Transcatheter tricuspid valve-in-valve implantation for degenerative surgical bio-prosthesis using SAPIEN 3: A case series

Mann Chandavimol | Tawai Ngernsitrakul | Krissada Meemook | Sirin Apinyasawat | Tarinee Tangcharoeng | Pavit Pienvichit | Piya Samankatiwat | Sarana Boonbaichaiyapruck

Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Correspondence
Mann Chandavimol, Intervention Cardiology, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, 270 Rama VI Road, Sor Gor 2, Thung Phaya Thai, Ratchathewi, Bangkok 10400, Thailand.
Email: mchandavimol@gmail.com

Abstract
We evaluated early outcomes of transcatheter valve-in-valve (ViV) implantation in patients with degenerated bio-prosthesis in tricuspid position. Total of 5 patients were included in our case series. Baseline native tricuspid valve etiology were highly varied ranging from chest wall trauma, Ebstein anomaly, rheumatic heart disease, infective endocarditis and complex congenital heart disease. These differences also made patient comorbidities highly varied. Procedure details were also varied due to different clinical and technical challenges. All cases underwent successful Tricuspid ViV implantation with satisfactory hemodynamics results. All patients experienced improved clinical symptoms at follow up.

KEYWORDS
cardiothoracic surgery, structural heart intervention, transcatheter heart valve intervention, tricuspid valve intervention, valvular heart disease

INTRODUCTION

In patient with degenerative tricuspid surgical bio-prosthesis, redo tricuspid valve replacement (TVR) remains a major surgery with considerable morbidity and mortality.1 Transcatheter tricuspid valve-in-valve (ViV) has emerged as a viable treatment option for these patients with encouraging outcomes for both short and mid-term in most patients.2-5 These patients usually had variable etiology of original tricuspid valve disease that can be congenital or acquired.2

The first-in-man tricuspid ViV was reported in 2011 using Edwards SAPIEN valve (Edwards Lifesciences) via internal jugular access.6 Since then, the tricuspid ViV procedures have gained popularity with transfemoral access being the most popular.7,8 Reports from the international VIVID registry (Valve-in-Valve International database) demonstrated that TVIV can be performed successfully and safely in most cases.9 The state-of-the-art review by Sanon et al. has highlighted the proper preprocedural planning, procedure techniques, and principle of tricuspid ViV implantation.10

The experience has been described mostly in the Western communities. We report our case series of transcatheter tricuspid ViV that performed in Asia, where patients’ primary tricuspid valve etiology, comorbidities, and choices of original tricuspid valve surgery may be different. In addition, transcatheter ViV has not yet been...
reimbursable in the region; thus, case selection and procedure techniques may be different.

2 | CASE REPORTS

All consecutive patients who underwent transcatheter ViV for the treatment of a degenerated bio-prosthesis in the tricuspid position at our institution were included. All patients were at a high risk for redo tricuspid valve (TV) operation as assessed by our heart team. Informed consents were obtained from all patients. All patients underwent transthoracic echocardiographic (TTE) assessment to confirm the etiology and severity of tricuspid regurgitation (TR) and/or tricuspid stenosis (TS).

Prosthesis sizing was obtained by using an original operative report and Valve-in-Valve Mitral application. The SAPIEN 3 valves were selected to offer a 10%-15% oversizing over Internal diameter of the bio-prosthesis. All procedures were performed with the patients underwent general anesthesia (GA) and fluoroscopic guidance. Valve deployment was performed under fluoroscopy in perpendicular view, usually in RAO projection. Rapid ventricular pacing was not necessary unless in specific situations. Gradient post-implantation of TViV was obtained using direct hemodynamic measurements, using 2 transducers. Transthoracic echocardiography (TTE) also measured TViV gradient and paravalvular regurgitation before procedure completion. All patients were followed postoperatively with TTE and outpatient clinic visits.

A total of 5 patients underwent transcatheter TViV implantation at our institution from June 2019 to September 2020. The clinical characteristics at the time of index TViV are summarized in Table 1. Patient age ranged from 23 to 77 years old with NYHA class II to IV symptoms. Underlying native TV disease was highly varied ranging from chest wall trauma, Ebstein anomaly, rheumatic heart disease, infective endocarditis, and complex congenital heart disease. Bio-prosthesis type and size were also varied with year since last surgery ranged from 5 to 15 years. Bioprosthetic TS was defined when mean tricuspid valve gradient was >5 mmHg. Two cases had bioprosthetic failure causing severe TS and three had bioprosthetic failure causing severe TR. Comorbidities were significant for all patients which posted significant risk, should the patients undergo another redo TVR.

