Evolution of Percutaneous Coronary Intervention in Patients with Diabetes

A report from the National Heart, Lung, and Blood Institute–sponsored PTCA (1985–1986) and Dynamic (1997–2006) Registries

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OBJECTIVE — To evaluate the association of successive percutaneous coronary intervention (PCI) modalities with balloon angioplasty (BA), bare-metal stent (BMS), drug-eluting stents (DES), and pharmacotherapy over the last 3 decades with outcomes among patients with diabetes in routine clinical practice.

RESEARCH DESIGN AND METHODS — We examined outcomes in 1,846 patients with diabetes undergoing de novo PCI in the multicenter, National Heart, Lung, and Blood Institute–sponsored 1985–1986 Percutaneous Transluminal Coronary Angioplasty (PTCA) Registry and 1997–2006 Dynamic Registry. Multivariable Cox regression models were used to estimate the adjusted risk of events (death/myocardial infarction [MI], repeat revascularization) over 1 year.

RESULTS — Cumulative event rates for postdischarge (31–365 days) death/MI were 8% by BA, 7% by BMS, and 7% by DES use ($P = 0.76$) and for repeat revascularization were 19, 13, and 9% ($P < 0.001$), respectively. Multivariable analysis showed a significantly lower risk of repeat revascularization with DES use when compared with the use of BA (hazard ratio [HR] 0.41 [95% CI 0.29–0.58]) and BMS (HR 0.55 [95% CI 0.39–0.76]). After further adjustment for discharge medications, the lower risk for death/MI was not statistically significant for DES when compared with BA.

CONCLUSIONS — In patients with diabetes undergoing PCI, the use of DES is associated with a reduced need for repeat revascularization when compared with BA or BMS use. The associated death/MI benefit observed with the DES versus the BA group may well be due to greater use of pharmacotherapy.

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The practice of percutaneous coronary intervention (PCI) has evolved rapidly in the past 3 decades, with technological advancements from balloon angioplasty (BA) to bare-metal stents (BMS) and the more recent drug-eluting stents (DES) (1). Comparisons of device-specific outcomes have yielded similar results, with a recent meta-analysis reporting a significant reduction in the rate of target lesion revascularization, but not mortality, with DES use compared with BMS use (2).

Coronary angioplasty in patients with diabetes has been shown to have a higher rate of infarction and a greater need for additional revascularization procedures (3). In a large consecutive series of patients treated by elective stent implantation, patients with diabetes were at higher risk for in-hospital mortality and subsequent revascularization, which ultimately resulted in a significantly lower cardiac event-free survival rate (4). Yet, the benefit of DES over BMS remains unclear. A pooled analysis (5) reported a significant difference in survival in favor of BMS over the DES, whereas no significant difference in mortality was observed in another analysis of 14 randomized controlled trials (6). Given these inconsistent findings and the growing percentage of diabetic patients undergoing PCI, the impact of advances in PCI technology and adjunct improvement in pharmacotherapy on outcomes in patients with diabetes needs to be assessed.

We, therefore, investigated the effectiveness of PCI in patients with diabetes by comparing 1-year rates of death/myocardial infarction (MI) and repeat revascularization across the three device modalities: BA, BMS, and DES. Data from the multicenter, National Heart, Lung, and Blood Institute (NHLBI)-sponsored 1985–1986 Percutaneous Transluminal Coronary Angioplasty (PTCA) Registry and the 1997–2006 Dynamic Registry were used for this purpose.

RESEARCH DESIGN AND METHODS

— The NHLBI-sponsored PTCA and Dynamic Registries were prospective multicenter studies that enrolled patients undergoing coronary interventions in centers from North America (7–9). The 1985–1986 PTCA Registry recruited 2,000 consecutive patients undergoing de novo BA. The Dynamic Registry was initiated after the advent of BMS

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and enrolled patients in recruitment waves of ~2,000 patients (1: 1997–1998, $n = 2,524$; 2: 1999, $n = 2,105$; 3: 2001–2002, $n = 2,047$; 4: 2004, $n = 2,112$; 5: 2006, $n = 2,178$). Information on patient characteristics and detailed angiographic and procedural data were ascertained at baseline. Written informed consent was obtained from participants, all of whom agreed to be contacted annually after discharge. The study protocol was approved by the Institutional Review Boards of the coordinating center (University of Pittsburgh) and all the clinical sites.

