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Abstract

Background: For patients with combined tricuspid and pulmonary valve disease, operative intervention carries high mortality risk. Published reports of combined transcatheter tricuspid and pulmonary valve replacement have been limited to single cases. **Methods:** A retrospective chart review was performed including all patients undergoing combined transcatheter tricuspid and pulmonary valve replacement at the Ahmanson/UCLA Adult Congenital Heart Disease Center. **Results:** Combined transcatheter tricuspid and pulmonary valve replacement was undertaken in five adult patients (median age: 46 years; range: 24-64 years). Three had congenital heart disease and two had carcinoid syndrome. Four patients had previous surgical tricuspid valve replacement and one had a surgical incomplete annuloplasty ring. Four patients had previous surgical pulmonary valve replacement and one had a right ventricle-to-pulmonary artery homograft conduit. Two patients underwent Medtronic Melody valve implantation in both tricuspid and pulmonary positions and three underwent Edwards Sapien S3 implantation in both tricuspid and pulmonary positions. Valve implantation was successful in all. Follow-up ranged from 0.9 to 3.0 years. One patient underwent redo transcatheter tricuspid valve replacement 12 months after the first transcatheter intervention for progressive regurgitation of a Melody valve. This patient died 2.5 years after combined valve placement of complications from refractory heart failure. The remaining patients were alive and free of valve reintervention at follow-up. **Conclusions:** Combined transcatheter tricuspid and pulmonary valve replacement can be performed successfully, with an acceptable complication rate. This strategy is a feasible option for appropriately selected patients.

Keywords

adult congenital heart disease, tricuspid valve, pulmonary valve; cardiac catheterization/intervention, heart valves, multiple, heart valve, transapical, percutaneous

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Introduction

For patients with combined tricuspid and pulmonary valve disease, tricuspid valve surgery may carry up to 10% mortality risk,¹⁻⁴ and similar outcomes have been reported after multiple valve surgery.⁵ The risks of mortality and major morbidity are higher in the setting of redo sternotomy.^{1,5}

Combined transcatheter tricuspid valve replacement and pulmonary valve replacement (TTVR and TPVR, respectively) has been reported in patients with carcinoid heart disease^{6,7} and congenital heart disease^{8,9} whose cases were deemed to be high risk for operative intervention. Published data on combined TTVR/TPVR thus far have been limited to single case reports. Here, we report a single-center series of five patients who underwent combined TTVR/TPVR.

Materials and Methods

Regulatory approval was obtained from the institutional review board. A retrospective chart review was performed including

all patients who underwent combined TTVR/TPVR at the Ahmanson/UCLA Adult Congenital Heart Disease Center. Cases were ascertained through the center's interventional cardiology database.

Data on underlying condition, medical comorbidities, prior operative procedures, and functional status were obtained from

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Table 1. Demographic and Diagnostic Data.

Patient	1	2	3	4	5
Age at procedure, years	46	36	63	64	24
Etiology of original disease	Tetralogy of Fallot	Double-outlet right ventricle	Carcinoid syndrome	Carcinoid syndrome	Congenital pulmonary stenosis
Number of prior cardiac surgeries	3	6	1	1	4
Hospitalized prior to procedure	No	Yes	No	No	No
Atrial fibrillation or flutter	Yes	Yes	Yes	No	No
Acute/chronic renal insufficiency	No	Yes	No	No	No
Chronic lung disease	No	No	No	No	No
Prior history of endocarditis	No	No	No	No	Yes
Existing permanent pacemaker	No	Yes ^a	No	No	Yes ^a
NYHA functional class	III	IV	III	III	III
Right ventricular systolic function	Decreased	Decreased	Normal	Normal	Decreased
Prior tricuspid intervention	Carpentier Edwards incomplete annuloplasty ring	St Jude Epic tissue valve	Edwards Magna Ease tissue valve	Edwards Magna Ease tissue valve	Medtronic Mosaic tissue valve
Size, mm	28	29	31	29	29
TR severity	Moderate	Mild	Severe	Mild	Moderate
Mean TV Doppler inflow gradient, mm Hg	6	9	6	12	5
Prior pulmonary intervention	Medtronic Mosaic tissue valve	Aortic homograft	Edwards Magna Ease tissue valve	Edwards Magna Ease tissue valve	Medtronic Mosaic tissue valve
Size, mm	23	18	23	23	29
PR severity	Severe	Unknown	Mild	Moderate	Severe
Peak/mean Doppler gradient, mm Hg	28/17	Unknown	63/36	36/24	14/7

^aBoth pacemakers were epicardial.

