11-1-2021

TCT-414 Safety and Efficacy of Dedicated Guidewire, Microcatheter, and Guide Catheter Extension Technologies for Chronic Total Coronary Occlusion Revascularization: Primary Results of the Teleflex Chronic Total Occlusion Study

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Recommended Citation

Kandzari D, Alaswad K, Jaffer FA, Brilakis E, Croce K, Kearney K, Spaedy A, Yeh R, Thompson C, Nicholson W, Wyman RM, Riley R, Lansky A, and Karmpaliotis D. TCT-414 Safety and Efficacy of Dedicated Guidewire, Microcatheter, and Guide Catheter Extension Technologies for Chronic Total Coronary Occlusion Revascularization: Primary Results of the Teleflex Chronic Total Occlusion Study. J Am Coll Cardiol 2021; 78(19):B169-B170.

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implications of the HFA-PEFF score in patients with preserved ejection fractions after TAVR.

METHODS This was a single-center study at the University Hospital Schleswig-Holstein, Campus Kiel, which is a tertiary center in Germany. A total of 570 consecutive TAVR patients with preserved ejection fractions (≥50%) were eligible for analysis. The HFA-PEFF score was calculated according to the 3 following domains: 1) functional; 2) morphologic; and 3) biomarkers. Patients with HFA-PEFF scores ≥ 5 (n = 239 [41.9%]) were compared with those with scores < 5 points (n = 331 [58.1%]). The primary outcome was a composite of all-cause mortality or first heart failure rehospitalization within 1 year after TAVR. Secondary endpoints were the individual components of the primary outcome.

RESULTS TAVR patients with HFA-PEFF scores ≥ 5 had a significantly higher burden of comorbidities associated with HFpEF and a higher rate of new pacemaker implantation after TAVR. Patients with HFA-PEFF scores ≥ 5 were at increased risk for the primary composite endpoint (25.5% vs 10.0%; $P < 0.001$), as well as the individual components of all-cause mortality (16.7% vs 6.0%; $P < 0.001$) and rehospitalization for heart failure (11.7% vs 3.9%; $P < 0.001$). After multivariable analysis, an HFA-PEFF score ≥ 5 was confirmed as an independent risk factor for the composite endpoint (hazard ratio [HR]: 2.70; 95% confidence interval [CI]: 1.70-4.28; $P < 0.001$) and for all-cause mortality (HR: 2.58; 95% CI: 1.464.53; $P = 0.001$).

CONCLUSION The HFA-PEFF score is associated with all-cause mortality and heart failure rehospitalization in patients with preserved ejection fractions after TAVR. The HFA-PEFF score is a practical tool that may be implemented into risk stratification algorithms for TAVR patients.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-412

Use of Intravascular Lithotripsy in a Population With a High Prevalence of Renal Disease and Diabetes: Insights From Real-World Data

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BACKGROUND Rapid adoption of intravascular lithotripsy (IVL) into calcium modification algorithms follows trials that demonstrate its efficacy in reduction of stent underexpansion and malposition. Some debate about the translatability of IVL performance in trials versus complex real-life patients exists. We present data from a high-volume PCI center encompassing a patient cohort with a high prevalence of renal disease and diabetes.

METHODS We retrospectively analyzed 102 consecutive IVL from a single PCI center. Intracoronary imaging was performed to assess calcium arc and minimal luminal and stent areas. Specialized adjuncts were used in target lesion preparation. We assessed stent expansion > 80% of reference diameter and safety endpoints (30-day major adverse cardiovascular events [MACE; myocardial infarction, stroke, or cardiovascular mortality] and periprocedural events [adverse events relating to and occurring within 24 hours of the index procedure]).

RESULTS One hundred two patients with a mean age of 70.1 years were included, with a preponderance of diabetes (57%) and renal disease (25%). Forty-eight percent presented with acute coronary syndromes. The target IVL lesion was the left main coronary artery in 11%, left anterior descending coronary artery in 32%, and right coronary artery in 24, while de novo lesions constituted 66%, chronic total occlusions 8%, and in-stent restenoses 26%. Overall, intravascular imaging was used in 89%: intravascular ultrasound (IVUS) (before and after percutaneous coronary intervention [PCI]) in 52%, IVUS (pre-PCI only) in 9%, and optical coherence tomography in 29%. Circumferential calcification was present in 27%, with an arch > 180° in others. There was good deliverability of IVL in 95%. Additional calcium modification adjuncts (noncompliant 100%, cutting 11%, OPN 10%, cutting 12%, and rotablation 7%) were necessary. Mean minimal luminal area was 3.1 mm^2, with >80% stent expansion achieved in all patients. The rate of periprocedural complications was 7% (2 slow-flow, 5 perforations). Two perforations occurred following OPN balloon use post-IVL, with no long-term morbidity. The 30-day MACE rate was 4% (no cardiovascular death was reported).

CONCLUSION This study confirms that "real-world" performance of IVL is representative of trial data. However, the increasing complexity of these patients meant that greater adjunctive calcium modification therapy was necessary. Complication rates were higher but comparable with the DISRUPT CAD III trial.

