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New insights into optimal duration of DAPT for high-risk "TWILIGHT-like" patients with diabetes mellitus undergoing PCI: a focus on diabetes mellitus as a high-risk patient group

Haoyu Wang, Kefei Dou

Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College

Abstract

Background: Patients with diabetes mellitus (DM) are known to be at high-risk for both ischemic and bleeding complications post-percutaneous coronary intervention (PCI). The ischemic benefit vs. bleeding risk associated with extended dual antiplatelet therapy (DAPT) in high-risk "TWILIGHT-like" patients with diabetes mellitus after PCI has not been established. Methods: All consecutive high-risk patients fulfilling the "TWILIGHT-like" criteria undergoing PCI were identified from the prospective Fuwai PCI Registry. High-risk "TWILIGHT-like" patients were defined by at least one clinical and one angiographic feature based on the TWILIGHT trial selection criteria. The present analysis evaluated 3,425 diabetic patients with concomitant high-risk angiographic features who were event-free at 1 year after PCI. Median follow-up was 2.4 years. The primary effectiveness endpoint was a composite of death, myocardial infarction, or stroke (termed major adverse cardiac and cerebrovascular events), and primary safety endpoint was clinically relevant bleeding according to the Bleeding Academic Research Consortium types 2, 3, or 5. Results: On inverse probability of treatment weighting (IPTW) analysis, prolonged-term (>1-year) DAPT with aspirin and clopidogrel decreased the risk of primary effectiveness endpoint compared with shorter (≤1-year) DAPT (1.8% vs. 4.3%; hazard ratio [HR]IPTW: 0.381; 95% confidence interval [CI]: 0.252-0.576; P<0.001) and reduced cardiovascular death (0.1% vs. 1.8%; HRIPTW: 0.056 [0.016-0.193]). Prolonged DAPT was also associated with a reduced risk of definite/probable stent thrombosis (0.2% vs. 0.7%; HRIPTW: 0.258 [0.083-0.802]), and non-significantly lower rate of myocardial infarction (0.5% vs. 0.8%; HRIPTW: 0.676 [0.275-1.661]). There was no significant difference between groups in clinically relevant bleeding (1.1% vs. 1.1%; HRIPTW: 1.078 [0.519-2.241]; P=0.840). Similar results were observed in multivariable Cox proportional hazards regression model. The risk differences between the two groups with respect to the primary efficacy and safety endpoints, and the composite net clinical benefit outcome were independent of the progressive number of high-risk clinical and angiographic criteria fulfilled (1-3 [n=980], 4-5 [n=1827], or 6-9 [n=618] high-risk factors), with no significant treatment interactions (all P for interaction>0.05). Conclusions: In this real-world retrospective analysis of diabetic patients with concomitant high-risk angiographic features who were event-free at 1 year after PCI, extended-term (>1-year) DAPT with clopidogrel and aspirin reduced the risk of MACCE and mortality compared with DAPT discontinuation within 1 year without significant differences in terms of clinically relevant bleeding. As such, long-term DAPT may be considered when contemplating an antiplatelet therapy in high-risk PCI patients with DM for a broader coronary atherothrombotic events protection.

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None.