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CASE REPORT
Structural intervention

Heterotopic caval valve-in-valve procedure for prosthetic migration: two case reports

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Background Heterotopic bicaval stenting or caval valve implantation (CAVI) either with non-dedicated balloon-expandable Sapien™ valves (Edwards Lifesciences) or with dedicated TricValve™ (Products + Features) has emerged as a safe and effective percutaneous treatment for high-risk patients with severe tricuspid regurgitation (TR). One technical difficulty of CAVI is the lack of native calcified structures to anchor the device, which may lead to paravalvular leak or migration.

Cases summary We describe two patients with severe TR and high surgical risk who underwent CAVI procedures, both of them complicated with device migration to the right atrium (one inferior vena cava device and one superior vena cava device). Both cases were treated with a caval valve-in-valve procedure, with good technical and clinical results.

Discussion With the recent development of several percutaneous interventions for high-risk patients with severe TR, the rate of some possible complications is not well established, and neither are the better managing strategies. Device embolization is a rare complication of transcatheter heart interventions but with potential catastrophic consequences. Less invasive strategies such as the valve-in-valve procedure may be preferable in order to avoid the exposure of these patients to complex heart surgeries with extracorporeal circulation.

Keywords Tricuspid regurgitation • Bicaval prosthetic valves • Prosthetic migration • Paravalvular leak • Valve-in-valve procedure • Case report

ESC Curriculum 4.5 Tricuspid regurgitation • 4.10 Prosthetic valves

Learning points

- Device migration/embolization after heterotopic caval valve implantation for high-risk patients with severe tricuspid regurgitation is a rare complication, but its risk is not negligible, with potential catastrophic consequences.
- Valve-in-valve procedures pose a less invasive interesting approach in these cases, allowing to avoid exposure of these patients to complex heart surgeries with extracorporeal circulation.

Introduction

Untreated severe tricuspid regurgitation (TR) is independently associated with increased morbidity and mortality.[1,2] Several transcatheter strategies have been developed to avoid high-risk surgical tricuspid valve (TV) interventions.[3] Those include edge-to-edge repair, orthotopic replacement strategies, and the latest heterotopic bicaval stenting or caval valve implantation (CAVI) either with non-dedicated balloon-expandable Sapien™ valves (Edwards Lifesciences) or with dedicated TricValve™ (Products + Features) and Tricento™ (NVT) systems. Early reports on CAVI have demonstrated safety and effectiveness in improving quality of life and functional capacity in patients with

