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Drug-Eluting Stents and the Use of Percutaneous Coronary Intervention Among Patients With Class I Indications for Coronary Artery Bypass Surgery Undergoing Index Revascularization

Analysis From the NCDR (National Cardiovascular Data Registry)

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Objectives Our purpose was to evaluate percutaneous coronary intervention (PCI) attempt rates in patients with class I indications for coronary artery bypass graft (CABG) surgery after the introduction of drug-eluting stents (DES).

Background In patients with severe, multivessel coronary disease, CABG has historically been recommended over PCI. Practice guidelines for CABG were last updated before the emergence of data on DES efficacy.

Methods We analyzed 265,028 procedures from the NCDR (National Cardiovascular Data Registry) meeting American College of Cardiology/American Heart Association class I indications for surgical revascularization. Temporal trends in PCI attempt rates were analyzed during 3 consecutive time periods: pre-DES (before April 1, 2003), DES diffusion (April 1, 2003 to December 31, 2004), and DES (January 1, 2005 to September 30, 2006).

Results The attempted rate of PCI in patients with class I indications for CABG increased over the 3 time periods (pre-DES: 29.4%, DES diffusion: 33.4%, and DES era: 34.7%, $p < 0.001$). In a hierarchical multivariable logistic model adjusting for patient and PCI site characteristics, PCI attempts were more likely in the DES compared with pre-DES era (odds ratio: 1.44, 95% confidence interval: 1.40 to 1.48) and the DES diffusion era (odds ratio: 1.20, 95% confidence interval: 1.17 to 1.23). PCI attempt rates increased in all 3 time periods, although the average rate of increase during the DES era was 0.6% per quarter compared with 0.3% per quarter for both the DES diffusion and the pre-DES eras ($p = 0.03$).

Conclusions DES use in clinical practice was associated with a significant overall increase in PCI to treat patients with class I indications for CABG. Long-term follow-up of this cohort of patients is warranted. (J Am Coll Cardiol Intv 2009;2:614–21) © 2009 by the American College of Cardiology Foundation

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Coronary artery bypass grafting (CABG) has been the standard revascularization strategy for patients with left main and severe multivessel coronary artery disease (CAD) (1,2). Multivessel percutaneous coronary intervention (PCI) with bare-metal stents (BMS) has achieved similar freedom from mortality and myocardial infarction (MI) as CABG but at a significant cost of repeat revascularization (3). The introduction of drug-eluting stents (DES) dramatically improved vessel patency compared with BMS (4,5) and may

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have impacted physician judgment on the appropriateness of PCI in patients with multivessel disease. Recent data suggest that multivessel PCI with DES has comparable survival to CABG at long-term follow-up (6). However, discordant data have also been published from the New York State CABG and PCI databases demonstrating improved survival among those with multivessel CAD treated with CABG compared with DES-PCI (7).

There has been little data to evaluate whether the introduction of DES has influenced clinical practice with regard to the use of PCI rather than CABG surgery among patients with indications for CABG. Thus, we examined data from the NCDR (National Cardiovascular Data Registry) to determine whether the introduction and adoption of DES in clinical practice has led to greater use of PCI among patients with class I indications for CABG.

Methods

Study population and definitions. A description of the NCDR has been previously published (8,9). Analysis was limited to centers reporting data on both diagnostic coronary angiography and PCI procedures from January 1, 2001 to September 30, 2006. Centers not reporting both procedures or changing reporting methods over time were excluded.

Eligible patients had ≥1 of the following American College of Cardiology/American Heart Association class I indications (2) for isolated CABG surgery: 1) left main stenosis >50%; 2) left main equivalent disease (proximal left anterior descending coronary artery [LAD] and left circumflex stenosis >70%); 3) 3-vessel disease; 4) proximal LAD >50% and left ventricular ejection fraction <50%; 5) 2- or 3-vessel disease and left ventricular ejection fraction <50%; or 6) 2-vessel disease including proximal LAD with either angina or demonstrable ischemia on stress testing (2). Patients having emergency or salvage indications for PCI or CABG, history of CABG or PCI, an indication for catheterization of aortic or mitral valve disease, ST-segment elevation MI, or prior cardiac transplant were excluded.

