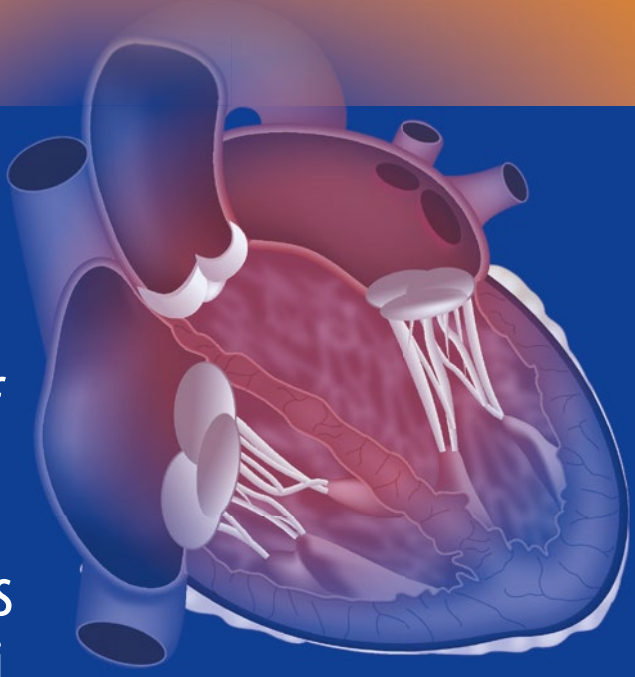
Complex Cases in Structural Heart Intervention



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To my beloved wife, Regina, and our kids, Ilay and Emma,

Thank you for turning our life into a beautiful and pleasant adventure and supporting me with every new idea that pops into my head.

–Ofir–

About the Editors

Koren Ofir, MD is a senior interventional cardiologist, researcher, and entrepreneur focusing on structural heart interventions. He has vast experience in coronary interventions, and, over the last few years, meticulously explored the field of structural heart intervention. Dr. Koren is a faculty lecturer at the Technion-Institute of Technology and a nominee for an associate clinical professor. He taught for many years and was repeatedly awarded as an outstanding lecturer by faculty, students, and colleagues. He conducted multiple national trials as a prime investigator and led as a subinvestigator for major international studies. Dr. Koren published numerous manuscripts and book chapters in leading peer-reviewed journals, presented them at major international conferences, and was awarded for his research achievements. Dr. Koren is the founder and CEO of D-flare, a company that aims to find a solution for heart failure patients.

Raj Makkar, MD is a world-renowned leading expert in interventional cardiology and one of the most widely cited researchers on the management of valvular heart disease. He has performed the largest number of transcatheter valve implantation (TAVI) procedures worldwide and has led the field in the pursuit of the best patient outcomes. In 2020, he performed the most transcatheter mitral valve repair procedures with the MitraClip system in the United States. He has been the national principal investigator for numerous clinical trials in structural heart interventions. He has authored over 500 manuscripts, abstracts, and book chapters in

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Vivek Patel, MS is a biomedical engineer who has a keen interest and expertise in transcatheter structural cardiovascular devices and imaging. Vivek has a strong level of knowledge, a diverse skill set, and solid research capabilities in structural heart disease intervention. Vivek Patel has contributed and reviewed multiple manuscripts for leading peer-reviewed journals. He has provided a key role in the national CT Imaging Core lab in numerous clinical transcatheter devices studies.

Danon Kaewkes, MD is a senior interventional cardiologist at the Department of Medicine of Khon Kaen in Thailand and a faculty member at Khon Kaen University. He has expertise in TAVR, edge-to-edge mitral repair procedure, and published multiple manuscripts in leading peer-reviewed journals. Dr. Kaewkes was a fellow in interventional cardiology at Cedars-Sinai Medical Center from 2019 to 2021.

Hasan Jilaihawi, MD is a senior interventional cardiologist at Cedars-Sinai Medical Center. He was one of the first two cardiologists to perform TAVI in the UK and has been performing structural heart interventions for over 15 years. He is involved in all aspects of cardiology, with a particular interest in advanced imaging of structural heart disease, complex valvular and coronary intervention, and device and patient selection within the novel field of transcatheter valve therapies. His international reputation in the field has earned him the prestigious responsibility of running the CT Corelab for the pivotal US trial of the Portico device, the world's first fully repositionable and retrievable TAVR, as well as the CT Corelab for China's first TAVR trial. He is co-founder and Executive Director of China Structural

Week, the largest online educational meeting for structural heart intervention worldwide. He has authored more than 140 manuscripts in peer-reviewed journals, including *the New England Journal of Medicine*, *the Journal of the American College of Cardiology*, and *the European Heart Journal*.

