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Economic Outcomes of Bioresorbable Vascular Scaffolds Versus Everolimus-Eluting Stents in Patients Undergoing Percutaneous Coronary Intervention

1-Year Results From the ABSORB III Trial

Suzanne J. Baron, MD, MSc,[a] Yang Lei, MS,[a] Khaja Chinnakondepalli, MS,[a] Katherine Vilain, MS,[a] Elizabeth A. Magnuson, ScD,[a] Dean J. Kereiakes, MD,[b] Stephen G. Ellis, MD,[c] Gregg W. Stone, MD,[d] David J. Cohen, MD, MSc,[a] on behalf of the ABSORB III Investigators

ABSTRACT

OBJECTIVES The purpose of this study was to evaluate the economic impact of the Absorb bioresorbable vascular scaffold compared with the Xience everolimus-eluting stent in patients undergoing percutaneous coronary intervention.

BACKGROUND The ABSORB III trial (Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease) demonstrated that the Absorb scaffold was noninferior to the Xience stent with respect to target lesion failure at 1 year. Whether health care costs differ between the Absorb scaffold and the Xience stent is unknown.

METHODS We performed a prospective health economic study alongside the ABSORB III trial, in which patients undergoing percutaneous coronary intervention for stable or unstable angina were randomized to receive the Absorb scaffold (n = 1,322) or Xience stent (n = 686). Resource use data were collected through 1 year of follow-up. Costs were assessed using resource-based accounting (for procedures), MedPAR data (for other index hospitalization costs), and Medicare reimbursements (for follow-up costs and physician fees).

RESULTS Initial procedural costs were higher with the Absorb scaffold than the Xience stent ($6,316 ± 1,892 vs. $6,103 ± 1,895; p = 0.02), driven mainly by greater balloon catheter use and the higher cost of the scaffold in the Absorb group. Nonetheless, index hospitalization costs ($15,035 ± 2,992 for Absorb vs. $14,903 ± 3,449 for Xience; p = 0.37) and total 1-year costs ($17,848 ± 6,110 for Absorb vs. $17,498 ± 7,411 for Xience; p = 0.29) were similar between the 2 groups.

CONCLUSIONS Although initial procedural costs were higher with the Absorb scaffold, there were no differences in total 1-year health care costs between the 2 cohorts. Longer term follow-up is needed to determine whether meaningful cost savings emerge after scaffold resorption. (A Clinical Evaluation of Absorb™ BVS, the Everolimus-Eluting Bioresorbable Vascular Scaffold in the Treatment of Subjects With de Novo Native Coronary Artery Lesions; NCT01751906) (J Am Coll Cardiol Intv 2017;10:774–82) © 2017 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

From the [a]Saint Luke's Mid America Heart Institute, University of Missouri-Kansas City School of Medicine, Kansas City, Missouri; [b]Christ Hospital Heart and Vascular Center and The Lindner Research Center, Cincinnati, Ohio; [c]Cleveland Clinic, Cleveland, Ohio; and the [d]New York-Presbyterian Hospital, Columbia University Medical Center and the Cardiovascular Research Foundation, New York, New York. The ABSORB III clinical trial and economic substudy were funded by a research grant from Abbott Vascular. Dr. Baron has received speaker honoraria and consulting income from Edwards Lifesciences; and consulting income from St. Jude Medical. Dr. Magnuson has received research grant support from Abbott Vascular, AstraZeneca, Boston Scientific, Daiichi-Sankyo, Edwards Lifesciences, Eli Lilly, and Medtronic. Dr. Kereiakes has received consulting income from Abbott Vascular, Boston Scientific, and Sanofi. Dr. Ellis has received consulting income from Abbott Vascular, Boston Scientific, and Medtronic.

Since their introduction more than a decade ago, drug-eluting stents (DES) have been the dominant device used in percutaneous coronary revascularization. In recent years, first-generation DES have been supplanted by second-generation DES due to their improved efficacy and safety, both acutely and in the long term (1,2). Nonetheless, even current generation DES are limited by late adverse events, including stent thrombosis and restenosis (3–5). It has been hypothesized that these suboptimal long-term outcomes may be related to effects caused by the permanent implantation of metal and polymers in the vessel wall, including inflammation, endothelial dysfunction, ongoing tissue growth within the stent frame, and neoatherosclerosis (6,7). To reduce these late clinical consequences, fully bioresorbable stents that also elute antiproliferative drugs were developed.

