

## Case Report

# First in Greece Transcatheter Aortic Valve Implantation using the CoreValve Evolut-R Retrievable and Repositionable Bioprosthesis with the InLine Sheath and the EnVeo Loading Guiding Catheter: A Major Advantage for Small-Diameter Access Vessels

MANOLIS VAVURANAKIS<sup>1</sup>, DIMITRIOS A. VRACHATIS<sup>1</sup>, GERASIMOS SIASOS<sup>1</sup>, SOPHIA VAINA<sup>1</sup>, KONSTANTINOS FILIS<sup>2</sup>, FRAGISKA SIGALA<sup>2</sup>, KONSTANTINOS KALOGERAS<sup>1</sup>, ANGELOS-MICHAIL KOLOKATHIS<sup>1</sup>, CARMEN MOLDOVAN<sup>1</sup>, THEODORE G. PAPAIOANNOU<sup>1</sup>, CONSTANTINA AGGELI<sup>1</sup>, DIMITRIOS TOUSOULIS<sup>1</sup>

<sup>1</sup>First Department of Cardiology, <sup>2</sup>First Department of Propaedeutic Surgery, Vascular Surgery Division, Hippokraton Hospital, National & Kapodistrian University of Athens, Greece.

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We report the first TAVI procedure in Greece to use the CoreValve Evolut-R (23 mm profile) bioprosthesis with the InLine sheath and the EnVeo loading guiding catheter in a patient with small anatomical characteristics (aortic annulus, access vessel) and severe comorbidities. The procedure was successfully conducted under general anesthesia through a surgically prepared, extensively calcified, left femoral artery.

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Address:  
Manolis Vavuranakis

13 Astypaleas St.  
145 69 Anoixi, Attiki  
Greece  
[vavouran@otenet.gr](mailto:vavouran@otenet.gr)  
[dvrachatis@gmail.com](mailto:dvrachatis@gmail.com)

Since the advent of transcatheter aortic valve implantation (TAVI), the subgroup of patients who are rejected for aortic stenosis correction is continually shrinking. Nevertheless, patients with small anatomical characteristics may not be eligible for TAVI.

First generation TAVI devices would not allow the procedure in patients with an aortic annulus <20 mm, while sheaths larger than 18 F required surgical cut-down and quite a large diameter. Once 18 Fr sheaths were introduced, true percutaneous TAVI procedures were possible.<sup>1</sup> Technical advances made upgraded bioprosthetic devices available and provided introduction systems that enabled truly percutaneous TAVI procedures in a wider “anatomical” substrate of patients.<sup>2</sup> Indeed, introduction systems that feature a

14 Fr equivalent diameter profile are currently available. In addition, some of the new devices have been equipped with the benefit of repositionability and/or retrievability during implantation. Furthermore, a wider range of bioprostheses profiles has been developed, which may be accommodated within the native aortic valve, even in the case of a small aortic annulus.

We describe the first implantation in Greece of a CoreValve Evolut R device (Medtronic Inc.), suitable for small diameter access arteries, with retrievability and repositionability capabilities, which was implanted in a patient with several comorbidities and anatomical “obstacles”.

## Case presentation

A 79-year-old female with symptomatic

(New York Heart Association classification III) severe aortic stenosis was referred to our department for evaluation. The patient's medical history included coronary artery bypass grafting (CABG), right carotid endarterectomy, arterial hypertension, non-insulin-dependent diabetes mellitus and dyslipidemia. At baseline echocardiography, the left ventricular ejection fraction was ~50%, aortic valve area was 0.59 cm<sup>2</sup>, and mean and peak aortic valve gradients were 47 and 83 mmHg, respectively. The logistic EuroSCORE was estimated to be 29.75%.

