SCIENTIFIC LETTER

HETEROTOPIC PERCUTANEOUS IMPLANTATION FOR SYMPTOMATIC TRICUSPID REGURGITATION

ABSTRACT

Tricuspid regurgitation (TR) has shown great interest in recent years. Transcatheter endovascular procedures have acquired great relevance demonstrating to be a feasible therapy to improve the quality of life of these patients.

We report our experience implanting a bicaval valve prosthesis in an 85-year-old patient with severe symptomatic and inoperable TR.

A bicaval valve implantation (CAVI) in superior vena cava (SVC) and inferior vena cava (IVC) was performed. At the 2-month follow-up, a significant enhancement in NYHA functional class and quality of life was noted.

We believe these procedures are a feasible and safe option for patients experiencing severe heart failure with progressing symptoms and at high surgical risk. Long-term follow-up is still uncertain, and an improvement in survival should be demonstrated to be considered for lower-risk patients.

Keywords: *tricuspid regurgitation; transcatheter valves therapies; bicaval valve implantation*

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INTRODUCTION

Far from being disregarded, tricuspid regurgitation (TR) is now a disease that is being studied with a more profound interest. However, the natural history of TR remains in doubt and unpredictable, with a variable temporal evolution due to its association with confounding factors and related to its etiology (primary vs. functional)[1].

The impact of TR on morbidity and mortality is even more recognized. But despite this, this entity is still undertreated in clinical practice and underused in current surgical practice[2].

Unfortunately, outcomes and responses to the best medical treatment (stages C and D) vary widely and are limited, with a 5-year mortality approaching 50%[3]. On the other hand, the ideal timing of surgical repair or replacement of the tricuspid valve (TV) continues to be unclear and is only offered to a small group of patients. The poor reputation of TV surgery (especially in the case of isolated TR) related to its high morbidity and mortality could be the likely cause of delay in surgical intervention for this group of patients[3]. Most of them are treated after the onset of symptoms and signs of heart failure or multiple organ failure. A range of transcatheter strategies has been developed for targeting severe TR at high-risk medical patients according to the underlying mechanism of disease.

CASE PRESENTATION

An 85-year-old woman was received in our Cardiovascular Department with symptoms and signs of right ventricular dysfunction.

She was well-known in our department for her history of recurrent hospitalizations due to heart failure (HF) and isolated functional tricuspid regurgitation (ITR). The patient referred a new onset of worsening dyspnea, fatigue, aggravation of her peripheral edema, and decreased exercise tolerance. Further known comorbidities included arterial hypertension and chronic renal failure.

A new transthoracic echocardiogram (TTE) confirmed known massive functional tricuspid regurgitation (TR) with corresponding annular dilation (anteroposterior: 54 mm). Right ventricular function was preserved (FAC 50%) without pulmonary hypertension. The jet was located mainly in the central area of the valve but also extended into the anteroseptal commissure.

After optimizing medical treatment, further treatment options were discussed in the interdisciplinary heart team. Due to the high surgical-risk constellation (EuroSCORE II: 9%, STS: 12%, and Charlson Comorbidity Index [CCI] Score: >3), surgical repair/replacement was abandoned, and interventional therapies were discussed. We decided to opt for caval valve implantation (CAVI), and an interventional heterotopic tricuspid valve replacement was eventually planned. After image-based preoperative planning, we used a 25-mm size valve for the superior vena cava (SVC) and a 32-mm valve for the inferior vena cava (IVC).

The procedure was performed under local anesthesia and sedation with TTE monitoring in a Cath Lab-hybrid operating room. An 18F venous catheter was placed in the right common femoral vein by open surgical approach. After inserting a 6F introducer sheath in the left common femoral vein, a pigtail catheter was advanced and placed distally in the right pulmonary artery to position the SVC device. Right heart catheterization was performed, confirming severe TR with regurgitation of contrast into the caval and hepatic veins. A self-expanding percutaneous SVC valve was positioned under continuous pressure monitoring. Next, the IVC valve was deployed (avoiding occlusion of the marked suprahepatic vein by previous repositioning of the pigtail). After TTE confirmed the satisfactory position, both valves were unloaded and released. No leaks were observed, and the delivery system was removed. The femoral vein access site was manually compressed and closed (*Figure 1*). The patient was transferred to the intensive care unit and discharged on the sixth postoperative day. Before discharge, TTE confirmed an adequate caval valve function with no signs of regurgitation, while right ventricular function remained unchanged.

