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Original article

Three-year Follow-up of Patients With Bifurcation Lesions Treated With Sirolimus- or Everolimus-eluting Stents: SEAside and CORpal Cooperative Study

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ABSTRACT

Introduction and objectives: To compare the 3-year incidence of major events in patients with bifurcation lesions treated with provisional sirolimus-eluting stents vs everolimus-eluting stents.
Methods: A pooled analysis of 2 prospective randomized trials with similar methodology (SEAside and CORpal) was performed. In these trials, 443 patients with bifurcation lesions were randomly assigned to treatment with either sirolimus-eluting stents or everolimus-eluting stents. The clinical follow-up was extended up to 3 years to assess major adverse cardiovascular events (death or acute myocardial infarction or target vessel revascularization).
Results: At 3 years, survival free of major adverse cardiovascular events was 93.2% vs 91.3% in the everolimus-eluting stent group vs the sirolimus-eluting stent group (P=.16). Exploratory land-mark analysis for late events (occurring after 12 months) showed significantly fewer major adverse cardiovascular events in the everolimus-eluting stent group: 1.4% vs 5.4% in the sirolimus-eluting stent group (P = .02).
Conclusions: Provisional stenting with either sirolimus-eluting stents or everolimus-eluting stents in bifurcation lesions is associated with low rates of major adverse events at 3-years' follow-up. The results of a subanalysis of events beyond 1 year, showing a lower event rate with everolimus-eluting stents than with sirolimus-eluting stents, suggest that studies exploring the long-term clinical benefit of the latest generation of drug-eluting stents are warranted.
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Seguimiento de 3 años de pacientes con lesiones de bifurcación tratados con *stents* liberadores de sirolimus o everolimus: estudio de colaboración de SEAside y CORpal

Palabras clave:
Lesiones de bifurcación
Enfermedad coronaria
Stent liberador de fármaco

RESUMEN

Introducción y objetivos: Comparar la incidencia en 3 años de eventos mayores en pacientes con lesiones de bifurcación tratados con implante condicional de *stents* liberadores de sirolimus frente a *stents* liberadores de everolimus.
Métodos: Se llevó a cabo un análisis combinado de dos ensayos prospectivos y aleatorizados de metodología similar (SEAside y CORpal). En dichos ensayos, se asignó aleatoriamente a 443 pacientes con lesiones de bifurcación a tratamiento con *stents* liberadores de sirolimus o everolimus. El seguimiento clínico se amplió a 3 años para evaluar los eventos adversos cardiovasculares mayores (muerte o infarto agudo de miocardio o revascularización de vaso diana).
Resultados: A los 3 años, la supervivencia libre de eventos adversos cardiovasculares mayores fue del 93,2 y el 91,3% en los grupos de *stents* liberadores de everolimus y sirolimus respectivamente (p = 0,16). El análisis exploratorio de referencia para los eventos tardíos (aparecidos después de los primeros 12 meses) mostró una frecuencia de eventos adversos cardiovasculares mayores significativamente inferior en el grupo de *stents* liberadores de everolimus: el 1,4 frente al 5,4% en el grupo de *stents* liberadores de sirolimus (p = 0,02).
Conclusiones: El implante de *stents* condicionales liberadores de sirolimus o everolimus en lesiones de bifurcación se asocia a unas tasas bajas de eventos adversos mayores a los 3 años de seguimiento. Los resultados de un subanálisis de los eventos que se produjeron después del primer año indican una tasa de eventos con los *stents* liberadores de everolimus inferior que con los liberadores de sirolimus, lo cual

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indica que está justificado realizar estudios exploratorios del beneficio clínico a largo plazo obtenido con los *stents* liberadores de fármacos de última generación.

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Abbreviations

DES: drug-eluting stents
EES: everolimus-eluting stents
MACE: major adverse cardiovascular events
MV: main vessel
SB: side branch
SES: sirolimus-eluting stents

INTRODUCTION

Provisional side branch (SB) stenting is the currently recommended percutaneous approach for the treatment of patients with coronary bifurcation lesions.[1] However, their outcome may be influenced by the type of drug-eluting stents (DES) implanted in the main vessel (MV). Indeed, during the treatment of a bifurcation, both the metal platform of the stent may be deformed and the polymer damaged.[2] Moreover, blood flow turbulences occurring at the level of stents implanted across bifurcations may facilitate both restenosis and thrombotic events. Accordingly, specific clinical trials in patients with bifurcation lesions need to be designed to establish differences among currently available DES.