Jubin Joseph, MD is a senior interventional cardiologist with expertise in structural intervention. He completed undergraduate medical education at Cambridge and Oxford University before undertaking postgraduate clinical training in Oxford and London. Dr. Joseph has broad experience across the whole range of structural interventions. Since 2020, he has been working at Cedars-Sinai Medical Center with a particular focus on mitral and tricuspid intervention.

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Introduction

Structural heart interventions have grown exponentially over the past two decades as patients and physicians seek minimally invasive methods to treat a variety of cardiac pathologies. Due to an aging population and a decline in rheumatic heart disease, degenerative aortic stenosis and mitral regurgitation have emerged as the predominant valvular pathologies of the new era.

The transcatheter transfemoral technique for replacing stenotic and calcified aortic valves, and the transeptal edge-to-edge repair technique for treating regurgitant mitral valves have both demonstrated excellent procedural safety, clinical efficacy, and have been established as the gold standard therapies in certain patients.

These advances have helped to define the basic concepts for valvular heart interventions, and iterative improvements are constantly being pursued to improve patient outcomes and reduce procedural complications.

Our book provides a unique insight into the world of structural heart diseases using highly illustrated and detailed cases. We have included different clinical scenarios, discussed technical dilemmas, and shared our collective experiences as we continue to learn in this ever-evolving field.

We wish that these experiences may inform readers as they charter uncertain territory and ultimately benefit the patients we help.

Hope you enjoy the book and we wish you a pleasant reading.

Raj Makkar
Ofir Koren

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Part I
Aortic Valve

TAVR Procedure in a Patient with a Significant Large Aortic Valve Annulus

Danon Kaewkes, Robert Naami, and Andrew Luxhoj

1 Clinical Presentation

A 77-year-old male presented for a moderate aortic stenosis (AS) follow-up. The patient's medical history was notable for hypertension, hyperlipidemia, atrial fibrillation on a direct oral anticoagulant, and moderate AS regularly followed for 1.5 years. Three months prior to the follow-up, he underwent left-knee replacement surgery due to severe osteoarthritis at an outside hospital, which was complicated by cardiac arrest requiring cardiopulmonary resuscitation for 15 minutes and prolonged intubation for 15 days. He was told he did not have a myocardial infarction or stroke. Since discharge, he has continued to experience dyspnea with minimal exertion (5–10 steps).

2 Images and Supported Data

Transthoracic echocardiography (TTE) revealed normal left ventricular (LV) size and preserved LV systolic function with an LV ejection fraction of 55%. The aortic valve was trileaflet with moderate calcification. There was moderate to severe AS and mild aortic regurgitation. The aortic valve area (AVA) by the continuity equation was 0.81 cm^2, and the peak and mean gradient across the aortic valve were 45

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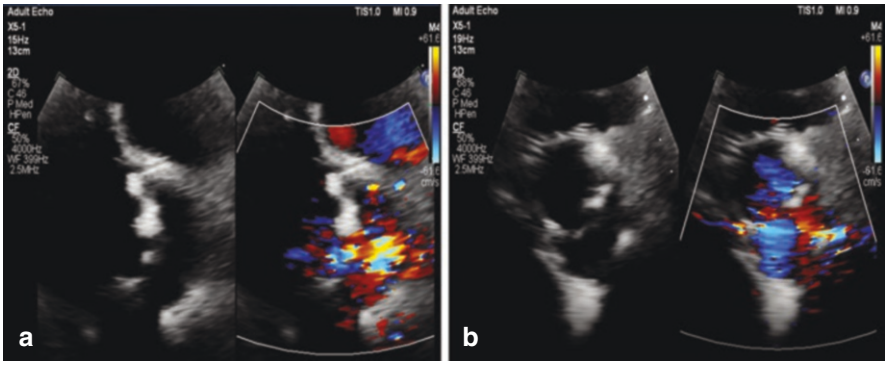

