#### **Evidence Reports of Kampo Treatment**

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

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

#### Reference

Ikemoto T. The role of Kampo in gastrointestinal surgery and the effectiveness of daikenchuto (大建中湯) for intestinal stress - From bacterial translocation to microbiome\*. *Progress in Medicine* 2011; 31: 466-7 (in Japanese). MOL, MOL-Lib

### 1. Objectives

To verify the anti-inflammatory effects of daikenchuto (大建中湯) on intestinal distress in the aftermath of gastrointestinal surgery.

## 2. Design

Randomized controlled trial (RCT).

### 3. Setting

One center: Gastrointestinal and Transplant Department, Tokushima University Hospital, Japan.

### 4. Participants

Thirty-one patients who had either minimally invasive laparoscopic colon surgery or invasive hepatectomy.

## 5. Intervention

Arm 1: DKT group: oral administration of TSUMURA Daikenchuto (大建中湯) Extract Granules (2.5 g t.i.d.) before meals for 7 days beginning on the first day after surgery (n=15).

Arm 2: no daikenchuto (大建中湯) treatment (n=16).

#### 6. Main outcome measures

Body temperature, number of days till flatus, and blood C-reative protein (CRP) concentration monitored beginning on the first postoperative day.

#### 7. Main results

Body temperature was 36.2 °C in arm 1 and 36.9 °C in arm 2 on the third postoperative day. The number of days till flatus was significantly shorter in arm 1 (1.7  $\pm$  0.4) than in arm 2 (2.9  $\pm$  0.8) (P<0.05). Blood CRP concentration was significantly lower in arm 1 (5.1  $\pm$  2.3 mg/dL vs 7.7  $\pm$  4.7 mg/dL) (P<0.05).

#### 8. Conclusions

Daikenchuto is clearly effective in controlling the increase in body temperature after surgery, in shortening the number of days till flatus, and in controlling inflammation.

# 9. From Kampo medicine perspective

None.

## 10. Safety assessment in the article

Not mentioned.

### 11. Abstractor's comments

This study investigated the clinical efficacy of daikenchuto for reducing inflammation. The results are valuable because they help elucidate the mechanisms underlying well-known problems that develop following intestinal surgery. The paper refers to experiments in fasted rats showing that oral administration of daikenchuto maintains diversity in the intestinal microbiome (which is the collective genome of all intestinal microorganisms) and suggesting that the microbiome is relevant to expression of daikenchuto's anti-inflammatory effects. However, further research is needed before it is known whether these animal data are relevant to the mechanism of action in humans.

The paper deserves praise for investigating daikenchuto's mechanism of action from the perspective of enteric bacterial diversity. Hopefully the researchers will conduct further study with a more adequate number of participants, and use clinically applicable protocols.

## 12. Abstractor and date

Ushiroyama T, 31 December 2013.