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The Absorb bioresorbable vascular scaffold (Abbott Vascular, Abbott Park, Illinois) consists of a 150-μm-thick bioresorbable poly(L-lactide) scaffold with an everolimus-eluting 7-μm-thick bioresorbable poly(D, L-lactide) coating. Although several modest sized trials have compared the angiographic and mechanistic performance of the Absorb scaffold with standard DES, only recently has this device been tested in a large clinical trial that was appropriately powered to detect differences in clinical outcomes. The ABSORB III (Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease) trial was designed to evaluate the clinical effectiveness and safety of an everolimus-eluting bioresorbable vascular scaffold (Absorb) as compared with an everolimus-eluting cobalt-chromium stent (Xience) in the treatment of patients with stable and unstable coronary artery disease. At 1 year, the Absorb scaffold was found to be noninferior to the Xience stent with respect to target lesion failure (7.8% vs. 6.1%; 95% CI: -0.5 to 3.9; $p = 0.007$ for noninferiority) (8). The results of the ABSORB III trial led to approval of the Absorb scaffold in July 2016 by the U.S. Food and Drug Administration.

Given the economic challenges facing the U.S. health care system today, understanding the costs and cost-effectiveness of novel therapies is critical, especially when the therapies are costly and the potential target population is large. Although bioresorbable scaffolds have the potential to reduce long-term cardiac events, this has not yet been demonstrated in clinical studies. Moreover, there are no data directly comparing the short- and long-term costs of bioresorbable scaffolds versus DES. To better understand the cost-effectiveness of bioresorbable scaffolds, we performed a prospective economic study alongside the ABSORB III trial to compare the in-hospital and 1-year follow-up health care costs of percutaneous coronary intervention (PCI) using the Absorb scaffold versus the Xience Stent.

ABBREVIATIONS AND ACRONYMS

DES = drug-eluting stent(s)

MI = myocardial infarction

PCI = percutaneous coronary intervention

METHODS

PATIENT POPULATION AND TREATMENT PROTOCOL. The design of the ABSORB III trial has been described previously (8). Briefly, 2,008 patients undergoing PCI for 1 or 2 native coronary artery lesions for stable or unstable angina were enrolled at 193 sites in the United States and Australia. Each lesion was required to be <24 mm in length in a reference vessel that was between 2.5 and 3.75 mm in diameter (by visual estimation). After successful pre-dilation of the target lesion, patients were randomized in a 2:1 ratio to receive either the Absorb scaffold (Abbott Vascular) or the Xience DES (Abbott Vascular). The ABSORB III trial is registered at: clinicaltrials.gov (NCT01751906). The study was designed as a noninferiority trial (prespecified noninferiority margin of 4.5%) with a primary endpoint of target lesion failure (composite of cardiac death, target vessel myocardial infarction [MI], or ischemia-driven target lesion revascularization) at 1 year. Although the primary endpoint was assessed at 1 year, clinical follow-up will continue for all patients through 5 years.

ASSESSMENT OF IN-HOSPITAL OUTCOMES AND CLINICAL FOLLOW-UP

Case report forms documenting baseline patient characteristics, procedural details, and clinical outcomes during the initial hospitalization were collected for all patients. Data on all adverse events, cardiovascular testing, repeat revascularization

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procedures, medication use, and rehospitalizations during the 1-year follow-up period were also collected. Major adverse cardiac events were adjudicated by an independent clinical events committee, who were blinded to treatment assignment.

DETERMINATION OF MEDICAL CARE COSTS

Medical care costs for the initial hospitalization as well as for the 1-year follow-up period were assessed using a combination of "bottom-up" and "top-down" methods as described previously (9-11). All costs were assessed in 2015 U.S. dollars. Costs that were incurred in earlier years were converted to 2015 U.S. dollars using the medical care component of the Consumer Price Index. Discounting was not performed because costs were assessed only for 1-year of follow-up.

Index procedure costs. Catheterization laboratory logs were obtained for each initial PCI procedure, and detailed procedural resource use was abstracted by a trained research assistant. The unit costs of individual devices were based on 2015 industry audit data or on local data from Saint Luke's Mid-America Heart Institute when industry audit data were unavailable. Intraprocedural medication costs were based on average wholesale prices assuming a typical weight-based dosing regimen. The costs of other disposable equipment, overhead, nonphysician personnel, and depreciation for the cardiac catheterization laboratory were estimated from the average cost per procedure at Saint Luke's Mid-America Heart Institute during the same time frame and adjusted for observed procedure duration. For our base case analysis, the cost of the Xience DES was assumed to be $1,250 per stent, and we assumed that the cost of the Absorb scaffold would be $100 more per device based on a survey of 5 U.S. hospitals conducted in August 2016 (i.e., a price of $1,350 per scaffold). These values were varied in sensitivity analyses. Of note, as of December 2016, the median difference in acquisition cost between the 2 devices at U.S. centers was $0 (IQR: $0 to $200).

