The First TricValve® Transcatheter Implantation in the Philippines: A Case Report on Novel Management of Severe Tricuspid Regurgitation

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DISCLOSURE: None

Abstract

The patient is an 86-year-old female with isolated symptomatic severe tricuspid regurgitation (TR) who presented with worsening right-sided heart failure, deemed to be high risk for surgical repair. She underwent transcatheter bi-caval valve implantation (CAVI) with the Relisys TricValve® device which resulted in improvement of symptoms and quality of life. This marks the first successful transcatheter CAVI with the TricValve® device in the Philippines.

KEYWORDS: TricValve®, tricuspid regurgitation, transcatheter tricuspid valve intervention, CAVI, bi-caval valve implantation.

INTRODUCTION

Severe symptomatic tricuspid regurgitation (TR) is a challenging clinical condition associated with significant morbidity and mortality, often presenting as right-sided heart failure with systemic venous congestion and reduced functional capacity. In the Asian population, the impact of TR is heightened by factors such as higher prevalence of rheumatic heart disease, atrial fibrillation, and delayed clinical presentation due to limited access to healthcare resources.[1,2] Despite its clinical impact, TR is frequently underdiagnosed and untreated, partly due to the high perioperative risk of surgical tricuspid valve repair or replacement, especially in elderly patients with multiple comorbidities.[3]

Recent advances in transcatheter tricuspid valve intervention (TTVI) have provided new therapeutic avenues for patients deemed unsuitable for surgery. Current TTVI modalities include edge-to-edge repair (surgical and transcatheter), direct annuloplasty, orthotopic or valve replacement and heterotopic bi-caval stenting. Each approach is tailored to address specific aspects of TR pathophysiology. Among these, the TricValve® Transcatheter Bi-caval Valve System represents a promising heterotopic approach and has gained attention as a palliative approach for severe symptomatic TR. While it is not curative, this intervention provides significant symptomatic relief, reduces venous congestion and improves quality of life in carefully selected high-risk patients.[4,5]

This case report highlights the clinical relevance of severe symptomatic TR in the Asian population and presents the first successful treatment of a patient using the TricValve® system in the Philippines. It underscores the role of heterotopic bi-caval stenting as a viable palliative option in the evolving landscape of TTVI.

CASE PRESENTATION

An 86-year-old female with a history of degenerative valvular heart disease, including severe mitral regurgitation, moderate calcific aortic stenosis and severe tricuspid regurgitation presented with exertional dyspnea, easy fatigability and bipedal edema, which was classified as New York Heart Association (NYHA) functional class III-IV. Her medical history was significant for stage II hypertension, dyslipidemia, chronic atrial fibrillation and a cerebrovascular infarct in 2012.

In 2023, she underwent a successful mitral transcatheter edge-to-edge repair (M-TEER) using the Abbott MitraClip®. However, her symptoms persisted and progressively worsened, now including prominent neck vein distension, abdominal bloatedness and bilateral leg swelling attributed to hepatic venous congestion. This occurred despite being on optimal tolerated medical therapy including diuretics, a phosphodiesterase-5 (PDE-5) inhibitor and angiotensin receptor blocker (ARB).

Transthoracic echocardiogram (TTE) showed severe TR with dilated right atrium (RA) and right ventricle (RV) dimensions (Figure 1A). The RV systolic function was preserved with RV fractional area change (RVFAC) and tricuspid annular plane systolic excursion (TAPSE) of 41% and 23 mm, respectfully. The tricuspid annulus diameter was dilated with a coaptation gap of 7 mm. Left ventricular (LV) function was normal. The MitraClip® was in place with mild mitral regurgitation (MR). Systolic pulmonary artery (PA) pressure was 55 mmHg.