Data on events including all-cause death, MI, coronary artery bypass surgery (CABG), and repeat PCI were ascertained, and hospital records were examined to ensure consistency with protocol definitions. Specifically, the definition of MI was revised to match prevailing expert consensus; in the PTCA Registry, it was defined as evidence of two or more of the following: *1*) typical chest pain >20 min not relieved by nitroglycerin, *2*) serial ECG recordings showing changes from baseline or serially in ST-T and/or Q-waves in two or more contiguous leads, or *3*) serum enzyme elevation of CK-MB >5% of total creatinine kinase (CK) (total CK more than twice that of normal; LDH subtype 1 > LDH subtype 2); in the Dynamic Registry, cardiac troponin level was incorporated as a major criteria.

This analysis was restricted to patients with reported diabetes at baseline. In the PTCA Registry, history of diabetes was ascertained through review of medical records by site coordinators and through patient self-report. Baseline treatment status (insulin or hypoglycemic agent versus diet controlled) was not identified or recorded by site coordinators (7). The Dynamic Registry identified study patients with diabetes according to the use of oral hypoglycemic agents, diet, or treatment with insulin (9). Both registries did not explicitly identify the type of diabetes (type 1 versus type 2). Patients were then categorized by the type of device received (BA, BMS, or DES) at the time of the index procedure. Because of the availability of multiple treatment modalities in some recruitment waves, a selection bias was anticipated. Given this, BA patients were drawn from the PTCA Registry and only from wave 1 of the Dynamic Registry, BMS patients were selected from waves 1–3 of the Dynamic Registry, and DES patients were from waves 4 and 5 of the Dynamic Registry. Patients who received both BA and BMS were categorized as BMS, and those who received both BMS and DES were classified as DES.

Table 1—*Baseline patient characteristics by device type in 1,846 patients with diabetes*

	BA	BMS	DES	*P**
n	459	795	592	
Age (years)	61.0 ± 10.4	64.4 ± 10.9	63.3 ± 11.7	<0.001
Female (%)	41	42	38	0.20
Prior CABG (%)	15	16	20	0.07
Prior MI (%)	40	25	15	<0.001
BMI (kg/m^2)	29.1 ± 5.7	30.5 ± 6.2	32.0 ±7.0	<0.001
Congestive heart failure (%)	14	15	14	0.81
Hypertension (%)	66	76	87	<0.001
Hypercholesterolemia (%)	42	65	81	<0.001
Treatment of diabetes (%)†				
None	—	5	4	0.51
Diet (no medical Rx)	—	13	11	
Oral medications (no insulin)	—	52	54	
Insulin	—	30	31	
Cigarette smoker (%)				
Never	40.8	38.4	37.1	0.61
Current	20.6	19.2	19.5	
Former	38.5	42.4	43.4	
Severe noncardiac disease (%)†	17	44	46	<0.001
Cerebrovascular	—	8	9	0.58
Peripheral vascular disease	—	11	10	0.54
Pulmonary	—	10	8	0.26
Cancer	—	8	9	0.72
Renal	—	9	17	<0.001
Other	—	15	16	0.66

Data are means ± SD and percentage unless otherwise indicated. **P* value for differences in characteristics across the device groups obtained using the Kruskal-Wallis test for continuous variables and χ^2 test for categorical variables; †*P* value is for differences between BMS and DES groups, as information on diabetes treatment and subclasses of noncardiac disease were not collected in the NHLBI 1985–1986 PTCA Registry, which comprises a major portion of BA group.

