

EuroPCR 2011: Highlights from "La Ville Lumière"

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Pak Hei Chan, MD, Nicola Viceconte, MD, Carlo Di Mario, MD, PhD, FESC, FACC

Cardiovascular Biomedical Research Unit, Royal Brompton Hospital and Harefield Trust, London, UK



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The purple flashing lights on the gigantic stage of the 3000-seat main arena were switched off after a closing ceremony during which awards for the winners of the EuroPCR 2011 competitions (including best technical innovation, best abstract, best case report, and most educational complication) and the 2011 European Association of Percutaneous Coronary Interventions (PCIs) Research and Training Fellowships were presented. What is left after this large 4-day congress with 12 567 attendees? It is difficult to summarize, in a limited number of pages, a program that covers coronary, peripheral, and structural interventions with many different specialists involved. The variety of symposia, talks, live demonstrations, oral abstract presentations of well-designed studies, and case presentations meant that one had to spend some time choosing where to be each morning. Undoubtedly, attendees had the feeling that regardless of what sessions they attended, they would bring home new ideas to share and discuss.

Renal denervation

Having been awarded the EuroPCR innovation award last year, renal sympathetic nerve denervation had already become the highlight of EuroPCR 2011's opening session in the main arena. Horst Sievert (CardioVascular [CV] Center, Frankfurt, Germany) performed a live case in Frankfurt showing a step-by-step account of this new procedure. Thomas Lüscher (University Hospital Zurich, Zurich, Switzerland) suggested that young patients with hypertension, in whom the sympathetic tone is high, are the most suitable patients for this procedure. Long-term data from the non-randomized Symplicity[®] HTN-1 [Renal Denervation in Patients with Refractory Hypertension-1]

pilot study (n=153) showed a sustained blood pressure (BP) reduction of 23/11 mmHg at 12 months and 32/14 mmHg at 2 years in patients with resistant hypertension who underwent renal denervation, with no late adverse events such as renal artery stenosis or aneurysm [1]. After a promising result from Symplicity HTN-2 was presented – a 6-month BP reduction of 32/12 mmHg in the renal denervation group versus no change in the control group [2] – there was discussion on whether the use of renal denervation could be expanded to treat patients with less severe hypertension or other conditions such as congestive cardiac failure. Patrick Serruys (Erasmus University, Rotterdam, The Netherlands) highlighted that larger trials providing outcome data to show that this treatment can lead to improvements in hard CV endpoints are required.

TAVI

How should we deal with co-existing coronary artery disease (CAD) in patients undergoing transcatheter aortic valve implantation (TAVI)? Significant symptomatic CAD often involves the left main stem and affects up to 60% of patients undergoing TAVI. Data from the Italian CoreValve registry on 662 patients undergoing TAVI, 54% of whom had significant CAD, showed similar 1-year rates of mortality, major adverse CV events (MACEs), and angina symptoms between the CAD and non-CAD groups [3]. Single-center series showed a great discrepancy in treatment. In some series, severe coronary artery disease was left untouched unless the Heart Team (comprising surgeons and interventional cardiologists) determined an intervention to be critical, in some it was treated with bare-metal stents, and in others drug-eluting stents were used with dual antiplatelet therapy during the TAVI procedure. In conclusion, in the absence of data from controlled trials and

Address for correspondence: Carlo Di Mario, Department of Cardiology, Royal Brompton Hospital and Harefield Trust, Sydney Street, London, SW3 6NP, UK. Email: c.dimario@rbht.nhs.uk

registries, the implication of significant CAD being present in the setting of TAVI remains unclear.

Moderate aortic insufficiency is a frequent finding after TAV replacement (TAVR). Jan-Malte Sinning (Universitätsklinik Bonn, Bonn, Germany) described a German study of 127 consecutive patients who were treated with TAVR; 21 (16.5%) severe incidences of paravalvular aortic regurgitation (AR) post-procedure occurred, which were associated with significantly higher rates of 30-day and 1-year mortality as well as acute kidney injury [4]. Predictors of paravalvular AR included low baseline left ventricular ejection fraction (LVEF) and inadequate sizing of the annulus of the TAVR device or the device itself. Kensuke Takagi (San Raffaele Hospital, Milan, Italy) stressed that low implantation of the bioprosthesis is a strong predictor of paravalvular AR.

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Olaf Wendler (King’s College Hospital, London, UK) gave an update from the SOURCE (Sapien® Aortic Bioprosthesis European Outcome) registry, tracking >2300 patients who were treated with Edwards Sapien® and Edwards Sapien XT® valves (both Edwards Lifesciences, Delaware, CA, USA); the 1-year survival rate for the entire cohort was 76.5%, increasing to 80.1% among patients in the transfemoral group and decreasing to 74.2% among those in the transapical group, but these data were not comparable because those in the transapical group had a higher EuroSCORE than those in the transfemoral group [5]. Vascular-access-related complication was a significant predictor of 1-year mortality, whereas most deaths at 1 year were non-cardiac related (51.6%) and generally reflected comorbidities of the patients. Stroke rates post-TAVR ranged from 3.8% (among patients in Cohort A of the PARTNER [Placement of Aortic Transcatheter Valve] trial) to up to 3.6% (among those in a multicenter registry) [6].

