Evidence Reports of Kampo Treatment

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Okabayashi T, Tanaka N, Orita K. The effect of a Kampo medicine, inchinko-to, on rate of bilirubin reduction after biliary drainage in patients with obstructive jaundice. *Nihon Rinsho Geka Gakkaishi* (*Journal of Japan Surgical Association*) 1998; 59: 2495-500 (in Japanese with English abstract). Ichushi Web ID: 1999080276, J-STAGE

1. Objectives

2. Design

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

3. Setting

First Department of Surgery, Okayama University School of Medicine and 14 associated facilities, Japan.

4. Participants

Twenty-four patients with obstructive jaundice undergoing biliary drainage procedures such as percutaneous transhepatic cholangio-drainage (PTCD). The patients satisfying any of the following criteria were excluded: 1) age <15 years or ≥80 years; 2) oral intake not possible; 3) presence of serious cirrhosis or complications; and 4) ineligibility as judged by the patient's physician.

5. Intervention

Arm 1: drainage +oral administration of TSUMURA Inchinkoto (茵チン蒿湯) Extra Granules 2.5 g t.i.d., either for 4 weeks or before the surgery (n=11; of these, 10 were analyzed [the reason of study withdrawal not shown]).

Arm 2: drainage alone (n=13).

6. Main outcome measures

Total bilirubin, direct bilirubin, and daily volume of bile. Bilirubin reduction rate as determined by the formula of Shimizu et al. Changes in anorexia and general malaise rated on a 4-point scale.

7. Main results

Bilirubin reduction rate was significantly improved in arm 2 (P<0.05). AST, ALT, ALP, and γ -GTP were similarly improved in both arms, although more favorable results were obtained in arm 2. Anorexia was significantly improved in arm 2 early after the start of drainage (at Day 3, P<0.1; at Week 1, P<0.05). From week 2 onwards, however, subjective symptoms were also improved in arm 1, and there was no significant between-arm difference.

8. Conclusions

Inchinkoto improves the bilirubin reduction rate and subjective symptoms, suggesting its efficacy for obstructive jaundice after biliary drainage.

9. From Kampo medicine perspective

This paper mentions the choleretic action of 6, 7-demethyl-esculetin and capillarisin contained in inchinko (茵チン蒿), and geniposide contained in sanshishi (山梔子), in the discussion section from a pharmacognostic perspective.

10. Safety assessment in the article

No adverse events were observed.

11. Abstractor's comments

This paper discusses the effect of inchinkoto on bilirubin reduction. Combination of inchinkoto with drainage had only a slight additional effect on reduction of bilirubin level. Notably, however, no patients were rated grade 3 (i.e., as having relatively poor bilirubin reduction) after the inchinkoto treatment. Future reports on the mechanism of its action are awaited.

12. Abstractor and date

Nakata H, 1 January 2009, 6 January 2010, 1 June 2010, 31 December 2013.