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Review

# Catheter-based Interventions in Tetralogy of Fallot Across the Lifespan

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## ABSTRACT

**Surgical treatment of tetralogy of Fallot (TOF) involves surgical relief of right ventricular outflow tract (RVOT) obstruction and closure of ventricular septal defect. However, some patients may require staged palliation before surgical repair. This traditionally was achieved only with surgery but recently evolved to include catheter-based techniques. RVOT dysfunction occurs inevitably after the surgical repair of TOF and, depending on the surgical approach, manifests as either progressive stenosis, regurgitation, or a combination of both. This predisposes the individual to repeated RVOT interventions with the attendant risks of multiple open-heart surgeries. The advent of transcatheter pulmonary valve replacement has reduced the operative burden, and the expansion of transcatheter pulmonary valve replacement device platforms has widened the type and size of RVOT anatomies that can be treated. This review will discuss the transcatheter therapies available throughout the lifespan of the patient with TOF.**

## RÉSUMÉ

**Les traitements chirurgicaux de la tétralogie de Fallot (TF) comprennent la correction de l'obstruction de la voie de chasse du ventricule droit (VCVD) et la fermeture de la malformation du septum interventriculaire. Toutefois, chez certains patients, une palliation par étapes doit être entreprise avant la correction chirurgicale. Cette palliation était autrefois réalisée par des interventions chirurgicales, mais des techniques de cathétérisme interventionnel sont récemment apparues. La dysfonction de la VCVD survient inévitablement après une correction chirurgicale de la TF et peut se manifester par une sténose progressive, une régurgitation ou les deux, selon l'approche chirurgicale utilisée. Les personnes qui vivent avec la TF sont ainsi susceptibles de subir plusieurs interventions à cœur ouvert et d'être exposées aux risques que cela comporte. L'arrivée de la valvulation pulmonaire percutanée (VPP) a permis de réduire le fardeau chirurgical, et la multiplication des plateformes pour les appareils de VPP rend possible le traitement d'une plus grande diversité d'anomalies de la VCVD. Notre article de synthèse présente les traitements par cathétérisme interventionnel qui peuvent être offerts aux patients atteints de TF au fil de leur vie.**

Tetralogy of Fallot (TOF) is the most common cyanotic congenital heart disease.[1,2] The pathognomonic hallmarks include right ventricular outflow tract (RVOT) obstruction, ventricular septal defect (VSD), an overriding aorta, and right ventricular hypertrophy. Surgical treatment requires closure of the defects and restoration of physiological blood flow through the heart. However, some patients may require additional procedures such as a staged palliation before surgical repair or repeat RVOT interventions after the initial surgical relief of RVOT obstruction. Hence, the individual with TOF is exposed to a lifetime burden of procedures, and each surgery comes with its accompanying mortality and morbidity risks. Recent advancements in transcatheter interventions and device technologies have made replacing some of these surgical procedures a reality. There is however great anatomic variation between patients with TOF, which makes it difficult to standardize management—the choice of therapy has to be customized for the individual, and in-depth understanding of the available therapies is required to make these decisions. In our review, we present the current landscape of transcatheter therapies that may be encountered during the lifespan of the patient with TOF. This is broadly categorized into those performed before or after surgical repair.

## Before Surgical Repair

Although many patients are asymptomatic until surgical repair, a subset of patients will be symptomatic at an early stage and will undergo either a staged palliation or a full neonatal repair. Traditionally, surgical staged palliation was performed, with surgical procedures dating back to the first Blalock-Taussig-Thomas (BTT) shunt.[3] Other surgical palliations have been performed, but due to improvements in catheter-based technologies and outcomes, many patients now

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undergo staged palliations in the catheterization lab before complete surgical repair. There are 3 common interventions that allow for staged palliation in patients with TOF—balloon pulmonary valvuloplasty, RVOT stenting, and patent ductus arteriosus (PDA) stenting. Choosing which intervention is both patient- and institution-specific.

## Balloon valvuloplasty

Balloon valvuloplasty (Fig. 1) is a minimally invasive procedure that was first described for patients with valvar pulmonary stenosis but has been well described in patients with TOF.[4] This can be applied to patients with TOF who have significant narrowing or stenosis of the pulmonary valve. Balloon valvuloplasty is often not successful in patients with significant infundibular or supravalvar pulmonary stenosis.

Balloon valvuloplasty involves the use of a catheter with a deflated balloon at its tip, which is inserted through the femoral vein and guided to the site of the pulmonary valve. Once positioned, the balloon is inflated to dilate the narrowed valve and improve blood flow from the right ventricle (RV) to the pulmonary artery (PA).[5] For balloon sizing, it is often best to first have an angiogram that shows the valve well. Subsequently, a balloon that is approximately 120% the size of the annulus should be chosen and used for the dilation.[6]

The procedure aims to relieve the obstruction caused by the stenotic pulmonary valve, allowing better blood flow to the lungs. This can alleviate symptoms such as cyanosis and dyspnea in patients with TOF.[7] The operator and anaesthesia team do need to be aware that during balloon valvuloplasty the patient could have a major hypercyanotic spell and be ready to treat appropriately. It is important to note that the appropriateness of balloon valvuloplasty in patients with TOF depends on various factors, including the severity of the stenosis, the anatomy of the heart, and the overall condition of the patient. Often times these patients do not respond to just a balloon valvuloplasty due to other areas of stenosis (often infundibular obstruction).

## RVOT stenting

RVOT stenting (Fig. 2) is becoming a procedure more commonly performed in patients with TOF.[7] The purpose of RVOT stenting in patients with TOF is to relieve the obstruction by having the stent cover the infundibular, valvar, and supravalvar stenoses, all of which will allow for improved blood flow from the RV to the PA. By placing an RVOT stent, the patient has relief of the obstruction to the pulmonary circulation and can be managed like other patients with TOF before complete surgical repair.

During the RVOT stenting procedure, a catheter is inserted into a blood vessel, typically through the groin, and guided to the site of RVOT obstruction. A long sheath is then usually advanced over a wire and past the area of stenosis. A balloon-expandable stent is then advanced through the long sheath over the wire to the area of stenosis and deployed across the RVOT. Oftentimes a single stent can be used, but if not all areas are covered by the stent, another stent can be used to fully relieve all levels of RVOT obstruction. The key to the procedure is ensuring that all areas of the RVOT are covered by the stent. Selecting a stent long enough from the start allows for a simpler procedure without having to add a second stent.

