JACC: CASE REPORTS VOL. 23, 2023

CASE REPORT

ADVANCED

CLINICAL CASE SERIES

Contrast-Sparing Intravascular Ultrasound–Guided Caval Valve Implantation for Severe Symptomatic Tricuspid Regurgitation

Kara Denby, MD, Nikolaos Spilias, MD, Serge C. Harb, MD, Samir R. Kapadia, MD, Rishi Puri, MD, PhD

ABSTRACT

Patients with severe tricuspid regurgitation and right ventricular dysfunction have limited therapeutic options due to anatomic complexity, advanced disease at presentation, and comorbidities. Caval valve implantation is an emerging transcatheter therapy. We present a case series of contrast-sparing caval valve implantation using intravascular ultrasound guidance in patients with renal failure. (**Level of Difficulty: Advanced.**) (J Am Coll Cardiol Case Rep 2023;23:102007) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Severe symptomatic tricuspid regurgitation (TR) is a condition with limited treatment options. Isolated tricuspid surgery is associated with relatively high rates of short-term mortality and unclear long-term benefits.[1] Transcatheter tricuspid edge-to-edge repair (TEER) is currently undergoing evaluation in the United States, however, many patients are not ideal candidates due to large coaptation gaps. Caval valve implantation (CAVI) is an emerging technology, consisting of self-expandable valves implanted in the superior vena cava (SVC) and inferior vena cava (IVC). The landing zones for the valve frames are typically determined using preprocedural computed tomographic and intraprocedural SVC, IVC, and hepatic venograms, however, contrast administration may not be desirable due to high rates of concomitant renal insufficiency. We present a case series of successful, contrast-sparing CAVI using intravascular ultrasound (IVUS) guidance.

LEARNING OBJECTIVES

- To present the role of IVUS as an important adjunctive tool during CAVI, especially in patients with renal dysfunction.
- To emphasize the importance of real-time assessment of vena caval dimensions for proper CAVI sizing.
- To highlight the feasibility of contrast-sparing CAVI, with use of IVUS for fluoroscopic marking of key anatomic landmarks.

METHODS

All patients underwent preprocedural transthoracic echocardiogram (TTE) and computed tomography angiography (CTA) or magnetic resonance imaging (MRI) for anatomic assessment of the SVC and IVC and for CAVI sizing. The procedures were performed in the hybrid operating room under monitored

From the Heart, Vascular, and Thoracic Institute, Cleveland Clinic, Cleveland, Ohio, USA.
The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

Manuscript received May 8, 2023; revised manuscript received August 3, 2023, accepted August 7, 2023.

