Five Key Messages From EuroPCR 2019

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For another year, the attention of the interventional cardiology community was drawn to Paris, France, for the annual rendezvous at EuroPCR 2019, held at the Palais des Congrès from the 21st–24th May. The educational, learning, and networking opportunities lived up to the known high standards maintained by the course year after year, and catered to the needs of both senior physicians and those making their first steps in their careers. The latter benefited from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) fellows course, traditionally held just prior to the EuroPCR event, where fundamentals for good clinical practice inside the catheterisation lab are presented by renowned senior operators. In addition, a multitude of interactive sessions during the 4 days, organised by the NextGen group as well as the Learn the Technique track, provided a step-by-step guide to common clinical scenarios in the catheterisation lab. Regarding cutting-edge science and how this should shape clinical practice, the hot line sessions presented the results of the late-breaking clinical trials. Putting recent developments in perspective, five PCR statements on key topics were released in the aftermath of recently published conflicting data

1

A percutaneous edge-to-edge repair (using the MitraClip device) in patients with heart failure and secondary mitral regurgitation (MR), who remain symptomatic despite optimal medical therapy (OMT) and cardiac resynchronisation therapy, should be sought.

In the aftermath of the COAPT trial that demonstrated a lower rate of heart failure hospitalisations and all-cause mortality at 24 months with the use of the technique, the role of percutaneous edge-to-edge repair is now solidified for symptomatic heart failure patients with at least moderate-to-severe MR. Dr Kar, from the Centre for Advanced Cardiac and Vascular Interventions, Los Angeles, California, USA, presented data from the trial exploring the mechanistic relation between MR reduction and the observed outcomes. Lower residual MR at 30 days was strongly associated with reduced hospitalisations, all-cause mortality, and improved quality of life compared with residual MR of 3+/4+. The improvement in MR was significantly more durable over time compared to OMT alone.

A PCR statement presented by Prof Prendergast from St Thomas' Hospital, London, UK, highlighted the role of the Heart Team for the assessment of patients, optimisation of therapy, consideration of device therapy, transcatheter mitral intervention, and surgery.

The transcatheter edge-to-edge repair is appropriate in carefully selected patients who remain symptomatic despite OMT (including cardiac resynchronisation therapy) and have:

- Severe MR (effective regurgitant orifice area [EROA] ≥30 mm^2, regurgitant volume ≥45 mL, or regurgitant fraction ≥50%).
- Suitable valve morphology (assessed by comprehensive echocardiography).
- Left ventricular systolic dimension <70 mm.
- Absence of significant right ventricular dysfunction, tricuspid regurgitation, and pulmonary hypertension.

The role of other transcatheter interventions remains under investigation, while surgical treatment may be considered as an add-on to surgical revascularisation. Circulatory support devices or transplant should be considered for cases with extreme left or right ventricle failure.

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2

The use of stents with thinner struts results in fewer repeat revascularisations but does not further reduce hard endpoints.

According to the thin strut hypothesis, stents with thinner struts result in less vessel injury, inflammation, and thrombus formation compared to thicker struts. In the mid-term, this leads to faster endothelialisation and early vascular healing, and possibly lowers the risk of uncovered or malapposed struts in the long term.

Dr von Birgelen from the Thorax Centrum Twente and University of Twente, Enschede, Netherlands, presented an analysis of the BIORESORT trial with the 3-year results of treatment of small coronary target lesions (diameter <2.5 mm). A stent with ultrathin struts (Orsiro, strut thickness of 60 µm, sirolimus-eluting) was compared to a very thin strut stent (Synergy, everolimus-eluting) and a thin strut stent (Resolute Integrity, zotarolimus-eluting). No statistical significance in target lesion failure, cardiac death, and target vessel myocardial infarction was evident. However, all-comer patients with small lesions treated with the ultrathin strut stent experienced fewer repeat target lesion revascularisations than patients treated with the thin strut stent (2.1% versus 5.3%).

