Valvular disease - Aortic: TAVR

Washington Convention Center, Lower Level, Hall A
Saturday, September 13, 2014, 5:00 PM–7:00 PM

Abstract nos: 684-785

TCT-684
Impact Of Mixed Aortic Valve Stenosis On VARC-2 Outcomes And Post-Procedural Peri-Prosthetic Aortic Regurgitation In Patients Undergoing Transcatheter Aortic Valve Implantation: Results From The International Multicentric Study PRAGMATIC (Pooled Rotterdam – Milan – Toulouse In Collaboration)

Gennaro Giustino1, Alaida Chieffo2, Nicolas M. Van Mieghem1, Didier Tchetche3, Nicolas DUMONTEIL2, Robert M. van der Boon4, Bertrand Marcheix2, Patrick W. Serruy5, Damien Millischer1, Didier Carrière6, Peter De Jaegere6, Antonio Colombo7
1San Raffaele Scientific Institute, Milan, Italy, 2San Raffaiul Scientific Institute, Milan, Italy, Milan, Italy, 3Erasmus MC, Rotterdam, Netherlands, 4Clinique Pasteur, Toulouse, France, 5Cardiovascular and Metabolic Pole, Rangueil Hospital, Toulouse, France, 6Thoraxcenter, Erasmus Medical Center, Rotterdam, Rotterdam, Netherlands, 7Thoraxcenter, Rotterdam, MD, 8Cochin Hospital, Paris, Paris, 9EMO GVM Centro Cuore Columbus/San Raffaele Hospital, Milan, Italy

Background: Only few data are available on the impact of mixed aortic stenosis (MAS) on clinical outcomes and post-procedural aortic regurgitation (PPAR) after transcatheter aortic valve implantation (TAVI). The aim of this study was to assess the impact of MAS on PPAR and clinical outcomes after TAVI.

Methods: Data from a multicenter registry were retrospectively analysed. Outcomes were compared between patients with pure aortic stenosis (PAS: associated AR < 1+ or 3+ or 5+ and MAS (associated AR > 1+ or 3+ or 5+). Study objectives were PPAR incidence and 1-year Academic Research Consortium 2 (VARC-2) outcomes at long-term follow-up.

Results: In total, 1091 patients were included: 432 (39.5%) with MAS and 659 (60.4%) with PAS. At 30 days, there were no differences in all-cause (6.4% vs. 6.3%; p = 0.930) and cardiovascular mortality (5.5% vs. 4.2%; p = 0.315), however a greater incidence of major bleeding (23% vs. 16.5%; p = 0.011), spontaneous myocardial infarction (2% vs. 0.3%; p = 0.019) and PPAR ≥ 1+ or 3+ (43% vs. 27%; p < 0.001) was observed in patients with MAS. Of note, MAS was an independent predictor of PPAR ≥ 1+ or 3+ at multivariable analysis. At a median follow-up period of 421 days (IQR 252 – 710), patients with MAS had a higher all-cause (30% vs. 24%; p = 0.047) and cardiovascular mortality (17% vs. 12%; p = 0.023). Conversely, in patients that developed PPAR ≥ 2+ or 3+, the presence of baseline MAS was associated with a trend of lower long-term all-cause and cardiovascular mortality (46% vs. 73%; p = 0.188 and 17% vs. 50%; p = 0.095).

Conclusions: MAS was associated with a higher PPAR incidence and increased all-cause and cardiovascular mortality when compared to patients with PAS. However, in patients who developed PPAR ≥ 2+ or 3+, baseline MAS trended to be associated with improved long-term survival.

TCT-685
Costs Of Peri-Procedural Complications Among Patients Treated With A Self-Expanding Transcatheter Aortic Valve Prosthesis: Results From The CoreValve US Pivotal Extreme Risk Study

Suzanne J. Baron1, Suzanne V. Arnold2, Matthew B. Reynolds3, Yang Lei4, Elizabeth Magno1, Timothy J. Byrne5, Tanvir Bajwa6, Daniel O’Huir6, David Adams7, Jeffrey Poppma8,9, David Cohen10
1St. Luke’s Mid America Heart Institute, Kansas City, MO, 2Saint Lukes Mid America Heart Institute, Kansas City, MO, 3Harvard Clinical Research Institute, Boston, Massachusetts, 4Saint Luke’s MidAmerica Heart Institute, Kansas City, MO, 5Saint Luke’s MidAmerica Heart Institute, Saint Louis, MO, 6Banner Good Samaritan, Phoenix, AZ, 7ACS, Aurora Sinai/St Luke’s Med Ctrs, Univ Wisconsin School of Medicine and Public Health, Milwaukee, WI, 8Aurora St. Luke’s Medical Center, Milwaukee, WI, 9The Mount Sinai School of Medicine, New York, NY, 10Beth Israel Deaconess Medical Center, Boston, United States

Background: In patients (pts) with severe aortic stenosis, transcatheter aortic valve replacement (TAVR) improves survival compared with medical therapy but is associated with higher costs. Prior studies have shown that peri-procedural complications have a sizeable effect on cost in pts treated with a balloon-expandable prosthesis, but no studies to date have examined the impact of complications on costs in pts treated with a self-expanding prosthesis.

