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THE HEART TEAM REVIEW

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TAVR in Patients with Left Ventricular Assist Device: Case Report and Literature Review

Alessandro Iadanza, MD, Flavio D'Ascenzi, MD, PhD, Andrea Torrisi, MD, Giuseppe Sinicropi, MD, Eugenio Neri, MD, Sonia Bernazzali, MD, Massimo Maccherini, MD, and Carlo Pierli, MD

Dipartimento Cardio-Toracico-Vascolare Policlinico Santa Maria alle Scotte, Azienda Ospedaliera Universitaria Siena, Siena, Italy

ABSTRACT

The use of left ventricular assist devices (LVADs) as a bridge-to-transplant or destination therapy in patients with end-stage heart failure has been increased during the last years. However, a potential obstacle to the success of long-term LVAD support is represented by the development of *de novo* aortic valve lesions leading to aortic regurgitation or, more rarely, to commissural fusion and stenosis. The paper addresses the main pathophysiological factors in the development of aortic valvular regurgitation in patients with LVAD and describes an updated review of all transcatheter aortic valve replacement (TAVR) cases to treat aortic regurgitation currently available. We also report on a case of a patient with a Jarvik 2000 requiring transcatheter aortic valve replacement for aortic regurgitation. The procedure was performed using a 31-mm CoreValve prosthesis. The first check after the positioning of the prosthetic valve revealed a good result. However, a second 10-min check, performed as per protocol at the end of the procedure, showed a sliding of the prosthetic valve downward toward the apex of the left ventricle with a severe periprosthetic regurgitation. Therefore, a second 31-mm CoreValve was deployed within the previous valve prosthesis and a 10-min check revealed a stable position and a mild residual leak. The management of LVAD patients with aortic regurgitation remains challenging. Although transcatheter techniques have demonstrated feasibility in these patients, technical adjustments and further expertise are needed to optimize these procedures.

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KEYWORDS Transcatheter aortic valve replacement (TAVR); left ventricular assist device (LVAD); aortic regurgitation; aortic regurgitation; Jarvik

Introduction

Over the past decade, left ventricular assistance devices (LVADs) have assumed an increasing role in the management of patients with advanced heart failure.[1,2] Currently, more than 20,000 implants have been carried out all over the world and the durability of the device has exceeded 10 years in some cases. There is a growing interest in LVAD implantation as temporary assistance for myocardial recovery (bridge to recovery).[1] However, the use of LVAD as a definitive therapy (destination therapy, DT) has led to an almost exponential increase in implants in recent years and currently accounts for 42% of total implants in the United States.[1] In non-candidate subjects for heart transplantation, LVADs significantly improved survival, providing a concrete therapeutic option for these patients.[1,2] For this subset of patients implanted as DT, the adverse events related to the LVAD itself acquire even more importance and it is necessary to develop strategies for their optimal clinical management.[2]

Literature review

For the last decade, the vast majority of patients treated with an implantable LVAD received a continuous flow (CF) device, either a centrifugal pump such as the HeartWare HVAD (Medtronic, St. Paul, MN, USA) or an axial flow pump such as the HeartMate II (St. Jude Medical, Minneapolis, MN, USA). Recently a new generation of magnetically levitated centrifugal pumps (HeartMate III, St. Jude Medical) has successfully completed a CE mark study and is available in Europe. Irrespective of design, the pumps unload the heart by pumping blood from the left ventricle to the ascending aorta. Contemporary LVADs are driven electrically via a percutaneous driveline connected to a controller and external energy source, either batteries that are replaced every 4–12 h depending on the pump model or an AC power source. The pumps generate up to 10 L/min of flow, and as flow is continuous most patients have an undetectable peripheral pulse or a very small pulse pressure. The HeartMate III has a pump speed variability algorithm creating a small artificial pulse every 2 seconds that may improve washing of the blood-contacting surfaces of the device. While the original pulsatile pumps had a limited life span, in most cases of < 2 years, the CF devices may last >10 years

Initially introduced as pulsatile flow devices, the new generation LVADs have been designed to generate a continuous flow. The Jarvik 2000 FlowMaker® (Jarvik Heart, Inc., New York, NY, USA) is the new generation of ventricular assist devices that have gradually become miniaturized. The Jarvik

CONTACT Alessandro Iadanza, MD alessandro.iadanza@gmail.com Policlinico Le Scotte UOC Emodinamica (III PIANO-III LOTTO), Aou Siena - Viale Bracci, Siena 16 53100, Italy.

