cardiovascular medicine

MDPI

Case Report

A Clinical Experience with a Complex Case Treated with TriCValve®: Narrative Review of the Medical Literature and Rehabilitative Implications

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Abstract

Tricuspid regurgitation (TR) is being increasingly recognized in the patient population. It is a common cardiac cause of chronic disability. This pathology is characterized by a heterogeneous and broad spectrum of clinical manifestations with signs and symptoms. The results from various and different analyses and studies suggest that TR-related deaths may have increased over the last 20 years. This trend may justify a greater focus on timely diagnosis and management of TR. For a long time, this problem has been underestimated or treated with only pharmacological therapy (diuretics). The use of the isolated surgical option remains infrequent, especially in patients at high surgical risk, for whom a significant number of patients with TR are still not treated, and a disability remains that is difficult to manage and rehabilitate. To date, there are emerging as an alternative to surgery in high-risk patients with severe TR multiple transcatheter devices that aim to reduce TR through different functional mechanisms. There are numerous minimally invasive treatments for TR, and many devices used for the treatment of this disabling pathology. In fact, there are various treatments with a transcatheter approach using ever-new devices. The use of heterotopic implantation of bioprosthetic valves in the superior and inferior vena cava represents an additional therapeutic armamentarium that, through caval reflux, can constitute an additional resource, too. Starting from a single clinical experience and describing a clinical case report, a narrative review has been undertaken by reviewing the various studies that have investigated this type of approach and their impact on the general, cardiac, and functional sides, to then discuss the cost–benefit ratio in light of knowledge on this specific topic.

Keywords: tricuspid regurgitation; echocardiogram; transcatheter interventions; TricValve®; rehabilitation; multi-professional management

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1. Introduction

Considering its incidence, tricuspid regurgitation (TR) is an important pathology both because of its high prevalence [1] and because of its implications for patients' functional status, long-term survival, quality of life [2], and treatment and rehabilitation possibilities [3–5].

Cardiologists, internists, geriatricians, and Physical and Rehabilitation medicine (PRM) specialists (also known as physiatrists) are often consulted to evaluate patients with acute, subacute, or chronic manifestations and outcomes of this pathology [6–8]. Yet, TR is still undertreated. Thanks to current knowledge and new technologies, there has been a parallel increase in interest in an effective interventional treatment for this condition, including a transcatheter approach [9–11]. In this article, the focus will exclusively be on the transcatheter treatment of tricuspid valve regurgitation, with a focus on the use of the TricValve®. Compared to other transcatheter devices, the implantation of the bicaval valve, known as CAVI (caval valve implantation), may be a viable option for many patients with severe tricuspid regurgitation.

A case is presented that has come to the authors' attention in daily clinical practice; current evidence and uncertainties related to the use of the TricValve® are also described with a particular focus on its implications in the field of rehabilitation.

In this review, the scientific work has tried to delve deeper into the topic, considering both the large regulatory trials of these techniques and the equally important clinical experiences published in the literature. As cardiologists, geriatricians, internists, and PRM specialists, the care of cardiopathic patients is of particular concern to us.

Likewise, the management of cardiovascular diseases is an integral part of the PRM daily routine.

2. The Importance of Tricuspid Regurgitation and Its Implications for Patient Health

According to recent statistics, clinically relevant tricuspid regurgitation (i.e., moderate-to-severe) affects approximately 0.8% of the general population. A recent Chinese study highlights the prevalence of this condition in patients undergoing echocardiography: A total of 2299 significant TR cases were identified in individuals aged over 18 years old, accounting for 10.3% of the total population. In the Framingham Heart Study, these percentages vary by gender, affecting approximately 5.6% of women and 1.5% of men over 70 years of age [12–15]. Secondary TR is observed not only in cardiac diseases [16–18] but also in pulmonary diseases. In the latter case, the simultaneous presence of pulmonary arterial hypertension (PAH) and secondary TR is associated with poor outcomes [19–21]. Heart failure with preserved ejection fraction (HFpEF) is a common cause of this condition [22–24]. Atrial secondary TR is a distinct phenotype of secondary TR with predominant dilation of the right atrium and normal right and left ventricular function. It most commonly occurs in elderly women with atrial fibrillation and in HFpEF in sinus rhythm [25,26]. In the absence of left-sided cardiac or pulmonary disease, functional TR is referred to as isolated or idiopathic [27] (Figure 1).

At the pathophysiological level, the overload of the right ventricle due to cardiac pathologies and/or PAH leads to dilation of the tricuspid ring, papillary muscle diastasis, and tethering of the valve leaflets, resulting in loss of coaptation. Mortality is strictly correlated with the severity of tricuspid regurgitation, as demonstrated by Kelly BJ et al. on approximately 20,000 patients [28] independently of pulmonary pressure and left ventricular systolic function [29]. The prognosis of TR is also influenced by the presence of other valvular diseases and how they are treated: For example, the presence of moderate or severe tricuspid regurgitation is associated with a significant increase in mortality, even in patients undergoing percutaneous treatment for aortic stenosis with transcatheter aortic valve implantation (TAVI) [30] or in patients with mitral insufficiency who undergo transcatheter edge-to-edge repair [31,32]. The consequences of the presence of tricuspid regurgitation are also evident in rehabilitation. These are patients who have demonstrated a low exercise capacity and variations in mean peak oxygen consumption. Right atrial

pressure increases at peak exercise, with an equal increase in PCWP. Cardiac output (CO) decreases, resulting in a low CO reserve (Figure 2).

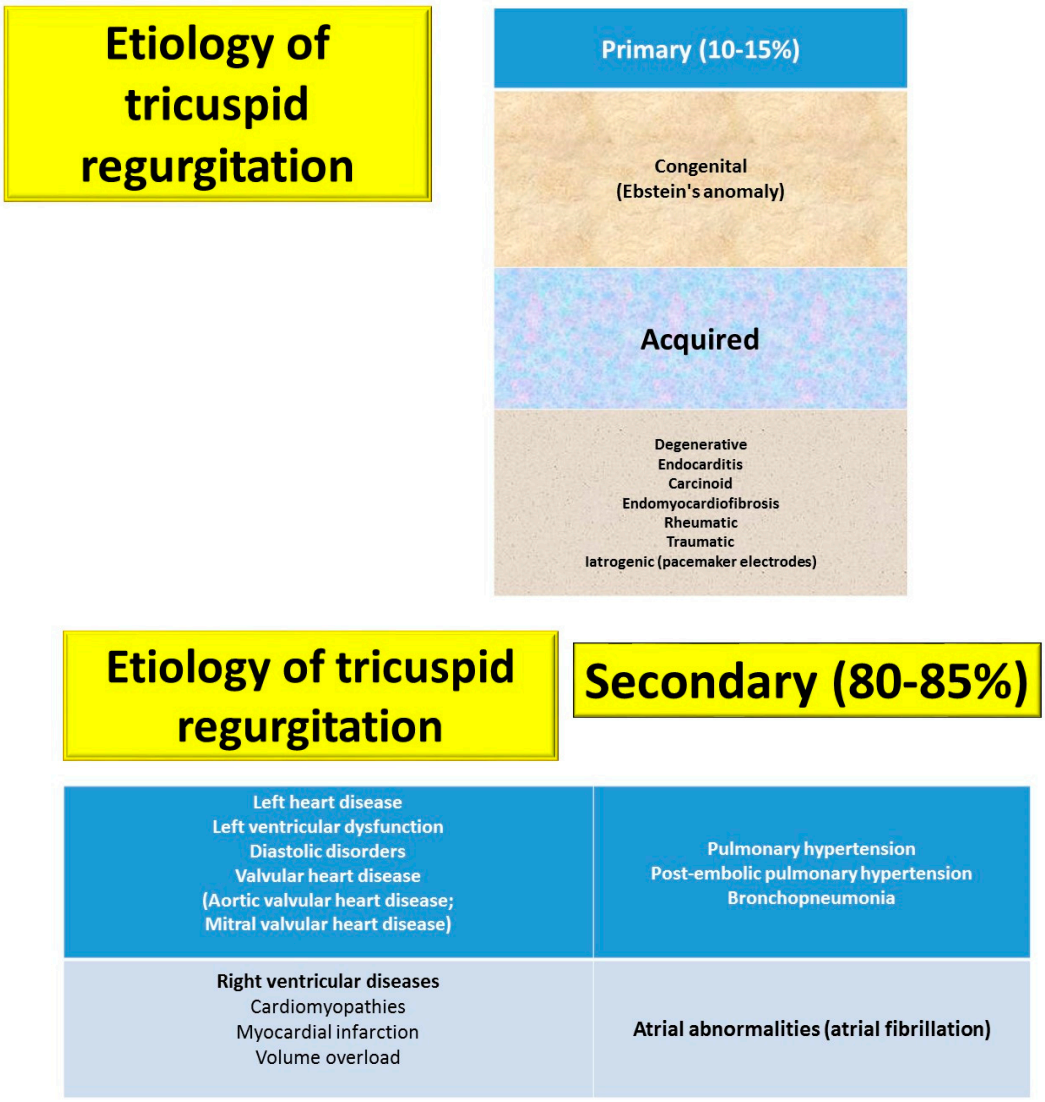

Figure 1. The division of tricuspid insufficiency with its related etiological characterization.

Tricuspid regurgitation: ECHOCARDIOGRAPHIC DIAGNOSIS

Grade of TR	Mild	Moderate	Severe	Massive	Torrential
VC (Biplane)	<3 mm	3–6.9 mm	7–13 mm	14–20 mm	≥21 m
EROA (PISA)	<20 mm^2	20–39 mm^2	40–59 mm^2	60–79 mm^2	≥80 mm^2
3D VCA or quantitative EROA	-	--	75–94 mm^2	95–114 mm^2	≥115 mm^2

Figure 2. Hemodynamic characteristics of the various stages of tricuspid regurgitation, with related echocardiographic parameters of severity.

