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

Reference

Watanabe S, Yokoyama Y, Oda K, et al. Choleretic effect of inchinkoto, an herbal medicine, on livers of patients with biliary obstruction due to bile duct carcinoma. *Hepatology Research* 2009; 39: 247–55. Ichushi Web ID: 2009201648

1. Objectives

To evaluate the drug efficacy of inchinkoto (茵チン蒿湯) as a choleretic drug on livers of patients with biliary obstruction due to bile duct carcinoma.

2. Design

Randomized controlled trial (RCT).

3. Setting

Department of Surgery, Nagoya University Graduate School of Medicine, Department of Gastroenterology and Hepatology, University of Tsukuba, and Department of Strategic Surveillance for Functional Food and Comprehensive Traditional Medicine, Wakayama Medical University, Japan.

4. Participants

From December 2006 to June 2006, a total of 31 patients with perihilar cholangiocarcinoma or gallbladder carcinoma with hilar invasion were enrolled. Of these patients, 4 were excluded because they underwent probe laparotomy due to peritoneal dissemination.

5. Intervention

Arm 1: Inchinkoto (Tsumura Inchinkoto (茵チン蒿湯) Extract Granules (TJ-135) 7.5 g/day for at least one week before surgery (average 21 days) (n=13).
Arm 2: no treatment with inchinkoto (n=14).

6. Main outcome measures

Levels of MRP2, MRP3, and MRP4 mRNAs and proteins in the liver were determined.

7. Main results

There were no significant between-arm differences in MRP2, 3, and 4 mRNA levels. MRP2 and 3 protein levels were significantly increased in the inchinkoto arm. Postoperatively, there were no between-arm differences in serum total bilirubin, direct bilirubin, and alanine aminotransferase (ALT). Bile samples were collected from some of the patients in arm 1 by percutaneous transhepatic biliary drainage (PTBD) before and after administration of inchinkoto, and increase in the concentration of bilirubin was observed after administration.

8. Conclusions

Inchinkoto may be useful for treating obstructive cholestasis due to bile duct carcinoma, and its beneficial effect may be mediated through induction of MRP2 expression.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No significant adverse drug reactions were observed for inchinkoto treatment.

11. Abstractor's comments

MRP2 protein is a transporter involved in bile acid secretion. It is interesting that the authors found and increase in MRP2 protein levels but no change in MRP2 mRNA levels. They demonstrated increased bilirubin concentration in the bile samples collected by PTBD only in the subjects in the inchinkoto arm, however, they should have studied the subjects in the both arms to make the data more reliable. Some of the documentation in this article is insufficient; even though the MRPs gene expression data for the control group is shown, the background data of the control group is not. Although there are issues regarding the methodology used in this study, it is very meaningful that administration of inchinkoto is shown clinically to increase MRP2 protein levels.

12. Abstractor and date

Nakata H, 1 June 2010, 31 December 2013.