Background: The SYNTAX trial represents the most comprehensive comparison of percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG). Newer generation everolimus-eluting stents (Xience™ V; EES) have however been shown to have superior efficacy and safety profile compared to first generation paclitaxel-eluting stents (Taxus™ Liberté; PES) used in the SYNTAX trial. As a result the only randomized trial comparing EES to PES in a true all-comers population (Boston Scientific; Natick, MA), based on a similar incidence of the primary endpoint target vessel failure (TVF), a composite of cardiac death, target vessel revascularization (TVR), or myocardial infarction (MI). No other follow-up data beyond 12 months have been published from a randomized head-to-head comparison of both stents.

Methods: In 4 study centers in the Netherlands, 1,811 patients were 1:1 randomly assigned to treatment with one of both stents. Patients with any clinical syndrome, any lesion type, and any number of lesions or vessels to be treated were included. Study monitoring and clinical event adjudication were performed by two independent Dutch contract research organizations (Diagram, Zwolle, and Cardialysis, Rotterdam, respectively).

Results: DUTCH PEERS examines an all-comer patient population that included 59% of patients with acute coronary syndromes (20% of all patients presented with an acute STEMI) and 66% of patients with complex target lesions. We will compare for both stent groups the 2-year incidence of TVF (primary endpoint) and various secondary endpoints, including individual components of the primary endpoint, the incidence of stent thrombosis, and other composite endpoints, such as target lesion failure, major adverse cardiovascular events, and the patient-oriented composite endpoint. In addition, we will report the outcome of patients with longitudinal stent deformation after discontinuation of dual anti-platelet therapy.

Conclusions: Clinical outcome of the DUTCH PEERS trial at 2-year follow-up will be presented.

TCT-587

What if current generation drug-eluting stents were used in the SYNTAX trial? Analysis of the COMPARE and SYNTAX trials 5 year follow-up

Pieter C. Smits1, Georgios J. Vlachojannis1, Kees-Jan Royaards1, Marielle A. Koper1, Martin van der Ent1, Pieter C. Smits2
1Maassstad Hospital Rotterdam, Rotterdam, Netherlands, 2Maassstad Hospital, Rotterdam, Netherlands, 3Manchester Royal Infirmary/ThoraxCenter Rotterdam, Rotterdam, Netherlands, 4Thoraxcenter, Rotterdam, MD

Background: The COMPARE trial was a prospective, randomized, single-center, all-comer trial comparing EES to PES (1:1). As of present is the only randomized trial comparing EES to PES in an all-comers population, which included complex multi-vessel (MV) and/or left main (LM) disease, and had an independent adjudicated 5-year follow-up. To mirror the SYNTAX population, a sub-analysis of COMPARE was performed in subjects undergoing PCI for MV and/or LM disease (n=466; 234 treated with PES and 232 with EES). For both trials identical adjudicated composite endpoint major adverse cardiac events (MACE: death, myocardial infarction, or target vessel revascularization) were used at 5 years. Results were stratified by anatomical complexity using the SYNTAX score.

Results: The incidence of MACE in COMPARE and SYNTAX with EES, PES or CABG are tabulated.

<table>
<thead>
<tr>
<th>SYNTAX score</th>
<th>COMPARE trial</th>
<th>SYNTAX trial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MACE (%)</td>
<td>MACE (%)</td>
</tr>
<tr>
<td>PES (n=234)</td>
<td>29.5</td>
<td>23.3</td>
</tr>
<tr>
<td>EES (n=232)</td>
<td>18.0</td>
<td>18.6</td>
</tr>
<tr>
<td>PES (n=871)</td>
<td>30.8</td>
<td>34.3</td>
</tr>
<tr>
<td>CABG (n=805)</td>
<td>24.7</td>
<td>22.1</td>
</tr>
</tbody>
</table>

Conclusions: The results of this analysis suggest that in subjects with MV and/or LM disease, newer generation EES might be superior to CABG in patients with low SYNTAX score, and equivalent in intermediate SYNTAX score, latter group currently recommended for CABG. Only the high SYNTAX score group showed a clear long-term benefit of CABG over PCI irrespective of stent type used. Newer generation drug eluting stents may allow for further refinement of the boundaries between PCI and CABG, which may have important clinical and economical implications.