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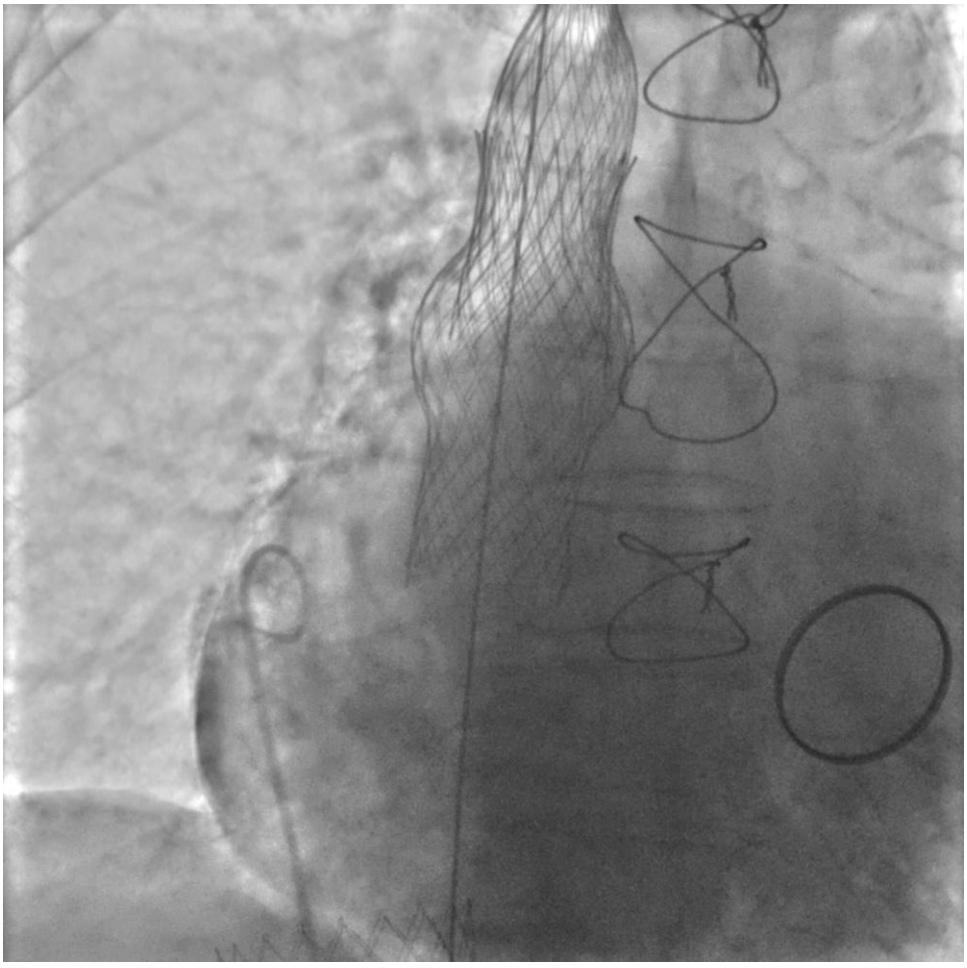
severe symptomatic TR.[4–9] Several limitations have restrained wide adoption of CAVI procedures. One technical difficulty of CAVI is the lack of native calcified structures to anchor the device, which may lead to paravalvular leak or migration. These can potentially result in haemodynamic deterioration and even sudden cardiac death.[10] The novel dedicated caval valves have apparently reduced the migration risk, but this is still not negligible. The TRICUS EURO study described device embolization in up to 3% of cases.[9] In most reports, the migrated/embolized valves were retrieved surgically, but some percutaneous approaches such as the caval valve-in-valve procedure have been suggested as efficient.[11] We described two cases of caval valve migration with the TricValve system [one in the inferior vena cava (IVC) and one in the superior vena cava (SVC)] treated successfully with percutaneous valve-in-valve procedures.

Summary figure



Clinical case description—Patient 1

A 76-year-old male patient presented with fatigue, New York Heart Association (NYHA) functional class III, ascites, and peripheral oedema. He had had three hospital admissions for decompensated heart failure in the past year. His medical history is remarkable for non-ischaemic dilated cardiomyopathy, with a previous mitral ring annuloplasty (CE ring 34 mm), primary prevention implantable cardio-defribillator (ICD) implantation 15 years ago, and permanent atrial fibrillation. He was under optimal medical therapy, with warfarin, furosemide 60 mg b.i.d., sacubitril/valsartan 24 mg/26 mg b.i.d., carvedilol 6.25 mg b.i.d., spironolactone 25 mg, and dapagliflozin 10 mg. The laboratory evaluation pointed to an N-terminal pro-B type natriuretic peptide (NT-proBNP) level of 2580 pg/mL, with other unremarkable parameters. The transthoracic echocardiogram (TTE) revealed biventricular dilation, with left ventricle ejection fraction (LVEF) of 30%, tricuspid annular plane systolic excursion (TAPSE) 15 mm, fractional area change (FAC) of 42%, bi-atrial enlargement, a prosthetic ring in the mitral position without obstructive flow or significant regurgitation, and torrential TR (regurgitant volume estimated in 95 mL), due to tricuspid annulus dilation and the presence of an endocavitary eletrocatheter (*Figure 1A*). The case was discussed in the Heart Team, and due to high surgical risk (EuroSCORE II of 6.78%) and previous heart surgery, the patient was selected for a percutaneous approach. Due to the presence of a large coaptation gap of the leaflets and the presence of an ICD

