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CLINICAL RESEARCH — Interventional Cardiology

Percutaneous Coronary Intervention and Drug-Eluting Stent Use Among Patients ≥85 Years of Age in the United States

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Objectives This study assessed the comparative effectiveness of drug-eluting stents (DES) versus bare-metal stents (BMS) among patients ≥85 years of age.

Background Despite an aging population, little is known about the comparative effectiveness of DES versus BMS among patients age ≥85 years undergoing percutaneous coronary intervention (PCI).

Methods We examined 471,006 PCI patients age ≥65 years at 947 hospitals in the National Cardiovascular Data Registry between 2004 and 2008 and linked to Medicare claims data. Long-term outcomes (median follow-up 640.8 ± 423.5 days) were compared between users of DES and BMS.

Results Patients age ≥85 years comprise an increasing proportion of PCIs performed among elderly subjects, yet rates of DES use declined the most in this age group. Compared with BMS, use of DES was associated with lower mortality: age ≥85 years, 29% versus 38% (adjusted hazard ratio [HR]: 0.80 [95% confidence interval (CI): 0.77 to 0.83]); age 75 to 84 years, 17% versus 25% (HR: 0.77 [95% CI: 0.75 to 0.79]); and age 65 to 74 years, 10% versus 16% (HR: 0.73 [95% CI: 0.71 to 0.75]). However, the adjusted mortality difference narrowed with increasing age ($p_{interaction}$ <0.001). In contrast, the adjusted HR for myocardial infarction rehospitalization associated with DES use was significantly lower with increasing age: age ≥85 years, 9% versus 12% (HR: 0.77 [95% CI: 0.71 to 0.83]); age 75 to 84 years, 7% versus 9% (HR: 0.81 [95% CI: 0.77 to 0.84]); and age 65 to 74 years, 7% versus 8% (HR: 0.84 [95% CI: 0.80 to 0.88]) ($p_{interaction}$ <0.001).

Conclusions In this national study of older patients undergoing PCI, declines in DES use were most pronounced among those aged ≥85 years, yet lower adverse-event rates associated with DES versus BMS use were observed. (J Am Coll Cardiol 2012;59:105–12) © 2012 by the American College of Cardiology Foundation

With a progressively aging U.S. population (1), there is a need to evaluate the treatment of coronary heart disease and associated outcomes in older adults. Previous studies consistently demonstrate lower use of evidence-based therapies among elderly patients in community practice (2). These practices may, in part, be attributed to the under-

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Abbreviations and Acronyms

BMS = bare metal stent(s)

DES = drug-eluting stent(s)

HR = hazard ratio

MI = myocardial infarction

PCI = percutaneous coronary intervention

representation of older adults (particularly those aged ≥85 years) in clinical trials, leading to lingering uncertainty about the risk-benefit balance of such treatments in these patients (3).

Few studies have compared the effectiveness and safety of drug-eluting stents (DES) with bare-metal stents (BMS) among older patients for whom DES are frequently used "off-label," and age-related physiological changes may influence treatment outcomes, as well as patient ability to tolerate long-term antiplatelet therapy. Accordingly, we examined data from the National Cardiovascular Data Registry CathPCI (Catheterization Percutaneous Coronary Intervention) Registry linked to Medicare inpatient claims to characterize the treatment and longitudinal outcomes of older PCI patients, particularly those age ≥85 years, and assess the comparative effectiveness of DES versus BMS among each age group.

Methods

Study population. The CathPCI Registry is the largest U.S. registry of patients undergoing PCI. As previously described (4), trained data abstractors at participating hospitals retrospectively collect detailed clinical information for consecutive PCI patients using standardized data elements and definitions. This study started with all PCI patients ≥65 years of age in the CathPCI Registry from January 2004 to December 2008. International Classification of Diseases-Ninth Revision procedure codes were used to identify index PCI procedures in the Medicare files, which were then linked to CathPCI records using a combination of indirect identifiers (5). The final study population included 471,006 patients from 947 sites successfully matched to Medicare fee-for-service data (Fig. 1).

