The Accuracy of Patient-Specific Computer Modelling in Predicting Device Size and Paravalvular Aortic Regurgitation in Complex Transcatheter Aortic Valve Replacement Procedures

Jorn Brouwer, MD *, Vincent J. Nijenhuis, MD *, Livia Gheorghe, MD, Jurrien M. ten Berg, MD, PhD, Benno J. W. M. Rensing, MD, PhD, Leo Timmers, MD, PhD, and Martin J. Swaans, MD, PhD

Department of Cardiology, St. Antonius Hospital, Nieuwegein, The Netherlands

ABSTRACT

Background: Transcatheter aortic valve replacement (TAVR) is an accepted treatment in patients with severe aortic stenosis. Dedicated and validated computer simulation modeling offers additional information, accurately predicting patient and device-specific calcium displacement, presence, and severity of paravalvular aortic regurgitation (AR) and conduction disturbances post TAVR. We retrospectively assessed whether patient-specific computer modeling accurately predicted the device size and paravalvular AR in certain complex TAVR procedures.

Methods: This single-center case series investigated retrospectively the accuracy of patient-specific computer modeling of six complex TAVR procedures with the self-expandable Evolut R (Medtronic, Minneapolis, USA) or mechanical expanded Lotus (Boston Scientific, Marlborough, USA). A dedicated patient-specific computer simulation was performed in each case and simulated the best fitting valve and predicted the presence and severity of paravalvular AR at different implantation depths. These simulation results were compared with procedural outcomes using transoesophageal echocardiography and aortography.

Results: The dedicated patient-specific computer model accurately predicted valve size and paravalvular AR (severity and location). In two cases, there was a significant paravalvular AR post-implantation with Evolut R 34 mm, which was correctly predicted by the model, suggesting that these cases were not suitable for TAVR. In four cases, we have switched to a larger valve during the procedure. The computer model, indeed, showed better results with these large valves.

Conclusion: Personalized computer can accurately predict valve size and paravalvular AR in complex cases and may, therefore, offer additional support during decision-making, possibly preventing ad-hoc intra-procedural change of device. Before clinical implementation, prospective validation is necessary in a larger study population.

Abbreviations: AR: Aortic regurgitation; TAVR: Transcatheter aortic valve replacement; MSCT: Multi-slice computer tomography; TEE: Transoesophageal echocardiography

ARTICLE HISTORY Received 14 October 2019; Accepted 30 April 2020

KEYWORDS Aortic valve disease; transcatheter aortic valve replacement; dedicated patient specific computer modeling; imaging; MSCT

Introduction

Transcatheter aortic valve replacement (TAVR) is an accepted treatment in patients with severe aortic stenosis.1–8 Despite this early successful growth, intra- and post-procedural clinical complications remain a relevant issue, with post-deployment paravalvular aortic regurgitation (AR) as one of the most important drawbacks. Moderate to severe postprocedural paravalvular AR is a strong predictor of acute and mid-term mortality.9,10 However, developments in next-generation devices and different sizing have successfully reduced the rate of paravalvular AR.5–8 On the other hand, the availability of different device types and sizes and consequent differences in device–host interaction, complicates pre-procedural planning. Currently, multi-slice computed tomography (MSCT) rendered scan of the heart is the standard method for the selection of the valve size.11 This method does not take into account any mechanical interaction between the device and host. For this purpose, a dedicated and validated computer simulation model offers additional information, accurately predicting patient and device-specific calcium displacement, presence, and severity of post-procedural paravalvular AR and conduction disturbances post TAVR.12–18

In the current case series, we retrospectively assessed whether patient-specific computer modeling and simulation accurately predicted the device size and paravalvular AR in certain complex TAVR procedures using the Medtronic Evolut R and Lotus Valve prosthesis.
Materials and methods

This single-center case series investigated retrospectively the accuracy of patient-specific computer modeling of six complex TAVR procedures with the self-expandable Evolut R (Medtronic, Minneapolis, USA) or the mechanically expanded Lotus Valve (Boston Scientific, Marlborough, USA). All patients referred for TAVR were discussed in a Heart Team, consisting of at least one cardiothoracic surgeon, interventional cardiologist, and imaging cardiologist. As standard work-up, pre-operative MSCT was performed for aortic annulus sizing, assessment of peripheral access feasibility using 3MENSIO (Medical Pie Imaging, Best, Netherlands) and also to generate a retrospective patient-specific computer model. Aortic annulus sizing, with the use of 3MENSIO, was performed by an experienced imaging cardiologist, who used the mean of three repeated perimeter-derived measurements.

