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Cost-effectiveness of sirolimus-eluting stents compared with vascular brachytherapy for the treatment of in-stent restenosis

Matthew R. Reynolds, MD, MSc^{a,b}, Duane S. Pinto, MD^a, Chunxue Shi, MSc^b, Joshua Walczak, BA^b, Ronna Berezin, MPH^b, David R. Holmes Jr, MD^c, and David J. Cohen, MD, MSc^d

a Division of Cardiology, Beth Israel Deaconess Medical Center

b Division of Cardiology, Harvard Clinical Research Institute, Boston, MA

c Division of Cardiology, Mayo Clinic, Rochester, MN

d Division of Cardiology, Mid America Heart Institute, Kansas City, MO

Abstract

Background—Sirolimus-eluting stents (SESs) were recently shown to be superior to vascular brachytherapy for the treatment of restenosis within a bare metal stent. No economic comparison of these alternative strategies has yet been reported.

Methods—We conducted a prospective health economic study involving all patients randomized to SES (n = 259) or brachytherapy (n = 125) in the SISR trial. Procedural, hospital, and outpatient costs, as well as physician fees, were estimated through 12 months based on measured resource use and itemized hospital bills. Cost-effectiveness was assessed in terms of the cost per repeat revascularization avoided, cost per major adverse cardiac event avoided, and cost per event-free patient.

Results—Although initial device costs were approximately \$1100/patient higher in the SES group, this was offset by higher physician fees associated with brachytherapy, such that initial hospitalization costs were similar for the 2 groups. Because SES significantly reduced repeat revascularization procedures and major adverse cardiac event compared with brachytherapy during follow-up, cumulative 12-month costs were significantly lower in the SES group (\$16482 vs \$19435, mean difference −\$2953, 95% CI −\$5470 to −\$792). Sirolimus-eluting stenting was thus both more effective and less expensive than brachytherapy, as confirmed in >98% of bootstrap replications for each of the cost-effectiveness outcomes.

Conclusions—Compared with vascular brachytherapy, SES is an economically dominant strategy for the treatment of in-stent restenosis.

Restenosis within a treated arterial segment has long been recognized as a major limitation of percutaneous coronary intervention (PCI). Although drug-eluting stents have greatly reduced the incidence of restenosis, there is debate about the appropriateness of using drug-eluting stents in all PCI procedures. Until recently, vascular brachytherapy was considered the most effective option for treating restenosis within a bare-metal stent, and several device systems were approved by the Food and Drug Administration for this purpose.^{1–3} However, the recently reported SISR trial showed that treatment with sirolimus-eluting stents (SESs) is superior to vascular brachytherapy for this condition.⁴

Reprint requests: David J. Cohen, MD, MSc, Saint-Luke's Mid America Heart Institute, Kansas City, MO 64111. E-mail: dcohen@saint-lukes.org.

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The impact these alternative strategies for treating in-stent restenosis have on health care economic outcomes has not been previously reported. We conducted a prospective study alongside the SISR trial to evaluate the cost-effectiveness of SESs, relative to brachytherapy, for this indication.

Methods

Study population

Between February 2003 and July 2004, 384 patients with coronary ischemia due to in-stent restenosis in a native vessel were randomized at 26 US and Canadian sites for the treatment of the target lesion with either an SES (n = 259) or vascular brachytherapy (n = 125) in the SISR trial. The overall study design and clinical results of the trial have been reported previously.

⁴ An economic substudy involving all study patients was performed in parallel with the randomized clinical trial. The study protocol was approved by the institutional review board at each site, and each patient provided informed consent before enrollment, including express permission for the collection and analysis of economic data.

Data collection and follow-up

Data regarding baseline clinical and demographic variables, clinical outcomes, and the resources used during the initial procedure, initial hospitalization, and 12 months of follow-up were collected on standardized case report forms by research coordinators at each study site and forwarded to the data coordinating center (Harvard Clinical Research Institute, Boston, MA). An independent clinical events committee that was blinded to the study group assignment adjudicated all clinical end points, including whether repeat revascularization procedures were clinically driven.

Summary of clinical results

As reported previously,⁴ the primary end point of the SISR trial was target vessel failure, defined as the composite of cardiac death, myocardial infarction (MI), or target vessel revascularization, which was significantly less common at 9 months for the SES group, compared with brachytherapy (12.4% vs 21.6%, $P = .02$). Revascularization of the target lesion was performed in 8.5% of patients in the SES group compared with 19.2% of the brachytherapy group. No differences in death or MI were observed at 9 months.

