

WHAT WOULD YOU DO?

TAVR in Small Anatomy

MODERATOR: MATIAS SZTEJFMAN, MD

PANELISTS: GUILHERME ATTIZZANI, MD; CRISTIAN BAEZA, MD; HEMAL GADA, MD, MBA; ANTHONY MAIN, MD; AND HENRIQUE BARBOSA RIBEIRO, MD, PhD

CASE PRESENTATION

An 83-year-old woman was referred to our institution for transcatheter aortic valve replacement (TAVR). She had hypertension and dyslipidemia as cardiovascular risk factors and had exertional dyspnea and chest pain when walking for 2 months before presenting. At the time of consultation, the patient was stable without angina or signs of heart failure. She lived by herself and was able to perform activities of her daily life.

Her medical history included breast cancer that was treated 11 years earlier with chemotherapy and 35 radiotherapy sessions. An electrocardiogram showed

a sinus rhythm of 70 bpm (Figure 1). Her kidney function was slightly impaired, with a glomerular filtration rate of 54 mL/min and a creatinine of 1.3 mg/dL.

Physical examination revealed that she had a low body weight and was frail, with a body mass index of 21.3 kg/m². She had a systolic murmur with absent S2.

The echocardiogram showed severe aortic stenosis and mild-to-moderate aortic regurgitation without any other valvulopathy. The peak and mean pressure gradients were 69 and 40 mm Hg (Figure 2), respectively, with a valve area of 0.6 cm². The ejection fraction was preserved at 64%.

Coronary angiography did not show significant lesions except for a 50% obstruction in the left anterior descending artery. Hemodynamic assessment showed a mean aortic gradient of 60 mm Hg (Figure 3). The Society of Thoracic Surgeons (STS) predicted risk of mortality was 15.4, mainly due to the patient's age, frailty, chest radiation, and chronic kidney disease.



Figure 1. Electrocardiogram trace before implantation.

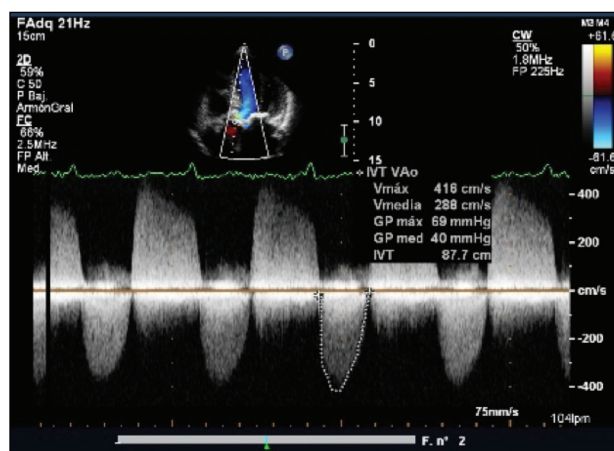


Figure 2. Echocardiogram before implantation.

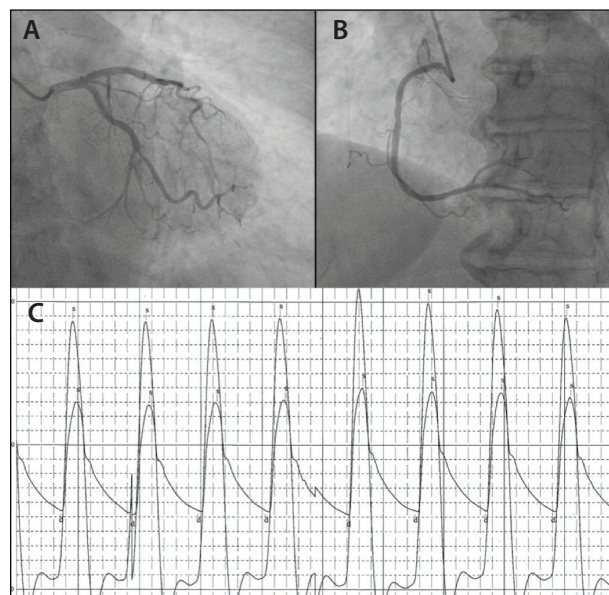


Figure 3. Angiogram (left [A] and right [B] coronary artery) and hemodynamic measurement (C) during catheterization.