Patients were classified a priori into 3 separate time periods according to DES availability and prior data suggesting an increased usage rate until the year 2005 (10): 1) pre-DES era (before April 1, 2003, date of sirolimus-eluting stent approval); 2) DES diffusion era (April 1, 2003 to December 31, 2004, date >75% DES use achieved); and 3) DES era (January 1, 2005 to September 30, 2006). The last quarter of 2006 was not included as the first data on late stent thrombosis associated with DES use were presented at the World Congress of Cardiology in Barcelona during this time (11). These dates were then re-evaluated by examining participating centers that submitted uninterrupted data to the NCDR in at least 2 of the 3 time periods for all and among patients with class I indications for CABG.

Statistical analysis. Baseline characteristics were compared in each pre-specified time period using a chi-square test for categorical variables and a 1-way analysis of variance test for continuous variables. Average quarterly DES utilization rates were calculated for all patients and patients with class I indications for CABG, with results graphically displayed to validate the a priori time grouping. Unadjusted slope comparisons of PCI attempt rates over time between the 3 periods were performed using a generalized linear model weighting the quarterly mean PCI rates at each site in patients with class I indications. To further evaluate PCI use during each time period, a hierarchical multivariable logistic regression model was generated using hospital site as the second order. Covariates included age, sex, race, body mass index, acute coronary syndrome, history of congestive heart failure, New York Heart Association functional class, ejection fraction, hypercholesterolemia, left main stenosis >50%, number of diseased vessels, and absence of diabetes, renal failure, cerebrovascular disease, peripheral vascular disease, prior MI, hypertension, and tobacco use. An additional time covariate was not included due to collinearity with the 3 specified time periods (variance inflation factor = 7.9 and highly correlated eigenvalues >0.5). Variables in the model determined to be statistically significant are displayed in a forest plot. Further analysis was performed to determine the effect of DES utilization on PCI attempt rates in the DES era by calculating the quarterly DES utilization rate for all PCI procedures at each site. A hierarchical multivariable logistic model using the same covariates as above was performed with quarterly DES utilization rate as the main effect of interest. From this model, an adjusted PCI attempt rate was calculated across deciles of DES utilization rates and displayed using a skeletal box and whisker plot. Statistical significance was defined as $p \leq 0.05$. Analyses were performed using SAS version 9.1 (SAS Institute, Cary, North Carolina).

Abbreviations and Acronyms

BMS = bare-metal stent(s)
CABG = coronary artery bypass grafting
CAD = coronary artery disease
DES = drug-eluting stent(s)
LAD = left anterior descending coronary artery
MI = myocardial infarction
PCI = percutaneous coronary intervention

Results

DES utilization rates for the entire NCDR PCI population (N = 1.06 million) and PCI patients with class I indications for CABG (n = 265,028) are shown in Figures 1A and 1B, respectively. Among all patients undergoing PCI, use of DES increased steadily to approximately 84% in 2005 (Fig. 1A). In patients with class I indications for CABG, DES utilization also increased and reached a plateau of 88% during the DES era.

Baseline clinical characteristics, class I indications for CABG, and medical center characteristics are shown in Table 1. Among patients with class I indications for CABG during the study period, 87,139 (33%) underwent PCI. There were 299 centers included in the analysis, although all were not equally represented during all 3 time periods (216 pre-DES, 292 DES diffusion, and 299 DES era). There were no statistically significant differences in in-hospital events including death and vascular complications.

Since the adoption of DES, there was a decrement in patients identified as having a class I indication for CABG (12.4% in the pre-DES vs. 11.7% in the DES diffusion and 10.7% in the DES era, $p < 0.001$) and a statistically significant decrease in the rate of in-hospital CABG (33.0% vs. 30.1% and 30.7%, respectively, $p < 0.001$). However, PCI attempt rates increased steadily over time among patients with any class I indication (29.4% vs. 33.4% and 34.7%, respectively, $p < 0.001$) (Fig. 2), although the average rate of increase during the DES era was 2-fold greater (0.6% per quarter) than the DES diffusion and the pre-DES eras (0.3% per quarter for both, $p = 0.03$). Results of the hierarchical multivariable logistic model controlling for hospital site are displayed in Figure 3. After adjustment, PCI attempt rates in patients with class I indications for CABG were greatest in the DES compared with pre-DES era (odds ratio: 1.44, 95% confidence interval: 1.40 to 1.48) and the DES diffusion era (odds ratio: 1.20, 95% confidence interval: 1.17 to 1.23).