Right heart catheterization was performed. The patient had markedly elevated superior vena cava (SVC) V wave of 28 mmHg, inferior vena cava (IVC) V wave of 26 mmHg, RA V wave of 26 mmHg. These pressures are all consistent with the severity of TR. The PA pressure was 43/16 mmHg (mean: 25 mmHg) (Figure 2A).

She was deemed to be at high-risk for open heart surgery with the Society Thoracic Surgeons (STS) score of 7.39% for mortality, EuroScore II score of 3.86, Triscore of 4/12 and NT-pro brain natriuretic peptide (NT pro-BNP) level of 3,297 ng/ml at baseline. After a thorough discussion, the multi-disciplinary heart team advised her to undergo bi-caval valve implantation using the Relisys TricValve® device.

A multidetector computed tomography venogram was performed for accurate device sizing. For the implantation of the SVC valve, several CT parameters were measured (Figure 1B).

For the implantation of the IVC valve, several parameters were also obtained (Figure 1C).

Based on the manufacturer's instruction for use (IFU) recommendations, an SVC valve size of 25 mm and IVC valve size of 31 mm were selected.

The procedure was performed in the cardiac catheterization laboratory under general anesthesia with fluoroscopic and transesophageal echocardiography (TEE) guidance.

Bilateral femoral venous access was obtained percutaneously via modified Seldinger technique. Two sheaths (6F and 7F) were placed in the left common femoral vein. A 6F femoral sheath was placed in the right common femoral vein.

A 6F multipurpose (MP) catheter supported by a 0.035 inch J-wire was inserted through the left common femoral vein via the 7F femoral sheath and was advanced into the right pulmonary artery to serve as a marker for the SVC valve implantation. A 6F pigtail catheter supported by a 0.035-inch J-wire was inserted through the left common femoral vein via the 6F femoral sheath and was advanced to the left innominate vein. A 6F MP catheter supported by a 0.035 inch J-wire was inserted through the right common femoral vein and advanced to the SVC. The J-wire was removed and exchanged for a 0.035 x 260 cm Superstiff Amplatz (Boston Scientific) wire. The MP catheter and sheath were removed over the Amplatz wire. The right common femoral vein was sequentially dilated with 16F and 22F Sentrant (Medtronic) sheaths. This was followed by the introduction of the 27.5F TricValve® delivery system via the Super Stiff Amplatz wire.Before SVC valve implantation, SVC angiography was performed with a 6F pigtail located in the left brachiocephalic vein to delineate the SVC anatomy with attention focused on the confluence of the left and right brachiocephalic veins and the SVC-right atrium (RA) junction. The SVC-25 valve was positioned and implanted with the belly of the valve above the right PA (demarcated with the MP catheter) and its skirt not obstructing the left brachiocephalic vein. The SVC valve was slowly deployed to allow the nitinol frame to take the shape of the SVC (Figure 3A). After releasing the SVC valve, the delivery system was withdrawn into the IVC and the capsule closed.

Before IVC valve implantation, the catheter in the right PA was withdrawn into the IVC and IVC angiography was performed with pigtail in the hepatic vein (Figure 3B). The SVC valve delivery system was exchanged for the IVC valve delivery system. The IVC-31 valve was positioned at the IVC-RA junction with the guidance of angiography and TEE. The IVC valve was slowly deployed and assessed with angiography during valve opening to ensure that the skirt will not occlude the entire ostium of the hepatic vein. After IVC valve deployment, the capsule was closed (Figure 3C).

Post-procedure hemodynamics showed decrease in IVC V wave from a baseline of 26 mmHg to 14 mmHg (Figure 2B).

Post-procedure TEE showed that the new CAVI valves were seen with good opening and closing with no paravalvular leaks (Figure 1D).

The IVC delivery system was removed and right common femoral vein closed via figure-of-eight sutures. The patient was then transferred to the telemetry for close post-procedure care and monitoring.