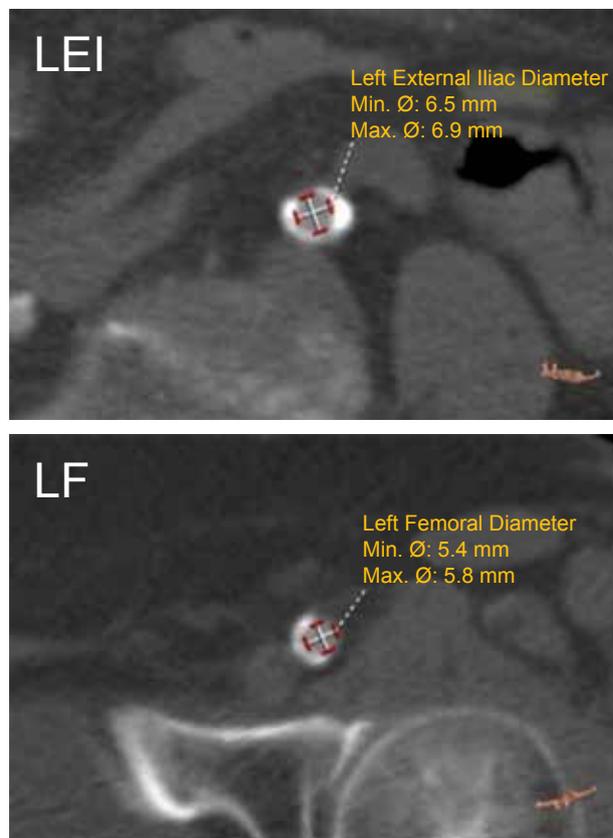
Left heart catheterization revealed a patent left internal mammary graft (to the left anterior descending artery) and a saphenous vein graft (to the right coronary artery). Multislice computed tomography (MSCT) showed an aortic annulus diameter (min × max) of 17.0 mm × 22.4 mm with an aortic annulus perimeter of 62.1 mm (derived average diameter 19.8 mm); coronary ostia height of 10.6 and 12.8 mm for the left and right coronary arteries, respectively. The left subclavian, right and left common iliac, external iliac and femoral arteries were severely calcified and had small diameters that would exclude the use of 18 Fr sheaths for transfemoral TAVI (Table 1; Figure 1).

Taking into account the small aortic annulus size and the potentially endangered coronary ostia, the CoreValve Evolut R 23 mm device was chosen for its repositionable and retractable capabilities. This choice was also dictated by the small available access route of the left femoral artery, which could be accessed with the (narrowest available) 14 Fr introduction sheath of the aforementioned device. Nonetheless, in view of the extensive and circumferential vessel calcification, surgical cut-down was decided upon. This approach provided direct left femoral artery evaluation and precise identification of a relatively safe arterial puncture site.

The procedure was conducted under general anesthesia and transesophageal echocardiography (TEE) was used to assess the aortic valve pre- and post-implantation. After surgical preparation of the left femoral artery, the puncture site was guided by direct palpation and tactile sensation of the arterial wall texture, in order to avoid calcification at the entry point (Figure 2A). Subsequently, balloon aortic valvuloplasty was performed through a 14 Fr sheath (Figure 2B). The 14 Fr sheath was then removed and the EnVeo-R™ delivery catheter system, which houses the capsule in which the bioprosthesis is loaded, was inserted, while contact between its back end and