We performed an angio CT to evaluate the feasibility of performing TAVR in this patient. The aortic annulus was not elliptical but was very small (the perimeter was 62 mm with an area of 299.1 mm², the perimeter-derived diameter was 19.7 mm, and the area-derived diameter was 19.5 mm) (Figure 4). The sinus of Valsalva width was average (25 mm). The left main height was 9.8 mm and the right coronary artery height was 13.7 mm (Figure 5). The bilateral femoral and iliac arteries had moderate calcification and an average diameter of 5.5 mm. The bilateral subclavian arteries were < 5 mm (Figure 6).

According to the data presented, do you think that this patient is a good candidate for transfemoral or nontransfemoral TAVR? Do you anticipate prosthesis-patient mismatch (PPM) due to the small annulus? What are the major complications that you can observe in this scenario?

Drs. Attizzani, Baeza, Main: The patient clearly has severe, symptomatic aortic stenosis. Based on her STS score, she is at high surgical risk and would be an appropriate TAVR candidate. We do not anticipate any difficulty performing the transfemoral approach in this patient based on the CT results. Her annulus size would likely put her at risk for PPM, and we would consider a self-expanding supra-annular valve for her.

The other concerning feature in this case is the low height of her left main coronary artery; however, because her sinuses of Valsalva are 25 mm, the chances of coronary occlusion with a self-expanding valve are very low.

Dr. Ribeiro: This is a very interesting case because a small annulus is where I think TAVR may have a major advantage over standard surgical aortic valve replacement (SAVR) in patients with aortic stenosis. This is because compared with SAVR, transcatheter heart valves (THVs) (especially those with supra-annular designs) provide much better hemodynamics with less PPM. Of note, there are limited femoral arteries due to the mean diameter of < 6 mm, so newer THVs with lower-profile sheaths are advisable, but the femoral approach could be chosen in this case. Given such lim-

ited femoral arteries, vascular complications could be anticipated; therefore, contralateral protection with a guidewire is recommended.

Dr. Gada: This is not an infrequently encountered clinical scenario. This is a patient of at least high surgical risk who would be considered for TAVR. The major issue is the risk of PPM with a small surgical or transcatheter aortic valve, which, if severe, significantly worsens quality of life and mortality. This has been well described by Herrmann et al in an analysis of the Transcatheter Valve Therapy registry, showing a valve size $\leq$ 23 mm as a major predictor of PPM.¹ Considering the commercially available devices in the United States, this patient would size for a 20-mm Sapien 3 device (Edwards Lifesciences) or a 23-mm CoreValve Evolut R/Pro device (Medtronic)