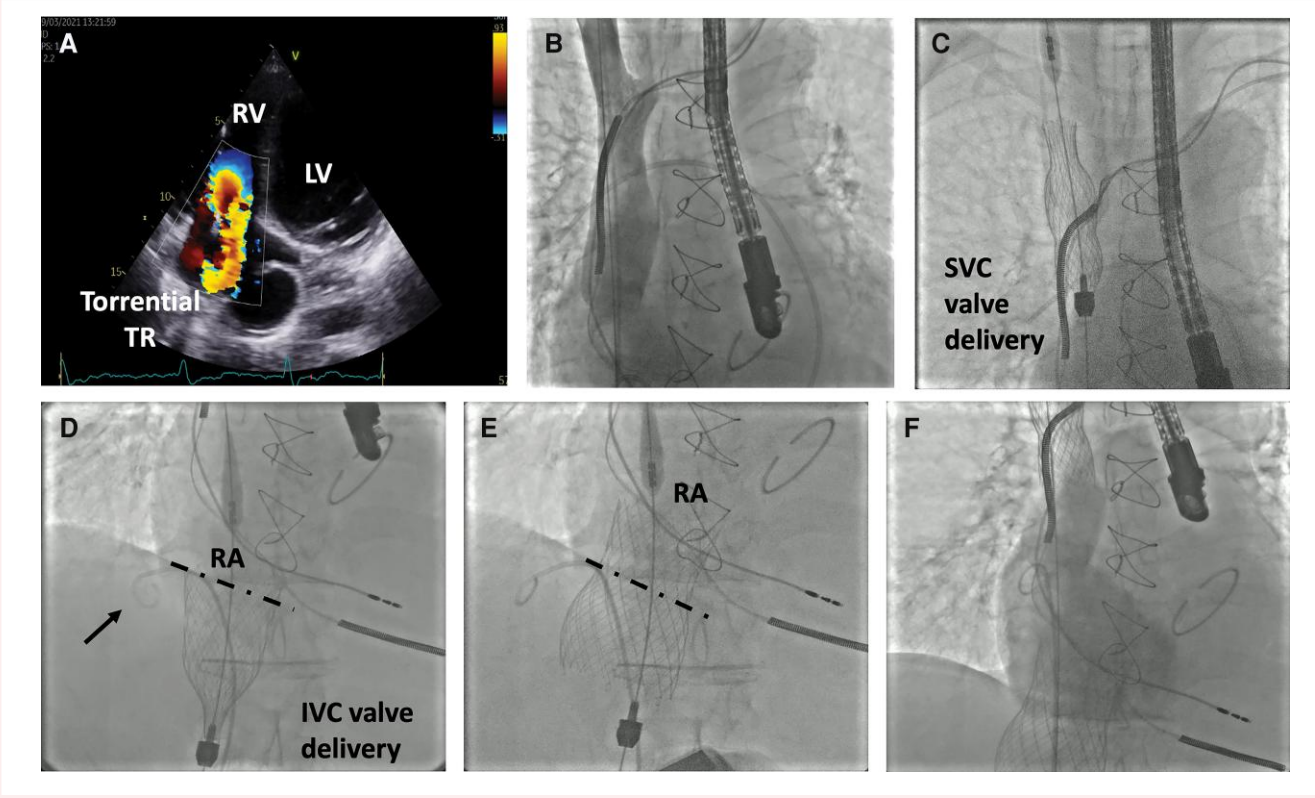


Figure 1 Initial echocardiogram and procedure of Patient 1. (*A*) Transthoracic echocardiogram (apical four-chamber view) showing torrential tricuspid regurgitation. (*B*) Initial venography with substantial iodine contrast reflux. (*C*) Superior vena cava valve deployment. (*D*, *E*) Consecutive images of inferior vena cava valve deployment, with a pigtail catheter in the supra-hepatic veins (arrow). Using the ICD lead as a landmark, it is possible to appreciate cranial device displacement after release. (*F*) Final venography showed no significant leak. TR, tricuspid regurgitation; RV, right ventricle; LV, left ventricle; SVC, superior vena cava; IVC, inferior vena cava; RA, right atrium.

