

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

Usuba A, Gao L. S., Motoki R. Effect of sho-saiko-to (xao-chai-hu-tang) on liver dysfunction after surgery - the benefits of preoperative administration and the importance of diagnosis according to traditional Chinese logic -. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine)* 1992; 43: 1–12 (in Japanese).

1. Objectives

To evaluate the efficacy of shosaikoto (小柴胡湯) for postoperative liver disorder.

2. Design

Randomized controlled trial (RCT).

3. Setting

Department of Surgery 1, Fukushima Medical University, Japan.

4. Participants

Sixty-six patients who underwent respiratory or gastrointestinal surgery.

5. Intervention

Arm 1: shosaikoto (小柴胡湯) (manufacturer not specified) at a dose of 5.0 g for 7–33 days before surgery (n=16).

Arm 2: shosaikoto (小柴胡湯) (manufacturer not specified) at a dose of 5.0 g for 8–45 days before surgery and 11–45 days after surgery (n=17).

Arm 3: no treatment (n=33).

6. Main outcome measures

General malaise, anorexia, performance status (PS), and blood biochemistry.

7. Main results

Two weeks after surgery (Week 2), the level of glutamic-pyruvic transaminase (GPT—a measure of hepatic function) was significantly decreased in arms 1 ($P<0.01$) and 2 ($P<0.01$) compared with arm 3 (53.6 ± 26.40 , 35.9 ± 16.95 , and 91.3 ± 61.84 IU/L in Arms 1, 2, and 3, respectively), and this significant decrease persisted at Weeks 4 and 6. Similar results were observed for glutamic-oxaloacetic transaminase (GOT) and γ -glutamyl transpeptidase (γ -GTP) levels. At Week 2, direct bilirubin was significantly increased to 0.80 ± 0.84 mg/dL in Arm 3, but not in Arms 1 (0.36 ± 0.24 mg/dL, $P<0.01$) or 2 (0.48 ± 0.44 mg/dL, $P<0.05$). In addition, improvement in general malaise, anorexia, and PS was greater in arms 1 and 2 than in arm 3.

8. Conclusions

Shosaikoto is effective in reducing postoperative liver disorder.

9. From Kampo medicine perspective

The efficacy of shosaikoto was evaluated according to preoperative *sho* (証, pattern).

10. Safety assessment in the article

No adverse reactions were reported.

11. Abstractor's comments

In this article, shosaikoto (even prophylactic shosaikoto) was effective for postoperative liver disorder. It seems difficult to associate the efficacy of shosaikoto with *shoko* (証候, manifestation patterns) because of the variety of surgical stresses and diversity of diseases in this trial. The efficacy of shosaikoto (as indicated by change in GOT level) did not appear to be related to *shoko*. Nonetheless, it is desirable to use simpler designs in future controlled trials.

12. Abstractor and date

Okabe T, 22 August, 2008, 1 June 2010, 31 December 2013.