Index hospitalization costs. Nonprocedural hospital care costs were estimated from a regression model based on ABSORB III-eligible patients who underwent elective PCI procedures performed between 2012 and 2013 and whose data were included in the Medicare Provider and Review database (n = 290,776) (12). Hospital charges were converted to costs using hospital- and cost center-specific cost-to-charge ratios (13,14). A linear regression model was then developed, with total index hospitalization cost as the outcome and length of stay and in-hospital complications (including repeat PCI, MI, coronary artery bypass graft surgery, stroke, atrial or ventricular arrhythmia, pacemaker placement, vascular complication, or death) as predictors. To avoid double counting of procedural costs, the intercept for the model was adjusted for the cost of an average PCI in 2014 to remove the costs related directly to the index procedure. These methods are identical to those used in several recent economic analyses of PCI (15,16). Physician fees for major cardiovascular procedures performed during the index hospitalization as well as daily intensive care and nonintensive care were estimated based on the Medicare fee schedule.

Follow-up costs. Follow-up costs were assessed for all cardiovascular rehospitalizations as well as outpatient care related to the diagnosis and treatment of coronary artery disease. Each follow-up hospitalization was mapped to the most appropriate Medicare severity diagnosis-related group, and costs were assigned based on mean Medicare reimbursement rates for fiscal 2015 (17). Physician fees associated with follow-up admissions were assumed to be 20% of the hospital costs (or reimbursement) for each admission (18).

TABLE 1 Baseline Characteristics*

	Absorb Scaffold (n = 1,322)	Xience Stent (n = 686)
Clinical characteristics		
Age (yrs)	63.5 ± 10.6	63.6 ± 10.3
Male (%)	70.7	70.1
Hypertension (%)	84.9	85.0
Hyperlipidemia (%)	86.2	86.3
Diabetes (%)		
Any	31.5	32.7
Insulin treated	10.5	11.2
Prior MI (%)	21.5	22.0
Renal insufficiency (%)	10.8	11.1
Tobacco use within 1 month (%)	21.3	20.7
Clinical presentation (%)		
Silent ischemia	10.0	10.2
Stable angina	57.3	60.8
Unstable angina	26.9	24.5
Angiographic characteristics of the target lesions†		
Coronary artery treated (%)		
Left anterior descending artery	44.5	42.2
Left circumflex artery	26.2	30.6
Right coronary artery	29.2	27.2
Diameter stenosis (%)	65.3 ± 12.5	65.9 ± 11.7
Reference vessel diameter (mm)	2.67 ± 0.45	2.65 ± 0.46
Lesion length (mm)	12.6 ± 5.4	13.1 ± 5.8

Values are mean ± SD or %. *There were no differences between the Absorb and Xience cohorts except for lesions treated in the left circumflex artery (p = 0.03) and lesion length (p = 0.05). †There were 1,385 target lesions were treated in the Absorb group and 713 target lesions treated in the Xience group.
MI = myocardial infarction.

Events associated with outpatient clinic visits, emergency room visits, procedures, and testing were mapped to Current Procedural Terminology codes, and costs were assigned based on the Medicare fee schedule. Outpatient antiplatelet agent use was assessed at each follow-up visit, and costs were assigned using the most current average wholesale prices from the Micromedex Red Book (19). Because there were no differences in the use of any other cardiac medications between the 2 groups, costs for these medications were excluded from our analysis.

STATISTICAL ANALYSIS. Baseline characteristics are summarized as mean ± SD for continuous variables and proportions for categorical variables. Continuous variables were compared using the Student *t* test; categorical variables were compared by the chi-square test or Fisher exact test, as appropriate. Cost data are reported as both mean and median values and were compared using *t* tests for in-hospital costs (which were normally distributed) and nonparametric bootstrapping for long-term costs (1,000 replicates).

RESULTS

PATIENT POPULATION. Baseline clinical and angiographic characteristics were well-matched between the 2 treatment groups (Table 1). The mean age was 63 years, and the majority of patients were male. Of subjects, 30% were diabetic and 20% were current smokers. The most common indication for PCI was stable angina; however, approximately one-quarter of patients had unstable angina. The mean target lesion length was 15 mm with a mean diameter stenosis of 68% by quantitative coronary angiography.