Figure 3 demonstrates the relative odds of PCI attempt rates in subgroups of clinical interest. The absence of presumed high risk clinical demographics including diabetes mellitus, renal failure, cerebral vascular disease, peripheral vascular disease, MI, hypertension, and tobacco use were associated with increased odds of attempted PCI. Increased likelihood of attempted PCI was also evident in younger patients, women, non-Caucasians, and patients with acute coronary syndromes, higher ejection fraction, and less diffuse disease.

PCI attempt rates among patients with selected class I indications by time period are shown in Table 2. For each indication, PCI was more likely to be attempted after than before the adoption of DES in clinical practice.

Although the rate of DES use during the DES era appeared to be steady, intracenter and intercenter variability in PCI attempt rates and DES utilization was apparent. Figure 4 displays the relationship between PCI attempt rate and DES use by site during the DES era. On average, centers using more DES were more likely to attempt PCI in patients with class I CABG indications.

Discussion

Over a 6-year period from 2001 to 2006, we found that use of PCI as the initial form of revascularization among patients with a class I indication for CABG increased in a fashion that was temporally related to the introduction and adoption of DES into U.S. practice. This increase was seen across all categories of patients regardless of clinical char-

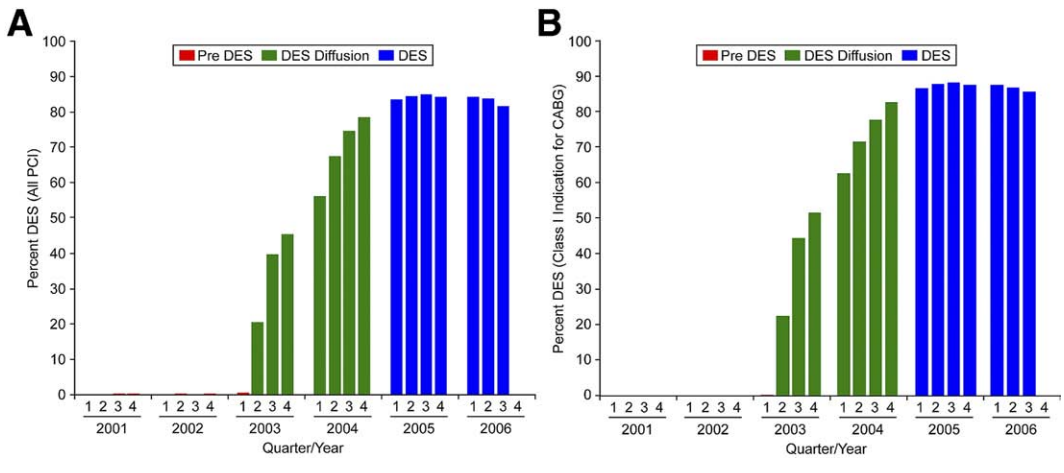

Figure 1. DES Use in PCIs

The proportion of patients undergoing percutaneous coronary interventions (PCIs) with drug-eluting stents (DES) by quarter from 2001 to 2006 during the pre-DES, DES diffusion, and DES era in the entire National Cardiovascular Data Registry population **(A)** and limited to patients with class I indications for coronary artery bypass grafting (CABG) **(B)**. DES use increased to a maximum of 88% in all PCIs during the second quarter of 2005. Definitions of each time interval as in Table 1.

Table 1. Clinical Characteristics, Class I Indications for CABG, and Medical Center Characteristics