In small non-randomized trials of the cerebral protection devices Embrella® (Embrella Cardiovascular, Delaware, PA, USA; n=18) and Claret™ (Claret Medical, Santa Rosa, CA, USA; n=36), described by Eberhard Grube (Universitätsklinik Bonn, Bonn, Germany), TAVI performed under cerebral protection was shown to reduce the number of cerebral events documented clinically and by imaging techniques [7]. Various new closure devices and use of cross-over balloon occlusion techniques were presented by Gregg Stone (Columbia University Medical Center, New York, NY, USA) in the same session, highlighting the ongoing effort to reduce major or minor vascular complications according to the Valve Academic Research Consortium definitions.

Left main revascularization

In a well-attended session in the main arena, the topic of revascularization in patients with complex left main stenosis generated an intense discussion among panelists comprising interventional cardiologists and cardiac surgeons. After an obsessive revisitation of slides from the left main component of the SYNTAX (Synergy between PCI with Taxus® and Cardiac Surgery) trial [8], live cases from Kuwait and Poland offered a practical application of the SYNTAX score and other clinical and anatomical characteristics (e.g. age, diabetes, cardiac function, prior coronary artery bypass grafting (CABG) or PCI, left main anatomy, length of lesion, involvement of distal bifurcation, size of left circumflex artery, presence of calcification, and quality of distal run-offs) for determining whether patients should receive surgery or PCI. The panelists concluded that despite the promising results of the SYNTAX left main sub-study, before data from the ongoing EXCEL (Evaluation of Xience Prime® Everolimus-Eluting Coronary Stent System [EECSS] or Xience V® EECSS Versus CABG for Effectiveness of Left Main Revascularization) trial are available, CABG should still be considered as the first choice for most left main patients, particularly those with complex left main disease.

Transradial PCI

According to a retrospective analysis of the Swedish Coronary Angiography and Angioplasty Registry, including >25 374 STEMI cases, transradial PCI was associated with a 22% reduction in mortality rate, a lower rate of bleeding (1% vs. 2.2%; p<0.001), and a shorter hospital stay (4.8 days vs. 5.2 days; p<0.001) compared with the transfemoral approach [9]. However, Jeffrey Moses (Columbia University Medical Center, New York, NY, USA) highlighted that the exclusion of patients who had both radial and femoral punctures may have biased the results in favor of the radial approach. The more frequent application of the radial approach in the study period (2005–2010) saw a concomitant increase in the use of bivalirudin and a declining use of glycoprotein IIb/IIIa inhibitors, which potentially explains the reduced bleeding and mortality rates.

Use of FFR or OCT in PCI guidance

In the session entitled “Glimpse into the future – future treatment decision-making based on intracoronary lesion assessment”, different speakers presented the use of various intracoronary imaging techniques to guide decision-making on whether lesions should be stented or not [10]. Use of fractional flow reserve (FFR) is supported by long-term follow-up data from the FAME (FFR Versus Angiography for Multivessel Evaluation) and DEFER (Deferral of PCI) trials, with FFR-guided intervention demonstrated to have a survival benefit over conventional

angiography-guided intervention. While the use of intravascular ultrasound (IVUS) in daily catheter laboratory work was illustrated by Antonio Columbo (San Raffaele Hospital, Milan, Italy) and Evelyn Regar (Erasmus Medical Center, Rotterdam, The Netherlands), optical coherence tomography (OCT), with a much higher resolution, can be utilized in a similar fashion to IVUS but will give a more accurate assessment of vessel size, stent apposition, and causes of drug-eluting stent (DES) failure. Angiography co-registration with IVUS and OCT appears to provide better information to interventionalists during the stent implantation process and potentially reduces radiation exposure and contrast. Patrick Serruys concluded this informative session by introducing the new concept of non-invasive FFR with computed tomography scanning (FFRCT), which uses FFR to quantify and characterize atherosclerosis in the coronary arteries. FFRCT also featured in another session on the DISCOVER-FLOW (Diagnosis of Ischemia-Causing Stenoses Obtained Via Non-Invasive FFR) study presented by Bon-Kwon Koo (Seoul National University Hospital, Seoul, Korea) [11]. According to this study, the incorporation of computational FFR can increase the specificity and positive-predictive values by 25%, to a range of 80–90%.