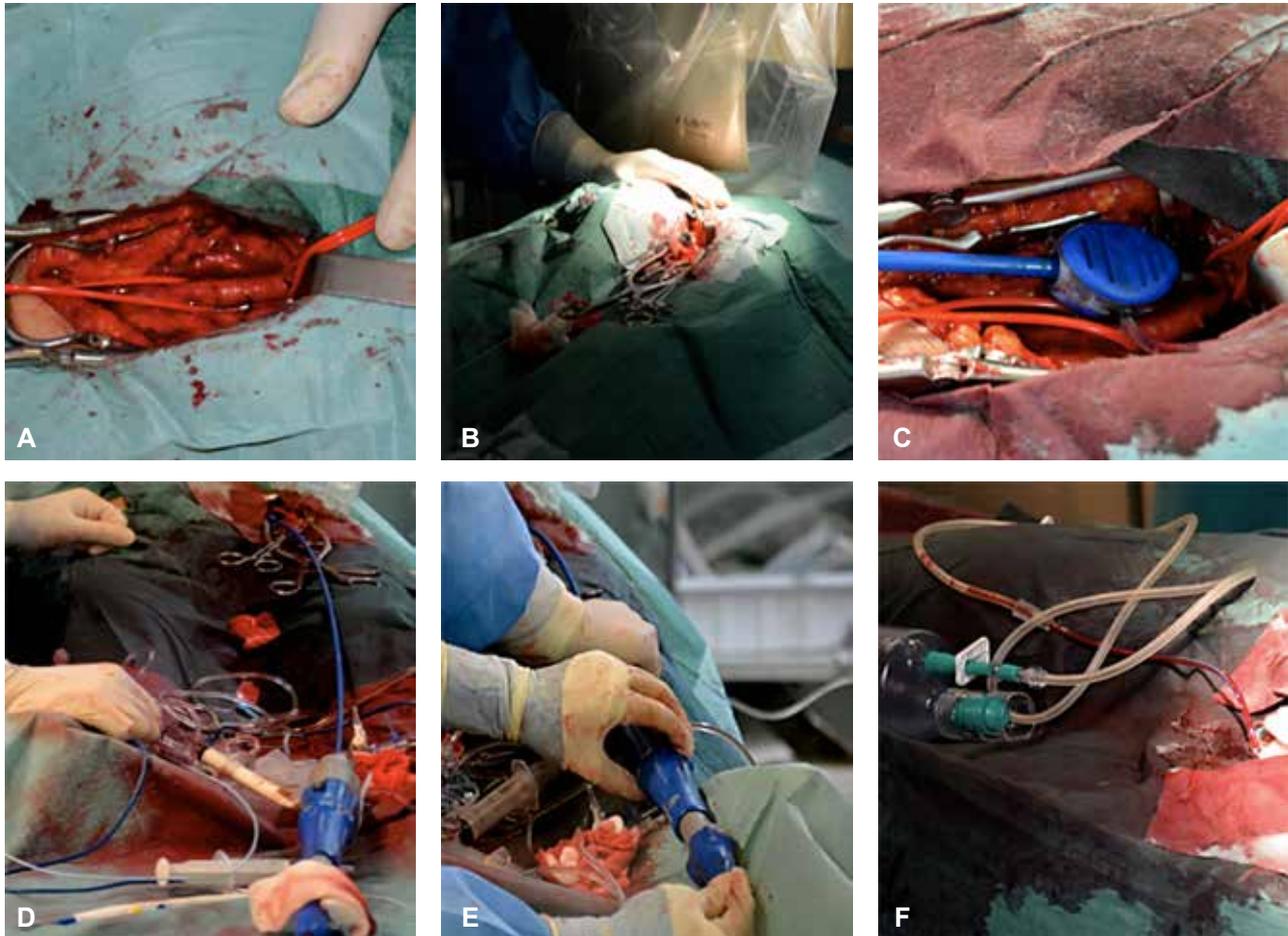
**Table 1.** Multislice computed tomography arteriography measurements.

Artery	Minimum diameters (mm)
Left subclavian	5.3 × 5.3
Left common iliac	4.8 × 7.3
Left external iliac	6.5 × 6.9
Left femoral	5.4 × 5.8
Right common iliac	3.6 × 4.5
Right external iliac	4.1 × 4.5
Right femoral	5.3 × 5.8



**Figure 1.** Multislice computed tomography evaluation of left external iliac (LEI) and femoral (LF) arteries.

the InLine™ (14 Fr equivalent sheath) was maintained during the whole insertion process (Figures 2B-2E, 3). When the InLine sheath was fully inserted, the CoreValve Evolut-R 23 mm device was advanced and successfully deployed within the native aortic valve (Figure 4). There was no need for repositioning during prosthesis deployment, since fluoroscopic data indicated optimal positioning. TEE was also used to assess the good functionality of the implanted prosthesis and to exclude the existence of any major paravalvular leak (Figure 5). Finally, the access vessel was surgically secured and a drain tube was placed



