Congress Review

Review of the EuroPCR Congress 2019

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Paris: The city of love, oozing with art and culture, is celebrated for its wine, cheese, wide boulevards, and idyllic strolls along the river Seine; how fitting that the city associated with amour should play host each year to hordes of interventional cardiologists with intrigue and passion for the human heart. The country too has a strong association with heart medicine; in 1844, French physiologist Claude Bernard coined the term 'cardiac catherisation': using catheters to measure intracardiac pressures in animals.[1] Not long after, French surgeon Alexis Carrel performed the first canine bypass surgery, and in 1912, was awarded the Nobel Prize in Physiology or Medicine for his pioneering work in vascular suturing techniques.[2,3]

On the beautiful spring morning of Tuesday 21st May, the Palais de Congrès opened its doors to >11,000 participants: interventional cardiologists, surgeons, imaging specialists, nurses, researchers, industry representatives, and other practitioners and innovators, from around the world, all excited to learn and be challenged over the next 4 days. It really was the place to be to learn about the hottest news in cardiovascular interventions and cutting-edge techniques, with topics including acute heart failure, bifurcation lesions, carotid stenting, mitral valve replacement and repair, ST-elevation myocardial infarction (STEMI), stents and scaffolds, and transcatheter aortic valve implantation (TAVI), to name a few.[4]

The congress kicked off with a live case demonstration from Clinique Pasteur, Toulouse, France. As the main arena began to fill, a buzz of excitement filled the air, along with a flurry of whispers on what was to come. Dr William Wijns, Chairman, PCR, and Farrel Hellig took to the stage to address the audience.[5] "Each course is different and this one is very special because we are celebrating the 30th anniversary of PCR," said Dr Wijns. A large projector took the audience live to Toulouse, where Dr Jean Fajadet and Dr Bruno Farah were performing percutaneous coronary

intervention (PCI) of distal left main (LM) and proximal dominant LCx lesions on an 86-year-old female. The audience watched in near silence for an hour and a half: the only sound was that of pens scratching frantically in fresh notepads.

After the live demonstration, an interview with both operators was streamed, with >250 questions having flooded in from audience members. Speaking to Dr Fajadet, Dr Wijns said: "It was 30 years ago today that this adventure started in France when Jean Fajadet and Jean Marco decided that they would create a new course in Toulouse." He asked Dr Fajadet "I'm sure you remember it as if it were yesterday?"[5]

Outside the operating room, still dressed in his scrubs, Dr Fajadet spoke into the microphone: "It's very emotional for me – 30 years is a long time and it's been a fantastic adventure. When the course began, we had only a simple device: the PTCA [percutaneous transluminal coronary angioplasty] balloon catheter. We wanted to extend the treatment of simple lesions to more complex lesions and so we designed a course where we could invite everyone and expand knowledge."[5]

Now, 30 years on, the founders have, without a doubt, created a meeting where individuals can come together to learn from one another, share, and become better healthcare professionals. In addition to the live session from Toulouse, the congress included many other live sessions from around the world including Spain, Italy, Germany, UK, Denmark, and Singapore.

Over the next 4 days, a cornucopia of session formats were offered to attendees in the extensive programme: abstract presentations; case discussions; late-breaking trials; imaging learning centres; symposiums; tutorials; and a session named 'an image is worth a 1,000 words', in which attendees were presented with rare, interesting, and puzzling images, and topics were discussed on what they saw, what diagnostic elements they recognised, and finally how they would go about treating such a case.

