EuroIntervention

EuroPCR 2007 highlights

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Marie-Claude Morice

We all know how this year's edition was characterised by an important change. Indeed, because the capacity of the Palais des Congrès in Paris had become inadequate to accommodate the congress, EuroPCR moved to the dynamic, modern and southern European city of Barcelona.

This change of venue has been positively welcomed, as evidenced by the event bringing more than 11,000 attendees together from over 80 countries throughout the world; including: cardiologists, surgeons, nurses, radiologists as well as industry representatives.

The other specificity of this year's meeting, and a major one, was that the guest faculty comprised of four specialties or poles of interest: cardiac surgery, percutaneous coronary interventions, non-coronary percutaneous cardiac interventions and peripheral interventions. All four had their own individual scientific programs throughout the entire four days of the meeting and these programs were complementary, each to the other.

The underlying objective of this "Four-in-One" system of courses was to emphasise the need for a global synergy encompassing multi-disciplinary patient management supported by cooperation between the various teams involved.

As always in EuroPCR tradition, the purpose of the meeting was to promote education through live case demonstrations. Live cases were transmitted from 15 centres worldwide connected to Barcelona via satellite.

Coronary heart disease

A major part of this program was dedicated to coronary heart disease. In the opening session, Prof. Bassand unveiled the ESC guidelines for the management of acute coronary syndromes without ST segment elevation. These guidelines were simultaneously presented during the EuroPCR and published in the European Heart Journal as a consequence of the new collaboration between the European Society of Cardiology (ESC) and EuroPCR under the auspices of the ESC's former interventional cardiology working group now transformed into the European Association of Percutaneous Cardiovascular Interventions (EAPCI) presided over by William Wijns. It has been agreed that the EuroPCR congress would represent the European Society of Cardiology and the presentation of the ESC guidelines constituted one the highlights of the meeting and underlined this new approach and relationship.

The safety issues related to the use of DES were widely addressed during the session. Though the recent meta-analyses data are much less worrying than those presented by Camenzind last September at the ESC scientific sessions, there is still substantial concern among the interventional cardiology community. No one is prepared to take the slightest risk with patient safety for the sake of reducing the rate of restenosis. In the conclusion of his opening lecture, Patrick Serruys clearly stated that abolition of neo-intimal proliferation was no longer the ultimate goal, and that development of increasingly biocompatible and even bio-absorbable stents facilitating adequate endothelialisation was expected in the very near future. The good news is that such stents are becoming available on the market. Dr Renu Virmani presented data showing that the new generation stents have less polymer and thinner struts, which foster the re-endothelialisation process in the animal model, such as the Xcience™ which is now available.

Conversely, the results of the Costar reservoir-stent presented in the 'late breaking trials' sessions proved to be less satisfactory than initially (Eurostar trial/Costar 2 trial). As a consequence, the current

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Costar program has been discontinued by Cordis who have recently purchased Costar. During these sessions, the Endeavor Resolute stent, an outgrowth of the Endeavor zotarolimus stent with a completely different, presumably more bio-compatible polymer with enhanced drug-release kinetics, showed an excellent 9-month angiographic results with 0.22 mm late lass (similar to that of SES). The presentation of two trial programs involving completely bioresorbable stents, which incidentally won the EuroPCR innovation prize, was of particular interest.

One program, the Absorb trial, is investigating an everolimus-eluting stent with a resorbable polymer, the 9-month results of which are acceptable (late loss: 0.44 mm). Another extremely innovative technology presented during the EuroPCR is that of Genous, a stent coated on its endoluminal side with antibodies able to capture circulating pro-endothelial cells, thus allowing for very fast endothelialisation.

Several studies are currently under way to further investigate these very promising stents. These, as well as other new devices are expected to provide increased safety, especially in patients at high thrombogenic risk such as those included in the Healing AMI study (Swolle) or in patients with contra-indications to Plavix and long-term aspirin use.

