TCT-696

Predictive Value for Paravalvular Regurgitation of 3-Dimensional Anatomic Aortic Annulus Shape Assessed by Multidetector Computed Tomography post-Transcatheter Aortic Valve Replacement

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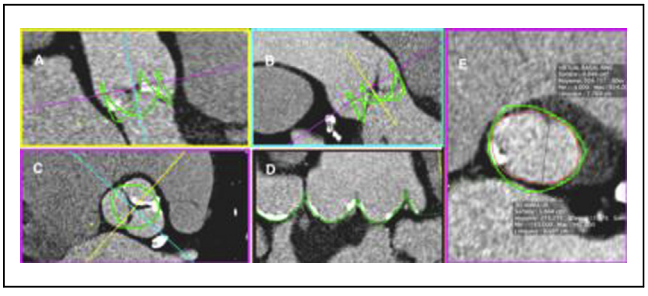
BACKGROUND Paravalvular regurgitation (PAR) remains a serious complication after Transcatheter aortic valve replacement (TAVR). Multidetector computed tomography (MDCT) based measurements of the aortic basal virtual ring (BVR) are considered the gold standard for trans-catheter heart valve (THV) sizing. However, the real anatomic aortic annulus is a 3-dimensional structure. Aim: To compare measurement of 3D-Anatomic Annulus with BVR and secondly to assess independent predictive parameters that may impact on PAR > mild post TAVR (PAR+).

METHODS MDCT was performed in 92 patients before and after balloon or self-expandable TAVR. 3D-AAA shape was obtained point-by-point following the semilunar attachment of aortic cusps (Osirix MD 2.8.2). 3D-Oversizing index (nominal THV area/3D-AA area-1) x100 was calculated as well as 2D-Oversizing Index using BVR area instead of 3D-AA area. PAR was quantified by planimetry of vena-contracta in transthoracic echocardiography short axis view. Valvular calcium volume and annulus calcium area were measured using Hounsfield-intensity detection. ROC Curves and logistic regression for PAR(+) were performed.



RESULTS BVR area overall underestimated 3D-AA area by 19±9% (p<0.001), significantly more in PAR(+) (26±7 %) versus PAR(-) (17±9%, p<0.001). 3D-Oversizing Index had greater predictive value for PAR>mild (AUC=0.88) with 88% sensibility (Se) and 82% specificity (Sp) than 2D-Oversizing index (AUC=0.68) with 84% Se, but only 41% Sp (p<0.0001). Also, valvular calcium volume and annulus calcium area were less predictors for PAR>mild (AUC=0.68, respectively AUC=0.75, p=0.002). In a Multivariate analysis, only 3D-Oversizing Index showed an independent value for PAR>mild (OR=18.6, p<0.001). BVR area systole-diastole varies significantly which implies limitation for 2D annulus sizing. 3D-annulus showed no significant changing throughout the cardiac cycle.

Variable	AUC for PAR>mild	p Value	Cutoff	Se	Sp	PPV	NPV
3D-Oversizing Index	0.88 (0.81-0.94)	-	0%	88%	82%	65%	95%
2D-Oversizing Index	0.68 (0.56-0.78)	0.0001	25%	84%	41%	36%	93%
Delta (3D AAA/BVR)	0.82 (0.73-0.91)	0.2	21%	84%	73%	54%	92%
Annulus Calcium Area	0.75 (0.66-0.85)	0.047	14mm^2	87%	61%	45%	93%
Valve Calcium Volume	0.68 (0.56-0.79)	0.002	150mm^3	84%	55%	41%	90%

CONCLUSIONS Basal ring CT measurement significantly underestimated the real 3D Anatomic Aortic Annulus area. This may impact on THV sizing and PAR incidence. 3D-Oversizing Index is the most predictive factor for PAR>mild.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS CT sizing, Paravalvular leaks, TAVR

TCT-697

Relationship between the degree of device oversizing and clinical outcomes in patients treated with transcatheter aortic valve replacement using balloon-expandable or self-expanding valves: Insights from the randomized CHOICE trial

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BACKGROUND A certain degree of transcatheter heart valve(THV) oversizing is considered to be important to prevent significant paravalvular leakage after transcatheter aortic valve replacement(TAVR). However, data on the degree of oversizing and its impact on clinical outcomes are limited. The objective of this analysis was to study the effect of the degree of oversizing on clinical outcomes in the CHOICE randomized trial comparing balloon-expandable(BE) and self-expanding(SE) valves.

