

CRT-700.12

3D Printing and Computer Modeling to Predict Paravalvular Leak in Transcatheter Aortic Valve Replacement

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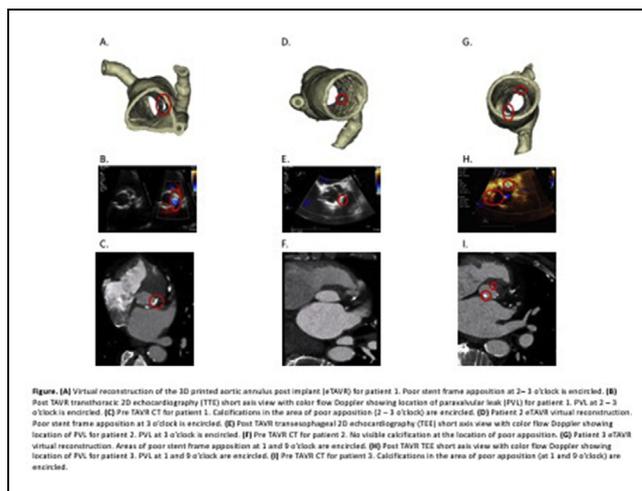


INTRODUCTION Paravalvular regurgitation (PVL) is common after transcatheter aortic valve replacement (TAVR) and associated with worse long-term outcomes when moderate or severe.

METHODS Three patients undergoing TAVR for severe, calcific aortic stenosis and at risk for PVL had Pre-TAVR CT images analyzed and segmented for printing of 3D models using Ninjabflex (Ninjabtek Mannheim, PA) on MakerBot 2X (MakerBot Industries, Brooklyn, NY). 3D aortic root models were then implanted with Sapien XT (Edwards Lifesciences, California) frames at nominal pressure. Ex-vivo implanted 3D models (eTAVR) were then scanned using Siemens SOMATOM flash dual source CT (Siemens, Malvern, PA). eTAVR were then evaluated using Mimics software (Materialise NV, Leuven, Belgium) for final analysis of PVL location. These were then compared to in-vivo implanted TAVR (iTAVR) echocardiograms.

RESULTS Patients 1 and 2 were implanted with 26 mm and patient 3 with 23 mm Sapien XT valves. Patient 1 had mild PVL (2+) at the 1 - 3 o'clock position after TAVR (figure 1B). On 3D analysis, we noted incomplete apposition of the valve stent frame at this location (figure 1A). Similarly, Patient 2 had mild PVL at 3 o'clock (figure 2B) with poor stent frame apposition at the 3 o'clock position (figure 2A). Finally, patient 3 had two small PVLs at 1 and 9 o'clock positions (figure 3B). Both sites showed poor stent frame apposition at these locations (figure 3A). When compared with pre TAVR CT images, Patient 1 and 3 had significant calcifications in areas of poor stent apposition (figures 1C and 3C). Patient 3 had no notable calcification at the annular plane (figure 2C).

CONCLUSION Virtual reconstruction of the aortic annulus with 3D printing and computer modeling of valve implantation prior to TAVR may predict location of PVL site.



CRT-700.13

Increased Mortality in Patients with Low Gradient and Normal Ejection Fraction Severe Aortic Stenosis Undergoing Transcatheter Aortic Valve Replacement



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BACKGROUND There is an increased awareness of the existence of patients with severe aortic stenosis (AS) (aortic valve area < 1 cm²) that have low mean Doppler gradients (<40 mmHg) despite having a normal ejection fraction (EF) (>50%). In a study performed in a surgical population s/p aortic valve replacement, patient with severe AS with low gradient and normal EF had worse outcomes compared to patients with severe AS and high gradients. The aim of this retrospective analysis was to evaluate the 1 year outcomes after transcatheter aortic valve replacement (TAVR) in patients with low gradient severe AS and normal EF (LT40) compared to patients with severe AS, normal EF and high gradients (GT40).

