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Original article

Randomized Comparison of Stent Strut Coverage Following Angiography- or Optical Coherence Tomography-guided Percutaneous Coronary Intervention

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ABSTRACT

Introduction and objectives: The clinical benefits of optical coherence tomography-guided percutaneous coronary intervention are unclear. Therefore, in this study we sought to evaluate the impact of optical coherence tomography guidance on stent strut coverage following drug-eluting stent implantation.
Methods: A total of 101 patients in 105 lesions were randomly assigned to receive percutaneous coronary intervention under either optical coherence tomography guidance (n = 51 lesions of 50 patients) or angiography guidance (n = 54 lesions of 51 patients), and underwent a follow-up optical coherence tomography examination 6 months after zotarolimus-eluting stent implantation. The primary and secondary end points were the percentage of uncovered and malapposed struts, respectively, on 6-month follow-up optical coherence tomography.
Results: The percentage of uncovered struts was significantly lower in the optical coherence tomography-guided arm (1.60% [1.84]%, [median, 1.06%] vs 4.51% [5.43]% [median, 2.38%]; P = .0004) at 6-month follow-up. The incidence of stents with $\geq$ 5.9% uncovered struts was also significantly lower in the optical coherence tomography-guided arm (2 patients [3.9%] vs 14 patients [25.9%]; P = .002). In addition, the percentage of malapposed struts was significantly lower in the optical coherence tomography-guided arm (0.19% [0.51]% [median, 0.0%] vs 0.98% [2.53]% [median, 0.0%]; P = .027).
Conclusions: Optical coherence tomography-guided percutaneous coronary intervention significantly reduced the incidence of uncovered stent struts at 6 months compared to angiography-guided percutaneous coronary intervention. These findings suggest that optical coherence tomography-guided percutaneous coronary intervention has a beneficial effect on drug-eluting stent strut coverage.

Estudio aleatorizado de comparación de la cobertura de los *struts* de los *stents* tras la intervención coronaria percutánea guiada por angiografía y la guiada por tomografía de coherencia óptica

Palabras clave:
Tomografía de coherencia óptica
Stent liberador de fármaco
Enfermedad coronaria

RESUMEN

Introducción y objetivos: Los efectos beneficiosos clínicos de la intervención coronaria percutánea guiada por tomografía de coherencia óptica no están claros. Por ello en este estudio se intenta evaluar la influencia del uso de la guía de tomografía de coherencia óptica en la cobertura de los *struts* de los *stents* tras el implante de *stents* liberadores de fármacos.
Métodos: Se asignó aleatoriamente a 101 pacientes con 105 lesiones a tratamiento de intervención coronaria percutánea guiada por tomografía de coherencia óptica (n = 51 lesiones de 50 pacientes) o por angiografía (n = 54 lesiones de 51 pacientes), y se les realizó un examen de seguimiento por tomografía de coherencia óptica a los 6 meses del implante de un *stent* liberador de zotarolimus. Los objetivos principal y secundario eran el porcentaje de *struts* no cubiertos y con mala aposición, respectivamente, en el seguimiento realizado a los 6 meses con tomografía de coherencia óptica.
Resultados: El porcentaje de *struts* no cubiertos fue significativamente inferior en el grupo de tomografía de coherencia óptica (el 1,60 ± 1,84% [mediana, 1,06%] frente al 4,51 ± 5,43% [mediana, 2,38%]; p = 0,0004)

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en el seguimiento realizado a los 6 meses. La incidencia de *stents* con ≥ 5,9% de *struts* no cubiertos fue también significativamente inferior en el grupo de tomografía de coherencia óptica (2 pacientes [3,9%] frente a 14 [25,9%]; p = 0,002). El porcentaje de *struts* con mala aposición fue significativamente inferior en el grupo de tomografía de coherencia óptica (el 0,19 ± 0,51% [mediana, 0,0%] frente al 0,98 ± 2,53% [mediana, 0,0%]; p = 0,027).

Conclusiones: La intervención coronaria percutánea guiada por tomografía de coherencia óptica redujo significativamente la incidencia de *struts* de *stents* no cubiertos a los 6 meses, en comparación con la intervención coronaria percutánea guiada por angiografía. Estos resultados indican que la intervención coronaria percutánea guiada por tomografía de coherencia óptica tiene un efecto beneficioso en cobertura de los *struts* de los *stents* liberadores de fármacos.