The in-hospital TAVR database consisting of 1120 TAVR cases from 2007 to 2018 was retrospectively screened for complex cases. Cases were defined as complex when patients had large aortic annulus anatomy (upper limit of the largest valve size) with one of the following: (I) a significant residual paravalvular AR despite several repositioning maneuvers (N = 2), or (II) a periprocedural conversion to a large prosthesis due to persistent significant paravalvular AR or locking problem even after several repositioning attempts (N = 4). Patients with bicuspid aortic valve stenosis, with a periprocedural switch to a different prosthetic valve device (e.g. Evolut R to Lotus Valve) or with other implanted valve types than the Evolut R or Lotus Valve were excluded from this study.

HeartGuide (FEops, Ghent, Belgium) was used to retrospectively perform a patient-specific computer simulation of the TAVR procedure using the same pre-operative MSCT images, which includes image segmentation, finite element analysis, and computational fluid dynamics. Details of the software have been described previously. In summary, HeartGuide generated patient-specific 3D anatomical models from the MSCT images, containing LVOT, calcified native leaflets, ascending aorta, and coronary arteries (Mimics version 18.0, Materialize, Leuven, Belgium). Thereafter, finite-element computer modeling (Abaqus/Explicit version 6.12, Dassault Systèmes, Paris, France) was used to virtually implant an Evolut R or Lotus Valve in the 3D anatomical models, leading to a prediction of the device and aortic root deformation and contact pressure associated with conduction abnormalities. Potential paravalvular AR was quantified using computational fluid dynamics (OpenFOAM, v5, OpenCFD, Bracknell, United Kingdom), which modeled the diastolic blood flow with the aim of predicting the severity of post-procedural paravalvular AR based on the predicted TAVR device frame and aortic root deformation.

The patient-specific computer model provided an overview of the best fitting prosthetic valve size (based on aortic annulus measurements) and simulated this valve on three different implantation depths (low, medium, and high), with the corresponding prediction of the device and aortic root deformation, potential presence and severity of paravalvular AR, and contact pressure on the conduction system. In case of borderline aortic annulus measurements (more valve sizes possible), both valve sizes were simulated in order to compare the outcomes of both sizes. Implantation depth of the prosthetic valves was measured using fluoroscopy images during the procedure and is defined as the maximal distance between the non-coronary cusp and the intraventricular edge of the prosthetic valve. An implantation depth lower than 3 mm was considered as high, 3–5 mm as medium and more than 5 mm as low. Paravalvular AR predicted by the simulation model was described in milliliters per second (ml/s) of which a paravalvular AR more than 16 ml/s was considered as significant. Moderate to severe paravalvular AR (grade 3–4/4) on contrast aortography or transoesophageal echocardiography (TEE) was considered as significant. Procedural findings based on peri-procedural fluoroscopy images and transoesophageal echocardiography (TEE), were compared with the predicated simulation outcomes. The aim of this case series was to investigate if dedicated patient-specific simulation software could predict the procedural complexity in these TAVR cases.

All cases are described briefly and providing details of baseline, TAVR procedure, patient-specific computer simulation, and conclusion. Table 1 displays an overview of all cases.

All cases were retrospectively obtained from our in-hospital TAVR registry including all TAVR patients from our hospital. This registry was submitted to the Ethical committee who had no objection to the registry. From this registry, it is possible to investigate different objectives, such as this case series. According to the Dutch law (Wet Medisch-Wetenschappelijk Onderzoek met Mensen), no need for obtaining informed consent was necessary for patients in this registry and for this case series due to its retrospective character.