INDEX PROCEDURAL RESOURCE USE AND COSTS. Resource use and costs associated with the index procedure are summarized in Table 2. In general, procedural resource use was similar for the 2 groups. There were no differences in contrast volume, number of guiding catheters and guidewires used, or stent/scaffold implants between the 2 groups. Although the time required to treat the target lesion was slightly longer in the Absorb group (42 vs. 38 min; $p < 0.001$), the overall procedure duration did not differ between the 2 groups (92 vs. 90 min in the Absorb and Xience groups, respectively; $p = 0.43$). Patients in the Absorb group were treated with an average of 1.1 Absorb scaffolds, and 0.21 other stents per patient, whereas patients in the Xience group were treated with 1.29 Xience stents and 0.02 other stents per patient. More angioplasty balloon catheters were used in the Absorb group than in the Xience group (2.17 vs. 1.86; $p < 0.001$), and post-dilation was performed more frequently in the Absorb group (64.8% vs. 49.9%; $p < 0.0001$).

Because of the higher cost of the Absorb scaffold compared with the Xience stent, the mean cost for stents and scaffolds was $105 per patient higher in the Absorb group than the Xience group ($1,743 vs. $1,638; $p = 0.005$). The cost of other (nonstent) PCI devices was also $90 per patient higher in the Absorb group ($917 vs. $871; $p < 0.001$). This difference was driven mainly by the increased use of balloon catheters in the Absorb cohort. All other procedure-related

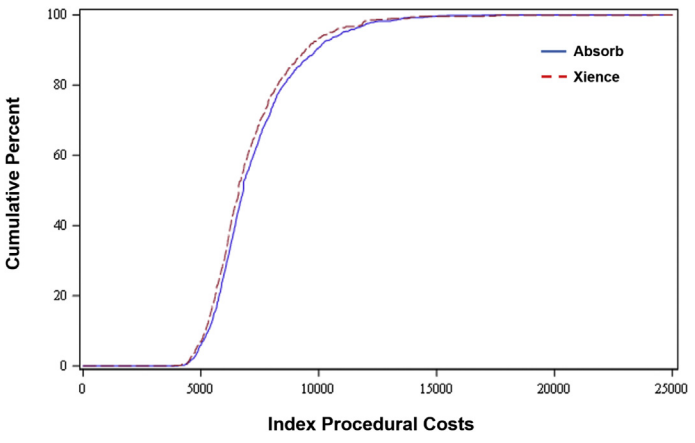
TABLE 2 Index Procedural Resource Use and Cost

	Absorb Scaffold (n = 1,322)	Xience Stent (n = 686)	p Value
Procedure resource use			
Procedure duration (min)			
Target lesion related	42 ± 23	38 ± 21	<0.001
Total	92 ± 47	90 ± 55	0.43
Contrast volume (ml)	173 ± 98	167 ± 107	0.16
Guide catheters	1.20 ± 0.76	1.18 ± 0.63	0.44
Coronary guidewires	1.22 ± 0.81	1.19 ± 0.78	0.38
Balloons	2.17 ± 1.17	1.86 ± 1.14	<0.001
Stents/scaffolds			
Absorb scaffold	1.10 ± 0.40	0.00 ± 0.05	<0.001
Xience	0.20 ± 0.50	1.29 ± 0.64	<0.001
Other DES	0.01 ± 0.13	0.01 ± 0.15	0.33
Bare metal stent	0.00 ± 0.03	0.00 ± 0.00	0.47
Total	1.31 ± 0.63	1.31 ± 0.64	0.91
Intravascular imaging/assessment			
Pressure wire/fractional flow reserve	0.15 ± 0.37	0.15 ± 0.37	0.82
Intravascular ultrasonography	0.17 ± 0.38	0.15 ± 0.36	0.34
Optical coherence tomography	0.04 ± 0.20	0.03 ± 0.17	0.34
Closure devices	0.36 ± 0.49	0.35 ± 0.50	0.73
Intraprocedural anticoagulants (%)			
Glycoprotein IIb/IIIa inhibitors	10.1	12.4	0.11
Bivalirudin	60.7	58.7	0.39
Low-molecular-weight heparin	8.1	8.3	0.87
Costs (US$)			
Stents/scaffolds			
Absorb Scaffold	1,377 ± 494 [1,350]	4 ± 73 [0]	<0.001
DES	256 ± 648 [0]	1,634 ± 794 [1,250]	<0.001
Bare metal stent	0.44 ± 16 [0]	0 ± 0 [0]	0.47
Total	1,744 ± 813 [1,350]	1,638 ± 804 [1,250]	0.01
Other PCI devices*	961 ± 571 [792]	871 ± 551 [700]	<0.001
Medications	814 ± 780 [897]	832 ± 769 [897]	0.61
Other supplies	158 ± 33 [153]	156 ± 35 [151]	0.19
Room/overhead	2,155 ± 624 [2,123]	2,127 ± 718 [2,080]	0.37
Nonphysician personnel	486 ± 141 [479]	479 ± 162 [469]	0.37
Total index procedure cost (excluding physician fees)	6,316 ± 1,892 [5,875]	6,103 ± 1,895 [5,707]	0.02