Abbreviations: NYHA, New York Heart Association; TV, tricuspid valve; TR, tricuspid regurgitation; PR, pulmonary regurgitation

clinical progress notes. Echocardiogram reports were reviewed to determine preprocedure transvalvular gradients and degree of valvular regurgitation.

Each valve implantation procedure was performed at the discretion of the implanting physician. The decision to proceed with transcatheter versus surgical intervention was made in each case after a detailed discussion of the anticipated risks associated with both techniques. In the three patients with congenital heart disease, the presence of significant functional impairment and multiple prior sternotomies influenced the decision to proceed with a transcatheter approach. Of the patients with carcinoid syndrome, one (#3) had planned resection of liver metastases, so a transcatheter approach with a short recovery time was thought to be favorable because oncologic surgery could be expedited afterward. The other (#4) had portal hypertension and thrombocytopenia which significantly increased operative risk. With all patients, the potential need for future surgery even after transcatheter intervention was discussed.

Procedural details were obtained from catheterization procedure reports. These included access site, pre- and postprocedure hemodynamic measurements, wire choice, valve choice, use of pretesting and postdilation, intraprocedural imaging method, delivery balloon size, concomitant procedures, and intraprocedural complications.

Postprocedural follow-up data including details of postprocedure complications, death, and patient functional status at

follow-up were obtained from clinical progress notes. Given the small sample size, descriptive statistics were used to summarize the results.

Results

Baseline variables are displayed in Table 1. Combined TTVR/TPVR was successfully performed in five adult patients, with a median age of 46 years (range: 24-64 years). Three had congenital heart disease (one with tetralogy of Fallot, one with double-outlet right ventricle, and one with congenital pulmonary stenosis) and two had carcinoid syndrome with cardiac involvement. The number of prior cardiac surgeries ranged from one to six, and all had New York Heart Association (NYHA) class III to IV symptoms. Valve-related data are displayed in Table 2. Four patients had previous bioprosthetic surgical tricuspid valve replacement (surgical valve sizes 29-31 mm) and one had a 28-mm Carpentier-Edwards Physio surgical incomplete annuloplasty ring (Edwards Lifesciences, Irvine, California). Four patients had previous bioprosthetic surgical PVR (sizes 23-29 mm) and one had an 18-mm right-ventricle-to-pulmonary-artery homograft conduit. All patients had a combination of stenosis and regurgitation except for the patient with the surgical annuloplasty ring, who had predominant tricuspid regurgitation. Decision to proceed with transcatheter valve placement was made based on severe stenosis, severe regurgitation, or moderate stenosis plus moderate

Table 2. Procedural Variables.

Patient	1	2	3	4	5
Wire	0.035" Amplatz Super Stiff	0.035" Amplatz Super Stiff	0.035" Amplatz Super Stiff	0.035" Amplatz Super Stiff	0.035" Lunderquist
Transcatheter tricuspid valve type	Medtronic Melody	Medtronic Melody	Edwards Sapien 3	Edwards Sapien 3	Edwards Sapien 3
Tricuspid balloon diameter used for valve implantation, mm	24	22	29	29	26
Transcatheter tricuspid valve size, mm	22	22	29	29	26
Tricuspid presten?	No	No	No	No	No
Tricuspid postdilated?	Yes	No	No	No	No
Transcatheter pulmonary valve type	Medtronic Melody	Medtronic Melody	Edwards Sapien 3	Edwards Sapien 3	Edwards Sapien 3
Pulmonary balloon diameter, mm	22	22	23	23	26
Pulmonary valve size, mm	22	22	23	23	26
Pulmonary presten?	No	Yes	No	No	No
Pulmonary postdilated?	No	Yes	No	No	No
Vascular access	Femoral vein	Femoral vein	Femoral vein	Femoral vein	Jugular vein
General anesthesia	Yes	Yes	No	Yes	Yes
Intraprocedural imaging	TEE	TEE + ICE	ICE	ICE	TEE
Rapid pacing during implant?	No	No	No	No	No
Other procedures performed?	None	None	None	None	Subcutaneous ICD placement
Fluoroscopy time, minutes	51	63	37	46	64
Radiation dose–area product, Gy × cm ²				72.5	59.7
Radiation dose, Gy	1.76	1.68	1.22		
Procedural complications?	None	None	Fascicular VT, fluid collection at access site	Pulmonary hemorrhage due to wire trauma, coil embolized during procedure	None

