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Case report

Severe tricuspid regurgitation and transcatheter bicaval valves system implantation. Importance of the load to indication

Walter Serra[1], Alessandro Palumbo[2], Iacopo Tadonio[1], Stefano Coli[1], Andrea Agostinelli[3], Luigi Vignali[1]

[1]Cardiology Division, Cardio-Thoracic and Vascular Department, University Hospital-Parma, Italy; [2]Radiology Department, University Hospital-Parma, Italy; [3]Heart Surgery, Cardio-Thoracic and Vascular Department University Hospital-Parma, Italy

Abstract. *Background and aim:* To date, some specific evidence or criteria is supporting the selection of patients with PH and severe tricuspid valve regurgitation that can be initiated to correct tricuspid valvulopathy. Studying the load on the right ventricle and the interaction between the ventricle, valve, and pulmonary artery could be the key to detecting such patients. *Methods:* Case Report V.M., Female 83 years old Previous replacement of mitral valve with mechanical prosthesis and precapillary pulmonary hypertension associated with severe tricuspid regurgitation. The patient was in NYHA class III, with lower limb edemas and signs of liver congestion, with severe tricuspid regurgitation associated with mild pulmonary hypertension and sPAP/PAAT Ratio was 0,6 in a specific therapy. It has been necessary to involve the heart team in evaluating a percutaneous interventional treatment, also considering the patient's comorbidities, which do not lead to cardiac surgery. A bicaval device was implanted. *Results:* After implantation, the patient was given low doses of dobutamine for three days. At the Cardiac TC control, the dimensions of the IVC were reduced (30 mm from 41 mm) while at TTE control the hepatic vein backflow did not occur and the oscillation of the leaflets was normal, PAAT 92msc; sPAP/PAAT ratio 0,43, TR grade III. *Conclusions:* The management of patients with severe symptomatic tricuspid regurgitation remains extremely challenging for the Cardiac Heart Team. The patient's selection, the ventricular-arterial coupling, and the type of device, depending on the anatomic functional conditions, are still challenging factors. (www.actabiomedica.it)

Key words: tricuspid regurgitation, transcatheter valves implantation, right ventricular function

Introduction

The management of patients with severe symptomatic tricuspid regurgitation (TR) is still extremely challenging for Cardiac Heart Teams. Medical therapy consisting primarily of escalating doses of diuretics becomes ineffective in the long term, as patients develop increasing diuretic resistance because of worsening renal function (1-4). Severe TR can be treated with tricuspid valve surgery, but the operation can be too risky for many patients who need it. In the last years, several percutaneous devices, direct annuloplasty, and orthotopic or heterotopic valve replacement have been developed to replace or repair the tricuspid valve (5). However, they are unsuitable for most patients with severe TR due to anatomic factors or owing to the presence of pacemaker leads. Anyway, to date some specific evidence or criteria is supporting the selection of patients with PH and severe tricuspid valve regurgitation that can be initiated to correction of tricuspid valvulopathy. Studying the load on the right ventricle and the interaction between the ventricle, valve

