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Interventional cardiology highlights of the European Society of Cardiology congress, 2008

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The annual meeting of the European Society of Cardiology (ESC), this year organised in Munich, had again a lot to offer to the interventional cardiologist. Important new data were presented on important topics such as: real life safety of the first generation drug eluting stents, new stent technology and the timing of adjunctive antithrombotic therapy in conjunction with primary PCI. Long awaited data was also released on large scale randomised trials comparing contemporary percutaneous (PCI) and surgical (CABG) revascularisation.

The main session on DES safety "Two years after Barcelona" stressed the importance of large scale registries because these reflect real or daily life practice, often excluded from randomised trials. Mendiz et al presented the OLYMPIA registry, including 22,345 PCI patients treated by the TAXUS Liberté stent. Expanded use (beyond simple stenting) was performed in 74.9% of cases. At one year follow-up, the stent thrombosis rate was 0.8% while the total adverse events rate (including the need for reintervention) was 3.8%. The German Cypher registry (Zahn et al) reported on 11,070 PCI at six month follow-up. The registry population presented with more complex pathology (unstable syndromes: 42%, multivessel disease: 70.2%). The overall adverse events rate was therefore 10.9%. Both strategies reflect the current opinion, largely debated at this years congress, that DES demonstrate sustained safety in a broad range of indications. Efficacy, however, depends on anatomy as the need for reintervention increases with lesion complexity.

Late stent thrombosis remains the important safety issue of DES. Sirbu et al presented different imaging modalities (IVUS, OCT) and thrombus aspiration analysis to demonstrate – *in vivo* – different mechanisms of this phenomenon: positive remodelling up to aneurysm formation, uncovered stent struts, aggressive restenosis and hypersensitivity reactions. In line with this last author, Alfonso et al documented 1.25% of cases of coronary aneurysms during systemic angiographic follow-up in 1,197 patients treated with DES. There were significantly more adverse events in these patients indicating that these patients need a careful follow-up. Unfortunately, at present, it is unclear how to follow or treat these patients.

Timing of adjunctive anti-thrombotic therapy in ST elevation MI remains an important issue. The On-Time 2 study (Van 't Hof et al) tested the impact of pre-hospital administration of a glycoprotein IIb/IIIa inhibitor (high-dose tirofiban) or placebo in MI patients treated with aspirin and 600 mg clopidogrel. There was improved resolution of ST segment elevation (primary endpoint) and the frequency of aborted infarction was increased (odds ratio 1.38, p=0.04). The combined incidence of death/re-MI/urgent TVR/stroke/major bleeding (net clinical outcome) at 30 days was 8.0% in the tirofiban group as compared to 11.6% in the no-tirofiban group (p=0.024). Interestingly, the benefits were especially marked in those presenting within seventy-five minutes of symptom onset. The study is not definitive, in part because it is a pooled analysis of two study phases, but it does raise important questions about the timing of adjunctive anti-thrombotic therapy in ST elevation MI.

In the same context of acute myocardial infarction, Montalescot et al

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presented a sub-analysis of the TRITON-TIMI 38 trial of 3,534 STEMI patients treated with clopidogrel or prasugrel for primary or secondary PCI. Compared with clopidogrel, the composite endpoint of cardiovascular (CV) death, MI or stroke at 15 months was significantly reduced with prasugrel (12.4% vs 10.0%, P=0.02). There was no significant difference between prasugrel and clopidogrel for non-CABG related TIMI major haemorrhage, nor for minor bleeding. Valgimigli et al, reported on the optimal antithrombotic strategy in elective PCI. Enrolled in their multicentre study 3T/2R were 263 patients (out of 1,277 initially screened) who were poor responders to aspirin and/or clopidogrel, based on a point-of-care assay and who underwent PCI for stable or low-risk unstable coronary artery disease. Patients were randomly assigned in a double blind manner to receive either high-dose bolus (HDB) tirofiban or placebo on top of standard aspirin and clopidogrel therapy. Periprocedural myocardial infarction (troponin release > 3 times upper limit of normal) occurred in 20.4 percent of patients treated with HDB tirofiban, compared to 35.1 percent of patient treated with placebo (p=0.009), without increase in bleeding. Gp IIB/IIIA inhibitors are of course already part of the recommended medication during PCI and questions also arose if the antiplatelet assay used was the optimal one.

