

2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)**Reference**

Hanazaki K, Ichikawa K, Munekage M, et al. Effect of Daikenchuto (TJ-100) on abdominal bloating in hepatectomized patients. *World Journal of Gastrointestinal Surgery* 2013; 5: 115-22. Pubmed ID: 23671738

1. Objectives

To evaluate the effect of daikenchuto (大建中湯) on abdominal bloating in patients who underwent hepatectomy for liver malignancies

2. Design

Randomized controlled trial (RCT).

3. Setting

Surgery Department, Kochi Medical School Hospital, Japan.

4. Participants

Eighteen patients who underwent hepatectomy for liver malignancies.

5. Intervention

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules 15.0 g/day (5.0 g t.i.d.) for 3 days before surgery and for 10 days after surgery (n=9).

Arm 2: TSUMURA Daikenchuto (大建中湯) Extract Granules 15.0 g/day (5.0 g t.i.d.) + lactulose at least 48 g/day for the same period as above (n=9).

6. Main outcome measures

Visual analog scale (VAS) scores for abdominal bloating (at baseline and on postoperative days 2, 4, 6, 8, and 10), Gastrointestinal Symptom Rating Scale (GSRS) scores (on the day before surgery, before daikenchuto treatment, and on postoperative day 10), and GSRS scores for abdominal bloating in sub-analyses.

7. Main results

A total of 18 patients were included in the analysis. The VAS score for abdominal bloating peaked on postoperative day 2, and then decreased gradually to the preoperative level with no statistically significant difference by postoperative day 10. Although no significant difference was noted in overall GSRS score, GSRS score for abdominal bloating was significantly higher on postoperative day 10 than prior to surgery ($P<0.05$). The VAS score for abdominal bloating had recovered to preoperative levels by postoperative day 6 in arm 1 but not to preoperative levels even on postoperative day 10 in arm 2. On postoperative days 2 and 10, the VAS scores for abdominal bloating were significantly lower in arm 1 than in arm 2 ($P<0.05$). On postoperative day 10, the overall GSRS score was significantly lower in arm 1 than in arm 2 ($P<0.05$). GSRS scores for abdominal bloating were similar preoperatively and on postoperative day 10 in arm 1, but significantly higher on postoperative day 10 than preoperatively in arm 2 ($P<0.05$). Patients in arm 1 showed a tendency for fewer postoperative complications (biliary tract infection, bile leaks, etc.) and shorter postoperative hospital stays compared with arm 2.

8. Conclusions

Daikenchuto monotherapy relieves and ameliorates abdominal bloating early in hepatectomized patients compared to combination therapy with lactulose.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Notably, no adverse event was associated with administration of daikenchuto.

11. Abstractor's comments

This is a report of the first RCT to demonstrate the effectiveness of daikenchuto in relieving abdominal bloating in hepatectomized patients. Lactulose, which has been used to reduce ammonia production, has been found not to alleviate abdominal bloating when combined with daikenchuto. Although the Discussion section describes the mechanism by which daikenchuto suppresses inflammatory cytokine production, the mechanism by which daikenchuto alleviates abdominal bloating remains to be elucidated because both groups were treated with daikenchuto in this study. Therefore, it may be necessary to add a daikenchuto-untreated group. As stated by the authors, additional RCTs of daikenchuto in a large number of patients are needed to further evaluate its efficacy and safety in postoperative recovery. Although the present study does not use Kampo diagnosis, most patients become *kyo-sho* (虚証, deficiency pattern) after surgery, and most patients with liver malignancies have underlying chronic liver diseases (especially liver cirrhosis). In addition, the *sho* (証, pattern) for daikenchuto includes cold abdomen, abdominal pain, and abdominal bloating. Therefore, it is hoped that the authors will clearly state that the outcome measures in this study were the *sho* for daikenchuto.

12. Abstractor and date

Motoo Y, June 2015