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Review

Transcatheter Pulmonary Valve Implantation After Native Right Ventricular Outflow Tract Reconstruction: State-of-the-Art Review

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Abstract

Transcatheter pulmonary valve implantation (TPVI) has become an important therapy for pulmonary regurgitation after surgical repair of congenital heart disease involving native right ventricular outflow tract (RVOT) reconstruction (NRVOTR). Moreover, in contrast to patients with right ventricle–pulmonary artery conduits, those with a native reconstructed outflow tract typically present with a dilated, irregular, and dynamically deformable landing zone, which limits the use of balloon-expandable valves due to an increased risk of device displacement and embolization. This challenge has driven the development of self-expanding transcatheter pulmonary valves designed to adapt to complex anatomy. Successful intervention relies on comprehensive preprocedural imaging to assess RVOT dimensions, dynamic changes, landing zone length, proximity to coronary arteries, and the anatomy of the branch pulmonary arteries. Although early and mid-term outcomes have been encouraging, several evidence gaps remain. Comparative data across different self-expanding platforms are lacking; long-term durability beyond five years remains largely undefined; the true incidence of rare complications such as coronary compression, infective endocarditis, and stent fracture in the native RVOT setting is not well established. This state-of-the-art review synthesizes current evidence on morphology-driven decision-making, device characteristics, and unresolved clinical questions to guide TPVI in patients with NRVOTR.

Keywords: transcatheter pulmonary valve implantation; native right ventricular outflow tract reconstruction; pulmonary regurgitation; balloon-expandable transcatheter pulmonary valve; self-expanding transcatheter pulmonary valve

1. Introduction

In patients with congenital heart disease with dysplastic right ventricular outflow tract (RVOT), such as tetralogy of Fallot (with or without pulmonary atresia), pulmonary stenosis, double-outlet right ventricle, or truncus arteriosus, surgical correction often involves native right ventricular outflow tract reconstruction (NRVOTR), including pulmonary valvuloplasty, infundibulectomy, or transannular patch repair, etc. [1,2,3]. Compared with right ventricle (RV)-to-pulmonary artery (PA) conduits, the most common long-term postoperative complications are pulmonary regurgitation (PR) and RVOT dilation rather than pulmonary stenosis or conduit stenosis [4,5,6].

Since Bonhoeffer et al. [7] first successfully performed transcatheter pulmonary valve implantation (TPVI) in 2000, balloon-expandable transcatheter pulmonary valves (TPVs) have become a routine treatment for failed conduits [8]. However, in patients after NRVOTR, the RVOT is often severely dilated, and balloon-expandable TPVs are of limited applicability due to a significantly increased risk of valve displacement or embolization [9].

Over the past decade, self-expanding TPVs have been increasingly used in this population, with encouraging clinical follow-up results [10,11,12,13,14]. Nevertheless, in patients with irregular or large RVOT morphology, the acceptance rate of percutaneous TPVI is low, and risks such as valve displacement, stent fracture, and tricuspid valve injury cannot be ignored [15,16,17]. A recent comprehensive review by Castaldi et al. [18] provided a broad state-of-the-art overview of TPVI, covering device technologies, multimodality imaging, and complications across various anatomies. The present manuscript complements this work by focusing specifically on the unique challenges of TPVI following NRVOTR. This review explores the RVOT morphology distribution after NRVOTR, its relationship with right heart function, how morphology guides device selection, and summarizes current evidence on self-expanding TPVs, morphology-specific complications, and follow-up outcomes.

2. Review Methodology

This narrative review was conducted to synthesize available evidence on TPVI following NRVOTR. A literature search was performed in PubMed/MEDLINE, Embase, Web of Science Core Collection and Scopus for articles published between January 2000 and April 2026. Search terms included: “transcatheter pulmonary valve implantation”, “TPVI”, “native right ventricular outflow tract”,

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Table 1. Quantitative distribution of RVOT morphology types across studies.

Morphology category	Shen et al. (2021) [20]	Schievano et al. (2007) [25]	Van De Bruaene et al. (2019) [21]	Capelli et al. (2010) [24]
Proximally wide, distally narrow	18.9%	44.6%	45%	69.3%
Uniform diameter	41.3%	16.9%	15%	14.5%
Narrowed centrally	34.5%	13.3%	9%	3.2%
Proximally narrow, distally wide	5.3%	3.6%	14%	1.6%
Widest centrally	–	19.3%	17%	11.3%
Other/Unclassifiable	–	2.4%	–	–

It should be noted that the four studies used different RVOT classification schemes and patient inclusion criteria; direct comparison of percentages across studies is therefore not statistically valid. The table is presented to illustrate the range of reported distributions rather than to imply a unified classification.

Table 2. Study characteristics and key clinical associations of RVOT morphology.

Aspect	Cohort	Key findings
Shen et al. (2021) [20]	206 rTOF patients, non-conduit repair, PR ≥20%	• Pyramid shape associated with largest RV volumes • Bilateral PA size discrepancy linked to worse exercise capacity • Inverted trapezoid shape was protective against RV dilation
Schievano et al. (2007) [25]	83 patients with RVOT dysfunction post-CHD repair	• Type I most common, often with transannular patch • Morphology is a major determinant of TPVI suitability • Type I associated with higher PR fraction
Van De Bruaene et al. (2019) [21]	100 adult rTOF patients without conduit/bioprosthesis	• Convergent anatomy most common and linked to more severe PR • Divergent morphology associated with worse clinical status
Capelli et al. (2010) [24]	62 patients who underwent surgical PVR	• Patient-specific simulation showed TPVI suitability could rise to ~70% with new TPV • Type I morphology remained most challenging for TPVI

PR, pulmonary regurgitation; PA, pulmonary artery; PVR, pulmonary valve replacement; rTOF, repaired tetralogy of Fallot; CHD, congenital heart disease; RV, right ventricle; RVOT, right ventricular outflow tract; TPVI, transcatheter pulmonary valve implantation; TPV, transcatheter pulmonary valve.

"NRVOT", "self-expanding pulmonary valve", "Harmony valve", "Venus P-Valve", "Pulsta valve", "Alterra Adaptive Prestent", "Salus valve", and "Med Zenith PT-Valve". Only English-language articles were considered. In addition, the reference lists of retrieved articles and relevant reviews were manually screened to identify further relevant studies, including those from journals not fully indexed in the primary databases. The authors prioritized prospective studies, multicenter registries, and device-specific clinical trials; case reports were included only when they described unique complications or novel techniques. The final selection was based on relevance to the NRVOTR population and the strength of evidence.

