TCT-47

Two-Year Clinical Outcome of the TWENTE Trial, a Randomized Controlled Trial Comparing Second-Generation Zotarolimus-Eluting Resolute Stents Versus Everolimus-Eluting Xience V Stents in Real-World Patients

Clemens von Birgelen[1], Kenneth Tandjung[1], Hanim Sen[1], Mounir Basalus[1], J. Hans Louwerenburg[1], Martin Stoel[1], K Gert van Houwelingen[2], Gerard Linssen[3], Salah Saïd[4], Mark Nienhuis[5], Marije Löwik[1], Job van der Palen[6], Patrick Verhorst[1], Frits de Man[7]
[1]Thoraxcentrum Twente, Enschede, The Netherlands, [2]Thoraxcentrum Twente, Enschede, Netherlands, [3]Ziekenhuisgroep Twente, Almelo, The Netherlands, [4]Ziekenhuisgroep Twente, Hengelo, The Netherlands, [5]Streekziekenhuis Koningin Beatrix, Winterswijk, Netherlands, [6]Measurement and Data Analysis, University of Twente, Enschede, Netherlands, [7]Thoraxcentrum Twente, Enschede, Netherlands

Background: In the prospective, randomized TWENTE trial, the zotarolimus-eluting Resolute stent was at 1 year follow-up non-inferior to the everolimus-eluting Xience V stent for the primary endpoint target vessel failure. This composite endpoint consisted of cardiac death, clinically indicated target vessel revascularization, or target vessel-related myocardial infarction (MI). So far, few long-term data of prospective head-to-head comparisons between both DES have been reported.
Methods: Patients requiring percutaneous coronary interventions (PCI) with DES implantation at Thoraxcentrum Twente in Enschede were randomization between Resolute (Medtronic Vascular, Santa Rosa, CA, USA) and Xience V (Abbott Vascular, Santa Clara, CA, USA) in a 1:1 fashion. Inclusion of all coronary or bypass graft lesions and all clinical settings was permitted except for primary PCI (i.e. acute ST-elevation myocardial infarction (STEMI) was an exclusion criterion). Both external monitoring and clinical event adjudication were performed by an independent external contract research organization (Cardialysis, Rotterdam, the Netherlands). Two year clinical follow-up was performed as indicated in the study protocol.
Results: A total of 1,391 patients were enrolled in the TWENTE trial between June 2008 and August 2010. The study population comprised 21.6% diabetics with a vast majority of complex lesions and "off-label" indications for drug-eluting stents (77.4%). Patients presented with either stable angina (48.5%) or unstable angina/Non-STEMI (51.5%). Demographics, baseline angiographic and procedural data, and 2-year clinical follow-up data will be presented. This includes the primary endpoint of the study: Target vessel failure (TVF) at 2 year follow-up. Secondary endpoints include the individual components of the primary endpoint and the incidence of very late stent thrombosis. In addition, results of subgroup analyses will be reported.
Conclusions: Results of pre-specified analyses of 2-year clinical outcome of the TWENTE trial will be presented at TCT 2012.

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Two Year Follow-Up And Sub-group Analysis Of A Polymer-Free Sirolimus- And Probucol-Eluting Stent vs. A New Generation Zotarolimus-Eluting Stent In Coronary Artery Disease

Lamin King[1], Lamin King[1], Robert Byrne[2], Salvatore Cassese[3], Tomohisa Tada[4], Julinda Mehilli[2], Adnan Kastrati[2]
[1]Deutsches Herzzentrum, Munich, Munich, Germany, [2]Deutsches Herzzentrum Munich, Munich, Germany, [3]Deutsches Herzzentrum, Munich, BAVARIA, [4]Deutsches Herzzentrum Munich, Munich, Bayern

