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Risk and Consequences of Periprocedural Myocardial Infarction Following Off-Label Use of Second Generation Drug-Eluting Stents: Two-Year Follow-up in the TWENTE Trial

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Background: Drug-eluting stents (DES) were initially used 'on-label' in simple lesions and low-risk patients. Contemporary second-generation DES are more often used in 'off-label' settings, while there is limited knowledge about the potential increase in event risk.

Methods: We analyzed the 2-year clinical outcome data of 1387 TWENTE trial patients treated with liberal off-label use of second-generation everolimus-eluting Xience V or zotarolimus-eluting Resolute stents. Periprocedural myocardial infarction (PMI) was defined as myocardial infarction (MI) < 48 hours following PCI. MI was defined as 2x the upper reference limit of creatine kinase (CK).

Results: Off-label patients (n = 1033; 74.5%) had more diabetes (22.9% vs. 17.5%; p < 0.05), previous MI (35.9% vs. 22.3%; p < 0.05), complex lesions (76.1% vs. 60.7%; p < 0.05), and acute coronary syndromes (57.8% vs. 33.3%; p < 0.05). There was a higher incidence of periprocedural MI in off-label patients (5.0% vs. 1.4%; p < 0.05), of whom merely 1.1% developed creatine kinase levels > 5x ULN. Consequently, target vessel-related MI was higher in off-label patients (6.4% vs. 2.8%; p < 0.05). Nevertheless, cardiac death and target vessel revascularization rates were similar for both groups (p > 0.8).

Conclusions: Patients with off-label DES use had more periprocedural MI. Despite a higher risk profile and a higher rate of periprocedural MI, 2-year clinical outcome did not differ from that of patients with on-label DES use. Our findings underline the favorable safety profile of these second-generation DES in off-label settings.

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Does The National Cardiovascular Data Registry Bleeding Risk Score Accurately Predict Bleeding In African American Patients Undergoing Percutaneous Coronary Intervention?

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Background: The National Cardiovascular Data Registry (NCDR) bleeding risk score rates have been reported. We aim to analyze the post-PCI bleeding rates in a better-refined cohort.

Methods: From our own PCI registry, bleeding (defined as transfusion, prolonged hospital stay and/or drop in hemoglobin) rates were reported. The NCDR bleeding risk score was calculated for each patient and compared with observed bleeding event rates.

Results: A total of 22438 PCI patients were evaluated, of which 6396 (28.5%) were AA. Although NCDR bleeding risk score was higher in AA than in non-AA (median (IQR) 13 (8-18) vs 11 (6-17), p < 0.001), overall observed bleeding event rates were similar (5.0% vs. 5.6%; p=NS). Observed bleeding event rates across risk scores are presented in Figure 1. The NCDR model predicted post-PCI bleeding similarly in AA and non-AA (AUC 0.68 vs 0.72, p=0.09) (Figure 2), and the model’s predictability was not enhanced by adding AA race as a variable using NRI analysis (NRI 4.8%, p=0.20).

Conclusions: The predicted post-PCI bleeding risk was higher in AA compared to non-AA; however, observed bleeding rates were similar. The NCDR bleeding risk score remained predictive of post-PCI bleed in both groups.