METHODS The multicenter CHOICE trial randomized 241 high surgical risk aortic stenosis patients in a 1:1 fashion to receive either a BE(Edwards Sapien XT) or a SE(Medtronic CoreValve) THV, primary endpoint being Valve Academic Research Consortium defined rate of device success. 178 patients in this trial had 3D multidetector CT data for degree of device oversizing and were included in the present posthoc analysis. Oversizing was determined as percent perimeter oversizing ({THV perimeter/annulus perimeter-1} x100) and percent area oversizing ({THV area/annulus area-1} x100). Patients were divided into a moderate oversizing group(upto 20% area oversizing or upto 9.5% perimeter oversizing) and a large oversizing group (>20% area or 9.5% perimeter oversizing). Comparison of periprocedural and 1 year clinical outcomes for both device types were performed.

RESULTS There were 129 patients in the large oversizing group(-BE,n=51;SE,n=78) and 49 in the moderate oversizing group(-BE,n=39;SE,n=10). In the moderate oversizing group, device success occurred in 36(92.3%) of the BE patients as compared to 5(50%) in the SE group(p=0.005). In the large oversizing group, device success occurred in 50(98%) of the BE patients as compared to 64(82.1%) for SE group(p=0.005). More than mild aortic regurgitation (AR) by angiographic core lab assessment occurred more commonly with SE valve implantations in both oversizing groups (30% vs 7.7%,p=0.09 for moderate oversizing;14% vs 2%,p=0.03 for large oversizing). The need for a second valve was significantly higher for SE device in the moderate oversizing group (30% vs none;p=0.007). There was no annulus rupture or immediate mortality in either group. Need for permanent pacemaker was higher for SE valve patients in the moderate oversizing group (55.6% vs17.6%;p=0.03). At 1 year, no BE valve patient had more than mild AR, which occurred respectively in 50% and 12.7% of the moderate and large oversizing groups of SE THV implantations.There were no significant differences between the devices with regard to cumulative mortality, stroke rate and rates of hospitalizations at 1 year in the two groups.

CONCLUSIONS The BE TAVR group had less periprocedural and 1 year rates of AR as well as higher device success rate as compared to the SE valve group irrespective of the degree of oversizing. For SE valves, device success was higher in the large oversized group as compared to the moderate one. These findings underscore the importance of significant device oversizing with the SE valve.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Device Sizing, TAVI, TAVR

TCT-698

Incremental Value of Computed Fractional Flow Reserve in Patients Referred to Transcatheter Aortic Valve Replacement

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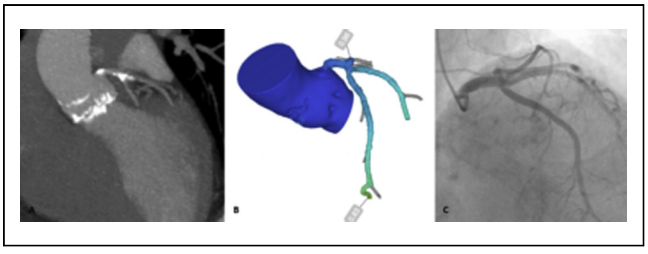
BACKGROUND The high prevalence of significant coronary artery disease (CAD) in patients referred to trans-catheter aortic valve replacement (TAVR) has been demonstrated by multiple large studies. Whereas computer tomography angiography (CTA) is becoming an indispensable component of TAVR work up, CAD assessment by CTA has been challenging in patients undergoing TAVR due to the heavy calcification burden and beta blockers use restrictions. Computed fractional flow reserve (FFR CT) has been shown to improve diagnostic accuracy and discrimination compared to CTA alone for the diagnosis of hemodynamically significant coronary artery disease when compared to invasive FFR. However, its performance in TAVR population is still unknown. The goal of this study is to determine the incremental benefit and to assess the diagnostic ability of FFR CT derived from CTA for CAD assessment in patients referred to TAVR over CTA alone as compared to invasive coronary angiography (ICA).

METHODS A total of 19 consecutive CTA exams with at least one non diagnostic major coronary segment due to calcium presence were processed by HeartFlow, Inc. to compute FFR CT. The major coronary artery branches were divided in 10 segments per patient, and when deemed visually interpretable and categorized in binomial fashion as non-significant or significant coronary disease using 50% cutoff value. Results were then compared to ICA results that were graded by different expert in similar fashion using more than 70% stenosis for significant disease. Figure 1: (A) CTA showing uninterpretable LM and proximal LAD segments due to calcification blooming. (B) FFR CT of the same segments quantified from the same set of CTA images is interpretable, revealing normal values of 0.96 and 0.83, respectively. (C) ICA demonstrates normal LM and mild stenosis of the proximal portion of the LAD.