RVOT stenting offers several advantages over traditional surgical interventions, including less invasiveness, shorter hospital stays, and quicker recovery times. It is particularly beneficial for patients with significant RVOT obstruction who may not be suitable candidates for open-heart surgery due to various factors, such as age, associated medical conditions, or anatomic considerations. Another added benefit is the assumption that it provides a more physiological pulmonary blood flow pattern (over a surgical shunt) that allows for improved PA growth before surgical repair.[8] RVOT stenting has also shown a morbidity and mortality benefit over BTT shunt or PDA stenting.[9]

There are, however, some possible morbidity risks to RVOT stenting in patients with TOF. RVOT stenting does commit the patient to have a more extensive surgical repair that requires stent removal, obviates the ability to do a valve sparing TOF repair, and the possibility that the RVOT stent is too far into the RV and thus results in damage to tricuspid valve chordae. At the time of RVOT stenting, there is also a possibility of stent embolization or injury to the tricuspid valve. The stent can also migrate either too deep into the PA or too far back into the RV body. Given that there is a VSD in these patients, there are also reports of the stent migrating from the RVOT and causing distortion to the aortic valve.[10]

## PDA stenting

Gibbs et al.[11] described the first human PDA stent placement in 1992 for a patient with pulmonary atresia. However, PDA stenting (Fig. 3) has only gained popularity with refinements in stent technology and delivery. PDA stenting has now become a common and accepted procedure in patients with ductal-dependent pulmonary blood flow, such as symptomatic patients with TOF before complete surgical repair or patients with TOF/pulmonary atresia.[12]

PDA stenting has become more common at a wider range of centres, and it is being performed on ductal anatomies that were previously not thought to be conducive to stenting. The improvement in PDA stent technology using coronary artery stents has allowed for a larger patient cohort. The use of a computed tomography (CT) scan to better understand PDA and PA anatomy has become more common for preprocedure planning. The preprocedure CT scan allows for the operator to choose an ideal sheath location, wire position, and stent length, all before starting the case. Although previously these procedures were performed via femoral access, it is much more common to use the CT scan to plan either percutaneous carotid or axillary access. These vessels are larger than the femoral artery, so there is a reduced risk of vascular injury. When accessing either the carotid or axillary artery, it is also beneficial to flip the patient on the table so that the patient's legs are towards the anaesthetist. These techniques have provided greater technical success in stenting tortuous or unusual PDA anatomy and have resulted in shorter procedure times.[13]

Low-profile coronary stents are the predominant stents used for PDA stenting. These stents are designed to track over a 0.014″ wire and go through a 4 French (F) sheath. These stents are flexible and will readily adapt to the PDA

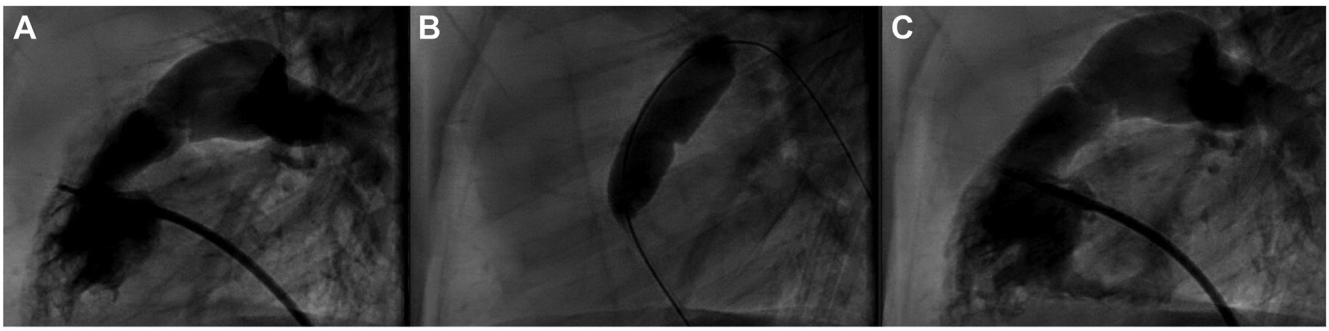


**Figure 1.** (**A**) Lateral angiogram of pulmonary stenosis before intervention. (**B**) Balloon dilation of the pulmonary valve with a small residual waist. (**C**) Lateral angiogram after valvuloplasty that shows improved pulmonary valve size.

morphology. When stenting a PDA, it is important to cover its full length. An area left uncovered can result in PDA constriction and reduced pulmonary blood flow and a need for reintervention. It is important to pay attention to the aortic side of the PDA and try to have as little stent in the aorta as possible to minimize impediment of systemic blood flow. Ideally, we should avoid jailing of the PA anatomy, but this is more difficult given the varying PDA-PA insertion, PA anatomy, and stent length. If PA jailing does occur, there is usually adequate flow through the side cells of the stents, and if not, the side cells can be dilated to promote PA flow. Jailing of the PAs has not been shown to impact long-term PA growth.[14]

Survival after PDA stenting vs BTT shunt placement in patients with TOF has demonstrated similar early survival outcomes but improved midterm outcomes in the PDA stenting group.[15] There have also been fewer complications, shorter hospital stays, and larger branch PAs in patients who have had PDA stenting compared with the BTT shunted cohort.[16] PDA-stented patients do have a higher reintervention rate compared with patients who had a BTT shunt.[17] This is likely due to these patients having multiple comorbidities and smaller size at the time of stent placement. Although these patients require reintervention, this might be beneficial in the long-term plan before surgical repair because it will allow for further growth of the patient and of the PA anatomy before complete repair.

## After Surgical Repair

Surgical repair for TOF involves the relief of RVOT obstruction and closure of VSD. There is however a great variability in RVOT morphology that requires careful selection of operative techniques to achieve optimal RV outflow. This often involves muscular resection and a transannular patch (TAP) repair. In certain situations, such as pulmonary atresia or an anomalous left coronary artery running in close proximity of the RVOT, reconstruction of RV-PA continuity with a conduit may be required. Surgical correction of TOF restores normal intracardiac blood flow necessary for survival and symptomatic relief, but the limited lifespan of these repairs frequently manifests as the child reaches teenage or adult years. Severe pulmonary regurgitation (PR) ensues after TAP, which over time leads to progressive RV dilatation, contractile dysfunction, arrhythmia, and heart failure.[18–21] In those with an RV-PA conduit, failure most eventually occurs due to calcific degeneration or somatic outgrowth, leading predominantly to conduit stenosis, but regurgitation or a combination of both can occur. The need for reinterventions is hence inevitable, and traditionally, the only treatment option is another open surgical procedure that gets increasingly complex with each redo sternotomy.[22] This was until the first transcatheter pulmonary valve replacement (TPVR) in 2000 was performed on a 12-year-old boy with RV-PA conduit dysfunction, which revolutionized the way we manage valvular heart disease and ushered in an era of transcatheter valve interventions.[23]

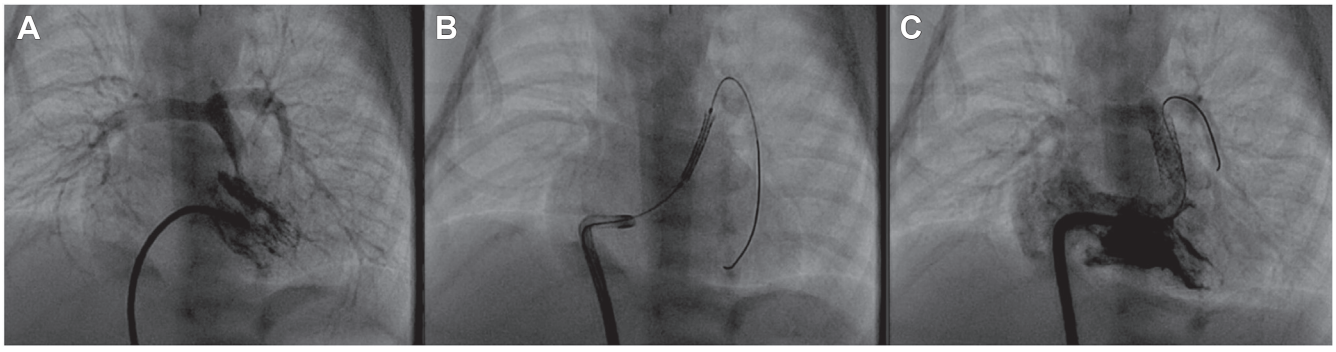


**Figure 2.** (**A**) Right ventricle angiogram demonstrating valvar and infundibular stenosis. (**B**) Right ventricular outflow tract (RVOT) stent in place with a wire in the distal left pulmonary artery (PA). The long sheath was pulled back to uncover the stent before inflation. (**C**) Angiogram after RVOT stenting demonstrated no infundibular stenosis and good flow to the branch PAs without evidence of jailing.

