Abstract:
Clinical data on the early and midterm outcomes of bioresorbable vascular scaffolds (BVS) in routine clinical practice are limited. To fill this gap, we report on the early and midterm clinical outcomes of PCI with everolimus-eluting BVS from the large multicentre GHOST-EU registry. Between November 2011 and January 2014, 1,189 patients underwent percutaneous coronary intervention with one or more BVS (Absorb BVS; Abbott Vascular, Santa Clara, CA, USA) at 10 European centres. The primary outcome of interest was target lesion failure (TLF), defined as the combination of cardiac death, target vessel myocardial infarction, or clinically driven target lesion revascularisation (TLR). A total of 1,731 Absorb BVS were implanted at a mean of 12.3±3.4 atm. Technical success was achieved in 99.7% of cases. TLF was recorded in 67 of 1,189 patients at a median of 109 (interquartile range 8-227) days after implantation. The cumulative incidence of TLF was 2.2% at 30 days and 4.4% at six months. The annualised rate of TLF was 10.1%. At
six months, the rate of cardiac death was 1.0%, target vessel myocardial infarction was 2.0%, TLR was 2.5%, and target vessel revascularisation was 4.0%. Diabetes mellitus was the only independent predictor of TLF (hazard ratio 2.41, 95% confidence interval: 1.28-4.53; p=0.006). The cumulative incidence of definite/probable scaffold thrombosis was 1.5% at 30 days and 2.1% at six months, with 16 of 23 cases occurring within 30 days. "Real-world" outcomes of BVS showed acceptable rates of TLF at six months, although the rates of early and midterm scaffold thrombosis, mostly clustered within 30 days, were not negligible.