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Comparison of drug eluting stents (DESs) and bare metal stents (BMSs) with STEMI: who received BMS in the era of 2nd generation DES?

Rajkumar Doshi, MD MPH [a,*], Jay Shah, MD [b], Varun Jauhar [a], Dean Decter, BS [a], Rajiv Jauhar, MD FACC FSCAI [a], Perwaiz Meraj, MD FACC FSCAI [a]

[a] Department of Cardiology, North Shore University Hospital, Northwell Health, Manhasset, New York
[b] Department of Internal Medicine, Mercy Saint Vincent Hospital, University of Toledo, Toledo, OH

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ABSTRACT

Background: The aim of this study was to analyze the indications for using bare metal stents (BMSs) in hospitalizations with ST segment elevation myocardial infarction (STEMI) undergoing percutaneous coronary intervention (PCI).
Methods: The study cohorts were identified from the National Inpatient Sample database from 2010–2014 using appropriate, *International Classification of Diseases, 9th Revision, Clinical Modification,*, diagnostic and procedural codes.
Results: A total of 123,487 hospitalizations were identified for this study. Drug eluting stent (DES) use demonstrated lower in-hospital mortality (5.8% vs. 3.3%, P = < 0.01) and other in-hospital outcomes, thus resulting in lower hospitalization stay. Higher age, black race, greater comorbidity burden, inferior wall myocardial infarction, and the use of mechanical circulatory devices were all associated with BMS use.
Conclusion: DES was the preferred standard of care in the era of 2nd generation DES; however, BMSs were used in hospitalizations with high-risk procedures and multiple risk factors.

Introduction

Previous studies have indicated that drug eluting stents (DESs) are associated with better outcomes than bare metal stents (BMSs); however, a debate exists among physicians when selecting the optimal stent for certain high-risk patients.[1–3] The early successes of 1st generation DESs over BMSs have been curtailed by frequently encountered long term adverse events, which often result in hypersensitivity reactions associated with the polymer coating or delayed stent endothelialization.[4] The usage of BMSs has continuously declined following the initial approval of 2nd generation DESs.[1] With more research focused on advancing DES device technology, studies have demonstrated that these newer 2nd generation DESs may yield better outcomes than their 1st generation antecedents.[5,6] Furthermore, two randomized clinical trials indicated the safety, efficacy, and superiority of 2nd generation DESs when compared to BMS.[7,8] However, both studies were limited by comparatively low cohort sizes and the exclusion of high-risk patients. There are only a few studies, composed of "real-world" cohorts, which compare the outcomes of DESs and BMSs.[9]

As the frequency of DES implantation has increased significantly in the last decade, the indications for BMSs have become nearly obsolete.[1] One of the most common reasons to choose DESs over BMSs is the patient's ability to take double antiplatelet therapy (DAPT).[10] Current guidelines suggest 3–6 months of DAPT following implantation of a 2nd generation DES but only 1 month of DAPT after BMS implantation.[11,12] Although DESs yield less repeat revascularization and in-stent thrombosis when compared to BMS,[13] there still remains compelling evidence in favor of BMSs in limited patient populations. Furthermore, previous studies have demonstrated disparities among stent type based on race, occupation, and primary payment method.[14–17] There are relatively few studies indicating the use of BMSs in "real-world" cohorts in the era of 2nd generation DES.

The goal of this nationally representative study was to compare the efficacy of BMSs versus DESs in ST segment elevation myocardial infarction (STEMI) hospitalizations undergoing percutaneous coronary intervention (PCI). All STEMI hospitalizations without "any" exclusion criteria were included. Finally, a variety of variables were analyzed, which predicted the use of BMS in the era of 2nd generation DES.

Conflicts of interests: None.
* Corresponding author. Fax: 516-562-2087.
E-mail address: raj20490@gmail.com (R. Doshi).

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Material and methods

Data source

We performed a retrospective, observational study using the Health Care Cost and Utilization Project (HCUP)'s Nationwide Inpatient Sample (NIS) database, which is sponsored by the agency for healthcare research and quality.[18] The NIS is the largest, publicly available, all-payer database of hospitalizations in the United States (US). Design of this database has been previously explained.[19] The NIS is a 20% stratified sample and can be converted, using discharge weights, to nationally representable observations. Forty-four states participate in this database, which includes over 1000 hospitals and represents more than 95% of the US general population. Each individual hospitalization is de-identified in this study and were deemed exempted by the institutional review board.

Study design and population

The study cohorts were derived from HCUP-NIS years 2010–2014. *International Classification of Diseases, Ninth Edition, Clinical Modification* (ICD 9 CM) diagnoses codes 410.0, 410.1, 410.2, 410.3, 410.4, 410.5, 410.6, 410.8, and 410.9 were used to identify all admissions diagnosed with STEMI. Hospitalizations were then identified based on those who underwent percutaneous coronary intervention (PCI) procedures and were treated with DESs (*ICD 9 CM Procedure code 36.07*) or BMS (*ICD 9 CM Procedure code 36.06*). All hospitalizations below eighteen years of age or with missing observations in age, gender, or in-hospital mortality were excluded. Additionally, cohorts treated with DESs and BMSs in the same admission were excluded. A total of 123,487 (*Unweighted*) procedures with either drug-eluting or BMSs were included in the final analysis (Supplementary Figure 1).