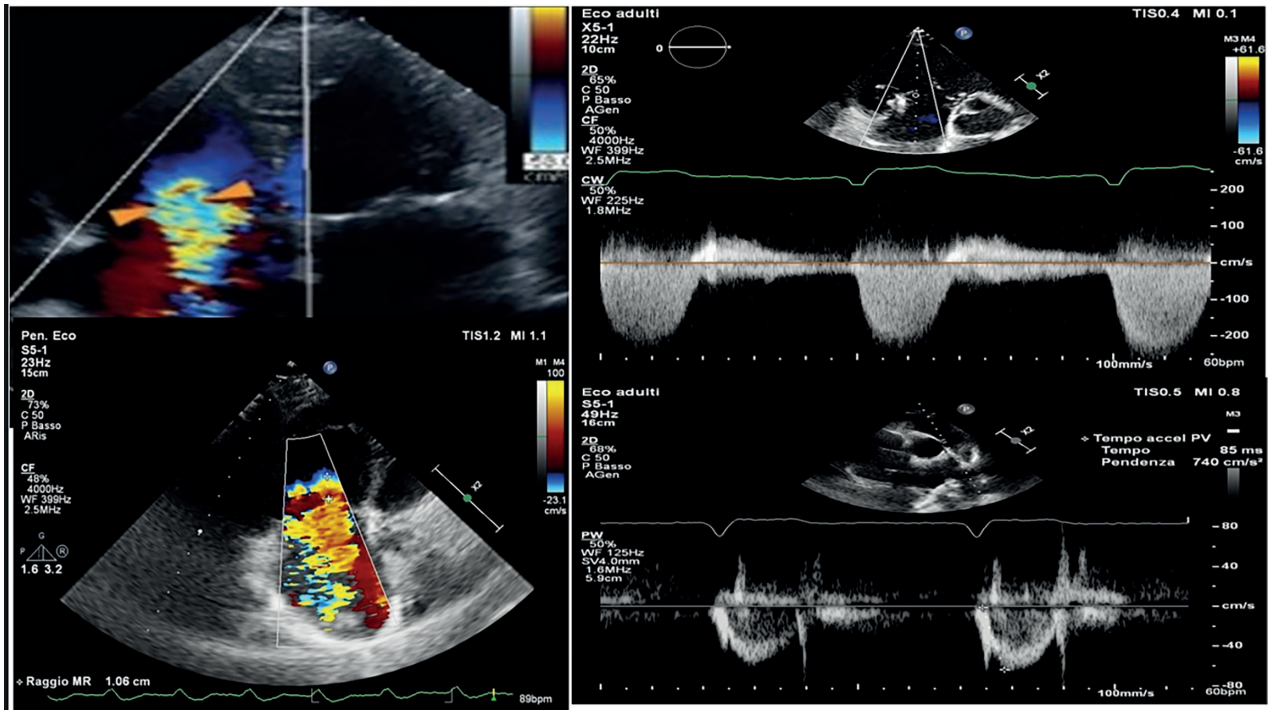

Figure 1. A) TTE Four-chamber view. The transthoracic echocardiogram showed torrential tricuspid regurgitation by dilation of the annulus; Vena contracta 9 mm; PISA IV. B) TTE Four chamber view: CW Doppler Estimated pulmonary hypertension mild degree 50 mm/Hg. PAAT 92msc. sPAP/PAAT ratio 0,6.

and pulmonary artery could be the key to detecting such patients. The systolic pulmonary artery pressure (sPAP)/pulmonary artery acceleration time (PAAT) ratio (Figure 1) could be an indicator of pulmonary vascular load (6), in order to identify patients who could benefit from transcatheter tricuspid valve repair (TTVR).

Case Report

Patient: V. M., Female 83 years old; Weight: 66 Kg, Height: 150 cm BSA: 1.61 m^2. Previous replacement of mitral valve with mechanical prosthesis and subsequent echocardiographic feedback of pre-capillary pulmonary hypertension associated with severe tricuspid regurgitation. In 2021 in class NYHA IIb she underwent right cardiac catheterization showing mild, not vasoreactive pre-capillary pulmonary hypertension (mPAP 28 mm/Hg; PCWP 14 mm/Hg) and began therapy with macitentan 10mg/day with temporary benefit. Currently, she is in NYHA class III with lower limb edemas and orthopnoea nocturnal decubitus. The transthoracic echocardiogram showed torrential tricuspid severe regurgitation due to extreme dilation of the annulus (Figure 1A, 1B).

Diameter max gap 1.8cmq. Enlarged right ventricle (64 mm). RVdp/dt 699 mm/Hg/sec right acromegaly. Reversal flow in vena cava. Estimated pulmonary hypertension mild degree 50 mm/Hg. PAAT 92msc. sPAP/PAAT ratio 0,6; TAPSE 22; FEVS 50% for movement paradox septal. The transesophageal echocardiographic examination (Figure 2), shows severe tricuspid regurgitation due to the absence of coaptation of the leaflets for retraction (gap of 15 mm). Vena contracta 9 mm PISA IV. Annulus dilated (68 mm). Right ventricle dilated but normocinetic. VCI dilated (>30 mm). Very dilated coronary sinus. Mitral prosthesis with normal gradients and physiological leaks.