In the growing field of percutaneous aortic valve implantation, a consensus session was held by both cardiologists and surgeons (De Jaegere, Vahanian, Walther, Nataf et al). It was stated that after more than 2,500 implants worldwide little doubt remained about feasibility. Due to scattered data, questions remained about safety. Procedural mortality was around 10 to 15% in most series. Better patient selection, technical refinements in the field of valve devices and imaging and continuing collaboration were key messages of a rather positive and hopeful session.

The SYNTAX trial was the major study presented at this year's congress. Patients with multivessel coronary artery disease were evaluated by both an interventional cardiologist and heart surgeon for the amenability of both revascularisation strategies. If yes, they were randomised to CABG or multivessel PCI with TAXUS stents. If not, patients were followed up in a CABG or PCI registry. This multicentre trial in 85 European and US sites was characterised by very few exclusion criteria: previous or planned cardiac interventions and/or acute myocardial infarction. In addition to the classical surgical EuroSCORE the investigators had developed a PCI risk score called SYNTAX score. The role of this purely anatomical score will be further investigated in the future. At the meeting, the primary endpoint (adverse events being a composite of all cause death, myocardial infarction, CVA and repeat intervention at one year) as well as the registry results were presented (Serruys et al). At one year, adverse events were as follows: CABG 12.1%, PCI 17.8%, p=0.0015. In terms of overall safety (death, CVA, myocardial infarction), there was no difference: CABG 7.7%, PCI 7.6%, p=0.98. Therefore, the difference in the primary endpoint was mainly driven by a higher need for reintervention in the PCI group: CABG 5.9%, PCI 13.7%, p<0.0001. Further analysis indicated a higher incidence of CVA in the CABG group: CABG 2.2%, PCI 0.6%, p<0.003. Symptomatic graft occlusion (3.4%) and stent thrombosis (3.3%) were similar, p=0.89. Interestingly, a subgroup analysis in 138 patients with left main disease and additional single vessel involvement showed no difference in primary endpoint at one year. Finally, the CABG registry showed comparable adverse event rates at one year (8.8%), despite the presence of a much higher SYNTAX score (37.8±13.3 vs 29.1±1.4 for the randomised CABG patients) (Mohr et al). The key-messages from SYNTAX as they were reported from the investigators and discussants were therefore: 1) equal safety of both revascularisation procedures; 2) significant difference in the primary endpoint driven by a higher need for reintervention in the PCI group; 3) lesion complexity, as assessed by the SYNTAX score, should guide the cardiologist - surgeon team in terms of the optimal revascularisation strategy as this score has no impact on adverse outcome after CABG.

The CARDIA trial randomised 510 diabetics with multivessel disease (excluding left mains) to PCI or CABG (Kapur). The primary endpoint was a composite similar to SYNTAX but excluding the need for reintervention. At one year, there was no difference in terms of death, myocardial infarction and stroke (CABG 10.2% vs PCI 11.6%, p=0.63). However, there was again a higher need for intervention with PCI (CABG 2.0% vs PCI 9.9%, p=0.001). CARDIA refined the previous conclusions of SYNTAX on the safety of both PCI and CABG to diabetics specifically. Further follow-up will be essential to maintain these conclusions.

Finally, the LEADERS trial (Windecker et al) investigated the role of new stent technology (biodegradable polymer [within six to nine months] with biolimus on top). A total of 1,707 "all comers" patients were randomised to this stent vs a classical sirolimus eluting stent. At nine months there was no difference in the primary endpoint of death, myocardial infarction and need for reintervention (biolimus: 9.2% vs sirolimus: 10.5%, p=0.88). This study demonstrates efficacy at nine months, as well as safety expected to be maintained because of the principle of a drug eluting stent turning into "bare metal" after six to nine months. However, long-term follow-up will be crucial to confirm this hypothesis.