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Original Article

Evaluation of the XIENCE™ V Everolimus-Eluting Coronary Stent System in the Female Latin American Population of the SPIRIT Women Single-Arm Study: One-year Clinical Follow-up Data

Liliana Grinfeld[1], Carla R. Agatiello[2], Alexandre Abizaid[3], Jorge Belardi[4], Pedro Lemos[5], Marcos Marino[6], José M. Torres Viera[7], Marrianne Stuteville[8], Florencia Rolandi[9], Cécile Dorange[10], Marie Claude Morice[11]

ABSTRACT

Background: Drug-eluting stent trials have predominantly examined male populations of European descent. SPIRIT Women single-arm study evaluates the XIENCE™ V everolimus-eluting stent in complex de novo lesions in a real world female population, including Latin American patients. This analysis provides an insight into how this population responds to stenting when compared to non-Latin American patients. **Methods:** Of the 1,572 patients enrolled from 73 non-US sites, 138 (9%) were recruited from Argentina, Brazil and Venezuela. **Results:** Target lesions had reference vessel diameter ranging between 2.25 mm and 4 mm and lesion length ≤ 28 mm. Baseline characteristics were similar between the groups, with exception to a higher prevalence of hypertension, anterior myocardial infarction (MI) and family history of coronary artery disease in the Latin American cohort. Lesions tended to be more complex in Latin American women with a smaller reference vessel diameter, longer lesion length, increased eccentricity and angulation, and more type B2/C lesions. Events were adjudicated according to the guidelines of the Academic Research Consortium. At 1 year, the composite endpoint of death, MI and target vessel revascularization (TVR) was 12.1% in the non-Latin American population and 10.1% in the Latin American population (P = 0.58). **Conclusions:** At 1 year, the low rates of adverse cardiac events, including stent thrombosis, target lesion failure, cardiac death, MI and TVR

RESUMO

Avaliação do Stent Coronário Eluidor de Everolimus XIENCE™ V na População Feminina Latino-Americana do Estudo de Braço Único SPIRIT Women: Acompanhamento Clínico de Um Ano

Introdução: Os estudos com stents farmacológicos têm avaliado predominantemente populações masculinas de descendência europeia. O estudo de braço único SPIRIT Women avalia o stent eluidor de everolimus XIENCE™ V em lesões *de novo* complexas em uma população feminina do mundo real, incluindo pacientes latino-americanas. Esta análise permite compreender como essa população responde ao implante de stent, comparativamente a pacientes não-latino-americanas. **Métodos:** Das 1.572 pacientes matriculadas em 73 locais fora dos Estados Unidos, 138 (9%) foram recrutadas na Argentina, no Brasil e na Venezuela. **Resultados:** As lesões-alvo tinham diâmetro de referência do vaso entre 2,25 mm e 4 mm e extensão da lesão ≤ 28 mm. As características basais foram semelhantes entre os grupos, com exceção de maior prevalência de hipertensão arterial, infarto do miocárdio (IM) de parede anterior e história familiar de doença arterial coronária na coorte latino-americana. As lesões tendiam a ser mais complexas em mulheres latino-americanas, com menor diâmetro de referência do vaso-alvo, maior extensão da lesão, maior excentricidade e angulação e mais lesões tipo B2/C. Os eventos

[1] MD PhD. Head of the Hemodynamics and Interventional Cardiology Service, Invasive Cardiology Unit, Hospital Italiano de Buenos Aires. Buenos Aires, Argentina.
[2] MD. Interventional cardiologist, Invasive Cardiology Unit, Hospital Italiano de Buenos Aires. Buenos Aires, Argentina.
[3] "Livre-docente". Director, Invasive Cardiology Service, Instituto Dante Pazzanese de Cardiologia. São Paulo, SP, Brazil.
[4] MD. Director, Cardiology Division, Instituto Cardiovascular de Buenos Aires. Buenos Aires, Argentina.
[5] "Livre-docente". Director, Hemodynamics and Interventional Cardiology Service, Instituto do Coração do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo. São Paulo, SP, Brazil.
[6] MD. Interventional cardiologist, Hospital Madre Teresa. Belo Horizonte, MG, Brazil.
[7] MD. Clinical and interventional cardiologist, Clinica Santa Sofia. Caracas, Venezuela.
[8] Clinical scientist. Employee of Abbott Vascular. Diegem, Belgium.
[9] MD. Cardiologist, Clinical Cardiology Unit, Hospital Italiano de Buenos Aires. Buenos Aires, Argentina.
[10] Master in sciences. Employee of Abbott Vascular. Diegem, Belgium.
[11] MD. Head of Institut Cardiovasculaire Paris Sud. Paris, France.