**Figure 2.** A: Surgically prepared left femoral artery; B: 14 Fr sheath used for balloon valvuloplasty; C: InLine 14 Fr equivalent sheath (18 Fr outer diameter) introduced into the femoral artery; D: EnVeo-R delivery catheter system introduced into the femoral artery; E: EnVeo-R system during prosthesis deployment; F: Surgical drain.

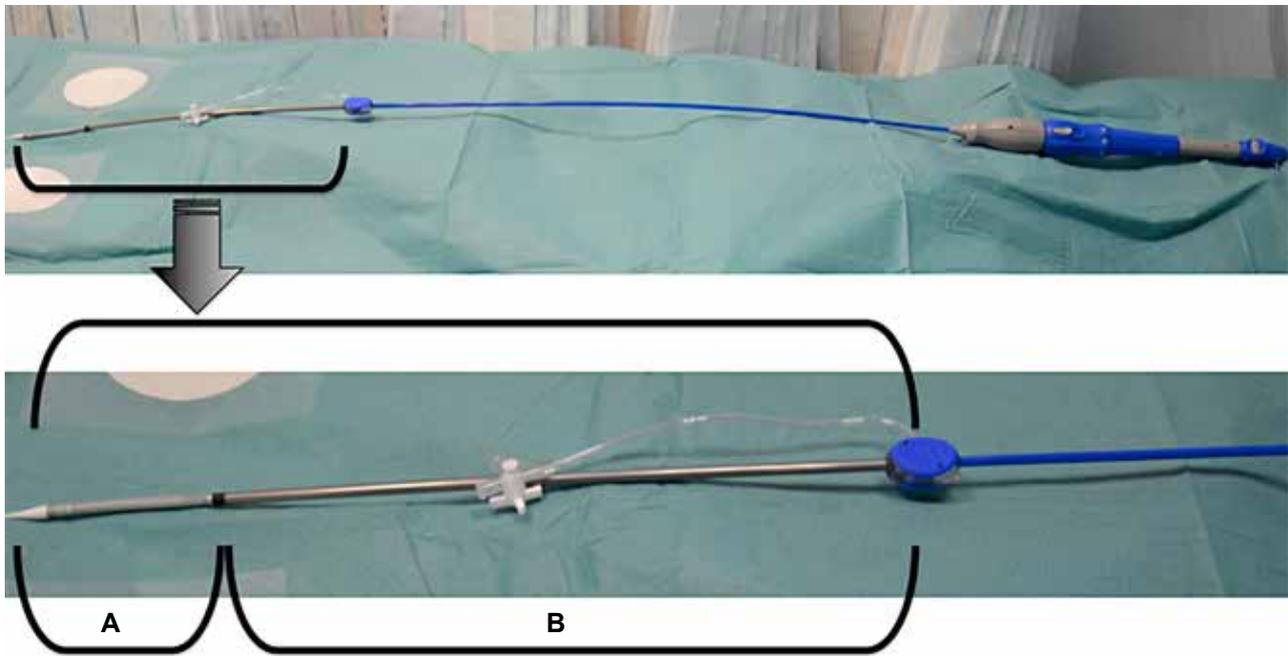
in the wound (Figure 2F). The patient was discharged on day 5 post-TAVI, without the need for permanent pacemaker implantation.

## Discussion

We report the first experience in Greece with the new CoreValve Evolut-R 23 mm with the InLine sheath and the EnVeo loading guiding catheter. This case is illustrative of how novel TAVI technologies offer interventionalists the chance to overcome issues related to a relatively small patient's anatomy. In particular, our patient received the smallest available size (23 mm) of the chosen type of bioprosthesis, inserted through the narrowest available sheath (14 Fr equivalent). This device had the capability to be repositioned or recaptured, if deemed necessary. Additionally, whilst a true percutaneous approach is feasible in

most TAVI cases, in our case femoral artery calcification led to the decision to use surgical cut-down of the artery. A left femoral artery approach was chosen, as according to MSCT, the related ascending artery tree was of slightly wider dimensions compared to the right system (Table 1).

