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

P. Blin[1], P. Darmon[2], P. Henry[3], E. Guiard[1], M-A. Bernard[1], C. Dureau-Pournin[1], H. Maizi[1], F. Thomas-Delecourt[4], R. Lassalle[1], C. Droz-Perroteau[1], N. Moore[1]

[1]Bordeaux PharmacoEpi, INSERM CIC1401, Université de Bordeaux, Bordeaux, France – [2]Hôpital La Conception, Marseille, France – [3]Hôpital Lariboisière, Paris, France – [4]AstraZeneca, Courbevoie, France

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Purpose

- The THEMIS randomized trial showed a lower incidence of ischemic cardiovascular events but a higher incidence of major bleeding in ticagrelor plus aspirin group than in placebo plus aspirin group in patients with stable coronary artery disease and type 2 diabetes (CAD-T2M) without prior myocardial infarction (MI) or stroke (Steg *et al*, NEJM 2019).
- The objective was to estimate the incidence of major outcomes for patients with CAD-T2DM, without history of MI-stroke and, more specifically, for THEMIS-like patients in a real world setting.

Methods

- **Design:** Cohort study in the French nationwide claims database (SNDS, 86% of the 66 million people).
- **Data source:** The SNDS contains individual pseudonymised information from birth to death and includes outpatient and inpatient information (drug dispensing, hospital discharge summaries, date of death…).
- **Study populations:**
  - **CAD-T2DM population without prior MI-stroke**: all CAD-T2DM prevalent patients without MI-stroke within the 5-year history period identified on 1st January 2014, and followed for 2 years or until death in the database.
  - **THEMIS-like population**: all patients of the previous population with specific criteria (≥ 50 years at index date, without renal failure with dialysis, cirrhosis/liver cancer history, intracranial/gastro-intestinal bleeding for the last 6 months, or anticoagulant/antiplatelet agent 2 months around index date).
- **Outcomes (primary diagnosis):** ischemic/unknown stroke, MI, heart failure, major bleeding* (associated diagnosis also considered), all-cause death, and a composite event (1st event among stroke, MI, death).
- **Data analysis:** Two-year cumulative incidence/probability of outcomes using Kaplan-Meier estimate (death, composite) or cumulative incidence function (CIF, other outcomes) to take into account death as competing risk.

** Intracranial bleeding, haemorrhagic stroke, other critical organ or site bleeding, other bleeding, fatal bleeding (ICD-10 codes)*

Results

- **Main characteristics of populations:** 258 260 patients in the CAD-T2DM population without prior MI-stroke and 64 334 in the THEMIS-like population were included, and presented similar main characteristics (**Table 1**).
- **Two-year cumulative incidence/probability of outcomes** (**Figures 1 and 2**)

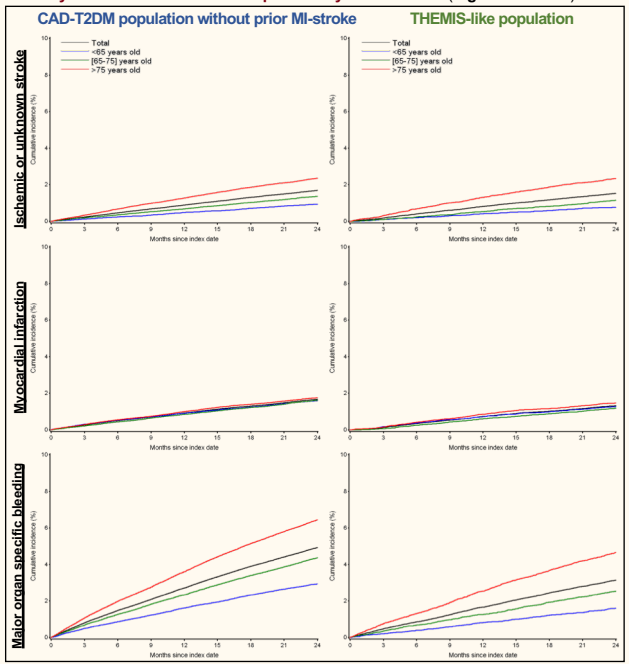

Figure 1. Cumulative incidence/probability of outcomes during two years of follow-up

Table 1. Main characteristics of the study populations at index date

	CAD-T2DM population without prior MI-stroke n = 258 260		THEMIS-like population n = 64 334	
Male, n (%)	176 407	(68.3)	42 238	(65.7)
Median age (in years)	73.0		72.0	
> 4 years of CAD/T2DM diagnosis history, n (%)	67 040	(26.0)	16 346	(25.4)
History of hypertension, n (%)	204 943	(79.4)	48 554	(75.5)
History of diabetic complications, n (%)	101 419	(39.3)	20 301	(31.6)

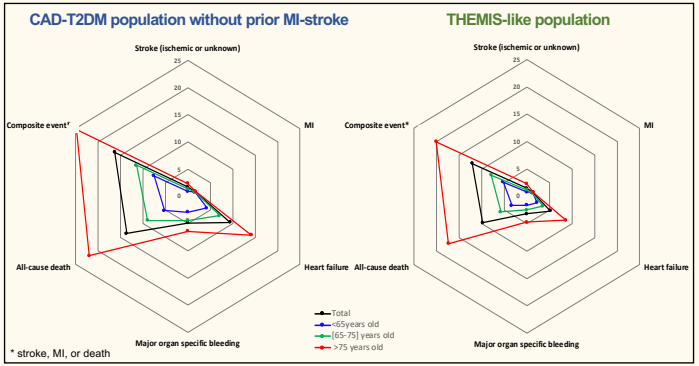

Figure 2. Cumulative incidence/probability of outcomes at two years of follow-up (%)

Conclusions

- In current French practice, the median age of the THEMIS-like population was 6 years older than in the THEMIS trial (i.e. 72 vs 66 years).
- The incidences observed in real world setting for THEMIS-like population after 2 years of follow-up were about double for the composite outcome (i.e. 12.0 vs 6,2%), triple for deaths (i.e. 9.7 vs 3,2%) and quadruple for major bleeding compared to TIMI major bleeding (3,2 vs 0.8%) than those of the placebo arm of the THEMIS trial.

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