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Transcatheter bicaval valve system for the treatment of severe isolated tricuspid regurgitation. Features from a single-Centre experience

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ABSTRACT

Background: The isolated tricuspid valve (TR) has evolved into an entity in its own right. In contrast to TR treatment in left valve surgery, the benefit of surgery for isolated TR remains controversial. In this context, transcatheter valve interventions (TTVI) are becoming increasingly important. In this report, we present our experience with TricValve in a single center.

Methods: From March 2022 to September 2023, 13 patients with at least severe isolated TR were scheduled for TricValve implantation. The mean age was 81 years (77–87), 5 were female and 8 were male. All patients were older than 70 years and had at least severe TR, hepatic or peripheral congestion and high surgical risk.

Results: No procedure failure or device embolization was recorded. One case died in hospital 6 days after implantation and 1 case died after 124 days from irreversible renal and hepatic failure. The survival rate was 80.2% ± 12.8; the proportion of patients in NYHA class I increased significantly to 45% at follow-up. Among the 11 survivors, the median NT -proBNP decreased from 2873 to 148 pg/mL at follow-up ($p = 0.003$). In addition, a significant reduction in furosemide dosage from 125 mg to 50 mg at follow-up was observed over time. Finally, TR grade improved significantly along with RV size.

Conclusions: This procedure appears to be safe and effective in carefully selected patients. Given the extreme simplicity of the procedure, the TricValve will increasingly represent one of the most viable treatment options for this patient group in the future.

1. Introduction

Severe tricuspid regurgitation (TR) has a significant prognostic impact on the general population [1]. In a cohort of 5507 consecutive patients who underwent echocardiography over a four-year period [2], 819 patients had moderate (11.8%) or severe (3.8%) TR. One-year survival rates were as follows: 91.7% for patients without TR, 90.3% for mild TR, 78.9% for moderate TR, and 63.9% for severe TR. Significantly, severe TR was associated with increased mortality, independent of pulmonary pressure and left ventricular ejection fraction (LVEF).

More recently, isolated TR has emerged as a distinct entity [2], characterized by TR without other valvular heart disease. The incidence of this condition appears to be increasing, possibly due to the increasing prevalence of atrial fibrillation (AF), intracardiac devices and intravenous drug use [2–8]. In contrast to the treatment of TR during left valve surgery, the benefit of surgery for isolated TR remains controversial [9–11]. Moreover, surgery for isolated TR is still associated with a high mortality rate, ranging from 4% to 20% [11], mainly due to delayed referral.

In this context, transcatheter valve interventions (TTVI), including repair (TTV Repair) or replacement (TTVR), are becoming increasingly important [2,12]. TTVR is particularly indicated in cases of severe tethering, restricted leaflet motion or perforation [2,13,14]. However, questions remain regarding the feasibility of valve implantation in pa-

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tients with transvalvular pacemaker leads and high-grade right ventricular (RV) dysfunction, which is considered a limiting factor for TEER or orthotopic TTVR [15]. In addition to orthotopic TTVR, heterotopic TTVR, such as the TricValve (P&F Products Features Vertrieb, Vienna, Austria), has gained renewed interest [16,17].

The TricValve is a transcatheter bicaval valve system consisting of two self-expanding biological valves implanted in the superior and inferior vena cava without interfering with the natural valve. This procedure aims to reduce systemic venous congestion, especially hepatic congestion, and thus alleviate the extracardiac manifestations of severe TR and ultimately improve quality of life and functionality.

In this report, we present our experience with the TricValve in a single center.

2. Methods

2.1. Study design and population

This retrospective observational study was approved by our local ethics committee ("Regione Abruzzo" Ethics Committee). All patients were admitted and treated at the "Pierangeli" Hospital, in Pescara, from March 2022 and September 2023, with the following inclusion criteria: adult subjects with symptomatic (symptoms and signs of right heart failure and New York Heart Association [NYHA] functional class III or IV) severe or more TR despite optimal medical therapy, suitable for implantation of the TricValve® Transcatheter Bicaval Valves System according to anatomic criteria assessed by computed tomography, LVEF ≥35% assessed by echocardiography and who were not eligible for other treatments after Heart Team discussion; exclusion criteria were: known significant intracardiac shunt or congenital structural heart disease, need for other cardiac procedures (90 days after the procedure or 30 days before the procedure), systolic pulmonary arterial pressure > 65 mmHg assessed by Doppler echocardiography, patient life expectancy of less than one year, cerebro-vascular event within the last 3 months, thrombocytopenia (absolute platelet count <lock> < </lock> 100.000/mm3), any form of dialysis, patients with gastrointestinal bleeding within 90 days prior to screening.