As shown in Figure 1, the left femoral calcification was distributed in a clockwise direction from 4 to 1 o'clock of the circumference, sparing only part of the outer lateral wall. This would have been quite difficult to approach percutaneously without risking vessel rupture. Moreover, the vascular surgical team that was consulted favored surgical cut-down. Indeed, open surgical preparation of the artery offered the chance to identify a relatively non-calcified area by tactile sensation of the vessel wall, which was then used uneventfully for sheath introduction. Alternatively, if a percutaneous approach was preferred,



**Figure 3.** Enveo-R delivery catheter system with integrated InLine 14 Fr sheath (18 Fr outer diameter). A: Bioprosthesis capsule (not loaded); B: Sheath.

surface ultrasound evaluation of the target artery, if available, should have been used to guide the selection of the puncture site. In general the best available techniques should be applied in such difficult anatomies in order to minimize access vessel-related vascular complications.<sup>7-9</sup> However, vessel calcification still remains a negative prognostic factor for vascular complications after TAVI.<sup>10</sup>

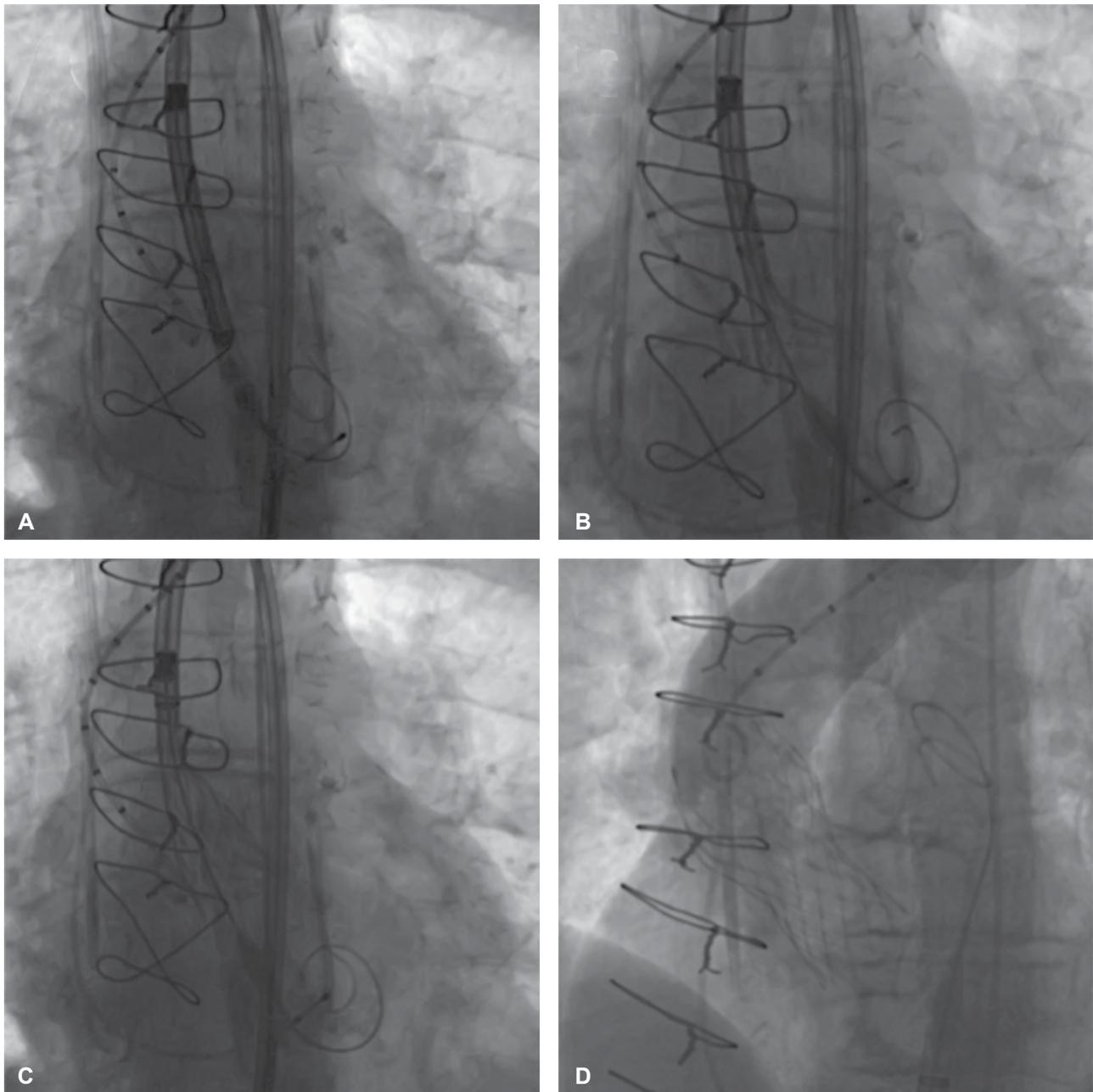
TAVI through the left subclavian artery was contraindicated, because of both its dimensions (5.3 mm minimal diameter) and the presence of a patent LIMA graft.<sup>5,6</sup> Moreover, while a transapical or transaortic approach would theoretically have been an option, it would not be preferable in a patient with previous CABG.