Fig. 1 Preprocedural transthoracic echocardiography. (**a**) Accelerated flow across the aortic valve consistent with severe AS in the parasternal long-axis, (**b**) short-axis view of aortic valve

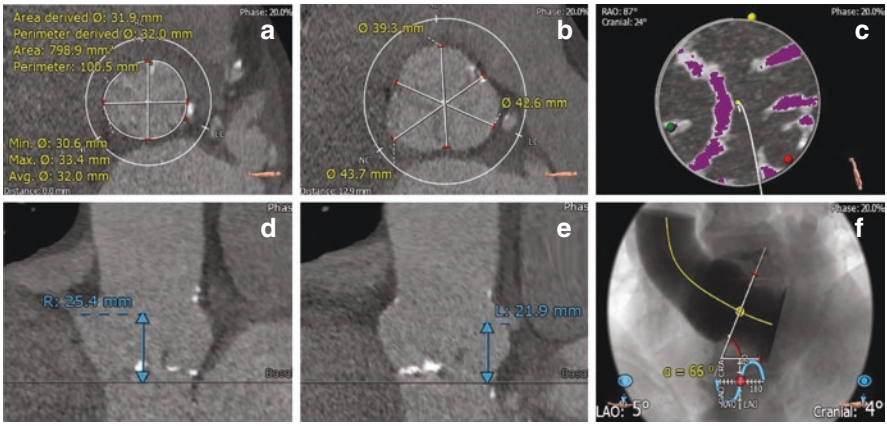

Fig. 2 Cardiac CT analysis. (**a**) Aortic annulus area and diameters; (**b**) sinus of Valsalva diameters; (**c**) aortic valve calcium; (**d**) right coronary height; (**e**) left coronary height; (**f**) aorto-ventricular angle

and 25 mmHg, respectively. Estimated pulmonary systolic pressure was 21 mmHg (Fig. 1). Cardiac computed tomography (CT) confirmed severe AS (AVA = 0.99 cm^2 by direct 3D planimetry). It showed a large aortic annulus with an area of 799 mm^2, a perimeter of 100 mm, and a mean diameter of 32 mm. The mean sinus of Valsalva, sinotubular junction, and LV outflow tract diameters were 42, 35, and 31 mm, respectively. The right and left coronary ostia were located 25 and 22 mm above the aortic annular plane, respectively. The calcium volume, measured over the annulus area using an 850 Hounsfield unit cut-off, indicated a moderate amount (187 mm^3) of calcium. A high aorto-ventricular angulation (66°) was also noted (Fig. 2). Iliofemoral arteries were adequate for transfemoral transcatheter aortic valve replacement (TAVR).

3 Preprocedural Consideration: Pitfalls, Dilemmas, and Challenges

"According to the heart team's assessment, the patient was 77 years old with moderate surgical risk as well as an oversized aortic annulus with respect to the available commercial transcatheter heart valves (THV). Based on our previous experiences, the balloon-expandable THV could be oversized to 32 mm. However, the patient strongly preferred TAVR to surgical aortic valve replacement. With this in mind, their aortic valve calcium seemed adequate for the THV anchoring, so we planned to perform TF TAVR with 29 mm Edward Sapien 3.

4 Technique

We successfully deployed the 29 mm Edward Sapien 3 using a standard TF TAVR technique along with 5 mL extra volume in the indeflator (Fig. 3). Postprocedural TEE revealed no central aortic regurgitation and no paravalvular leakage.

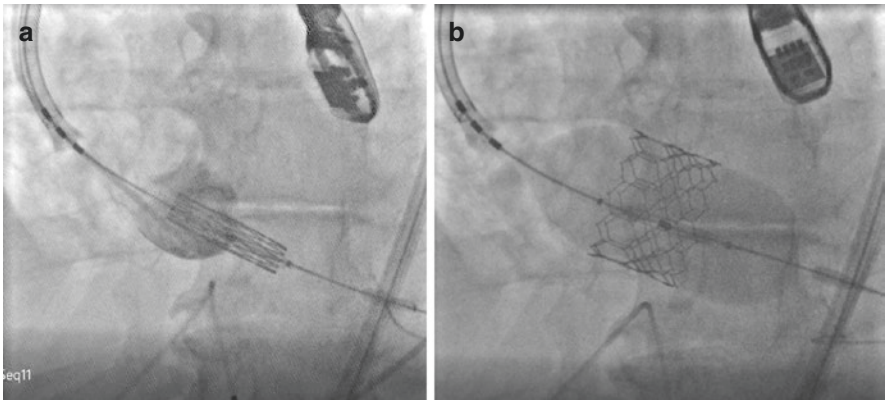

Fig. 3 Fluoroscopic images of TAVR procedure. (**a**) 29 mm Sapien-3 positioned at the aortic valve; (**b**) deployment of 29 mm Sapien-3 with 5 mL extra volume