In this context, Patrick Serruys presented his 'ideal stent' with a similar coating and various additional features. Lectures on emerging technologies, currently tested in animal models, have introduced a wealth of innovative devices illustrating the limitless inventiveness of engineers and interventional cardiologists.

Most noteworthy among these is a stent composed of anti-inflammatory and completely resorbable salicylic polymer, as well as other techniques such as electro-grafting, allowing for very fast stent endothelialisation. Safety is clearly the major criterion.

As in previous years, the numerous live case sessions were greeted with much enthusiasm.

General sessions were held in the main auditorium, as well as more specific live demonstrations involving certain lesion types such as chronic occlusions, bifurcations or left main disease. One of the conference rooms even proposed an uninterrupted program of live procedures.

Finally, one of the prominent features of this year's edition was the introduction of the 'Learning the Techniques' sessions aimed at young physicians. For the first time, procedures were performed live by fellows under the guidance of a senior interventional cardiologist in constant interaction with the audience. These sessions proved highly successful due to their educational quality.

In conclusion, safety problems associated with the first generation of drug-eluting stents were submitted to thorough analysis – albeit in a more serene manner than during the last European congress.

Even though the occurrence of late stent thrombosis is very low in absolute numbers, it has generated a loss in confidence which has affected the current use of DES. Indeed, the DES implantation rate has decreased in various countries, especially in those where it had reached almost 100%.

The main purpose of EuroPCR is the transmission, from one generation to the next our experience and knowledge in PCI indications and techniques via live-case demonstrations. The 'Learning the Techniques' sessions were a perfect illustration of this endeavour.

Peripheral angioplasty

There has been a significant increase in the volume of endo-vascular interventions worldwide, with a corresponding decrease in surgical procedures. The rate of carotid stenting has increased by 11% whereas carotid surgical treatment has decreased by 8%. Similarly, there has been an 8.3% increase in the percutaneous treatment of the femoro-popliteal axis and a simultaneous 11% reduction in the volume of surgical procedures. Carotid angioplasty is increasingly performed thanks to the development of new protection systems and stent designs adapted to this pathology. This new approach is associated with excellent results. Patients with thoracic-abdominal aneurysm are now amenable to percutaneous treatment. Though still preliminary, the results of this therapeutic option are promising. Drug-eluting stents are now involved in peripheral interventions, especially in distal lesions of the lower limbs where the recurrence rate is usually very high. Emphasis was once again placed on the importance of multi-disciplinary teams comprising vascular surgeons, interventional radiologists, neuro-radiologists, interventional cardiologists and clinicians.

Alberto Cremonesi and Dierk Scheinert, discuss the specifics of their programme below.

Cardiac surgery

Many cardiac surgeons took part in the course this year and generated numerous stimulating discussions. A live demonstration of all arterial by-pass grafting by Prof. Nataf was transmitted from the Hôpital Bichat in Paris and a consensus was reached on the improvement of outcome and potential reduction in mortality rate associated with all arterial and off-pump CABG. During the surgical sessions, it was demonstrated that patients with multivessel disease and insulin-dependent diabetes treated with surgery had a higher life expectancy compared to those undergoing angioplasty. Pending the results of randomised trials comparing surgery and PCI, the use of the Syntax score establishing the severity of coronary lesions will allow a better identification of patients likely to benefit the most from each technique. The improvement of patient management when carried out by a multi-disciplinary team was reiterated.

We look forward to an increasing participation by cardiac and vascular surgeons within the course structure.

Percutaneous treatment of valve and non-coronary cardiac disease

The TVS course has now joined with EuroPCR presenting their own dedicated programme introduced by Carlos Ruiz below. These sessions included 'return to basics', imaging, new technologies and future clinical prospects illustrated by live cases in our EuroPCR tradition.

Percutaneous treatment of mitral, aortic and pulmonary valve disease is being increasingly carried out.

There were three live case performed during the meeting: a pulmonary valve replacement procedure (Great Ormond Street Hospital, London, United Kingdom), two aortic valve replacements (Institut Jacques Cartier, Massy, France and Erasmus University Medical Center, Rotterdam, The Netherlands) and a transapical implantation of an aortic valve (Universität Leipzig Herzzentrum, Leipzig, Germany).

