Conclusions: Patients with off-label DES use had more periprocedural MI. Despite a higher risk, death did not differ from that of patients with on-label DES use. Our 2.8%; p = 0.05). Nevertheless, cardiac death and target vessel revascularization rates were similar for both groups (p = 0.8).

Results: 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.

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 TWENTÉ 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.