2000 pump is made of titanium and has the dimensions of an alkaline battery, weighing 90 grams. It has a DC motor, a rotor supported by two ceramic bearings and a moving element: a small, titanium rotating spinning that pumps blood from the heart up to 7 liters per minute. This mechanical circulatory support, however, produces marked changes in the circulation with respect to the normal physiology of flows, causing unexpected adverse effects in particular in continuous flow LVADs.[3]

Aortic regurgitation (AR) is one of these complications; approximately one third of patients develop mild-to-moderate AR around 6 months after implantation.[4] The etiology of AR associated with LVAD with continuous flow is due to several factors (Figure 1), including the reduced opening of the aortic valve, the altered dynamics of the blood flow, the transvalvular pan-cyclic gradients, and the high shear stress and mal-coaptation of cusps.[5] These processes promote fusion of cusps, valve degeneration and remodeling of the aortic wall, which progress to AR.[6–8] These functional and anatomical changes develop over time and approximately 15% of patients will eventually develop moderate-severe AR,[4] which can negatively affect the "stability" of LVAD therapy. The volume of aortic regurgitation prevents an adequate discharge of the left ventricle and causes an increase in the end-diastolic pressure. In addition, anterograde cardiac output is compromised by a continuous cycle situation in which blood circulates through the LVAD into the aorta, but is then regurgitated into the left ventricle through the aortic valve, then anterograde through the LVAD, and so on. If the volume of regurgitation is large enough, symptoms of heart failure can develop. At this point, it is necessary to take into account a modulation of the speed of the LVAD, an intervention on the aortic valve or eventually an urgent heart transplant.[9]

However, the evaluation of AR and its true hemodynamic impact is a challenge.[10,11]

Transcatheter aortic valve replacement (TAVR) is currently indicated for the treatment of senile calcific degenerative aortic stenosis. Benefit and safety profiles in patients with AR post-LVAD[12–17] are poorly understood, due to the very limited number of cases performed in the world and reported in the literature to date (Table 1).

Role of the Heart Team: A tailored approach to decision-making

In this particular clinical context, the multidisciplinary role of the Heart Team is crucial in order to select for each individual case the most effective and appropriate therapeutic approach, minimizing

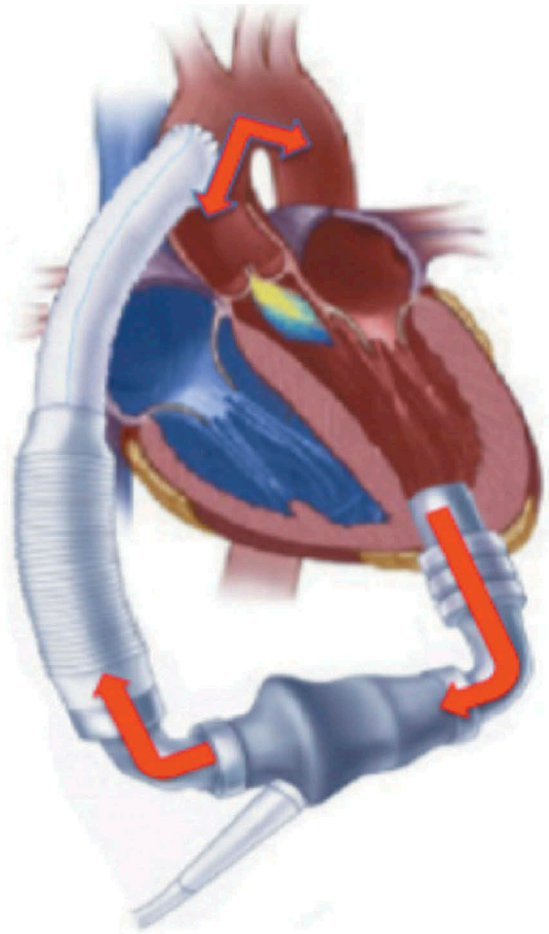

Figure 1. Causes of aortic regurgitation in patients with left ventricular assist device.

Hemodynamic anomalies: (1) reduced aortic valve opening; (2) local stasis; (3) high shear stress; (4) inversion of trans-valve gradient; (5) pancyclic pressure gradient. **Histological abnormalities**: (1) retraction and malcoaptation of aortic cusps; (2) thrombotic apposition and fibrosis at the valvular level; (3) fusion of aortic commissures; (4) remodeling of the aortic wall. Figure 1 has been adapted and modified with permission of the authors James C. Fang and Omar Wever-Pinzon.[5]

the risks. The optimal method for the management of native aortic valve insufficiency (AI) at the time of device implantation remains controversial. Several procedures intended to treat AI have been recommended. Simple suture closure of the aortic valve has been reported to provide effective and lasting elimination of AI. Patch closure of the aortic outflow tract has also been proposed. AI may be treated with surgical AVR or surgical aortic valve closure. In patients with contraindications for cross clamping, TAVI remains an option. Anchoring of transcatheter heart valves, however, is challenging in patients with pure AI because of the absence of annular or leaflet calcifications.

It has been reported that balloon expandable valve prostheses are less favorable for use in non-calcific valves. Conversely, the function of self-expansion of transcatheter valves in nitinol makes it more likely to be suitable for cases in which there are no significant valvular calcifications useful for anchoring the prosthesis.[12] Large valves were used in some of the patients for AI post-LVAD in the absence of aortic valve calcification[18] in order to overcome the problem of the absence of anchoring. However, in the event of valve dislocation or persistence of AI, it is sometimes necessary to implant a second prosthesis according to the valve-in-valve technique,[12,16] as performed in our clinical case. Another relevant clinical problem is the durability of these prostheses. However, the urgent clinical conditions of the patient required a rapid solution in order to solve the hemodynamic instability. Furthermore, a second procedure with a valve-in-valve technique can be used in case of deterioration of the prosthesis.

Although they have yet to be Food and Drug Administration-approved in the United States for treatment of native aortic regurgitation, transcatheter heart valves with "pinning and docking" features such as the Medtronic Engager valve (Medtronic), the JenaValve (JenaValve Technology GmbH, Munich, Germany), and the Edwards HELIO Transcatheter Dock (Edwards Lifesciences, Irvine, CA, USA) may play a future significant role in the treatment of aortic regurgitation in this patient population.[22,23]

Finally, we have to consider the ethical implications of treating these patients with a poor prognosis with an expensive approach that may have limited efficacy. Observational studies considering also ethical and economic implications are needed in order to choose the best clinical treatment.

Clinical case

A 72-year-old male patient (height, 180 cm, weight, 76 kg), LVAD carrier, was admitted to our Department for dyspnea

Table 1. Previous procedures of transcatheter aortic valve replacement through percutaneous and surgical accesses performed for aortic regurgitation in patients with left ventricular assist device.

