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Comparison of Bare-Metal Stents and Drug-Eluting Stents in Coronary Ostial Lesions (from the National Heart, Lung, and Blood Institute Dynamic Registry)

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Abstract

We compared the effectiveness of drug-eluting stents (DESs) to bare-metal stents (BMSs) in ostial lesions from an unrestricted patient cohort with 3-year follow-up. DESs have proved more effective at decreasing repeat revascularization rates compared to BMSs in patients with uncomplicated coronary artery disease. Whether DESs provide similar benefits in ostial lesions is not clearly defined. We analyzed data from 775 patients in the National, Heart, Lung, and Blood Institute Dynamic Registry undergoing stenting of ostial lesions with DESs or BMSs. Patients were followed for 3 years for the occurrence of myocardial infarction (MI), repeat revascularization (coronary bypass surgery/repeat percutaneous coronary intervention), and death. In total 439 patients had 464 ostial lesions treated with BMSs and 336 patients had 351 ostial lesions treated with DESs. Adjusted DES versus BMS 3-year hazard ratios were 1.03 (95% confidence interval 0.60 to 1.78, p = 0.90) for death, 1.40 (0.83 to 2.37, p = 0.21) for MI, and 0.81 (0.59 to 1.11, p = 0.19) for repeat revascularization. In patients undergoing percutaneous coronary intervention for aorto-ostial disease (n = 200), death and repeat revascularization did not differ between stent types, but DES-treated patients had more MI during follow-up. For coronary ostial disease (n = 574), 3-year observed rates of death or MI did not differ; however, repeat revascularization was more common in the BMS group. In conclusion, use of DESs for ostial lesions was associated with no difference in the hazard of death, MI, or overall rates of repeat revascularization compared to BMS use.

Drug-eluting stents (DESs) have proved more effective than bare-metal stents (BMSs) in decreasing the need for repeat revascularization.[1–3] Complex lesions, however, have generally been excluded from initial randomized comparisons. As a result, the effectiveness of DESs compared with BMSs in complex coronary lesions including ostial lesions is less clear. Ostial lesions present a unique challenge given the higher prevalence of calcification, turbulent blood flow patterns, rigidity, elastic recoil, and ability to achieve correct stent placement compared to nonostial lesions.[4–6] Further more, aorto-ostial lesions, representing aortic wall disease, are a unique subset of ostial lesions where the pathology of ostial lesion is different. Previous studies comparing DESs to BMSs in ostial lesions are limited in the number of patients studied, location of lesions, and duration of follow-up.[7–17] The purpose of this report is to describe 3-year outcomes after unrestricted use of DESs versus BMSs in

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ostial coronary lesions from the National, Heart, Lung, and Blood Institute (NHLBI) Dynamic Registry.

Methods

This dynamic registry is a multicenter NHLBI-sponsored prospective observational study of consecutive patients undergoing percutaneous coronary intervention (PCI) at selected centers in North America. It is composed of 5 “waves” of patient enrollment, each enrolling <2,000 patients since 1997, with the intent to study changes in PCI technology over time. Waves 1 to 3 enrolled patients when only BMSs were available. Waves 4 (2004) and 5 (2006) enrolled patients during the DES era. To decrease election bias, BMS-treated patients were selected only from waves 1 to 3.

Trained research coordinators collected demographic, clinical, angiographic, and procedural data pertaining to the index PCI procedure and vital status, repeat hospitalization, and medication use information during follow-up using standardized report forms. Hospital charts and coronary angiograms were reviewed to assess inpatient outcomes. Follow-up data were collected at 1 month, 6 months, and annually thereafter by direct patient contact. Patients enrolled in waves 1 and 3 were followed for 1 year and follow-up for patients in waves 2, 4, and 5 was extended. Routine follow-up angiography was not performed and staged PCI was not considered repeat PCI. Lesion-specific data were collected to determine target vessel revascularization rates.

Death was included as all-cause mortality. Other end points evaluated were myocardial infarction (MI) and any repeat revascularization (PCI or any coronary artery bypass grafting after index PCI). MI was defined as the presence of ≥2 of the following findings: typical chest pain lasting 20 minutes and not relieved by nitroglycerin; serial electrocardiograms showing changes from baseline in ST and T waves and/or Q waves in <2 contiguous leads; increase in creatine kinase to <2 times upper limit of normal with a creatine kinase-MB index of <5%; and increase in troponin to <2 times upper limit of normal. Ostial lesions were defined as aorto-ostial lesions (right coronary artery, left main coronary artery, saphenous vein graft, or arterial graft ostial lesions) or coronary ostial lesions within the coronary tree of <50% stenosis severity by visual assessment.

