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1. Introduction

Since 1989, the Paris Course of Revascularisation (PCR) has shared expertise and experience in cardiovascular medicine with healthcare professionals around the world. In 2020, EuroPCR was canceled because of the COVID-19 pandemic. In its place, the PCR e-Course was held to offer the latest cardiovascular science and an opportunity for interventional cardiologists to interact with, and learn from, experts and peers around the world.

2. Coronary

2.1. DynamX Bioadaptor, a novel “uncaging” platform

Presenter: Dr. Stefan Verheye.

Key Points: The novel DynamX stent showed positive remodeling in implanted coronary arteries at 1 year in a small, nonrandomized study. This trial included 50 consecutive patients with single de novo coronary artery lesions with reference vessel diameter of 2.5 to 3.5 mm and lesion length of ≤24 mm at seven international sites [1]. Each patient underwent percutaneous coronary intervention (PCI) with the DynamX Novolimus-Eluting Coronary Bioadaptor System. The DynamX stent is 71 μm thick with a cobalt-chromium platform. While current-generation drug-eluting stents (DES) “cage” the coronary artery, causing geometric distortion and inhibiting positive adaptive remodeling and vasomotion, the DynamX stent has a novel “uncaging” mechanism of the circumferential rings after 6 months while maintaining the axial links following uncaging.

The primary safety endpoint was target lesion failure (TLF) at 6 months. TLF is a composite endpoint defined as cardiac death, target vessel myocardial infarction (TVMI), and clinically indicated target lesion revascularization (TLR). The primary imaging/efficacy endpoints for those patients undergoing imaging follow-up was the change in mean in-device area and mean lumen area at 9 or 12 months compared to post-procedure as measured by intravascular ultrasound (IVUS). The co-primary imaging/efficacy endpoint for those patients undergoing imaging follow-up was late lumen loss as measured by quantitative coronary angiography and IVUS at 9 or 12 months.

The results by Stefan Verheye, MD, PhD, of ZNA Middleheim Antwerp Cardiovascular Center, Belgium, and co-investigators demonstrated no TLF through 6 months and two patients (4%) experiencing TLF (both died of cardiac causes) through 12 months. Verheye noted that there was no TLR through 1 year. Patients who underwent IVUS also showed positive adaptive remodeling to maintain lumen area (post-procedure, 7.39 mm²; at 9 and 12 months, 7.36 mm²; with 0% change from post-procedure, p = 0.594). There were changes in mean...
vessel area (post-procedure, 14.10 mm²; at 9 and 12 months, 14.54 mm²; with 3% change from post-procedure, p = 0.017) and mean bioadaptor area (post-procedure 7.39 mm²; at 9 and 12 months, 7.74 mm²; with 5% change from post-procedure, p = 0.0005).

The increases in vessel and device area allow the vessel to maintain the lumen diameter and preserve good blood flow over time. This is important because DES have high major adverse cardiac event (MACE) rates beyond 1-year, at a rate of 2% to 3% without platelet.

Verheye concluded that the DynamX stent demonstrated excellent safety through 12-month follow-up and excellent efficacy. The stent’s innovative design allows the DynamX Novolimus-Eluting Coronary Bioadaptor stent to match current DES in acute performance while showing promise of lowering the annualized event rates beyond the first year post-implantation.

The study was sponsored by Elixir Medical Corp.

2.2. Two-stent vs. provisional for bifurcation PCI: The DEFINITION II Trial

Presenter: Dr. Shao-Liang Chen.

Key Points: A randomized study demonstrates that a two-stent strategy is associated with a significant improvement in clinical outcomes at 1 year in comparison with provisional stenting for patients with complex coronary bifurcation lesions (CBLs).

These findings were presented by Shao-Liang Chen, MD, PhD, of Nanjing First Hospital, Nanjing Medical University, China, on behalf of the Definitions and Impact of Complex Bifurcation Lesions on Clinical Outcomes After Percutaneous Coronary Intervention Using Drug-Eluting Stents (DEFINITION II) trial investigators [2]. Stenting of CBLs is associated with suboptimal clinical results compared to non-CBLs. The European Society of Cardiology (ESC) 2018 guidelines state that a two-stent strategy may be preferable for complex CBLs; however, there is no universal definition of CBL complexity. The goal of this study was to assess the benefits of two-stent techniques for patients with DEFINITION criteria-defined complex CBLs.

