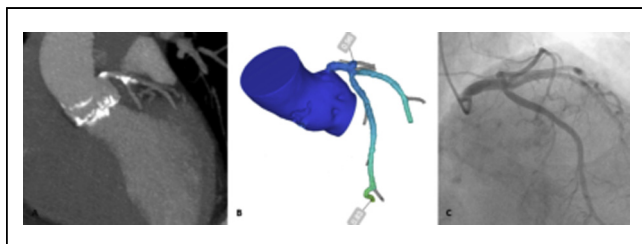


BACKGROUND The high prevalence of significant coronary artery disease (CAD) in patients referred to trans-catheter aortic valve replacement (TAVR) has been demonstrated by multiple large studies. Whereas computer tomography angiography (CTA) is becoming an indispensable component of TAVR work up, CAD 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

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. Transcatheter TAVR access may be an option for these patients.

METHODS The French Transcatheter TAVR Registry is a voluntary database that has prospectively collected patient demographics, clinical and procedural characteristics, and clinical outcomes on patients undergoing transcatheter 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 transcatheter 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 Transcatheter vascular access for TAVR is feasible and is associated with encouraging short and medium-term clinical outcomes. Prospective studies are required to ascertain if transcatheter TAVR yields equivalent safety and efficacy to other non-femoral vascular access routes.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic