Heterotopic caval valve implantation in severe tricuspid regurgitation

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ABSTRACT

Severe symptomatic tricuspid regurgitation (TR) with right heart failure is associated with significant morbidity and mortality. Medical therapy is often ineffective and surgical correction is not feasible due to prohibitive perioperative risk. Transcatheter caval valve implantation (CAVI) is an evolving therapeutic option for this condition. It refers to the heterotopic placement of a valve into the inferior vena cava alone or with a second valve in the superior vena cava to restrict the backflow from the failing tricuspid valve. We hereby describe a patient with previous mitral valve surgery with chronic severe TR who underwent successful CAVI at our institute.

Keywords: Caval valve implantation, structural heart disease intervention, transcatheter therapy, tricuspid regurgitation

INTRODUCTION

Severe symptomatic tricuspid regurgitation (TR) with right heart failure is associated with significant morbidity and mortality in patients with previous mitral or aortic valve surgery and in many medically treated patients of various etiologies.¹²³ Medical therapy, consisting primarily of escalating doses of diuretics, is often ineffective, either due to refractoriness of the disease or due to side effects and worsening of renal function. Only a small proportion of these patients undergo tricuspid valve surgical repair or replacement considering the high risk of perioperative complications. Multiple, less invasive nonsurgical percutaneous treatment options are under evaluation to overcome this challenge. Transcatheter caval valve implantation (CAVI) is one such procedure [Figure 1].²³ It refers to the heterotopic placement of a valve into the inferior vena cava (IVC) alone or in combination with a second valve in the superior vena cava (SVC) to restrict the regurgitant jet from the failing tricuspid valve. Protection of the hepatic and renal veins from the effects of this chronic volume overload may significantly relieve the symptoms of right heart overload, mainly ascites and lower extremity edema. In addition, a decrease in TR due to increased right atrial (RA) pressure and an increase in forward cardiac output over a period of time are another possible mechanisms of benefit, provided right ventricular (RV) systolic function is relatively preserved. We hereby describe a patient with previous mitral valve replacement who presented with chronic congestive heart failure due to severe TR and underwent CAVI at our institute. There is no previous published report of CAVI in India.

Access this article online

Website: www.annals.in

DOI: 10.4103/aca.ACA_72_20

How to cite this article: Sharma NK, Chouhan NS, Bansal M, Chandra P, Singh A, Juneja R, et al. Heterotopic caval valve implantation in severe tricuspid regurgitation. Ann Card Anaesth 2021;24:365-8.
Sharma, et al.: Caval valve implantation

**CASE HISTORY**

An elderly (80 years) gentleman, who had undergone mitral valve replacement (bioprosthetic valve) 14 years back and percutaneous mitral paravalvular leak closure 5 years back, presented with New York Heart Association (NYHA) class IV dyspnea, ascites, and anasarca for the last 6 months. His symptoms were largely resistant to treatment. Clinical examination revealed significant lower limb pitting edema, markedly elevated jugular venous pulse, ascites, and hepatomegaly. Echocardiogram revealed normally functioning prosthetic valve at mitral position with severe functional TR with TR gradient 37 mmHg [Figure 2]. Left ventricular (LV) ejection fraction was normal but RV systolic function was mildly impaired [tricuspid annular plane systolic excursion (TAPSE) 16 mm, RV fractional area change 32%]. Liver function tests were normal and serum creatinine was 1.3 mg/dL. His EuroSCORE II and Society of Thoracic Surgeons (STS) score were 10.5% and 26.8%, respectively. Considering the high surgical risk for a redo valve surgery, a percutaneous approach of transcatheter CAVI was suggested by the heart team as a palliative measure for improving his symptomatic status. After a detailed discussion with the patient and his family, the decision to proceed with CAVI procedure was taken. The patient had been on acenocoumarol for atrial fibrillation, which was temporarily substituted with low molecular-weight heparin during the periprocedural period.

