Results: A total of 164 robotic-enhanced PCI procedures were performed by 23 interventional cardiologists in 9 sites. Of these, 60 cases were part of the first 3 cases of each investigator (roll-ins). There were no differences between the roll-in and later cases in patient demographics, and clinical and anatomical characteristics. Procedure characteristics and outcomes are summarized in the Table. After the first 3 cases, there were no additional improvement in experience parameters or outcomes.

<table>
<thead>
<tr>
<th>Roll-in Cases n=60</th>
<th>Late Cases n=104</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conversion to manual</td>
<td>0</td>
<td>2 (1.9%)</td>
</tr>
<tr>
<td>Procedure Duration, min</td>
<td>51.1 ± 25.5</td>
<td>42.3 ± 16.4</td>
</tr>
<tr>
<td>PCI duration, min</td>
<td>42.0 ± 17.5</td>
<td>34.3 ± 14.1</td>
</tr>
<tr>
<td>Robotic duration, min</td>
<td>28.4 ± 15.5</td>
<td>22.2 ± 12.8</td>
</tr>
<tr>
<td>X-ray duration, min</td>
<td>12.8 ± 7.9</td>
<td>12.2 ± 4.8</td>
</tr>
<tr>
<td>Contrast volume, ml</td>
<td>138.3 ± 53.1</td>
<td>147.6 ± 78.8</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Non-Q MI</td>
<td>2 (3.3%)</td>
<td>2 (1.9%)</td>
</tr>
<tr>
<td>TVR</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MACE</td>
<td>2 (3.3%)</td>
<td>2 (1.9%)</td>
</tr>
</tbody>
</table>

Conclusions: We observed a short learning curve in the performance of robotic-enhanced PCI in the multi-center PRECISE study. With experience of over 3 cases, interventional cardiologists were able to complete the robotic-enhanced PCI faster and with shorter duration of radiation without compromising safety.

TCT-334
Validation of Transapical Access Accuracy of Computed Tomographic Angiography-Fluoroscopy Fusion Guided Structural Heart Disease Interventions
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Background: Transapical (TA) access has been increasingly utilized for structural heart disease interventions and is most commonly obtained under fluoroscopic guidance. However, a major limitation of fluoroscopy is its ability to provide only 2D projections with inadequate spatial information. Computed tomographic angiography (CTA)-fluoroscopy fusion can offer the 3D information necessary for accurate planning and guidance for TA puncture. Although its utility and safety have been described, the accuracy of TA access by fusion guidance has not been previously validated.

Methods: We reviewed 15 consecutive patients (mean age 69.1 ± 11.8 years, male:female 60:60) presenting to our center from June 2011 to June 2012 who underwent percutaneous left ventricular (LV) puncture, and subsequent closure, using CTA-fluoroscopy fusion guidance, and who had post-procedural CTA. We used a prototype software, HeartNavigator (Philips, Best Netherlands), that allowed for landmark placement on the LV epicardial surface (planned puncture site-PSS) to guide needle entry. These landmarks were compared to the position of the TA closure device on the post-procedure CTA (actual puncture site-APS). ImageJ software was used to calculate the difference between the PPS and APS. Each distance measurement was taken in three planes: lateral (X), antero-posterior (Y), and vertical (Z). The mean LV puncture accuracy error in each of the X, Y, and Z planes was 4.66 mm and 8.55 mm, respectively. The mean error in puncture accuracy with respect to the left anterior descending artery (LAD) was 2.89 mm.

Results: We observed a short learning curve in the performance of robotic-enhanced PCI at the Kokura Live demonstration by inserting bifurcation lesions, tortuous lesions and CTO lesions. The bifurcation model lesion was needed qillette stenting. The tortuous model lesion was needed mother and child technique for adequate stent delivery and deployment. The CTO model lesion was set so with the antegrade approach the wire would enter a sub lumen and the operator was forced to switch to the retrograde approach. As the current inside the model was rhythmically beating, we were able to use this model in our usual cath lab and was not different at all to our usual day to day practices.

Conclusions: This new Rhythmically beating vascular model is more similar to actual patients and as many kinds of lesions can be made, it is a very adequate training tool for not only beginners but also advanced cardiologists.

