JACC: CARDIOVASCULAR INTERVENTIONS VOL. 4, NO. 11, 2011
© 2011 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC. DOI: 10.1016/j.jcin.2011.10.002

Transcatheter Valve-in-Valve Implantation Using CoreValve Revalving System for Failed Surgical Aortic Bioprostheses

Francesco Bedogni, MD,* Maria Luisa Laudisa, MD, PHD,* Samuele Pizzocri, MD,* Corrado Tamburino, MD,† Gian Paolo Ussia, MD,† Anna Sonia Petronio, MD,‡ Massimo Napodano, MD,§ Angelo Ramondo, MD,‖ Patrizia Presbitero, MD,¶ Federica Ettori, MD,# Gennaro Santoro, MD,** Silvio Klugman, MD,†† Federico De Marco, MD,†† Nedy Brambilla, MD,* Luca Testa, MD, PHD*

Milan, Catania, Pisa, Padua, Vicenza, Brescia, and Florence, Italy

Objectives The purpose of this study was to evaluate the performance of CoreValve Revalving System (CRS) (Medtronic, Minneapolis, Minnesota) implantation in patients with failed aortic bioprostheses.

Background Transcatheter aortic valve implantation with the CRS is an effective option in high-risk patients with severe aortic stenosis. It may be an option for patients with a failed aortic bioprosthesis, especially when the risk of a surgical redo is deemed prohibitive.

Methods CRS "valve-in-valve" implantation was performed in 25 high-risk patients with a failed bioprosthesis. Their mean age was 82.4 ± 3.2 years. New York Heart Association functional classes III and IV were present in 21 and 4 patients, respectively. The logistic EuroSCORE was 31.5 ± 14.8%, whereas the Society of Thoracic Surgeons score was 8.2 ± 4.2. Patients/prostheses were divided in type A (mainly stenotic, n = 9) and type B (mainly regurgitant, n = 16).

Results The implantation success rate was 100%. In group A, the peak aortic gradient significantly decreased from 77.6 ± 21.6 mm Hg to 34.6 ± 19.4 mm Hg (p = 0.001). In all but 2 patients in group B, no significant regurgitation was observed post-implantation. No patients died during the procedure. At 30 days, there were 3 deaths (12%), 2 myocardial infarctions (8%), and 3 atrioventricular blocks requiring pacemaker implantation (12%). At a mean follow-up of 6 months, there were another death (survival rate of 84%) and a pacemaker implantation (cumulative incidence of 16%). New York Heart Association functional class improved in all patients to I and II.

Conclusions CRS implantation was feasible and effective regardless of the prevalent mode of failure. This finding may significantly affect the treatment of patients with a failed bioprosthesis deemed at a prohibitive risk for surgical redo. (J Am Coll Cardiol Intv 2011;4:1228–34) © 2011 by the American College of Cardiology Foundation

From the *Istituto Clinico S. Ambrogio, Department of Interventional Cardiology, Milan, Italy; †Ferrarotto Hospital, Catania, Italy; ‡Cardiothoracic and Vascular Department, Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy; §Department of Cardiac Thoracic and Vascular Sciences, University of Padua, Padua, Italy; ‖Ospedale di Bassano del Grappa, Vicenza, Italy; ¶Istituto Clinico Humanitas, Milan, Italy; #Cardiothoracic Department, Spedali Civili, Brescia, Italy; **Careggi Hospital, Florence, Italy; and the ††Niguarda Ca Granda Hospital, Milan, Italy. Drs. Bedogni, Ussia, Petronio, Ramondo, Ettori, and Santoro are consultants for Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received August 29, 2011; revised manuscript received October 3, 2011, accepted October 5, 2011.

Surgical valve replacement has been the treatment of choice for patients with severe aortic stenosis or regurgitation for decades (1). Aortic prostheses can be basically divided into mechanical or biological, each having specific indications as well as inherent advantages and drawbacks.

Mechanical prostheses, having longer durability, require lifelong oral anticoagulation therapy. On the other hand, bioprostheses, although not requiring prolonged oral anticoagulation therapy, are invariably destined to deteriorate (1).

So far, the treatment of choice for a failed bioprosthesis has been a surgical redo, despite the higher mortality and morbidity compared to the first surgical treatment, as a consequence of comorbidities and technical hurdles (2).

Transcatheter aortic valve implantation (TAVI) is currently considered a valid option for patients with severe aortic stenosis deemed at prohibitive surgical risk to improve survival and quality of life compared with medical therapy (3).

Although neither the CoreValve Revalving System (CRS) (Medtronic, Minneapolis, Minnesota) nor the Edwards SAPIEN Transcatheter (EST) heart valve (Edwards Lifesciences, Irvine, California) have been approved for use in patients with failed aortic bioprostheses, there are reports of successful implantation in patients refused by surgeons for an unreasonable surgical risk (4–9).

We report a multicenter experience with CRS valve-in-valve implantation for a failed aortic bioprosthesis.

Methods

Patients. Valve-in-valve implantation with the CRS for aortic bioprosthesis failure was performed in 25 patients (Table 1) at 8 Italian centers with a high volume of TAVIs. Before the procedure, a thorough evaluation by the heart team, which included cardiologists, interventional cardiologists, anesthesiologists, and cardiac surgeons, was performed to determine surgical eligibility.

Clinical criteria for high risk were considered to be age 75 years and older, coronary artery disease, malignancy, hepatic cirrhosis, frailty, chronic obstructive pulmonary disease, severe pulmonary hypertension, porcelain aorta, low ejection fraction, diabetes, renal failure, and peripheral obstructive artery disease. The logistic EuroSCORE and STS score were calculated.

At the time of enrollment in study, all patients had symptomatic heart failure (New York Heart Association functional classes III and IV) despite intense medical therapy. Echocardiographic criteria for bioprosthesis dysfunction were aortic valve area <1 cm^2 and/or aortic regurgitation grade of 3 or higher.

Once consensus on the therapeutic approach and informed written consent were obtained, evaluation of the patient was performed to select the vascular access and to assess the presence of coronary artery disease. Percutaneous coronary revascularization, when indicated, was performed before TAVI.

Procedure. Implantation of a third-generation 18-F CRS (Medtronic) was performed in all patients. A transfemoral or axillary approach was chosen on the basis of anatomic considerations (vessel diameter, tortuosity, calcification, significant stenosis). General anesthesia or sedation was left to the anesthesiologist's discretion. A temporary pacemaker was placed in all patients in the absence of a previous permanent one. Valvuloplasty during rapid pacing before CRS implantation was optional. Cardiopulmonary support was not used. The CRS size was chosen according to nominal internal diameter of the failed prosthesis.

Transthoracic echocardiography was performed postprocedure and at hospital discharge. Clinical follow-up evaluation was performed at 30 days, 3 and 6 months, and then yearly thereafter.

Double antiplatelet therapy was administered in all patients. Acetylsalicylic acid was continued indefinitely and clopidogrel (75 mg/day) for the next 6 months. For patients previously treated with percutaneous coronary intervention (PCI), dual antiplatelet therapy was continued as planned.

Definitions. Endpoint definitions were according to Valve Academic Research Consortium consensus document criteria (10). Safety and efficacy endpoints were recorded in the hospital, at 30 days, and at last follow-up.

Statistical analysis. Numerical values are expressed as mean ± SD. Continuous variables were compared between groups using the paired *t* test (for normally distributed variables) or the Mann-Whitney *U* test (for non-normally distributed variables). All reported probability values were 2 tailed, and $p < 0.05$ was considered statistically significant. Analyses were performed with the SPSS statistical software package, version 17 (SPSS, Inc., Chicago, Illinois).

Abbreviations and Acronyms

CRS = CoreValve Revalving System

EST = Edwards SAPIEN transcatheter

OA = orifice area

STS = Society of Thoracic Surgeons

TAVI = transcatheter aortic valve implantation

Results

The mean age of the patients was 82.4 ± 3.2 years (10 men, 15 women). The mean logistic EuroSCORE was 31.5 ± 14.8, whereas the mean STS score was 8.2 ± 4.2 (see Tables 1 and 2 for baseline clinical and echocardiographic characteristics). Patients were further characterized according to the cause of failure: predominantly stenosis (group A, n = 9, 36%) and predominantly regurgitation (group B, n = 16, 64%). Eighteen prostheses were stented, 7 were stentless. Among the stentless bioprostheses, the most frequent cause of

Download English Version:

https://daneshyari.com/en/article/2940795

Download Persian Version:

https://daneshyari.com/article/2940795

Daneshyari.com