Retrospective, real world data from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) comparing the Orsiro ultrathin strut stent to several other newer generation drug-eluting stents were presented by Dr Buccheri from Uppsala University, Uppsala, Sweden. Low rates of definite stent thrombosis coupled with significantly lower rates of target lesion revascularisation (1.6% versus 2.3%) and a trend for lower in-stent restenosis with the Orsiro stent (4,561 patients) were reported, as compared to the newer generation stents (69,570 patients).

Dr Hudec from Succh, Banksa Bystrica, Slovakia, presented similarly favourable outcomes with the use of the BioMime stent (strut thickness of 65 µm, sirolimus-eluting) in 520 patients. At 9 months, the rates of all-cause mortality, myocardial infarction, and target lesion revascularisation were 0.39%, 0.58%, and 0.97%, respectively; no cases of stent thrombosis were observed. The same stent platform was studied in the MILES-UK registry; data presented by Dr Menown from the Craigavon Cardiac Centre, Craigavon, UK, pointed to a cumulative rate of 2.08% for target vessel failure at 9 months.

Taken together, these reports point to a favourable outcome regarding repeat revascularisations with ultrathin strut stents, both in the setting of a clinical trial and in the real world.

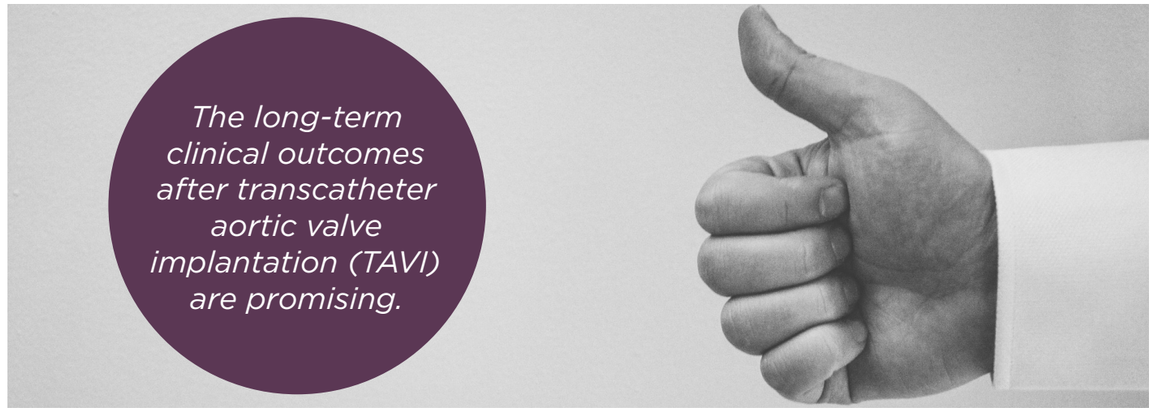
3

The long-term clinical outcomes after transcatheter aortic valve implantation (TAVI) are promising.

The recent publication of two trials regarding the use of TAVI in patients at low surgical risk was followed by an updated meta-analysis comparing TAVI and surgical aortic valve replacement (SAVR); throughout 2 years of follow-up, a 12% and 19% relative risk reduction for all-cause mortality and stroke were noted.[1] Accordingly, the PCR statement on the evolving indications for TAVI highlights the superiority of TAVI to SAVR with respect to death, stroke, and rehospitalisation, as well as the improved healthcare resource utilisation. Surgical risk estimation is no longer the basis to guide the choice between TAVI and SAVR, and prosthesis selection should be determined by life expectancy and durability (mechanical valves in younger patients and bioprostheses in older [>65 years of age] patients).

As a consequence of the expanded indications for TAVI, the question of long-term performance arises. Of note, currently the durability of the valves has been established for up to 5 years in clinical trials; data from registries can give us indications of the performance of TAVI beyond that.

