Validation of a computational model of transcatheter aortic valve implantation in bicuspid aortic valve disease

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Introduction: Transcatheter aortic valve implantation (TAVI) is expanding into younger patients, who often have bicuspid aortic valve (BAV) disease. Complex geometry and concurrent aortopathy make the treatment of BAV with TAVI challenging, with a high incidence of paravalvular leak (PVL) and permanent pacemaker (PPM) implantation. The development and validation of a computational model to simulate the deployment of the transcatheter aortic valve (TAV) in a patient-specific BAV geometry would allow for the identification of patients at risk for PVL and PPM and aid in identifying the optimal size and position of TAV for the patient’s geometry.

Materials and Methods: Pre- and post-procedural computed tomography (CT) scans were retrospectively collected from 37 BAV patients who had undergone TAVI. Patients were implanted with Lotus (Boston Scientific, Marlborough, MA), CoreValve, Evolut R and Evolut PRO (Medtronic, Minneapolis, MN) TAVs. For each patient, a computational model of the aortic root was generated and the interaction between the TAV and the patient-specific geometry simulated via finite element numerical simulations. A successive fluid dynamics simulation was used to simulate paravalvular regurgitation. The method described in this analysis is based on TAVIguide technology [1], with additional features added to the computational model to account for the BAV geometry. The simulations were run such that the deployed device matches the implant depth of the TAV device, as measured on the post-procedural CT scan. Measures of the TAV deformation at several frame locations were extracted from the simulation and compared to corresponding measurements obtained from the post-operative CT scans. Correlation between the simulation and post-procedural CT scans was quantified with a coefficient of determination ($R^2$) and assessed visually with a Bland-Altmann plot. The PVL values obtained from the fluid dynamics simulations were compared to those clinically measured at discharge and statistical significance assessed with a Mann-Whitney test. To analyze conduction abnormalities, a region of interest (ROI) was identified at the bundle of His location. The maximum pressure exerted by the TAV on the ROI and the percentage of the ROI subject to pressure by the TAV were extracted and compared to the clinical detection of conduction disturbances after the procedure [2].

Results and Discussion: There was good correlation between the predicted and actual post-operative measurements of the TAV frame perimeter ($R^2=0.84$) (Figure 1, left panel), confirming the reliability and predictive power of the presented method. The Bland-Altmann plot (Figure 1, right panel) showed no major bias.

Predicted PVL was lower in patients who developed none or mild PVL, when compared with patients who developed moderate or greater PVL (5 vs 36 mL/sec, p<0.001). For 19 patients it was possible to quantify the contact pressure parameters and, even though no statistical calculation has been performed due to the limited number of patients, the trend of the results show that the contact pressure and the percentage of the ROI subjected to contact pressure are likely to be reliable predictors for the development of conduction abnormalities.

Translational Impact: Our findings demonstrate that numerical simulations could be used by clinicians to risk-stratify patients with BAV who are being considered for TAVI, by identifying patients who are at risk for unfavourable clinical outcome. Furthermore, numerical simulations could be used to guide clinicians on TAV sizing and positioning in BAV geometry.

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