Statistical methods

Differences in baseline patient and procedural characteristics across the three device types were evaluated using the Kruskal-Wallis test for continuous variables and the χ^2 test for categorical variables. Kaplan-Meier (KM) estimates of 1-year event rates for combined death/MI and repeat revascularizations (repeat PCI or CABG) were compared using the log-rank test. Hazard ratios (HRs) and 95% CI for events 31–365 days after index PCI ("late" events) were estimated using Cox regression analysis models for *1*) BMS and DES versus BA groups, and *2*) DES versus BMS groups. For multivariable adjustment, only those data available in both registries with significant univariate differences across the three device categories and outcomes were considered. All analyses were performed with SAS version 9.1 (SAS Institute, Cary, NC).

RESULTS

Baseline patient characteristics

Table 1 shows baseline characteristics by the type of device used for the 1,846 patients with diabetes who underwent de novo PCI. On average, although the BMS patients were older, patients who received DES were more likely to report concomitant comorbidities (history of hypertension, dyslipidemia, and renal disease). No significant differences were noted in the type of treatment for diabetes among the BMS- and DES-treated patients.

Angiographic, procedural, and lesion characteristics

The DES patients were more likely to have triple vessel disease and more significant lesions at baseline (Tables 2 and 3). Index PCI in all three device groups was performed more often for acute coronary syndromes (BA 63%, BMS 69%, DES 65%; $P < 0.001$) and as such, was more often nonelective in nature. Among those

Table 2—*Procedural by device type in 1,846 patients with diabetes*

	BA	BMS	DES	*P**
n	459	795	592	
Ejection fraction	56.4 ± 13.5	50.7 ± 14.2	52.5 ± 14.0	<0.001
Number of vessels diseased (%)				
Single	40	37	29	<0.001
Double	29	34	32	
Triple	32	30	40	
Any total occlusion (%)	37	40	40	0.57
Significant lesions	3.1 ± 2.2	3.1 ± 2.1	3.4 ± 2.2	<0.01
Amenable to complete revascularization by PCI (%)	80	77	87	<0.001
Amenable to complete revascularization by CABG (%)	85	80	79	0.45
Primary reason for index PCI (%)				<0.001
Asymptomatic coronary artery disease/other reasons	7	13	18	
Stable angina	30	19	18	
Unstable angina	51	40	35	
Acute myocardial infarction	12	29	30	
Cardiogenic shock	32	14	2	<0.001
Circumstances of procedure (%)				<0.001
Elective	70	57	57	
Urgent	23	31	33	
Emergent	8	12	10	
Number of vessels attempted (%)				<0.01
Single vessel	77	81	74	
Double vessels	16	11	19	
Triple vessels	7	8	7	
Number of lesions attempted (%)				
1	64	67	65	0.13
2	24	25	26	
≥3	13	8	9	
Procedural use of clopidogrel or ticlopidine (%)	7	57	87	<0.001
Procedural use of glycoprotein IIb/IIIa inhibitor (%)	6	40	35	<0.001

Data are means ± SD and percentages unless otherwise indicated. **P* value for differences in characteristics across the device groups obtained using the Kruskal-Wallis test for continuous variables and χ^2 test for categorical variables.

who underwent PCI for acute MI, the proportion of patients in cardiogenic shock was higher in the BA group (BA 32%, BMS 14%, DES 2%; $P < 0.001$). Procedural use of thienopyridine was higher in the DES patients (BA 7%, BMS 57%, DES 87%; $P < 0.001$). Attempted lesions among DES-treated patients were more often classified as type C lesions (BA 20%, BMS 19%, DES 26%; $P < 0.001$).