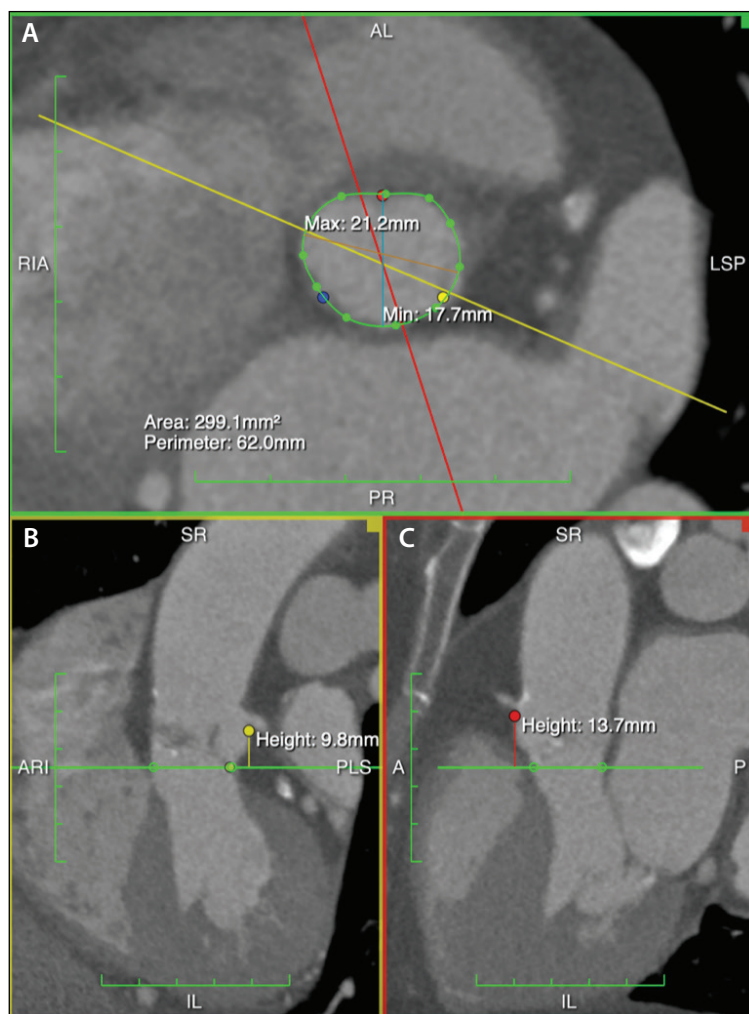


Figure 4. Angio CT measurements: annulus of 62 mm (A), left main takeoff of 9.8 mm (B), right coronary takeoff of 13.7 mm (C).

based on the instructions for use for sizing these particular valves using the previously described patient measurements. Additionally, the patient would likely size for a 19-mm surgical prosthesis or a 21-mm surgical prosthesis with a possibly challenging root enlargement.

The patient's transfemoral access anatomy appears relatively straightforward, with no significant tortuosity or protruding calcification in the iliofemoral distributions and adequate bilateral diameters. Of note, there is a branch of the profunda to be cognizant of near the top of the right femoral head. I believe that there is significant benefit to ultrasound-guided access and use it routinely to avoid vascular complications.

CASE CONTINUED

After a heart team discussion, we choose to perform transfemoral TAVR.

What is your device of choice: self-expandable or balloon-expandable?
What is your strategy: coronary protection, minimalistic TAVR or under total anesthesia, transesophageal echocardiography [TEE] or no echo during implantation, predilatation or direct implantation?

Dr. Gada: In this case, we have a significant difference with regard to hemodynamic outcomes between a self-expandable and balloon-expandable prosthesis. As shown by Hahn et al in the description of the anticipated functioning of THVs, a Sapien 3 implanted in this annular area would have a predicted mean gradient of 13.96 ± 5.28 mm Hg and an effective orifice area index of 0.80 ± 0.16 cm²/m², whereas the CoreValve Evolut would have a predicted mean gradient of 7.94 ± 3.10 mm Hg and an effective orifice area index of 0.99 ± 0.27 cm²/m².²

Therefore, I would choose the CoreValve Evolut in this case. Further supporting this choice would be the borderline coronary heights that would increase the risk of coronary occlusion with the Sapien 3. The risk of coronary occlusion would be low with the CoreValve Evolut because of adequate sinus of Valsalva width. I would perform this procedure with a "minimalist" approach because there are excellent data supporting the safety and efficacy of this approach regardless of valve choice.³ I do not believe TEE is necessary in this case, but I would perform transthoracic echocardiography (TTE) after valve deployment to assess valve function and to rule out significant paravalvular regurgitation. In this particular case, I do not believe there is a significant benefit to predilatation when using the CoreValve Evolut Pro, but further assessment of leaflet calcium burden would assist with this decision.

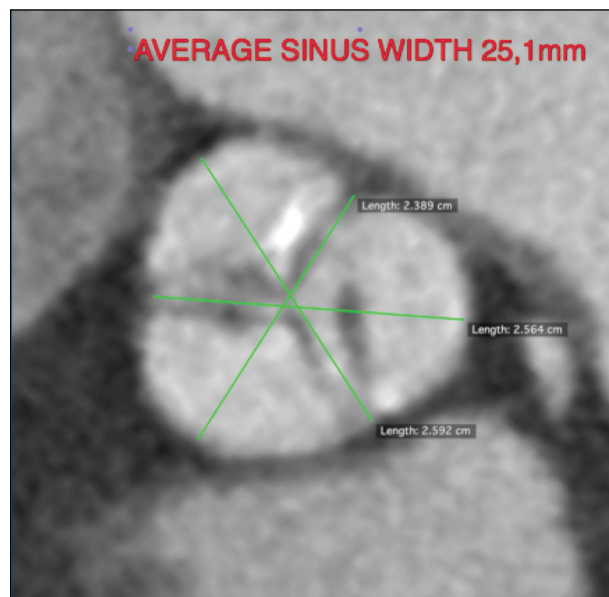


Figure 5. Measurements at the level of the sinus of Valsalva.

