Surgically Assisted Transcatheter Balloon-Expandable Valve in Inferior Vena Cava for Torrential Tricuspid Regurgitation

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INTRODUCTION

Isolated tricuspid regurgitation (TR) is associated with decreased survival independent of risk factors such as ventricular dysfunction and pulmonary hypertension.[1] Of the 1.6 million patients with moderate to severe TR, each year <8,000 undergo surgery.[1] The operative mortality rate is 8%–10%.[2] Although symptoms typically diminish, there is no literature suggesting a survival benefit.[1,3] The progression of severe TR devolves into right heart failure, liver dysfunction, and renal failure. It is unclear how to manage these patients when end organ dysfunction precludes surgical intervention.

Novel therapies have emerged to treat patients with passive congestion whose TR is too severe for other transcatheter valve therapies. Adaptation of transcatheter aortic valve technology has been used to treat the upstream effects of severe TR by placing a transcatheter valve into the inferior vena cava (IVC) alone[4] or in addition to a valve in the superior vena cava.[5] This technique involves implanting a one-way valve at the right atrial–IVC junction, preventing regurgitation of blood into the caval veins. We discuss the first surgically assisted transcatheter implantation of the SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA) into a markedly dilated IVC. In this approach, the IVC diameter is reduced by an external ring.

CASE PRESENTATION

Two patients with torrential TR,[6] effective regurgitant orifice areas of 2.12 and 3.1 cm^2, respectively, and reduced right ventricular function were referred for a percutaneous approach for the treatment of TR because of multisystem organ disease. Patient A was a 64-year-old man with rheumatic heart disease and a history of mechanical aortic and mitral valve replacements 22 years before presentation. His history was also notable for pulmonary hypertension and hepatic encephalopathy. Patient B was an 85-year-old man with severe aortic stenosis treated with surgical aortic valve replacement, pulmonary hypertension, and myelodysplastic syndrome. Preoperative computed tomographic angiography in both cases revealed large IVC diameters,

and the patients were scheduled for surgically assisted percutaneous caval valve implantation (CAVI).

Intraoperative transesophageal echocardiography was used to quantify the torrential TR, as demonstrated in Figure 1. We also illustrated the coaptation defect from a deep transgastric view (Figure 2), with en face three-dimensional imaging (Video 1, Figure 3), and confirmed the size of the IVC, measuring 40.5 and 48.0 mm, respectively (Figure 4). Most CAVIs use an IVC stent that serves as a landing zone for the SAPIEN 3 valve. A caval diameter of <30 mm is desired to correctly accommodate the largest available SAPIEN 3 valve, but diameters of up to 35 mm may be downsized by implanting multiple intravascular stents. In our case, the IVC was too large for a stent-based approach.

Bilateral femoral venous and arterial access was obtained by the surgeons. Right lateral thoracotomy was performed to access the right atrial–IVC junction. In patient A, minor IVC injury with bleeding precluded surgical visualization, and elective cardiopulmonary bypass was initiated via femoral cannulation. Patient B's anatomy did not allow adequate dissection via right thoracotomy, and a mini lower median sternotomy was performed to aid surgical exposure. In both patients, the IVC was encircled with a #34 Simulus semirigid mitral annuloplasty ring (Medtronic, Minneapolis, MN). The ring was cut in the middle, and after encircling the IVC, the two ends were sutured together, and the ring was fixed to the diaphragm with three sutures to prevent movement. A #29 SAPIEN 3 valve was percutaneously advanced along the guidewire and deployed under fluoroscopic and transesophageal echocardiographic guidance, positioned across the ring, which served as a landing zone at the right atrial–IVC junction (Figures 5–7, Video 2). Valve positioning was at the level of the diaphragm, superior to the convergence of the IVC with the hepatic veins (Figure 8). The valve was oriented approximately 5 mm into the IVC and best visualized with the modified bicaval view (Figure 9, Video 3). Patient A had a slight reduction in effective regurgitant orifice area by proximal isovelocity surface area, and patient B developed a 21% decrease in TR (Figures 10 and 11).

Postoperatively, both patients were transferred to the cardiothoracic intensive care unit intubated, on vasopressor and inotropic support. Patient A gained full recovery and was discharged home on postoperative day 14 with improvement in ascites and lower extremity edema. Three-month surveillance transthoracic echocardiography revealed diminished TR. Patient B developed recurrent bleeding of the right hemithorax compromising respiratory status and renal failure requiring renal replacement therapy. The patient was placed on comfort measures and died on postoperative day 21.