In-hospital and 1-year outcomes

Procedural success was achieved and maintained more often with BMS and DES compared with BA (BA 81%, BMS 97%, DES 99%; $P < 0.001$), reflective of technological advances. Rates of in-hospital mortality, MI, and repeat revascularizations were significantly higher in the BA group (Fig. 1*A*). The average length of stay among patients alive at discharge was higher for those in the BA group (mean number of days: BA 4.2, BMS 2.8, DES 2.1 days, $P < 0.001$). The prescribed use of recommended medications such as aspirin, ACE inhibitors, β-blockers, lipid-lowering therapy, and antiplatelet therapy among those alive at discharge was significantly higher in the BMS and DES groups (Fig. 1*B*).

Significant differences were observed in the 1-year unadjusted cumulative event rates by device type following index PCI. The overall incidence rates of death/MI (BA 16%, BMS 13%, DES 10%; $P = 0.01$) and repeat PCI/CABG (BA 30%, BMS 20%, DES 13%; $P < 0.001$) were much lower in the BMS and DES patients than in the BA groups. However, the restriction of the analysis to late events (31–365 days) revealed similar rates of mortality or MI (Fig. 2). Multivariable Cox regression analysis models comparing BMS and DES with BA, and adjusting for baseline characteristics, showed a lower risk of mortality/MI, which did not achieve statistical significance for BMS (Fig. 3). Further adjustment for the discharge use of cardiac medications altered the pattern for death/MI for DES, which became statistically nonsignificant with BA as reference (DES, HR 0.60 [95% CI 0.29–1.22]; $P = 0.16$), and the risk of repeat revascularization remained statistically significant only with DES use with BA as reference (DES, 0.57 [0.36–0.91]; $P = 0.02$). Multivariable models comparing DES to BMS use showed no statistically significant difference in the risk of death or MI but significant reduction in

Table 3—*Lesion characteristics by device type in 1,846 patients with diabetes*

	BA	BMS	DES	*P**
n	767	1,006	790	
Lesion length (mm)	11.8 ± 8.7	13.0 ± 6.9	17.6 ±12.3	<0.001
Preprocedure diameter stenosis (%)	83.4 ±14.4	83.7 ± 13.3	83.7 ± 10.8	0.18
Postprocedure diameter stenosis (%)	30.1 ± 22.7	3.0 ± 9.9	0.9 ± 5.4	<0.001
Evidence of thrombus	13	20	13	<0.001
Ulcerated	7	16	14	<0.01
Bifurcation	13	11	9	0.23
Calcified	14	29	32	<0.001
ACC/AHA Classification				
A	10	12	11	0.03
B1	32	35	33	
B2	39	34	31	
C	20	19	26	

Data are percentages unless otherwise indicated. **P* value for differences in characteristics across the device groups obtained using the Kruskal-Wallis test for continuous variables and χ^2 test for categorical variables. ACC, American College of Cardiology; AHA, American Heart Association.