Values are mean ± SD, %, or mean ± SD [median]. *Other PCI devices includes balloon catheters, coronary wires, guiding catheters, vascular closure devices, intravascular imaging devices, pressure wires, hemodynamic support devices, and plaque-modifying tools.

DES = drug-eluting stent(s); PCI = percutaneous coronary intervention.

FIGURE 1 Comparison of Index Procedure Costs



Cumulative distribution plot of index procedure costs for the Absorb scaffold and Xience groups.

costs including other supplies, drugs, and catheterization laboratory overhead, and personnel did not differ significantly between the 2 groups. Altogether, the mean index procedural costs were $212 per patient higher in the Absorb group compared with the Xience group ($6,316 vs. $6,103; 95% CI for difference: $38 to $387; p = 0.02) (Figure 1).

TABLE 3 Index Hospitalization Outcomes and Cost

	Absorb Scaffold (n = 1,322)	Xience Stent (n = 686)	p Value
Outcomes			
Death (%)	0.2	0.0	0.55
Stent thrombosis (%)	0.2	0.6	0.19
MI (%)	3.0	3.1	0.96
Stroke (%)	0.1	0.0	0.99
Repeat revascularization (%)			
Coronary artery bypass grafting	0.0	0.1	0.34
PCI	0.4	0.6	0.50
Bleeding (GUSTO) (%)			0.93
Mild	2.9	3.4	
Moderate	0.2	0.1	
Severe	0.2	0.1	
Vascular complication (%)	4.1	3.2	0.33
Duration of stay (d)	1.08 ± 1.03	1.12 ± 1.13	0.44
Costs ($)			
Index procedural costs (without physician fees)	6,316 ± 1,892 [5,875]	6,103 ± 1,895 [5,707]	0.02
All other hospital costs	7,557 ± 2,063 [7,195]	7,632 ± 2,632 [7,195]	0.48
Physician fees	1,162 ± 123 [1,103]	1,167 ± 218 [1,103]	0.47
Total index hospitalization cost	15,035 ± 2,992 [14,312]	14,903 ± 3,449 [14,073]	0.37

Values are %, mean ± SD, or mean ± SD [median].

GUSTO = Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries; MI = myocardial infarction; PCI = percutaneous coronary intervention.

INDEX HOSPITALIZATION OUTCOMES, RESOURCE USE, AND COSTS. Table 3 summarizes the clinical outcomes as well as the costs associated with the index hospitalization. There were no differences in any in-hospital outcomes, including death, stent thrombosis, repeat revascularization, or duration of stay between the 2 groups. As a result, the overall costs for the index hospitalization (including index procedure costs) were similar for the 2 groups ($15,035 vs. $14,902 in the Absorb and Xience groups, respectively; 95% CI for difference: $159 less to $424 more; p = 0.37).

FOLLOW-UP RESOURCE USE AND COSTS. Resource use and costs through the 1-year follow-up are shown in Table 4. Although there were no differences in the rates of death or MI, there was a trend toward increased rates of repeat PCI in the Absorb group at 1 year (8.2% vs. 5.8%; p = 0.06). The numerical excess of repeat PCI in the Absorb group was present for both target lesion revascularization (2.5% vs. 1.3%; p = 0.08) as well as nontarget lesion revascularization (6.8% vs. 5.7%; p = 0.33). Consequently, the follow-up costs were slightly higher in the Absorb group compared with the Xience group ($2,813 vs. $2,596; 95% CI for difference: $339 less to $708 more; p = 0.43). Nonetheless, there was no difference in the cumulative 1-year costs between the 2 groups ($17,848 vs. $17,498 for the Absorb and Xience groups, respectively; mean difference: $350; 95% CI for difference: $328 less to $928 more; p = 0.29). Based on bootstrap resampling, the probability that the total 1-year costs were lower with Absorb than Xience was 14.6% (Figure 2), and the probability that the difference in 1-year costs between Absorb and Xience was <$500 was 68.1%.