Abbreviations: ICD, internal cardioverter–defibrillator; ICE, intracardiac echocardiography; TEE, transesophageal echocardiography; VT, ventricular tachycardia.

regurgitation. When possible, severity of stenosis or regurgitation was determined based on the 2014 AHA/ACC Valvular Heart Disease Guideline.¹⁰ Moderate pulmonary valve stenosis was defined as peak instantaneous transpulmonary gradient between 36 and 64 mm Hg without an alternative explanation (eg, high-flow state). Moderate pulmonary regurgitation was defined as regurgitation not meeting criteria for severe but not subjectively mild. Moderate tricuspid stenosis was defined as elevated trans-tricuspid inflow gradients not meeting criteria for severe and without an alternative explanation (eg, high-flow state). In one patient (#2), severity of pulmonary valve stenosis and regurgitation within a homograft conduit could not be assessed by transthoracic, transesophageal, or intracardiac echocardiography. Intraprocedural fluoroscopy demonstrated heavy calcification of the conduit, and right ventriculography demonstrated moderate luminal stenosis at its proximal portion. Since the patient had severe right ventricular failure with these findings, decision was made to proceed with pulmonary valve placement. In the three patients with congenital heart disease, right ventricular systolic function, as assessed by echocardiography, was decreased. In those with carcinoid heart disease, right ventricular systolic function was normal.

Procedural variables are included in Table 2. Transesophageal echocardiography was used for procedural guidance in

two cases, intracardiac echocardiography was used in two cases, and both modalities were used in one case. The choice of imaging modality was made by the operating physician. Anesthesia courses were uncomplicated in all patients. One of the two patients with carcinoid syndrome received octreotide infusion during the procedure; the other received octreotide briefly after the procedure.

Vascular access for valve implantation was obtained via the femoral vein in four patients and the right internal jugular vein in one patient with chronically obstructed femoral veins. The choice of transcatheter valve was made at the discretion of the operating physician. Two patients underwent Melody valve (Medtronic Inc, Dublin, Ireland) implantation in both tricuspid and pulmonary positions and three patients underwent Sapien S3 (Edwards Lifesciences, Irvine, California) implantation in both tricuspid and pulmonary positions. The change from Melody to Sapien valve implantation coincided with a change in institutional preference; the Melody valves were implanted earlier in time than the Sapien valves. The wire used for delivery in four of the five cases was a 0.035" Amplatz Super Stiff wire (Boston Scientific, Marlborough, Massachusetts); in one case, a 0.035" Lunderquist wire was used (Cook Medical, Bloomington, Indiana). In each procedure, the pulmonary valve was replaced first, followed by the tricuspid valve. In

Figure 1. Sixty year-old patient with carcinoid syndrome (patient #4). A, Prior to pulmonary valve replacement, a continuous wave Doppler tracing is obtained using intracardiac echocardiography (probe in right ventricular outflow tract (RVOT)). Moderate pulmonary valve stenosis (PS) with a peak systolic velocity of 3 m/s, peak instantaneous gradient (PIG) 36 mm Hg, mean gradient 24 mm Hg, and moderate pulmonary valve regurgitation (PR) are present. B, A fluoroscopic image, right anterior oblique (RAO) cranial projection demonstrates a 23-mm Sapien 3 valve deployed within a dysfunctional 23-mm Magna Ease bioprosthesis (Valve-in-valve transcatheter pulmonary valve replacement, ViV TCPVR). Note that the valve delivery system is advanced from the inferior vena cava across a 29-mm Magna Ease tricuspid valve replacement (TVR). C, Repeat continuous wave Doppler tracing shows a reduction in the PS severity (peak velocity 2 m/s, PIG 17 mm Hg, mean gradient 12 mm Hg) and cessation of pulmonary regurgitation after transcatheter pulmonary valve replacement (TCPVR).