She underwent cardiac CT as an evaluation of the tricuspid valve documenting: Tricuspid Annulus

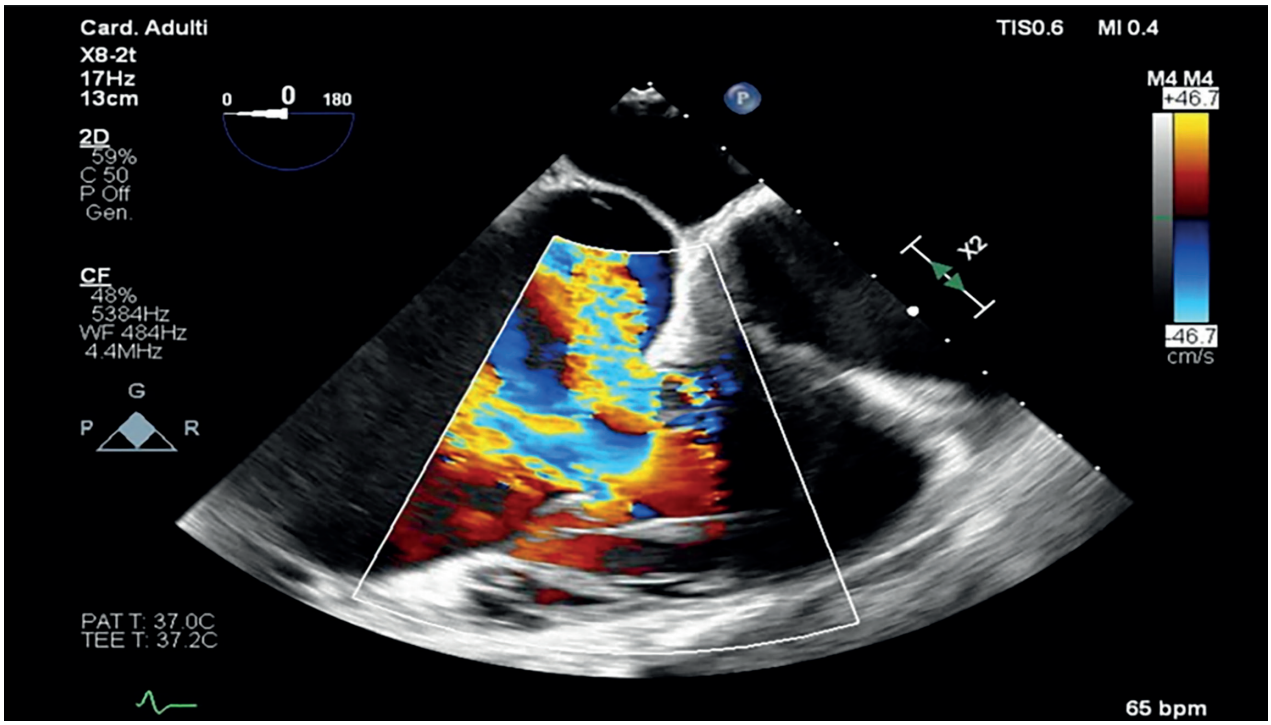

Figure 2. Transverse midesophageal TEE (0°) shows severe (torrential) tricuspid insufficiency due to absence of coaptation of the leaflets.

(AT): -maximum/minimum diameter: 47x37 mm - perimeter: 95 mm - area: 15,27 cm² Right atrium length: 91 mm; Distance between the TA and the apex of the right ventricle: 74 mm; Distance from the tip of the papillary muscle to the TA 19 mm and the septum 44 mm; Inferior vena cava: - maximum/minimum diameter: 41x26 mm - perimeter: 110 mm - area: 9.2 cm²; Functional evaluation of the left ventricle, normalised parameters (Biometrics 166 cm, 80 kg): FE 58 %, EDV 53 ml/m², ESV 22 ml/m², SV 31 ml/m², CI 2.23 l/min/m²; Functional evaluation of the right ventricle: FE 60 %, EDV 180 ml/m², ESV 72 ml/m², SV 108 ml/m², CI 7.75 l/min/m² (Figure 3). In summary, the patient was in NYHA class III, with lower limb edemas and signs of liver congestion, with severe tricuspid regurgitation associated with mild pulmonary hypertension and sPAP/PAAT Ratio was 0,6 in a specific therapy. It has been necessary to involve the heart team in evaluating a percutaneous interventional treatment, also considering the patient's comorbidities, which do not lead to cardiac surgery. It is a mixed phenotype with severe annulus enlargement and mild pulmonary hypertension according to Rebecca Haan classification (7).

