

**3. Blood Diseases including Anaemia****Reference**

Hatano T. Mitigation of postoperative lymphopenia and protection of T cells by preoperative administration of xial-chai-hu-tang. *Saitama Ika Daigaku Zasshi (Journal of Saitama Medical School)* 1990; 17: 357–63 (in Japanese with English abstract).

**1. Objectives**

To evaluate the preventive effect of preoperative administration of shosaikoto (小柴胡湯) on postoperative lymphopenia in female patients.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One university hospital (Second Department of Surgery, Saitama Medical Center, Saitama Medical School), Japan.

**4. Participants**

Hundred and twenty-two postoperative female patients (breast cancer, 37; cholecystolithiasis, 65; gastric cancer, 20).

**5. Intervention**

Arm 1: preoperative administration of TSUMURA Shosaikoto (小柴胡湯) Extract Granules 2.5 g t.i.d. for a mean of 7.3 days in breast cancer patients, 5.4 days in cholecystolithiasis patients, and 9.0 days in gastric cancer patients (n=27: breast cancer, 9; cholecystolithiasis, 14; gastric cancer, 4).

Arm 2: no administration of Kampo medicines (n=95).

**6. Main outcome measures**

(1) Lymphocyte counts and subsets (OKT3, OKT4, OKT8, OKIA, and Leu 7).

These were measured before and after preoperative administration of shosaikoto and on 14 consecutive postoperative days.

(2) Assessment of the impact of surgery (blood loss, duration of surgery, anesthesia, postoperative stay, and complications).

**7. Main results**

(1) Lymphocyte counts: only the mean value was plotted on a line chart, standard deviation (error) was not shown. No significance test between arms was performed.

(2) Comparison of lymphocyte counts and subsets before and after preoperative administration of shosaikoto: in cholecystolithiasis patients, no significant differences between arms were observed.

(3) Lymphocyte subsets at 1 day after surgery (in cholecystolithiasis patients): OKT3 and OKT4 decreased significantly in arm 2, while no significant decrease was observed in arm 1. No significance test between arms was performed.

(4) Impact of surgery: blood loss, duration of surgery, anesthesia, and postoperative stay, and complications did not differ significantly between arms.

**8. Conclusions**

Preoperative administration of shosaikoto attenuates postoperative lymphopenia. This effect is supposed to be due to protection of the biomembranes of mature cells, especially helper/inducer T-cells.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

In the Method section, the authors noted that the number of peripheral blood lymphocytes and the number of lymphocyte subsets were sequentially measured beginning before surgery and ending on postoperative day 14. However, the available results do not include lymphocyte counts for postoperative days 8–13 and show only mean lymphocyte count at each measurement day without standard deviation (error). The tests might not have been performed for all patients included. Moreover, lymphocyte subsets in breast or gastric cancer patients are not provided. Since statistical tests between arms for disease-specific lymphocyte counts were not performed, it cannot be concluded that “preoperative administration of shosaikoto attenuated postoperative lymphopenia.” Besides, a clinical trial (like an animal study) should not collect blood postoperatively for 14 consecutive days to sequentially measure lymphocyte counts and subsets.

**12. Abstractor and date**

Hoshino E, 26 April 2009, 1 June 2010.