2.2. Echocardiography

All patients underwent transthoracic echocardiography by the same physician on admission. Right ventricular size and function were assessed according to the latest ASE guidelines [18]. Left ventricular ejection fraction was calculated according to the Simpson method [19]. Tricuspid valve anatomy was also assessed and TR was graded from mild to torrential according to the new classification [20]. Right ventricular dysfunction was defined as at least two of the following: RV fractional area change <35%, tricuspid annular plane systolic excursion (TAPSE) < 16 mm and tricuspid annular systolic excursion velocity < 10 cm/s [21].

2.3. Follow up

All patients underwent clinical and echocardiographic follow-up in our outpatient clinic. The last follow-up was used for the analysis. The follow-up stated on August 20 and ended on September 15, 2023 and was 100% complete.

2.4. Definition of terms

Right heart failure was defined as severe distension of the jugular vein, ascites, marked peripheral edema [22]. Liver congestion was defined as elevated liver enzymes and/or presence of ascites [23]. Chronic kidney disease was defined as glomerular filtration rate (GFR) < 60 mL/min/1.73 m2 [24]. Three scores were used for risk assessment: Euroscore II [25], MELD score [23,26] and TriScore [22]. End-stage was defined as the simultaneous presence of three risk scores that were higher than their median value.

2.5. Sizing and procedure

The sizing of SVC and IVC prostheses requires the analysis of the measurements of the location of valve implants in the vena cava using a Gated-ECG Cardiac Multidetector Computed Tomography (MDCT) or Cardiac Multi-slice Computed Tomography. For implantation of SVC valve 7 measurements (all measurements in mm) are required as directed in the following checklist: 1. Diameter of confluence; 2. Diameter of SVC at level of top of Pulmonary Artery; 3. Diameter of SVC at level of middle of Pulmonary Artery; 4. Diameter of SVC at level of bottom of Pulmonary Artery; 5. Diameter of SVC-Right Atrium junction; 6. Length between 1 and 3; 7. Length between 1 and 5; on the basis of these measurements two sizes can be chosen: 25 or 29 mm. For implantation of the IVC valve 5 measurements are required as directed in the following checklist: 1. IVC-RA transition diameter; 2. IVC at top of Hepatic Veins; 3. IVC just below Hepatic Veins; 4. IVC at 5 cm below IVC-RA transition; 5. IVC-RA transition (1) to IVC top of HV (2) length; on the basis of these measurements two sizes can be chosen: 31 or 35 mm.

Two venous accesses are required for implantation: a right common femoral venous access for deployment of the device and a left common femoral venous access for the pigtail control injection, which is placed in the right pulmonary artery branch to serve as a landmark during deployment of the SVC valve. Using the pigtail, an angiogram of the SVC is typically obtained to identify the optimal level of SVC valve deployment. A stiff wire placed in the internal jugular vein is recommended for valve deployment. Deployment should be performed slowly, starting in a high position with gentle downward device traction until it arrives at the target position.

For IVC deployment, a hepatic vein venogram centered on the junction of the IVC with the right atrium is obtained serving as a reference for deployment. The IVC prosthesis is deployed in a similar way to the SVC prosthesis, starting in a high position, toward the right atrium, while gently simultaneously retracting the system until the target position (proximal edge of the prosthesis landing between the right atrium and suprahepatic vein confluence. An ideal IVC deployment usually involves <15-mm inflow protrusion into the right atrium. Pacemaker leads are not a contraindication to the therapy. The SVC valve is deployed in the standard fashion, and the lead is jailed against the SVC wall. Normal lead function is assessed after implantation. All procedural steps are performed under anticoagulation with unfractionated heparin, aiming for an activated clotting time of >300 s. Valves are fully recapturable up to 80% of deployment. No general anesthesia was performed. Patients were sedated while conscious.

