中文題目:慢性Ｂ型Ｃ型肝炎合併感染病患使用長效型干擾素合併雷巴威林之個人化治療：一隨機分配之研究

英文題目: **Personalized Therapy of Chronic Hepatitis C and B Dually Infected Patients with PEGylated interferon plus Ribavirin: A Randomized Study**

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Background & Aims: We aimed to investigate whether response-guided therapy (RGT) with peginterferon-alpha plus ribavirin by using hepatitis C virus (HCV) genotype, pretreatment HCV RNA levels and rapid virological response (RVR, undetectable HCV RNA at treatment week 4) could be applied for active HCV/hepatitis B virus (HBV) dually-infected patients, without compromised the treatment efficacy.

Methods: Two hundred and three patients, seropositive of HCV antibody, HCV RNA and HBV surface antigen (HBsAg) and seronegative for HBV e antigen for >6 months, were randomized to receive peginterferon-alpha/ribavirin by either genotype-guided therapy (GGT, n=102: HCV genotype 1 [HCV-1], 48 weeks; HCV-2/3, 24 weeks) or RGT (n=101: HCV-1, 48 weeks or 24 weeks if patients with baseline VL <400,000 IU/ml and RVR; HCV-2/3, 24 weeks or 16 weeks if patients with RVR). The primary endpoint was HCV sustained virological response (SVR).

Results: The HCV SVR rate was comparable between the GGT (77.5%, 79/102) and RGT groups (70.3%, 71/101, p=0.267), either among HCV-1/HBV (69.4% [43/62] vs. 63.5% [40/63], p=0.571) or among HCV-2/3/HBV (90.0% [36/40] vs. 81.6% [31/38], p = 0.342) dually-infected patients based on intention-to-treat analysis. In HCV-1/HBV dually-infected patients, RVR (odds ratio [OR]: 6.05; 95% confidence intervals [CI]: 2.148–17.025, p = 0.001) and lower pretreatment blood glucose levels (OR: 0.97; CI: 0.944 -0.989, p = 0.003) were independent predictors of HCV SVR. While RVR (OR: 10.68; CI: 1.948 – 58.514, p = 0.006) was the only significant factor associated with HCV SVR in HCV-2/3/HBV dually-infected patients. HBsAg loss at one year post-treatment was observed in 17 of 185 (9.2%) patients. The rates of discontinuation and adverse events were similar between the two groups.

Conclusions: RGT with peginterferon-alpha/RBV may be considered for HBeAg-negative HBV/HCV dually-infected patients.