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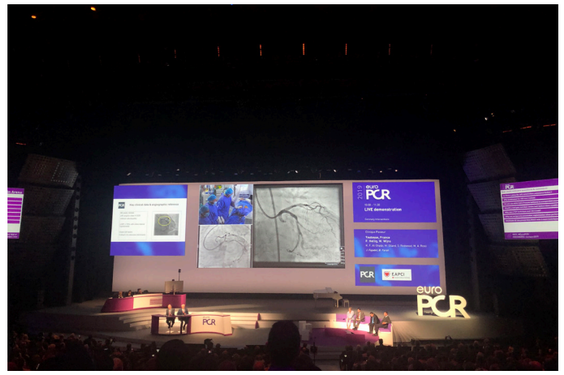

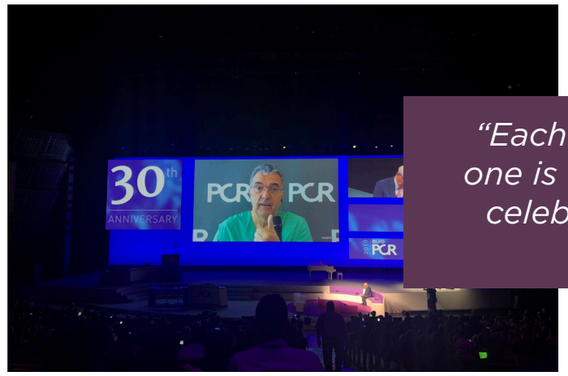

At the end of the congress, everyone left with much to discuss, having experienced presentations on the latest research and late-breaking trials. These included: clinical uses of intracoronary imagine; interventions and outcomes with paclitaxel drug coated balloons, evolving indications for TAVI patients with severe symptomatic aortic stenosis, defining high bleeding risk in patients undergoing PCI, and percutaneous edge-to-edge repair in patients with heart failure and secondary mitral regurgitation.[4]

As the 30th anniversary of EuroPCR drew to a close, Prof Jean Marco, co-founder of the congress, took the stage to give the audience some food for thought and to receive the EuroPCR 2019 Andreas Grüntzig Ethica Award, for his lifelong service to interventional cardiology and its community. *EMJ Interventional Cardiology 7.1* covers this content for you in the coming pages, so please sit back, relax, and read all the brilliance that EuroPCR 2019 had to offer. We are already looking forward to next year's annual meeting and hope to see you there in Paris.

References

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"Each course is different and this one is very special because we are celebrating the 30th anniversary of PCR..."

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Severe Symptomatic Aortic Stenosis Intervention Options

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INTERVENTION in Europe and the USA is most commonly necessitated by severe symptomatic aortic stenosis. The degenerative disease and the interventions associated with it were discussed in a session at the EuroPCR congress, and reported in a EuroPCR press release dated 21st May 2019. The session reviewed several pieces of research into two interventions to identify a preference, as well as offering recommendations for the method of deciding which intervention is the most appropriate.

Heart failure and angina are among the symptoms of aortic stenosis, and the disease can lead to obstruction of the left ventricle outflow due to immobilisation and calcification of the aortic valve leaflets. For aortic stenosis, no medical treatment currently exists that is effective, so intervention is key to avoiding further problems; however, the diseased valve can only be repaired by replacement via transcatheter aortic valve implantation (TAVI) or by surgical aortic valve replacement (SAVR). TAVI is less invasive and a series of randomised controlled trials have been carried out; prior to the development of TAVI, the field was lacking in randomised evidence.

Guidelines surrounding severe aortic stenosis in patients who are extreme, high, or intermediate-surgical risk recommended TAVI for extreme-surgical risk patients as the therapy of choice. At increased surgical risk, TAVI was recommended as an alternative treatment to SAVR; the heart team made decisions on a case-by-case basis depending on the patient's characteristics. For example, TAVI was preferred in elderly patients. SAVR remains to be the standard intervention for low-risk patients.

After comparing several pieces of research, this session concluded that TAVI has a superiority over SAVR at 2-year follow-up regarding improvements in risk of stroke, death, and hospitalisation. Utilisation of healthcare resources was also associated with TAVI due to its shorter interventions, shorter hospital stays, decreased need for rehabilitation, and quicker recovery to everyday life. These preferential outcomes of TAVI were consistent across findings; there is a suggestion that basing decisions on surgical risk is no longer ideal. Heart teams should consider characteristics to identify the best intervention option. The session authors recognised the need for further research to address further uncertainties and enhance outcomes, such as TAVI in asymptomatic aortic stenosis patients.

