## 11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

**Reference**

Tajiri H, Kozaiwa K, Sawada A, et al. Efficacy of shosaikoto for chronic non-A, non-B hepatitis in children (non-A, non-B hepatitis in children and shosaikoto)*. *Nihon Shoni Toyo Igaku Kenkyukai Kaishi*（*Journal of the Japan Pediatric Society for Oriental Medicine*）1996; 12: 12-7 (in Japanese).

**1. Objectives**

To evaluate the efficacy of shosaikoto (小柴胡湯) for chronic non-A, non-B hepatitis in children.

**2. Design**

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

**3. Setting**

One university hospital, Japan.

**4. Participants**

Patients were children with liver dysfunction persisting for at least 6 months and infected with viruses known to cause liver damage (hepatitis A virus [HAV], hepatitis B virus [HBV], cytomegalovirus [CMV], and Epstein-Barr virus [EBV]) were excluded. Six patients positive for hepatitis C virus (HCV) were included.

**5. Intervention**

Arm 1: treatment with TSUMURA Shosaikoto (小柴胡湯) Extract Granules 7.5 g/day (dose adjusted for age) for at least 6 months (n=5).
Arm 2: natural course monitoring group (n=5).
One patient who took shosaikoto (小柴胡湯) for more than 6 months following natural course monitoring for 6 months was enrolled in both arms 1 and 2.

**6. Main outcome measures**

Levels of glutamic-pyruvic transaminase (GPT), glutamic-oxaloacetic transaminase (GOT), serum neopterin, soluble interleukin-2 (IL-2) receptor, and HCV-RNA.

**7. Main results**

GPT and GOT levels were reduced significantly at 2, and 6 months in arm 1 ($P<0.05$). Serum neopterin was increased at 1 month in the 3 patients of arm 1 who had measurements. Soluble IL-2 receptor was also increased only at 1 month. One of the patients who showed reduction in GPT level remained positive for HCV-RNA.

**8. Conclusions**

Shosaikoto is effective for improving liver function in chronic non-A, non-B hepatitis, including chronic hepatitis C, in children.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

The present paper is valuable in that it analyzed the clinical effects of Kampo medicine on chronic hepatitis in children—who are rarely the focus of clinical trials. Unfortunately, the between-arm comparison was insufficient because of the small number of patients enrolled.

**12. Abstractor and date**

Kogure T, 8 August 2008, 6 January 2010, 31 December 2013.