Research Article

Interventional Cardiology

Transcatheter bicaval valve implantation in patients with symptomatic severe tricuspid regurgitation: Initial experience and 2-year follow-up in a Chilean center

Abstract

Aim: To determine the safety and clinical impact of TricValve two years after implantation.

Background: Tricuspid Regurgitation (TR) causes a decrease in functional capacity with an associated increased mortality. In patients unsuitable for percutaneous orthotopic strategies, TricValve bicaval valve implantation is an option.

Patients and methods: Retrospective study of a cohort of 6 patients with severe TR and NYHA CF III-IV despite medical therapy who underwent TricValve implantation between January and December, 2022. The primary endpoint was the device safety and functional status of patients 2 years after implantation.

Results: Six patients were included. Mean age was 66 ± 10 years, 50% were women. TriScore (risk scoring model for isolated tricuspid valve surgery) was 7.0 ± 2.4. Improvement was achieved at 2 years in all patients as measured by improvement in CF (p=0.024), NT-ProBNP (p=0.028), renal function (p=0.068) and consequent reduction in diuretic dose (p 0.028). No deaths were reported during follow-up and no rehospitalizations for heart failure were reported.

Conclusion: TricValve implantation is safe and associated with clinical improvements at 2 years.

Keywords: Tricuspid regurgitation • TricValve • Renal function • Heart valve prosthesis implantation • Patients

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Introduction

TR refers to the incapacity of the tricuspid valve apparatus to maintain an adequate closure, generating backward flow from the Right Ventricle (RV) to the right atria. Hemodynamically significant TR (moderate to torrential) is not uncommon, with prevalences ranging from 0.55% in the general population, 4% in patients over 75 years-old, 10% in patients with underlying heart diseases [1,2]. Patients with significant TR often develop Right Heart Failure (RHF), hepatic and renal dysfunction. Furthermore, patients with significant TR exhibit worse survival at increasing degrees of TR severity [3].

Significant TR has limited treatment options. Medical therapy, including diuretics, left Heart Failure (HF) medication or pulmonary vasodilators are often used to treat symptoms of fluid overload and slow progression of RV failure, potentially improving but not reversing primary or secondary TR [4,5]. Surgical replacement or repair has reported 8%-10% in-hospital mortality, mainly due to concomitant comorbidities (RV, hepatic and renal failure) [6]. Recently developed transcatheter interventions, including

transcatheter edge-to-edge repair, annuloplasty and transcatheter tricuspid valve implantation have generated promising results for this population.

Our aim is to report our initial experience with heterotopic Caval Valve Implantation (CAVI) as a treatment of symptomatic significant TR.

Materials and Methods

Retrospective observational study at a tertiary healthcare center (National center of reference in Chile of cardiothorax disease). The study included adult patients with severe TR, symptomatic despite medical therapy and at high surgical risk (EuroScore II ≥ 4% and/or TricScore ≥ 7%). Patients underwent preoperative assessment including echocardiography, cardiac catheterization, cavography and cardiac CT, confirming the absence of exclusion criteria, suitability for implantation and sizing. Patients were discussed at Heart Team and deemed candidates for CAVI, undergoing intervention between January and December, 2022. The study was approved by our local ethics committee.

Procedural success was defined by survival to the procedure, adequate prosthetic position and function. Mayor adverse events were determined according to Valve Academic Research Consortium-37, including non-existence of death, myocardial infarction, tricuspid valve surgery, cardiac tamponade, stroke major bleeding and HF hospitalizations. Clinical, laboratory (N Terminal-pro B-type Natriuretic Peptide (NT-proBNP, creatinine) and echocardiographic assessments were performed at 6-months from CAVI. The glomerular filtration rate was estimated by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. The Civil Registry database was reviewed for survival statistics on October 31, 2024.

Statistics

Continuous data are expressed as mean ± standard deviation, qualitative data as absolute number. Wilcoxon test for repeated measurements prior and following CAVI were performed. Statistical significance was achieved at p-value <0.05. Analyses were performed in IBM SPSS Statistics 20.0.