The Best Innovations in Cardiovascular Medicine: A Discussion

Interventional cardiologists Ran Kornowski (Rabin Medical Centre, Petah Tikva, Israel) and Nicolo Piazza (McGill University Health Centre, Montreal, Canada) were on-hand at EuroPCR to engage in a spirited discussion on the most exciting developments presented as part of 'Innovators Day.' Innovators Day is a platform through which various experts across the cardiovascular landscape, including scientists, clinicians, and industry representatives, can discuss newly emerging incentives to help innovate the cardiovascular field.

Piazza highlighted how innovation can occur across many cardiovascular areas, for instance in coronary research, structural heart disease, cardiovascular neurology, and heart failure. When asked about the developments in coronary intervention, Kornowski proceeded to discuss how at this year's EuroPCR there was an increased focus on improving the efficacy of drug-eluting balloons and drug distribution, as well as for tackling the problem of microvascular dysfunction. He commented on how a new outlook has emerged in which both coronary and structural/intervention-based aspects must be considered simultaneously to provide optimal treatment for patients with cardiovascular disease. "There is a perception that the field of coronary intervention has plateaued, but I know there is still room for improvement."

Piazza next broached the topic of ancillary devices for structural heart disease. Kornowski mentioned several new and exciting ideas, including a new artificial tricuspid valve and new procedures for performing mitral regurgitation. These include the 'cerclage' technique, a very provocative concept that could serve as a platform for additional interventions. "A lot of attention is being given towards improving mitral care and tricuspid care. Hopefully in years to come we will see these developments become standard of care." Kornowski emphasised the importance of resilience and patience in bringing these original ideas to clinical fruition.

Piazza next turned the topic of conversation to cardiovascular neurology, particularly the potential for targeting stroke or the para/sympathetic nervous system to improve cardiovascular outcomes. Koronowski explained how he was fascinated by the idea of selective brain cooling as a means to treat stroke and expressed his wish for it to enter the next developmental stage in clinical trials. As a lot of stroke patients are not being treated with percutaneous devices or acute interventions, this merging of fields holds true therapeutic potential by increasing the number of ways in which we can tackle stroke.

Piazza concluded the interview by highlighting the fact that Innovators Day is clearly a very healthy addition to EuroPCR, with a number of devices being developed across the aforementioned cardiovascular areas. He agreed with Kornowski on the importance of resilience to see these developments through to clinical utility and patient benefits. Koronowski added that an acceptance and meeting of hurdles and the potential for failure is a hallmark of being an innovator, truly a key message to take home from the congress.

Industry-Wide Pooled Analysis Planned to Determine the True Long-Term Safety of Paclitaxel-Based Interventions

Following the publication of a meta-analysis by Dr Katsanos, Patras University Hospital, Rion, Greece, in 2018, there was widespread concern for the safety of paclitaxel-eluting stents and paclitaxel drug-coated balloons (DCB). However, many in the interventional community think that there are serious limitations to the study, and that the results may not be as conclusive as first conceived. Alexandra Lansky presented a discussion of this in a statement on 21st May 2019 at EuroPCR, Paris, France.

This controversial study claimed that use of these paclitaxel interventions in femoropopliteal disease was associated with increased death between 1 and 5 years post treatment compared with uncoated versions. These conclusions lead to an industry-wide discussion into the safety of these interventions, and even resulted in the suspension of two large, prospective, randomised trials (BASIL 3 and SWEDPAD).

The methods of the study have particularly been criticised. In addition to limited long-term data and a high drop-out rate (resulting in >80% loss of patient data at 4–5 years), the meta-analysis used study-level (rather than patient-level) data, did not know the occurrence of repeated exposure to paclitaxel during re-interventions, had a lack of judgement on the causes of death, and had corrections to primary source data.