Post-procedural anticoagulation with either warfarin/coumadin or non-vitamin K antagonist oral anticoagulants (NOAC) was required in patients with AF or mechanical prosthesis. Patients in sinus rhythm with no other indication for anticoagulation should use the same antiplatelet regimen as after transcatheter mitral valve repair (usually 4 weeks of aspirin plus clopidogrel, followed by aspirin daily) [14].

2.6. End-points

The main end-points were periprocedural complications or failure and follow up mortality; Secondary end-points were NYHA class, TR grade, dosage of furosemide and NT-BNP value at follow up.

2.7. Statistics

Continuous variables were expressed as medians and quartiles, whereas categorical variables were expressed as number and percentage. Paired comparison was performed with paired *t*-test or Wilcoxon

signed-rank test according to the distribution of evaluated parameters, in case of continuous variables, otherwise, in case of categorical data, McNemar test was used. R-Studio version 1.1.463 (2009–2018) was used for all statistics. Significance of differences was considered at a p value of <0.05.

3. Results

Thirteen patients with at least severe secondary isolated TR were scheduled for TricValve implantation by our heart team. The mean age was 81 years (77–87), 5 were female and 8 were male. All patients were older than 70 years and had at least severe TR, a history of repeated hospitalization for right heart failure (RVH), hepatic or peripheral congestion and a high surgical risk. In all cases, very severe TV tethering was present, together with severe tricuspid annular dilatation; in 3 cases, pacemaker (PM) leads impaired valve closure. Right ventricular dysfunction was present in 6 patients: TAPSE was 15 mm (12–17), TDIs were 9 cm/s (9–10) and FAC was 32% (29–34). The main baseline parameters are listed in Table 1.

Table 1
Baseline clinical, echocardiographic and technical characteristics.

Variables	$N = 13$
Age (years)	81 (77–87)
Gender	
Female	5 (38%)
Male	8 (62%)
Causative Disease Process[§]	
Atrial secondary TR	10 (77%)
CIED-related TR	3 (23%)
Ventricular secondary TR *	3 (23%)
NYHA class	
III	4 (31%)
IV	9 (69%)
LVEF (%)	50 (41–58)
No. of previous hospital admission for RHF	
1	3 (23%)
2	7 (54%)
3	2 (15%)
4	1 (8%)
CRD	10 (77%)
Liver congestion	6 (46%)
Bilirubine mg/dl)	1.49 (1.02–1.86)
AST (U/L)	40 (30–76)
ALT (U/L)	31 (21–55)
PAL (U/L)	212 (113–324)
Ascites	5/6
Peripheral oedema	13 (100%)
RHF	13 (100%)
TR grade	
Severe	3 (23%)
Massive	6 (46%)
Torrential	4 (31%)
RVD	6 (46%)
sPAP (mmHg)	39 (30–45)
Furosemide dosage	125 (125–250)
EuroSCORE II (%)	9 (5–15)
TriSCORE	8 (6–9)
MELD SCORE	14 (9–16)
End-stage condition	2 (16%)
SVC/IVC prosthesis size	
25/31	6 (46%)
25/35	7 (54%)

Legend: TR = tricuspid regurgitation, CIED = Cardiac implantable electronic devices, NYHA = New York Heart Association, LVEF = left ventricular ejection fraction, CRD = chronic renal disease, RHF = right heart failure, RVD = right ventricular dysfunction, sPAP = systolic pulmonary artery pressure, SVC = superior vena cava, IVC = inferior vena cava.

* In 3 cases, more than one causative disease was present.

No procedural failure or device embolization was recorded. One case died in hospital 6 days after implantation due to irreversible AKI; the patient was very old (90 years) and had severe chronic renal insufficiency (GRF = 23 ml/min/1.73 m2), ascites, multiple hospitalizations for right heart failure (RHF) and was taking 250 mg of furosemide per day at home. Echocardiography at baseline showed biventricular dysfunction and massive TR. Risk score assessment confirmed that he was at very high risk, as predicted mortality was 14.9%, 19.6% and 65% using Euroscore II, MELD and TriSCORE, respectively.