Results

CAVI was performed in 6 patients, baseline characteristics are shown in Table 1. Mean age was 66 ± 10 years, 50% were male. Four patients had atrial fibrillation under vitamin K antagonist anticoagulation, one patient had a neuroendocrine tumor and one patient had chronic alcoholic liver disease. Two patients had dual-chamber pacemakers, three patients had prior cardiac surgery: One heart transplant, one mitral valve replacement and one aortic valve replacement with subsequent valve-in-valve replacement. One patient had severe TR after myocardial infarction complicated with Ventricular Septal Defect (VSD), percutaneous coronary intervention and percutaneous VSD closure were performed. Prior con CAVI, patients exhibited RHF signs and reduced New York Heart Association (NYHA) class. All received furosemide, while one patient also received metolazone 5 mg and spironolactone 100 mg daily. Mean NT-proBNP was 1872 ± 1379 pg/ml, creatinine 1.34 ± 0.53 mg/dl (glomerular filtration rate 55±22 ml/min/m2). All patients had left ventricular ejection fraction ≥ 40%, Tricuspid Annular Plane Systolic Excursion (TAPSE) >13 mm. Pulmonary Artery Systolic Pressure (PASP) over 65 mmHg was present in one patient, nonetheless all patients had mild pulmonary hypertension according to mean pulmonary artery pressure (28 ± 2 mmHg) and normal pulmonary vascular resistance (1.6 ± 0.4 WU). CAVI was performed with the TricValve system (Products and Features), consisting of two self-expanding biological valves for implantation at Superior Vena Cava (SVC) and inferior Vena Cava (IVC). Procedures were performed under conscious sedation through bifemoral venous access. Procedural time was 60 ± 6 minutes. Total number of valves implanted was 13. Procedural results are displayed in Table 2. No periprocedural deaths, cardiac tamponate, conversion to surgery, vascular complications or need for a new pacemaker were observed. Device embolization of SVC prosthesis to the right atrium was observed in one patient, the prosthesis was retrieved to IVC and entrapped using the IVC prothesis. One patient had a small paravalvular leakage of IVC prosthesis. All patients reported post-operative shoulder pain, which was handled with acetaminophen. The mean hospital stay was 4 ± 2 days. At 6 months follow-up (Table 3), significant improvements were observed in NYHA class, creatinine, NT-proBNP and diuretic dosages. We observed no changes in RV diameter, TAPSE, PASP or TAPSE/PASP. At 2 years of follow-up, all patients remained alive and reported no HF hospitalizations.

Table 1: Baseline Characteristics .

Patient	1	2	3	4	5	6
Age	75	77	65	49	70	62
Gender	Male	Female	Male	Female	Male	Female
Coronary artery disease	No	No	No	Yes	No	No
Atrial fibrillation	Yes	Yes	Si	No	No	Yes
Chronic pulmonary disease	No	No	No	No	No	No

Cancer	No	No	No	No	Yes	No
Prior cardiac surgery	Aortic	No	Transplant	No	No	Mitral
Prior percutaneous intervention	TAVI	No	No	PCI VSD	No	No
New York Heart Association class	III	III	III	IV	IV	III
NT-ProBNP (pg/ml)	1560	1340	825	4560	1967	980
Creatinine (mg/dl)	1.5	1.1	0.9	2.3	1.3	0.9
Glomerular filtration rate (ml/min/m2)	45	48	89	24	53	69
Echocardiography						
Left ventricular ejection fraction (%)	40	67	51	42	57	57
Right ventricular diastolic diameter (mm)	51	45	43	44	40	39
Tricuspid annular plane systolic excursion (mm)	17	16	18	16	18	16
Systolic pulmonar artery pressure (mmHg)	41	52	35	67	44	34
Tricuspid regurgitation severity	Massive	Massive	Massive	Torrential	Torrential	Massive
Right heart catheterization						
Mean pulmonary artery pressure (mmHg)	28	29	30	29	29	24
PCP (mmHg)	20	12	12	12	11	13
Pulmonary resistance (Wood units)	1.6	1.2	1.5	2.1	1.1	1.9
Risk scores						
Euroscore-II (%)	4.5	4	6.3	12.7	4.1	13
TricScore (%)	5	6	5	11	9	6

Note: TAVI: Transcatheter aortic valve implant; PCI: Percutaneous coronary intervention; VSD: Ventricular septal defect closure.

Table 2: Procedural results.

Procedural results	N=6
Procedural success	6
Periprocedural deaths	0
Device embolization	1
Cardiac tamponade	0
Conversion to surgery	0
Major bleeding	0
Acute ischemic stroke	0
Myocardial infarction	0
New pacemaker implantation	0
Paravalvular leak	1
Heart failure	0
Length of hospital (days)	4 ± 2

Table 3: Comparison of clinical, biochemical and echocardiographical variables at baseline and at 6 months of follow-up after TricValve®.