TR may undergo various stages with different hemodynamic characteristics, all with related echocardiographic parameters of severity (Figure 2). The biplane vena contracta (VC) measurement is an advanced echocardiographic parameter used to accurately assess the severity of blood reflux from the tricuspid (right) valve into the right atrium. It represents the narrowest point of the "jet" of blood flowing back through the malfunctioning valve. A VC measured in 2D greater than or equal to 7 mm is considered a marker of severe regurgitation. This parameter is often analyzed in conjunction with other indices, such as the 3D vena contracta area (VCA), for greater precision. The EROA (effective regurgitant orifice area) measures the size of the area that remains open between the cusps of the tricuspid valve when it should be closed, allowing blood to flow from the right ventricle into the right atrium. It is usually calculated using the PISA (Proximal Isovelocity Surface Area) echocardiographic method. An EROA value of 40 mm^2 is considered indicative of severe tricuspid regurgitation. Higher values (>80 mm^2) have been proposed to define "massive" or "torrential" forms [33].

In short, tricuspid regurgitation contributes to the development of symptoms of advanced heart failure, characterized by a low exercise capacity, increased atrial filling pressures, and reduced cardiac output at rest and during exercise [34]. There is little data on cardiac re-education (CR) for these patients in the medical literature. These are case studies involving small numbers of patients or case reports of patients with multivalvular disease who benefited from rehabilitation treatment, enabling them to return to their previous occupations and lifestyle habits [35–37].

3. Treatments for Tricuspid Regurgitation: Repair vs. Replacement

For a long time, the tricuspid valve was known as "the forgotten valve" [38]. This was for several reasons. Firstly, diuretics provided good symptom control, which was believed to guarantee a longer survival and, in any case, a good prognosis without the need for further interventions. Secondly, there was the (false) belief that the right circulation had a lesser impact on survival than the left circulation. Finally, surgery for isolated tricuspid regurgitation was historically associated with a questionable prognostic value and a high hospital mortality.

However, studies revealed that severe TR negatively impacts prognosis. For the treatment of TR, either repair or replacement of the tricuspid valve can be performed. The most common technique for tricuspid valve repair is anuloplasty with a prosthetic ring. Prosthetic rings designed for the tricuspid valve are typically incomplete in order to respect the anatomy of the conduction tissue; they can also be flexible, semi-rigid, or rigid [39–41]. For patients with significant "tethering" of the valve leaflets, a technique that increases the surface area of the anterior leaflet of the tricuspid valve can be employed [42,43]. Another repair technique is that of "biscupidization" of the tricuspid valve, which is obtained by suturing together the antero-posterior and postero-septal commissures along the posterior segment of the native ring [44,45]. When tricuspid valve replacement is indicated, a biological prosthesis is preferable due to its lower risk of thromboembolic complications compared to a mechanical prosthesis. However, mechanical and bioprosthetic valves provide comparable survival rates, reoperation rates, and recovery of right ventricular systolic function and size after tricuspid valve replacement (TVR) [46].

In case of particularly destructive infective endocarditis, the valve leaflets and the entire subvalvular apparatus may need to be excised. This leaves ample communication between the right atrium and ventricle. Once the infection has been controlled, a prosthetic valve implant can be considered [47,48].

4. Transcatheter Treatment of Tricuspidal Insufficiency

Several devices for the transcatheter treatment of functional TR have been evaluated in preclinical and clinical studies.

The use of the TriClip® (Abbott Vascular, Santa Clara, CA, USA) is the percutaneous approach for the treatment of tricuspid regurgitation with the largest case series. The grasping of the tricuspid leaflets has been successfully used in the treatment of selected high-risk patients with a tricuspid valve coaptation defect [32,49,50]. Other coaptation systems include: the Forma® system (Edwards Lifesciences, Irvine, CA, USA), which consists of a spacer that is placed in the regurgitant orifice and anchored to the endocardial surface of the right ventricle [51]; the PASCAL® system (Edwards Lifesciences, Irvine, CA, USA), which is a device that combines the mechanisms of the TriClip and the Forma systems [52,53]; and the Trialign® system (Mitralign Inc., Tewksbury, MA, USA) is a transjugular annuloplasty system that aims to reduce the diameter of the annulus through plication and bicuspidization [54].

Although other devices have been used with good results, they have not been widely adopted due to their high procedural complexity: Cardioband® (Edwards Lifesciences, Irvine, CA, USA), TriCinch® (4Tech Cardio, Galway, Ireland), MIA® (Micro Interventional Devices, Newtown, PA, USA), PASTA® (Pledget Assisted Suture Tricuspid Annuloplasty), and TRAIPTA® (Transatrial Intrapericardial Tricuspid Annuloplasty) [55–57].

Table 1 compares heterotopic CAVI/TricValve, TEER devices, and orthotopic TTVR systems in terms of mechanism, anatomical target, patient profile, and main limitations.

Table 1. Overview of transcatheter treatment options for severe tricuspid regurgitation, comparing heterotopic CAVI/TricValve, transcatheter edge-to-edge repair (TEER), and orthotopic TTVR devices in terms of mechanism of action, anatomical targets, candidate profile, and main limitations.

Technique	Mechanism of Action	Anatomical Target	Typical Patient Profile	Main Limitations/Complications
Heterotopic CAVI/TricValve	Bicaval valve implantation to block caval backflow and reduce systemic venous congestion without directly correcting TR	Superior and inferior vena cava at predefined landing zones (above hepatic veins, near RA junction)	Severe functional TR, high/prohibitive surgical risk, advanced right HF with systemic congestion, anatomy suitable for bicaval anchoring, not candidates for orthotopic TTVR or TEER	Palliative strategy (TR persists), dependence on adequate caval anatomy, risk of valve migration/embolization, device–lead interactions, thrombosis, uncertain long-term RV remodeling
TEER (TriClip/PASCAL)	Edge-to-edge leaflet approximation to reduce effective regurgitant orifice area	Native tricuspid leaflets (typically septal-anterior and/or septal-posterior)	Symptomatic functional TR with suitable leaflet anatomy and coaptation gap, preserved RV function, acceptable venous access, intermediate-high surgical risk	Requires favorable leaflet anatomy and coaptation gap, risk of single or partial clip detachment, residual significant TR, challenging imaging guidance, limited data in torrential TR
Orthotopic TTVR (e.g., EVOQUE)	Valve replacement in tricuspid position with transcatheter prosthesis, aiming at near-complete elimination of TR	Native tricuspid annulus and surrounding structures	Severe symptomatic TR with suitable annular dimensions and anchoring structures, often with high surgical risk but adequate RV function and life expectancy	Complex device size/anchoring requirements, risk of RV outflow or conduction system interference, thrombosis, pacemaker need, uncertain long-term durability, and impact on RV remodeling

5. Heterotopic Bioprosthesis Implantation in the Caval Site

Transcatheter Tricuspid Valve Replacement (TTVR) is a minimally invasive, percutaneous, transvenous procedure for treating severe tricuspid regurgitation (TR) in patients at high surgical risk. Two main approaches are distinguished based on the implant site: orthotopic and heterotopic. In orthotopic TTVR, the prosthetic valve is positioned precisely in the anatomical site of the native tricuspid valve (tricuspid annulus). It replaces the malfunctioning native valve with a bioprosthesis, almost completely eliminating TR, even in the presence of large coaptation defects. It uses advanced devices (e.g., EVOQUE®, NaviGate®, and Intrepid®) with anchoring systems to the annulus or valve leaflets. Among the advantages mentioned is a reported greater efficacy in eliminating TR (up to 87% of cases with mild TR at 1 year). In heterotopic TTVR (caval valve implantation—CAVI), the transcatheter valve is placed in the superior vena cava (SVC) and/or inferior vena cava (IVC) to manage blood reflux, rather than at the level of the valve itself. It does not eliminate tricuspid regurgitation, but it reduces venous hypertension in the organs (and resulting congestion) in patients with massive tricuspid regurgitation. It is often considered a palliative procedure for inoperable patients who cannot undergo repair (T-TEER) or orthotopic replacement.

TricValve® (Transcatheter Bicaval Valve System) is a bicaval transcatheter tricuspid valve implantation system, which includes the TricValve® Transcatheter Bicaval Valve for Superior Vena Cava (SVC) and the TricValve® Transcatheter Bicaval Valve for Inferior Vena Cava (IVC). The bioprosthesis is designed to treat caval reflux in cases of severe TR with a high risk for open-heart surgery. The bioprosthesis is designed to treat severe TR without removing the defective tricuspid valve. The bioprosthesis is available in two different diameters for each model (SVC and IVC), which are specifically designed to adapt to the anatomic features of the SVC and IVC. It consists of a self-expandable, radiopaque nitinol tubular structure with three valve leaflets of bovine pericardium sutured and complemented by a skirt of polyester to avoid paravalvular leaks. The leaflets are processed with anti-calcification treatment and undergo chemical dehydration [58] (Figures 3–5).

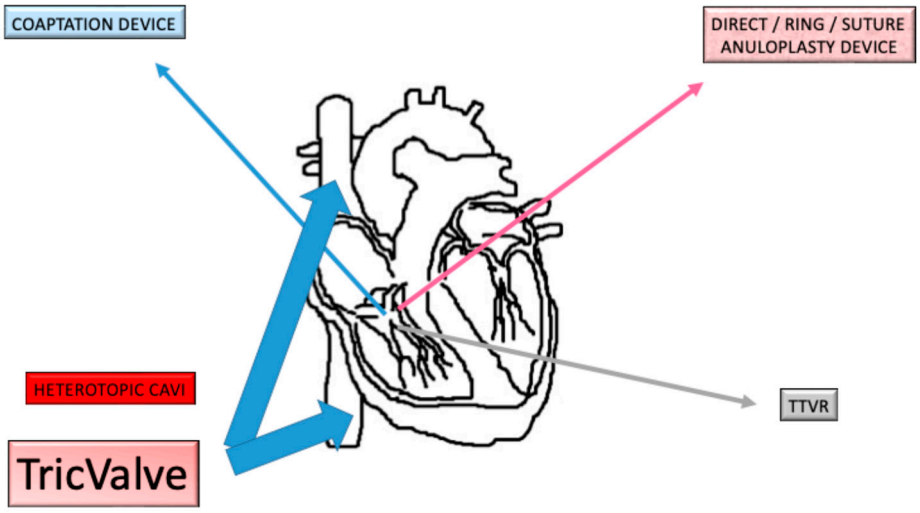

Figure 3. Interventional approaches to tricuspid regurgitation. For further explanation, please see the main text.

