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Caval Valve Implantation Procedure in 7 Cases of Torrential Tricuspid Regurgitation and Step-by-Step Description of the Procedure

CASE REPORT

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INTRODUCTION

Tricuspid regurgitation (TR) is an increasingly prevalent and clinically significant health problem.[1] Due to the growing understanding of the importance of TR, the tricuspid valve has transitioned from being a forgotten valve to one of significant concern. Tricuspid regurgitation is often functional, and as it progresses to moderate or severe stages, hospital admissions increase and prognosis worsens.[1,2] There are no effective pharmacological treatments for TR, and the 5-year survival rate with medical management is reported to be less than 50%.[3] Therefore, early diagnosis and timely intervention for TR is crucial. Both surgical and percutaneous treatment options are available for severe TR. The mortality rate for isolated TR surgery is generally high.[4] In recent years, transcatheter treatments have become feasible for this patient group, and accumulating evidence shows that transcatheter treatment is superior to medical management.[5,6] Transcatheter interventions for TR can be performed in 4 ways, 2 involving repair and 2 involving valve implantation.[7]

We aimed to present our experience with transcatheter caval valve implantation (CAVI) in 7 patients with torrential TR who were not suitable for surgical intervention or transcatheter edge-to-edge repair (T-TEER) due to severe coaptation defects, review the current literature, and provide a step-by-step description of the procedure.

CASE REPORTS

Case 1

An 84-year-old female patient, who underwent aortic and mitral valve replacement surgery 20 years ago, presented with symptoms and signs of right heart failure. She had severe edema and shortness of breath, even at rest. There was jugular venous distention in the sitting position, and v-waves were very prominent (Lancisi's sign) (Video 1). Transthoracic echocardiography (TTE) showed torrential TR, Tricuspid Annular Plane Systolic Excursion (TAPSE) of 17 mm, systolic pulmonary artery pressure (sPAP) of 45 mm Hg, and left ventricular ejection fraction (LVEF) of 40% (Video 2). The TRI-SCORE was used to predict in-hospital mortality.[8] Her TRI-SCORE was calculated as 14. Computed tomography (CT) was performed to visualize the vena cavae, and device sizes were determined. The patient underwent CAVI using the TricValve system (P&F Products Features Vertrieb, Vienna, Austria) under sedation and local anesthesia. A 29 mm valve was placed in the superior vena cava (SVC), and a 35 mm valve was placed in the inferior vena cava (IVC). She was discharged after 4 days of hospitalization with significant improvement in functional capacity [from New York Heart Association (NYHA) 3-4 to NYHA 2]. Her edema regressed, and the need for diuretics decreased (furosemide 20 mg/day). Jugular venous distention disappeared (Video 3).

Case 2

A 71-year-old female patient presented with signs of right heart failure and had been hospitalized 4 times in the last 3 months. She was using 240 mg of furosemide

per day and had a history of cardiorenal and cardiohepatic syndrome. Transthoracic echocardiography showed torrential TR. The TRI-SCORE was calculated as 48. Computed tomography angiography was performed to visualize the vena cavae and assess device suitability. She underwent CAVI under sedation and local anesthesia. The diameters of the SVC and IVC devices implanted were 25 mm and 45 mm, respectively. She died a week after the procedure due to multiple organ failure.

Case 3

A 74-year-old female patient presented to a local hospital with complaints of shortness of breath, fatigue, loss of appetite, and swelling in her legs and abdomen, which had been worsening for 6 months. Transthoracic echocardiography showed torrential TR, dilation of the right heart chambers, and mild-to-moderate reduction in RV function (TAPSE 17 mm). The in-hospital predicted mortality rate was calculated as 14 using the TRI-SCORE. The coaptation gap was 20 mm, making the patient unsuitable for T-TEER. Computed tomography angiography was performed. A 29 mm valve was selected for the SVC, and a 41 mm valve for the IVC. The procedure was completed successfully under sedation and local anesthesia. The patient benefited from the procedure well, and her diuretic dosage decreased.

Case 4

A 62-year-old female patient, who underwent mitral valve annuloplasty 10 years ago, presented with right heart failure symptoms, including severe dyspnea, ascites, and leg edema. TTE showed torrential TR, TAPSE of 16 mm, sPAP of 48 mm Hg, and LVEF of 35%. Her TRI-SCORE was calculated as 12. After CT angiography, the patient underwent CAVI using the TricValve system under sedation and local anesthesia (SVC 25 mm, IVC 35 mm). She was discharged after 3 days of hospitalization with significant improvement in functional capacity (from NYHA 3-4 to NYHA 2). Peripheral edema decreased, and jugular venous distention disappeared. After discharge, the daily diuretic dosage was reduced (furosemide 20 mg/day).

Case 5

A 70-year-old female patient, who had AVR and mitral repair in 1983 and MVR surgery in 1989, presented with symptoms and signs of right heart failure. She had been hospitalized twice in the last 6 months. On TTE, LVEF was 50% with normal AVR and MVR functions. There was torrential TR, a coaptation gap of 8 mm, a D-shaped septum, sPAP of 60 mm Hg, and TAPSE of 15 mm. Her TRI-SCORE was 34. After CT angiography measurements, a CAVI procedure was performed under sedation and local anesthesia (SVC 25 mm, IVC 35 mm).

Case 6

A 72-year-old female patient, who had undergone MVR 15 years ago and CRT-D implantation 5 years ago, presented with right heart failure symptoms, including severe dyspnea, ascites, and leg edema. Transthoracic echocardiography showed severe TR, TAPSE of 16 mm, sPAP of 45 mm Hg, and LVEF of 40%. The patient's TRI-SCORE was 12. Device sizes were determined via CT measurements, and the patient underwent CAVI using the TricValve system under sedation and local anesthesia (SVC 25 mm, IVC 35 mm). She was discharged after 3 days of hospitalization with significant improvement in functional capacity (from NYHA 3-4 to NYHA 2). Peripheral edema decreased, and jugular venous distention disappeared.

Case 7

A 53-year-old male patient, who underwent mitral repair with a ring and 3-vessel coronary bypass in 2021, was admitted with symptoms and signs of right heart failure. Paracentesis had been performed 4 times in the past year due to massive ascites. The mitral valve in ring procedure was performed due to moderate-to-severe mitral regurgitation. On TTE, LVEF was 40%, torrential TR, coaptation defect was 17 mm, and TAPSE was 12 mm. He had cardiorenal and cardiohepatic syndrome. His TRI-SCORE was 34. The CAVI procedure was successfully carried out using the TricValve system (SVC 25 mm, IVC 35 mm).

Step-By-Step Description of the Procedure:

1. A 6F sheath was placed in the left femoral vein. A pigtail catheter was advanced to the right pulmonary artery (rPA) (to be used for alignment of the SVC valve) and to the hepatic vein (to be used for alignment of the IVC device).
2. An 8F sheath was placed in the right femoral vein, and 1 ProGlide was left in place. A pigtail catheter was advanced to the SVC. Venography was performed to visualize venous return and SVC anatomy.
3. A stiff wire was placed through the pigtail catheter to the jugular vein, providing support for advancing the valve.
4. The 8F sheath was removed from the right femoral vein, and a 22F dilator was used to dilate the entry site to facilitate the passage of the valve delivery system. The SVC device was advanced through the right femoral vein using a 27F valve delivery system.
5. The device was aligned with the pigtail catheter placed in the rPA (Figure 1). The device was slowly deployed to allow it to conform to body temperature and the shape of the vessel.
6. Once the proper deployment of the device was confirmed, it was released. The nose cone was retracted, keeping the stiff wire in place.
7. The pigtail catheter was withdrawn from the rPA and advanced to the hepatic vein. Hepatic venography was performed.
8. The IVC device was advanced to protrude 10-15 mm into the right atrium (Figure 1). Transthoracic echocardiography and hepatic venography were performed to ensure that the device did not obstruct the hepatic vein (Video 4).
9. Gentle tension was applied to prevent upward movement of the device during deployment. The device was slowly opened. Hepatic venography was performed as needed during deployment. Final checks were performed with TTE and hepatic venography. Once the device's position was confirmed, the pigtail catheter was withdrawn, and the device was released. The nose cone was retracted.
10. The pigtail catheter was advanced through the implanted IVC device into the right atrium.

