



What Interventional Cardiologists Are Still Leaving to the Surgeons?

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Nowadays, development of new technologies is still ongoing with the ultimate goal of maximizing treatment outcomes with less invasiveness and reduced procedural risk. This review is intended to update on when interventionalists need surgical support in common or emerging problems in congenital heart disease.

Keywords: catheter intervention, surgical therapy, congenital heart disease, interventional cardiologist, collaboration

EVOLUTION OF TECHNOLOGY FOR CATHETER INTERVENTION MAKES THE IMPOSSIBLES POSSIBLE

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Promphan W and Qureshi SA (2016) What Interventional Cardiologists Are Still Leaving to the Surgeons? Front. Pediatr. 4:59. doi: 10.3389/fped.2016.00059 During the last 60 years, medical engineering technology has helped to make important advances in transcatheter treatment of congenital and structural heart disease. Catheter-based therapy in congenital heart disease (CHD) became a reality in 1953 with the first description of pulmonary valvoplasty by Rubio-Alvarez et al. (1). Since then, balloon dilation has proved its efficacy (2, 3) and has become treatment of choice for pulmonary valve stenosis. The next paradigm shift of transcatheter CHD therapy was the novel approach of balloon atrial septostomy (BAS) for cyanotic patients with transposition of the great arteries (TGA) in 1966 by Rashkind and Miller (4). Later in the late 1960s, the first percutaneous occlusion of patent ductus arteriosus (PDA) using Ivalon (polyvinyl alcohol) plug was reported (5). In the ensuing 10 years, transcatheter closure of atrial septal defect (ASD) became a reality with a specially designed Dacron-covered stainless steel umbrella device, reported by King & Mills (6). Thereafter, the 1980s was the era of stainless steel material for endovascular stents and occlusion devices (7-9). In the early 1990s, laser and radiofrequency technologies became major contributors of balloon-assisted valvoplasty in pulmonary valve atresia (10). In the late 1990s, novel design of shape-memory devices made from a nickel and titanium (nitinol) metal alloy completely changed the way physicians treat common CHDs (11-13). Nitinol technology has also been used in self-expandable stent platforms for endovascular stents and percutaneous bioprosthesis valves (14, 15).

ATRIAL SEPTOSTOMY

Percutaneous creation or enlargement of the interatrial communication is the earliest collaborations between interventionalist and surgeon in the history of CHD treatment. Over 50 years, BAS has been stabilizing hypercyanotic transposition of TGA babies prior to corrective surgical repair. However, from recent publications, 43–62% of the cases cannot discontinue prostaglandin E1 after the successful BAS (16–18). Apart from enhancing the oxygenated–deoxygenated blood mixture, BAS remains indicate to augment cardiac output in patients with the right or left heart obstructions (e.g., tricuspid atresia, pulmonary valve atresia associated with RV coronary dependent circulation, mitral atresia, aortic atresia). The complications after BAS are unlikely to occur nowadays. These include balloon rupture, failure in balloon deflation, rupture of the atrial appendage, injury of cardiac structures, and

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transitory rhythm disturbances (19). Although various additional techniques have been developed over the years for creation or enlargement of the septum in complex anatomy (e.g., blade atrial septostomy, static balloon dilation, radiofrequency perforation or transeptal puncture, and stent implantation of the interatrial septum), the goal of these methods is a bridge to definite surgical treatment.

The majority of common CHDs are now treatable percuteneously. However, surgery is still an option for many of these common CHDs and surgeons are still needed to treat some of these defects.

