Use of newer-generation drug-releasing stent results in lower rate of adverse cardiac events

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Compared with a bare-metal stent, the use of a stent with a biodegradable polymer that releases the drug biolimus resulted in a lower rate of major adverse cardiac events at 1 year among patients with ST-segment elevation myocardial infarction (STEMI; a certain pattern on an electrocardiogram following a heart attack) undergoing primary percutaneous coronary intervention (PCI; procedures such as balloon angioplasty or stent placement used to open narrowed coronary arteries), according to a study in the August 22/29 issue of *JAMA*.

"The efficacy and safety of drug-eluting [releasing] stents compared with bare-metal stents remains controversial in patients with STEMI undergoing primary PCI," according to background information in the article. "Early generation drug-eluting stents releasing sirolimus or paclitaxel from durable polymers reduce the need for repeat revascularization compared with bare-metal stents. However, vessel healing is delayed with evidence of chronic inflammation related at least in part to the persistence of durable polymer components in patients with acute STEMI. … Newer-generation drug-eluting stents with biodegradable polymers provide controlled drug release with subsequent degradation of the polymer rendering the stent surface more closely to a bare-metal stent after the period of biodegradation."

Lorenz Räber, M.D., of Bern University Hospital, Bern, Switzerland, and colleagues compared the efficacy and safety of stents eluting biolimus from a biodegradable polymer with bare-metal stents of otherwise identical design. The randomized controlled trial included 1,161 patients with STEMI at 11 sites in Europe and Israel between September 2009 and January 2011. Clinical follow-up was performed at 1 and 12 months. Patients were randomized to receive the biolimus-eluting stent (n = 575) or the bare-metal stent (n = 582). The primary outcome measured for the study was the rate of major adverse cardiac events, a composite of cardiac death, target vessel-related reinfarction, and ischemia-driven target-lesion revascularization at 1 year. The average age of patients was 61 years and 79 percent were men.

The researchers found that at one year, the primary end point of major adverse cardiac events occurred in 4.3 percent of patients receiving biolimus-eluting stents and 8.7 percent of patients receiving bare-metal stents, which is a significant 4.4 percent absolute reduction and 51 percent relative reduction in the risk of major adverse cardiac events (and the prevention of 42 events per 1,000 patients treated with biolimus-eluting stents compared with bare-metal stents at 1 year). "For cardiac death alone, the percentages were smaller [(2.9 percent vs. 3.5 percent, respectively]. The treatment effect in favor of patients receiving biolimus-eluting stents was attributable to both a lower risk of target vessel-related reinfarction (0.5 percent vs. 2.7 percent) and ischemia-driven target-lesion revascularization (1.6 percent vs. 5.7 percent)." At 1 year, rates of definite stent thrombosis amounted to 0.9 percent among patients receiving biolimus-eluting stents and 2.1 percent among patients receiving bare-metal stents.

The authors also observed no differences in all-cause and cardiac mortality between the groups at 1 year. "In addition to the device-oriented primary outcome measure, we recorded a lower risk of the comprehensive patient-oriented composite of death, any reinfarction, and any revascularization in favor of biolimus-eluting stents (8.4 percent vs. 12.2 percent)."

"… our results suggest better clinical

outcomes in terms of major adverse cardiac events of a stent releasing biolimus from a biodegradable polymer compared with a bare-metal stent for the treatment of patients with STEMI."

In an accompanying editorial, Salvatore Cassese, M.D., and Adnan Kastrati, M.D., of the Technische Universitat, Munich, Germany, write that the findings from this study (COMFORTABLE AMI) and from a series of previous trials on drug-eluting stents (DESs) in patients with heart attack provide several important lessons.

"First, the efficacy of DESs vs. bare-metal stents (BMSs) in STEMI is already established and, therefore, further studies comparing these interventions might not be needed. Second, concerns about a possible very late safety issue with DESs are apparently DES-type specific, mostly related to first-generation DESs and less justified with newer DESs. Larger randomized trials with longer follow-up and head-to-head comparisons of the available DES technologies are, however, required to completely eliminate these concerns. These studies should also take broader advantage of intravascular imaging technologies to provide mechanistic insights into the clinical findings. Third, although there is almost no rationale for performing DES vs. BMS studies anymore, it might be conceivable to expect studies that test the hypothesis of noninferiority of new, improved BMSs to available DESs. Until then, recent studies such as the COMFORTABLE AMI trial should make cardiologists feel more comfortable with the use of new-generation DESs in patients with STEMI."

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