

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

Tarao K, Shibuya A, Ohkawa S, et al. Prevention of hepatocarcinogenesis by anti-inflammatory therapy: is combination anti-inflammatory therapy targeting an ALT level of under 80 units effective for hepatitis C virus-related cirrhosis (Child A)?: comparison with monotherapy*. *Kanagawa Cancer Center – Nenpo (Annual Report)* 2003; 19: 92 (in Japanese).

Tarao K. Persistent inflammation and hepatocarcinogenesis in chronic hepatitis C and hepatitis C virus-related cirrhosis*. *Kanagawa Igakkai Zasshi (The Journal of the Kanagawa Medical Association)* 2006; 33: 115-8 (in Japanese).

Tarao K. Prevention of HCC by anti-inflammatory agents in patients with chronic hepatitis C. *Rinsho Shokaki Naika (Clinical Gastroenterology)* 2007; 22: 961-9 (in Japanese).

1. Objectives

To evaluate the efficacy of liver protectors for preventing carcinogenesis in patients with chronic hepatitis C.

2. Design

Randomized controlled trial (RCT).

3. Setting

None (the author belongs to a specialized hospital), Japan.

4. Participants

One hundred and fifty-six patients with hepatitis C virus-related cirrhosis (stage Child A).

5. Intervention

Arm 1: target alanine aminotransferase (ALT) level ≤ 80 ; monotherapy with Stronger Neo-Minophagen C (SNMC; 40–100 mL, two or three times per week), ursodeoxycholic acid (UDCA), shosaikoto (小柴胡湯), or jumentaihoto (十全大補湯) (manufacturers, not specified) was administered. When the target level was not achieved in 2–3 months, dual therapy with SNMC + UDCA, UDCA + jumentaihoto (十全大補湯), or UDCA + shosaikoto (小柴胡湯) was administered. If the target level was still not achieved, triple therapy with SNMC + UDCA + shosaikoto (小柴胡湯) or SNMC + UDCA + jumentaihoto (十全大補湯) was administered. The choice of the therapy in each patient was not described, n=78.

Arm 2: monotherapy with UDCA, SNMC, shosaikoto (小柴胡湯), or jumentaihoto (十全大補湯) was administered; the choice of the drug was based on the ALT-lowering effect. Details, including the drug used, dose, and the number of patients who received each drug, were not available, n=50.

6. Main outcome measures

Incidence of liver cancer.

7. Main results

The incidence of liver cancer was lower in arm 1 than in arm 2.

8. Conclusions

Therapy consisting of combined Kampo medicines for liver protection is effective for suppressing carcinogenesis in patients with chronic hepatitis C.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study reports an effective treatment for suppressing carcinogenesis in patients with chronic hepatitis C. But since the specific design was not described and details (such as the choice of the therapy or the number of patients who received each drug in arm 2) were unclear, we cannot decide which of the treatments resulted in response. Studies employing easy-to-understand designs are desired.

The two studies by Tarao et al (2003) and Tarao (2008) are the interim reports

12. Abstractor and date

Kogure T, 26 January 2009, 31 December 2013.