Determination of medical care costs

Medical care costs were assessed from the perspective of the US healthcare system using a combination of resource-based accounting and hospital billing data, as previously described,⁵ and are reported in 2005 US dollars. All major categories of cost (procedural, inpatient, outpatient, and physician fees) were determined for the index hospitalization, discharge to 6 months, 6 to 12 months, and cumulatively at 6 and 12 months. Specific methods for cost calculation are described below.

Cardiac catheterization laboratory costs

Catheterization laboratory costs were calculated for each patient using resource-based cost accounting methods.⁶ The use of major disposable items (including angioplasty balloons, drug-eluting and bare metal stents, guidewires, guiding catheters, and other equipment), use and quantity used of glycoprotein IIb/IIIa inhibitors and thrombin inhibitors, procedure duration, contrast volume, and type of brachytherapy were recorded on a standardized data form for each procedure. The cost of these items, other disposables, depreciation, and overhead for catheterization laboratory maintenance, and non-physician personnel were estimated based on the 2005 acquisition cost or average cost per procedure (adjusted for measured procedure

duration) at Boston's Beth Israel Deaconess Medical Center during the same timeframe. The cost of 1 SES was set at \$2400.

Other hospital costs

Itemized hospital bills and UB-92 forms (summary bills) were collected whenever possible for patients admitted to US nonfederal hospitals for all initial admissions and for readmissions related to cardiovascular disease. Admissions clearly not related to cardiovascular disease, as adjudicated by a reviewer blinded to the treatment group, were excluded from the analysis. For the initial hospitalization, 24 occurred at non-US hospitals, and billing data were obtained for 316 of 360 US admissions (88%). Of the 232 cardiovascular readmissions analyzed, 14 were to non-US hospitals, 7 were to US federal facilities, and bills were successfully obtained for 169 of the remaining 211 (80%).

For each admission, costs for all services other than cardiac catheterization laboratory procedures were estimated using "top-down" accounting methods based on each hospital's annual Medicare Cost Report. Hospital room and nursing costs were based on the average per diem cost for the specific patient care unit (eg, cardiac care unit [CCU], cardiac step-down unit, general medical unit) multiplied by the length of stay on the particular unit. Ancillary costs were determined by multiplying itemized hospital charges by the direct cost-to-charge ratio for the specific cost center providing the service. We have previously shown this method to correlate well with data from detailed cost accounting systems.⁷

For admissions without available bills, ancillary hospital costs were estimated from resource use multiplied by unit cost estimates derived from the available billing data from the study population. For each index hospital admission, "big ticket" medical care items were recorded for all patients, including overall length of stay, number of intensive care unit/CCU days, and numbers of diagnostic coronary angiograms, coronary interventions, vascular repair procedures, blood transfusions, and other diagnostic studies. Ten quantile regression models (at the 0.05, 0.15 ... 0.95 quantiles) for nonprocedural hospital costs were estimated from the complete data patients, and the resulting coefficients were used to impute the missing cost data. Imputations for subsequent cardiovascular hospitalizations were handled in an analogous fashion, with the predictive models using only repeat hospitalization data.

Outpatient costs

Outpatient medical costs were estimated for all patients based on data collected during follow-up interviews regarding the number of outpatient medical visits, emergency department visits, and nonprotocol diagnostic tests performed during the follow-up period. The costs of protocol-mandated follow-up angiography were not included. These measures of medical care resource use were converted to costs using the 2005 Medicare Fee Schedule. Outpatient costs included the cost of dual antiplatelet therapy for the duration during which it was actually prescribed to each patient. Costs for outpatient medications were assigned based on average wholesale prices at the time of study completion.⁸

Professional fees

Professional fees for inpatient services (admission and daily care), major cardiac procedures (coronary revascularization, stent placement, and diagnostic catheterization), surgical procedures, follow-up tests, and follow-up office visits were derived from the 2005 Medicare Fee Schedule.⁹

Statistical methods

Discrete data are reported as frequencies and compared by the Fisher exact test. Continuous data are described as mean $\pm$ SD; medians are also reported for nonnormally distributed data (eg, costs) to show the results for a *typical* patient. The distribution and CIs for between-group comparisons of mean costs were derived using a bias-corrected nonparametric bootstrapping approach.¹⁰ Given the nonnormal distribution of cost data, statistical comparisons of cost variables were performed using nonparametric Wilcoxon tests. All comparisons were made on an intention-to-treat basis, and a 2-tailed *P* value of $<.05$ was considered statistically significant.

