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Low-Dose Aspirin Therapy in Patients With Type 2 Diabetes and Reduced Glomerular Filtration Rate

Subanalysis from the JPAD trial

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OBJECTIVE—Type 2 diabetes accompanied by renal damage is a strong risk factor for atherosclerotic events. The purpose of this study was to investigate the efficacy of low-dose aspirin therapy on primary prevention of atherosclerotic events in patients with type 2 diabetes and coexisting renal dysfunction.

RESEARCH DESIGN AND METHODS—The Japanese Primary Prevention of Atherosclerosis With Aspirin for Diabetes (JPAD) trial was a prospective, randomized, open-label trial conducted throughout Japan that enrolled 2,539 type 2 diabetic patients without a history of atherosclerotic diseases. Patients were assigned to the aspirin group (81 mg/day or 100 mg/day) or the nonaspirin group and followed for a median of 4.37 years. The primary end points were atherosclerotic events of fatal and nonfatal ischemic heart disease, stroke, and peripheral arterial disease.

RESULTS—The analysis included 2,523 patients who had serum creatinine measured. In 1,373 patients with baseline estimated glomerular filtration rate (eGFR) 60–89 mL/min/1.73 m^2, the incidence of primary end points was significantly lower in the aspirin group than in the nonaspirin group (aspirin, 30/661; nonaspirin, 55/712; hazard ratio 0.57 [95% CI 0.36–0.88]; $P = 0.011$). Low-dose aspirin therapy did not reduce primary end points in patients with eGFR ≥90 mL/min/1.73 m^2 (aspirin, 9/248; nonaspirin, 11/270; 0.94 [0.38–2.3]) or those with eGFR <60 mL/min/1.73 m^2 (aspirin, 29/342; nonaspirin, 19/290; 1.3 [0.76–2.4]). The Cox proportional hazard model demonstrated a significant interaction between mild renal dysfunction (eGFR 60–89 mL/min/1.73 m^2) and aspirin ($P = 0.02$).

CONCLUSIONS—These results suggest a differential effect of low-dose aspirin therapy in diabetic patients with eGFR 60–89 mL/min/1.73 m^2.

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Diabetes is a strong risk factor for cardiovascular (CV) events. However, the primary prevention strategy for CV events remains to be established (1). In patients with type 2 diabetes, the presence of coexisting renal damage is associated with an increased incidence of CV events (2–4). Although diabetic nephropathy is diagnosed by pathological examination, the presence of albuminuria is clinically adopted as pathognomonic manifestation of diabetic nephropathy.

Recently, the National Kidney Foundation (5) defines chronic kidney disease as persistent kidney damage of any underlying cause, as reflected by estimated glomerular filtration rate (eGFR) of <60 mL/min/1.73 m^2 for more than 3 months. eGFR <60 mL/min/1.73 m^2 is the cutoff because it has been identified as a predictor of CV events in the general population (6), in patients with diabetes (3,4), and in patients with other CV risk factors (6,7). Given that nearly two thirds of diabetic patients with eGFR <60 mL/min/1.73 m^2 have normal albuminuria (8), American Diabetes Association (ADA) guidelines (9) recommend that serum creatinine should be measured at least annually and used to calculate eGFR in all diabetic patients, regardless of the degree of albuminuria (8,9). Thus, to establish the primary prevention strategy for diabetic patients with renal damage, a GFR-based approach might be helpful.

Low-dose aspirin therapy has previously been recommended by several key guidelines for primary prevention of CV events in patients with diabetes, although with some inconsistencies (1,9). In 2010, the ADA, the American Heart Association, and the American College of Cardiology Foundation convened a group of experts to create updated recommendations for the primary prevention strategy of low-dose aspirin use in patients with diabetes (1). They performed a new meta-analysis that included two recent randomized controlled trials of aspirin, the Japanese Primary Prevention of Atherosclerosis With Aspirin for Diabetes (JPAD) trial (10), and the Prevention of Progression of Arterial Diseases and Diabetes (POPADAD) trial (11). Both trials enrolled only patients with diabetes and neither showed any significant effect of aspirin to prevent atherosclerotic events.

Based on the currently available evidence (12,13), aspirin appears to have a

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