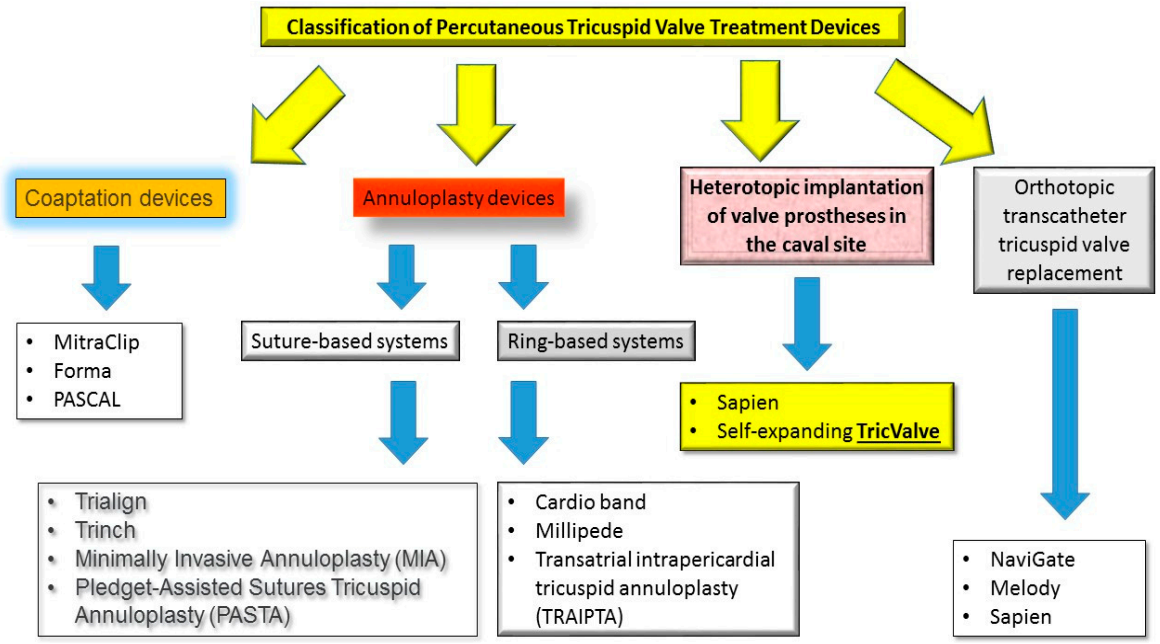

Figure 4. Classification of devices used in the percutaneous approach to tricuspid regurgitation.

Transcatheter Tricuspid Valve Replacement (TTVR) Type	Orthotopic TTVR	Heterotopic TTVR
Definition	The prosthetic valve is positioned exactly in the anatomical site of the native tricuspid valve (tricuspid annulus)	The transcatheter valve is placed in the superior vena cava (SVC) and/or inferior vena cava (IVC) to manage blood reflux, rather than at the level of the valve itself
Functioning	It replaces the malfunctioning native valve with a bioprosthesis, almost completely eliminating tricuspid regurgitation (TR), even in the presence of large coaptation defects	It does not eliminate tricuspid regurgitation, but reduces venous hypertension in the organs (congestion) in patients with massive tricuspid regurgitation
Complications	It requires specific anatomy and can introduce an afterload mismatch on the already suffering right ventricle	Risk of embolization, thrombosis, hepatic vein occlusion and does not directly treat right ventricular dysfunction

Figure 5. Transcatheter Tricuspid Valve Replacement (TTVR) Type.

Candidates for TricValve implantation are typically patients with severe symptomatic tricuspid regurgitation, New York Heart Association (NYHA) class III–IV, who remain highly symptomatic despite optimal medical therapy and are deemed ineligible for conventional surgery [59,60].

Anatomical suitability is mainly determined by computed tomography (and, in selected cases, intravascular ultrasound), which is used to assess the diameters and geometry of the superior and inferior vena cava at predefined landing zones, the relationship with the hepatic veins, and the distance between the inferior vena cava–right atrium junction and the hepatic vein confluence. Current TricValve prostheses are available in multiple sizes for both the SVC and IVC, and anatomical criteria include appropriate caval diameters (typically up to 35–40 mm), sufficient length above and below the hepatic veins, and the absence of marked tapering or severe elongation that could compromise anchoring or sealing [61,62].

In patients with severe tricuspid regurgitation, chronic systolic backflow from the right atrium into the venae cavae generates large right atrial and caval V-waves, leading to venous engorgement, hepatic and renal congestion, and progressive right-sided chamber dilation. By positioning dedicated bioprosthetic valves at the cavo-atrial junctions, bicaval CAVI with TricValve abolishes or markedly attenuates caval backflow, reduces the amplitude of V-waves in the superior and inferior vena cava, and eliminates pulsatile flow in downstream venous beds, such as the hepatic and portal veins, thereby alleviating systemic venous congestion [63]. This hemodynamic effect translates into increased forward stroke volume of the right ventricle and improved cardiac output, as supported by invasive monitoring with CardioMEMS in patients undergoing bicaval TricValve implantation. However, the therapeutic concept remains predominantly palliative: CAVI does not repair the native tricuspid valve, and long-term right ventricular remodeling may remain unfavorable or only partially reversible, especially in advanced disease stages [64,65].

The physiological and anatomical contraindications for the TricValve, primarily related to CT assessment of the venous system and right heart, are: (1) Inadequate dimensions of the vena cava [Superior Vena Cava (SVC): unsuitable diameter (too small or too large for available valve sizes (generally >40 mm)]; (2) Inferior Vena Cava (IVC): Unsuitable diameter (most cases require specific sizes, e.g., over 35 mm or unsuitable for the 31/35 or 41/45 mm prosthesis); (3) Venous thrombosis: Presence of thrombi in the vena cava or presence of caval (inferior) filters that prevent correct positioning; (4) Unsuitable anatomy of the vena cava: Anatomy of the atrio-caval junction that does not guarantee the stability of self-expanding prostheses; (5) Congenital heart disease or significant shunts: Presence of congenital structural heart defects, such as significant intracardiac shunts (e.g., ventricular septal defect), which contraindicate the procedure; (6) Severe right ventricular dysfunction: Although clinical, severe anatomical/functional impairment of the right ventricle (TAPSE < 13 mm) is considered an exclusion; and (7) severe pulmonary hypertension: Systolic pulmonary artery pressure > 65 mmHg (assessed by Doppler ultrasound). Additional exclusion factors (clinical/anatomical) are: (8) Inability to tolerate long-term anticoagulant therapy, and (9) active infections. The final assessment of anatomical feasibility is performed by CT angiography by the Heart Team.

6. Case Presentation: Cardiac Evaluation

A 55-year-old patient was admitted to the emergency department (ED) complaining of dyspnoea, abdominal pain, and ankle swelling. His past medical history included the following conditions: Previous Guillain–Barré syndrome, systemic hypertension, type 2 diabetes, dyslipidaemia, progressive liver cirrhosis, hepatic steatosis, and chronic ischemic heart disease.

The patient had previously undergone percutaneous coronary angioplasty on the left anterior descending coronary artery. There was no evidence of acute ischemia on the ECG (Figure 6), and the laboratory tests showed N-terminal pro-brain natriuretic peptide.

(NT-proBNP) levels of 7803 pg/mL (normal values < 900 pg/mL for people aged 50–75). Myocardial necrosis indices were negative.

The patient was diagnosed with a recurrence of heart failure. The next day, he was transferred to the Coronary Intensive Care Unit (CCU). Instrumental and laboratory tests performed during the CCU stay are reported in Table 2. Chest X-ray image is reported in Figure 7, Echocardiographic picture is in Figure 8.

Thus, a CT scan of the chest on the third day of hospitalization in the CCU revealed dilation of the cardiac chambers with wall thinning at the apical site of the left ventricle, associated with late enhancement, similar to post-infarction findings, and the presence of apical intracavitary hypodensity suspicious for a possible stratified thrombus.

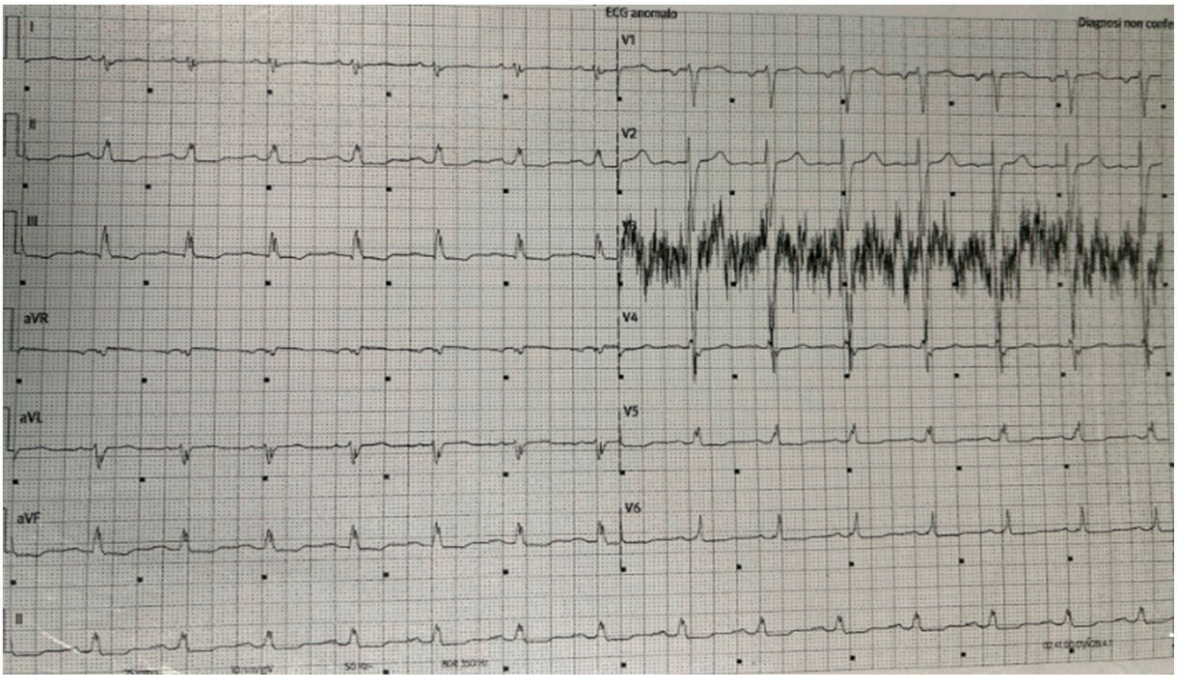

Figure 6. Electrocardiographic examination of the patient.

Table 2. Diagnostic tests performed during hospitalization in the CCU.

Imaging	Key Findings	Interpretation
Chest X-ray	Diffuse cotton-wool opacities, cephalad redistribution, increased vascular markings, cardiomediastinal silhouette at upper limits, increased bilateral pleural effusions	Pulmonary congestion/edema with bilateral pleural effusions and borderline cardiomegaly
Chest CT	Worsening cotton-wool pleuroparenchymal changes, stable bilateral pleural effusions, enlarged cardiac shadow	Progression of pulmonary edema and persistent volume overload with cardiomegaly
Echocardiogram	Severely dilated LV, global hypokinesia, EF 20%, grade III diastolic dysfunction, dilated hypocollapsible IVC, no pericardial effusion	Severe systolic and diastolic LV dysfunction with high filling pressures and systemic venous congestion
Brain MRI	Multiple millimetric gliotic foci (Fazekas 1) in bilateral fronto-temporo-parietal subcortical white matter	Mild chronic small-vessel ischemic disease
	Ventricles normal and midline; slight enlargement of convexity periencephalic CSF spaces	Mild cortical atrophy, no hydrocephalus
	Retrovermian arachnoid cyst 27 mm; inflammatory-retentive change in right maxillary sinus	Incidental arachnoid cyst and sinus inflammatory component
Laboratory	Normal WBC; platelets 157,000/μL	No leukocytosis; platelets low-normal to mildly reduced
	CRP 75 mg/L; procalcitonin negative	Significant inflammation without strong marker of severe bacterial sepsis
	1 peripheral broth: Staphylococcus capitis; 2 arterial-catheter broths: Staphylococcus epidermidis; targeted antibiotics started	Catheter-related bacteremia by coagulase-negative staphylococci, treated per ID advice

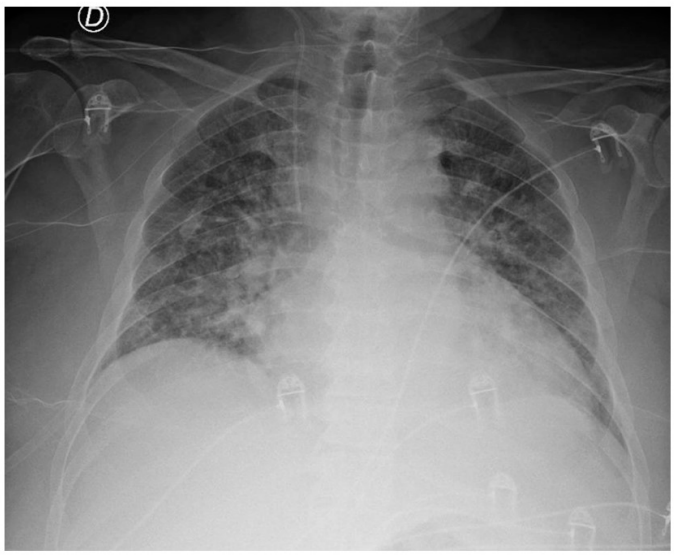

Figure 7. Electrocardiographic examination of the patient. Chest X-ray. Detailed explanations are provided in the main text.

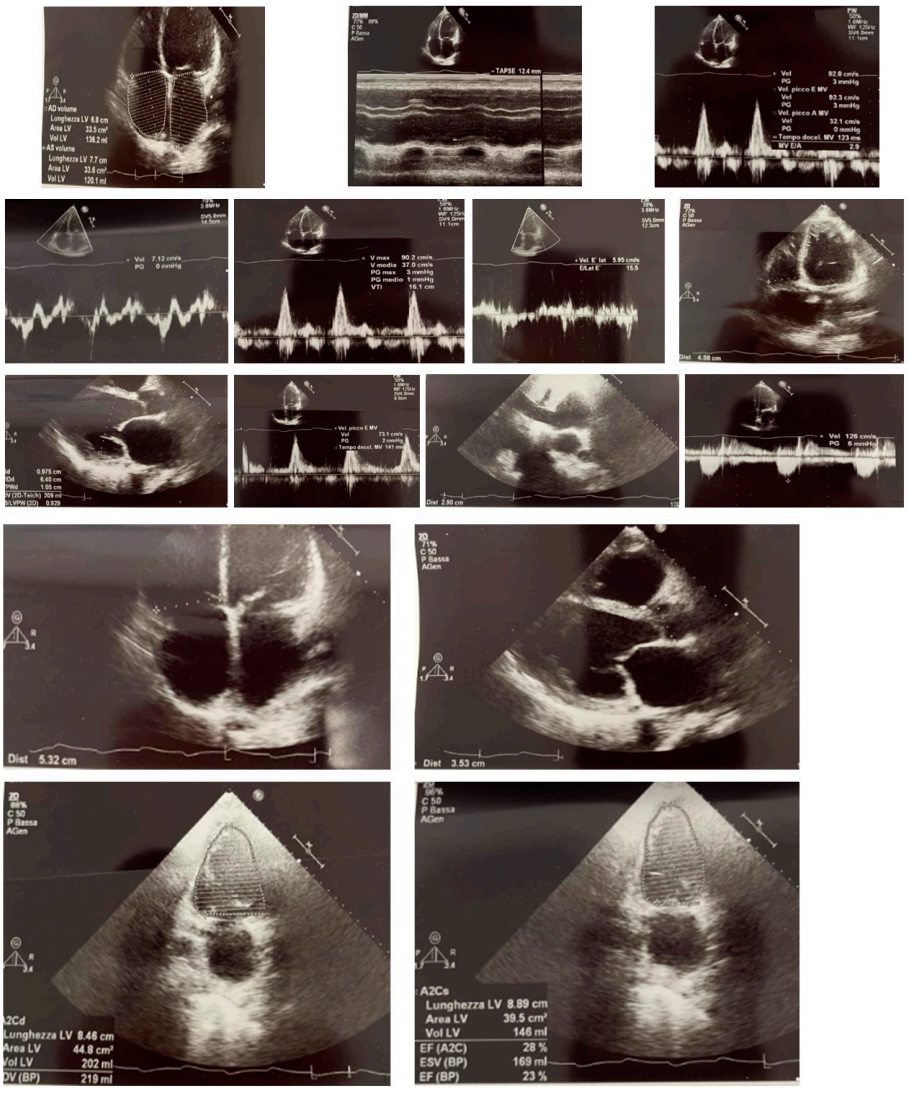

Figure 8. Echocardiographic picture of the patient. Detailed explanations are provided in the main text.

This finding, combined with the anamnesis and the (transesophageal) echocardiographic data performed the same day, supported the hypothesis of tricuspid valve endocarditis. Cardiac surgery was not performed due to the prohibitive surgical risk. The patient was subjected to the TRI-SCORE evaluation, too (Figure 9).

Risk factors and scoring system for in-hospital mortality after isolated TV surgery	
Risk factors	Scoring
Age ≥ 70 years	1
NYHA functional class III-IV	1
Right sided heart failure signs	2
Daily dose of furosemide ≥ 125 mg	2
Glomerular filtration rate < 30mL/min	2
Elevated total bilirubin	2
LVEF < 60%	1
Moderate/severe RV dysfunction	1
Total	12

Figure 9. Risk factors and the TRI-SCORE scoring system.

Three days later, a cardiac CT scan was performed using cardiac synchronization to study the right cardiac chambers, and the day following this study, the patient was sent for angiography to evaluate the coronary tree, which documented the presence of sub-occlusive stenosis in the middle and distal segments of the left trunk, critical stenosis in the ostial segment of the anterior descending artery with chronic intra-stent occlusion in the middle segment, significant stenosis in the ostial and middle segments of the circumflex artery, sub-occlusive stenosis in the proximal segment, and moderate stenosis in the middle segment of the right coronary artery, treated by angioplasty with the implantation of a drug-eluting stent in the right coronary artery and two drug-eluting stents in the common trunk-circumflex artery. On the same day, he underwent a TricValve® placement procedure for right heart failure and massive tricuspid regurgitation in the absence of peri-procedural complications (Figures 10–12).

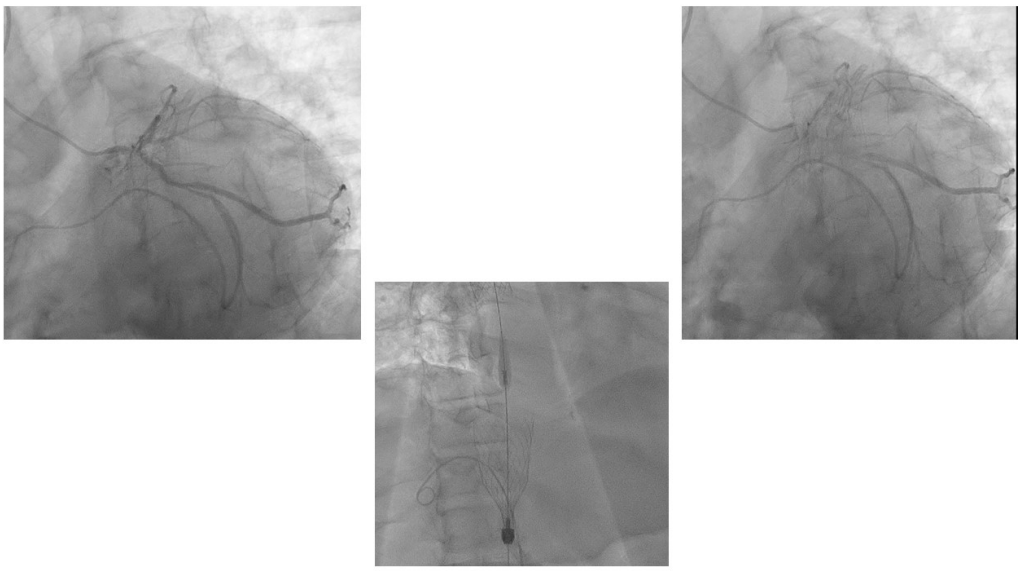

Figure 10. Coronary angiography with coronary artery assessment and subsequent treatment, combined with device placement. The main text provides further explanations of the progress of the procedures performed on the patient.

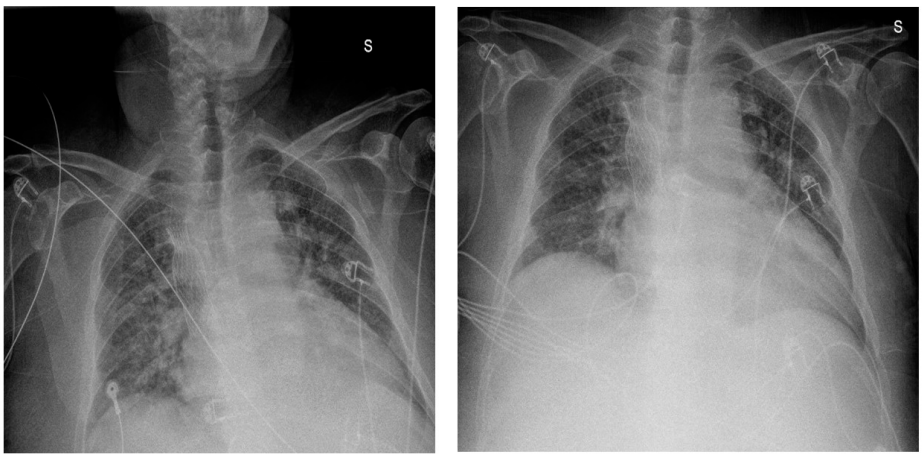

Figure 11. Post-procedural chest radiological control. The main text provides further explanations of the progress of the procedures performed on the patient.

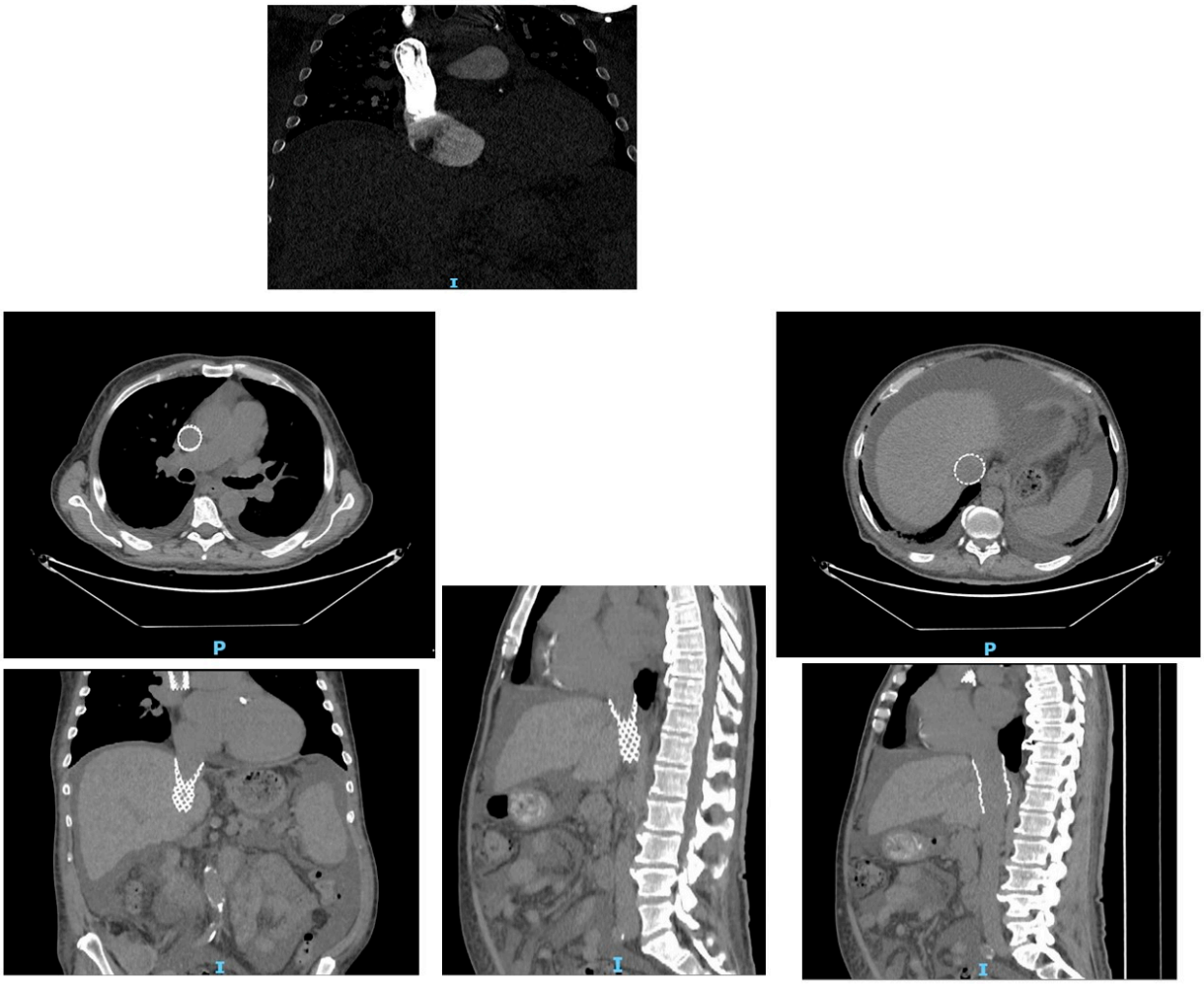

Figure 12. Control by computed tomography (also used by the physical medicine and rehabilitation specialist for co-evaluation of the spine) in Figures 11 and 12.

7. Case Presentation: PRM Specialist's Evaluation

A PRM specialist was called in for a consultation. On examination, the patient was alert and oriented in all three axes, and cooperative, although profoundly asthenic. However, he reported no symptoms of angina. He was under cardiac monitoring and had a peripheral venous catheter (PVC), a Peripherally Inserted Central Catheter (PICC), a vesical catheter,

and an absorbent pad in place. A sacral dressing had been applied due to a pressure sore. The main articular fulcrums of all four limbs appeared free and painless. Muscle strength in the main muscle groups of the upper limbs was graded as 3/5 according to the Medical Research Council (MRC), and in the lower limbs, it was graded as 2/5 on the right and 3/5 on the left. Manual grip and digital forceps appeared to be effective bilaterally. The patient performed a lateral decubitus position change with moderate assistance. At this time, the spine was assessed, and pressure and percussive spinal pain were negative throughout. No further postural changes were performed due to reported asthenia. Biceps and patellar tendon reflexes (TOFs) were normal bilaterally. Superficial tactile sensation appeared intact in the explored areas. Mobility in all four limbs was therefore preserved, but significant strength deficits persisted. Two days later, the patient was reassessed with improved vital signs and optimized diuretic therapy. Despite the fatigue, there was improvement in strength, and this time, under supervision, the patient was able to sit up in bed (Figure 13).

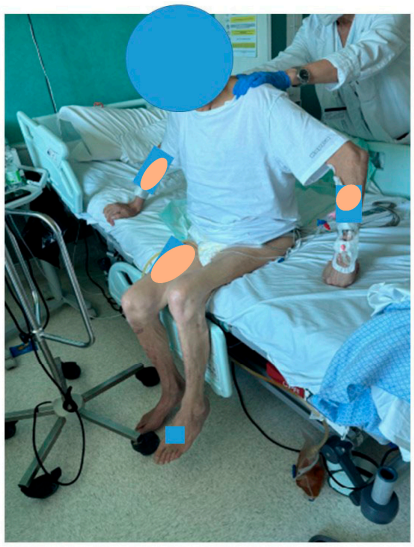

Figure 13. Physiatric assessment directly in the cardiology department.

After discussing the case with the cardiologists and considering the absence of further treatment in the hospital's acute cardiology department, as well as the patient's improved clinical and health conditions and performance thanks to the movement programs initiated after the TricValve procedure, the patient was transferred to a suitable rehabilitation setting. The following indices and scores were then calculated: Six-Minute Walking Test (6MWT): 0 m; Barthel index of 15/100; Cumulative Illness Rating Scale (CIRS): Severity index: 2.1 and Comorbidity index: 4. There was also an improvement in the Barthel index for dyspnea. Therefore, rehabilitation treatment was initiated, comprising sessions of individual motor re-education for severe simple movement injury (the patient was unable to transition from a supine to a sitting position and complained of sacral pain) during hospitalization. After this, the patient was referred to a post-acute rehabilitation facility (in Italy, such facilities are known as code 56).

8. Methods

Unlike a systematic review, this article was intentionally designed as a narrative, qualitative synthesis, without a preregistered protocol. The aim was to integrate clinical experience, emerging evidence on CAVI/TricValve, and rehabilitation perspectives, rather than to provide a quantitative pooled estimate of treatment effects.

For this purpose, a focused literature search in PubMed was performed, exploring clinical experiences and studies using the following key terms, alone and in combination with Boolean operators "AND"/"OR": "tricuspid regurgitation", "TricValve", "heart failure", "caval reflux", and "rehabilitation". The search was limited to studies in humans and to article types considered most relevant for an emerging technology, including case reports, clinical trials, randomized controlled trials, and narrative or systematic reviews. Reference lists of the retrieved articles were screened to identify additional pertinent publications.

Papers were considered if they reported clinical use of TricValve or other forms of caval valve implantation in patients with severe tricuspid regurgitation; described hemodynamic, clinical, or functional outcomes (e.g., symptoms, NYHA class, exercise capacity, and quality of life) and, when available, rehabilitation aspects; papers written in English or in other European languages (e.g., Italian, French, or Hungarian) were accepted in accordance with authors' language expertise. Reports in animal models and studies in which TR was primarily related to systemic conditions or valvular/ischemic disease treated exclusively from a surgical standpoint, without a clear focus on CAVI/TricValve or on the functional implications of severe TR, were excluded.

9. Clinical Experiences Published in Medical Literature Regarding the TricValve®: Narrative Review

In a 2016 study, Figulla HR et al. [66] evaluated two therapeutic approaches: orthopic valve replacement and heterotopic valve replacement. Caval valve implantation (CAVI) in the superior vena cava (SVC) and inferior vena cava (IVC) could represent an alternative to orthopic approaches. The study examined the function of the device observed up to 24 months after implantation, the design of the vena caval valve, and the anatomical and hemodynamic consequences following implantation. The study demonstrated that CAVI was a relatively simple procedure and that its use resulted in clinical improvement, with patients moving from NYHA class IV to class II. However, the valve design must accommodate a wide variety of vena caval anatomy, and clinical experience is currently limited to compassionate cases. In 2018, Figulla et al. conducted a multicenter, observational trial of CAVI in 25 high-risk patients with severe symptomatic TR who were ineligible for surgery [67]: self-expanding bioprosthetic valves were implanted in both venae cavae under fluoroscopic and echocardiographic guidance. The procedure proved to be technically feasible, with a 96% success rate and no intraprocedural mortality. Although three patients died within 30 days, the survivors experienced significant clinical improvement: 80% improved by at least one NYHA class, right atrial pressures decreased by 3–4 mmHg, and hepatic vein systolic reversal was markedly reduced. Therefore, this pioneering study showed that heterotopic caval implantation could relieve venous congestion and enhance functional capacity in an otherwise untreatable population. This experience has demonstrated the feasibility of the method. In 2020, the first large Spanish cohort study was reported. Indeed, Aparisi et al. published a case study of a 74-year-old woman with massive TR and a history of double valve surgery. The transfemoral bicaval implant abolished caval V waves and improved hemodynamics. Within 30 days, the patient's condition improved from NYHA class IV to class II, her 6MWT increased by 80 m, and her pulmonary pressures decreased. Despite residual TR, the case demonstrated how the TricValve® could improve functional status and reduce venous congestion in cases where surgery is not an option [68]. Donà C et al. reported the case of a 78-year-old patient with severe TR, RV dilation, and poor RV systolic function. The patient had a history of paroxysmal atrial fibrillation (AF) and had a dual-chamber pacemaker. An angiography and right cardiac catheterization revealed normal coronary arteries and slightly elevated

pulmonary pressures. Various options were evaluated to treat TR. However, due to the presence of the pacemaker, the patient's fragility, and the high surgical risk, the option of a transcatheter TricValve® implant was considered. Three months after surgery, the patient showed significant improvement in symptoms, with a decrease in the TR severity from torrential to mild–moderate. This case study demonstrated how the TricValve® transcatheter implant may represent a new interventional treatment option where other types of intervention are not suitable [69]. In a 2021 study [70], Kültürsay B et al. reported a complication that occurred during TricValve® implantation in an 86-year-old patient. Upon placement, the SVC valve migrated into the right atrium. The surgical team decided to place another SVC valve protruding into the right atrium, overlapping the migrated valve, to secure it in a stable position. The procedure was successful, with no paravalvular leakage or caval reflux evident on subsequent venous angiography. The patient was discharged three days after the procedure. Maintaining euvolemic status is difficult in patients with severe renal insufficiency due to their sensitive and variable fluid status, so device sizing, particularly for the IVC, could pose a potential challenge. Therefore, prior to performing the procedure, it was necessary to promptly and carefully evaluate the device size, taking the patient's volume status into account. In this case, the complication was successfully managed by placing a second IVC prosthesis over the migrated valve, thus avoiding cardiac surgery for a high-risk patient. The acceleration came with the TRICUS EURO study (2022), a prospective, single-arm, multicenter trial involving 12 European centers and 35 high-risk patients with severe TR refractory to medical therapy [71]. The investigators used the Kansas City Cardiomyopathy Questionnaire (KCCQ) score, which ranges from 0 to 100, with higher scores indicating better health status in terms of symptoms, physical functioning, social functioning, and quality of life. Technical success was achieved in 94% of cases, with an overall procedural success rate of 88.6%. Complications were rare, mainly limited to device embolization in two cases. At six months, patients experienced significant benefits. Median KCCQ scores increased by 18 points, with nearly 80% improving by at least one NYHA class, and 6MWT distance increasing by ~60 m. Hemodynamics confirmed reduced caval reflux and right atrial V-waves, while rehospitalizations for heart failure fell markedly. Mortality at six months was 8.6%, which was lower than the expected rate for such frail cohorts. TRICUS EURO provided the most robust early evidence that the TricValve® implantation was not only technically feasible, but also clinically effective in improving symptoms and quality of life. Lauten A et al. [72] reviewed the pathophysiological aspect and the potential role of caval valve implantation in the treatment of severe TR., while Estévez-Loureiro et al. [64] presented a case of right heart catheterization following transcatheter bicaval valve implantation in a patient with persistent NYHA class II–III heart failure, six months after TricValve® implantation. Evaluation demonstrated normal venous pressure without a persistent V wave in the IVC. Simultaneous recording of RA pressure via a Swan–Ganz catheter inserted through a femoral vein and at the SVC level via a basilic vein confirmed the persistence of the elevated V wave and that the pressure at the SVC level is influenced by the prosthesis rather than by catheter interference.

Following the TRICUS EURO, a series of case reports published between 2022 and 2023 demonstrated the adaptability of the TricValve® device across different patient groups. In Asia, Jin QW and colleagues described the first TricValve® case in an Asian patient—a 67-year-old woman with atrial functional TR refractory to medical therapy. Successful bicaval implantation resulted in a rapid improvement in symptoms, reduced NT-proBNP levels, and increased walking distance [73]. Since HF with or without associated TR is a chronic, persistent, disabling condition that affects quality of life (QoL), studies have focused on optimizing HF therapy, improving drug adherence, and remotely managing daily treatments, even with the aid of specific implantable devices. Specifically, CardioMEMS®

(CardioMEMS HF System, Abbott, Sylmar, CA, USA) is a small implantable device [74,75]. It is a remote pulmonary artery pressure (PAP) monitoring system. For example, Abdul-Jawad Altisent O et al. employed CardioMEMS® hemodynamic monitoring in a high-risk patient undergoing TricValve® implantation [76]. For the first time, continuous invasive data demonstrated an immediate increase in cardiac output, proving that CAVI reduces congestion and enhances forward flow, providing a physiological rationale for the symptomatic relief observed in prior studies. Alongside monitoring systems, the device has been studied in conjunction with other conditions and surgical treatments, including transplantation. In 2023, Adsuar-Gómez A et al. reported the first successful heart transplantation following TricValve® implantation. Although the surgery required careful dissection and cannulation, it demonstrated that heterotopic prostheses do not preclude later definitive therapy [77]. A Chilean publication by Cataldo P et al. reached the same conclusions [78].

Similarly, in patients with end-stage heart failure and left ventricular assist devices (LVADs), concomitant TR can be problematic, with up to 25% of patients having residual TR one year after LVAD implantation [79]: Chandran K et al. described the first TricValve® implantation in a patient with an LVAD, an 80-year-old female patient with ischemic cardiomyopathy and massive TR who had previously received destination therapy in the form of a HeartMate II LVAD® (Abbott Cardiovascular, Abbott Park, IL, USA). The procedure alleviated ascites and edema without interfering with the LVAD cannula, offering a new palliative strategy for this complex patient group [80]. In 2023, Gonzálvez-García A et al. showcased the possibility of multi-modal percutaneous therapy, reporting a case of a patient who was treated sequentially with MitraClip®, Amplatzer septal occluder®, and TricValve®. During the two-year follow-up period, the patient showed a reduction in TR, which highlights the safety of integrating multiple devices in high-risk patients with multivalvular disease [81]. The rate of possible complications and effective management strategies is not well established. Grazina A et al. reported two cases of TricValve® migration requiring percutaneous valve-in-valve rescue. Both frail and inoperable patients avoided surgery through repeat TricValve® implantation, achieving good mid-term outcomes. Although migration remains rare (~3% in registries), these cases demonstrate that percutaneous solutions are feasible even when complications arise [82]. In order to further reduce the rate of iatrogenic adverse events and thus make the procedures safer, models and simulations were tested prior to the execution of the procedures. Crascì F et al. performed patient-specific computational simulations of TricValve® biomechanics. Their models confirmed stable anchoring, symmetric leaflet motion, reduced caval backflow, and an acceptable stress distribution. This supports the durability and safety profile of the device while reinforcing the physiological plausibility of its benefits [83].

10. Data from the TRICUS and TRICUS EURO Trials and Other Related Studies

The results from the TRICUS and TRICUS EURO studies were also reviewed. Both of these were prospective, non-blinded, non-randomized, single-arm studies that provided an early insight into the use of the TricValve® system. The TRICUS study, conducted between September 2018 and February 2020, involved nine patients from Lithuania who presented with symptomatic severe tricuspid regurgitation (grade $\geq$ 3 in a 5-grade classification) and significant reflux in the IVC and/or VCS. Despite receiving excellent treatment, they were not eligible for open-heart surgery. The TRICUS EURO study was conducted on 35 patients enrolled from 12 centers in Spain and Austria between December 2019 and February 2021, all of whom were in NYHA functional class III or IV at baseline.

The study demonstrated the safety of the TricValve® bicaval CAVI system, as well as functional improvements (95.0%), with a KCCQ-12 score of $\geq$15 points at 1 year, as well as

an improvement in NYHA functional class (change from NYHA class III or IV to II or I at six months) in 79.4% of patients [84]. The hospitalization rate for HF was 29.5% with an all-cause mortality rate of 6.8%.

In 2023, Amat-Santos IJ et al. [65] published the TRICUS STUDY EURO, which demonstrated significant improvements in both QoL and functional parameters at 6 months with the TricValve® transcatheter bicaval valve. There was also a significant increase in RV and RA volumes, and a decrease in RV function. This study focuses on right heart CT volume imaging to provide new insights into right heart remodeling at 6-month follow-up.

In a study published in 2024, Blasco-Turrión S et al. [60] evaluated the impact of TricValve® in 44 patients with severe TR in NYHA functional class III or IV who were ineligible for open-heart surgery. The primary endpoint was a clinical improvement, as assessed by the composite of: change in QOL at 1 year as measured by an increase of $\geq$15 points from baseline in the 12-item KCCQ score; an improvement in NYHA functional class to I or II; and an increase in functional exercise capacity, as measured by the 6MWT, with a significant improvement being defined as an increase of $\geq$40 m from baseline.

Stocker TJ, in a study dated January 8, 2024 [85], reviews all types of interventions in patients with severe TR, with reduced quality of life and symptoms of right HF, covering all the techniques from transcatheter edge-to-edge repair (TEER) to TTVR up to the last but not least technique, that of the TricValve® system in patients not suitable for the two previously mentioned techniques. He reports the results of the Blasco-Turrión study [60] one year after the TricValve® implant, including a 6.8% reduction in the mortality rate and a 29.5% reduction in the rate of hospitalization for HF. Currently, this approach provides important clinical outcomes, such as symptomatic relief for treated patients. More mortality data are needed to draw conclusions about this crucial endpoint.

This author also noted that large-scale international registries, such as the TRICUS registry, will be needed to validate the transferability of the results to clinical practice and clarify the significance of certain clinical complications, such as thrombotic complications. He also believed that new devices for orthopic and heterotopic TTVR should be developed to increase therapeutic options for patients with congestive HF.

Table 3 summarizes device–lead interactions and complications.

Table 3. Device–lead interactions and complications.

Complication	Source/Registry	Frequency	Prevention/Management Strategies
Prosthesis migration/embolization	Single case reports; TRICUS EURO and early registries	≈3% valve migration in early registries	Careful CT (and, when available, IVUS)-based sizing; accurate selection of anchoring zones; in case of migration, percutaneous valve-in-valve implantation or, rarely, surgical retrieval.
Pacemaker/ICD lead interference	Case reports of lead dislocation or failure	Not systematically quantified	Pre-procedural imaging to define lead course; use of snaring and intra-procedural repositioning when needed; close post-procedural device follow-up and lead revision if necessary.
Prosthetic thrombosis or thromboembolism	CAVI/TricValve series and registries; narrative reviews	Rare; data still limited	Individualized antithrombotic/anticoagulant therapy; optimization of hemodynamics and hepatic function; periodic imaging to assess prosthesis patency.

Table 3. *Cont.*

Complication	Source/Registry	Frequency	Prevention/Management Strategies
Persistent congestion/limited clinical benefit	Registries (TRICUS, TRICUS EURO) and very advanced cases	Not reported as a single consistent percentage	Careful patient selection (avoiding "end-stage" RV disease and advanced multi-organ failure); optimal diuretic management; early reassessment of rehabilitation setting and treatment goals.
Unfavorable RV remodeling or deterioration	Right-heart imaging studies after CAVI	Increase in RA/RV volumes and reduction in RV function in a proportion of patients	Systematic follow-up with echocardiography and CT/CMR when indicated; counseling about the predominantly palliative nature of the procedure; consideration of additional HF optimization and targeted rehabilitation.

11. Refining Peri-Procedural Care and Imaging (2023–2024)

Beyond device performance, success with TricValve® hinges on optimal procedural support. In 2023, Pieri M et al. published the first detailed anesthetic case report, highlighting strategies to minimize right ventricular overload, maintain hemodynamic stability, and utilize TEE guidance during implantation [86]. In 2024, Garrote-Coloma C et al. proposed a novel suprasternal transthoracic echocardiographic view to visualize the SVC valve [87]. This technical innovation allowed clearer non-invasive follow-up of TricValve prostheses, overcoming a recognized imaging limitation.

12. Device–Lead Interactions: New Challenges (2024)

Jiménez Melo O et al. provided a detailed follow-up of a 60-year-old female patient with a history of thoracic radiation therapy for Hodgkin's lymphoma and severe radiation-induced aortic stenosis treated with TAVI. Follow-up revealed severe TR resulting in persistent NYHA Class III symptoms. The patient subsequently underwent transcatheter CAVI. The SVC prosthesis encapsulated the pacemaker leads as they exited the left subclavian vein. An initial 1-year post-implantation evaluation showed normal lead function. The authors aimed to demonstrate the importance of procedural caution when implanting a TricValve® device in patients with pacemaker leads [88]. As TricValve® use increased, reports emerged of complications in patients with pre-existing pacing or defibrillator leads. Chen M et al. described a pacemaker lead dislocation during implantation in a patient with a small SVC [89]. With careful snaring and repositioning, the procedure was successfully completed, demonstrating practical troubleshooting in real time. Similarly, Plant A et al. reported the first ICD lead failure after TricValve® implantation, which was successfully managed with revision [90]. These cases highlight that, although CAVI is generally safe, device–lead interactions must be anticipated and planned.

13. Other Narrative Review Syntheses and Registry Insights Published over the Years 2024–2025

By 2024, the field had matured enough to warrant comprehensive reviews of this topic, such as that by Sammour YM et al. The review provides a contemporary overview of various transcatheter tricuspid valve interventions for patients with severe TR and evaluates the available clinical data on the safety and efficacy of these devices in this rapidly evolving field [91]. The review emphasized the consistent symptomatic benefit of CAVI, while noting its palliative nature and the need for randomized comparisons.

Di Mauro M et al. provided the largest single-center series to date, involving 13 elderly patients (mean age 81) undergoing TricValve® for isolated TR [92]. Procedural success was 100%, with significant reductions in NT-proBNP levels, diuretic use, and hepatic congestion. Although two deaths occurred, most patients improved to NYHA functional class I–II, confirming the effectiveness of the CAVI in routine practice. The innovation pipeline continued into 2025, with Chen V et al. publishing a new review [93]. Finally, Yansen et al. published their early experience of TricValve® implantation in Indonesia, describing a striking "super responder" case: a 68-year-old man who was previously bedbound with NYHA IV symptoms achieved NYHA II status and was free from rehospitalization after TricValve® implantation [77]. This extraordinary turnaround demonstrated the therapy's potential when patient selection aligns with the pathophysiological mechanism of caval backflow. The article published in August 2025 by Kecskeméti D et al. [94] presented the first TricValve® implantation in Hungary in a 74-year-old woman hospitalized for right-sided HF due to severe secondary TR. At the time of admission, she was in NYHA functional class IV. TVR could have been a therapeutic option, but the Heart Team advised against this surgical technique due to the high mortality risk. Furthermore, while the anatomy of the tricuspid valve was not suitable for percutaneous interventions, the anatomy of the vena cava was suitable for TricValve® implantation. Following CAVI and CR, the patient transitioned to NYHA functional class II, reduced her diuretic intake, and experienced fewer hospital admissions. The authors therefore concluded that TricValve® implantation could represent a solution for patients with severe TR if medical treatment was insufficient and surgical or percutaneous valve repair was contraindicated; however, long-term survival data are not yet available.

14. Positive Factors, Limitations of Scientific Evidence, and Future Prospects

This narrative review describes the evolution of TricValve® and CAVI approaches through pivotal studies, registries, case reports, and technical contributions published between 2016 and 2025, showing how this therapy has moved from an experimental concept to a globally validated treatment option. All scientific experiences in these articles demonstrated the therapeutic advantages of implanting the TricValve® system, including the ability to choose SVC or ICV valves of various sizes and reduce TR-related complications, as well as determining a clinical improvement with a transition from NYHA class III/IV to class II or I. However, there are also limitations, such as its current use in compassionate cases in several clinical studies and economic and commercial constraints, as only a few companies still produce the valve, and it is not available in all countries. Furthermore, the limited choice of different types of caval valves and the limited number of studies and case series may make it difficult for physicians to make decisions.

The TRICUS and TRICUS EURO studies are also characterized by some limitations. These limitations include the small sample size and the fact that many patients were enrolled during the COVID-19 pandemic, the impact of which on functional QoL metrics cannot be underestimated. Therefore, while the studies demonstrated the safety of the device and stable, significant improvements at 1 year from enrollment, RCTs will provide further long-term clinical and mechanistic insights.

A new study called the TRICAV trial (a trial of the TricValve® Transcatheter Bicaval Valve System in Subjects with Severe TR; ClinicalTrials.gov identifier: NCT06137807) has recently begun to investigate the efficacy and safety of the technique. It is a prospective, multicenter, single-arm trial currently enrolling participants in the United States (US) [95]. The inclusion and exclusion criteria are similar to those in the TRICUS studies. The TRICAV-1 early feasibility study is a 15-patient, 30-day follow-up, single-arm study that is currently

enrolling patients across select centers in the US. This will be followed by TRICAV-2, a randomized controlled pivotal trial involving >400 patients randomized to TricValve® versus medical therapy and aiming for US FDA premarket approval submission.

15. Role of the PRM Specialist and Rehabilitation Perspectives

The PRM specialists are frequently called upon to provide their services to highly complex and demanding patients [96,97]. Patients with cardiovascular diseases often present a daunting challenge for rehabilitation [98]. For these reasons and considering the authors' personal background and expertise, a section focused on the rehabilitative needs of people undergoing TAVI seemed essential to the research. To maintain high readability and streamlined discussion, this section has been organized into two subsections on the current picture and future perspectives.

15.1. Current Rehabilitation Practice in Patients with Severe TR and CAVI

In patients with severe TR, cardiac re-education remains a cornerstone of multidisciplinary care and typically combines medical optimization (including diuretic therapy), supervised exercise training, education, and risk factor management, in line with current rehabilitation guidelines [99]. In the presented case and in the published CAVI series, functional status is routinely assessed with NYHA class, the KCCQ, and the 6MWT by both cardiologists and PRM specialists, as these measures capture symptoms, health-related QoL, and exercise capacity [100–103]. Furthermore, TR and right ventricular myocardial indexes should be evaluated using echocardiography. In any case, this series of assessments may be insufficient, and a multidimensional assessment is necessary. This should not only assess the impact of TR on the patients' independence but also allow for an overall assessment of disability [8]. As emphasized by Ishihara K et coll., multidisciplinary management is imperative [35]. In clinical practice, PRM specialists integrate cardiological outcomes with indices such as lower limb muscle strength, Barthel index, and comorbidity scores to select the most suitable rehabilitation setting (e.g., intensive in-hospital programs, comparable to Italian "code 56" for severely disabled but hemodynamically stable patients, versus less intensive pathways, similar to "code 60" for those with lower rehabilitation potential or persistent instability).

After TricValve implantation, many patients improve from NYHA class III–IV to class I–II and show meaningful gains in KCCQ scores and 6MWT distance, providing an objective basis for progressing from strictly bed-based mobilization to upright activities and, when appropriate, to more intensive exercise-based cardiac rehabilitation. Depending on the severity of the condition, exercising with TR can, however, present significant risks (e.g., heart failure, fatigue, and ankle swelling) [104]. For this reason, patient monitoring as described is essential [105,106].

On the contrary, developing a structured CR program that considers the patient's clinical status can positively influence physical recovery, reduce blood pressure, reduce disease severity, and improve ventricular ejection fraction [107]. Therapeutic exercise can improve cardiopulmonary function and, consequently, patients' QoL, increasing myocardial blood flow reserve, improving vascular endothelial cell function, improving oxygen uptake and utilization in skeletal muscle, and reducing mitochondrial damage in cardiomyocytes, and thus promoting the body's metabolism [108]. To date, the most effective rehabilitation strategy seems to be a combination of adequate clinical monitoring, physical exercise programs, and educational and psycho-behavioral interventions [109].

15.2. Unmet Needs and Research Priorities in Rehabilitation After CAVI

Despite growing evidence that CAVI and other transcatheter tricuspid interventions improve NYHA class, KCCQ scores, and 6MWT distance, specific rehabilitation protocols tailored to this population are still lacking, and current practice largely extrapolates from left-sided heart failure and valve surgery programs [110]. Recent studies have validated the KCCQ in patients with tricuspid regurgitation and highlighted its usefulness for capturing changes in symptoms and QoL, but its integration with multidimensional functional assessments and cardiopulmonary exercise testing in post-CAVI rehabilitation remains to be formally studied.

The latest European guidelines still recommend surgery as the "gold standard" for severe primary and secondary TR, particularly during left heart surgery or in cases with right ventricular dilation [110].

Nevertheless, in highly symptomatic TR patients who had a prohibitive risk of cardiac surgery, TricValve implantation led to a reduction in symptoms in a 6-month period, as in the prospective register of Rdzanek et al. [111], in the recent systematic review of Kourek C et al. [112], and in the paper by Rostagno C et al. [113]. A major apparent contradiction is still not revealed, and yet long-term survival was limited mainly by heart failure progression and severe concomitant disorders. The analysis of the TricBicaval registry showed a significant reduction in inferior vena cava pressure, along with a marked reduction in signs of right heart failure. At one year, hospitalizations for heart failure had significantly decreased during follow-up compared to the year before implantation, the rate of major adverse events was 19.1%, and mortality increased with increasing TRI-SCORE [114]. However, the TRICUS EURO imaging substudy shows increased right atrial and ventricular volumes with reduced right ventricular function at follow-up [65]. So, further patients with longer-term follow-up are required to establish this evolving concept. This raises important questions: (1) Does CAVI delay or accelerate adverse RV restructuring? (2) Do symptomatic improvements mask progressive right ventricular dysfunction? There are no precise data from studies that allow us to answer these questions comprehensively. These questions certainly deserve in-depth studies and specifically designed trials, using echocardiographic parameters (right ventricular volume, TAPSE) and technologies (speckle tracking) that correlate these data with symptoms, the number of hospitalizations, and short- and long-term survival, and that are, therefore, sufficiently long. Accurate RV function assessment necessitates advanced imaging modalities like 3D echocardiography, Cardiac Magnetic Resonance Imaging (CMR), and computed tomography (CT), along with strain analysis. Following TTVI, RVRR typically manifests as a biphasic reduction in RV volume overload, improved myocardial strain, and enhanced RV-pulmonary arterial coupling, too. Emerging molecular biomarkers alongside advanced imaging-derived biomechanical markers like CT-based 3D-TAPSE and RV longitudinal strain are proving valuable. Artificial intelligence and machine learning are transforming prognostication by integrating diverse clinical, laboratory, and multi-modal imaging data, enabling unprecedented precision in risk stratification and optimizing TTVI strategies [115].

Future research should therefore address several priorities: Defining safe and effective exercise intensity targets after CAVI, identifying which patients benefit most from intensive in-hospital rehabilitation versus lower-intensity or home-based programs, and validating composite outcome measures that combine NYHA class, KCCQ, 6MWT, and disability scales to guide rehabilitation planning and track long-term recovery. Dedicated prospective studies from a rehabilitation perspective are needed to determine whether structured cardiac rehabilitation can amplify and stabilize the functional gains observed after TricValve implantation and reduce rehospitalizations in this frail population.

16. Conclusions

In less than a decade, TricValve® has progressed from a pioneering to an internationally validated therapy. Feasibility studies have demonstrated its technical safety, registries have confirmed its clinical benefits, mechanistic cases have provided physiological rationale, and computational simulations have supported its durability. The cumulative evidence established TricValve® as an option for symptomatic relief for patients who are not candidates for surgery. Current data suggest that early intervention, before irreversible right ventricular dysfunction and multi-organ failure set in, can maximize outcomes.

The evolution of the TricValve® reflects a broader transformation in the treatment of structural heart disease, with innovations dedicated to patients with complex and fragile conditions who were previously dependent on medical therapy alone. With ongoing randomized trials and ever-expanding registries, the coming years will determine the extent to which this technology can extend survival, improve QoL, and redefine the standard of care for right-sided valvular disease.

However, limitations remain, including residual TR, migration complications, or interactions with catheters. New studies, especially from a rehabilitation perspective, need to be developed for these patients.

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Abbreviations

Tricuspid regurgitation: TR; Physical and Rehabilitation Medicine specialist: PRM specialist (a.k.a. physiatrist); caval valve implantation: CAVI; pulmonary arterial hypertension: PAH; Heart failure: HF; heart failure with preserved ejection fraction: HFpEF; pulmonary capillary wedge pressure: PCWP; cardiac output: CO; cardiac rehabilitation: CR; right ventricle: RV; vena contracta: VC; vena contracta area: VCA; effective regurgitant orifice area: EROA; Proximal Isovelocity Surface Area: PISA; tricuspid valve replacement: TVR; superior vena cava: SVC; inferior vena cava: IVC; magnetic resonance imaging: MRI; emergency department: ED; Percutaneous Coronary Intervention: PCI; N-terminal pro-brain natriuretic peptide: NT-proBNP; Coronary Intensive Care Unit: CCU; computerized tomography: CT; C-reactive Protein: CRP; peripheral venous catheter: PVC; Peripherally Inserted Central Catheter: PICC; Medical Research Council: MRC; tendon reflexes: TOFs; Six-Minute Walking Test: 6MWT; Cumulative Illness Rating Scale: CIRS; randomized controlled trials: RCTs; atrial fibrillation: AF; coronary artery bypass grafting: CABG; chronic obstructive pulmonary disease: COPD; transcatheter tricuspid valve therapy: TTVT; trans-

esophageal echocardiogram, TEE; Kansas City Cardiomyopathy Questionnaire: KCCQ; pulmonary artery pressure: PAP; quality of life: QOL; left ventricular assist devices: LVADs; right atrium: RA; transcatheter edge-to-edge repair: TEER; United States: US; right ventricular flow assist devices: RVFDs; Cardiac Magnetic Resonance Imaging: CMR; transcatheter tricuspid valve intervention: TTVI; right ventricular reverse remodeling: RVRR; artificial intelligence: AI; machine learning: ML.

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