Subsequent sponsor-driven analyses have been performed using patient-level data from clinical trials and have not been able to replicate the claims from the Katsanos study. However, the interventional community is planning an industry-wide pooled analysis to compare long-term safety outcomes, and this will be presented to the US Food and Drug Administration (FDA) in mid-June. EuroPCR acknowledged the vital need for further studies and strongly supports resuming the BASIL 3 and SWEDPAD trials.

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Expert Guidance on Intracoronary Imaging

SUBSTANTIAL differences amongst regions and institutions in the use of intracoronary (IC) imaging exist today. The technique, which has been utilised for over two decades, has seen an increase in use during that time for diagnostic assessment and guiding percutaneous coronary interventions. This increase has been fuelled by the creation of software improvements and new modalities.

In the context of this usage variability, the European Association of Percutaneous Cardiovascular Interventions (EAPCI) has produced two expert consensus documents to guide clinicians worldwide. The first expert consensus document was published in 2018, and it focussed on the impact of intracoronary imaging guidance on cardiovascular outcomes. The document highlighted the patients who were deemed the most likely to clinically benefit from an intervention guided by imaging and examined the strengths and limitations of using intravascular ultrasound and optical coherence tomography to guide percutaneous coronary interventions, among other topics.

The second expert consensus document detailed the use of IC imaging for three areas:

1. To clarify angiographic ambiguity.
2. To guide decision-making about the severity of a lesion.
3. To delineate the extent of coronary artery disease.

This document was presented at the EuroPCR congress and its key points were disseminated in a EuroPCR press release dated 21st May. There were a number of takeaway messages:

- The OPINION and ILUMIEN III randomised controlled trials have confirmed the equivalence of intravascular ultrasound and optical coherence tomography.
- IC imaging is of great assistance to the clinician when preparing for a left main stem intervention. Its use facilitates understanding of the anatomical complexity, enabling an optimal plan to be put in place for the percutaneous coronary intervention.
- Intravascular ultrasound can be used in the assessment of the functional significance of left main stem disease. A minimal lumen area of <4.5 mm^2 suggested that revascularisation should be considered. A minimal lumen area of >6 mm^2 suggested optimal medical therapy should be used for a conservative treatment approach.
- Prior to undertaking percutaneous coronary intervention, IC imaging is a crucial step. This is because it enables the clinician to better understand the underlying lesion substrate.

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It is hoped that the development of this pair of expert consensus documents will provide pertinent guidance for the international cardiology community and help to ensure optimal patient care.

New Definition of Patients at High Bleeding Risk After Percutaneous Coronary Intervention

BLEEDING during percutaneous coronary intervention (PCI) is a major risk to patients, but, until now, a standardised definition for high bleeding risk (HBR) patients has not existed. Now, the Academic Research Consortium for High Bleeding Risk (ARC-HBR) has stepped up to the challenge, creating a consensus document to better stratify HBR patients after PCI. In a dedicated session on 22nd May, reported in a EuroPCR press release, panellists presented information on the background of these risks, the importance of understanding how these risks affect certain patient populations, and how the updates to the guidelines can be adopted into clinical practice.

Prof Roxana Mehran, Mount Sinai Hospital, New York City, New York, USA, began her presentation discussing bleeding as a predictor of mortality. She summarised the findings of the ACUITY and ADEPT-DES trials, highlighting the findings that within 1 year, more patients died of major bleeding than of myocardial infarction, and within 2 years, post-discharge bleeding was a major predictor of mortality. Comorbidities, bleeding history, age, and haematological factors are just some of the indications of HBR, which can be predictable or unpredictable. Historically, the patients with these indications have been excluded from clinical trials, meaning that a better understanding of these populations is vital to improving patient outcomes.