5 Outcome and Follow-Up

Pre-discharge TTE presented normal LV systolic function. A good functioning bioprosthetic stented valve was detected in the aortic position. No paravalvular leakage was found (Fig. 4). The patient's symptoms improved and was discharged the next day.

6 Discussion

Currently, TAVR is an effective and less invasive treatment for patients with severe AS across all surgical risk categories [1]. Nonetheless, there is a paucity of choices for large aortic annuli. Using commercially available THVs beyond their limits for extra-large annuli (area $\geq$ 683 mm^2; perimeter $\geq$ 94.2 mm) is considered off-label and may increase risks of THV embolization and PVL after implantation [2]. Several studies reported TAVR results in patients with extra-large annuli and found that TAVR using 29 mm Sapien 3 and 34 mm Evolut was safe and feasible. The device success rate was 94%, with acceptable rates of post-procedure paravalvular leakage and 30-day and 1-year mortality [2–5]. One study reported higher prevalences of significant paravalvular leakage, second valve implantation, and valve embolization in patients implanted with Evolut than those implanted with Sapien 3 [2]. However, using Evolut may prevent the valve from flipping upside down and obstructing blood flow. In addition, the strategy of using Sapien 3 instead of Evolut may be beneficial in cases with extensive annuli yet minimal leaflet calcification. In this patient, the valve calcification facilitated an anchoring of Sapien 3 and resulted in successful implantation without immediate complications. Our case demonstrated the feasibility of TAVR using a balloon-expandable valve in a patient with an extra-large aortic annulus. Preprocedural planning with cardiac CT is crucial for appropriately selecting patients, devices, and techniques.

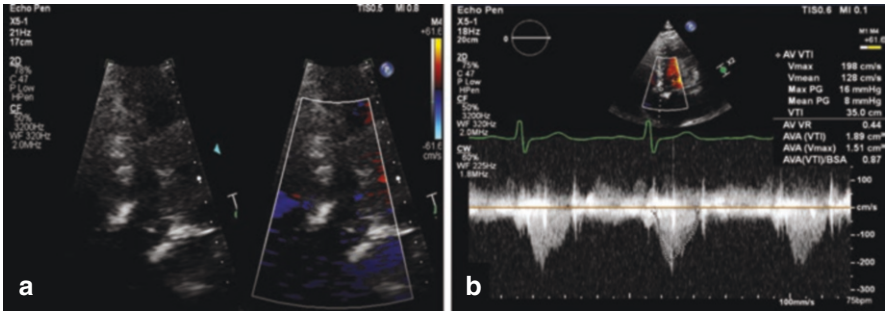

Fig. 4 Pre-discharge TTE. (**a**) A bioprosthetic stent valve can be seen in the aortic position without paravalvular leakage; (**b**) no significant gradient across the aortic valve

Key Points

- TAVR in patients with extra-large aortic annuli is feasible.
- In the real world, 29 mm Sapien 3 and 34 mm Evolut R are the commercially available THVs used off-label to treat patients with extra-large annuli.
- Preprocedural cardiac CT is crucial for selecting appropriate patients, devices, and techniques in patients with extra-large annuli.

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TAVR in Patients with Bicuspid Aortic Valve

Ofir Koren, Edmund Naami, and Vivek Patel

1 Clinical Presentation

The patient is a 69-year-old male with a past medical history of aortic stenosis, chronic diastolic heart failure (NYHA Class III), paroxysmal atrial fibrillation (not anticoagulated), hypertension, hyperlipidemia, prostate cancer, and childhood tuberculosis. The patient was referred for an evaluation of aortic stenosis and to discuss treatment options. Recent left heart catheterization showed no significant obstructive artery disease. Given worsening shortness of breath, he was considered for aortic valve intervention.

