Determinants of Bare-Metal Stent Use in Patients With ST-Elevation Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention

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ABSTRACT: Bare-metal stent (BMS) use in patients with ST-elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI) has been associated with higher rates of adverse cardiac events, including target lesion and target vessel revascularization. The purpose of the present study was to determine which clinical characteristics predict BMS use in patients with STEMI undergoing primary PCI. Data were prospectively collected from all patients who underwent primary PCI for STEMI between January 1, 2004 and December 31, 2007 at four New York State academic medical centers. Demographics, baseline medical history, procedural characteristics, and in-hospital outcomes were compared in patients receiving DESs versus BMSs. Of the 1394 patients studied, a total of 290 (20.8%) patients received a BMS while 1104 (79.2%) received a DES. Patients receiving a BMS were more likely to have higher rates of primary coronary artery bypass graft surgery, prior PCI, peripheral vascular disease, and diabetes mellitus, and were more likely to be Hispanic and uninsured. They were also more likely to present with stent thrombosis and worse left ventricular ejection fraction (LVEF). Patients receiving a BMS had significantly longer hospital length of stay and a trend toward higher all-cause in-hospital mortality. In multivariable analysis, independent predictors of BMS use included uninsured status (versus private insurance) (odds ratio [OR], 2.81; 95% confidence interval [CI], 1.70-4.67), peripheral vascular disease (OR, 1.96; 95% CI, 1.08-3.56), and LVEF (OR, 0.98; 95% CI, 0.97-0.99). In conclusion, in this analysis of a contemporary cohort of patients undergoing primary PCI, lack of health insurance, peripheral vascular disease, and diabetes mellitus were independent predictors associated with higher rates of BMS implantation in patients with STEMI undergoing primary PCI.

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Although primary percutaneous coronary intervention (PCI) is the preferred reperfusion strategy for patients presenting with ST-elevation myocardial infarction (STEMI), the choice of optimal stent type in this setting remains controversial. Drug-eluting stents (DESs) have been associated with reduced neointimal hyperplasia, decreased risk of restenosis, and lower target vessel revascularization (TVR) rates compared with bare-metal stents (BMSs). However, despite these advantages, DESs are not universally implanted in STEMI patients by operators for a variety of different reasons, most of which encircle the patient’s candidacy for prolonged dual-antiplatelet therapy (DAPT) with aspirin and a thienopyridine.

The aim of the present analysis was to identify demographic and clinical determinants of BMS use in patients with STEMI undergoing primary PCI.

Methods

Data were prospectively collected from all patients who underwent PCI in the setting of an acute STEMI between January 1, 2004 and December 31, 2007 at four New York State academic medical centers that participate in the New York State Percutaneous Coronary Interventions Reporting System (PCIRS) and are high-volume centers that perform primary PCI. The four centers involved in this study were Stony Brook University Medical Center, Winthrop University Hospital, New York Methodist Hospital, and The Heart Center, St Francis Hospital. Data elements in the registry include patient demographic information, insurance status, baseline clinical, angiographic and procedural characteristics, as well as in-hospital outcomes. To protect the anonymity of patients, all data were stripped of 20 potential identifiers by each individual center and submitted to a central databank for analysis. The Institutional Review Boards of each participating institution approved the study.

Stent type (BMS or DES) served as the primary predictor in this study. From the study population, a total of 1649 patients with STEMI who underwent primary PCI were identified. Two hundred fifty patients were excluded because they were treated with either a combination of DES and BMS or underwent only balloon angioplasty. Of the remaining 1349 patients, demographic and medical history were extracted and included age, gender, race, ethnicity, ejection fraction, prior coronary artery bypass graft (CABG) surgery, prior PCI, prior myocardial...
infarction (defined as myocardial infarction occurring more than 72 hours prior to PCI), prior stroke or cerebrovascular accident, diabetes mellitus, peripheral vascular disease, chronic obstructive pulmonary disease, congestive heart failure, serum creatinine, left ventricular ejection fraction (LVEF), and stent thrombosis. Coronary arteries (and their respective branches) were grouped as left main, left anterior descending, left circumflex, right coronary artery, vein graft, and arterial graft. Clinical outcomes collected included in-hospital mortality and hospital length of stay.

Data were summarized by descriptive statistics. Univariable analyses were performed to compare characteristics of patients receiving DES versus BMS. Chi-squared test (or Fisher’s exact test, when applicable) was used to compare differences in categorical variables and student’s t-test was used for continuous variables. Multivariable logistic regression was utilized to evaluate independent clinical determinants of BMS placement in STEMI patients while controlling for demographic characteristics, medical history, clinical presentation, and procedural characteristics. Predictors for the logistic regression were selected based on statistical significance in the univariate analysis ($P < .1$) and included age, race, Hispanic ethnicity, LVEF, prior CABG, peripheral vascular disease, diabetes mellitus, congestive heart failure, and stent thrombosis. Prior PCI was found to be highly collinear with stent thrombosis and was not included in the model. SPSS version 17.0 (SPSS, Inc) was used for data analysis and a two-tailed $P$-value of .05 was regarded as statistically significant.

