TCT-697
Is Transcatheter Aortic Valve Replacement the Best Option for Patients with Severe Aortic Stenosis and Small Aortic Annulus? Insights From the PARTNER Trial
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Background: We sought to evaluate the effects of aortic annular size on valve hemodynamics and clinical outcomes in those patients included in the PARTNER randomized controlled trial (RCT) cohort A and the PARTNER non-randomized comparative cohort (PARTNER B).

Methods: Patients included the RCT (n=574) and NRCA (n=1358) cohorts were divided in tertiles according to aortic annular diameter (small, medium, large aortic annulus; SAA, MAA and LAA, respectively) as measured by transthoracic echocardiography. Moderate-to-severe-prosthesis-patient mismatch (PPM) was defined as an effective aortic orifice area of <0.85 cm²/m².

Results: In the RCT cohort, patients in the SAA tertile who underwent TAVR had a lower incidence of PPM (39% vs. 63%, P=0.01), and only a trend toward a higher incidence of moderate-to-severe paravalvular leak (PVL) compared to SAVR (5.7% vs. 2.1% in SAA, respectively). In the NRCA cohort, there were no differences in the rate of PPM between groups and a significant increase in moderate-to-severe PVL was associated with TAVR (9% vs. 0%, P=0.01). In the NRCA cohort, there were no differences in PPM between the SAA and LAA tertiles, but a higher rate of moderate-to-severe PVL was observed in the MAA tertile (9.5% vs. 11.5%, P=0.004). Patients in the LAA tertile had a higher mortality rate at 1-year follow-up compared to the SAA and MAA tertiles (24.8%, 18.3% and 18.7%, respectively, P=0.02), and differences persisted in multivariable analysis (P=0.048 for LAA vs. MAA, P=0.035 for LAA vs. SAA).

Conclusions: Aortic annulus size had a major impact on valve hemodynamics and clinical outcomes following AVR. This study highlights the importance of considering aortic annulus size in the evaluation of high-risk patients who are candidates for AVR, and suggests that TAVR may be the preferred strategy for those with smaller aortic annulus.

TCT-698
Aortic Valve-in-Valve Implantation inside Stented vs. Stentless Bioprostheses: Insights from the Global Valve-in-Valve Registry
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Background: Transcatheter aortic valve-in-valve (ViV) implantation inside failed bioprostheses is increasingly being performed. Stentless surgical valves lack fluoroscopic markers and may pose unique challenges. We aimed to evaluate clinical outcomes following aortic ViV procedures in stentless bioprostheses, using a large global registry.

Methods: Aortic ViV procedures included in the Global Valve-in-Valve Registry were investigated (553 procedures: 441 in stented bioprostheses, 112 stentless).

Results: Patients with failed stentless bioprostheses were younger and had similar STS score in comparison with those with stented (73.4 ± 13.9 vs. 78.6 ± 8, p = 0.001; 10.7 ± 8.3 vs. 12.1 ± 10.6, p = 0.20, respectively). Stentless bioprostheses had a longer mean time to failure and failed more commonly with predominant regurgitation (11 vs. 9 years, p = 0.02 and 58.9% vs. 21.8% in stented, p < 0.001), were larger (23.8 ± 2.1 vs. 23.0 ± 2.1 in stented, p = 0.002) and had lower degree of stenosis in comparison with stented valve: area 1.28 ± 0.62cm² vs. 0.88 ± 0.43cm², mean gradient 48 ± 28.6mmHg vs. 64.7 ± 26.4mmHg, respectively, p < 0.001 for both). Stentless bioprostheses were more commonly treated by a CoreValve (65.1% vs. 34.7% SAPIEN, p < 0.001) and TEE was utilized more during these procedures (75.2% vs. 62.0% in stented, p < 0.01). Device malposition was more common in stentless surgical valves (16.1% vs. 4.0% vs. 9.0% in non-Mosaic stented valves, p = 0.03). Coronary occlusion was more common in stentless bioprostheses (5.4% vs. 1.4% in stented, respectively, p = 0.01). Post procedural mean aortic valve gradient was lower post stentless ViV procedures (11.7 ± 7.2mmHg vs. 16.9 ± 9.1mmHg in stented, p < 0.001). Thirty-day and 1-year mortality rates were similar, when comparing stented and stentless procedures: 8.9% vs. 6.6% (p = 0.39), 17.9% vs. 16.6% (p = 0.68), respectively.