Continuous variables were compared by Student's *t* or Wilcoxon nonparametric tests and categorical variables by chi-square or Fisher's exact tests. Three-year cumulative event rates were estimated with the Kaplan-Meier method, and un-adjusted survival curves were compared using log-rank statistic. Cox proportional hazards model was used to estimate 3-year hazard ratios (HRs) for clinical events in relation to stent type. Covariate adjustment was performed with demographic, clinical, and lesion/procedural characteristics entered into outcome-specific models including an indicator variable for stent type. For each outcome potential confounders were adjusted for in a forward stepwise manner to determine the final model, and variables with a p value <0.10 were included in age-adjusted final models. Proportionality assumptions for Cox models were met. Patients not developing an event of interest by 3 years for those enrolled in waves 2, 4, and 5 were censored at 3 years and the same was done at 1 year for patients enrolled in waves 1 and 3. A 2-sided p value <0.05 was considered significant for all statistical analyses. We performed a subgroup analysis evaluating clinical event rates in patients treated with aorto-ostial and coronary ostial lesions.

Results

Baseline characteristics comparing differences between BMS- and DES-treated patients are presented in Table 1. The 2 groups were of similar age and had a similar proportion of woman patients. DES-treated patients were more likely to have a history of diabetes, hypertension, hypercholesterolemia, and previous PCI. BMS-treated patients were more likely to present with acute coronary syndromes and cardiogenic shock and less likely to receive periprocedural thienopyridine therapy.

In total 439 patients had 464 ostial lesions attempted with BMSs compared to 351 ostial lesions attempted with 336 DESs (Table 2). At the lesion level, the location of lesions and reference vessel diameter were similar between the 2 groups. Lesions treated with DESs were significantly longer, treated with more stents/lesion, and more likely to be class C compared to BMS-treated lesions. BMS-treated lesions were more likely to be thrombotic, which is consistent with higher rates of acute coronary syndromes in BMS-treated patients. Overall angiographic and procedural success rates were high and similar for the DES and BMS groups.

Rate of in-hospital death (BMS 2.5% vs DES 0.6%, p = 0.04) was higher in the BMS group. Rates of MI (BMS 4.8% vs DES 4.5%, p = 0.83), coronary artery bypass grafting (BMS 1.1% vs DES 0.0%, p = 0.05), stroke (BMS 0.9% vs DES 0.3%, p = 0.29), and bleeding requiring transfusion (BMS 3.9% vs DES 2.1%, p = 0.15) were similar between groups. DES-treated patients were more likely to receive dual antiplatelet therapy, statins, β blockers, and angiotensin-converting enzyme inhibitors on discharge, possibly reflecting different practice patterns during BMS and DES recruitment phases.

At 3-year follow-up, observed rates of death, MI, and repeat revascularization did not differ (Table 3 and Figure 1). In patients undergoing repeat procedures, repeat PCI did not dif fer; however, coronary artery bypass grafting was significantly higher in the BMS group. After adjustment, there was no difference in rate of death, MI, and repeat revascularization (Figure 2). Overall 3-year target vessel revascularization rates from available data were not different for the DES versus BMS groups.

Of 775 patients in the study cohort, 200 (26%) underwent PCI for aorto-ostial lesions (right coronary artery, left main coronary artery, and vein grafts). For the DES versus BMS comparison in patients with aorto-ostial disease, 3-year observed rates of death (BMS 21.8% vs DES 15.9%, p = 0.40; adjusted HR 2.6, 95% confidence interval [CI] 0.8 to 8.1, p = 0.10) and repeat revascularization (BMS 17.4% vs DES 32.1%, p = 0.33; adjusted HR 1.6, 95% CI 0.8 to 3.1, p = 0.15) did not differ; however, DES-treated patients had more MI on follow-up (BMS 3.9% vs DES 16.2%, HR 5.4, 95% CI 1.3, 22.6, p = 0.02). DES-treated patients had a trend toward a higher rate of repeat PCI compared to BMS-treated patients (BMS 9.9% vs DES 28.3%, p = 0.06; adjusted HR 2.1, 95% CI 1.0, 4.7, p = 0.06).

