Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Early Clinical Experience With the TRICENTO Bicaval Valved Stent for Treatment of Symptomatic Severe Tricuspid Regurgitation: A Multicenter Registry

Mirjam G. Wild, MD; Edith Lubos, MD; Ignacio Cruz-Gonzalez, MD, PhD; Ignacio Amat-Santos, MD, PhD; Marco Ancona, MD; Martin Andreas, MD, PhD; Niklas F. Boeder, MD; Christian Butter, MD; Fernando Carrasco-Chinchilla, MD; Rodrigo Estevez-Loureiro, MD, PhD; Jörg Kempfert, MD; Benedikt Köll, MD; Matteo Montorfano, MD; Holger M. Nef, MD; Stefan Toggweiler, MD; Axel Unbehaun, MD; Paul Werner, MD; Stephan Windecker, MD; Fabien Praz, MD

BACKGROUND: Patients with severe tricuspid regurgitation present late and are often ineligible for surgery or transcatheter repair systems. Transfemoral venous implantation of a bicaval valved stent has been proposed as therapeutic option in selected patients. The aim of this study was to summarize the early procedural and clinical outcomes of the novel TRICENTO system for the treatment of patients with symptomatic severe tricuspid regurgitation.

METHODS: All consecutive patients treated with the custom-made TRICENTO implant at the participating centers were included in this retrospective multicentre registry.

RESULTS: A total of 21 high-risk patients (mean age 76±7 years; 67% female) with severe or higher grade tricuspid regurgitation were analyzed. The majority of the patients were in New York Heart Association class III/IV (95%), had peripheral edema (95%), and previous hospitalization for right heart failure (67%). Technical success was 100%, and there was no case of in-hospital mortality. During follow-up (median 61 days), symptomatic improvement was observed (65% in New York Heart Association class I/II; $P<0.001$). Computed tomography revealed asymptomatic fractures of the TRICENTO prosthesis in 3 patients. Cardiac magnetic resonance imaging obtained in 7 patients showed a significant decrease (252±65 mm^3 at baseline versus 216±58 mm^3 at follow-up, $P=0.006$) of right ventricular end-diastolic volume. The overall-survival rate was 76% at 1 year.

CONCLUSIONS: The present data indicate the feasibility of transfemoral bicaval valved stent implantation for the treatment of severe tricuspid regurgitation. Functional improvement and signs of right ventricular reverse remodeling were observed. Stent fractures did not impair valve function, but require refinement of prosthesis design and careful assessment of eligibility criteria.

GRAPHIC ABSTRACT: A graphic abstract is available for this article.

Key Words: heart failure ■ heart valve diseases ■ stent ■ tricuspid valve ■ tricuspid valve insufficiency

Despite its high prevalence and substantial impact on morbidity and mortality, tricuspid regurgitation (TR) remains largely undertreated due to clinical and anatomic limitations.[1,2] Owing to age, previous cardiac surgery, late referral, comorbidities, pulmonary hypertension, and right ventricular (RV) dysfunction, patients are often ineligible for surgery. Recently, several transcatheter systems have been approved for commercial

Correspondence to: Mirjam G. Wild, MD, Department of Cardiology, University Hospital Bern, Freiburgstrasse 18, 3010 Bern, Switzerland. Email mirjamg.wild@gmail.com
Supplemental Material is available at https://www.ahajournals.org/doi/suppl/10.1161/CIRCINTERVENTIONS.121.011302.
For Sources of Funding and Disclosures, see page 289.

Circulation: Cardiovascular Interventions is available at www.ahajournals.org/journal/circinterventions

WHAT IS KNOWN

- Tricuspid regurgitation leads to high morbidity and mortality.
- Many patients are ineligible for current treatment options due to advanced disease.

WHAT THE STUDY ADDS

- Bicaval stenting is a safe and efficient treatment strategy in selected patients.
- Besides symptomatic improvement, treatment might lead to right ventricular reverse remodeling.

Nonstandard Abbreviations and Acronyms

CT	computed tomography
NYHA	New York Heart Association
RA	right atrium
RV	right ventricular
TR	tricuspid regurgitation

use in Europe as therapeutic alternative to tricuspid surgery.[3,4] Depending on valve anatomy, leaflet approximation (PASCAL, Edwards Lifesciences or TriClip, Abbott Vascular)[5] or direct annuloplasty (Cardioband, Edwards Lifesciences)[6] are used.

In patients at advanced stage of the disease with severe leaflet tethering and a large coaptation gap, most transcatheter tricuspid repair systems are unsuitable.

Transfemoral implantation of a bicaval valved stent has been proposed as an alternative in selected patients. The device is intended to prevent backflow into the venous system and hence, reduce TR-related congestive symptoms. Owing to its custom-made design, it may overcome anatomic and technical limitations of other transcatheter systems. The first implantation of the TRICENTO system (Medira AG, Balingen, Germany) has been reported in 2018.[7] This study summarizes the early experience with this system in 21 patients treated at 12 European centers.

METHODS

The authors declare that all supporting data are available within the article.

Study Design and Patients

The study is designed as a retrospective observational registry, including data from 12 tertiary care centers in 5 European countries (Germany, Switzerland, Austria, Italy, and Spain). Baseline, procedural, and follow-up data up to 1 year from 21 consecutive patients treated with the TRICENTO system are reported. Patients with symptomatic severe TR ineligible for surgery or other transcatheter treatment systems were evaluated for clinical and anatomic suitability by the local Heart Team, as well as the device manufacturer. TR severity was assessed using echocardiography and graded according to the recently proposed 5-grade scheme.[8] The study was approved by the respective local ethic committees and patients gave informed consent.

