Efficacy of amlodipine and olmesartan medoxomil in patients with hypertension: the AZOR Trial Evaluating Blood Pressure Reductions and Control (AZTEC) study

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Abstract

The aim of the present study was to use ambulatory blood pressure (BP) monitoring (ABPM) to determine the efficacy of a fixed-dose combination of amlodipine (AML) and olmesartan medoxomil (OM) over the 24-hour dosing interval. This 12-week, titrate-to-goal study was conducted in 185 patients with hypertension. Patients were initially treated with AML 5 mg/day and uptitrated to AML/OM 5/20, 5/40, and 10/40 mg/day every 3 weeks if mean seated BP (SeBP) was ≥120/80 mmHg. The primary efficacy endpoint was the change from baseline in mean 24-hour systolic BP at week 12 as assessed by ABPM. At baseline, the mean 24-hour ambulatory BP (±standard deviation [SD]) was 144.8±11.1/85.7±7.9 mmHg. At week 12, the change from baseline in mean 24-hour ambulatory BP (±standard error of the mean [SEM]) was -21.4±0.8/-12.7±0.5 mmHg (p < 0.0001 versus baseline). At baseline, the mean SeBP (±SD) was 158.2±12.6/92.8±8.6 mmHg and at week 12, the mean SeBP change (±SEM) from baseline (last observation carried forward) was -24.1±1.1/-12.1±0.7 mmHg (p < 0.0001 versus baseline). Proportions of patients achieving mean 24-hour ambulatory BP prespecified study targets were 70.9% (<130/80 mmHg), 48.3% (<125/75 mmHg), and 40.7% (<120/80 mmHg). Cumulatively, 76.8% of patients uptitrated to AML/OM 10/40 mg/day attained an SeBP goal of <140/90 mmHg. The study drug was well tolerated with few adverse events (peripheral edema, 2.2%; dizziness, 1.1%). An AML/OM-based titration regimen effectively reduces BP in patients with hypertension.