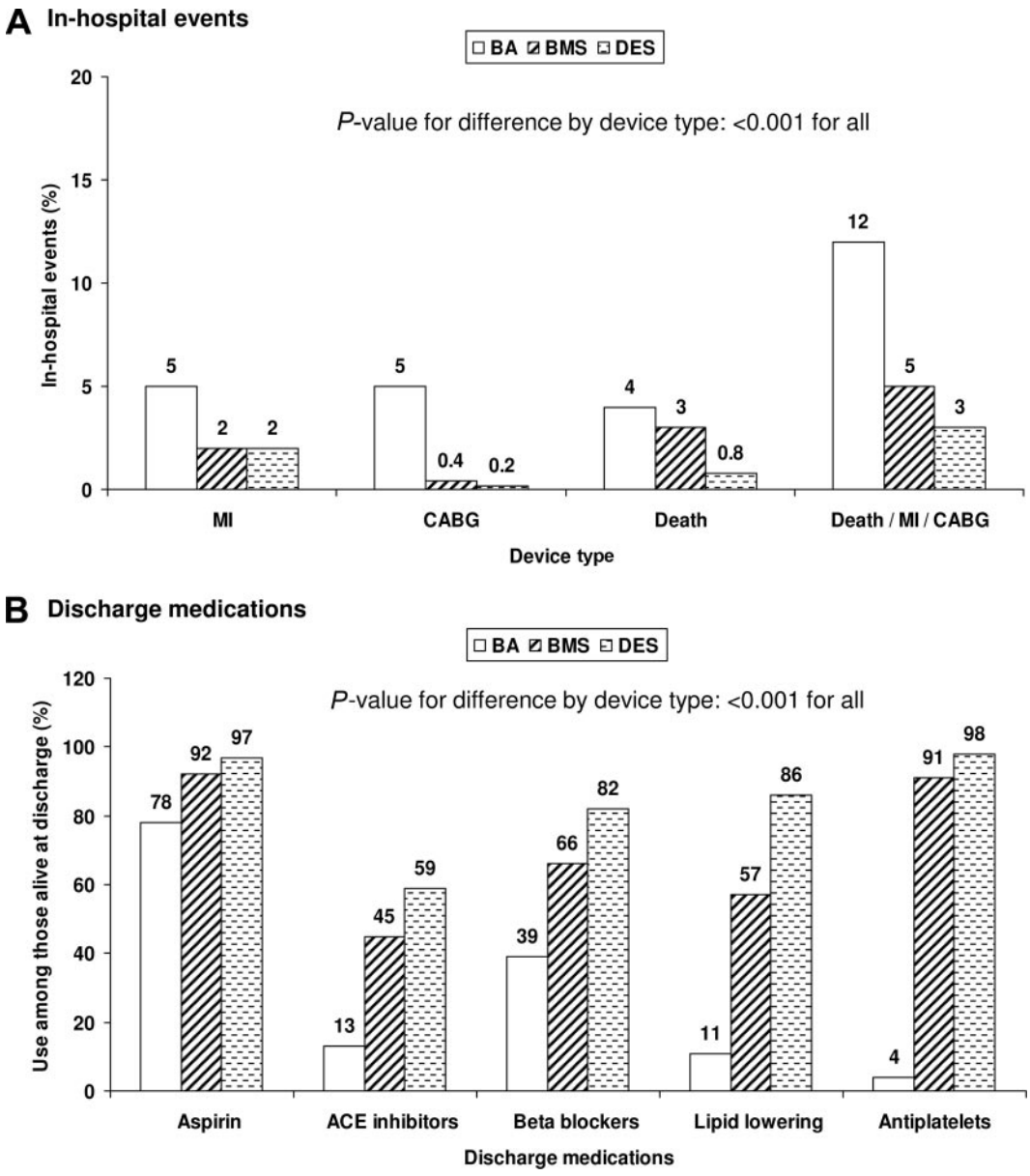

Figure 1—*In-hospital outcomes (A) and discharge medication* use (B) after PCI by device type in patients with diabetes. *Percentages of antiplatelets and lipid-lowering drugs predominantly reflect information from the NHLBI-sponsored Dynamic Registry patients.*

the need for repeat revascularization (Fig. 3).

CONCLUSIONS — Using data from the multicenter, NHLBI-sponsored PTCA and Dynamic Registries, we describe the characteristics of patients with diabetes undergoing de novo PCI and compare related outcomes across the three key devices—BA, BMS, and DES in the field. The profile of patients and lesions undergoing PCI today has expanded to include sicker cases with greater disease burden. Compared with BA, patients treated with BMS or DES were also more likely to be discharged on evidence-based cardiac medications. Importantly, DES use was associated with a comparable risk of death/MI once adjusted for pharmacotherapy in this high-risk subset.

There have been questions regarding the risk of late stent thrombosis associated with DES in higher-risk patients, and the danger of early discontinuation of antiplatelet therapy (10). Recent data from Europe however has shown that compared with BMS, DES is associated with a similar long-term incidence of death or MI but provides a clinically important reduction in the rate of restenosis among high-risk patients (11). Our analysis found significant reductions in the need for repeat revascularization with DES use compared with BA and BMS and no difference in death/MI once adjusted for pharmacotherapy.