Percutaneous access				
Bibliographic reference	Type LVAD	Valve type	Access/method	Complications/outcome
Santini et al, 2012[12]	Heart Mate II[a]	Core Valve[b]	Percutaneous implant	Periprosthetic insufficiency treated with implantation of a second Core Valve. Minimum residual leak. Patient survived.
Khan et al, 2013[13]	Heart Mate II[a]	Melody[b]	Percutaneous implant in calciferous "homograft" conduit	Minimal aortic regurgitation. Patient survived.
Atkins et al, 2013[14]	Heart Mate II[a]	Melody[b]	Percutaneous implant in insufficient biological prosthetic valve	Minimal aortic regurgitation. Patient survived.
Wilson et al, 2014[15] Parry et al, 2014[18]	Heart Mate II[a]	Core Valve[b]	Percutaneous implant after closing by aortic valve suture	No paravalvular leak. Complete block. Patient has survived post-implantation, death after attempted to explant the LVAD, with fusion of cusps and pseudomembrane formation, observed 33 days after implantation
Lavee et al 2013[19]	Heart Mate II[a]	Core Valve[b]	Percutaneous implant	Direct implant; mild paravalvular AR. Patient survived.
Kornberger et al 2015[20]	HVAD[c]	SAPIEN S3[d]	Percutaneous implant	Aortic balloon valvuloplasty to confirm size and immediately implant with rapid ventricular pacing; Absent paravalvular AR. The patient immediately regained hemodynamic stability. Patient survived.
Garvey Rene et al 2017[21]	HVAD[c]	Core Valve Evolut R[b]	Percutaneous implant. Use of E-sheath in case of bail out use of Edwards device	Direct implant. Due to ventricular migration following six initial partial deployments and recaptures, the valve was removed and a new 29-mm valve was successfully implanted. No paravalvular leak. Patient survived
Surgical access				
Krause et al, 2014[16]	Heart Mate II[a]	Core Valve[b]	Surgical approach: direct aortic access through a partial upper sternotomy	Migration to the outflow tract of the Vsn with moderate aortic regurgitation treated with implantation of a second Core Valve valve-in-valve Patient survived. No evidence of aortic regurgitation at 12 months
D'Ancona et al, 2013[17]	HVAD[c]	SAPIEN XT[d]	Surgical approach: transapical implant in ECC	No paravalvular leak. Patient survived.

[a]Thoratec, Pleasanton, CA, USA; [b]Medtronic, Inc, Minneapolis, MN, USA; [c]HeartWare, Inc, Framingham, MA, USA; [d]Edwards Lifesciences, Inc, Irvine, CA, USA.

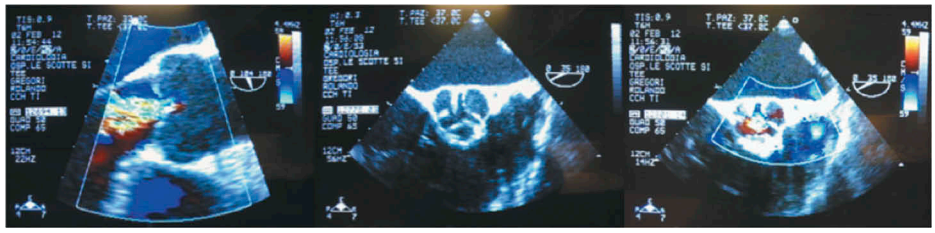

Figure 2. Transesophageal echocardiogram documenting severe aortic regurgitation due to reduced coaptation and fibrous retraction of the cusps in the subject carrying the left ventricular assist device (Jarvik 2000 FlowMaker®).

with progressive worsening during the previous few months. Dyspnea was present at rest upon admission with a New York Heart Association (NYHA) functional class IV. The patient was diagnosed with an idiopathic dilated cardiomyopathy with severe peripheral vascular disease and type II diabetes mellitus. The patient had been implanted with LVAD (Jarvik 2000 FlowMaker®) in June 2010, as DT.

At the time of admission, 3 years after LVAD implantation, transesophageal echocardiography documented severe aortic valvular insufficiency from a coaptation defect of aortic cusps in the absence of other pathological findings. Notably, no calcifications or fibrous degeneration were present at the level of the cusps and the ring (Figure 2). At the time of evaluation, the patient was taking anticoagulation therapy (warfarin) and was within the recommended INR range.

Despite the supporting medical therapy, including infusion of dobutamine i.v., the symptoms of congestive heart failure did not regress. The combination of an ineffective LVAD (likely correlated to AI), refractory pulmonary edema with desaturation, and the presence of ventricular hyperkinetic arrhythmias necessitated intubation and ventilatory support. Since neither the medical therapy nor the regulation of the flow of the LVAD allowed hemodynamic stability, the Heart Team decided to perform a transcatheter aortic valve replacement (TAVR) in order to treat severe AI, having concluded that the patient was not a surgical candidate. (Euroscore I log: 64.8%, Euroscore II: 48.2%, STS Score: 46.4%)