Figure 2. Patient #4: A, Prior to transcatheter tricuspid valve replacement, a continuous wave Doppler tracing is obtained of the dysfunctional 29-mm Magna Ease bioprosthesis using intracardiac echocardiography with the probe in the right atrium. Severe tricuspid valve stenosis is noted with mean inflow gradient 12 mm Hg (TS). There is minimal tricuspid regurgitation. B, A fluoroscopic image, steep right anterior oblique (RAO) view, of a 29-mm Sapien 3 valve deployed on a Commander delivery balloon in the tricuspid position, valve-in-valve transcatheter tricuspid valve replacement (ViV TCTVR), also seen is the pulmonary valve replacement (ViV TCPVR). C, Repeat continuous wave Doppler tracing shows a reduction in trans-tricuspid inflow gradient after ViV TCTVR with a mean inflow gradient 3 to 4 mm Hg.

each case, including the patient with a preexisting incomplete tricuspid annuloplasty ring, appropriate valve size was determined by balloon sizing of the annulus prior to valve delivery. Even when preprocedural imaging was done, balloon sizing was thought to add additional sizing data and, in the pulmonary position, was useful to ensure no compression of adjacent structures would result from valve implantation.

In the pulmonary position, balloon sizes for Melody valve delivery were both 22 mm; Sapien S3 valves implanted were 23 and 26 mm. Images from a Sapien S3 pulmonary valve implantation procedure are shown in Figure 1. In the tricuspid position, balloon sizes used for Melody valve delivery were 22 and 24 mm; Sapien S3 valves implanted were 26 and 29 mm. Images from a Sapien S3 tricuspid valve implantation procedure are shown in Figure 2. Valve implantation was successful in all patients. After implantation, one patient developed a suspected abscess at her femoral access site as well as nonsustained fascicular ventricular tachycardia during outpatient follow-up. This patient's arrhythmia was managed medically,

and the suspected abscess was treated with antibiotics. Another patient had an acute pulmonary hemorrhage due to wire trauma during the procedure. This was successfully embolized with coils immediately after diagnosis.

Follow-up data are displayed in Table 3. Follow-up ranged from 0.9 to 3.0 years. One patient underwent redo TTVR with a Melody valve 12 months after the first transcatheter intervention for progressive regurgitation of a previously placed Melody valve. Of note, an echogenic mass was noted on this patient's tricuspid annulus. Although blood cultures were negative, the patient received both anticoagulation and antimicrobial therapy for presumed thrombosis and infection, respectively, prior to repeat TTVR. This patient died 2.5 years after combined valve placement due to complications of heart failure. Of note, she had undergone combined TTVR/TPVR while in cardiogenic shock, from which she recovered and was discharged. The remaining four patients did not require reintervention on the tricuspid or pulmonary valves. Right ventricular systolic function at latest follow-up appeared stable in all

Table 3. Follow-Up Data.

Patient	1	2	3	4	5
Follow-up time after procedure, years	2.9	2.5	3.0	0.8	0.9
NYHA functional class at follow-up	II	IV	I	II	II
Mean Doppler TV inflow gradient, mm Hg	5	8	2	I	5
TR severity	Trivial ^a	None	Trivial	Trivial	Trivial
Peak/mean Doppler PV gradient, mm Hg	17/10	5/3	32/22	42/28	15/10
PR severity	None	Mild	Mild	Trivial	None
Anticoagulant/antiplatelet regimen	Warfarin	None ^b	Rivaroxaban	None ^c	Rivaroxaban
Death?	No	Yes	No	No	No
Reintervention on PV or TV?	No	Yes ^d	No	No	No

Abbreviations: TPVR, transcatheter pulmonary valve replacement; TTVR, transcatheter tricuspid valve replacement.

^aParavalvular regurgitation was noted.

^bHeparin was held in-hospital due to symptomatic anemia with a history of gastrointestinal bleeding.

^cAspirin was held due to thrombocytopenia with hematochezia.

^dRepeat TTVR was undertaken 12 months after initial intervention for progressive tricuspid regurgitation, which was associated with a mobile mass seen on the Melody tricuspid valve. Reported transvalvular gradients after the second TTVR.

four patients. Their symptoms at follow-up were NYHA class I-II. Both patients with carcinoid syndrome were maintained on monthly octreotide, as well as receiving peptide receptor radionuclide therapy, with good clinical response. Both had stable disease at the end of follow-up.