One case died of irreversible renal and liver failure at 124 days of follow-up. He was 70 years old and had already undergone aortic and mitral valve replacement and tricuspid valve repair. He was admitted with a history of frequent hospitalizations for RHF (3 in the last year), with severe impairment of LV function and moderately impaired RV function. On echocardiography, the TR grade was assessed as stormy. The patient had ascites and marked peripheral edema despite taking 250 mg of furosemide per day at home. Laboratory tests also showed severe renal (GRF = 21 ml/min/1.73 m2) and liver dysfunction (MELD score = 27); finally, his estimated risk was very high (Euroscore II = 23%, MELD = 19.6% and TriSCORE = 65%).

Regarding laboratory data, no significant difference was found between baseline and discharge (Supplementary Table 1). Transient shoulder pain was noted in 4 (31%) of the cases, probably due to compression of the phrenic nerve by the IVC prosthesis [17]. All patients were discharged on oral anticoagulant treatment (warfarin or direct oral anticoagulants); in 3 cases who did not have permanent AF, anticoagulation was switched to antiplatelet therapy after 3 months. The median length of stay after implantation was 3 days (3–4).

After a median follow-up of 170 days (25–428), the survival rate was 80.2% ± 12.8, and no patient showed signs of RHF.

Symptoms improved significantly over time, with 82% of discharged patients in NYHA class II (73% NYHA II and 9% NYHA I). The proportion of patients in NYHA class I increased significantly to 45% at follow-up, while the proportion of patients in NYHA class II decreased to 36% (Fig. 1). At the same time, a significant improvement in TR grade was observed at follow-up with a simultaneous reduction in RV (Fig. 2, Table 2).

In the 11 survivors, median NT-proBNP was 2873 pg/ml (2828–4423) on admission and decreased to 901 pg/ml (817–1365) at discharge ($p = 0.023$) with a further significant decrease at follow-up to 148 pg/ml (124–567), $p = 0.003$ (Suppl Fig. 1). Furosemide dosage was significantly reduced over time, from 125 mg (125–250) to 125 mg (100–175) at discharge and to 50 mg (50–100) at follow-up (Suppl Fig. 2).

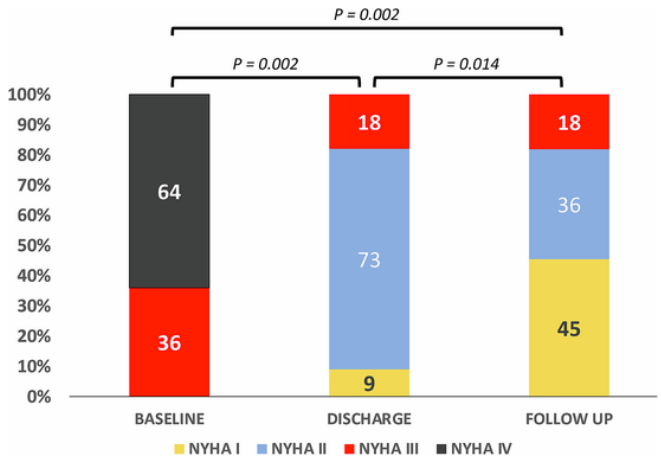

Fig. 1. Modification of New York Heart Association (NYHA) class across time.

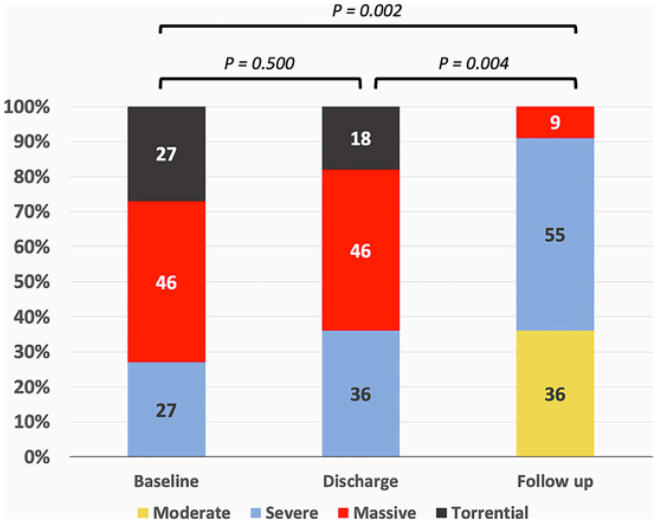

Fig. 2. Modification of Tricuspid grade (TR) class across time.