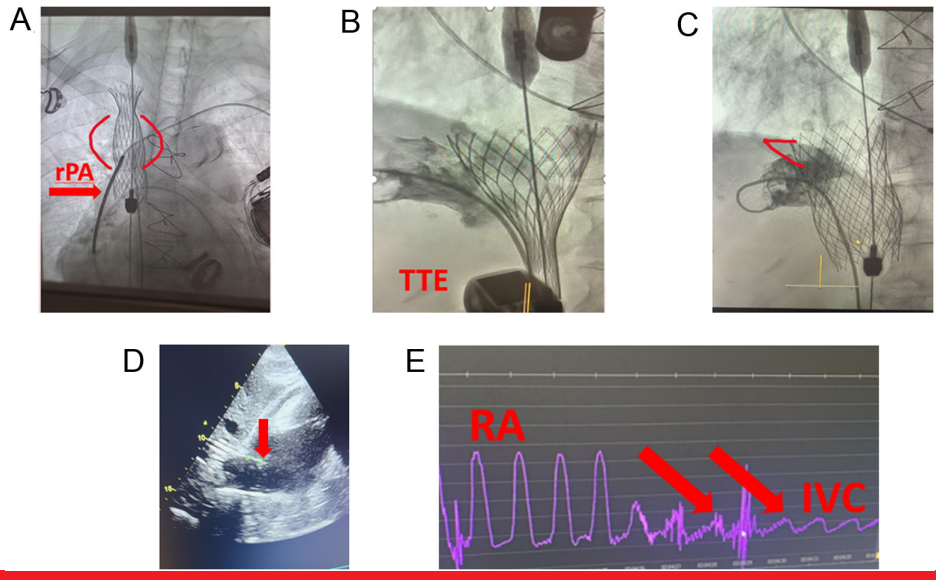

Figure 1. Echocardiographic and fluoroscopic images from different stages of the procedure. (A) Deployment of the SVC valve by aligning it. The belly part of the device is positioned over the catheter placed in the rPA. (B) Alignment of the IVC valve by both TTE and hepatic venography. (C) Right atrial protrusion of the IVC device observed on scopy. (D) A subcostal image on TTE showing the measurement of the device protruding into the right atrium. (E) Pressure recording demonstrating a significant difference between the RA and IVC, indicating procedural success.

11. Right atrial angiography was performed to confirm no paravalvular leakage from the SVC and IVC valves (Video 5).
12. After recording right atrial pressure, the pigtail catheter was withdrawn to the IVC. A significant pressure gradient between the RA and IVC was noted, indicating procedural success (Figure 1).
13. The device capsule was retracted. This step is critical to prevent vessel injury.
14. After removing the system from the femoral vein, the ProGlide stitch was deployed, followed by the "8 stitch."

DISCUSSION

Transcatheter treatment for TR can be in the form of repair or replacement. Repair can be achieved through (1) T-TEER or (2) annuloplasty devices. In suitable patients, edge-to-edge repair is the first choice as it is more physiological and preferred in patients with a coaptation gap of less than 10 mm. In this method, the tricuspid leaflets are clipped, similar to the MitraClip procedure, reducing the degree of TR. Repair with annuloplasty devices is also possible, but data on this approach are still limited.

Transcatheter valve placement can be done in 2 ways: 1) orthotopic or 2) heterotopic. In the orthotopic method, a new valve is placed inside the native tricuspid valve. This method is effective in eliminating TR; however, it has 2 important considerations. First, there is a 10%-15% risk of requiring a pacemaker.[9] Secondly, although it appears more physiological, it can significantly increase the afterload on the right ventricle, potentially worsening right ventricular failure in patients with borderline right ventricular function.

When the annulus is dilated and there is a significant coaptation defect, the success rate of T-TEER decreases. If the annulus is very large, orthotopic valve implantation also becomes challenging, with risks of incomplete anchoring or embolization of the implanted valve. Therefore, repair and orthotopic valve placement may not be suitable for a significant proportion of patients with massive and torrential TR. In such patients, heterotopic valve placement should be considered.

In the heterotopic method, valves are placed in the vena cavas. In this method, the right atrium serves as a reservoir for the regurgitant blood, cushioning the sudden pressure increase and reducing the afterload on the right ventricle. This feature is particularly important for patients with borderline right ventricular function. In the CAVI using TricValve, 1 valve is implanted in the SVC and the other in the IVC. Computed tomography angiography is performed to determine the appropriate valve size based on the vena cava diameters.

Transcatheter CAVI is a good alternative for patients with severe TR who are at high surgical risk and not suitable for T-TEER. The procedure is relatively easy to perform and can be completed with low risk to the patient. The TricValve system is designed for this patient group with advanced TR and limited treatment options, and it received CE Mark approval in May 2021. The specially designed self-expanding biological valves are first implanted in the SVC and then in the IVC. The device can be recaptured up to 80% of its deployment. When both devices are implanted, retrograde flow from the vena cavas is prevented, reducing venous congestion.

Initial study data are promising.[10,11] We presented 7 patients treated with CAVI. All 7 patients were at high surgical risk and unsuitable for T-TEER due to large coaptation gaps. The first patient showed significant clinical improvement

over the past 15 months, with a reduced need for diuretics (20 mg oral furosemide daily), increased walking capacity, disappearance of leg swelling, and resolution of neck vein distention (NVD) (Video 3). The disappearance of NVD post procedure is a good indicator of how the TricValve system works. We lost the second patient 1 week after the procedure due to multiple organ failure. This patient had a history of cardiohepatic and cardiorenal syndrome and a very high TRI-SCORE. We initially canceled the procedure due to a low GFR (15 mL/min), and the patient returned to their previous hospital. After treatment there, renal function improved, and based on similar cases in the literature, we decided to proceed with the procedure. The patient was in a late stage. We performed the procedure on the third patient 3 months ago, and the patient showed early clinical and laboratory improvement. The pre-procedure GFR was 40 mL/min, which increased to 53 mL/min post procedure. The patient experienced significant edema reduction and a 7 kg weight loss within 3 months (while taking 40 mg of furosemide every other day and 25 mg of spironolactone once daily). The remaining 4 patients underwent the procedure in the last 2 months and also benefited significantly.

In the 1-year follow-up of the TRICUS and TRICUS-EURO studies, patients showed significant benefits.[10] The increasing use of this device worldwide is also being observed. With more experience and clinical study results in the coming years, we will gain more knowledge and experience with this device.

Concerns may arise regarding device placement due to low-pressure flow in the vena cava. However, literature reports very rare cases of device embolization.[12] The diaphragm provides support for the IVC part. The crown part of the SVC device opens within the brachiocephalic vein, and the belly part opens above the PA, providing good support. Only 1 case of thrombosis has been reported.[13] In this case, an 80-year-old female patient had a 30 × 30 mm thrombus in the IVC device, which completely resolved with parenteral anticoagulation followed by oral anticoagulation (warfarin).

Regarding postprocedural anti-thrombotic management, most of these patients (>90%) have atrial fibrillation and are already on anticoagulation. However, if AF is not present, several alternative antithrombotic treatment strategies can be considered. Patients can be managed with NOAC or warfarin, 1-3 months of DAPT followed by SAPT, or 1-3 months of OAC/NOAC followed by antiplatelet therapy.

CONCLUSION

Caval valve implantation appears to be a good option for patients with severe TR, high surgical risk, and who are unsuitable for T-TEER.

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Video 1: Very prominent neck vein distention when the patient is sitting upright.

Video 2: TTE demonstrating torrential TR.

Video 3: Complete disappearance of neck vein distention occurred after the procedure.

Video 4: Confirmation of hepatic vein patency by performing hepatic venography while aligning the IVC device.

Video 5: Demonstration of the absence of paravalvular leakage by performing right atrial angiography after the placement of the SVC and IVC valves.

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