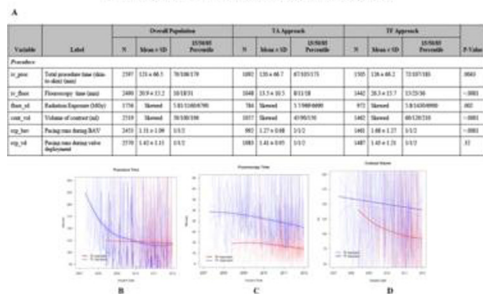


Methods: 2,621 patients underwent TAVR with the SAPIEN heart valve via TF (N=1521) or TA (N=1100) delivery routes between April 2007 and January 2012. The study was divided into 2 time domains for this analysis, 1st half (2007 – 2009) and 2nd half (2010 – 2012). The Shapes of the learning curves were assessed using a semi-parametric mixed effects model.

Results: Figure 1A details the outcomes of the technical performance variables. Using the date of implant, there appeared to be a significant downward trend in procedure times (Figure 1B), fluoroscopy times and contrast volume. (Figure 1C and D) The improvement in these parameters was particularly striking in TF cases $p < 0.005$.

Figure 1 A, B, C and D: Details the Technical Performance Variables (TA) and the Profile of TAVR and procedure time, Fluoroscopy time and contrast volume according to date of TAVR and stratified by TA (red) vs. TF (blue) delivery approach (B, C and D)



Conclusions: Our results demonstrate that in the PARTNER trial there is an important TAVR learning curve with significant improvement in procedural and performance variables over time. Although the differences in primary operator skill sets between TA and TF approaches may explain some of the observed heterogeneity in learning curves, a critical volume of cases appears necessary to become proficient in the safe performance of TAVR, particularly via the TF route.

TCT-748

Incidence And Prognosis Of Acute Kidney Injury After Transcatheter Aortic Valve Implantation

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Background: Acute Kidney injury (AKI) after cardiac surgery is associated with increased mortality, but very few data exist on the occurrence of AKI associated with Transcatheter Aortic Valve Implantation (TAVI). The objective of this study was to determine the incidence and prognosis of AKI after percutaneous implantation of the CoreValve aortic prosthesis.

Methods: Between April-2008 and January-2011, 223 patients with severe aortic stenosis were treated with the CoreValve prosthesis. The AKI was defined according to Valve set by the Academic Research Consortium, as the absolute increase in serum creatinine ≥ 0.3 mg/dl at 72 hours a percutaneous procedure.

Results: AKI was identified in 37 patients (16.6%) and none required renal replacement therapy. After implantation there was a slight improvement in renal function, baseline serum creatinine decreased from 1.29 ± 0.5 mg/dl to 1.22 mg/dl, $P=0.023$ and glomerular filtration rate (GFR) increased from 49.6 ± 22 to 52 ± 23 , $P=0.015$. In patients with AKI, the mortality at 30 days was 13.5% compared to 1.6% of patients without AKI, $P=0.001$ and late mortality after a mean of 16.7 ± 11 months was 18.8% in those patients with AKI compared to 8.2% in those without AKI, $P=0.068$. In the multivariate analysis AKI was an independent predictor of cumulative total mortality (HR=3.516, 95% CI from 1.098 to 11.255, $P=0.034$).

Conclusions: Deterioration of renal function in patients undergoing TAVI with the CoreValve prosthesis is a serious and frequent complication. The occurrence of AKI was associated with increase early mortality and also was a predictor of worse outcomes in the long-term follow-up.

TCT-749

Comparison of Area and Perimeter Derived Effective Annulus Diameter with Direct Intraoperative Sizing

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Background: Accurate sizing of the aortic annulus is an important premise for successful Transcatheter aortic valve implantation (TAVI). Multislice computed tomography (MSCT) may have advantages over other imaging modalities, but there is uncertainty whether 1) measurements should be performed in systole or diastole and 2) if calculation of the effective annulus diameter should be based on area or

perimeter. Aim of our study was to compare MSCT results with direct intraoperative sizing of the annulus.