eletrocatheter, the patient was not eligible for a transcatheter edge-to-edge repair (TEER) procedure and was selected for a bicaval valve (TricValve™) implantation. Right heart catheterization showed V waves of 26 mmHg in both the SVC and the IVC, and coronary angiography did not show significant stenosis. Pre-procedural cardiac computed tomography angiography (CTA) was performed, resulting in prosthetic sizing of 25 mm for the SVC and 35 mm for the IVC. The SVC valve was deployed with good technical results (*Figure 1B and C*). The IVC valve delivery position was assessed with fluoroscopic guidance and with a pigtail catheter in the supra-hepatic veins (SHV). After IVC valve delivery, mild device displacement to the right atrium was noted (*Figure 1D–F*). At that moment, the valve appeared to be in a stable position, and no significant leak was observed, so a conservative approach was chosen, and the patient was discharged clinically well after 7 days. Three months later, the patient has a re-hospitalization for decompensated heart failure. The TTE revealed a significant perivalvular leak with flow inversion in the SHV. Invasive angiography was repeated, and despite the valve being in the same position, a major perivalvular leak was observed with significant contrast reflux to the IVC (*Figure 2A*). Cardiac CTA (*Figure 2B*) was performed to better characterize the leak dimensions and plan a possible re-intervention. The evaluation revealed a 39.2 mm × 19.7 mm posterior peri-device leak (area 2.82 cm^2). At this point, several options were considered by the Heart Team including surgery, valve-in-valve procedures either with dedicated TricValve™ devices or with non-dedicated balloon-expandable valves, percutaneous leak closure with a plug, and, at last, medical therapy. There was no experience in the centre at closing leaks with these dimensions at venous structures using plugs, and the dimensions of the IVC demanded a dedicated valve for an eventual valve-in-valve procedure, so it was decided to perform a valve-in-valve procedure with an IVC 35 mm prosthetic caval valve (TricValve™). The valve-in-valve procedure (*Figure 2C and D*) occurred without complications and with a good final result (mild leak in the final angiography). The patient was discharged at 6 days after the procedure under medical therapy. At 6 months of follow-up, he is clinically well, in NYHA class II and without other hospital admissions.

Clinical case description—Patient 2

A 76-year-old female patient presented with 6 months onset of fatigue, NYHA functional class III, and exertional dyspnoea. The patient had a past medical history of valvular heart disease with a mechanical mitral prosthetic valve implanted 23 years ago, permanent atrial fibrillation, rheumatoid arthritis, and chronic obstructive pulmonary disease. She was under optimal medical therapy, with acenocoumarol, furosemide 40 mg b.i.d., ramipril 2.5 mg, nebivolol 2.5 mg, linagliptin 5 mg, and simvastatin 20 mg. The TTE is shown in *Figure 3* and revealed a well-functioning mitral mechanical valve and massive TR shown (effective regurgitant orifice area (EROA) 80 mm^2, SHV flow inversion), with preserved biventricular systolic function (TAPSE 18 mm and annular tricuspid velocity 8 cm/s), confirmed with TTE. The case was discussed in the Heart Team, and due to high surgical risk and previous heart surgery, the patient was selected for a percutaneous CAVI procedure.

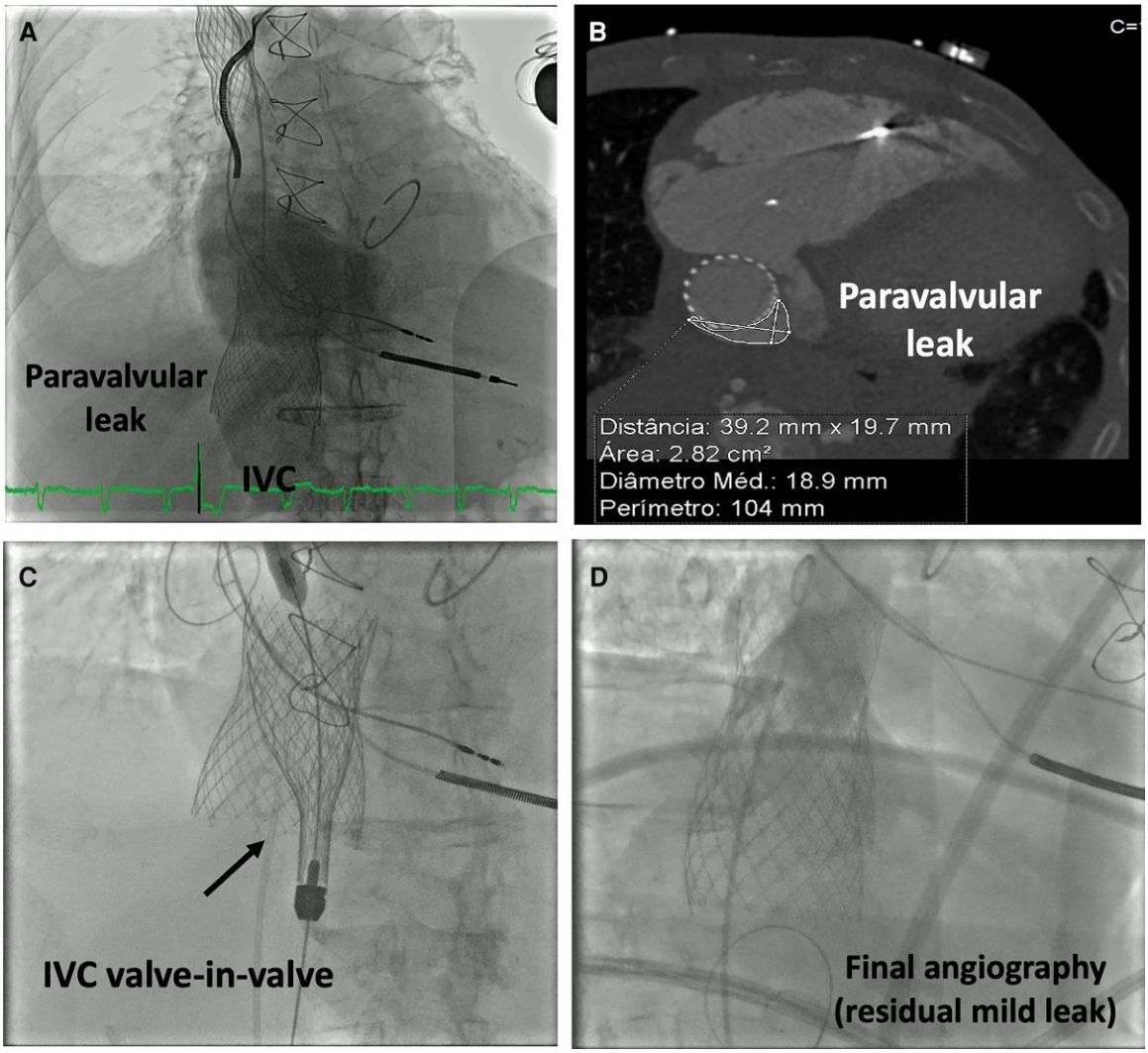


Figure 2 Paravalvular leak and re-intervention of Patient 1. (*A*) Venography performed during decompensated heart failure re-admission showing a major peri-valvular leak in the inferior vena cava prosthesis. (*B*) Cardiac computed tomography angiography to assess the leak dimensions in order to plan the valve-in-valve re-intervention, where a 35 mm valve was selected. (*C*, *D*) Valve-in-valve procedure using a 35 mm inferior vena cava caval prosthetic valve (black arrow) and final venography after valve release showing only a mild residual leak.

Right heart catheterization showed V waves of 28 mmHg in the IVC and 27 mmHg in the SVC, and coronary angiography did not show significant stenosis. Pre-procedural cardiac CTA was performed, resulting in prosthetic sizing of 25 mm for the SVC and 35 mm for the IVC. During SVC delivery, the prosthesis completely migrated to the right atrium (RA) (*Figure 4A*). This is believed to be a consequence of a marked tapering of the SVC. The operators managed the migration by pushing the prosthesis back to the SVC (*Figure 4B*) with the loop end of a stiff Safari™ guidewire (Boston Scientific). This was also used to hold the valve in place while a second SVC 25 mm valve was deployed (*Figure 4C–E*). The IVC valve was then deployed with good technical results (*Figure 5A*). The patient was discharged at 8 days after the procedure under medical therapy. The TTE prior to discharge (*Figure 5C and D*) revealed a well-positioned IVC valve and well-functioning valve-in-valve procedure in the SVC position. The distal segment of the first SVC valve is significantly protruding into the RA, but no significant paravalvular leak is noted. At 6 months of follow-up, she is clinically well, in NYHA class II and without hospital admissions.