Cost-effectiveness analysis

The primary prespecified end point of the economic study was the cost per repeat revascularization avoided, defined as the difference in mean 1-year costs between the SES and brachytherapy groups, divided by the difference between the 2 treatments in the rate of repeat revascularization (with the sign of the denominator reversed because avoidance of adverse events is the desired health outcome). Because the direct economic benefits of reduced repeat revascularization are already captured in the numerator of the cost-effectiveness ratio, it is important to note that the denominator of the ratio refers only to the health benefits of avoiding recurrent angina and the need for repeat revascularization. This approach is reasonable because previous studies from our group and others have demonstrated that avoidance of coronary restenosis is associated with improved health-related quality of life^{11,12} and improved quality-adjusted life expectancy,¹³ at least in the short run. This approach has been used previously by our group to evaluate cost-effectiveness in the Stent-PAMI and Gamma-1 trials,^{13,14} and in the economic analyses of the Benestent II and ARTS trials.^{15,16}

We also calculated the cost per major adverse cardiac event (MACE) avoided, where MACE was defined as the composite of death, MI, or any repeat revascularization. However, because no differences in death or MI rates were expected or observed in the clinical study, this latter comparison is of secondary interest. Finally, because some patients may experience multiple adverse events or revascularization procedures, cost-effectiveness was also calculated as the cost per event-free patient, which focuses on the proportion of patients who did not experience the relevant event (or events) at 1 year.

Variability of the cost-effectiveness estimates within the trial population was assessed with bootstrap resampling.¹⁰ Using this nonparametric technique, the joint distribution of costs and clinical benefits was estimated across 1000 replications of the study sample and described in terms of a cost-effectiveness acceptability curve.¹⁷

Role of the sponsor

Dr Cohen, the Harvard Clinical Research Institute, and Cordis Corporation, Warren, NJ (the study sponsor), were responsible for the study design and the execution of the study. All analyses were performed by the authors, under the direction of Dr Cohen, without input or involvement from the sponsor.

Results

Baseline patient characteristics

Selected baseline characteristics of the SISR trial population are shown in Table I. The 2 groups were well matched. Just more than half of the patients had single-vessel coronary disease at the study entry, and most had preserved left ventricular systolic function. Approximately one-third of the population was diabetic.

Initial revascularization procedure and hospital outcomes

Table II details resource use, clinical events, and costs for the initial revascularization procedure and hospital stay in the 2 study groups. Compared with brachytherapy, SES procedures were shorter in duration (mean difference 11 minutes, $P < .001$) and were associated with less frequent use of bare-metal stents. Bivalirudin was used significantly more often in SES compared with brachytherapy procedures (17% vs 5.6%, $P = .002$). Primarily because of the difference in device costs, SES procedures were more expensive than brachytherapy procedures (mean difference \$1111, 95% CI \$760 to \$1466).

Adverse events during the initial hospital stay were infrequent and occurred at similar rates between the 2 groups. As shown in Table II and Figure 1, the higher cost of the initial revascularization procedures in the SES group was largely offset by higher physician fees in the brachytherapy group, such that total costs for the index hospitalization were similar for the 2 groups (mean difference \$331, 95% CI -\$152 to \$917). These higher physician fees mainly reflect the need for a radiation oncologist to be present during the brachytherapy procedures.

Follow-up clinical events, medical resource use, and costs

At 12 months, the rates of repeat target vessel revascularization (12.7% vs 24.0%, $P = .008$) and any repeat revascularization (20.5% vs 33.6%, $P = .008$) were significantly lower with sirolimus-eluting stenting versus brachytherapy (Table III). In particular, assignment to the SES group was associated with a significant reduction in the need for bypass surgery (1.5% vs 6.4%, $P = .02$). There was also a trend toward a lower cardiac rehospitalization rate in the SES group. There were no significant differences in the incidence of death, nonfatal MI, or their composite between the 2 groups.