Cardiac surgery was ruled out. Another device as "Triclip" was excluded due to the dilatation of the tricuspid annulus and the retraction of the flaps. The choice of the device was directed toward a bicaval device called 'TricValve'. The implantation of this device does not touch the native valve and allows for all future tricuspid valve surgical and procedural options, including transcatheter edge-to-edge repair, tricuspid valve repair and transeptal puncture, and pacemaker implantation. Device implantation: Both fully premounted devices are implanted via femoral access with fluoroscopy and transesophageal echo guidance under monitored anaesthesia care. The nitinol stents contain bovine pericardium leaflets with a long skirt on the SVC valve designed to minimise perivalvular leak and with a short skirt on the IVC valve to prevent hepatic vein flow occlusion. Several sizes are available, with the choice based on IVC and SVC measurements from a preprocedural CT scan. The procedure is hemodynamically stable, involving slow, controlled release

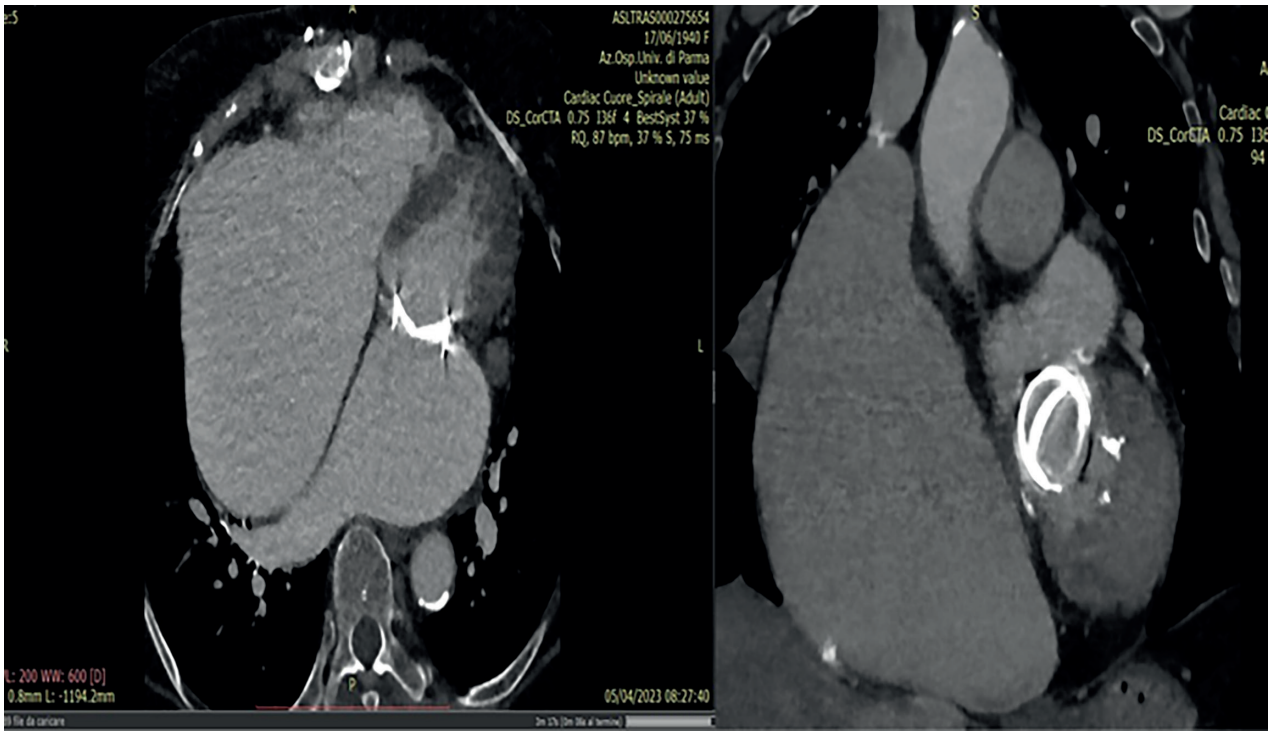

Figure 3. Cardiac CT measures Tricuspid Annulus (AT): - maximum/minimum diameter: 47x37 mm - perimeter: 95 mm - area: 15,27 cm² Right atrium length: 91 mm Distance between the TA and the apex of the right ventricle: 74 mm; Distance from the tip of the papillary muscle to the TA 19 mm and the septum 44 mm ; Inferior vena cava: - maximum/minimum diameter: 41x26 mm - perimeter: 110 mm - area: 9.2 cm².

of the device. The time for implant was 45-60 minutes (Figure 4).

After implantation, the patient was given low doses of dobutamine for three days and CVC placement for hemodialysis due to the onset of hypotension and acute renal failure, then resolved. At the Cardiac TC control, the dimensions of the IVC were reduced (30 mm from 41 mm) while at TTE control the hepatic vein backflow did not occur, (Figure 5) and the oscillation of the leaflets was normal, PAAT 92msc; sPAP/PAAT ratio 0,43, TR grade III; the device was correctly positioned in VCS (Table 1; Figure 6).

Discussion

In 2022, Cleveland Clinic interventional cardiologists performed the first implantation of the Transcatheter Bicaval Valves System (8). TricValve shows potential for use even in patients with end-stage disease (despite having complicated tricuspid valve anatomy), as caval anatomy is less complex compared with that of the right heart and tricuspid valve. The concept of Caval Valve Implantation (CAVI) by placing a valve in the inferior vena cava and one in the superior vena cava, is to redirect the regurgitant jet from the failed tricuspid valve. Protection of the hepatic and renal veins from the effects of this chronic volume overload may help mitigate the symptoms of right heart congestion, especially ascites and lower extremity edema. In this case, device placement prevents regurgitant flow in the IVC and SVC reduces liver congestion and right ventricle stroke volume into the pulmonary system. Future studies must better clarify the role of bicaval implantation versus IVC implant only and their effect on hemodynamics and patient outcomes. In the 'TRICUS EURO Study' a dedicated bicaval system for treating severe symptomatic TR was associated with a high procedural success rate and significant improvements in both QOL and functional classification at