ISSN 2666-0849 https://doi.org/10.1016/j.jaccas.2023.102007

ABBREVIATIONS AND ACRONYMS

CAVI = caval valve implantation

CKD = chronic kidney disease

CTA = computed tomography angiography

eGFR = estimated glomerular filtration rate

IVC = inferior vena cava

IVUS = intravascular ultrasound

MRI = magnetic resonance imaging

PA = pulmonary artery

RA = right atrium

SVC = superior vena cava

TEER = transcatheter edge-to-edge repair

TR = tricuspid regurgitation

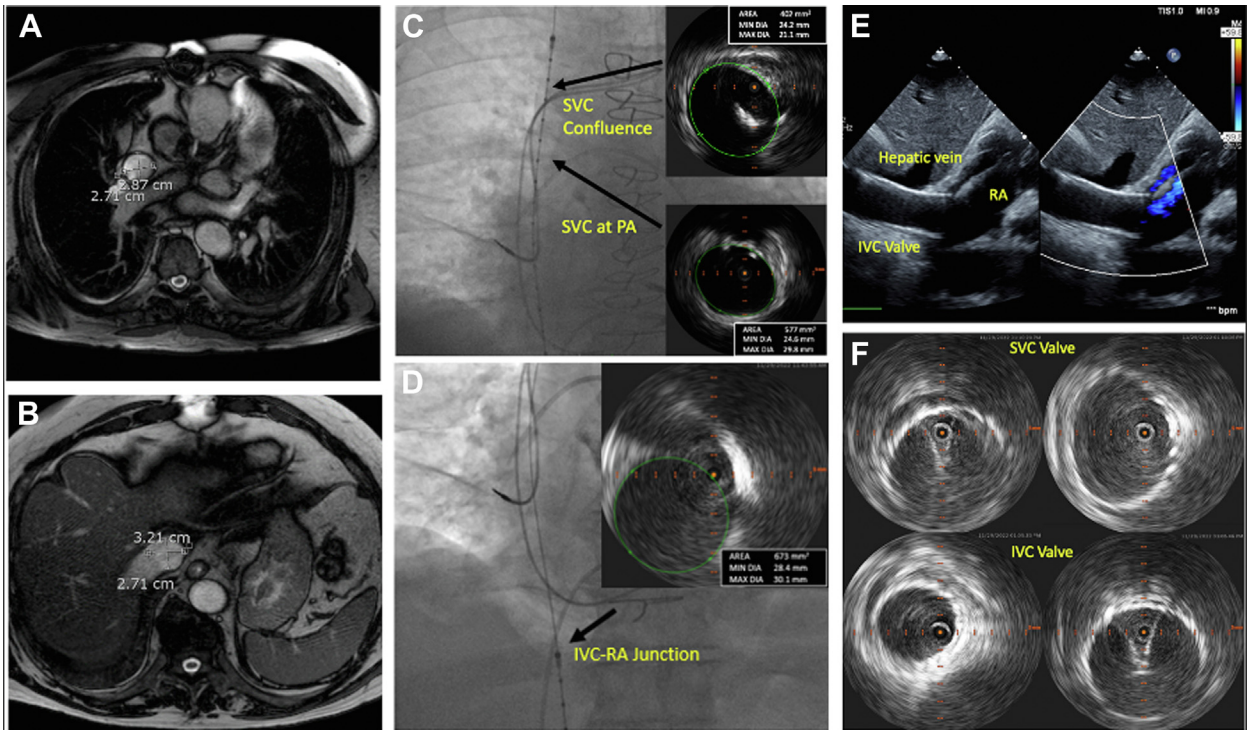
TTE = transthoracic echocardiogram

anesthesia care with fluoroscopic, TTE, and IVUS guidance. Vascular access was obtained in bilateral femoral veins and a balloon wedge pressure catheter was placed in the right pulmonary artery (PA) to serve as a fluoroscopic marker during SVC valve deployment. An IVUS catheter was advanced into the right brachiocephalic vein and pull-back was performed for the measurement of key dimensions and fluoroscopic marking of the following anatomic landmarks: confluence of right and left brachiocephalic veins, SVC at the top of right PA, SVC at the mid of right PA, and SVC-right atrial (RA) junction. For the IVC, the following landmarks were marked fluoroscopically and dimensions were measured: IVC-RA junction, IVC-hepatic vein confluence, IVC just below the hepatic vein, and IVC 5 cm below the hepatic vein. The SVC and IVC valves were deployed successfully according to the Instructions for Use and without contrast. We used the TricValve (Products & Features) caval valve system for each implantation.