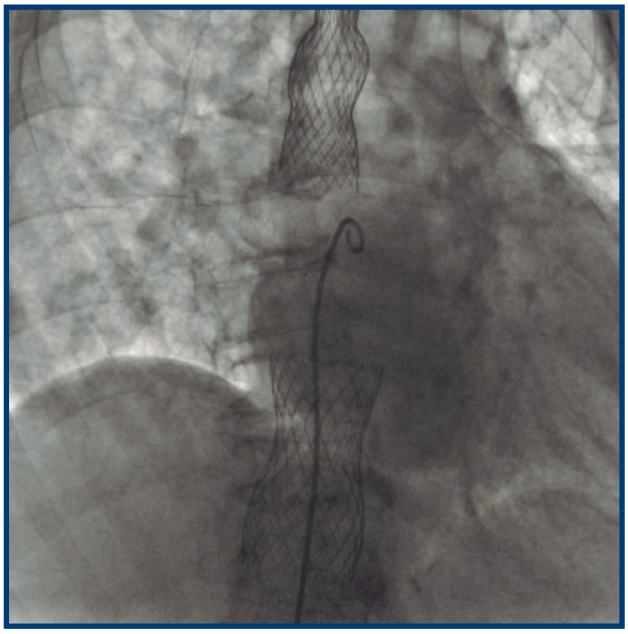

FIGURE 1. Bicaval valve implantation.

Clinical and echocardiographic at the 2-month follow-up showed a substantial improvement. Clinical signs of right-sided HF decreased compared with baseline, including peripheral edema and ascites requiring a lower dose of diuretics.

A considerable enhancement in NYHA functional class (II-IV to I-II), KCCQ score (57 vs. 90 points), and 6-min walk test (6MWT) distance was noted. No significant changes in ventricular function or echocardiographic measurements were perceived (*Table 1 and Figure 2*).

Parameter	Preprocedure	Post procedure
Heart rate (HR) (bpm)- Chronic atrial fibrilation	72	79
Diastolic blood pressure (mmHg)	20	20
Inferior cava vein (mm)	31 mm (w/inspiratory collapse)	27 mm (prior to prosthesis)
Tricuspid annulus (mm)	52	49
Tricuspid annular plane systolic excursion (TAPSE) (mm)	15	21
Tricuspid annulus velocity (cm/s)	8	10
Severity of tricuspid regurgitation	Torrential	Torrential
Right ventricle (RV) basal diameter in 4 chambers (mm)	62	55
RV systolic pressure (mmHg)	47	47.9
Pulmonary valve TAC (mseg)	76	80
Suprahepatic vein	S-wave inversion	Anterograde S-wave
NYHA	II-IV	I-II
KCCQ-Score	57	90
6 MWT	340 mts. Borg Scale: 5. Initial O2 sat.: 98%; final O2 sat.: 92%. Initial HR: 92, final HR: 134. Initial BP: 130/80, final BP: 140/80	480 mts. Borg Scale: 1. Initial O2 sat.: 99%, final O2 sat.: 96%. Initial HR: 86, final HR: 11. Initial BP: 120/70, final BP: 10/90

TABLE 1. Echocardiographic parameters pre and post procedure. NYHA: New York heart Association, KCCQ-Score: puntuación del cuestionario de cardiopatías de Kansas City; 6 MWT: prueba de caminata de 6 minutos; BP: blood pressure.

Suprahepatic Veins

Before **After**

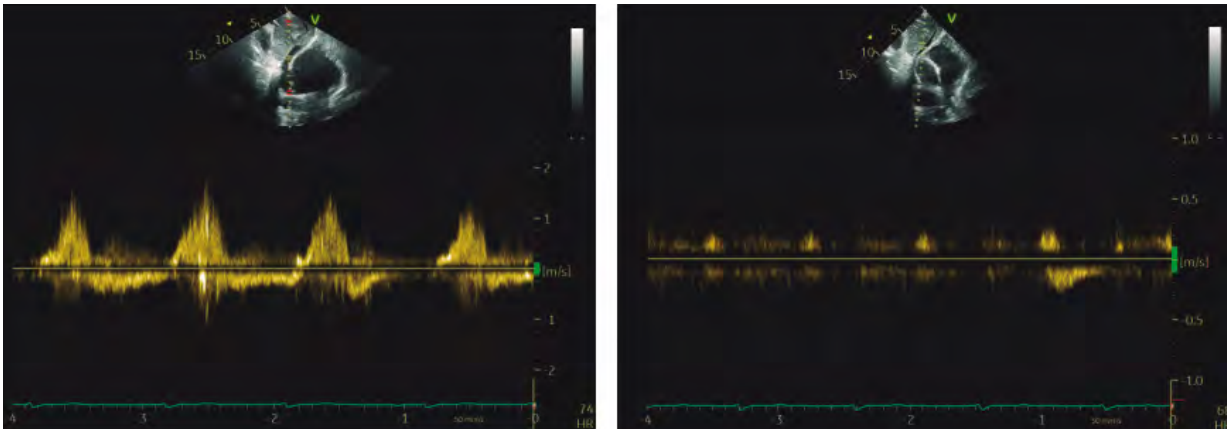

FIGURE 2. Suprahepatic veins.

