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DRUG-COATED BALLOON ANGIOPLASTY VERSUS DRUG-ELUTING STENT IMPLANTATION FOR THE TREATMENT OF BARE-METAL AND DRUG-ELUTING STENT RESTENOSIS: RESULTS FROM THE DAEDALUS STUDY

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10.1136/heartjnl-2020-ICS.15

Background In patients with coronary in-stent restenosis (ISR) requiring re-intervention, it is unclear if the choice of treatment strategy depends on whether the restenotic stent was a bare-metal stent (BMS) or a drug-eluting stent (DES).

Objectives We aimed to assess the comparative efficacy and safety of the two most frequently used treatments – angioplasty with drug-coated balloon (DCB) and repeat stenting DES – in patients with BMS- and DES-ISR.

Methods The DAEDALUS study was a pooled analysis of individual patient data from all 10 existing randomized clinical trials comparing DCB angioplasty vs. repeat DES implantation for the treatment of coronary ISR. In this prespecified analysis, patients were stratified according to BMS- vs. DES-ISR, and treatment assigned. The primary efficacy endpoint was target lesion revascularization (TLR) at 3 years. The primary safety endpoint was a composite of all-cause death, myocardial infarction, or target lesion thrombosis at 3 years. Primary analysis was performed by Cox mixed-effects models accounting for the trial of origin. Secondary analyses included non-parsimonious multivariable adjustment accounting also for multiple lesions per patient and two-stage analyses.

Results A total of 710 patients with BMS-ISR (722 lesions) and 1248 with DES-ISR (1377 lesions) were included. In patients with BMS-ISR, no significant difference between treatments was observed in terms of primary efficacy (9.2% vs. 10.2%; HR 0.83, 95% CI 0.51–1.37) and safety endpoints (8.7% vs. 7.5%; HR 1.13, 95% CI 0.65–1.96); results of secondary analyses were consistent. In patients with DES-ISR, the risk of the primary efficacy endpoint was higher with DCB angioplasty compared with repeat DES implantation (20.3% vs. 13.4%; HR 1.58, 95% CI 1.16–2.13), while

the risk of the primary safety endpoint was only numerically lower (9.5% vs. 13.3%; HR 0.69, 95% CI 0.47–1.00) and interaction was not significant ($p=0.146$); results of secondary analyses were consistent. The risk of TLR was lower in BMS- vs. DES-ISR (9.7% vs. 17.0%; HR 0.57, 95% CI 0.42–0.74), while safety was not significantly different between ISR types.

Conclusions At 3-year follow-up, DCB angioplasty and repeat stenting with DES are similarly effective and safe in the treatment of BMS-ISR, while DCB angioplasty is significantly less effective than repeat DES implantation in the treatment DES-ISR without statistically significant differences in safety endpoints. Overall, DES-ISR is associated with higher rates of treatment failure and similar safety compared with BMS-ISR.

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BLOOD PRESSURE REDUCTION AFTER CATHETER-BASED RENAL DENERVATION IN THE ABSENCE OF ANTIHYPERTENSIVE MEDICATIONS: SPYRAL HTN-OFF MED PIVOTAL TRIAL RESULTS

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10.1136/heartjnl-2020-ICS.16

Objective The SPYRAL HTN-OFF MED Pivotal Trial was designed to assess the efficacy of renal denervation (RDN) to lower blood pressure (BP) in the absence of anti-hypertensive medications.

Methods In this international, randomized, sham-controlled trial, patients with hypertension and office systolic blood pressure (SBP) ≥ 150 mmHg and < 180 mmHg were randomised 1:1 to RDN or sham control. Patients were required to abstain from anti-hypertensive medications prior to randomization. The primary efficacy endpoint was baseline-adjusted change in 24-hour SBP from baseline to 3 months. The secondary efficacy endpoint was baseline-adjusted change in office SBP from baseline to 3 months. Bayesian statistics were used to utilize evidence from the pilot and pivotal studies.