We will now briefly discuss the decision algorithm that was followed. Initial patient assessment ruled out surgical aortic valve replacement, as the surgical risk was prohibitive. Subsequent evaluation with MSCT angiography during the screening process<sup>1</sup> revealed a small aortic annulus (17.0 mm × 22.4 mm), borderline access vessel dimensions, and extensive peripheral vessel calcification.

Currently, the narrowest sheaths for delivery of bioprostheses are: the 14 Fr equivalent InLine sheath (Medtronic Inc., for implantation of a CoreValve Evolut R 23 mm bioprosthesis), which features a con-

stant outer diameter (18 Fr = 6 mm);<sup>3</sup> and the 14 Fr equivalent e-sheath (Edwards LifeSciences Inc., for implantation of a SAPIEN-3 23 mm or 26 mm bioprosthesis), the outer diameter of which transiently expands to 8 mm (24 Fr) during passage of the bioprosthesis delivery system.<sup>4</sup> Since the InLine sheath may only be used with the 23 mm CoreValve Evolut R device, only a small fraction of patients – those with an annulus diameter of 18-20 mm – may benefit from its use. Patients with a very low-diameter access vessel but greater annulus diameters (18-26 mm) may therefore be treated with the 14 Fr equivalent sheath for TAVI with a SAPIEN 3 device (23 or 26 mm, respectively, although the access vessel diameter should be able to accommodate transient expansion of the sheath's outer diameter up to 8 mm. However, the SAPIEN 3 device does not feature repositionability or retrievability. Currently, apart from the Medtronic CoreValve Evolut R, a series of devices (Boston Lotus, Edwards Centra, Direct Flow, Symetics ACURATE, JenaValve) feature such characteristics, but require larger introductory sheaths.