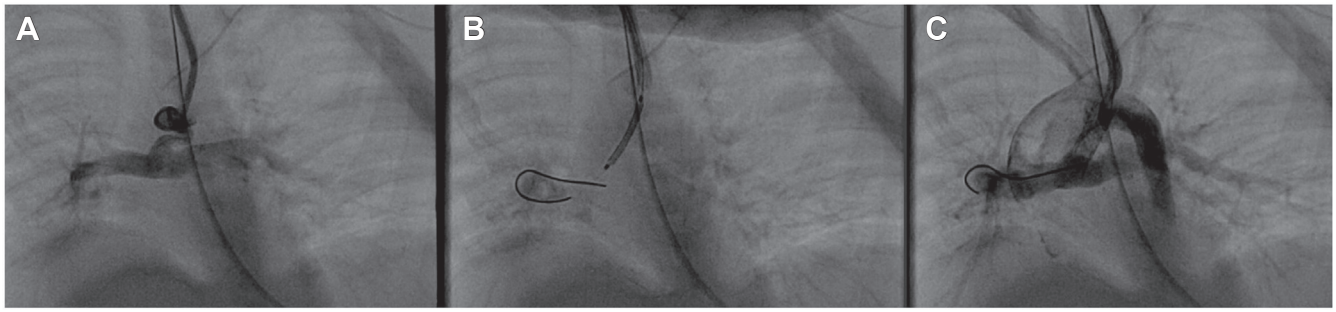


**Figure 3.** (**A**) Patent ductus arteriosus (PDA) angiogram via a carotid artery approach. The patient had been flipped on the catheterization table. There was a mildly tortuous PDA present with good size branch pulmonary arteries (PA) and no main PA. (**B**) Demonstration of stent placement across the PDA before stent inflation. (**C**) Angiogram after stenting demonstrated good flow to the branch PAs with no jailing of the branch PAs and a single stent that covers the full length of the PDA.

## TPVR procedure

Over the past 2 decades, since the first TPVR device was implanted, a variety of balloon-expandable and self-expanding TPVR devices have been developed. Even though these devices have different deployment methods and delivery systems, the general procedural steps remain largely the same. TPVR can be safely performed with conscious sedation, but general anaesthesia should be considered if a prolonged and complex procedure is anticipated. Femoral venous access is typically used for most transcatheter pulmonary valve (TPV) delivery, but certain anatomic angulations may necessitate a transjugular approach. Arterial access is obtained for coronary angiography and continuous blood pressure monitoring. Baseline right heart haemodynamic assessment and biplane angiography are performed to define the RV-PA anatomy and identify optimal implantation projections (Fig. 4A). A balloon-tipped end-hole catheter is advanced into the PA to establish a chord-free path for equipment to reach the implantation site. Depending on the pathology and TPV used, balloon predilatation and stenting may be required (Fig. 4, B and D). If there is concern of coronary artery compression, simultaneous RVOT balloon angioplasty and coronary angiography are performed (Fig. 4C). The technical steps of TPV deployment depend on the delivery systems of the respective devices. After deployment of the TPV, final haemodynamic assessment and angiography are performed to ensure a satisfactory outcome (Fig. 4, E and F).

## Periprocedural imaging for TPVR

Transthoracic echocardiogram (TTE) is the first step to evaluate the type and severity of RVOT dysfunction as well as the haemodynamic impact on RV size and function. Importantly, it serves as a baseline for comparison with postprocedural and follow-up TTE. Cardiac magnetic resonance imaging is frequently the next imaging modality for precise quantification of PR severity, ventricular size, and function to determine the optimal timing for intervention. Cardiac CT is critical for procedural planning. Contrast-enhanced electrocardiogram-gated acquisition covering the entire cardiac cycle is recommended to account for the dynamic changes in RVOT dimensions throughout the cardiac phases. The RVOT anatomy is assessed for its dimensions, morphology, angulations, and other relevant anatomic considerations such as calcification, residual leaflet tissue, branch PA anatomy, and distances to the coronary arteries (Fig. 5, A and B). In the Harmony valve preprocedural CT analysis, a perimeter plot of the RVOT is drawn in both systole and diastole with a Harmony TPV superimposed within to determine device fit (Fig. 5C). These detailed CT evaluations will guide appropriate device selection and sizing as well as the procedural conduct (vascular access location and the need for predilatation). Procedural imaging relies predominantly on fluoroscopic guidance. TTE or transesophageal echocardiogram may at times be used, but due to the anterior and superior location of the RVOT and PA, these structures are frequently suboptimally visualized. Intracardiac echocardiography has emerged as a useful imaging adjunct during the procedure. The imaging probe can be manoeuvred into the RV to face the RVOT, allowing for excellent close proximity imaging and for the Doppler signal to align in parallel to the RV outflow for the precise assessment of the presence and severity of paravalvular leaks (Fig. 5, D and E).

## TPVR devices

**Medtronic Melody valve.** The first TPVR performed went on to be known as the Melody valve (Medtronic, Minneapolis, MN) and received CE Mark in September 2006. The US Investigational Device Exemption (IDE) study began in 2007, and in January 2010, the Food and Drug Administration (FDA) approved the use of the Melody valve under Humanitarian Device Exemption for dysfunctional conduits, becoming the first transcatheter heart valve (THV) to be approved for commercial use in the United States. It subsequently received full FDA approval in January 2015 for failing pulmonary conduits and in February 2017 for failed surgical pulmonary bioprosthetic valves (BPVs).

The Melody is a balloon-expandable valve comprising a valved bovine jugular vein sutured within a platinum-iridium frame (Fig. 6A). There are 2 available valve sizes—Melody TPV 20, which consists of a 16 mm valve that can be deployed up to 20 mm, and Melody TPV 22, which consists of an 18 mm valve that can be deployed up to 22 mm. The TPV 22 has been shown to be dilated up to 24 mm without compromising on valve function.[24] The ensemble delivery system comes in 3 outer balloon sizes (18 mm, 20 mm, and 22 mm) with a 16 F shaft and a distal portion having a 22 F outer diameter.

