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Clinical Research

Serial Randomized Comparison of Strut Coverage of Everolimus- and First-Generation Sirolimus-Eluting Stents

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ABSTRACT

Background: There has not been sufficient data to evaluate the serial vascular healing pattern after everolimus-eluting stent (EES) implantation. Using optical coherence tomography, we compared serial changes in strut coverage of the EES and the first-generation sirolimus-eluting stent (SES).

Methods: Sixty patients were randomly assigned to receive either EES (n = 30) or first-generation SES (n = 30) for coronary artery disease. Serial optical coherence tomography evaluation immediately after the procedure, and 3- and 12-month follow-ups were performed in 50 patients with 54 stents (25 patients with 28 EES vs 25 patients with 26 SES). The percentage of uncovered struts was defined as the ratio of uncovered struts to total struts. The primary end point was the percentage of uncovered struts at 12-month follow-up. The secondary primary end point was the percentage of uncovered struts at the 3-month follow-up and the comparative percentage change (Δ) of uncovered struts at 3- and 12-month follow-ups of EES vs SES.

Results: The percentage of uncovered struts was significantly lower in the EES group compared with the SES group (median value, 6.9%; interquartile range [IQR], 3.9-10.6% vs 11.1%; IQR, 5.5-29.4%, respectively) at the 3-month follow-up ($P = 0.03$), and at the 12-month follow-up (median value, 1.3%; IQR, 0.3-3.5% vs 3.6%; IQR, 1.0-9.4%;

RÉSUMÉ

Introduction : Nous ne disposons pas suffisamment de données pour évaluer le profil sériel de la cicatrisation vasculaire après l'implantation de l'endoprothèse à élution d'évérolimus (EÉÉ). À l'aide de la tomographie par cohérence optique, nous avons comparé les changements sériels de la couverture d'entretoises de l'EÉÉ et de l'endoprothèse à élution de sirolimus (EÉS) de première génération.

Méthodes : Nous avons réparti de manière aléatoire 60 patients souffrant d'une coronaropathie vers l'implantation d'EÉÉ (n = 30) ou de EÉS de première génération (n = 30). Nous avons réalisé l'évaluation sérielle de la tomographie par cohérence optique de 54 endoprothèses chez 50 patients (28 EÉÉ chez 25 patients *vs* 26 EÉS chez 25 patients) immédiatement après l'intervention, et aux suivis à 3 mois et à 12 mois. Le pourcentage d'entretoises non couvertes a été défini par le ratio des entretoises non couvertes par rapport aux entretoises totales. Le critère de jugement principal était le pourcentage des entretoises non couvertes au suivi à 12 mois. Le critère de jugement secondaire était le pourcentage des entretoises non couvertes au suivi à 3 mois et le changement dans le pourcentage comparatif (Δ) des entretoises non couvertes des EÉÉ *vs* EÉS aux suivis à 3 mois et à 12 mois.

Résultats : Le pourcentage d'entretoises non couvertes était significativement plus faible dans le groupe d'EÉÉ que dans le groupe d'EÉS

Optimized vascular healing after drug-eluting stent (DES) implantation has been the crucial factor in preventing stent thrombosis.[1,2] Although use of the first-generation DES significantly reduced in-stent restenosis compared with the bare-metal stent, incomplete endothelialization and neointimal formation has led to serious concern regarding stent thrombosis after DES implantation.[3] To improve the vascular healing process after DES implantation, advanced DESs have been developed with diverse stent platforms, eluting drugs, and polymer coatings.[3] The sirolimus-eluting stent (SES; Cypher, Cordis, Miami Lakes, FL) is a first-generation DES with a stainless steel platform and a nonbiocompatible polymer coating; the everolimus-eluting stent (EES; Xience Prime, Abbott Vascular, Santa Clara, CA) is a second-generation DES with cobalt chromium-based thin struts and a biocompatible polymer (fluoropolymer) coating, which is designed to minimize adverse tissue reaction and enhance the stent healing process.[3,4]

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$P = 0.02$). The percentage Δ of uncovered struts from the 3- to the 12-month follow-up was similar ($-7.0 \pm 6.9\%$ in EES vs $-10.5 \pm 13.6\%$ in SES; $P = 0.24$).

Conclusions: The EES group showed more favourable stent strut coverage than the first-generation SES group at the early and late periods after stent implantation. These findings suggest that EES have a more beneficial effect for vascular healing.

(valeur médiane, 6,9 %; intervalle interquartile [IIQ], 3,9-10,6 % *vs* 11,1 %; IIQ, 5,5-29,4 %, respectivement) au suivi à 3 mois ($P = 0,03$) et au suivi à 12 mois (valeur médiane, 1,3 %; IIQ, 0,3-3,5 % *vs* 3,6 %; IIQ, 1,0-9,4 %; $P = 0,02$). Le pourcentage Δ des entretoises non couvertes des suivis à 3 mois et à 12 mois était similaire ($-7,0 \pm 6,9$ % dans le groupe EÉÉ *vs* $-10,5 \pm 13,6$ % dans le groupe EÉS; $P = 0,24$).