CASE 1

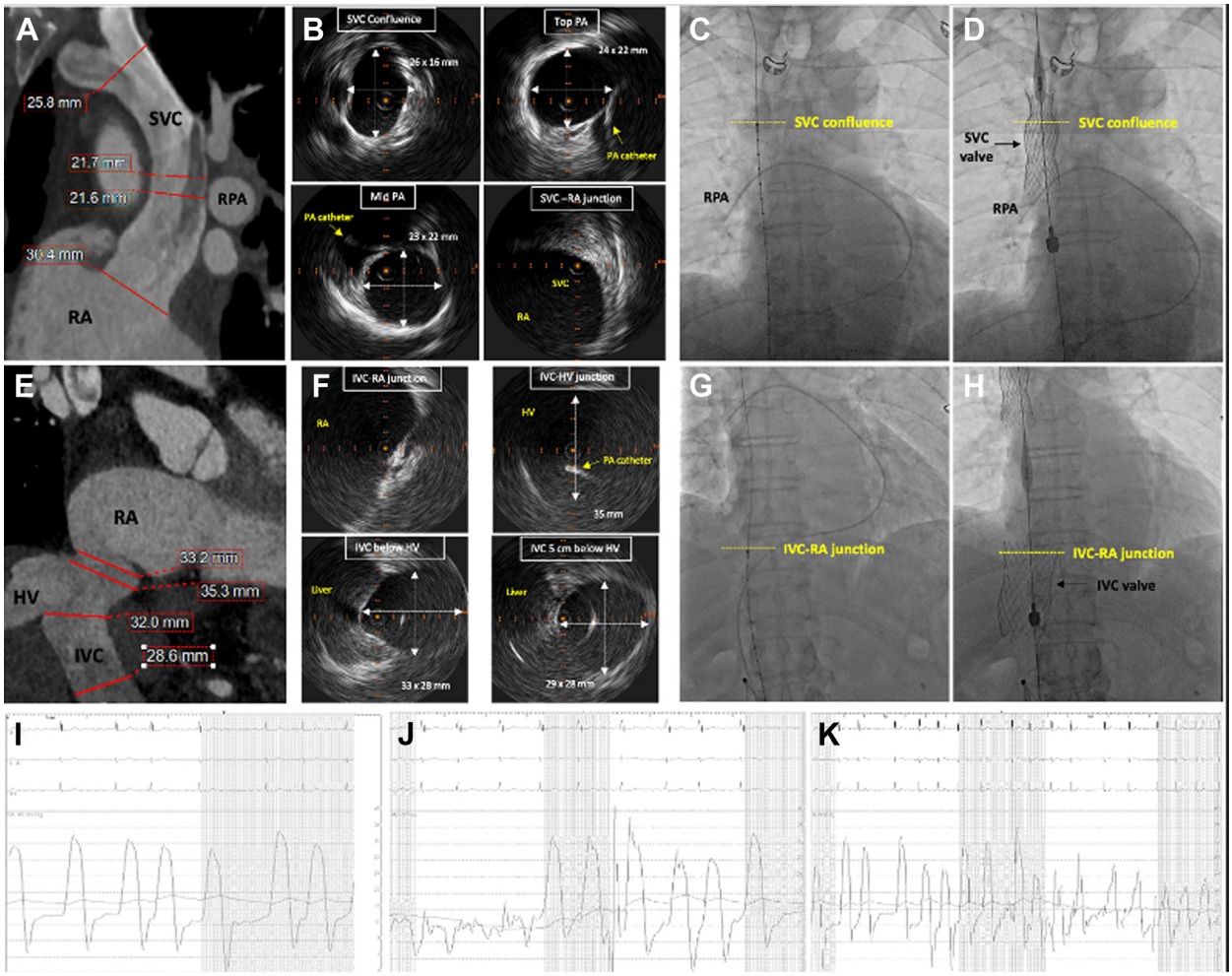
A 74-year-old patient with 2 prior cardiac surgeries and recent mitral and tricuspid TEER was hospitalized with acute decompensated heart failure in the setting of persistent severe TR and worsening chronic kidney disease (CKD) IV (estimated glomerular filtration rate [eGFR]: 29 mL/min/1.73 m^2). Due to high operative risk, the patient was evaluated for compassionate use CAVI. A MRI without gadolinium was performed for the measurement of SVC and IVC dimensions. IVUS was used during the CAVI procedure with the intention to avoid contrast administration. The IVUS measurements correlated well with MRI (Figures 1A to 1D). Based on IVUS, a 29-mm valve was deployed in the SVC and a 35-mm valve in the IVC with good hemodynamic result. The proximal landing zone of the IVC valve at the RA-IVC junction was also confirmed using TTE subcostal views (Figure 1E). IVUS

FIGURE 1 Preprocedural MRI



Preprocedural MRI showing measurements of the SVC **(A)** and IVC **(B)**. Intraprocedural IVUS with measurements of the SVC **(C)** and IVC **(D)**. Confirming appropriate valve position at RA-IVC junction with intraprocedural TTE subcostal views **(E)**. IVUS of IVC and SVC valves after deployment showing good stent apposition and leaflet coaptation **(F)**. IVC = inferior vena cava; IVUS = intravascular ultrasound; MRI = magnetic resonance imaging; RA = right atrium; SVC = superior vena cava; TTE = intravascular ultrasound.