TCT-588

2-Year Clinical Outcome of the Randomized, Multicenter DUTCH PEERS (TWENTE II) Trial, Comparing Cobalt-Chromium Zotarolimus-Eluting Resolute Integrity Stents and Platinum-Chromium Everolimus-Eluting Promus Element Stents in “All-Comer” Patients

Clemens von Birgelen1, Ming Kai Lam2, Lieffe van der Heijden2, Peter W. Danse2, Gillian A. Jessurun1, Melyn Tjon Joe Gin3, Rutger Anthonio2, Gert van Houwelingen2, Frits H. de Man2, Martin G. Stoel2, Hans W. Lauweren2, Gerard C. Linssen4, Marc Hartmann2, Marije M. Lówik5, Kenneth Tandjung2, Maarten J. Ijzerman1, Carine J. Doggen1, Hanim Sen2
1Thoraxcentrum Twente & University of Twente, Enschede, Netherlands, 2Thoraxcentrum Twente, Medisch Spectrum Twente, Enschede, Netherlands, 3Background Hospital, Arnhem, Netherlands, 4Ziekenhuis Groep Twente, Amel, Netherlands, 5MIRA – Institute for Biomedical Technology and Technical Medicine, University of Twente, Enschede, Netherlands

Background: The multicenter, prospective, randomized, single-blinded, investigator-initiated DUTCH PEERS (TWENTE II) “All Comers” Trial demonstrated at 1-year follow-up the non-inferiority of third-generation Resolute Zotarolimus-eluting stents (Medtronic Vascular, Santa Rosa, CA) versus Promus Element everolimus-eluting stents (Boston Scientific; Natick, MA), based on a similar incidence of the primary endpoint target vessel failure (TVF), a composite of cardiac death, target vessel revascularization (TVR), or myocardial infarction (MI). No other follow-up data beyond 12 months have been published from a randomized head-to-head comparison of both stents.

Methods: In 4 study centers in the Netherlands, 1,811 patients were 1:1 randomly assigned to treatment with one of both stents. Patients with any clinical syndrome, any lesion type, and any number of lesions or vessels to be treated were included. Study monitoring and clinical event adjudication were performed by two independent Dutch contract research organizations (Diagram, Zwolle, and Cardialysis, Rotterdam, respectively).

Results: DUTCH PEERS examines an all-comer patient population that included 59% of patients with acute coronary syndromes (20% of all patients presented with an acute STEMI) and 66% of patients with complex target lesions. We will compare for both stent groups the 2-year incidence of TVF (primary endpoint) and various secondary endpoints, including individual components of the primary endpoint, the incidence of stent thrombosis, and other composite endpoints, such as target lesion failure, major adverse cardiovascular events, and the patient-oriented composite endpoint. In addition, we will report the outcome of patients with longitudinal stent deformation after discontinuation of dual anti-platelet therapy.

Conclusions: Clinical outcome of the DUTCH PEERS trial at 2-year follow-up will be presented.

TCT-589

Comparison of everolimus-eluting and paclitaxel-eluting coronary stents in diabetic patients: 5 year follow up from the COMPARE I trial

Georgios J. Vlachojannis1, Kees-Jan Royaards1, Marielle A. Koper1, Adriaan O. Kraaijveeld1, Bianca M. Bosma-de Klerk1, Jochem Wassing1, Martin van der Ent1, Pieter C. Smits2
1Maassstad Hospital, Rotterdam, Netherlands, 2Maassstad Hospital Rotterdam, Rotterdam, Netherlands

Background: Long-term comparison data of the current generation everolimus-eluting stent (Xience™ V; EES) with the first generation paclitaxel-eluting stent (Taxus™ Liberté; PES) in an all-comers diabetic cohort undergoing percutaneous coronary intervention (PCI) are scarce. Initial results at 2 year follow-up indicated no differences in clinical outcomes between the two stent types in diabetic patients.

Methods: The COMPARE I study was a prospective, randomized, single-center, all-comer trial randomly allocating (1:1) patients to receive either EES or PES. It is to date the only randomized trial comparing EES to PES in a true all-comers population with an independent adjudicated 5-year follow-up. Randomization was stratified by the presence of diabetes. The primary endpoint was major adverse cardiovascular events (MACE) defined as the composite of the safety endpoints death or myocardial infarction (MI) and the efficacy endpoint target vessel revascularization (TVR).

