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New clinical outcome of Fimasartan on reducing proteinuria in Korean diabetic nephropathy patients: FANTASTIC trial

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Chronic kidney disease (CKD) is common in people with both type 1 and type 2 diabetes. It is defined by the presence of reduced glomerular filtration rate (GFR) and/or increased urinary albumin excretion for at least three months. Globally, diabetic kidney disease (DKD) is a major cause of CKD and is the most common cause of end-stage kidney disease (ESKD). As an example, Lee et al. reported the epidemiology of ESKD in Korea using the nationwide NHIS-NHS database, which revealed that the incidence of ESKD with diabetes was 13.8 times higher than the incidence of ESKD without DM in 2015[1]. In patients with diabetes, the goal of blood pressure control is suggested as follows; a goal blood pressure of 120 to 125/<80 mmHg (using the non-routine [preferred] measurement methods including standardized office-based measurement, AOBPM, home blood pressure, and ABPM) or 125 to 130/<80 mmHg (using routine office measurements)[2].

FimAsartaN proTeinuriA SusTaIned reduCtion in comparison with losartan in diabetic chronic kidney disease (FANTASTIC) trial (Clinicaltrials.gov, NCT02620306) was designed to assess the reno-protective effects of fimasartan compared to those of losartan as a primary outcome[3]. This study is a prospective, phase III, randomized, double-blind, active-controlled, non-inferiority, four-parallel group, dose-titration, multicenter trial. Patients with hypertensive diabetic CKD with albuminuria were enrolled. Participants were randomized into four groups (1:1:1:1): fimasartan standard SBP control (SBP < 140 mmHg); fimasartan strict SBP control (SBP < 130 mmHg); losartan standard SBP control; and losartan strict SBP control. The primary endpoint is the rate of change in proteinuria at 24 weeks, which is assessed using the spot urine albumin–creatinine ratio. A total of 341 patients participated in the study, with a mean age of 61.96 years old, and mean baseline SBP of 154.58 mmHg. Baseline spot urine albuminuria was 1,396 vs 1,521 mg/g for each fimasartan group vs losartan group. Fimasartan was noninferior to losartan for the primary endpoint, with a decrease rate of albuminuria at 24 weeks of - 37.6 % vs -20.6 % from the baseline, respectively (P<0.0001 for non-inferiority). Fimasartan was superior to losartan for primary endpoint; -17% more albuminuria reduction. Based on the results of the FANTASTIC study, fimasartan has acquired an indication for "reduction of proteinuria in patients with type 2 diabetic kidney disease with hypertension" as of December 30, 2020.

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3. Kim, J.-Y. et al. FimAsartaN proTeinuriA SusTaIned reduCtion in comparison with losartan in diabetic chronic kidney disease (FANTASTIC): study protocol for randomized controlled trial. Trials 18, 632 (2017).