Rendimiento excepcional del stent ultra fino Orsiro

Resultados más recientes del ensayo clínico BIOSCIENCE, presentados por el Dr. T. Pilgrim en la sesión Hot Line del ESC 2014 y publicados en paralelo en The Lancet

- Orsiro demostró que no es inferior a Xience Prime a los 12 meses en lo que respecta al fallo de la lesión tratada (TLF), el criterio de valoración clínico principal de este ensayo clínico controlado y aleatorizado de gran envergadura (n = 2.119).
- Tasas de trombosis del stent* reducidas y similares en esta población de pacientes compleja y variada (Orsiro 2,8 % frente a Xience Prime 3,4 %, p = 0,45).
- Además, Orsiro se relacionó con mejores resultados en el subgrupo de pacientes con IM con elevación del segmento ST (TLF Orsiro 3,3 % frente a Xience Prime 6,7 %, p = 0,024).
Resultados del subgrupo de pacientes con IM con elevación del segmento ST

Tasa de fallo de la lesión tratada (TLF) hasta los 12 meses
Orsino: n = 211 / Xience Prime: n = 196

[p = 0,024]

Orsino 3,3

Xience Prime 8,7

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* Trombosis del stent evidente y probable según la definición del Consorcio de Investigación Académica (ARC)

Actualmente no disponible en Estados Unidos
Ultrathin strut biodegradable polymer sirolimus-eluting stent versus durable polymer everolimus-eluting stent for percutaneous coronary revascularisation (BIOSCIENCE): a randomised, single-blind, non-inferiority trial

Thomas Pilgrim MD 1, Dik Heg PhD 1, Prof Marco Roffi MD 2, David Tüller MD 3, Olivier Muller MD 4, André Vuilliomenet MD 5, Prof Stéphane Cook MD 1, Daniel Weilenmann MD 6, Prof Christoph Kaiser MD 1, Peiman Jamshidi PhD 1, Prof Stéphane Noble MD 7, Prof Franz R Ebert MD 8, Prof Peter Wenaweser MD 2, Prof Peter Jüni MD 1, Prof Stephan Windecker MD 1

Summary

Background
Refinements in stent design affecting strut thickness, surface polymer, and drug release have improved clinical outcomes of drug-eluting stents. We aimed to compare the safety and efficacy of a novel, ultrathin strut cobalt-chromium stent releasing sirolimus from a biodegradable polymer with a thin strut durable polymer everolimus-eluting stent.

Methods
We did a randomised, single-blind, non-inferiority trial with minimum exclusion criteria at nine hospitals in Switzerland. We randomly assigned (1:1) patients aged 18 years or older with chronic stable coronary artery disease or acute coronary syndromes undergoing percutaneous coronary intervention to treatment with biodegradable polymer sirolimus-eluting stents or durable polymer everolimus-eluting stents. Randomisation was via a central web-based system and stratified by centre and presence of ST segment elevation myocardial infarction. Patients and outcome assessors were masked to treatment allocation, but treating physicians were not. The primary endpoint, target lesion failure, was a composite of cardiac death, target vessel myocardial infarction, and clinically- indicated target lesion revascularisation at 12 months. A margin of 3.5% was defined for non-inferiority of the biodegradable polymer sirolimus-eluting stent compared with the durable polymer everolimus-eluting stent. Analysis was by intention to treat. The trial is registered with ClinicalTrials.gov, number NCT01443104.

Findings
Between Feb 24, 2012, and May 22, 2013, we randomly assigned 2191 patients with 3139 lesions to treatment with sirolimus-eluting stents (1063 patients, 1594 lesions) or everolimus-eluting stents (1056 patients, 1545 lesions). 407 (19%) patients presented with ST-segment elevation myocardial infarction. Target lesion failure with biodegradable polymer sirolimus-eluting stents (69 cases; 6.5%) was non-inferior to durable polymer everolimus-eluting stents (70 cases; 7.6%) at 12 months (absolute risk difference −0.14%, upper limit of one-sided 95% CI 1.97%, p for non-inferiority <0.0004). No significant differences were noted in rates of definite stent thrombosis (9 [0.9%] vs 4 [0.4%], rate ratio [RR] 2.26, 95% CI 0.70–7.33, p=0.16). In pre-specified stratified analyses of the primary endpoint, biodegradable polymer sirolimus-eluting stents were associated with improved outcome compared with durable polymer everolimus-eluting stents in the subgroup of patients with ST-segment elevation myocardial infarction (7 [3.3%] vs 17 [8.7%], RR 0.38, 95% CI 0.16–0.91, p=0.024, p for interaction=0.014).

Interpretation
In a patient population with minimum exclusion criteria and high adherence to dual antiplatelet therapy, biodegradable polymer sirolimus-eluting stents were non-inferior to durable polymer everolimus-eluting stents for the combined safety and efficacy outcome target lesion failure at 12 months. The noted benefit in the subgroup of patients with ST-segment elevation myocardial infarction needs further study.

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