By virtue of being the first available TPV, the Melody valve has the longest and largest amount of clinical evidence thus far. The US IDE study was a prospective nonrandomized study of the Melody valve that began enrolment in January 2007. Over a period of 3 years, 171 patients were enrolled from 5 centres and 150 had a Melody valve implanted. The study initially included only those with dysfunctional conduits but subsequently expanded to include those with failed surgical bioprosthesis. In 2022, the 10-year follow-up was published, providing us with the longest outcomes in patients who received a TPV.[25] At 10 years, the estimated survival was 90%, freedom from reoperation was 79%, and freedom from any reintervention was 60%. In those who survived and did not require reintervention, sustained clinical and haemodynamic benefits were demonstrated at 10 years. They had minimal symptoms with 78% in New York Heart Association (NYHA) class I and all in NYHA class II or less, 98% with mild PR or less, and the mean RVOT gradient was 19.2 ± 10.2 mm Hg.

**Edwards SAPIEN valve.** The next device to enter the pulmonary space is the SAPIEN (Edwards Lifesciences, Irvine, CA) THV series. This balloon-expandable THV was originally developed for transcatheter aortic valve replacement, but its versatility allows for use in the mitral, tricuspid, and pulmonary positions. The first TPVR with the Edwards valve was performed in 2006 on a 16-year-old patient with a stenotic RV-PA homograft.[26] The SAPIEN XT eventually received FDA approval 10 years later in 2016 for the same indication as the Melody valve.

The SAPIEN THV consists of bovine pericardial leaflets mounted on a cobalt chromium frame. In the SAPIEN 3 THV, the next iteration after the SAPIEN XT, an outer skirt was incorporated to reduce the incidence of paravalvular leak (Fig. 6B). It comes with 4 different valve sizes (20, 23, 26, and 29 mm) to treat a larger range of anatomies. Of note, the 29 mm valve can be expanded up to 31 mm without compromise in valve function.[27,28] Similar to transcatheter aortic valve replacement, the THV is mounted on the SAPIEN-specific delivery system (Commander; Edwards Lifesciences), which confers unidirectional steering capability that can be useful when traversing through the right heart chambers.

COMPASSION (Congenital Multicenter Trial of Pulmonary Valve Regurgitation Studying the SAPIEN Interventional THV) was a prospective, nonrandomized, IDE study of the SAPIEN THV for the treatment of dysfunctional RVOT conduits with moderate-to-severe PR and/or obstruction. A total of 81 patients from 7 centres in the United States were enrolled between April 2008 and November 2014. After further exclusion due to screen failure, 70 patients had device implantation attempted, and 69 patients had a successful device implantation. The 3-year results reported excellent symptomatic and haemodynamic improvement.[29] A total of 98.3% were in NYHA class I to II; peak and mean conduit gradients were 17.8 ± 12.4 mm Hg and 10.2 ± 7.8 mm Hg, respectively, and 91.1% had mild PR or less. Survival at 3 years was 98.4%, and freedom from reintervention was 93.7%.

The COMPASSION S3 was a prospective, single-arm, multicentre study seeking to evaluate the safety and effectiveness of the third-generation SAPIEN 3 for treating dysfunctional RVOT conduits and pulmonic surgical valves.[30] Among 11 sites in the United States, 58 patients were enrolled, and 56 had the device implanted. At 1 year, there was no mortality or RVOT reintervention. The mean RVOT gradient reduced from a baseline of 28.0 ± 1.7 mm Hg to 14.2 ± 1.0 mm Hg at 1 year, and 97.9% had mild PR or less.

**Medtronic Harmony valve.** However, the balloon-expandable valves have significant size limitations. Frequently, patients with TOF have had a TAP repair that predisposes them to develop dilated and aneurysmal RVOTs that are beyond the available size ranges of the Melody and SAPIEN valves. This unmet need was approached with a self-expanding platform, and the first implantation was performed in 2010 for a 42-year-old patient with severe PR and dilated RVOT.[31] This valve evolved to be known as the Harmony valve (Medtronic) and received FDA approval in March 2021 for the treatment of severe PR in both native and surgically repaired RVOT.

The Harmony valve is made of porcine pericardial tissue mounted on a self-expanding nitinol frame sewn to polyester fabric. The Harmony comes in 2 sizes (labelled the TPV22 and TPV25) and has an asymmetrical hourglass design (Fig. 6C). The TPV22 measures 41 mm at the proximal end, 22 mm at the level of valve housing, and 32 mm at the distal end, with a total length of 55 mm. It accommodates proximal PA/RVOT dimensions between 23 and 39 mm and distal PA/PA bifurcation dimensions between 22 and 28 mm. For the TPV25, the proximal end measures 54 mm, 25 mm at the valve housing, 43 mm at the distal end, and a total length of 51 mm. It can accommodate proximal PA/RVOT dimensions between 32 and 48 mm and distal PA/PA bifurcation dimensions between 25 and 38 mm. However, there are other anatomic considerations in deciding the implant size such as the shape, ellipticity, and curvature of the RVOT/PA anatomy. The delivery catheter is a triaxial system with a 25 F outer diameter.

The Harmony device was first evaluated in the Early Feasibility Study (EFS), which included 20 patients who had a TPV22 device implanted. The 1-month, 3-year, and 5-year results had been reported, which demonstrated the feasibility and sustained benefits of this device despite the very early experience.[32–34] There were 1 mortality, 2 surgical explants, and 2 TPV-in-TPV reinterventions. Of the remaining patients with available data, all had mild or less PR, and the mean RVOT gradient was 15.5 mm Hg at 5 years. Importantly, the data on those who failed screening (45 of 66 patients rolled) allowed for the design of the larger TPV25 device, which currently became the most commonly implanted valve size.

The largest study analysis to date on the Harmony valve was recently published, which consisted of the 1-year outcomes of a pooled cohort of 87 patients from 3 clinical studies—the Harmony EFS, Pivotal, and Continued Access studies.[35] There were no mortalities but 2 surgical explants with the TPV22 from the EFS study, as mentioned earlier, and 2 transcatheter reinterventions for the TPV25. Most patients had mild PR or less (TPV22 98%, TPV25 97%) and