The procedure was performed in a hybrid operating room, under general anesthesia. Under standard cardiac monitoring, consisting of invasive arterial blood pressure monitoring, anesthesia was induced with midazolam 0.05 mg/kg, fentanyl 2 µg/kg, and etomidate 0.3 mg/kg. Tracheal intubation was facilitated with vecuronium 0.1 mg/kg. Maintenance of anesthesia was achieved with isoflurane in oxygen and air. A central venous catheter was placed in the left internal jugular vein under ultrasound guidance, sparing the right internal jugular vein for insertion of sheath for implantation of the valve by the interventionist, if required. Dobutamine and norepinephrine infusions were kept ready for any hemodynamic instability during the procedure.

Intravenous unfractionated heparin (5000 international units at the time of sheath insertion, followed by 2500 units 45 min later) was used during the procedure to maintain activated clotting time between 250 and 300 s. Right femoral venous access was used for the procedure. Successful implantation of 31 mm size self-expandable TricValve (P&F, Vienna, Austria) into IVC and a 25 mm size valve into SVC were performed under fluoroscopic and transesophageal echocardiographic (TEE) guidance [Figures 3 and 4]. The procedure resulted in near-complete elimination of flow reversal in vena cava, as confirmed by a significant reduction of the IVC v-waves on pressure tracing and by direct jet visualization on color Doppler. There was only mild paravalvular leak and trivial valvular leak through the valve in the IVC but no hepatic vein obstruction. No leak was seen in relation to the SVC valve. There was no hemodynamic instability and the patient was extubated in the operation room itself and shifted to cardiac intensive care unit without any inotropic support. His postprocedure period was uneventful. Postprocedure pain control was achieved with oral paracetamol and tramadol. Oral anticoagulation with acenocoumarol was resumed on the next day. Transthoracic echocardiography done on 1st postprocedure day revealed moderate TR with preserved RV function. He was transferred to ward on the second postprocedure day and discharged on day 4. By the time of discharge, he has had significant improvement in generalized swelling and breathing difficulty. There was no intraprocedural or postprocedural morbidity, despite the high-risk profile of the patient. During his last follow-up visit at 3 months, he was in NYHA class II with significantly reduced edema feet and ascites.

**DISCUSSION**

CAVI represents an innovative percutaneous option for the treatment of severe symptomatic TR in inoperable
patients. The objective of heterotopic CAVI, which does not specifically address the severity of TR \textit{per se}, is to prevent caval backflow of TR and mitigate systemic venous congestion. In addition, unless there is severe pulmonary hypertension or significant RV systolic dysfunction (described below), a decrease in TR severity is observed after the procedure due to transient increase in RA pressure.\textsuperscript{[4]} RV forward cardiac output also increases over a period of time. Early treatment of TR may help to avoid irreversible liver fibrosis or cirrhosis from long-standing venous congestion. Hemodynamic proof of pulsatile blood flow and caval backflow is required prior to heterotopic valve implantation. The procedure is presently approved only on a compassionate basis by the Drug Controller General of India.

Inclusion criteria for TricValve implantation are 1) symptomatic severe TR leading to NYHA class III or IV symptoms, 2) demonstration of significant backflow in caval veins by echocardiography and right heart catheterization showing right atrial (RA) v-wave $\geq 25$ mmHg, 3) IVC and SVC size within anatomic criteria by computed tomography, 4) pulmonary artery systolic pressure below 60 mmHg, 5) preserved RV systolic function, and 6) a left ventricular ejection fraction $\geq 30\%$. Exclusion criteria for the procedure are intracardiac shunts (e.g., atrial or ventricular septal defect), any significant congenital structural heart disease, RV failure (evidenced by TAPSE $\leq 13$ mm), systolic pulmonary artery pressure $\geq 60$ mmHg, and liver cirrhosis grade C by Child Pugh classification. In addition, transcatheter bivalve is contraindicated for patients suffering from recent or evolving stroke, recent ($<$30 days) myocardial infarction, hypersensitivity to nitinol, sepsis, active endocarditis, thrombosis of lower venous system, or those with previously placed vena cava filter.

