

THEMIS-PCI – Ticagrelor added to aspirin in patient with diabetes and stable coronary artery disease with a history of prior percutaneous coronary intervention.

Purpose: to understand if patients with prior PCI (previously treated with DAPT) would be a group more likely to have a favorable balance of efficacy and safety.

Trial Design: Randomized, double-blind, placebo-controlled trial of ticagrelor vs- placebo on top of low-dose aspirin (75mg-150mg) in patients with type 2 DM receiving anti-hyperglycemic medications for at least 5 months and with stable CAD.

Primary Endpoints: CV death, MI or stroke (ITT analysis)

Safety: TIMI major bleeding

*KM = Kaplan Meier

	Ticagrelor	Placebo	Hazard Ratio	P- value
Cardiovascular Death, MI or stroke				
History of PCI	6.5% KM* at 36 mos.	7.7% KM* at 36 mos.	0.86 (95% CI 0.74-0.97)	P=0.013
No history of PCI	7.4% KM* at 36 mos.	7.5% KM* at 36 mos.	0.98 (95% CI 0.84-1.14)	P=0.76
TIMI Major Bleeding				
History of PCI	Events in pts. N=111, 2.0%	Events in patients, n=62, 1.1%	2.03 (95% CI 1.48-2.76)	P=<0.0001
History of no PCI	Events in pts. N=95 (2.4%)	Events in patients, n=38 (1.0%)	2.79 (95% CI 1.91-4.06)	P=<0.0001

Results: In stable CAD patients with DM, and prior PCI, ticagrelor with aspirin reduced CV death, MI or stroke events. While more bleeding occurred in the ticagrelor group, ticagrelor had an favorable net benefit in patients with prior PCI.