In patients undergoing PCI for coronary ostial lesions, 3-year cumulative rates of death (BMS 13.3% vs DES 12.0%, p = 0.18) and MI (BMS 11.8% vs DES 10.9%, p = 0.43) did not differ; however, repeat revascularization was more common in the BMS group (BMS 26.4% vs DES 23.3%, p = 0.02; adjusted HR 0.7, 95% CI 0.5 to 1.0, p = 0.04).

Discussion

Previous studies comparing DESs to BMSs for off-label indications have reported that up to 20% of patients in the “off-label” group undergo PCI for ostial lesions. As a result, a separate analysis evaluating stent use in this lesion category is warranted. In this prospective observational cohort study of patients undergoing PCI for ostial lesions with DESs versus

BMSs, we noted no difference in rates of death, MI, or repeat revascularization by 3 years according to stent type. Observed and adjusted coronary artery bypass grafting rates were significantly higher in BMS-treated patients. Previous randomized and observational studies have consistently shown lower target vessel revascularization rates with DESs compared to BMSs in other lesion subsets, a benefit not evident in our analysis.[1–3,18]

Our data are derived from the NHLBI Dynamic Registry. BMS data were acquired from patients undergoing stenting before DES introduction to lessen selection bias because currently the types of patients treated with DESs versus BMSs differ markedly in several respects. Despite this approach, residual baseline differences remained between the DES versus BMS groups. When differences were present, some high-risk features were higher in the BMS group and others in the DES group.

As a whole, patients enrolled in this study more commonly had features associated with poor clinical outcomes than patients in published randomized DES versus BMS trials.[1–3] For example, patients in our study were older and had higher rates of diabetes, previous MI, previous coronary artery bypass grafting, low ejection fraction, peripheral vascular disease, cerebrovascular disease, renal failure, multi-vessel and left main coronary artery disease compared to patients studied in randomized DES versus BMS trials. Patients in this study had higher annual mortality rates compared to patients enrolled in randomized stent trials and observational studies.[7,8,10,14] The greater prevalence of morbid conditions and higher mortality noted in our study cohort likely reflects unrestricted use of DESs and consecutive enrollment of patients in each of the 5 waves. A proportion of the aorto-ostial subgroup included patients with previous coronary artery bypass grafting (ostial saphenous vein graft lesions), making this is a higher-risk cohort compared to previous analyses.

We did not have lesion level data available on follow-up, and as a result target lesion revascularization rates could not be calculated. The inability to distinguish between target lesion revascularization and nontarget lesion revascularization rates has the propensity to underestimate the benefit of DES in regard to rate of repeat target lesion revascularization procedures because disease progression in nonstented regions cannot be determined.

We noted a significantly higher rate of coronary artery bypass grafting in the BMS group and a trend toward a higher rate of repeat PCI in the DES group. The most likely explanation is that patients presenting for repeat procedures in the BMS era were more commonly referred for coronary artery bypass grafting as the preferred revascularization strategy in the setting of stent failure. Strategies available for treatment of stent restenosis, i.e., repeat balloon angioplasty or additional stenting with BMS, had limited success. The sharp decrease in rates of restenosis noted with DES treatment increased the likelihood to treat target lesion revascularization or nontarget lesion revascularization lesions with repeat DES before referring a patient for surgery.[19–21]

Our subgroup analysis included an evaluation of patients according to location of ostial lesions, specifically aortoostial and coronary ostial lesions. Aorto-ostial lesions differ from coronary ostial lesions by histopathologic characteristics such as more fibrous cellularity, calcification, and sclerosis.[6,22,23] Long-term stent recoil may play a more important role in the aorto-ostial lesion type compared to ostial lesions located within the coronary tree.[6]

In patients undergoing PCI for aorto-ostial lesions, death and target vessel revascularization were similar, whereas MI was more frequent in the DES group. Our finding of a higher rate of MI during follow-up in the DES group in patients undergoing PCI for aorto-ostial lesions differs from previous reports. Park et al[8] reported no difference in MI (BMS 0.5% vs DES 1.2%, $p = 0.6$) in 356 patients undergoing PCI with DESs versus BMSs for aorto-ostial disease. However, that study excluded patients with high-risk features. Furthermore, very

few patients were treated for saphenous vein graft lesions. No obvious explanation for this finding is apparent from our analysis and it is likely that, given the small numbers of patients in this subgroup analysis, the difference may be due to chance alone.