Results: Of the 1,900 study patients, 325 patients were diabetic (18.1%) of whom 153 were treated with EES and 172 with PES. At 5 years EES reduced MACE compared to PES in non-diabetic patients (17.1% vs. 23.0%, p<0.01), TVR (7.0% vs. 10.4%, p<0.01), death or myocardial infarction (MI) and the efficacy endpoint target vessel revascularization (TVR).

Conclusions: The results of this analysis suggest that in subjects with MV and/or LM disease, newer generation EES might be superior to CABG in patients with low SYNTAX score, and equivalent in intermediate SYNTAX score, latter group currently recommended for CABG. Only the high SYNTAX score group showed a clear long-term benefit of CABG over PCI irrespective of stent type used. Newer generation drug eluting stents may allow for further refinement of the boundaries between PCI and CABG, which may have important clinical and economical implications.
Conclusions: At 5-years EES was superior with regards to efficacy and safety to PES in non-diabetic patients. In diabetic patients a late trend towards reduction of MACE was observed with EES compared to PES, mainly driven by a lower rate of non-inferiority of the biodegradable polymer-coated biolimus-eluting stent (Nobori®; BES) compared to the durable polymer-coated everolimus-eluting stent (Xience™ or Promus®; EES) with regards to safety and efficacy at 1 year. However, these trials were not powered to detect differences in low-frequency events.

Methods: The all-comers COMPARE II and NEXT clinical trials randomly assigned 5942 patients to BES or EES and is at present the largest pooled analysis of BES in all-comers requiring percutaneous coronary intervention (PCI). The pre-specified composite endpoint was target vessel failure (TVF) defined as cardiac death, target vessel related myocardial infarction (MI), or clinical-indicated target vessel revascularization (TVR-CI).

Results: The pooled unadjusted 1-year clinical outcomes of the 5942 study patients (8094 lesions) are tabulated. Covariate adjusted analyses accounting for baseline imbalances between trials confirmed non-significant differences between stent type and clinical outcomes. The trend for a higher definite stent thrombosis rate in the BES group was by multivariate analysis less prominent (HR 2.05 [CI95% 0.75-5.60]; p=0.16).

Conclusions: At 1-year the biodegradable polymer-coated BES has similar safety and efficacy outcomes as the durable polymer-coated EES. Longer follow-up data is needed to determine the role of biodegradable polymer-coated BES in real world clinical practice.

TCT-592

Lower Five Year Event Rates In The Genous Endothelial Progenitor Cell Capturing Stent Compared With A Drug Eluting Stent In de-novo Coronary Artery Lesions With A High-risk Of Restenosis: A Randomized Controlled Trial

Pier Woudstra1, Marcel A. Beijk2, Karel T. Koch1, Jan Baan1, Marije M. Vis2, Jose P. Henriquez3, Jan Piek3, Jan G. Tijssen3, Robbert J. de Winter2

1Academic Medical Center - University of Amsterdam, Amsterdam, Netherlands, 2Academic Medical Center - University of Amsterdam, Amsterdam, The Netherlands, 3Academic Medical Center - University of Amsterdam, Amsterdam, Netherlands

Background: These are the first long-term randomized adjudicated trial data of five year results of the Genous bio-engineered endothelial progenitor cell capturing stent (OrbusNeich BV, Fort Lauderdale, FL, USA) compared with a paclitaxel-eluting stent (PES).

Methods: In this prospective randomized trial, patients with de-novo coronary artery lesions carrying a high risk of restenosis (chronic total occlusion, lesion length > 23mm, vessel diameter < 2.5mm or any lesion in a diabetic patient) were randomized 1:1 to the Genous or a PES. The current primary endpoint is adjudicated target vessel failure (TVF) at 5-years, a composite of cardiac death, myocardial infarction (MI) and target vessel revascularization. Clinical event rates were estimated by Kaplan-Meier method and compared with a log-rank test.

Results: A total of 193 patients were included with complete follow-up in 97% of the subjects. The primary endpoint of TVF was similar at 5 years with Genous 23.8% vs