In a hot line late-breaking trial session, Dr Testa from IRCCS Policlinico San Donato, Milan, Italy, presented data from the Italian registry regarding the long-term performance of the self-expanding aortic valve implant. At 8 years, mortality occurred in 80% of the 990 patients that were included in the registry. For those that survived, the mean transvalvular gradient remained stable over time, comparable to the gradient immediately post-implantation. In addition, the rates of paravalvular leakage and structural valve deterioration were consistently low. Similar findings were reported by Dr Sathananthan from St Paul's Hospital, Vancouver, Canada, regarding the 10-year follow-up of TAVI patients. Of the original cohort of high-risk patients, 6.6% survived up to 10 years. Of these patients, 76.5% did not have any moderate-to-severe structural valve deterioration, and 89.5% had freedom from reintervention. The mean gradient remained stable at 10 years. Data on prosthetic valve endocarditis from the Finnish registry (FinnValve registry) were presented by Dr Moriyama from the Heart and Lung Centre, Helsinki University, Helsinki, Finland. At 8 years, the rates of endocarditis were comparable between transcatheter (1.28%) and surgically implanted (1.39%) valves. Mortality rates following prosthetic valve endocarditis, however, remain high (52.5% at 1 year). Dr Bjursten from Skåne University Hospital, Scania, Sweden, corroborated these results by presenting respective data from Sweden for a follow-up of up to 10 years; 6-month survival was 58.0% and independent risk factors for the development of endocarditis were obesity, poor renal function, a transapical access, and a high preoperative aortic gradient.



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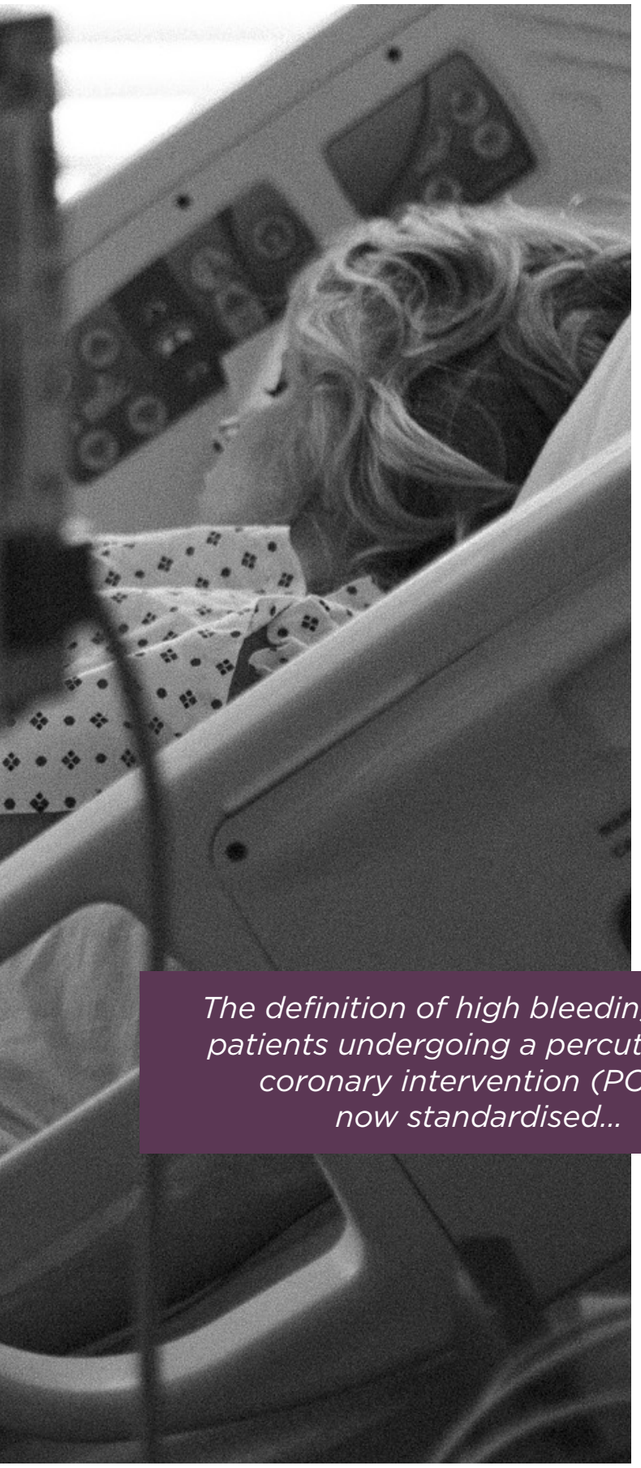

The definition of high bleeding risk in patients undergoing a percutaneous coronary intervention (PCI) is now standardised, facilitating the identification of this vulnerable patient group in clinical practice, homogenising trial design, and reporting of results.

