

Evidence Reports of Kampo Treatment

Task Force for Evidence Reports, the Japan Society for Oriental Medicine

Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine.

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

Reference

Higuchi K, Watanabe A. Study on liver cancer-preventive effect of jumentaihoto in patients with liver cirrhosis*. *Methods in Kampo Pharmacology* 2000; 5: 29-33 (in Japanese).

1. Objectives

To evaluate the hepatocellular carcinoma-preventive effect of jumentaihoto (十全大補湯) administered for liver cirrhosis.

2. Design

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

3. Setting

A university hospital (Department of Internal Medicine, Toyama Medical and Pharmaceutical University [now Toyama University Hospital]), Japan.

4. Participants

Seventy-two patients with liver cirrhosis due to hepatitis B or C virus (B, n=14; C, n=58). However, one patient who had liver cancer within half a year after entry into the study was excluded.

5. Intervention

Arm 1: jumentaihoto (十全大補湯)-treated group (B, n=8; C, n=18).

Arm 2: jumentaihoto (十全大補湯)-untreated group (B, n=6; C, n=39).

6. Main outcome measures

Cumulative survival curve by Kaplan-Meier method (log-rank test [Mantel-Cox]).

Cumulative hazard curve for hepatocellular carcinoma development by Kaplan-Meier method (log-rank test [Mantel-Cox]).

The threshold of liver cancer development was set at the time when liver cancer was first detected on imaging-based clinical diagnosis.

7. Main results

For overall liver cirrhosis, there was no significant difference in the cumulative survival curve between arms (chi-square=3.167, $P=0.0751$), but jumentaihoto-treated patients tended to have a more favorable prognosis. For overall liver cirrhosis, the cumulative hazard curve for hepatocellular carcinoma development showed the risk was significantly lower in the jumentaihoto-treated group than in jumentaihoto-untreated group (chi-square=5.832, $P=0.0157$). Analysis limited to liver cirrhosis type C also revealed significantly lower risk in the jumentaihoto-treated group (chi-square=4.197, $P=0.0405$).

8. Conclusions

It is suggested that administration of jumentaihoto prevents hepatocellular carcinoma from developing in patients with liver cirrhosis.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study is valuable, since hepatocellular carcinoma frequently develops as a result of underlying hepatitis virus infection. Using sealed envelopes for allocation, this study is regarded as a randomized controlled trial. Information on the method of jumentaihoto administration and blinding may have made this report clinically more meaningful.

12. Abstractor and date

Tsuruoka K, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.