TCT-335
Fusion of a fullscale patient simulator with an endovascular simulator to improve quality of human factors trainings with cathlab teams
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1Center for Cardiology and Angiology Bethanien, Frankfurt, Germany, 2Klinik für Kardiologie, Universitätsklinikum Rostock, Rostock, Germany, 3University of Applied Sciences Wiesbaden, Wiesbaden, Germany, 4Johann Wolfgang Goethe University Frankfurt, Frankfurt, Germany

Background: Interventional endovascular procedures are frequently associated with complications. The use of endovascular virtual reality simulators allow the training of procedural complications. Periprocedural complications can be only trained with additional use of a fullscale patient simulator. Until today no integration of an endovascular simulator into a fullscale patient simulator has been shown.

Methods: We invented and constructed a totally new fusion of two simulators to put the idea into action. The hardware of both the endovascular simulator and the patient simulator was modified. We integrated the endovascular simulator into the body of the patient simulator. The construction had to fulfill several safety and maintenance issues. The handling of the newly designed simulator was evaluated by Cardioskills-technicians and the clinical Cardioskills-Trainer Team that brings mult-year experience in simulator based trainings with cathlab teams.

Results: We were able to present a fully functioning new fusion of two formerly separate virtual reality simulators. Procedural and periprocedural complication management could be trained with high realism with cathlab teams. Initial technical problems of the implementation could be handled and no compromises had to be accepted.

Conclusions: Simulator based trainings of procedural and periprocedural complications in the cathlab should be trained with our new simulator set-up instead of the formerly used simulators alone as we were able to deliver a higher grade of realism and were able to present technical feasibility.

TCT-336
MITOS Multimodality Imaging Operating System
Andreas Melzer1, Luc Bidaud2
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Background: A new Clinical Research Imaging Facility has been established with a unique combination of the MRI, PET/CT and an interconnecting Interventional Surgical Suite.

Methods: A novel layout provides access to a MRI suite, PET/CT and further connection into an interventional suite with standard image guidance. Interventional TAVI / cardiovascular probes can be placed under MR imaging, and EP ablation performed under MRI guidance. Alternatively, a procedure that initially starts with MR imaging - e.g., for planning purposes - may proceed into the ISS or under continued MR guidance to access
pathology. To refresh the imaging data, patient can be moved from ISS to MC suites, data acquisition takes place, and the patient is then returned to the ISS where the new MR imaging data can be used to complete the procedure.

**Results:** The current set up also permits utilisation of PET in conjuction with ISS procedures, e.g., as the final imaging modality to control whether PET-enhancing pathology was completely removed or angioplasty performed. For instance, after completion of ablation under MR imaging, the patient can be moved into the PET/CT suite. A PET image produced after tracer injection and uptake can then be used to assess the completeness of the ablation procedure.

**Conclusions:** A room layout combining 3T MRI and PET/CT with other interventionald modalities (e.g., fluoroscopy, ultrasound, CT) has been realized for integrated multimodality image-guided diagnosis and therapy of cardiovascular diseases. Such a design enables corollary studies into novel workflows for taking full advantage of the integrated design.

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**TCT-336**

Patient-Specific Rehearsal Prior To Endovascular Aneurysm Repair: A Pilot Study

Liesbeth Desender1, Zoran Rancic2, Rajesh Aggarwal1, Michael Glenck2, Mario Lachat2, Frank Vermassen1, Isabelle Van Herzele1

1University Hospital Ghent, Ghent, Belgium, 2University Hospital Zurich, Zurich, Switzerland

**Background:** Patient-specific rehearsal (PsR) of an endovascular aortic aneurysm repair (EVAR) enables the interventionalist to practice the case prior to treat the real patient. This pilot study aimed to evaluate if PsR for EVAR is feasible, influences technical performance, to evaluate face validity and the subjective sense of utility.

**Methods:** Nine patients were enrolled. EVAR procedures were performed by 7 different teams. The patient's anatomy was generated using the PROcedure rehearsal software within the Gore & Assoc, Sunnyvale, California, USA) were enrolled in three centres. A 3D model of the patient's anatomy was generated using the PROCedere rehearsal software within the Angiomentor (Simbionix, Ohio, Cleveland). Less than 24 hours before the real case, the PET image produced after tracer injection and uptake can then be used to assess the completeness of the ablation procedure.

**Conclusions:** A room layout combining 3T MRI and PET/CT with other interventionald modalities (e.g., fluoroscopy, ultrasound, CT) has been realized for integrated multimodality image-guided diagnosis and therapy of cardiovascular diseases. Such a design enables corollary studies into novel workflows for taking full advantage of the integrated design.