End Points and Follow-Up

The primary end point of the study was technical success defined as absence of procedural mortality, successful access, delivery, and retrieval of the device delivery system, successful deployment and correct positioning of the device, freedom from emergency surgery or reintervention related to the device or access procedure assessed at the end of the procedure. Secondary end points included all-cause and cardiovascular mortality, cerebrovascular events, myocardial infarction, bleeding complications, acute kidney injury, rehospitalization for heart failure, as well as functional status according to New York Heart Association (NYHA) class.

Clinical follow-ups were performed according to the center's schedule and consisted of a visit with transthoracic echocardiography and, in some cases, laboratory exam, computed tomography (CT), and cardiac magnetic resonance imaging. All patients were followed-up 1 year after the procedure. Vital status was obtained systematically for all patients at 1 year follow-up.

TRICENTO System

The transcatheter bicaval valved stent graft consists of a self-expanding nitinol stent frame which is internally covered by thin porcine pericardium. It is designed based on the individual patient's anatomy in a custom-made fashion. Diameters of the inferior and superior vena cava (minimum 16 mm–maximum 35 mm), right atrial length (40–80 mm), as well as the distance from the right atrium (RA) to the liver veins (minimum 10 mm) are considered during screening. Preprocedural evaluations include transthoracic echocardiography and CT. The lateral bicuspid pericardial valve element faces the RA, allowing diastolic inflow and preventing systolic backflow (Figure 1A). The aim of the therapy is to lower the pressure in the venous circulation and improve congestive symptoms. The system is inserted via the right femoral vein over an integrated 24 French sheath and positioned into the superior vena cava (Figure 1B). It is then stepwise deployed in a cranial-caudal direction (Figure 1C through 1E). Radiopaque markers facilitate the orientation of the graft, especially of the valve element. The procedure is mainly guided by fluoroscopy and projection angles are derived from the preprocedural CT. Transesophageal echocardiography may be used to monitor position and function of the deployed system but is not mandatory. Depending on the use of echocardiographic guiding, the implantation is performed either under general or local anesthesia. Fusion imaging has been described as a possible additional tool to facilitate procedural visualization.[9,10] The stent graft is resheathable up to 90% of its length and can be easily repositioned. Valve position and function are assessed by RV and caval angiography at the end of the procedure and by transthoracic echocardiography (transthoracic echocardiography) during follow-up.

Statistical Analysis

We expressed continuous variables as mean with SD and compared them using the paired *t* test. Categorical variables were

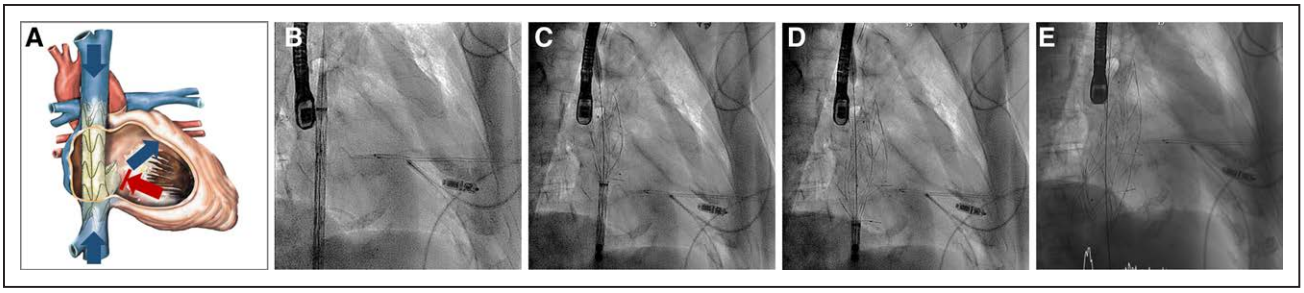

Figure 1. TRICENTO concept and steps of implantation.
A, Schema of the implanted stent graft, lateral bicuspid valve element facing towards right atrium allowing for diastolic inflow (blue arrows) and prohibiting systolic backflow (red arrow). Courtesy of Medira AG. **B**, Insertion of sheath into the superior vena cava in a patient with leadless pacemaker. **C** and **D**, Stepwise deployment of prosthesis to the cranial (**C**) and caudal (**D**) valve element. **E**, Fully deployed prosthesis. Fluoroscopy (right anterior oblique 50°/caudal 0°).

presented as counts and percentages and were compared using the Wilcoxon signed-rank test. All statistical tests used the 2-sided *P* value of 0.05 as their significance threshold. Statistical analysis was performed with IBM SPSS Statistics 25 (SPSS, Chicago, IL).

RESULTS

Between March 2017 and October 2019, 21 patients (mean age 76±7 years, 67% female) with symptomatic severe or higher grade TR and prohibitive surgical risk (mean EuroScore II 11±7%) were treated with the TRICENTO system at 12 European tertiary care centers. Baseline clinical and echocardiographic characteristics of the cohort are summarized in Table S1. With the exception of 1 patient (NYHA functional class II), all patients (95%) had NYHA functional class III or IV and peripheral edema. Two-thirds of patients had previously been hospitalized for heart failure (mean 2.4±1.8 times) and 6 patients (29%) had ascites at baseline. Thirteen patients (62%) had undergone previous open-heart surgery, and 2 patients (10%) had undergone previous transcatheter aortic valve replacement. At the time of the intervention, 3 patients (14%) had a transvalvular pacemaker-lead and 1 patient had a leadless pacemaker (Medtronic Micra) implanted after explantation of a previous transvenous lead that was suspected to have contributed to TR. Atrial fibrillation and chronic renal failure were highly prevalent (Table S1). Most patients were on previous anticoagulation (n=19 [90%]).

