Tratamiento de la Reestenosis Intra-Stent

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Programa Estudios RIBS

3-Year Clinical Follow-Up of the RIBS IV Clinical Trial

A Prospective Randomized Study of Drug-Eluting Balloons Versus Everolimus-Eluting Stents in Patients With In-Stent Restenosis in Coronary Arteries Previously Treated With Drug-Eluting Stents

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ABSTRACT

OBJECTIVES This study sought to compare the long-term safety and efficacy of drug-eluting balloons (DEB) and everolimus-eluting stents (EES) in patients with in-stent restenosis (ISR) of drug-eluting stents (DES).

BACKGROUND Treatment of patients with DES-ISR remains a challenge.

METHODS The RIBS IV (Restenosis Intra-Stent of Drug Eluting Stents: Drug Eluting Balloons vs Everolimus Eluting Stents) trial is a prospective, multicenter, randomized clinical trial comparing DEB and EES in patients with DES-ISR. The pre-specified comparison of the 3-year clinical outcomes obtained with these interventions is the main objective of the present study.

RESULTS A total of 309 patients with DES-ISR were randomized to DEB (n = 154) or EES (n = 155). At angiographic follow-up, the in-segment minimal lumen diameter was larger in the EES arm (2.03 ± 0.7 mm vs. 1.80 ± 0.6 mm; p < 0.01). Three-year clinical follow-up was obtained in all enrolled patients (100%). The combined clinical outcome measure of cardiac death, myocardial infarction and target lesion revascularization was significantly reduced in the EES arm (19 [12.3%] vs. 31 [20.1%]; p = 0.04; hazard ratio: 0.57 [95% confidence interval: 0.34 to 0.96]), driven by a lower need for target lesion revascularization (11 [7.1%] vs. 24 [15.6%]; p = 0.015; hazard ratio: 0.43 [95% confidence interval: 0.21 to 0.87]). The need for "late" (>1 year) target lesion revascularization (2.6% vs. 4%) and target vessel revascularization (4% vs. 6.5%) was similar in the 2 arms. Rates of cardiac death (3.9% vs. 3.2%), myocardial infarction (7.0% vs. 4.5%), and stent thrombosis (1.3% vs. 2.6%) at 3 years were also similar in both arms.

CONCLUSIONS The 3-year clinical follow-up of this randomized clinical trial demonstrates that in patients with DES-ISR, EES reduce the need for repeat interventions compared with DEB. (Restenosis Intra-Stent of Drug Eluting Stents: Drug-Eluting Balloons vs Everolimus-Eluting Stents [RIBS IV]; NCT01299844) (J Am Coll Cardiol Intv 2018;11:981–91)
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Bioresorbable Vascular Scaffolds for Patients With In-Stent Restenosis

The RIBS VI Study

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ABSTRACT

OBJECTIVES This study sought to assess the value of bioresorbable vascular scaffolds (BVS) in patients with in-stent restenosis (ISR).

BACKGROUND Currently both drug-eluting stents (DES) and drug-eluting balloons (DEB) are recommended in patients with ISR. However, the value of BVS in this setting remains unclear.

METHODS RIBS VI (Restenosis Intra-stent: drug-eluting balloon vs everolimus-eluting stent) was a prospective multicenter study (19 Spanish sites) that included 141 patients treated with BVS for either bare-metal stent (BMS) ISR or DES ISR. Late angiography was scheduled at 6 to 9 months. Inclusion/exclusion criteria were similar to those used in the RIBS IV (patients with DES-ISR) and RIBS V (patients with BMS-ISR) trials, where DEB (n = 249) was compared with everolimus (EES) DES (n = 240). Results of BVS in RIBS VI were compared with those obtained with DEB and EES in the RIBS IV and V trials.

