1. Infections (including Viral Hepatitis)

**Reference**

1. **Objectives**
To confirm the efficacy of shosaikoto (小柴胡湯) for interferon-resistant chronic hepatitis C.

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

3. **Setting**
One university hospital and general hospitals, Japan.

4. **Participants**
One hundred patients with chronic active hepatitis C who completed interferon therapy.

5. **Intervention**
Arm 1: treatment with squalene 1500 mg/day. (n=33)
Arm 2: treatment with cepharanthine (1 mg/kg body weight per day). (n=33)
Arm 3: treatment with shosaikoto (小柴胡湯) 6.0 g/day. (n=34)
In all arms, study drugs were orally administered in three divided daily doses before meals for 5 years.

6. **Main outcome measures**
Levels of aspartate aminotransferase (AST), alanine aminotransferase (ALT), procollagen III peptide (PIIIP), type IV collagen, and hepatitis C virus (HCV)-RNA.

7. **Main results**
AST and ALT showed overall significant decreases, except for transient elevations after 6 and 30 months of treatment. Type IV collagen, PIIIP, and HCV-RNA also decreased significantly in all arms. No significant differences in these variables were observed among the three arms. AST and ALT were significantly decreased at 50 months in arm 3, but not in arms 1 and 2. Choline esterase (Ch-E) did not change in arm 3, but decreased significantly in arms 1 and 2. Type IV collagen and HCV-RNA decreased significantly in arm 3 and increased significantly in arms 1 and 2. Changes in PIIIP were similar to those of type IV collagen.

8. **Conclusions**
Shosaikoto is effective for the treatment of chronic hepatitis C and its efficacy is equivalent to that of squalene or cepharanthine.

9. **From Kampo medicine perspective**
One patient with “in-sho (陰証, yin pattern)” and “kyo-sho (虚証, deficiency pattern)” was excluded before the allocation, and the study was actually conducted in 99 patients.

10. **Safety assessment in the article**
None.

11. **Abstractor’s comments**
This study confirmed the efficacy of shosaikoto for the treatment of chronic hepatitis C.

12. **Abstractor and date**
Kogure T, 15 June 2007, 1 April 2008.