Cardiovascular outcome in THEMIS-like type 2 diabetes patients in Sweden: a nationwide observational study

Authors:
L P Hasvold¹, D Erlinge², B Svennblad³, M Janzon³, D Lindholm⁴, KA Sundell⁴, T Jernberg⁵, S James³, ¹AstraZeneca Nordic-Baltic, Medical department - Södertälje - Sweden, ²Lund University - Lund - Sweden, ³Uppsala Clinical Research Center - Uppsala - Sweden, ⁴AstraZeneca - Gothenburg - Sweden, ⁵Karolinska University Hospital - Stockholm - Sweden.

Topic(s):
Coronary Artery Disease – Epidemiology, Prognosis, Outcome

Citation:
AstraZeneca

Background
The THEMIS study (NCT01991795; in analysis phase; n= 19,349) compares the effect of dual antiplatelet therapy (DAPT) vs ASA alone for the prevention of major cardiovascular (CV) events in type 2 diabetes (T2D) patients with coronary artery disease (CAD) at high CV risk, but without prior myocardial infarction (MI) or stroke. However, there is a lack of real-life data on CV risk in a THEMIS-like population compared to MI patients, where treatment with DAPT is guideline standard. The aim of this study was to investigate the CV risk in a THEMIS-like population vs an MI population.

Methods
Patients invasively managed in Sweden (2006-2014) were identified using the SWEDHEART registry and the National Patient Registry. Two populations were studied: a THEMIS-like population including patients with CAD and T2D, = 1 vessel disease or elective percutaneous coronary intervention [PCI], and no prior stroke or MI, and a MI patient population alive at discharge. The cumulative incidence of the primary composite outcome (CV death(CVD)/MI/stroke) was estimated 3 years after index using the Kaplan-Meier method, and with probability plots adjusted for age, sex, atrial fibrillation, and heart failure. A 30 days blanking period for outcome was added to ensure capture of new events (index THEMIS-pop.: after angiography; index MI-pop.: after discharge).

Results
Overall, 6,534 THEMIS-like patients and 96,638 MI patients were included. At index, the THEMIS-like patients (CAD and T2D without previous MI/stroke) were aged 67.1 years (mean), 26.6% women, 9.2% AF, and 4.7% HF, while the MI patients were aged 67.3 years (mean), 30.7% women, 15.5% T2D, 17.9% previous MI, 5.2% stroke, 6.4% AF, and 4.8% HF. Three-year cumulative incidence for the composite outcome CVD/MI/stroke was 0.149 (95% CI 0.140, 0.158) for THEMIS-like patients, and 0.148 (95% CI 0.145, 0.15) for MI patients (p=0.88 log rank test) (Figure). Corresponding adjusted probably plots: 0.135 (95% CI 0.127, 0.143) and 0.131 (95% CI 0.128, 0.133). MI was the main risk driver with greatest cumulative incidence in both populations (0.091 vs 0.087) (Figure).

Conclusions
In this Swedish real-life setting, THEMIS-like patients, followed from 30 days after invasive intervention, had a similar long-term risk for CV events compared with MI patients surviving 30 days after discharge, with MI as the main risk driver, despite having no previous ischemic events. The present data indicate that long-term ischemic risk prevention should be a key strategy in coronary artery disease patients with diabetes requiring elective invasive intervention.
Abstract: Cardiovascular outcome in THEMIS-like type 2 diabetes patients in Sweden: a nationwide observational study

Authors: L P Hasvold, D Erlinge, B Svennblad, M Janzon, D Lindholm, KA Sundell, T Jernberg

Topic(s): Coronary Artery Disease – Epidemiology, Prognosis, Outcome

Background
The THEMIS study (NCT01991795; in analysis phase; n= 19,349) compares the effect of dual antiplatelet therapy (DAPT) vs ASA alone for the prevention of major cardiovascular (CV) events in type 2 diabetes (T2D) patients with coronary artery disease (CAD) at high CV risk, but without prior myocardial infarction (MI) or stroke. However, there is a lack of real-life data on CV risk in a THEMIS-like population compared to MI patients, where treatment with DAPT is guideline standard. The aim of this study was to investigate the CV risk in a THEMIS-like population vs an MI population

Methods
Patients invasively managed in Sweden (2006-2014) were identified using the SWEDEHEART registry and the National Patient Registry. Two populations were studied: a THEMIS-like population including patients with CAD and T2D, = 1 vessel disease or elective percutaneous coronary intervention [PCI], and no prior stroke or MI), and a MI patient population alive at discharge. The cumulative incidence of the primary composite outcome (CV death(CVD)/MI/stroke) was estimated 3 years after index using the Kaplan-Meier method, and with probability plots adjusted for age, sex, atrial fibrillation, and heart failure. A 30 days blanking period for outcome was added to ensure capture of new events (index THEMIS-pop.: after angiography; index MI-pop.: after discharge).

Results
Overall, 6,534 THEMIS-like patients and 96,638 MI patients were included. At index, the THEMIS-like patients (CAD and T2D without previous MI/stroke) were aged 67.1 years (mean), 26.6% women, 9.2% AF, and 4.7% HF, while the MI patients were aged 67.3 years (mean), 30.7% women, 15.5% T2D, 17.9% previous MI, 5.2% stroke, 6.4% AF, and 4.8% HF. Three-year cumulative incidence for the composite outcome CVD/MI/stroke was 0.149 (95% CI 0.140, 0.158) for THEMIS-like patients, and 0.148 (95% CI 0.145, 0.15) for MI patients (p=0.88 log rank test) (Figure). Corresponding adjusted probably plots: 0.135 (95% CI 0.127, 0.143) and 0.131 (95% CI 0.128, 0.133). MI was the main risk driver with greatest cumulative incidence in both populations (0.091 vs 0.087) (Figure).

Conclusions
In this Swedish real-life setting, THEMIS-like patients, followed from 30 days after invasive intervention, had a similar long-term risk for CV events compared with MI patients surviving 30 days after discharge, with MI as the main risk driver, despite having no previous ischemic events. The present data indicate that long-term ischemic risk prevention should be a key strategy in coronary artery disease patients with diabetes requiring elective invasive intervention.

Figure. 3-year cumulative incidence for THEMIS-like patients and MI patients for CVD/MI/stroke (left), and myocardial infarction (right).