	Baseline	Follow-up	p
NYHA class	3.3 ± 0.5	1.3 ± 0.5	0.024
Furosemide (mg/day)	110 ± 56	18 ± 12	0.028
Creatinine (mg/dl)	1.34 ± 0.53	1.00 ± 0.34	0.042
Glomerular filtration rate (ml/min/m2)	55 ± 22	69 ± 12	0.068
NT-ProBNP (pg/ml)	1872 ± 1379	414 ± 248	0.028
Right ventricular basal diameter (mm)	43.7 ± 4.3	42.5 ± 5.1	0.705
TAPSE (mm)	16.8 ± 1.0	16.0 ± 1.7	0.317
PASP (mmHg)	45.5 ± 12.4	45.3 ± 10.7	0.786
TAPSE/PASP (mm/mmHg)	0.37 ± 0.08	0.37 ± 0.08	1

Discussion

CAVI was developed as a strategy for treating the systemic effects of significant TR in patient's ineligible for surgery or percutaneous repair [7,8]. CAVI has been associated to improvements in physical capacity ever since the first-in-human procedure by Lauten et al., [9]. A multicenter observational study by Lauten et al., (n=25), using either IVC-only or bicaval percutaneous implantation of heterotopic valves, revealed a 96% procedural success rate and marked improvements in NYHA class [10]. A report by Blasco-Turrión et al., combining results from TRICUS (n=9) and TRICUS EURO (n=35), single-arm, multicenter prospective trials of severe TR patients treated with TricValve, showed 97% of technical success, described significant improvements 95.5% of patients in the NYHA and QOL after 1-year of follow-up [11,12]. Our study reflects similar results regarding procedural success and improvements in NYHA class with TricValve, the only device available in Chile for percutaneous treatment of TR during the study period.

CAVI reduces backward flow towards IVC, diminishing systemic venous pressure and congestion. Venous renal congestion is increasingly recognized as a cause of renal dysfunction in HF patients, which leads to increased renal interstitial hydrostatic pressure, reduction of the glomerular filtration rate and diuretic resistance [13]. Our results encompassed decreases in congestive symptoms, NT-proBNP, diuretic dosages needed, creatinine levels and a tendency towards greater glomerular filtration rate. The experience by Lauten et al., concurred with our results despite combining IVC-only and bicaval CAVI10 [9]. Blasco-Turrión et al., reported a decrease in congestive symptoms, NT-proBNP and furosemide dose after CAVI, nonetheless no differences in renal and hepatic function laboratory were described at follow-up [12]. The series from Blasco-Turrión et al., had an older population and higher prevalence of hypertension and diabetes, which could potentially explain differences regarding improvements in glomerular filtration rate [12].

The impact of CAVI over on RV remodeling and function seems debatable. Lauten et al., revealed no significant changes in tricuspid annulus size, TAPSE or right atrial pressure through echocardiography after CAVI10 [9]. TRICUS EURO showed a significant increase in right chamber diameters and a decrease in TAPSE at 3-month follow-up. RV remodeling has nonetheless been suggested by a TRICUS EURO substudy, which revealed a decrease in RV volumes addressed through cardiac CT at 6 months follow-up [14]. We found no improvements in RV diameter, TAPSE or TAPSE/PASP ratio, a marker of right ventricular-arterial coupling and prognosis in the secondary TR population [15,16].

Preoperative risk in a significant TR population is complex. STS score and EuroScore II, show limitations in this TR population. STS score is mostly validated for myocardial revascularization and/or left-sided valvular interventions, while EuroScore II does not discriminate between valvular intervention types. The TRI-SCORE, a novel dedicated risk score for isolated TR based on eight easily available parameters, showed considerably better prediction for in-hospital mortality in isolated TR surgery (TRI-SCORE AUC 0.81 vs. EuroScore II AUC 0.63) [17]. EuroScore II and TRI-SCORE both revealed high in-hospital mortality in our sample, nonetheless all scores ignored some important features from our patients, mainly prior percutaneous procedures and heart transplants.

Our data suggests that CAVI was safe, similar to prior reports. We observed no periprocedural deaths, no major bleeding or vascular access complications. Device embolization occurred in one patient, being resolved percutaneously, without the need for surgical conversion. Four cases of device embolization have been previously described, three of which were resolved through surgical intervention, one IVC prothesis embolization was managed percutaneously as in our case by deploying a second IVC prosthesis to overlap with the migrated valve [18]. Paravalvular leakage has been reported in one patient by Blasco-Turrion et al., requiring percutaneous closure [12]. In our series, one patient had a small paravalvular leakage, conservatively managed and at follow-up we observed improved NYHA class and 50% reductions in NT-proBNP and furosemide doses. In our 2 years' follow-up, all treated patients survived with no HF hospitalizations, an astonishing 2 years' result considering the previously described survival rate of 50% for severe TR and survival free from HF hospitalizations or death neighboring 25% for massive TR [19].

Conclusion

CAVI is a safe and feasible procedure for the management of patients with massive and torrential TR in our country. Our initial experience suggests possible clinical benefits of this intervention. Further registries are needed to yield further insights into long-term benefits from this intervention.

Limitations

Study limitations include the small number of patients and its retrospective design, which preclude further analysis. We lacked quality-of-life questionnaires or 6-minute walk test or a follow-up volumetric analysis through cardiac CT or 3D echocardiography as a surrogate could have been of interest for further comparisons with the currently available literature. In Chile we do not have orthotopic devices for the treatment of TR.

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