Unrestricted use of DES has been shown to have better outcomes than BMS, with fewer clinically driven revascularization procedures and similar rates of death and MI at 1 year (12). However, pooled analyses in patients with diabetes have shown conflicting results regarding survival when comparing BMS- and DES-treated patients (5,6). In a previous report from the 1997–1999 Dynamic Registry patients with diabetes were shown to have

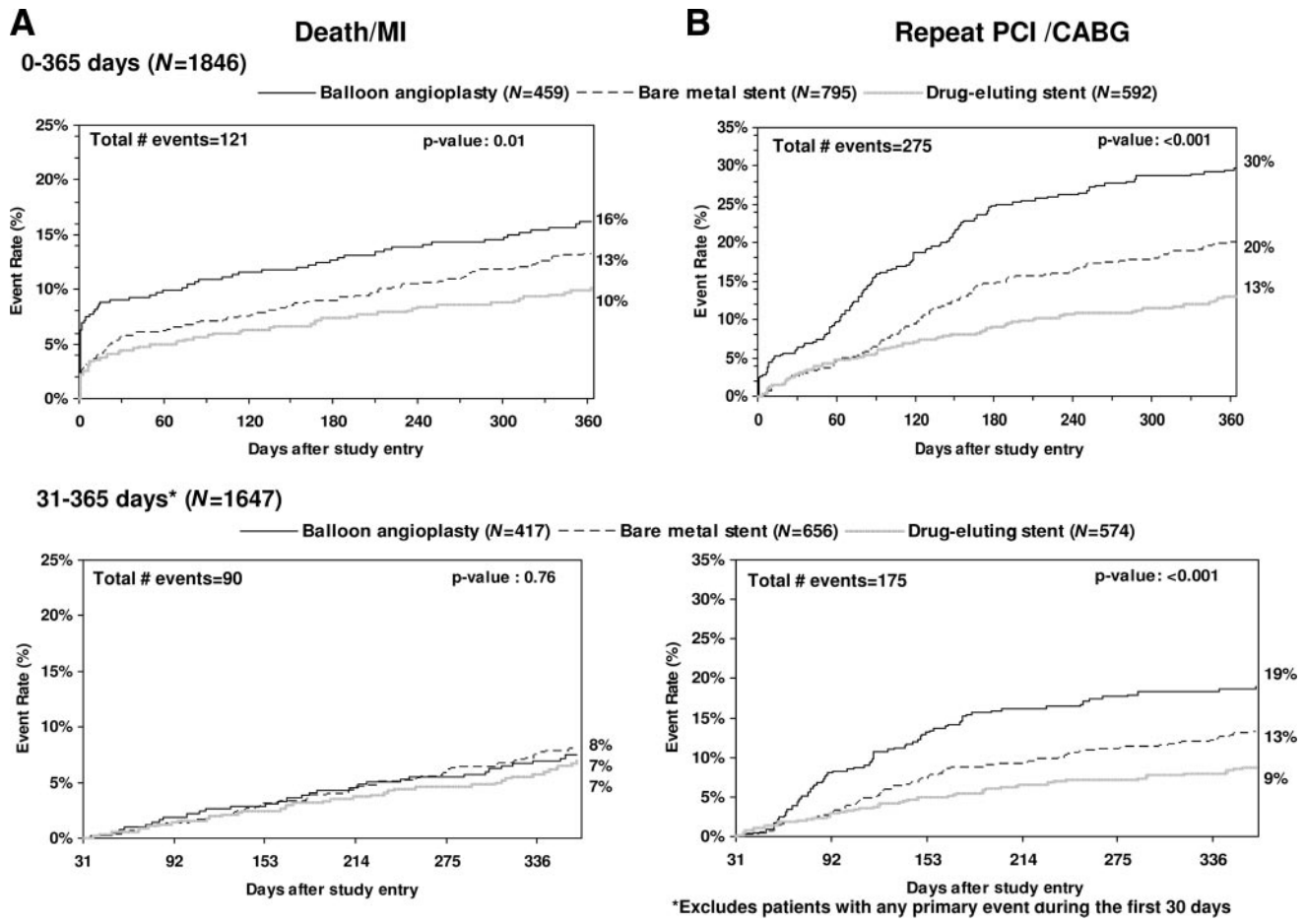

Figure 2—*Cumulative (Kaplan-Meier) event rates for death/MI* (A) *and repeat revascularization* (B) *by device type at 1 year and 31–365 days after discharge.*

had a significantly higher adjusted risk of mortality and need for repeat revascularization than those without diabetes (13). Another study from the Dynamic Registry compared the efficacy of DES with BMS in patients with insulin- and non–insulin-treated diabetes and showed that DES was associated with a lower risk for repeat revascularization compared with BMS in both insulin- and non–insulin-treated patients (14). More recent data from this group extended these findings to show that, among this high-risk subset, PCI outcomes did not differ by the type of DES (sirolimus- or paclitaxel-eluting) used (15).

Pharmacotherapy has also evolved over recent decades and has contributed to the reduction in the number of cardiac deaths (16). The impact of the evolution of both devices and pharmacotherapy, especially among patients with diabetes undergoing PCI over the last 3 decades, remains a matter of interest. Our study explored the use of pharmacotherapy at discharge to show that recommended medications such as aspirin, ACE inhibitors, β-blockers, lipid-lowering therapy, and antiplatelet therapy is considerably higher in the BMS and DES groups and may have played an important role in the observed favorable outcomes in these groups.