Baseline TR was severe in 13 (62%) patients, and massive or torrential in 8 (38%). Functional etiology was present in the majority of the patients (n=17 [81%]). The mean vena contracta was 12±5 mm and the mean tricuspid annular diameter was 41±7 mm. RV function was impaired (tricuspid annular plane systolic excursion <17 mm) in 9 (43%) patients and the mean RV/RA-gradient was 27 mm Hg (Table S1). Mean fractional area change was 46±12%.

Procedural Characteristics and Outcome

Procedural details are summarized in Table 1. The procedure was performed under general anesthesia with transesophageal echocardiography–guidance in all but 1 case (95%). Technical success was achieved in all patients—the mean total procedure time was 92±48 minutes and the mean device time was 20±7 minutes. Four patients (19%) had vascular complications, requiring blood transfusion (2 units) in 1 patient. In 4 cases, postprocedural acute kidney injury occurred (stage 1 in 2, stage 2 and stage 3 in 1 case each). In 1 patient with previously impaired renal function, temporary dialysis was required. One patient developed a systemic inflammatory syndrome of unclear origin with hypotension 1 day after the procedure requiring intensive care measures and intravenous vasopressors. Blood cultures did not show any bacteremia and the patient stabilized within 24 hours. There was no in-hospital death. Echocardiography at discharge confirmed correct positioning of the prosthesis in all cases and revealed paraprosthetic leakage in 2 cases, graded as severe in 1 case. In the latter, the RA was severely dilated (198 mL), which lead to an insufficient seal at the transition of the prosthesis to the inferior vena cava. In patients with a previous transvalvular lead, there were no procedural aberrations or lead-related events during clinical follow-up. The median length of hospital stay was 7 days (interquartile range [IQR], 5–12 days). Postprocedural anticoagulation with a vitamin K antagonist was continued or started in all patients except 1 who was maintained on a non-vitamin K antagonist oral anticoagulant.

Follow-Up Outcomes

Clinical follow-up was obtained for all patients. One patient died from a noncardiovascular cause (suicide) within the first 30 days after the procedure. Within 6 months, 2 patients (10%) died from cardiovascular causes and 1 from terminal kidney failure. The overall-survival rate was 76% at 1 year (Figure 2). Throughout the follow-up period, there were 4 (19%) cases of

Table 1. Procedural Characteristics

Procedural characteristics	
Type of anesthesia	
General	20 (95)
Local	1 (5)
Intraprocedural TEE	20 (95)
Total duration of the procedure, min	92±48
Device time, min	20±7
Technical success	21 (100)
Minor vascular complication	3 (14)
Major vascular complication	1 (5)
Acute kidney injury	4 (19)
Requiring dialysis	1 (5)
Conversion to surgery	0
Cerebrovascular event	0
In-hospital mortality	0
Mean length of hospital stay, d	10±8

Values are given in n (%) or mean with SD. TEE indicates transesophageal echocardiography.

rehospitalization for right heart failure (1 occurred in the context of sepsis unrelated to the procedure). There was no case of new pacemaker implantation. Events during follow-up outcomes are shown in Table 2.

Functional outcome was available for 20 patients (median 107 days, IQR, 50–189 days) and showed sustained symptomatic improvement, with the majority of patients in functional NYHA functional class I or II (n=13, 65%; *P*=0.001 for paired analysis; Figure 3). No significant changes of ALT [alanine aminotransferase]; 14 paired values: 22.6±10.3 versus 20.7±6.7 U/l, *P*=0.48), creatinine (18 paired values: 149±100 versus 171±122 µmol/L, *P*=0.16; after exclusion of dialysis patients 14 paired values: 106±44 versus 115±44 µmol/L, *P*=0.443) and pro-B-type natriuretic peptide (14 paired values: 5006±6479 versus 6948±2770 mg/dL, *P*=0.375; after exclusion of dialysis patients 10 paired values: 2106±2261 versus 2098±2399 mg/dL, *P*=0.998) were observed. Clinical signs of congestion resolved in the majority of patients with 7 patients (37%) still showing peripheral edema (versus 95% at baseline, *P*<0.001), and 1 (5%) persisting ascites (versus 29% at baseline, *P*=0.125). Body weight decreased significantly in patients with previously elevated weight ([body mass index >25 kg/m^2], 85±11 kg versus 76±11 kg, *P*=0.022), whereas it remained unchanged in the overall cohort (71±14 kg, versus 68±14 kg, *P*=0.276). The dosage of diuretics at follow-up was reduced in 61% of patients (n=11/18), while it was increased in 1 patient (6%). Other heart failure mediation (ACE [angiotensin-convertig enzyme]-inhibitors/angiotensin II blocker, beta-blocker, aldosterone antagonist) remained unchanged.

Echocardiographic follow-up by transthoracic echocardiography (median 93 days; IQR, 55–134 days) was available for 17 patients and showed no substantial change in left or RV function or dimensions. The patient with post-procedurally detected severe paraprosthetic leakage experienced no major adverse cardiac event during the follow-up period, although severity of the leakage remained unchanged.

Follow-up CT was available for 6 patients (median 55 days, IQR, 35–84 days). It showed correct positioning in all cases but revealed evidence of stent strut fractures in 3 patients who were treated for massive TR. In 2 cases, the structural damage was minor and had no impact on device function, whereas in 1 case, increased systolic compression of the atrial portion of the stent was observed compared to procedural and immediate postprocedural imaging (Figure 4). In all 3 patients, the valve function remained intact without associated clinical sequelae.

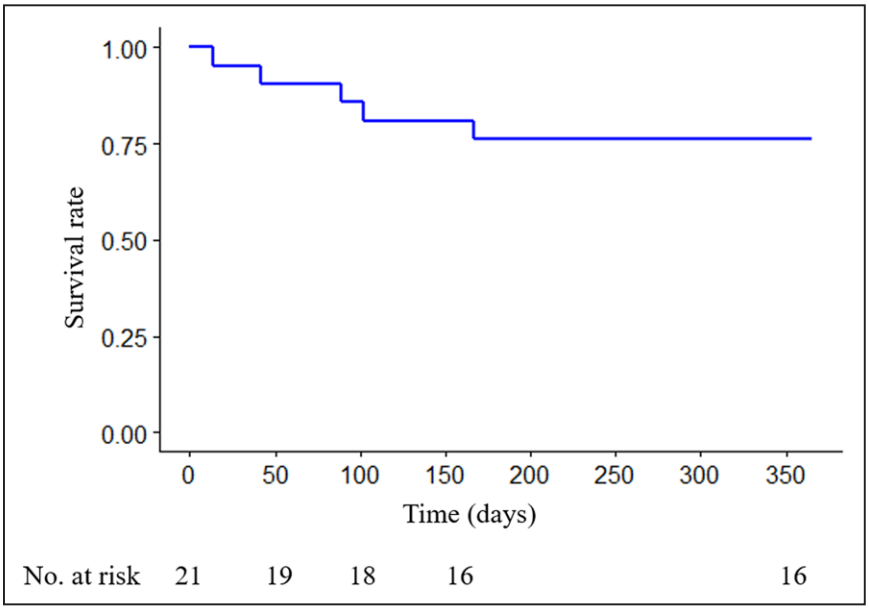

Figure 2. Kaplan-Meier curve showing survival during follow-up.
Values are given in %.

Table 2. Follow-Up Outcomes

Outcomes during follow-up (N=21); median 107 d, IQR 50–189 d	
All-cause mortality	
30 d	1 (5)
1 y	5 (24)
Cardiovascular mortality	
30 d	0
1 y	2 (10)
Documented prosthesis fracture	3 (14)
Rehospitalization for heart failure	4 (19)
Major bleeding	0
Cerebrovascular event	0
Myocardial infarction	0
NYHA functional class (n=20)	
I	6 (30)
II	7 (35)
III	6 (30)
IV	1 (5)
Body weight, kg (n=16)	67±14
Peripheral edema (n=19)	7 (37)
Ascites (n=19)	1 (5)
Laboratory examination	
Creatinine, µmol/L (n=18)	171±129
NT-proBNP, pg/mL (n=14)	6865±10398
ALT, U/L (n=14)	37±40
AST, U/L (n=12)	37±40
GGT (n=11)	132±96
Echocardiographic outcomes (n=17); median 93 d; IQR 55–134 d	
LVEF, %	48±18
LVEDD, mm	40±9
RVEDD basal, mm	47±10
TAPSE, mm	18±6
FAC, %	43±14
TR severity	
Moderate (2+)	2 (12)
Severe (3+)	6 (35)
Massive (4+)	7 (41)
Torrential (5+)	2 (12)

Values are given in n (%) or mean with SD. ALT indicates alanine aminotransferase; AST, aspartate aminotransferase; FAC, fractional area change; GGT, gamma-glutamyl transferase; IQR, interquartile range; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal pro-brain natriuretic peptide; NYHA, New York Heart Association; RVEDD, right ventricular end-diastolic diameter; TAPSE, tricuspid annular plane systolic excursion; and TR, tricuspid regurgitation.

Cardiac magnetic resonance imaging was obtained in 7 patients (median 188 days, IQR, 146–264 days; Table 3). Left and RV function, as well as left ventricular dimensions, remained unchanged, whereas there was a significant decrease of the RV end-diastolic volume (252±65 mm^3 at baseline versus 221±46 mm^3 at follow-up, *P*=0.018; Figure 5). Cardiac output did not change significantly (3.9±1.1 versus 4.9±0.2 L/min, *P*=0.172).

DISCUSSION

The salient findings of our study can be summarized as follows (1) The TRICENTO bicaval valved stent can be implanted with high technical success and low peri-procedural complication rate in selected patients; (2) two-thirds of patients remained in NYHA class I or II during the follow-up period; (3) asymptomatic stent fractures were observed in 3 patients but did not compromise valve function; (4) cardiac magnetic resonance imaging obtained in a subset of patients showed a significant reduction of the RV end-diastolic volume after implantation, whereas RV function remained unchanged.

Transcatheter treatment of the tricuspid valve is an emerging domain of the interventional cardiology. So far, leaflet approximation remains the most widely used method for transcatheter treatment of the tricuspid valve.[5,11] The recently reported results of the TRILUMINATE (Study With Abbott Transcatheter Clip Repair System in Patients With Moderate or Greater TR; TriClip)[12] and TR CLASP (Edwards PASCAL Transcatheter Valve Repair System in Tricuspid Regurgitation Early Feasibility Study; PASCAL)[13] study demonstrated the feasibility and safety of the technique with improvement of TR by at least 1 grade in the majority of cases, although TR remained severe in 40% to 48% of patients at 30-day follow-up. Similarly, the TRI-REPAIR study (Tricuspid Regurgitation Repair With Cardioband Transcatheter System; Cardioband)[14] reported persisting severe TR in 45% and 37% of the patients at discharge and 1 year follow-up, respectively. Transcatheter tricuspid valve replacement either through the transatrial[15] or the transfemoral[16] access is another emerging technology that has the potential advantage to achieve effective TR reduction, irrespective of the valve anatomy (≤1+ in >92% of the patients). Functional improvement was reported in all aforementioned studies.