Abbreviations

DES: drug-eluting stent
IVUS: intravascular ultrasound
OCT: optical coherence tomography
PCI: percutaneous coronary intervention

INTRODUCTION

Delayed vascular and endothelial healing is associated with stent thrombosis following implantation of a drug-eluting stent (DES) in pathologic studies.[1,2] High-resolution assessment of stent struts in vivo[3] using optical coherence tomography (OCT) shows that uncovered stent struts are associated with late stent thrombosis after DES implantation.[4,5] Previous studies show that larger-sized acute stent malapposition may be responsible for persistent stent malapposition and the development of uncovered stent struts during follow-up.[6,7] Compared to intravascular ultrasound (IVUS), high-resolution OCT results in superior apposition of stent struts to the vessel wall. To determine if this improved strut apposition was associated with improved stent strut coverage, we performed a prospective randomized study comparing strut coverage during follow-up after either OCT-guided or angiography-guided DES implantation.

METHODS

Study Population

This study was a prospective, open-label, randomized, single-center trial, registered at ClinicalTrials.gov (NCT01869842). A total of 117 patients with 124 coronary lesions were enrolled between December 2011 and December 2012 and randomly assigned to receive either OCT- or angiography-guided implantation of a zotarolimus-eluting stent (Endeavor Resolute™, Medtronic CardioVascular; Santa Rosa, California, United States). Inclusion criteria were: *a)* age ≥ 20 years old and significant coronary *de novo* lesion(s) (≥ 70% diameter stenosis on visual estimation), and *b)* a native coronary artery with a reference vessel diameter between 2.5 mm and 4.0 mm that could be covered by a single stent. Exclusion criteria were the following: *a)* refusal to participate; *b)* participation in other study protocols; *c)* lesions with significant left main disease or chronic total occlusion; *d)* lesions in a grafted vessel, thrombosis, or bifurcation lesions requiring 2 stents; *e)* an ejection fraction ≤ 30%; *f)* allergy to either antiplatelet agents or the contrast dye; *g)* known renal failure with baseline creatinine level ≥ 2.0 mg/dL, or end-stage renal disease; *h)* life expectancy < 1 year; *i)* prior DES treatment of a different vessel within 3 months; *j)* presence of an overlapping stent or long stent (> 3 0 mm); *k)* lesion calcification visible on angiography, and *l)* current pregnancy, or women of childbearing potential. During the same study period, percutaneous coronary intervention (PCI) was performed in 1300 patients. Of these patients, 1183 were excluded. Twenty-five patients refused participation, 405 were participating in other study protocols, and 753 met the remaining criteria, as follows: left main disease in 75, chronic total occlusion in 55, graft vessel disease in 23, totally occluded thrombotic lesion in 125, bifurcation lesions requiring 2 stents in 45, ejection fraction < 30% in 48, chronic renal failure (creatinine level ≥ 2 mg/dL) in 92, long lesion (> 30 mm stent) or overlapping stents in 135, and anatomy not suitable for OCT procedure in 155. This randomized study was approved by the institutional review board of our institute and written consent was obtained from all enrolled patients.

Randomization and Study Procedures

All study participants fulfilling the enrollment criteria of this study were randomly assigned in a 1:1 ratio by an interactive web-based response system to receive OCT- or angiography-guided PCI. To preserve a balance between the 2 strategies, randomization was stratified according to the presence of diabetes mellitus, acute coronary syndrome, and the estimated length and diameter of the prospective DES implant. All patients received at least 75 mg of acetylsalicylic acid and a loading dose of 300 mg of clopidogrel at least 12 hours pre-PCI. Unfractionated heparin was administered as needed to maintain the activated clotting time of > 250 seconds. All PCI procedures were performed according to current standard techniques. In the OCT-guided arm, adjuvant postdilation was performed at operator discretion based on OCT findings. In the angiography-guided arm, stent optimization including adjuvant postdilation was based on a visual estimation of angiographic findings and procedural success was defined as ≤ 20% residual stenosis after stent placement by visual estimation. Postprocedure treatment included a 12-month prescription of dual antiplatelet therapy with 100 mg acetylsalicylic acid and 75 mg clopidogrel daily.

Quantitative Coronary Angiography Analysis

Quantitative coronary angiography analysis was performed before and after stent implantation, and at 6-month follow-up using an off-line quantitative coronary angiographic system (CASS system, Pie Medical Instruments; Maastricht, The Netherlands) in an independent core laboratory (Cardiovascular Research Center, Seoul, Korea). Reference vessel and minimal luminal diameters were obtained by comparison to the guidance catheter from diastolic frames in a single, matched view showing the smallest minimal luminal diameter: post-PCI and follow-up angiograms were evaluated in the same projection. Acute gain was defined as the difference between preprocedure and postprocedure minimal luminal diameter. Late loss was defined