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Review of Recent US Cost Estimates of Revascularization

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Abstract

Objective: To review recent US cost estimates of revascularization and discuss their implications for third-party payers.

Study Design and Methods: A literature review was performed using MEDLINE. The review was limited to English-language articles published between January 2000 and September 2003. The most recently published articles that included US-derived clinical outcomes and costs of revascularization were selected for review. Cost estimates were abstracted and updated to 2003.

Results: Coronary revascularization procedures, including percutaneous coronary interventions (PCIs) and coronary artery bypass graft (CABG), are commonly performed in the United States. These procedures are costly. Costs for PCI in single-vessel disease are lower than costs for PCI in multivessel disease. Although initial estimated costs are lower for multivessel PCI (with or without stenting) than CABG, longer-term costs and lifetime costs are similar. Drug-eluting stents have the potential to alter treatment and economics dramatically, although it is too early to draw definitive conclusions about their costs. It is imperative that cost comparisons be placed in the appropriate context.

Conclusion: Revascularization procedures are costly, and short-term cost differences in procedures may not exist when considered long term. Importantly, recent cost data may be conservative given the rapid innovation in revascularization procedures and technology and the lag in publication of cost data reflecting these advances.

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ardiovascular disease (CVD) exacts an enormous clinical and economic toll on the population of the United States. CVD affects 64.4 million Americans and ranks as the leading cause of death in the United States, accounting for 38.5% of more than 2.4 million total US deaths in 2001. In 2004, the predicted direct and indirect cost of CVD is \$368.4 billion.

Coronary revascularization is commonly performed in the United States on a variety of patient populations who have CVD. In 2001, an estimated 1.051 million angioplasty procedures were performed in the United States, including 571 000 percutaneous transluminal coronary angioplastics (PTCAs) performed on 559 000 patients, and 475 000 stenting procedures. From 1987 to 2001, the number of PTCA procedures increased 266%. In addition, 516 000 coronary bypass procedures were performed on 305 000 patients in the United States.

These procedures are costly. Data from the 2001 National Healthcare Cost and Utilization Project show mean *charges* of \$28 558 for PTCA and \$60 853 for coronary artery bypass graft (CABG). Estimates of cost include more than \$30 000 per procedure for CABG and approximately \$12 000 per percutaneous coronary intervention (PCI) procedure, giving total US direct costs for coronary revascularization of more than \$28 billion annually.

While the clinical advantages and disadvantages of both PCIs and CABG are well documented in both randomized and nonrandomized trials, older published study outcomes and cost and cost-effectiveness estimates may not be based on current treatment approaches because of the rapid improvements in PCI and CABG technology and procedures.²⁻⁴ PCIs, including PTCA, atherectomy, laser angioplasty, and implantation of intracoronary stents and other catheter devices (including the use of platelet inhibitors) are undergoing continuous refinement and modification. CABG procedures have also advanced. Treatment choice today is complex, and cost and costeffectiveness are important considerations. Incorporating the most current economic and elinical information is critical to making informed treatment decisions. To gain a better understanding of the cost of revascularization procedures, we examined some of the more recent literature on relevant costs.

Current Costs of Revascularization in the United States

It is critical that the current costs and cost effectiveness of revascularization be analyzed in the context of specific patient subpopulations and the alternative treatments available. Treatments that may demonstrate lower costs and/or higher value in one context may not provide either lower costs or higher value relative to available options in another context.²⁻⁴ The literature we reviewed generally reports cost data in the context of either single-vessel or multivessel disease and often compares PCI (with or without stenting) with CABG. Because of this, we report findings in 2 major categories: PCI with stenting in single-vessel disease and PCI versus CABG in multivessel disease. Finally, we report the limited available cost data on drug-eluting stents.