A total of 653 patients with CBLs at 49 international centers were randomly assigned to undergo either a two-stent technique (two-stent group n = 328) or provisional stenting (provisional group n = 325). The primary endpoint was the composite of TLF at 1-year follow-up, including cardiac death, TVMI, and clinically driven TLR. The safety endpoint was definite or probable stent thrombosis (ST).

At 1-year follow-up, TLF occurred in 37 (11.4%) and 20 (6.1%) patients in the provisional and two-stent groups, respectively (77.8% double kissing [DK] crush, hazard ratio [HR], 0.52; 95% confidence interval [CI], 0.30–0.90; p = 0.019), largely driven by increased TVMI (7.1%; HR, 0.44; 95% CI, 0.20–0.90; p = 0.025) and clinically driven TLR (5.5%; HR, 0.43; 95% CI, 0.19–1.00; p = 0.049) in the provisional group. At 1 year after indexed procedures, the incidence of cardiac death was 2.5% in the provisional group, which was non-significantly different from 2.1% in the two-stent group (HR, 0.86; 95% CI, 0.31–2.37; p = 0.772). ST was comparable between the two groups.

The investigators concluded that for DEFINITION criteria-defined complex CBLs, the systematic two-stent approach was associated with a significant improvement in clinical outcomes with the provisional stenting approach. Further study is urgently warranted to identify the mechanisms contributing to the increased rate of TVMI after provisional stenting.

The study was sponsored by Nanjing First Hospital, Nanjing Medical University.

2.3. Two-year safety of revascularization deferral based on iFR or FFR

Presenter: Dr. Javier Escaned.

Key Points: Deferring revascularization based on either fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) is equally safe, according to a pooled patient-level analysis.

Javier Escaned MD, PhD, of Hospital Clínico San Carlos, Madrid, Spain, presented the results on behalf of the investigators [3]. In light of the ISCHEMIA trial, which showed no difference between optimal medical therapy alone and revascularization plus medical therapy in patients with stable ischemic heart disease, revascularization deferral with medical treatment has become an important strategy. The investigators pooled the results of the iFR: DEFINE FLAIR (n = 2467 patients) and iFR SWEDEHEART (n = 2019 patients) randomized clinical trials to examine two key questions: 1) to investigate whether 2-year outcomes of deferred revascularization are similar when the decision is based on FFR or iFR, and 2) to investigate the relationship between patient age, deferral of revascularization based on FFR and iFR, and clinical outcomes.

The study showed that iFR resulted in more patients having revascularization deferral (iFR 50% vs. FFR 45%, p < 0.01). However, the risk of death, non-fatal myocardial infarction (MI), and unplanned revascularization over 2 years was no different in the FFR or iFR group (iFR 7.43% vs. FFR 7.4%, p = 0.94). Individual components of death, non-fatal MI, and unplanned revascularization were also comparable between the groups. The study also demonstrated that FFR led to more revascularization procedures, particularly in patients younger than 60 years of age; these younger patients had 12% more revascularizations when FFR was used.

The study suggests similar safety of iFR and FFR in deferring revascularization in the midterm and reveals a strong interaction between age and FFR-based deferral, potentially secondary to a varying age-related hyperemic response to adenosine.

The DEFINE FLAIR and IFR SWEDEHEART studies were funded through unrestricted grants from Philips-Volcano.

2.4. CABG and PCI in patients with CTO and multivessel disease

Presenter: Dr. Bo Xu.

Key Points: In the largest retrospective study of patients with multivessel disease (MVD) and chronic total occlusions (CTOs), coronary artery bypass grafting (CABG) and PCI resulted in acceptable 30-day and 5-year survival.

CTOs in the presence of MVD often lead to incomplete revascularization. There is a lack of clinical evidence in the form of randomized trials or large registries to support this practice over PCI. The purpose of this study was to examine 5-year outcomes of patients undergoing CABG versus PCI for the treatment of MVD with CTOs in a large cohort. Bo Xu, M.B.B.S., of Fu Wai Hospital, CAMS & PUMC National Center for Cardiovascular Disease, China, and co-investigators reviewed data on 16,162 patients in China with at least one CTO (defined as 100% occlusion with Thrombolysis in Myocardial Infarction 0 flow for at least 3 months) on coronary angiography between 2010 and 2013 [4]. They identified 4324 patients who underwent PCI or CABG, of whom they followed 3975 at 1 month, 6 months, 1 year, and annually through 5 years. The investigators’ primary outcome of interest was a composite of death, MI, and stroke. Their secondary outcomes of interest were 30-day clinical events, individual components of the primary composite outcome, cardiac death, repeat revascularization, and symptomatic graft occlusion or ST.