CATEGORIES CORONARY: Cutting and Scoring Balloons

TCT-413

Outcomes of Adults With Severe Aortic Stenosis Undergoing Elective Versus Urgent or Emergent Transcatheter Aortic Valve Replacement Within an Integrated Health Care Delivery System

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BACKGROUND Transcatheter aortic valve replacement (TAVR) may be used to treat severe aortic stenosis in urgent or emergent clinical scenarios, but outcomes for this population have not been well characterized.

METHODS We identified all adults who underwent TAVR for primary aortic stenosis between 2013 and 2019 within an integrated health care delivery system in California. Elective and urgent or emergent procedure status was based on standard definitions. Data were obtained from electronic health records, the Society of Thoracic Surgeons/American College of Cardiology TVT Registry, and state and national reporting databases. Logistic regression and Cox proportional hazard models were performed using backward selection.

RESULTS Among 1,564 eligible adults who underwent TAVR, 1,483 (94.8%) were classified as elective and 81 (5.2%) as urgent or emergent. Patients undergoing urgent or emergent versus elective TAVR were more likely to have prior aortic valve procedures (15% vs 6%), heart failure (63% vs 47%), and reduced left ventricular ejection fractions (21% vs 12%). These patients also experienced higher crude rates of 30-day and 1-year morbidity and mortality (Table 1). In multivariable analyses, urgent or emergent TAVR status was independently associated with no improvement in 30-day quality of life and a higher rate of acute kidney injury at 1 year. There was a trend toward increased adjusted 1-year mortality with urgent/emergent TAVR.

	Overall (N = 1,564) Rate per 100 Person-Years (95% CI)	Elective (n = 1,483) Rate per 100 Person-Years (95% CI)	Urgent/Emergent (n = 81) Rate per 100 Person-Years (95% CI)	Urgent/Emergent vs Elective (Reference) HR (95% CI)	*P* Value
Death, 30 d	0.8 (0.5-1.1)	0.7 (0.5-1.1)	2.3 (0.7-7.1)	2.02 (0.37-11.19)	0.42
Death, 1 y	3.9 (3.3-4.5)	3.6 (3.1-4.3)	10.7 (6.3-18.0)	1.85 (0.93-3.71)	0.08
All-cause hospitalization, 30 d	77.5 (63.6-94.3)	78.4 (64.1-95.8)	60.9 (22.9-162.3)	0.77 (0.27-2.21)	0.63
All-cause hospitalization, 1 y	44.9 (41.3-48.9)	44.9 (41.2-49.0)	45.3 (31.1-66.1)	0.82 (0.53-1.28)	0.38
HF hospitalization, 30 d	15.4 (9.9-23.8)	16.2 (10.4-25.1)	0.0 (0.0-0.0)	No events	—
HF hospitalization, 1 y	6.5 (5.3-8.0)	6.7 (5.5-8.3)	2.9 (0.7-11.5)	0.29 (0.07-1.31)	0.11
AKI, 30 d	18.5 (12.4-27.5)	18.6 (12.4-28.0)	15.1 (2.1-107.0)	0.46 (0.05-4.14)	0.48
AKI, 1 y	13.6 (11.7-15.6)	13.0 (11.2-15.1)	24.7 (15.1-40.3)	2.11 (1.18-3.77)	0.01
No improvement in QoL, 30 days	8.4% (6.7%-10.1%)	8.1% (6.4%-9.7%)	16.7% (5.4%-27.9%)	4.87 (1.56-15.23)	<0.01

CONCLUSION In a community-based cohort of adults undergoing TAVR, urgent or emergent status was uncommon and associated with high-risk clinical features and higher crude rates of short- and long-term morbidity and mortality. Procedure status may be useful to identify patients unlikely to experience significant improvement in quality of life post-TAVR.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-414

Safety and Efficacy of Dedicated Guidewire, Microcatheter, and Guide Catheter Extension Technologies for Chronic Total Coronary Occlusion Revascularization: Primary Results of the Teleflex Chronic Total Occlusion Study

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BACKGROUND Description of procedural outcomes using contemporary techniques that apply specialized coronary guidewires, microcatheters, and guide catheter extensions designed for chronic total occlusion (CTO) percutaneous revascularization is limited.

METHODS A prospective, multicenter, single-arm trial was conducted to evaluate procedural and in-hospital outcomes among 150 patients undergoing attempted CTO revascularization using specialized guidewires, microcatheters, and guide extensions. The primary endpoint was defined as successful guidewire recanalization and absence of in-hospital cardiac death, myocardial infarction (MI), or repeat target lesion revascularization (major adverse cardiac events [MACE]).

