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QUALITY OF CARE AND OUTCOMES ASSESSMENT

COMPARISON OF EVEROLIMUS-ELUTING AND PACLITAXEL-ELUTING CORONARY STENTS IN PATIENTS UNDERGOING MULTI-VESSEL STENTING: POOLED ANALYSIS FROM THE SPIRIT III AND SPIRIT IV RANDOMIZED TRIALS

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Background: The SYNTAX trial has raised questions regarding optimal treatment of patients with multi vessel disease. SPIRIT III and IV trials evaluated the performance of XIENCE V® everolimus-eluting stent (EES), a second generation drug-eluting stent (DES), vs. TAXUS® Express2 paclitaxel-eluting stent (PES) in patients with multiple treated coronary arteries.

Methods: The SPIRIT III (n=1001) and IV (n=3687) trials were pooled and analyzed EES vs. PES in 4688 total patients, randomized 2:1. Both trials enrolled patients with de novo lesions <28 mm in length and reference vessel diameter of 2.5 − 3.75 mm. Inclusion and exclusion criteria were comparable with similar baseline characteristics and event definitions. SPIRIT III enrolled patients with a single lesion in 1 or 2 coronary arteries, while SPIRIT IV enrolled patients with 1-2 lesions in 1, 2 or 3 coronary arteries (maximum 2 lesions per vessel). Clinical outcomes up to 1 year were analyzed in patients with either a single treated (n=3823), or two or more treated vessels (n=765).

Results: Adverse outcomes were significantly lower in EES vs. PES patients with a single treated vessel for major adverse cardiac events (MACE: cardiac death, myocardial infarction [MI] or target lesion revascularization [TLR]) (4.3% vs. 6.5%, p=0.003) and target lesion failure (TLF: cardiac death, target vessel MI or TLR) (4.1% vs. 6.4%, p=0.003). The observed difference between EES and PES was relatively greater in the multivessel group for MACE (6.2% vs. 12.5% p=0.004) and TLF (6.0% vs. 12.2%, p=0.005). Reductions in TLR rates were observed for EES patients with a single treated vessel (2.4% vs. 4.2% PES, p=0.004) and two or more treated vessels (4.2% vs. 8.0%, p=0.04). In addition, stent thrombosis (ARC definite or probable) tended to be lower in EES vs. PES for a single treated vessel (0.3% vs. 0.6%, p=0.10) and two or more treated vessels (1.2% vs. 2.7%, p=0.15).

Conclusions: Treatment with EES vs. PES resulted in lower rates of adverse events in patients undergoing single and particularly multi vessel stenting. Improved safety and efficacy with EES vs. PES may influence clinical outcomes of revascularization strategies in future clinical trials such as SYNTAX.