DISCUSSION

Based on observations in high-risk or inoperable patients, new percutaneous transcatheter therapies have recently emerged with promising initial results for treating symptomatic TR[4].

However, despite this varied range of new devices, many patients cannot be treated due to individual anatomical characteristics or frailty conditions. Furthermore, some new technologies are often limited to highly trained operators in high-volume centers, thus restricting the generalization of procedures to a broader group of symptomatic patients.

CAVI procedures initially emerged as an alternative therapy for those patients considered "out of options" in treating severe TR and when optimal medical treatment or heterotopic valve implantation could be regarded as a palliative strategy[5].

The CAVI concept focuses on the heterotopic placement of a valve in the inferior vena cava (IVC) and another in the superior vena cava (SVC), at the level of the cavo-atrial junctions. Preventing regurgitant flow within the vena cava is attempted, reducing hepatic congestion and improving hepatorenal function with subsequent reductions in abdominal congestion, ascites, and peripheral edema4. In addition, an increase in RV stroke volume into the pulmonary circulation has been observed, improving cardiac output. CAVI would enhance the quality of life and decrease the rate of hospitalization for heart failure. Whether life expectancy can be improved remains to be proven.

CAVI can be single (IVC only) or bicaval, using two different prosthesis platforms: non-dedicated balloon expandable devices (commonly used for transcatheter aortic valve replacement) and dedicated self-expandable CAVI devices. To date, three other CAVI devices have been investigated and designed explicitly for caval anatomy: the TricValve™ system, the Tricento® system, and the Trillium™ system.

CAVI procedures have some inherent advantages due to vena cava´s relative anatomical simplicity concerning the tricuspid valve´s complex structure and its right heart.

Consequently, the procedure is relatively simple and faster than other transcatheter TV devices, enabling both the learning curve (more straightforward) and the generalization of the method to novice operators or less experienced centers.

CAVI may also be a good option for patients with TR induced by electrodes (pacemaker-ICD). The device does not interfere with the tricuspid valve.

TricValve™ (P&F Products and Features, Vienna, Austria) is a set of two self-expandable heterotopic THVs, with each having nitinol frames and different designs because intended to be deployed into superior and inferior vena cava, respectively, at cavoatrial inflow. It is available in sizes from 28 mm to 43 mm.

For the first time, in 2011, a custom-made self-expanding heart valve was implanted into the inferior vena cava (IVC) through the right femoral vein. Later, Figulla et al. placed the device, for compassionate use, in an 83-year-old patient with severe TR and prohibitive surgical risk reducing caval pressure and improving functional status[6].

Safety and feasibility of the TricValve system® have been demonstrated in the study TRICUS EURO[6-7]. Thirty-five patients withNYHA II-IV and EuroSCORE 5.8 were treated. At 30 days, procedural success was 94%, with no procedural deaths or conversions to surgery and a significant increase in QoL at 6- month follow-up correlating with a significant improvement in NYHA functional class (79.4% NYHA I-II). Two more studies are expected to provide further data on the application of this new device. The TRICUS REGISTRY (retrospective/prospective multicentric study) focused on the clinical follow-up, and the TRICAV (in progress) focused on evaluating the safety and effectiveness of the TricValve® transcatheter bicaval valves system compared with standard medical therapy in patients with symptomatic severe tricuspid regurgitation who are at high risk for cardiac surgery[8].

CONCLUSION

In our first experience, the TRICVALVE system is friendly and easy to handle, achieving accurate implantation and hemodynamic stability parameters. Our patient showed a notable quality of life improvement as assessed by the Kansas City Cardiomyopathy Questionnaire (KCCQ) and 6-minute walk, which are, undoubtedly, expected and desired results for this group of patients. We believe these procedures are a feasible and safe therapeutical strategy to relieve signs and symptoms of right heart failure, even for high-risk or inoperable patients. However, as in other TV interventions, the long-term prognosis is uncertain, and quality of life improvement is yet to be demonstrated. There are currently no randomized controlled trials (RCTs) available yet. There is an urgent need to develop and validate TV-specific risk scores to predict the clinical futility of these interventions and long-term durability before being adopted globally.

Declarations

The authors declare no conflict of interest.

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