METHODS Within our TAVR database we identified 99 subjects with normal EF severe AS and mean gradient lower than 40 mmHg and 440 patients with normal EF severe AS and mean gradient higher or equal to 40 mmHg. Mortality at 1 year was assessed and proportional Cox hazard model analyses was performed to assess outcome after adjustment for baseline characteristics summarized in the STS score as a continuous variable (including age, sex, height, weight, heart failure/cardiac symptoms, renal function, prior myocardial infarction, lung disease, diabetes, hypertension, presence of aortic, tricuspid and mitral valvular disease) and right ventricular dysfunction

RESULTS There was no difference between the two groups in the rate of 30 days mortality (6.6% vs 8.1%; p=0.6). The 1 year unadjusted death rate was 18.7% in the GT40 group and 28.2 % in the LT40 group (p<0.05). After adjustment for STS score and right ventricular dysfunction the LT40 group had significantly worse outcome compared to the GT40 group (p=0.02).

CONCLUSIONS Patients with low gradient normal EF have worse outcomes compared to patients with high gradient normal EF after TAVR in a single center population analysis. Further studies are needed to identify the causes associated with increased mortality in this patient population.

CRT-700.14

Reduction in Radiation and Contrast Dose in Transcatheter Aortic Valve Replacement Over Time: A Single-Center Experience



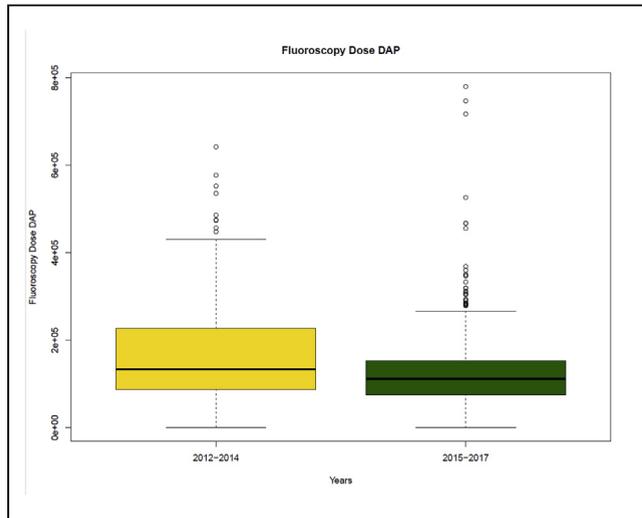
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BACKGROUND Transcatheter aortic valve replacement (TAVR) is recommended for severe aortic valve stenosis (AS). This study aims to evaluate the association between radiation dose, time and contrast dose in TAVR with improved experience over time.

METHODS A Retrospective analysis of 570 patients with severe AS who underwent TAVR between March 2012 and March 2016. We compared 2012-2014 vs. 2015-2016. Primary endpoints were fluoroscopy time, absorbed dose (Air Kerma in mGy) and dose-area product (DAP) and contrast volume in mL. Welch 2-sample t-test was used.

RESULTS At baseline there was no significant difference in baseline characteristics in regards of age, race, gender, or baseline characteristics including hypertension, hyperlipidemia, diabetes or coronary artery disease. Mean fluoroscopy time reduction was 20% (23.81 vs. 19.12 min; P<0.001). DAP was reduced by 23% (16722237.1 vs. 129153 Gycm²; P=0.0004). Absorbed dose was reduced by 37% (1580.5 mGy vs. 984.9 mGy; P< .0001). Mean contrast dose was reduced by 16% (107.24 ml vs 87.6 ml; P= 0.0005).

CONCLUSIONS Radiation exposure and contrast dose has dramatically decreased over the last 5 years during TAVR and is related to operator experience, case volume and technology evolution. This has significant implications for both patient and operator long-term risk.



CRT-700.15
Impact of Severity of Renal Dysfunction on 30-Day Readmission Following Transcatheter Aortic Valve Replacement with Contemporary Valves



