HR: 1.37; 95% CI: 1.25–1.54; p<0.0001), and ACC/AHA type B2C lesions (HR: 1.47; 95% CI: 1.34–1.90; p<0.003). The influence of these factors varied over time (Table 1).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Early ITE HR [95% CI]</th>
<th>Late ITE HR [95% CI]</th>
<th>Very Late ITE HR [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Age (per year increase)</td>
<td>-</td>
<td>-</td>
<td>HR: 1.02 [1.00 – 1.04]</td>
</tr>
<tr>
<td>Diabetic Mellitus</td>
<td>-</td>
<td>-</td>
<td>HR: 2.25 [1.46 – 3.47]</td>
</tr>
<tr>
<td>Arterial Hypertension</td>
<td>HR: 1.50 [1.10 – 2.06]</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>-</td>
<td>HR: 2.30 [1.45 – 3.64]</td>
<td>-</td>
</tr>
<tr>
<td>First-generation DES</td>
<td>-</td>
<td>-</td>
<td>HR: 1.64 (1.07 – 2.51)</td>
</tr>
<tr>
<td>Number of Stents implanted (per additional stent)</td>
<td>HR: 1.44 [1.32 – 1.58]</td>
<td>-</td>
<td>HR: 1.50 [1.24 – 1.82]</td>
</tr>
<tr>
<td>ACC/AHA Type B2C lesions</td>
<td>HR: 1.45 [1.08 – 1.95]</td>
<td>HR: 2.02 [1.20 – 3.39]</td>
<td>-</td>
</tr>
</tbody>
</table>

RESULTS AND CONCLUSIONS The DFS is designed to provide controlled release of sirolimus through an internally loaded drug platform, thus eliminating the need for a polymeric matrix. RevElution is the first study to assess the vascular responses, efficacy, and safety of this novel device. One-month OCT outcomes from the RevElution study will be reported at TCT 2015, providing an early assessment of neointimal coverage and stent apposition after DFS implantation.

CATEGORIES CORONARY: Stents: Drug-Eluting
KEYWORDS Drug-eluting stent, OCT

TCT-579
Novel Drug-Filled Coronary Stent and its Impact on Mechanical Attributes
Nicolas Foin,1 Justin Goshgarian,2 Alexandre Abizaid,3 Ajay J. Kirtane,4 Daniel Simon,5 Stephan Windecker,6 Gregg W. Stone7
1National Heart Centre Singapore, Singapore, Singapore; 2Medtronic, Santa Rosa, CA; 3Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil; 4Columbia University/Cardiovascular Research Foundation, New York, NY; 5Case Western Reserve University School of Medicine, Cleveland, United States; 6Bern University Hospital, Bern, Switzerland; 7The University of Adelaide, Adelaide, Australia; 8Columbia University Medical Center and the Cardiovascular Research Foundation, New York, United States

BACKGROUND A novel drug-filled coronary stent (DFS; Medtronic, Inc., Santa Rosa, CA) provides controlled drug elution from an internally-loaded drug platform without using a polymeric matrix, and thus may avoid chronic inflammation and adverse vascular responses associated with a polymer. The stent is formed from a continuous tri-layered wire with the innermost layer removed to function as a reservoir that elutes sirolimus from small holes (~20 μm) in the abluminal side of the stent. The impact of the reservoir and holes on mechanical properties of the stent and its radiopacity has not been previously reported.

METHODS Stent integrity and mechanical strength with the DFS were compared to the current generation Resolute Onyx® drug-eluting stent (DES, Medtronic, Inc.). Radial strength was tested by measuring the force required to radially compress the stent (diameter 3.0 mm) in a standard iris test. Longitudinal stent deformation was tested by measuring the peak force required to compress the stent by 1 cm after deployment in a 1.5 cm radius curved mock vessel (3.0 x 18 mm). Results are reported as average ± standard deviation. Radiopacity was tested under fluoroscopy in a porcine coronary artery model.