FIGURE 2 **Preprocedural CTA**



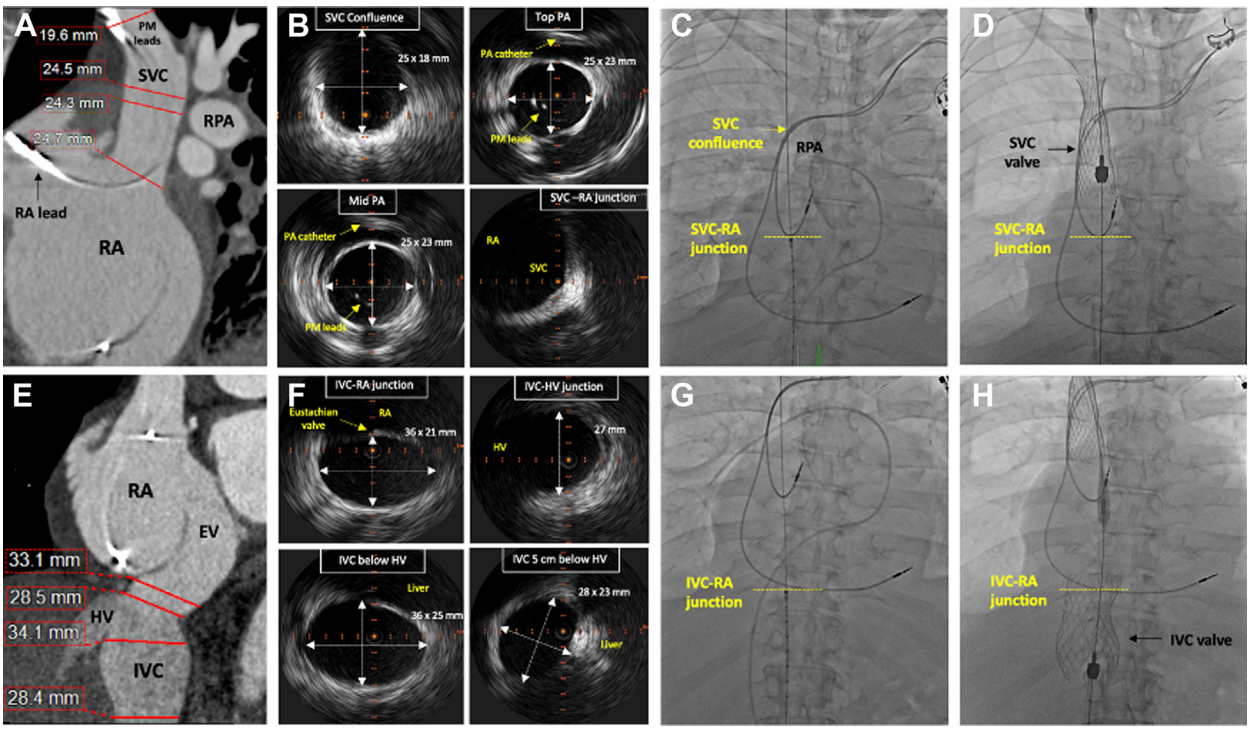
Preprocedural CTA with measurements of the SVC **(A)** and IVC **(E)**. Intraprocedural IVUS of the SVC **(B)** and IVC **(F)** at the different levels demonstrated in the CTA. Fluoroscopic marking of the key anatomic landmarks with the IVUS catheter and a balloon wedge catheter in the right PA **(C, D)**. Deployment of the SVC **(D)** and IVC **(H)** valves based on the IVUS assessment of dimensions and anatomic landmarks **(D, H)**. Invasive baseline hemodynamics **(I)** showing severely elevated SVC-RA pressures with equalization. SVC-RA **(J)** and RA-IVC **(K)** pullback post-CAVI with significant change in pressure across the valves. CTA = computed tomography angiography; PA = pulmonary artery; other abbreviations as in Figure 1.

after valve deployment demonstrated good stent apposition to the vessel walls and normal leaflet motion (Figure 1F). No contrast was used during this procedure.

