CoreValve® Evolut™ R 23 for the treatment of severe regurgitation in a Mitroflow® 21 prosthesis

Case presentation
An 81-year-old man was admitted to our institution with symptoms and signs consistent with acute lung oedema. He had a history of hypertension and hypercholesterolaemia and had undergone cardiac surgery in July 2005 due to severe aortic stenosis and three vessels disease. Coronary artery bypass grafting (CABG) with a saphenous vein graft (SVG) to left anterior descending (LAD) and a sequential SVG to first and second obtuse marginal branches (OM) were performed. Distal right coronary artery (RCA) was diffusely diseased and non-grafted. A Mitroflow® 21 (Sorin S.p.A, Milan, Italy) was implanted in aortic position. In August 2005 he had a permanent dual-chamber, rate-modulated pacing (DDDR) pacemaker implanted due to bradycardia–tachycardia syndrome, and in September 2005 he underwent percutaneous coronary intervention (PCI) and stenting of the proximal SVG–OM anastomosis.

He had been well until 3 weeks prior to the current presentation, when progressive effort dyspnoea developed following an upper respiratory tract infection.

Discussion
The differential diagnosis of the aetiology of heart failure (HF) in a patient with known heart disease is mainly based on the detection of new or worsening cardiac anomalies, as well as investigation of precipitating factors, such as infections and anaemia. Therefore, clinical diagnosis at admission was decompensated HF. Laboratory tests (including troponin) were within normal ranges except for haemoglobin (11.2 g/dl) and NTproBNP (4.100 pg/ml), supporting the clinical diagnosis of decompensated HF.

ECG showed atrial-paced rhythm at 60 bpm and left bundle branch block (LBBB).

Urgent transthoracic echocardiography (TTE) suggested significant prosthesis dysfunction. Aortic gradients were 70 mmHg (maximal) and 36 mmHg (mean) and a poorly visualized, eccentric aortic regurgitant jet was reported. There was moderate mitral regurgitation and a mean mitral gradient of 2.7 mmHg. Ejection fraction was 50%.

Investigations performed

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Transoesophageal echocardiography (TEE) confirmed severe aortic prosthesis dysfunction mainly due to severe regurgitation that was intraprosthesis, with a very eccentric jet and holodiastolic flow reversal in the descending aorta (figure 1). Velocity-time integral ratio (ITV1/ITV2) was 0.29 and aortic valve area 1.1 cm². Mitral regurgitation grade was 2/4.

On coronary angiography, LAD was occluded at the ostium and received a patent SVG. There was diffuse left circumflex artery (LCX) disease with severe ostial and mid-stenosis, and the sequential SVG was occluded at the proximal anastomosis. RCA was severely and diffusely diseased.

fig. 1
Severe aortic prosthesis dysfunction was confirmed by transoesophageal echocardiography.
Computed tomography angiography (CTA) of abdominal aorta reported diffuse disease and calcification of right and left ileo-femoral systems, with minimal lumen area smaller than 6 mm in the right common femoral and iliac arteries. Minimal lumen area was less than 6 mm just above the left femoral bifurcation, 6 mm in the common left femoral artery and progressively increased along the rest of the left system.

ECG-gated CTA of the thoracic aorta reported an internal annulus diameter of 17 x 18 mm and a distance from the prosthesis annulus to the left main ostium of 8 mm and 10 mm to RCA ostium.

Management
The final diagnosis was decompensated HF due to severe aortic prosthesis dysfunction with severe intraprosthetic regurgitation.

The Heart Team considered the patient at high surgical risk (log EuroSCORE 19.37%). As regurgitation was intraprosthesis, CoreValve® (Medtronic Inc., Minneapolis, USA) was proposed. While the Mitroflow 21 does not meet Medtronic criteria for CoreValve implantation due to its inner size of 17.3 mm, there is growing experience showing good procedural outcomes in patients with 19 and 21 mm prosthesis undergoing transcatheter aortic valve implantation (TAVI) with the CoreValve 23. Despite slightly high residual mean gradients, which are often above 20 mmHg, clinical improvement is consistently shown. Furthermore, the 23 mm CoreValve Evolut™ R recapturable prosthesis has recently received CE mark for annulus ranging from 18–20 mm, and it is compatible with a new, 14F delivery system and sheath (EnVeo™; Medtronic, Inc.).