DISCUSSION

The unique geometry of the tricuspid valve makes transcatheter therapies challenging. The annulus is large, elliptical, and nonplanar in shape, with the absence of calcification in secondary TR to anchor

Figure 1 Three-dimensional (3D) quantification of effective regurgitant orifice area indicates torrential TR. *Circ*, Circumference.
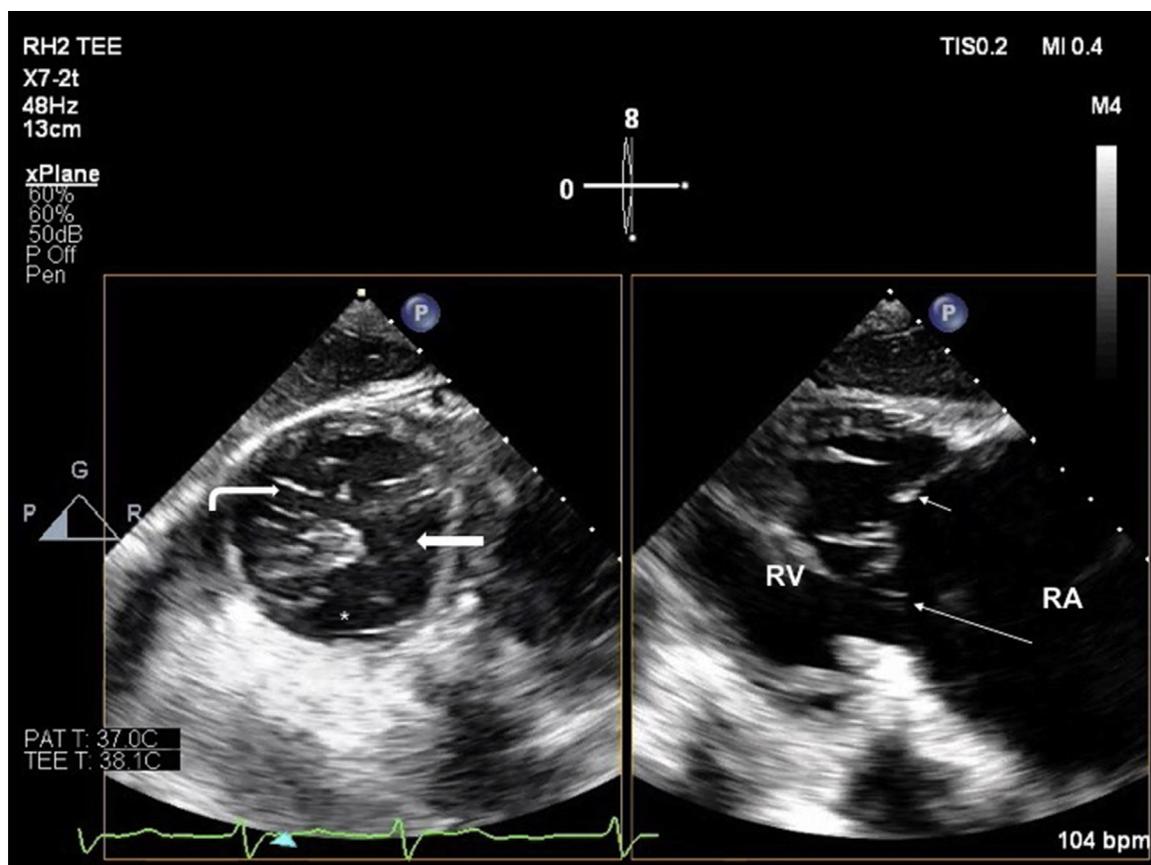
Figure 2 Transgastric x-plane view of the tricuspid valve in systole. (*Right*) Tricuspid valve in long-axis view showing coaptation defect between the anterior tricuspid valve leaflet (*long arrow*) and posterior tricuspid valve leaflet (*short arrow*), right ventricle (RV), and right atrium (RA). (*Left*) Transgastric short-axis view of tricuspid valve: anterior tricuspid valve leaflet (*asterisk*), posterior tricuspid valve leaflet (*curved arrow*), and septal tricuspid valve leaflet (*bold arrow*).
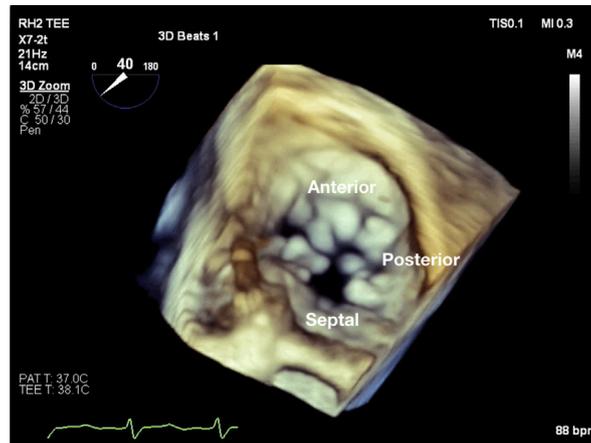
**Figure 3** Three-dimensional en face surgical view of coaptation defect.
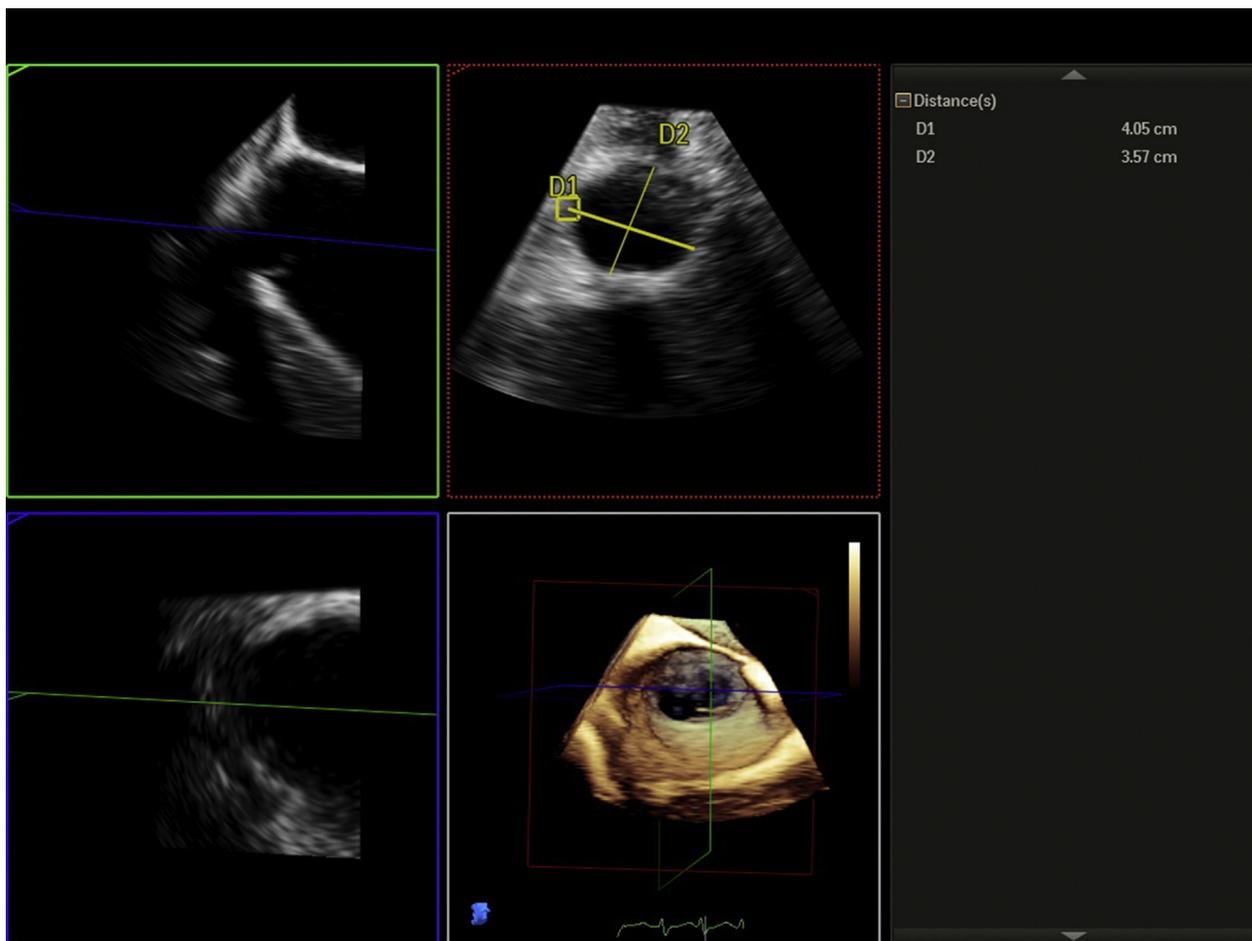
Figure 4 Three-dimensional IVC dimensions, which preclude the use of a stent-based approach.

