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Editorial

State-of-the-Art Stent Technology to Minimize the Risk of Stent Thrombosis and In-Stent Restenosis: Abluminal-Coated Biodegradable Polymer Drug-Eluting Stent

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▸ See the article "Osstem Cardiotec Centum Stent Versus Xience Alpine Stent for De Novo Coronary Artery Lesion: A Multicenter, Randomized, Parallel-Designed, Single Blind Test" in volume 52 on page 354.

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Since its introduction in 1977, various technological advances have been made in percutaneous coronary interventions (PCIs). Coronary stents, made of metallic scaffolds, have been developed to maintain luminal integrity and overcome the shortcomings of standalone balloon angioplasty with substantially improved procedural efficacy and safety. However, early bare-metal stents (BMSs) are greatly limited by a high restenosis rate of up to 50% and frequently require repeat revascularization due to neointimal hyperplasia.[1)]
To address this inherent limitation of BMS, drug-eluting stents (DESs) coated with anti-proliferative agents were developed and first introduced in 2003.[2)] Early generation DES using paclitaxel or sirolimus dramatically reduced the rate of in-stent restenosis compared to BMS[3)]; however, its long-term safety has been in question due to the increased incidence of late and very late stent thrombosis.[4)]

To overcome the limitations of early generation DES, intensive efforts on stent technology have been made over the last 2 decades, and new-generation DES has been developed to minimize the risk of in-stent restenosis and stent thrombosis. Contemporary new-generation DES represents multiple conceptual innovations in each structural component constituting the stent technology: 1) thinner metallic stent strut platform using cobalt-chromium or platinum-chromium, 2) new polymer coatings with improved biocompatibility, and 3) controlled release of new anti-proliferative drugs with greater lipophilicity.[2)5)6)] In particular, abluminal polymer coating technology allows for the effective delivery of anti-proliferative drugs to the vascular beds and reduces intraluminal thrombogenicity simply by removing the polymer on the luminal side.[7)8)] This has been correlated with greater biocompatibility, enhanced re-endothelialization, reduced thrombogenicity, and diminished chronic inflammatory response.

To test the superiority of the technological advances of new-generation DES, Yoon et al.[9)] reported a prospective, multi-center, parallel, single-blind, randomized study investigating the clinical efficacy and safety of Osstem Cardiotec Centum DES (Osstem Cardiotec Co., Seoul, Korea) compared to Xience Alpine DES, the contemporary new-generation DES of

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Data Sharing Statement

The data generated in this study is available from the corresponding author upon reasonable request.

Author Contributions

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the Xience family (Abbott Laboratories, Chicago, IL, USA). Osstem Cardiotec Centum is a cobalt-chromium everolimus-eluting stent with an abluminal-coated biodegradable polymer and a strut thickness of 85 μm consisting of an open 6-cell structure supported by peak-to-valley connectors. This unique stent strut design provides a lower metal-to-artery ratio, enhances both radial and longitudinal strength, and enables high flexibility and cross-ability. Collectively, these structural features are expected to improve overall stent performance and have a positive effect on the procedural success rate. Fifty-five patients in the Osstem Cardiotec Centum DES group and 58 patients in the Xience Alpine DES group were enrolled in this study. The primary efficacy endpoint was in-segment late lumen loss (LLL) as assessed by quantitative coronary angiography (QCA) at 9 months and the secondary endpoints were target lesion failure (TLF) at 9 months and clinical success rate. Angiographic findings at the 9-month follow-up showed similar minimal lumen diameter and diameter stenosis values in both groups. However, in-segment LLL of the Osstem Cardiotec Centum DES group was significantly lower compared to that of the Xience Alpine DES group (0.09±0.13 mm vs. 0.12±0.14 mm; p=0.034). In addition, the Osstem Cardiotec Centum DES demonstrated angiographic non-inferiority to Xience Alpine DES. The procedural success rate was excellent, reporting 100% in both groups, and only one TLF episode occurred in the Xience Alpine DES group.

In the present comparative study, the 9-month angiographic outcome of the novel Osstem Cardiotec Centum DES was comparable to Xience Alpine DES. However, despite showing promising angiographic results, a few issues must still be addressed. First, this study was conducted only on clinically stable patients with non-complex coronary artery disease. Therefore, the present stent technology needs to be further validated in various clinical settings, including complex high-risk PCI (e.g., left main disease, bifurcation lesion, heavily calcified lesion, chronic total occlusion, and acute myocardial infarction), to ensure broader application. Second, the present study was statistically underpowered to detect significant benefits on clinical outcomes due to the small sample size. Future studies with larger sample sizes are required for the appropriate assessment of clinical outcomes. Third, the main outcomes were investigated solely by angiographic assessment without the implementation of intravascular imaging, which could have provided a more comprehensive insight on stent strut coverage and intimal hyperplasia.[10] The angiographic outcome of this study should be further validated using intravascular imaging modalities in future studies. Finally, based on the present results, future studies should aim to provide large-scale real-world evidence to confirm the long-term clinical benefit of this novel everolimus-eluting, abluminal-coated biodegradable polymer stent technology.

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