This concept of caval valve was first evaluated by heterotopic off-label use of a 29-mm balloon-expandable SAPIEN valve (Edwards Lifesciences) by Laule \textit{et al.} in 2013.\textsuperscript{[5]} The procedure has undergone significant evolution since then. In the present form, the procedure involves the placement of the valve either in the IVC alone or in both IVC and SVC, depending on anatomic suitability. Two different devices have been used for CAVI: Nondedicated balloon-expandable devices commonly used for transcatheter aortic valve replacement and dedicated self-expandable CAVI devices (e.g., TricValve, P&F Products Features Vertriebs, Vienna, Austria).

The TricValve is a dedicated self-expandable pericardial valve, mounted on a belly-shaped nitinol stent with little radial force, not requiring prestenting of the landing zone, specially designed for low-pressure circulation [Figure 1]. Implantation of the TricValve can be safely performed using a single- or dual-valve approach, with landing zone diameters $\leq 35$ mm. The maximum available sizes are 38 and 43 mm for SVC and IVC, respectively. Considering that the valve is implanted in a low-pressure system, lifelong anticoagulation is often required.

Imaging remains critical for CAVI. Accurate valve sizing for CAVI relies on computed tomographic reconstruction to assess caval sizes. The IVC size is measured at the junction of superior-most hepatic vein, where the skirt of the valve will prevent venous back flow.\textsuperscript{[6]} Magnetic resonance imaging has been advised in patients with renal dysfunction, and noncontrast magnetic resonance imaging has also been used.\textsuperscript{[7]} During the procedure, TEE guidance is crucial. TEE helps in confirming proper deployment of the valve with adequate resolution of caval backflows.
It also helps in assessing the immediate impact of the procedure on right side hemodynamics and in excluding procedural complications.

Anesthetic management of patient with severe TR can be quite challenging. Stress, pain, ventilation, and procedure-related inflammation can increase pulmonary pressures, further worsening TR. The RV contractility can be affected directly or indirectly by either depression from anesthetic drugs or acute changes in the sympathetic/parasympathetic balance. Therefore, during induction, hypovolemia, tachycardia, myocardial depression, and systemic vasodilatation must be avoided. Hypoxia, hypercarbia, hypothermia, and pain must also be avoided as it can lead to an increase in pulmonary vascular resistance and hence precipitating RV failure. We chose general anesthesia for better control of hemodynamics, oxygenation, ventilation, pain, and stress. Postoperatively, these patients should be monitored in an intensive care unit to ensure the adequacy of oxygenation, perfusion, and pain management.

Despite being the first successful transcatheter tricuspid valve therapy used in humans, hemodynamic concerns following CAVI, including the long-term impact of RA ventricularization, persistent RA volume overload, and increased RV afterload, have perhaps prevented the broader use of CAVI for treating TR,[4,8,9] Future studies will need to evaluate long-term outcomes of this therapy. The role of bicaval implantation versus IVC implant only will also have to be assessed. Finally, TricValve is currently the only device designed specifically for CAVI. Other device designs are in various stages of development at present. Results of the ongoing studies will help us determine the real place of this therapy in clinical practice and the optimal technique for this purpose.

Nonetheless, in our first experience with heterotopic CAVI, our heart team successfully implanted TricValve of 31 mm and 25 mm sizes in IVC and SVC, respectively, under general anesthesia, using fluoroscopic and TEE guidance. The patient achieved gradual symptomatic relief from heart failure resulting from severe TR.

CONCLUSION

Heterotopic valve implantation in both IVC and SVC, known as CAVI, can be a simple and safer alternative to redo tricuspid valve surgery in patients with severe symptomatic TR with high surgical risk. The procedure results in significant hemodynamic and symptomatic improvement in these patients, as was observed in our patient also. Long-term outcomes in patients undergoing this procedure are yet to be determined.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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