PATENT DUCTUS ARTERIOSUS CLOSURE

Patent ductus arteriosus is one of the most common CHDs in all ages. Since the first report of transcatheter closure 50 years ago, currently, transcatheter PDA closure has become a widely accepted procedure worldwide with comparable results to surgical therapy (20, 21). Major adverse events of transcatheter PDA occlusion (i.e., device embolization, hemolysis, and obstruction of the left pulmonary artery/aortic isthmus) can occur with incidence of 0.6–83.3% depending upon the selected device (18, 19). It is indicated for a symptomatic moderate to large PDA with leftto-right shunt or previously known occurrence of endocarditis. However, for a small or silent PDA, transcatheter PDA closure may be considered in some countries and avoided in others (22). A variety of devices are available for closing PDAs (23, 24). These have their own advantages and disadvantages. In general, for a small PDA of <2 mm at its narrowest point, closure can be achieved with coils or the Amplatzer Duct Occluder II (ADOII; St Jude Medical, MN, USA) (Figures 1A,B). For a large PDA, the disk devices are preferred (Figure 1C). With custom-made disk devices, a duct of 16-mm diameter or more can be occluded successfully nowadays with a lower risk (25). In addition, with reduction of the delivery system from 18Fr (in 1967) to 3-4 Fr, the feasibility of transcatheter PDA closure is considerably improved, even in newborns (26, 27), and is associated with a shorter recovery time than surgical ligation (28). However, percutaneous PDA closure in neonates and infants is an emerging field with some limitations of available devices and instruments. It seems to have relatively higher major adverse events than in older children (29). Therefore, the procedure has to be balanced with the experience of the operators and the capabilities of the unit, as surgical PDA ligation remains a standard and safe procedure in small babies (30). Further development of a robust device and delivery system that fits to a unique morphology of the duct in prematurity (31) will make transcatheter PDA closure become treatment of choice for symptomatic preterm and/or low-bodyweight infants in the near future.

ATRIAL SEPTAL DEFECT CLOSURE

Double-disk devices are now becoming universal for percutaneous closure of secundum ASDs (Figure 2). In common practice, patients with the body weight more than 15 kg who have hemodynamic significant secundum ASD and suitable anatomical features are indicated for percutaneous ASD closure (22). Transcatheter closure has shown comparable outcome to surgery in pediatric and adult patients, with low complication rates, short anesthetic times, and short hospitalization (32–34). However, once a complication occurs, it sometimes leads to urgent surgical treatment, which is then associated with a higher morbidity and mortality than elective surgical ASD closure (35). Complications after device implantation include device embolization, cardiac perforation, thrombo-embolic events, cardiac arrhythmia, or significant residual shunt. Although the risk of long-term complications after device implantation is very low, several case reports and literature review have shown that these particular problems, such as erosions, may occur 8 years after the initial device closure (36, 37). Therefore, patient selection and comprehensive short- and long-term follow-up are necessary for

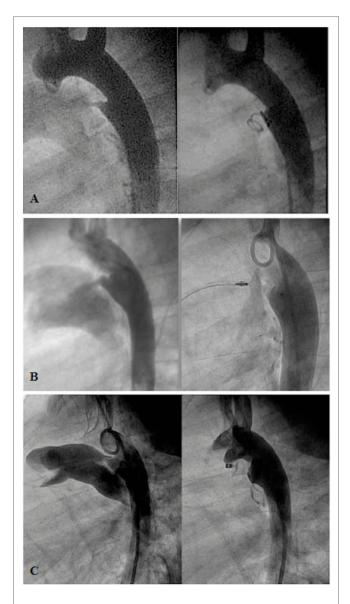


FIGURE 1 | Angiogram in lateral projection of PDA closed by coil (A), Amplatzer Duct Occluder II (ADOII) (B), and Occlutech Duct Occluder (C).

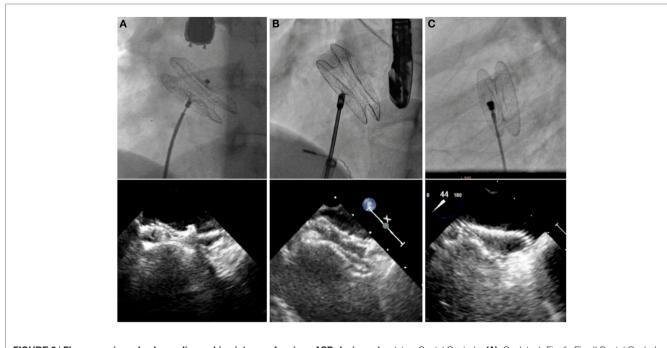


FIGURE 2 | Fluoroscopic and echocardiographic pictures of various ASD devices. Amplatzer Septal Occluder (A), Occlutech Figulla Flex II Septal Occluder (B), and CeraFlex ASD Occluder (C).

all transcatheter ASD closure patients. There are some defects with deficient rims in more than one area or very large ASDs, which still require surgical treatment.