3. RVOT and PA Branch Morphology

The anatomy of the RVOT demonstrates considerable complexity and variability [19], especially after NRVOTR [20,21]. RVOT interventions such as pulmonary annular reconstruction or augmentation of the main pulmonary artery (MPA) can lead to varying degrees of postoperative PR. Over time, persistent PR further reshapes the RVOT morphology, amplifying its anatomical diversity and morphological intricacies [22,23]. Current researchers tend to classify RVOT morphology into four or five types (Fig. 1), "pyramidal/convergent (proximally wide, distally narrow)" morphology is consistently reported as one of the most common outcomes, particularly associated with transannular patch repair and more significant PR (Table 1, Ref. [20,21,24,25]). These distributional differences likely reflect variations in the patient cohorts. The RVOT geometry is not merely anatomical but is closely associated with RV size, function, exercise capacity, and crucially, with eligibility for transcatheter interventions such as TPVI (Table 2, Ref. [20,21,24,25]).

Among the available classification systems, the Schievano classification (proximally wide/distally narrow, uniform diameter, narrowed centrally, proximally narrow/distally wide, widest centrally, and unclassifiable) serves as the anchor framework for this review, as it is the most widely cited and has been used in subsequent computational modeling studies [25]. The other studies summarized in Table 1 used different classification schemes. Shen et al. [20] employed a four-type system (pyramidal,



Fig. 1. Representative RVOT morphology types and their implications for TPVI. (A) Widest centrally (fusiform). (B) Proximally wide, distally narrow (pyramidal/convergent—most common after transannular patch repair, associated with higher risk of device migration). (C) Uniform diameter (cylindrical—most suitable for balloon-expandable valves if diameter ≤22 mm). (D) Narrowed centrally (concave). (E) Proximally narrow, distally wide (inverted pyramid). The morphological type directly influences landing-zone stability, valve sizing, and complication risks (see Table 1 and Section 7 for associated complication risks). RVOT, right ventricular outflow tract; TPVI, transcatheter pulmonary valve implantation.

inverted trapezoid, tubular, and other), which roughly corresponds to the Schievano types I, III, II, and V/VI, respectively. Van De Bruaene et al. [21] used a three-way descriptive system (convergent, divergent, and other), with "convergent" broadly matching Schievano type I. Capelli et al. [24] grouped patients into "type I" (proximally wide/distally narrow), "uniform", and "other". Direct percentage comparisons across studies are not statistically valid due to these differences in classification and patient selection criteria. The data in Table 1 are therefore presented to illustrate the range of reported distributions rather than to imply a unified numerical summary.

RVOT morphology represents a key limiting factor for the applicability of percutaneous TPVI [26]. In cases of irregular RVOT morphology, larger valve sizes are often selected intraoperatively to reduce the risk of paravalvular

Table 3. Comparison of balloon-expandable transcatheter pulmonary valves.

Valve	Valve material	Frame material	Available sizes (mm)	Max recommended diameter (mm)	Sheath size (Fr)
Melody	Bovine jugular vein	Platinum-iridium	16, 18 (expandable to ~22)	22	22
Edwards SAPIEN	Bovine pericardium	Cobalt-chromium	20, 23, 26, 29	29	14–20
Myval	Bovine pericardium	Nickel-cobalt alloy	20–32 (1.5-mm steps)	32 (expandable to 35*)	14

*Custom-made 35-mm valve available.

leakage (PVL) and TPV migration/embolization [10]. The associated risks, including stent fracture, are discussed in Section 7. For patients with severely dilated RVOT, the available TPV sizes are limited by the diameter of the transfemoral delivery sheath, making it difficult to match the valve dimensions to the RVOT diameter [27]. Recently, a hybrid therapeutic approach combining surgical annuloplasty and RVOT remodeling with TPVI has been explored to create a stable valve landing zone, demonstrating favorable clinical outcomes while significantly expanding the indications for TPVI [28,29,30,31,32,33]. Such a combined strategy is particularly relevant when the native right ventricular outflow tract (NRVOT) diameter exceeds the largest available transcatheter valve size, precluding adequate anchoring, or when the required valve length substantially exceeds the NRVOT length, which may predispose to infundibular irritation, ventricular arrhythmias, and stent fracture. Using patient-specific computational models to overcome the anatomical limitations of current TPVs, and thereby achieving personalized treatment planning and device design, may represent a promising future direction. Therefore, further studies on the morphological characteristics of RVOT in patients with NRVOT are still necessary.

Postoperative alterations in the geometry of the PA branches, often resulting from surgical reconstruction of RVOT, constitute a primary cause of branching morphology differences [34,35,36]. These differences are typically manifested as an acute angulation of the left PA relative to the MPA and asymmetric branch dimensions. Computational fluid dynamics analyses reveal that such abnormal geometry promotes disturbed hemodynamics, including flow separation, vortex formation, and regions of low/oscillatory wall shear stress at the bifurcation [37,38,39]. This flow environment directly exacerbates PR by creating recirculation zones that impede forward flow and facilitate diastolic retrograde flow, particularly into the left PA, thereby increasing volume load on the RV and the pulmonary valve [40]. Therefore, optimized surgical repair that restores near-normal PA bifurcation geometry may equalize branch angles, maintain a favorable laminar flow state, minimize turbulent energy loss and abnormal shear stress, and ultimately improve long-term valve function and patient prognosis [41,42].

4. Balloon-Expandable TPV

TPVI has emerged as a viable alternative to surgical pulmonary valve replacement in patients with dysfunctional NRVOT. Currently, balloon-expandable TPVs such as the Melody valve (Medtronic) and the Edwards SAPIEN valve (Edwards Lifesciences) are widely used [43]. The Melody valve is approved for RVOT diameters ≤22 mm, while the SAPIEN valve can accommodate diameters up to 29 mm. Recently, the Myval transcatheter heart valve (Meril Life Sciences) has been introduced [44], offering sizes from 20 mm to 32 mm in 1.5-mm increments, with potential for expansion up to 35 mm in customized versions [45]. A comparison of technical features is summarized in Table 3.

Ideal candidates for balloon-expandable TPVs in the NRVOT setting are a minority, limited to patients with relatively uniform, non-aneurysmal diameters (≤22 mm for Melody, ≤29 mm for SAPIEN), an adequate landing zone (>30 mm), and no risk of coronary artery compression (CAC). The often irregular and dilated morphology of the post-NRVOTR anatomy restricts their broader application [9]. For patients exceeding these dimensions, several off-label techniques have been employed to create a stable landing zone, including the “Russian dolls and jailing procedure” technique (sequential implantation of multiple stents), hybrid surgical plication, and branch pulmonary artery valve implantation [29,46,47]. However, these approaches are supported by limited, single-center case series, carry higher procedural costs and risks, and lack long-term follow-up data. Consequently, balloon-expandable TPVs remain a niche option in the NRVOT population, with self-expanding devices having emerged as the primary treatment modality for the majority of patients with dilated, irregular anatomy.

