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Review

Review of Late-Breaking Trials From CRT 2022

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Contents

1. Introduction

After two years of virtual meetings, Cardiovascular Research Technologies (CRT) 2022 was the first fully in-person cardiology meeting held since the onset of the COVID-19 pandemic. CRT 2022 featured presentations of eight late-breaking trials. Of these, four trials related to coronary artery disease and percutaneous coronary intervention and four to structural heart intervention. This review will cover these trials, which were presented February 27 and 28, 2022, at the Omni Shoreham Hotel in Washington, DC.

2. Coronary intervention

2.1. AutocathFFR versus invasive FFR physiology indices

Presenter: Prof. Hector M. Garcia-Garcia, MD, PhD

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Key Points: *An artificial intelligence-based system, AutocathFFR, an angio-derived fractional flow reserve (FFR) method, demonstrated an excellent diagnostic performance against invasive FFR.*

The results were reported by Hector M. Garcia-Garcia, MD, PhD, from MedStar Washington Hospital Center [1].

The most commonly used method to assess hemodynamically significant coronary artery disease (CAD) in contemporary practice is FFR, but it comes with the limitations of being invasive and time consuming, with a 2% rate of complications. Alternatively, AutocathFFR (automated FFR calculation software; MedHub, Tel Aviv, Israel) is an artificial intelligence noninvasive software that measures FFR from digital angiography images and relies on machine learning and artificial intelligence for FFR calculation. It analyzes the angiography images and automatically suggests the areas of narrowing in the coronary vessels without the need of user selection or markings. The objective of this study was to compare the diagnostic performance of the noninvasive AutocathFFR measurements to "gold standard" invasive FFR measurements in patients with hemodynamically significant coronary lesions.

The authors prospectively analyzed the study data from retrospectively acquired imaging and physiology data of study subjects with known or suspected CAD in whom invasive coronary angiography and FFR had been performed. The subjects, age >18 years, presented with stable angina pectoris, unstable angina pectoris, or non-ST-segment elevation myocardial infarction (NSTEMI) and underwent invasive FFR to assess a non-culprit narrowing in at least one coronary artery were enrolled. The key exclusion criteria were vessel diameter <2 mm, chronically occluded vessel, history of prior percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) in the target vessel, history of heart transplant or valve surgery, left ventricular ejection fraction (LVEF) <30%, Thrombolysis in Myocardial Infarction (TIMI) flow grade ≤2, left main coronary artery stenosis >50%, and presence of diffuse coronary disease. The co-primary endpoints were sensitivity and specificity of AutocathFFR per vessel compared to invasive FFR. To assess the repeatability of the AutocathFFR measurements, manually identified lesions were analyzed three times by different operators. To further study the reproducibility of the AutocathFFR results, all cases (based on the automated software selection) were analyzed twice.

A total of 297 subjects were enrolled. Baseline characteristics of the patient population included mean age of 63.7 ± 10.0 years, with a majority (78.8%) being male. The most common presentation was unstable angina (27.6%), followed by NSTEMI (18.5%).

The study demonstrated that the accuracy of AutocathFFR in comparison to invasive FFR (304 vessels) was 93.7%, with an area under the curve (AUC) of 0.93 (0.88–0.97). The study successfully achieved the primary endpoints of sensitivity and specificity of 91.3% and 94.5%, respectively, beyond the prespecified target of 75%. When assessing the AutocathFFR performance in the gray zone areas (FFR 0.77–0.87) in 136 vessels, the accuracy, sensitivity, and specificity were even better and remained above 93%. The repeatability of the study assessed by three different operators was 0.85 ± 0.06, 0.85 ± 0.05, and 0.86 ± 0.05, $p = 0.436$. Additionally, the reproducibility was noted to be 100%.

The AutocathFFR computation takes only 45 s and is hands-free per lesion, said Dr. Garcia-Garcia. It requires only two views per lesion and is not adenosine-dependent like invasive FFR. The study concluded that AutocathFFR has an excellent diagnostic performance against invasive FFR, with 100% reproducibility and excellent repeatability.

2.2. Randomized trial of Cobra PzF stenting to reduce duration of triple therapy: Final results of COBRA-REDUCE trial

Presenter: Robert A. Byrne, MD, BCh, PhD

Key Points: *The Cobra PzF NanoCoated coronary stent (NCS) with 14-day dual antiplatelet therapy (DAPT) failed to reduce bleeding versus standard drug-eluting stents (DES) with 3–6 months of DAPT in patients undergoing PCI for acute or chronic coronary syndromes while on oral anticoagulation.*

The results were reported by Robert A. Byrne, MB, BCh, PhD, of RCSI University of Medicine and Health Sciences, Dublin, Ireland [2]. The CeloNova Biosciences' polyzene-F (COBRA PzF) stent is the first in a new category of non-drug-eluting NCS aimed at reducing the minimum DAPT requirement. The strut is composed of cobalt chromium alloy with thickness of 71 μm and has demonstrated the properties of being thromboresistant, non-inflammatory, and pro-healing in preclinical studies. In his presentation, Dr. Byrne highlighted the previous data, including 9-month clinical and angiographic data, of the PzF Shield trial assessing the device safety and efficacy in the treatment of *de novo* coronary artery lesions, which concluded that performance goals had been met. Target vessel failure occurred in 33 (11.5%) of the 287 patients who completed the primary endpoint analysis.

COBRA-REDUCE was sponsored by CeloNova under the hypothesis that Cobra PzF stenting with an ultrashort 14-day DAPT would provide superior bleeding outcomes (Bleeding Academic Research Consortium [BARC]-2) in patients undergoing coronary intervention who are receiving oral anticoagulation (with or without dose reduction) versus 3 to 6 months of DAPT after stenting with a standard U.S. Food and Drug Administration (FDA)-approved DES (e.g., Xience/Promus, Resolute, or Synergy) in patients with an indication for chronic oral anticoagulation. The randomized, open-label, active-controlled, assessor-blinded trial also set out to prove non-inferiority versus commercially approved DES in the composite of death, myocardial infarction (MI), stent thrombosis (ST), and ischemic stroke [3].

A total 996 patients over the age of 18 with ischemic symptoms or evidence of MI in the presence of 50% or greater *de novo* stenosis located in a native coronary vessel were enrolled across 60 sites (35 in the US and 25 in Europe) between February 2016 and May 2020. The patients could have a maximum of two lesions in a maximum of three vessels. Exclusion criteria included cardiogenic shock, target lesion located in the left main, bifurcation interventions with a planned two-stent strategy, and active bleeding. Of those enrolled, 495 patients were given Cobra PzF plus 14 days of DAPT and 501 were given a standard DES with 3 to 6 months of DAPT, with similar weightings for age, gender, and smoking status. They had an even distribution for other conditions such as diabetes, hypertension, prior heart failure, and previous MI. Of the COBRA-plus-short-DAPT group, 27% were indicated for PCI with acute coronary syndrome and 73% with chronic coronary syndrome, versus 32% and 68%, respectively, in the DES-plus-standard-DAPT group. Radial and femoral access was performed evenly between the two groups.

One component of the co-primary endpoint, BARC class ≥2 bleeding after hospital discharge or after 14 days (whichever is later), was seen in 7.79% of those given the COBRA-plus-short-DAPT regimen compared to 9.75% of those on the standard DES treatment (hazard ratio [HR]: 0.70; 95% confidence interval [CI]: 0.51–1.21; $p = 0.14$). The thrombotic co-primary endpoint, the composite rate of all-cause death, MI, definite and probable ST, and ischemic stroke at 6 months post-randomization was seen in 7.52% of those on the COBRA treatment compared to 4.90% of those on standard DES regimens (HR: 1.57; 95% CI: 0.94–2.62). Secondary bleeding endpoints included BARC class 3–5 after 14 days (3.8% in COBRA vs. 4.6% in DES, $p = 0.629$), TIMI major and minor bleeding (3.59% in COBRA vs. 3.95% in DES, $p = 0.866$), TIMI major bleeding (1.69% in COBRA vs. 2.49% in DES, $p = 0.499$), and TIMI minor bleeding (1.9% in COBRA vs. 1.68% in DES, $p = 0.812$). The composite secondary endpoint of cardiac death and MI, ischemia-driven target lesion revascularization (ID-TLR), ST (definite and probable), and ischemic stroke at 12 months post-randomization was seen in 13.1% of those on the COBRA treatment vs. 8.7% of those on DES (p-superiority analysis = 0.030). Dr. Byrne stated that the significantly higher rate of Cobra PzF patients experiencing the 12-month thromboembolic endpoint was driven mainly by an increase in the rate of ID-TLR.

The study limitations included the open-label design and a difference in anticoagulation dose-intensity reduction between the groups, which confounds comparison of bleeding events.

The study showed that treatment with the Cobra PzF stent was found to be safe, with ST rates considerably lower than those seen in earlier trials with high-bleeding-risk patients, despite DAPT duration of only 14 days. The authors concluded that though the results do not support a routine strategy of Cobra PzF stenting with 14 days of DAPT in patients receiving oral anticoagulation, the investigational device may benefit selected patients at high bleeding risk or in whom an early interruption of DAPT is anticipated.

2.3. Ultrathin bioresorbable-polymer sirolimus-eluting stents versus thin durable-polymer everolimus-eluting stents in patients undergoing coronary revascularization: Final five-year outcomes from the randomized BIOFLOW-V trial

Presenter: David Kandzari, MD

Key Points: *Patients who underwent PCI with the Orsiro stent showed numerically lower, but not statistically significantly different, rates of target lesion failure (TLF) compared to the Xience stent at 5 years, according to new BIOFLOW-V trial results. However, the individual outcomes of target vessel myocardial infarction (TVMI) and late and very late definite or probable ST and very late ST were significantly lower among patients who received the Orsiro stent.*

David E. Kandzari, MD, of Piedmont Heart Institute, Atlanta, presented these findings [4]. BIOFLOW-V was an international, 2-to-1 randomized trial comparing the Orsiro (Biotronik) ultrathin-strut (60 μm) bioresorbable-polymer sirolimus-eluting stent (BP-SES) with the Xience (Abbott) thin-strut (81 μm) durable-polymer everolimus-eluting stent (DP-EES). The study received funding from Biotronik.

The patients in the study had a mean age of 64.5 ± 10.3 years in the BP-SES group and 64.6 ± 10.7 years in the DP-EES group, with a majority of patients being male (74.7% vs 72.9%). The most common comorbidities included hypertension, hyperlipidemia, and diabetes in both cohorts. The average reference vessel diameter in the BP-SES and DP-EES arms was 2.59 ± 0.54 mm vs 2.60 ± 0.58 mm, respectively. The mean stent length per lesion was 20.8 ± 9.1 mm and 21.8 ± 10.5 mm in each group.

The trial randomized 1334 patients (884 BP-SES [1051 lesions], 450 DP-EES [561 lesions]) in 13 countries [5]. The primary endpoint was 12-month TLF. Prespecified outcomes through the study duration of 5 years were assessed. At 5 years, 807 patients (91.3%) were available in the BP-SES arm and 411 (91.3%) were available in the DP-EES arm. The BP-SES did meet the primary endpoint at 1 year, showing significantly lower TLF than the DP-EES, and maintained that advantage through 3 years. However, the rates became similar by 5 years (BP-SES 13.2% vs. DP-EES 16.5%; $p = 0.136$). The trial also showed significantly lower rates of ID-TLR at 2 and 3 years in the BP-SES arm, but while the rate was still numerically lower in the BP-SES arm at 5 years, the significance had disappeared (BP-SES 5.9% vs. DP-EES 7.7%; log-rank $p = 0.202$). TVMI was significantly lower at 5 years in patients receiving BP-SES (7.3%) than in the DP-EES arm (11.5%; $p = 0.02$). The same was true of very late (1–5 years) ST (0.1% vs. 1.0%; $p = 0.047$) and late or very late (30 days through 5 years) definite or probable ST (0.3% vs. 1.6%; $p = 0.021$).

Dr. Kandzari concluded that the findings of the study affirm the durability of longer comparative outcomes with the ultrathin-strut BP-SES and demonstrate superiority in late ischemic events.

2.4. UZ clear study

Presenter: Carlos Collet, MD, PhD

Key Points: *Invasive functional assessment that accounts for the epicardial and microvascular compartments could improve the limited diagnostic accuracy of cardiac stress tests in diagnosing CAD, according to the UZ Clear study in 107 patients. Further, assessing coronary microcirculation in stable patients presenting with evidence of ischemia was found to increase the diagnostic accuracy of the exercise stress tests.*

The results were reported by Carlos Collet, MD, from the Cardiovascular Center OLV-Aalst, Belgium [6]. The study was sponsored by the University of Brussels and received an unrestricted grant from Abbott Vascular.

Cardiac stress tests remain the cornerstone for suspected CAD, but this kind of testing has been shown to have moderate accuracy in detecting CAD. It detects myocardial ischemia, typically due to epicardial narrowing. The presence of microvascular disease can also induce alterations of non-invasive tests, which can be interpreted as false-positive tests.

The current study, therefore, sought to determine the false discovery rate of exercise stress tests using an interventional diagnostic procedure (IDP) with indexes of epicardial FFR and microvascular resistance (index of microcirculatory resistance [IMR]) as clinical references. Its goal was to determine the false discovery rate of cardiac exercise stress tests with both FFR and IMR as references and to assess the impact of an interventional diagnostic procedure with IMR on the accuracy of cardiac stress test.

The multicenter, investigator-initiated, prospective study enrolled 107 patients with an intermediate pre-test probability of CAD and positive exercise stress tests who were referred for conventional angiography. The patients' mean age was 62.1 ± 8.7 years, the majority (78%) were male, 55.1% had hypertension, 17% had diabetes mellitus, and 66% had Canadian Cardiovascular Society angina class ≥ II. The patients underwent an invasive protocol including FFR measurements and IMR in at least one coronary vessel.

In the exercise tests, average time to ST-deviation was 5.8 ± 1.3 min, with a mean ST depression of 1.6 ± 0.1 mm, while the mean diameter stenosis was 37.2% ± 14.4%, FFR 0.84 ± 0.06, IMR 15.24 ± 9.12, and coronary flow reserve 2.54 ± 1.02. In patients with positive exercise tests, 34% had epicardial disease with diameter stenosis >50%, 46% had normal FFR and IMR, 17% had microvascular disease, and only 3% had abnormal FFR and IMR. The false discovery rate, defined as the number of false positives divided by all positives, was highest with IMR at 79%, followed by FFR at 63% and quantitative coronary angiography (QCA) at 60%. The lowest false discovery rate was with the combined FFR and IMR reference standard, at 46% ($p < 0.05$ compared to QCA). The prevalence of abnormal IMR in ischemia with no obstructive coronary arteries (INOCA subgroup) was 27%.

The key limitation of the study was that diagnostic performance in terms of sensitivity and specificity could not be evaluated, as patients with negative stress test were not enrolled.

The authors concluded that approximately half of the patients presenting with chest pain at an intermediate pre-test probability for CAD and positive stress tests have evidence of epicardial or microvascular CAD. Invasive functional assessment accounting for both epicardial and microvascular assessment led to a significant reduction in the proportion of false-positive tests. Lastly, the evaluation of coronary microcirculation in stable patients reclassified 1 out of 5 patients with evidence of ischemia otherwise considered to have false-positive results.

3. Structural

3.1. Low Risk TAVR trial: 4-year results

Presenter: Ron Waksman, MD

Key Points: *Transcatheter aortic valve replacement (TAVR) continued to be safe in patients with symptomatic, severe aortic stenosis who are at low surgical risk 4 years after the procedure.*

Ron Waksman, MD, of MedStar Washington Hospital Center, presented these results [7].

The Low Risk TAVR (LRT) trial, an investigator-initiated, prospective, multicenter study, was the first US FDA-approved investigational device exemption trial to evaluate the feasibility of TAVR in low-risk patients. The trial enrolled 200 low-risk patients with symptomatic, severe aortic

stenosis to undergo TAVR at 11 centers. Their mean age was 73.6 ± 6.1 years, and 61.5% were men [8]. The average Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score was 1.8 ± 0.5.

At 4-year follow-up, 174 patients were available. The all-cause mortality rate was 12.1%, the stroke rate was 7.9% (disabling stroke 2.0%), and the permanent pacemaker implantation rate was 12.3%. Four subjects (2.7%) underwent surgical reintervention for endocarditis. At 30 days, 14% of TAVR subjects had hypoattenuated leaflet thickening (HALT), but there was no evidence that this impacted valve hemodynamics, endocarditis, or stroke at 4 years. There was no significant difference in LVEF between patients with HALT (65.5% ± 4.2%) and those who without HALT (64.9% ± 5.8%; $p = 0.84$). The same was true of left ventricular end-diastolic dimension (HALT 4.1 ± 0.4 cm vs. no HALT 4.3 ± 0.6 cm; $p = 0.48$). The following measurements were also similar between HALT and no-HALT patients: mean gradient, aortic valve area, and dimensionless index. No severe structural valve degeneration was noted in patients with HALT vs no HALT. Also, at 4 years, no greater than mild paravalvular leak was reported, and 6.1% of subjects had been rehospitalized for heart failure. The study demonstrated excellent outcomes at 4 years, including low rates of mortality and stroke.

Dr. Waksman concluded that TAVR is safe and effective in low-risk patients, with low adverse event rates, and excellent valve hemodynamics were maintained through 4 years.

3.2. Transcatheter mitral cerclage ventriculoplasty

Presenter: Toby Rogers, MD, PhD

Key Points: *A novel technique and device developed to treat functional mitral regurgitation (MR) called transcatheter mitral valve cerclage (TMVC) annuloplasty, known as cerclage, showed significant and sustained improvements in MR and heart failure quality-of-life assessments.*

Findings from the first-in-man feasibility trial [9] indicate that the cerclage device and procedure was safe and resulted in high technical and procedural success. Led by Toby Rogers, MD, PhD, from the National Heart, Lung, and Blood Institute at the National Institutes of Health (NIH), Bethesda, Maryland, and MedStar Washington Hospital Center, the authors noted that cerclage is a catheter procedure performed under X-ray and ultrasound guidance without surgery. The trial evaluated the safety and feasibility of TMCV in patients with MR and either heart failure with reduced ejection fraction (HFrEF) or heart failure with preserved ejection fraction (HFpEF), and subjects with prior transcatheter edge-to-edge repair (TEER) but persistent or recurrent symptomatic MR. The prospective, multicenter, single-arm, open-label study was funded by the NIH. The primary endpoint was technical success measured at exit from the catheterization laboratory, while the secondary outcome was procedural success at 30-day follow-up and no TMCV-related serious adverse device effects. Other measures at follow-up included heart failure quality-of-life assessments and serial imaging with echocardiography and cardiac computed tomography (CT).

The study enrolled 19 subjects from 3 sites who underwent cerclage. The key inclusion criteria included age ≥21 years with symptomatic functional MR on optimal medical therapy for at least 1 month, LVEF ≥20%, and suitable coronary venous anatomy for TMCV based on pre-procedural cardiac CT or invasive coronary venogram. Subjects with a prior history of TEER were enrolled if they had undergone the procedure at least 30 days previously. The mean age of the patients was 73 years, and a majority (63%) were female. Of the study population, 37% had HFpEF and 63% had HFrEF, while ischemic cardiomyopathy was present in 26% and non-ischemic in 74% of patients.

The primary endpoint was met in 17/19 subjects. The team noted that cerclage was aborted in one subject without sequelae because the chosen intramyocardial trajectory was too close to the left anterior descending artery and caused compression upon tensioning. The subject completed 30-day follow-up and then re-enrolled under a new subject identifier and underwent successful implantation. In a second patient, cerclage was also aborted without sequelae because a suitable intramyocardial trajectory could not be found, presumably because of fibrosis from prior surgery.

The secondary endpoint of procedural success was met in 16/19 subjects, adding that in addition to the two patients who did not meet the primary endpoint, the device fractured in one subject between hospital discharge and 30 days. In this patient, there were no complications related to device fracture other than loss of efficacy.

There were no procedural deaths, strokes or transient ischemic attacks (TIAs), or other major cardiovascular adverse events. Three post-procedure deaths occurred on day 79, 159, and 756, respectively, said Dr. Rogers, noting that these were all unrelated to cerclage. Six patients had heart block, of whom 2 had pre-existing pacemakers, and 4 were subsequently implanted with new pacemakers. The procedure resulted in a sustained reduction in MR volume (−41%) and effective orifice area (−33%) after a median 337 days. There was also an improvement in New York Heart Association functional class over time. Furthermore, cerclage resulted in improvements in 6-minute walking test distance (+78 m) and Kansas City Cardiomyopathy Questionnaire (KCCQ-23) with overall summary score of +22 at 30 days, and the team also noted that these improvements were maintained after a median 265 days' follow-up. The follow-up CT showed that cerclage appeared to arrest left atrial and ventricular dilatation.

Dr. Rogers concluded that TMCV was safe, with high technical and procedural success.

3.3. Real-world outcomes with Watchman FLX: Early results from SURPASS

Presenter: Samir Kapadia, MD

Key Points: *The latest registry analysis of the real-world observational WATCHMAN FLX Device SURveillance Post Approval AnalySiS Plan (SURPASS) study found that left atrial appendage (LAA) closure with the device was associated with low 45-day adverse event rates and peri-device leaks.*

The findings were reported by Samir R. Kapadia, MD, of the Cleveland Clinic [10]. SURPASS acquired data from the U.S. National Cardiovascular Data Registry (NCDR) Left Atrial Appendage Occlusion (LAAO) Registry and includes consecutive patients who had a WATCHMAN FLX (Boston Scientific) implant attempt between September 2020 and March 2021. Increased thromboembolic stroke risk and history of major bleeding were the main indications for LAAO. Registry data will be collected through 2 years post-implant via the LAAO Registry, the researchers noted in a study abstract, with a plan for longer-term follow-up via linkage to claims data from the Centers for Medicare and Medicaid Services (CMS).

The registry had enrolled 16,646 patients as of March 2021, 14,363 of whom had 45 ± 14 days follow-up. The patients had a mean age of 76 ± 8 years at enrollment, 40.3% were female, and 94.2% were White. The mean procedure time, counted from when the patient entered the procedure location until the time when the operator broke scrub at the end of the procedure, was 81 ± 42 min, and the mean number of WATCHMAN FLX Left Atrial Appendage Closure devices used was 1.2 ± 0.4 per procedure. The patients' mean CHA_2DS_2-VASc score was 4.8 ± 1.51, and the mean HAS-BLED score was 2.4 ± 1.01. SURPASS safety endpoints were a composite of all-cause death, ischemic stroke, systemic embolism, or device-/procedure-related events requiring open cardiac surgery or major endovascular intervention between device implantation and 7 days or hospital discharge (whichever is later). The key efficacy endpoint was occurrence of ischemic stroke or systemic embolism at 24 months post-implant.

Successful implantation (defined as device released and deployed) occurred in 98% of patients. Of the 16,048 patients, 0.37% (60 patients, of whom 21 died, 19 had ischemic stroke, and 20 had events requiring intervention) hit the key safety endpoint (95% CI: 0.29% to 0.48%). Key clinical events at discharge included 11 deaths (0.07%), 15 cases of

stroke (0.09%), 157 cases of major bleeding (0.98%), 19 incidents of major vascular complications (0.12%), eight patients with device-related thrombus (0.05%), and two with device embolization (0.01%).

At 45 days, 508 had major bleeding (3.55%), 125 patients had died (0.91%), 54 had suffered stroke (0.38%), one had systemic embolism (0.01%), 30 had device-related thrombus (0.23%), and five had device-related embolization (0.03%). At 45 days, peri-device leak >5 mm was present in 0.4% of subjects and 82% had no leaks. The pericardial effusion rates requiring surgical or percutaneous intervention were 0.32% and 0.51% at discharge and 45 days, respectively. The results were similar to those of the real-world PINNACLE FLX study for the same device [11].

Dr. Kapadia concluded that LAAO with WATCHMAN FLX was associated with a low incidence of adverse events and peri-device leak at 45 days.

3.4. Transcaval versus transaxillary TAVR in contemporary practice: A propensity-weighted analysis

Presenter: Robert J. Lederman, MD

Key Points: *Among experienced TAVR operators, contemporary transcaval access resulted in a lower risk of stroke, similar vascular complications, and similar or lower bleeding complications in comparison with transaxillary access, although both of these alternative approaches showed increased complications compared to transfemoral access, according to an analysis of the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry.*

Robert J. Lederman, MD, of the National Heart, Lung and Blood Institute, presented data from eight experienced centers that contributed data to the TVT Registry between 2017 and 2020 [12]. The results were later published in *JACC: Cardiovascular Interventions* [13].

Non-femoral TAVR access confers a high risk of mortality and complications. Transaxillary access has been widely adopted as an alternative access, and transcaval access has a reputation for complications since its original 2017 Investigational Device Exemption trial. The new analysis sought to determine whether transcaval complications are any worse than transaxillary complications and whether the stroke rate is comparable between the two approaches. Transcaval access was used in 238 TAVR patients and transaxillary in 106, and these results were compared to those from 7132 who underwent transfemoral TAVR. Most baseline characteristics were similar between patients undergoing transaxillary and transcaval access, but there were a few differences. Specifically, transcaval patients were more likely to be female (56.3% vs. 43.4%), minority (20.9% vs. 9.1%), have private insurance (56.3% vs. 42.0%) and have moderate to severe chronic lung disease (40.3% vs. 34.0%). Procedural characteristics showed several differences. In the transcaval arm, moderate sedation was used more often (45.4% vs. 14.2%), fluoroscopy time was longer (33.60 min vs. 24.90 min), contrast volume was higher (130.5 ml vs 101.3 ml), and all transcaval procedures were fully percutaneous as compared to 84% of transaxillary procedures.

In-hospital stroke or TIA was less common after transcaval compared to transaxillary (2.5% vs. 13.2%), and the same was true at 30 days (2.9% vs. 13.2%). Major or life-threatening bleeding was comparable between the two (10.1% vs. 13.2%). All of these rates were higher with the alternative access compared with the transfemoral approach (stroke/TIA in-hospital 1.7% and 2.1% at 30 days). Similarly, major or life-threatening bleeding was lower in the transfemoral cohort, 3.5% at 30 days, compared to the other two cohorts. The average length of stay (LOS) was slightly better in the transcaval group (5.6 days vs 6.4 days) compared to the transaxillary group. Discharge directly home without TIA or stroke was far more common in the transcaval arm (87.8% vs 62.3%).

To account for baseline changes, inverse-propensity weighting (doubly robust) analysis was performed, and the results with regard to in-hospital and 30-day stroke, direct discharge to home, and discharge to home without stroke and hemoglobin drop favored the transcaval group.

Dr. Lederman said the analysis shows that compared with transaxillary access, transcaval access resulted in lower stroke rate (similar to that of transfemoral access), comparable or lower bleeding, comparable vascular complications, more discharge to home without stroke, and fewer complications than in previously reported studies.

He concluded that given superior neurovascular outcomes and ergonomics for the operator, transcaval access appears to be an attractive, first-choice non-femoral access route for TAVR.

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Declaration of competing interest

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References

[1] Garcia-Garcia HM. Hands Free Artificial Intelligence Based Angiographic Derived Fractional Flow Reserve Assessment. February 27, 2022. Available at: https://www.crtonline.org/presentation-detail/hands-free-artificial-intelligence-based-angiograp.

[2] Byrne RA. Randomized Trial of COBRA PzF Stenting to REDUCE Duration of Triple Therapy (COBRA-REDUCE). February 27, 2022. Available at: https://www.crtonline.org/presentation-detail/randomized-trial-of-cobra-pzf-stenting-to-reduce-d-2.

[3] Colleran R, Joner M, Cutlip D, Urban P, Maeng M, Jauhar R, et al. Design and rationale of a randomized trial of COBRA PzF stenting to REDUCE duration of triple therapy (COBRA-REDUCE). Cardiovasc Revasc Med. 2022;34:17–24.

[4] Kandzari DE. Ultrathin Bioresorbable Polymer Sirolimus-Eluting Stents versus Thin Durable Polymer Everolimus-Eluting Stents for Coronary Revascularization: Final 5-year Outcomes from the Randomized BIOFLOW V Trial. February 27, 2022. Available at: https://www.crtonline.org/presentation-detail/bioflow-v-trial.

[5] Kandzari DE, Mauri L, Koolen JJ, Massaro JM, Doros G, Garcia-Garcia HM, et al. Ultra-thin, bioresorbable polymer sirolimus-eluting stents versus thin, durable polymer everolimus-eluting stents in patients undergoing coronary revascularisation (BIOFLOW V): a randomised trial. Lancet. 2017;390:1843–52.

[6] Collet C. UZ CLEAR Study: Redefining the Diagnostic Performance of non-invasive Stress Tests for the Detection of Coronary Artery Disease. February 27, 2022. Available at: https://www.crtonline.org/presentation-detail/uz-clear-study.

[7] Waksman R. Transcatheter Aortic Valve Replacement in Low-Risk Patients with Symptomatic Severe Aortic Stenosis: 4 – Years Results from the LRT Trial. March 1, 2022. Available at: https://www.crtonline.org/presentation-detail/4-years-results-from-lrt-trial.

[8] Waksman R, Rogers T, Torguson R, Gordon P, Ehsan A, Wilson SR, et al. Transcatheter aortic valve replacement in low-risk patients with symptomatic severe aortic stenosis. J Am Coll Cardiol. 2018;72:2095–105.

[9] Rogers T. Transcatheter mitral cerclage ventriculoplasty: results from the first-in-man early feasibility trial. March 1, 2022. Available at: https://www.crtonline.org/presentation-detail/transcatheter-mitral-cerclage-ventriculoplasty-res.

[10] Kapadia SR. Real-world outcomes with WATCHMAN FLX: early results from SURPASS. March 1, 2022. Available at: https://www.crtonline.org/presentation-detail/real-world-outcomes-with-watchman-flx-early-result.

[11] Kar S, Doshi SK, Sadhu A, Horton R, Osorio J, Ellis C, et al. Primary outcome evaluation of a next-generation left atrial appendage closure device: results from the PINNACLE FLX trial. Circulation. 2021;143:1754–62.

[12] Lederman RJ. Transcaval versus transaxillary TAVR in contemporary practice: a propensity weighted analysis. March 1, 2022. Available at: https://www.crtonline.org/presentation-detail/transcaval-versus-transaxillary-tavr-in-contempora.

[13] Lederman RJ, Babaliaros VC, Lisko JC, Rogers T, Mahoney P, Foerst JR, et al. Transcaval versus transaxillary TAVR in contemporary practice. JACC Cardiovasc Interv. 2022;15:965–75.