METHODS
Paravalvular leak in the RESPOND post-market study: predictors and impact on 2-year clinical outcomes following TAVR with a fully repositionable and retrievable aortic valve in routine clinical practice

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BACKGROUND
Paravalvular leak (PVL), a common complication of transcatheter aortic valve replacement (TAVR), has been linked to increased mortality risk. The RESPOND post-market study represents the largest population of TAVR patients treated with the Lotus valve (Boston Scientific, Marlborough, MA). Here we seek to identify predictors of mild PVL-related outcomes following TAVR and evaluate the impact of mild PVL on clinical outcomes.

METHODS
Of the 1014 patients enrolled in RESPOND, 996 were implanted with a Lotus valve (mean age: 80.8 years; SSTS score: 6.0±6.9). Aortic regurgitation was assessed by an independent echocardiography core laboratory pre-procedure, at discharge, and 1 year post-TAVR. For this analysis, patients were stratified into 2 groups: no/trace PVL vs >mild PVL. A multivariate regression model was used to evaluate baseline and procedural predictors of >mild PVL at discharge.

RESULTS
Two-year follow-up was available for 934 patients (94%). At hospital discharge, PVL was assessed as none/trace in 92% of patients, mild in 7.7%, and moderate in 0.3%; no patient had severe PVL. Significant predictors (Odds Ratio [95% CI]) of >mild PVL included: history of cerebrovascular accidents (4.09 [1.58, 5.84]; P<0.001), history of renal failure (6.78 [1.55, 29.63]; P=0.011), and elevated baseline mean aortic pressure gradient (1.02 [1.00,1.04]; P=0.022). Annuar overstretch (ratio of valve diameter/annulus diameter) was associated with a lower risk of PVL (0.92 [0.89,0.96]; P<0.001). The table below details 2-year clinical outcomes in patients with no/trace PVL vs those with >mild PVL.

<table>
<thead>
<tr>
<th>VASC Events during 2 Years</th>
<th>PVL none or trace (N = 859)</th>
<th>PVL mild or greater (N = 75)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>17.2% (149)</td>
<td>24.5% (18)</td>
<td>0.14</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>11.3% (92)</td>
<td>14.6% (10)</td>
<td>0.43</td>
</tr>
<tr>
<td>Non-cardiovascular</td>
<td>7.2% (57)</td>
<td>11.6% (8)</td>
<td>0.17</td>
</tr>
<tr>
<td>Stroke</td>
<td>5.7% (47)</td>
<td>4.0% (3)</td>
<td>0.62</td>
</tr>
<tr>
<td>Disabling</td>
<td>4.7% (38)</td>
<td>2.7% (2)</td>
<td>0.50</td>
</tr>
<tr>
<td>Non-Disabling</td>
<td>1.2% (10)</td>
<td>1.4% (1)</td>
<td>0.89</td>
</tr>
</tbody>
</table>

CONCLUSION
The majority of patients had no PVL or trace PVL after implantation of a Lotus valve. There was no statistical difference in the 2-year cardiovascular mortality rate between patients with no/trace PVL or >mild PVL. RESPOND follow-up will continue annually and may help to determine if PVL has an impact on longer-term clinical outcomes.

CATEGORIES STRUCTURAL
Valvular Disease: Aortic
RESULTS A total of 1980 patients were included. Mean age of the study population was 81.3±9.1 years and 65.3% were males. STS and EuroSCORE II mean values were 7.2±1.1 and 6.5±2.4%, respectively, with 35.5% of diabetes mellitus, 13.9% of prior myocardial infarction, and left ventricular ejection fraction <40% in 32.6% of the patients. Of them, 706 (39.5%) received RAS blockade therapy after the procedure. At a median follow up of 3 years post-TAVR, the RAS blockade group had significantly lower cumulative mortality than the no-RAS blockade group (9.5% vs 16.5%; log-rank test, p = 0.001). After matching, RAS blockade therapy was still associated with significantly lower mortality (HR, 0.581; 95%CI 0.310 to 0.893; p = 0.002). In addition, the rates of myocardial infarction, new-onset atrial fibrillation, stroke, and re-admission due to heart failure remained lower in the RAS blockade group for the entire cohort and the matched one.

CONCLUSION Post-TAVR RAS blockade therapy is associated to lower all-cause mortality at 3-year follow up and presents a global cardiovascular protective effect irrespective of the left ventricular ejection fraction and the residual aortic regurgitation. An ongoing randomised controlled trial (RASTAVI Study, NCT03201185) will help to determine the accuracy of these findings.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-689
Comparison of Transcatheter Aortic Valves: Stent and Leaflet Stresses of Sapien vs. CoreValve
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BACKGROUND Balloon-expandable and self-expanding transcatheter aortic valve replacement (TAVR) devices are FDA approved and have been equally efficacious in treatment of severe aortic stenosis. However, long-term durability of these TAVR devices are unknown and durability is dependent upon valve design, in particular leaflet stresses. The objective of our study was to compare leaflet stresses of Medtronic CoreValve (Medtronic, Inc) vs Edwards Sapien (Edwards Lifesciences, Inc) using finite element analyses.

METHODS Edwards Sapien and Medtronic CoreValve (both sized 26mm) underwent micro-CT scanning. Precise geometries were reconstructed based on radiologic images. Finite element simulations were performed at diastolic pressure using ABAQUS software.

RESULTS Maximum principal stresses on Sapien and CoreValve leaflets were 1.8MPa vs 0.8MPa respectively at diastolic pressure (figure 1); while minimum principal stresses were -1.08MPa and -0.53MPa respectively. For TAVR stents, peak first principal stresses were 56.8MPa vs 3.61MPa for Sapien and CoreValve, respectively at diastolic pressure; while minimum principal stresses were -44.6MPa and -4.17MPa, respectively.

CONCLUSION Our study demonstrated that maximum leaflet stresses appeared in similar locations at the commissural tips for both balloon-expandable and self-expanding devices. Magnitudes of peak leaflet stresses on CoreValve was lower than Sapien. Our results suggest that leaflet stresses which may impact long-term durability were lower for self-expanding TAVRs. Comparison of newer generations of TAVR may lead to further insight into relative TAVR durability.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

PCI IN THE ELDERLY - I

TCT-690
Incremental Age-related 1-year MACCE after Acute Myocardial Infarction in the drug-eluting stent era (from KAMIR-NIH registry)
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BACKGROUND We evaluated the age-related 1-year major adverse cardiocerebrovascular events (MACCE) after percutaneous coronary intervention (PCI) in acute myocardial infarction (AMI). We analyzed the association between age and 1-year MACCE after AMI

METHODS A total of 13,104 AMI patients from Korea Acute Myocardial Infarction Registry-National Institute of Health (KAMIR-NIH) between November 2011 and December 2015 were classified into 4 groups according to age (Group I; n = 1419< 60 years, Group II; > 60 < 70 years, Group III; > 70 < 80 years, Group IV; > 80 years, n = 1918). Patients were analyzed for 1-year composite of MACCE (cardiac death, myocardial infarction, target vessel revascularization, cerebrovascular events) after AMI

RESULTS After adjustment for confounding parameters, the analysis results showed that patients with AMI had incremental risk of 1-year MACCE (Group II; aHR 1.224, 95% CI 0.965-1.525, p = 0.096, Group III; aHR 1.316, 95% CI 1.037-1.671, p = 0.024, Group IV; aHR 1.316, 95% CI 1.500-2.601, p< 0.001) compared to Group I. Especially, cardiac death in the composite of primary end point played a major role in this effect (Group II; aHR 1.335, 95% CI 1.041-1.859, p = 0.106, Group III; aHR 1.575, 95% CI 1.122-2.120, p = 0.009, Group IV; aHR 2.803, 95% CI 1.937-4.054, p< 0.001).

CONCLUSION Our study demonstrated that maximum leaflet stresses appeared in similar locations at the commissural tips for both balloon-expandable and self-expanding devices. Magnitudes of peak leaflet stresses on CoreValve was lower than Sapien. Our results suggest that leaflet stresses which may impact long-term durability were lower for self-expanding TAVRs. Comparison of newer generations of TAVR may lead to further insight into relative TAVR durability.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic