Journal of the American College of Cardiology
© 2014 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 63, No. 14, 2014
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.10.053

A Prospective Randomized Trial of Everolimus-Eluting Stents Versus Bare-Metal Stents in Octogenarians

The XIMA Trial (Xience or Vision Stents for the Management of Angina in the Elderly)

Adam de Belder, MD,* Jose M. de la Torre Hernandez, MD, PhD,† Ramon Lopez-Palop, PhD,‡ Peter O'Kane, MD,§ Felipe Hernandez Hernandez, MD,‖ Julian Strange, MD,¶ Federico Gimeno, PhD,# James Cotton, MD,** Jose F. Diaz Fernandez, MD,†† Pilar Carrillo Saez, PhD,‡ Martyn Thomas, MD,‡‡ Eduardo Pinar, PhD,§§ Nick Curzen, PhD,‖‖ Jose A. Baz, MD,¶¶ Nina Cooter, RCN,* Inigo Lozano, PhD,## Nicola Skipper, RCN,* Derek Robinson, PhD,*** David Hildick-Smith, MD,* on behalf of the XIMA Investigators

Brighton, Bournemouth, Bristol, Wolverhampton, London, Southampton, and East Sussex, England; and Santander, Alicante, Madrid, Valladolid, Huelva, Murcia, Vigo, and Oviedo, Spain

Objectives The aim of this study was to determine whether drug-eluting stents (DES) are superior to bare-metal stents (BMS) in octogenarian patients with angina.

Background Patients ≥80 years of age frequently have complex coronary disease warranting DES but have a higher risk of bleeding from prolonged dual antiplatelet therapy.

Methods This multicenter randomized trial was conducted in 22 centers in the United Kingdom and Spain. Patients ≥80 years of age underwent stent placement for angina. The primary endpoint was a 1-year composite of death, myocardial infarction, cerebrovascular accident, target vessel revascularization, or major hemorrhage.

Results In total, 800 patients (83.5 ± 3.2 years of age) were randomized to BMS (n = 401) or DES (n = 399) for treatment of stable angina (32%) or acute coronary syndrome (68%). Procedural success did not differ between groups (97.7% for BMS vs. 95.4% for DES; p = 0.07). Thirty-eight percent of patients had ≥2-vessel percutaneous coronary intervention, and 66% underwent complete revascularization. Patients who received BMS had shorter stent implants (24.0 ± 13.4 mm vs. 26.6 ± 14.3 mm; p = 0.01). Rates of dual antiplatelet therapy at 1 year were 32.2% for patients in the BMS group and 94.0% for patients in the DES group. The primary endpoint occurred in 18.7% of patients in the BMS group versus 14.3% of patients in the DES group (p = 0.09). There was no difference in death (7.2% vs. 8.5%; p = 0.50), major hemorrhage (1.7% vs. 2.3%; p = 0.61), or cerebrovascular accident (1.2% vs. 1.5%; p = 0.77). Myocardial infarction (8.7% vs. 4.3%; p = 0.01) and target vessel revascularization (7.0% vs. 2.0%; p = 0.001) occurred more often in patients in the BMS group.

Conclusions BMS and DES offer good clinical outcomes in this age group. DES were associated with a lower incidence of myocardial infarction and target vessel revascularization without increased incidence of major hemorrhage. (Xience or Vision Stent–Management of Angina in the Elderly [XIMA]; ISRCTN92243650) (J Am Coll Cardiol 2014;63:1371–5) © 2014 by the American College of Cardiology Foundation

From the *Brighton and Sussex University Hospitals National Health Service Trust, Brighton, England; †Hospital Marqués de Valdecilla, Santander, Spain; ‡Hospital San Juan de Alicante, Alicante, Spain; §Royal Bournemouth Hospital, Bournemouth, England; ‖Hospital 12 de Octubre, Madrid, Spain; ¶Bristol Royal Infirmary, Bristol, England; #Hospital Clínico de Valladolid, Valladolid, Spain; **Royal Wolverhampton Hospital, Wolverhampton, England; ††Hospital Juan Ramón Jiménez, Huelva, Spain; ‡‡St Thomas' Hospital, London, England; §§Hospital Virgen de la Arrixaca, Murcia, Spain; ‖‖Southampton University Hospitals National Health Service Trust, Southampton, England; ¶¶Hospital Meixoeiro, Vigo, Spain; ##Hospital Central de Asturias, Oviedo, Spain; and the ***Department of Mathematics, University of Sussex, East Sussex, England. This study was endorsed by the Spanish Working Group on Interventional Cardiology and was funded by an unrestricted educational grant from Abbott Vascular. Dr. de la Torre Hernandez has served as an advisory board member for Boston Scientific, Medtronic, and Biotronik; and has received speaker fees from Volcano Corp., St. Jude Medical, Boston Scientific, AstraZeneca, and Eli Lilly and Company. Dr. O'Kane has served as a proctor for Biosensors and Spectranetics. Dr. Curzen has received unrestricted grants from Haemonetics, St. Jude Medical, and Medtronic; and has served as a speaker and consultant for Haemonetics, St. Jude Medical, Boston Scientific, Daiichi Sankyo, and Abbott Vascular. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received July 11, 2013; revised manuscript received October 1, 2013, accepted October 8, 2013.