RESULTS On late angiography (n = 134; 95% of eligible) the in-segment minimal lumen diameter (primary endpoint) was 1.87 ± 0.5 mm, late lumen loss was 0.23 ± 0.4 mm, and restenosis rate was 11%. At 1-year follow-up (100% of patients) no patient died, 4 (2.8%) experienced a myocardial infarction, and 16 (11.3%) required target lesion revascularization. One patient (0.7%) who discontinued antiplatelet therapy experienced definitive BVS thrombosis. Freedom from cardiac death, myocardial infarction, and target lesion revascularization was 86%. The minimal lumen diameter at follow-up after BVS was similar to that obtained with DEB (1.95 ± 0.6 mm; p = NS) but smaller than that achieved after EES (2.16 ± 0.7 mm; p < 0.001). Likewise, target lesion revascularization rates after BVS were similar to those seen with DEB (10.4%) but higher than with EES (3.2%; p < 0.001). Results remained unchanged after adjusting for potential confounders in baseline characteristics.

CONCLUSIONS This study suggests the safety and efficacy of BVS in patients with ISR. In this challenging anatomic scenario BVS obtained late angiographic and clinical results similar to DES but inferior to EES. (Bioresorbable Vascular Scaffolds Treatment [RIBS VI]; NCT02672878) (J Am Coll Cardiol Intv 2017;10:1841–51)

J Am Coll Cardiol Intv 2017;10:1841–5

RIBS 6 “scoring”

Restenosis Intrastent: Bioresorbable Vascular Scaffolds Treatment With Scoring Balloon Pre-dilatation

- ✓ Registro español multicéntrico prospectivo (Sección + SEC)
- ✓ Absorb en pacientes con reestenosis intrastent (BMS/DES)
- ✓ Predilatación con “scoring” balón
- ✓ Fecha inicio estudio: enero 2016

RIBS 6 “scoring”

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 03/02/2017 08:09

ClinicalTrials.gov ID: NCT03069066

Study Identification

Unique Protocol ID:	RIBS VI scoring
Brief Title:	Restenosis Intrastent: Bioresorbable Vascular Scaffolds Treatment With Scoring Balloon Pre-dilatation (RIBS VI Scoring)
Official Title:	Prospective Study of Bioresorbable Vascular Scaffold Treatment With Scoring Balloon Pre-dilatation in Patients With In-stent Restenosis
Secondary IDs:	