In our primary analysis, we assumed that the acquisition cost of the Absorb scaffold was $100 higher than the acquisition cost of the Xience stent. To understand the influence of pricing on the economic impact of Absorb more fully, we performed a sensitivity analysis on the price difference between the Absorb scaffold and Xience stent (Figure 3). As expected, the greater the cost difference between Absorb and Xience, the greater the 1-year cost difference between the 2 groups. If the acquisition cost of the Absorb scaffold was identical to that for the Xience stent, the 1-year cost difference would be $240.

DISCUSSION

This is the first prospective study to evaluate the economic outcomes associated with the use of a

bioresorbable scaffold versus a conventional DES among patients undergoing PCI. In this randomized trial involving 2,008 patients with stable and unstable coronary artery disease, we found that the use of the Absorb scaffold was associated with slightly higher procedural costs and index hospitalization costs when compared with the Xience stent. Although the total 1-year costs were also numerically higher in the Absorb group, the cost difference was small (approximately $350/patient) and was not significant. Taken together with clinical outcomes demonstrating statistical noninferiority of the Absorb scaffold to the Xience DES, these findings demonstrate roughly comparable clinical and economic outcomes with these 2 devices within 1 year (assuming a $100 per device price difference). However, these results remain uncertain at present, because the ABSORB III trial was underpowered to exclude small differences in both clinical and economic outcomes. Furthermore, the results reported herein are sensitive to assumptions regarding the price of the Absorb scaffold as compared with the Xience stent, which may vary between hospitals and geographical regions. Regardless of one's perspective, it is clear from our results that both the clinical and economic "value" of bioresorbable scaffolds compared with current generation DES will ultimately lie in their ability to reduce late events, an unproven hypothesis at present.

The finding that the Absorb scaffold was associated with higher initial procedural costs than the Xience stent was not surprising. Although some of this higher cost reflects differences in device costs between bioresorbable scaffolds and DES, procedural resource use was also greater with the Absorb scaffold, with respect to both procedure duration as well as balloon catheter use. As a result, the total cost for the initial PCI procedure was approximately $200 greater per patient in the Absorb group. Greater balloon catheter use in the Absorb group most likely reflects the need for more aggressive lesion preparation and post-dilation with bioresorbable scaffold implantation to reduce acute recoil (20) and improve scaffold expansion and apposition (21). With the increasing emphasis on post-dilation after Absorb implantation, it is certainly possible that differences in balloon catheter use (and their associated costs) will be even greater in contemporary practice. Although it is also recommended that intravascular imaging be used to assist with assessment of vessel size and stent expansion with bioresorbable scaffold implantation, we did not observe an increase in the use of intravascular imaging with the Absorb scaffold. This lack of difference may reflect differences in practice early in the experience with this device as

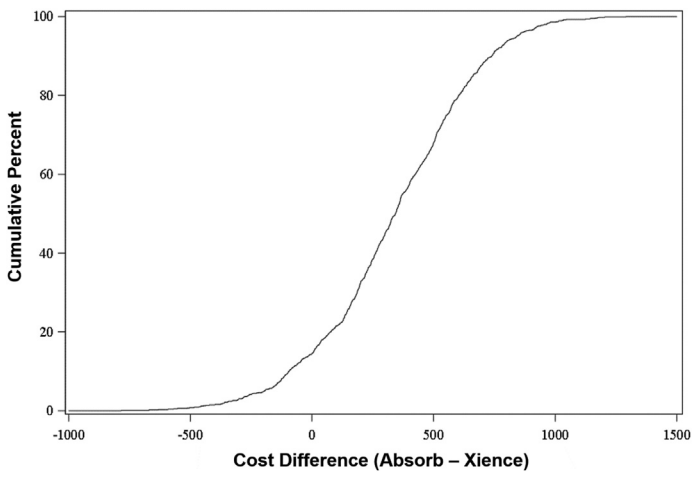
TABLE 4 Follow-Up Outcomes, Resource Use, and Costs