Prof Mehran continued to compare the inclusion criteria, endpoints, and findings of a number of shorter dual antiplatelet therapy (DAPT) trials that included HBR patients, such as ZEUS, LEADERS FREE, and SENIOR. The findings from these studies suggest that bare-metal stents were not suitable for these patients, in particular elderly patients >80 years of age. Prof Mehran concluded that there was an unmet need for standardised definitions of HBR and related risk scores. Without these, Prof Mehran suggested that treatment decisions are left much more to chance, putting patients at risk. When asked, the audience estimated ~40% of patients in their hospitals to be at HBR, suggesting that current guidelines apply to only ~50% of patients seen daily.

Prof Davide Capodanno, University of Catania, Catania, Italy, followed this presentation by discussing current guidelines for DAPT in HBR and non-HBR patients in more depth. He noted that there were differences between the definitions of the American College of Cardiology (ACC)/American Heart Association (AHA) and the European Society of Cardiology (ESC). While the former defines HBR as a history of prior bleeding, oral anticoagulant therapy, female sex, advanced age, low body weight, chronic kidney disease, diabetes, anaemia, and/or chronic steroid or NSAID therapy,[1] the ESC defines this as 'an increased risk of spontaneous bleeding during DAPT (e.g., PRECISE-DAPT score ≥25)' and assigns scores to the differing risk factors, such as age ≥75 years (0–19 points), renal disease (0–25 points), anaemia or transfusion (0–15 points), actionable bleeding (0–26 points), and high white blood cell count (0–15 points).[2] Thus, predicting bleeding remains a challenge for clinicians.

Prof Capodanno alluded to Prof Mehran's presentation as he moved on to discuss the inclusion criteria for clinical trials of HBR patients. He noted that these criteria were mixed between trials, so, as well as standardised definitions and risk scores being necessary, more consistent inclusion criteria for clinical trials are also necessary to ensure the most useful results. He then continued to discuss the work of the ARC-HBR and their new definitions of HBR.

The ARC-HBR comprises expertise from many related fields, including physician–scientists, regulatory authorities, and leading research organisations. This group examined available evidence, developing a consensus-based definition of HBR, elucidating 14 major criteria and 6 minor criteria. This was done by first reviewing bleeding rates in published DAPT trials and the HBR criteria in completed and ongoing clinical trials. Following this, the committee analysed the bleeding risk scores and assessed the impact of baseline variables. These criteria were announced in a EuroPCR press release following the session.

The major criteria were defined as:

- The use of oral anticoagulation.
- Severe or end-stage chronic kidney disease (estimated glomerular filtration rate <30 mL/min).
- Moderate or severe anaemia (haemoglobin <110 g/L).
- Spontaneous bleeding requiring hospitalisation or transfusion in the past 6 months, or recurrent bleeding.
- Moderate or severe thrombocytopenia (<100x10^9/L).
- Chronic bleeding diathesis.
- Liver cirrhosis with portal hypertension.
- Active malignancy in the last year.
- Previous spontaneous intracranial bleeding.
- Traumatic intracranial bleeding in the past 6 months.
- Recent major surgery or trauma in the past 30 days.
- Planned surgery on dual antiplatelet therapy.
- Known brain arteriovenous malformation.
- Moderate or severe stroke in the last 6 months.

The minor criteria were defined as:

- Patient aged ≥75 years.
- Moderate chronic kidney disease (estimated glomerular filtration rate 30–59 mL/min).
- Mild anaemia (haemoglobin 110–129 g/L in males, 110–119 g/L in females).
- Spontaneous bleeding requiring hospitalisation or transfusion 6–12 months before PCI.
- Chronic NSAID or steroid use.
- Ischaemic stroke >6 months before PCI.

If at least one major criterion or two minor criteria are met, the patient is at HBR.

This consensus document represents the first step in providing guidance for both clinical trial recruitment and clinical decision making in patients who may undergo PCI. The work of the ARC–HBR is ongoing and will next consider design principles for clinical trials of devices or drugs for HBR patients.

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