There was no difference in rate of death or MI between the DES and BMS groups for coronary ostial lesions, a finding consistent with randomized stent trials. However, unlike aorto-ostial lesions, we did detect a decrease in target vessel revascularization in patients undergoing PCI for coronary ostial lesions. Aorto-ostial lesions represent aortic wall disease, the progression of which is possibly not altered by drugs selected to attenuate neointimal hyperplasia. This mechanism, combined with the generally larger reference vessel diameter of aorto-ostial lesions, could explain the lack of DES benefit in this lesion subset.[24]

Results from the present study should be interpreted within the context of the overall design. This was an observational study, and patients were not randomized to receive DESs versus BMSs. As a result, significant baseline patient characteristics and procedural differences were present before adjustment and residual confounding may be present after adjustment, as is expected in any observational study. Patients did not undergo routine angiographic follow-up and we were unable to determine rates of target lesion revascularization or in-stent restenosis. Lesion progression in nonstented segments may underestimate the benefit of DESs. Information on stent thrombosis was not available in all waves of the dataset. However, previous analyses from the same dataset and other registries have shown stent thrombosis rates to be ≤1%, even when off-label indications are included.[18,25,26]

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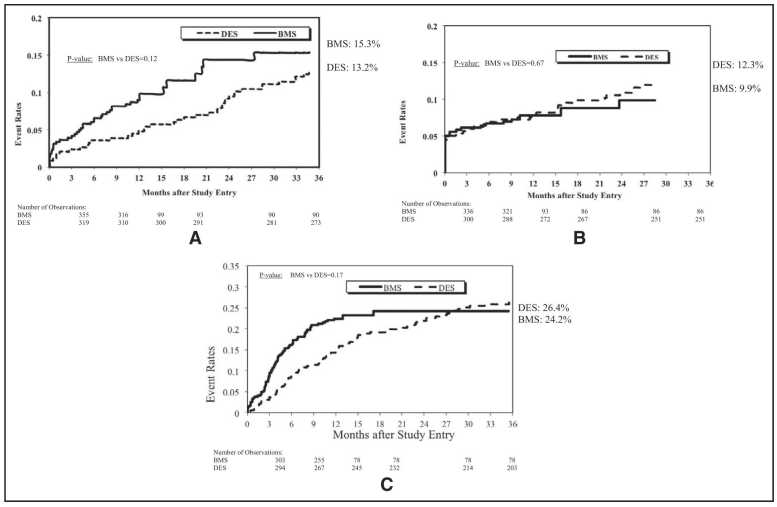

Figure 1.

Kaplan–Meier plots of 3-year cumulative incidence of *(A)* death, *(B)* myocardial infarction, and *(C)* coronary artery bypass grafting/repeat percutaneous coronary intervention in patients undergoing percutaneous coronary intervention for ostial lesions using bare-metal versus drug-eluting stents.

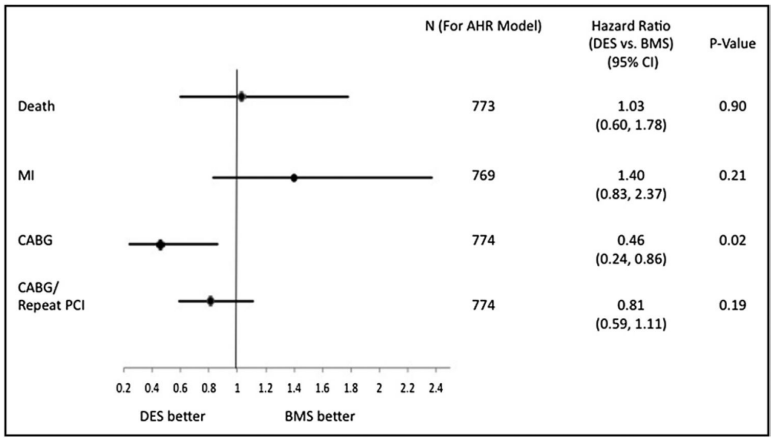

Figure 2.

Adjusted hazard rates/relative risk of patients undergoing percutaneous coronary intervention for ostial lesions. AHR = adjusted hazard ratio; CABG = coronary artery bypass grafting.