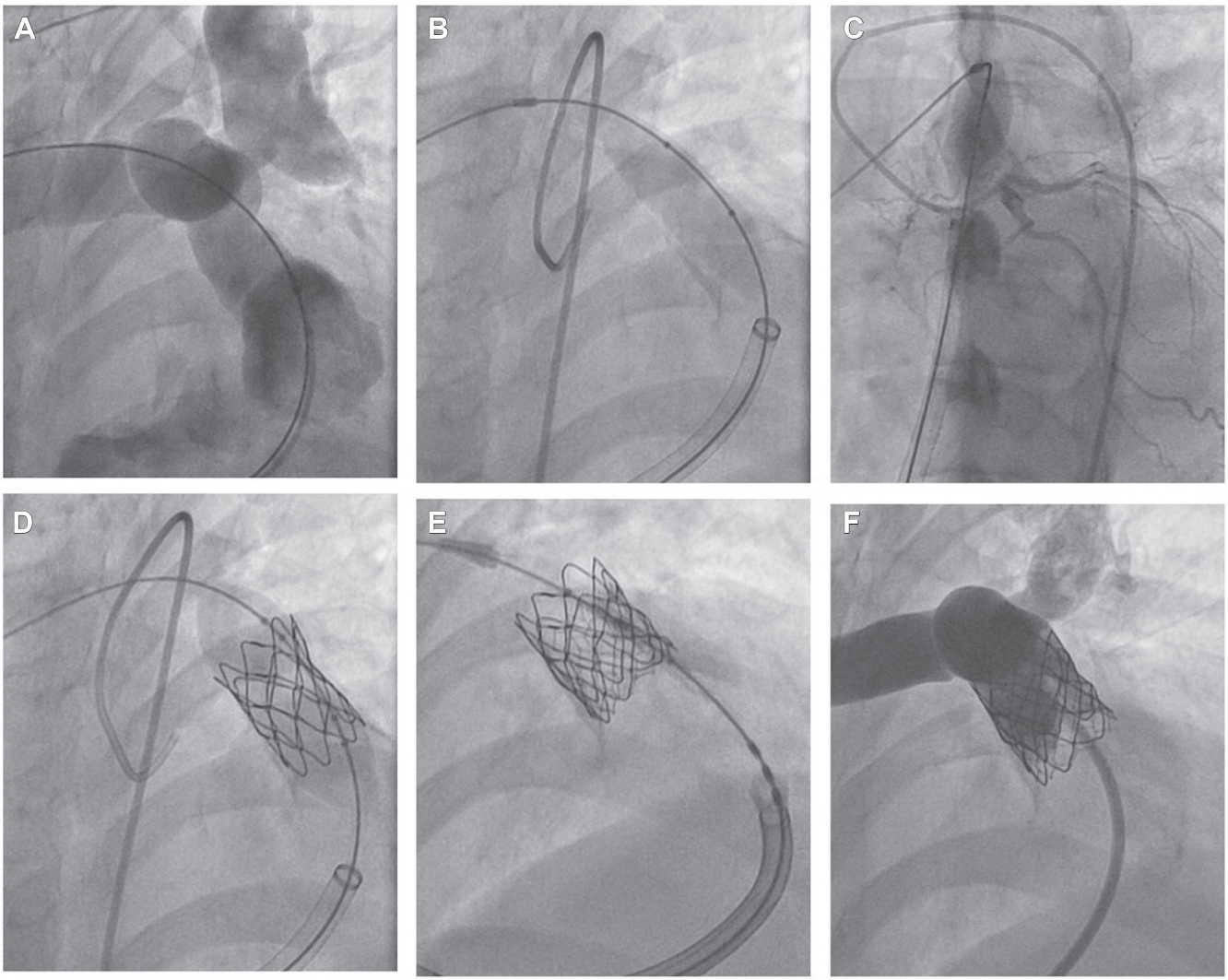


**Figure 4.** (**A**) Right ventricle-pulmonary artery (RV-PA) angiography to define fluoroscopic anatomy and optimal implantation projections. (**B**) Balloon dilatation of an RV-PA conduit. (**C**) Simultaneous coronary angiography and balloon dilatation to assess risk of coronary artery compression. (**D**) Prestenting of the RV-PA conduit. (**E**) SAPIEN 3 valve deployed within prestent. (**F**) Final PA angiography demonstrating no pulmonary insufficiency or RV outflow tract injury.

satisfactory mean RVOT gradients (TPV22 16.2 mm Hg and TPV25 10.9 mm Hg).

**Venus P-valve.** The Venus P-valve (Venus Medtech, Hangzhou, China) is another self-expanding TPV, which received CE Mark in April 2022. The valve leaflets consist of porcine pericardial tissues that are mounted on a self-expanding nitinol frame. The frame has proximal and distal flares and pericardial tissue covering most of the length of the device except the distal flare that has open cells to allow access into the left and right PAs (Fig. 6D). Radio-opaque markers are placed at the junction between the straight section and the proximal and distal flares for radiographic identification. The valve is located approximately 5 mm distal to the proximal marker. The device has a symmetrical hourglass design, with the proximal and distal flare being 10 mm wider than the diameter of the straight section. The Venus P-valve has a wide range of sizes to fit a variety of anatomies—the diameter of the straight section ranges from 28 mm to 36 mm (2 mm increments), with 2 lengths 25 mm and 30 mm. Hence the currently available Venus P-valve sizes can accommodate RVOT/PA dimensions of approximately 24-34 mm. The delivery catheter system comes in either 22 or 24 F and is matched to the size of the valve used.

The early short-term experience with the Venus P-valve has been encouraging.[36–39] The largest midterm results were of 55 patients from 6 centres in China.[40] The procedural success rate was 98.2% with 1 failure from valve migration into the RV 2 days after the procedure, which required surgical correction. At 1 year, there were 2 mortalities: 1 from infective endocarditis and 1 from a road traffic accident. Remarkably, no patients were lost to follow-up at 1 year. The peak pulmonary gradient was 16.3 ± 7.4 mm Hg, and all patients had mild PR or less. In addition, magnetic resonance imaging–derived indexed RV end-diastolic volume was reduced from

