Clinical outcomes between different stent designs with the same polymer and drug: comparison between the Taxus Express and Taxus Liberte stents

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Background/Aims: The Taxus Liberte stent (Boston Scientific Co.) evolved from the Taxus Express stent, with enhanced stent deliverability and uniform drug delivery. This study was designed to compare angiographic and clinical outcomes in real-world practice between the Taxus Liberte and Taxus Express stents.

Methods: Between 2006 and 2008, 240 patients receiving the Taxus Liberte stent at three centers were registered and compared to historical control patients who had received the Taxus Express stent (n = 272). After propensity score matching, 173 patients treated with the Taxus Liberte stent and the same number of patients treated with the Taxus Express stent were selected. The primary outcome was a composite of major adverse cardiac events (MACE), including cardiac death, myocardial infarction (MI), ischemia driven target vessel revascularization (TVR), and stent thrombosis (ST) at 1 year. An additional angiographic assessment was conducted at 9 to 12 months.

Results: The study showed no significant difference between the Taxus Express and Taxus Liberte stents (death, 1.73% vs. 2.31%, p = 1.000; MI, 0% vs. 1.73%, p = 0.2478; TVR, 2.31% vs. 1.16%, p = 0.6848; and ST, 0% vs. 1.16%, p = 0.4986). The total MACE rate at 1 year did not differ between the groups (4.05% in Taxus Express vs. 4.05% in Taxus Liberte, p = 1.000). In addition, the binary restenosis rate did not differ (2.25% in Taxus Express vs. 1.80% in Taxus Liberte, p = 0.6848).

Conclusions: In real-world experience with the two Taxus stent designs, both stents showed similarly good clinical and angiographic outcomes at 1 year. A long-term follow-up study is warranted.

Keywords: Angioplasty; Drug-eluting stents; Polymers
INTRODUCTION

Drug-eluting stents have shown great efficacy in the reduction of restenosis as compared with bare-metal stent (BMS) by suppressing neointimal growth [1-5]. The second-generation Taxus Liberte stent (paclitaxel-eluting stent, Boston Scientific Co., Natick, MA, USA) evolved from the Taxus Express stent in order to enhance stent deliverability and uniform drug delivery.

However, there is little comparative data from real-world daily clinical practice with these stents. The aim of this study was to compare angiographic and clinical outcomes between the new Taxus Liberte stent and the old Taxus Express stent in real-world clinical practice.

METHODS

Device description
The Taxus Liberte-SR stent consists of a balloon-expandable Liberte stent with a polymer coating containing 1 μg/mm² of paclitaxel in a slow-release formulation. Drug dosing and release kinetics are identical to that of the Taxus Express-SR stent. Both stents are made from 316 L stainless steel, but the Liberte platform has a more uniform strut pattern and thinner struts (0.097 mm) than the Express platform (0.132 mm) [6].

Study population
From May 2006 to June 2008, 240 patients receiving the Taxus Liberte stent at three qualified centers in South Korea (Yeungnam University Medical Center, Keimyung University Dongsan Medical Center, Inje University Busan Paik Hospital, and Inje University Haeundae Paik Hospital) were registered and compared with Taxus Express historical control patients that were treated from January 2005 to April 2006 (n = 272). After performing propensity matching, we were able to successfully match 173 Taxus Express patients with 222 lesions to 173 Taxus Liberte patients with 222 lesions. Patients with a left main lesion and a bifurcation lesion requiring two stents in both the mother and side branch were excluded.

Procedures and medications
Percutaneous coronary intervention (PCI) was performed using standard techniques. All patients received aspirin 325 mg orally and a loading dose of 300 mg of clopidogrel before coronary angiography (CAG) or after PCI in emergency cases. After PCI, the patients were treated routinely with aspirin 100 mg/day, clopidogrel 75 mg/day, and/or cilostazol 200 mg/day at the operator’s discretion. The patients were advised to maintain life-long aspirin therapy. The duration of taking clopidogrel was at the operator’s discretion, which depended on the complexity of the lesion and procedure.

Quantitative coronary analysis
Intracoronary nitroglycerin (0.2 mg) was administered before and after each intervention to achieve maximal dilatation. Quantitative CAG was performed immediately before and after stenting by an experienced technician who was blinded to the type of stent deployed. Angiographic measurements included proximal and distal reference, minimum lumen diameter (MLD), percentage of lesion diameter stenosis, and lesion length. Acute gain was measured and defined as the difference between the MLD after stent deployment and baseline MLD. Late lumen loss was calculated as the difference in MLD immediately after the procedure and at angiographic follow-up. All measurements were performed for both the stented segment (in-stent) and 5-mm proximal and distal margins of the stented segment (in-segment). Quantitative coronary angiographic analysis was performed using the computer-assisted automated edge detection method (Centricity, Cardiology CA1000, GE Healthcare, Milwaukee, WI, USA) in the angiography analysis core laboratory at Yeungnam University Medical Center.

Study outcomes and definitions
The study outcome was a composite of major adverse cardiac events (MACE), including cardiac death, myocardial infarction (MI), ischemia-driven target vessel revascularization (TVR), and stent thrombosis (ST). MI was defined as a recurrent ischemic symptom and/or ECG change with creatine kinase-myocardial band fraction elevation up to twice the upper limit of normal. Ischemia-driven TVR was defined as emergency or elective CABG or repeat PCI in the target vessel for chest pain or a positive test for ischemia [7]. ST was