the valve (Video 1). In addition, the coronary sinus, right coronary artery, atrioventricular node, and bundle of His are in close proximity to the annulus. In the United States, the only transcatheter option outside of a trial would be off-label use of the MitraClip (Table 1). In early feasibility trials, patients with end-stage right heart failure are typically excluded. Moderate to severe pulmonary hypertension is also an exclusion criteria, because when present it may precipitate right ventricular failure if the tricuspid valve was competent.

CAVI avoids these anatomic challenges by placing the valve in a heterotopic position.[4,13] This is a palliative procedure designed to alleviate signs and symptoms of right heart failure in patients who are not surgical candidates. The procedure decreases the
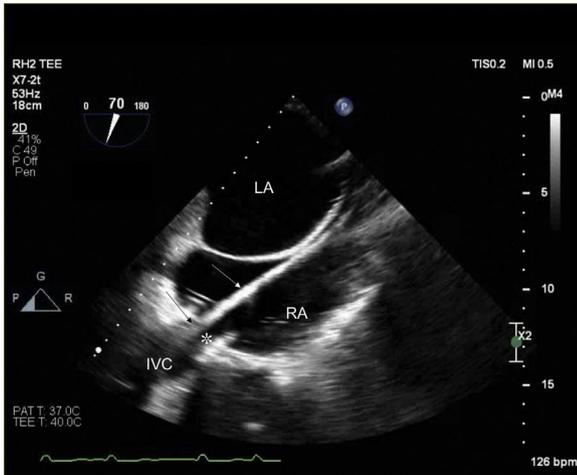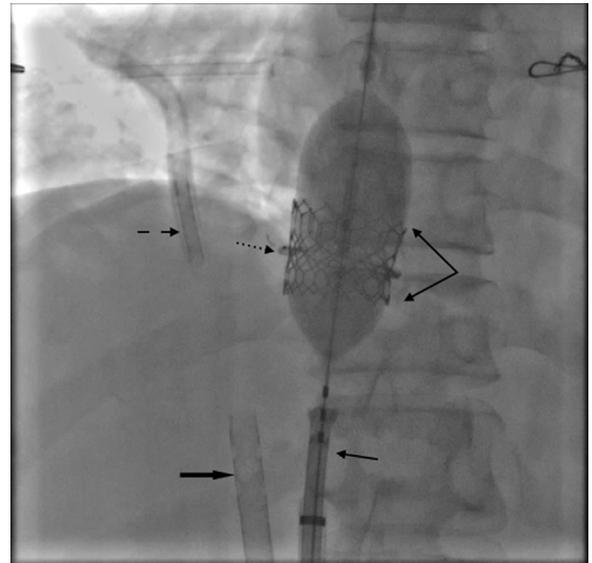
Figure 5 Modified bicaval view with focus on the inferior vena cava (IVC) showing SAPIEN 3 (*asterisk*) advanced over guidewire (*arrows*) at right atrial–IVC junction. *LA*, Left atrium; *RA*, right atrium.
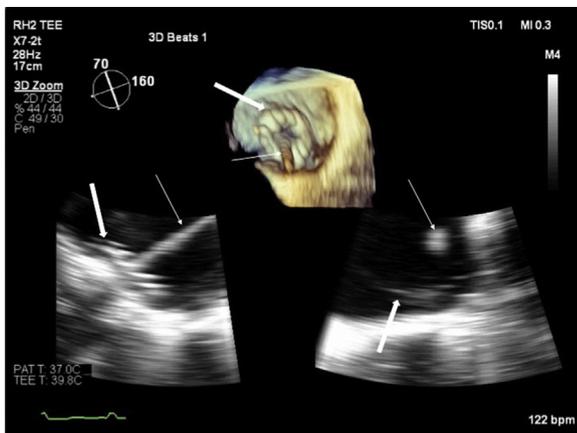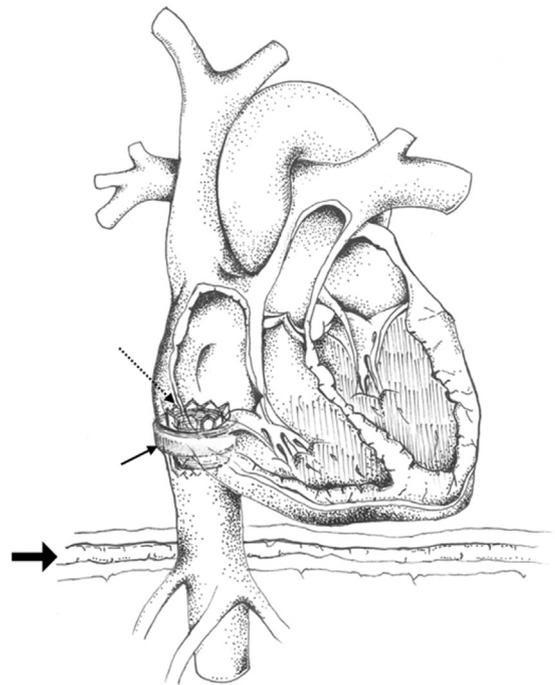