1.1 Images and Supported Data

Pre-procedural TTE revealed an aortic valve area of 0.5 cm^2, mean gradient of 53 mmHg, a peak gradient of 80 mmHg, and preserved ejection fraction (Video 1, Fig. 3c). Cardiac reconstructed CT indicated an annular mean internal diameter of

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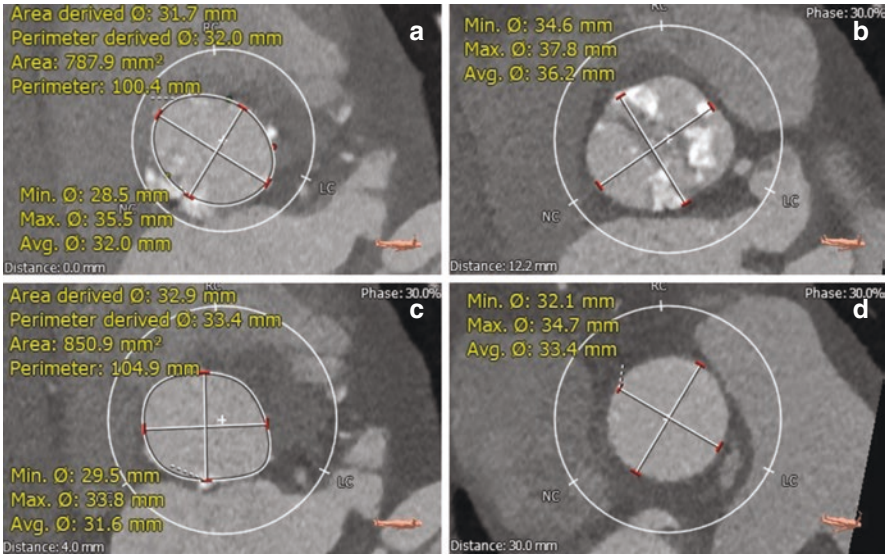

Fig. 1 Reconstructed CT images. (**a**) Bicuspid AV area of 787 mm^2 and a 100.4 mm perimeter. (**b**) The left and right coronary cusps are fused by calcified raphe. (**c**) The LVOT area is 850 mm^2. (**d**) Sinotubular junction area is 850 mm^2

32.0 mm, area of 787.9 mm^2, and perimeter of 100.4 mm. The following mean diameters were measured: 36.2 mm at the sinus of Valsalva, 31.6 mm at the left ventricular outflow tract, and 33.4 mm at the sinotubular junction dimension. The left ventricular outflow tract was measured with an area and perimeter of 850.9 mm^2 and 104.9 mm, respectively (Video 2, Fig. 1). The maximal diameter of the ascending aorta was measured to be 45.0 mm. The right and left coronary ostia originated 22.0 and 21.1 mm above the annular plane respectively. The aortic valve demonstrated severe calcification and measured 1961.8 Housefield units (Fig. 2).

1.2 Pre-Procedural Consideration

The patient was evaluated by CT surgery and deemed to be at low surgical risk; however, the patient adamantly refused cardiothoracic surgery. Thus, the patient was considered for transfemoral TAVR using FDA-approved Edwards Sapien S3 bioprosthesis. Transfemoral access was deemed feasible (Fig. 2f).