Finally, given that the patient was considered at high risk for surgery and had ileo-femoral disease, TAVI with the Corevalve Evolut R 23 and the EnVeo delivery system was chosen as the best treatment option.

Our protocol evaluation includes CTA of the thoracic and abdominal aorta to find a suitable access for TAVI, as well as a thoracic ECG-gated CTA to evaluate the aortic prosthesis and its relation to adjacent structures, mainly the coronary arteries. A short distance between the annulus and coronary ostia, and the presence of an aortic prosthesis – especially if it is a Mitroflow valve (in which the leaflets are sutured outside the stent) – may increase the risk of coronary occlusion.

Quiz Questions
1. What essential information did TEE provide over TTE?
   TEE demonstrated that dysfunction was mainly due to aortic regurgitation and that this regurgitation was intraprosthetic and not peri-prosthetic, and therefore treatable with TAVI.

2. Might TAVI be an option for this patient even if the inner prosthesis diameter is not within the range that the companies define for available TAVI prosthesis?
   Although not yet an established indication, there is growing experience showing good procedural results and clinical improvement with TAVI in small degenerated surgical bioprosthesis, and therefore it might be a reasonable option in patients considered at high risk for reoperation.

3. Is there any specific characteristic of the Mitroflow 21 that may pose an additional risk for the TAVI valve-in-valve procedure?
   Surgical bioprosthesis with the leaflets sutured outside the stent have been related to a higher rate of coronary obstruction.

4. Might a repositionable TAVI valve be preferred in patients with significant prosthetic regurgitation, given the difficulties in prosthesis positioning posed by the absence of severe calcification and the high stroke volume?
   The ability to deploy and recapture a TAVI valve allows for optimal position of the device presenting an opportunity to deliver optimal outcomes even in patients with challenging complications.

5. What additional advantage may the EnVeo delivery system offer to this patient?
   Femoral access through a conventional 18F sheath may pose this patient at an additional risk for vascular complications, given the femoral diameters (6 mm or less in the common femoral artery) and grade of calcification. The new EnVeo system is just 14F and therefore may reduce this risk.
Nevertheless, in this patient a SVG to LAD was patent, and therefore this myocardial area was not at risk.

Ten days after hospital admission, TAVI was performed under conscious sedation through a left femoral access. A Prostar XL® (Abbott Vascular, Santa Clara, USA) was inserted before the introduction of the 14F EnVeo delivery system sheath. Haemodynamic data are shown in figure 2. Baseline diastolic aortic pressure (dAP) was 40 mmHg and left ventricle end-diastolic pressure (LVEDP) 33 mmHg. Direct implantation of a CoreValve Evolut R 23 was performed, and a 14F Cook sheath (Cook Medical Inc., Bloomington, USA) was inserted following retrieval of the EnVeo delivery system to avoid bleeding through the access site. Balloon post-dilatation with a 20 mm BALT balloon (BALT, Montmorency, France) was performed under fast ventricular pacing, to minimize risk of CoreValve embolization during post-dilatation.

Residual angiographic regurgitation was trivial (figure 3), transvalvular peak-to-peak gradient was 14 mmHg, final dAP 73 mmHg and LVEDP was 27 mmHg (figure 2). Access site haemostasis was achieved with the pre-inserted Prostar XL system. Post-TAVI TTE reported a mean transvalvular gradient of 20.7 mmHg and mild regurgitation (figure 4).

The patient was walking down the corridor 48 hours after TAVI and was discharged on the fifth day post procedure.
Take-home messages

1. TAVI has emerged as an alternative to surgery in aortic bioprosthesis dysfunction either by stenosis or intraprosthesis regurgitation. TEE is essential in the characterization of the origin of the regurgitant jet to check for suitability for TAVI.

2. There is growing experience in the treatment of small failing bioprosthesis with the CoreValve, showing good clinical outcomes despite the moderately elevated residual gradients reported.

3. Repositionable TAVI valves and smaller profile devices, such as the CoreValve Evolut R prosthesis and the EnVeo delivery system, will ease the procedure and widen the range of patients suitable for TAVI.

DISCLOSURES: RV has nothing to declare. CM is proctoring for Medtronic and is a member of advisory board also for Medtronic.