Results of the DEB-AMI Trial reported at TCT 2011

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A clinical trial that compared the use of drug-eluting balloons (DEB) and bare metal stents (BMS) to both bare metal stents alone and drug-eluting stents (DES) found that the drug-eluting balloon group did not meet the primary endpoint of reduced late lumen loss. Results of the DEB-AMI (Drug Eluting Balloon in Acute Myocardial Infarction) trial were presented today at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

Concerns regarding the safety of DES in ST-segment elevated acute myocardial infarctions (STEMI) continue to exist, including the risk of stent thrombosis. The use of drug-eluting balloons in angioplasty show potential as an alternative to treat STEMI.

In this randomized, international two-center, single-blinded three-arm study, patients were randomly assigned (ratio 1:1:1) to one of the following treatment groups: DEB plus BMS (n=50); BMS (n=50); or DES (n=49) after successful thrombus aspiration.

All patients underwent stenting with an identical stent platform. The primary endpoint was six- month angiographic late lumen loss. Secondary end points were six-month binary restenosis, stent malapposition and re-endothelialization assessed by OCT, endothelial function assessed through acetylcholine testing, and major adverse cardiac events (MACE: death, myocardial infarction, target vessel revascularization).

Late lumen loss at six months was as follows:

- DEB+BMS: 0.64±0.56
- BMS: 0.78±0.59
- DES: 0.21±0.32

The rates of major adverse cardiac events were as follows:

- DEB+BMS: 10 (20.0%)
- BMS: 12 (23.5%)
- DES: 2 (4.1%)

"Results of the DEB-AMI trial indicate that drug-eluting stents induce more pronounced morphological changes (compared to drug-eluting balloons), resulting in superior angiographical and clinical outcomes with respect to bare metal stents and drug-eluting stents," said Pieter R. Stella, MD, PhD, the lead investigator of the trial. Dr. Stella is Director of the Heart Catheterization Laboratories and Director of Clinical Cardiovascular Research at the University Medical Centre Utrecht in The Netherlands.

Researchers noted however, that experience of the operators and discrepancies between the two trial sites may have impacted the findings.

Provided by Cardiovascular Research Foundation

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