

## ESC 2012 - Interventional highlights

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This year Munich was host to the diamond jubilee meeting of the European Society of Cardiology (ESC). Over 28,000 attendees –despite the current global economic circumstances– is testament to its continued attraction as one of the premier cardiology congresses. The size of the five-day event, which included 423 sessions and 4,203 original abstracts, was matched by the increasingly comprehensive and sophisticated electronic media and communication platforms available.

For the interventional community there were accolades bestowed upon Patrick W. Serruys who received the ESC gold medal in recognition of his achievements and William Wijns who was invited to deliver the Andreas Gruntzig lecture entitled “From coronary angioplasty to percutaneous interventional cardiovascular medicine”.

Five updated practice guidelines<sup>1</sup>, of relevance to all practicing cardiologists, were launched on valvular heart disease, AMI-STEMI, a universal definition of myocardial infarction, atrial fibrillation, cardiovascular disease prevention and heart failure.

For valvular heart disease, which is a field with relatively few randomised data, the importance of the Heart Team concept to help decision-making was strongly emphasised and reflected in the fact that the guideline document was prepared by the ESC and the European Association for Cardiothoracic surgery. The updated changes relate mainly to aortic stenosis and mitral regurgitation. Following the PARTNER trials, TAVI is given a IB recommendation in inoperable severe symptomatic aortic stenosis and a IIa B recommendation for high-risk severe aortic stenosis (AS).

In the STEMI guidelines, the development of improved integrated networks and pre-hospital logistics to deliver guideline-mandated contact and door-to-balloon times for PPCI were emphasised. Also incorporated are positive recommendations for a direct to a PCI-capable hospital strategy, drug-eluting stents, the

radial approach and secondary prevention. These guidelines thus complement the Stent for Life Initiative launched in 2008 to reduce the variability in access to acute interventional therapy and clinical outcomes that persists across Europe. The importance of national registries in this field was highlighted by data from four cumulative French STEMI registries covering a 15-year period (1995-2010). These reported that the crude mortality rate for a total of 6,707 patients had fallen from 11.7% to 4.4%, which was associated with greater implementation of guideline-based treatment (either with PPCI and thrombolysis), but was also associated with a decreasing mean age of presentation including younger women, a growing proportion of whom were smokers.

The updated guideline for the definition of myocardial infarction aims to standardise, both for daily clinical practice and investigators, the diagnosis of infarction in the light of high sensitivity troponin assays. In this third iteration of the definition, procedure-related MI is defined as an elevation of cardiac troponin greater than five times the 99th percentile upper reference limit in patients with a normal baseline value, or a 20% increase in a stable chronically elevated or falling troponin level. This raises the threshold that was used in the previous guideline whereby any post-procedural rise in troponin was regarded as sufficient to constitute a periprocedural infarction. Furthermore, the document clarifies the difference between myocardial injury (secondary elevations of troponin not due to acute coronary syndromes) and infarction (primary troponin release).

All large congresses aim to present new clinical data that have the potential to alter practice and this year was no exception. With respect to interventional cardiology several studies were showcased.

The “What is the Optimal antiplatelet and anticoagulation therapy in patient with oral anticoagulation and coronary StenTing”

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(WOEST) study<sup>2,3</sup> was an investigator-led multicentre random controlled trial (RCT) comparing “standard” triple therapy (aspirin 80 mg, clopidogrel 75 mg and warfarin) vs. clopidogrel 75 mg and warfarin in 573 patients with an indication for chronic anticoagulation post-PCI (predominantly with DES). The primary endpoint of fewer haemorrhagic events at 12 months (44.9% vs. 19.5%  $p=0.001$ ) was met unsurprisingly. This was driven by minor to moderate bleeding episodes which are clinically important as they can lead to premature discontinuation of therapies. Importantly, the secondary endpoint of death, stroke, MI and stent thrombosis was not increased in the comparator arm, and indeed all-cause mortality was reduced. It is noteworthy that current guidance recommends three to six months of triple therapy post PCI with DES rather than the 12 months in this study. Nevertheless, this is the first RCT to look at this challenging problem frequently encountered in interventional practice, and is a big first step. Longer-term follow-up and further investigations are clearly desirable, but it is almost certain that these data will be important for future study design as well as influencing practitioners and guideline committees.

The intra-aortic balloon pump SHOCK-2 study<sup>4</sup> was another investigator-led multicentre RCT that will inform guidelines and practice. Six hundred patients with acute STEMI and cardiogenic shock were randomised to IABP or medical therapy following revascularisation. The majority of IABPs were placed following rather than before PPCI. No benefit was seen in the primary endpoint of mortality at 30 days, 119 (39.7%) vs. 123 (41.4%) (CI 0.79-1.17  $p=0.69$ ). In addition, there were no positive signals from the secondary endpoints or pre-specified subgroups.