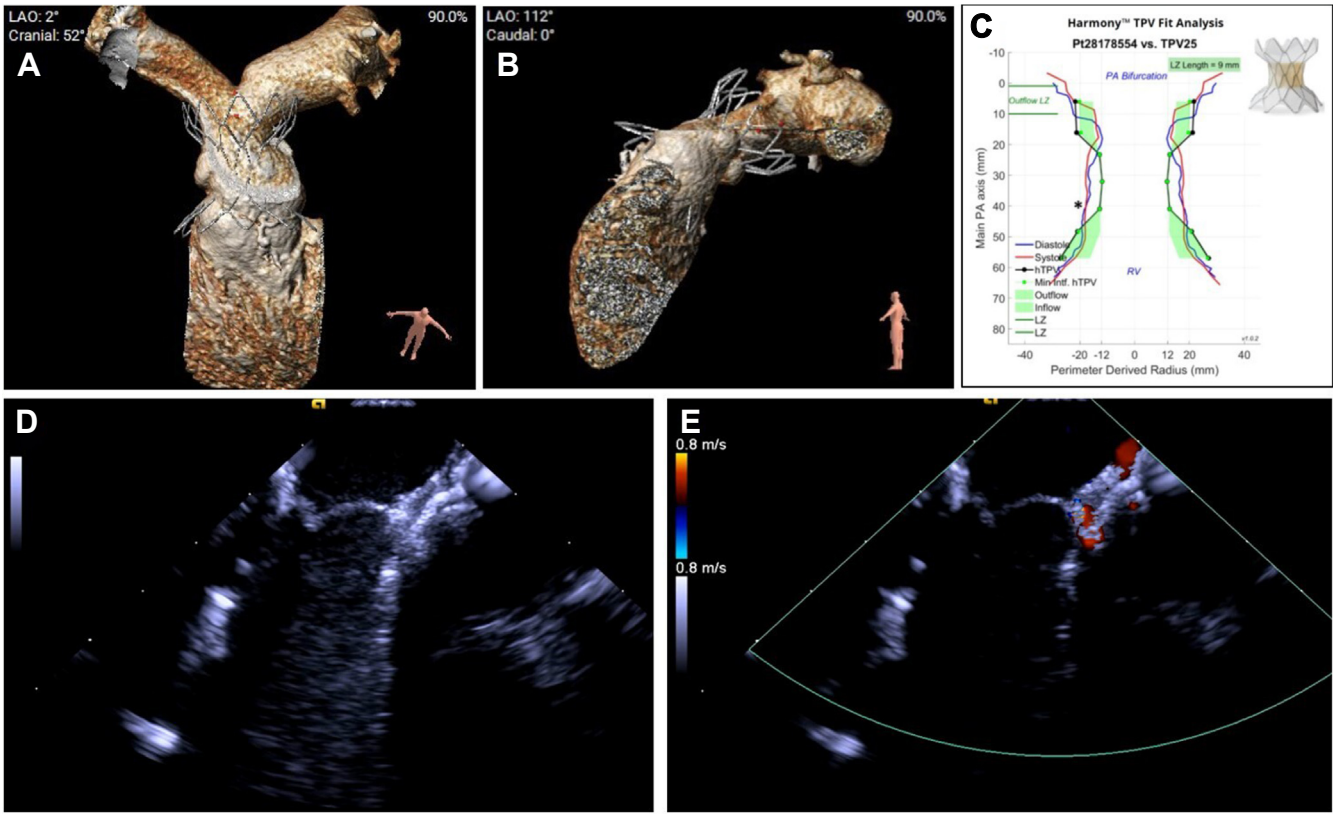


**Figure 5.** (**A**, **B**) Computed tomography 3-dimensional reconstruction of the right ventricular outflow tract (RVOT) to assess morphology and angulation as well as a Harmony TPV25 virtual valve in place to envision device fit. (**C**) Perimeter plot of the RVOT in both systole and diastole with the Harmony TPV25 valve dimensions superimposed within to assess device fit. (**D**, **E**) Intracardiac echocardiographic images showing excellent close proximity imaging of a newly deployed Venus P-valve with trivial paravalvular leak and no transvalvular leak. hTPV, harmony transcatheter pulmonary valve; LZ, landing zone; Min Intf, minimum interference; PA, pulmonary artery; RV, right ventricle; TPV, transcatheter pulmonary valve.

137.6 ± 15.8 mL/m$^2$ to 83.9 ± 16.0 mL/m$^2$ at 6 months, demonstrating desirable RV remodelling after TPVR with the Venus P-valve. In another pooled cohort of 38 patients from 6 countries outside China, the implantation success rate was 97%, and 1 required surgical intervention for valve migration.[41] At a midterm follow-up of 6-12 months, the peak RVOT gradient was 15.8 ± 6 mm Hg, and no patients had more than mild PR.

**Edwards Alterra Adaptive Prestent system.** The Alterra Adaptive Prestent (Edwards Lifesciences) is a self-expanding docking frame that seeks to reduce and reconfigure the widely variable RVOT morphology to make it suitable to land a 29 mm SAPIEN 3 valve within. It is made of nitinol with the polyethylene terephthalate skirt covering most parts of the frame except the outflow to allow blood to flow through the open cells into the branch PAs. It has a symmetrical design with inflow and outflow diameters measuring 40 mm and a central waist of 27 mm that serves as a landing zone for the 29 mm SAPIEN valve (Fig. 6E). The total length measures 48 mm. The device is recapturable and repositionable up to 50% of deployment. It received FDA approval in December 2021, soon after the Harmony valve.

The ALTERRA (Multicenter Early Feasibility Study of Congenital Pulmonic Valve Dysfunction Studying the SAPIEN 3 THV with the Alterra Adaptive Prestent) EFS study demonstrated the feasibility and safety of the device among 15 patients with moderate or greater PR, RVOT diameters between 27 and 38 mm, and length >35 mm.[42] The short-term results at 6 months reported no mortalities or reinterventions; all patients had no or trace PR, and the mean RVOT gradient was 9.0 (6.8-14.3) mm Hg.

## Complications and considerations with TPVR

The safety and feasibility of TPVR have been demonstrated in the studies mentioned above. However, there are some important complications and considerations to be aware of.

**Conduit rupture and coronary artery compression.** Conduit rupture is a dreaded complication that can occur during balloon angioplasty to prepare the RVOT landing zone before TPVR (Fig. 7A). Although RVOT injuries are not uncommon, fortunately clinically significant ruptures are rare.[43,44] Heavily calcified, small, aortic homografts pose the highest risk of conduit rupture.[43,45] In these high-risk anatomies, if serial balloon dilations are anticipated, it may be prudent to implant a covered stent before further dilating with larger balloons at higher pressures. Most conduit ruptures can be managed percutaneously with timely recognition and deployment of covered stents.

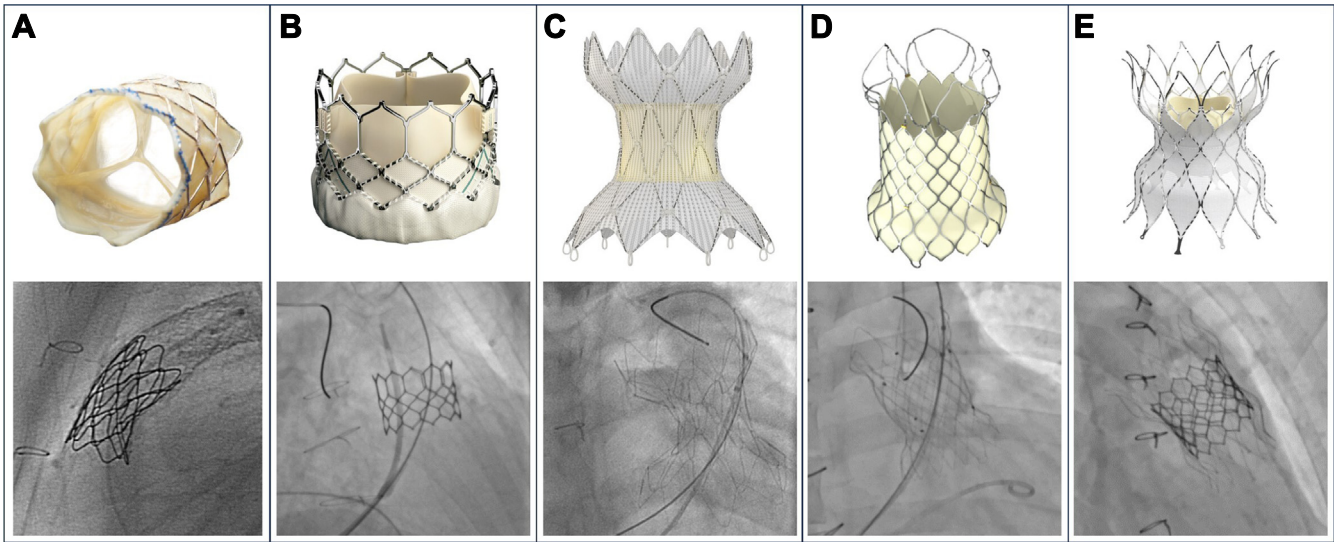


**Figure 6.** Transcatheter pulmonary valve device and fluoroscopic images for (**A**) Melody, (**B**) SAPIEN 3, (**C**) Harmony, (**D**) Venus P-valve, and (**E**) Alterra Adaptive Prestent with SAPIEN 3 within.

