conclusions

Compared to the hepatoprotective agents, shosaikoto tends to decrease HBe antigen titer and significantly increase anti-HBe antibody titer.

9. From Kampo medicine perspective

Nothing special.

10. Safety assessment in the article

Not evaluated.

11. Abstractor's comments

It is admirable that a multicenter RCT was conducted. However, the difference in the percentage of patients with SC or SN was not significant. Thus, caution should be used in prescribing this intervention.

12. Abstractor and date

Kogure T, 8 August, 2008, 1 June 2010, 31 December 2013.