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Insurance Type Influences the Use of Drug-Eluting Stents

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Objectives We sought to examine the effect of insurance type upon the likelihood of receiving a drug-eluting stent (DES).

Background Recent guidelines suggest that consideration of a patient's resources should play a role in decisions to use DES. Previous studies have also documented disparities in both access to care and cardiovascular outcomes according to race, insurance, and socioeconomic status. The effect of insurance status upon the decision to use DES is unclear.

Methods Patients undergoing percutaneous coronary intervention (PCI) with stenting from April 2003 to June 2009, the so-called DES era, were retrospectively analyzed. Multivariable logistic regression was performed separately for patients <65 years and patients ≥65 years, with receipt of ≥1 DES during PCI as the outcome variable of interest. Insurance type was categorized as private, Medicare, Medicaid, and uninsured, based upon the primary insurance at discharge. Data regarding duration of clopidogrel therapy at 1 month, 6 months, and 1 year was also collected.

Results Among the 12,584 patients who underwent PCI with stenting, 6,157 (48.9%) had private insurance, 5,689 (45.2%) had Medicare, 467 (3.7%) had Medicaid, and 271 (2.2%) were uninsured at the time of hospital discharge. There were no significant differences by insurance type in duration of dual antiplatelet therapy at 1 year. Both multivariable logistic regressions showed that Medicaid patients (odds ratio [OR]: 0.60; 95% confidence interval [CI]: 0.46 to 0.78 for age <65 years; OR: 0.45; 95% CI: 0.24 to 0.85 for age ≥65 years) and patients without insurance (OR: 0.57; 95% CI: 0.42 to 0.78 for age <65 years; OR: 0.20; 95% CI: 0.05 to 0.86 for age ≥65 years) were less likely to receive DES.

Conclusions Insurance status has a significant impact upon the decision to use DES. Efforts to address this disparity should focus on the patient-provider level. (J Am Coll Cardiol Intv 2010;3: 773–9) © 2010 by the American College of Cardiology Foundation

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Drug-eluting stents (DES), compared with bare-metal stents, reduce in-stent restenosis and repeat revascularization (1–5). Furthermore, data from both randomized clinical trials and real-world registries indicate that DES are both safe and effective in a wide range of patients and lesions (6). Drug-eluting stents, however, also result in delayed re-endothelialization and likely expose patients to a higher risk for very late stent thrombosis, although

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overall rates of stent thrombosis are similar to bare-metal stents (2,3,7). Therefore, recent guidelines recommend dual antiplatelet therapy (DAPT) with aspirin and clopidogrel for at least 12 months in percutaneous coronary intervention (PCI) patients with DES (8,9). Because of the risk of stent thrombosis associated with premature cessation of DAPT (10–13), the same guidelines also caution that a physician should not select DES for patients without access to or unlikely to be compliant with DAPT (8).

Abbreviations and Acronyms

CABG = coronary artery bypass grafting
CI = confidence interval
DES = drug-eluting stent(s)
MI = myocardial infarction
OR = odds ratio
PCI = percutaneous coronary intervention
STEMI = ST-segment elevation myocardial infarction

This decidedly vague recommendation raises questions about the impact of patient-level socioeconomic factors upon the decision to use DES. Although clinical factors like the risk of bleeding might be objectively assessed, the impact of factors like type of insurance upon the clinical decision to use DES is less easily quantified. There are also wide-ranging published data documenting disparities in access to care and outcomes according to race, insurance type, and socioeconomic status (14–20). More specifically, African-American, poor, and uninsured patients are less likely to be referred for invasive cardiac procedures (18,19,21). The influence of a patient's insurance type upon individual decisions to use DES, however, is less well-documented. We therefore sought to examine the impact of insurance type upon the receipt of ≥1 DES during PCI, hypothesizing that uninsured patients would be less likely to receive DES.