Hospitalization characteristics

Age, gender, race, primary payer, and admission type were extracted directly from the NIS database. Comorbidities like smoking, prior myocardial infarction (MI), family history of coronary artery disease (CAD), and other Elixhauser comorbidities were included. ICD 9 Codes are given in the Supplementary Table S1. The Elixhauser comorbidities were previously used in the NIS database.[20] The severity of comorbidities was defined using the Charlson/Deyo's comorbidity index (CCI),[21] which contains seventeen comorbid conditions with different weights. CCI scores range between 0–33; a higher score indicates a greater burden of comorbidities. (Supplementary Table S2). Procedural characteristics were identified using appropriate ICD 9 CM procedural codes (Supplementary Table S1).

In-hospital outcomes

In-hospital mortality, length of hospitalization Stay (LOS), and dispositional variables were used directly from the NIS database. Other in-hospital outcomes, including: acute renal failure (ARF), cardiac arrest, acute pulmonary edema, blood transfusion, iatrogenic cardiac complications, pericardial complications, vascular injuries requiring surgery, perioperative stroke, postoperative shock, and perioperative infections were identified using appropriate ICD 9 CM diagnosis or procedural codes (Supplementary Table S1). Therefore, secondary diagnostic and procedural codes were used; whereas, primary diagnostic and procedural codes were excluded. In-hospital mortality was the primary outcome of this study.

Statistical analysis

SAS 9.4 (SAS Institute Inc. Cary, North Carolina) was used for statistical analysis. To obtain national estimates, weighted observations were obtained by applying discharge weights to the hospital discharge data.[22] Continuous data was analyzed using the T-test and expressed as mean ± standard deviation. Categorical data was analyzed using a Chi-Square test and expressed as frequencies in percentage. A P-value of less than 0.05 was considered significant.

Propensity score matched analysis

A propensity score matched model was developed using a logistical regression model in line with a non-parsimonious approach. Age, gender, primary payment method, admission type, all comorbidities, procedural details, and lesion site were included in the model. Race (9.3% missing) and CCI (Variable included as individual co-variate) were not included in this model. A propensity score was assigned to each hospitalization using a unique identification number given by NIS. Finally, hospitalizations with similar propensity scores were matched using a nearest neighbor matching algorithm with a 1:1 model without replacement (Caliper width 0.1). In-hospital outcomes were calculated in this matched cohort using McNemar's Test or Paired T Test as required. This method has been used previously.[23]

Multivariate logistic regression model

To estimate predictors of either type of stent use, a multivariate logistical regression model was created. The variables included were age, gender, race, primary payment method, median household income, hospital type, hospital bed size, CCI, single/multiple vessel disease, bifurcation, anterior/inferior myocardial infarction, atherectomy use, and use of mechanical circulatory support (MCS) (composite of intra-aortic balloon pump (IABP), percutaneous Left ventricular assist device (pLVAD), and extra corporeal membranous oxygenation (ECMO) use).

Results

Comparison of DES and BMS before matching

Between January 2010 and December 2014, a total of 125,464 procedures were performed for STEMI. After the exclusion of missing variables, 123,487 hospitalizations were included in the final analysis. The mean age of this study cohort was 61.7 years, and hospitalizations treated with BMSs were older compared to those treated with DESs (62.2 vs. 61.2 years, $p = < 0.01$). The study population included predominantly white (77.9%) males (71.3%), whose predominant primary payment method was Medicare/Medicaid (48.1%) for both groups. Moreover, hospitalizations with private insurance were treated with DESs more often than BMSs (29.7% vs 42.2 %, $p = < 0.01$). Baseline differences existed between the groups. Hospitalizations implanted with DESs presented with more hypertension, diabetes mellitus, obesity, and family history of CAD. On the contrary, those implanted with a BMS presented with more heart failure, chronic pulmonary disease, renal failure, neurological disorders, coagulation disorders, liver disease, pulmonary circulation disorders, valvular diseases, and smoking. Patients treated with BMSs had a significant baseline burden of comorbidities with a CCI score of ≥3 (24.7% vs. 19.6%, $p = < 0.01$). When comparing procedural characteristics, greater atherectomy use (2.5% vs. 2.7%, $p = 0.02$), IVUS use (3.9% vs. 4.8%, $p = < 0.01$), and FFR use (0.4% vs 0.6%, $p = < 0.01$) was noted when using DESs; whereas, IABP use was more common (9.9% vs.6.2%, $p < 0.01$) when using BMS. Furthermore, when treating