PCI With Stenting in Single-Vessel Disease

Two recently published articles evaluated stenting in single-vessel disease. Neil and colleagues⁵ compared the economic and health status impacts of primary coronary stenting versus optimal PTCA with provisional stenting using the resource utilization data from 479 patients randomly assigned between 1996 and 1998 in the Optimal PTCA Utilization versus Stent (OPUS-I) trial. The study showed that primary stenting in patients undergoing single-vessel angioplasty reduced the 6-month composite incidence of death, myocardial infarction (MI), cardiac surgery, or target vessel revascularization compared with the strategy of initial PTCA with provisional stenting. Itemized hospital cost estimates, exclusive of professional fees, for procedure- and nonprocedure-related costs were derived from primary hospital charge data gathered in 2 previous multicenter, prospective clinical trials evaluating coronary stents. Costs were derived by adjusting charges using Medicare cost to charge ratios specific to each center. Procedure-related costs included the costs of equipment and use of the catheterization

laboratory. Nonprocedure-related costs were calculated using a multivariate log-linear regression. Costs of initial hospitalization were higher in the primary stent group than provisional stenting (**Table 1**). Mean 6-month costs were similar between the groups, with a slightly reduced cost associated with primary stenting. The authors concluded that, for patients undergoing single-vessel angioplasty, routine stenting improves clinical outcomes at a comparable cost versus angioplasty with provisional stenting.

The most recent study that describes the costs of PCI with stenting in single-vessel disease is a retrospective economic analysis of the Enhanced Suppression of the Platelet IIb/IIIa Receptor with Integrilin Therapy (ESPRIT) trial.6 ESPRIT was a randomized, double-blind, crossover-permitted trial of the study drug compared with placebo. The economic analysis included 2064 patients. In-hospital costs were estimated for each patient on the basis of hospital resource consumption, occurrence of adverse events, and treatment received. Procedural costs were estimated based on resource consumption, using a published regression model. Length of stay and adverse event costs were estimated from a second regression model, which was based on hospital costs for 3241

Table 1. Recent Cost Estimates of PCI With Stenting in Single-Vessel Disease

Cost Category	Mean Cost (\$) Population (2003) Source (year)		
Initial hospitalization	PCI with planned stent	10 452*	Cohen (2002)
	Provisional stent group	10 681	Neil (2002)
	Primary stent group	11 694	Neil (2002)
Total cost at 6 month	s Primary stent group	12 925	Neil (2002)
	Provisional stent group	13 285	Neil (2002)

^{*}Median cost.

Original costs from each source are updated to 2003 US dollars based on the Consumer Price Index-All Urban Consumers, Medical Care.

PCI indicates percutaneous coronary intervention.

The studies providing the cost estimates had different designs and each cost estimate should be considered in the context of the clinical and cost studies from which it is derived.

patients who underwent PCI at 89 US hospitals, as part of a number of PCI multicenter clinical trials. Cost data from these trials were obtained using a variety of standard techniques, including bottom-up cost accounting, conversion of charges to costs based on department-level cost to charge ratios, and the Medicare fee schedule for professional services. The study found median total initial hospital costs of \$10 452 (Table 1) for PCI with planned stent implantation (placebo group). Studies are under way to determine longer-term costs.

PCI Compared With CABG in Multivessel Disease

Two recent articles have analyzed longterm costs of PTCA versus CABG for multivessel disease. Weintraub and colleagues analyzed costs in the Emory Angioplasty versus Surgery Trial (EAST), a randomized trial that compared, by intent-to-treat analysis, the clinical outcomes and costs of PTCA and CABG for multivessel coronary artery disease in patients without prior coronary artery revascularization. The single-center study included 392 randomly assigned patients and 450 registry patients, entered between 1987 and 1991 and followed up annually for 8 years. For randomized patients with comparable disease who were suitable for revascularization by CABG or PTCA, there was an initial clinical advantage to CABG in angina status but long-term outcomes were similar. For registry patients, who had their care directed by their clinician, sicker patients (eg, patients who were older and patients with 3-vessel CAD) were treated with CABG and less sick patients were treated with PTCA. Patients in the randomized and registry groups were similar overall in baseline characteristics and longterm outcome. Costs were assessed for initial hospitalization, cumulative costs of the initial hospitalization, and additional revascularization procedures. CABG and PTCA mean costs of initial hospitalization at 3 and 8 years are shown in Table 2. Despite a large initial cost advantage to PTCA in the randomly assigned group, this advantage is reduced by 3 years and not discernable by 8 years because additional revascularization procedures are required for patients treated with PTCA. In the registry group, costs for PTCA were lower than for CABG, but these procedures were used to treat different patients, as noted above. The authors comment that lower costs in the registry group at 3 and 8 years suggest that physician decision making can contribute to lower costs. These cost data illustrate the observation that the relative costs of PTCA and CABG depend on the population concerned (eg, randomly placed vs registry populations).

