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## **Major infections after PCI or surgery, drug-coated balloons in NSTEMI, left atrial appendage closure versus direct oral anticoagulants, TAVI in nonagenarians, and “CAVI”**

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“In April sleep is sweet”, as they say in Italy. Well, this is very subjective, and certainly not true for EuroIntervention, which is always in motion. Indeed, our Editorial Board is truly global, meaning that, even when someone is (sweetly) sleeping in one continent, someone else is actively working for the Journal in another time zone. This month we have as usual many new original articles to share, starting with the section on coronary interventions.

You are probably aware of the social media debate around the 5-year outcomes of the EXCEL trial, the latest large randomised study comparing PCI and CABG in patients with left main coronary artery disease. In the NEJM report, a statistically significant difference in all-cause death was reported at 5 years, driven by non-cardiovascular mortality, including death attributable to cancer and infections. It is always puzzling to comment on mortality in PCI trials, when differences are not due to cardiovascular causes and are difficult to explain mechanistically. However, dismissing differences in death due to infection in the PCI arm might be simplistic – as noted by a cardiac surgeon I was speaking to some months ago – because “the sterility of the two procedures is dramatically different”. Maybe, or maybe not. Anyway, I found the observation both interesting and unexpected. In this context, the study from **Massimo Mancone**,

**Patrick W. Serruys and colleagues** reports on the 5-year incidence of major infections in the 1,800 patients randomised to PCI or CABG in the SYNTAX trial. A notable finding of the study is the significant 2.6-fold association of major infections with all-cause death. I will let the readership discover the results in the two arms for themselves. The study is accompanied by an editorial from **Sripal Bangalore**.

We are also pleased to host the primary report of the PEPCAD NSTEMI trial, by **Bruno Scheller, Bernward Lauer and colleagues**. The trial randomised 210 patients with NSTEMI to drug-coated balloon (with bail-out stenting in 15% of cases) or stent (bare metal stents in 56% of cases) treatment. The included patients had an identifiable culprit lesion without angiographic evidence of large thrombus. The primary endpoint, target lesion failure at 9 months, occurred in 3.8% of patients treated with drug-coated balloons and 6.6% of patients treated with stents ( $p=0.53$ ); non-significant numerical reductions were noted in the composite of major adverse cardiac events with drug-coated balloons ( $p=0.056$  in the per protocol analysis). Read the accompanying editorial by **Fernando Alfonso** for more reflections on the strengths and limitations of this study in the current landscape of treatment options for NSTEMI.

Data on left atrial appendage occlusion are accumulating and there is interest in the results of ongoing randomised trials versus the most logical contemporary control group, non-vitamin K antagonist oral anticoagulants. Meanwhile, observational studies are informative, including the comparative, hypothesis-generating report of 382 patients at high bleeding risk from **Cosmo Godino, Matteo Montorfano and colleagues**, using propensity score matching for statistical adjustment of baseline confounders. The study is accompanied by an editorial from **David Holmes**.

Let's now move to the section on interventions for valvular heart disease and heart failure. With multiple positive studies of TAVI in patients across different strata of surgical risk, there is some suggestion that a key determinant of treatment selection for TAVI or surgery in the near future will be age. When is a patient too young for TAVI (and for receiving a bioprosthesis, either surgical or transcatheter, but this is another story)? An interesting question, but equally important is the specular question at the other end of the spectrum: when is a patient too old for TAVI? A study from **Pierre Deharo, Laurent Fauchier and**

**colleagues** reports on the outcomes of TAVI in 71,095 nonagenarians from the French nationwide registry. These patients were compared with matched patients with aortic stenosis on medical therapy and further compared with younger patients undergoing TAVI. With such a large sample size, this study was well suited for the search of predictors of adverse clinical outcomes and – possibly – futility. The study is accompanied by an editorial from **Eberhard Grube**. Also dealing with risk stratification, the second study on TAVI in this issue is a systematic review and meta-analysis from **Tariq Jamal Siddiqi, Deepak L. Bhatt and colleagues** on the performance of current risk models for predicting short-term mortality after the procedure. The authors looked at the performance of 11 models in terms of discrimination and observed/expected ratios, pooling 68,215 patients from 24 studies. In all cases, the discriminatory ability was suboptimal, but some TAVI-specific models were more reliable than other TAVI-adapted surgical models. The STS/ACC TVT model (in-hospital and 30-day) and the STS model emerged as the most calibrated, which make them useful for comparison of centre-level risk-adjusted mortality.

From the aortic valve, let's now move the spotlight to the tricuspid. **Henryk Dreger, Michael Laule and colleagues** report the results of the TRICAVAL trial, a study comparing the implantation of a balloon-expandable transcatheter valve into the inferior vena cava (CAVI) versus medical therapy in patients with severe tricuspid regurgitation. The study is small (N=28) and was stopped prematurely for safety reasons, including an unexpectedly high rate of valve dislocations leading to open heart surgery. The report we are publishing is very informative, with a primary endpoint of maximal oxygen uptake three months after randomisation, and multiple secondary endpoints including six-minute walk test, NYHA class, NT-proBNP levels, unscheduled hospitalisation for heart failure progression, and quality of life. The tricuspid valve is certainly not forgotten in this issue, where another study from **Mohamad Alkhoul, Sorin V. Pislaru and colleagues** illustrates the possible complementary roles of intracardiac and transoesophageal echocardiography in guiding transcatheter tricuspid interventions.

That's it for this month. We hope you will enjoy this April issue. Please do not hesitate to let us know your opinion, suggestions and reactions, on the website or through social media, to what you read here.