This article is the result of a cooperative study to compare the efficacy and safety between 2 of the most widely used DES. We performed a pooled analysis of the 2 available prospective randomized trials with similar methodology (SEAside and CORpal)[3,4] with a clinical follow-up extended up to 3 years. The primary objective of this study was to analyze differences in major adverse cardiovascular events (MACE) during this period between the groups of patients treated with an sirolimus-eluting stent (SES) or an everolimus-eluting stent (EES).

METHODS

The Studies

This pooled analysis, the SEAside study, included 150 patients with bifurcation lesions undergoing DES implantation using a provisional stenting strategy. The patients were randomized to receive an SES (n = 75) or an EES (n = 75) before the intervention. The diameter of the MV and SB were required to be $\geq$ 2.5 mm and $\geq$ 2.0 mm, respectively, by visual estimation; data collected at the 18-month follow-up have previously been reported.[3] The investigators in the CORpal study randomly assigned 293 patients with bifurcation lesions to treatment with either an SES (n = 145) or an EES (n = 148). The diameters of the MV and SB were required to be $\geq$ 2.50 mm and $\geq$ 2.25 mm, respectively, by visual estimation. The 1-year follow-up has also previously been reported.[4]

Patients

During the years 2007 and 2008, 443 patients with bifurcation lesions treated with provisional SB stenting from 3 centers (2 in Spain and 1 in Italy) were recruited and randomly assigned to receive an SES (Cypher Select, Cordis; Warren, New Jersey, United States) or an EES (Xience V, Abbott Vascular, Santa Clara, California, United States) at the MV. The cooperative study flowchart is summarized in Figure 1. Patients fulfilled the following inclusion and exclusion criteria: *a)* the lesion was $>$ 50% and located in a major bifurcation point, regardless of the length, morphology, or angulation; *b)* the $\geq$ 2.50 mm in diameter; *c)* the SB was $\geq$ 2.00 mm in diameter, in the SEAside study and $>$ 2.25 mm in the CORpal study, and *d)* the SB stenosis length was $<$ 10 mm in the CORpal study, while no limitations were made in the SEAside concerning SB lesion length. The exclusion criteria were as follows: *a)* contraindications to prolonged dual antiplatelet therapy; *b)* acute phase of myocardial infarction (direct or rescue angioplasty). In the SEAside trial, patients had to have no acute (within 48 h) ST-segment elevation acute myocardial infarction, while researchers, from the CORpal trial included patients with an acute myocardial infarction after 24 h of intravenous thrombolysis and *c)* cardiogenic shock. Written informed consent was obtained from all patients.

Procedure

Percutaneous coronary interventions were performed by the radial or femoral approach according to the physician's preference. All patients were treated with stents using a simple approach or provisional SB stenting. Thus, a first stent was implanted at the MV, leaving a wire at the SB that became jailed between the metallic structure of the stent and the vessel wall. At this point, the SB ostium was evaluated. If there was SB compromise, a simultaneous or sequential SB postdilation was performed. After this maneuver, the SB ostium was evaluated again and a second stent was implanted in the SB if deemed necessary by the operator in the SEAside study and if there was a residual stenosis $>$ 50% or a coronary TIMI (Thrombolysis in Myocardial infarction) flow $<$ 3 flow in the CORpal study. SB stenting was performed according to the T-stenting technique.[5] Procedural success was defined as TIMI flow grade 3 in both the MV and the SB and visual residual stenosis $\leq$ 20% in the MV. At the time of the percutaneous coronary intervention, all patients were on dual antiplatelet therapy with acetylsalicylic acid and thienopyridines. Procedural anticoagulation was achieved with unfractionated heparin (70-100 U/kg intravenous bolus with further dose adjustment to maintain an activated clotting time of approximately 300 s). In both studies, the

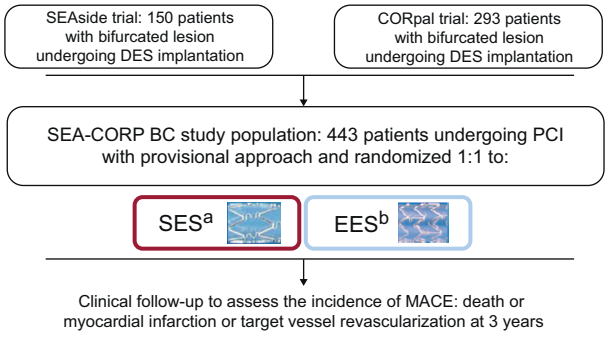

Figure 1. Study flowchart. DES, drug-eluting stents; EES, everolimus-eluting stents; MACE, major adverse cardiovascular events; PCI, percutaneous coronary intervention; SES, sirolimus-eluting stents.
[a]Cypher.
[b]Xience V.

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