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Short communication

## A case study on implantation strategies to mitigate coronary obstruction in a patient receiving transcatheter aortic valve replacement

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## ABSTRACT

Coronary obstruction is a life threatening complication during and post-transcatheter aortic valve replacement (TAVR). The objective of this preliminary work is to investigate the mechanisms underlying coronary obstruction in a patient after TAVR, in whom coronary obstruction was confirmed in addition to highlighting the importance of pre-procedural planning. The aortic root of an 80-year old male patient with coronary obstruction during TAVR—where a 29 mm SAPIEN 3 was deployed—was segmented from Computed Tomography scans and 3D-printed with compliant material. Flow and pressure data were acquired in this 3D-printed model in-vitro using a pulse duplicator under physiological conditions for the cases: a 29 mm SAPIEN 3, a 26 mm SAPIEN 3 expanded with a 29 mm balloon, and a 31 mm Medtronic-CoreValve deployed annularly, supra and sub-annularly respectively. Only the CoreValve in sub-annular axial position and the 29 mm SAPIEN 3 yielded pressure gradients (PG) lower than 10 mmHg ( $6.76 \pm 0.52$  and  $5.72 \pm 0.13$  mmHg respectively) while the 26 mm SAPIEN 3, CoreValve in normal and supra-annular positions yielded higher PGs ( $15.5 \pm 0.48$ ,  $12.2 \pm 0.15$  and  $10.8 \pm 0.24$  mmHg respectively). 29 mm SAPIEN 3 implantation yielded an FFR value of  $45.7 \pm 0.6\%$ . However, 31 mm CoreValve in any of the three different annular positions yielded FFR values going from  $89.6 \pm 1.1\%$  in supra-annular position to  $98.3 \pm 1.1\%$  in sub-annular position. Implantation with a 26 mm SAPIEN 3 expanded with a 29 mm balloon also yielded an FFR of  $92.1 \pm 1.2\%$ . Coronary obstruction in this patient could have been prevented through usage of different valve types and/or through usage of a different combination of valve size-balloon sizes.

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### 1. Introduction

Transcatheter aortic valve (TAV) replacement (TAVR) emerged as an alternative to surgical valve replacement procedure that is highly invasive for high-risk patients (Dasi et al., 2017). Despite being percutaneous and less invasive, TAVR is associated with several adverse effects such as elevated pressure gradients, regurgitation, subclinical leaflet thrombosis and coronary obstruction (Dasi et al., 2017). Particularly, coronary obstruction is a life threatening (Ribeiro et al., 2013) complication during and post-transcatheter aortic valve replacement, that can occur when the TAV stent pushes the calcified native leaflets to partially or totally occlude the coronary ostium (Webb, 2007). Prevention of this adverse effect is indispensable. While coronary ostium height and sinus

of Valsalva size have emerged as predictive of the complication (Salemi and Worku, 2017), there is a need to better investigate the sensitivity of coronary obstruction with respect to TAV type, size, and positioning to help bring TAVR benefits to patients at risk. The objective of this preliminary work is to investigate the mechanisms underlying coronary obstruction in a patient after TAVR, in whom coronary obstruction occurred in addition to highlighting the importance of pre-procedural planning. In addition, this study aims to assess whether different deployment heights could have avoided coronary obstruction seen in this patient. The overarching goal of this study is to introduce pre-procedural patient-specific analysis as a pre-requisite for every patient case at high-risk of coronary obstruction.