Due to the lower revascularization rates, follow-up costs over 12 months were approximately \$3300/patient lower in the SES group compared with the brachytherapy group (\$5574 vs \$8858, 95% CI for difference -\$5788 to -\$1182), as shown in Table III and Figure 1. Because index hospitalization costs differed only slightly, mean cumulative costs at 12 months were also substantially lower in the SES group (\$16483 vs \$19436, mean difference -\$2953, 95% CI -\$5470 to -\$792). Median per patient costs tended to favor SES as well (\$14440 vs \$15005, $P = .08$).

Cost-effectiveness analysis

The base case finding from the trial data was that sirolimus-eluting stenting was economically dominant—both more effective and less expensive by approximately \$3000/patient—compared with brachytherapy as a treatment of in-stent restenosis. This held true whether the measure of effectiveness was the need for repeat revascularization (difference -13.1%, 95% CI -22.8% to -3.5%) or MACE (difference -11.2%, 95% CI -20.6% to -1.9%).

Variability within the study sample is reflected in Figure 2, in which the mean difference in costs between study groups is plotted against the mean difference in repeat revascularization for each of 1000 bootstrap replications of the study data. The bootstrap analysis found the SES group to be dominant compared with brachytherapy in >99% of replications. When the effectiveness measure was the number of major adverse cardiovascular events avoided and when outcomes were expressed as dollars per event-free survivor rather than dollars per event avoided, the SES group remained economically dominant in >98% of bootstrap replications.

Discussions

This report from the SISR randomized trial is the first to provide formal comparative economic analysis of the 2 therapies that have been shown to be more effective than repeat balloon dilation

alone for the treatment of in-stent restenosis. Our analysis shows that initially higher device costs with SES implantation were largely counterbalanced by higher physician fees with brachytherapy such that initial treatment costs (when assessed from the perspective of the health care system) were similar between the 2 groups. Over the 12-month follow-up period, significantly lower rates of repeat revascularization (both percutaneous and surgical) and rehospitalization with SES reduced costs compared with brachytherapy by approximately \$3000.

Although these findings clearly indicate that the treatment of in-stent restenosis with SES implantation is preferred over vascular brachytherapy on both economic and clinical grounds, whether SES implantation is, itself, cost-effective for this indication cannot be addressed directly by our study. Nonetheless, previous studies by our group and others have demonstrated that patients who require repeat revascularization procedures after the initially successful PCI experience a measurable short-term decrement in quality of life^{11–13} and that patients assign a substantial monetary value to avoidance of such procedures.¹⁸ For these reasons, the incremental cost-effectiveness of vascular brachytherapy compared with balloon angioplasty (≈\$10000 per repeat revascularization avoided) in the Gamma-1 trial was within the range felt to be reasonably acceptable from the perspective of the US health care system.¹⁴ Thus, by extension, we may infer that SESs are reasonably cost-effective for this indication as well.

The SISR trial data demonstrate with a high level of certainty that the clinical superiority of SES over brachytherapy for the treatment of in-stent restenosis is accompanied by significant cost savings. This leaves little doubt regarding which is the optimal strategy for treating in-stent restenosis, at least after bare-metal stent implantation. The use of brachytherapy has also fallen out of favor because of the description of a “late catch-up” phenomenon, manifested as increased revascularization rates compared with placebo between 6 months and 5 years,¹⁹ that, over time, reduces but does not eliminate the benefit of this technology. No late increase in revascularization rates compared with bare-metal stents has been demonstrated with SES, at least out to 5 years, implying that SES will most likely continue to remain superior to brachytherapy both clinically and from an economic perspective.

It is important to recognize that the results of the SISR trial apply exclusively to the treatment of in-stent restenosis after bare-metal stent implantation. Although drug-eluting stents are currently the dominant form of PCI, recent concerns over late stent thrombosis with drug-eluting stents^{20–22} have led to resurgence in the use of bare-metal stents, which will likely translate into an increased incidence of restenosis as a clinical challenge. We therefore believe that both the clinical and economic results of the SISR trial have sustained relevance at both the individual clinical as well as the policy level.