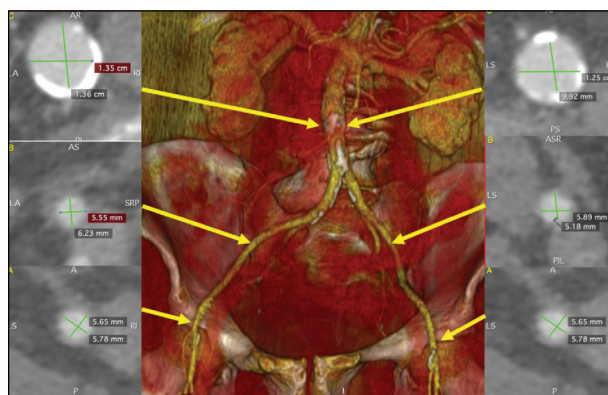


Figure 6. Angio CT of the peripheral vascular access.

Dr. Ribeiro: In such small anatomy, I would choose a THV with a supra-annular design, such as CoreValve Evolut R/Pro or Acurate neo (Boston Scientific Corporation), which are available in my region and provide good hemodynamics with lower gradients and larger aortic valve area. Given the limited diameter of the femoral arteries in this specific case, even with the advent of the new smaller-profile introducer sheath for the Acurate neo, I would prefer Evolut R because it can better navigate in such small iliofemoral anatomy. If the patient cooperates well with the procedure, is not very obese, and could tolerate conscious sedation well, I would definitely prefer a minimalistic TAVR approach with sedation and TTE guidance. Finally, given the very small sinus of Valsalva diameter with low left coronary height, I would consider protecting the left coronary with a guidewire, possibly by leaving an undeployed stent.

Drs. Attizzani, Baeza, Main: We would choose a 23-mm Evolut Pro. At our center, we perform all transfemoral TAVRs using the minimalist approach, and we perform all of our procedures in the cath lab with minimal procedural sedation. In some patients, we use no sedation, only local anesthesia, as well as TTE after valve deployment. We would deploy in the left anterior oblique view, aiming for shallow implantation to minimize the risk of paravalvular leak (PVL) and conduction disturbances. We would want to review the CT scan to examine the left ventricular out-flow tract (LVOT) to determine its size and the presence of any significant calcification but would elect to predilate with an 18- X 40-mm True Dilatation balloon (BD Interventional).

CASE CONTINUED

We chose a self-expandable valve. We predilated with a noncompliant balloon (18 X 40 mm) and performed balloon sizing (Figure 7).

? Does this image change your strategy in terms of coronary protection or device size choice? Would you recommend wire pacing in this case?

Drs. Attizzani, Baeza, Main: We do not routinely use sizing balloons in our center. Some centers find this to be helpful to size the valve and predict the risk of coronary obstruction, but this is not something that we have found to be necessary. We would continue with the plan

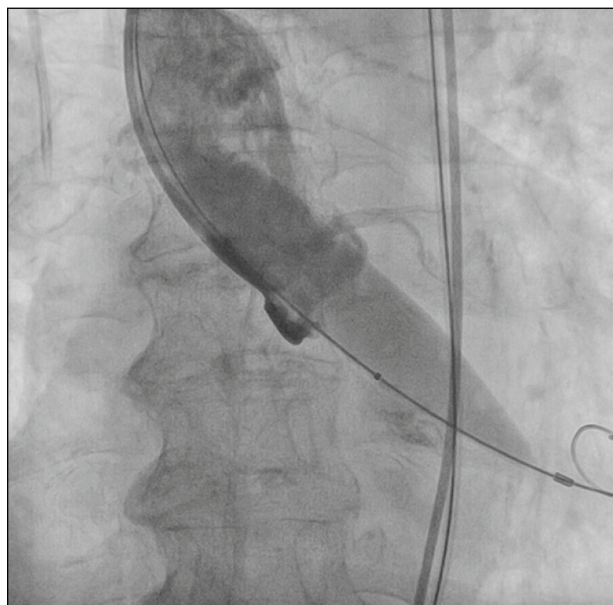


Figure 7. An 18- X 40-mm noncompliant balloon sizing and predilatation.