One day post procedure, abdominal breathing was noted and her chest x-ray showed an elevated right hemidiaphragm, blunted costophrenic sulci and bilateral lower lung field infiltrates. A chest ultrasound showed 220 ml of free fluid on the right and absence of fluid in the left. There were symmetric upward and downward excursions of bilateral hemidiaphragm, hence phrenic nerve paralysis was ruled out. She was managed with antibiotics, intravenous diuretics and PDE-5 inhibitor. She was discharged clinically stable and improved on the sixth day

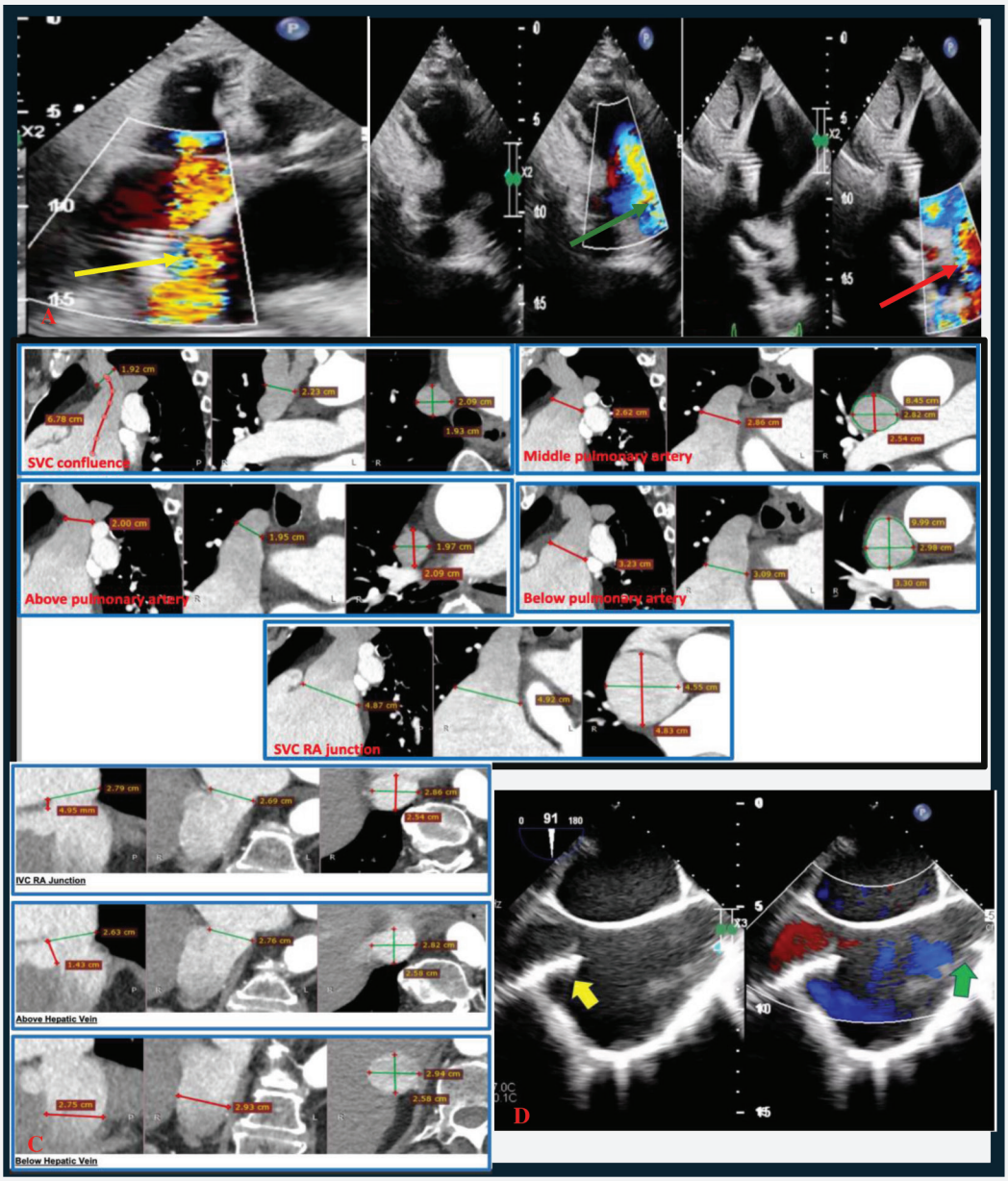

Figure 1. (A). Transthoracic echocardiogram showing severe TR (yellow arrow) in apical 4 chamber view, RV inflow view demonstrating reflux to the inferior vena cava (green arrow), subcostal bi-caval view demonstrating reflux to the superior vena cava (red arrow); (B). CT venogram measurements for the SVC showing SVC confluence diameter (19 mm), SVC at the level of above the PA diameter (21 mm), SVC at the level of the middle of PA diameter (26 mm), SVC at the level of the bottom of the PA diameter (33 mm), and length of confluence to SVC-RA junction (68 mm); (C). CT venogram measurements for the IVC showing IVC-RA junction diameter (26 mm), IVC above the hepatic vein (HV) diameter (27 mm), IVC just below the HV diameter (27 mm), HV distance is 4.95 mm below the IVC-RA junction, HV ostium diameter (14 mm);(D). TEE post CAVI demonstrating the IVC prosthesis (yellow arrow) and SVC prosthesis (green arrow) anchored to the right atrium and with no paravalvular leaks.

post procedure with direct oral anticoagulant (rivaroxaban), moderate dose of diuretics and PDE-5 inhibitor.

At 1-month follow-up, repeat TTE showed preserved LV and RV function. Both caval valves were in place with no significant paravalvular leak. The MitraClip® was in place with mild mitral regurgitation. Systolic PA pressure was 54 mmHg. RV dimensions decreased to 46 mm from 48 mm. The patient had significant improvement in symptoms to NYHA functional class I–II with a reduction in abdominal and neck vein distention and bilateral leg edema.

At 6-month follow-up, repeat TTE showed no significant change from the previous echo except for reduction in RV dimension