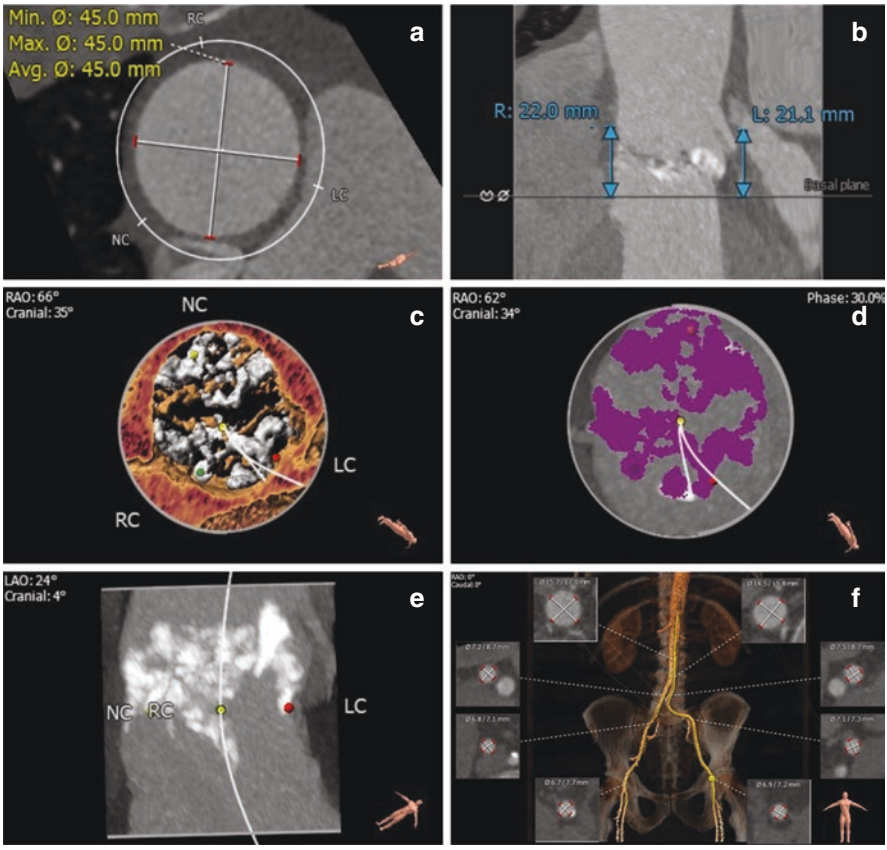

Fig. 2 Reconstructed CT images. (**a**) Maximal diameter of the ascending aorta, (**b**) the coronary artery height, (**c**) calcium distribution of the aortic valve, (**d**, **e**) the extent of valve calcification, (**f**) the dimension of the iliofemoral arteries

2 Outcome and Follow-Up

After initiating general anesthesia, a transesophageal echocardiographic probe was advanced into the mid-esophagus in order to obtain and record baseline images including aortic annulus measurements and aortic valve gradients (Fig. 3). Aortic annulus measurement was consistent with the previous CT angiographic study.

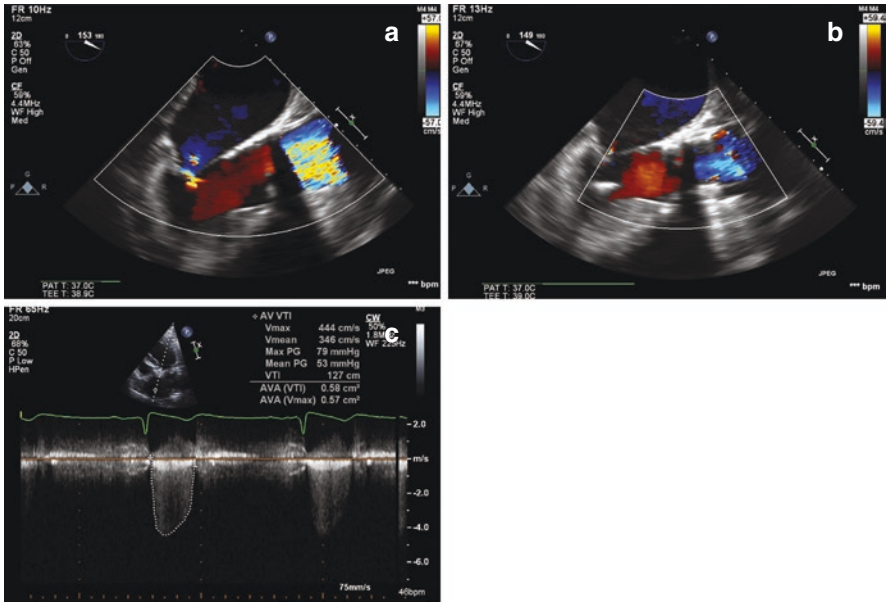

Fig. 3 TEE views before the TAVR procedure. (**a**, **b**) Aortic valve anatomy and color Doppler flow across aortic valve, (**c**) the pressure gradient over the AV

After obtaining femoral access, a 23 mm × 4.0 cm Z-Med II balloon was advanced across the stenotic aortic valve. With rapid pacing at 180 beats per minute, the balloon was inflated twice (Video 3, Fig. 4a, b). Next, a 29-mm Edwards Sapien S3 valve was positioned across the stenotic aortic valve, and was deployed using the standard technique (−5 mL in the inflation device) (Video 4, Fig. 4c). A post-procedure TEE revealed reduced aortic stenosis, no central aortic regurgitation, and no paravalvular regurgitation (Video 5).