XXIX REUNIÓN ANUAL
DE LA SECCIÓN HEMODINÁMICA
Y CARDIOLOGÍA INTERVENCIONISTA

7 y 8 Junio 2013 GIJÓN

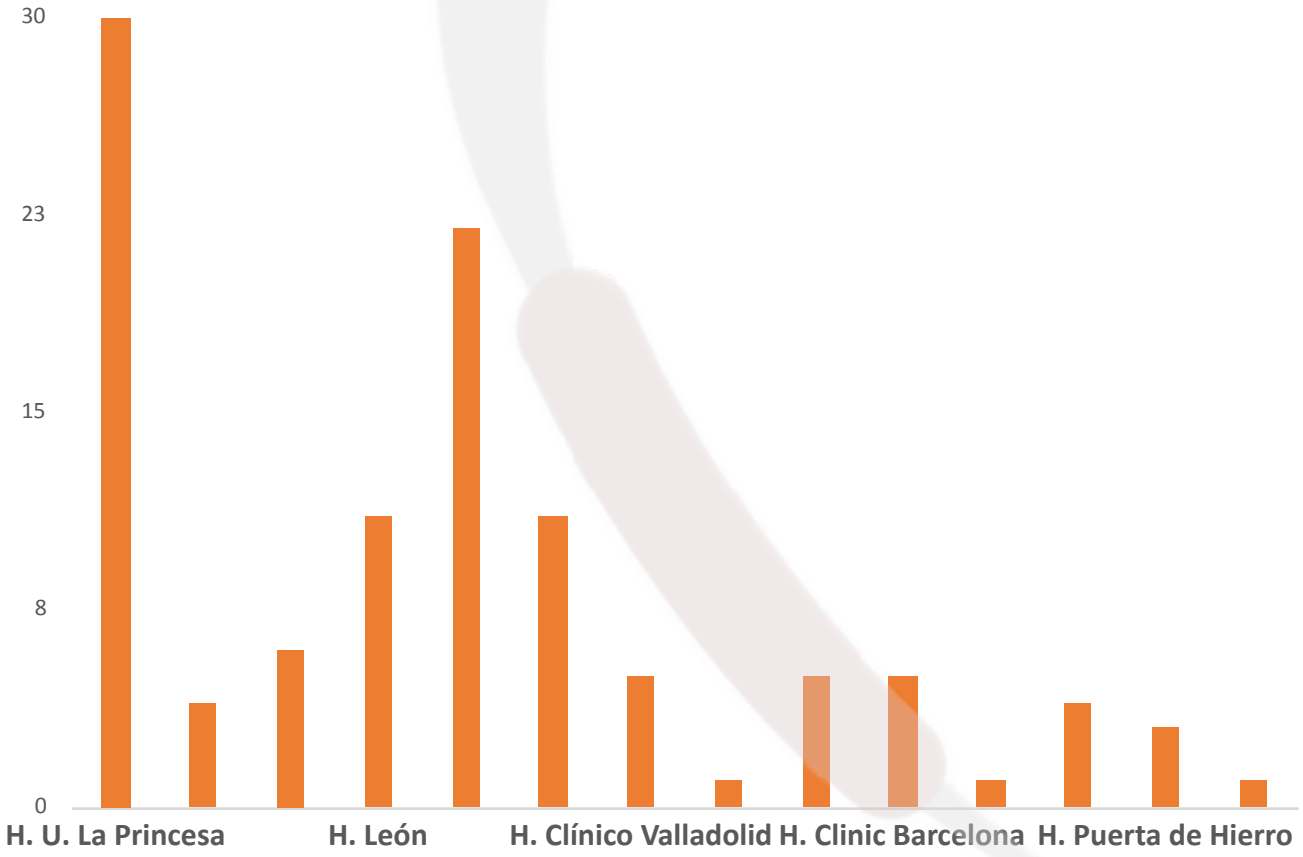
RIBS 6 “scoring”

Restenosis Intrastent: Bioresorbable Vascular Scaffolds Treatment With Scoring Balloon Pre-dilatation

- ✓ **Objetivo Primario Angiográfico**: Diámetro luminar mínimo en el seguimiento (Recurrencia de reestenosis, Pérdida angiográfica tardía, Ganancia neta, Porcentaje de estenosis luminal)
- ✓ **Objetivo Primario Clínico**: variable clínica combinada (muerte cardiaca, infarto de miocardio o necesidad de nueva revascularización).
- ✓ **Objetivos Secundarios** predeterminados (ClinicalTrials)

RIBS 6 “scoring”

Restenosis Intrastent: Bioresorbable Vascular Scaffolds Treatment With Scoring Balloon Pre-dilatation



TOTAL PACIENTES: 109 pacientes
(80 + 29 RIBS 6)

- ✓ Finalizada inclusión: septiembre 2017
- ✓ Seguimiento angiográfico: junio 2018
- ✓ Seguimiento clínico anual: septiembre 2018
- ✓ TCT 2018?

RIBS 7

Restenosis Intrastent: Treatment of Bioresorbable Vascular Scaffolds Restenosis (RIBS 7)

- ✓ Registro español multicéntrico prospectivo (Sección + SEC)
- ✓ Reestenosis de dispositivo vascular bioabsorbible
- ✓ Fecha inicio estudio: enero 2016