Coronary artery compression is another potentially life-threatening intraprocedural complication (Fig. 7B). This is preventable with simultaneous coronary angiography and balloon angioplasty with a balloon sized to the diameter of the desired TPV for implantation.[46] If coronary artery compression occurs at this stage, the TPVR procedure should be modified or abandoned.

**Endocarditis after TPVR.** Endocarditis after TPVR has been associated with significant mortality and morbidity and is a source of continuous debate (Fig. 7C). Our initial understanding had been based on results from smaller observational studies and predominantly on the longest available Melody valve. McElhinney et al[47] published the largest analysis thus far on endocarditis after TPVR and gave greater clarity on the incidence, risk factors, and consequences. In a multicentre registry of 2476 patients from 15 centres that included both Melody and SAPIEN valves, 182 patients were diagnosed with endocarditis at a median of 2.7 years after TPVR. The hazard for endocarditis was constant over time and similar to previous reports; the incidence rate was 2.2 per 100 patient-years.[48] With multivariable analysis, younger age of TPVR, prior history of endocarditis, higher postimplant peak RVOT gradient, certain congenital heart disease diagnoses, and having a BPV in the RVOT conferred a higher risk of developing endocarditis. Of great interest, although the incidence of endocarditis was higher with Melody than the SAPIEN valve, after multivariable analysis, there was no significant difference in the hazard of endocarditis between the 2 valves. This highlights the importance of taking into consideration the inherent difference in patient populations being treated with either the Melody or SAPIEN valves, of which many are competing risks for endocarditis themselves. Those treated with the Melody valve were significantly younger, more likely to have a conduit or BPV than a native/patched RVOT, more likely to have a stenotic than a regurgitant indication for TPVR, and have higher postimplant gradients—many of which were factors associated with endocarditis. Consequences were serious with 44% of endocarditis being classified as severe (death, use of extracorporeal membrane oxygenation, presentation in extremis, severe RVOT obstruction, or severe RV dysfunction) and 6.6% leading to death.

The exact reasoning for the increased incidence of endocarditis after TPVR is uncertain. Turbulence and nonlaminar flow causing endothelial damage has been postulated and is supported by the finding of high residual RVOT gradient being a risk factor. Therefore, it is paramount to achieve as low an RVOT gradient as possible within safety limits. The importance of antibiotic prophylaxis and dental hygiene must be enforced as these patients represent one of the highest risk populations for developing endocarditis—young patients with congenital heart disease and prosthetic heart valves who are exposed to a lifetime of repeated procedures.

**Stent fractures.** Stent fractures (SFs) have been another concern after TPVR and a common reason for reintervention (Fig. 7D). Multiple factors have been implicated that include the practice of prestenting, conduit environment, and possibly the type of TPVR device.

Cabalka et al[49] reported the incidence, risks, and outcomes of SFs among 309 patients from 3 prospective Melody valve multicentre studies. The focus of the analysis was on the 251 patients who had a stentless conduit (homograft, valved bovine jugular vein, nonvalved synthetic tube, or stentless biological valve). The 58 patients who had a prior stented BPV had a lower incidence of SFs than those who had a homograft or stentless conduit. This was congruent to earlier reports that support the logical deduction that the rigid scaffold provided by the BPV shields the implanted TPV from compressive stresses.[50,51] However, in this study, the lower incidence of SFs did not translate to a lower rate of reintervention—a reason that could not be explained. In the analytic population, SF occurred in 81 patients (32%), and

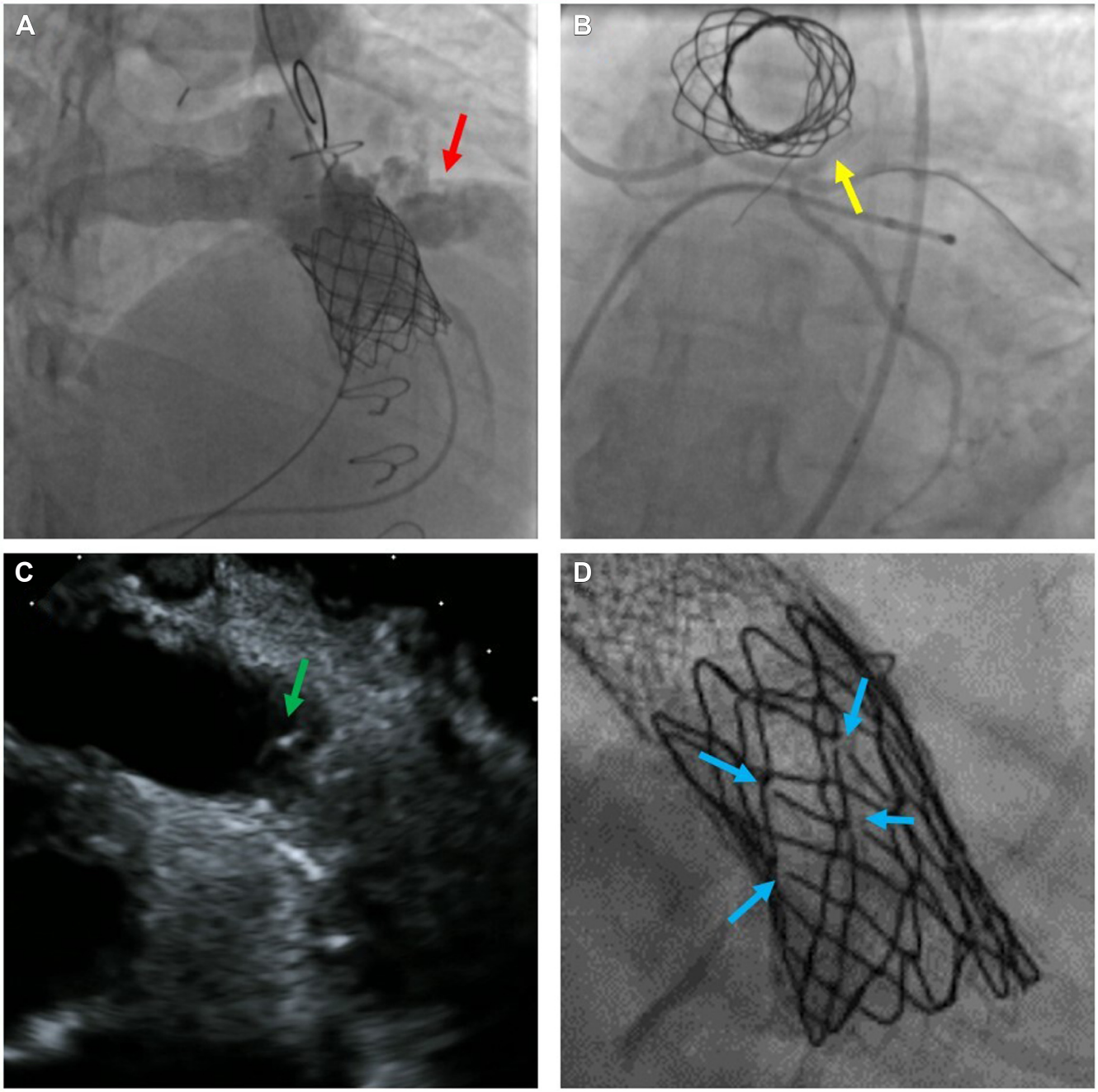


**Figure 7.** (**A**) Pulmonary angiography demonstrating contrast extravasation (**red arrow**) indicative of conduit rupture. (**B**) Coronary angiography showing occlusion of the proximal left anterior descending artery (**yellow arrow**). (**C**) Endocarditis of transcatheter pulmonary valve device (**green arrow**). (**D**) Multiple stent fractures (**blue arrows**) of the Melody valve.