Results

Case 1

Baseline: A 77-old male, with known replacement of the aortic valve and aorta ascendens using a homograft, was referred to our hospital for a degenerated aortic valve homograft (insufficiency) in order to investigate the possibility of TAVR in this complicated anatomy. MSCT measurements of the aortic annulus lay within the range of an Evolut R 34 mm (calcium volume of 799.6 mm³) and were considered suitable for TAVR.

Procedure: During the procedure, an Evolut R 34 mm was implanted at low implantation depth (Figure 1A). Due to the large neo-LVOT, it was impossible to implant the valve higher. The valve morphology was round with a significant paravalvular AR, located between the left and non-coronary aortic valve cusp and the left and right coronary aortic valve cusp (Figure 1B,C).

Patient-specific computer simulation: Retrospective computer simulation model showed aortic annulus measurement outside the range of an Evolut R 34 mm, with no device deformity and significant paravalvular AR at all implantation depths (high 14.6 ml/s, medium 16.5 ml/s, low 26.0 ml/s)
located between the left and non-coronary aortic valve cusp and the left and right coronary aortic valve cusp (Figure 1D).

Conclusion: The computer simulation correctly predicted the significant paravalvular AR including its location, suggesting that this patient was not suitable for TAVR with an Evolut R 34 mm. The aortic valve measurements on the computer model were outside the range of this 34 mm valve in combination with less calcification, which can explain the complexity of the TAVR procedure.

Case 2

Baseline: A 74-year-old male, with a history of two times coronary bypass surgery and severe aortic valve stenosis was referred for TAVR. Based on MSCT measurements of the aortic annulus (calcium volume of 1179.8 mm³) (Figure 2A), implantation with an Evolut R 34 mm was suitable.

Procedure: An Evolut R 34 mm was implanted at medium implantation depth. Even after post-dilation, valve morphology was not completely round with a significant paravalvular AR located between the left and non-coronary aortic valve cusp (Figure 2B). Patient died 1 day after the procedure due to acute heart failure related to the significant paravalvular AR.

Patient-specific computer simulation: Retrospective computer simulation model showed aortic annulus measurements inside the range of an Evolut R 34 mm, with slight device deformity (Figure 2C). A significant paravalvular AR was observed at all implantation depths (high 22.7 ml/s, medium 22.4 ml/s, low 20.3 ml/s) located between the left and non-coronary aortic valve cusp (Figure 2D), suggesting that implantation with an Evolut R 34 mm was not suitable in this patient.

Conclusion: The computer simulation correctly predicted the valve morphology and significant paravalvular AR, including the location of paravalvular AR. Based on the patient-specific computer simulation, this patient was not suitable for TAVR with an Evolut R 34 mm.

Case 3

Baseline: An 81-year-old male was referred to our hospital for a severe aortic valve stenosis. MSCT measurements of the aortic annulus on the upper range of an Evolut R 29 mm with a calcium volume of 923.5 mm³ (Figure 3A). TAVR using an Evolut R 29 mm was chosen.

Procedure: During the procedure, we unsuccessfully attempted to implant an Evolut R 29 mm. Due to severe paravalvular AR and valve anchoring difficulties at different implantation depths, we decided to switch to the larger Evolut R 34 mm, which was implanted successfully at low implantation depth (Figure 3B). After deployment, post-dilation was necessary for optimizing valve morphology, with a good result and 2 residual non-significant paravalvular AR, located between the left and non-coronary aortic valve cusp and the left and right coronary aortic valve cusp (Figure 3C).

Patient-specific computer simulation: Retrospective computer simulation model showed aortic annulus measurement within the range of an Evolut R 34 mm, with a non-significant paravalvular AR at low implantation depth (11 ml/s) and a significant paravalvular AR at high and medium implantation.

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Table 1. Summary of the cases.