RIBS 7

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 08/09/2017 08:21

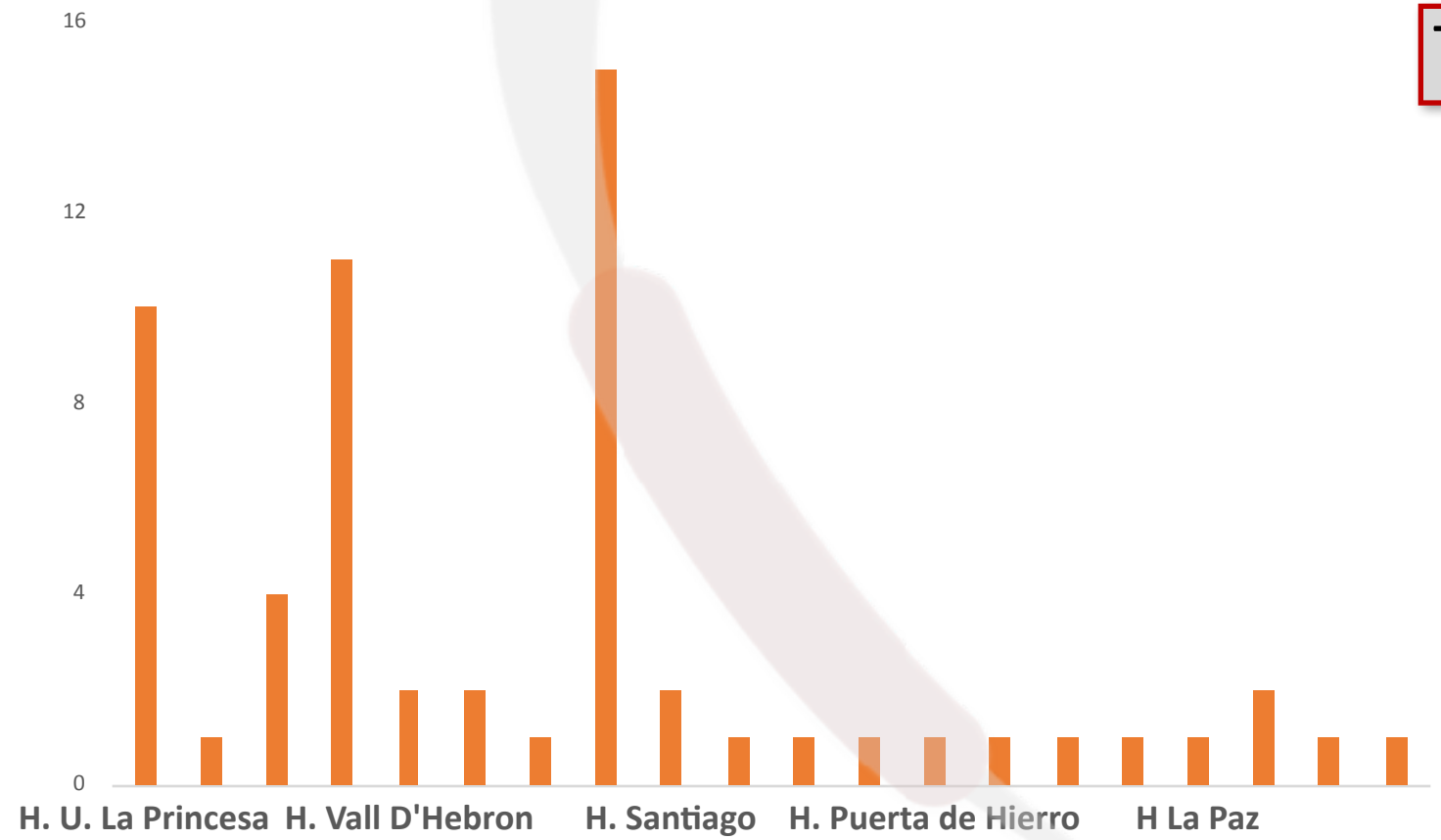
ClinicalTrials.gov ID: NCT03167424

Study Identification

Unique Protocol ID:	RIBS VII
Brief Title:	Restenosis Intrastent: Treatment of Bioresorbable Vascular Scaffolds Restenosis (RIBS VII)
Official Title:	Observational Study of Treatment of Bioresorbable Vascular Scaffolds Restenosis
Secondary IDs:	

RIBS 7

Restenosis Intrastent: Treatment of Bioresorbable Vascular Scaffolds Restenosis (RIBS 7)



TOTAL PACIENTES: 60 pacientes

- ✓ Inicio inclusión: enero 2016
- ✓ Número objetivo pacientes: 100 pacientes

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Gracias