	Absorb Scaffold (n = 1,322)	Xience Stent (n = 686)	p Value
Clinical outcomes (proportion of patients)			
Death (%)	0.9	0.4	0.25
MI (%)	3.8	2.5	0.12
Repeat revascularization (%)			
CABG	0.4	0.7	0.32
PCI	8.2	5.8	0.06
Any	8.5	6.4	0.10
Resource use (number of events per 100 patients)			
Rehospitalization			
Associated with PCI	9.2 ± 32.9	6.9 ± 29.0	0.11
Associated with CABG	0.4 ± 6.1	0.7 ± 8.5	0.29
Not associated with revascularization	12.1 ± 36.6	11.8 ± 40.7	0.87
Outpatient visits	12.8 ± 44.5	10.8 ± 38.6	0.32
Emergency room visits	5.6 ± 29.1	6.4 ± 27.9	0.55
Costs ($)			
Hospitalizations			
Associated with PCI	955 ± 3,520 [0]	701 ± 3,337 [0]	0.12
Associated with CABG	103 ± 1,737 [0]	135 ± 1,798 [0]	0.69
Not associated with revascularization	469 ± 1,822 [0]	522 ± 2,811 [0]	0.65
Outpatient care/testing	53 ± 205 [0]	44 ± 198 [0]	0.33
Physician fees	340 ± 905 [0]	303 ± 1,026 [0]	0.43
Antiplatelet therapy	881 ± 216 [947]	876 ± 222 [947]	0.57
Total follow-up costs	2,813 ± 5,368 [964]	2,596 ± 6,137 [963]	0.43
Total costs through 1 yr (including index hospitalization) ($)	17,848 ± 6,110 [15,818]	17,498 ± 7,411 [15,425]	0.29

Values are %, mean ± SD, or mean ± SD [median].

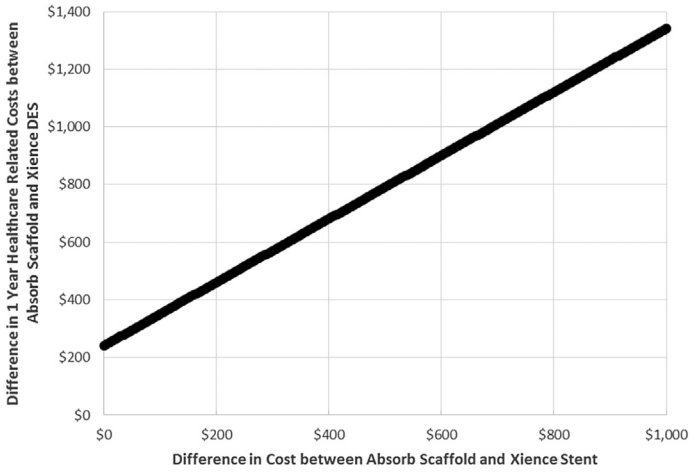
CABG = coronary artery bypass grafting; MI = myocardial infarction; PCI = percutaneous coronary intervention.

FIGURE 2 Difference in 1-Year Costs



Cumulative distribution of the difference in aggregate 1-year health care related costs between the Absorb scaffold and Xience groups, based on bootstrap resampling (1,000 replicates).

FIGURE 3 Impact of Device Cost Difference on 1-Year Health Care-Related Costs



Sensitivity analysis demonstrating the effect of varying the incremental cost of the Absorb scaffold (relative to the Xience stent) on the mean difference in 1-year health care related costs between the Absorb and Xience groups.

well as the relatively straightforward nature of the lesions treated in the ABSORB III trial.

Given the modest increase in procedural complexity and cost with Absorb scaffold implantation as compared with the Xience DES, the ultimate economic value of a bioresorbable scaffold will depend on its ability to reduce late cardiovascular events and, consequently, the health care-related costs associated with such events. When health care resource use was evaluated over the 1-year follow-up period in the ABSORB III trial, the rate of repeat PCI was numerically higher in the Absorb group resulting in an increase of approximately $220 per patient in follow-up health care costs, a difference that was not significant. Whether this minor increase in follow-up costs is real or simply statistical play of chance remains unclear, although it should be noted that approximately one-half of the increase in repeat revascularization events in the Absorb group was due to non-target lesion-related events, which may suggest some random variation. Furthermore, a recent patient-level meta-analysis of 1-year outcomes from randomized trials comparing the Absorb scaffold versus standard DES demonstrated no significant differences in a broad range of outcomes including death, MI, device thrombosis, or target lesion revascularization (22).

