Real-World Use of Drug-Eluting Stents Versus Bare-Metal Stents

Abbott JD, Voss MR, Nakamura M, et al. Unrestricted use of drug-eluting stents compared with bare-metal stents in routine clinical practice: findings from the National Heart, Lung, and Blood Institute Dynamic Registry. J Am Coll Cardiol 2007;50:2029–36.

Study Overview

Objective. To evaluate the effectiveness and safety of drug-eluting stents (DES) as used in clinical practice.

Design. Prospective cohort study.

Setting and participants. 1460 patients in the National Heart, Lung, and Blood Institute Dynamic Registry enrolled in February 2004 to May 2004 who received at least 1 DES were compared with 1763 patients enrolled in October 2001 to March 2002 before the approval of DES who received at least 1 bare-metal stent (BMS).

Main outcome measures. Major adverse cardiac events, including death (all-cause mortality), myocardial infarction (MI), and any repeat revascularization, and repeat percutaneous coronary intervention (PCI) in either target or non-target vessels (composite endpoint) at 1 year. Target vessel revascularization was defined as a repeat revascularization procedure involving the initial treated artery.

Main results. At 1 year, rates of death and MI did not differ significantly between the DES and BMS groups (7.6% and 8.7%, respectively; adjusted hazard ratio [HR], 0.88 [95% confidence interval {CI}, 0.68–1.15]; $P = 0.34$). Target vessel revascularization was lower in the DES group versus BMS group (5% vs. 9.2%; $P < 0.001$). Overall repeat revascularization by PCI or coronary bypass was lower in DES patients (adjusted HR, 0.38 [95% CI, 0.25–0.60]; $P < 0.001$). Patients with both simple and complex lesions benefited from DES, with lower risk of repeat target vessel revascularization compared with BMS.

Conclusion. Generalized use of DES resulted in better outcomes compared with BMS, with fewer clinically driven revascularization procedures and similar rates of death and MI at 1 year.

Commentary

The use of DES has been one of the most confusing and controversial topics among interventional cardiologists over the past few years. The U.S. Food and Drug Administration originally approved the use of DES for previously untreated coronary lesions of less than 30 mm in length and a vessel diameter of 2.50 to 3.75 mm [1]. However, in practice, DES are often used for more complex lesions. The hope was that these more complex lesions (longer, larger, branching lesions) could be stented safely with DES and decrease the need for target vessel revascularization in these difficult lesions, which are more prone to restenosis. Currently, it is estimated that 60% of DES use is off-label for complex lesions [1]. Recent studies [2,3] have suggested that use of DES confers a higher risk of death and MI over the long term compared with BMS. In these studies, the alarming findings were attributed to differences in patient selection; specifically, patients with more complex lesions and diabetic patients were receiving DES (likely selection bias). Additionally, complexity of the lesions was not quantified.

The present study by Abbott et al used the National Heart, Lung, and Blood Institute Dynamic Registry to compare BMS with DES. Cumulative death and MI at 1 year were similar in BMS and DES groups. Target vessel revascularization at 1 year was lower in DES patients, and patients with both simple and complex lesions benefited from DES as compared with BMS.

The authors chose to address the selection bias present in previous studies by evaluating BMS patients from an earlier period when DES was not available (2001–2002 vs. 2004 for DES patients). The authors carefully chose baseline patient and lesion characteristics so that proper adjustment for these characteristics could be made. However, several factors may confound the study's findings. Because DES and BMS groups were enrolled in the Dynamic Registry at different times, secular trends may be a limitation. Rates of death from MI decreased during the study period, which is most likely due to better medication regimens. Between 2001 and 2004, institutions began to focus on quality of care, and the American College of Cardiology/American Heart Association developed and disseminated guidelines that identified optimal standards of care. Also, the optimal duration of clopidogrel use following DES was not clear in 2004. In

addition, this study only evaluated outcomes over 1 year.

Applications for Clinical Practice

In a real-world registry, DES were found to be as safe as BMS and decreased the need for revascularization in both simple and complex lesions at 1 year. Long-term, randomized controlled trials controlling for medications, types of coronary artery lesions, and stent types are needed to determine optimal indications for DES use.

—Review by Robert L. Huang, MD, MPH

References

1. Farb A, Boam AB. Stent thrombosis redux—the FDA perspective. N Engl J Med 2007;356:984–7.
2. Lagerqvist B, James SK, Stenestrand U, et al. Long-term outcomes with drug-eluting stents versus bare-metal stents in Sweden. N Engl J Med 2007;356:1009–19.
3. Camenzind E, Steg PG, Wijns W. Stent thrombosis late after implantation of first-generation drug-eluting stents: a cause for concern. Circulation 2007;115:1440–55.