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EDITORIAL COMMENT

The Bioresorbable Drug-Eluting Coronary Stent

The Price Is Right?*

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This year of 2017 will mark the 40th anniversary of the first percutaneous coronary intervention (PCI), performed by Andreas Gruentzig in Zurich, Switzerland, on September 16, 1977 (1). Since that "game-changing" event, the technology of PCI has evolved in a spectacular fashion. Dr. Gruentzig would be pleased.

The original "balloon" angioplasty involved the dilatation of an obstructive atherosclerotic coronary plaque. No foreign body was left behind. It was theorized that the coronary plaque would "remodel" and be resorbed by the "natural" body healing process. However, there was a high risk for acute coronary dissection and occlusion and the late-term effects of a significantly high restenosis rate. In retrospect, it is a wonder that the majority of balloon-treated coronary obstructions resolved at all.

The evolution of the balloon-delivered bare-metal intracoronary stent to stabilize the vessel, and the subsequent development of drug-eluting stents to reduce restenosis through a mechanism of preventing hyperproliferation, were major breakthroughs. But the potential downside was to leave a metal foreign body permanently in the coronary lumen. The "holy grail" of the past 2 decades has been to develop a fully bioresorbable drug-eluting stent that would treat the plaque and coronary lumen without inflicting a permanent foreign body in the coronary artery.

The ABSORB II trial 1-year analysis set the mark for the safety and efficacy of the Abbott Vascular bioresorbable everolimus-eluting stent compared with conventional permanent polymer drug-eluting stents (2). The Absorb stent was quickly adopted in Europe. The robust ABSORB III trial again reaffirmed the safety and efficacy of the bioresorbable platform (3) and led to Food and Drug Administration approval in the United States. But questions still remain about extended long-term outcomes. In addition, there is the major question of whether the cost of this innovative new technology is worth the benefit.

The study by Baron et al. (4) reported in this issue of *JACC: Cardiovascular Interventions* is an economic substudy of the ABSORB III trial. Their study was based on accepted economic analyses that have been developed by the Mid America Heart Institute (5). The investigators, in particular the senior investigator, Dr. David Cohen, are highly respected interventional cardiology economic authorities.

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The investigators performed a prospective health economic study alongside the ABSORB III trial, in which patients with stable or unstable angina were randomized to receive the ABSORB (bioresorbable) stent (n = 1,322) or the conventional XIENCE (metal drug-eluting) stent (n = 686). Resource utilization data were collected for 1 year of follow-up. Costs were assessed using hospitalization "bottom-up" and "top-down" methods, resource-based accounting for procedures, Medicare Provider and Analysis Review data for other index hospitalization costs, and Medicare reimbursements for follow-up costs and physician fees.

Baron et al. (4) report that initial procedural costs were higher with the Absorb stent than the XIENCE stent ($6,316 ± 1,892 vs. $6,103 ± 1,895, p = 0.02). This difference was driven mainly by greater balloon

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catheter use for pre- and post-dilatation in the Absorb stent group. In addition, there was a higher cost of the Absorb stent (assumed to be $100 more than XIENCE). However, index hospitalization costs for Absorb versus XIENCE ($15,035 ± 2,992 vs. $14,903 ± 3,449; p = 0.37) and total 1-year costs ($17,848 ± 6,110 vs. $17,498 ± 7,411; p = 0.29) were similar between the 2 groups.

The investigators conclude that although initial procedural costs were higher with the Absorb stent, there were no significant differences in total 1-year health care costs between the 2 cohorts. The investigators recommend longer term follow-up to determine whether meaningful cost savings emerge after the potential theoretical benefits of scaffold resorption with the Absorb stent.

This is a well-designed classic economic analysis. One could quibble that the cost of the Absorb stent would be only $100 more than the current XIENCE stent. The calculated assumption seems extremely optimistic and rather low. This could really skew the economic analysis to be more favorable to the Absorb stent than what may occur in the real world. However, Baron et al. (4) have appropriately addressed this issue in their sensitivity analysis in Figure 3 and in their discussion. Nevertheless, the price of the Absorb stent could vary significantly from 1 institution to another depending on preferred vendor status and global contracts.

There are some worries to darken the horizon of the Absorb stent that could affect long-term cost-effectiveness. The recently published 3-year follow-up of the ABSORB II study found a higher late stent thrombosis rate and repeat PCI intervention (6). In addition, the theoretical advantage of restoring coronary vasoreactivity with a fully resorbable stent compared with a stiff permanent metal stent was not found. The fact that the Absorb stent was generally used in straightforward noncomplex stenoses is also disturbing.

Another issue that could increase cost and morbidity is the duration of dual antiplatelet therapy (DAPT). On the basis of the long-term findings of the ABSORB II study, the tendency may be to keep patients with Absorb stents on longer DAPT. With the recently revised guidelines of DAPT therapy (7), there is a push to shorten rather than lengthen the duration.

The bigger issue is whether the present or future generations of the Absorb stent could be true "workhorse" stents. There is a price to pay for having limited ordnance on the catheterization laboratory shelf and the decision process of when and where to use a bioresorbable stent. The current third generations of conventional drug-eluting fixed polymer on a metal stent frame serve well as workhorse devices. In addition, the recently developed Synergy stent (Boston Scientific, Natick, Massachusetts) combines the tensile strength and maneuverability of a conventional metal stent with 1-direction abluminal absorption of a polymer infused with everolimus. Results from the published EVOLVE-II 1-year follow-up and presented 2-year follow-up are promising (8). There is now an EVOLVE short-DAPT study under way to assess whether a 3-month duration of DAPT with the Synergy stent is safe and effective.

In conclusion, one must put into perspective that the Absorb stent is a first-generation bioresorbable scaffold that is still significantly evolving and improving. The theoretical concept is sound. Long-term findings from the ABSORB III and ABSORB IV studies will be crucial. Dr. Baron and her colleagues at the Mid America Heart Institute, especially Dr. Cohen, should be commended for reflecting due economic diligence on how to measure the cost to the patient and to society of this new and promising bioresorbable stent technology—and other PCI technologies to come. Yes, indeed, Dr. Gruentzig would be pleased.

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