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Disappearing and Reappearing Differences in Drug-Eluting Stent Use by Race

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Abstract

Aim—Drug-eluting coronary stents (DES) rapidly dominated the marketplace in the United States after approval by the Food and Drug Administration in April 2003, but utilization rates were initially lower among African-American patients. We assess whether racial differences persisted as DES diffused into practice.

Methods—Medicare claims data were used to identify coronary stenting procedures among elderly patients with acute coronary syndromes (ACS). Regression models of the choice of DES versus bare metal stent controlled for demographics, ACS type, comorbidities, and hospital characteristics. Diffusion was assessed in the short run (2003–2004) and long run (2007), with the effect of African-American race calculated in each period to allow for a varying effect.

Results—The sample included 381,887 Medicare beneficiaries treated with stent insertion; approximately five percent were African-American. Initially (May 2003–February 2004), African-American race was associated with lower DES use compared to other races (44.3% vs. 46.5%, $p<0.01$). Once DES usage was high in all patients (March–December 2004), differences were not significant (79.8% vs. 80.3%, $p=0.45$). Subsequent concerns regarding DES safety caused broad reductions in DES use, with African-Americans having lower rates of use than other racial groups in 2007 (63.1% versus 65.2%, $p<0.01$).

Conclusions—Racial disparities in DES use initially disappeared during a period of rapid diffusion and high usage rates; the reappearance of disparities in use by 2007 may reflect DES use tailored to unmeasured aspects of case mix and socioeconomic status. Further work is needed to whether underlying differences in race reflect physician decisions regarding appropriateness of treatment.

Keywords

Drug-eluting stents; Health Care Disparities; Biomedical Technology

Introduction

Following approval by the United States Food and Drug Administration (FDA) in April 2003, drug-eluting coronary stents (DES) quickly dominated the American market for percutaneous coronary intervention (PCI). One study estimated that the use of DES increased from 19.7% of all PCI procedures in April 2003 to 78.2% in December 2004 [1]. This rapid adoption can be credited to several factors, including evidence of superiority compared to traditional bare metal stents (BMS) at reducing rates of repeat procedures due to restenosis (i.e., the reoccurrence of narrowing of the arteries) [2–4], increasing product availability, and the approval of a second DES product in March 2004 [1, 5, 6]. After the rapid rise in use of DES, safety concerns emerged, particularly among categories of patients who were not included in the clinical trials of DES [7]. A warning issued by the FDA in late 2006 noted that off-label DES implantation, which comprised the majority of usage, may be considerably more dangerous than use in the originally targeted groups [8]. Rates of use subsequently dropped from greater than 90% in 2005 to 64% by the end of 2007; use increased back to 76% by 2009 after publication in 2008 of studies showing that outcomes were as good and possibly better from use of DES versus BMS as long as recommendations for prolonged antiplatelet therapy were followed [9].

The diffusion of DES provides an interesting context for an analysis of racial disparities, which remain a topic of concern for the cardiology community in the United States in terms of processes of care and outcomes [10, 11]. Relative to their Caucasian counterparts, African-Americans experience poorer outcomes and higher mortality from coronary artery disease (CAD) [12–14]. These differences may be partly explained by the demonstration that African-Americans are less likely than whites to be referred for or undergo invasive cardiac procedures including coronary catheterization, angioplasty and stent placement.[11, 15–17] Alternatively, the outcome differences could be due to underlying differences in disease state or socioeconomic resources needed to enable good outcomes.

Several studies have used registry data to examine racial disparities in use of DES during the initial period of diffusion and have demonstrated overall lower utilization of DES in African-Americans undergoing PCI compared to whites.[1, 6, 18] Although these prior studies of DES usage show evidence of lower utilization of DES shortly after clinical adoption in African-Americans, each study has limitations or analyzed a different group of patients than the population analyzed here (e.g., additional payers besides Medicare or a broader set of cardiovascular conditions). Some studies of DES use by race did not control for comorbidities that might influence choice of stent technology.[19, 20] Hannan and colleagues [6] were limited by a study population from a single state and excluded substantial groups of patients from their analysis, including those with recent myocardial infarction and previous revascularization. Rao and colleagues [1] identified lower rates of DES utilization for African-Americans, although the data for this study were limited to facilities participating in the National Cardiovascular Data Registry's CathPCI Registry and may not reflect use in all facilities. Additionally, Rao and colleagues only examined

diffusion through 2004 and were thus unable to analyze disparities in DES usage after placement of DES became more clinically selective due to safety concerns.[1] Roe and colleagues [18] also used registry data but they only analyzed the later period of diffusion and warnings of safety concerns (2006–2008). In the study most similar to this investigation, Rathore and colleagues [21] found that disparities in 2003 dissipated by 2004 but then reappeared by 2007, with differences primarily due to within-hospital variation in use of DES by race. Since their study used all-payer data from a sample of inpatient hospitalizations from 30 states, their results may not reflect the potentially heterogeneous experience for patients according to age, insurance coverage, or medical condition.