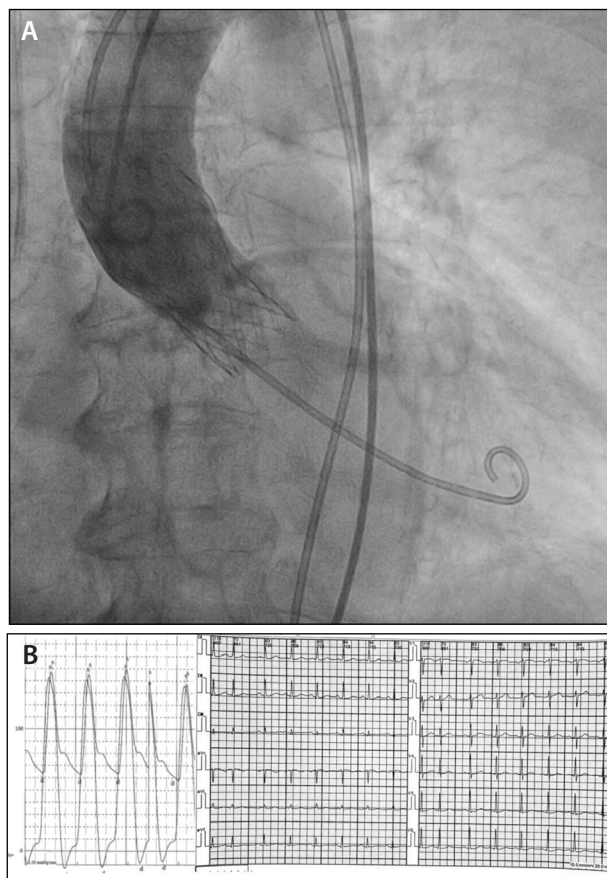


Figure 8. Final aortic root shot (A). Hemodynamics and electrocardiogram after valve deployment (B).

of the 23-mm Evolut Pro. We would not use wire pacing during valve deployment.

Dr. Gada: This is an undersized balloon to the annular plane, although not by much. It is encouraging that there is good flow into the left main on aortography while the balloon is inflated. The need for coronary protection appears less pressing, but it is definitely worth considering with regard to potential complications, should the patient have hemodynamic distress or new wall motion abnormalities after valve deployment.

It is always recommended to rapid pace balloon-expandable valve deployments. We tend to do the same with self-expanding prostheses after they have made annular contact (to a rate of 180 bpm, hemodynamics permitting) to prevent movement of the prosthesis and create a more efficient procedure. We have performed routine left ventricular wire pacing in these cases with no significant issues; capture is very reliable if the wire is correctly positioned.

Dr. Ribeiro: Predilatation in this case confirms that the annulus was small and that a 23-mm Evolut R was the correct device size. In addition, during balloon inflation and aortography, the coronaries were normally perfused. Therefore, a strategy of not protecting the left coronary could probably have been advocated during THV deployment. Wire pacing could be an elegant strategy in this case for balloon valvuloplasty and also for mild pacing during THV implantation.

CASE CONTINUED

After implanting an Evolut R valve (23 mm) in a shallow position, we achieved this result (Figure 8), with peak gradients of 11 mm Hg and mild regurgitation. There were no conduction disturbances.



Do you finish the case as it is or recommend performing postdilatation?

If you recommend postdilatation, what size and what type of balloon would you use? Would you transfer the patient to the coronary unit with a temporarily pace lead or not, and do you recommend fast-track discharge?

Drs. Attizzani, Baeza, Main: You obtained a very nice result: very shallow implantation, no conduction disturbances, and only mild PVL. As the valve continues to expand over the coming days and weeks, we think you will find that her valve gradients and PVL will further decrease. We would not postdilate based on these results. We have a standardized protocol in our center; if the patient develops or has a preexisting bundle branch block, we keep the transvenous pacemaker in overnight and reassess in the morning. In this case, we would be comfortable removing the pacemaker in the cath lab. As part of the minimalist approach, we discharge 90% of our transfemoral TAVR patients to home the next day. Assuming this patient has good vascular hemostasis at the end of the case, we do not see any reason she cannot be discharged to home the next day.

