INTERVENTIONAL CARDIOLOGY

The importance of patient-related factors on PCI outcomes

Patient-related factors, such as comorbidities and overall severity of coronary artery disease (CAD), might be more important determinants of the outcome of percutaneous coronary intervention (PCI) with second-generation drug-eluting stents (DES) than intrinsic stent characteristics. This hypothesis has been generated by the findings of the 2-year follow-up of the Resolute All Comers trial, published in the *Lancet*.

The Resolute All Comers trial included patients with chronic stable angina or acute coronary syndromes enrolled between April and October 2008 at 17 centres in Europe and Israel. The trial was designed to compare the efficacy of two types of new-generation stents, the Resolute® zotarolimus-eluting stent (Medtronic, Santa Rosa, CA, USA) and the Xience V® everolimus-eluting stent (Abbott Vascular, Santa Clara, CA, USA). Importantly, early trials of new-generation DES were conducted in patient populations that are atypical of those found in clinical practice, as these studies excluded individuals with complex and/or severe CAD and comorbidities such as diabetes mellitus and renal failure. In line with the opinion of an FDA panel, which recommended that trials of DES include a more representative range of patients, the researchers of the Resolute All Comers trial did not apply any restrictions to patient enrolment, with the exception of medication intolerance, allergies to stent components, and need for surgery within the first 6 months after PCI. Among 2,292 patients initially enrolled, 1,140 were randomly assigned to receive the zotarolimus-eluting stent and 1,152 to receive the everolimus-eluting stent. The 1-year follow-up results of the trial have been previously published.

Obtaining long-term follow-up information on the outcomes of DES

implantation is important, particularly owing to concerns about the rate of late-stent thrombosis. The new study by the Resolute All Comers investigators corroborates the researchers' earlier findings by showing that the efficacy and safety of the two types of stents continues to be similar 2 years after PCI. This similarity was observed in the frequency of the patient-related (all-cause death, myocardial infarction, and revascularization) and stent-related (target-lesion failure, including cardiac-related death, target-vessel myocardial infarction, and ischemia-driven target-lesion revascularization) efficacy end points, and also in the rate of very-late stent thrombosis (safety end point). "Data for long-term safety and efficacy of new-generation DES in patients treated in routine clinical practice for 'off-label' indications, including higher-risk lesion subsets, are limited," points out Professor Seung-Jung Park, from the Asan Medical Center, Seoul, South Korea, who was not involved in the study.

The data also indicate that patient-related adverse events might be much more frequent than stent-related events in patients undergoing PCI with second-generation DES. Among the 1,121 patients who received the zotarolimus-eluting stent and who completed the 2-year follow-up, 231 (20.6%) experienced the patient-related end point, whereas 126 (11.2%) experienced the stent-related end point. Among the 1,128 patients with the everolimus-eluting stent who were seen at follow-up, these numbers were 231 (20.5%) and 121 (10.7%), respectively. Thus, the frequency of adverse events related to the general health status of patients was almost double the frequency of events related to the stents themselves. "This trial is very valuable and informative to provide [data about] both patient-related

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and stent-related events in the concept of [a] total patient care approach," comments Professor Park.

The researchers acknowledge that the comparisons between stent-related and patient-related outcomes are hypothesis-generating and were not prespecified. However, they believe that the results show that "optimization of secondary prevention and overall medical management during long-term follow-up seems to be more important than the initial choice between advanced, new-generation DES".

Professor Park agrees with the importance of secondary prevention in these patients. "With improving PCI technology afforded by new DES technologies and acute pharmacologic therapy, chronic optimal medical therapy and concomitant lifestyle care (exercise, diet, smoking cessation, etc.) are critically important for best care of patient with CAD treated with stent devices."

The researchers plan to continue to monitor the trial population and provide yearly reports on clinical outcomes. The results of the 5-year follow-up of the trial are expected in January 2014.

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Original article Silber, S. *et al.* Unrestricted randomised use of two new generation drug-eluting coronary stents: 2-year patient-related versus stent-related outcomes from the RESOLUTE All Comers trial. *Lancet* 377, 1241–1247 (2011)