Methods: Using hospital cost data from 506 pts enrolled in the CoreValve US Pivotal Extreme Risk study, we developed multivariable models to estimate the incremental cost associated with specific complications of TAVR. Complications were defined according to the VARC-1 criteria and adjudicated by an independent events committee. Attributable costs were calculated by multiplying the incremental cost of each event by its frequency.

Results: Mean cost for the initial hospitalization (including physician fees and cost of the valve) was $73,701 + 26,981. Overall, complications accounted for $10,197 per pt in the ilio-femoral access (IF) cohort and $12,541 per pt in the non-IF access cohort (25% and 27% of non-implant related costs, respectively). For IF pts, permanent pacemaker implantation and bleeding complications accounted for the largest attributable cost, whereas bleeding complications and arrhythmias contributed most in non-IF pts.

Conclusions: In this initial US experience with the Medtronic CoreValve device, peri-procedural complications accounted for up to 27% of non-implant related hospital costs. Both the absolute and relative costs increases were greater among pts treated via a non-IF approach. In the future, avoidance of complications should improve the cost-effectiveness of TAVR in inoperable pts treated with a self-expanding prosthesis – particularly for pts unsuitable for IF access.

Table. Incremental and attributable hospital costs associated with peri-procedural complications of TAVR

<table>
<thead>
<tr>
<th>Complication</th>
<th>Incremental Cost (per event)</th>
<th>Overall (n = 506)</th>
<th>IF group (n = 397)</th>
<th>Non-IF group (n = 109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>$10,176</td>
<td>$519</td>
<td>$509</td>
<td>$560</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>$20,769</td>
<td>$623</td>
<td>$312</td>
<td>$1,724</td>
</tr>
<tr>
<td>AHI Stage 3</td>
<td>$29,587</td>
<td>$473</td>
<td>$444</td>
<td>$533</td>
</tr>
<tr>
<td>Bleeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life-threatening</td>
<td>$15,845</td>
<td>$2,123</td>
<td>$1,870</td>
<td>$3,058</td>
</tr>
<tr>
<td>Major</td>
<td>$7,130</td>
<td>$1,932</td>
<td>$1,740</td>
<td>$2,617</td>
</tr>
<tr>
<td>Arhythmia</td>
<td>$7,740</td>
<td>$1,618</td>
<td>$1,440</td>
<td>$2,276</td>
</tr>
<tr>
<td>Perc. Pacemaker Implant</td>
<td>$13,861</td>
<td>$2,523</td>
<td>$2,717</td>
<td>$1,774</td>
</tr>
<tr>
<td>Repeat TAVR</td>
<td>$118,732</td>
<td>$934</td>
<td>$1,167</td>
<td>–</td>
</tr>
</tbody>
</table>

Total Cost of Complications: $10,745 $10,197 $12,541

*IF of model = 0.36

*IP—if lumenal access; Non-IF—Non-lumenal access; AHI — acute kidney injury

TCT-686
Impact Of Left Ventricular Remodeling On Clinical Outcomes after TAVR: Insights from the PARTNER I Trial

Sammy Elmariah1, Jonathan J. Passe1, Ignacio Inglessis1, Joshua N. Baker2, William Stewart3, Brian R. Lindman4, Ke Xu5, Gus J. Vlahakes6, Jacob P. Dal-Bianco7, Serguei Melnitchouk8, Martin Leon9, Lars Svensson10, Neil Weissman8, Philippe Pibarot11, Igor F. Palacios12,13
1Massachusetts General Hospital, Harvard Medical School, Boston, MA, 2Massachusetts General Hospital, Boston, MA, 3Cleveland Clinic, Cleveland, OH, 4Washington University School of Medicine, St Louis, MO, 5Cardiovascular Research Foundation, New York, NY, 6Columbia University Medical Center, New York, NY, 7Cleveland Clinic, Cleveland, USA, 8MedStar Washington Hosp Center, Washington, United States, 9Quebec Heart and Lung Institute, Quebec City, Canada, 10Massachusetts General Hospital, Boston, United States

Background: Aortic stenosis (AS) induces adaptive left ventricular (LV) remodeling, with some geometric patterns associated with increased morbidity and mortality after surgical aortic valve replacement (AVR). Whether the geometric pattern of LV remodeling at baseline impacts outcomes after transcatheter AVR (TAVR) remains unknown.

Methods: The PARTNER randomized trial and continued access registry included high-risk (n=2,184) and inoperable (n=508) patients with symptomatic severe AS. Using relative wall thickness cut points for concentric geometry (≤0.42) and sex-specific LV mass index thresholds for severe LV hypertrophy (>149 g/m2 for men and >122 g/m2 for women) on baseline echocardiograms, patients were stratified into four LV geometric patterns: normal geometry, concentric remodeling (cLRV), concentric hypertrophy (cLVH), and eccentric hypertrophy (eLVH). Clinical outcomes associated with each geometric pattern were assessed.

Results: Of 2,692 patients (mean age, 85 years; 52% male) with mean LV ejection fraction 52±13%, normal geometry, cLRV, cLVH, and eLVH were present in 13, 37, 40, and 10%, respectively. Rates of all-cause and cardiac death were comparable across groups at 30 days. Patients with normal LV geometry demonstrated the worst survival at 6 months (20.7% vs 14.6% with eLVH; P=0.008) and 1 year (26.2% vs...