Data definition. Death, revascularization, and bleeding were defined both during the index PCI hospitalization (using CathPCI data) and post-discharge (using Medicare data). The International Classification of Diseases-Ninth Revision codes used to identify events were: major bleeding (430 to 432, 578.X, 719.1X, 423.0, 599.7, 626.2, 626.6, 626.8, 627.0, 627.1, 786.3, 784.7, or 459.0), revascularization (36.00, 36.06, 36.07, 36.09, or 36.10 to 36.19), and myocardial infarction (MI) rehospitalization (410.X1). Acute PCI was defined as PCI for ST-segment elevation MI, non–ST-segment elevation MI, or unstable angina.

Statistical analysis. Baseline characteristics and periprocedural treatments were categorized according to age (65 to 74, 75 to 84, and ≥85 years), PCI setting (acute vs. elective), and stent type (DES versus BMS) and were compared using chi-square tests for categorical variables and Wilcoxon rank sum or Kruskal-Wallis tests for continuous variables.

The cumulative incidence rates for time-to-event outcomes were estimated using Gray's method. For adjusted analyses comparing DES with BMS, a propensity score model was created within each age group comparing DES versus BMS and conditioned on 96 covariates obtained from linked clinical and claims data (6). These covariates included the Charlson index and recent bleeding hospitalization, factors that play a significant role in stent selection among older adults. The propensity score logistic regression models had c-indexes of 0.741 for ages 65 to 74 years, 0.739 for ages 75 to 84 years, and 0.747 for age ≥85 years. The Greedy 5→1 Digit Matching Algorithm was used to match each pair of device types based on the propensity scores. After matching, the distribution of estimated propensity scores for DES patients closely matched that for BMS patients. Adjusted hazard ratios (HRs) comparing DES with BMS were calculated among matched pairs. An inverse probability–weighted method was used as a secondary approach to calculate adjusted HRs.

Results

Baseline characteristics and treatment. Among 471,006 patients age ≥65 years undergoing PCI in our study cohort, 42,154 (9%) were age ≥85 years, 187,656 (40%) were age 75 to 84 years, and 241,196 (51%) were age 65 to 74 years. From 2005 to 2008, the proportion of patients age ≥85 years increased from 7% to 9% among those undergoing elective PCI and from 10% to 13% among those undergoing acute PCI (p_{trend} <0.001 for both). With increasing age, elective and acute PCI patients were more likely to be female and white, have a higher prevalence of prior heart failure and stroke, and have higher Charlson index scores (Table 1).

Patients age ≥85 years were more likely to undergo multivessel PCI than younger patients (Table 2). Use of DES decreased with age for both elective and acute PCIs. Although lesion complexity increased with age, the use of more complex PCI techniques (e.g., atherectomy) did not differ significantly between age groups. Periprocedural glycoprotein IIb/IIIa inhibitor use decreased with age. Bivalirudin and low-molecular-weight heparin use increased with age among elective PCI patients.

Outcomes across age groups. In-hospital mortality rates were significantly higher among patients age ≥85 years compared with younger patients. The mean duration of follow-up post-discharge was 640.8 ± 423.5 days. Patients ≥85 years of age had the highest long-term mortality among any group, regardless of PCI setting (Fig. 2). Higher rates of MI rehospitalization and bleeding occurred among patients age ≥85 years undergoing acute PCI. Repeat

Data Registry. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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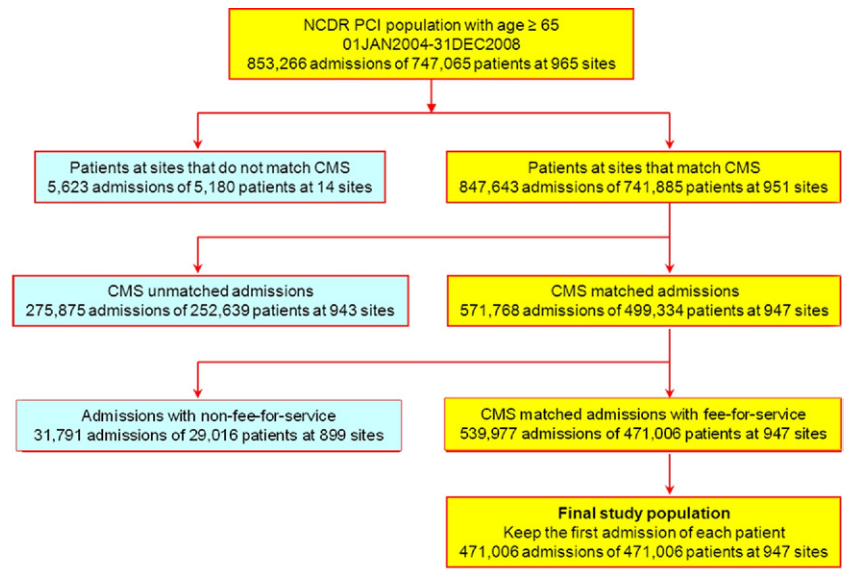

Figure 1 **Study Population**

CMS = Centers for Medicare and Medicaid Services; NCDR = National Cardiovascular Data Registry; PCI = percutaneous coronary intervention.

revascularization rates were lowest among patients age ≥85 years treated with acute PCI. These associations persisted after multivariable adjustment (Fig. 3).

Comparison of DES and BMS. Between 2005 and 2008, rates of DES use dropped across all age groups, but the largest decline occurred among patients age ≥85 years (Fig. 4).

Table 1 **Baseline Characteristics Compared Among Age Groups and Stratified According to Elective and Acute PCI**

	Elective PCI			Acute PCI		
Characteristics	Age 65–74 yrs (n = 174,384)	Age 75–84 yrs (n = 134,679)	Age ≥85 yrs (n = 26,540)	Age 65–74 yrs (n = 66,812)	Age 75–84 yrs (n = 52,977)	Age ≥85 yrs (n = 15,614)
Demographic						
Age, yrs	69.0 (67.0–72.0)	79.0 (77.0–81.0)	87.0 (85.0–88.0)	69.0 (67.0–72.0)	79.0 (77.0–81.0)	87.0 (86.0–89.0)
Male	62.7	54.9	47.6	63.7	51.9	41.4
White race	87.4	89.8	91.2	86.7	89.3	90.8
Clinical history						
Bleeding hospitalization in previous year	0.5	0.7	0.8	0.4	0.6	0.9
Prior MI	26.9	27.0	28.5	22.6	23.3	22.9
Prior CABG	24.6	26.7	21.7	16.9*	19.4*	13.8*
Prior PCI	33.1	31.3	29.0	23.7	22.4	19.1
Prior heart failure	12.5	16.4	22.0	9.4	13.6	16.9
Prior stroke	14.5	18.9	20.6	12.0	16.8	18.7
Peripheral vascular disease	15.3	17.6	17.0	11.9	14.4	13.3
Diabetes	38.5	32.7	24.1	31.7	29.2	22.2
Hypertension	83.3	84.5	84.8	75.0	78.6	80.0
Chronic lung disease	19.9	19.3	16.7	18.6	18.6	14.8
Dialysis	2.1	1.8	1.3	1.9	1.8	1.2
CrCL among nondialysis, ml/min	58.1 (46.4–70.6)	44.9 (35.4–55.6)	35.0 (27.5–43.8)	57.8 (45.9–70.2)	43.7 (34.0–54.6)	33.6 (26.1–42.3)
Charlson index						
0	75.7	71.0	59.9	26.2	25.0	18.6
1	21.2	25.3	35.3	68.8	68.8	75.0
2	2.5	3.1	4.1	3.8	5.0	5.5
≥3	0.6*	0.6*	0.6*	1.2	1.2	0.9
Pre-procedural cardiogenic shock	0.7	0.8	1.0	6.4	7.3	8.3

Values are median (interquartile range) or %. All p values <0.05 except where denoted by asterisk.
CABG = coronary artery bypass graft; CrCL = creatinine clearance; IQR = interquartile range; MI = myocardial infarction; PCI = percutaneous coronary intervention.

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Table 2 Procedural Characteristics Compared Among Age Groups and Stratified According to Elective and Acute PCI

	Elective PCI			Acute PCI		
Variable	Age 65–74 yrs (n = 174,384)	Age 75–84 yrs (n = 134,679)	Age ≥85 yrs (n = 26,540)	Age 65–74 yrs (n = 66,812)	Age 75–84 yrs (n = 52,977)	Age ≥85 yrs (n = 15,614)
Femoral access	97.8	97.9	98.2	97.9	98.1	98.6
Distribution of coronary disease						
Single-vessel disease	45.3	41.6	36.4	40.4	36.0	31.4
2-vessel disease	30.8	31.0	32.7	33.0	33.4	34.8
3-vessel disease	22.9	26.5	30.2	26.0	30.0	33.4
ACC/AHA type C (complex) lesions	38.6	39.8	43.2	51.8	52.7	55.5
Multivessel PCI	15.7	16.5	19.1	11.0	12.6	14.5
≥2 Stents per patient	36.6	36.9	38.6	36.5	36.7	38.5
Procedural devices						
Bare-metal stent	22.3	26.3	32.8	30.4	33.7	41.2
Drug-eluting stent	75.0	70.7	64.0	64.5	60.7	52.8
Sirolimus-eluting	41.5*	41.7*	40.6*	42.1*	41.8*	42.8*
Paclitaxel-eluting	51.6*	51.3*	51.2*	50.3*	50.5*	48.9*
Everolimus-eluting	5.7*	5.6*	6.2*	6.3*	6.3*	6.7*
Zotarolimus-eluting	2.8	2.9	3.7	2.9*	3.0*	3.4*
Cutting balloon	4.6*	4.7*	4.7*	2.6*	2.7*	2.5*
Atherectomy	1.3	1.7	2.3	0.7	1.0	1.2
Closure device	47.5	46.6	47.7	46.8	46.1	46.2
Periprocedural pharmacology						
Unfractionated heparin	48.1	48.5	48.6	69.0	68.2	68.0
Low-molecular-weight heparin	14.5	15.3	18.2	20.9*	20.7*	20.8*
Bivalirudin	45.7	46.0	47.4	25.5	27.7	29.0
Glycoprotein IIb/IIIa inhibitors	33.2	30.4	26.2	59.5	53.7	47.9
Procedure success	94.5*	94.5*	94.1*	92.3	91.7	90.6
In-hospital mortality	0.5	1.0	2.2	3.6	6.3	10.7

Values are %. All p values <0.05 except where denoted by asterisk.
ACC = American College of Cardiology; AHA = American Heart Association; other abbreviation as in Table 1.

During elective PCI, DES were less frequently used among patients with prior coronary artery bypass graft or stroke (Table 3). Regardless of PCI indication, DES were more commonly used among patients with low Charlson index scores and those undergoing multivessel PCI (Table 4). Risk-adjusted mortality was lower among DES patients than among BMS patients; however, this difference narrowed with increasing age ($p_{interaction}<0.001$) (Table 5). Risk of MI rehospitalization was also significantly lower among DES patients than among BMS patients, with greater risk difference observed with increasing age ($p_{interaction}<0.001$). Use of DES was not associated with lower revascularization risk among patients age ≥85 years. Bleeding risk was similar between DES and BMS patients across all age groups.

Discussion

Several insights emerge from this study, which represents, to the best of our knowledge, the largest report of PCI patients age ≥85 years to date. First, among older patients, an increasing proportion of PCIs are performed in those ≥85 years of age. Second, DES use declined significantly since 2005, with the largest decrease among those age ≥85 years. Third, compared with BMS use, DES use was associated with lower mortality and MI risks across all older age groups without significant difference in repeat revascularization risk.

Although surgical revascularization offers similar or better outcomes compared with PCI (7,8), concerns regarding physical and neurocognitive recovery limit its use among many older adults (9). We observed a greater uptake of newer periprocedural anticoagulant agents that minimize bleeding risk among older patients than younger patients. Thus, the increasing proportion of PCI patients age ≥85 years shown in this study may reflect both an aging population as well as an increased willingness of providers to consider PCI given the contemporary low rates of periprocedural complications (10).

Pivotal DES trials have found a reduction in the need for repeat revascularization but no significant differences in mortality and MI risks compared with BMS (11,12). Nevertheless, these trials enrolled very few elderly patients (<2% age >85 years), and no dedicated, randomized DES-to-BMS comparison has been performed among those aged ≥65 years. In the observational setting, however, use of DES has been associated with lower risks of mortality and MI (6,13,14). Our study expands on the existing literature by focusing on patients ≥85 years of age, adjusting for a comprehensive list of variables relevant to stent

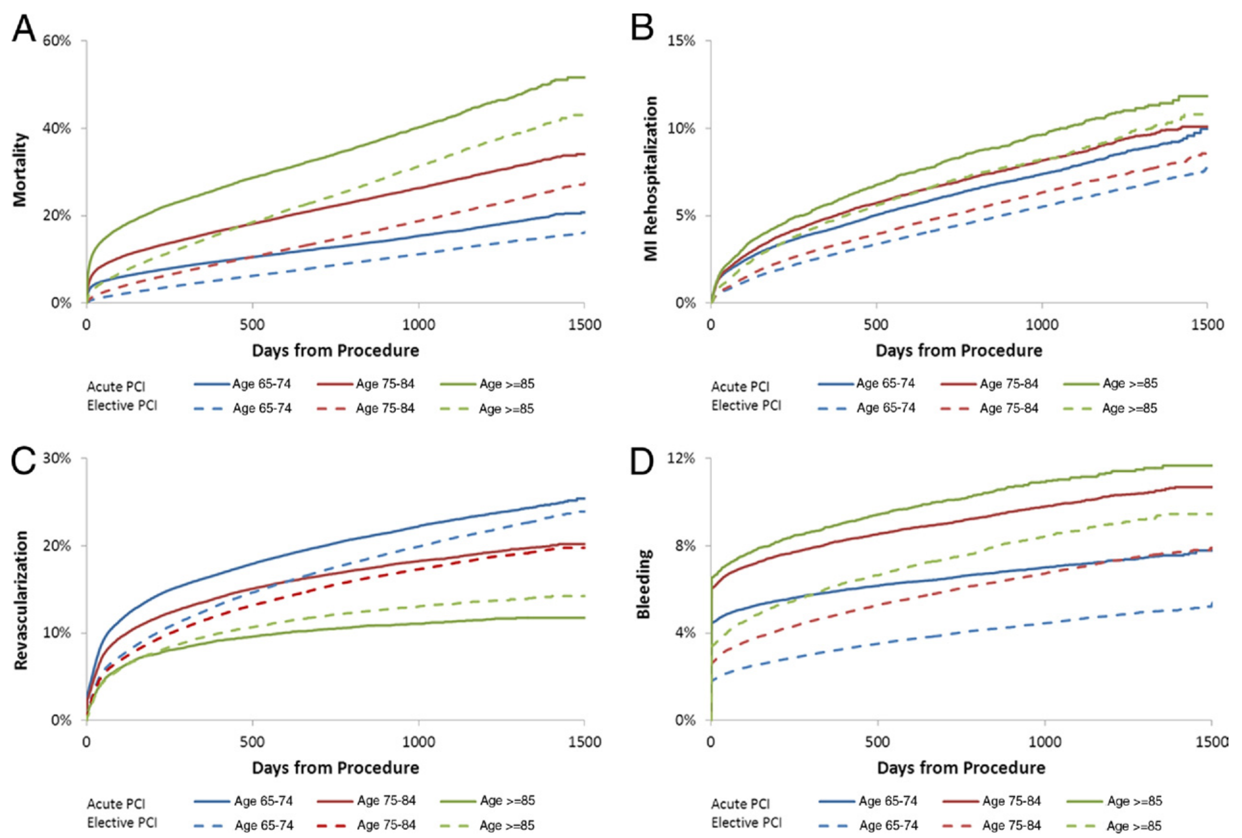

Figure 2 **Unadjusted Rates of Long-Term Adverse Outcomes**

Each **line** represents the cumulative incidence of each outcome stratified according to age and percutaneous coronary intervention (PCI) type. **(A)** mortality; **(B)** myocardial infarction (MI) rehospitalization; **(C)** revascularization; and **(D)** bleeding.

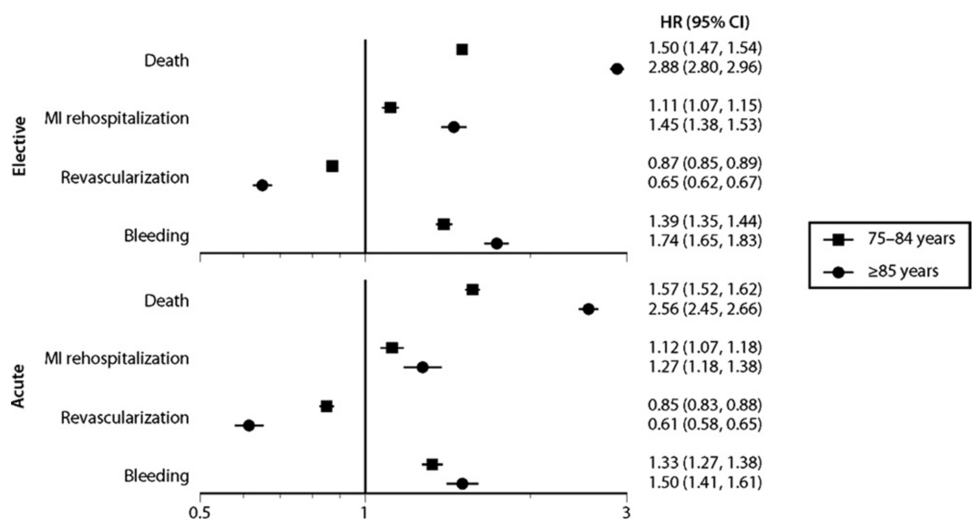

Figure 3 **Adjusted Risk of Long-term Adverse Outcomes**

The adjusted hazard ratios (HRs) (95% confidence intervals [CIs]) are displayed for each age group relative to patients age 65 to 74 years.

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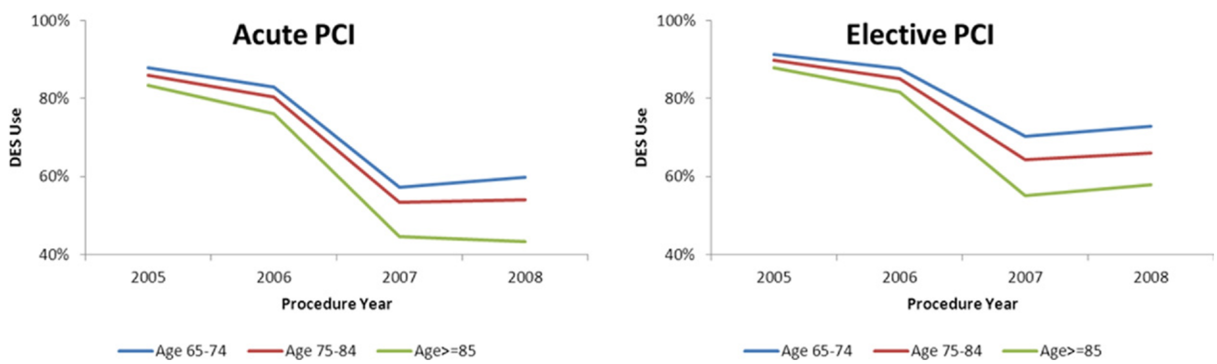

Figure 4 **Trends in DES Use Over Time**

Each **line** represents the incidence of drug-eluting stent (DES) use over time stratified according to age and percutaneous coronary intervention (PCI) type. Acute PCI: p value for trend in age range 65 to 74 years, <0.0001; in age range 75 to 84 years, 0.001; in age group ≥85 years, <0.0001; interaction between age group and procedure year trend, <0.0001. Elective PCI: p value for trend <0.0001 for all age groups; interaction between age group and procedure year trend: <0.0001.

selection among older adults, and using several adjustment methods to provide consistent results. In contrast to previous studies (6,13), DES use was not associated with lower repeat revascularization risk among older adults, which may in part be driven by a less invasive attitude in this patient population. However, DES in patients age ≥85 years were associated with a lower risk of MI rehospitalization compared with younger patients.

With reports highlighting the risks of DES thrombosis (15), we observed a decline in DES use, with the largest drop occurring among patients age ≥85 years. The possibility that DES may confer a greater clinical benefit for this high-risk population should be considered. This finding may reflect an outcome difference not observed in randomized trials simply as a function of inadequate statistical power or may represent true differences in DES performance in a community population for whom more than two-thirds of DES implantations were for nonapproved indications (14). Treatment goals for older adults differ from those of younger patients. Reducing repeat

Table 3 **Unadjusted Comparison of Baseline Characteristics Between DES and BMS Users Stratified According to Age Group: Elective PCI**

	Age 65–74 yrs		Age 75–84 yrs		Age ≥85 yrs	
Characteristic	DES (n = 130,774)	BMS (n = 32,320)	DES (n = 95,256)	BMS (n = 30,195)	DES (n = 16,993)	BMS (n = 7,595)
Male	62.1	65.0	54.1	57.0	47.3*	48.0*
White race	87.5*	87.1*	89.8	90.2	91.3*	91.1*
Prior MI	26.2	27.6	26.5	27.4	27.9*	28.8*
Prior CABG	23.2	27.9	25.4	29.0	20.7	22.8
Prior PCI	33.4	27.9	32.0	26.2	30.0	24.8
Prior heart failure	11.5	15.4	15.5	18.7	21.0	23.6
Prior stroke	13.9	16.4	18.3	20.5	19.8	21.6
Peripheral vascular disease	14.4	17.8	16.8	19.6	16.3	17.6
Diabetes	38.2	38.8	32.4*	32.7*	23.9*	24.5*
Hypertension	83.0	83.5	84.4*	84.5*	84.4	85.5
Chronic lung disease	19.0	23.2	18.5	21.7	16.3	17.6
Dialysis	1.8	3.2	1.6	2.2	1.2	1.5
Hospitalized with bleeding in previous year	0.4	0.7	0.6	1.0	0.7	1.0
CrCl among nondialysis, ml/min	58.1 (46.5–70.5)	58.3 (46.2–71.3)	45.0 (35.5–55.5)	44.7 (35.2–55.7)	35.0 (27.6–43.8)*	35.2 (27.4–43.9)*
Charlson index						
0	77.4	70.2	72.8	66.0	61.9	55.8
1	20.0	25.5	23.9	29.0	34.0	38.2
2	2.2	3.4	2.7	4.1	3.6	5.1
≥3	0.5	1.0	0.5	0.9	0.5	0.9
Multivessel PCI	17.7	11.4	18.8	12.8	22.0	15.9
ACC/AHA type C (complex) lesions	38.7	37.2	39.9	38.1	43.5	41.9

Values are % or median (interquartile range). All p values <0.05 except where denoted by asterisk.
BMS = bare-metal stent(s); DES = drug-eluting stent(s); other abbreviations as in Tables 1 and 2.

Table 4 **Unadjusted Comparison of Baseline Characteristics Between DES and BMS Users Stratified According to Age Group: Acute PCI**

	Age 65–74 yrs		Age 75–84 yrs		Age ≥85 yrs	
Characteristics	DES (n = 43,081)	BMS (n = 18,092)	DES (n = 32,178)	BMS (n = 16,004)	DES (n = 8,238)	BMS (n = 5,898)
Male	62.5	65.7	50.8	53.4	41.6*	41.5*
White race	87.1	86.2	89.5*	89.2*	91.1*	90.5*
Prior MI	22.1*	21.5*	23.4	21.9	23.4	21.6
Prior CABG	16.4*	17.0*	19.3*	18.8*	14.0*	13.3*
Prior PCI	24.2	19.6	23.6	18.3	21.0	15.3
Prior heart failure	8.8	9.8	13.0	14.2	16.6*	16.5*
Prior stroke	11.6	12.2	16.0	17.5	18.2*	18.8*
Peripheral vascular disease	11.4	12.4	14.0	15.0	13.1*	13.2*
Diabetes	31.6	30.8	29.3	28.3	22.3*	22.0*
Hypertension	75.2	73.8	78.9	77.9	80.9	78.5
Chronic lung disease	17.7	20.2	17.8	20.1	15.0*	14.3*
Dialysis	1.6	2.2	1.6	2.1	1.1*	1.4*
Hospitalized with bleeding in previous year	0.3	0.6	0.4	0.9	0.6	1.2
CrCl among nondialysis, ml/min	57.9 (46.4–70.2)	57.6 (45.6–70.3)	44.0 (34.4–54.8)	43.3 (33.6–54.4)	34.2 (26.6–42.7)	33.0 (25.8–42.0)
Charlson index						
0	29.9	18.2	28.2	19.5	21.0	15.9
1	65.9	75.5	66.4	73.3	73.1	77.4
2	3.3	4.4	4.4	5.7	5.2*	5.5*
≥3	0.9	1.9	1.0	1.6	0.7	1.2
Multivessel PCI	13.4	7.5	15.4	9.6	18.2	11.5
ACC/AHA type C (complex) lesions	50.5	53.6	51.7	53.4	54.6*	55.3*