Procedure

TAVR was performed through the right common femoral artery. Using an 18-F introducer, an extra-stiff guidewire (Amplatzer extra stiff®; Boston Scientific, Marlborough, MA, USA) with a short 3 cm tip was modeled to obtain a wide-range coil and placed in the left ventricle to avoid entrapment in the Jarvik pump. A CT scan with Multi Plane Reconstruction was performed, measuring an aortic annulus diameter 31 mm (max), 22 mm (min), perimeter 85 mm, area 5.4 cm^2 (Figure 3). No calcium was identified. The TAVR procedure was then performed, implanting a CoreValve® 31 mm (Medtronic) under fluoroscopic guidance.

The release of the CoreValve 31 mm was performed with direct implantation, using an extra stiff guidewire, reducing the cardiac output through modulation at the minimum value of the LVAD centrifugal pump power, and with simultaneous rapid pacing (150 bpm). The implant was immediately optimal as regards the positioning of the prosthesis and the minimum paravalvular leak without interfering with the mitral valve. However, 10 minutes after the implantation, a gradual dislocation of the aortic prosthesis in the left ventricular slope was observed leading to a severe paravalvular regurgitation.

The valve was not snared because of absence of calcium resistance and high risk of valve dislocation/embolization. Given this complication, it was necessary to perform an immediate valve-in-valve procedure with an additional CoreValve 31 mm device, obtaining a correct positioning and the consequent reduction of the paravalvular leak to a mild degree (Figure 4). It was therefore decided to conclude the intervention. In the immediate post-operative course, the patient did not develop neurological complications and no atrio-ventricular conduction disturbances were observed. The hemodynamic state was stable in the days following the procedure, but following prolonged low cardiac output before the procedure described, the patient developed abdominal ischemia with ileal necrosis complicated by septic shock which determined the death.

Discussion

This case highlights the feasibility of TAVR with a self-expanding transcatheter valve for pure aortic regurgitation in a noncalcified aortic valve in a patient with a prior LVAD. Technical feasibility of TAVR in patients with pure AI post-LVAD remains a challenge not only because available second-generation transcatheter valves were not primarily designed to treat patients with severe aortic regurgitation, but there also remain limited data with regards to methods of optimal valve selection, particularly with regards to the range of oversizing and valve stability. The presence of the LVAD inflow cannula further complicates valve positioning due to inflow forces in the ventricle. Appropriate oversizing is of utmost importance to maximize anchoring of the valve at the annulus, to reduce the possibility of ventricular migration, and to optimize hemodynamics in the setting of a LVAD. Among the previous nine cases of TAVR in patients with LVAD and aortic valve insufficiency in noncalcified or minimally calcified aortic valve described in the literature[17,18,22–26] only two were performed with a balloon-expandable valve as the sole valve.[17–20,22–27] Among the seven cases performed with a Medtronic CoreValve, one required further post-dilation for residual aortic regurgitation[12] and two experienced ventricular migration of the transcatheter valve,[16–18,22–25] one of which was treated with the implantation of a second CoreValve.[16] Two required additional implantation of