Yock and colleagues⁸ modeled the cost effectiveness of surgical and angioplastybased revascularization for multivessel disease in patients without prior coronary artery revascularization. Outcomes and cost data from the Study of Economics and Quality of Life (SEQOL), a substudy of the randomized, multicenter Bypass Angioplasty Revascularization Investigation (BARI), were updated to reflect technology changes since the time of enrollment for BARI. Lifetime costs and quality-adjusted life-years (QALYs) were projected using a Markov decision model. Total lifetime costs for CABG with provisional stenting in follow-up angioplasty procedures, CABG without stenting in follow-up angioplasty procedures, CABG with primary stenting in follow-up angioplasty procedures, initial angioplasty with provisional stenting, and initial angioplasty with primary stenting are shown in Table 2. The authors found that despite short-term advantages with stents, the improvements are not sufficient to make primary stenting less costly and more effective than CABG for relieving angina in this patient population.

Data from a recent study showed a significant difference in stenting versus CABG costs both in initial hospitalization and at 2 years. In the single center, retrospective, matched cohort study, Reynolds and colleagues9 compared the clinical and economic outcomes of multivessel stenting (n = 100)and CABG (n = 200, n_{Total} = 300) over a median of 2.8 years of follow up (enrollment between 1994 and 1998). Initial hospitalization costs and total costs at 2 years of multivessel stenting versus CABG (Table 2) demonstrate a significant cost advantage to multivessel stenting over CABG at 2 years of follow up (27% relative reduction), despite a higher rate of revascularization in the stent group. The 2 treatment strategies resulted in

Table 2. Recent Cost Estimates of PCI Versus CABG in Multivessel Disease

Cost Category	PCI Population	Mean Cost (\$) (2003)	CABG Population	Mean Cost (\$) (2003)	Source (year)
Initial hospitalization	Multivessel stenting	13 454	CABG	23 438	Reynolds (2003)
	PTCA registry group	17 682	CABG registry group	36 877	Weintraub (2000)
	PTCA randomized group	25 105	CABG randomized group	31 732	Weintraub (2000)
Total 2 year	Multivessel stenting	20 088	CABG	27 669	Reynolds (2003)
Total 3 year	PTCA registry group	32 988	CABG registry group	59 588	Weintraub (2000)
	PTCA randomized group	50 400	CABG randomized group	55 553	Weintraub (2000)
Total 8 year	PTCA registry group	35 002	CABG registry group	59 869	Weintraub (2000)
	PTCA randomized group	56 343	CABG randomized group	58 948	Weintraub (2000)
Total lifetime	Initial angioplasty with provisional stenting	154 360	CABG with provisional stenting	154 018	Yock (2003)
	Initial angioplasty with primary stenting	163 587	CABG with primary stenting CABG without stenting	159 258 154 588	Yock (2003) Yock (2003)

The studies providing the cost estimates had different designs and each cost estimate should be considered in the context of the clinical and cost studies from which it is derived.

Original costs from each source are updated to 2003 US dollars based on the Consumer Price Index-All Urban Consumers, Medical Care. PCI indicates percutaneous coronary intervention; CABG, coronary artery bypass graft; PTCA, percutaneous transluminal coronary angioplasty.

comparable risks of death and MI for the study period. The authors note that, while clinical findings were consistent with previously reported randomized trials, cost differences were more robust. The authors attribute this, at least partially, to their study being more reflective of current US practice patterns at the time. The authors note that recent developments in both stenting and CABG procedures were incorporated into the study to a limited extent because of the study's relatively long-term follow-up.