reintervention was most often due to obstruction associated with SF. Through multivariable analysis, a larger conduit size and having a prestent were associated with a lower incidence of SF. In addition, having multiple prestents provided a greater protective effect from SF as compared with those who received 1 or no prestent. The type of prestent used was looked into during the analysis. There was a higher incidence of SF with the Cheatham-Platinum (CP) stent as compared with the Palmaz XL or ev3, but this was no longer significant after adjusting for preimplant RVOT gradients. Although no definite conclusion can be raised, this nonetheless raises some concerns on the radial strength of the CP stent, which is the scaffold used for the Melody TPV. The SAPIEN valve in turn has a cobalt-chromium alloy frame that provides high radial strength. Literature on the use of SAPIEN for TPVR is still limited, but in the early studies and to the best of our knowledge, there has been no evidence of SF so far.[29,30] Morgan et al[41] reported on their experience with the Venus P-valve—although SF occurred in 27% (8 of 30 patients), 7 had just single-wire fractures, and none of them had an impact

on valve function on echocardiography. As for the Harmony valve, in the pooled cohort of 87 patients, there was only 1 major SF (1.1%), but 11 minor SFs (12.6%) that did not pose a haemodynamic impact.[35]

Therefore, avoiding SF is critical to lengthen the time to reintervention. Prestenting is mandatory for the Melody valve, and in our opinion, multiple stents are recommended especially if the first stent is a CP stent. There is great variability in how SFs are classified and reported, as well as the imaging modality used (fluoroscopy or chest radiograph) for diagnosing SF during follow-up. Although most SFs are incidental isolated wire fractures with no haemodynamic impact, some are severe enough to compromise valve function or result in prosthesis instability. Hence there is a need for a standardized classification system that takes into account the anatomic extent of SF and the haemodynamic sequelae to allow for a more uniform reporting of SF.

**Ventricular arrhythmias.** Sudden cardiac death presumably from ventricular arrhythmias (VA) is the leading cause of death among patients with TOF, and its incidence increases in the second and third decade after surgical repair.[52,53] VA in patients with TOF arises as a sequela of ventricular dysfunction as well as from anatomically defined isthmuses after surgical repair. For the latter, catheter ablation has demonstrated excellent success with durable results.[54,55] However, the implantation of TPVR devices has raised growing concerns over the long-term management of VA. Current iterations of self-expanding valves are large with prosthetic material covering the RVOT, rendering the VA substrates inaccessible to catheter ablation in the future if clinically indicated. A preemptive approach of the routine electrophysiological study with programmed ventricular stimulation before PVR was assessed in a prospective study of 120 patients with TOF.[56] There was a substantial rate of patients with inducible ventricular tachycardia (VT) (27 patients, 22.5%), and this resulted in a change in peri-PVR management for 23 patients (19.2%), either with the addition of catheter ablation, surgical cryoablation, or having an implantable cardioverter-defibrillator. In a follow-up of 13 months, no patients experienced a sustained VA. Importantly, the procedure was safe with only 1 minor vascular complication that did not require interventional management. However, how this approach will impact future incidences of VA and sudden cardiac death remains to be elucidated. Further, larger studies with longer follow-up, preferably with a control group, are required to determine the optimal strategy—routine electrophysiological study and programmed ventricular stimulation with preemptive catheter ablation before TPVR or a risk-stratified approach.

VA that occurs after TPVR implantation is another topic of interest. The incidence of VT has been reported as high as 40% after the Harmony self-expanding TPV25 and 31% after balloon-expandable TPV with the Melody and SAPIEN valves.[57,58] Fortunately, majority of VA are transient with the highest incidence in the immediate postprocedure period and resolve with time. In addition, most are benign nonsustained VT, but 1 incidence of sustained VT degenerating into Torsades de Pointes was reported. Although the exact mechanism has yet to be defined, it is postulated to be mechanically driven from irritation of the RV myocardium by the newly implanted prosthetic material. This is supported by the observation of ventricular ectopy during the release of the inflow segment of self-expanding valves and the association of a higher incidence of ventricular ectopy with a lower annular implant position compared with a higher supra-annular implant.[58] There will be a need for further studies focusing on arrhythmia outcomes to determine the longer-term incidence and prognosis as well as the identification of risk factors.

**Survival and reintervention.** In the same multicentre cohort of 2476 patients who underwent TPVR for which endocarditis outcomes were reported above, mid- to long-term survival and RVOT reinterventions were evaluated.[59] At 8 years, the cumulative incidence of mortality was 8.9%. Not unexpected, those older and with more cardiac comorbidities were at higher risk of death. This was reflected on multivariable analysis that identified increased age at the time of TPVR, having a prosthetic valve in other positions and preexisting cardiac implantable electrical devices as risk factors associated with death. Endocarditis as a cause of death was more common among the younger patients, whereas the older patients were more likely to succumb from cancer or heart failure. The cumulative incidences of any TPV reintervention and surgical TPV explant at 8 years were 25.1% and 14.4%, respectively. Close to one-half of first reinterventions were another transcatheter procedure (balloon angioplasty or TPVR), and of note, only 10 of these 122 patients subsequently needed a surgical replacement. By multivariable analysis, the risk factors for reintervention include a younger age of TPVR, having a prior Ross procedure, and a higher postimplant RVOT gradient.

Thus far, there are no randomized controlled trials between transcatheter and surgical pulmonary valve replacement (SPVR), but the 8-year outcomes reported above are comparable with surgical data.[60−63] Similarly, in studies that compared TPVR and SPVR, survival and reintervention rates were largely similar with 1 meta-analysis demonstrating lower mortality with TPVR and a nonstatistically significant higher reoperation rate with TPVR.[64−67] However, these results should be interpreted with caution especially due to selection bias and the marked heterogeneity in the patient cohorts between studies and among those who received TPVR or SPVR.

## Conclusion

In this article, we reviewed the available transcatheter therapies for patients with TOF. Before surgical repair, staged palliative procedures are now more commonly performed through transcatheter means as compared with traditional surgical methods. RVOT dysfunction inevitably follows initial surgical relief of RVOT obstruction and manifests as either stenosis, regurgitation, or a combination of both pathologies. The comparable safety and efficacy of TPVR with SPVR as well as the addition of self-expanding platforms have led to a wider population that can be treated with TPVR. With technological advancement, maturation of procedural techniques, and greater operator experience, catheter-based interventions will likely have an increasing role in the lifetime management of the patient with TOF.

## Ethics Statement

There is no new data reported here and the research reported has adhered to the relevant ethical guidelines.

## Patient Consent

The authors confirm that patient consent is not applicable to this article.

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