Figure 6 Modified bicaval view with focus on the IVC in x-plane and three-dimensional guidewire (*thin arrow*) with SAPIEN 3 valve (*bold arrow*) at the right atrial–IVC junction, approximately 5 mm into the right atrium while avoiding occlusion of the hepatic veins.

Figure 7 Fluoroscopic deployment of the SAPIEN 3 valve above the level of the diaphragm at the right atrial–IVC junction. *Thin arrow*, Edwards delivery sheath; *bold arrow*, venous extracorporeal membrane oxygenation cannula; *dotted arrow*, deployed SAPIEN 3 within ring encircling the IVC; *interrupted arrow*, field suction.

backflow of blood into the vena cava but does not address the tricuspid valve itself. Regurgitation of blood from the superior vena cava still occurs, though mean IVC pressures have been shown to decrease postprocedurally, and this is the likely mechanism for symptom relief.[8] The first-in-human bicaval CAVI procedure resulted in continued improvement in mean caval pressures over 12 months of follow-up, reduction in symptoms, and normalization of liver function.[14]

Short- and long-term outcome data are limited because of the compassionate use of the device and small sample size. Of 10 patients who underwent CAVI using the stent-based approach, nine had improvement by at least one New York Heart Association functional class. The exception was a patient in cardiogenic shock at baseline. Right ventricular function assessed by tricuspid annular plane systolic excursion improved in nine patients. Thirty-day mor-
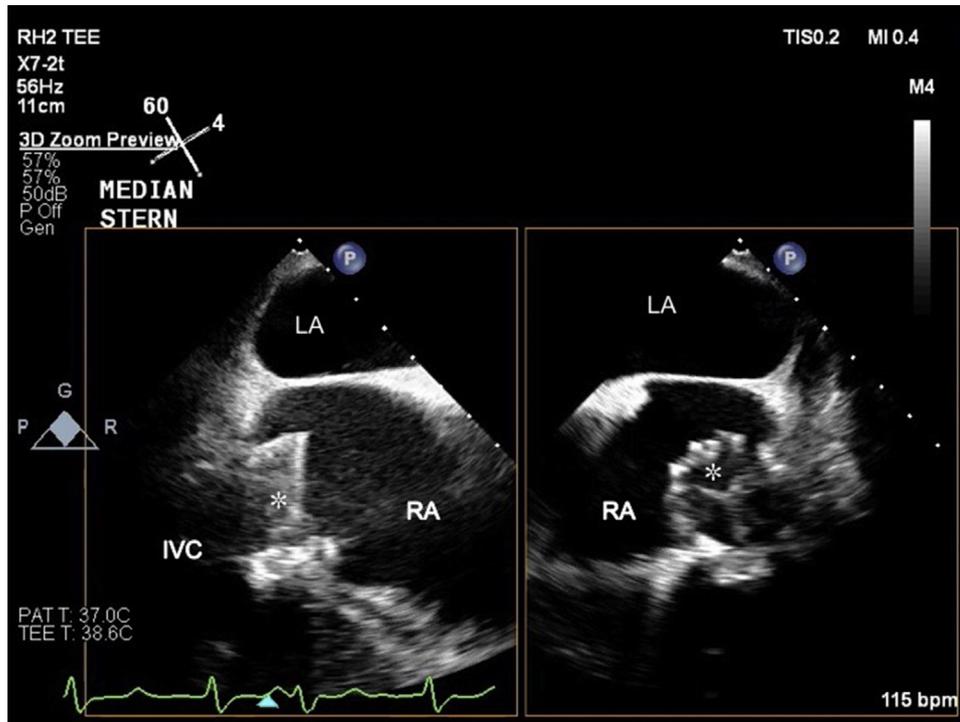

Figure 8 Medical illustration of the SAPIEN 3 valve deployed within the mitral annuloplasty ring. The valve is positioned at the right atrial–IVC junction, above the level of the hepatic veins. *Bold arrow*, diaphragm; *thin arrow*, ring encircling the IVC; *dotted arrow*, SAPIEN 3 valve.

Figure 9 X-plane bicaval view of deployed SAPIEN 3: modified bicaval view in x-plane with focus on the inferior vena cava (IVC) showing correct heterotopic deployment of SAPIEN 3 valve (*asterisk*) at the IVC–right atrial junction. *LA*, Left atrium; *RA*, right atrium.
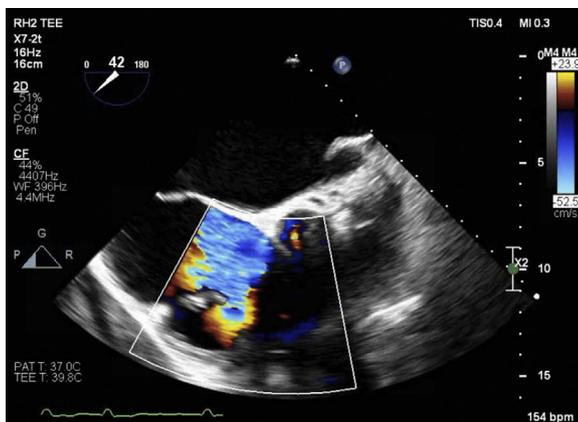
Figure 10 Evaluation of the proximal isovelocity surface area (PISA) shell after CAVI, with an aliasing velocity of 23.0 cm/sec and a PISA radius of 1.68 cm.
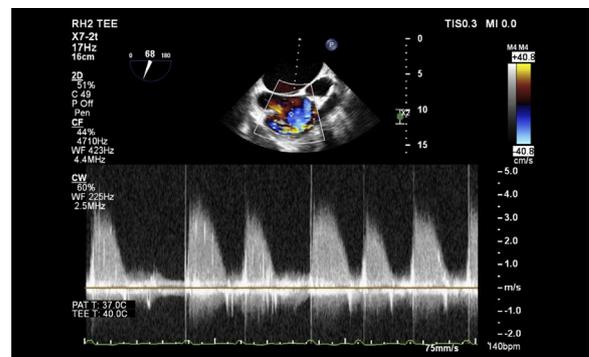
Figure 11 Postprocedural evaluation of TR illustrating a maximum TR velocity of 344 cm/sec. The tricuspid valve effective regurgitant orifice area after the procedure is calculated to be 1.23 cm^2 by proximal isovelocity surface area, indicating a reduction from baseline.

tality was 20%, and during the 913-day follow-up, no device malfunction was detected.[8]

Transesophageal echocardiography is an integral part of the procedure. Echocardiography is the ideal method to identify structural abnormalities of the tricuspid valve and to quantify annular dimensions and the effective regurgitant orifice area. Transesophageal echocardiography can assess the size of the vena cava, assist in the placement of a caval stent or ring, guide transcatheter valve deployment, assess for device migration, and evaluate the presence of paravalvular leak.

Visualization of the hepatic veins and caval flow into the right atrium is also useful in quantifying hepatic flow reversal or its resolution postprocedurally (Figures 12 and 13).