Conclusions: Aortic ViV implantation inside stentless bioprostheses is challenging and associated with more device malposition and coronary occlusion events. Nevertheless, ViV procedures performed in stentless bioprostheses resulted in better valve hemodynamics than in stented surgical valves and patient survival was similar.

TCT-700
The Effect of Tricuspid Regurgitation and Right Ventricular Dysfunction on Mortality in High Risk Patients Undergoing Transcatheter Aortic Valve Replacement: An Analysis of the PARTNER II Inoperable Cohort
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Background: Is it important to elucidate factors that are associated with a poor outcome after transcatheter aortic valve replacement (TAVR) to improve patient selection. Tricuspid regurgitation (TR) and right ventricular dysfunction (RVD) adversely affect outcomes in patients with heart failure or mitral valve disease, but their impact on outcomes in patients with severe aortic stenosis (AS) treated with TAVR has not been well characterized.

Methods: Patients enrolled and treated in the PARTNER II trial (inoperable cohort) (n=553) were included and stratified according to the presence and severity of TR and RVD (qualitatively measured) on the baseline (pre-TAVR) echocardiogram as determined by a core lab. Multivariable Cox PH models were used to evaluate the association between TR and RVD and 1-year all-cause death.

Results: TR severity and RV function were measured in 507 and 488 patients, respectively. Patients with none/trace (n=167), mild (n=205), moderate (n=117), and severe (n=18) TR had 1-year all-cause death rates of 16.9%, 17.2%, 32.6%, and 61.1%, respectively (p=0.001). Patients with normal RV function (n=335) and mild-moderate RVD (n=23) had 1-year all-cause death rates of 19.0%, 25.5%, and 38.5%, respectively (p=0.001). Increasing severity of TR (p=0.003) and RVD (p=0.01) were also associated with increased re-hospitalizations rates at 1 year. After adjusting for age, sex, BMI, STS score, prior infarct, prior CABG, frailty, permanent pacemaker, atrial fibrillation, left ventricular ejection fraction, aortic transcatheter mean gradient, and mitral regurgitation, moderate/severe TR was associated with increased 1-year mortality (adjusted HR 1.73, 95% CI 1.09-2.75, p=0.01), whereas RVD was not (p=0.67).

Conclusions: In very high risk patients with severe symptomatic AS undergoing TAVR, moderate or severe TR is independently associated with increased 1-year mortality whereas RVD was only associated with mortality in univariable analysis. This may have implications for treatment decisions, including assessment of anticipated benefit from TAVR and whether concomitant surgical treatment of TR should be considered in operable patients.
more post balloon dilatation and 30-day major stroke in comparison with those treated by SAPIEN XT (16.3% vs. 5.7%, p<0.02, respectively).

Conclusions: Optimal clinical performance of CoreValve and SAPIEN XT appears to be reached with different degrees of device oversizing. An individualized-device-approach during TAVR, utilizing a specific device for a specific annulus size, allows favorable degree of oversizing, may improve clinical outcomes. This approach should be further validated in randomized trials.