Methods: Conventional aortic valve replacement was performed in 25 patients who were primarily screened for TAVI, but were deemed inappropriate for several reasons, and the annulus was measured intraoperatively after decalcification using metric sizers. All patients had undergone transesophageal echocardiography (TEE) and MSCT for TAVI workup and effective annulus diameter was determined derived by area (AsysA, AdiaA) and perimeter (AsysP, AdiaP) in systole and diastole, respectively. Additionally, potential change of strategy for the different approaches compared to intraoperative annulus sizing in case of TAVI using the Edwards Sapien XT valve was simulated.

Results: Best agreement with direct operative sizing (intraop) was observed for AsysA in the Bland-Altman analysis (mean difference between intraop vs. AsysA -0.17 mm, limits of agreement -1.98 – 1.64; intraop vs. AdiaA 0.65 mm, limits of agreement -1.56 to 2.86; intraop vs. AsysP -0.92 mm, limits of agreement -2.81 to 0.97 and intraop vs. AdiaP -0.29 mm, limits of agreement -2.85 to 2.27), TEE 1.5 mm, limits of agreement -2.77 to 2.27). Least change of strategy would have occurred with AsysA (20%), followed by AdiaP (28%), AdiaA (30%) and AsysP (40%).

Conclusions: Compared to surgical sizing area derived measurement in systole represents the best approach for annulus determination with least strategy change. Perimeter derived measurement in systole may lead to overestimation of the true annulus size.

TCT-750

Positioning and Implantation of the Direct Flow Medical Transcatheter Heart Valve without contrast media

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Background: The 18F Direct Flow Medical (DFM) THV has conformable sealing rings which minimizes aortic regurgitation and permits full hemodynamic assessment of valve performance prior to permanent implantation.

Methods: The DISCOVER trial was a prospective, multicenter evaluation of 100 patients who underwent TAVI with the DFM THV. Within this study, 3 patients were at risk for receiving contrast media: 2 due to severe CKD (eGFR < 30 mL/min/1.73 m²) and 1 due to a recent hyperthyroid reaction to contrast. The valve was positioned under fluoroscopic and transesophageal guidance without aortography during either positioning or to confirm the final position. Valve positioning was based on the optimal angiographic projection as calculated by the pre-procedural multi-slice CT scan. Precise optimization of valve position was performed to minimize transvalve gradient and aortic regurgitation. Prior to final implantation, transvalve hemodynamics were assessed invasively and by TEE.

Results: The average age was 81 years. The baseline logistic EuroSCORE were 15, 18 and 24. LVEF was 33, 40, and 62%. The post procedure mean gradients were 7, 10, 11 mmHg. The final AVA by echo was 1.70, 1.40 and 1.68 cm². Total aortic regurgitation post procedure was none or trace in all 3 patients. Total positioning and assessment of valve performance time was 4, 6, and 12 minutes, and total skin to skin procedure time were 29, 47, and 64 minutes. A 25mm valve was used in all 3. There was 100% freedom from all cause mortality at 30 days. VARC defined device success was 100% and patient safety freedom from events was 100%. One had a permanent pacemaker due to AV block. Contrast was only used to confirm successful percutaneous closure of the femoral access site. The total contrast dose was 5, 8, 12 cc. Baseline eGFR and creatinine was 28, 22, 74 mL/min/1.73 m² and 2.35, 2.98, and 1.03 mg/dL, respectively. Renal function was unchanged post procedure: eGFR=25, 35, and 96 mL/min/1.73 m² and creatinine=2.58, 1.99, and 1.03 mg/dL, respectively.

Conclusions: The DFM THV provides the ability to perform TAVI with minimal or no contrast. The precise and predictable implantation technique can be performed with fluoro and echo guidance.

TCT-751

Aortic Stenosis in the Elderly: number of TAVR candidates

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Background: Severe AS is a leading cause of morbidity and mortality in elderly. A proportion of patients is now considered for transcatheter aortic valve replacement (TAVR). We i) performed a meta-analysis on the prevalence of AS in the elderly and ii) systematically estimated the number of candidates for TAVR.

Methods: A systematic search was conducted in multiple databases and prevalence rates of patients (>75 years) were pooled. A model was based on a second systematic