Study limitations

Our study has several important limitations. As with any clinical trial, the results of our study may not be generalizable to the full population of PCI patients. In particular, our results provide no direct insight into the economic value of SES implantation for the treatment of post-DES in-stent restenosis or the cost-effectiveness of other DES systems for this application. The SISR trial incorporated routine angiographic follow-up, which has been shown to increase the rates of target vessel revascularization compared with routine clinical follow-up.²³ Although the costs of angiographic follow-up, itself, were excluded from our analysis, and we made every effort to exclude procedures driven solely by the oculostenotic reflex, it is possible that angiographic follow-up led to a differential effect on revascularization rates in the SES and brachytherapy groups. It seems unlikely, however, that the magnitude of this effect would completely eliminate the cost offsets seen in our study. Finally, our study was limited to a 1-year follow-up period. Longer-term follow-up may have been helpful to clarify concerns for a late increase in revascularization rates and/or stent thrombosis with SES. However, because

brachytherapy itself is associated with increased rates of both of these complications in late follow-up, it is unlikely that the rates of these complications would be so substantially increased with SES that the benefit demonstrated in this analysis would be abolished.

Conclusions

Sirolimus-eluting stent implantation is superior to brachytherapy for the treatment of in-stent restenosis both from a clinical and economic standpoint. Although initial device costs are higher with SES, physician costs and follow-up costs are lower, resulting in approximately \$3000 cost saving for SES compared with brachytherapy at 12 months.

References

1. Waksman R, White RL, Chan RC, et al. Intracoronary gamma-radiation therapy after angioplasty inhibits recurrence in patients with in-stent restenosis. *Circulation* 2000;101:2165–71. [PubMed: 10801757]
2. Leon MB, Teirstein PS, Moses J, et al. Localized intracoronary gamma-radiation therapy to inhibit the recurrence of restenosis after stenting. *N Engl J Med* 2001;344:250–6. [PubMed: 11172151]
3. Popma JJ, Suntharalingam M, Lansky AJ, et al. Randomized trial of 90Sr/90Y beta-radiation versus placebo control for treatment of in-stent restenosis. *Circulation* 2002;106:1090–6. [PubMed: 12196334]
4. Holmes DR, Teirstein P, Satler L, et al. Sirolimus-eluting stents vs. vascular brachytherapy for in-stent restenosis within bare-metal stents. The SISR randomized trial. *JAMA* 2006;295:1264–73. [PubMed: 16531619]
5. Cohen DJ, Krumholz HM, Sukin CA, et al. In-hospital and one-year economic outcomes after coronary stenting or balloon angioplasty: results from a randomized clinical trial. *Circulation* 1995;92:2480–7. [PubMed: 7586348]
6. Eisenberg J. Clinical economics: a guide to the economic analysis of clinical practices. *JAMA* 1989;262:2879–86. [PubMed: 2509745]
7. Taira DA, Seto TB, Siegrist R, et al. Comparison of analytic approaches for the economic evaluation of new technologies alongside multicenter clinical trials. *Am Heart J* 2003;145:452–8. [PubMed: 12660668]
8. Red book. Montvale (NJ): Thomson PDR; 2002.
9. Hsiao WC, Braun P, Dunn D, et al. Results and policy implications of the resource-based relative-value study. *New Engl J Med* 1988;319:881–8. [PubMed: 3045557]
10. Efron, B. An introduction to the bootstrap. New York (NY): Chapman & Hall; 1993.
11. Rinfret S, Grines CL, Cosgrove RS, et al. Quality of life after balloon angioplasty or stenting for acute myocardial infarction. One-year results from the Stent-PAMI trial. *J Am Coll Cardiol* 2001;38:1614–21. [PubMed: 11704371]
12. Weaver WD, Reisman MA, Griffin JJ, et al. Optimum percutaneous transluminal coronary angioplasty compared with routine stent strategy trial (OPUS-1): a randomised trial. *Lancet* 2000;355:2199–203. [PubMed: 10881893]
13. Cohen DJ, Taira DA, Berezin R, et al. Cost-effectiveness of coronary stenting in acute myocardial infarction: results from the Stent Primary Angioplasty in Myocardial Infarction (Stent-PAMI) Trial. *Circulation* 2001;104:3039–45. [PubMed: 11748097]
14. Cohen DJ, Cosgrove RS, Berezin RH, et al. Cost effectiveness of gamma radiation for treatment of in-stent restenosis: results from the Gamma-1 trial. *Circulation* 2002;106:691–7. [PubMed: 12163429]
15. Serruys PW, Unger F, Sousa JE, et al. Comparison of coronary-artery bypass surgery and stenting for the treatment of multivessel disease. *N Engl J Med* 2001;344:1117–24. [PubMed: 11297702]
16. Serruys PW, van Hout B, Bonnier H, et al. Randomised comparison of implantation of heparin-coated stents with balloon angioplasty in selected patients with coronary artery disease (Benestent II). *Lancet* 1998;352:673–81. [PubMed: 9728982]

