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Original Article

One-year cardiovascular outcomes of drug-eluting stent versus bare-metal stent implanted in diabetic patients with acute coronary syndrome

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Abstract

Background: The outcomes of drug-eluting stent (DES) versus bare-metal stent (BMS) use in patients with diabetic mellitus (DM) and acute coronary syndrome (ACS) are rarely reported in Taiwan. This study aimed to investigate the 1-year cardiovascular outcomes of DESs versus BMSs implanted in Taiwanese patients with DM and ACS.

Methods: For this study, we collected and analyzed patient information from the database of the Taiwan ACS Full Spectrum registry regarding characteristics and cardiovascular events in participants with DM and ACS who received implantation of either BMS (BMS group) or DES (DES group) from October 2008 to January 2010.

Results: We found that several characteristics significantly varied between the groups. Compared with the BMS group ($n = 575$), the DES group ($n = 199$) had significantly lower rates of in-hospital cardiogenic shock (1.5% vs. 4.9%, $p = 0.037$) and acute renal failure (0.5% vs. 4.5%, $p = 0.008$), all-cause mortality (5.0% vs. 8.9%, $p = 0.048$), and major adverse cardiac events (MACEs) at 1 year (11.1% vs. 18.6%, $p = 0.006$) with an identical target vessel revascularization (TVR) rate (6.0% vs. 7.3%, $p = 0.395$). The BMS group had significantly higher risk-adjusted all-cause mortality [hazard ratio (HR) = 2.4, 95% confidence interval (CI) 1.0–5.7; $p = 0.048$] and MACE (HR = 2.2, 95% CI 1.2–3.9; $p = 0.011$) at 1 year with identical risks of TVR (HR = 1.3, 95% CI 0.6–2.9; $p = 0.505$) and nonfatal myocardial infarction (HR = 1.5, 95% CI 0.5–4.4; $p = 0.478$).

Conclusion: The results of this study support the use of DES over BMS in Taiwanese patients with DM and ACS, providing the clinical benefits of lower rates of total mortality and MACE, and without increased TVR at 1 year in a real-world setting.

Keywords: acute coronary syndrome; bare-metal stent; diabetes mellitus; drug-eluting stent; outcome; percutaneous coronary intervention

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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1. Introduction

Acute coronary syndrome (ACS) is generally caused by acute atherothrombosis, and it characteristically presents with ST-segment elevation myocardial infarction (STEMI), non-STEMI (NSTEMI), or unstable angina (UA). Both ACS and diabetes mellitus (DM) are powerful independent predictors for adverse cardiovascular events such as target lesion revascularization, target vessel revascularization (TVR), major adverse cardiac events (MACEs), or mortality after percutaneous coronary intervention (PCI).[1–9] Studies including randomized controlled trials (RCTs),[10,11] observational trials,[3,8,9,12–21] and meta-analysis trials[22–24] have well-established that use of drug-eluting stents (DESs) is safe and effective in patients with acute myocardial infarction (AMI)[3,12,13] or in patients with DM,[12–21] as compared with use of bare-metal stents (BMSs). Placement of DES primarily benefits patients with lower repeat revascularization, but inconsistent results have been observed concerning mortality, myocardial infarction (MI), or MACE.[3,8–24] Studies comparing the impact of implantation of DES versus BMS on cardiovascular outcomes in patients with both DM and ACS are very rare,[12,13] especially those in Taiwan, although DES has been popularly used in Taiwan. This study was therefore designed to analyze real-world data involving Taiwanese patients with DM and ACS who received either BMS or DES implantation. Patient data were collected from the database of the Taiwan ACS Full Spectrum (ACS FS) registry, which was a multicenter, prospective, and observational registry study performed to evaluate real practices in ACS management.[25–27] This study aimed to describe patterns of use of BMS and DES for Taiwanese patients with DM and ACS, and to investigate the 1-year clinical outcome between the BMS and DES groups in a real-world setting.

2. Methods

2.1. Study design

The Taiwan ACS FS registry study was performed in accordance with guidelines set forth in the Declaration of Helsinki and local regulatory guidelines. The Medical Ethics Committee (Joint Institutional Review Board Number: 08-070-A) approved the study protocol at each participating site, and written informed consent was obtained from all participants. The study protocol was reviewed and allowed by the Publication Committee of the Taiwan ACS FS registry. In addition, the authors were authorized to collect the relevant data from the database of the registry and report the analysis. This study was designed to analyze the data involving participants with DM and ACS undergoing either DES or BMS implantations and to compare 1-year clinical outcomes between the DES and BMS groups. The registry study was a multicenter, prospective, nonrandomized, observational study with an intention to recruit over 3000 ACS participants and evaluate real practices in ACS management. The names of the principal investigators who participated in the registry study are listed in Appendix 1.

2.2. Study population

Participants were recruited from 39 participating sites, which were distributed throughout the country and selected by the Scientific Committee of the Taiwan Society of Cardiology according to the annual volume of PCI performed. Approximately 50–200 consecutive ACS patients were recruited as eligible patients in each participating site. Eligible patients were aged 20 years or older, were hospitalized within 24 hours after the onset of ACS symptoms, or transferred in from a nonparticipating site with less than a 12-hour stay. Diabetic participants were confirmed clinically according to the guidelines and treated by diet control alone, oral hypoglycemic agents, insulin, or a combination of these. Participants with DM and ACS implanted with either DES alone or BMS alone were categorized as the DES group and the BMS group, respectively. Any type of BMS or DES available in the domestic health care system was allowed at the interventionists' discretion. One or more stents implanted were also permitted in the index PCIs. The classes of DES used in the study included sirolimus-, paclitaxel- (PES), zotarolimus-, and everolimus-eluting stent during the registry period. Excluded patients were those who presented with ACS secondary to comorbidity such as trauma or bleeding, or participated in an investigational drug study. Patients who were not diagnosed with DM, did not undergo coronary stenting, or received hybrid stenting with both BMS and DES were also excluded. Physicians independently determined the treatment strategies and made all clinical decisions. Thereafter, all participants were followed at scheduled 3 months, 6 months, 9 months, and 12 months after discharge. Participant data with respect to characteristics, clinical presentations, index PCI procedures, medication prescriptions, and relevant adverse events between groups were gathered from the case record forms. Medication prescriptions of aspirin, clopidogrel, dual antiplatelet therapy (DAPT) with aspirin plus clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and statins were also compared during the 1-year follow-up between groups.

2.3. In-hospital and 1-year events

The in-hospital and 1-year relevant adverse events were compared between the stent groups. Cardiovascular end points at 1 year including mortality, nonfatal MI, nonfatal hemorrhagic or ischemic stroke, ischemia-driven TVR, and composites of cardiovascular events such as MACE (defined as a composite of total mortality, nonfatal MI, and TVR) were primarily observed. In-hospital adverse events included mortality, nonfatal MI, unplanned revascularization, nonfatal hemorrhagic or ischemic stroke, cardiogenic shock, ventricular arrhythmia, and acute renal failure. A study end point was clinically confirmed by investigators at study sites and headquarters according to the symptoms, electrocardiographic findings, cardiac enzymes, and/or images. Acute renal failure was defined as a rise (>0.5 μg/dL) in serum creatinine level beyond the baseline value.[28]