### 2. Methods

From an institutional review board (IRB) approved database, the aortic root of an 80-year-old male patient in whom coronary

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obstruction during TAVR occurred (Fig. 1 and Video 1) was selected. Contrast in Fig. 1 and Video 1 was injected in the left coronary main to highlight the obstruction. The aortic root was segmented at the 70% phase from pre-operation Computed Tomography (CT) scans using anatomic modeling software (Mimics, Materialise, Belgium) and 3D-printed with compliant material using a Stratasys Connex Printer as shown in Fig. 2. Cusp calcification was generated from the patient-specific CT scans using rigid print material Vero-White clear (Stratasys, Farmington Hills, Mich) and soft tissue structures were replicated using a rubber-like material (TangoPlus FLX930, Stratasys). Further Methodology details can be found in previous publications (Hatoum et al., 2018). The patient's mean pressure gradient (PG) was 43 mmHg and the aortic valve area was calculated to be 0.56 cm<sup>2</sup>. He was treated with a 29 mm SAPIEN 3 TAV which immediately led to coronary obstruction. Pre-TAVR hemodynamics (Cardiac output 4 L/min; mean aortic pressure 71 mmHg, heart rate 81 beats per minute) were recreated through the 3D-printed aortic root with a pulse duplicator left heart simulator which included a physiological left coronary circuit as previously described (Hatoum et al., 2018). Briefly, the left coronary flow is controlled by a Starling resistor that was collapsed or expanded during specific intervals to match the changes in coronary flow during myocardial contraction or relaxation respectively. Sixty cycles of aortic and left coronary flow waveforms and pressure waveform data were acquired at 100 Hz. In order to explore novel strategies to mitigate the risk of coronary

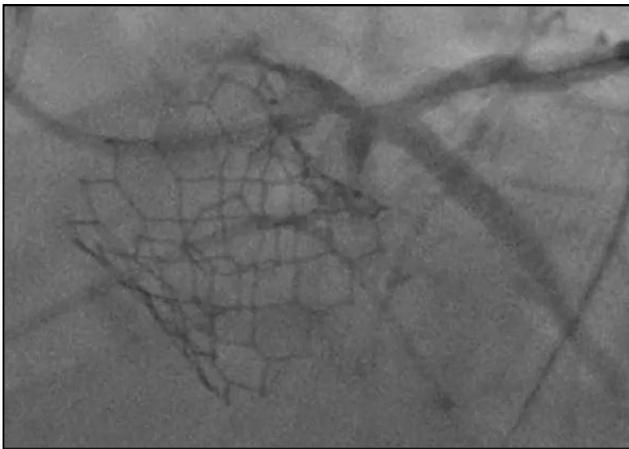


Fig. 1. Coronary obstruction at the time of the procedure.



Fig. 2. Representative 3D printed patient-specific aortic root model.

obstruction, measurements were repeated following implantation of (a) Edwards 29 mm SAPIEN 3; (b) 26 mm SAPIEN 3 expanded with a 29 mm balloon; and (c) Medtronic CoreValve 31 placed in normal, supra-annular and sub-annular positions respectively. Fractional flow reserve (FFR) was computed directly from measured coronary flow rate. FFR measures the maximum myocardial blood flow in the presence of a vessel obstruction as a percentage of the maximum flow in the case of a completely normal and unobstructed vessel.



Video 1. Coronary obstruction fluoroscopy video at the time of TAVR procedure. Contrast is injected from the left coronary main.

### 3. Results

Fig. 3 shows the results of PGs and FFRs of the different valves. Only the CoreValve in sub-annular axial position and the 29 mm SAPIEN 3 yielded PGs lower than 10 mmHg ( $6.76 \pm 0.52$  and  $5.72 \pm 0.13$  mmHg respectively) while the 26 mm SAPIEN 3, Core-Valve in normal and supra-annular positions yielded higher PGs ( $15.5 \pm 0.48$ ,  $12.2 \pm 0.15$  and  $10.8 \pm 0.24$  mmHg respectively).

The 29 mm SAPIEN 3 implantation yielded an FFR value of  $45.7 \pm 0.6\%$ . However, 31 mm CoreValve in any of the three different annular positions yielded FFR values going from  $89.6 \pm 1.1\%$  in supra-annular position to  $98.3 \pm 1.1\%$  in sub-annular. Implantation with a 26 mm SAPIEN 3 expanded with a 29 mm balloon also yielded an FFR of  $92.1 \pm 1.2\%$ .