Besides arterial access issues that can limit device options for TAVI, attention should also be paid to the low coronary ostia height (left: 10.6 mm; right: 12.8 mm). The silhouette of the CoreValve Evolut R frame is designed to protect coronary artery orifices



**Figure 4.** CoreValve Evolut-R deployment. A: Initial positioning; B & C: Deployment, D: Final aortography.

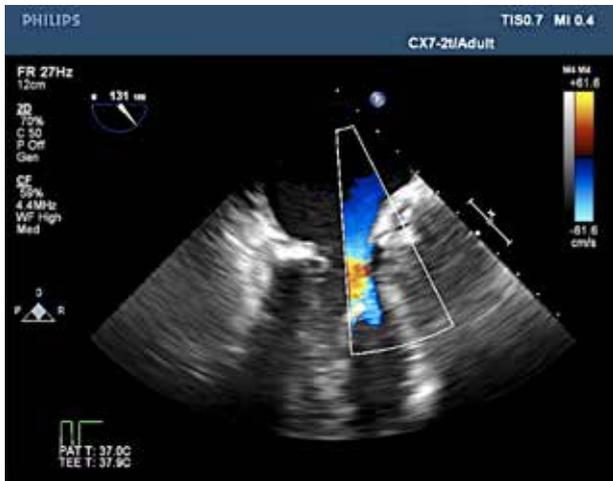
and would thus be preferable to a SAPIEN device. But most importantly, the device can be retracted or repositioned (prior to final deployment) if any signs of coronary flow obstruction are observed.

In conclusion, recent advances in available TAVI devices may make “complex” procedures feasible. Individualized patient assessment is a prerequisite. Newer devices with improved capabilities will be available in the near future and will broaden the

range of patients eligible for TAVI. These are patients who would have previously been rejected from treatment because of their complex anatomical characteristics.

#### Disclosures

Manolis Vavuranakis is a Proctor for CoreValve (Medtronic Inc.),



**Figure 5.** Transesophageal echocardiography immediately after bioprosthesis implantation indicating no paravalvular leak.

## References

1. Vavuranakis M, Voudris V, Vrachatis DA, et al. Transcatheter aortic valve implantation, patient selection process and procedure: two centres' experience of the intervention without general anaesthesia. *Hellenic J Cardiol.* 2010; 51: 492-500.
2. Tchetché D, Van Mieghem NM. New-generation TAVI devices: description and specifications. *EuroIntervention.* 2014; 10 Suppl U: U90-U100.
3. Sinning JM, Werner N, Nickenig G, Grube E. Medtronic CoreValve Evolut R with EnVeO R. *EuroIntervention.* 2013; 9 Suppl: S95-96.
4. Binder RK, Rodés-Cabau J, Wood DA, et al. Transcatheter aortic valve replacement with the SAPIEN 3: a new balloon-expandable transcatheter heart valve. *JACC Cardiovasc Interv.* 2013; 6: 293-300.
5. Vavuranakis M, Vrachatis DA, Filis K, Stefanadis C. Transcatheter aortic-valve implantation by the subclavian approach complicated with vessel dissection and transient left-arm paralysis. *Eur J Cardiothorac Surg.* 2011; 39: 127-129.
6. Vavuranakis M, Vrachatis DA, Toutouzas K, Economopoulos G, Kalogeras KI, Stefanadis C. Successful percutaneous aortic valve implantation via a stenotic left subclavian artery access. *Heart Vessels.* 2010; 25: 359-362.
7. Vavuranakis M, Kalogeras K, Vrachatis D, et al. Inferior epigastric artery as a landmark for transfemoral TAVI. Optimizing vascular access? *Catheter Cardiovasc Interv.* 2013; 81: 1061-1066.
8. Vavuranakis M, Kalogeras KI, Vrachatis DA, et al. A modified technique to safely close the arterial puncture site after TAVI. *J Invasive Cardiol.* 2013; 25: 45-47.
9. Vavuranakis M, Vrachatis DA, Kalogeras KI, Stefanadis CI. Vascular sealing implications in transfemoral transcatheter aortic valve implantation. *Rev Esp Cardiol.* 2014 Aug 21. pii: S0300-8932(14)00347-9. doi: 10.1016/j.recresp.2014.05.014. [Epub ahead of print].
10. Vavuranakis M, Kariori M, Voudris V, et al. Predictive factors of vascular complications after transcatheter aortic valve implantation in patients treated with a default percutaneous strategy. *Cardiovasc Ther.* 2013; 31: e46-54.