These preliminary results illustrate the limitations of current systems that are not yet able to treat the entire spectrum of TR patients. Indeed, patients with a large coaptation gap (>10 mm), severe leaflet tethering (tenting area >3.15 cm^2), noncentral or -anteroseptal jet, pacemaker-induced TR, previous or failed transcatheter valve repair with resulting recurrent severe TR or iatrogenic tricuspid stenosis, as well as those with severe RV dysfunction and large annulus size may have suboptimal results or be unsuitable for current transcatheter solutions.[4,17] For this subgroup of usually highly symptomatic patients, heterotopic caval valve implantation may represent an alternative. So far, the evidence concerning dedicated devices for this indication essentially consisted of case reports[18–20]; this is the first multicentre study on this topic.

The magnitude of functional improvement according to NYHA class observed in our study (65% in class I or II at follow-up) was comparable to the one observed in

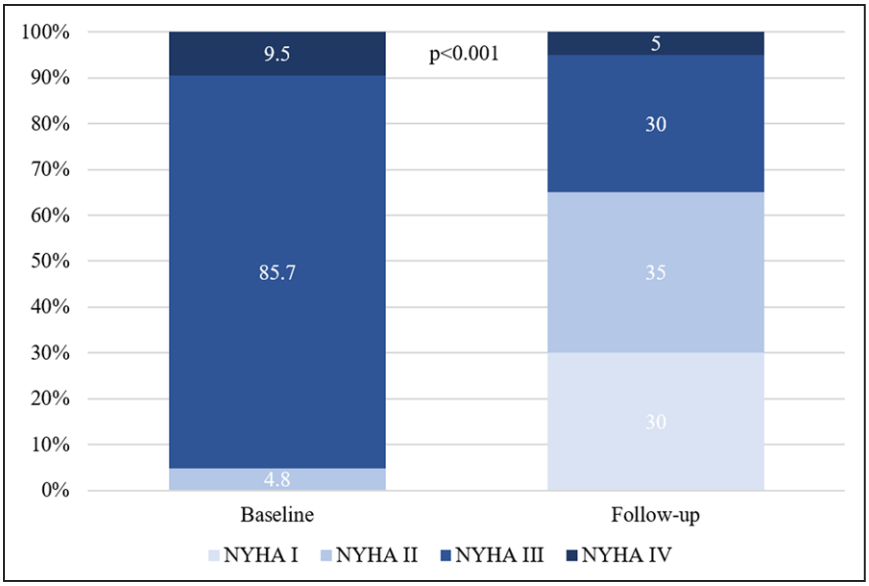

Figure 3. Functional outcome according to New York Heart Association (NYHA) functional class. Baseline and follow-up. Values given in %.

the TriValve registry[17] (NYHA class I or II in 61% at 30 days and 54% at 6 months). Although in the TriValve registry, a lower NYHA class was strongly correlated to TR reduction after treatment, functional improvement after TRICENTO implantation may rather relate to a decrease of congestive signs, in particular resolution of chronic pleural effusion and ascites (Figure 5).

Similarly, cardiac magnetic resonance imaging obtained in a subgroup of 7 patients showed significant reduction of RV end-diastolic volume (by about 14%) in our population. In contrast to the results of the TRILUMINATE study, no improvement of the RV function was observed, which may be explained by the persisting volume overload of the RV.

Previous experience of caval valve implantation was obtained using nondedicated devices and has shown important technical limitations. In the TRICAVAL trial,[21] 28 patients were randomized to caval valve implantation in the inferior vena cava or medical treatment alone. The study was prematurely stopped due to the occurrence of major complications. Four patients required open-heart surgery due to stent migration and valve dislocation, demonstrating the challenges of safely anchoring commercial transcatheter valves designed for the aortic position in the dilated caval veins. The concept of a stent graft with a lateral valve element may overcome these issues, whereas the custom-made design of the prosthesis helps to ensure safe anchoring, even in grotesque anatomic scenarios. However, the production of the prosthesis is time-consuming and delays the procedure.

Similarly to caval valve implantation, the anatomic eligibility is essentially limited by the caudal landing zone, in particular the distance from the RA to the liver veins. Although study populations appear comparable, the 1 year all-cause mortality rate in TRICAVAL, as well as in the North American Caval Valve Registry,[22] were considerably higher (57% and 58%, respectively). Furthermore, functional improvement was less pronounced in TRICAVAL, where NYHA functional class remained unchanged in 38% of the patients with only around 40% in class I or II at 3 to 6 months. These differences might in part relate to insufficient reduction of the venous backflow when implanting only 1 valve in the inferior vena cava.

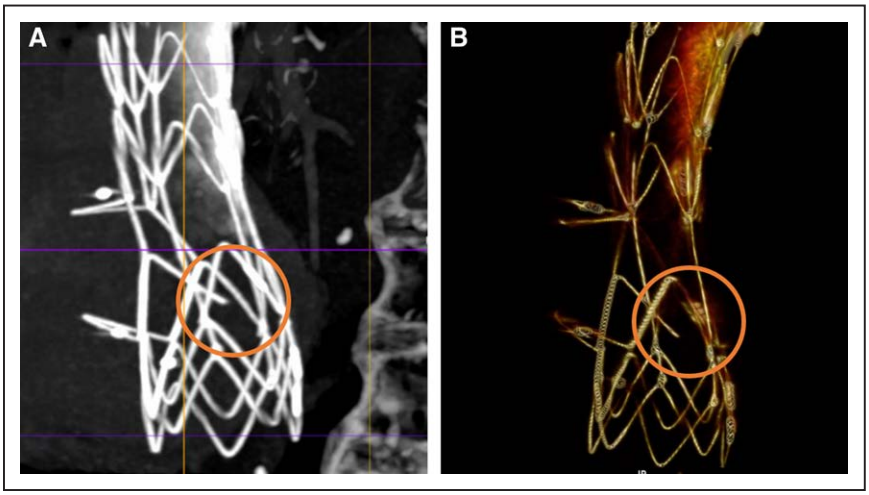

Figure 4. Computed tomography imaging of stent strut fractures. Orange circle marking area of fracture.