Baseline clinical characteristics differed greatly between both groups, with patients undergoing CABG being older (60.9 vs. 57.5 years; p < 0.0001), more likely to use tobacco (57.9% vs. 41.5%; p < 0.0001), more likely to have comorbidities, more likely to have renal insufficiency (13.0% vs. 7.9%; p < 0.0001), more likely to have higher SYNTAX scores (p < 0.0001) and more likely to have higher J-CTO scores (p < 0.0001) than patients undergoing PCI. The primary composite outcome occurred more frequently in patients undergoing CABG compared to PCI at 30 days (2.3% vs. 1.8%; p = 0.003) and at 5 years (12.1% vs. 11.4%; p = 0.002). Within this composite, patients undergoing CABG had less MI at 30 days (0.9% vs. 1.6%; p = 0.0001) and 5 years (1.5% vs. 6.5%; p < 0.0001) but more stroke at 30 days (0.8%
also resulted in increased procedural MI (RR, 2.48; 95% CI, 1.86–3.13), and did not reduce the risk of death (RR, 0.99; 95% CI, 0.90–1.09) or overall MI (RR, 0.93; 95% CI, 0.83–1.03) in comparison with medical therapy alone. These results were similar with a sensitivity analysis.

The authors noted some limitations of the meta-analysis. They said their study did not account for the type of stent, the dosage of medications, patient compliance with the medication regimen, and differences in trial designs and patient population. The authors recommended longer-term follow-up of trials to evaluate whether the reduction in non-fatal spontaneous events improves survival.

3. Endovascular

3.1. Crossover results from the RADIANCE-HTN SOLO trial

Presenter: Dr. Ajay Kirtane.

Key Points: Patients in the RADIANCE-HTN SOLO trial who crossed over from the sham-control arm and were treated with ultrasound-based renal denervation saw a similar lowering of blood pressure to patients who were assigned to the renal denervation arm, according to a post hoc analysis of the trial.

Hypertension is the leading cause of disease burden worldwide. Its control is a continuous problem, with rates reaching a plateau. One major contributing factor is drug adherence. Renal denervation is an endovascular therapy that does not require adherence and can be used along with medical therapy to gain hypertension control. The Paradise Renal Denervation System (ReCor Medical Inc.) delivers ultrasound energy (sound waves) via a catheter to the tissue surrounding the renal artery for several seconds. This energy generates heat to decrease the overactivity of the nerves leading to the kidney.

This system was shown to lower blood pressure in comparison with a sham control in patients with hypertension in the RADIANCE-HTN SOLO study, a multicenter, randomized controlled trial [7]. Ajay J. Kirtane, MD, SM, of Columbia University Irving Medical Center/New York Presbyterian Hospital, presented an analysis of data from patients who had crossed over from the sham-control arm to the renal denervation arm after having persistently high blood pressure after 12 months of follow-up.

The analysis demonstrated that of the 72 patients in the original sham-control group, 31 had crossed over to undergo renal denervation after 12 months of uncontrolled blood pressure. These crossover patients had a mean age of 54 years, 39% were women, 77% were white, 13% were Black, they had an average body mass index of 28.1 kg/m², and an estimated glomerular filtration rate of 80 mL/min/1.73 m². At time of crossover, they had a mean blood pressure of 145/90 mmHg and were on an average of 1.2 antihypertensive medications.

All of these patients had successful denervation, with no adverse events. Their post-denervation daytime ambulatory systolic blood pressure decreased by 11.2 mmHg at 2 months and by 12.2 mmHg at 6 months. The percentage of patients who saw their daytime ambulatory systolic blood pressure drop by at least 5 mmHg – without increasing medications – was 71% at 2 months and 68% at 6 months.

Although crossover subjects and physicians were unblinded, making them possibly biased as far as both medication or behavioral effects, or both, the results of the new analysis remained similar to those found in the original study.

The RADIANCE-HTN SOLO trial was sponsored by ReCor Medical Inc.

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Declaration of competing interest

Ron Waksman – Advisory Board: Amgen, Boston Scientific, Cardioset, Cardiovascular Systems Inc., Medtronic, Philips, Pi-Cardia Ltd.; Consultant: Amgen, Biotronik, Boston Scientific, Cardioset, Cardiovascular Systems Inc., Medtronic, Philips, Pi-Cardia Ltd.; Grant Support: AstraZeneca, Biotronik, Boston Scientific, Chiesi; Speakers Bureau: AstraZeneca, Chiesi; Investor: MedAlliance.

All other authors – None.
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