Comment

For patients with combined tricuspid and pulmonary valve disease, a transcatheter approach to intervention is a feasible option, particularly in those who are considered to be high risk for reoperation. This single-center series of combined TTVR/TPVR demonstrates a high rate of procedural success with few complications and offers a reasonable alternative to high-risk valve replacement surgery.

Combined surgical pulmonic and tricuspid valve replacement carries high risk of perioperative and intermediate-term mortality in patients with carcinoid heart disease.¹¹ Two studies report one-year mortality at approximately 30%.^{11,12} Fewer data are available to determine prognosis after surgical pulmonic and tricuspid valve replacement in those with congenital heart disease or for all indications combined. It is clear that the risk of pulmonic valve replacement is substantially lower than tricuspid valve replacement,^{1,4,13} which carries a 9% risk of perioperative mortality.^{1,4} For surgical pulmonary valve replacement per se, perioperative mortality has been reported at less than 1%.¹³ For those undergoing tricuspid valve replacement as compared to repair, and those undergoing reoperation, the risk of mortality is higher.²⁻⁴ All patients included in this series would have been classified as high risk by conventional criteria.

The patients described in this series all had advanced right-sided heart failure signs and symptoms; all were NYHA class III or IV, and one was hospitalized with cardiogenic shock prior to undergoing combined TTVR/TPVR. Considering their risk factors and the need for multivalve replacement, the risk of operative mortality in this cohort would likely have exceeded the 9% described in a broader population of tricuspid valve

surgery patients. The technical success and favorable clinical outcomes described here with combined TTVR/TPVR strongly suggest that this is a reasonable alternative to surgery. The one death in this cohort occurred 2.5 years after TTVR/TPVR in a patient who underwent intervention while in cardiogenic shock. This patient subsequently recovered from shock and was discharged to home.

For anticoagulant/antiplatelet therapy in this series of patients, two have been maintained on rivaroxaban, one on warfarin, and two had anticoagulation held at the time of latest follow-up due to concern for gastrointestinal bleeding. One of these patients (#2) developed severe tricuspid valve regurgitation and a presumed thrombus on the tricuspid annulus while still taking apixaban. In addition to anticoagulation, she also treated at the time with a prolonged course of intravenous antibiotics given concerns for infection of the thrombus. She underwent redo TTVR 12 months after combined transcatheter valve replacement, and anticoagulation was later held due to risk of ongoing gastrointestinal bleeding. In the other patient in whom anticoagulation was held (#4), transpulmonary gradients were noted to have increased slightly at follow-up, but anticoagulation was not restarted due to ongoing bleeding concerns.

The choice of transcatheter valve was made at the discretion of the operating physician. The Sapien S3 valves were implanted universally in landing zones larger than 24 mm and preferentially later in time than the Melody valves, as the Sapien valve became commercially available and experience with the Sapien valve increased. This parallels institutional practice and relates also to the larger sizes available for the Sapien valve family, which makes the Sapien S3 attractive for use in an adult population with larger native or prosthetic landing zones.

Given the young age of this cohort, reintervention long term is likely. Data regarding the longevity of transcatheter pulmonary and tricuspid valves are limited. Transcatheter valve-in-valve-in-valve tricuspid intervention was performed in one patient, as described, for early failure of a Melody valve. This technique is feasible and perhaps favorable in larger prostheses. In those patients requiring surgical reintervention, transcatheter

valve replacement as elucidated in this series can still delay redo sternotomy.

This study is limited by its small number of patients and by its single-center design. Referral for combined transcatheter valve replacement was made on an individualized basis. Procedural decisions such as imaging guidance and valve choice were also individualized. These factors limit external validity.

Conclusions

Combined transcatheter tricuspid and pulmonary valve replacement can be performed successfully, with an acceptable complication rate. Given the risk of operative intervention, this strategy is a reasonable alternative to surgery for appropriately selected patients.

Declaration of Conflicting Interests

The authors wish to disclose the following potential conflicts of interest: Dr. Aboulhosn and Dr. Levi are paid consultants for Edwards Lifesciences and Medtronic, Inc. Dr. Aboulhosn and Dr. Levi also receive research funding and serve as proctors for Edwards Lifesciences.

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