CASE 2

An 89-year-old patient with severe symptomatic TR due to anterior flail leaflet, annular dilatation, and CKD IIIb (eGFR: 37 mL/min/1.73 m^2) was hospitalized for acute decompensated heart failure. TEER or orthotopic valve replacement were not feasible due to a large coaptation gap and a severely dilated tricuspid annulus. Therefore, the decision was made to proceed with compassionate use CAVI. A screening CTA was performed for anatomic evaluation of CAVI feasibility (Figures 2A and 2E). Several months transpired between the CTA and the date of the CAVI procedure, with a subsequent further hospitalization for significant volume overload. Due to concern for interim changes in caval dimensions that could have implications for the success of the CAVI procedure,

FIGURE 3 Preprocedural CTA



Preprocedural CTA with measurements of the SCV **(A)** and IVC **(E)**. Intraprocedural IVUS of the SVC **(B)** and IVC **(F)** at the different levels demonstrated in the CTA. Note the presence of pacemaker leads and a prominent Eustachian valve. Fluoroscopic marking of the key anatomic landmarks with the IVUS catheter and a balloon wedge catheter in the right PA **(C, D)**. Deployment of the SVC **(D)** and IVC **(H)** valves based on the IVUS assessment of dimensions and anatomic landmarks **(D, H)**. Abbreviations as in **Figures 1 and 2**.

and to avoid further contrast administration for a new CTA, we decided to use intraprocedural IVUS for real-time assessment of the caval dimensions. IVUS correlated closely with the original CTA measurements (**Figures 2B and 2F**). Based on IVUS and fluoroscopy, a 25-mm valve was implanted in the SVC and a 35-mm IVC valve in the IVC with an excellent hemodynamic result (**Figures 2C, 2D, 2G, and 2H**, Video 1A through 1F and Video 2A through 2C). At 2 months postprocedural follow-up, the patient reported improvement in symptoms and exercise capacity without any interim hospitalizations. The diuretic dose was decreased and the renal function improved (serum creatinine decreased from 1.37 mg/dL to 1.26 mg/dL).

CASE 3

An 89-year-old patient with severe symptomatic TR due to annular dilatation, permanent atrial fibrillation, cardiac amyloidosis, and a dual-chamber pacemaker due to complete heart block, was referred for transcatheter tricuspid therapies. Given the large coaptation gap, enlarged annulus, and pacemaker dependence, the patient was not a candidate for TEER or valve replacement. Therefore, compassionate use CAVI was considered. A preprocedural CTA was performed for SVC and IVC assessment and valve sizing (**Figures 3A and 3E**).

Due to CKD IIIa (eGFR: 49 mL/min/1.73 m^2), a contrast-sparing strategy with IVUS guidance was pursued during the CAVI procedure. In addition to the fluoroscopic position of the IVUS catheter relative to key anatomic landmarks, the pacemaker leads also served as a marker for the brachiocephalic vein confluence into the SVC (**Figure 3C**). The IVUS measurements of the SVC and IVC correlated well with the preprocedural CTA (**Figures 3B and 3F**). Based on IVUS and fluoroscopy, a 25-mm valve was placed in the SVC and a 35-mm valve in the IVC with an excellent hemodynamic result (**Figures 3C, 3D, 3G, and 3H**). The patient tolerated the procedure well and was discharged several days later with oral torsemide and a home physical-occupational therapy program.