<table>
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<th>Case</th>
<th>1</th>
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<th>3</th>
<th>4</th>
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<tr>
<td>3Mensio</td>
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<td>- Calcium volume (mm³)</td>
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<td>923.5</td>
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<td>- Area (mm²)</td>
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<tr>
<td>- Mean diameter (mm)</td>
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<td>No paravalvular AR</td>
<td>Not completely</td>
<td>No paravalvular AR</td>
</tr>
</tbody>
</table>

Note. AR: Aortic regurgitation.
depth (high 16 ml/s, medium 19 ml/s), all located between the left and non-coronary aortic valve cusp and the left and right coronary aortic valve cusp (Figure 3D). This simulation would advise implantation with an Evolut R 34 mm at a low implantation depth.

Conclusion: Patient-specific computer simulation correctly predicted the paravalvular AR and its location at the actual implanted implantation depth. In cases where a low implantation depth is advised for the best result, the risk for conduction disorders post TAVR increase.
Case 4

Baseline: A 79-year-old male, with a history of two times coronary bypass surgery and severe aortic valve stenosis, was referred to our hospital for TAVR. Based on MSCT measurements of the aortic annulus (calcium volume of 1489.4 mm$^3$), implantation with a Lotus 25 mm was suitable.

Procedure: We unsuccessfully attempted to implant a Lotus 25 mm. It was unable to lock the valve in the native aortic valve, due to severe calcification (and significant paravalvular AR). After several attempts, we decided to switch to the larger Lotus 27 mm, which was successfully implanted. Implantation depth was medium and there was no paravalvular AR (Figure 4A,B).

Figure 3. Case 3. Legend: (A): 3MENSIO image of native aortic valve with calcification. (B): Contrast injection on fluoroscopy image with Evolut R 34 mm at low implantation depth. (C): Procedural TEE image of Evolut R 34 mm with a non-significant paravalvular AR on short axis. (D): Simulation of Evolut R 34 mm at low implantation depth with a non-significant paravalvular AR. TEE = transoesophageal echocardiography, AR = Aortic regurgitation.

Figure 4. Case 4. Legend: (A): Contrast injection on fluoroscopy image with Lotus 27 mm at medium implantation depth. (B): Procedural TEE image of Lotus 27 mm with no paravalvular AR on long axis. (C): Simulation of Lotus 25 mm at medium implantation depth with significant paravalvular AR. (D): Simulation of Lotus 27 mm paravalvular AR at medium implantation depth with no paravalvular AR. TEE = transoesophageal echocardiography, AR = Aortic regurgitation.
Patient-specific computer simulation: Retrospective computer simulation model showed aortic annulus measurements within the range of the Lotus 27 mm, with non-significant paravalvular AR at high implantation depth (9 ml/s) and no paravalvular AR at medium and low implantation depth (Figure 4D). The simulation also displayed the Lotus 25 mm, with significant paravalvular AR at high and medium implantation depth (36 ml/s and 28 ml/s) (Figure 4C) and non-significant paravalvular AR at low implantation depth (2 ml/s). According to the simulation, implantation with a Lotus 27 mm valve at medium implantation depth would be advised over a 25 mm or 27 mm at low implantation depth (higher risk of conduction disorders and equal paravalvular AR).

Conclusion: Based on patient-specific computer simulation a Lotus 27 mm would be advised in this patient. The simulation correctly predicted the outcome, with no paravalvular AR. It also showed that implantation with smaller Lotus 25 mm was less beneficial.

Case 5
Baseline: A 78-year-old male, with impaired left ventricular ejection fraction (<30%), was referred for TAVR. MSCT measurements of the aortic annulus lay within the range of both the Lotus 23 mm and 25 mm. In combination with severe calcification (calcium volume of 1795.9 mm$^3$) (Figure 5A), the TAVR Team decided on implantation with a Lotus 23 mm valve instead of the 25 mm.

Procedure: During the procedure, implantation with the Lotus 23 mm valve was unsuccessful. Due to severe calcification and severe paravalvular AR at different implantation depths (Figure 5B), we decided to switch to the larger Lotus 25 mm. Implantation depth was high, with a non-significant paravalvular AR located between the left and non-coronary aortic valve cusp (Figure 5C).