Methods

Study population. Clinical, procedural, and follow-up data for patients undergoing PCI with stenting at a single center were prospectively entered and retrospectively analyzed. Indications for PCI included stable angina, unstable angina, and acute myocardial infarction (MI). This study was restricted to patients receiving any stent between April 23, 2003 and June 22, 2009, the so-called "DES era." Stent selection was at the operator's discretion and not dictated by differences in cost or availability, because pricing of DES platforms was approximately equal and contracts for individual DES were not in force. This database was then merged with the hospital billing database, which includes primary insurance type (or lack thereof) and zip code for each patient at the time of hospital discharge. Zip code was matched with U.S. Census Bureau data regarding median household income by zip code to approximate patient household income (22).

Anticoagulation regimen. All patients received aspirin 325 mg and clopidogrel 300 to 600 mg (at the operator's discretion) before the procedure. Anticoagulation regimens were chosen at the operator's discretion and included unfractionated heparin targeted to achieve an activated clotting time of 200 to 300 s, with or without a glycoprotein IIb/IIIa inhibitor, or bivalirudin 0.75 mg/kg followed by an infusion of 1.75 mg/kg/h for the duration of the procedure. After the procedure, aspirin 81 to 325 mg daily was prescribed indefinitely, and clopidogrel was prescribed for a minimum of 1 month in patients receiving bare-metal stents and 6 months in patients receiving drug-eluting stents.

Clinical data and follow-up. The Institutional Review Board at Washington Hospital Center and MedStar Research Institute (Washington, DC) approved this study. A dedicated data coordinating center performed all data management and analyses. Pre-specified clinical and laboratory data during hospital stay periods were obtained from hospital charts reviewed by independent research personnel blinded to the objectives of the study. Clinical follow-up at 30 days, 6 months, and 1 year was conducted by telephone contact or office visits. Patients were asked if they were still taking clopidogrel; if they had stopped taking clopidogrel, the total number of days on clopidogrel was recorded.

Study definitions. Patients were placed in the DES group if they underwent PCI with ≥1 DES, for both on- and off-label indications. Primary insurance type was categorized as private, Medicare, Medicaid, or uninsured. Race was defined on the basis of the patient's response upon admission. Patients identified themselves as African-American, Caucasian, Asian, Hispanic, or Native-American and could only select one. Patients were then defined as African-American or non–African-American for purposes of comparison. Acute presentation was defined as presenting with unstable angina, non–ST-segment elevation myocardial infarction, or ST-segment elevation myocardial infarction (STEMI).

Statistical analysis. Continuous variables are presented as mean ± SD; categorical variables are presented as percentages. Differences in continuous variables between groups were compared with the Student *t* test. Categorical variables were compared with the chi-square test or Fisher exact test when appropriate. A p value <0.05 was considered statistically significant. To test the independent effect of insur-

ance type upon the likelihood of receiving ≥1 DES, we constructed 2 multivariable logistic regression models. Given that all patients 65 years or older are eligible for Medicare, we performed separate multivariable logistic regressions for patients <65 years of age and patients ≥65 years of age. Private insurance was used as the reference group for both regressions. Covariables for both models were selected on the basis of significant univariable p values and overall clinical relevance, with particular attention to clinical factors that would make DES usage less likely. Covariables for the multivariable models included insurance type, race, age, sex, current smoking status, baseline hematocrit, presentation with STEMI, presentation with shock, and a history of the following: PCI, coronary artery bypass grafting (CABG), congestive heart failure (CHF), hypertension, peripheral vascular disease, chronic renal insufficiency (CRI), and diabetes mellitus. We tested for interaction terms, including age and insurance, African-American race and insurance, and smoking and insurance; none of these terms was significant. Insurance type and median household income by zip code were collinear, although an interaction term between these 2 variables was not significant; therefore median income was excluded from multivariable analysis. Covariables in the models are expressed as odds ratios (ORs) with 95% confidence intervals (CIs). Statistical analyses were performed with SAS version 9.1 (SAS Institute, Cary, North Carolina).

Results

Baseline characteristics. This study included 12,584 patients who underwent PCI with stenting after April 25, 2003 (Table 1). Six thousand one hundred fifty-seven (48.9%) had private insurance, 5,689 (45.2%) had Medicare, 467 (3.7%) had Medicaid, and 271 (2.2%) were uninsured at the time of hospital discharge after PCI. Fifty-two percent of patients were younger than 65 years of age; of this group, 5,318 (81.3%) had private insurance, 576 (8.8%) had Medicare, 396 (6.1%) had Medicaid, and 254 (3.9%) were uninsured. Eight thousand three hundred five (66.0%) patients were Caucasian, 3,272 (26.0%) were African-American, 408 (3.2%) were Asian, 133 (1.1%) were Hispanic, and 47 (0.4%) were Native American. Patients with Medicare ($59,657), no insurance ($55,358), and Medicaid ($40,871) all had lower household median incomes than patients with private insurance ($62,680; $p < 0.001$ for trend).

Procedural characteristics. Overall, 9,389 (74.6%) patients received ≥1 DES. The proportion of patients by insurance type receiving ≥1 DES was 4,833 (78.5%) with private insurance, 4,111 (72.3%) with Medicare, 281 (60.2%) with Medicaid, and 164 (60.5%) without insurance ($p < 0.001$ for trend). African Americans were less likely to receive DES than non–African Americans (69.8% vs. 76.6%, $p < 0.001$). Patients receiving DES, compared with patients not

Table 1. Baseline Characteristics by Insurance Type

Variable	Private (n = 6,157)	Medicare (n = 5,689)	Medicaid (n = 467)	Uninsured (n = 271)	p Value
Male	4,534 (73.7%)	3,284 (57.8%)	249 (53.5%)	200 (73.8%)	<0.001
Race					
Caucasian	4,251 (69.0%)	3,820 (67.1%)	91 (19.5%)	143 (52.8%)	<0.001
African American	1,393 (22.6%)	1,476 (25.9%)	314 (67.2%)	89 (32.8%)	<0.001
Asian	204 (3.3%)	174 (3.1%)	16 (3.4%)	14 (5.2%)	0.270
Hispanic	62 (1.0%)	47 (0.8%)	15 (3.2%)	9 (3.3%)	<0.001
Age	57.4 ± 9.4	73.2 ± 9.5	55.0 ± 10.7	53.5 ± 9.0	<0.001
Median household income by zip code	$62,680 ± 20,821	$59,657 ± 20,908	$40,871 ± 15,597	$55,358 ± 16,412	<0.001
STEMI	809 (14.8%)	556 (10.9%)	113 (25.5%)	84 (33.5%)	<0.001
NSTEMI or unstable angina	2,232 (40.8%)	1,905 (37.2%)	148 (33.3%)	71 (28.3%)	<0.001
Shock on presentation	189 (3.1%)	234 (4.2%)	34 (7.4%)	19 (7.1%)	<0.001
Previous coronary artery bypass surgery	787 (12.8%)	1,345 (23.8%)	59 (12.7%)	20 (7.4%)	<0.001
Previous percutaneous coronary intervention	1,356 (23.2%)	1,342 (26.1%)	98 (23.0%)	43 (16.7%)	<0.001
Congestive heart failure	517 (8.7%)	1,124 (20.4%)	82 (18.1%)	32 (12.2%)	<0.001
Diabetes mellitus	1,915 (31.3%)	2,177 (38.6%)	205 (44.4%)	75 (27.9%)	<0.001
Hypertension	5,120 (83.4%)	5,146 (90.8%)	412 (88.4%)	203 (75.2%)	<0.001
Hyperlipidemia	5,447 (88.9%)	5,052 (89.7%)	392 (84.7%)	208 (77.6%)	<0.001
Chronic renal insufficiency	436 (7.1%)	1,165 (20.6%)	81 (17.6%)	10 (3.7%)	<0.001
Peripheral vascular disease	567 (9.3%)	1,215 (21.6%)	59 (12.9%)	12 (4.4%)	<0.001
Baseline hematocrit	41.2 ± 15.2	38.6 ± 10.7	39.2 ± 5.1	42.5 ± 25.1	<0.001
Current smoker	1,717 (27.9%)	787 (13.8%)	234 (50.1%)	157 (57.9%)	<0.001

Values presented as n (%) or mean ± SD.
NSTEMI = non–ST-segment elevation myocardial infarction; STEMI = ST-segment elevation myocardial infarction.

Table 2. Patients Still Taking Clopidogrel by Insurance Status and Receipt of at Least 1 DES

	1 Month			6 Months			1 Yr		
	DES	No DES	p Value (Row)	DES	No DES	p Value (Row)	DES	No DES	p Value (Row)
Private (n = 6,157)	2,881/2,904 (99.2%)	334/336 (99.4%)	1.0	2,561/2,665 (96.1%)	261/291 (89.7%)	<0.001	1,990/2,188 (91.0%)	177/202 (87.6%)	0.12
Medicare (n = 5,689)	2,526/2,555 (98.9%)	357/363 (98.4%)	0.43	2,181/2,335 (93.4%)	265/298 (88.9%)	0.005	1,678/1,925 (87.2%)	183/212 (86.3%)	0.73
Medicaid (n = 467)	146/149 (98.0%)	24/25 (96.0%)	0.47	137/141 (97.2%)	20/21 (95.2%)	0.51	113/121 (93.4%)	15/17 (88.2%)	0.36
Uninsured (n = 271)	80/80 (100%)	8/8 (100%)	—	64/70 (91.4%)	8/8 (100%)	1.0	52/59 (88.1%)	7/7 (100%)	1.00

Percentage values represent the proportion of patients with a specific type of insurance and type of stent still taking clopidogrel; p values apply only to the specified time period.
DES = drug-eluting stent(s).

receiving DES, were less likely to present with STEMI or in shock, more likely to have undergone PCI in the past, and less likely to have a history of CRI, CHF, and smoking ($p < 0.001$ for all comparisons). There was a trend for patients receiving DES to be younger (62.6 vs. 64.7 years, $p = 0.06$).

Patients with Medicare were more likely to have PCI of the left main (2.5% vs. 1.5% overall) or of a saphenous vein graft (6.2% vs. 4.5% overall). Stented length (19.8 ± 6.7 mm overall) and procedural success (98.1% overall) were similar in all 4 insurance groups. Patients with Medicaid or without insurance, compared to patients with private insurance, were more likely to receive a glycoprotein IIb/IIIa inhibitor and less likely to receive bivalirudin or have intravascular ultrasound used.

Duration of clopidogrel. We collected data regarding the length of clopidogrel therapy for 6,420 patients at 1 month, 5,829 patients at 6 months, and 4,731 patients at 1 year after PCI (Table 2). This amounted to clopidogrel data available for 52% of patients alive at 1 month, 48% alive at 6 months, and 39% alive at 1 year after PCI. When analyzed by insurance type, there were no significant differences between the DES and no DES groups regarding the length of clopidogrel therapy.

Multivariable analysis. Results of the 2 multivariable logistic regressions were similar, showing that patients with Medicaid (OR: 0.60; 95% CI: 0.46 to 0.78 for age <65 years; OR: 0.45; 95% CI: 0.24 to 0.85 for age ≥65 years) and patients without insurance (OR: 0.57; 95% CI: 0.42 to 0.78 for age <65 years; OR: 0.20; 95% CI: 0.05 to 0.86 for age ≥65 years) (Table 3) were less likely to receive DES than patients with private insurance. African Americans, compared with non–African Americans, were also less likely to receive DES (OR: 0.80; 95% CI: 0.68 to 0.93 for age <65 years; OR: 0.77; 95% CI: 0.65 to 0.90 for age ≥65 years). DES use was also less likely in patients with STEMI, shock, male sex, current smoking history, lower baseline hematocrit, and history of hypertension. A history of CABG, CRI, diabetes mellitus, and peripheral vascular disease were not significant after multivariable adjustment.

There were some differences between the multivariable logistic regressions for patients <65 and ≥65 years. Specifically, older age increased the likelihood for receipt of DES in the younger cohort but had the opposite effect in the

Table 3. Adjusted Odds Ratios for Receipt of at Least 1 DES

	Age <65 yrs			Age ≥65 yrs		
Variable	Odds Ratio	95% CI	p Value	Odds Ratio	95% CI	p Value
Uninsured	0.57	0.42–0.78	0.0004	0.20	0.05–0.86	0.03
Medicaid	0.60	0.46–0.78	0.0001	0.45	0.24–0.85	0.01
Medicare	0.83	0.64–1.06	0.14	0.89	0.72–1.09	0.25
African-American	0.80	0.68–0.93	0.004	0.77	0.65–0.90	0.0008
Age (per 10 yrs)	1.08	1.00–1.17	0.05	0.76	0.68–0.85	<0.0001
Male	0.71	0.60–0.84	<0.0001	0.83	0.71–0.96	0.01
Current smoker	0.80	0.69–0.93	0.003	0.73	0.59–0.89	0.003
Baseline hematocrit (per 5%)	1.18	1.10–1.26	<0.0001	1.10	1.03–1.18	0.008
STEMI	0.41	0.34–0.49	<0.0001	0.44	0.36–0.55	<0.0001
Shock	0.40	0.29–0.55	<0.0001	0.32	0.23–0.46	<0.0001
HTN	0.75	0.62–0.92	0.005	0.75	0.58–0.96	0.02
CHF	0.88	0.70–1.11	0.27	0.83	0.70–0.99	0.04

CHF = history of congestive heart failure; CI = confidence interval; HTN = history of hypertension; Shock = presented with shock; STEMI = presented with STEMI; other abbreviation as in Table 2.

older cohort. In addition, history of CHF slightly decreased the likelihood for receipt of DES in the older cohort; this effect in the younger cohort, however, was not significant. Most importantly, however, Medicaid, no insurance, and African-American race were associated with less use of DES in both models; Medicare was not.

Discussion

We found that patients with Medicaid or no health insurance were less likely to receive DES than patients with private insurance. We also found that African-American patients were less likely to receive DES than non–African-American patients. These differences remained significant after multivariable adjustment. Our results suggest that insurance status and race influence the decision to use DES.

Numerous studies have shown that the uninsured and patients with Medicaid suffer worse cardiovascular outcomes, are less likely to receive evidence-based therapies for acute coronary syndromes, are less likely to be referred for coronary angiography and for revascularization (14,16,23–26). Robust published data also document that African-American patients have worse cardiovascular outcomes and are less likely to be referred for cardiac catheterization, PCI, CABG, and defibrillator implantation (19–21,27,28). Previous studies have documented similar disparities regarding use of DES, with some caveats. An analysis of the CRUSADE (Can Rapid Risk Stratification of Unstable Angina Patients Suppress Adverse Outcomes with Early Implementation of the ACC/AHA Guidelines) multicenter registry in 2005 showed that patients with Medicaid—but not Medicare or without insurance—were less likely to receive DES than patients with private insurance (28). A similar analysis of the National Cardiovascular Data Registry in 2006 found that lack of insurance reduced the likelihood of receiving a DES, as did African-American race (29). And another study of this national registry in 2008 showed that government insurance and lack of insurance were associated with less use of DES (30). The use of ≥1 DES varied widely in these studies, from 55% to 96%; in our study this prevalence was 75%.

This disparity in receipt of DES is unique in that it arises after the referral for catheterization, when the barrier of access to care has been removed. This implies that its genesis might be at the patient-provider level. We found that, even if one assumes that a patient without insurance is less likely or able to take clopidogrel for an extended period, patients with Medicaid were also less likely to receive DES. The reasons for this are obscure.