We recognize that this procedure has limitations. As evidenced by our experience, surgical intervention of any type in this patient population carries substantial risk. A thoracotomy or sternotomy is invasive and, some argue, equivalent to open heart surgery, especially if emergent cardiopulmonary bypass is initiated. In addition, collateral blood flow through the azygous, left-sided thoracic veins and esophageal

Table 1 Transcatheter tricuspid investigational devices

Investigational device	Mechanism	Trial	Outcome
TriAlign[7]	Plication of tricuspid annulus by bicuspidization of tricuspid valve	SCOUT (ClinicalTrials.gov identifier NCT02574650)	30-day results: reduction in EROA, increased LV stroke volume, improvements in NYHA functional class and 6-min walk distance
TriCinch[8]	Percutaneous annuloplasty device. anchors corkscrew in the anteroposterior commissure, tightens septal-lateral dimension using stent delivery system	PREVENT (ClinicalTrials.gov identifier NCT02098200)	Improvements in NYHA functional class and 6-min walk distance
FORMA[9]	Polymer balloon spacer anchored to the RV myocardium, reduces EROA	ClinicalTrials.gov identifier NCT02471807	Decrease in RA and RV size, decrease in TR, improvement in NYHA functional class
Cardioband[10]	Annuloplasty device	TRI-REPAIR (ClinicalTrials.gov identifier NCT02981953)	Outcome analysis pending
Mitral Clip[11]	Coaptation device used in the tricuspid position with edge-to-edge technique	Triluminate (ClinicalTrials.gov identifier NCT3227757)	Reduction in TR EROA by at least one grade, improvements in NYHA functional class and 6-min walk distance
Tricuspid valve in valve[12]	Orthotopic valve implantation		Improvements in tricuspid valve area and mean transvalvular gradients
Transcatheter valve	Orthotopic valve implantation		No published data

EROA, Effective regurgitant orifice area; *LV*, left ventricular; *NYHA*, New York Heart Association; *RA*, right atrium; *RV*, right ventricular; *TR*, tricuspid regurgitation.
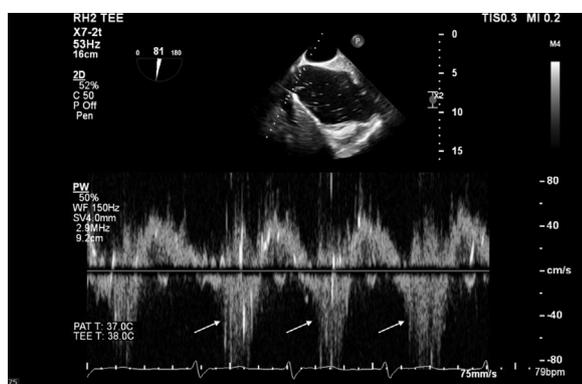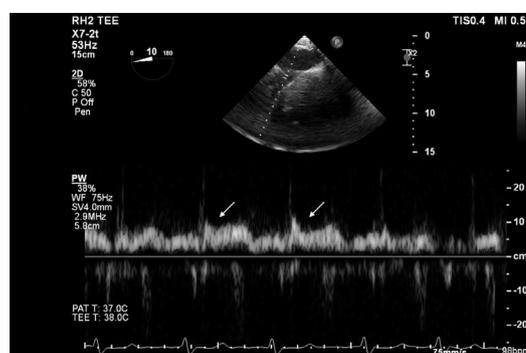

Figure 12 Pulsed-wave Doppler illustrating systolic flow reversal in the hepatic veins secondary to severe TR before CAVI. *Arrows*, S wave below the baseline indicating systolic flow reversal.

varices may limit the intermediate and long-term efficacy of the procedure.

CONCLUSION

CAVI is a novel, palliative, transcatheter technique for the treatment of severe TR that avoids the anatomic challenges of the tricuspid valve by placing the valve in a heterotopic position. These cases illustrate the feasibility of surgically assisted CAVI in patients with large IVC diameters. Such cases require a multidisciplinary approach as well as close postoperative surveillance while we continue to learn about the long-term effects of this intervention on patient outcomes.

Figure 13 Pulsed-wave Doppler illustrating the absence of systolic flow reversal in the hepatic veins after CAVI. *Arrows*, S wave above the baseline indicating resolution of systolic flow reversal.

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.case.2018.04.009.

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