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Cardiovascular Event Hazards over Time in TECOS

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Abstract

Background: Event accumulation patterns in event-driven trials inform forecasting of trial size and duration. It is hypothesized that trials enrol a healthier cohort who have lower early cardiovascular (CV) event rates that increase during follow-up as surviving patients age and accumulate comorbidities. We present hazard rate patterns for incident CV events in the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS).

Methods: Using adjudicated endpoints from the intention-to-treat population, Weibull models show whether hazards for these CV events were increasing



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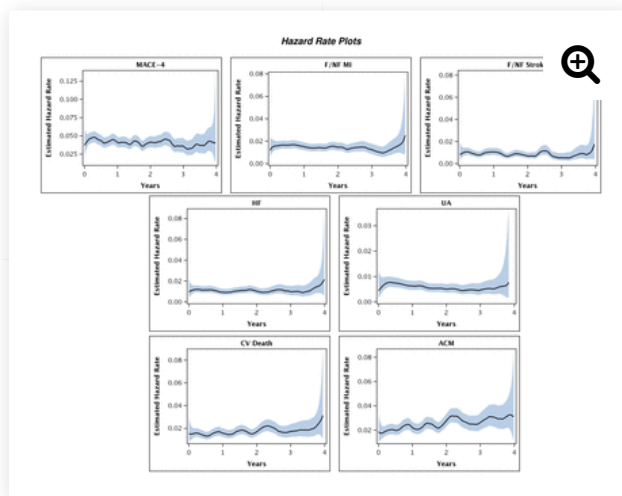
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myocardial infarction [NFMi], nonfatal stroke [NFSt], and unstable angina hospitalization [UA]; fatal (F) or NFMi, F/NFSt, UA, CV death, all-cause mortality (ACM), and heart failure hospitalization (HF).

Results: The Figure shows hazard rate over time. Weibull shape point estimates (95% CI) were MACE-4 0.96 (0.92, 1.01); ACM 1.14 (1.08, 1.21); CV death 1.1 (1.01, 1.16); F/NFMi 0.96 (0.89, 1.03); F/NFSt 0.93 (0.85, 1.03); UA 0.90 (0.79, 1.01); HF 0.98 (0.90, 1.08). Annual event rates (per 100 pt-years) were CV death: 1.5, 1.6, 2.0, 1.9, 2.7; ACM: 2.1, 2.3, 2.8, 3.0, 3.8.

Conclusions: Hazard rates were constant for all events except CV death and ACM, which had small significant increased risk over time. Our findings may inform the planning and conduct of future trials in diabetes.



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Disclosure M. Bethel: Research Support; Self; AstraZeneca, Merck Sharp & Dohme Corp., Merck Serono. Advisory Panel; Self; Boehringer Ingelheim Pharmaceuticals, Inc.. Consultant; Self; Novo Nordisk Inc.. Advisory Panel; Self; AstraZeneca. Other Relationship; Self; Sanofi. Consultant; Self; Theracos, Inc.. Research Support; Self; GlaxoSmithKline plc. **H. Sourij:** Speaker's Bureau; Self; Boehringer Ingelheim GmbH, Novo Nordisk A/S, Amgen Inc., Sanofi, MSD K.K.. Research Support; Self; AstraZeneca, Boehringer

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