To date, 188 pulmonary and 428 aortic valves have been implanted worldwide. Experience with mitral valves is more limited with, nevertheless, 79 E-valve mitral procedures (comparable with Alfieri procedure) having been accomplished. Future prospects are indeed very promising since all interventions performed so far have been carried out in patients ineligible for surgical treatment. The present indications should broaden provided that the satisfactory results currently reported prove to be durable in the mid-term.

Alberto Cremonesi and Dierk Scheinert

The endovascular treatment of peripheral disease is becoming more prominent; increasingly the first choice treatment option for patients is endovascular, whether we are dealing with carotid, iliac or a femoral-popliteal obstructive disease.

During EuroPCR 2007, many scientific and live case sessions addressed all the existing evidence, as well as the clinical and technical issues as they relate to peripheral endovascular procedures. There were several points that came out of this meeting that we believe will play a significant role in our daily practice, and which we would like to point out here.

The first of these hot topics concerns the treatment of patients with severe carotid artery stenosis. Two recent randomised trials (EVA 3S and SPACE) failed to demonstrate the non-inferiority of carotid stenting when compared to endarterectomy. Apart from the criticism on the part of the scientific community about the way these trials had been conducted, their potential negative rebounds were discussed in several sessions. What is clear is that when high complication rates for carotid stenting occur and subsequently published, there can be no doubt that we must take them into account as we approach our daily practice.

The main questions raised by the experts was always the same: What do the EVA 3S and SPACE results represent in the interventional world? And if those catastrophic results represent the "reality" of carotid artery stenting, then shouldn't we stop to use it as a safe and effective therapy?

However, EuroPCR sessions dedicated to carotid stenting showed an altogether different "reality". Carotid stenting is far from being an "experimental therapy", but has become today a well established alternative for preventing strokes in patients with severe carotid lesions, both symptomatic and asymptomatic. Moreover, carotid bifurcation is perhaps the best site to use bare metal, self-expanding stents. In-stent restenosis itself is a rare phenomenon here, with a documented rate ranging from 3 to 5%. The major problems of this endovascular treatment protocol were clearly discussed during EuroPCR 2007 and it is clear that carotid stenting is anything but a simple procedure, which should be performed by only the most experienced and well trained operators. This point it critical, and was further supported by the analysis of the outcome data reported by the Cristallo Registry Investigators. The Cristallo prospective registry has been conducted in four high-volume European centres. The primary endpoint of this study was to evaluate the incidence of all strokes and neurological death related to the use of a new hybrid carotid stent (Cristallo Ideale) through to 30 days after stent implantation. Interestingly, no severe adverse neurological events have been detected in more than 120 recruited patients, demonstrating that in those centres where a serious training and accreditation programme in endovascular procedures is in place, that these programmes represent a high standard of care, allowing operators using this new hybrid stent to achieve exceptionally high safety levels fitting it to a variety of unselected anatomies .

In peripheral circulation, obstructions of the superficial femoral artery, which represent more than 50% of all peripheral arterial lesions, are still one of the major challenges for interventional treatment. Nevertheless, data obtained from recent clinical trials on SFA-stenting are encouraging. During EuroPCR 2007, the two year follow-up data of the randomised VIENNA-ABSOLUT-trial was presented, showing a sustained benefit of primary stenting as compared to primary PTA with bailout stenting in terms of the restenosis rate (30.8% vs. 54.3%, p=0.02). Although data from other ongoing randomised trials are pending, primary stenting seems to be gaining acceptance as the primary option for patients with complex femoral lesions.

