

## Real world risk of major outcomes for type 2 diabetes with stable coronary artery disease without prior MI or stroke and THEMIS-like patients using the SNDS French nationwide claims database

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**Background:** The THEMIS randomized controlled trial showed that patients with stable coronary artery disease and type 2 diabetes mellitus (CAD-T2DM), without a history of myocardial infarction (MI) or stroke, and who received ticagrelor plus aspirin, had a lower incidence of ischemic cardiovascular events but a higher incidence of major bleeding than those who received placebo plus aspirin. After 3 years of follow-up, the incidence of major outcomes in the placebo arm was 1.8% for ischemic stroke, 3.3% for MI, 4.9% for all-cause death, 9.2% for a composite of all-cause-death, MI or stroke, and 0.38 per 100 patients-years for TIMI major bleedings. The risk of these outcomes is not well known in current practice.

**Purpose:** To estimate the incidence of major outcomes for CAD-T2DM patients without prior MI-stroke and more specifically for THEMIS-like patients in a real world setting.

**Methods:** Cohort within the main scheme of the SNDS (Système National des Données de Santé), the French nationwide claims database, representing about 86% of 66 million people. All CAD-T2DM prevalent patients without prior MI-stroke were identified on January 1st, 2014 (inclusion date), based on a 5-year database history, and followed for two years. The THEMIS-like population included CAD-T2DM patients without prior MI-stroke  $\geq 50$  years at inclusion date without renal failure with dialysis, cirrhosis or liver cancer history, as well as no intracranial and gastro-

intestinal bleeding for the last 6 months, or anticoagulant or antiplatelet agent 2 months before and after inclusion date. The Kaplan-Meier method was used to estimate the 2-year cumulative incidence of all-cause death and a composite of all-cause death, MI and stroke, and the cumulative incidence function, taking into account death as competing risk for other clinical outcomes.

**Results:** From 258,260 CAD-T2DM patients without prior MI-stroke, 64,334 were included in the THEMIS-like population (24.9%) with the same median age of 72 years, with 68.3% and 65.7% men, respectively. The 2-year cumulative incidence for the CAD-T2DM without prior MI-stroke and THEMIS-like populations was 1.7% and 1.5% for ischemic stroke, 1.7% and 1.3% for MI, 9.5% and 5.3% for heart failure, 4.9% and 3.2% for major bleeding, 13.6% and 9.7% for all-cause death, and 16.2% and 12.0% for the composite outcome, respectively.

**Conclusions:** In current practice, the median age of the THEMIS-like population was 6 years older than in the THEMIS trial (i.e. 66 years), with an observed risk after 2 years of follow-up, about double for the composite outcome, triple for deaths and quadruple for major bleedings than those of the placebo arm of the trial (estimation after 2 years of follow-up in the THEMIS trial placebo arm assuming constant risk across time according to Kaplan-Meier graph).