

EDITORIAL



Drug-Eluting Coronary Stents — Promise and Uncertainty

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In this issue of the *Journal*, we publish five Original Articles and two Perspective articles on the subject of drug-eluting coronary stents.¹⁻⁷ Our motivation is the recent concern that the implantation of drug-eluting stents, as compared with bare-metal stents, may be associated with a small increased risk of late stent thrombosis, a potentially fatal complication (Fig. 1). At a meeting of the Circulatory System Devices Advisory Panel of the Food and Drug Administration (FDA) on December 7 and 8, 2006, presentations were made on virtually every aspect of this complex clinical problem.⁸ In order to inform the medical community, we are publishing these articles, which are representative of the presentations and discussions that took place at the panel meeting. In some cases we provide two views of the same data sets, because different investigators looked at the same data using different analytic approaches. Readers will see that the details of analysis are critical for understanding the conclusions of each of these reports.

In addition to the data reported in the Original Articles, the two Perspective articles, by Dr. Andrew Farb and Ashley Boam of the FDA Center for Devices and Radiological Health and by Dr. William Maisel, who served as chair of the Circulatory System Devices Advisory Panel, synthesize a great deal of information on both the benefits and the potential risks of drug-eluting stents. These stents were approved for use in stable patients with relatively noncomplex coronary stenoses, but they have been used in many patients whose clinical features and coronary anatomy fall outside the original specifications. Such off-label use has made assessments of stent safety beyond the setting of clinical trials considerably more challenging. There is also the important matter of adjunctive antiplatelet therapy. Although a science advisory recommending 12 months of dual

antiplatelet therapy after placement of a drug-eluting stent was published electronically in January,⁹ the optimal duration of therapy has not yet been precisely determined.

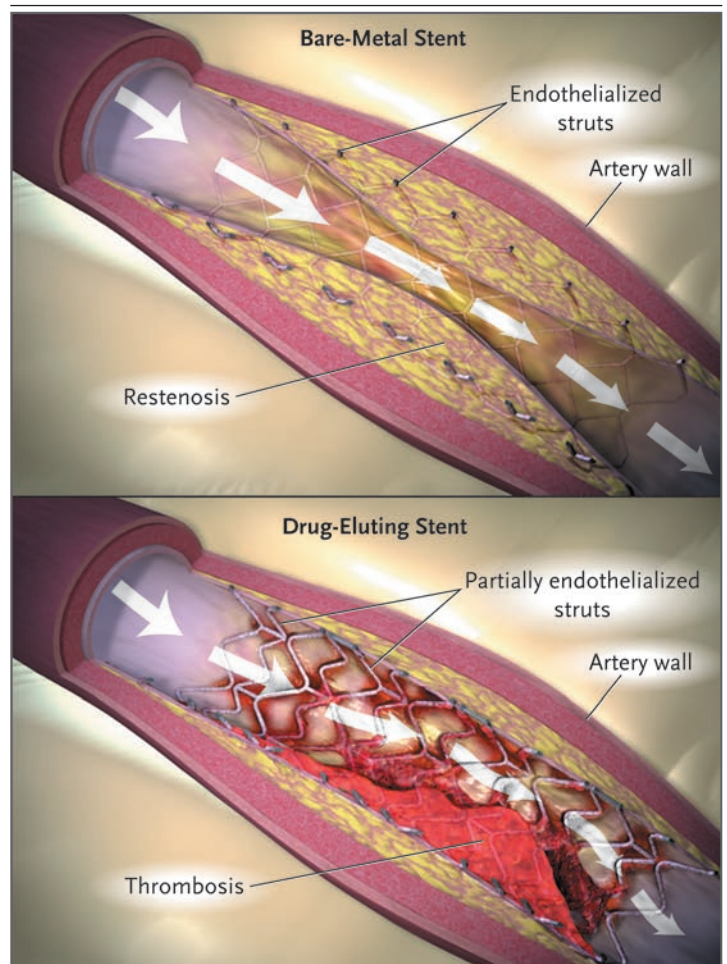


Figure 1. Potential Complications of Coronary Stenting: Restenosis in a Traditional Bare-Metal Stent and Late Thrombosis in a Drug-Eluting Stent.

Arrows indicate blood flow. An animation showing restenosis and stent thrombosis can be viewed at www.nejm.org.

Millions of patients with coronary artery disease worldwide have received coronary-artery stents, and the enormous health benefits of this technology are not in dispute. Still, when a potentially serious albeit uncommon complication such as stent thrombosis is detected, it is mandatory that everything possible be done to aggressively examine the complication, assess the risk, understand the pathophysiological characteristics, and develop preventive measures. Although not all questions have been answered and areas of uncertainty remain, the FDA acted appropriately by taking expeditious action. We understand that these matters are far from resolved, but our hope is that the articles in this issue of the *Journal* will inform the medical community and help health professionals make the best decisions for their patients.

This article (10.1056/NEJMe068306) was published at www.nejm.org on February 12, 2007.

1. Spaulding C, Daemen J, Boersma E, Cutlip DE, Serruys PW.

A pooled analysis of data comparing sirolimus-eluting stents with bare-metal stents. *N Engl J Med* 2007;356:989-97.

2. Stone GW, Moses JW, Ellis SG, et al. Safety and efficacy of sirolimus- and paclitaxel-eluting coronary stents. *N Engl J Med* 2007;356:998-1008.

3. Lagerqvist B, James SK, Stenestrand U, Lindback J, Nilsson T, Wallentin L. Long-term outcomes with drug-eluting stents versus bare-metal stents in Sweden. *N Engl J Med* 2007;356:1009-19.

4. Mauri L, Hsieh W, Massaro JM, Ho KKL, D'Agostino R, Cutlip DE. Stent thrombosis in randomized clinical trials of drug-eluting stents. *N Engl J Med* 2007;356:1020-9.

5. Kastrati A, Mehilli J, Pache J, et al. Analysis of 14 trials comparing sirolimus-eluting stents with bare-metal stents. *N Engl J Med* 2007;356:1030-9.

6. Maisel WH. Unanswered questions — drug-eluting stents and the risk of late thrombosis. *N Engl J Med* 2007;356:981-4.

7. Farb A, Boam AB. Stent thrombosis redux — the FDA perspective. *N Engl J Med* 2007;356:984-7.

8. Shuchman M. Debating the risks of drug-eluting stents. *N Engl J Med* 2007;356:325-8.

9. Grines CL, Bonow RO, Casey DE Jr, et al. Prevention of premature discontinuation of dual antiplatelet therapy in patients with coronary artery stents: a science advisory from the American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association, with representation from the American College of Physicians. *Circulation* (in press).

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