

#ESCCongress: THEMIS/THEMIS-PCI Findings - Minimal Benefits Observed



Investigators from Brigham and Women's Hospital and Greater Paris University Hospitals - AP-HP/Université de Paris presented the results from The Effect of Ticagrelor on Health Outcomes in Diabetes Mellitus Patients Intervention Study (THEMIS) study at the ESC Congress in Paris.

The THEMIS trial evaluated whether adding ticagrelor to aspirin improved outcomes for patients with stable coronary artery disease and diabetes mellitus without a history of heart attack or stroke. THEMIS-PCI looked specifically at THEMIS patients with a history of PCI including stenting, versus the overall THEMIS population.

Findings from the THEMIS study show that the incidence of ischaemic cardiovascular events was lower in the ticagrelor group as compared to the placebo group, but the incidence of major bleeding and intracranial haemorrhage was higher in the ticagrelor group. No significant differences were observed in the incidence of fatal bleeding. The incidence of death from any cause, myocardial infarction, stroke, fatal bleeding or intracranial haemorrhage was similar in both groups.

Overall, THEMIS results suggest that there was a reduction in primary composite but a neutral effect on secondary endpoint. And while there was a reduction in endpoint death/MI/stroke, major bleeding increased. There was also a higher discontinuation rate with ticagrelor.

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"With prolonged dual-antiplatelet therapy, we need to be thoughtful in considering which patients are most suited to taking the regimen -- that is, those at high ischaemic risk and low bleeding risk," said THEMIS co-chair Deepak L. Bhatt, MD, MPH, executive director of Interventional Cardiovascular Programs at the Brigham and professor of medicine at Harvard Medical School.

Among patients in THEMIS-PCI, the reductions outweighed the increased bleeding risks and ticagrelor provided a favourable balance of benefit versus risk. Thus, long term therapy with ticagrelor in addition to aspirin should be considered in patients with diabetes and a history of PCI with high ischaemic risk and low bleeding risk.

Results of THEMIS are published in [The New England Journal of Medicine](#) and results from THEMIS-PCI are published in [The Lancet](#).

Source: NEJM/The Lancet/ESC Congress 2019

Slide Credit: Dr. Deepak Bhatt

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