Whether the use of bioresorbable scaffolds will ultimately result in improved clinical and economic outcomes compared with metallic DES is currently unknown. It has been hypothesized that the lack of a permanent metallic implant in the vessel wall may lead to less endothelial dysfunction and decreased in-stent neoatherosclerosis, thereby resulting in reduced rates of very late stent thrombosis and restenosis in the long term. A subgroup analysis from the early ABSORB trials demonstrated impaired vascular compliance early after scaffold implantation, which subsequently normalized after scaffold resorption (23). Furthermore, vasodilatory response to acetylcholine in the treated segments improved over time as the scaffold resorbed (24). Despite these promising findings, the 3-year results from the ABSORB II randomized trial demonstrated no difference in vasomotion between the Absorb and Xience groups (25). Furthermore, there was a trend toward increased rates of very late stent thrombosis with the Absorb scaffold (25). As such, it is unknown whether the hypothesized physiological vascular responses after bioresorbable scaffold implantation will lead to lower rates of adverse cardiac events over time when compared with permanent metallic stent implantation. If the Absorb scaffold is shown to be associated with improved late clinical outcomes (likely primarily through lower rates of repeat revascularization), then an economic advantage for the device may emerge. Prior economic analyses comparing DES with bare metal stents have demonstrated that, despite the higher initial costs of a DES, lower repeat revascularization rates with DES may translate into reasonable cost effectiveness given the quality-of-life benefits associated with reductions in restenosis (10,11,26,27). As such, longer term follow-up of ongoing trials (including ABSORB III and ABSORB IV) will be necessary to more fully characterize any late clinical and economic advantages or disadvantages associated with bioresorbable scaffold implantation.

STUDY LIMITATIONS. First, hospital billing data were not collected in the ABSORB III trial. As such, costs for the index procedure, index hospitalization, and follow-up care were estimated from measured resource use and clinical outcomes using a combination of national average cost data and statistical models. Given the relatively modest differences in clinical outcomes observed to date, it is unlikely that the use of billing data would have resulted in substantially different findings, although it is possible that the variance of our cost estimates would have been somewhat greater. Second, the ABSORB III trial was underpowered to detect small differences between the treatment groups and this could lead to an erroneous conclusion of noninferiority from both an economic and clinical standpoint. Third, because the

Absorb scaffold was only recently approved in the United States, the cost of this device relative to other DES is both uncertain and likely to evolve over time. Given these considerations, we believe that our approach of performing a sensitivity analysis with respect to alternative pricing was reasonable.

Finally, and most important, the ABSORB III trial was limited to a patient population with stable or unstable angina who had relatively straightforward coronary lesions, which necessitated 1- or 2-vessel PCI. Given the current emphasis on aggressive lesion preparation and the use of adjunctive intravascular imaging at the time of Absorb scaffold implantation, it is likely that the treatment of patients with more complex coronary artery disease would have increased procedural costs significantly, particularly for patients in the Absorb group. Moreover, prior studies have demonstrated increased rates of complications and repeat revascularizations after PCI in patients with complex coronary lesions (e.g., long lesions, small vessels, vein graft lesions) (28-30). Because repeat revascularization procedures as well as post-procedural complications can lead to increased health care-related costs (31), it follows that treatment of more complex disease may result in higher resource use both during the index procedure as well as during follow-up. The ongoing ABSORB IV trial will include more complex patients and will therefore provide complementary information to the current study with respect to both clinical and economic outcomes.

CONCLUSIONS

In patients with noncomplex coronary artery disease enrolled in the ABSORB III trial, procedural costs were slightly higher with the Absorb scaffold compared with the Xience DES, although there was no difference in total 1-year health care costs. Longer follow-up will be necessary (and is on-going) to determine whether meaningful cost savings with Absorb will emerge after complete scaffold resorption to establish the ultimate value of bioresorbable scaffolds compared with standard DES in this patient population.

ADDRESS FOR CORRESPONDENCE: Dr. David J. Cohen, Saint-Luke's Mid America Heart Institute, University of Missouri-Kansas City School of Medicine, 4401 Wornall Road, Kansas City, Missouri 64111. E-mail: dcohen@saint-lukes.org.

PERSPECTIVES

WHAT IS KNOWN? The Absorb bioresorbable vascular scaffold was recently approved by the Food and Drug Administration after the ABSORB III trial found the Absorb scaffold to be noninferior to the Xience stent with respect to target lesion failure in patients with stable and unstable coronary artery disease. Given the economic challenges facing the U.S. health care system today, understanding the short and long-term costs associated with bioresorbable scaffolds versus standard DES is critical.

WHAT IS NEW? We found that initial procedural costs were significantly higher with the Absorb scaffold than with the Xience stent (mainly due to greater balloon catheter use and the higher cost of the scaffold in the Absorb group); however, total 1-year costs did not differ between the 2 groups.

WHAT IS NEXT? Based on these 1-year data, there does not seem to be a major economic downside to the use of the Absorb scaffold at the present, although the true economic value of the device will be depend on whether late clinical outcomes (and associated effects on cost) emerges between the 2 groups.

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