

 INTERVENTIONAL CARDIOLOGY

Drug-eluting or bare-metal stents?

“The results of this trial should increase confidence in choosing to implant bare-metal stents in selected patients **”**

Patients receiving newer-generation drug-eluting stents have similar rates of death or spontaneous myocardial infarction than those receiving contemporary bare-metal stents, but the rate of repeat revascularization is lower with the use of drug-eluting stents. These findings come from the NORSTENT trial that was presented at the ESC Congress 2016 in Rome, Italy, and simultaneously published in *The New England Journal of Medicine*. “The study was conducted in the setting of real-world patient care, which supports the generalizability of the results,” highlight the NORSTENT investigators.

Previous studies had shown that drug-eluting stents were more effective in the prevention of restenosis than bare-metal stents. However, new bare-metal stents have been developed with improved stent design, different metal composition, and thinner struts. In addition, newer-generation drug-eluting stents might reduce the rate of stent thrombosis, myocardial infarction, and death compared with first-generation devices. However, the trials comparing the newer drug-eluting stents with contemporary bare-metal stents so far have

had limited generalizability and statistical power.

Bønaa and colleagues designed the multicentre, randomized NORSTENT trial to compare the long-term effectiveness of second-generation drug-eluting stents with newer-generation bare-metal stents. Eric Bates (University of Michigan Medical Center, USA) points out in an accompanying editorial that the NORSTENT trial was pragmatic, very inclusive, properly powered, inexpensive, and not sponsored by industry. “Each of these points makes this trial unique in coronary-stent research and sets new standards for subsequent studies,” explains Bates.

The trial included 72.5% (9,013) of all patients with stable or unstable coronary artery disease undergoing percutaneous coronary intervention who met the eligibility criteria during the 29-month enrolment period. The investigators randomly assigned the patients to receive contemporary drug-eluting stents (82.9% were everolimus-eluting stents and 13.1% zotarolimus-eluting stents) or contemporary bare-metal stents.

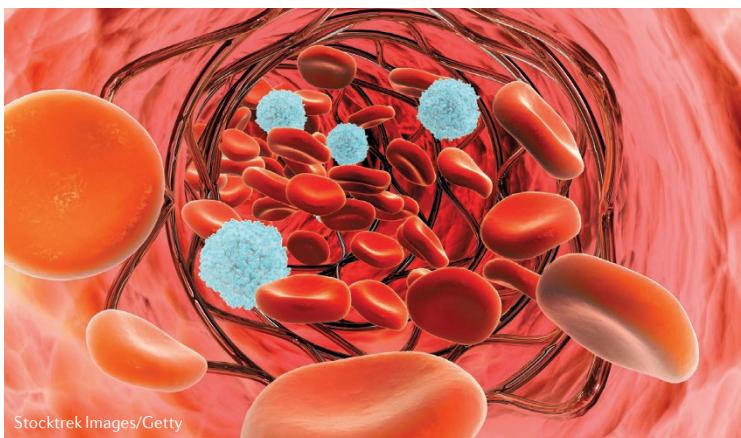
After a median of 5 years of follow-up, no significant differences

were found between the two groups for the primary composite outcome of death from any cause or nonfatal spontaneous myocardial infarction, with a cumulative rate of 16.6% in the drug-eluting stent group versus 17.1% in the bare-metal stent group (HR 0.98, 95% CI 0.88–1.09; $P=0.66$). No significant differences were detected in any of the individual end points of death from cardiac, vascular, or noncardiovascular causes, myocardial infarction, stroke, or hospitalization for unstable angina.

Newer-generation drug-eluting stents performed better than the newer-generation bare-metal stents for the secondary outcomes of repeat revascularization and stent thrombosis. The rates of any repeat revascularization were 16.5% for the drug-eluting stent group and 19.8% for the bare-metal stent group (HR 0.76, 95% CI 0.69–0.85; $P<0.001$), with rates of target-lesion revascularization of 5.3% and 10.3%, respectively ($P<0.001$). The rate of definite stent thrombosis was low in both groups, but was significantly lower in the group that received drug-eluting stents than in the bare-metal stent group (0.8% versus 1.2%; $P=0.0498$).

“The results of this important trial should increase confidence in choosing to implant bare-metal stents in selected patients if clinical indications favour that decision and should support guideline recommendations endorsing that option,” concludes Bates in his editorial.

Irene Fernández-Ruiz



ORIGINAL ARTICLE Bønaa, K. H. et al. Drug-eluting or bare-metal stents for coronary artery disease. *N. Engl. J. Med.* <http://dx.doi.org/10.1056/NEJMoa1607991> (2016)

FURTHER READING Harada, Y. & Kastrati, A. Interventional cardiology: Polymer-free drug-eluting stents — a safe and effective option for ACS. *Nat. Rev. Cardiol.* **13**, 447–448 (2016)