Discussion

Patients with severe TR have high variations in the fluid status and in the caval vein size because they have highly distensible vascular structures. Hence, this difficulty in maintaining a euvolaemic status could be a pitfall in the sizing of valves with pre-procedural cardiac CTA. With the recent development of several percutaneous interventions for high-risk patients with severe TR, the rate of some possible complications is not well established, and neither are the better managing strategies. Among those, device embolization remains a rare complication of transcatheter heart interventions but with potential catastrophic consequences.[10] In the early trials of heterotopic caval valve implantation, migration/embolization cases were treated with surgical retrieval of valves.[12] Less invasive strategies may be preferable in order to avoid the exposure of these patients to complex heart surgeries with extracorporeal circulation. We described two cases of caval valve migration with the TricValve™ system (one IVC valve that migrated some weeks after the procedure and one SVC valve that migrated instantaneously to

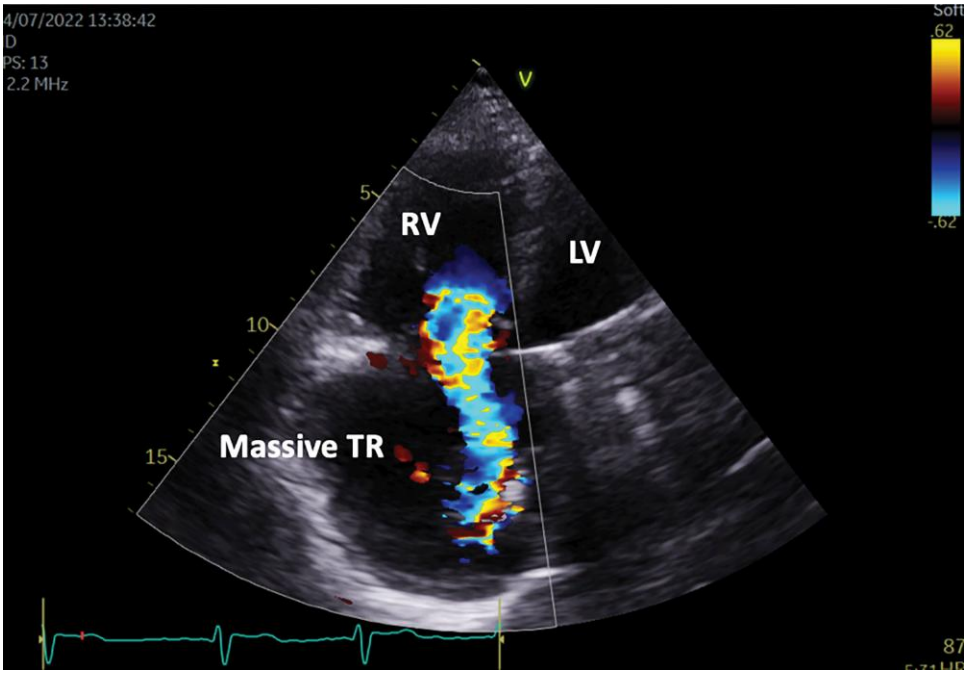


Figure 3 Transthoracic echocardiogram of Patient 2 (apical four-chamber view), showing a massive tricuspid regurgitation. TR, tricuspid regurgitation; RV, right ventricle; LV, left ventricle.