Dr. Ribeiro: The final result achieved in this case is excellent, with the THV looking well expanded and very

low gradients for such a small annulus. I would definitely accept this final result with no additional maneuvering. If there was a concern for the PVL grading, I would also calculate the aortic regurgitation index with hemodynamic assessment of the aortic and ventricular pressures. If postdilatation had been considered, I would have initially chosen a 20-mm semicompliant balloon. Concerning the very high implantation with narrow QRS on the electrocardiogram, I would consider retrieving the pace lead in the cath lab with a fast-track discharge to home within 2 to 3 days.

Dr. Gada: This appears to be an acceptable result with great hemodynamic results given the anatomic impairment. There seems to be great diastolic separation of left ventricular and aortic pressure and an early preserved aortic valve closure, which would be indicative of no hemodynamically significant aortic insufficiency. However, our goal is to leave the operating room with as little regurgitation as possible; therefore, if the jet was defined well on echocardiography and there are no worrisome features (eg, protruding LVOT calcium), I would tend to postdilate. I would choose an 18-mm noncompliant balloon in this case.

Electrocardiography performed postprocedure shows no significant conduction abnormalities. If we are comfortable with our depth of implantation, as we would be in this case, we would discontinue the pacing lead and recover the patient on the telemetry floor. This patient appears to be one we would fast track—targeting discharge the next day if there were no unanticipated complications. We would keep close follow-up with the patient, including a courtesy call within the first few days, an outpatient visit at 1 week, and another outpatient visit 1 month after the procedure. ■

1. Herrmann HC, Daneshvar SA, Fonarow GC, et al. Prosthesis-patient mismatch in patients undergoing transcatheter aortic valve replacement: from the STS/ACC TVT registry. *J Am Coll Cardiol*. 2018;72:2701-2711.
2. Hahn RT, Leipsic J, Douglas PS, et al. Comprehensive echocardiographic assessment of normal transcatheter valve function. *JACC Cardiovasc Imaging*. 2019;12:25-34.
3. Thiele H. A 2x2 randomized trial of self-expandable vs. balloon-expandable valves and general vs. local anesthesia in patients undergoing transcatheter aortic valve implantation—SOLVE-TAVI. Presented at: Transcatheter Cardiovascular Therapeutics (TCT) 2018; September 21–25, 2018; San Diego, California.

Matias Szejfman, MD

Director, Valve and Structural Heart Disease Center
Sanatorio Finochietto
Buenos Aires, Argentina
Director of Valve and Structural Heart Disease Center
Sanatorio Guemes
Buenos Aires, Argentina
szejfman@gmail.com
Disclosures: Proctor and consultant to Medtronic and Boston Scientific Corporation.

Guilherme Attizzani, MD

Director, Valve and Structural Heart Disease Center
Harrington Heart and Vascular Institute
University Hospitals
Associate Professor of Medicine
Case Western Reserve University
Cleveland, Ohio
guilherme.attizzani@uhhospitals.org
Disclosures: Proctor and consultant to Medtronic and Abbott Vascular.

Cristian Baeza, MD

Cardiovascular Surgeon
University Hospitals
Associate Professor of Surgery
Case Western Reserve University
Cleveland, Ohio
cristian.baeza@uhhospitals.org
Disclosures: None.

Hemal Gada, MD, MBA

Medical Director, Structural Heart Program
UPMC Pinnacle
Harrisburg, Pennsylvania
hemalgada@gmail.com
Disclosures: Consultant to Abbott Vascular, Bard, Boston Scientific Corporation, and Medtronic.

Anthony Main, MD

Structural Heart Disease Fellow
University Hospitals
Cleveland, Ohio
anthony.main@uhhospitals.org
Disclosures: None.

Henrique Barbosa Ribeiro, MD, PhD

Interventional Cardiologist
Heart Institute (InCor), University of São Paulo
Director, Valve and Structural Heart Disease Center
Samaritano Paulista Hospital
São Paulo, Brazil
hbribeiro@gmail.com
Disclosures: Proctor and consultant to Boston Scientific Corporation, Edwards Lifesciences, and Medtronic.