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Feasibility of precise commissural and coronary alignment with balloon-expandable TAVI

Factibilidad del alineamiento comisural y coronario precisos con TAVI balón-expandible

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Abstract

Introduction and objectives

We aimed to describe the feasibility and preliminary outcomes of commissural alignment (CA) for the balloon-expandable transcatheter heart valve.

Methods

The relationship among native commissures and transcatheter aortic valve implantation neocommissures was analyzed in 10 consecutive patients with tricuspid severe aortic stenosis undergoing transcatheter aortic valve implantation after guided implantation based on computed tomography analysis with a self-developed software. CA was predicted by *in silico* bio-modelling in the 10 patients and the calculated rotation was applied during crimping. Degrees of CA and coronary overlap (CO) were measured through 1-month follow up computed tomography. Transvalvular residual gradients and the rate of paravalvular leak were also analyzed.

Results

Mean commissural misalignment was 16.7±8°. Four patients showed mild misalignment but none of them showed a moderate or severe degree of misalignment. The *in silico* model accurately predicted the final in vivo position with a correlation coefficient of 0.983 (95%CI, 0.966-0.992), P <.001. Severe CO with right coronary ostium occurred in 3 patients likely due to ostial eccentricity, and CO was not present with the left coronary artery in any of the patients. Mean transaortic gradient was 6.1±3.3mmHg and there were no moderate-severe paravalvular leaks.

Conclusions

Patient-specific rotation during valve crimping based on preprocedural computed tomography is feasible with balloon-expandable devices and is associated with the absence of moderate or severe commissural misalignment and left main CO.

Resumen

Introducción y objetivos

Nuestro objetivo fue describir la factibilidad y resultados preliminares de una estrategia de alineamiento comisural preciso (ACP) con implante percutáneo de válvula aórtica balón-expandible.

Métodos

Métodos

Se analizó la relación entre las comisuras nativas y las neocomisuras en 10 pacientes consecutivos con estenosis aórtica grave trivalva y sintomática tras orientar el implante de TAVI basándose en la tomografía computarizada (TC) a través de un programa de análisis específicamente desarrollado. El ACP se predijo en base a modelos *in silico* que permitieron estimar cuantos grados había que girar la prótesis en el momento del crimpado. El grado de ACP y de solapamiento con los ostium coronarios se midió mediante TC al mes. Se recogieron gradientes transvalvulares y fuga perivalvular.

Resultados

El mal alineamiento medio fue de 16,7±8°. Cuatro pacientes presentaron mal alineamiento ligero, pero ninguno moderado o grave. El análisis *in silico* predijo la posición final de las neocomisuras con un coeficiente de correlación de 0,983 (IC95%, 0,966-0,992), p <0,001. Se produjo solapamiento coronario severo con el ostium de la coronaria derecha en 3 casos en relación con excentricidad de su origen, pero en ningún caso con el ostium coronario izquierdo. El gradiente transaórtico medio fue de 6,1±3,3mmHg y no hubo casos de fuga perivalvular moderada o grave.

Conclusiones

Es posible calcular una rotación paciente-específica de la prótesis balón-expandible en el momento del crimpado basándose en la TC preprocedimiento. De este modo, se logró evitar el mal alineamiento moderado o grave de las neo-comisuras y el solapamiento con el ostium coronario izquierdo en todos los casos.

Section snippets

INTRODUCTION

In recent years, the indications for transcatheter aortic valve implantation (TAVI) have been expanded from patients who are ineligible or at high risk for surgical aortic valve replacement to patients who have a lower risk profile.1, 2

Despite advances in technology and improvements in valve devices, several factors can affect the mid- to long-term durability of the prosthesis such as the degree of expansion, the geometry of the stent frame, calcifications, and left ventricular outflow tract

METHODS

The relationship among native aortic commissures and transcatheter heart valve (THV) commissures was analyzed in 10 patients undergoing TAVI with the Myval device. All patients were included in the accurate CA project approved by the local ethics committee and provided informed consent. Computed tomography (CT) based models were analyzed leading to: *a)* in silico model for TAVI simulation preprocedurally; and *b)* in vivo determination of the degree of CA and coronary overlap. Pre- and

RESULTS

A patient-specific clockwise or counter-clockwise rotation was performed to match the commissural posts of the prosthesis with the native commissures in the aortic root biomodel. Then, the TAVI procedure was performed as standard of care, after crimping the valve into the delivery system, as previously described, to achieve the predicted angle (figure 1).

As shown in table 1, in silico simulation suggested correct alignment in all patients and in vivo procedures demonstrated correct alignment in

DISCUSSION

CA is crucial for 2 reasons: *a)* commissural misalignment might be related to more difficult coronary reaccess if eventually needed and could be related to higher rates of central aortic regurgitation, greater residual gradients, and increased blood stagnation in the leaflets/sinuses of Valsalva, potentially linked to faster prosthesis degeneration[5]; *b)* coronary overlap occurring when coronary ostia are too close to the prosthesis commissural posts, is relevant if there is an eventual need for

CONCLUSIONS

CA of the balloon-expandable Myval TAVI device can be achieved based on the analysis of the CT allowing a patient-specific orientation of the valve when crimped. As a result, moderate and severe CMA and the risk of coronary overlap of the left main can be successfully avoided. Cross validation of this technique in larger series is ongoing

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AUTHORS' CONTRIBUTIONS

A. Redondo, C. Baladrón, and I.J. Amat-Santos conceived the original idea. S. Santos-Martínez, A. Redondo, E. Gonzalez-Bartol, A. Barrero, P. Sánchez-Luna, A. Revilla-Orodea, C. Baladrón, A. Serrador, J.A. San Román, and I.J Amat-Santos conducted the research. All authors approved the final version of the manuscript.

CONFLICTS OF INTEREST

I.J Amat-Santos is proctor for Meril Life, Medtronic, and Boston Scientific.

WHAT IS KNOWN ABOUT THE TOPIC?

- Commissural alignment (CA) has emerged as a topic of great interest in parallel with the growing number of low-risk patients treated with TAVI. The greater long-term survival implies an increased number of patients requiring coronary re-access and showing valve degeneration and need for TAVI-in-TAVI with the potential risk of coronary obstruction. While several strategies for CA have been developed for self-expandable

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