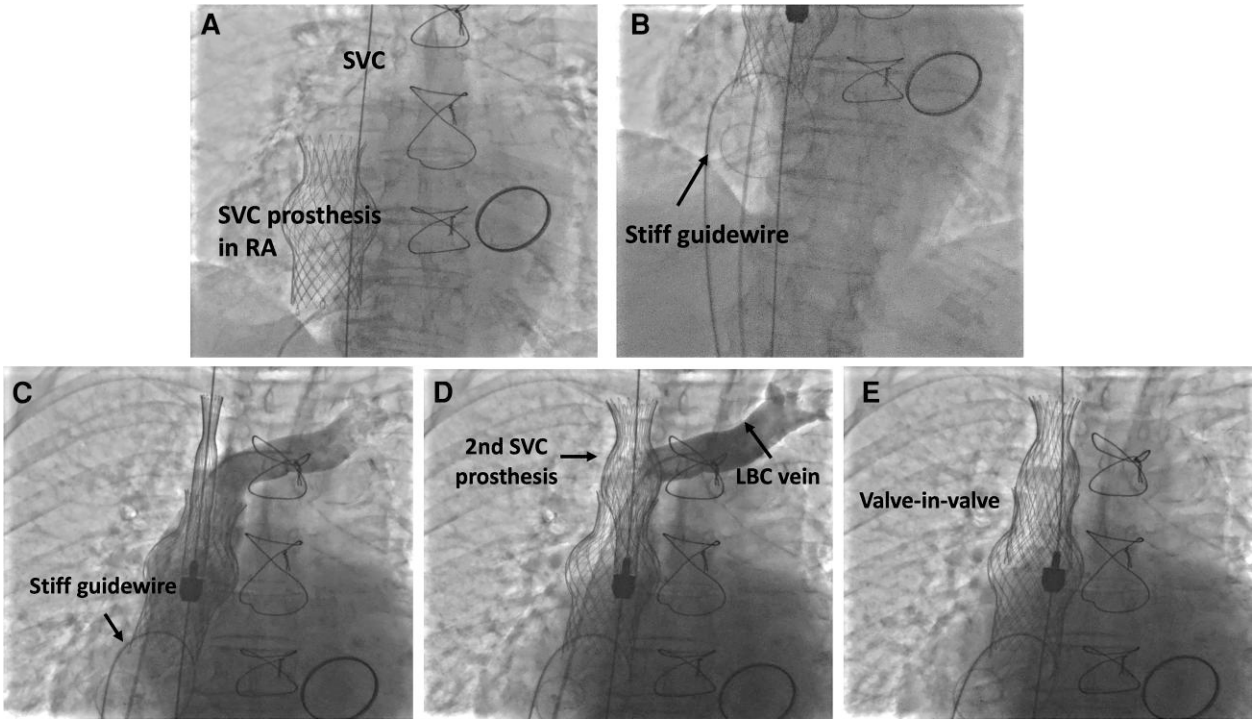


Figure 4 Fluoroscopic images of superior vena cava valve delivery of Patient 2. (*A*) Complete migration into the right atrium. (*B*, *C*) Partial repositioning into the superior vena cava using the loop end of a stiff Safari guidewire. Note the loop end of a Safari guidewire holding the first superior vena cava valve in place during the valve-in-valve procedure. (*D*) Second 25 mm size superior vena cava valve was positioned in the superior vena cava proximally to the first valve, which also served as an anchor to stabilize the second valve. Left brachiocephalic venography documents its patency after the valve-in-valve procedure. (*E*) Final result. SVC, superior vena cava; RA, right atrium; LBC, left brachiocephalic.