Coronary stents

A new meta-analysis with 3-year data, presented by Robert Byrne (The German Heart Centre Munich, Munich, Germany), showed that DES with biodegradable polymers were associated with a lower rate of stent thrombosis (1.2% vs. 2.1%; $p=0.013$) and better clinical outcomes than DES with permanent polymers [12]. Pooled data ($n=2358$) from the ISAR-TEST-3 (Intracoronary Stenting and Angiographic Restenosis – Test Rapamycin-Eluting Stents With Different Polymer Coating to Reduce Restenosis), ISAR-TEST-4 (Intracoronary Stenting and Angiographic Restenosis – Test Three Limus Agent-Eluting Stents with Different Polymer Coating; Yukon[®] Choice Stent [Translumina Therapeutics, Hechingen, Germany]), and LEADERS (Limus Eluted from a Durable Versus Erodable Stent Coating; Biolimus-eluting BioMatrix Flex[®] Stent [Biosensors International, Singapore City, Singapore]) compared with Cypher[®] sirolimus-eluting stents (SES; Cordis Corporation, Miami Lakes, FL, USA; $n=1704$) trials demonstrated that, at 3 years, the composite primary endpoint of cardiac death, MI, and target lesion revascularization (TLR) was lower with the use of biodegradable-polymer stents (18.2% vs. 20.1%; $p=0.04$). The design of comparison studies of DES with biodegradable polymers with newer-generation stents using biostable fluoropolymers in all comers was presented.

Run-Lin Gao (Cardiovascular Institute and Fu Wai Hospital, Beijing, People's Republic of China), awardee of the Ethica, announced the results of NOYA-I [13], a prospective randomized trial of 300 patients treated with the Noya[™] SES (Medfavour Medical, Beijing, People's Republic of China) with

biodegradable polymers or the Firebird-2[®] (MicroPort Shanghai, People's Republic of China), a SES with durable coating. The Noya SES was shown to be non-inferior for in-stent late loss at 9 months (0.11 ± 0.18 mm in Noya vs. 0.14 ± 0.23 mm in Firebird-2). MACE rates at 12 months were similar in both groups (4.7% vs. 4.7%).

Could a bare-metal stent be “non-inferior” to a second generation DES? This is the question everybody was asking before attending this late-breaking clinical trials session. The BASE-ACS (A Randomized Comparison of a Titan-2[®] Bioactive Stent with Xience-V EES Stent in ACS) trial, presented by Pasi Karjalainen (Satakunta Central Hospital, Pori, Finland) showed that the bare-metal Titan-2 bioactive stent (Hexacath, Rueil-Malmaison, France), which is a stent coated with titanium nitride-oxide, had similar MACE rates at 12 months, 9.6% for Titan-2 and 9.0% for Xience [14]. Stent thrombosis rates were low in both groups (0.7% in Titan-2 vs. 2.2% in Xience; $p=0.07$). This trial randomized a total of 827 patients presenting with ACS in a 1:1 ratio with MACE (MI, TLR, and cardiac-related death) at 12 months being the primary endpoint. Results showed that the Titan-2 was a safe stent to be used in ACS patients. William Wijins (Cardiovascular Center Aalst, Aalst, Belgium) highlighted that, given the possible higher rates of repeat revascularization and restenosis rate with bare-metal stents, larger and longer term trials are needed.

Percutaneous assist device

Evidence for the use of these devices is limited and should be tailored to individual cases. The PROTECT-II (Prospective Multicenter Randomized Trial Comparing Impella[®] to IABP in High Risk PCI) trial ($n=426$) presented at the late breaking trial sessions showed that use of Impella (Abiomed, Aachen, Germany; 2.5 L/min) for hemodynamic support during high-risk PCI has a similar safety profile compared with IABP [15]. A significant reduction of 29% in the rate of major adverse events at 90 days in the pre-specified high risk PCI without atherectomy subgroup (88% of study) was demonstrated in the Impella arm. However, further analysis would be needed to clarify the nature and causes of this observation, but surely such new assist devices might provide alternative options for unloading the left ventricle in these high-risk PCI procedures.

Antiplatelet therapy

Results from the RECLOSE-2-ACS (Responsiveness to Clopidogrel and Stent-Related Events in ACS) study, presented by David Antoniucci (Careggi Hospital, Florence, Italy), showed that patients identified as “poor responders” to 600 mg loading dose of clopidogrel had a two-fold risk of cardiac-related death compared with responders [16]. This single-center, open-ended, observational, cohort registry showed that

248 patients out of a total of 1789 patients had high residual platelet reactivity (HRPR), defined as ADP 10 $\mu\text{mol/L}$ >70% using light-transmittance aggregometry. The primary composite endpoint of cardiac death, MI, urgent revascularization and stroke at 2 years was significantly higher in the HRPR group compared with the normal-response group (14.6% vs. 8.7%; $p=0.003$). The rate of stent thrombosis in the HRPR group was also double that of the normal-response group (6% vs. 2.9%; $p=0.1$). Findings from this study indicate that the focus for platelet function tests could be narrowed to those ACS patients. Alternative drugs such as prasugrel or ticagrelor may offer solutions for patients with HRPR.

Conclusion

EuroPCR has become the largest interventional cardiology meeting worldwide. More than in the presentation of true new breaking trials, the strength of the congress is in the prepared demonstrations and Live-In-A-Box cases that show how experts from around the world solve procedural problems, and in other educational sessions such as the “Learn-The-Technique” session. With interactive discussion between facilitators and the audience, the abstract session is a late addition of the past 2 years to the program and offers a valid scientific alternative with true new data to the predominant educational content of the Congress.

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Disclosures

The authors' have no relevant financial interests to disclose.

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