Effects of pitavastatin on Japanese patients with chronic heart failure: a subanalysis of the PEARL

A. Kubota1, H. Takano2, H. Mizuma1, Y. Kuyukabara1, Y. Sato3, N. Kotooka4, T. Inoue5, K. Node4, I. Komuro6, Y. Kobayashi1. 1Chiba University Graduate School of Medicine, Department of Cardiology, Chiba, Japan; 2Chiba University Graduate School of Pharmaceutical Sciences, Chiba, Japan; 3Chiba University Hospital, Clinical Research Center, Chiba, Japan; 4Saga University, Department of Cardiovascular Medicine, Saga, Japan; 5Dokkyo Medical University, Department of Cardiovascular Medicine, Mbu, Japan; 6The University of Tokyo, Department of Cardiovascular Medicine, Tokyo, Japan

Purpose: HMG-CoA reductase inhibitors (statins) are known to have pleiotropic effects in addition to their lipid-lowering effect. Many studies have suggested cardio-protective effects of statins, however, recent large-scale clinical trials using rosuvastatin, a hydrophilic statin, have failed to show beneficial effects on cardiovascular events in patients with severe heart failure. We have performed the study to evaluate the effects of pitavastatin, a lipophilic statin, on Japanese patients with heart failure and reported the results (Takano H, et al. Circ J. 2013). In this subanalysis of the PEARL, we evaluated the effects of pitavastatin on Japanese patients with dilated cardiomyopathy (DCM).

Methods: The PEARL study is a multi-center, prospective, randomized, open-label, blinded-endpoint (PROBE) trial being carried out in Japan. Patients with stable and symptomatic heart failure (NYHA class III-II) with systolic dysfunction were eligible. After consent by the document, patients were randomly allocated to either the pitavastatin group (2 mg/day) or the control group (no statin) by using the minimization method. The primary outcome was a composite of cardiac death and hospitalization for worsening heart failure. The secondary outcomes were all-cause death, cardiac death, hospitalization for worsening heart failure, malignant infarction, unstable angina, stroke, percutaneous coronary intervention, and surgical therapy for worsening heart failure.

Results: In the PEARL study, a total of 574 Japanese patients with chronic heart failure were enrolled, 149 patients were assigned to the pitavastatin group and 161 to the control group. The mean LVEF was 34.0% and 89.7% of the patients were classified to NYHA class II. In this subanalysis, 310 patients with DCM were analyzed. No significant differences in baseline characteristics between the two groups. The mean duration of follow-up was 35.5 months. There were no significant differences in baseline characteristics between the two groups.

Conclusions: Pitavastatin did not reduce cardiac death and hospitalization for worsening heart failure in the patients with DCM.