Table 2
Echocardiographic data at baseline and follow up.

Variables	Baseline	Follow up	*p*-value
LVEF (%)	50 (41–58)	55 (41–58)	0.075
RV dysfunction	4 (36%)	2 (18%)	0.555
RV diameter, basal (mm)	43 (40–45)	38 (36–41)	0.011
RA diameter, major (mm)	60 (53–65)	60 (54–66)	0.534
RA diameter, minor (mm)	51 (44–56)	52 (45–56)	0.058
Hepatic vein backflow	10 (91%)	5 (45%)	0.054

Legend. LVEF = left ventricular ejection fraction, RV = right ventricle, RA = right atrium.

4. Discussion

From analyzing these experiences with the TricValve over the last two years, we have gained some interesting insights.

4.1. AF and isolated TR

First, we confirmed a significant upward trend in isolated severe or more severe TR due to permanent AF, especially in the elderly population. Indeed, in our cohort, 77% of patients had atrial secondary TR (ASTR) secondary to AF, followed by CIED-related type A and ventricular secondary TR due to previous MV surgery. Permanent atrial fibrillation is more frequently associated with isolated TR than with concomitant MV and TV insufficiency. Ortiz-Leon et al. [27] compared the area of the mitral (MA) and tricuspid annulus (TA) in three groups of patients: Patients with atrial fibrillation and normal left ventricular (LV) function, with atrial fibrillation and LV systolic dysfunction, and in sinus rhythm. They found that patients with atrial fibrillation had greater dilatation of MA and TA compared to control subjects regardless of LV function. However, the increase in TA was greater than that of MA when LV function was normal and similar when LV function was impaired. This may explain the high prevalence of isolated TR in patients with permanent atrial fibrillation. In the TRICUS EURO study [17], the prevalence of atrial fibrillation was even higher (94.2%).

4.2. Survival

In our series, one patient died during hospitalization after implantation and one died four months later. This result is consistent with the TRICUS EURO study [17]. In this non-blinded, non-randomized, single-arm, multicenter, prospective study involving 35 patients from 12 European centers, 3 patients died after a follow-up period of 6 months. As in this study, the deaths in our study were not device- or cardiac-related, but due to irreversible liver and kidney function. Both patients were end-stage and had a very high Euroscore II, MELD and TriSCORE . In particular, the patient who died in hospital was very old before implantation and had severe renal (GRF =23 ml/min/1.73 m2) and liver dysfunction (ascites).

This is perhaps the most important lesson we draw from our data, namely that end-stage patients may not benefit from this therapy.

The current target population of transcatheter therapies for severe TR is generally elderly and frail, with significant comorbidities and impaired quality of life. In particular, cavity valve implantation (CAVI) was originally considered as an alternative therapy for patients for whom there were no other options to treat their severe symptomatic TR and who had concomitant liver congestion and right heart failure [28]. Pratz et al. [14] proposed an algorithm according to which CAVI procedures, including the TricValve, should be indicated in patients with late-onset and advanced disease. In contrast, Estévez-Loureiro R et al. [17] excluded patients with severe RV dysfunction (tricuspid systolic excursion [TAPSE] < 13 mm) and/or the presence of severe systolic pulmonary hypertension >65 mmHg) and significant renal dysfunction (creatinine >3,0 mg/dL) or dialysis within the last 4 weeks and at the time of screening, liver cirrhosis type C, a life expectancy of <1 year due to non-cardiac disease. This cut-off value given by the TRICUS-Euro study is probably the correct limit within which to select patients for TricValve.

4.3. Re-hospitalization and functional status

The main goals of TricValve are to improve functional status and reduce hospitalization rates. We achieved both, as 82% of patients were in NYHA class I-II shortly after implantation. At follow-up, the rate was the same, but the prevalence of patients in NYHA class I increased significantly from 9% to 45%. This result is in complete agreement with the literature [16], where almost 80% of patients were in NYHA class I-II at 6 months.