Recent guidelines specify " . . . in patients not expected to comply with 12 months of thienopyridine therapy, whether for economic or other reasons, strong consideration should be given to avoiding a DES . . . " (9). Patients not expected to comply, however, are not further defined. In the PREMIER registry (Prospective Registry Evaluating Myocardial Infarction: Events and Recovery), older age, less than a high school education, unmarried status, a lack of discharge instructions regarding clopidogrel, and avoiding health care because of cost were associated with premature cessation of clopidogrel in DES-treated patients (13). Our study found that duration of clopidogrel therapy (up to 1 year) was more or less similar in different insurance groups, regardless of DES status. These data almost certainly bias toward higher rates of compliance with clopidogrel therapy at 1 year, because patients without adequate follow-up are more likely to stop clopidogrel or not receive a DES in the first place. In addition, our clopidogrel data only account for approximately one-half of the patients in the present study. Nevertheless, these data are at the very least hypothesis-generating and suggest that patients' capacities and resources to take clopidogrel for an extended period of time might be underestimated by physicians.

The cost to the patient for clopidogrel therapy might also play a role in decisions to use DES. The out-of-pocket cost for a 1-month supply of clopidogrel, for example, can be as high as $150. Although we do not have patient-level data regarding prescription costs, the copayment for Medicaid patients in the area of this study (District of Columbia, Maryland, Virginia) is typically $1 to $3 per month. This is in contrast to the cost of Medicare copayments (for patients with Medicare prescription coverage), which ranges from $20 to $80/month. Therefore, the high out-of-pocket cost for patients without insurance might influence individual decisions to use DES, but this factor alone is inadequate to explain the disparity in patients with Medicaid (or the absence of a disparity in patients with Medicare).

There is a paucity of published data regarding the identification of patients more or less likely to comply with clopidogrel. Some evidence suggests that African Americans are less willing than Caucasians to undergo PCI or CABG (31). Similar research focused upon beliefs and attitudes toward DES and thienopyridine therapy, and accompanying physician perception of the capacity to take prolonged thienopyridine therapy, is sorely lacking. It is also unclear what role physician reimbursement for DES or lack thereof plays in this equation.

Our analysis is unique in that all patients were referred for PCI at a single center, unlike previous analyses of disparities in DES use. It is also in a high-volume setting, which eliminates the impact of hospital-level characteristics that influenced the use of DES in previous studies (29). We were also able to study the use of DES in a "real-world" setting, in a racially and socioeconomically diverse cohort of patients, for both on- and off-label indications. Nevertheless, given the retrospective nature of our analysis, it is prone to difficulties common to all nonrandomized studies. Specifically, there might be confounding variables not accounted for by the final logistic regression model for receipt of DES. In addition, propensity score matching was not practical, given the 4 insurance subgroups of differing sizes. We were

unable to assess the impact of median household income by zip code upon the receipt of DES, because of collinearity between insurance status and median household income by zip code; an interaction term between income and insurance status, however, was not significant. Furthermore, previous studies have shown that increasing income does not significantly attenuate the impact of insurance status upon health outcomes (32). In addition, we did not have access to particularly detailed income data; our use of median income by zip code might result in misclassification of actual income (33,34). Also, race was self-reported but coded as mutually exclusive categories. Federal guidelines specify self-reporting of race as the preferred method but recognize race (e.g., African-American, Caucasian) and ethnicity (e.g., Hispanic or non-Hispanic) as separate categories and acknowledge that individuals might identify with >1 race (35). Lastly, we defined insurance status on the basis of the primary coverage at discharge. Given that patients might be uninsured at the time of PCI and then receive insurance coverage during their hospital stay, we likely underestimated the number of uninsured at the time of PCI.

Conclusions

This analysis does not presume that DES are a panacea for improvement in cardiovascular outcomes. Nevertheless, recognition of this disparity in use and a more nuanced understanding of factors at the patient-provider level that contribute to this disparity would undoubtedly lead to less target vessel revascularization in underserved and minority populations.

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