A PCR statement was issued on the matter, accompanying a consensus document from the Academic Research Consortium for High Bleeding Risk (ARC-HBR) that was recently published in the European Heart Journal.[2]

Major criteria include 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), prior spontaneous bleeding requiring hospitalisation or transfusion during the prior 6 months (or at any time if recurrent), moderate or severe thrombocytopaenia (<100x10^9/L), chronic bleeding diathesis, liver cirrhosis with portal hypertension, active malignancy during the prior 12 months, prior spontaneous intracranial bleeding at any time, previous traumatic intracranial bleeding during the prior 12 months, known brain arteriovenous malformation, moderate or severe stroke during the 6 months, recent major surgery or trauma during the prior 30 days, and planned major surgery on dual antiplatelet therapy.

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Minor criteria include being aged ≥75, moderate chronic kidney disease (estimated glomerular filtration rate 30–59 mL/min), mild anaemia (haemoglobin 110–129 g/L for men and 110–119 g/L for women), spontaneous bleeding requiring hospitalisation and/or transfusion 6–12 months prior to PCI, chronic non-steroidal anti-inflammatory drug or steroid use, and ischaemic stroke more than 6 months prior to PCI.

Patients are considered to be at high bleeding risk if at least one major criterion or two minor criteria are satisfied.

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Data on the safety of paclitaxel for peripheral interventions and drug-coated balloons for coronary interventions.

Following the turmoil caused by a meta-analysis reporting increased death beyond 1 year with the use of paclitaxel-eluting stents or drug-coated balloons for peripheral vascular disease, a PCR statement looked into the details of the matter. According to Dr Lansky from Yale University School of Medicine, New Haven, Connecticut, USA, who presented the statement, the meta-analysis has a number of limitations that preclude the deduction of a clear message regarding paclitaxel-coated balloons, such as data being on the study (and not patient) level, high drop-out rates (>80% at 4–5 years), limited long-term data, problematic adjudication of causes of death, and corrections to the primary source data. Data from subsequent individual sponsor-driven analyses have contested the result of the meta-analysis. In conclusion, results from an adjudicated, industry-wide patient level pooled analysis are awaited to further clarify this controversy.

Regarding the use of drug-eluting balloons in the coronaries, Dr Jeger from University Hospital Basel, Basel, Switzerland, presented the angiographic results from the BASKET-SMALL 2 trial; in small coronary arteries (diameter: <3 mm) compared to drug-eluting stents, the use of a drug-eluting balloon resulted in a lower acute lumen gain and more residual stenosis. At follow-up after 1 year, the late lumen loss was similar for both groups, while eight thrombotic occlusions of the target lesions were noted in the stent group, as opposed to none in the balloon group. Dr Silverio from Uppsala University presented real-world data from the SCAAR registry regarding the treatment of small coronary vessels with drug-eluting balloons. After matching the patients treated with balloons to patients receiving a new-generation stent, drug-eluting balloons were associated with a higher risk of restenosis and myocardial infarction at 3-years follow-up compared to stents. Dr Vos from OLVG Hospital, Amsterdam, Netherlands, shared the results of the REVELATION trial, a small (N=120), prospective, randomised, controlled trial, where drug-eluting balloons were compared to stents in patients with ST-elevation acute myocardial infarction. Fractional flow reserve, late lumen loss, and major adverse cardiac events at 9 months did not differ between the two groups.

References

1. Siontis GCM et al. Transcatheter aortic valve implantation vs. surgical aortic valve replacement for treatment of symptomatic severe aortic stenosis: An updated meta-analysis. Eur Heart J. 2019;ehz275.
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