RESULTS At patient level, out of the 19 cases, 11 (58%) were found interpretable by HeartFlow and 8 (42%) uninterpretable for FFR CT analysis. At segment level analysis of the 11 interpretable cases, the sensitivity and specificity of FFR CT compared to ICA were 100% and 90%, respectively.

CONCLUSIONS FFR CT analysis can enhance CTA diagnostic ability to rule out significant CAD while maintaining high sensitivity. If these findings are reproducible in larger series, a significant percent of TAVR candidates would be spared from unnecessary ICA.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Computed tomography angiography, TAVI, PCI, Aortic stenosis, CAD

TCT-699

The Italian DFM Registry: real world results of a next generation fully repositionable TAVI device

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BACKGROUND The Direct Flow Medical transcatheter aortic valve system has a non-metallic design with a pressurized support structure, which allows precise positioning, retrieval and full hemodynamic assessment of valve performance prior to permanent implantation. The Direct Flow Italian registry is a nationwide registry enrolling patients treated with the Direct Flow Device in the aortic position since early 2012 to evaluate outcomes of the device in a real world setting.

METHODS A group of 142 consecutive patients treated after February 2012 in 5 Italian centers has been enrolled in the registry.

RESULTS Mean age was 82.8±6.1 years, mean EuroSCORE was 20.4±15.3%. Patient comorbidities were: COPD in 27.8%; moderate or severe kidney disease in 31%; peripheral vessel disease in 33.3%; previous MI in 19.1%, previous CABG in 17.0%; 67.9% of patients were in class NYHA 3 or 4. At a median follow up of 11.2 (IQR 3.0-19.0) months, 9.2% of patient died and the stroke rate was 2.1%. PM rate within 30 days of the procedure was 12.7%. Vascular complications occurred in 2.1%, conversion to cardiac surgery in 1.4% and the Direct Flow device was retrieved to switch to a different valve in 2.1% of patients. A procedural learning curve was apparent and mean fluoroscopy times significantly decreased with greater operator experience from 45.4±22.8 to 29.6±8.6 minutes when comparing the first and fourth quartiles (p=0.02). Moderate or severe PV leak at the last available echo at a median follow up of more than 11 months was present in only 2.1% of cases.

CONCLUSIONS The Direct Flow Medical transcatheter aortic valve system demonstrates excellent real-world outcomes in high-risk patients with severe aortic stenosis, with an overall low death stroke and pacemaker rate and a good valve performance.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Real world, TAVI

TCT-700

Transcarotid Transcatheter Aortic Valve Replacement: Feasibility and Safety

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BACKGROUND A considerable proportion of potential TAVR candidates have challenging vascular anatomies that is unsuitable for transfemoral TAVR. Transcarotid TAVR access may be an option for these patients.

METHODS The French Transcarotid TAVR Registry is a voluntary database that has prospectively collected patient demographics, clinical and procedural characteristics, and clinical outcomes on patients undergoing transcarotid TAVR since 2009. All patients underwent pre-operative multimodal imaging assessment, including multislice computed tomography and cerebral magnetic resonance angiography. All outcomes are reported according to the updated Valve Academic Research Consortium.

RESULTS Among 96 patients undergoing transcarotid TAVR in France at 3 sites between April 2009 and December 2013, the mean age was 79.4±9.2 years and the average STS PROM score was 7.1±4.1%. Successful carotid artery access was achieved in all patients. The Medtronic CoreValve and Edwards SAPIEN THV were implanted in 89 (92.7%) and 7 (7.3%) patients, respectively. Procedural complications included: THV embolization (3.1%); implantation of a second THV (3.1%); and cardiac tamponade due to left ventricular wire perforation (4.2%). There were no major bleeds or major vascular complications related to the carotid access site. There were 3 (3.1%) procedural deaths and 6 deaths (6.3%) at 30-days. There were 3 (3.1%) cases of VARC-defined in-hospital stroke (n=0) or TIA (n=3). No patient achieved the criteria for stroke and none had new ischemic lesions on neuroimaging. At 30-days, a further 3 TIAs were observed, giving an overall stroke/TIA rate of 6.3%.

CONCLUSIONS Transcarotid vascular access for TAVR is feasible and is associated with encouraging short and medium-term clinical outcomes. Prospective studies are required to ascertain if transcarotid TAVR yields equivalent safety and efficacy to other non-femoral vascular access routes.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic