Rev Bras Cardiol Invasiva. 2015;**23(3)**:166-172

Original Article

Transcatheter valve-in-valve implantation for surgical aortic bioprosthesis dysfunction

Rafael Alexandre Meneguz-Moreno[a,*], Dimytri A. Siqueira[a,b], Auristela Isabel de Oliveira Ramos[a], Antônio de Castro Filho[a], Andreia Dias Jeronimo[a], Tannas Jatene[a], David Le Bihan[a], Rodrigo Barretto[a,b], Magaly Arrais[a,b], Adriana Moreira[b], Alexandre Abizaid[a,b], Amanda Guerra M. R. Sousa[a,b], J. Eduardo M. R. Sousa[a,b]

[a] *Instituto Dante Pazzanese de Cardiologia, São Paulo, SP, Brazil*
[b] *Hospital do Coração, São Paulo, SP, Brazil*

ARTICLE INFO

Article history:
Received 22 June 2015
Accepted 31 August 2015

Keywords:
Bioprosthesis
Aortic valve stenosis
Transcatheter aortic valve replacement

ABSTRACT

Background: Recent studies have demonstrated the efficacy of the transcatheter valve-in-valve implantation for the treatment of bioprosthesis dysfunction in high-risk surgical patients. This study presents the initial experience with valve-in-valve implantation.
Methods: Clinical, echocardiographic, and procedural profiles were characterized, and the mid-term results of patients with surgical bioprosthesis dysfunction submitted to valve-in-valve implantation in the aortic position were reported.
Results: Seven male patients were included, aged 72.6 ± 10.0 years. The STS score was 9,6 ± 10,5%, and the logistic EuroSCORE was 22.7 ± 14.7%. Three patients had combined aortic bioprosthesis failure; two had isolated regurgitation; and two had isolated stenosis. The transfemoral access was used in six cases, and the transapical access in one case. Implanted devices included Sapien XT (n = 5) and CoreValve (n = 2) prostheses. Procedural success was achieved in six (85.7%) cases. After the procedure, the mean gradient decreased from 38.2 ± 9.6 mmHg to 20.9 ± 5.9 mmHg, and the valve area increased from 1.2 ± 0.4 cm^2 to 1.5 ± 0.5 cm^2. After 1 year, there were no deaths and no other significant adverse outcomes; 80% of patients were in NYHA functional class I/II. The transvalvular gradients and valve area remained unchanged in this period.
Conclusions: The valve-in-valve procedure was effective in most high-risk surgical patients with bioprosthesis dysfunction. When performed in well-selected patients, it results in satisfactory clinical and hemodynamic outcomes.

Implante transcateter *valve-in-valve* para disfunção de biopróteses cirúrgicas aórticas

Palavras-chave:
Bioprótese
Estenose da valva aórtica
Substituição da valva aórtica transcateter

RESUMO

Introdução: Estudos recentes têm demonstrado a eficácia do implante transcateter *valve-in-valve* para o tratamento de disfunção de biopróteses em pacientes de alto risco cirúrgico. Apresentamos nossa experiência inicial com o implante *valve-in-valve.*
Métodos: Caracterizamos o perfil clínico, ecocardiográfico e do procedimento, e reportamos os resultados de médio prazo de pacientes com disfunção de bioprótese submetidos a implante *valve-in-valve* em posição aórtica.
Resultados: Incluímos sete pacientes do sexo masculino, com idade de 72,6 ± 10,0 anos. O escore STS foi 9,6 ± 10,5%, e o EuroSCORE logístico foi 22,7 ± 14,7%. Três pacientes apresentavam dupla disfunção; dois tinham insuficiência; e dois exibiam estenose isolada. A via transfemoral foi utilizada em seis casos, e a transapical, em um caso. Os dispositivos implantados incluíram as próteses Sapien XT (n = 5) e CoreValve (n = 2). O sucesso do procedimento foi obtido em seis (85,7%) casos. Após o procedimento, o gradiente médio reduziu-se de 38,2 ± 9,6 mmHg para 20,9 ± 5,9 mmHg, e a área valvar elevou-se de 1,2 ± 0,4 cm^2 para 1,5 ± 0,5 cm^2. Ao final de 1 ano, não

DOI of original article: http://dx.doi.org/10.1016/j.rbci.2016.06.004
* Corresponding author: Av. Dr. Dante Pazzanese, 500, Vila Mariana, CEP: 04012-909, São Paulo, SP, Brasil.
E-mail: rafael.meneguz@yahoo.com.br (R.A. Meneguz-Moreno).
Peer review under the responsibility of Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista.

ocorreram óbitos e nem outros desfechos adversos significativos; 80% dos pacientes encontravam-se em classe funcional NYHA I/II. Os gradientes transvalvares e a área valvar permaneceram inalterados nesse período.
Conclusões: O procedimento *valve-in-valve* foi eficaz na maioria dos pacientes de alto risco cirúrgico com disfunção de bioprótese. Quando realizado em pacientes bem selecionados, resulta em desfechos clínicos e hemodinâmicos satisfatórios.