The PROTECT randomised study<sup>5</sup> compared ARC criteria definite and probable stent thrombosis rates between the first-generation sirolimus-eluting CYPHER<sup>®</sup> stent (Cordis, Johnson & Johnson, Warren, NJ, USA) against the second-generation zotarolimus Endeavor<sup>®</sup> stent (Medtronic, Minneapolis, MN, USA). In the 8,709 patients, thrombosis event rates were low and not significantly different out to three years’ follow-up (1.8% vs. 1.4% respectively). Rates on non-fatal MI were also similar (5.3% vs. 6.0%, respectively). Improved attention to stent deployment technique, duration and compliance with dual antiplatelet therapy (DAPT) are plausible explanations for the low-recorded incidence. The one-year compliance with DAPT was greater than 80% in the C-SES arm and so it remains to be seen whether at even longer follow-up the event curves diverge significantly.

The FAME-2 study<sup>6</sup> on 1,220 patients with stable coronary artery disease confirmed the importance of intervention for ischaemia. Patients with one, two or three vessel disease and a fractional flow reserve (FFR) of  $<0.8$  were randomised to an FFR-guided PCI with DES plus optimal medical therapy (OMT) versus optimal medical therapy alone. Those with an FFR  $>0.8$  were followed-up in a registry. The primary endpoint was the 24-month rate of overall major adverse cardiac events defined as all cause death, documented myocardial infarction (MI) or unplanned hospitalisation leading to urgent revascularisation. There was a more than a fourfold increase in the hazard of MACE in patients randomised to OMT alone (8.0% vs. 2.0%; hazard ratio [HR] 4.36 [95% CI 1.90 to 10.03]), which

was driven by an increase in the hazard of unplanned hospitalisation with urgent revascularisation (5.9% vs. 0.6%, HR 11.20 [95%CI 2.62-47.92]). There was no difference in mortality between the groups.

A number of observational studies in the field of structural intervention were of interest. The ACCESS-EU multicentre prospective observational cohort<sup>7</sup> of 567 patients with severe mitral regurgitation, inoperable with high EuroSCORE provided data demonstrating that the MitraCLIP procedure is technically feasible with no embolisation reported and an 8% rate of single leaflet attachment and/or a need for a second procedure. Symptoms were improved in 74% of 347 patients with matched clinical data. Being a group with a greater burden of comorbidities than that which was investigated in Everest 2, these data may prompt a further randomised trial.

The EURObservational Research Programme<sup>8</sup> looked at contemporary TAVI practice (using either the CoreValve ReValving system<sup>®</sup> or the SAPIEN XT<sup>™</sup>) and included 4,751 patients from 10 countries. Patients had a mean age of  $81.4\pm 7.1$  with a high prevalence of comorbidities. There was no difference in overall mortality (6.7% vs. 7.9%  $p=0.15$ ). The transfemoral route had the lowest complication rate (5.9% vs. 12.8% for transapical and 9.7% for trans-subclavian  $p<0.01$ ). Permanent pacemakers were required in 23.8% of CoreValve and 6.0% of SAPIEN XT patients ( $p<0.01$ ). Hospital length of stay varied widely  $9.3\pm 8.1$ , days as did the use of general anaesthesia and recommended post-procedural dual antiplatelet therapy.

In the emerging field of renal denervation for resistant hypertension the 18 month follow-up data of the 106 patient cohort from the SYMPPLICITY HTN-2 randomised study<sup>9</sup> were presented. Forty-three patients initially randomised to denervation demonstrated a mean reduction of 32/12 mmHg from baseline. Thirty-one patients in the crossover group had a reduction of 28/11 mmHg. Neither group demonstrated any renal function deterioration, thus giving further reassurance that the procedure in this selected group is both safe and efficacious.

The scientific content, whilst integral to any large medical congress, has to be matched to its commitment to education; to this end the ESC have added to their long list of initiatives the ESCel online learning platform. Consisting of MCQs and case studies, this tool covers six subspecialties including intervention and is based on the ESC and EuroPCR-EAPCI textbook series. It is primarily aimed at trainees, and is designed to assist formative rather than summative assessment. Other key educational innovations include the ESC 365 “rubik’s cube” portal<sup>10</sup> for accessing a vast range of medical resources related to the congress.

Fifty years on from the first ESC congress in London, the current meeting remains a unique congress in the cardiology calendar and occupies a principal position for showcasing new interventional scientific data, continuing medical education as well as giving exposure to the many branches of cardiology. Being a part of the ESC meeting should help broaden the perspective of the interventionist by fostering a multidisciplinary and cardiovascular approach to practice.

## Conflict of interest statement

The author has no conflicts of interest to declare.

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