Polymer-free sirolimus-eluting stents in a large-scale all-comers population

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ABSTRACT
Objective The objective of this study was to assess the safety and efficacy of a polymer-free sirolimus coated, ultrathin strut drug-eluting stent (PF-SES) in an unselected patient population with a focus on acute coronary syndrome (ACS). Furthermore, stable coronary artery disease (CAD) with short (<6 months) versus long (>6 months) dual antiplatelet therapy (DAPT) were also studied.
Methods Patients who received PF-SES were investigated in an unselected large-scale international, single-armed, multicenter, all-comers observational study. The primary endpoint was the 9-month target lesion revascularisation (TLR) rate, whereas secondary endpoints included the 9-month major adverse cardiac events (MACE) and procedural success rates. A priori defined subgroups such as patients with ACS, diabetes, lesion subsets and procedural characteristics relative to DAPT were investigated.
Results A total of 2877 patients of whom 1084 had ACS were treated with PF-SES (1.37±0.75 stents per patient). At 9 months, the accumulated overall TLR rate was 2.3% (58/2513). There was no significant difference between ACS and stable CAD (2.6% vs 2.1%, p=0.389). However, the overall MACE rate was 4.3% (108/2513) with a higher rate in patients with ACS when compared with the stable CAD subgroup (6.1%, 58/947 vs 3.2%, 50/1566, p=0.001).
Conclusions PF-SES angioplasty is safe and effective in the daily clinical routine with low rates of TLR and MACE in an unselected patient population. Our data are in agreement with prior clinical findings that extended DAPT duration beyond 6 months do not improve clinical outcomes in patients with stable CAD (ClinicalTrials.gov Identifier NCT02629575).
Trial registration number NCT02629575.

INTRODUCTION
Drug-eluting stents (DES) have greatly reduced the need for repeat revascularisation despite studies revealing that first-generation DES were associated with stent thrombosis (ST) rates that were less favourable when compared with bare-metal stents.

The theoretical advantage of new coating technologies such as bioabsorbable polymers or non-polymer coating and the potential patient benefit of a shortened dual-antiplatelet therapy (DAPT) may herald a new milestone in DES development. This, in turn, may enable patients to undergo other non-coronary treatments with a reduced risk of bleeding.

Currently, there are polarised opinions regarding the length of DAPT which range from an extended DAPT duration beyond 12 months with more favourable long-term