

**Comparative effectiveness and safety of new- versus early-generation drug-eluting stents according to the complexity of coronary artery disease. A patient-level pooled analysis of 6,081 patients**

**Authors:**

R. Piccolo<sup>1</sup>, D. Heg<sup>2</sup>, J. Rat<sup>2</sup>, A. Franzone<sup>1</sup>, S. Silber<sup>3</sup>, P.W. Serruys<sup>4</sup>, T. Pigrim<sup>1</sup>, P. Juni<sup>2</sup>, S. Windecker<sup>1</sup>,  
<sup>1</sup>Bern University Hospital, Cardiology Department - Bern - Switzerland, <sup>2</sup>University of Bern - Bern - Switzerland, <sup>3</sup>Heart Centre at the Isar - Munich - Germany, <sup>4</sup>Erasmus Medical Center - Rotterdam - Netherlands,

**Topic(s):**

PCI / stents: devices and technique

**Citation:**

European Heart Journal ( 2015 ) 36 ( Abstract Supplement ), 29

**Background and introduction:** Although new-generation drug-eluting stents (DES) are considered the standard-of-care in patients undergoing percutaneous coronary intervention, it is unknown whether the clinical benefit associated with their use is preserved with more advanced coronary artery disease.

**Purpose:** To compare the 1-year effectiveness and safety of new-generation vs. early-generation DES according to the severity of coronary artery disease as assessed by the SYNTAX Score.

**Methods:** Patient-level data from four contemporary, all-comer DES trials were pooled. The primary endpoint was the composite of cardiac death, myocardial infarction, or target-lesion revascularization (TLR). The principal effectiveness endpoint was TLR, and the principal safety endpoint was definite stent thrombosis (ST). Adjusted hazard ratios (HR) with 95% confidence intervals (CI) were calculated at 1-year for overall comparisons as well as stratified for low-complexity (SYNTAX score  $\leq 11$ ) and high-complexity (SYNTAX score  $> 11$ ) patients.

**Results:** A total of 6,081 patients were included in the study. New-generation (n=4,554) vs. early-generation DES (n=1,527) significantly reduced the primary composite endpoint (HR [95% CI] 0.70 [0.58–0.86],  $p < 0.001$ ), without significant interaction ( $p = 0.412$ ) between patients with low-complexity (HR [95% CI] 0.78 [0.56–1.09],  $p = 0.143$ ) and high-complexity (HR [95% CI] 0.65 [0.51–0.81],  $p = 0.001$ ). Among patients with SYNTAX score  $> 11$ , new-generation DES significantly reduced TLR (HR [95% CI] 0.41 [0.30–0.56],  $p < 0.001$ ) and definite ST (HR [95% CI] 0.28 [0.15–0.55],  $p < 0.001$ ) without interaction with the low-complexity group. New-generation DES decreased the risk of cardiac mortality in patients with SYNTAX score  $> 11$  (HR [95% CI] 0.45 [0.27–0.76],  $p = 0.003$ ) but not in patients with SYNTAX score  $\leq 11$  ( $p$  for interaction = 0.015). There was no modulating effect of the SYNTAX score when introduced in Cox regression analyses.

**Conclusions:** New-generation DES improved clinical outcomes compared with early-generation DES and the greater safety and effectiveness profile is maintained across the entire spectrum of anatomical severity of coronary artery disease. Additional benefits conferred by new-generation DES can be expected in patients with high SYNTAX scores, which may have important implications in the comparative effectiveness of PCI versus coronary artery bypass grafting.