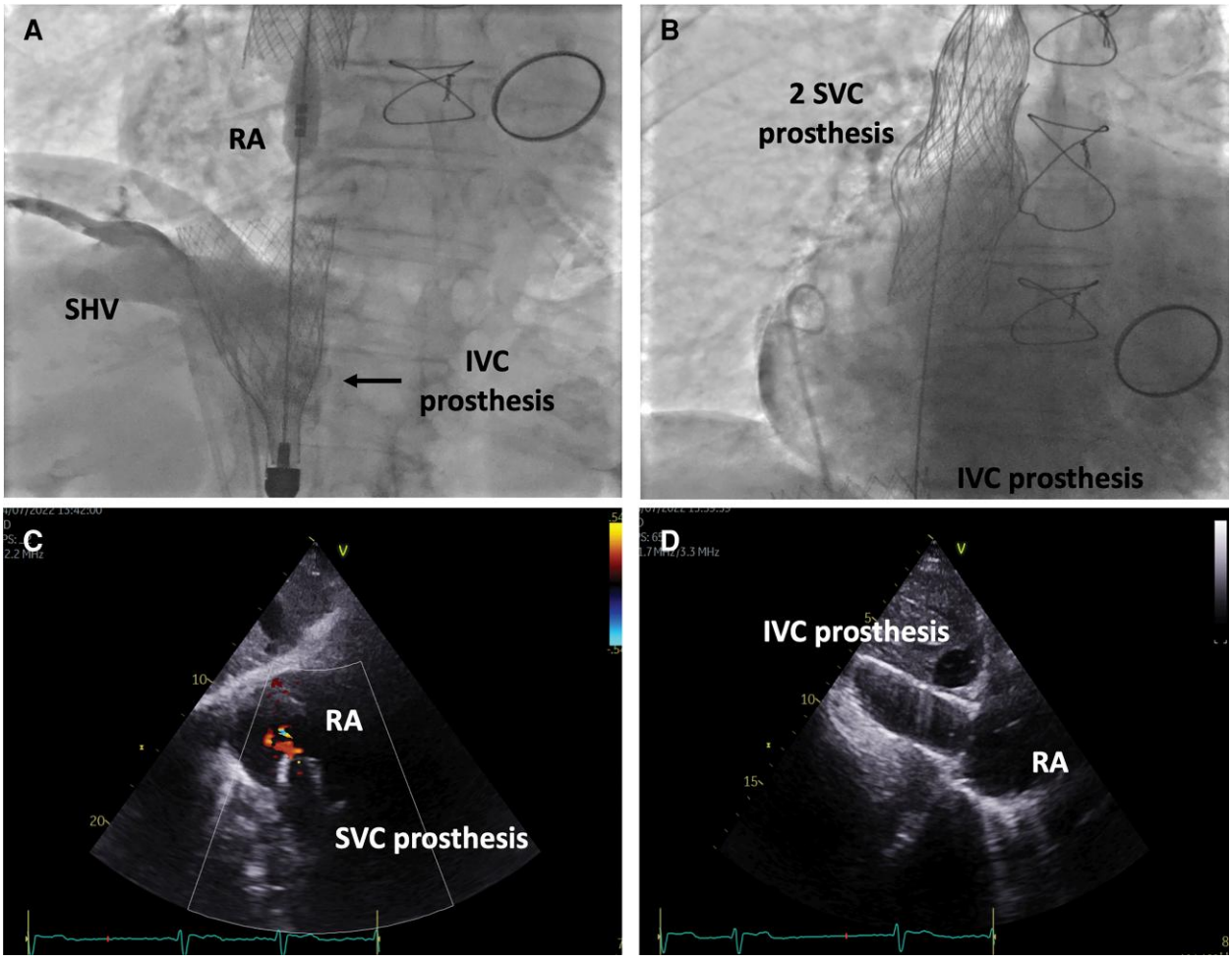


Figure 5 Fluoroscopic images of inferior vena cava valve delivery and post-procedural echocardiogram of Patient 2. (*A*) Inferior vena cava valve delivery under fluoroscopic guidance with caution to avoid occlusion of the supra-hepatic veins. (*B*) Final venous angiogram without significant peri-prosthetic leaks in the caval valves. (*C*, *D*) Post-procedural transthoracic echocardiogram showing a partially migrated prosthesis in the superior vena cava, without peri-prosthetic leak or tricuspid obstruction and a well-positioned inferior vena cava valve. RA, right atrium; SHV, supra-hepatic veins; IVC, inferior vena cava; SVC, superior vena cava.

the RA after valve release) treated successfully with percutaneous valve-in-valve procedures.

Lead author biography

André Grazina is a cardiology resident from Santa Marta Hospital, Lisbon, dedicated to interventional cardiology, mainly coronary intervention and percutaneous valvular intervention.

Consent: Written informed consent was obtained from the patients for the publication of these case reports, in compliance with the COPE guidelines and ICMJE recommendations.

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Data availability

No new data were generated or analysed in support of this research.

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