Table 3. CMR Baseline and Follow-Up

CMR (n=7)	Baseline	Follow-up	*P* value
LVEF, %	58±4	57±3	0.917
LVEDV, mm³	123±49	122±37	0.366
RVEF, %	54±8	52±8	0.636
RVEDV, mm³	252±65	221±46	0.018

Values given in mean with SD. CMR indicates cardiac magnetic resonance imaging; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; RVEDV, right ventricular end-diastolic volume; and RVEF, right ventricular ejection fraction.

The dedicated TricValve system (UniMedTech) addresses this limitation by means of implantation of 2 valves in the superior and inferior vena cava, respectively. Recently presented results concerning 9 patients showed acceptable technical success (89%), despite valve migration requiring conversion to open-heart surgery in 1 case.[23] In addition, asynchronous opening and closing of the valve elements may disturb laminar blood inflow into the RA.

The 3 observed prosthetic fractures detected in our study occurred in patients with massive TR and were all located in the stent segment facing the caudal valve element, which is exposed to a particularly high mechanical stress during systole. In patients with advanced TR, ventricularization of the right atrial hemodynamics may occur and therefore expose the prosthesis to a peak systolic pressure that comes close to the one of the RV. As a response to the observed technical failures, patient selection criteria have been refined, excluding patients with a peak systolic pressure in the RA exceeding 25mmHg, and the structure of the stent has been reinforced. Furthermore, better understanding of the anatomy, pathophysiological, and hemodynamic aspects of advanced tricuspid disease is needed.

Limitations

There are inherent limitations of the study due to its observational and retrospective nature, as well as the lack of a control group. Follow-ups were at the discretion of the participating centers with variability in terms of schedule and protocols, and some data were missing. Imaging analysis was performed on-site without independent core laboratory evaluation, which may have introduced interobserver variability. The small patient population, especially with regards to advanced imaging studies (cardiac magnetic resonance imaging and CT) may limit generalization of the findings.

Conclusions

The present data show the feasibility of transfemoral bicaval valved stent implantation for the treatment of advanced TR. Functional improvement and signs of RV reverse remodeling were observed. The detected stent fractures did not impair valve function, but require refinement of prosthesis design and careful assessment of eligibility criteria.

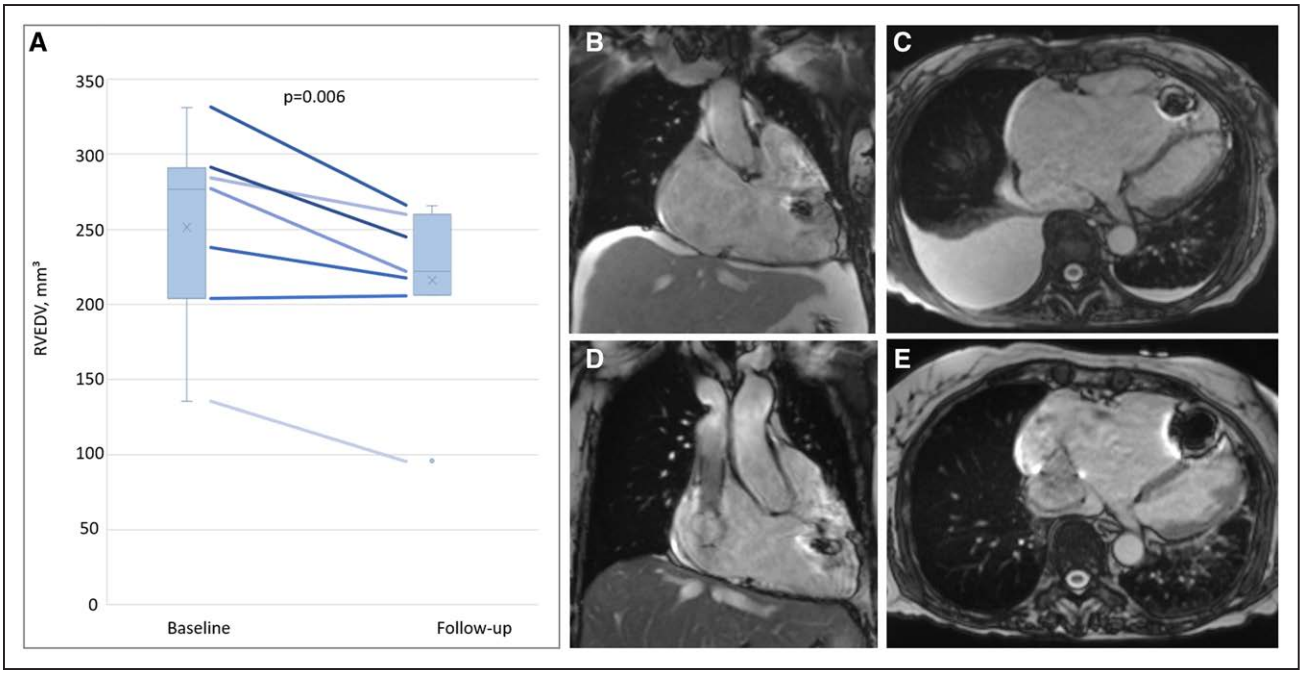

Figure 5. Cardiac magnetic resonance imaging (CMR).
A, Right ventricular end-diastolic volume (RVEDV) baseline and follow-up. Values are given in mm³. **B** and **C**, Baseline CMR. **D** and **E**, Follow-up CMR 2 mo after TRICENTO implantation with resolution of ascites and pleural effusion as well as visual decrease of right ventricular dimensions.