Conclusions : Le groupe EÉÉ a montré une couverture d'entretoises plus favorable que le groupe EÉS de première génération aux périodes précoce et tardive après l'implantation. Ces résultats suggèrent que les EÉÉ ont un effet plus bénéfique sur la cicatrisation vasculaire.

Optical coherence tomography (OCT) can be an essential intravascular imaging modality to evaluate the vascular healing process in vivo with good resolution.[5-7] Information from serial OCT evaluation of vascular healing after DES implantation could be valuable to determine antiplatelet therapeutic strategies in real clinical practice. Although in one prospective OCT study the serial changes of strut coverage and apposition after EES implantation were assessed,[8] there remains only limited research on evaluation of the serial vascular healing pattern after EES implantation. Therefore, we compared stent strut coverage of the EES and the first-generation SES, using serial OCT evaluations (immediately after the procedure, and at 3- and 12-month follow-ups).

Methods

Study population

This study was a prospective, randomized, open-label, 2 × 2 factorial designed single-centre trial. Each patient was assigned to either type of DES and intensity of statins. A total of 60 patients who fulfilled the inclusion criteria and were willing to undergo serial OCT follow-up examinations were included in this trial, which was performed between August 2011 and January 2013. Each patient was randomly assigned into either the EES or first-generation SES group (ClinicalTrials.gov Identifier: NCT01856374). The EES was the target DES in this study, and the first-generation SES was selected as an active comparator. Serial OCT examinations were performed at 3 time points, including immediately after the procedure, and at 3 and 12 months after the procedure. Patients were ≥ 20 years old with stable or unstable angina and non-ST-elevation myocardial infarction. Patients were visually examined and deemed eligible for participation if they were considered to be candidates for percutaneous coronary intervention (PCI) of a de novo lesion with a reference vessel diameter of 2.5-3.5 mm, a stenosis diameter ≥ 70%, and a stent length ≤ 24 mm. Exclusion criteria were: (1) ST-elevation myocardial infarction or hemodynamically unstable status; (2) complex lesion morphologies (bifurcation lesions treated with 2-stent techniques, untreated significant unprotected left main coronary artery diseases, chronic total occlusion, in-stent restenosis, and vein-graft lesion); (3) DES treatment within the preceding 6 months; (4) serum creatinine level ≥ 2.0 mg/dL or existence of end-stage renal disease; (5) contraindication to receiving antiplatelet agents; (6) left ventricular ejection fraction < 35%; (7) pregnant women or women of child-bearing potential; and (8) life expectancy < 1 year. This randomized study was approved by our institutional review board, and written informed consent was obtained from all enrolled patients.

Randomization and study procedures

Study patients who fulfilled the enrollment criteria were randomly assigned in a 1:1 ratio to receive either an EES (n = 30) or a first-generation SES (n = 30), and either atorvastatin 40 mg (n = 29) or pravastatin 20 mg (n = 31) (2 × 2 design) using a concealed interactive Web-based response system. To preserve a balance between the 2 DES groups, stratified randomization was performed according to the estimated length and diameter of the implanted DES.

All patients received at least 75 mg aspirin and a loading dose of 300 mg clopidogrel at least 12 hours before PCI. Unfractionated heparin was administered to maintain an activated clotting time of > 250 seconds. All PCI procedures were performed according to current standard techniques. Treatment after the procedure included a 12-month prescription for dual antiplatelet therapy with 100 mg aspirin and 75 mg clopidogrel daily.

Quantitative coronary angiography

Quantitative coronary angiography analysis was performed before and after stent implantation and at 3- and 12-month follow-ups using an off-line quantitative coronary angiographic system (CAAS system; Pie Medical Instruments, Maastricht, Netherlands) in an independent core laboratory (Cardiovascular Research Center, Seoul, Korea). Using the guiding catheter for magnification-calibration, reference vessel diameter and minimum luminal diameter were measured from diastolic frames in a single, matched view showing the smallest minimum luminal diameter. Late loss was defined as the difference between immediately after the procedure and follow-up minimal luminal diameter. Angiographic restenosis was defined as ≥ 50% diameter stenosis inside the stent or within a 5-mm segment proximal or distal to the stent at follow-up.

OCT imaging and analysis

Patients were examined immediately after the procedure and at 3 and 12 months after the procedure. Basically, preintervention OCT examination was not mandatory and additional poststent balloon dilation was performed using angiography guidance. Imaging of the target lesion was performed using a frequency-domain OCT system (C7-XR OCT imaging

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