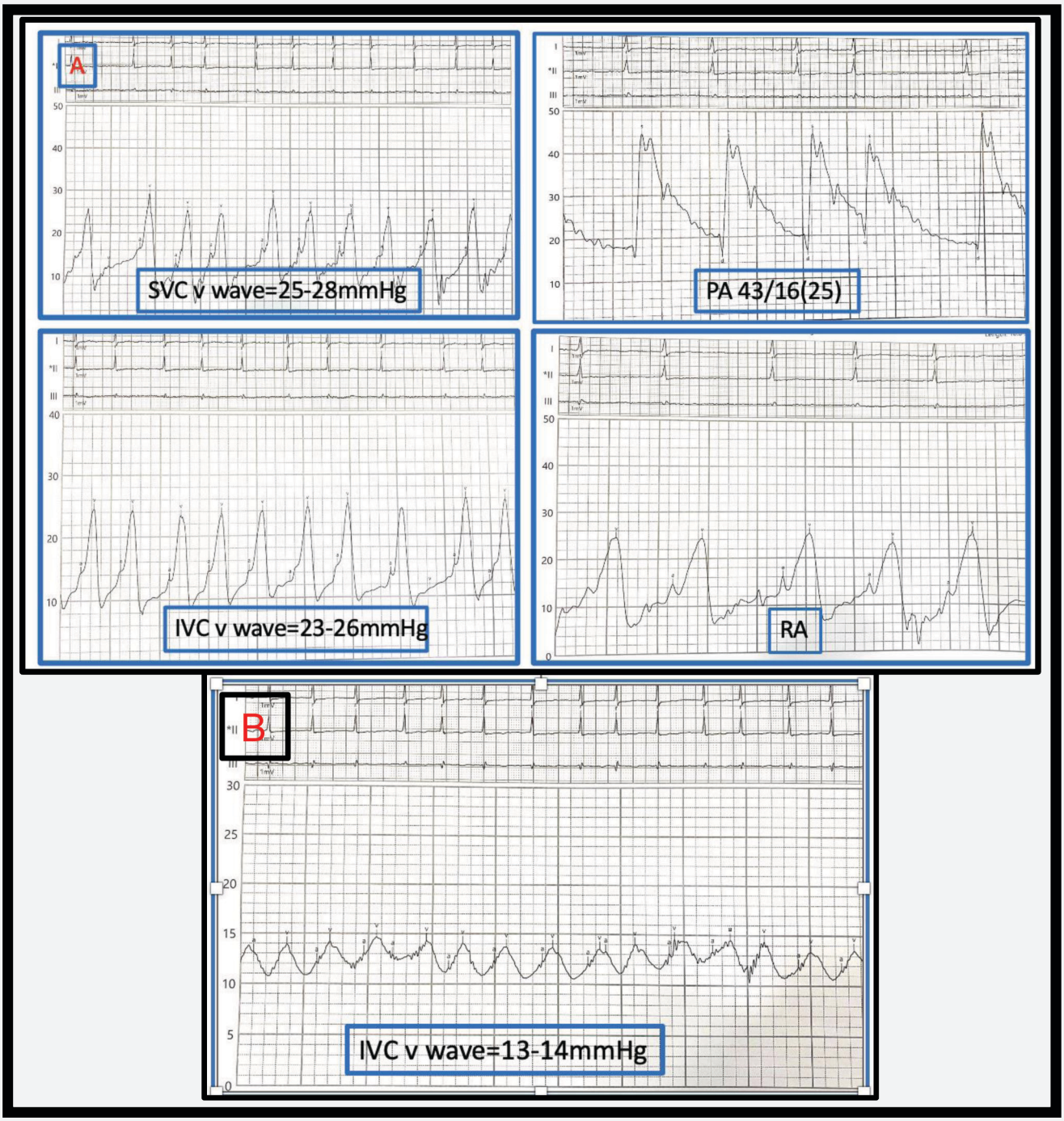

Figure 2. (A). Hemodynamic study pre-CAVI showed elevated SVC and IVC V wave pressures, mean PA pressure of 25 mmHg, RA pressure of 25 mmHg; (B). IVC V wave post CAVI

from 46 mm to 37 mm. NT-Pro BNP level was also decreased by 50%. The patient had marked improvement in symptoms and was now even able to climb the stairs in her house.

CASE DISCUSSION

CAVI may be considered an alternative option for palliative treatment when direct tricuspid intervention, transcatheter or surgical, is deemed unsafe, unsuitable or not available.[6]

This case highlights the successful use of bi-caval valve implantation as a palliative approach in an 86-year-old female with isolated severe TR who was deemed unsuitable for surgical tricuspid valve replacement (TVR). Orthotopic TVR, though an ideal option, is not feasible due to unavailability of the device locally. Transcatheter tricuspid edge-to-edge repair (T-TEER) is not ideal due to the degree of tricuspid annular dilation and fairly wide coaptation gap. While it is possible, it can be challenging, and as of now is unavailable locally.

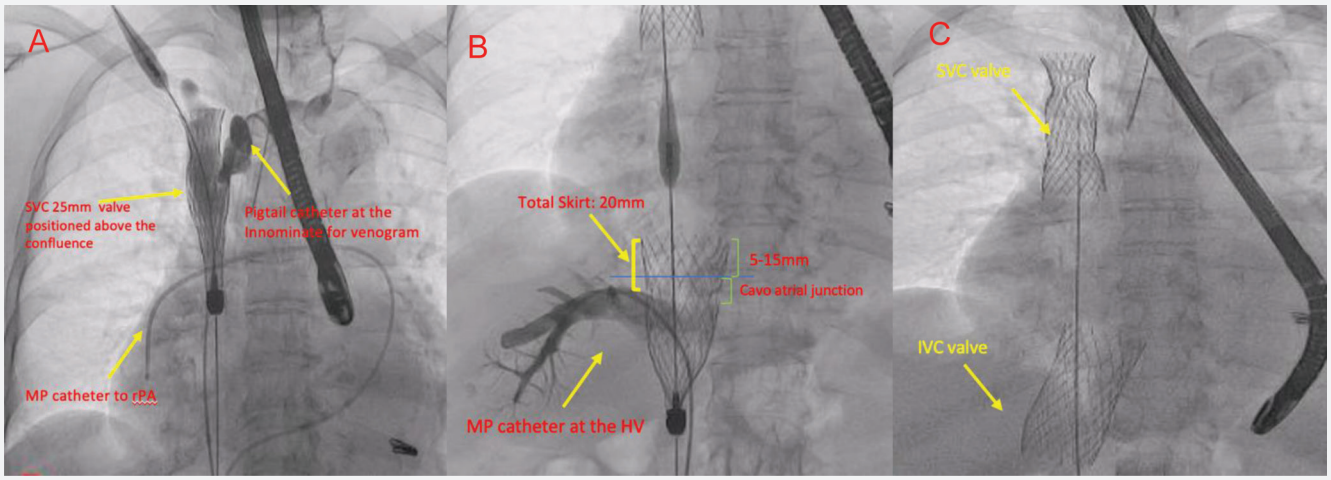

Figure 3. Deployment of TricValve® (A) The crown of the SVC valve 25mm was positioned above the SVC confluence, with the belly of the SVC bioprosthesis positioned above the right pulmonary artery. (B) The IVC valve was positioned with a catheter in the HV, ensuring that the proximal edge of the valve was between 5-15 mm into the right atrium and ensuring that flow to the hepatic vein was not covered. (C) SVC and IVC prosthesis in place

The bi-caval valve implantation using the Relisys TricValve® device provided significant improvement in hemodynamics by reducing venous backflow, as evidenced by a reduction in inferior vena cava (IVC) V wave pressure and a decrease in NT-pro BNP levels by 50% at six months. Imaging follow-up showed stabilization of RV function and remodeling with a reduction in RV dimensions from 48 mm to 37 mm. Clinically, the patient improved from NYHA functional class III-IV to class I-II and regained functional independence.

There are some important considerations for CAVI. First, caval reflux needs to be demonstrated as pulsatile flow in the SVC and IVC is required for proper valve function. For this to be present, there needs to be significant TR and a certain preservation of RV systolic function. Post CAVI, the RV may experience an acute increase in afterload, which may cause decompensation in a patient with RV dysfunction. In a study by Brener, et al, the prognostic significance of RV-PA coupling in patients with TR who underwent transcatheter tricuspid valve repair or replacement (TTVR) was evaluated. The RV-PA coupling ratio was calculated by dividing the TAPSE by the PA systolic pressure (PASP). The study showed that low RV-PA coupling ratio of less than 0.406 was associated with increase in mortality and absence of afterload reserve. Patients with a high baseline TAPSE/PASP ratio may have more afterload reserve to tolerate the abrupt increase in afterload following TTVR.[7] In this case, the patient had a borderline RV-PA coupling ratio but met minimum criteria for intervention. This maybe one of the reasons for the moderate decompensation post procedure that was eventually successfully managed medically.

Second, lifelong anticoagulation is required to prevent device thrombosis post valve implantation in a slow-flow and low-pressure venous circulation. Lastly, the size of the veins can fluctuate depending on volume status. It is therefore recommended to withhold diuretics before CT for accurate sizing.[8]Certain issues may be encountered after CAVI. As mentioned in some case reports, there can be right shoulder pain from compression of the phrenic nerve branches after IVC valve implantation, which are self-limited and responsive to analgesia.[9] Unilateral diaphragmatic paralysis can also be a rare potential complication post CAVI as noted in some case reports. Routine chest radiographs following CAVI could be beneficial for early detection and facilitate optimization of respiratory function. Prosthesis oversizing may play a role in this complication. This stresses the importance of careful preoperative CT planning for selecting appropriate valve size.[10]

CONCLUSION

This case demonstrates the Philippines' first successful CAVI using Relisys TricValve® device as a palliative treatment for severe TR in a high-risk patient deemed unsuitable for surgical or transcatheter orthotopic TVR. Further studies however, are needed to evaluate the long-term outcomes, durability of CAVI, and its impact on RV remodeling.

REFERENCES

1. Kang DH, Kim MJ, Kang SJ. Tricuspid regurgitation: Clinical impact and treatment options in an Asian population. *Korean Circ J*. 2020;50(5):389–400.
2. Asmarats L, Puri R, Latib A, Navia JL, Rodés-Cabau J. Transcatheter tricuspid valve interventions: Landscape, challenges, and future directions. *J Am Coll Cardiol* [Internet]. 2018;71(25):2935–56. Available from: http://dx.doi.org/10.1016/j.jacc.2018.04.031
3. Dreyfus GD, Martin RP, Chan KMJ, Dulguerov F, Alexandrescu C. Functional tricuspid regurgitation: a need to revise our understanding. *J Am Coll Cardiol* [Internet]. 2015;65(21):2331–6. Available from: http://dx.doi.org/10.1016/j.jacc.2015.04.011

4. Lauten A, Figulla HR, Unbehaun A, Fam N, Schofer J, Doenst T, et al. Interventional treatment of severe tricuspid regurgitation: Early clinical experience in a multicenter, observational, first-in-man study: Early clinical experience in a multicenter, observational, first-in-man study. *Circ Cardiovasc Interv* [Internet]. 2018;11(2):e006061. Available from: http://dx.doi.org/10.1161/CIRCINTERVENTIONS.117.006061
5. Wild MG, Praz F. Caval valve implantation for advanced tricuspid regurgitation: Closing a therapeutic gap? *JACC Cardiovasc Interv* [Internet]. 2022;15(13):1378–81. Available from: http://dx.doi.org/10.1016/j.jcin.2022.05.043
6. Blusztein DI, Hahn RT. New therapeutic approach for tricuspid regurgitation: Transcatheter tricuspid valve replacement or repair. *Frontiers in Cardiovascular Medicine* [Internet]. 2023; Available from: http://dx.doi.org/10.3389/fcvm.2023.1080101
7. Brener MI, Lurz P, Hausleiter J, Rodés-Cabau J, Fam N, Kodali SK, et al. Right ventricular-pulmonary arterial coupling and afterload reserve in patients undergoing transcatheter tricuspid valve repair. *J Am Coll Cardiol* [Internet]. 2022;79(5):448–61. Available from: http://dx.doi.org/10.1016/j.jacc.2021.11.031
8. Luk KS, Wong CK. Right heart failure after TricValve implantation for symptomatic torrential tricuspid regurgitation: a case report. *Journal of the Hong Kong College of Cardiology* [Internet]. 2024;31(5). Available from: http://dx.doi.org/10.55503/2790-6744.1541
9. Wong N, Jappar IA, Ho JS, Ewe SH, Tan SY, Tan JWC, et al. Torrential tricuspid regurgitation treated with TricValve. *J Asian Pac Soc Cardiol* [Internet]. 2022;1. Available from: http://dx.doi.org/10.15420/japsc.2022.11
10. Marschall A, Rivero F, Bastante T, Cuesta J, Del Val D, Sarnago F, et al. Diaphragmatic paralysis after heterotopic bicaval stenting. *JACC Case Rep* [Internet]. 2024;29(15):102422. Available from: http://dx.doi.org/10.1016/j.jaccas.2024.102422