Values are % or median (interquartile range). All p values <0.05 except where denoted by asterisk.
All abbreviations as in Tables 1, 2, and 3.

revascularization risk may be less of a priority whereas the desire to maximize quality of life by avoiding MI rehospitalization may take precedence for patients age ≥85 years. As such, our study supports consideration of DES use among eligible older adults. The recognition that older adults comprise a growing proportion of PCI patients encourages interest in trials pre-specifying an adequately powered population of enrolled elderly patients to help correct knowledge deficits in this population and incorporating outcomes of relevance (e.g., quality of life).

Study limitations. Given the observational design, associations between treatments and outcomes cannot prove causality. Despite rigorous multivariable adjustment, residual unmeasured factors that influence stent selection and outcomes may skew the benefit toward DES use and cannot be fully accounted for with any adjustment methods. The use of claims data for event classification may result in

Table 5 **Unadjusted 900-Day Event Rates and Adjusted HRs Comparing DES Versus BMS Stratified According to Age Group**

		Unadjusted Rate			Propensity Matched			Inverse Probability Weighted		
Outcome	Age Group, yrs	DES, %	BMS, %	p Value	HR	95% CI	p Value	HR	95% CI	p Value
Death	65–74	9.7	16.2	<0.001	0.75	0.72–0.78	<0.001	0.73	0.71–0.75	<0.001
	75–84	16.8	24.8	<0.001	0.80	0.77–0.83	<0.001	0.77	0.75–0.79	<0.001
	≥85	28.4	38.3	<0.001	0.80	0.76–0.84	<0.001	0.80	0.77–0.83	<0.001
MI rehospitalization	65–74	6.7	8.2	<0.001	0.83	0.78–0.88	<0.001	0.84	0.80–0.88	<0.001
	75–84	7.4	9.2	<0.001	0.80	0.75–0.85	<0.001	0.81	0.77–0.84	<0.001
	≥85	9.2	11.6	0.008	0.77	0.69–0.86	<0.001	0.77	0.71–0.83	<0.001
Revascularization	65–74	24.2	26.0	0.004	0.89	0.86–0.92	<0.001	0.87	0.85–0.88	<0.001
	75–84	20.2	20.4	0.66	0.98	0.94–1.02	0.23	0.93	0.90–0.91	<0.001
	≥85	14.2	13.3	0.35	0.96	0.88–1.05	0.38	0.98	0.91–1.04	0.47
Bleeding	65–74	5.0	6.2	0.02	0.92	0.84–1.01	0.09	0.88	0.84–0.92	<0.001
	75–84	7.6	9.2	0.11	0.93	0.86–1.01	0.07	0.88	0.85–0.92	<0.001
	≥85	9.4	9.9	0.40	0.99	0.85–1.14	0.85	0.90	0.84–0.97	0.006

Interaction terms between stent type and age group for all endpoints are significant with $p_{interaction}<0.001$.
CI = confidence interval; HR = hazard ratio; all other abbreviations as in Tables 1 and 3.

under-reporting or misclassification of risks; however, these errors should be equally distributed between groups. Angiographic data were reported without central core laboratory adjudication. Finally, we do not have information on longitudinal medication use; this information is key to preventing long-term adverse outcomes.

Conclusions

Patients age ≥85 years are a growing subset of patients undergoing PCI in the United States. In contrast to pivotal stent studies, there was no difference in repeat revascularization between DES and BMS patients age ≥85 years in our study. Compared with BMS use, DES use was associated with lower risks of MI rehospitalization among older PCI patients, particularly among those ≥85 years of age, yet DES use declined the most in this age group. These results emphasize the need to further compare the effectiveness and safety of PCI treatments among elderly patients, focusing on endpoints relevant to this population.

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