Table 1

Baseline characteristics of patients with ostial lesions treated with bare-metal stent versus drug-eluting stent

Variable	BMS (n = 439)	DES (n = 336)	p Value
Mean age (years)	65.5	65.4	0.86
Women	39.2%	35.7%	0.32
Body mass index (kg/m^2)	28.3	29.7	<0.001
Diabetes mellitus	30.9%	39.7%	0.01
Insulin therapy	10.4%	16.4%	0.01
Hypertension	69.6%	84.0%	<0.001
Hy perch ole sterole mia	65.7%	83.6%	<0.001
Smoker			0.79
Current	18.8%	18.8%	
Former	43.3%	45.5%	
Previous myocardial infarction	37.5%	27.5%	0.004
Previous angioplasty	29.1%	40.2%	<0.001
Previous coronary bypass	28.3%	32.0%	0.54
Co-morbidities			
Cerebrovascular	8.3%	11.4%	0.15
Renal insufficiency	7.2%	9.3%	0.28
Peripheral arterial disease	12.9%	11.1%	0.43
Ejection fraction, mean (%)	51.1	51.9	0.27
Number of coronary arteries diseased			0.06
1	32.3%	23.5%	
2	30.3%	34.5%	
3	37.1%	41.7%	
Mean left main coronary artery stenosis >50%	12.1%	22.0%	<0.001
Reason for revascularization			
Myocardial infarction	20.1%	18.5%	0.57
Unstable angina	50.0%	35.4%	<0.001
Stable angina	21.0%	27.4%	0.04
Cardiogenic shock	3.9%	0.6%	0.003
Periprocedural medications			
Thienopyridines	61.3%	86.6%	<0.001
Heparin	96.6%	65.8%	<0.001
Low-molecular-weight heparin (waves 2–5)	2.9%	3.3%	0.79
Glycoprotein IIb/IIIa inhibitor	41.5%	36.3%	0.15
Discharge medications			
Aspirin	91.1%	98.5%	<0.001
Angioten sin-converting enzyme inhibitor	38.8%	51.2%	<0.001
β Blocker	64.7%	84.1%	<0.001
Calcium channel blocker	26.9%	16.8%	<0.001
Statins	56.3%	83.8%	<0.001

Variable	BMS (n = 439)	DES (n = 336)	p Value
Thienopyridines	89.2%	99.1%	<0.001
Mean number of lesions	3.7	3.9	0.20
Mean lesions attempted	1.8	1.5	0.001
Procedural success	96.1%	98.2%	0.09
Mean stents/patient	1.85	1.83	0.82
Insurance status			0.075
Medicare	50.3%	42.4%	
Public	11.8%	12.2%	
Private	36.0%	41.5%	
Serf	1.8%	3.9%	

Table 2

Lesion characteristics and outcomes of bare-metal versus drug-eluting stent-treated patients undergoing stenting for ostial lesions

Variable	BMS (n = 464)	DES (n = 351)	p Value
Location			0.43
Left main coronary artery	5.6%	7.7%	
Left anterior descending coronary artery	36.9%	34.8%	
Left circumflex coronary artery	21.2%	25.1%	
Right coronary artery	24.2%	22.2%	
Bypass graft	12.1%	10.3%	
Mean reference vessel diameter (mm)	3.2	3.2	0.72
Mean lesion length (mm)	11.7	15.5	<0.001
Complex lesion types			
Total occlusion	8.4%	6.8%	0.41
Thrombus present	12.8%	7.8%	0.02
Calcified lesion	36.4%	40.5%	0.24
Ulcerated lesion	10.5%	11.4%	0.70
American College of Cardiology/American Heart Association classification			<0.001
A	4.6%	1.7%	
B1	17.3%	22.6%	
B2	52.7%	37.4%	
C	25.4%	38.3%	
Sirolimus-eluting stent		65.8%	
Paclitaxel-eluting stent		34.2%	
Procedural complications			
Major dissection	5.2%	2.3%	0.03
Perforation	0.4%	0.0%	0.22
Embolization	1.3%	1.4%	0.87
Side branch occlusion	1.9%	2.3%	0.74
Angiographic success	97.8%	98.0%	0.87
Stents/lesion (mean)	1.17	1.28	0.006

Table 3

Observed three-year event rates

Variable	BMS (n = 439)	DES (n = 336)	p Value
All-cause death	15.30%	13.20%	0.12
Myocardial infarction	9.90%	12.30%	0.67
Repeat percutaneous coronary intervention	16.30%	23.80%	0.68
Coronary artery bypass grafting	10.40%	5.30%	0.002
Coronary artery bypass grafting/repeat percutaneous coronary intervention (repeat revascularization)	24.20%	26.40%	0.17
Target vessel revascularization	9.30% (137) *	7.80% (314)	0.6

* For the bare-metal stent group, follow-up beyond 1 year was available only for wave 2.