

Highlights from TCT 2009

This year, the Transcatheter Cardiovascular Therapeutics (TCT) congress was held in San Francisco, CA, USA, from 21–25th September. As the largest global medical and scientific symposium dedicated to interventional cardiovascular medicine, it attracted almost 15,000 visitors.

It's all about the patients

This year's congress had a strong focus on the importance of the individual patient in treatment decisions and a multidisciplinary approach involving the entire 'heart team' (surgeons, cardiologists, anaesthetists, nurses and technicians). Reporting results from the ongoing PARTNER trial evaluating the SAPIEN™ valve (Edwards Lifesciences, Irvine, CA, USA) in patients who are considered high risk for conventional open-heart valve surgery, C Miller (USA) described what he has learned from transcatheter aortic valve implantation (TAVI). "Working hand in hand with (interventional) cardiologists is really stimulating intellectually. It's fun, gratifying and, ultimately, I think it's better for patients. Of course, it can be terrifying at times, but it's terrifying for both of us," he said.

Key trial data

As ever, TCT showcased the latest results from current trials in interventional cardiology including data from some key stent trials. SPIRIT IV is a prospective, single-blinded, multicentre clinical trial, with 3,690 patients randomised 2:1 to either the Xience V™ (Abbott, Abbott Park, IL, USA) stent or the Taxus Express™ (Boston Scientific, Natick, MA, USA) stent. This year G Stone (USA) presented results from SPIRIT IV. The primary endpoint was the rate of ischaemia-driven target lesion failure (TLF) after 1 year. At 1-year follow up,

the rate of TLF was 4.2% for the Xience V group and 6.8% for the Taxus Express group ($p < 0.0001$). Furthermore, the results showed a significant difference in ischaemia-driven target lesion revascularisation of 2.5% in the Xience V group vs. 4.6% in the Taxus Express group ($p < 0.001$) while the rate of stent thrombosis was lower with 0.17 in the Xience V group compared with 0.85 in the Taxus group. Using the Academic Research Consortium definition of definite/probable stent thrombosis, the rates were 0.29 for Xience V and 1.10 for Taxus Express. These data suggest a newer generation of drug-eluting stents (DESs) may have benefits over first-generation versions.

Cardiologists have used DESs off-label to treat in-stent restenosis for some time with limited clinical data to support this indication. This year, R Byrne (Germany) presented some promising data from the ISAR-DESIRE 2 study. This open-label study randomised 450 patients with sirolimus-eluting stent (SES) restenosis to the Taxus Express (paclitaxel-eluting) or Cypher™ (Cordis Corporation, Bridgewater, NJ, USA; sirolimus-eluting) stents. Results showed no difference in late lumen loss between stents at 0.40 and 0.38 mm ($p = 0.75$) in the Taxus and Cypher groups, respectively. Event rates for binary restenosis (20.6% vs. 19.0%, respectively) and target lesion revascularisation (14.6% vs. 16.6%, respectively) were also similar in both groups. These data suggest that treating in-stent restenosis with either Cypher or Taxus results in comparable anti-restenotic efficacy.

K Volker (Germany) presented 2-year follow-up data from the LEADERS trial demonstrating the safety and efficacy of a biolimus A9



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*Kerckhoff Klinik Heart
and Thorax Center,
Bad Nauheim, Germany*

eluting stent with a bioabsorbable polymer (BES) versus SES with a durable polymer. This trial included 1,700 patients (with stable angina or acute coronary syndrome [ACS]) randomised to receive either SES or BES. After 2 years, both groups had similar outcomes with respect to the primary endpoints of a major adverse cardiac event (MACE), cardiac death or myocardial infarction (MI) and clinically-driven need for target vessel revascularisation. Patients with ST-elevation myocardial infarction (STEMI) treated with BES experienced a significant reduction in the rate of MACE in comparison with SES-treated patients: 8.1% vs. 19.3% for BES and SES, respectively ($p < 0.01$). The rate of very late stent thrombosis was remarkably low for both groups: 0.2% vs. 0.5% for BES and SES, respectively ($p = 0.73$).

Results from a separate analysis of the CURRENT OASIS-7 – The CURRENT STEMI PCI trial – were presented by S Mehta (Canada). This analysis looked specifically at patients undergoing PCI for STEMI. Of the original cohort, 6,346 patients presented with STEMI, a significant majority of whom underwent primary PCI. These data demonstrated that at 30 days, there was a notable reduction in the risk for ischaemic events, (specifically a 37% reduction in MI) in patients who received a double dose of clopidogrel. This reduction is most likely due to a 46% reduction in the risk of definite stent thrombosis (hazard ratio [HR] 0.54; 95% confidence interval [CI] 0.35–0.84) and a 30% reduction in risk in the combined end-point of MI and all stent thrombosis was shown.

Finally, G Stone (USA) also presented data from the PROSPECT study, which investigated whether culprit or non-culprit lesions are responsible for later MACE. The study included 700 patients with ACS who underwent successful PCI in one or

two major coronary arteries. The investigators performed quantitative coronary angiography of the entire coronary tree, along with intravascular ultrasound and virtual histology. Over a median follow-up period of 3.4 years, the culprit and non-culprit lesions led to similar levels of MACE. The non-culprit lesions were not linked to any cases of cardiac death or arrest, but were most commonly associated with increasing angina (8.5%), unstable angina (3.3%) and MI (1.0%).

Looking to the future

R Bonow (USA) discussed the challenges of making appropriate treatment decisions in high-risk patients with aortic stenosis. Current guidelines state that asymptomatic patients are at low risk for cardiac death until symptoms develop, yet also advise that such patients should be followed frequently and carefully. Concerns remain about whether all asymptomatic patients are truly without symptoms and whether there are some subgroups of asymptomatic patients who are at particularly high risk. Moreover, most patients in this subgroup are likely to progress to symptomatic disease within 5 years. “Perhaps in some patients, doing planned elective aortic valve replacement before symptoms appear would be very reasonable, since this outcome is so predictable,” Bonow commented. “Even symptomatic patients often fall through the cracks,” he said, adding that another subgroup to consider is high-risk patients with low-gradient aortic stenosis. “These are the challenges facing the cardiologist seeing these patients on the front lines. In the future we’ll have the opportunity to refer them to the interventional cardiologist or the surgeon,” he concluded. “Hopefully, we’ll be referring them to a team of cardiologists and surgeons working together.”

Address for correspondence

Holger M Nef MD
Kerckhoff Klinik Heart and
Thorax Center, Department of
Cardiology, Benekestrasse 2-8,
61231 Bad Nauheim, Germany

H.Nef@Kerckhoff-fgi.de

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