JACC Vol. 63, No. 14, 2014
April 15, 2014:1371–5

Abbreviations and Acronyms

BMS = bare-metal stent(s)
CVA = cerebrovascular accident
DAPT = dual antiplatelet therapy
DES = drug-eluting stent(s)
MI = myocardial infarction
PCI = percutaneous coronary intervention
TVR = target vessel revascularization

Improved health care has led to an increase in the proportion of elderly patients in the population. As a consequence, patients are presenting with stable coronary disease and acute coronary syndromes at a much older age, and very elderly patients (age >80 years) are an increasing slice of day-to-day practice. Coronary stenting is feasible for and beneficial to elderly patients with anginal syndromes (1,2) but is associated with higher complication rates (3,4). Many trial protocols exclude elderly patients, and the data for longer-term outcomes with intervention are limited to retrospective analyses (5–9).

See page 1376

Elderly patients often have complex coronary artery disease warranting use of drug-eluting stents (DES), but prolonged dual antiplatelet therapy (DAPT) puts them at higher risk for major bleeding complications (10). Noncompliance with DAPT may also be more likely in elderly patients, and this would put them at higher risk for stent thrombosis (11–14).

We designed a prospective randomized trial to examine the hypothesis that treatment of complex coronary disease with DES in patients ≥80 years of age with angina would prove superior to bare-metal stents (BMS) with respect to a combined endpoint of mortality, myocardial infarction (MI), target vessel revascularization (TVR), cerebrovascular accident (CVA), or severe hemorrhage.

Methods

Patients ≥80 years of age were considered for the trial at participating centers. Coronary disease warranting use of DES (≥15 mm long or <3 mm wide) was a requirement. Other subsets of disease that have a high risk of restenosis (chronic total occlusions, bifurcations, left main stem disease) were included. Second-generation everolimus-eluting stents (Xience, Abbott Vascular, Santa Clara, California) and bare-metal Vision stents (Abbott Vascular) were used.

Patients with non–ST-segment elevation myocardial infarction, unstable angina, and stable angina were eligible to participate in this study. Patients with acute ST-segment elevation myocardial infarction, cardiogenic shock, thrombocytopenia ($<50 \times 10^9/mm^3$), poor life expectancy, gastrointestinal hemorrhage ≤3 months, or previous intracerebral bleeding were excluded.

Patients were randomized on a 1:1 basis using web-based methodology. Before revascularization, all patients underwent an assessment of angina status, angina medication, physical examination, and measurement of creatine kinase/troponin levels. Techniques for stent deployment were left to the discretion of the operator. Lesion preparation before stent deployment was encouraged.

Before percutaneous coronary intervention (PCI), loading doses of aspirin 300 mg and clopidogrel 600 mg were given unless the patients were established on these drugs. Long-term treatment with warfarin was not a contraindication, but caution was emphasized. The use of glycoprotein IIb/IIIa inhibitors was at the discretion of the operator, but caution was urged.

Creatine kinase and troponin levels were measured 16 to 22 h after PCI. For patients receiving BMS, 1 month of DAPT was mandatory. For patients receiving DES, DAPT was prescribed for 1 year.

After discharge from the hospital, patients were followed up at 6 months and 1 year to determine progress, drug compliance, and clinical events. All clinical events were adjudicated by an independent adjudication committee in Spain and the United Kingdom (see the Online Appendix).

Definitions. Death was determined to be cardiac or noncardiac. For patients with undetermined cause, the full circumstances of demise were considered by the endpoints committee before adjudication. MI was defined using the European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Heart Federation 2007 definition (15). Bleeding endpoints were defined by the Thrombolysis In Myocardial Infarction classification (16) as none, minor, or major. TVR was defined as any stented vessel requiring revascularization with balloon angioplasty, stenting, or coronary artery bypass grafting within 1 year of the original procedure. CVA was defined as a new neurological deficit lasting >24 h confirmed with appropriate imaging abnormality. Stent thrombosis was defined using the Academic Research Consortium criteria (17).

Statistics and data management. The expected composite primary endpoint rate for this group of patients treated with BMS was estimated to be 20% at 1 year based on ARTS (Arterial Revascularization Therapies Study) I and II (18,19). We estimated the composite primary endpoint for the DES group would be 12%. Using this estimate, a sample size of 658 patients would achieve 80% power to a 5% significance level. We were concerned about loss to follow-up in this age group and therefore proposed to recruit 800 patients. Data were collected on a dedicated web-based secure site, entered by the host institution, and validated by the trial organization (Sussex Cardiac Centre, Brighton, England, and RPS Research Ibérica, Barcelona, Spain). All clinical events were adjudicated by an independent committee using pre-defined endpoints. The Data and Safety Monitoring Committee was responsible for the analysis of the data. All analyses were based on an intention-to-treat principle.

Categorical variables are reported as frequencies and percentages and compared using the chi-square test or, in the case of low frequencies, the Fisher exact test. Continuous variables are reported as mean ± SD and compared using the Student *t* test. Event-free survival was estimated using

Download English Version:

https://daneshyari.com/en/article/2944636

Download Persian Version:

https://daneshyari.com/article/2944636

Daneshyari.com