DISCUSSION

CAVI is an emerging and promising transcatheter therapy for patients with severe symptomatic TR. The CAVI system consists of 2 self-expanding nitinol frames with bovine pericardial valves, which are deployed percutaneously in the SVC and IVC. Mitigation of caval backflow may ameliorate the deleterious effects of venous congestion and, over time, lead to a degree of reverse right-sided heart remodeling and an improvement in net cardiac output through the systemic circulation.[2] The TRICUS EURO (Safety and Efficacy of the TricValve Transcatheter Bicaval Valves System in the Superior and Inferior Vena Cava in Patients With Severe Tricuspid Regurgitation) study demonstrated high procedural success rates with significant improvements in New York Heart Association class and quality of life metrics.[3] Although commercially available in Europe, Asia, and Latin America, a Food and Drug Administration pivotal randomized trial of the CAVI system vs medical therapy will likely commence later in 2023 in the United States.

Preprocedural imaging with TTE, CTA, and/or MRI for the anatomic assessment of the SVC, IVC, and proper valve sizing is required. SVC, IVC, and hepatic venograms are routinely performed during the procedure to determine the landing zones for the valve frames, resulting in contrast administration within a population with concomitant renal dysfunction and risk of contrast-induced nephropathy. In this case series, we presented 3 cases of contrast-sparing, IVUS-guided CAVI in patients with significant renal dysfunction.

IVUS serves a dual purpose during the procedure. First, it provides a real-time assessment of key caval dimensions for valve sizing and allows comparison with preprocedural noninvasive imaging. The SVC and IVC are highly compliant venous conduits with dynamic dimensions, depending on systemic volume status.[4] Assessing caval dimensions during a volume overloaded state may result in patient screening failure or inappropriate valve oversizing, especially in cases of significant time lag between noninvasive vena caval imaging and the actual CAVI procedure. Assessing caval dimensions in a more euvolemic state, after appropriate diuresis, is of paramount importance. Second, the IVUS catheter facilitates the fluoroscopic marking of relevant anatomic landmarks for the precise determination of proper valve landing zones, obviating the need for periprocedural venograms. The various bony landmarks, the presence of pacemaker leads in some cases, and the concomitant use of marking catheters in the right pulmonary artery can also serve as fluoroscopic markers in conjunction with IVUS.

In all 3 of our cases, IVUS measurements correlated closely with preprocedural caval imaging, and the choice of valve size was consistent between the methods. The procedures were performed safely and successfully without contrast.

CONCLUSIONS

CAVI is an emerging treatment for patients with severe TR. Intraprocedural IVUS can be easily used for reliable, real-time caval sizing and fluoroscopic marking of key anatomic landmarks for valve deployment, obviating the need for contrast use, especially in patients with renal dysfunction. As the application of this novel transcatheter therapy expands, IVUS can serve as an important adjunctive tool for procedural optimization and patient safety.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

Dr Puri is a consultant to Products & Features. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

ADDRESS FOR CORRESPONDENCE: Dr Rishi Puri, Department of Cardiovascular Medicine, Heart, Vascular & Thoracic Institute, Cleveland Clinic, Mail Code J2-208, 9500 Euclid Avenue, Cleveland, Ohio 44195, USA. E-mail: purir@ccf.org.

REFERENCES

1. Taramasso M, Alessandrini H, Latib A, et al. Outcomes after current transcatheter tricuspid valve intervention: mid-term results from the international. TriValve registry. *J Am Coll Cardiol Intv*. 2019;12:155-165.

2. Abdul-Jawad Altisent O, Benetis R, Rumbinaite E, et al. Caval valve implantation (CAVI): an emerging therapy for treating severe tricuspid regurgitation. *J Clin Med*. 2021;10:4601.

3. Estevez-Loureiro R, Sanchez-Recalde A, Amat-Santos IJ, et al. 6-Month outcomes of the TricValve system in patients with tricuspid regurgitation (the TRICUS EURO study). *J Am Coll Cardiol*. 2022;15:1366-1377.

4. Ivey-Miranda JB, Wetterling F, Gaul R, et al. Changes in inferior vena cava area represent a more sensitive metric than changes in filling pressures during experimental manipulation of intravascular volume and tone. *Eur J Heart Fail*. 2022;24:455-462.

KEY WORDS bicaval valve implantation, caval valve implantation, intravascular ultrasound, tricuspid regurgitation

APPENDIX For supplemental videos, please see the online version of this paper.