Correspondence: Liliana Grinfeld. Hospital Italiano de Buenos Aires – Gascón 450 – PB 1181 – Buenos Aires, Argentina
E-mail: liliana.grinfeld@gmail.com

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in Latin American women were comparable to those of the non-Latin American women, despite the higher complexity of lesions. These results demonstrate the safety and efficacy of the XIENCE™ V stent in this small cohort of Latin American patients, in line with what is observed in larger and more varied populations.

DESCRIPTORS: Coronary artery disease. Drug-eluting stents. Women. Latin America.

foram adjudicados de acordo com as definições do Academic Research Consortium. Em um ano, o desfecho combinado de morte por todas as causas, IM e revascularização do vaso-alvo (RVA) foi de 12,1% na população não-latino-americana e de 10,1% na população latino-americana (P = 0,58). **Conclusões:** Em um ano, os baixos índices de eventos cardíacos adversos, incluindo trombose do stent, falha da lesão-alvo, morte cardíaca, IM e RVA nas mulheres latino-americanas foram comparáveis aos das mulheres não-latino-americanas, apesar da maior complexidade das lesões. Esses resultados demonstram a segurança e a eficácia do stent XIENCE™ V nessa pequena coorte de pacientes latino-americanas, à semelhança do que é observado com populações maiores e mais variadas.

DESCRITORES: Doença da artéria coronariana. Stents farmacológicos. Mulheres. América Latina.

Environmental and genetic risk factors, such as abdominal obesity, diabetes, dyslipidemia, smoking, and hypertension have been identified as predisposing factors for the female Latin American population to a significantly increased risk of cardiovascular events. Drug-eluting stents are now widely accepted as safe and effective therapies for patients with coronary artery disease. Drug-eluting stents inhibit neointimal proliferation by locally delivering an anti-proliferative drug, reducing the restenosis rate and the need for repeat revascularization procedures.[1]

The XIENCE™ V (everolimus-eluting stent system Abbott Vascular, Santa Clara, USA) was extensively evaluated in the SPIRIT clinical trials. SPIRIT FIRST[2] and SPIRIT II[3], where XIENCE™ V was evaluated, respectively, against the bare metal MULTI-LINK VISION™ RX stent (Guidant Vascular Intervention, Santa Clara, USA) and the paclitaxel-eluting stent TAXUS ™ (Boston Scientific, Natick, USA), demonstrated superiority when compared to the latter in terms of in-stent late loss at 6 months. Subsequently, this improvement in clinical outcomes was demonstrated in up to 5 years of follow-up in SPIRIT FIRST.[4] SPIRIT III demonstrated superiority to XIENCE™ V when compared to TAXUS ™ in terms of in-segment late loss at 8 months and non-inferiority for the secondary endpoint of target vessel failure at 9 months.[5] In addition, patients treated with the everolimus eluting stent in this study had a significantly improved event-free survival at 2 years when compared to patients receiving the TAXUS ™ stent.[6]

The aforementioned SPIRIT trials were primarily carried out in male populations of European descent with a relatively low-risk profile and simple lesions. When compared to the rest of the world, the Latin America population has shown a higher prevalence of diabetes and hypertension[7] and a high proportion of smokers, especially in big cities.[8]

The present manuscript reports the clinical follow-up data at 1 year in the Latin American population compared to the non-Latin American (non-Latin American) population of the SPIRIT Women Single Arm Study. This study evaluated the performance of XIENCE™ V in complex de novo lesions in a real world female population (n = 1,572). A significant proportion of the study population (138 patients; 9%) was recruited from Latin American sites in Argentina, Brazil and Venezuela, thereby providing insight into how this population responds to the implant of everolimus eluting stents when compared to the non-Latin American patient population.

METHODS

Study design and patient selection

SPIRIT Women is a prospective, single arm, multi-center study aimed at evaluating the performance of XIENCE™ V in the real world, according to its instructions for use, in the treatment of female patients with *de novo* coronary artery lesions. The study protocol was approved by the medical ethics committee of each participating institution and all patients gave written informed consent.

Between July 2007 and March 2009, 1,572 patients were enrolled at 73 clinical sites outside the United States, of which 9% (n = 138) were recruited from sites in Argentina (36), Brazil (82) and Venezuela (20).

Patients (aged > 18 years) recruited from the general interventional cardiology population who had been admitted for a PCI procedure, were recruited for the study. Inclusion criteria included patients with evidence of myocardial ischemia, stable or unstable angina, silent ischemia or a positive functional study, or a reversible change in the ECG consistent with ischemia. Patients were required to be suitable candidates for myocardial revascularization and had to agree to undergo clinical follow-up as required per protocol. Patients of child bearing potential should have a negative pregnancy test within 7 days before treatment. In addition, coro-