ANGIOGRAPHY/QCA

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Device Success Algorithm of the European Association of Percutaneous Cardiovascular interventions (EAPCI) Prospectively Applied to the Pioneer IV Trial

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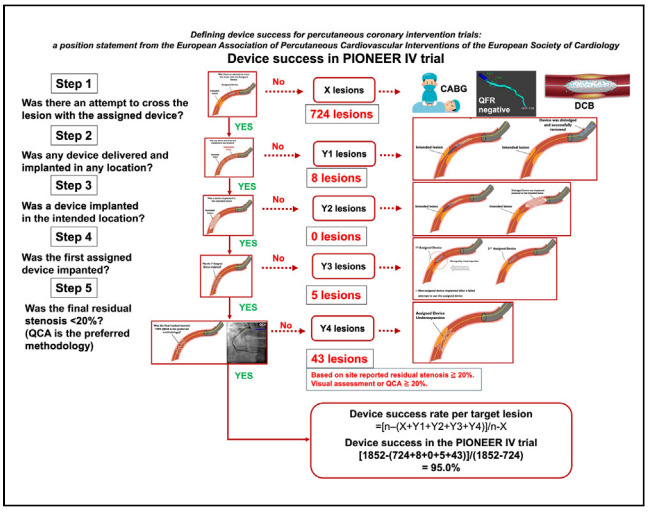
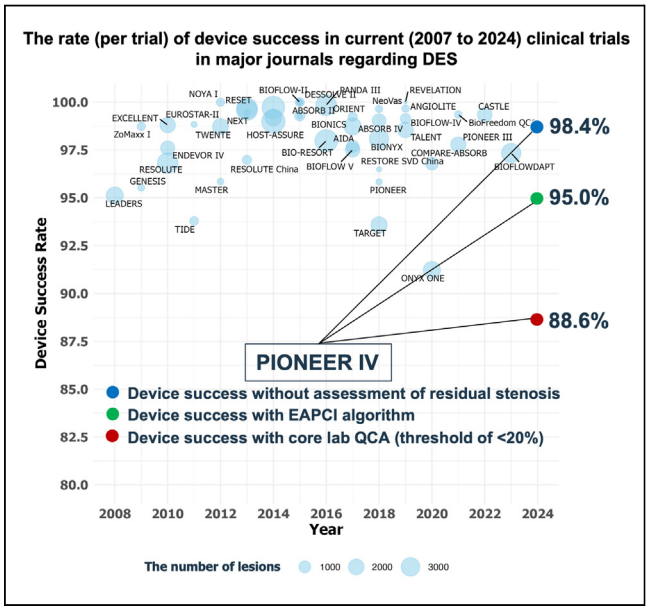
BACKGROUND Device success is a key intraprocedural endpoint and a critical performance metric for drug-eluting stents. However, definitions of device success vary across trials, resulting in a large discrepancy in success rate from 91.2-100%, making cross-comparison challenging. The European Association of Percutaneous Cardiovascular Interventions (EAPCI) has endorsed an algorithm to standardize device success, but it has not been prospectively applied with core lab quantitative coronary angiography (QCA) analysis.

METHODS We prospectively applied this algorithm (Figure 1) in the ongoing PIONEER IV trial (NCT04923191), all-comers, multicenter randomized controlled trial comparing PCI outcomes guided by angiography-derived quantitative flow ratio (QFR) or usual care and treating both arms with Healing-Targeted Supreme sirolimus-eluting stents (HT Supreme stent). Device success was adjudicated by an independent core lab (CORRIB core lab, Ireland) and compared with a performance index derived from 45 major recent DES trials (71875 lesions).

RESULTS Among the first 1270 patients,1128 lesions were treated, and 724 lesions were deferred. 98.4% of the HT supreme stent was implanted in the intended lesion and demonstrated a 95.0% device success rate based on site reports (with visual/QCA residual stenosis <20%). When independent core lab QCA was applied to adjudicate residual stenosis, the device success rate was 88.6%.





CONCLUSION The HT Supreme stent demonstrated a 95.0% device success rate based on operator assessment, while core lab QCA yielded more modest success rates, suggesting underestimated residual stenosis by the operator (Figure 2). Thus, in the next algorithm iteration, core lab QCA should be mandatory for unbiased device comparison, and QFR, which is now Class 1b in ESC guidelines, should be integrated. Post-PCI QFR results will be presented at CRT.