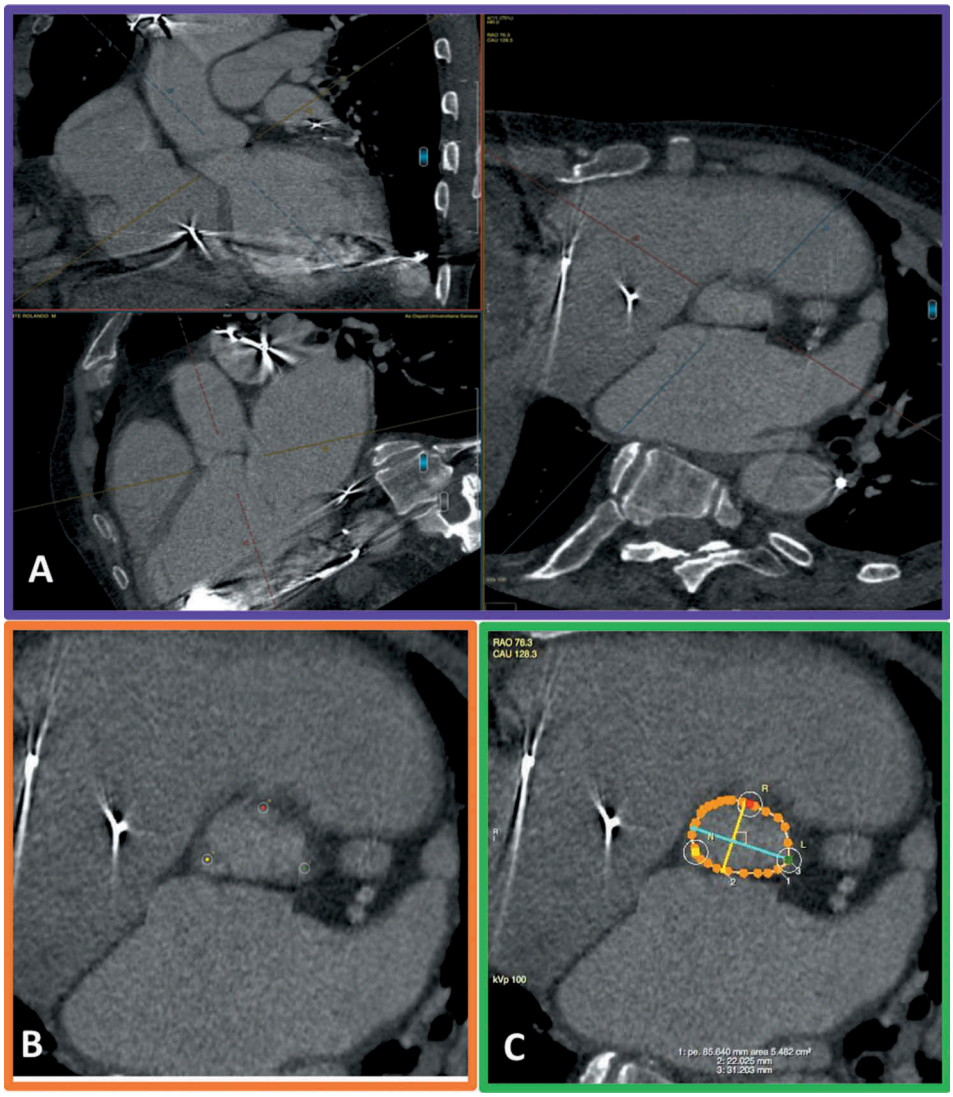

Figure 3. (A) Multi Planar Reconstruction CT scan reconstruction; (B) Aortic valve annulus with nadir point; (C) Aortic annulus sizing perimeter 85 mm, area 5.4 cm^2, max D 31 mm, min D 22 mm.

a balloon-expandable Edwards Sapien S3 prosthesis to treat significant residual paravalvular leak.[26] In a similar previously reported case of successful implantation without the need for additional valve implantation or balloon post-dilation, the oversizing of our valve perimeter was ≥ 20%. Among the two cases with reported ventricular migration[16,25] oversizing by perimeter was less than 15%, perhaps suggesting that a greater degree of oversizing by perimeter may be required to maximize TAVR success with self-expandable valves in non-calcified aortic valve with pure AI. It is also possible that the more aortic initial position, and the stabilization of the LVAD outflow cannula, may have contributed to the success in this patient.

Other approaches for treating AI in this specific setting are the closure of the aortic valve using an Amplatzer device[24] or the implantation of a JenaValve™ (JenaValve Technology, Irvine, CA, USA). However, although the first approach has been described,[18] the risk of device thrombosis and/or thrombosis of coronary arteries is high in patients implanted with Jarvik, due to the intermittent flow induced by the device. The second approach is feasible; however, at the time of our procedure, the JenaValve was available only using a transapical approach, not feasible in a patient implanted with a Jarvik device. Indeed, it has to be considered that at the time of the treatment of the described clinical case there were no commercially available devices of a larger size nor the possibility of recapturing and repositioning the expandable Valve widely used in today's practice.