Patient-specific computer simulation: Retrospective computer simulation model showed aortic annulus measurements within the range of both the Lotus 25 mm and 27 mm. Simulation of the Lotus 25 mm showed a significant paravalvular AR at high, medium, and low implantation depth (38 ml/s, 24 ml/s and 15 ml/s, respectively), all located between the left and non-coronary aortic valve cusp and the right and non-coronary aortic valve cusp. The larger Lotus 27 mm displayed a non-significant paravalvular AR of 6 ml/s at all implantation depths (Figure 5D). Based on the patient-specific computer simulation, implantation with a Lotus 27 mm would be advised.

Conclusion: The computer simulation correctly predicted that a Lotus 25 mm or 27 mm was more suitable than the smaller Lotus 23 mm. On the other hand, paravalvular AR rates of the Lotus 25 mm were not predicted correctly. Paravalvular AR was less severe than predicted by the simulation model.

Case 6
Baseline: An 86-year-old female was referred to our hospital for TAVR. MSCT measurements of the aortic annulus lay within the range of a Lotus 23 mm with a calcium volume of 425 mm$^3$ (Figure 6A).

Procedure: During the procedure, we attempted to implant a Lotus 23 mm. During valve release, a valve pop-out occurred, suggesting undersizing. Therefore, we implanted a Lotus 25 mm with success at low implantation depth and no residual paravalvular AR (Figure 6B).

Figure 5. Case 5. Legend: (A): 3MENSIO image of native aortic valve with severe calcification. (B): Procedural TEE image of Lotus 23 mm with significant paravalvular AR on the long axis. (C): Procedural TEE image of Lotus 25 mm with a non-significant paravalvular AR. (D): Simulation of Lotus 25 mm at high implantation depth with a non-significant paravalvular AR. TEE = transoesophageal echocardiography, AR = Aortic regurgitation.
Patient-specific computer simulation: Retrospective computer simulation model showed aortic annulus measurements within the range of a Lotus 23 mm. All implantation depths showed a significant paravalvular AR (High 27 ml/s, medium 32 ml/s, and low 26 ml/s) (Figure 6C), suggesting that this valve is, despite the aortic valve measurements, not suitable in this patient. The computer model also simulated the larger Lotus 25 mm, with no paravalvular AR at all implantation depths (Figure 6D). Based on the patient-specific computer simulation, implantation with a Lotus 25 mm would be advised.

Conclusion: Based on patient-specific computer simulation a Lotus 25 mm would be advised in this patient. Valve size and paravalvular AR were correctly predicted by the simulation model.

Discussion

This case series showed that patient-specific computational modeling and simulation accurately predicted the device sizing and positioning in complex TAVR procedures using the Medtronic Evolut R and Lotus prosthesis. The TAVR procedure was classified as complex due to large aortic annulus anatomy (upper limit of the largest valve size), with even after several repositioning maneuvers a significant paravalvular AR or when a peri-procedural switch to a larger valve size occurred, due to significant paravalvular AR after several repositioning attempts. Computer modeling and simulation could prevent an ad-hoc intra-procedural change of device size due to patient-prosthesis mismatch, based on valve size selection by the physician (using MSCT and dedicated software for quantitative aortic root measurements).

Currently, static quantitative MSCT analysis aortic root is the recommended method for the selection of the valve size. Contrary, dynamic computational modeling and simulation in device selection allows for analysis of device-host interaction in terms of paravalvular AR, contact pressure and conduction disturbances, and coronary obstruction, based on the integration of the detailed geometric and biomechanical properties of the device and host. Tissue biomechanical properties are derived from experimental data, refined during validation studies. Biomechanical properties of the frame are derived from in vitro testing.