ARTICLE INFORMATION

Received October 21, 2021; accepted December 24, 2021.

Affiliations

Department of Cardiology, Inselspital, University Hospital Bern, Switzerland (M.G.W., S.W., F.P.). Department of Cardiology, University Hospital Hamburg, Germany (E.L., B.K.). Department of Cardiology, University Hospital Salamanca, CIBER-CV, IBSAL, Spain (I.C.G.). Department of Cardiology, CIBER-CV, University Clinic Hospital Valladolid, Spain (I.A.-S.). Interventional Cardiology Unit, IRCCS Ospedale San Raffaele, Milano, Italy (M.A., M.M.). Department of Cardiac Surgery, Medical University of Vienna, Austria (M.A., P.W.). Department of Cardiology, University Hospital Giessen, Germany (N.F.B., H.M.N.). Department of Cardiology, Heart Center Brandenburg, Bernau, Germany (C.B.). Department of Cardiology, CIBER-CV, University Hospital Malaga, Spain (F.C.C.). Department of Cardiology, University Hospital Alvaro Cunqueiro, Vigo, Spain (R.E.-L.). Department of Cardiac Surgery, German Heart Center, Berlin, Germany (J.K., A.U.). Department of Cardiology, Lucerne Cantonal Hospital, Switzerland (S.T.).

Sources of Funding

None.

Disclosures

Dr Ancona is proctor/speaker/consultant (Edwards, Abbott, Medtronic), received institutional grants (Edwards, Abbott, Medtronic, LSI). Dr Estevez-Loureiro has received personal fees from Abbot, BostonSci, Edwards. Dr Amat-Santos is proctor for P&F, received personal fees from Abbott. Dr Toggweiler is consultant/proctor for Boston Scientific, Medtronic, and Biosensor/NVT, proctor for Abbott, consultant for Carag, Medira, Teleflex, Veosource, Shockwave, received institutional research grants from BostonScientific and Fumedica and is holding equity in Hi-D Imaging. SW reports research and educational grants to the institution from Abbott, Amgen, Bristol Myers Squibb, Bayer, BostonScientific, Biotronik, Cardinal Health, Cardiovalve, CSL Behring, Daiichi Sankyo, Edwards, Johnson&Johnson, Medtronic, Querbet, Polares, Sanofi, Terumo, and Sinomed; has served as unpaid member of steering/executive group of trials funded by Abbott, Abiomed, Amgen, Bristol Myers Squibb, BostonScientific, Biotronik, Cardiovalve, Edwards Lifesciences, MedAlliance, Medtronic, Polares, Sinomed, V-Wave and Xeltis for which he received no personal payments by any pharmaceutical company or device manufacturer; and has been a member of the steering/executive committee group of several investigated-initiated trials that receive funding by industry without impact on his personal remuneration. Dr Praz reports travel expenses from Edwards, Abbott, and Polares Medical. The other authors report no conflicts.