Drug-Eluting Stents

Drug-eluting stents have garnered significant attention because of their potential for decreasing restenosis and their increased costs over bare metal stents. Drug-eluting stent cost data from a substudy of the Sirolimus-Eluting Stent in Coronary Lesions (SIRIUS) trial were presented at the 52nd Annual Scientific Session of the American College of Cardiology (2003). In SIRIUS, 1058 patients (42% with multivessel disease) with a newly diagnosed native coronary artery lesion were randomly assigned to PCI treatment of the target lesion with either the

Cypher sirolimus-eluting stent or a bare metal stent (1 or 2 stents per target lesion).¹³ The substudy analyzed the costs and cost effectiveness of these procedures. The economic end points of the substudy included in-hospital and 1-year costs. The cost of the sirolimus-eluting stent was considered to be \$3000 compared with \$1000 for each bare metal stent. Median costs for the initial procedure for the sirolimus-eluting stent were \$2857 higher than for the bare metal stent (Table 3). However, because of the difference in the need for repeat revascularization procedures, 12-month follow-up costs for bare metal stents were \$2571 higher than sirolimus-eluting stents, resulting in only a slightly higher total 1-year cost for sirolimus-eluting stents (a difference of \$309). The investigators concluded that the sirolimus-eluting stent is highly cost effective for the trial's target population and that longer stents and improved technique should enhance the stent's cost effectiveness.

A recent economic model of stent use for William Beaumont Hospital's fiscal year 2003 budget showed that the hospital will lose \$3.8 million as it adopts drug-eluting stents.¹⁰ Key

Table 3. Recent Cost Estimates of Revascularization Using Drug-Eluting Stents

Cost Category	PCI Population	Median Cost (\$) (2003)
Initial procedure	Bare metal stent	4395
	Drug-eluting stent	7252
12-month follow-up	Bare metal stent	8040
	Drug-eluting stent	5468
Total 1 year	Bare metal stent	16 504
	Drug-eluting stent	16 813

PCI indicates percutaneous coronary intervention. *Source*: Reference 12.

model assumptions included the following: commercial availability in April 2003, stent availability in 2.5- to 4.0-mm diameters, 1.43 stents per case (current usage), diagnosisrelated group revenue increase of \$1800 for drug-eluting stent codes, 10% reduction in surgical volume, 50% reduction in coronary restenosis interventions, \$3500 per drug-eluting stent, and 50% usage. The anticipated loss stems from fewer repeat revascularization procedures plus fewer CABGs resulting in less revenue, while at the same time supply costs increase because of the costs of drug-eluting stents. It is acknowledged that cost concerns have slowed acceptance of drug-eluting stents in Europe and that a similar situation may occur in the United States.¹⁰

Of particular interest to payers may be a model developed to project the impact of drug-eluting stents on individual hospital budgeting. Hassed on PTCA and CABG cost and reimbursement data for 214 000 patients from 198 hospitals in 7 states and on expectations that drug-eluting stents will decrease repeat PTCA procedures, be widely adopted, and reduce the use of CABG, it was estimated that managed care organizations could provide "budget neutral" rate relief to hospitals of approximately \$3600 per drugeluting stent case.

Discussion

The most recently published articles on the costs of revascularization have been reviewed on the basis of outcomes and costs derived in the United States. Costs for PCI in single-vessel disease are lower than costs for PCI in multivessel disease. Although initial estimated costs are lower for multivessel PCI (with or without stenting) than CABG, longer-term costs and lifetime costs are similar. Drug-eluting stents have the potential to alter treatment and economics dramatically, although it is too early to draw definitive conclusions about their costs.

Revascularization procedures, including CABG and PCI with or without stenting, are costly, and new technologies have the potential to affect managed care organizations substantially. However, cost data are not only difficult to interpret but must also be placed in a suitable context, particularly if comparisons are to be made. It is important that the context of any cost analysis for revascularization procedures include the patient population, the length of follow up, the treatment practices in the country or region under consideration, the type of study on which the outcomes are based, and the current state-of-the-art treatment, among others. ^{2-4,6-9}

The most obvious examples herein lie within the Weintraub et al study. Patients in the randomized and registry groups were similar overall in baseline characteristics and long-term outcome, although within the registry group sicker patients were more likely to undergo CABG. PTCA registry group mean costs are lower than those for the PTCA randomized group for initial hospitalization, total 3-year costs and total 8year costs, while the opposite is true for the CABG groups. This is likely due to patient selection bias, as sicker registry patients were treated with CABG, making CABG registry costs higher than CABG randomized costs, and less sick registry patients were treated with PTCA, making PTCA registry costs lower than PTCA randomized costs. Additionally, while registry group mean costs for PTCA are 48% to 58% of those of CABG at the time intervals, the long-term costs in the randomized groups are comparable at 8 years likely due to repeat revascularizations necessary for patients undergoing initial PTCA.