VENTRICULAR SEPTAL DEFECT CLOSURE

Surgery has been the standard treatment of ventricular septal defects (VSDs) for decades. It has been shown to be effective and safe (38). However, with continuous development of novel occlusion devices, transcatheter VSD closure has become an effective alternative treatment modality in appropriately selected patients. The limitation of percutaneous VSD closure relates to the complexity of the defect and the proximity of the defect to adjacent structures, such as aortic, pulmonary, and tricuspid valves. In addition, those VSDs that are close to the membranous area, where the perforating branch of the conduction system lies underneath, closure with a high radial and compression force device may lead to the serious complication of permanent highgrade atrio-ventricular block. During the early phase of transcatheter treatment for perimembranous (pm) VSDs, the eccentric Amplatzer membranous VSD occluder (St Jude Medical, MN, USA) was thought to be effective (39). However, the incidence of post-procedural complete heart block (6-6.5%) was higher than surgery (40, 41). Currently, transcatheter perimembranous ventricular septal defect (pmVSD) closure has not been approved in the US and many countries in Europe. However, in the East, a variety of available devices, which are matched to the different defect morphology and exert less pressure onto the ventricular septum (Figure 3), transcatheter pmVSD closure is considered

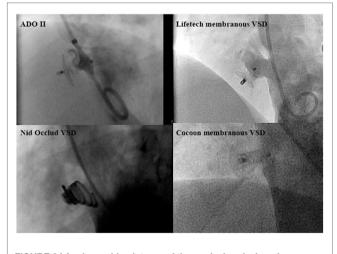


FIGURE 3 | Angiographic pictures of the occlusion devices for perimembranous ventricular septal defect (pmVSD).

to be acceptable efficacy, with low complication rates, especially complete heart block (incidence of 0-3%) (41–44). Recently, periventricular mini-thoracotomy VSD closure has emerged as a surgical alternative in China (45, 46). In the special circumstance of muscular or apical VSDs in infants or small children, working in close collaboration with surgeons, an interventional hybrid approach has become an attractive modality (22). Post myocardial infarction VSDs, where surgery may have been ruled out because of unacceptable high risk or in cases of postoperative residual shunt, percutaneous closure may be used (22). Most cyanotic CHDs usually require surgery. Catheter intervention is a complementary approach to fulfill the optimal treatments in the following circumstances.

PDA STENTING IN DUCT-DEPENDENT PULMONARY CIRCULATION DEFECTS

Surgical systemic-to-pulmonary shunt (SPS), which mimicked the function of a PDA, has provided effective palliative treatment for duct-dependent pulmonary circulation defects for almost 70 years. In the recent years, SPS has been more commonly performed in patients with more complex defects, such as singleventricle anatomy and pulmonary atresia than tetralogy of Fallot (TOF). In spite of wide clinical experience, neonatal mortality after SPS has ranged from 5 to 9% in the last two decades (47, 48). Recently, from the United Kingdom national database, the early mortality rate was 9.8%. In addition, at 1.5 years, 13.9% of patients had died, and 17.8% needed shunt reintervention (49). This is probably a reflection of the more complex types of defects in whom SPS has been performed. Currently, with the availability of flexible and low profile coronary artery stents, duct stenting can be performed safely through a 4F-5F sheath, as an alternative to SPS (Figure 4). However, not all the ducts can be stented. The success rate of PDA stenting depends on the complexity of the ductal morphology. Pulmonary atresia with intact ventricular septum is usually associated with a better chance of success with PDA stenting than the univentricular physiology or complex pulmonary atresia, in which the ductus arteriosus is usually tortuous (50, 51). Alwi and colleagues (52) reported an early mortality of 5.4% after ductal stenting with freedom from reintervention of 89% at 6 months and 55% at 12 months. It is reasonable to assume that none of the surgical and transcatheter palliative treatments for duct-dependent pulmonary circulation are perfect procedures. Both approaches have their own benefits

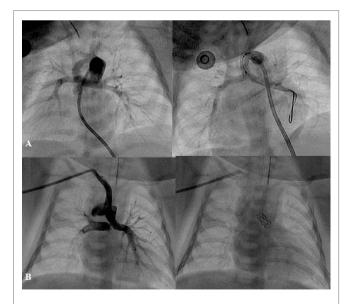


FIGURE 4 | Angiographic pictures of PDA stenting from different approaches: (A) from femoral artery and (B) from right axillary artery.

and drawbacks, which require particular choice of the treatment in accordance with the particular defects, the availability of the devices, and the preference of the individual institution.

