11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Kubo N, Uchida Y, Akiyoshi T, et al. Efficacy of daikenchuto for ileus - a multicenter study -*. *Progress in Medicine* 1995; 15: 1962-7 (in Japanese). Ichushi Web ID: 1996096062

1. Objectives

To evaluate the efficacy and safety of daikenchuto (大建中湯) for ileus in a multicenter study.

2. Design

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

3. Setting

Fourteen institutions, centered around Oita Medical University Hospital, Japan.

4. Participants

Thirty patients who developed simple adhesive ileus postoperatively and were judged by the investigator to need long tube placement. (Exclusion criteria were serious disorders of the heart, lungs, liver, or bone marrow; serious complications; determination of ineligibility by the treating physician.)

5. Intervention

Arm 1: treatment with TSUMURA Daikenchuto (大建中湯) Extract Granules dissolved in lukewarm water (5 g/20 mL) and infused through a gastric tube, three times daily for at least 5 days (n=18).
Arm 2: no treatment with daikenchuto (n=12).

6. Main outcome measures

Subjective symptoms (abdominal pain, nausea and vomiting, diarrhea, general malaise, anorexia, and abdominal bloating), radiograph, time to defecation and passage of flatus, number of days to removal of the ileus tube (long tube), number of days to resumption of oral intake, and rate of progression to surgery, as well as improvements in ileus, abdominal findings, and subjective symptoms, general improvement rating, and usefulness assessed by the attending physician.

7. Main results

There were no significant between-arm differences in the time to defecation, passage of flatus, and removal of the ileus tube, radiographic changes, and the proportion of patients who required surgery. Improvements in abdominal bloating and nausea and vomiting were significantly greater in arm 1 than arm 2. The rate of ileus resolution assessed by the attending physician was 94.4% in arm 1 and 66.7% in arm 2.

8. Conclusions

Daikenchuto is a safe and useful drug for treating postoperative adhesive ileus.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse drug reactions occurred. The global safety rating was 94.4%.

11. Abstractor's comments

Similar to the preceding papers "Nagashima Y, Tanaka N, Furukawa K, et al. Effects of daikenchuto (TJ-100) on intestinal paralysis after surgery for colorectal cancer*. *Progress in Medicine* 1998; 18: 903-5 (in Japanese)" and "Ohyabu H, Matsuda S, Kurisu S, et al. Evaluation of daikenchuto in patients with adhesive ileus in a randomized trial*. *Progress in Medicine* 1995; 15: 1954-8 (in Japanese)", the present paper describes an evaluation of the clinical efficacy of daikenchuto in patients with adhesive ileus. Although the number of patients was small and between-group differences fell short of significance, the clinical utility of daikenchuto seems to be demonstrated. Some kind of control drug should have been administered in the non-daikenchuto-treatment arm, and daikenchuto should have been compared with the control. This would not have required much additional effort.

12. Abstractor and date

Oikawa T, 19 September 2008, 6 January 2010, 1 June 2010.