## **AWARD WINNING**

## YHK, A Novel Herbal Remedy with Effective Antifibrotic Action, in Chronic Liver Disease: A Pilot Clinical Study Aiming to a Successful Integrative Medicine Development

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## ABSTRACT ONLY

Chronic liver disease (CLD) represents one of the major causes of mortality and morbidity worldwide. Related medical therapies are often difficult to handle, expensive and limited in efficacy and other treatments, either to complement or to replace standard care are often sought.

However the field of such non-standard approach is often biased by the lack of strictly science-based studies. We have recently shown that a novel natural agent, i.e.YHK (Kyotsu, Tokyo, Japan), has a powerful hepatoprotective action on experimental basis while markedly decreasing transaminases in HCV-CLD patients. This study was aimed to further validate its potential clinical application. Six patients (age 55-69) with HCV-CLD (history dating back 2 to 18 years) were enrolled into the study. All patients had a transaminases level 2- to 4-fold increased despite being on UDCA and glycyrrhizin acid therapy except one who had just finished a 6 month IFN trial. Patients underwent a liver biopsy which was blindly assessed and re-evaluated according to Maruyama classification.

Patients were then stopped any prior therapy and asked not to take any health or vitamin supplement while being put on YHK treatment at dosage of 4 tabs t.i.d for 10days and then maintained at 2-3 tabs t.i.d. throughout the study period. Patients were then monitored every 2-3 months with detailed biochemical and clinical assessment. All patients completed the study and along the observation period, no biochemical or clinical side effect was detected. Except one patient with high HCV-RAN titers which dramatically decreased at the end of the study, such parameter was not affected in the other patients. Transaminases levels significantly decreased in all patients within the first 2 weeks (p<0.01) being within normal limits in 3 of them and, in particular, GPT fell into normal level in all patients. Liver biopsy, repeated after 1 year in 5 patients and 18 months in the sixth one, showed a significant improvement of either fibrosis and of inflammatory infiltrate (p<0.05). These preliminary data further support the potential use of YHK in clinical practice while larger clinical trials together with experimental investigations are awaited.