RESULTS The DFS had greater radial strength as Resolute Onyx DES (Figure upper left panel), and comparable resistance to longitudinal deformation (Figure upper right panel). Under fluoroscopy, the DFS had greater radiopacity than the Integrity stent™ (Figure lower left panel), and similar radiopacity as the Resolute Onyx and Omega™ stents (Figure lower right panel).

CONCLUSIONS The DFS utilizes an internally loaded drug platform to provide controlled release of sirolimus without using a polymeric matrix. Mechanical strength, as well as radiopacity, are at least comparable to current-generation DES. These in-house tests are being independently validated and will be available for presentation at TCT 2015.
Impact of Vessel Size on Clinical Outcomes of Revascularization With Biolimus A9TM-Eluting Stent in Patients with Acute Coronary Syndrome

Guang-Won Seo,1 Ho-Chul Shin,2 Pil Sang Song,1 Dong-Kie Kim,1 Ki-Hun Kim,2 Sang-Hoon Seol,1 Han-Young Jin,1 Tae-Hyun Yang,2 Jeong-Sook Seo,2 Doo-Il Kim1

1Inje University Haeundae Paik Hospital, Busan, Busan; 2Inje University, Cardiology, Busan, LA

BACKGROUND Stenting of small vessels might be associated with higher rates of adverse events. The relationship between stent strut thickness and adverse clinical events remains particularly evident in smaller vessels. Recently published trial showed biolimus A9-eluting stent (BES) was non-inferior with sirolimus-eluting stent. However, smaller vessels. The primary endpoint was target vessel failure (TVF) defined as a composite of cardiac death, myocardial infarction, or clinical-driven target vessel revascularization at 12 months.

RESULTS Of 1,000 ACS patients with 1,251 lesions, 238 patients with 271 lesions had small vessel treated (n=238, 23.8%) and large vessel treated (n=756, 75.6%). Patients included in the small vessel group presented clinical profiles characterized by higher proportion of older age, diabetes, lower estimated creatinine clearance, multi-vessel coronary disease, or post-procedural TIMI flow grade <3. Patients in the small vessel group had a strong tendency of higher occurrence of TVF compared with those in the large vessel group (3.8% vs. 1.9%, unadjusted hazard ratio [HR] 2.05; 95% confidence interval [CI] 0.89-4.75; p = 0.09). In multivariate Cox proportional hazard analysis using age, diabetes, left ventricular ejection fraction, and aspirin during hospitalization, the small vessel group still showed a significantly higher incidence of TVF (adjusted HR 2.84; 95% CI 1.15 to 6.99; p = 0.023). The rate of TVF was consistently higher in the small vessel group than in the large vessel group across various high-risk subgroups.

CONCLUSIONS Stenting of BES at the small vessel appears to increase the risk of TVF in patients with ACS. Thus, in the PCI of the small vessels with BMS, cautious should be needed to obtain the best optimal results.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Acute coronary syndromes, Biolimus, Percutaneous coronary intervention

TCT-582
The frequency of the Stent Fracture per Lesion: the Comparison between First and New Generation Drug-Eluting Stent

Hiroto Yagasaki,1 Yusuke Hyodo,1 Suguru Otsuru,1 Daiji Hasegawa,2 Seiji Habara,1 Takeshi Tada,1 Hiroyuki Tanaka,1 Yasushi Fuku,1 Tsuyoshi Goto,1 Kazushige Kadota,1 Kazuaki Mitsudo1

1Kurashiki Central Hospital, Kurashiki, Okayama, Japan

BACKGROUND Stent fracture (SF) is related to restenosis after drug-eluting stent (DES) implantation. Although SF is rare complication in the era of new generation DES, the frequency of the SF per lesion is not known so much. We research the frequency of the SF per lesion, and compare between first and new generation DES implantation.

METHODS From November 2002 to May 2014, 10904 patients with 18068 lesions underwent DES implantation successfully. Of these, 14350 lesions were angiographically followed up after 6 to 8 months (midterm f/u) and 11387 lesions were followed up at 12 months after midterm f/u. First generation DES was defined as SES and PES. New generation DES was defined as EES and BES.

RESULTS The frequency of the SF in new generation DES is lower than that of the first generation DES (2.5% vs. 5.5%, P value < 0.005). This tendency applies, even in per lesion, especially in left anterior descending (LAD) artery. And, in the restenosis lesion, left anterior descending artery only decreases the frequency of the SF (0% vs. 2.3%, P value < 0.05). The frequency of the SF in right coronary artery (RCA) is higher than that in left coronary artery (LCA). The restenosis ratio in SF lesion is about 30%, and it is not improved even in new generation DES.

<table>
<thead>
<tr>
<th>Stent</th>
<th>First generation DES total</th>
<th>New generation DES total</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCA</td>
<td>9.1%(264/2912)</td>
<td>5.6%(137/2542)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>LMT</td>
<td>3.4%(277/795)</td>
<td>1.2%(8/655)</td>
<td>0.009</td>
</tr>
<tr>
<td>LAD</td>
<td>3.6%(168/3203)</td>
<td>0.5%(5/2870)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>LCX</td>
<td>3.2%(59/1833)</td>
<td>1.4%(21/1549)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Total</td>
<td>5.5%(441/8042)</td>
<td>2.5%(75/6920)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

CATEGORIES OPTIMAL: Acute coronary syndromes, Drug-eluting stent

KEYWORDS Acute coronary syndromes, Drug-eluting stent

TCT-581
Impact of Vessel Size on Clinical Outcomes of Revascularization With Biolimus A9TM-Eluting Stent in Patients with Acute Coronary Syndrome

Guang-Won Seo,1 Ho-Chul Shin,2 Pil Sang Song,1 Dong-Kie Kim,1 Ki-Hun Kim,2 Sang-Hoon Seol,1 Han-Young Jin,1 Tae-Hyun Yang,2 Jeong-Sook Seo,2 Doo-Il Kim1

1Inje University Haeundae Paik Hospital, Busan, Busan; 2Inje University, Cardiology, Busan, LA

BACKGROUND Stenting of small vessels might be associated with higher rates of adverse events. The relationship between stent strut thickness and adverse clinical events remains particularly evident in smaller vessels. Recently published trial showed biolimus A9-eluting stent (BES) was non-inferior with sirolimus-eluting stent. However, the stainless steel stent platform of BES has a strut thickness of 112 μm. We assessed the impact of vessel size on clinical outcomes of stenting with BES.

METHODS The BEAUTY registry was conducted to assess clinical performance of BiomatrixTM BES implantation in an unrestricted “real-world” cohort of patients with acute coronary syndrome (ACS) between May 2011 and July 2013. Clinical outcomes from the BEAUTY database were compared between patients with small (reference vessel diameter [RVD] ≤ 2.75 mm) versus large (RVD > 2.75 mm) vessels. The primary endpoint was target vessel failure (TVF) defined as EES and BES.

RESULTS Of 1,000 ACS patients with 1,251 lesions, 238 patients with 271 lesions had small vessel treated (n=238, 23.8%) and large vessel treated (n=756, 75.6%). Patients included in the small vessel group presented clinical profiles characterized by higher proportion of older age, diabetes, lower estimated creatinine clearance, multi-vessel coronary disease, or post-procedural TIMI flow grade <3. Patients in the small vessel group had a strong tendency of higher occurrence of TVF compared with those in the large vessel group (3.8% vs. 1.9%, unadjusted hazard ratio [HR] 2.05; 95% confidence interval [CI] 0.89-4.75; p = 0.09). In multivariate Cox proportional hazard analysis using age, diabetes, left ventricular ejection fraction, and aspirin during hospitalization, the small vessel group still showed a significantly higher incidence of TVF (adjusted HR 2.84; 95% CI 1.15 to 6.99; p = 0.023). The rate of TVF was consistently higher in the small vessel group than in the large vessel group across various high-risk subgroups.