Due to very limited trial data the value of antiproliferative drug coatings in terms of the further improvement of peripheral stents remains largely unknown. Moreover, the reported issues with stent fracture occurrence, particularly after long-segment femoral stenting with first-generation nitinol stents, generated a lot of interest in non-stent-based solutions for this vessel area. During EuroPCR 2007, Gunnar Tepe reported a subgroup analysis of the THUNDER trial which investigated the performance of a paclitaxel-coated balloon vs. plain balloon and vs. local paclitaxel infusion for treatment of SFA-lesions. Similarly to the overall study result, which showed a significant reduction of the late lumen loss using the paclitaxel-coated balloon in comparison to the other two groups at six months, this same treatment effect could be observed in all investigated subgroups including total occlusion, calcified and long lesions. Twelve month follow-up data of this exciting project are expected to be presented in the fall of this year.

Also in the area of the tibial circulation, which typically involves patients with critical limb ischaemia, the use of drug-eluting stents holds some promise for improved treatment options. Konstantinos Katsanos reported the one year follow-up data of a study investigating the value of sirolimus-eluting balloon-expandable stents in comparison with a bare-metal version of the same stent platform. The investigators could demonstrate a sustained benefit in stent patency, as well as a significant reduction in the target lesion revascularisation rate of 9% vs. 26% (p=0.02). While this data suggests that the use of DES may be an important step forward regarding interventional treatment options for tibial disease, Luca Dalla Paola emphasised that a successful treatment strategy for patients with critical limb ischaemia and diabetic foot lesions needs to remain a multidisciplinary approach.

Carlos E. Ruiz

The Transcatheter Valve Symposium (TVS) is the most comprehensive course on the newer transcatheter valve technologies and has become an integral part of EuroPCR. There were more than 45 selected presentations. The objectives of TVS@EuroPCR are to help clinicians understand the basics of valve disease, how to assess the pathology and what new therapeutic approaches are in the horizons. In order to cover this wide spectrum there were five main sessions:

1. *Back to basics* – a session dedicated to review the basics of anatomy, physiology and pathology of valve disease. Furthermore, a concise review of the latest diagnostic technologies to assess valvular heart disease was presented. In addition there were two sessions dedicated to the basics of transseptal cardiac catheterisation. There were also presentations on the theory of design and engineering of prosthetic cardiac valves, as well as the preclinical testing required.
2. *Imaging* – this session was dedicated to review the latest imaging technologies in assessing valvular heart disease and its critical relevance to the newer transcatheter valve technologies. There seems to be a trend towards coupling imaging technologies such as ultrasound, fluoroscopy, computerised axial tomography and magnetic resonance within the interventional theatre.
3. *Technology* – an extensive review of most of the newest transcatheter valve technologies for pulmonary, aortic and mitral valve repair and replacement was presented. These sessions covered in detail the technical aspects of each technology without describing results. The first transcatheter mitral valve replacement device concept was unveiled.
4. *Live transmissions*
   a. There was one live-transmission of a Medtronic Melody Pulmonary valve implant with magnetic resonance assessment pre- and post-implantation
   b. There were two transarterial aortic valve implantations. The first one with the Sapien-Edwards balloon expandable valve technique and the second one, completely percutaneous with the CoreValve self-expanding valve
   c. There was one transapical aortic valve implant using the Sapien-Edwards balloon expandable valve live transmission and a recorded video of the new transapical CoreValve in an animal model.
   d. There were several recorded live cases of mitral valve repair using the edge-to-edge technique with the MitraClip of Evalve, and the transcoronary sinus approach using the Edwards-Monarc device. In addition the FIM asymmetric annuloplasty using the PS3-Ample device implant was shown
5. *Clinical Perspective a Trials Results* – The up-to-date clinical results of the entire Medtronic Melody valve implantation trial, in Europe and in North America were presented showing a six year survival curve of 96%. The Cribier-Edwards and Sapien-Edwards aortic valve global experience was also presented on 428 patients in Europe and North America. Furthermore, the up-to-date clinical experience with the Evalve MitraClip, as well as the experience with Carrillon Cardiac Dimensions, the Edwards Mobious, Myocor-Coapsys and Viacor devices were presented. More important, the different points of view from expert cardiac surgeons, interventional cardiologist and clinicians were presented in order to reach a consensus of opinion on how best to approach these rapidly evolving technologies.