

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**Reference**

Okabayashi T, Mimura H, Orita K. Usefulness of Shosaikoto (TJ-9) in the treatment of postoperative liver dysfunction*. *Progress in Medicine* 1989; 9: 851-5 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of shosaikoto (小柴胡湯) in the treatment of postoperative liver dysfunction.

2. Design

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

3. Setting

One university hospital and 14 general hospitals, Japan.

4. Participants

Forty-six patients who had no hepatic dysfunction preoperatively and underwent surgery under general anesthesia for non-hepato-biliary-pancreatic disease, but developed liver dysfunction 2–8 weeks after surgery.

5. Intervention

Arm 1: TSUMURA Shosaikoto (小柴胡湯) Extract Granules 2.5 g t.i.d. (n=20).

Arm 2: Glycyron, a glycyrrhizin preparation, 3 tablets t.i.d. (n=26).

6. Main outcome measures

Improvements in subjective symptoms and liver function, global utility rating, and safety rating.

7. Main results

Subjective symptoms, liver function, and global utility ratings were improved in both arms, but without any significant between-arm differences in these improvements. Glutamic-oxaloacetic transaminase (GOT), glutamic-pyruvic transaminase (GPT), lactic dehydrogenase (LDH), alkaline phosphatase (ALP), γ -glutamyl transpeptidase (γ -GTP), and zinc sulfate turbidity test (ZTT) decreased in both arms but the between-arm differences were not significant. GOT, GPT, ALP, and γ -GTP tended to decrease slightly more rapidly in arm 1 than in arm 2. Abnormal total bilirubin (T-Bil) or blood urea nitrogen (BUN) was not noted postoperatively.

8. Conclusions

Shosaikoto is an effective and safe drug for the treatment of postoperative hepatic dysfunction and its efficacy is comparable to that of Glycyron.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse reactions were not observed in the shosaikoto-treated group.

11. Abstractor's comments

This paper is clinically highly significant in that the efficacy of shosaikoto for treating postoperative liver dysfunction was demonstrated in an RCT using Glycyron as a control. Safety was evaluated in a small number of patients (n=20) in this study. Further safety studies including larger number of patients are required.

12. Abstractor and date

Kogure T, 8 August 2008, 1 June 2010.