Supplemental Material

Table S1

REFERENCES

1. Nath J, Foster E, Heidenreich PA. Impact of tricuspid regurgitation on long-term survival. *J Am Coll Cardiol*. 2004;43:405–409. doi: 10.1016/j.jacc.2003.09.036
2. Topilsky Y, Maltais S, Medina Inojosa J, Oguz D, Michelena H, Maalouf J, Mahoney DW, Enriquez-Sarano M. Burden of tricuspid regurgitation in patients diagnosed in the community setting. *JACC Cardiovasc Imaging*. 2019;12:433–442. doi: 10.1016/j.jcmg.2018.06.014
3. Taramasso M, Benfari G, van der Bijl P, Alessandrini H, Attinger-Toller A, Biasco L, Lurz P, Braun D, Brochet E, Connelly KA, et al. Transcatheter versus medical treatment of patients with symptomatic severe tricuspid regurgitation. *J Am Coll Cardiol*. 2019;74:2998–3008. doi: 10.1016/j.jacc.2019.09.028
4. Mehr M, Taramasso M, Besler C, Ruf T, Connelly KA, Weber M, Yzeiraj E, Schiavi D, Mangieri A, Vaskelyte L, et al. 1-year outcomes after edge-to-edge valve repair for symptomatic tricuspid regurgitation: results from the trivalve registry. *JACC Cardiovasc Interv*. 2019;12:1451–1461. doi: 10.1016/j.jcin.2019.04.019
5. Nickenig G, Weber M, Lurz P, von Bardeleben RS, Sitges M, Sorajja P, Hausleiter J, Denti P, Trochu JN, Näbauer M, et al. Transcatheter edge-to-edge repair for reduction of tricuspid regurgitation: 6-month outcomes of the TRILUMINATE single-arm study. *Lancet*. 2019;394:2002–2011. doi: 10.1016/S0140-6736(19)32600-5
6. Nickenig G, Weber M, Schueler R, Hausleiter J, Näbauer M, von Bardeleben RS, Sotiriou E, Schäfer U, Deuschl F, Kuck KH, et al. 6-month outcomes of tricuspid valve reconstruction for patients with severe tricuspid regurgitation. *J Am Coll Cardiol*. 2019;73:1905–1915. doi: 10.1016/j.jacc.2019.01.062
7. Toggweiler S, De Boeck B, Brinkert M, Buhmann R, Bossard M, Kobza R, Cuculi F. First-in-man implantation of the Tricento transcatheter heart valve for the treatment of severe tricuspid regurgitation. *EuroIntervention*. 2018;14:758–761. doi: 10.4244/EIJ-D-18-00440
8. Hahn RT, Zamorano JL. The need for a new tricuspid regurgitation grading scheme. *Eur Heart J Cardiovasc Imaging*. 2017;18:1342–1343. doi: 10.1093/ehjci/jex139
9. Werner P, Russo M, Scherzer S, Aref T, Coti I, Mascherbauer J, Kocher A, Laufer G, Andreas M. Transcatheter caval valve implantation of the Tricento valve for tricuspid regurgitation using advanced intraprocedural imaging. *JACC Case Rep*. 2019;1:720–724. doi: 10.1016/j.jaccas.2019.11.020
10. Boeder NF, Bayer M, Dörr O, Nef HM. Fusion imaging guided implantation of a Tricento transcatheter heart valve for severe tricuspid regurgitation. *Catheter Cardiovasc Interv*. 2021;98:E780–E784. doi: 10.1002/ccd.29587
11. Braun D, Nabauer M, Orban M, Englmaier A, Rösler D, Hagl C, Massberg S, Hausleiter J. One-year results of transcatheter treatment of severe tricuspid regurgitation using the edge-to-edge repair technique. *EuroIntervention*. 2018;14:e413–e415. doi: 10.4244/EIJ-D-18-00186
12. Lurz P, Stephan von Bardeleben R, Weber M, Sitges M, Sorajja P, Hausleiter J, Denti P, Trochu JN, Nabauer M, Tang GHL, et al; TRILUMINATE Investigators. Transcatheter edge-to-edge repair for treatment of tricuspid regurgitation. *J Am Coll Cardiol*. 2021;77:229–239. doi: 10.1016/j.jacc.2020.11.038
13. Kodali S, Hahn RT, Eleid MF, Kipperman R, Smith R, Lim DS, Gray WA, Narang A, Pislaru SV, Koulogiannis K, et al; CLASP TR EFS Investigators. Feasibility Study of the Transcatheter Valve Repair System for Severe Tricuspid Regurgitation. *J Am Coll Cardiol*. 2021;77:345–356. doi: 10.1016/j.jacc.2020.11.047
14. Nickenig G, Weber M, Schüler R, Hausleiter J, Nabauer M, von Bardeleben RS, Sotiriou E, Schäfer U, Deuschl F, Alessandrini H, et al. Tricuspid valve repair with the Cardioband system: two-year outcomes of the multicentre, prospective TRI-REPAIR study. *EuroIntervention*. 2021;16:e1264–e1271. doi: 10.4244/EIJ-D-20-01107
15. Hahn RT, Kodali S, Fam N, Bapat V, Bartus K, Rodés-Cabau J, Dagenais F, Estevez-Loureiro R, Forteza A, Kapadia S, et al. Early multinational experience of transcatheter tricuspid valve replacement for treating severe tricuspid regurgitation. *JACC Cardiovasc Interv*. 2020;13:2482–2493. doi: 10.1016/j.jcin.2020.07.008
16. Fam NP, von Bardeleben RS, Hensey M, Kodali SK, Smith RL, Hausleiter J, Ong G, Boone R, Ruf T, George I, et al. Transfemoral Transcatheter tricuspid valve replacement with the EVOQUE system: a multicenter, observational, first-in-human experience. *JACC Cardiovasc Interv*. 2021;14:501–511. doi: 10.1016/j.jcin.2020.11.045
17. Taramasso M, Alessandrini H, Latib A, Asami M, Attinger-Toller A, Biasco L, Braun D, Brochet E, Connelly KA, Denti P, et al. outcomes after current transcatheter tricuspid valve intervention: mid-term results from the international trivalve registry. *JACC Cardiovasc Interv*. 2019;12:155–165. doi: 10.1016/j.jcin.2018.10.022
18. Cruz-González I, González-Ferreiro R, Amat-Santos IJ, Carrasco-Chinchilla F, Alonso Briales JH, Estévez-Loureiro R. TRICENTO transcatheter heart valve for severe tricuspid regurgitation. Initial experience and mid-term follow-up. *Rev Esp Cardiol (Engl Ed)*. 2021;74:351–354. doi: 10.1016/j.rec.2020.09.016
19. Montorfano M, Beneduce A, Ancona MB, Ancona F, Sgura F, Romano V, Ferri LA, Bellini B, Khawaja SA, Moroni F, et al. Tricento transcatheter heart valve for severe tricuspid regurgitation: procedural planning and technical aspects. *JACC Cardiovasc Interv*. 2019;12:e189–e191. doi: 10.1016/j.jcin.2019.07.010
20. Donà C, Goliasch G, Schneider M, Hengstenberg C, Mascherbauer J. Transcatheter TricValve implantation for the treatment of severe tricuspid regurgitation. *Eur Heart J Cardiovasc Imaging*. 2021;22:e92. doi: 10.1093/ehjci/jeaa348
21. Dreger H, Mattig I, Hewing B, Knebel F, Lauten A, Lembcke A, Thoenes M, Roehle R, Stangl V, Landmesser U, et al. Treatment of severe TRIcuspid regurgitation in patients with advanced heart failure with CAval vein implantation of the edwards sapien XT VALve (TRICAVAL): a randomised controlled trial. *EuroIntervention*. 2020;15:1506–1513. doi: 10.4244/EIJ-D-19-00901
22. O'Neill BP, Negrotto S, Yu D, Lakhter V, Depta J, McCabe JM, Dube S, Vaikom M, Wang DD, Patil P, et al. Caval valve implantation for tricuspid regurgitation: insights from the United States Caval Valve Registry. *J Invasive Cardiol*. 2020;32:470–475.
23. Amat-Santos IJ. TRICVALVE Solution - Preliminary data and ongoing trials overview. Paper presented at: AICT-ASIAPCR 2020; October 6–8 2022, Singapore.