Results of the TWENTE trial reported at TCT 2011

November 11 2011

The TWENTE clinical trial, which compared two second generation drug-eluting stents – zotarolimus and everolimus-eluting stents – established non-inferiority between the two stents as measured by the primary endpoint: target vessel failure (TVF) at one year. Both stents also demonstrated low rates of stent thrombosis. Trial results were presented today at the 23rd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

Early trials with first generation drug-eluting stents (DES) have demonstrated a reduction in restenosis rates compared to bare metal stents, but not lower mortality. One of the factors thought to be involved in this, is the lack of biocompatibility of coating on first generation stents, some of which were thought to be associated with hypersensitivity and vessel wall inflammation which can promote stent thrombosis. Second generation drug-eluting stents with improved coatings were developed to improve biocompatibility.

While more than two million drug-eluting stents are implanted annually worldwide (the majority of which is second generation DES), there are very few trials with a head-to-head comparison of second generation drug-eluting stents in 'real-world' patient populations.

The TWENTE study is a prospective, single-blinded, randomized controlled trial in patients requiring percutaneous coronary interventions (PCI) with drug-eluting stent implantation for the treatment of chronic

stable coronary artery disease or acute coronary syndromes. To allow for the inclusion of a broad patient population as seen in routine clinical practice, the study protocol defined no limit for lesion length, reference vessel size, and number of lesions or vessels to be treated. Patients with ST-elevation myocardial infarction requiring primary or rescue percutaneous coronary interventions during the past 48 hours were not eligible.

A total of 1,391 patients were enrolled, 82% of all eligible patients. The study population (age 64.3± 10.5 years; 72.5% male) included 21.6% diabetics. Patients presented with either stable angina (48.5%) or unstable angina/Non-STEMI (51.5%). Follow up information was obtained on 100% of the patients.

TVF at one year occurred in 8.2% of patients for the zotarolimus-eluting stent, and in 8.1% of patients for the everolimus-eluting stent (p=0.94). For the components of the primary endpoint, there were also no significant differences: cardiac death (1.0% vs. 1.4%, p=0.46), target vessel-related myocardial infarction (4.6% vs. 4.6%, p=0.98), and clinically driven target vessel revascularization (3.3% vs. 2.7%, p=0.53).

TWENTE showed similar and – considering the complexity of the patient population and the lesion characteristics – relatively low one-year rates of definite-plus-probable stent thrombosis for the zotarolimus and everolimus-eluting stents (0.86% and 1.16%, respectively). TWENTE also showed a low definite one-year stent thrombosis rate for zotarolimus and everolimus-eluting stents (0.58% and 0%, respectively).

"Results of the TWENTE trial show that zotarolimus-eluting stents were non-inferior to everolimus-eluting stents in terms of safety and efficacy for treating 'real-world' patients with a vast majority of complex lesions and 'off-label' indications for drug-eluting stents, which were implanted with liberal use of postdilatation," said Clemens von Birgelen, MD PhD,

the Principal Investigator of the trial. Dr. von Birgelen is Co-Director of the Department of Cardiology at Thoraxcentrum Twente and Professor of Cardiology at University of Twente in the Netherlands.

"The liberal use of stent postdilatation, applied in 82% of lesions, could have contributed to the positive results in both stent arms, despite the complex patient and lesion population examined in this trial," Dr. von Birgelen said.

TWENTE is the second published randomized study with minimal exclusion criteria to compare both stents head-to-head and it confirms the findings of the first study. Clinical events were scored by the same independent, external research organization as the first comparative study. Event rates in TWENTE were slightly lower.

"TWENTE did not have a STEMI subpopulation (STEMI is the most serious form of heart attack), but this does not explain the positive TWENTE results, as the STEMI subpopulation in the first comparative trial actually had lower clinical event rates than the overall population of that trial," Dr. von Birgelen said.

Provided by Cardiovascular Research Foundation