Original Article

Early and late outcomes of patients treated with hybrid sirolimus-eluting stent or everolimus-eluting stent

Cristiano de Oliveira Cardoso*, Clacir Staudt, Aldo Fernando Somavilla Duarte, La Hore Correa Rodrigues, Cristiane Cauduro Lima, Vasco Morosini Miller

CINECORS Cardiologia LTDA., Centro de Cardiologia do Hospital Ernesto Dornelles, Porto Alegre, RS, Brazil

ARTICLE INFO

Article history:
Received 30 January 2015
Accepted 2 April 2015

Keywords:
Percutaneous coronary intervention
Drug-eluting stents
Coronary thrombosis

ABSTRACT

Background: The Orsiro is a hybrid stent which has passive (amorphous silicon carbide) and active (poly-L-lactic acid, PLLA) coatings. The first layer encapsulates the stent struts, promoting lower local inflammation, whereas the second layer releases sirolimus through a biodegradable matrix. This study's aim was to compare the results of percutaneous coronary interventions (PCI) with Orsiro and Xience™ V stents (everolimus-eluting stent) in daily clinical practice.
Methods: Observational study in which patients were divided into two groups: those who received only one or more Orsiro stents, and those who received only Xience™ V stents. Early and late outcomes were prospectively collected.
Results: Between September 2012 and March 2014, this study included 92 and 108 patients treated with Orsiro and Xience™ V stents, respectively. Clinical, angiographic, and procedure characteristics were mostly similar between groups. Rates of procedure success (98.9% vs. 95.4%; $p = 0.22$), in-hospital mortality (1.1% vs. 0%; $p = 0.40$) and stent thrombosis (0% vs. 0.9%, $p = 0.30$) did not differ between groups. Time of follow-up was 434 ± 111 and 477 ± 66 days ($p = 0.23$), respectively, and differences in mortality (0.9% vs. 0%, $p = 0.30$), stent thrombosis (0% vs. 0.9%; $p = 0.30$), or need for repeat revascularization of the target lesion (0% vs. 0.9%; $p = 0.30$) were not observed.
Conclusions: Orsiro and Xience™ V stents showed similar performance, with low rates of early and late clinical and angiographic events.

Resultados iniciais e tardios de pacientes tratados com stent híbrido eluidor de sirolimus ou stent eluidor de everolimus

Palavras-chave:
Intervenção coronária percutânea
Stents farmacológicos
Trombose coronária

RESUMO

Introdução: O stent Orsiro é um stent híbrido que possui revestimentos passivo (carbeto de silício amorfo) e ativo (ácido poli-L-lático, PLLA). O primeiro encapsula as hastes do stent, promovendo menor inflamação local, e o segundo libera o sirolimus por meio de matriz biodegradável. Nosso objetivo foi comparar os resultados das intervenções coronárias percutâneas (ICP) dos stents Orsiro e Xience® V (eluidor de everolimus) na prática clínica diária.
Métodos: Estudo observacional em que os pacientes foram alocados em dois grupos: os que receberam exclusivamente um ou mais stents Orsiro e os que receberam exclusivamente stents Xience® V. Desfechos iniciais e tardios foram prospectivamente coletados.
Resultados: Entre setembro de 2012 e março de 2014, incluímos 92 e 108 pacientes tratados com stent Orsiro e Xience® V, respectivamente. Características clínicas, angiográficas e do procedimento foram, em sua maioria, semelhantes entre os grupos. As taxas de sucesso do procedimento (98,9% vs. 95,4%; $p = 0,22$), mortalidade (1,1% vs. 0%; $p = 0,40$) e trombose do stent (0% vs. 0,9%; $p = 0,30$) hospitalares não diferiram entre os grupos. O tempo de seguimento foi de 434 ± 111 e 477 ± 66 dias ($p = 0,23$), respectivamente, não sendo observadas diferenças na mortalidade (0,9% vs. 0%; $p = 0,30$), trombose do stent (0% vs. 0,9%; $p = 0,30$) e nem na necessidade de revascularização da lesão alvo (0% vs. 0,9%; $p = 0,30$).
Conclusões: Os stents Orsiro e Xience® V apresentaram desempenho semelhante, com baixas taxas de eventos clínicos e angiográficos iniciais e tardios.

DOI of original article: http://dx.doi.org/10.1016/j.rbci.2015.12.009
* Corresponding author: CINECORS Cardiologia LTDA., Avenida Ipiranga, 1.801, 8° andar, Azenha, CEP: 90160-092, Porto Alegre, RS, Brazil.
E-mail: cristiano@cinecors.com.br (C.O. Cardoso).
Peer Review under the responsability of Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista.

Introduction

The use of drug-eluting stents (DES) represented a major step forward in current interventional cardiology, as it has significantly reduced restenosis rates[1] and the need for repeat revascularization.[2] How-ever, some specific issues, such as late thrombosis[3] and local inflammatory response,[4,5] have promoted significant advances in the development of prostheses, to allow better stent performance associated with greater patient safety.

DES consist of a platform, a polymer, and an antiproliferative drug.[6] Bioengineering of materials has improved stent components, resulting in changes in the polymers and the use of several antiproliferative drugs. The Orsiro stent (Biotronik AG, Bulach, Switzerland), a hybrid sirolimus-eluting stent, is currently available for clinical use, but its utilization in Brazil is scarcely known.

