

Ticagrelor in patients with diabetes and stable coronary artery disease with a history of previous percutaneous coronary intervention (THEMIS-PCI): a phase 3, placebo-controlled, randomised trial

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Abstract: Summary Background Patients with stable coronary artery disease and diabetes with previous percutaneous coronary intervention (PCI), particularly those with previous stenting, are at high risk of ischaemic events. These patients are generally treated with aspirin. In this trial, we aimed to investigate if these patients would benefit from treatment with aspirin plus ticagrelor.

Findings Between Feb 17, 2014, and May 24, 2016, 11 154 patients (58% of the overall THEMIS trial) with a history of previous PCI were enrolled in the THEMIS-PCI trial. Median follow-up was 3·3 years (IQR 2·8–3·8). In the previous PCI group, fewer patients receiving ticagrelor had a primary efficacy outcome event than in the placebo group (404 [7·3%] of 5558 vs 480 [8·6%] of 5596; HR 0·85 [95% CI 0·74–0·97], $p=0·013$). The same effect was not observed in patients without PCI ($p=0·76$, pinteraction=0·16). The proportion of patients with cardiovascular death was similar in both treatment groups (174 [3·1%] with ticagrelor vs 183 (3·3%) with placebo; HR 0·96 [95% CI 0·78–1·18], $p=0·68$), as well as all-cause death (282 [5·1%] vs 323 [5·8%]; 0·88 [0·75–1·03], $p=0·11$). TIMI major bleeding occurred in 111 (2·0%) of 5536 patients receiving ticagrelor and 62 (1·1%) of 5564 patients receiving placebo (HR 2·03 [95% CI 1·48–2·76], $p<0·0001$), and fatal bleeding in 6 (0·1%) of 5536 patients with ticagrelor and 6 (0·1%) of 5564 with placebo (1·13 [0·36–3·50], $p=0·83$). Intracranial haemorrhage occurred in 33 (0·6%) and 31 (0·6%) patients (1·21

[0.74–1.97], $p=0.45$). Ticagrelor improved net clinical benefit: 519/5558 (9.3%) versus 617/5596 (11.0%), $HR=0.85$, 95% CI 0.75–0.95, $p=0.005$, in contrast to patients without PCI where it did not, $p_{interaction}=0.012$. Benefit was present irrespective of time from most recent PCI.

Interpretation In patients with diabetes, stable coronary artery disease, and previous PCI, ticagrelor added to aspirin reduced cardiovascular death, myocardial infarction, and stroke, although with increased major bleeding. In that large, easily identified population, ticagrelor provided a favourable net clinical benefit (more than in patients without history of PCI). This effect shows that long-term therapy with ticagrelor in addition to aspirin should be considered in patients with diabetes and a history of PCI who have tolerated antiplatelet therapy, have high ischaemic risk, and low bleeding risk.

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