

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

Nagatomo H, Shigehira M. Efficacy of TSUMURA Juzentaihoto for reducing the adverse effects of the anticancer drug cisplatin. *Kampo Igaku (Kampo Medicine)* 1992; 16: 116–9 (in Japanese).

1. Objectives

To evaluate the effect of juzentaihoto (十全大補湯) for reducing adverse effects of Spongel + Lipiodol + phosphatidyl choline + cisplatin treatment in transarterial embolization (TAE) for hepatocellular carcinoma.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital, Japan.

4. Participants

Twenty patients undergoing transarterial embolization with Spongel + Lipiodol + cisplatin 100 mg + phosphatidyl choline 300 mg for hepatocellular carcinoma. On the day of TAE, Primperan 1 mg/kg and Solu-Cortef 200 mg were administered for anti-emesis.

5. Intervention

Grouping by block randomization.

Arm 1: TSUMURA Juzendaihoto (十全大補湯) Extract Granules 2.5 g t.i.d. (from 3 days before through 5 days after TAE) (n=10).

Arm 2: no administration of juzendaihoto (十全大補湯) (n=10).

6. Main outcome measures

Gastrointestinal symptoms: number of nausea/vomiting episodes until 24 hr after TAE, number of days until recovery of food intake.

Renal disorder: blood urea nitrogen, creatinine (comparison between 7 days before and 7 days after TAE)

Nutritional state: albumin, total cholesterol, choline esterase (comparison between 7 days before and 7 days after TAE), number of weeks until recovery of body weight to pre-TAE level.

7. Main results

The number of nausea/vomiting episodes was significantly decreased in Arm 1 compared with Arm 2, but changes in the renal function and nutrition status indices were similar in both arms.

8. Conclusions

Juzentaihoto significantly suppresses nausea/vomiting after transarterial embolization (TAE) with Spongel + Lipiodol + phosphatidyl choline + cisplatin for hepatocellular carcinoma.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

The authors concluded that juzentaihoto administered before and after TAE for hepatocellular carcinoma relieved nausea/vomiting for 24 hr after TAE. However, whether juzentaihoto should have been administered within the timeframe 3 days before through 5 days after TAE has no basis and should have been investigated before beginning the controlled trial. Traditionally, juzentaihoto is not used to suppress nausea/vomiting. Therefore, a clinical study of the antiemetic use of this Kampo medicine should not have been performed in patients with advanced hepatocellular carcinoma who are not indicated for surgery and who are “relatively *kyosho* (虚証, deficiency pattern).” The traditional Kampo antiemetic medicines (shohangekabukuryoto [小半夏加茯苓湯], bukuryoin [茯苓飲], shinbuto [真武湯], and kankyoninjinhangegan [乾姜人參半夏丸]) should have been investigated first.

12. Abstractor and date

Hoshino E, 15 February 2009, 1 June 2010.