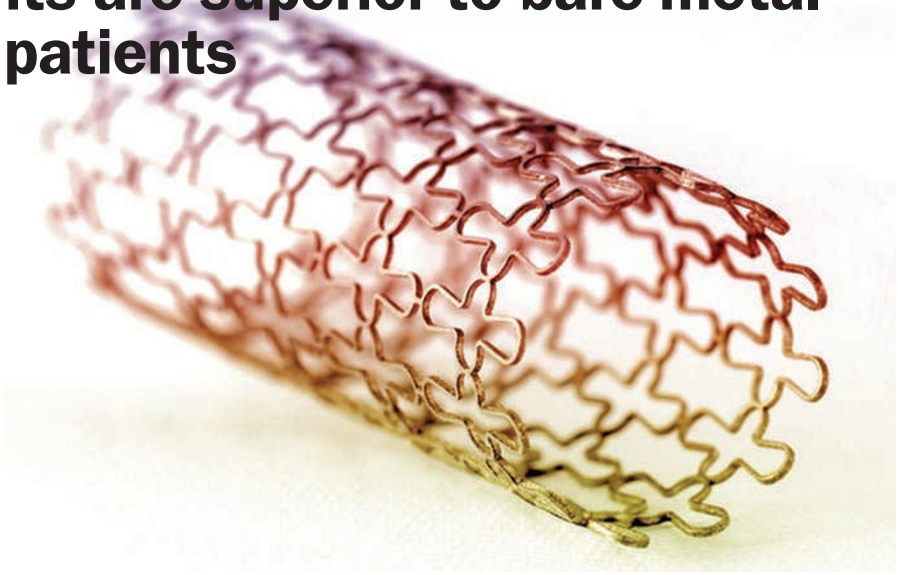
INTERVENTIONAL CARDIOLOGY

Drug-eluting stents are superior to bare-metal stents in elderly patients



The first drug-eluting stents (DESs) were approved by the FDA in 2003, after they were shown to significantly reduce rates of restenosis and repeat revascularization, when compared with bare-metal stents (BMSs), in patients undergoing percutaneous coronary intervention. Use of these stents rapidly became widespread in clinical practice. However, reports of safety concerns with DESs led Pamela Douglas and colleagues to initiate a study comparing long-term outcomes in older patients (≥65 years) undergoing percutaneous coronary intervention with DES or BMS implantation. The results of their analysis have now been published in the *Journal of the American College of Cardiology*, and show that rates of death and myocardial infarction were greatly reduced among patients who received DESs. "This was a surprise," explains Professor Douglas, as "we were expecting them to be similar or only slightly improved in DESs."

In this observational study, data from the ACC National Cardiovascular Data Registry and the US Medicare national claims database were linked to provide the largest ever contemporary, 'real-world' cohort of patients aged 65 years or over undergoing stent implantation. "The rarity of late DES complications means that extremely large sample sizes are required to clarify their frequency," write the authors, highlighting the importance of the very high number of patients in their study. The researchers also emphasize that these data are nationally representative, being sourced from 650 urban, surburban, and rural treatment centers across all regions of the continental US.

Between January 2004 and December 2006, 45,025 patients received at least one BMS and 217,675 patients received one or more DESs (46% sirolimus-eluting and 54% paclitaxel-eutling). Patients with both types of stent were excluded. There were significant differences in baseline characteristics between the two groups; congestive heart failure and hypertension were more common among patients who received DESs, whereas the incidence of peripheral vascular disease, stroke, and preprocedural shock was greater among those who received BMSs. However, these differences were reduced after propensity score adjustment. Over the course of the 30 month study, 21,254 patients (8.1%) died. Mortality was significantly higher in patients with BMSs than in those with DESs, both in the first 6 months after percutaneous coronary intervention and during the follow-up period. This reduction in mortality was recorded across all subgroups of patients. The investigators noted that patients who underwent DES implantation in 2005 and 2006 had even higher relative survival rates than those whose procedure was performed in 2004. Benefits for DESs were also found in terms of myocardial infarction, with a 26% relative reduction when compared with BMS implantation. The number of repeat revascularizations was also lower for DESs, although the difference between the two stent types was small after adjustment for covariates including ethnicity, age over 75 years, diabetes status, multivessel disease, prior myocardial infarction, prior revascularization, and the year that the stents were implanted. The authors cautioned that, because they did not differentiate between target-lesion and non-target-lesion revascularization, the results for this outcome should be interpreted with care. Importantly, the number of strokes and major bleeding events was low, with minimal differences between the DES group and the BMS group.

Encouraged by the results of this research, the investigators now plan to conduct additional analyses on these data to determine outcomes in clinical subgroups including the very elderly, ethnic minorities, women, and patients receiving stents for off-label indications. "The methodological implications are huge," says Professor Douglas. "Linkage of the ACC National Cardiovascular Data Registry with the Society of Cardiac Surgeons [database] and Medicare claims data is now underway to develop a national data set across all forms of cardiovascular care. This model opens the door to all sorts of comparative effectiveness research."

Alexandra King

Original article Douglas, P. S. *et al.* Clinical effectiveness of coronary stents in elderly persons: results from 262,700 Medicare patients in the American College of Cardiology National Cardiovascular Data Registry. *J. Am. Coll. Cardiol.* **53**, 1629–1641 (2009).