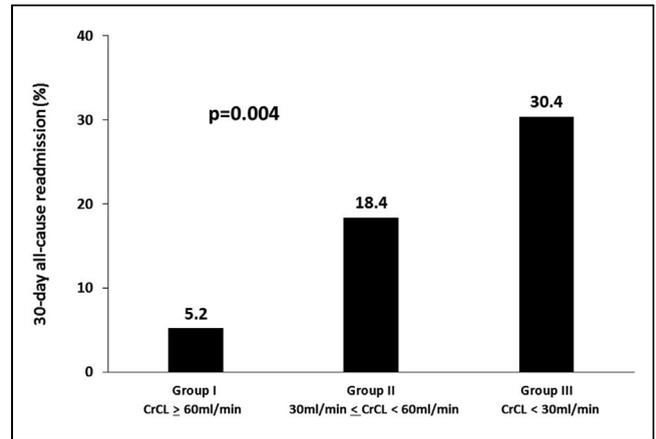
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BACKGROUND The impact of chronic renal disease on outcomes following transcatheter aortic valve replacement (TAVR) is not well known. Moreover, readmission rates following TAVR have not been adequately studied in the era of contemporary newer generation valves. We aimed to evaluate the impact of moderate and advanced chronic kidney disease on 30-day readmission following adults undergoing TAVR with contemporary valves.

METHODS The study population included 179 consecutive patients who underwent TAVR with a contemporary valve [Sapien 3 valve (Edwards Life Sciences, Irvine, CA) or Corevalve Evolut R or Evolut Pro (Medtronic, Minneapolis, MN) from December 2015-October 2017 at an academic tertiary medical center. Baseline and clinical characteristics, procedural data, and clinical outcomes were recorded. The primary endpoint was 30-day all-cause readmission (ACR).

RESULTS Patients were divided into 3 groups according to pre-TAVR creatinine clearance (CrCL): group I (CrCL ≤ 60ml/min), group II (30ml/min ≤ CrCL < 60ml/min), and group III (CrCL < 30ml/min). Patient with lower CrCL were older, had lower body mass index, and higher Society of Thoracic Surgeons score. They also had lower baseline hemoglobin and serum albumin levels. Overall 30-day ACR rate was 14.2%. ACR at 30 days was significantly higher in patients with lower CrCL (Figure). In multivariate analysis, CrCL was the only independent predictor of readmission at 30 days [referent group I: group II (OR 3.87, 95% CI 1.09-13.72, p=0.036) and group III (OR 6.09, 95% CI 1.39-26.67, p=0.016)].

CONCLUSIONS Lower CrCL is independently associated with higher rates of 30-day hospital readmission. Further studies are warranted to better understand high-risk features in patients with impaired renal function undergoing TAVR in order to optimize clinical outcomes in this growing population.



CRT-700.16
Predictive Method for Paravalvular Leakage After Transcatheter Aortic Valve Replacement (TAVR) Using Patient-Specific Computational Modeling



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INTRODUCTION Paravalvular Leakage (PVL) is a serious complication after transcatheter aortic valve replacement (TAVR)⁽¹⁾. In the present study two clinically approved devices, CoreValve and SAPIEN 3 (Figure 1A), were computationally implanted in a patient’s aortic root to predict the likelihood of PVL.

METHODS To study the role of valve selection on PVL, the 3D geometry of a 84 year-old male patient from pre-procedural CT images was reconstructed. Each valve was then implanted in the patient’s aortic root and the final deformation of native leaflets and stents were simulated. To capture diastolic PVL, 100 mmHg diastolic pressure was applied for 0.66 seconds and PVL was quantified using flow rate, flow resistance, number of leakage jets, and maximum jet velocity. Finally, the CoreValve simulation was validated against in-vivo echocardiographic color Doppler measurements (Figure 1B).

RESULTS AND CONCLUSION The patient was treated clinically using a 34 mm CoreValve and was then diagnosed with severe PVL secondary to calcification in LVOT during 1 month follow-up. Computational models showed three leakage jets of PVL with the maximum velocity of 5 m/s in the presence of 34 mm CoreValve with good agreement with Doppler measurements. However, only one jet with the maximum velocity of 4.1 m/s was observed with a simulated 29 mm SAPIEN 3 implantation. PVL flow rate significantly reduced from 4.94 L/min with CoreValve to 2.65 L/min for SAPIEN 3 (Figure 1C). This noticeable reduction in the PVL flow was the consequence of SAPIEN 3 design and expansion, which better seals the leakage gap in comparison with CoreValve (Figure 1D). This study is an illustrative proof of concept that patient-specific pre-procedural planning regarding valve selection can be improved by personalized computational modeling.

REFERENCE 1. Mack MJ, et al. The Lancet 2015;385:2477-2484.