In patients with an aortic root at the end of the maximal MSCT derived perimeter range for device selection, it might be challenging to decide whether a TAVR might be feasible. In such cases, device undersizing might lead to incomplete apposition resulting in paravalvular AR, or even device embolization. We described two complex cases in which we implanted the self-expanding Evolut R 34 mm in large aortic valve anatomies. We encountered difficulties in finding the optimal implantation depth, and a significant paravalvular AR remained despite post-dilation in these patients. Computational analysis showed a larger perimeter derived area compared to those measured by the physician on MSCT. These areas fell outside the range of the Evolut R 34 mm, and the computational model did not find a suitable alternative device for these patients. Moreover, it predicted the significance and location of paravalvular AR correctly. Thus, in retrospect, pre-procedural analysis of these patients using computational modeling might have steered the Heart Team to a different treatment option.

In case the MSCT measurement lies in the equivocal range between two device sizes, using computational modeling might prevent the intra-procedural necessity to change the...
device size due to patient-prosthesis mismatch. We describe four cases in which we switched to a larger device size, due to significant paravalvular AR or locking problem even after several repositioning attempts. In three of these patients, computational modeling correctly predicted the most optimal and eventually implanted larger device size, and level and location of paravalvular AR. This was partly due to the finding that these three patients had bulky leaflets and sub-anular calcifications preventing the smaller device frame from optimal sealing. In one patient, using computational modeling we were advised to implant a larger device than eventually implanted, due to a predicted paravalvular AR with the smaller device. Intraprocedural paravalvular AR in this patient was not confirmed using TEE. However, paravalvular AR in computational modeling is based on MRI measurements, and the difference might be related to the finding that echocardiography is inferior to MRI for the assessment of AR and underestimates the actual degree of AR.20

Paravalvular AR is highly dependent on the patient-specific anatomy and calcification distribution.21 Calcium volume at the LVOT and leaflets, valve eccentricity, and device under-expansion are all predictors of paravalvular AR.22,23 Furthermore, the incidence of paravalvular AR depends on the device implantation depth, but seems to interact with both device and anatomical properties. For example, an increased rate of paravalvular AR was associated with a high device position in a number of studies.24,25 A computer simulation study by Mao et al. found similar findings,26 although Bianchi et al.27 found that high implantation of the Medtronic CoreValve favored paravalvular AR reduction in one patient. In the latter study, a high-positioned Sapien valve increased paravalvular AR jets in two patients, suggesting that the effect of implantation depth is device-related. Blackman et al. showed that higher implantation of the Lotus is associated with an increased rate of paravalvular AR.28 Contrary, Rocatello et al. found no differences in the rate of paravalvular AR between different implantation depths of the Lotus valve.29 Computer simulation differentiates with good accuracy in a different type of devices (approximately 72%).30,31

This case series shows promising results of patient-specific computer modeling in complex anatomical TAVR cases. However, these simulations were retrospectively performed and were procedural outcome was known, with its coherent limitations. More interesting is the accuracy of this software, when performed prospectively, in predicting the outcome of complex cases prior to the TAVR procedure. Of particular interest is the amount of false positive and false negative predictions, before implementing this software, when performed prospectively, in predicting the computer modeling software used in this report is not able to simulate these influences separately. Further expansion of the computer modeling features may be interesting, especially the addition of simulation of specific procedural actions such as pre- and post-dilation and their effect on final TAVR outcomes.

Conclusion
Our findings indicate that optimal device size selection using conventional MSCT quantitative aortic root measurements in patients with a complex valvular anatomy is difficult and might lead to an ad-hoc intra-procedural change of device size due to patient-prosthesis mismatch. Personalized computer simulation that incorporates device-host interaction can accurately predict paravalvular AR in complex cases with aortic root measurements at the extreme side or in the equivar range. Computer simulation may, therefore, offer additional support during decision-making, possibly preventing an ad-hoc intra-procedural change of device. However, before clinical implementation, prospective validation is necessary in a larger study population.

ORCID
Jorn Brouwer  http://orcid.org/0000-0002-7815-1031

Funding
The authors report no funding in support of this paper.

Disclosure statement
No potential conflict of interest was reported by the authors.

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