### 4. Discussion

It is expected to obtain the lowest PG with the 29 mm SAPIEN 3 compared to the 31 CoreValve as the SAPIEN 3 balloon-expandable characteristic allows for more expansion upon implantation thus a higher orifice area.

Clinically, an ideal FFR is supposed to be nearly 100%. However, the FFR range of 75–80% is considered a gray zone, in which clinical judgment must complement quantitative assessments in forming the final treatment decision, thus the threshold adopted for this study is 75% (Shibata et al., 2015). Any value below 75% is considered to be indicating a probable inducible ischemia. The experiment recapitulated the patient's complication following the 29 mm SAPIEN 3 implantation with an FFR of  $45.7 \pm 0.6\%$ .

Despite being the appropriate TAV to be selected for this patient, the larger height of the 29 mm SAPIEN 3 frame may have contributed to the occlusion. The favorable FFR with 26 mm SAPIEN 3 with a 29 mm balloon implantation can be attributed to the TAV frame height shortening, significantly altering the apposition of the native leaflet thereby avoiding the occlusion. The self-expanding nature combined with the stent gaps characterizing the

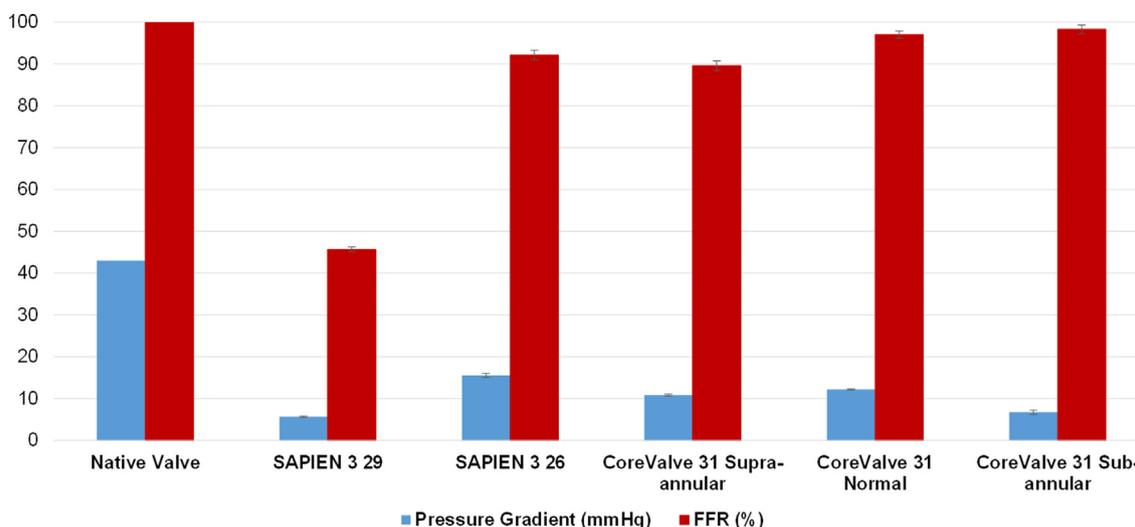


Fig. 3. Pressure Gradient and FFR results for the different valves.