Study limitations

For the purposes of this analysis, only those variables available in both the registries were considered. Compared with the PTCA Registry, ascertainment of data in the Dynamic Registry was revised to incorporate information related to the prevailing concerns in the field. Specifically, data regarding the treatment of diabetes and presence of renal disease or biochemical parameters of renal function were unavailable in the PTCA Registry, thus limiting our ability to account for differences in these parameters. Information on duration of diabetes, extent of glucose controls, or specific dosages of discharge pharmacotherapy was also not available. The registries did not specify, a priori, estimates of detectable effect sizes for individual devices used or subgroup analyses. Nonetheless, post hoc power calculations based on the observed late event rates showed an 80% power (two-sided type I error rate of 0.05 and 5% lost to follow-up) to detect modest-to-large effect sizes of 0.46 and 0.63 for death/MI and repeat revascularization, respectively, with DES use compared with BA use. Finally, as with all observational studies, there may be residual confounding not fully accounted for in the standard multivariable analyses.

In conclusion, our report from the large, prospective, multicenter, NHLBI-sponsored 1985–1986 PTCA (BA era) and 1997–2006 Dynamic Registry (BMS and DES era) documents the rapid evolution in PCI treatment options for patients with diabetes. Contemporary devices of PCI were used more often in patients with severe comorbidities and multivessel disease and were associated with improved discharge use of recommended cardiac medications. In patients with diabetes un-