RIGHT VENTRICULAR OUTFLOW TRACT STENTING

Right ventricular outflow tract (RVOT) stenting has been an effective palliative therapy in hypercyanotic neonates and young infants with TOF, in whom surgical therapy is considered unsuitable or a high risk (Figure 5). Stenting may promote symmetrical growth of the pulmonary arteries without branch distortion as shown from the literatures of significant increase of pulmonary branch diameters (53-55). Also, in those babies in whom the obstruction is predominately at infundibular level and the pulmonary valve is well functioning, stenting of the RVOT with pulmonary valve sparing placement of the stent may improve the oxygen saturation without compromising of the right ventricular outflow performance and without causing free pulmonary regurgitation. Some months later, once the patient is ready for a definitive repair, the RVOT stent can be removed with limited technical surgical difficulties. However, a majority of the RVOT stented patients may require transannular patch because of the size of the pulmonary valve annulus (56).

HYBRID PALLIATION FOR HYPOPLASTIC LEFT HEART SYNDROME AND COMPLEX SINGLE VENTRICLE

A combination of surgical and interventional catheterization as a targeted strategy, for example, by palliating a newborn with hypoplastic left heart syndrome (HLHS) using percutaneous ductal stenting (**Figure 6**) and bilateral branch pulmonary artery banding, was first described in 1992 (57). The aim of this approach is to minimize complications of HLHS Norwood Stage I operation for high-risk patients (e.g., small patient size, severe ventricular dysfunction, severe tricuspid regurgitation, small ascending aorta size, and multisystem organ failure) or as a bridge to transplantation. This strategy can also be performed in a variety of univentricular defects, in which systemic outflow or aortic arch

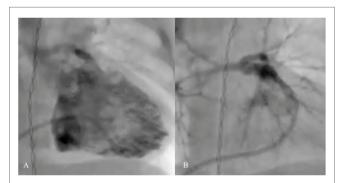
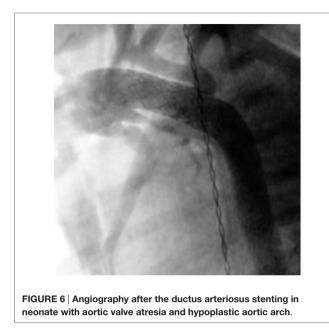


FIGURE 5 | Pre- (A) and post-procedural (B) angiography of the right ventricular outflow tract (RVOT) stenting in neonatal tetralogy of Fallot with severe infundibular stenosis.



appears hypoplastic (58, 59). Retrograde aortic arch obstruction with the PDA fully open is considered a contraindication to the hybrid stage I palliation, since the struts of the implanted stent may acutely compromise retrograde coronary blood flow (22). Reintervention after hybrid palliation is relatively frequent and reduction of mortality remains an opportunity to improve. Recently, Murphy et al. reported overall survival of 56.1% at a median follow-up of 32 months after hybrid palliation (59). Yerebakan et al. reported the follow-up results at 4.6 years after Giessen hybrid stage I palliation showing the operative mortality of hybrid stage I of 2.5%, comprehensive stage II of 4.9%, Fontan completion of 0%, and cumulative interstage mortality of 14.2% (60). The hybrid approach requires a novel mindset of collaboration between surgeons and interventionists along with high-end hybrid surgical suite. Hybrid palliation is a strong foundation of further collaboration for treatments of other complex congenital and structural heart defects.

CATHETER INTERVENTIONS IN FONTAN CIRCULATION

Surgical total cavopulmonary connection (TCPC), for the treatment of tricuspid atresia, was first described in 1971 by Fontan et al. (61). At present, with several modifications of the surgical technique, TCPC is the definitive treatment for most univentricular hearts. However, catheter intervention has become a major contributor pre-operatively or once these patients develop unstable hemodynamics, due to excessive pulmonary blood flow, low cardiac output, high venous pressure, progressive cyanosis, or obstruction in the pulmonary pathways. Pre-operative embolization of the excessive systemic-to-pulmonary collateral reduces the possibility of pulmonary hemorrhage and increased pulmonary arterial pressure due to overperfused lungs. Balloon angioplasty (BA) with or without stent implantation helps



FIGURE 7 | Failing extra-cardiac Fontan circuit (A) treated by stenting of the hypoplastic left pulmonary artery (B) and diablo stenting of the restrictive fenestration (arrow) (C).

to create unobstructed pathways, which aim to optimize the pressures in this circuit (**Figures 7A,B**). Dilation or creation of a fenestration may stabilize the cardiac output in the early postoperative period (**Figure 7C**). In patients in whom cyanosis has persisted, occlusion of abnormal venous collaterals or previously created fenestration will improve systemic saturation. Completion of the Fontan or Glenn type of circulation may also be achieved percutaneously in carefully selected patients (62, 63). In addition, taking down the Fontan by enlargement of the fenestration and occlusion of the conduit to pulmonary artery has been reported in patients with early failure of the Fontan circulation (64).