The cost-related findings of Weintraub and colleagues may be at odds with the find-

ings of Reynolds and colleagues.9 Although Reynolds and colleagues found no significant differences in mortality outcomes over a median 2.8-year follow up and that PCI patients required more frequent repeat revascularization, the difference in costs of multivessel stenting versus CABG was statistically significant at initial hospitalization and at 2 years in favor of multivessel stenting. It is possible that Reynolds and colleagues' stenting and CABG costs would converge over a longer term, as was the case with the randomized results from Weintraub and colleagues, or that advances such as minimally invasive CABG, not reflected in either study, would cause costs to converge over a shorter term. However, there are notable differences in the Reynolds et al study methods that may support a sustained difference in costs. For example, all PCI patients were treated with stenting, while stenting is represented to only a limited extent in the Weintraub et al study. This is an important consideration given that today, 70% to 90% of PCIs involve placing 1 or more stents, resulting in improved procedural safety and reduced rates of restenosis compared with balloon angioplasty. Furthermore, while baseline patient characteristics were similar between groups in the Reynolds et al study, similar to the randomized groups of the Weintraub et al study, many patients underwent PCI immediately after diagnostic coronary angiography and this resulted in 1 less diagnostic catheterization procedure and a reduction of preprocedure length of stay for many patients, which is perhaps more reflective of real-world practices. The cost differences in stenting versus CABG in the Reynolds et al study may be muted for drug-eluting stents given their increased costs, or may be enhanced because of decreased repeat revascularization procedures, when viewed in the context of the state-of-the-art treatment today. Lastly, the 2 studies used different approaches to deriving costs, which may affect comparison efforts.

The examples of issues noted above become even more important when comparing cost-related findings between geographies. A number of cost articles based on European outcomes and cost data¹⁵⁻¹⁷ are

fairly widely cited in the literature; however, these may not be relevant to US audiences because of differing practice patterns and resource costs. Variation in practice patterns may limit the applicability of cost and cost-effectiveness analyses.

Of particular concern in evaluating revascularization costs is how to balance longterm outcomes and cost data with procedures undergoing rapid technology improvement and advancement. The burden on managed care from technology and procedure advances may increase if these advances come at a premium price or increase the volume of use. However, premium prices and increased volume may be offset if these advances are able to save resources and costs.

Even recently published studies include long-term data from periods during which stents were just beginning to be adopted. However, as previously noted, it is estimated that 70% to 90% of current angioplasties involve placing 1 or more stents, and it is possible that many or the majority of these stents will be drug-eluting stents in the very near future. Recent clinical and economic models, such as those of O'Neill and Leon, 10 and Chumer and colleagues,14 provide insight into the potential impact of drug-eluting stents on hospitals. Though not captured in our original literature review because of its recent publication, data from a disease state-transition computer model simulated clinical and economic consequences 5 years after the introduction of drug-eluting stents to hospitals. The results showed that introducing these stents would change a \$2.29 million annual hospital profit (2003 dollars) to a loss of \$5.41 million in the first year and \$6.38 million in annual losses in later years, based on an annual volume of 3112 patients with 85% of stent procedures shifted to drugeluting stents in year 1, and assuming proposed changes in Medicare reimbursement policy.18 This would divert over \$28 million from the hospital over a 5-year period.

Revascularization procedures are costly, and short-term cost differences in procedures may disappear when considered over the long term. Recent cost data do not likely reflect current treatment practices given the rapid innovation in revascularization proce-

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dures and technology and the lag in publication of cost data reflecting these advances. Modeling provides insight into the potential effect of these advances, although models' assumptions have yet to bear out. It is common for physicians and payers to try to make informed clinical decisions with an eye toward cost containment. The costs of the procedures must be understood and placed in the appropriate context.

A limitation to this review is that the costs discussed may not reflect real world costs. Most of the costs referenced are based on resource utilization from protocol-driven clinical trials. Clinical trials often require resource utilization that may not be reflective of real-world practice. This is important for payers relying on such cost data to make informed decisions.

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