TCT-701
A Multidisciplinary, Multimodality, but Minimalist (3M) approach to trans femoral transcatheter aortic valve replacement facilitates safe next day discharge home in high risk patients: 1 year follow up


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Background: TAVR is an alternative to surgery in high risk operable patients; however, complications and cost currently limit expansion into lower risk populations. Although mortality, morbidity and length of stay (LOS) are expected to improve, we sought to determine if a multidisciplinary, multimodality, but minimalist (3M) approach could improve outcomes with currently available valve technology. Multicenter Assessment of TAVR in Failed Aortic Bioprostheses: Evaluation of Implant Depth and Association with Periprocedural Cerebrovascular Events (TCT-703)

One hundred and sixty-eight patients at high risk for surgery, but low enough risk for TAVR, were rigorously screened with functional and cognitive assessments as well as multimodality imaging. From a potential pool of 335 accepted transfemoral TAVR patients, 73 (22%) were selected for the 3M approach and underwent SAPIEN XT (Edwards Lifesciences Inc., CA, USA) valve implantation. All procedures in the second half of the cohort (38/73) were performed awake with no sedation and only fenoral monitoring. Thirty day and one year outcomes were reported according to VARC-2 guidelines.

Results: The mean patient age was 83.7±7.4 years with a mean STS score of 3.8±3.7%. All-cause mortality or major stroke at 30 days and 1 year was 1.4% (1/73) and 8% (4/73). The mean LOS for the initial intubated cohort (35/73) vs the awake cohort (38/73) was significantly lower in the latter (4.6±2.3 days vs 2.4±1.3 days, respectively (p=0.03)). Overall, 50/73 (68%) were discharged home one day post TAVR with 2 readmissions (2.7%) within 30 days. Aortic valve area increased from 0.7±0.14 cm² to 1.69±0.21 cm² (p<0.001) at 30 days and 1.5±0.25 cm² (p<0.001) at 1 year; mean trans-aortic gradient decreased from 43±18 mmHg (p<0.001) at 30 days and 1.5±0.5 mmHg (p<0.001) at 1 year. At 30 days and 1 year, 98% (71/73) and 92% (65/70) were NYHA class I or II with mild or less paravalvular regurgitation.

Conclusions: Significant contributors for elevated gradients are deep implantation of a CoreValve device and SAPIEN implantation inside a small surgical valve.

TCT-703
Impact of Periprocedural Stroke on Mid-term Mortality After Transcatheter Aortic Valve Implantation

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Background: Stroke occurs in patients undergoing transcatheter aortic valve implantation (TAVI) has been reported among complications in several studies. The aim of this study was to assess the impact of periprocedural stroke on mortality at mid-term follow-up after TAVI.

Methods: The hundred-fifty-six patients with aortic stenosis underwent TAVI with the CoreValve system (92.8%) or the Edwards SAPIEN valve system (7.2%). Stroke and transient ischemic attack were defined according to the Valve Academic Research Consortium-2 consensus document. A cerebrovascular accident (CVA) was defined as any stroke or transient ischemic attack. Periprocedural events were defined as events occurring within 72 hours from the index procedure. Multivariable Cox regression analyses were performed to calculate hazard ratio (HR) with 95% confidence intervals (CI) of mortality.

Results: Periprocedural stroke occurred in 9.4% of patients. The incidence of any stroke and of CVA after the index procedure was 2.4% and 2.7%, respectively. Periprocedural strokes accounted for 56.2% of all strokes and occurred in 1.4% of patients included in the study. Periprocedural CVA accounted for 55.6% of all CVA and occurred in 1.5% of patients. After a median follow-up of 434 days, all-cause mortality and cardiac mortality were significantly higher in patients with periprocedural stroke as compared to those without (66.7% vs 22.9%, logrank p=0.001; 66.7% vs 16.8%, logrank p<0.001, respectively); and among patients with periprocedural CVA as compared to those without (70.0% vs 22.8%, logrank p<0.001; 70.0% vs 16.7%, logrank p<0.001, respectively). Periprocedural stroke and CVA were significant independent predictors of all-cause mortality (HR 4.67, 95% CI 1.96-11.11, p<0.001; HR 4.66, 95% CI 2.06-10.5, p<0.001, respectively) and of cardiac mortality (HR 6.47, 95% CI 2.75-15.2, p<0.001; HR 6.74, 95% CI 3.05-14.9, p<0.001, respectively). Periprocedural stroke and CVA are independent predictors of all-cause mortality and cardiac mortality at mid-term follow-up. Strategies for periprocedural cerebrovascular events prevention are needed.