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**Diabetic Patients**

**Hall D**

**Tuesday, October 23, 2012, 8:00 AM–10:00 AM**

**Abstract nos:** 337-355

**TCT-337**

Clinical Outcome of Diabetic and Non-Diabetic Patients Treated With Second-Generation Zotarolimus-Eluting and Everolimus-Eluting DES

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1Thoraxcentrum Twente, Enschede, The Netherlands, 2Thoraxcentrum Twente, Enschede, Netherlands, 3Thoraxcentrum Twente, Enschede, Netherlands

**Background:** Diabetes is associated with a higher risk of adverse events following PCI with drug eluting stents (DES). Within the TWENTE trial, a randomized trial comparing zotarolimus-eluting Resolute and everolimus-eluting Xience V stents, a significant interaction was seen between diabetes and DES type with regard to target vessel failure (TVF). In diabetics, safety and efficacy data of these DES are scarce.

**Methods:** In this post-hoc analysis of TWENTE, clinical outcome of both DES in diabetic (n=301; 36.2% insulin-treated) and non-diabetic patients (n=1090) was compared. Clinical endpoints were adjudicated by an independent, external events committee. Multivariate logistic regression analyses were performed to adjust for differences in baseline variables.

**Results:** Groups stratified by DES were similar except for a higher prevalence of hypercholesterolemia in non-diabetic patients of the Xience V arm (p=0.04) and calcified target lesions in diabetic patients of the Resolute arm (p=0.04). In both diabetic and non-diabetic patients, multivariate analysis indicated no significant difference in clinical outcome between DES. Within non-insulin-treated diabetes, there was also no significant between-stent difference in clinical outcome. However, in insulin-treated diabetes, the Resolute arm showed higher rates of target vessel failure (TVF) (28.3% vs. 7.3%, p=0.015), target-lesion failure (26.4% vs. 5.5%, p=0.016), and patient oriented composite endpoint (32.1% vs. 10.9%, p=0.02). A significant interaction was observed between insulin treatment and DES type for TVF (p=0.029). In Resolute treated patients, insulin-treated diabetics had a higher rate of TVF compared to non-diabetics and non-insulin-treated diabetics (p<0.001). In the Xience V arm, rates of TVF were similar across all subgroups.

**Conclusions:** In non-diabetic patients and non-insulin-treated diabetics, Resolute and Xience V showed no significant difference in safety and efficacy up to 12 months. In the limited number of insulin-treated diabetics, Resolute was associated with inferior clinical outcome. This hypothesis-generating finding requires confirmation in large randomized trials.

**TCT-338**

Meta-analysis of Percutaneous Coronary Intervention Versus Coronary Artery Bypass Graft Surgery in Patients with Diabetes and Left Main and/or Multivessel Coronary Artery Disease

Yu-Jee Zhou1, Fei Gao2, Zhijian Wang2

1An Zhen Hospital, Capital Medical University, Beijing, China, Beijing, China, 2An Chen Hospital affiliated with Capital Medical University, Beijing, Beijing

**Background:** The optimal coronary revascularization strategy for patients with diabetes and left main and/or multivessel disease is undetermined. The aim of our study was to evaluate percutaneous coronary intervention (PCI) versus coronary artery bypass graft (CABG) in those patients.

**Methods:** We identified 13 articles, published before Oct 2011, enrolling 6992 patients, compared. Clinical endpoints were adjudicated by an independent, external events committee. Multivariate logistic regression analyses were performed to adjust for differences in baseline variables.

**Results:** Groups stratified by DES were similar except for a higher prevalence of hypercholesterolemia in non-diabetic patients of the Xience V arm (p=0.04) and calcified target lesions in diabetic patients of the Resolute arm (p=0.04). In both diabetic and non-diabetic patients, multivariate analysis indicated no significant difference in clinical outcome between DES. Within non-insulin-treated diabetes, there was also no significant between-stent difference in clinical outcome. However, in insulin-treated diabetes, the Resolute arm showed higher rates of target vessel failure (TVF) (28.3% vs. 7.3%, p=0.015), target-lesion failure (26.4% vs. 5.5%, p=0.016), and patient oriented composite endpoint (32.1% vs. 10.9%, p=0.02). A significant interaction was observed between insulin treatment and DES type for TVF (p=0.029). In Resolute treated patients, insulin-treated diabetics had a higher rate of TVF compared to non-diabetics and non-insulin-treated diabetics (p<0.001). In the Xience V arm, rates of TVF were similar across all subgroups.

**Conclusions:** In non-diabetic patients and non-insulin-treated diabetics, Resolute and Xience V showed no significant difference in safety and efficacy up to 12 months. In the limited number of insulin-treated diabetics, Resolute was associated with inferior clinical outcome. This hypothesis-generating finding requires confirmation in large randomized trials.