Introduction

Patients with surgical bioprosthesis valve dysfunction represent a clinical challenge because, although a new surgical replacement is considered the standard treatment, the reoperation is associated with high morbidity and mortality.[1,2] These patients are characterized as high surgical risk or inoperable, due to multiple comorbidities, advanced age, clinical frailty, or reduced ventricular ejection fraction.[3]

Originally developed for the approach of the native valve stenosis, transcatheter aortic prosthesis implantation is the standard treatment for symptomatic patients considered inoperable, in addition to representing an alternative therapeutic strategy to surgical valve replacement in high surgical-risk individuals.[4-8] Recent studies demonstrate the clinical efficacy of transcatheter valve-in-valve (VIV) prosthesis implantation for the treatment of aortic surgical bioprosthesis dysfunction. This is a less invasive treatment option, especially because it does not expose the patient to extracorporeal cardiopulmonary circulation and the inherent risks of reoperation. Although the prostheses have not been designed for this purpose, the published results have been encouraging.[9-14]

This study aimed to characterize the initial experience of a multidisciplinary cardiovascular team in employing the VIV procedures in patients with surgical bioprosthesis dysfunction in the aortic position. Clinical and echocardiographic profiles and the aspects related to the procedure were described, as well as the clinical results of the mid-term follow-up.

Methods

Patient selection and indication for the valve-in-valve procedure

This analysis included patients older than 18 years with symptomatic aortic bioprosthesis dysfunction, consecutively submitted to VIV procedure at two tertiary cardiology centers between January 2009 and June 2015. Patients with previous transcatheter aortic valve procedures or active infective endocarditis were excluded from the sample. The project was approved by the institutional Ethics Committee, and the patients signed an informed consent. Data were prospectively recorded in appropriate forms developed for the study, stored in spreadsheets, and collected from the database of each institution.

Pre-procedure clinical assessment

In general, patient assessment for the VIV procedure was similar to that performed in patients candidates for transcatheter aortic valve implantation in native position. The treatment indication was based on surgical risk, determined by clinical characteristics or technical reasons. For risk estimation, the Society of Thoracic Surgeons score (STS, available at http://riskcalc.sts.org/de.aspx) and the European System for Cardiac Operative Risk Evaluation score (logistic EuroSCORE, according to http://www.euroscore.org/calcold.html) were used. Risk factors not included in these scores, such as the presence of "porcelain aorta", frailty, hostile thorax caused by previous chest irradiation, liver diseases, and coagulation disorders, were also considered in this decision. All cases were analyzed and discussed by a multidisciplinary group (the Heart Team), consisting of clinical and interventional cardiologists, cardiovascular surgeons, and cardiac imaging specialists.

Specific characteristics of the surgical prosthesis were assessed to support the indication of VIV procedure. The type, model, size, and position (intra- or supra-annular) of the surgical valve prosthesis were identified. The internal diameter of each bioprosthesis was obtained from the manufacturer's information. Technical aspects of the employed surgery, such as the need for reconstruction of the aortic root and the presence of venous or arterial grafts, were also elucidated.

Complementary pre-procedure examinations

Laboratory tests, electrocardiogram, chest X-rays, transesophageal echocardiography, computed tomography angiography (CT-angiography) of the heart and total aorta, and coronary angiography were performed.

The main parameter considered for the choice of transcatheter aortic prosthesis to be implanted was the internal diameter of the previous surgical bioprosthesis, obtained from the manufacturer or as reported by the VIV Aortic application, developed by Bapat and UBQO Ltd. (London, United Kingdom).[15] Echocardiography was used to assess the mechanism and consequences of prosthetic dysfunction, defining the integrity and mobility of the leaflets, left ventricular function, and the presence of pulmonary hypertension and associated valve diseases. In cases of dysfunction due to prosthesis regurgitation, the transesophageal echocardiography excluded the presence of paravalvular reflux. The CT-angiography of the aorta was the method used to determine the best approach. In case of non-availability of previous surgical data, the CT-angiography helped to analyze the surgical prosthesis diameters and to choose the most appropriate transcatheter prosthesis for VIV procedure. Coronary angiography was used for the assessment of associated coronary artery disease and to estimate the risk of coronary occlusion during valve implantation.

Technical aspects of the procedure

Dual antiplatelet therapy (acetylsalicylic acid, 300 mg, and clopidogrel, 300 mg) was initiated with a loading dose 24 hours before the procedure. The procedures were preferably performed in the hybrid room. The decision regarding use of general anesthesia and transesophageal echocardiography was made at the discretion of the operators.

The femoral vascular access was the first choice for the implantation, and a specific hemostatic device was used for arterial repair mediated by ProGlide® suture (Abbott Vascular®, Santa Clara, USA). In case of the impossibility of using the femoral approach, the transapical access was used. After establishing the vascular access, a bolus of unfractionated heparin was administered (80 to 100 U/kg).

Considering the fact that, in most cases, the surgical bioprosthetic annulus is radiopaque, the identification of the best angiographic projection for the implant was obtained by fluoroscopy: a coplanar