17. Lothgren M, Zethraeus N. Definition, interpretation and calculation of cost-effectiveness acceptability curves. *Health Econ* 2000;9:623–30. [PubMed: 11103928]
18. Greenberg D, Bakhai A, Neumann PJ, et al. Willingness to pay for avoiding coronary restenosis and repeat revascularization: results from a contingent valuation study. *Health Policy* 2004;70:207–16. [PubMed: 15364150]
19. Waksman R, Ajani AE, White RL, et al. Five-year follow-up after intracoronary gamma radiation therapy for in-stent restenosis. *Circulation* 2004;109:340–4. [PubMed: 14732756]
20. Pfisterer M, Brunner-La Rocca HP, Buser PT, et al. Late clinical events after clopidogrel discontinuation may limit the benefit of drug-eluting stents: an observational study of drug-eluting versus bare-metal stents. *J Am Coll Cardiol* 2006;48:2584–91. [PubMed: 17174201]
21. Daemen J, Wenaweser P, Tsuchida K, et al. Early and late coronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study. *Lancet* 2007;369:667–78. [PubMed: 17321312]
22. 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. [PubMed: 17296822]
23. Pinto DS, Stone GW, Ellis SG, et al. Impact of routine angiographic follow-up on the clinical benefits of paclitaxel-eluting stents: results from the TAXUS-IV trial. *J Am Coll Cardiol* 2006;48:32–6. [PubMed: 16814645]

Figure 1.

Costs by the treatment assignment for the different study periods. Initial hospitalization costs include both procedural (hatched) and nonprocedural (white) components. The sums of these were similar between groups. Follow-up costs (discharge to 12 months, shown in black) and, therefore, total cumulative costs as well were significantly higher in the brachytherapy group.

Figure 2.

The joint distribution of incremental costs and clinical benefits observed in 1000 bootstrap replications of the study data. Each data point represents a single bootstrap replication. The mean difference in costs (SES—brachytherapy) is plotted on the y-axis versus the mean number of repeat revascularization avoided on the x-axis, with larger values indicating more adverse events avoided with SES. More than 99% of the points fall in the quadrant where SES is both less expensive and more effective than brachytherapy.

Table I

Baseline clinical characteristics

	SES (n = 259)	Vascular brachytherapy (n = 125)	<i>P</i>
Age (y)	63 ± 11	64 ± 12	.49
Sex, % male	68	66	.64
Medical history (%)			
Diabetes mellitus	33	30	.49
Hypertension	81	83	.58
Hyperlipidemia	92	89	.46
Current smoker	16	16	>.99
Prior CABG	15	13	.64
Prior MI	44	53	.15
No. of diseased vessels (%)			
1	57	50	.23
2	28	32	.48
3	15	18	.46
Ejection fraction (%)	57 ± 9	55 ± 9	.13

CABG, Coronary artery bypass surgery.