In the TRICUS EURO study [17], 7 patients were re-hospitalized, mainly due to right heart failure and/or worsening renal function; in our experience, no patient required rehospitalization for any reason.

4.4. Natriuretic peptides

Another interesting finding is the significant decrease in NT -proBNP levels over time. In another report [17], NT -proBNP levels actually worsened after 3 months (from 2654 to 3056). The authors attributed this finding to the ventricularization of the right atrium (RA), which acts as a reservoir; indeed, in the first phase after implantation, the pressure in the RA increases and stretches the atrial myocytes, which can produce natriuretic peptides [29]. Nevertheless, the TricValve lowers the pressure in the IVC and could increase cardiac output, as previously shown [16,30]. Similarly, reducing caval regurgitation volume may increase RV volume after stroke, which increases cardiac output and reduces RV overload [31]. This may explain the improvement in BNP levels that we have seen in our experience. Most of the clinical studies available to date describe a correlation between NYHA classification and NT-proBNP levels, which is consistent with our findings [32].

4.5. Furosemide dosing

Finally, both the improvement in NYHA class and BNP levels are consistent with the significant reduction in diuretic dose over time observed in our series; no patient had ascites or peripheral edema during follow-up, and the loop diuretic dose was gradually but significantly reduced since the early postimplantation phase. The TricValve prevents reflux from the cardiac cavity, reducing hepatic congestion, abdominal

congestion, ascites and peripheral edema, resulting in a reduced need for high-dose diuretics [17].

4.6. Echocardiographic changes

In our experience, these clinical and biohumoral improvements are supported by an improvement in TR grade, although TricValve does not act like TEER on the leaflets. One possible explanation could be that this reduction in TR grade is due to a reduction in RV size, resulting in less tethering of the heart valves. It is known that tricuspid TEER is able to reduce chronic RV volume overload without increasing RV afterload, improve RV performance and LV filling, and increase cardiac output, which translates into improvement in symptoms and function [33]. Our echocardiographic results suggest that the TricValve is also able to positively influence TR by relieving the RV from chronic overload without causing an increase in RA.

In the Tricus Euro study [17], an improvement in the degree of TR was also observed. The percentage of patients with severe to torrential TR decreased from 100% before implantation to 86.4% after 6 months. In our experience, there was a further decrease to 64%, probably due to the fact that the follow-up period was longer than six months in some patients, allowing time for the RV to remodel and tricuspid to improve.

4.7. Limitations of the study

This study has some limitations, most notably its retrospective nature, which prevented us from obtaining hemodynamic data to corroborate our findings. Certainly, a more detailed hemodynamic assessment both in the pre-implantation phase and in the late follow-up phase could provide more information on the possibility of RV remodeling reversal, which has not been observed so far [17].

5. Conclusions

To our knowledge, this study represents the largest single centre experience; it demonstrates once again that the TricValve is able to improve the functional and biochemical status of patients with isolated TR and RHF and significantly reduce organ dysfunction (liver and kidney), despite the aforementioned limitations. In addition, the clinical effects and discomfort of taking high-dose diuretics were significantly reduced, most likely due to the positive remodeling of the RV and the improvement in the degree of TR. This procedure appears to be safe, especially when patients are carefully selected. Given the extreme simplicity of the procedure combined with the low clinical impact during the procedure, we believe that the TricValve will increasingly become one of the most viable treatment options for this patient group in the future. Further prospective randomized studies comparing the TricValve with standard medical therapy are warranted.

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CRediT authorship contribution statement

Michele Di Mauro: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Stefano Guarracini:** Writing – original draft, Data curation, Conceptualization. **Lorenzo Mazzocchetti:** Writing – original draft, Data curation, Conceptualization. **Donato Capuzzi:** Validation, Supervision, Formal analysis, Data curation. **Lorenzo Salute:** Visualization, Data curation. **Massimo Di Marco:** Writing – review & editing, Validation, Supervision. **Roberto Lorusso:** Writing – review & editing, Validation, Supervision, Conceptualization. **Antonio M. Calafiore:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Conceptualization.

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