Background: The ISAR-TEST 5 clinical trial was a large-scale trial powered for clinical endpoints. It showed non-inferior safety and efficacy of a polymer-free sirolimus and probucol-eluting stent(SES)compared to a zotarolimus-eluting stent (ZES) at 1 year. We evaluated 2-year clinical outcomes in the study population and in pre-defined at-risk subgroups
Methods: In total 3002 patients undergoing PCI with minimal exclusion criteria received polymer-free SES (n=2002) or ZES. Follow-up was performed to 2 years. The primary endpoint (MACE) was the combined incidence of cardiac death, target vessel-related MI or target lesion revascularization (TLR) at 2 years. Secondary endpoints comprised: combined endpoint of death or any MI, TLR and probable or definite stent thrombosis. MACE was also evaluated in sub-groups according to sex, age, reference vessel diameter and diabetes.
Results: There was no difference in the occurrence of the primary endpoint between The polymer-free SES group and the ZES group demonstrated equivalent MACE (15.8%; vs: 15.9%; HR=0.98; P=0.87), death or MI (9.16% vs. 10.7% ; HR=0.83; P=0.12), target lesion revascularization (12.2% vs. 11.9%; HR=1.02; P=0.89) or stent thrombosis (0.56% vs.0.40%; HR=1.37; P=0.59). Sub-group analysis showed no differences in outcomes between polymer-free SES and ZES in patient sub-groups with the following characteristics: women, men, those at or above mean study age, patients below mean study age, vessel reference diameter above study median, vessel reference diameter at or below the study median, patients with diabetes mellitus or without diabetes mellitus.

subgroup	polymer free DES	ZES	P
AGE>67.8	15.9%	17.1%	0.86
AGE≤67.8	15.6%	14.5%	0.59
FEMALE	16.7%	13.8%	0.21
MALE	15.5%	16.6%	0.32
DIABETES	22.1%	21.3%	0.70
NO DIABETES	13.3%	13.7%	0.82
RD<2.79mm	16.7%	18.2%	0.26
RD≥2.79mm	15.0%	14.5%	0.39

Conclusions: In a large-scale trial powered for clinical endpoints, there were no differences in safety or efficacy between a polymer-free sirolimus and probucol-eluting stent and a new generation ZES at 2 years. This was consistenT across all sub-groups.

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A Comparison of 5 mg Prasugrel With 75 mg Clopidogrel in Very Elderly Coronary Artery Disease Patients: Pharmacodynamics and Rates of High on-Treatment Reactivity

Joseph Jakubowski[1], David Erlinge[2], Paul Gurbel[3], Chunmei Zhou[1], Kenneth Winters[1], Patricia Brown[1], Tomas Lindahl[4], Peter Svensson[5], Jurrien Ten Berg[6], Stefan James[7], Dominick Angiolillo[8]
[1]Eli Lilly and Company, Indianapolis, IN, [2]Lund University, Lund, Sweden, [3]Sinai Center for Thrombosis Research, Baltimore, MD, [4]Linköping University, Linköping, Sweden, [5]Lund University, Malmö, Sweden, [6]St Antonius Hospital, Nieuwegein, Netherlands, [7]Uppsala Clinical Research Center, Uppsala, Sweden, [8]University of Florida College of Medicine-Jacksonville, Jacksonville, FL

Background: Dual antiplatelet therapy (DAPT) with aspirin (ASA) + prasugrel (Pras, 10 mg maintenance dose (MD)) in the very elderly was associated with higher rates of bleeding than with DAPT comprising ASA + clopidogrel (Clop 75 mg MD). The GENERATIONS study was a blinded, randomized cross-over study that assessed the pharmacodynamics (PD) of 5 mg Pras in the very elderly (≥75 yrs) vs. 10 mg Pras in non-elderly (>45 to <65 yrs) in patients with stable coronary artery disease and included a comparison with 75 mg Clop. In the present analysis we compared the PD effects of 5 mg Pras with 75 mg Clop in the very elderly cohort.
Methods: In the study, 73 very elderly patients on low-dose ASA, mean age 78.9 ± 3 years, had PD assessments following 12 days of 5 mg Pras or 75 mg Clop. PD assays included LTA, VN-P2Y12 and VASP and consensus cut-off values of >50% MPA, >235 PRU and >50% PRI defined high on treatment platelet reactivity (HPR).
Results: Absolute measures of mean platelet reactivity (MPA, PRU and PRI) all indicated greater antiplatelet effects of 5 mg Pras compared to 75 mg Clop (Figure). Consistent with these data 5 mg Pras also resulted in lower rates of HPR by all 3 consensus cut-off values (Figure).
Conclusions: In very elderly coronary artery disease patients, 5 mg Pras results in greater suppression of platelet reactivity than 75 mg Clop; accordingly, 5 mg Pras may provide an alternative approach to DAPT in this high risk population.