5. Self-Expanding TPVs

Given the limitations of balloon-expandable TPVs in dilated, irregular NRVOTs, self-expanding TPVs with nitinol frames and flared ends have become the primary option. The nitinol frame provides adaptive conformability and secure anchoring in irregular RVOT anatomy. The following sections review currently available or investigational self-expanding TPVs. Device-specific risks are detailed in Section 7.

The self-expanding devices discussed in this section differ substantially in regulatory approval (Food and Drug Administration (FDA)-approved, Conformité Européenne

Table 4. Comparison of self-expanding TPVs.

Valve	Inflow (mm)	Outflow (mm)	Mid-section (mm)	Length (mm)	Pericardial material	Delivery route	Recapturability
Harmony TPV	41/54	32/43	22/25	55/51	Porcine	Percutaneous transfemoral	Not recapturable
Alterra Prestent + SAPIEN 3	40 (prestent)	40 (prestent)	SAPIEN 3: 29	48 (prestent)	Bovine (SAPIEN 3)	Percutaneous transfemoral	Pre-stent fully recapturable
Salus valve	22–36	22–36	18–32	31–43	Bovine	Hybrid transthoracic	No data available
Venus P-Valve	34–46	34–46	24–36	70, 77, 84	Porcine	Percutaneous transfemoral	Partially recapturable (<50%)
Pulsta Valve	22–36	22–36	18–32	28–38	Porcine	Percutaneous transfemoral	Recapturable (<1/3); full retrieval via hook
Med Zenith PT-Valve	28–44	28–44	20, 23, 26	38–54	Porcine	Percutaneous transfemoral	No data available

TPVs, transcatheter pulmonary valves.

(CE)-marked, or investigational), geographic availability, reported follow-up duration (months to >10 years), and evidence strength (multicenter registries to single-center series). The following descriptions highlight these differences to allow device evaluation on individual evidence bases.

The Harmony TPV (Medtronic, Minneapolis, MN, USA) features a distinctive asymmetrical hourglass-shaped frame constructed from self-expanding nitinol [48]. The Harmony TPV is the first U.S. FDA-approved device for the treatment of severe PR in the NRVOT and received CE marking in 2025. Its inflow end is slightly wider than the outflow end, creating a tapered profile that supports secure anchoring within the often dilated and irregular native or surgically repaired RVOT. The frame is covered with a polyester knit fabric, and the valve leaflets are made from porcine pericardial tissue. The Harmony TPV has two available sizes: TPV22 and TPV25. Specific parameters are provided in Table 4. Both valves are delivered using a single 25 French delivery system. The Harmony TPV cannot be recaptured once deployment has begun; therefore, precise positioning is critical. A pooled cohort of 86 patients (median follow-up 5 years) reported sustained valve competence, significant right ventricular end-diastolic volume index (RVEDVi) reduction, and improved quality of life. Adverse events up to 5 years included 2 endocarditis cases, 6 patients with RVOT obstruction and thrombosis resulting in valve-in-valve procedures and 1 major stent fracture resulting in surgical explantation [49]. A multicenter registry of 243 patients (median age 31 years) showed 19% required treatment for ventricular arrhythmias; 98% had acceptable hemodynamics at 13 months, with no procedural deaths [50].

The Alterra Adaptive Prestent (Edwards Lifesciences, Irvine, CA, USA) is a nitinol-based self-expanding stent, partially covered with expanded polytetrafluoroethylene [13]. The Alterra + SAPIEN 3 system—the only hybrid platform that remodels an irregular NRVOT via a self-expanding prestent to facilitate a balloon-expandable valve—received FDA approval in 2021 and CE mark in 2024. It is not a valve itself but functions as a docking adapter designed to internally remodel and reduce the dilated NRVOT diameter, thereby creating a stable and predictable landing zone for a subsequent 29-mm Edwards SAPIEN 3 balloon-expandable TPV. The dedicated delivery system allows full recapture and repositioning before final deployment of the prestent. In the ALTERRA pivotal trial (118 patients), 3-year outcomes showed 97.3% freedom from reintervention, 93.3% with mild or lesser pulmonary regurgitation, and no coronary compression or endocarditis [51]. Recently, the off-label placement of a 26 mm SAPIEN S3 valve into an Alterra Adaptive Prestent has also been reported to avoid CAC [52]. This hybrid approach combines self-expanding and balloon-expandable technologies.

The Salus valve (Balance Medical Technology, Beijing, China) is a self-expanding bovine pericardial valve on a nitinol frame, designed for hybrid transthoracic implantation without cardiopulmonary bypass [32]. The Salus valve is currently an investigational device without CE or FDA approval. The surgical approach (e.g., subxiphoid, intercostal, or sternotomy) is selected based on the procedure (TPVI alone or combined with PA plication) and surgeon preference. This strategy allows for concomitant PA plasty to optimize the landing zone and reduce PVL, making it particularly suitable for patients with dilated or irregular RVOTs where percutaneous options are limited. The valve features a symmetrical, trumpet-shaped design with minimal disparity between its inflow, central, and outflow diameters. With a relatively short length (31–43 mm), it corresponds well to the average MPA length post-NRVOT repair, thereby minimizing excessive interaction with the RVOT infundibulum and the associated risks of stent fracture or ventricular arrhythmia. No data on recapturability are currently available for this investigational device. The largest prospective experience to date includes 38 patients

Table 5. Key design features and clinical considerations of self-expanding TPVs for NRVOTR.