	Pre-DES Before April 1, 2003 (N = 67,316)	DES Diffusion April 1, 2003 to December 31, 2004 (N = 97,402)	DES January 1, 2005 to September 30, 2006 (N = 100,310)
Age*, yrs	67.0 ± 11.8	67.1 ± 11.8	66.4 ± 11.8
Men*, %	67.8	68.0	68.6
Caucasian*, %	89.8	88.8	86.6
Acute coronary syndrome*, %	59.6	57.5	59.4
Diabetes mellitus*, %	34.8	35.5	36.7
Renal failure*, %	5.8	6.8	6.9
Cerebrovascular disease, %	13.5	13.5	13.4
Peripheral vascular disease*, %	15.8	14.7	13.9
Prior myocardial infarction*, %	20.5	18.9	17.4
Current congestive heart failure*, %	14.4	13.9	15.1
Chronic lung disease*, %	16.9	17.3	17.8
Hypertension*, %	70.8	74.0	75.7
Current smoking*, %	23.8	23.5	25.2
Dyslipidemia*, %	59.3	63.9	67.7
Height*, cm	171.0 ± 10.8	171.0 ± 10.8	171.3 ± 11.1
Weight*, kg	85.2 ± 19.7	85.5 ± 20.2	86.2 ± 20.5
Body mass index*, kg/m^2	29.3 ± 12.7	29.3 ± 10.3	29.3 ± 6.3
Ejection fraction*, %	48.4 ± 14.4	48.5 ± 14.0	48.3 ± 13.4
Diseased vessels, %			
1	5.3	5.2	5.3
2	32.4	32.4	32.7
3	62.2	62.4	62.0
Class I CABG indications*, %			
Left main >50%	15.8	16.5	17.3
Left main equivalent	24.7	24.6	24.7
3-vessel disease >50%	32.6	32.6	31.5
Proximal LAD >50% and LVEF <50%*	10.6	10.2	10.4
2 or 3 vessels >50% and LVEF <50%*	9.8	9.2	8.7
Angina, positive stress test, and ≥2 vessels with proximal LAD >50%*	6.5	6.9	7.4
Center characteristics			
Diagnostic catheterizations/year, n	1,889.7 ± 1,270.5	1,841.9 ± 1,290.0	1,834.7 ± 1,284.5
PCI/year, n	787.3 ± 605.2	798.9 ± 642.8	795.0 ± 639.8
>400 PCI/year, %	71.1	71.2	70.9
Onsite CABG, %	91.7	89.0	89.0
Hospital type, %			
Government	1.8	1.4	1.3
Community	91.7	91.4	91.6
University	6.4	7.2	7.0
In-hospital events, %			
Death	1.8	1.6	1.6
Vascular complications	1.4	1.4	1.2
In-hospital CABG	33.0	30.1	30.7

*$p < 0.001$, 3-group comparison.
CABG = coronary artery bypass grafting; DES = drug-eluting stent(s); LAD = left anterior descending; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention.

acteristics, indications for surgical revascularization, comorbidities, or surgical risk score. Similarly, there was a corresponding decrease in in-hospital referral to CABG surgery. Although an increase in PCI attempt rates was observed in all pertinent subgroups, including patients with 3-vessel CAD, PCI was not performed indiscriminately, as evidenced by a higher likelihood for PCI in subjects with lower risk (e.g., 1- or 2-vessel disease) than higher-risk class I indications for CABG (i.e., left main or 3-vessel CAD). In risk-adjusted models accounting for site, PCI attempt rate

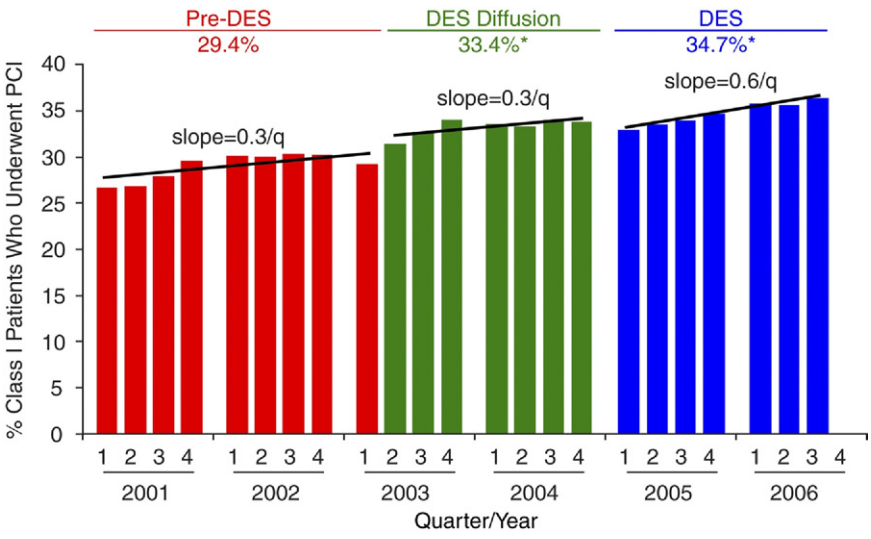

Figure 2. PCI Attempts in Patients With Class I Indications for CABG

The proportion of patients with class I CABG indications undergoing attempted PCI by quarter from 2001 to 2006 during the pre-DES, DES diffusion, and DES era. *$p < 0.001$ versus pre-DES era. The quarterly slope of increase was 2-fold greater in the DES than the DES diffusion and pre-DES eras. *$p = 0.03$ versus pre-DES era. Abbreviations as in Figure 1. Definitions of each time interval as in Table 1.

was independently associated with the DES era among patients with class I indications for CABG surgery.

Two earlier studies in more select populations demonstrated a similar association between the introduction of DES and the increased use of PCI in patients with indications for surgical revascularization. A previous study from the NCDR (12) showed that among 32,563 patients with unprotected severe left main artery disease, the use of PCI increased from 17.0% in 2002 to 21.9% in 2004—the year immediately after DES approval ($p < 0.0001$). At the same time, use of CABG in these patients decreased from 83.0% to 78.1% ($p < 0.0001$). Similar to our findings, these trends were seen among selected clinical subgroups, including elective procedures. In another previous study (13), investigators with the CRUSADE (Changes in Patterns of Coronary Revascularization Strategies for Patients With Acute Coronary Syndromes) quality improvement initiative found that among 25,068 patients presenting with non–ST-segment acute coronary syndromes and 3-vessel disease, the rate of PCI increased (51.1% to 60.1%), medical management remained relatively constant (27.8% to 25.5%), and the use of CABG decreased (48.9% to 39.9%). Our findings add to these studies in 2 ways. First, our cohort consisted of all patients with American College of Cardiology/American Heart Association class I indications for CABG and, therefore, included a much broader population of patients. Second, the study cohort also included large numbers of patients who presented with and without acute coronary syndromes (59% and 41%, respectively), demonstrating a similar association between increased PCI use and availability of DES regardless of presentation to the catheterization laboratory.

Early clinical trials demonstrated that CABG was preferred over medical therapy in patients with left main or severe multivessel CAD (1). Subsequent clinical trials demonstrated that multivessel PCI with BMS achieves similar freedom from mortality and MI as CABG, but at a cost of excess repeat revascularization (3). In a separate observational study, Park et al. (6) found that patients who had multivessel PCI with DES had comparable mortality at 3 years compared with CABG patients. These investigators also found that rates of repeat revascularization were higher in those who underwent PCI with DES than CABG. In contrast, using data from the New York State CABG and PCI registries Hannan et al. (7) reported that subjects with multivessel CAD who underwent DES-PCI had decreased survival at intermediate follow-up (18 months) compared with that seen with CABG. The absolute difference in mortality was 2.7%. Whether this survival difference persists beyond 18 months is not known. Moreover, although the authors attempted to adjust for selection bias using multivariable modeling and propensity analysis it is likely that at least some of the observed difference is related to unmeasured confounding (14). It should be noted that both of these studies were observational in design and, therefore, do not provide definitive evidence of the superiority of one strategy over the other.

The attractiveness of using DES-PCI over CABG may stem from risks of perioperative mortality and morbidity, including risk of stroke, neurocognitive decline, sternal

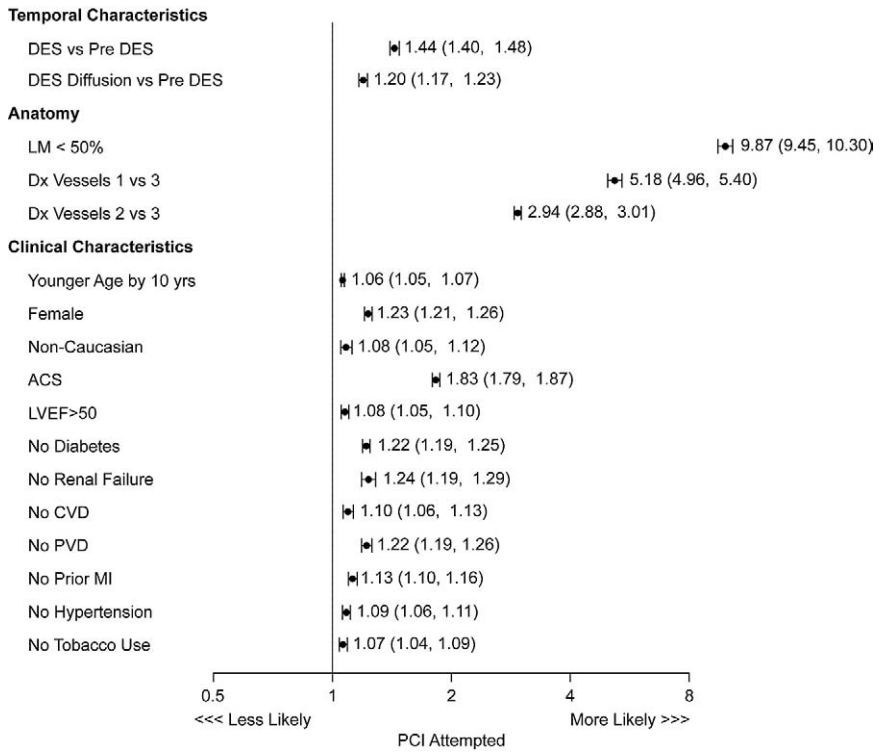

Figure 3. Hierarchical Multivariable Logistic Regression Model

Predictors of PCI in patients with class I coronary artery bypass grafting indications. **Solid circles** represent odds ratios; **lines** are 95% confidence intervals. ACS = acute coronary syndromes; CVD = cardiovascular disease; Dx = diseased; LM = left main; MI = myocardial infarction; PVD = peripheral vascular disease; other abbreviations as in Table 1.

wound infection, and bleeding in patients undergoing CABG (15). Also, in certain subgroups, PCI with BMS appears to be less expensive than CABG even at long-term follow-up (16). At the same time, DES-PCI reduces in-stent restenosis and repeat revascularization in a variety of clinical settings (17–21), potentially improving the risk-benefit ratio of multivessel PCI compared with CABG in patients whose clinical characteristics place them at higher risk for surgical complications.

Many questions remain on the efficacy of DES compared with CABG in this population, including rates of stent thrombosis and durability of vessel patency. A number of registries have demonstrated that DES-PCI in patients with unprotected left main or multivessel disease is not only feasible but may improve outcomes over BMS (22,23). It has also been shown that prior PCI is associated with an increased hazard for future CABG (24). Furthermore, the American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions guideline update for PCI leaves much to the discretion of the operator and provides only an explicit recommendation against unprotected left main stenting (25). Neverthe-

Table 2. PCI Attempts by Individual Class I Indication for CABG

	Pre-DES (N = 67,316)	DES Diffusion (N = 97,402)	DES (N = 100,310)	p Value
Left main stenosis >50%	609 (5.7)	1,131 (7.0)	1,134 (6.5)	<0.001
Left main equivalent	3,940 (23.7)	6,923 (28.9)	7,637 (30.9)	<0.001
3-vessel disease	6,076 (27.7)	10,242 (32.3)	10,497 (33.2)	<0.001
Proximal LAD >50% and LVEF <50%	3,681 (51.5)	5,435 (54.8)	6,044 (57.8)	<0.001
2- or 3-vessel disease and LVEF <50%	3,277 (49.4)	4,875 (54.2)	4,953 (56.8)	<0.001
Class I indication with abnormal stress test	2,241 (51.6)	3,885 (57.9)	4,559 (61.5)	<0.001

Data are n (%).
Abbreviations as in Table 1.