The main technical details and hemodynamic results of each procedure are summarized in Table 2. All cases were performed via Femoral vein access using E-sheath (Edwards Lifesciences). Guidewire of choice was Amplatz Super Stiff Guidewire (Boston Scientific) except one case we opted to use SAFARI 2™ ES pre-shaped Guidewire (Boston Scientific) parked in the ventricle, as the patient had pulmonic valve stenosis which make it difficult to place Amplatz Super Stiff™ guidewire into distal pulmonary artery as in other cases. We opted to use temporary LV lead back up in the Patient 1, as the patient was pacemaker dependent. We chose LV lead route over coronary sinus back up pacing, as the latter could be interfered with our delivery catheter. Rapid pacing was not necessary in most cases, except in the case that we used SAFARI 2™ wire, as we felt the support from this technique may not be adequate. We paced through SAFARI 2™ RV wire, similar to transcatheter aortic valve replacement (TAVR) guidewire pacing technique.

Two cases had combined procedures (one with leadless pacemaker and one with transcatheter pulmonic valve in valve). The Sapien S3 valve was deployed successfully in one attempt in all cases with acceptable low gradient across TViV prosthesis. There was also no residual valvular nor paravalvular regurgitation and no other periprocedural complication in all cases. All patients experienced improved clinical symptoms after the procedure at follow-up.

Each patient was described in details as followed.

3 | PATIENT 1

A 77-year-old woman.

Clinical presentation: Right-sided heart failure due to bioprosthetic failure causing tricuspid regurgitation (TR) due to permanent pacemaker (PPM) lead impingement.

Native TV disease: Chest wall trauma causing severe TR 2014.

Comorbidities: Chronic atrial fibrillation, diabetes mellitus, history of embolic stroke.

Previous surgery: TVR using Magna # 25 (Edwards, Lifesciences) 2014 with PPM implantation, as a result of complete heart block after the operation.

Pre-procedure TTE: LVEF 66.4%, RV TAPSE 1.6 cm, TR severe, TS MG 7 mmHg.

3.1 | Technical aspect (Figures 1 and 2)

Anesthesia: General anesthesia.

Access and delivery sheath: Right Femoral vein/Edwards E sheath 14 Fr, 6F right femoral artery for transarterial LV lead back up.

Guidewire: Amplatz Super Stiff™ guidewire (Boston Scientific) to left pulmonary artery.
### Table 1: The clinical characteristics at the time of index TVIV

| Case No. | Age | Gender | NYHA class | Native TV disease | Number of prior surgeries | Type of TV Bio-prosthesis | Bioprosthesis TV size (mm) | Years since last surgery | Comorbidities |
|----------|-----|--------|------------|-------------------|---------------------------|--------------------------|---------------------------|------------------------|-----------------|
| 1        | 77  | Female | III        | Chest wall trauma causing severe TR | 1 | Edwards Magna | 25 | 5 | Complete heart block, Chronic AF, diabetes mellitus, history of embolic stroke |
| 2        | 23  | Female | II         | Ebstein anomaly with sinus venous ASD, hypoplastic RPA | 2 | Medtronic Hancock II | 27 | 5 | AF, Hx of LT MCA infarction 2019 s/p thromboembolectomy |
| 3        | 42  | Female | II         | Rheumatic heart disease with severe AS and MS and severe TS | 1 | Edwards Magna | 25 | 5 | Mechanical On-X valve #27 MVR, mechanical On-X #21 AVR |
| 4        | 37  | Male   | II         | VSD with infective endocarditis to TV and PV | 2 | Edwards CE #33 | 33 | 15 | mechanical AVR, bioprosthetic PVR (CE#33 [Edwards Lifescience]) chronic atrial fibrillation |
| 5        | 24  | Male   | IV         | Straddling TV, double inlet RV, small MV, valvular PS, d-related great vessels, ASD, VSD | 2 | Edwards Magna | 29 | 6 | AF Hx of brain abscess s/p burr hole operation |

Abbreviations: AF, atrial fibrillation; AS, aortic stenosis; ASD, Atrial septal defect; AVR, aortic valve replacement; Hx, History; MCA, middle cerebral artery; MS, mitral stenosis; MV, mitral valve; MVR, mitral valve replacement; PS, pulmonic stenosis; PV, pulmonic valve; PVR, pulmonic valve replacement; RV, right ventricle; TR, tricuspid regurgitation; TS, tricuspid stenosis; TV, tricuspid valve; VSD, ventricular septal defect.
Pacing during deployment: Left ventricular (LV) pacing for back up.