Table II
Initial procedure and hospitalization: resources and costs

	SES (n = 259)	Vascular brachytherapy (n = 125)	SES—brachytherapy (95% CI)	P
Initial procedure resources				
Procedure duration (min)	58 ± 28	69 ± 24	−11 (−17 to −2)	<.001
DES used	1.8 ± 0.8	0.02 ± 0.15	1.7 (1.6 to 1.9)	<.001
BMS used	0.0 ± 0.06	0.12 ± 0.37	−0.12 (−0.16 to −0.07)	<.001
Brachytherapy used				
γ	0.0 ± 0.0	0.2 ± 0.4	−0.2 (−0.2 to −0.1)	<.001
β	0.0 ± 0.1	0.9 ± 0.5	−0.9 (−0.9 to −0.8)	<.001
GP IIb/IIIa inhibitor used (%)				
Abciximab	9.3	13.6	−4.3 (−11.3 to 2.6)	.22
Tirofiban	0.4	0.0	0.4 (−0.4 to 1.1)	1.00
Eptifibatide	20.8	23.2	−2.4 (−11.3 to 6.6)	.60
Bivalirudin used (%)	17.0	5.6	11.4 (5.3 to 17.5)	.002
Initial procedure costs (\$)				
Room/overhead	1610 ± 384 (1566)	1763 ± 324 (1751)	−154 (−222 to −74)	<.001
Devices	5209 ± 207 (5460)	3862 ± 968 (3560)	1347 (1058 to 1631)	<.001
Supplies and medications	563 ± 267 (445)	623 ± 272 (486)	−61 (−120 to −0.8)	.001
Nonphysician personnel	211 ± 55 (205)	233 ± 46 (231)	−22 (−32 to −11)	<.001
Total procedure cost	7592 ± 2328 (7460)	6481 ± 1217 (6343)	1111 (760 to 1466)	<.001
Hospital events/resources				
Repeat revascularization (%)	0	0	—	—
Death (%)	0	0	—	—
Nonfatal MI (%)	1.5	0	1.5 (0 to 3.0)	.31
Length of stay (d)	1.9 ± 1.6 (1.0)	1.6 ± 1.1 (1.0)	0.3 (−0.05 to 0.6)	.06
Initial hospital costs (\$)				
Hospital room/ancillary	1874 ± 1817 (1325)	1858 ± 1397 (1335)	16 (−289 to 377)	.34
Physician fees	1443 ± 200 (1370)	2239 ± 274 (2269)	−796 (−848 to −736)	<.001
Total*	10909 ± 3050 (10357)	10578 ± 2013 (10116)	331 (−152 to 917)	.49

DES, Drug-eluting stent; BMS, bare metal stent; GP, glycoprotein.

* Includes initial procedure. Values in parentheses represent medians unless otherwise indicated.

Table III
Clinical events, resource use, and costs over 12 months after discharge

	SES (n = 259)	Vascular brachytherapy (n = 125)	SES—brachytherapy (95% CI)	P
Events: discharge to 12 mo (%)				
Death	0.4	0.0	0.4 (−0.4 to 1.1)	1.00
MI	1.5	0.0	1.5 (0.0 to 3.0)	.31
Rehospitalization, any	41.3	51.2	−9.9 (−20.5 to 0.7)	.08
Cardiovascular	35.1	45.6	−10.5 (−21.0 to 0.0)	.06
Repeat revascularization, any	20.5	33.6	−13.1 (−22.8 to −3.5)	.008
CABG	1.5	6.4	−4.9 (−9.4 to −0.3)	.02
PCI	19.7	30.4	−10.7 (−20.1 to −1.3)	.03
Repeat revascularization, target vessel	12.7	24.0	−11.3 (−19.8 to −2.7)	.008
CABG	1.5	6.4	−4.9 (−9.4 to −0.3)	.02
PCI	11.6	20.8	−9.2 (−17.3 to −1.1)	.02
Resources: discharge to 12 mo				
Hospital days	1.1 ± 2.4	2.0 ± 4.9	−0.9 (−1.7 to −0.2)	.05
Intensive care unit/CCU days	0.2 ± 0.9	0.5 ± 3.3	−0.3 (−0.8 to 0.1)	.30
Office visits	1.6 ± 3.1	1.9 ± 2.9	−0.3 (−0.9 to 0.4)	.40
Time on clopidogrel (m)	11.1 ± 3.3	10.8 ± 3.5	0.3 (−0.4 to 1.0)	.40
Follow-up medical costs (\$)				
Hospitalizations*	3037 ± 5834 (0)	5692 ± 10288 (0)	−2654 (−4765 to −923)	.01
Physician fees	869 ± 134 9 (336)	1502 ± 2228 (758)	−632 (−1060 to −255)	.01
Outpatient testing	159 ± 320 (35)	190 ± 298 (70)	−31 (−101 to 26)	.07
Clopidogrel	1509 ± 421 (1643)	1474 ± 427 (1634)	35 (−60 to 122)	.61
Total follow-up costs	5574 ± 7165 (2131)	8858 ± 12363 (3763)	−3284 (−5788 to −1183)	.01

CABG, Coronary artery bypass surgery.

* Includes cost of repeat revascularization procedures. Values in parentheses represent medians unless otherwise indicated.