The aim of this study was to evaluate early and late outcomes of patients from daily clinical practice submitted to percutaneous coronary intervention (PCI) with Orsiro stents, and to compare them to those receiving the Xience™ V stent (Abbott Vascular, Santa Clara, USA).

Methods

Design

This was an observational study with prospective data collection.

Sample selection

Patients undergoing PCI for the treatment of ischemic heart disease in the CINECORS service of the Centro de Cardiologia do Hospital Ernesto Dornelles, in Porto Alegre (RS), Brazil were assessed. Variables related to risk factors for cardiovascular disease, procedure indication, technical details of the intervention, complications, and in-hospital and late follow-up were prospectively recorded on a specific form and entered in a dedicated database. For comparison, patients were divided into two groups: patients who received only Orsiro stents and patients who received only Xience™ V stents. All patients signed the free and informed consent form.

Percutaneous coronary intervention

The PCIs were carried out according to standard techniques and following the current guidelines,[7] through femoral or radial access. Lesion assessment was performed by quantitative angiographic analysis, after intracoronary nitrate administration. Lesions were classified according to the definition of the American College of Cardiology/American Heart Association (A, B1, B2 and C).[8] Pre- and post-dilation were used at the interventionist's discretion. All patients received unfractionated heparin at the begining of the procedure (70 to 100 U/kg), with additional doses administered if required, to maintain an activated clotting time (ACT) from 250 to 350 seconds. Dual antiplatelet therapy was used in all patients with the administration of aspirin, 75 to 200 mg a day, together with a P2Y12 inhibitor (clopidogrel, prasugrel or ticagrelor).

Orsiro stent description

The Orsiro stent (Registered with the Brazilian National Health Surveillance Agency [Agência Nacional de Vigilância Sanitária - ANVISA] No. 80224390190) has a PRO-Kinetic Energy stent platform (L605 Chromium Cobalt alloy with 60 µm thick struts). It is considered a hybrid stent, because it has two coatings: a passive (PROBIO - amorphous silicon carbide coating) and an active coating (BIOlute - poly-L-lactic acid, PLLA). The passive PROBIO coating encapsulates the stent struts and reduces the interaction between metal and the tissue. Consequently, it promotes less local inflammation. The BIOlute active coating contains a highly biocompatible polymer that releases sirolimus drug through a biodegradable matrix for 12 to 14 weeks. The BIOlute polymer is slowly degraded into carbon dioxide and water. After complete polymer degradation, only the PRO-Kinetic Energy stent remains (Fig. 1).

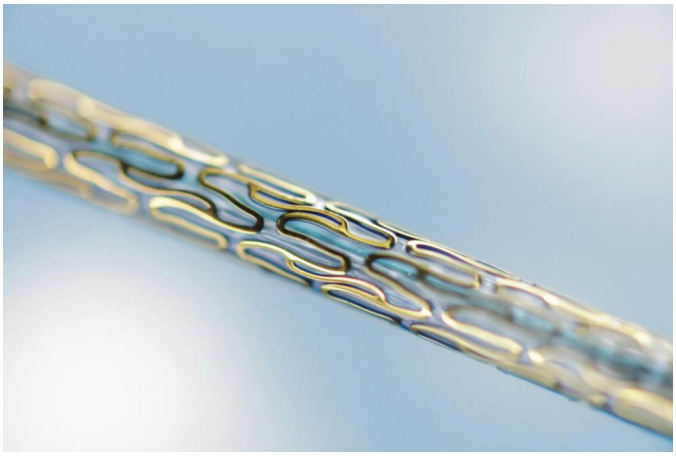

Figure 1. The Orsiro™ stent.

Clinical follow-up and outcomes

Patients were clinically followed during the hospital stay and later through clinical consultation, chart review, and/or telephone contact. The following were defined as hospital outcomes for the analysis: procedure success rate (stent implantation with residual lesion < 10% and Thrombolysis in Myocardial Infarction [TIMI] 3 flow after the procedure), hospital mortality, stent thrombosis, bleeding assessed by the GUSTO (Global Use of Strategies to Open Occluded Coronary Arteries) study criteria, contrast-induced nephropathy (50% increase over baseline serum creatinine), or need for dialysis. As for the late follow-up, the following were evaluated as outcomes: mortality, stent thrombosis, and symptom-guided target-lesion revascularization.

Statistical analysis

The variables are shown in percentages, as mean ± standard deviation (SD). For comparison between groups, the Chi-squared test or Student's *t*-test were used for categorical or continuous variables, respectively. The Mann-Whitney test was used for variables with normal distribution. A two-tailed *p*-value of < 0.05 was considered statistically significant. All data were analyzed using Statistical Package for the Social Science (SPSS) for Windows, version 18.0 (SPSS, Chicago, USA).

Results

Between September 2012 and March 2014, a total of 367 PCIs were performed in this service. After the inclusion criteria were applied, two groups of 92 and 108 patients participated in the study, treated exclusively with Orsiro and Xience™ V stents, respectively. As shown in Table 1, it was observed that both groups showed no differences in risk factors for cardiovascular disease, medications, and clinical indication for the procedure.

A total of 95 and 114 lesions were treated, respectively, in patients using Orsiro and Xience™ V stents. Vessel diameter (3.0 mm ± 0.2 vs. 3.0 ± 0.3 mm; $p = 0.51$) and mean lesion length (18.0 ± 6 mm vs. 20.0 ± 7 mm; $p = 0.08$) were equivalent in both groups. The numbers of Orsiro and