Valve name	Key design features for NRVOTR	Considerations/Limitations in NRVOTR	Evidence maturity/Key studies
Harmony TPV	Asymmetrical hourglass shape; tapered profile designed for proximally wide, distally narrow morphology	Fully covered stent; risk of CAC and pulmonary artery branch jailing if deployed too high	Pooled 5-year follow-up (n = 86) [49]; multicenter registry (n = 243) with 13-month follow-up [50]
Alterra Adaptive Prestent + SAPIEN 3	Prestent remodels dilated, irregular RVOT to a 27 mm central landing zone; enables use of balloon-expandable SAPIEN 3 valve	Requires two devices; extravascular protrusion reported on CT surveillance; potential for device interaction with adjacent structures	FDA-approved, CE-marked. ALTERRA pivotal trial 3-year outcomes (n = 118) [51]; 97.3% freedom from reintervention
Salus Valve	Short length (31–43 mm) reduces infundibular interaction, potentially lowering risks of stent fracture and ventricular arrhythmia	Hybrid transthoracic approach required (not fully percutaneous); limited long-term data	Investigational (no CE/FDA). Largest prospective series: 38 patients, median 24-month follow-up [32]; no mortality/reintervention
Venus P-Valve	Flared distal end anchors at PA bifurcation; open-cell distal flare maintains branch pulmonary artery access	Longer total length (70–84 mm) may increase infundibular irritation	CE MDR (2022), China NMPA (2022), >50 countries; not FDA-approved (PROTEUS IDE trial ongoing). 5–10 year follow-up (n = 58) [55]; 3-year CE study (n = 81) [11]; Italian registry, n = 65 [56]; Chinese 5-year study, n = 55 [27]
Pulsta Valve	Woven double-strand nitinol frame provides high fracture resistance; short length (28–38 mm) minimizes dynamic stress	Largest clinical experience limited to Asian countries; received CE MDR certification (Class III, 2026)	CE MDR Class III (2026); not FDA-approved. Multicenter experience (n = 182), median 29-month follow-up [57]; technical success 98.4%
Med Zenith PT-Valve	Symmetrical dumbbell-shaped frame; balanced anchoring at both RVOT and distal PA	Fully covered outflow segment necessitates precise positioning above PA bifurcation to avoid jailing branch pulmonary arteries	Investigational (no CE/FDA). Single-center feasibility trial (n = 12), median 4-month follow-up [58]; 100% procedural success

NRVOTR, native right ventricular outflow tract reconstruction; CAC, coronary artery compression; CT, computed tomography; FDA, Food and Drug Administration; CE, Conformité Européenne; MDR, Medical Device Regulation; NMPA, National Medical Products Administration.

(mean age 24 years) who underwent Salus valve implantation with a median follow-up of 24 months. All procedures were technically successful. Intraoperative valve displacement occurred in three patients but was managed without conversion to open surgery. At follow-up, significant RV reverse remodeling was observed (RVEDVi decreased from 141.5 to 110.0 mL/m^2, $p < 0.01$). No mortality or need for reintervention was reported [32].

The Venus P-Valve (Venus MedTech, Hangzhou, China) is a self-expanding TPV with a tri-leaflet porcine pericardial valve sewn onto a nitinol stent. The Venus P-Valve received the CE Medical Device Regulation (MDR) approval in April 2022, becoming a pioneering self-expanding TPV available in Europe. Subsequently, it gained approval from China's National Medical Products Administration (NMPA) in July 2022 as the first and only transcatheter pulmonary valve replacement system currently approved for commercial use in the country and the device has been commercially available in multiple countries across Europe, Asia, and other regions [53]. It is not FDA-approved; however, the PROTEUS IDE pivotal trial is underway to support future US registration. Its distinctive design includes a central straight segment that houses the valve, with flared proximal and distal ends to enhance anchoring in the dilated NRVOT and PA bifurcation, respectively. The proximal flare is fully covered with porcine pericardium to minimize PVL, while the distal flare has an open-cell structure to maintain access to the PA branches. The valve is available in a wide range of sizes, with straight section diameters from 24 mm to 36 mm (in 2-mm increments) and lengths from 20 mm to 30 mm (in 5-mm increments), allowing tailored treatment for a spectrum of RVOT morphologies. The valve can be partially recaptured if less than 50% of its structure has been deployed from the Dry-Seal sheath. Clinical studies have reported high procedural success rates and favorable follow-up outcomes in patients with large, patched, or NRVOTs [27]. A separate comparative analysis of 145 patients reported 100% procedural success for both Venus-P and SAPIEN 3 in NRVOT, but a higher incidence of early postoperative arrhythmias in the self-expanding group (21.1% vs 3.2%, $p < 0.001$) [54]. Extended single-center follow-up (58 patients, 5–10 years) showed wire-frame fractures in 23.2% (no functional compromise), no infective endocarditis (IE), and no malignant

Table 6. Preoperative anatomical assessment checklist for NRVOTR-TPVI.

Key question	Measured parameter	Anatomical/Clinical threshold	Potential implication
What is the minimum systolic diameter of the intended landing zone?	Diameter (mm)	≤22 mm → possible Melody; ≥30 mm → BE valves unsuitable	Guides BE vs. SE pathway
How dynamic is the landing zone?	% change (systolic minus diastolic diameter, divided by systolic diameter)	>30% → high risk of migration/embolization for BE valves; SE valves preferred	Consider hybrid plication if >50%
What is the available landing zone length?	Length (mm)	<30 mm → long SE valves risk arrhythmia/fracture; prefer short devices (Salus, Pulsta)	<25 mm → strongly consider hybrid plication
Is there coronary artery proximity?	Coronary-RVOT distance (mm) on CTA	<3 mm → avoid oversizing; prefer shorter, lower-radial-force devices; balloon testing mandatory	>5 mm → low risk
Is there evidence of arrhythmia substrate?	Pre-procedural 24-h Holter, CMRI scar imaging, history of VT/syncope	Sustained VT, extensive RVOT scar, or complex ectopy (>10% burden) → EP consultation	May require pre-procedural ablation, ICD consideration, or intraoperative mapping
Is there significant branch PA stenosis?	Echocardiography (peak velocity/gradient), angiographic/CTA diameter, perfusion mismatch	Diaphragm-like stenosis → balloon angioplasty feasible; diffuse hypoplasia → often requires surgical arterioplasty	Pyramidal RVOT morphology frequently associated with bilateral branch involvement
Are there triggers for a hybrid approach?	Composite anatomical assessment	Any of the following: • Landing zone length <25 mm • Dynamic change >50% • Coronary–RVOT distance <3 mm • Severely dilated RVOT exceeding the largest available valve diameter • Valve length > RVOT length, with the inflow segment extending into the infundibulum (risk of infundibular irritation, ventricular arrhythmia, or stent fracture)	Plan for hybrid surgery: surgical RVOT plication + transcatheter valve implantation

BE, balloon-expandable; SE, self-expanding; VT, ventricular tachycardia; EP, electrophysiology; ICD, implantable cardioverter-defibrillator; TR, tricuspid regurgitation; CTA, computed tomography angiography; CMRI, cardiac magnetic resonance imaging. The rationale for each hybrid trigger is further discussed in Section 3 and Section 6.

arrhythmias [55]. However, multicenter data report variable endocarditis rates: 1/81 in the 3-year CE study [11]; 1/65 in the Italian registry (13 months) [56]; and 5/55 (9.1%) in the Chinese 5-year study (4 within first year) [27]. Continued surveillance is needed.

The Pulsta Valve (Taewoong Medical, Gimpo, South Korea) is a self-expanding valve characterized by its unique woven, double-strand knitted nitinol wire stent frame, which provides high resistance to fracture under the dynamic forces of the RVOT [14]. FDA approval has not been granted. The valve features a compact tubular design with both ends flared 4 mm wider than the central outer diameter. This relatively short length and flared ends help secure anchoring while minimizing interaction with the RVOT. Delivery system sizes are 18 French for valves up to 28 mm and 20 French for 30 and 32 mm valves. The system allows controlled deployment, partial recapturability, and full retrieval via a hook mechanism. Specifically, the valve can be recaptured if less than one-third of the stent has been deployed from the sheath. A multicenter experience (182 patients, median follow-up 29 months) reported a technical success rate of 98.4%. The valve adapted to five distinct MPA shapes (conical, straight, reverse-conical, convex, concave). RVEDVi decreased from 163.1 to 123.6 mL/m^2 at 1 year. TPV migration/embolization requiring surgical retrieval occurred at a rate of 1.6% [57].

The Med Zenith PT-Valve (Med Zenith Medical Technology, Beijing, China) features a symmetrical dumbbell-shaped nitinol frame, covered with porcine pericardium. No data on recapturability are currently available for this investigational device. The Med Zenith PT-Valve remains an investigational device without CE or FDA approval. The proximal and distal flares have equal diameters, which anchor in the RVOT and distal PA, respectively, while the central valve housing is narrower. The valve is available in five frame sizes with flare diameters from 28 to 44 mm in 4-mm increments. Valve housing diameters are 20, 23, or 26 mm. A 21 French delivery system is used, with a 12 French shaft. Because the outflow end is fully covered with porcine pericardium, the valve cannot be deployed too distally or too high in the MPA, a positioning consideration that is similarly emphasized with the Harmony TPV. If positioned too close to the bifurcation, the covered outflow segment may extend into or overlap the origins of the PA branches, potentially compromising PA branch flow. A single-center feasibility trial (12 patients, median follow-up 4 months) showed 100% procedural success and mild or less valvular regurgitation in all patients [58].

Table 4 provides basic dimensional specifications. Table 5 (Ref. [11,27,32,49,50,51,55,56,57,58]) links each self-expanding device to its design features, anatomical niche, and limitations, emphasizing morphological suitability for the dilated, irregular NRVOT. Table 6 translates preoperative imaging into a practical checklist: minimum systolic diameter, dynamic change, landing zone length, and coronary-RVOT distance. The red-flag thresholds in Table 6 are derived from clinical studies and device specifications. The 30 mm length alert is based on trial criteria (e.g., Alterra required ≥35 mm); lengths of 30–35 mm may be acceptable with caution, but <30 mm raises risks of malposition, stent fracture, and arrhythmias, especially with longer self-expanding valves (Table 4). The >30% dynamic change threshold is a pragmatic cut-off: 4D-CT studies show NRVOT cross-sectional area can vary >50% (up to 150%) during the cardiac cycle [23,59]. Change >30% flags balloon-expandable valve instability, favoring self-expanding designs; change >50% suggests hybrid plication.

RVOT morphology (Table 1) and PA bifurcation anatomy further refine device selection. For example, a Type I (proximally wide, distally narrow) morphology with length >40 mm is well-suited to the Harmony valve, whereas a short landing zone (<35 mm) with a wide distal PA may favor Venus P-Valve (anchoring at the bifurcation) or a hybrid approach.

No evidence-based algorithm can definitively rank devices due to lack of head-to-head trials, heterogeneous study designs, and regional differences in availability (e.g., Pulsta widely used in Asia but not FDA-approved; Harmony FDA-approved, CE-marked 2025). Instead, the framework invites operators to match anatomical measurements with device characteristics (flared ends, covered vs. uncovered, total length, need for hybrid access). Final selection must also consider local expertise and hybrid surgical support.

6. Preoperative Assessment

Preoperative assessment of RVOT anatomy is a critical determinant in operational planning. In the setting of NRVOTR, several specific imaging considerations are warranted. Unlike patients with RV-PA conduits, who typically have a tubular, relatively uniform landing zone, the NRVOT after surgical reconstruction is often aneurysmally dilated, asymmetrical, and dynamically deformable throughout the cardiac cycle. This includes evaluation of the length from the RVOT to the PA bifurcation, the internal diameter of various RVOT segments, and the presence of non-diaphragmatic stenosis in the PA branches. For patients who have undergone the Barbero-Marcial procedure, the RVOT length may be short, sometimes less than 30 mm, whereas most TPVs exceed 30 mm in length. A short landing zone increases risks of migration, arrhythmias, and stent fracture (see Section 7 for details). When the only valve capable of matching the RVOT diameter has a length that exceeds the available landing zone, the risk of infundibular irritation becomes significant, and a hybrid approach with surgical RVOT plication should be considered. Given that the RVOT cross-section is not perfectly circular due to its proximity to the aortic root posteriorly and the sternum anteriorly, measurement of the internal diameter us-

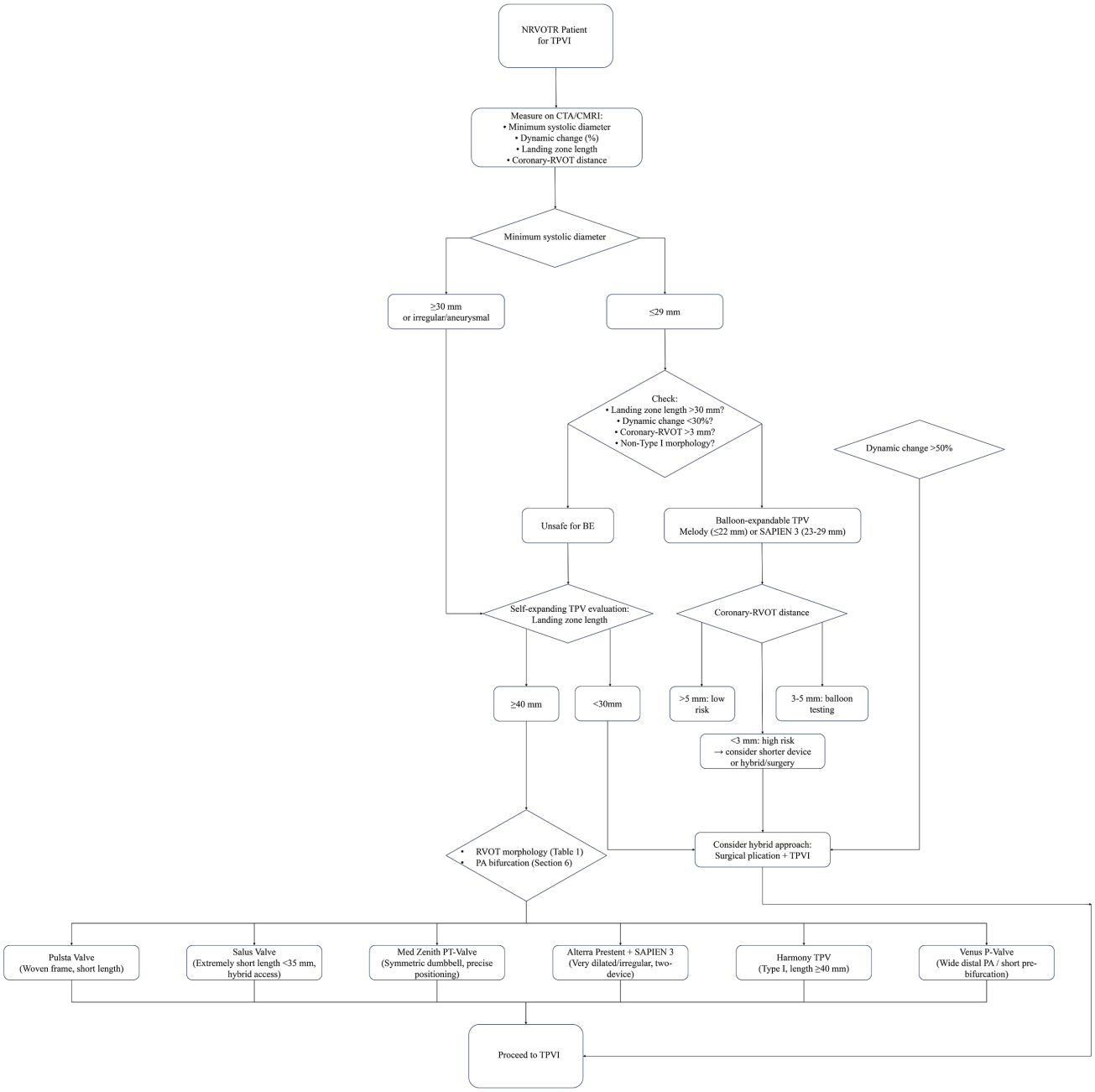


Fig. 2. Anatomy-driven decision algorithm for transcatheter pulmonary valve selection in patients after native right ventricular outflow tract reconstruction. The algorithm integrates four preoperative imaging parameters: minimum systolic diameter, dynamic change, landing-zone length, and coronary-RVOT distance. It first triages patients into balloon-expandable (BE) versus self-expanding (SE) pathways based on diameter and dynamic stability. Subsequent branches incorporate landing-zone length, RVOT morphology (Table 1), and PA bifurcation anatomy to recommend specific device categories or hybrid approaches. Red-flag thresholds (e.g., length <25 mm, coronary distance <3 mm, dynamic change >50%) are highlighted to alert the operator. Final device choice should also consider local availability and hybrid surgical support.

ing biplanar orthogonal views with perimeter-based calculation provides greater accuracy. Computed tomography angiography (CTA) or cardiac magnetic resonance imaging (CMRI) are generally the preferred and more reliable imaging modalities for this purpose. Different RVOT morphologies influence the choice of surgical approach, valve sizing, and the risks of PVL and TPV migration/embolization. In patients with type I RVOT (proximally wide, distally narrow), which is commonly seen after transannular patch repair, the risk of TPV migration/embolization is relatively high; therefore, percutaneous TPVI should be considered with caution [57].

Long-term complications following NRVOTR may include not only PR but also PA branch stenosis, tricuspid regurgitation, residual pulmonary stenosis, or RVOT obstruction [4,5,6]. In cases with concurrent anatomical anomalies requiring intervention, the selection of TPVI should also be approached prudently.

PA branch stenosis is a known complication after NRVOTR and may exacerbate PR. Reported incidence ranges from 20% to 40% [60]. Two morphological subtypes are typically encountered: diaphragm-like stenosis at the branch origin and diffuse hypoplasia involving a longer segment. Diaphragm-like stenosis is more amenable to balloon angioplasty alone, whereas diffuse stenosis responds poorly to balloon dilation and often requires stent implantation [61]. However, stenting in branch PAs carries a risk of device migration into the MPA or lung hilum due to the lack of a stable anchoring zone [62]. Furthermore, branch stenosis is most commonly observed in the "pyramidal" (proximally wide, distally narrow) RVOT morphology. In patients with diffuse bilateral branch involvement, concomitant pulmonary arterioplasty under cardiopulmonary bypass may be a more appropriate strategy.

Some patients present with frequent ventricular arrhythmias in the long-term follow-up. We routinely perform 24-hour Holter monitoring both preoperatively and within one week post-procedure, and have electrophysiologists assess whether further intervention is needed.

To translate the above anatomical measurements into a practical clinical decision, Fig. 2 provides a stepwise algorithm that guides the operator from basic imaging findings (minimum systolic diameter, dynamic change, landing zone length, coronary-RVOT distance) to appropriate device categories. The algorithm first distinguishes between balloon-expandable and self-expanding pathways based on diameter and dynamic stability, then refines the choice using landing zone length, RVOT morphology (Table 1), and PA bifurcation features. It also flags high-risk scenarios (e.g., coronary distance <3 mm, landing zone <25 mm, or dynamic change >50%) that may require hybrid plication or alternative strategies. This flowchart is intended as a decision-support tool, not a rigid prescription, and final device selection must always consider local availability, operator expertise, and hybrid surgical support.

7. Postoperative Complications

TPV migration/embolization is often caused by a mismatch between RVOT dimensions and the selected TPV size [57,63]. Reported rates of TPV migration/embolization vary considerably across studies (from 0% to >10%), reflecting differences in patient selection, RVOT morphology, and the degree of device oversizing or undersizing. Optimal matching of valve size to RVOT dimensions is critical to minimize this complication. When anatomical conditions are unfavorable (e.g., severely dilated or highly dynamic RVOT, short landing zone), alternative strategies such as hybrid plication or the use of self-expanding devices with flared ends should be considered. Therefore, in addition to preoperative assessment of RVOT diameter and morphology based on end-systolic measurements, it is essential to compare end-diastolic dimensions, as some patients may have aneurysmal dilation with significant phase-to-phase variation in RVOT diameter. Given the irregular morphology of the RVOT, PVL is a common intraprocedural complication, often resulting from a mismatch between TPV size and RVOT diameter or TPV displacement during implantation, with its reported occurrence varying across studies [10,58]. Management strategies for PVL are primarily conservative, as most cases are trivial or mild and do not necessitate immediate intervention. In instances where PVL is significant and leads to hemodynamic compromise or severe PR, reintervention may be required; this can involve valve-in-valve implantation or, less commonly, surgical correction [48].

As briefly noted in Sections 4–6, the risk of postprocedural arrhythmias is closely related to device length relative to RVOT length. The following provides a detailed mechanistic analysis. Ventricular arrhythmias frequently occur when the TPV length exceeds the RVOT length, given that the infundibulum of the RVOT is a common site for idiopathic premature ventricular contractions or ventricular tachycardia (VT) [13,50]. Ventricular arrhythmias, primarily premature ventricular contractions or non-sustained VT, are the most frequently reported, with an estimated occurrence in 10–20% of cases. Excessive length of the inflow stent segment may irritate the RVOT infundibulum, triggering frequent premature beats or tachycardia (Figs. 3,4). Most episodes are self-limited or respond to short-term beta-blocker therapy [15,48]. Sustained VT continues to be a significant long-term concern primarily because of the patient's underlying arrhythmogenic substrate [11]. Management of sustained VT is complex and may involve a combination of anti-arrhythmic drugs, catheter ablation to target the critical isthmus (often requiring advanced mapping techniques), and implantable cardioverter-defibrillator placement for secondary prevention or in high-risk patients with severely impaired ventricular function. Pre-procedural risk stratification with cardiac CMRI for scar assessment and, in selected cases, electrophysiological study is becoming increasingly integrated into the TPVI evaluation process.

CAC is a potentially catastrophic complication, but its incidence in NRVOTR patients appears substantially lower than in conduit patients [64]. However, the available literature consists of isolated case reports and small series; no prospective study has systematically evaluated CAC risk exclusively in NRVOTR patients. Thus, the true incidence remains uncertain, and current recommendations are based on expert consensus and extrapolation from conduit data. To mitigate this risk, strategies such as intraoperative balloon inflation with simultaneous coronary angiog-

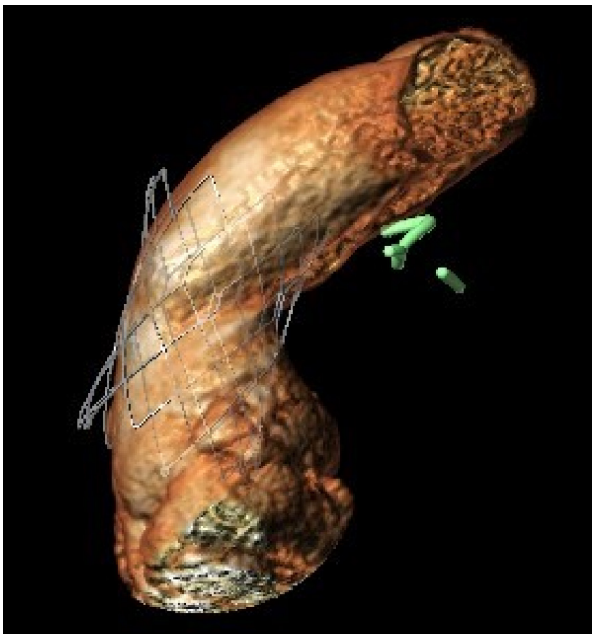


Fig. 3. Left sagittal view of the anatomical relationship between a transcatheter pulmonary valve and the RVOT. When the inflow segment of a self-expanding TPV extends beyond the native pulmonary annulus into the infundibulum, it may mechanically irritate the infundibular myocardium, serving as a trigger for post-procedural ventricular arrhythmias. Normal infundibular anatomy is shown in Fig. 4 for comparison.

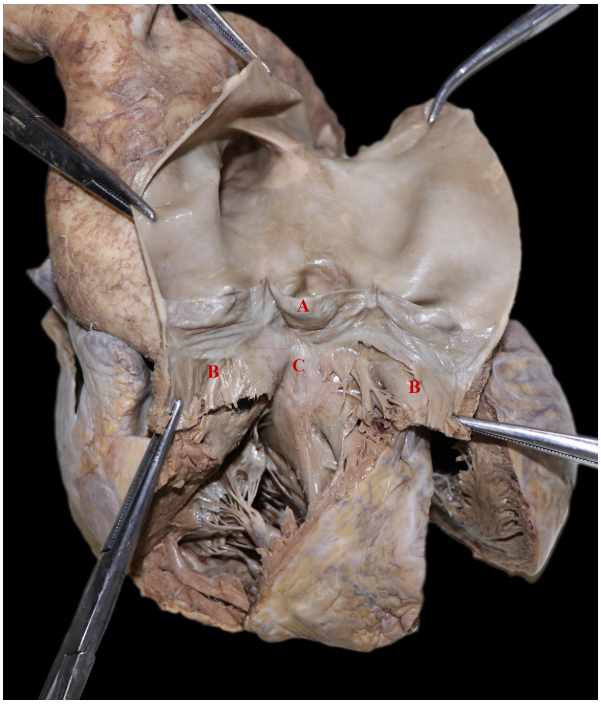


Fig. 4. Schematic diagram of the normal RVOT anatomy. (A) Pulmonary valve annulus and leaflets. (B) Infundibular sleeve (muscular infundibulum). (C) Infundibular septum. A clear understanding of these normal structures is essential for recognizing device-anatomy mismatch when the implanted TPV protrudes below the annulus or extends beyond the bifurcation, leading to arrhythmias, stent fracture, or branch PA compromise.

raphy (balloon testing) [65], as well as pre-procedural assessment of the coronary-RVOT and sternum-RVOT distances via CMRI or CTA [66], have been developed and have significantly reduced the incidence of CAC in percutaneous TPVI. Although aneurysmal dilation of the MPA can cause left main coronary compression, it should be noted that patients with a dilated NRVOT typically have sufficient anatomical space between the RVOT and the coronary arteries. Furthermore, in cases with severe RVOT dilation, the operator routinely performs intraoperative plication to reduce the volume of the RVOT. The TPV size is meticulously matched to the inner diameter of the RVOT, which further minimizes the risk of CAC. Nevertheless, it is important to acknowledge that recent studies have reported rare cases of CAC following self-expanding valve implantation in patients with NRVOT, albeit very infrequently [67,68]. Compression caused by a self-expanding valve may be associated with a mismatch between the oversized diameter of the TPV and the NRVOT.

Tricuspid valve injury, though uncommon (<2%), is a procedure-related complication usually resulting from entanglement of the subvalvular apparatus with large delivery systems during manipulation across the right heart, sometimes necessitating modified delivery techniques [13,69].

Stent fracture is a relatively common mid-to-late-term postoperative complication following implantation of self-expanding TPVs, primarily occurring at the proximal (inflow) end of the stent [13,48,58,63]. This is often due to the fact that the length of the self-expanding TPV frequently exceeds that of the RVOT. Reported stent fracture rates range from approximately 2% to 27%, but direct comparisons are confounded by differences in device length, frame design, imaging protocols (routine fluoroscopy vs. symptomatic evaluation), and follow-up duration. Most fractures are Type I (single strut without functional impairment) and are incidental findings. However, severe fractures (Type II/III) associated with frame infolding or loss of integrity can lead to restenosis or regurgitation, often mandating reintervention (surgical explant or valve-in-valve) [10,15]. The long-term clinical significance of wire-frame fractures without valve dysfunction remains unknown.

IE is a major late complication after TPVI, but most published data come from conduit-based cohorts (Melody and SAPIEN valves) with limited representation of NRVOTR patients. For self-expanding valves in the NRVOT, reported IE rates vary widely from 0% to 9.1% depending on study design, follow-up duration, and diagnostic intensity [11,27,58,70]. Given the small absolute number of events, pooled incidence estimates should be viewed as provisional. Longer-term surveillance with standardized event definitions is needed to define the true risk in this population. Management typically involves prolonged intra-

venous antibiotics, with reintervention reserved for cases with significant vegetation, persistent infection, or hemodynamic compromise. Hence, longer-term follow-up will be important for defining the incidence of endocarditis.

Thrombotic events following TPVI exhibit a broad temporal presentation, occurring from the early post-procedural period to several years after implantation [11,13,48,71]. Thrombus formation has been documented on various valve components, including leaflets, the distal flare of self-expanding stents, and the inflow portion of prestent structures. Subclinical leaflet thrombosis, detected as hypoattenuated leaflet thickening (HALT) on cardiac CTA, has been increasingly recognized. In self-expanding valves, HALT has been reported in 36.8% of Pulsta valves and in 56–71% of Venus P-Valve, although most cases were mild and not associated with significant valve dysfunction at short-term follow-up [71,72,73]. Thrombus formation after TPVI may promote bacterial adhesion to the prosthetic material, and IE may worsen thrombosis. Management consistently involves the initiation of therapeutic anticoagulation, typically with heparin or warfarin, leading to thrombus resolution, often followed by maintenance with antiplatelet therapy. These observations highlight the necessity for long-term surveillance beyond the initial procedural phase and the efficacy of prompt anticoagulation in managing such complications.

8. Long-Term Durability and TPV Degeneration

The long-term durability of TPVs for NRVOTR remains an area of ongoing evaluation, as robust clinical data beyond 10 years are currently lacking [11,12,14,27,49,58]. Among self-expanding devices, Venus P-Valve has the longest reported follow-up (up to 10 years), with no valve-related mortality, infective endocarditis, or severe PR, although wire-frame fractures occurred in 23.2% of patients without functional compromise. Harmony TPV has demonstrated sustained valve competence and favorable reverse remodeling at 3–5 years, with 10-year post-approval follow-up ongoing. For Alterra/SAPIEN 3, 3-year outcomes show 93.3% of patients with mild or less PR and no cases of endocarditis. Pulsta, Salus, and Med Zenith valves currently lack beyond-3-year data in the NRVOT setting, representing important knowledge gaps. Importantly, most existing long-term TPVI data derive from conduit-based cohorts and may not be directly generalizable to the dynamic, irregular NRVOT anatomy. Dedicated long-term registries for NRVOTR patients are urgently needed. Existing studies have demonstrated promising safety and functional performance for various self-expanding and adaptive devices [11,49,51,55]. Consequently, sustained long-term follow-up is essential to assess the incidence of late structural valve deterioration, stent integrity, and other potential failure modes, which will ultimately define the true lifespan and clinical utility of TPV therapies.

9. Conclusions

TPVI has profoundly changed the management of patients with pulmonary dysfunction after NRVOTR. This review underscores that, in contrast to the conduit population, successful TPVI in the NRVOTR setting is intrinsically dependent on a detailed, morphology-driven approach. The heterogeneity of RVOT shapes—from the common pyramidal/convergent type to the challenging divergent anatomy—directly dictates device selection (favoring self-expanding designs), procedural planning (often requiring hybrid techniques or plication), and the risk of specific complications (e.g., arrhythmias from infundibular irritation, stent fracture from dynamic compression). While devices like the Harmony, Venus P-Valve, Pulsta, and Alterra have expanded feasibility, their long-term durability, especially in the dynamic NRVOT, remains an area of active investigation. Importantly, the current evidence base is heterogeneous in study design, sample size, follow-up duration, and endpoint definitions; most data are observational, and comparative effectiveness studies across self-expanding platforms are lacking. Reported complication rates and long-term outcome estimates should therefore be interpreted cautiously, particularly for rare events and devices with limited post-marketing surveillance. Future studies should move beyond reporting aggregate outcomes and instead correlate specific RVOT morphological parameters with long-term valve performance and patient prognosis, thereby enabling truly personalized TPVI.

Abbreviations

CAC, coronary artery compression; CMRI, cardiac magnetic resonance imaging; CTA, computed tomography angiography; HALT, hypoattenuated leaflet thickening; MPA, main pulmonary artery; NRVOT, native right ventricular outflow tract; NRVOTR, native right ventricular outflow tract reconstruction; PA, pulmonary artery; PR, pulmonary regurgitation; PVL, paravalvular leakage; RV, right ventricle; RVEDVi, right ventricular end-diastolic volume index; RVOT, right ventricular outflow tract; TPVI, transcatheter pulmonary valve implantation; TPV, transcatheter pulmonary valve; VT, ventricular tachycardia.

Author Contributions

JD contributed to the conceptualization, literature search, study selection, data extraction, evidence evaluation, drafting of the original manuscript, and preparation of tables and figures. JS contributed to the conceptualization, supervision, critical revision of the manuscript for important intellectual content, and final approval of the version to be published. AL contributed to the literature search, study selection, data extraction, and critical revision of the manuscript. JW contributed to the literature search, evidence evaluation, and critical revision of the manuscript. JZ contributed to data extraction, evidence evaluation, and

critical revision of the manuscript. ZW contributed to the literature search, data interpretation, and critical revision of the manuscript. QB, HH, ZL, HF, and LL contributed to the literature search, data extraction, and critical revision of the manuscript. All authors participated in the drafting and critical revision of the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Figs. 1,3,4 in this manuscript were obtained from clinical cases at the authors' institution and have been anonymized to protect patient privacy.

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Conflicts of Interest

The authors declare no conflicts of interest.

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