Drug-eluting stents are associated with delayed healing after implantation compared to bare metal stents. This prolonged exposure of the device to the circulation extends the time interval during which a patient may be susceptible to thrombotic events. Initially, this risk was thought to persist only for three to six months after DES implantation. However, subsequent studies suggested that this phenomenon of “late stent thrombosis” was more likely among DES recipients for longer periods of time.[22, 23] After this late risk was identified, current guidelines were changed to recommend patients treated with DES take dual-antiplatelet therapy (typically aspirin with clopidogrel or prasugrel) for a minimum of 12 months after DES insertion [24, 25]. Rates of noncompliance with dual-antiplatelet therapy are historically high, at least prior to the implementation of drug coverage under Part D of Medicare as part of the Medicare Modernization Act of 2004 [26]. Mortality rates are significantly higher for non-compliers than compliers, and multiple clinical and socioeconomic factors influence the ability and willingness of the patient to comply with medical therapies [7]. Furthermore, it may be difficult for doctors to assess the likelihood of medication compliance before stent insertion, particularly if the stent insertion is the first encounter with the patient [7]. Doctors may be more likely to use BMS than DES in patients who they believe may not be compliant. Furthermore, doctors may perceive the likelihood of compliance to differ by characteristics they observe, such as socioeconomic status; regardless of whether doctors are correct in this perception, differences in socioeconomic status may then lead to observed differences in the use of DES by race [27].

Using data from the Medicare Provider Analysis and Review (MedPAR) files for all beneficiaries aged 65 or older treated with percutaneous coronary intervention with stent insertion for diagnosis of Acute Coronary Syndrome (ACS), we examine trends in the use of DES by race in the short-run (April 2003–December 2004) and long-run (2007) periods. We account for existing comorbidities that may indicate clinical differences among racial groups in their appropriateness for the use of DES as well as some limited measures of socioeconomic status. Our analysis has the advantage of focusing on a relatively homogeneous set of patients by virtue of having the same ACS diagnosis and Medicare coverage (Parts A and B).

Methods

Data

Study Cohort and Data Sources—We used 2003, 2004 and 2007 Medicare Provider Analysis and Review (MedPAR) records to identify fee-for-service Medicare beneficiaries age 65 or older who experienced a short stay admission for ACS, defined by the presence of *International Classification of Diseases, Ninth Edition*, Clinical Modification diagnosis codes 410.xx (myocardial infarction) and 411.1 (unstable angina). The first ACS-related hospitalization for each patient with an admission date of May 1, 2003 or later (the first full month in which DES were available in the United States) was considered the “index admission”. The cohort was limited to ACS episodes who received DES or BMS within 30 days of the index admission.

Treatment Variables—We used International Classification of Diseases diagnosis and procedure codes on the MedPAR records to identify whether patients received coronary revascularization during the 30 days following their index admission date for each ACS episode (the initial ACS admission and any additional inpatient stays within 30 days of the index admission date). Specifically, for each ACS episode we used procedure codes for BMS insertion (36.06) and DES insertion (36.07) to identify stent utilization. Patients were included if their initial revascularization with stent insertion was conducted between May 2003 and December 2004 or between January 2007 and December 2007.

Covariates—Clinical comorbidities were obtained by applying the Healthcare Cost and Utilization Project's comorbidity criteria to all diagnoses for the claims pertaining to the revascularization date [28]. These criteria normally require that comorbidities be unrelated to a claim's principal diagnosis (e.g., a chemotherapy-related hospitalization would not consider cancer to be a comorbidity); we relaxed this assumption to allow for the most comprehensive identification of all comorbidities. Patient demographic data were obtained primarily from the Medicare Denominator files. Race was coded as African-American or non-African-American to determine racial differences in the diffusion of DES. Measures of dual eligibility for both Medicare and Medicaid were not available; although a measure of dual eligibility can provide a strong control for socioeconomic status, we instead controlled for a ZIP code level measure of median household income that was obtained from the 2000 United States Census. A measure of urban and rural status was developed by linking patient ZIP code to Rural-Urban Commuting Areas [29].

Analysis

We estimated both logit and ordinary least squares (OLS) regression models to predict the probability of a patient receiving DES based on observed characteristics. The OLS models, which are also known as linear probability models (LPM) due to the dichotomous dependent variable, were preferred because the LPM model simplifies the presentation of marginal effects in models that use hospital fixed effects to control for all hospital characteristics (observed and unobserved) that do not vary over time. (Odds ratios rather than marginal effects are available from conditional logit models with fixed effects because the fixed effect is conditioned out.). LPM models are appropriate and very robust except for cases in which the outcome variable is either very rare or common. Since DES use rates averaged 65% over the study period and since results from logit models confirmed the LPM results in terms of sign and significance of results, we focus on the results from linear probability models with hospital fixed effects. The models also controlled for patient demographics such as age, gender, and race, socioeconomic status, and patient-level clinical characteristics including comorbidities as described above. We controlled for the category of ACS based on coded diagnoses: unstable angina (generally suggesting new onset of accelerating chest pain); non-ST segment elevation myocardial infarction or heart attack (NSTEMI) in which the blockage may be partial or temporary so that the extent of current damage is relatively minimal; and ST segment elevation myocardial infarction or heart attack (STEMI) which is characterized by a prolonged period of blocked blood supply that affects a large area of the heart muscle. To account for a time-varying effect of African-American race on DES use during the period of rapid diffusion, we estimated the effect of African-American race using separate regressions based on the month of PCI procedure. Rather than calculate monthly effects, three periods were estimated to increase statistical power. These three periods were 1) "early" short-run immediately after introduction of DES (May 2003-February 2004), 2) "late" short-run after the introduction of the second DES (March 2004-December 2004), and 3) long-run after DES safety concerns emerged (January 2007-December 2007). The dataset was constructed using the SAS System, version 9.2 (SAS Institute, Cary, NC). Data analyses

were conducted in SAS System as well as Stata/IC, version 11.1 (Statacorp, College Station, TX).

Results

The analysis cohort included 381,887 Medicare beneficiaries who were treated with DES or BMS as the initial choice of revascularization therapy (Figure 1), of which 19,679 (5.2%) involved African-American patients. When compared with non-African-American patients (Table 1), African-American patients were younger and more likely to be female. African-American patients lived in zip codes with lower median household income and were more likely to be receiving state Medicaid buy-in. STEMI was less common, and NSTEMI more common, among African-American patients. African-American patients were more likely to suffer from congestive heart failure, diabetes, peripheral vascular disease, anemia, and renal failure, but less likely to have chronic lung disease and valvular disease.

Overall for the sample, African-American race was associated with lower rates of DES usage (63.2% vs. 65.2%, $p < 0.001$). Figure 2 shows that DES use increased dramatically for both African-American and non-African-American patients during the short-run study period, with overall usage rising from 30% in May 2003 (the first month in which Medicare reimbursed for DES) to 86% in December 2004 (the end of the “late” short-run). Usage rates dropped after this period due to the development of safety concerns described earlier; in 2007 the overall use rate was 65%. The lines in Figure 2, which are not adjusted for factors other than race, show that unadjusted DES use rates were consistently lower for African-Americans during the “early” short-run but quite close and overlapping during the “late” short-run and the long-run. These relationships are confirmed by the unadjusted results by period and race in the first set of rows in Table 2.

Table 2 also provides the multivariate LPM analysis for the effect of race when adjusting for other patient characteristics as well as hospital fixed effects (full results are available upon request). In terms of statistical significance and direction/magnitude of effect, results from logistic regressions were identical except that the effect of African-American race was not statistically significant in the long-run (2007) regression controlling for patient covariates only. Also, regressions using individual monthly effects of race on DES usage were generally not significant, so results are presented only for the three periods indicated in Table 2. The remainder of the presentation of results focuses on the effects of race when controlling for patient characteristics and hospital fixed effects.

For patients admitted in the “early” short-run (May 2003 through February 2004), African-American patients were 2.1 percentage points *less* likely to get DES than non-African-American patients (95% CI of $[-3.4, -0.8]$). As rates of DES use rose in the sample of patients receiving PCI from roughly 46% in the “early” short run to roughly 80% in the “late” short-run, the effect of African-American race became statistically insignificant (95% CI of $[-1.6, 0.5]$), indicating that widespread increases in use of DES eliminated any disparity in use of DES by race, controlling for other factors. By 2007, however, the overall rate of DES use among PCI patients in the sample fell to roughly 65% due to the publication of concerns of poor outcomes such as late stent thrombosis from off-label use of DES; this decline in widespread use was accompanied by the re-emergence of a statistically significant lower likelihood of receipt of DES by African-American patients race of 2.1 percentage points (95% CI $[-3.2, -1.0]$).

Discussion

Our analysis finds that a small disparity (2.1 percentage points, or 4.5% of the likelihood of DES use) existed between African-American and non-African-American Medicare patients in DES receipt during the early diffusion of DES into clinical practice after controlling for patient-level clinical and demographic characteristics and hospital characteristics that were constant over time. An initial racial disparity in a rapidly diffusing technology has been shown with other cardiac technologies, including stress testing and cardiac stents.[30] This racial disparity dissipated within a year of DES introduction as DES became the dominant stent technology and approval of a second stent increased availability. In the long run (2007), a disparity in use of DES for African-Americans versus non-African-Americans reappeared at a smaller but statistically significant level (2.1 percentage point or 3.2% of the likelihood of DES use in 2007). Given that we controlled for the characteristics available from Medicare claims data, this re-emergence of a disparity in use raises some important questions.

First, given the evidence that ultimately emerged about possible harmful effects of off-label use of DES over BMS, it is possible that equal use of DES in African-Americans and non-African-American patients could represent a situation of inappropriate overuse of the technology in African-American patients. This consideration is especially pertinent if African-American patients are more likely than non-African-American patients to be unfit for dual anti-platelet therapy (i.e., to due to medical contra-indications) or unwilling/unable to adhere to the therapy (e.g., due to the drug cost). Although we are able to control for certain patient characteristics, the difference between African-Americans and non-African-Americans in the probability of receiving DES in 2007 may reflect clinical characteristics that are unobserved in our data or physician concern regarding the patient's ability to comply with the required drug regimen.

The inclusion of hospital-level fixed effects ensures that static inter-hospital differences in availability, cost, or access are not driving our results, since the hospital fixed effects control for all observed and unobserved time-invariant hospital characteristics. As with all observational studies, however, this analysis may not have corrected for all confounding characteristics that determine stent choice by the practitioner or the patient, and our sample is conditional upon the patients having been selected for revascularization with PCI. Medicare claims data cannot provide information about vessel and lesion characteristics such as vessel size and lesion length, which are the primary criterion for stent choice in most circumstances. The claims data also do not allow controls for private insurance coverage such as Medigap or retiree health insurance coverage. The start of coverage of ambulatory pharmaceuticals under Medicare Part D in January 2006 means that financial barriers to anti-platelet therapy were reduced for a number of beneficiaries, though prior research has shown that the major factor associated with Part D enrollment was demand (need) for drugs [31]; therefore, the start of Part D may not have contributed to any differences in access to drugs or type of stent used by race. Finally, we are unable to identify the effects of availability of DES due to the introduction of a second type of DES from changes in provider or patient behavior leading to greater usage of DES, as the data do not indicate the type of DES (e.g., sirolimus-eluting versus paclitaxel-eluting).

Therefore, whether the gap in use by race in 2007 reflects a clinically appropriate difference in usage rates (i.e., due to case mix differences or more selective use as providers learned the type of patients who would benefit the most from DES) or a case in which African-American patients are less likely to receive a technology that is more effective once certain criteria are met remains an open question. If African-Americans are less likely to be suitable candidates for DES placement due to comorbidities or factors that would reduce adherence

to antiplatelet agents (e.g., lack of insurance for pharmaceuticals), then lower rates of DES use for African-Americans could be consistent with appropriate treatment. While disparities in the likelihood of receipt of treatments solely due to race or ethnicity are undesirable, an understanding of the cause of disparities is important to determine the most efficient way to maximize health outcomes for all patients. Further study with more detailed clinical data and better measures of socioeconomic status will be helpful in examining these disparities.

Although the estimated differences were not large in absolute magnitude, failure to use the most clinically advanced and appropriate technology can result in worse outcomes. In total, this analysis demonstrates that as new technologies diffuse into practice, it is important to evaluate their use and effectiveness in minority populations. Finally, although firm policy recommendations would be premature (particularly since this analysis is limited to the experience in one country), it is important to remember that efficient policies to enable appropriate use of the most effective technologies without observed disparities by race may need to target underlying causes such as socioeconomic disparities. Given the additional information that physicians have when making decisions about which treatment will be most effective for a particular patient, differences in use of technology by race may simply reflect this important unobserved information to a great extent.

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Figure 1.
Cohort diagram for analysis sample

Figure 2.
Unadjusted trends in DES use by race

Table 1

Demographic and clinical characteristics of cohort [% or mean, with standard errors in parentheses]

	African- American (n = 19,679)	Non African- American (n = 362,208)	Total (n = 381,887)	p-value
Outcome				
Receipt 1 Drug-eluting stent	62.0	63.5	63.4	< 0.001
Patient Demographics				
Age	73.8 (6.5)	75.4 (6.8)	75.4 (6.8)	< 0.001
Female	54.2	43.1	43.7	< 0.001
ZIP Code Median Income (US\$1000s)	35.2 (13.3)	43.6 (15.9)	43.2 (15.9)	< 0.001
Rural-Urban Commuting Area				
Metropolitan	82.2	68.5	69.2	< 0.001 (joint)
Micropolitan	9.0	14.7	14.4	
Small Town	5.7	9.2	9.0	
Rural	3.2	7.6	7.4	
Clinical Factors				
Acute Coronary Syndrome Diagnosis				
STEMI	23.6	26.5	26.4	< 0.001 (joint)
Non STEMI	31.2	27.4	27.6	
Unstable Angina	45.2	46.1	46.0	
Congestive Heart Failure	23.6	18.4	18.6	< 0.001
Valvular Disease	9.4	10.9	10.8	< 0.001
Pulmonary Circulation Disorders	1.9	1.5	1.5	< 0.001
Peripheral Vascular Disease	10.8	9.7	9.7	< 0.001
Paralysis	1.5	0.5	0.6	< 0.001
Neurological Disorders	3.0	2.8	2.8	0.05
Chronic Lung Disease	15.1	16.9	16.8	< 0.001
Diabetes – w/o chronic complications	35.9	23.6	24.2	< 0.001
Diabetes - with chronic complications	4.2	2.3	2.4	< 0.001
Hypothyroidism	4.5	8.5	8.3	< 0.001
Renal Failure	11.4	5.8	6.1	< 0.001
Liver Disease	0.4	0.3	0.3	0.15
Ulcer	0.01	0.04	0.04	0.03
AIDS	0.06	0.01	0.01	< 0.001
Lymphoma	0.3	0.4	0.4	0.37
Metastatic Cancer	0.5	0.4	0.4	0.60
Solid tumor without metastasis	1.6	1.3	1.3	< 0.001
Rhematoid Arthritis	1.6	1.8	1.8	0.03
Coagulopathies	2.1	2.1	2.1	0.93
Obesity	6.3	4.8	4.9	< 0.001
Weight loss	0.6	0.4	0.5	< 0.001
Electrolyte disorders	9.4	7.3	7.4	< 0.001

	African- American (n = 19,679)	Non African- American (n = 362,208)	Total (n = 381,887)	p-value
Chronic blood loss anemia	1.1	0.9	0.9	0.01
Deficiency anemias	10.4	6.0	6.3	< 0.001
Alcohol abuse	1.2	0.7	0.7	< 0.001
Drug abuse	0.4	0.1	0.1	< 0.001
Psychoses	0.5	0.5	0.5	0.99
Depression	1.7	2.7	2.6	< 0.001
Hypertension, with complications	78.0	65.3	66.0	< 0.001

Table 2

Estimated Likelihood of DES Receipt by African-American Race versus Non-African American Race, by Period

	Period 1: Short-Run Early (5/2003–2/2004)	Period 2: Short-Run Late (3/2004–12/2004)	Period 3: Long-Run (1/2007–12/2007)
Number of patients	127,036	112,530	142,321
<u>Unadjusted</u>			
African-Americans	43.6%	79.8%	64.3%
Non-African-Americans	46.7%	80.3%	65.1%
Difference	–2.9 [–4.2, –1.7]	–0.6 [–1.7, 0.5]	–0.8 [–1.9, 0.3]
<u>Covariate Adjusted</u>			
African-Americans	44.3%	79.7%	63.0%
Non-African-Americans	46.5%	80.3%	65.2%
Difference	–2.2 [–3.4, –0.9]	–0.6 [–1.7, 0.5]	–2.2 [–3.4, –1.1]
<u>Covariate and Hospital Fixed Effects Adjusted</u>			
African-Americans	44.4%	79.8%	63.1%
Non-African-Americans	46.5%	80.3%	65.2%
Difference	–2.1 [–3.4, –0.8]	–0.6 [–1.6, 0.5]	–2.1 [–3.2, –1.0]

Note: The differences indicated are percentage point differences. Covariates include all factors listed in Table 1 and hospital fixed effects. 95% confidence intervals are listed in brackets below the estimated differences. Full linear probability model regression results are available upon request.