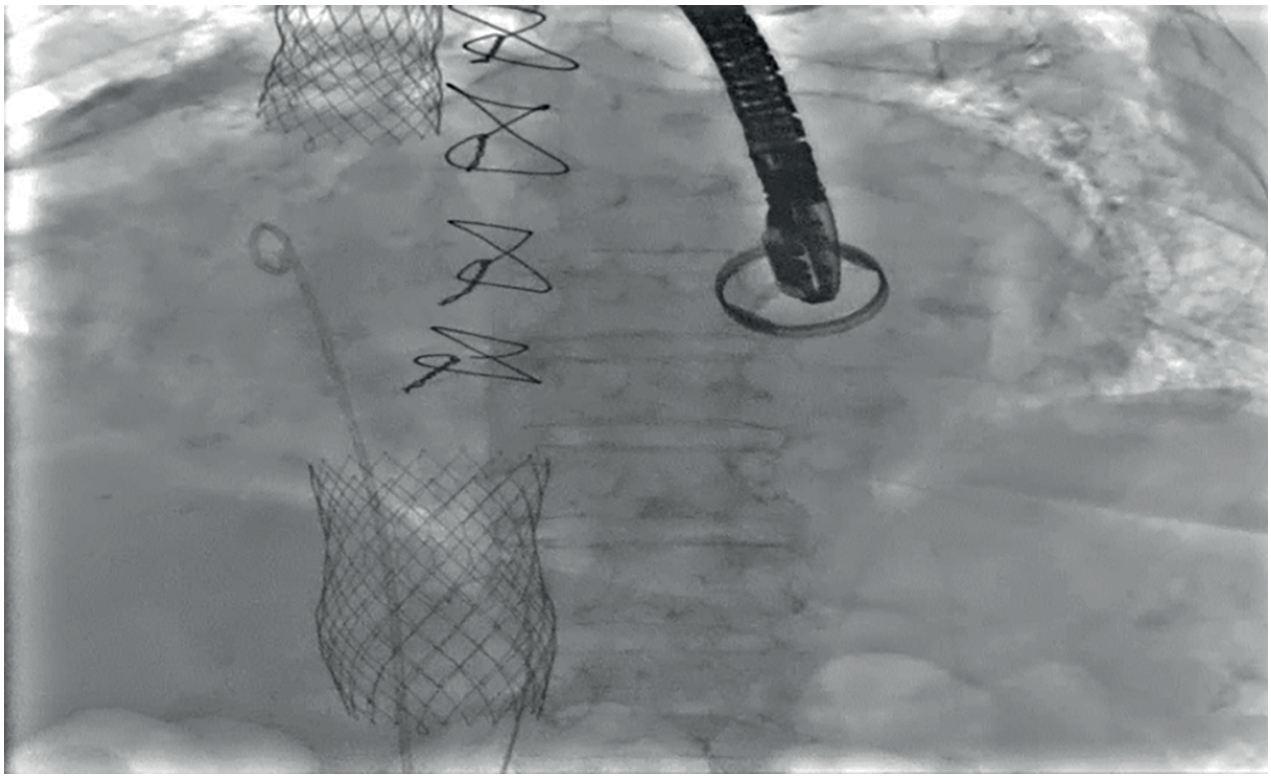

Figure 4. Angiographic Imaging. Device implantation: The two fully pre-mounted devices are implanted via femoral access with fluoroscopy guidance.

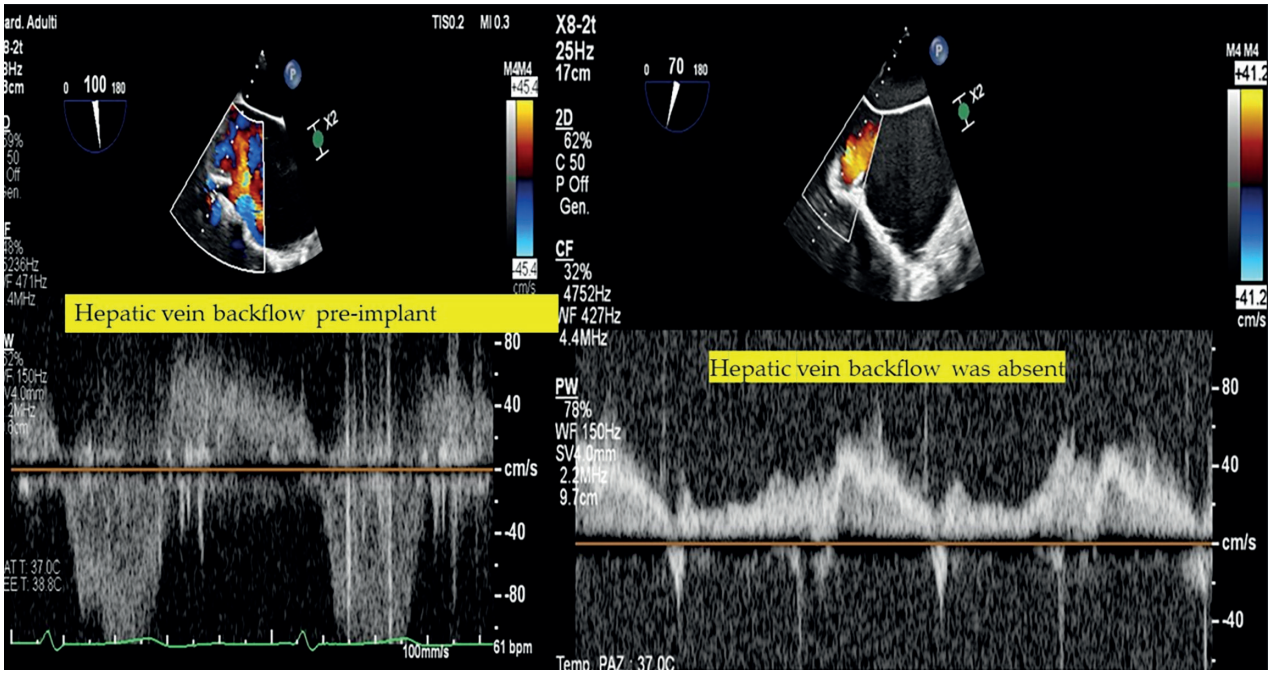

Figure 5. Transverse midesophageal TEE (100°,70°) shows VCI flow: Hepatic back vein flow pre-post device implantation.

Table 1. Comparison of echocardiographic parameters before and after implantation.

ECO PARAMETERS	BASAL	PRE-DISCHARGE
TAPSE	22mm	20mm
sPAP	50mm/Hg	40mm/Hg
RVDd	64mm	64mm
TA	65mm	64mm
VCI diameter	41mm	32mm
TR grade	IV	III
Epatic vein backflow	Y	N
PAAT	92msc	92msc
sPAP/PAAT	0,6	0,43

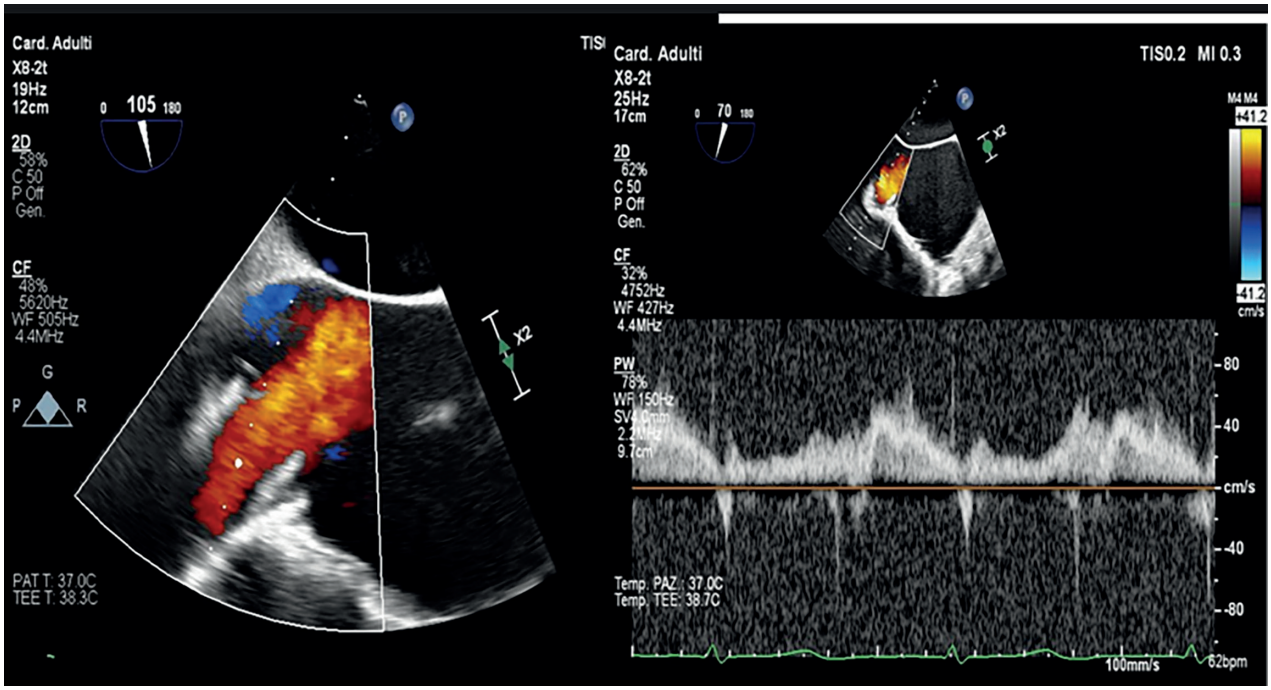

Figure 6. Transverse midesophageal TEE shows right atrial chamber and VCI flow: Hepatic vein flow post device implantation.

6 months follow-up (8). The main limitation for CAVI remains cava size, both distances from the superior most hepatic vein to the right atrium/cava junction, and cava diameter of the IVC or SVC. Similar to dilatation of the tricuspid valve annulus which occurs with long-standing severe TR, from the effects of chronic volume overload. In the current studies, the patients with an IVC diameter >35 mm were excluded. This is due largely to the limitations in sizing with current transcatheter valve technology.

sPAP/PAAT ratio could be used as an indicator of pulmonary vascular load, to identify patients who could benefit from transcatheter tricuspid valve repair (TTVR). sPAP/PAAT ratio<0,6 was a good predictor of a mild to moderate pulmonary vascular load.

Conclusion

The management of patients with severe symptomatic tricuspid regurgitation remains extremely challenging for the Cardiac Heart Team. The patient's selection, the ventricular-arterial coupling, and the type of device depending on the anatomic functional conditions are factors challenging.

Abbreviation: FTR = functional tricuspid regurgitation; HR= heart rate; LVEF= left ventricular ejection fraction; PAP= mean pulmonary artery pressure; NYHA= New York Heart Association; PAAT= pulmonary artery acceleration time; PAH= pulmonary arterial hypertension; PCWP= pulmonary capillary wedge pressure; PH= pulmonary hypertension; PVR= pulmonary vascular resistance; RHC= right heart catheterization; RV= right ventricle; RV-AC= right ventricular-arterial coupling; RVF= right ventricular failure; sPAP= systolic pulmonary artery pressure; TAPSE= tricuspid annular plane systolic excursion; TPG= trans-pulmonary gradient; TR-PG= tricuspid regurgitation pressure gradient; TTE= transthoracic echocardiogram; TTVR= transcatheter tricuspid valve repair; CAVI= Caval Valve Implantation; IVC= inferior vena cava; SVC= superior vena cava; CT= cardiac tomography; ESV= end systolic volume; EDV= end diastolic volume.

Ethic Approval: The study protocol was approved by Ethics Committee Area Vasta Emilia Nord (protocol number 12751 – 21 March 2023).

Conflicts of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Authors Contribution: All authors have participated in the work and reviewed and agree with the content of the article. In particular, WS designed, wrote the article and produced the additional material (Figures, Tables etc.) AP produced the CT imaging; IT produced additional material; AA and LV produced hemodynamic data.

Informed Consent: Written informed consent was obtained from the patient.

References

1. Frater R. Tricuspid insufficiency. J Thorac Cardiovasc Surg. 2001; 122:427–429. doi: 10.1067/mtc.2001.113170.
2. Nakanishi K, Homma S, Han J, et al. Prevalence, predictors, and prognostic value of residual tricuspid regurgitation in patients with left ventricular assist device. J Am Heart Assoc. 2018 un 24;7(13):e008813. 1-9 doi: 10.1161/JAHA.118.008813.
3. Santaló-Corcoy M, Asmarats L, Li CH, Arzamendi D. Catheter-based treatment of tricuspid regurgitation: state of the art. Ann Transl Med. 2020; 8:964. doi: 10.21037/atm.2020.03.219.
4. Benfari G, Antoine C, Miller WL, et al. Excess mortality associated with functional tricuspid regurgitation complicating heart failure with reduced ejection fraction. Circulation. 2019; 140:196–206. 10.1161/CIRCULATIONAHA.118.038946.
5. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021; 143:e35–e71. doi: 10.1161/CIR.0000000000009328.
6. Serra W, Chetta A. sPAP/PAAT Ratio as a New Index of Pulmonary Vascular Load: A Study in Normal Subjects and Ssc Patients with and without PH. Pathophysiology. 2022 Mar 15;29(1):134-142. doi: 10.3390/pathophysiology29010012.
7. Hahn RT. State-of-the-Art Review of Echocardiographic Imaging in the Evaluation and Treatment of Functional Tricuspid Regurgitation. Circ Cardiovasc Imaging. 2016 Dec;9(12):e005332. doi: 10.1161/CIRCIMAGING.116.005332.
8. Rodrigo E.-L, Angel S.-R, A-SI J. 6-Month outcomes of the tricvalve system in patients with tricuspid regurgitation. JACC Cardiovasc Interv 2022;15:136677.doi.org/10.1016/j.jcin.2022.05.022.

Correspondence:

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Walter Serra MD, PhD
Cardiology Division, Cardio-Thoracic and Vascular Department, University Hospital Parma, Italy,
Via Antonio Gramsci 14, 43100 Parma, Italy
E-mail: wserra@libero.it
ORCID: 0000-0002-3530-1239