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Acute Coronary Syndromes

ALOGLIPTIN IN PATIENTS WITH TYPE 2 DIABETES AFTER ACUTE CORONARY SYNDROMES: HEART FAILURE OUTCOMES AND CARDIOVASCULAR SAFETY IN HEART FAILURE PATIENTS

Poster Contributions

Hall C

Saturday, March 29, 2014, 3:45 p.m.-4:30 p.m.

Session Title: Acute Coronary Syndromes: Comorbid Considerations

Abstract Category: 1. Acute Coronary Syndromes: Clinical

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Background: The EXAMINE trial showed no increases in cardiovascular (CV) event rates for the DPP-4 inhibitor alogliptin compared to placebo. As concerns have been recently raised regarding increased rates of hospitalized heart failure for other DPP-4 inhibitors, we evaluated pre-specified and post hoc analyses of heart failure (HF) outcomes in EXAMINE.

Methods: Patients with type 2 diabetes (T2D) with an acute coronary syndrome (ACS) within the previous 15-90 days were randomly assigned to receive alogliptin or placebo added to existing anti-hyperglycemic and secondary CV prophylactic therapy. Patients with unstable CV disorders including uncompensated HF were excluded. Deaths and major CV events were independently adjudicated by a blinded committee. The risks of CV death, nonfatal MI and stroke, unstable angina, and hospitalized HF (HHF) were analysed using a Cox proportional hazards model.

Results: EXAMINE randomized 5380 patients for a median follow-up of 18 months. The pre-specified composite outcome of first occurrence of all-cause mortality, nonfatal MI and stroke, urgent revascularization due to unstable angina, and HHF was similar for alogliptin vs placebo [HR = 0.98, 95% CI, 0.86-1.12]. Within this composite endpoint, HHF occurred in 3.1% patients on alogliptin vs. 2.9% on placebo [HR=1.07, 95% CI, 0.79-1.46]. In addition, alogliptin showed no effect on the post hoc composite of CV death and HHF [HR = 0.98, 95% CI, 0.82-1.21], and no effect on its individual components: (CV death, 3.5% vs. 4.2%, HR = 0.84, 95% CI, 0.64-1.10) and (HHF, 3.9% vs. 3.3%, HR = 1.19, 95% CI, 0.90-1.58) for alogliptin vs. placebo, respectively. Subgroup analyses according to any (28%) or no (72%) pre-randomization history of HF or according to baseline NT-pro-BNP levels showed no significant interaction with primary CV outcomes or with the post hoc outcomes that included HHF.

Conclusion: In patients with T2D and recent ACS, CV outcomes inclusive of HHF were not increased with alogliptin compared with placebo, including in patients with a history of HF and/or with elevated NT-pro-BNP. Furthermore, alogliptin neither induced new onset HF nor worsened HF outcomes in patients with a history of HF.