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Comparison of very long-term clinical and angiographic outcomes of bare metal stent implants between patients with and without type 2 diabetes

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ABSTRACT

Background: Data on a large patient population regarding very long-term outcomes after bare metal stent (BMS) implantation in diabetic patients are lacking. The aim of this study was to evaluate the very long-term (8–17 years) clinical and 6-month angiographic outcomes of BMS implantations in patients with and without type 2 diabetes.

Methods and results: A total of 2391 patients (579 with and 1812 without diabetes) who received BMS implantations between November 1995 and May 2004 were enrolled from the Cardiovascular Atherosclerosis and Percutaneous TrAnsluminal INterventions (CAPTAIN) registry into this study. During a mean follow-up period of 152 ± 53 months, the diabetic patients had higher rates of all-cause mortality (28% vs. 15%, $p < 0.001$), re-infarction (6% vs. 5%, $p = 0.284$), target lesion revascularization (13% vs. 10%, $p = 0.049$), and a lower cardiovascular event-free survival rate (42% vs. 56%, $p < 0.001$) compared to the patients without diabetes. The diabetic patients also had a higher restenosis rate (26% vs. 18%, $p < 0.001$) at 6-month angiographic follow-up. The multivariate analysis of risk factors for cardiac event-free survival included age (hazard ratio [HR]: 1.011; $p = 0.001$), hypertension (HR: 1.168; $p = 0.011$), diabetes mellitus (HR: 1.353; $p < 0.001$), pre-existing coronary artery disease (HR: 1.341; $p < 0.001$), and left ventricular ejection fraction (LVEF) (HR: 0.992; $p = 0.002$) (Table 7). The Kaplan–Meier analysis showed a significant difference in cardiovascular event-free survival rate between the two groups ($p < 0.001$).

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Conclusion: The clinical and angiographic outcomes of diabetic patients with BMS implantations were worse than those of patients without diabetes after a very long-term follow-up period.

1. Introduction

The association between diabetes mellitus and coronary artery disease (CAD) is well known. In addition, diabetic patients have a high risk of cardiovascular morbidity, mortality and congestive heart failure [1]. Diabetic patients also have higher rates of major adverse cardiac events (MACEs) and target vessel revascularization than patients without diabetes [2]. Although surgical interventions are recommended for diabetic patients with multi-vessel CAD, recent advancements in interventional devices and techniques have expanded the scope of coronary artery revascularization [3–5].

Intracoronary stenting has improved the outcomes of CAD patients receiving percutaneous coronary interventions (PCIs). Currently, the procedural success rate of elective PCI is similar in patients with and without diabetes [4,5]. However, patients with diabetes have a higher rate of restenosis and lower rate of event-free survival than patients without diabetes in short-term clinical outcomes, whether undergoing bare-metal stent (BMS) or drug-eluting stent (DES) deployment [6–8]. Still a few decades ago, many diabetic patients with CAD could only receive BMS implantations. Although DESs are used much more recently, some BMSs are still used in certain lesions (i.e. large vessel and simple lesion) and in patients who cannot tolerate longer duration of dual antiplatelet therapy. However, very long-term follow-up data of patients with and without diabetes who undergo BMS implantation are lacking. Therefore, in this study we compared the very long-term (8–17 years) clinical outcomes and 6-month angiographic outcomes after BMS implantations between patients with and without diabetes.

2. Methods

2.1. Study population

The Cardiovascular Atherosclerosis and Percutaneous TrAnsluminal INterventions (CAPTAIN) registry is a prospective, physician-based, single-center observational database that includes the data of 7300 patients who received elective or emergency PCI at our institute between November 1995 and October 2015. This study enrolled 2391 patients, including 579 with diabetes and 1812 without diabetes from November 1995 to May 2004. We have obtained ethical approval of this study from the Institutional Review Board of Chang Gung Medical Foundation. All the patients had provided informed consent to undergo the procedure and follow-up protocol. In this manuscript, all the participants has given written informed consent to publish these case detail. The inclusion criteria was patients with ≥50% stenosis in a native coronary artery and evidence of myocardial ischemia that was suitable for stenting. The exclusion criteria were severe multi-vessel disease requiring bypass surgery, contraindication for the use of aspirin or ticlopidine/clopidogrel, and patients who refused to undergo the procedure. Definition of diabetes mellitus was based partially on previous medical records/medications and partially HbA1c ≥6.5%.

2.2. Stent procedure

The standard procedure through the radial artery or the femoral artery was used for all stent implantations [9]. After stent deployment, we used high-pressure balloon inflation to achieve adequate stent expansion. All patients were followed at our outpatient clinic. Repeat coronary angiography was arranged 6 months later or if recurrent myocardial ischemia was suspected. Dual antiplatelet therapy was prescribed for at least 6 months and changed to single agent according to patient's clinical condition.

2.3. Angiographic analysis

We used a contrast-filled guiding catheter as a reference for calibration, and quantitative angiographic analysis was conducted with selected end-diastolic cine frames. They were measured by two experienced angiographers randomly and blindly. The inter-observer correlation coefficient (r) was 0.93 ($p < 0.01$), and the intra-observer correlation coefficient was 0.95 ($p < 0.01$). We used automated edge detection or a digital caliber for all measurements of reference vessel diameter (RVD), minimal luminal diameter (MLD) before stenting, after stenting, and at 6-months follow-up angiography. Restenosis was defined as a diameter stenosis ≥50% during follow-up angiography. We had defined acute gain as the difference between the baseline and final MLD, and defined late loss as the difference between the final post-stenting and follow-up MLD. Net gain was defined as the difference between acute gain and late loss, and the loss index was defined as the ratio of late loss to acute gain. LVEF was measured from left ventricular angiograms at 30° right anterior oblique projections.

Besides, we defined stent thrombosis according to classification of Academic Research Consortium (ARC). Based on elapsed time since stent implantation, stent thrombosis can be classified as: early (0–30 days post-stent implantation), late (1–12 months) and very late (>12 months). Early stent thrombosis is further subdivided into acute (<24 h) and subacute (1–30 days) events.

2.4. Definitions

We defined an in-hospital MACE as death, ST-elevation or non-ST-elevation myocardial infarction (STEMI or NSTEMI, respectively), need for an emergent bypass surgery, and vas-

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