

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

References

Nishino T, Yoshida T, Goto M, et al. The effects of the herbal medicine Daikenchuto (TJ-100) after esophageal cancer resection, open-label, randomized controlled trial. *Esophagus* 2018; 15: 75-82. CENTRAL ID: CN-01440554, Pubmed ID: 29892933

1. Objectives

To evaluate the efficacy of daikenchuto (大建中湯) for postoperative recovery of patients with esophageal cancer

2. Design

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

3. Setting

One university hospital (department of surgery), Japan

4. Participants

Forty patients with esophageal cancer undergoing transthoracoabdominal subtotal esophagectomy with stomach tube reconstruction

5. Intervention

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules 15.0 g/day (5.0 g t.i.d.) via a tube from the day of surgery (postoperatively) to the 21st day (n=20)

Arm 2: no administration of daikenchuto (n=20)

6. Main outcome measures

Primary endpoints: nutritional condition (body weight and serum albumin), postoperative recovery of gastrointestinal function (number of days until the first flatus/defecation, number of days until becoming able to eat meals of 800 kcal/day).

Secondary endpoints: C-reactive protein (CRP), plasma adrenomedullin (ADM), incidence of postoperative complications, length of hospital stay after surgery

7. Main results

One patient in Arm 1 was found to have unresectable cancer, and thus was excluded. Thus, the analysis was conducted on 19 patients in Arm 1 and 20 patients in Arm 2. Change in body weight showed intergroup differences from postoperative day 3, with significantly greater body weight in Arm 1 than in Arm 2 at postoperative day 21 ($P=0.014$). No significant intergroup differences were shown for serum albumin, serum CRP, plasma ADM, incidence of postoperative complications, parameters of the postoperative recovery of gastrointestinal function, or length of hospital stay after surgery.

8. Conclusion

Postoperative tubal administration of daikenchuto suppresses body weight decrease after subtotal esophagectomy in patients with esophageal cancer.

9. From Kampo medicine perspective

None

10. Safety assessment in the article

The Methods section of the article states that adverse events were evaluated using the CTCAE ver. 3.0. However, the Results section does not include safety data.

11. Abstractor's comments

While daikenchuto has been used for ileus prevention or recovery of gastrointestinal function after surgery for colorectal cancer, gastric cancer, hepatocellular carcinoma, etc., this is the first report to evaluate the efficacy of daikenchuto after highly invasive surgery for esophageal cancer. A groundbreaking finding of this study is that the postoperative body weight change showed an intergroup difference from postoperative day 3, and body weight at postoperative day 21 was significantly greater in the daikenchuto arm than in the control arm. However, other endpoints showed no significant differences. CRP tended to be lower and ADM tended to be higher in the daikenchuto arm compared with the control group, suggesting the anti-inflammatory effect of daikenchuto. Further studies with increased sample sizes may yield significant differences. While daikenchuto can promote movement of the contents of the large intestine or a duodenal pouch, in the setting of post-subtotal esophagectomy, as reported in this article, our concern is the effect of daikenchuto on the residual esophagus and reconstructed stomach tube. Although the authors focused mainly on anti-inflammatory effect, further studies are awaited to characterize involvement of other factors such as gastrointestinal transit or increase in gastrointestinal blood flow.

12. Abstractor and date

Motoo Y, 1 June 2020.