**Results**

Of the 1394 patients studied, a total of 290 patients (20.8%) received a BMS while 1104 (79.2%) received a DES. Patient demographic and clinical characteristics are summarized in Table 1. Patients receiving a BMS had higher rates of prior surgical and percutaneous coronary artery revascularization, peripheral vascular disease, and diabetes mellitus, and were more likely to be of Hispanic background and uninsured. These patients also had higher rates of stent thrombosis on presentation with worse LVEFs. Angiographic characteristics are shown in Table 2. Patients receiving a BMS had more interventions involving the left main and the right coronary arteries. They also had a trend toward more saphenous vein graft interventions than their DES counterparts. With respect to in-hospital outcomes, patients receiving a BMS had significantly longer hospital length of stay (5.7 days vs 4.9 days; $P = .034$) and a trend toward higher all-cause in-hospital mortality (3.8% vs 2.0%; $P = .073$) (Figure 1).

In multivariate analysis, independent predictors of BMS use included uninsured status (versus private insurance) (odds ratio [OR], 2.81; 95% confidence interval [CI], 1.70-4.67), peripheral vascular disease (OR, 1.96; 95% CI, 1.08-3.56), and LVEF (OR, 0.98; 95% CI, 0.97-0.99; every 1% increase in LVEF was associated with...
a 2% reduction in BMS use; Figure 2). Age, race, Hispanic ethnicity, prior CABG, diabetes mellitus, congestive heart failure, and stent thrombosis were not independent predictors of BMS use.

Discussion
The findings of this large observational study, reflecting a sample of patients taken from a state administrative database who were treated with primary PCI for STEMI, showed that DESs were used more frequently than BMSs. However, BMSs were used more frequently than DESs in patients with certain clinical high-risk features, such as peripheral vascular disease, lack of health insurance, and patients with reduced ejection fraction. Other high-risk features such as age, prior CABG, diabetes mellitus, congestive heart failure, or stent thrombosis were not associated with an increased use of BMS in STEMI patients.

Although growing evidence has supported the use of primary PCI as the preferred reperfusion strategy for patients presenting with STEMI, some controversy still exists regarding the choice of stent type in this emergent setting. While DESs have demonstrated lower restenosis rates and target vessel revascularization in comparison to BMSs, stent thrombosis and its substantial mortality risk in patients receiving a DES is still a major concern.

Reduced mortality rates with DES use in primary PCI have been documented in state registries. The Massachusetts registry additionally documented reduced target vessel revascularization rates at 2 years with DESs in the setting of STEMI. These registry findings, however, were limited by stent selection bias and longer duration of clopidogrel therapy. The HORIZONS-AMI trial, which randomized nearly 3000 patients to either DES or BMS, demonstrated no significant difference in the composite safety endpoint of death, myocardial infarction, or stent thrombosis, but target vessel revascularization rates were decreased with DES use. These analyses had their limitations, which included a small sample size, variations in stent type, inclusion criteria, outcome definitions, and duration of follow-up and clopidogrel therapy. The HORIZONS-AMI trial, which randomized nearly 3000 patients to either DES or BMS, demonstrated no significant difference in the composite safety endpoint of death, reinfarction, stroke, or stent thrombosis at 12 months. Furthermore, the rates of ischemia-driven target vessel revascularization, target lesion revascularization, and restenosis, though, were significantly lower in the DES group (5.8% vs 8.7%, 4.5% vs 7.5%, and 10.0% vs 22.9%, respectively).

Despite being associated with reduced target vessel revascularization rates and no increase in mortality or stent thrombosis, DESs are not universally implanted in STEMI patients undergoing primary PCI. DESs are still used more frequently in younger patients with diabetes, more complex angiographic characteristics, and smaller vessels, whereas BMS use is reportedly higher in STEMI patients presenting with cardiogenic shock. Operators choose to implant BMSs in STEMI patients for different reasons, primarily encompassing the ability of the patient to obtain, comply with, and endure dual antiplatelet therapy for the appropriate time period. Since determination of a patient’s suitability and compliance for prolonged dual antiplatelet therapy must be done in a short period of time, demographic and clinical characteristics of the STEMI patient are quickly perused to make the best choice. In our study, we found that uninsured patients were nearly three times more likely to receive a BMS, while patients with peripheral vascular disease were almost two times more likely to receive a BMS. Peripheral vascular disease has been associated with higher rates of vascular and bleeding complications following PCI. In this regard, health insurance status and peripheral vascular disease are probably used by the interventionalist as surrogates of the patient’s ability to obtain and endure prolonged dual antiplatelet therapy, respectively. While patients receiving a BMS in this study were more likely to have other high-risk profiles, such as diabetes mellitus, prior CABG, and left main lesions, these factors were not independently predictive of stent type.
**Study limitations.** The database utilized for the present analysis was derived from only four New York State teaching hospitals that provide data to the New York State PCIRS, which was designed to track quality of care and clinical outcomes and was not prospectively designed to assess the impact of stent type on outcomes. While the New York State Department of Health does perform periodic audits of data submitted to the PCIRS registry, it is unknown whether the data provided for the present analysis had been subjected to an audit. As in all studies involving multicenter databases and registries, there was no independent audit of data quality and precision. Other possible prognostic variables in this population, including presence of cardiogenic shock, major bleeding, and adherence to guideline-based medications, were not collected in this particular database. Only in-hospital outcomes are collected for this registry and the lack of intermediate and long-term follow-up may be a limitation to the analysis.

**Conclusion**

In conclusion, in this analysis of a contemporary cohort of patients undergoing primary PCI, lack of health insurance, peripheral vascular disease, and worse LVEF were independently associated with higher rates of BMS implantation in patients with STEMI undergoing primary PCI.

**References**