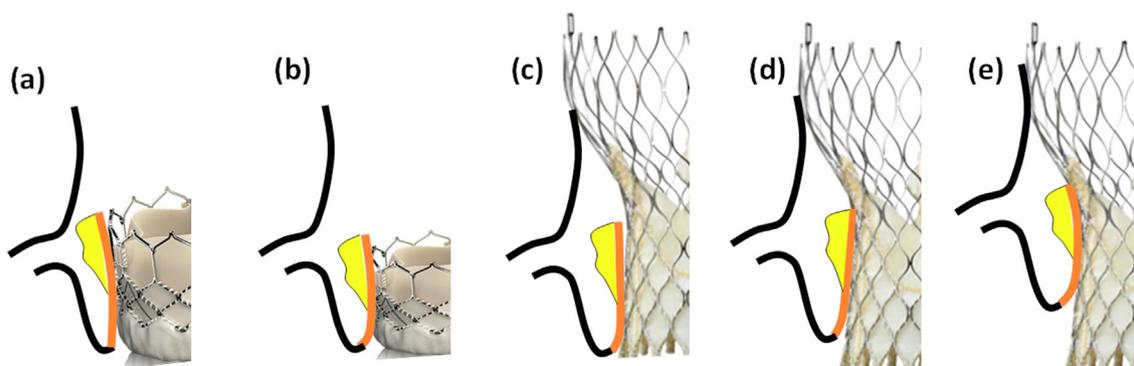


Fig. 4. Schematic showing the five different TAV cases in relation with the coronary ostium with (a) SAPIEN 3 29 mm, (b) SAPIEN 3 26 mm expanded with a 29 mm balloon, (c) CoreValve in supra-annular position, (d) CoreValve in normal position and (e) CoreValve in sub-annular position. The images of Medtronic CoreValve and Edwards SAPIEN 3 are taken from Refs. Available at: [Diagnostic and Interventional Cardiology](#) and Available at: [Edwards](#) respectively.

CoreValve stent, independently from axial position, may explain the improved FFR compared to that with the 29 mm SAPIEN 3. CoreValve supra-annular deployment yielded the lowest FFR compared to the normal and sub-annular positions. This may be attributed to several factors. One factor may be because of a higher radial force concentrated on the lower diamonds of the CoreValve stent. Deeper implants spare the native leaflets from stronger radial forces, explaining the decrease in likelihood of obstructing the coronary ostium. Another factor may be the space available for blood to flow towards the coronary ostium with deeper implants. The deeper the valve is implanted with respect to the sinotubular junction, the less likely that it will obstruct blood flow towards the ostium and more likely that the aortic sinus vortex will propagate towards the sinus entraining blood flow towards the coronary ostium (Hatoum et al., 2018). Fig. 4 summarizes these different deployment cases and their impact on the flow in the coronary ostium.

In this study, a confirmed case of coronary obstruction that occurred in a patient was not only re-created in-vitro, but alternatives that could have avoided this adverse outcome have been examined. The results of this study would generate new interest in pre-procedural biomechanical analysis for patients that may be at high risk of coronary obstruction. Knowing that patient-specific analysis is currently highly required, including such analysis for intra-procedural guidance and planning is not only benefi-

cial for a case like the one described in this study, but also for future clinical therapy. Overall, adverse outcomes such as the case highlighted in this study may be avoided when new knowledge and biomechanical insights are part of the heart team discussions.

## 5. Limitations

In this study, the CT scans were segmented in diastole. As the aortic root undergoes changes throughout the cardiac cycle, segmenting it at this particular phase is one of the limitations of this study. In addition, this study is a preliminary work with just one sample (case) that may not be applicable to other patients or geometries.

## 6. Conclusion

Coronary obstruction potential is not always easy to predict with traditional clinical means leading to unexpected risks once the TAV is deployed. In this specific study, it was demonstrated that coronary obstruction could have been mitigated with careful selection of another valve type or same valve type but with a smaller size combined with an appropriate balloon. Overall, pre-procedural patient-specific planning using biomechanical modeling is important to avoid such complications.

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## Conflict of interest statement

Dr. Juan Crestanello reports having grants from Medtronic, Boston Scientific and St Jude in addition to being part of the advisory board of Medtronic. Dr. Dasi reports having two patent applications on novel surgical and transcatheter valves. He also has a patent issued on vortex generators on heart valves and a patent application on super hydrophobic vortex generator enhanced mechanical heart valves. No other conflicts were reported.

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