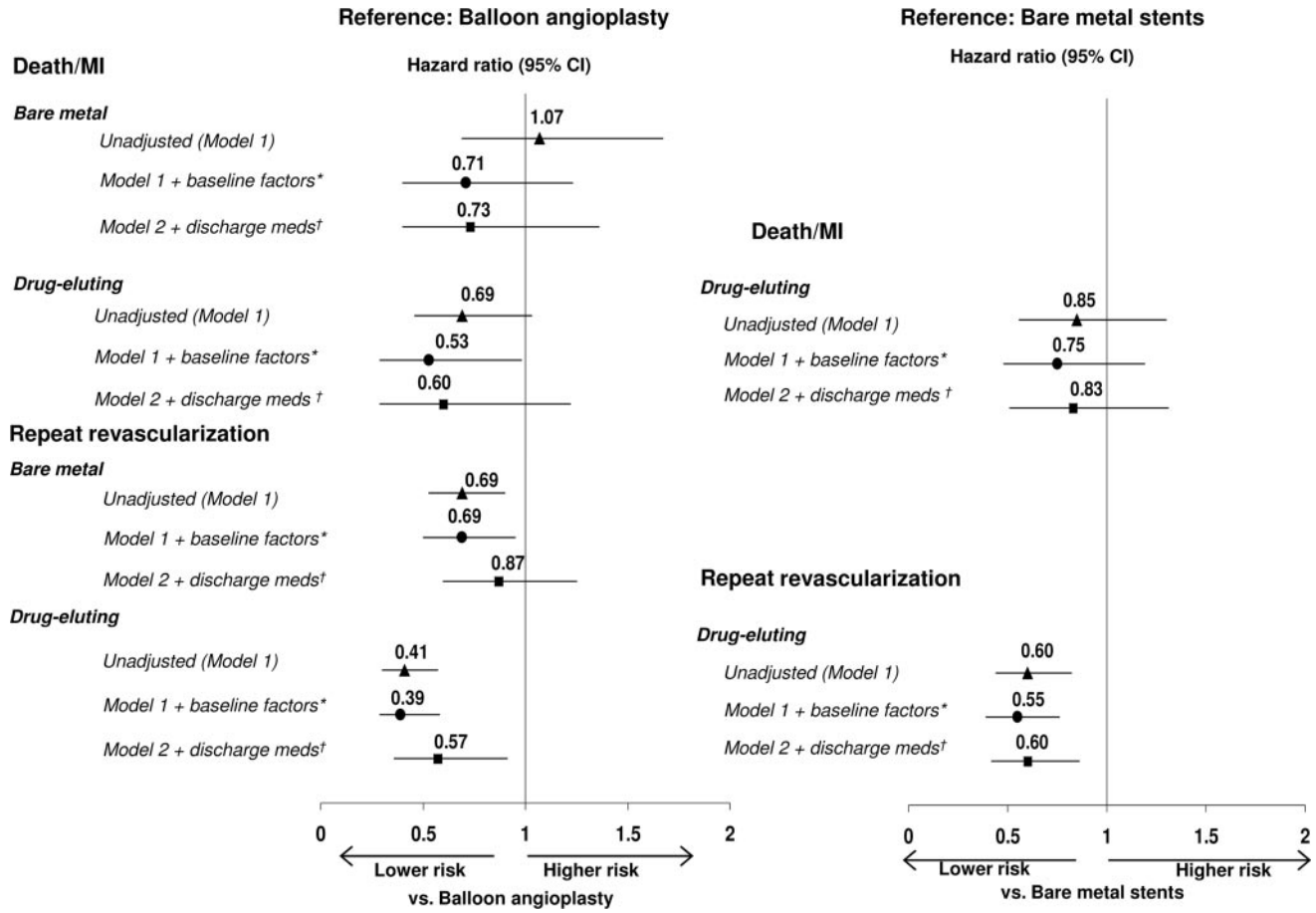

Figure 3—*Univariate and adjusted HRs (95% CI) for "late" (31–365 days) outcomes after percutaneous intervention by device type. *Adjusted for age, BMI, prior CABG, prior MI, history of hypertension, history of hypercholesterolemia, cardiogenic shock, severe noncardiac disease, vessel disease (single/double/triple), mean number of significant lesions, circumstances of index PCI, primary reason for index PCI (stable angina, unstable angina/acute MI asymptomatic CAD/others) and †discharge use of aspirin, β-blockers, lipid-lowering medications, ACE inhibitors, or angiotensin receptor blockers; thienopyridines were included only in models comparing BMS and DES.*

dergoing PCI, the use of DES is associated with a reduced need for repeat revascularization when compared with angioplasty or BMS use. The associated death/MI benefit observed with th eDES versus the BA group may well be due to greater use of pharmacotherapy.

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