Conclusions

The problem of treatment of AI in patients with LVAD remains challenging. In our clinical case, the aspirating effect of LVAD and the expansion latency of nitinol resulted in the progressive sliding of the CoreValve towards the left ventricle, requiring a second implant to reduce the

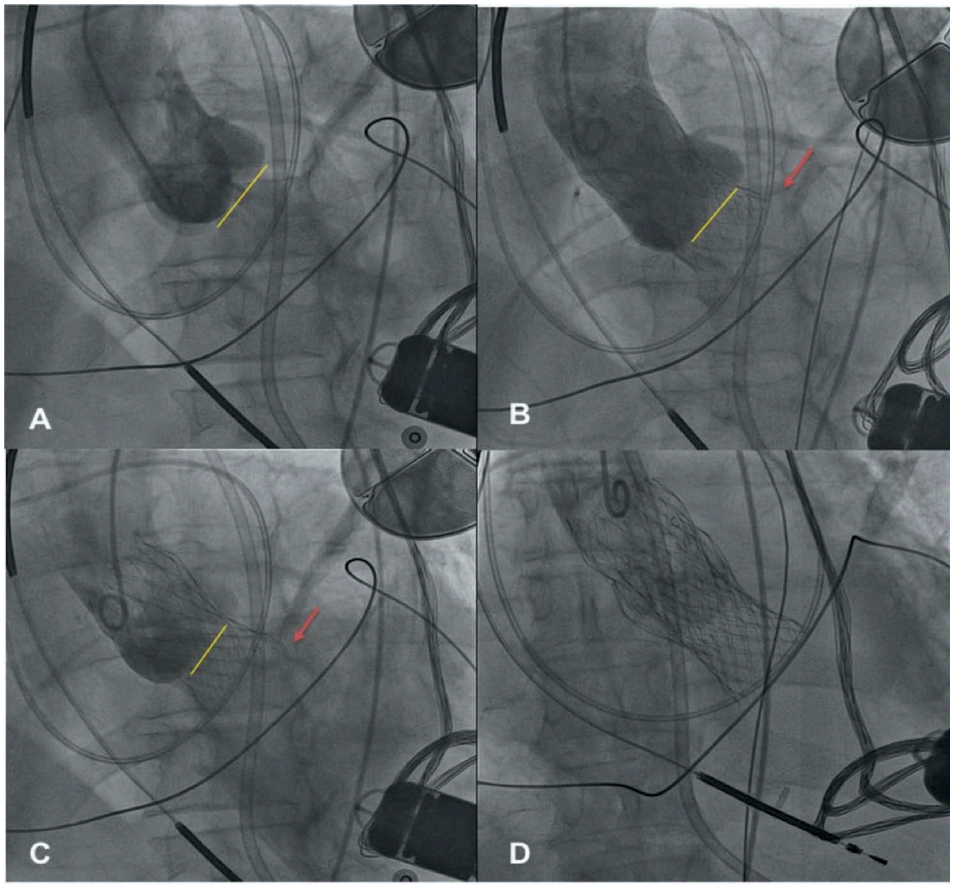

Figure 4. (A) Pre-implant aortography. The yellow line identifies the aortic annulus; (B) CoreValve 31 mm implant with device margins in the left ventricular outflow tract to 8 mm from the aortic annulus (red arrow); (C) Displacement of the CoreValve 31 mm towards the apex of the left ventricle; the prosthesis is now 16 mm from the aortic annulus and a severe paravalvular insufficiency is present; (D) Valve-in-valve procedure with placement of an additional 31 mm CoreValve and good final result. It is possible to observe a further sliding of the first implanted prosthesis towards the apex of the left ventricle.

severe periprosthetic leak that had occurred. The possibility of using new generations of devices, which can be recaptured, and larger devices, could allow a better anchoring of the device within the aortic annulus and the possibility of a possible recovery and/or repositioning necessary to optimize the implant. A longer follow-up and more experience are needed in this particular clinical context to understand the duration and effectiveness of this combination therapy in selected cases.

ORCID

Alessandro Iadanza http://orcid.org/0000-0002-6435-1155

Disclosure statement

The authors report no conflicts of interest.

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