TTE 30 days following the procedure measured a mean aortic valve gradient of 14 mmHg (Fig. 5). A cardiac reconstructed CT at 1-year follow-up demonstrated a well seated transcatheter heart valve (THV) within a calcified aortic annulus. The THV inner mean diameter and annulus area were 23.5 mm and 574.2 mm^2, respectively. The ascending aortic aneurysm showed no change in dimensions (Video 6, Fig. 6).

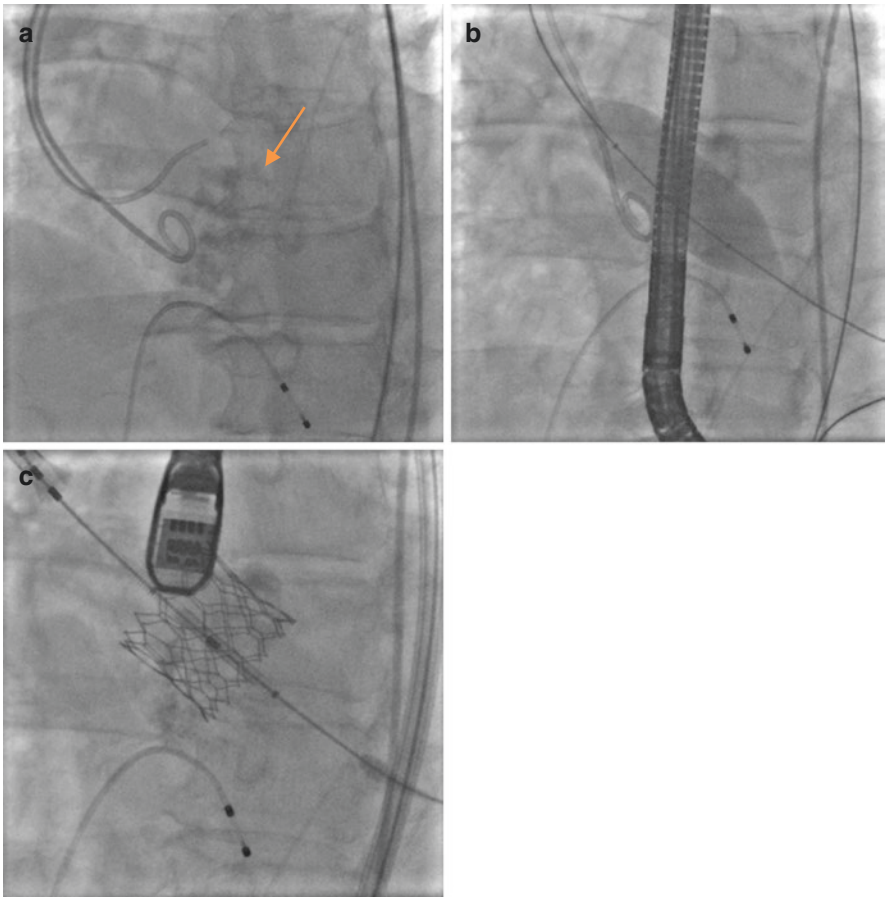

Fig. 4 Fluoroscopy views of the TAVR procedure. (**a**) The extent of calcification (yellow arrow), (**b**) pre-procedural AV dilatation, (**c**) a Sapien-3 THV seated in an aortic valve position

3 Discussion

Until recently, transcatheter aortic valve replacement in patients with bicuspid aortic valve stenosis had been the subject of controversy. The challenge of TAVR in bicuspid valves stems from the elliptical valve orifice that impedes device placement and asymmetric calcifications that serve as a potential embolic source during device deployment. Calcification is typically observed in the raphe and left cusp. Elevated left coronary cusp calcification has been associated with an increased risk for permanent pacemaker implantation following TAVR [1].

Previous studies have suggested that the first-generation TAVR valves had worse outcomes in patients with bicuspid aortic valves. However, newer-generation valves might have outcomes similar to those seen in patients with tricuspid valves [2].