RESULTS The prevalence of diabetes was 32.7%, of prior MI was 48.0%, and of previous bypass surgery was 32.7%. Average (mean ± SD) CTO length was 46.9 ± 20.5 mm, and mean J-CTO score was 1.9 ± 0.9. Combined radial and femoral arterial access was performed in 50.0% of cases. Devices used included guidewire support microcatheters in 100% and guide catheter extensions in 64.0%, and the mean number of CTO-specific guidewires per procedure was 5.11 ± 3.52. Overall, procedural success was observed in 75.3% of patients. The rate of successful guidewire recanalization was 94.7%, and the rate of absence of in-hospital MACE was 80.7%. Methods included antegrade (54.0%), retrograde (1.3%), and combined antegrade and retrograde techniques (44.7%). Total mean procedure time was 149 ± 91 minutes, mean radiation dose was 2,219 ± 1,608 mGy, and mean contrast utilization was 205 ± 95 mL. Clinically significant perforation resulting in hemodynamic instability and/or requiring intervention occurred in 16 patients (10.7%).

CONCLUSION In a multicenter, prospective registration trial, favorable procedural success and early clinical outcomes were achieved in a patient population with high lesion complexity using contemporary techniques and application of dedicated CTO guidewires, microcatheters, and guide catheter extensions.

CATEGORIES CORONARY: Complex and Higher Risk Procedures for Indicated Patients (CHIP)

TCT-415

Predictors of New-Onset Atrial Fibrillation Following Transcatheter Mitral Valve Repair: Insights From the Nationwide Readmissions Database

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BACKGROUND There are limited contemporary data on the predictors of new-onset atrial fibrillation (NOAF) after transcatheter mitral valve repair (TMVr) in the United States.

METHODS Patients who underwent TMVr between 2014 and 2017 were identified from the Nationwide Readmissions Database. Analyses were conducted on patients readmitted within 6 months of TMVr with NOAF.

RESULTS Of 3,124 patients who underwent TMVr, 1,231 (39.4%) had no atrial fibrillation (AF) during the index hospitalization. Of those who did not have AF at index hospitalization, 100 (8.8%) were readmitted with NOAF within 6 months post-TMVr. Independent predictors of NOAF post-TMVr included age (odds ratio [OR]: 1.28; 95% confidence interval [CI]: 1.04-1.58) and fluid and electrolyte disorders (OR: 1.75; 95% CI: 1.03-2.96). Furthermore, for every 1-unit increase in $CHADS_2$ score, odds of NOAF increased (OR: 1.35; 95% CI: 1.12-1.63).

	Odds Ratio (95% CI)
Age (+10 y)	1.28 (1.04-1.58)
Female sex	1.03 (0.67-1.58)
Fluid and electrolyte disorders	1.75 (1.03-2.96)
Hypertension	1.06 (0.69-1.62)
Coronary artery disease	0.91 (0.58-1.42)
Congestive heart failure	1.5 (0.88-2.54)
Tobacco use	0.97 (0.61-1.53)
Obstructive sleep apnea	1.1 (0.49-2.51)
$CHADS_2$ score (+1 score)	1.35 (1.12-1.63)

CONCLUSION In a nationwide cohort of patients who underwent TMVr, nearly 9% were readmitted with NOAF within 6 months after TMVr. NOAF post-TMVr was independently associated with age, fluid and electrolyte disorders, and $CHADS_2$ score.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

TCT-416

Clinical Impact of Tricuspid Regurgitation on Transcatheter Edge-to-Edge Mitral Valve Repair for Secondary Mitral Regurgitation: A Systematic Review and Meta-Analysis

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BACKGROUND Baseline tricuspid regurgitation (TR) is common among patients undergoing transcatheter edge-to-edge repair (TEER) for secondary mitral regurgitation (MR), although its impact on clinical outcomes is disputed.

METHODS The Cochrane Library, PubMed/MEDLINE, and Google Scholar were searched according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines from January 1, 2011, through January 31, 2021. Randomized controlled trials and nonrandomized prospective studies that evaluated baseline TR by echocardiography before TEER of secondary MR were included. The primary outcomes were a composite of mortality and heart failure hospitalization (HFH) at 30 days.

RESULTS A total of 5 studies (n = 1,430 patients) were included for analysis. Concurrent moderate or severe TR was associated with greater mortality and HFH at 30 days (odds ratio: 1.60; 95% confidence interval: 1.12-2.29; $P = 0.009$) after TEER for severe MR.

CONCLUSION Baseline moderate to severe TR was associated with increased 30-day mortality and HFH among patients undergoing TEER.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

TCT-417

Outcomes of Successful Versus Failed Contemporary Chronic Total Occlusion Percutaneous Coronary Intervention

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BACKGROUND There are limited contemporary data on the impact of success versus failure on the outcomes of chronic total occlusion (CTO) percutaneous coronary intervention (PCI).

METHODS We conducted a systematic review and a meta-analysis of contemporary studies that compared the outcomes in patients who underwent successful versus failed contemporary (2010 onward) CTO PCI. We performed a sensitivity analysis limited to studies that started enrollment after the publication of the hybrid algorithm in 2012.

RESULTS We included 5 studies with a total of 6,084 patients (successful CTO PCI, n = 4,861; failed CTO PCI, n = 1,223). During a median