TVIV: Successful TVIV using SAPIEN S3 # 26 nominal volume in TVR Magna # 25.

Concomitant procedure: Micra™ leadless pacemaker (Medtronic, Minneapolis, Minnesota) implantation.

Complication: None.

Special consideration: The potential injury to the pacemaker lead was one of the major concerns in this case. During the procedure, a temporary pacing wire was inserted into the left ventricle as a backup. Post-procedural permanent pacemaker interrogation showed a slight drop in right ventricular lead impedance (from 463 to 382 Ω) and a slight increase in right ventricular lead threshold (from 0.5 V at 0.4 ms to 1 V at 0.4 ms). The trends persisted 2 days afterward. Due to the absolute pacemaker dependency of the patient, the decision was made to proceed with the new pacemaker system implantation prior to hospital discharge and the choice of the system was leadless pacemaker.

3.2 | Outcomes

Immediate direct hemodynamic measurement: TVIV mean gradient 1 mmHg, no TR.

Echo follow-up at index admission: TVIV mean gradient 3.4 mmHg, no PV, RV TAPSE 1.9 cm, RVSP 29.5 mmHg.

Antithrombotic at discharge: Orfarin.

Hospital stays: 10 days.

Follow-up echo at 18 months: TVIV mean gradient 4.0 mmHg, no PVL no TR, TAPSE 1.99.

Clinical follow-up at 18 months: NYHA class I, Micra™ parameter: Battery longevity: >8 years, 100% pacing, threshold: 0.38 V at 0.24 ms, lead impedance 680 Ω.

4 | PATIENT 2

4.1 | Case presentation

A 23-year-old woman.

Clinical presentation: Severe tricuspid regurgitation with impaired RV systolic function, NYHA II.

Native TV disease: Ebstein anomaly with sinus venosus ASD, hypoplastic RPA.

Comorbidities: Atrial fibrillation, Hx of LT MCA infarction in 2019 s/p thromboembolectomy.

Previous surgery: (1) Rt MBT shunt in 1997 (2) TVR using Hancock II #27 (Medtronic Inc), ASD closure, RPA angioplasty in 2014.
Pre-procedure TTE: LVEF 51.4%, RV TAPSE 1.3 cm, TR severe, TS gradient 5.6 mmHg.

4.2 Technical aspect

Anesthesia: General anesthesia with A-line monitoring.

Access and delivery sheath: Right femoral vein/Edwards E sheath 14 Fr.

Guide wire: Amplatz super stiff™ (Boston Scientific) to LPA.

Pacing during deployment: No.

TVIV: Successful TVIV using SAPIEN S3#26 nominal volume in Hancock #27 (Medtronic Inc).

Concomitant procedure: No.

Complication: None.

Special considerations: In a straightforward case, there is no need for rapid pacing during deployment.
4.3 | Outcomes

**Echo follow-up at index procedure:** TVIV mean gradient 3 mmHg, no TR, no PVL, RV TAPSE 1.47 cm.

**Antithrombotic at discharge:** Orfarin, ASA.

**Hospital stays:** 2 days.

**Follow-up echo at 3 months:** No TR, no PVL, TVIV gradient 2.5 mmHg, RV TAPSE 1.5 cm.

**Clinical follow-up at 1 year:** NYHA I.

5 | PATIENT 3

5.1 | Clinical presentation

A 42-year-old woman.

**Clinical presentation:** TVR dysfunction: severe stenosis.

**Native TV disease:** Rheumatic heart disease with AV (severe AS), MV (severe MS), and TV (severe TS).

**Previous surgery:** Triple valve surgery including mechanical On-X valve #27 MVR, mechanical On-X #21 AVR, and bioprosthetic TVR Magna #25 (Edwards Lifescience) 2014.

**Pre-procedure TTE:** LVEF 71.6%, RV TAPSE 1.67 cm, TR moderate, TS severe (mean gradient 18 mmHg).

5.2 | Technical aspect

**Anesthesia:** General anesthesia with A-line monitoring.

**Access and delivery sheath:** Right femoral vein/Edwards E sheath 14 Fr.

**Guide wire:** Amplatz super stiff™ (Boston Scientific) to LPA.

**Pacing during deployment:** No.

**TVIV:** Successful SAPIEN S3 #29 nominal volume in TVR Magna #25 (Edwards Lifescience).

**Concomitant procedure:** No.

**Complication:** None.

**Special considerations:** As this patient has both mechanical AVR and MVR, anticoagulation management periprocedural is crucial.

5.3 | Outcomes

Immediate hemodynamic data post-TVIV: No residual gradient, no PVL.

**Echo follow-up at index procedure:** TVIV mean gradient 7 mmHg, no PVL, RV TAPSE 1.4 cm.

**Antithrombotic at discharge:** Orfarin, ASA.

**Hospital stays:** 2 days.

Follow-up echo at 6 months: TVIV residual gradient 7 mmHg, no PLV, TAPSE 1.4 cm.

Clinical follow-up at 1 year: NYHA I.

6 | PATIENT 4

A 37-year-old man.

**Clinical presentation:** TVR and PVR dysfunction causing severe tricuspid and pulmonic stenosis.

**Native TV disease:** VSD with infective endocarditis of aortic, tricuspid, and pulmonic valves.

**Comorbidities:** Chronic atrial fibrillation.

**Previous surgery:** Membranous VSD closure with triple valve replacement (mechanical AVR, bioprosthetic PVR (Carpentier-Edwards #21 (Edwards Lifescience)), and bioprosthetic TVR (Carpentier-Edwards #33 (Edwards Lifescience)) 2005).

**Pre-procedure TTE:** LVEF 55%, RV TAPSE 1.5 cm, TR mild-moderate, TS severe (mean gradient 11.35 mmHg), PS severe (PV Vmax 3.8 m/s, Max PG 57.7 mmHg), PR moderate.

6.1 | Technical aspect (Figure 3)

**Anesthesia:** General anesthesia with A-line monitoring.

**Access and delivery sheath:** Right femoral vein/Edwards E sheath 16F.

**Guide wire:** Lunderquist extra-stiff’ wire (Cook Medical) to RPA for transcatheter pulmonic ViV then exchanged to Amplatz Super Stiff™ guidewire (Boston Scientific) for transcatheter tricuspid ViV.

**Pacing during deployment:** No.

**TVIV:** Successful SAPIEN S3 #29 nominal volume to TVR CE #33 (Edwards Lifescience).

**Concomitant procedure:** SAPIEN S3 #23 nominal volume to PVR CE #21 (Edwards Lifescience).

**Complication:** None.

**Special consideration:** We intentionally performed TPVIV first, followed by TTVIV in the same index procedure. As the TVR was significantly stenosed, we predilated TVR using 20 mm Atlas™ gold balloon (BARD) to facilitate delivery system passing through TVR. After successful transcatheter pulmonic ViV, we encountered difficulty crossing the S3 #29 delivery system through TVR but was finally successful. As the wire was unable to properly replaced in left PA, TVIV deployment was deployed slowly with extreme caution.

6.2 | Outcomes

Immediate hemodynamic data post-TVIV and TPVIV: PV MG 9 mmHg, TV MG 1 mmHg.
Echo follow-up at index procedure: TVIV mean gradient 4 mmHg, no TR, no PVL, PVIV mean gradient 8 mmHg, no PVL.

Antithrombotic at discharge: Orfarin, ASA.

Hospital stays: 4 days.

Follow-up echo at 18 months: TVIV mean gradient 5 mmHg, no TR, no PVL, PVIV mean gradient 14 mmHg, no PR/PVL.

Clinical follow-up at 18 months: NYHA class I.

PATIENT 5

7.1 Case presentation

A 24-year-old man.

Clinical presentation: Worsening desaturation, TVR dysfunction causing severe TS.

Native TV disease: Straddling TV, double inlet RV, small MV, valvular PS, d-related great vessels, ASD, VSD.

Comorbidities: AF, Hx of brain abscess s/p burr hole operation 2019.

Previous surgeries: Bidirectional Glenn 2003, TVR Perimount Magna#29 (Edwards Lifescience) with atrial septectomy and epicardial permanent pacemaker implantation 2014.

Pre-procedure TTE: LVEF 60%, RVEF normal, TR no, TS mean gradient 7 mmHg, severe subvalvular PS, d-TGA normal systemic ventricular Function, moderate MR.

7.2 Technical aspects

Anesthesia: General anesthesia with A-line monitoring.

Access and delivery sheath: Right femoral vein/Edwards E sheath 16 Fr.

Guide wire: Pre-curved Safari™ ES guidewire (Boston Scientific).

Pacing during deployment: Yes, via RV wire pacing.

TVIV: Successful SAPIEN S3 #29 overfilled 2 ml to Perimount Magna#29 (Edwards Lifescience).

Concomitant procedure: None.

Complication: None.

Special consideration: This patient has unusual TV anatomy with challenge crossing TVR. There is also severe PS prohibited wiring to PA; therefore, Safari pre-curved wire positioned in RV was preferred. Slow deployment of S3 with rapid pacing into the proper position was then performed successfully.

8 DISCUSSION

Although small in numbers, our case series demonstrated a broad variety of native tricuspid valve pathology, as well as broad baseline patient characteristics and comorbidities. This suggested the possible high needs of this procedure in our region in the future.

Pre-procedural planning by understanding the failing bioprostheses, proper imaging as well as proper valve sizing and deployment techniques are the key for procedural success.
In uncomplicated cases, the procedure can be relatively simple and the patient can be discharged very early. Our series demonstrated satisfactory and anticipatory clinical and echocardiographic results. All our cases were on OAC at discharge for reasons, such as atrial fibrillation and/or mechanical valves in mitral or aortic position. However, it is probably reasonable to be on oral anticoagulant at least short term to prevent TVIV leaflet thrombosis.

Long-term durability is not yet known. Thus far, a recent mid-term report from VIVID registry of 306 patients underwent tricuspid VIV; the cumulative 3-year incidence of death, reintervention, and valved-related adverse outcomes (endocarditis, thrombosis, or significant dysfunction) were 17%, 12%, and 8%, respectively. In addition, the VIVID registry has reported tricuspid VIV and tricuspid VIR in the setting of trans-TV pacemaker leads without lead extraction or re-replacement can be performed safely with low risk for complication in majority of cases. Our case (patient 1) was exception as the patient was pacemaker dependent with persistent increase in right ventricular lead threshold after TVIV. The decision was made to proceed with the new pacemaker system implantation using leadless pacemaker; which decrease the chance of tricuspid VIV leaflet injury in the future.

TVIV indication is broad as long as the size of the failed bioprosthetic valve is suitable for available transcatheter heart valve. In the setting of using S3 valve, true internal diameter of the bioprosthetic valve can be ranged from 18.6 to 29.5 mm to accommodate S3 sized 20–29 mm. There is low risk of right ventricular outflow tract obstruction as in MVIV that may post the risk of left ventricular outflow tract obstruction. Procedural contraindication would be infective endocarditis that usually warrant surgical TV replacement.

The slight increase in trans-TVIV device was observed in our patients in follow-up. All patients reported improvement in symptoms and less peripheral edema. The higher gradient across TVIV prosthesis should be closely monitored via clinical and echocardiographic assessment. The possible etiology could range from leaflet thickening, leaflet thrombosis, early valve deterioration, or infective endocarditis.

Should TVIV fails in the future, the possibility of redo transcatheter tricuspid VIVIV is likely viable, as the valve is relatively large which granted the possibility of another ViV procedure.

The procedure can also be further optimized by using specific valves and delivery system. Transcatheter tricuspid VIV for degenerative surgical bio-prosthesis are expected to be standard treatment for this group of patients in the future.

9 | CONCLUSION

Transcatheter tricuspid valve-in-valve (TViV) for patients with failed tricuspid bio-prosthesis can be performed successfully and safely. Our series demonstrated a broad varieties of native tricuspid valve pathology, as well as broad baseline patient characteristics and co-morbidities. The procedures were adapted accordingly to baseline clinical and technical challenges and can be performed successfully as a single or combined procedure. This procedure opens new option for surgical valve selection in patients that required TV replacement at young age.

AUTHOR CONTRIBUTIONS
Mann Chandavimol MD served as a primary TVIV operator, primary physician for manuscript preparation, corresponding author, and heart team member. Tawai Ngernsritrakul MD served as a TEE and TTE cardiologist and heart team member, and involved in main manuscript and figure preparation. Krissada Meemook MD served as a operator for TVIV procedure and heart team member, and involved in main manuscript preparation. Sirin Apinyasawat MD served as a EP cardiologist, leadless pacemaker operator, and heart team member, and involved in main manuscript preparation. Tarinee Tangcharoen MD involved in referring and main manuscript preparation. Piya Samankatiwat MD served as CVT surgeon and heart team member, and involved in manuscript preparation. Sarana Boonbaichaiyapruck MD involved in manuscript preparation, and served as a Head of Cardiac catheterization laboratory and heart team member.

ETHICAL APPROVAL
An ethical statement by Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University (April 29, 2021) as attached.

CONSENT
All authors have confirmed that patient consent has been signed and collected in accordance with the journal’s patient consent policy.
DATA AVAILABILITY STATEMENT
Data available on request due to privacy/hospital restrictions.

ORCID
Mann Chandavimol https://orcid.org/0000-0001-8795-4103
Piya Samankatiwat https://orcid.org/0000-0003-1613-783X

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