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Editorial

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Reduction of In-Stent Restenosis and Inflammation with One Stent: New Concept of Sirolimus and Ascorbic Acid-Eluting Coronary Stent

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▸ See the article "A First-in-Man Clinical Evaluation of Sirolimus and Ascorbic Acid-Eluting Stent Systems: a Multicenter, Subject-Blinded, Randomized Study" in volume 51 on page 1001.

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Since coronary stent was first introduced in 1977, it has been greatly evolved. Stent implantation has been preferred method for revascularization of coronary artery disease due to improved procedural efficacy and safety as compared to balloon angioplasty.[1] However, bare-mental stent (BMS) has limitation of high restenosis rate anywhere between 20% to 50%.[2] This concern regarding BMS triggered the development of drug-eluting stent (DES) which included innovations in stent platforms, polymers along with anti-proliferative drugs. Evidences from systematic review and meta-analysis demonstrated a lower risk of stent thrombosis in the early generation DES using sirolimus or paclitaxel than BMS.[2][3] However, the use of early generation DES was associated with an increased risk of very late stent thrombosis. Thus, new generation DES has been emerged to counteract this limitation of early generation DES composed of the novel metallic alloys such as cobalt-chromium or platinum-chromium, allowing thinner strut stent platforms and use of new drug carriers offered improved biocompatibility of polymers.[4][5] In addition, ascorbic acid which is able to mitigate inflammatory process and subsequent oxidative damage may inhibit proliferation and migration of vascular smooth muscle cells.[6] D+Storm™ (CG Bio Co., Ltd., Seongnam, Korea) DES is a sirolimus-eluting stent coated with ascorbic acid, which is expected not only to reduce restenosis, but also to be effective in relieving inflammation and oxidative stress toward vessel wall.[7]

Lim et al.[8] have reported a prospective, multi-center, randomized, comparative, and pivotal study regarding D+Storm™ DES and BioMatrix Flex™ (Biosensors Interventional Technologies Pte, Ltd., Singapore) DES. Fifty-seven patients in the D+Storm™ DES group and 55 patients in the BioMatrixFlex™ DES group were enrolled in the study. D+Storm™ DES has a waved semi-open cell type, thin strut size of 75 μm using a cobalt-chrome material instead of stainless steel with biocompatible polymer with polylactic acid. This may attribute to be more flexible and easier to move smoothly even in complex and curved blood vessels. D+Storm™ DES was compared to BioMatrix Flex™ DES which is already widely used in current clinical practice. The primary endpoint was an in-segment late loss at 36 weeks. The secondary endpoints were in-stent late lumen loss, stent malapposition, mortality, target vessel revascularization and stent thrombosis at 36 weeks. Quantitative coronary angiography (QCA) and intravascular ultrasound (IVUS) were performed at baseline and at 36 weeks. D+Storm™ vs. BioMatrix Flex™ DES group showed no significant difference regarding

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in-segment late lumen loss based on QCA (0.08 ± 0.13 mm vs. 0.14 ± 0.32 mm, p=0.88) and also, based on IVUS (3.07 ± 4.21 mm^3 vs. 3.23 ±3.82 mm^3, p=0.42). Secondary endpoints were not significantly different between the 2 groups.

However, the result of current study should be interpreted cautiously. First, the study has limitation of underpowered for clinical outcomes due to the small number of subjects. Further studies with large number of all-comer patients are required. Second, IVUS was used to evaluate stent malapposition, which could have a limitation with low resolution. The stent malapposition may need to evaluate on optical coherence tomography more appropriately. Third, the study excluded complex percutaneous coronary intervention including ST-segment elevation myocardial infarction, cardiogenic shock, chronic total occlusion, restenotic lesion, left main coronary artery disease, and graft vessel.[9] Future studies will explore the further clinical impacts of this novel sirolimus and ascorbic acid-eluting stent in large of patients with long-term follow up.

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