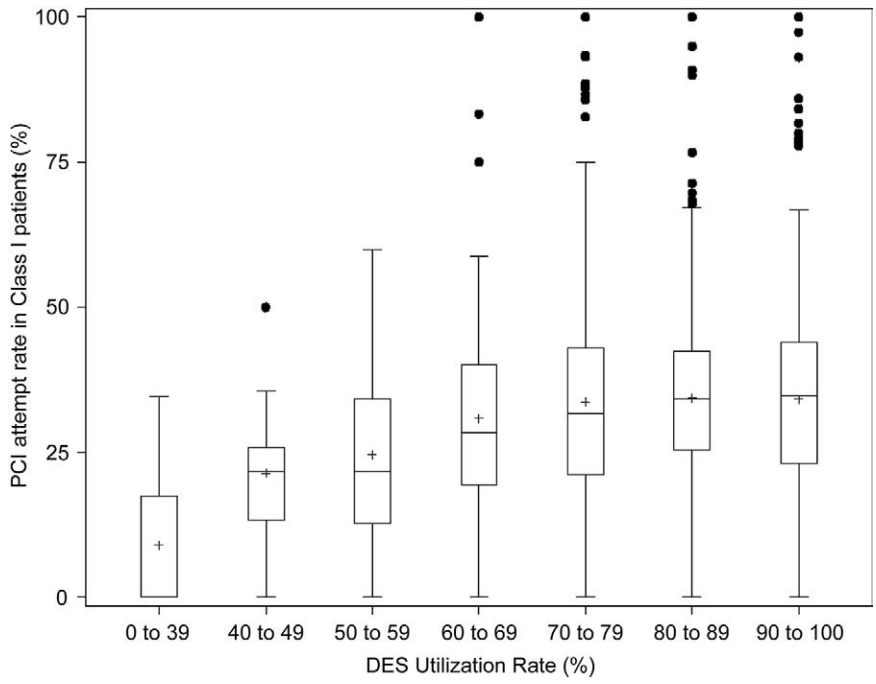

Figure 4. Quarterly PCI Attempts by Decile of DES Utilization

A hierarchical multivariable logistic regression model with quarterly DES utilization rate as the main effect of interest was developed to determine the adjusted rate of PCI attempted during the DES era at each hospital site ($p = 0.036$). The Y-axis is the PCI attempt rate in patients with a class I indication for coronary artery bypass grafting. The X-axis is the mean quarterly DES utilization rate by center. Abbreviations as in Figure 1.

less, randomized controlled trials comparing multivessel DES-PCI with CABG are needed to determine longitudinal outcomes including death, MI, and revascularization.

Reports of late and very late stent thrombosis and concomitant adverse clinical outcomes associated with DES (26) raise concerns that multivessel or left main stenting with DES may augment a very low but real risk of catastrophic events. In addition, risk factors for late stent thrombosis associated with DES have only recently emerged (27,28). Multivessel or left main stenting may introduce other factors that increase risk, such as off-label use of DES in small vessels or more complex lesions (29). These concerns are compounded by a report indicating a sizable number (14%) of patients who received DES during primary PCI discontinued thienopyridine therapy within 30 days and had a 10-fold increase in 1-year mortality (30). Although the clinical consequences and long-term implications of this significant shift toward PCI among patients with class I CABG indications have yet to be determined, our findings should emphasize that the widespread adoption of novel device technology platforms such as DES can occur in populations not represented in the initial clinical trials evaluating these technologies.

There are a number of limitations to our study. First, we cannot establish a causal relationship between the availability of DES and the observed revascularization trends. Other advances in coronary interventional practice and technology as well as adjunctive medical therapy may have contributed to this trend, although none are as prominent in the time period studied as the introduction of DES. Second, the NCDR does not record data on lesion anatomy or the role of patient preferences and procedure refusals, all of which may have impacted revascularization decisions. Third, we were unable to directly compare PCI and CABG rates among patients with class I indications because the NCDR captures data at diagnostic catheterization only for in-hospital referrals for CABG. Thus, a sizable proportion of patients may have returned for elective CABG. Fourth, we recognize that our unadjusted reported increase in use of DES in patients with class I indications for CABG at first glance seems modest. However, this actually represents a relative 18% increase in PCI, translating into several thousand patients undergoing attempted PCI. Extrapolated to all centers performing PCI in the U.S., we believe this increase is not only statistically significant but clinically important. Finally, we were unable to determine the impact of changes in revascularization strategy on long-term clinical outcomes, complications, or subsequent hospitalizations, because the NCDR is limited to periprocedural or in-hospital events.

Conclusions

The introduction and widespread adoption of DES was associated with a significant increase in the use of PCI to treat patients with severe multivessel CAD with class I indications for CABG. Long-term follow-up from randomized controlled trials among such patients is needed to understand the implications of this trend.

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