Stenosis of the valves or vessels can be treated percutaneously. However, surgery remains treatment of choice in small children, with complex anatomy, or with residual lesions, or those in whom complications may have occurred after an intervention.

PULMONARY VALVOPLASTY

Percutaneous balloon valvoplasty is feasible in most pulmonary valve stenosis patients (**Figure 8**). Post-procedural residual pressure gradient is usually <30 mmHg in 68–92% of the patients with low incidence of major adverse events after the procedure (65, 66). Approximately 80% of the patients are free from reintervention over 10 years (67, 68). Pulmonary valve insufficiency developed in 10–40% after balloon valvoplasty (69). This incidence and the severity appear to be less than after surgery (70). Surgical valvotomy, however, is the mainstay of treatment in patients with mainly subvalvar, supravalvar, and multi-level of obstructions.

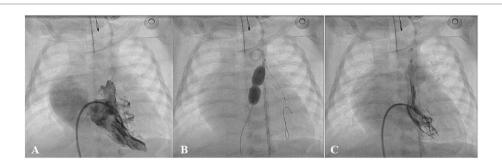
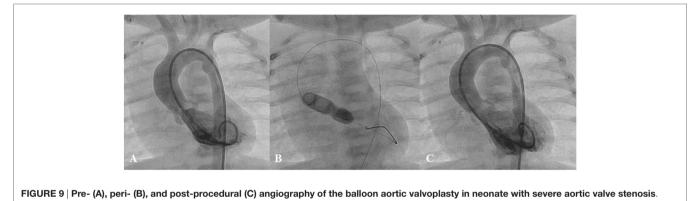


FIGURE 8 | Pre- (A), peri- (B), and post-procedural (C) angiography of the balloon pulmonary valvoplasty in neonatal critical pulmonary valve stenosis.



AORTIC VALVOPLASTY

Balloon aortic valvoplasty is now considered a safe procedure although it is less predictable with regard to the outcomes compared with balloon pulmonary valvoplasty. From the most recent multicentre registries (29, 70), 61.5–71% of procedures achieved a residual gradient \leq 35 mmHg after single-balloon aortic valvoplasty. Moderate-to-severe aortic regurgitation appeared in 17.4–19% after treatment, while unplanned cardiac surgery was needed in 1%. Neonatal balloon aortic valvoplasty and mixed obstructions are considered to be at high risk for complications, death, and suboptimal outcomes (70) (**Figure 9**). Surgical correction is indicated in patients who develop major complications, such as severe aortic regurgitation, or aortic cusp avulsion, or those who have a residual significant pressure gradient, or multi-level of obstruction, or when associated with other cardiac lesions.

TREATMENT OF COARCTATION OF THE AORTA

Surgery is accepted as an effective and preferred treatment in neonates and infants with coarctation of the aorta (COA) (71, 72). However, in older children or adults, surgical morbidity is more frequent and may be detrimental (73, 74). BA has become an alternative treatment to surgery since 1983 (75, 76). Although the immediate results were relatively good, this procedure carries the risk of restenosis and aortic wall complications, especially after BA in native COA patients (77-79). Currently, BA is recommended as the treatment of choice only for children with aortic re-coarctation (29). Stent technology has evolved rapidly over the past two decades. Stent implantation is associated with effective outcomes in older children or adults with native or recurrent coarctation compared with surgery (74, 80-82). With open-cell stent design, complex coarctations can be treated safely without sacrificing the head and neck branches. Covered stents may be used to overcome or even prevent complications, such as aortic wall injury (83). With evolution of device technology, stent implantation in complex anatomy, such as nearly or completely interrupted arch, or multi-level obstruction, is feasible with favorable outcomes (84) (Figure 10). However, stent therapy in infants and small children with native COA has remained challenging for many years because of the need to expand the implanted stent to an adult size. Several breakable, over-dilatable, and biodegradable stents have been developed to overcome these limitations. Currently, stenting of native COA, even in small children, is feasible with excellent short-term outcomes (85-87).

STENOSIS OF THE PULMONARY ARTERY

Stenosis of the proximal pulmonary artery branches, which are proximal to the hilum of the lungs, can either be tackled by surgery

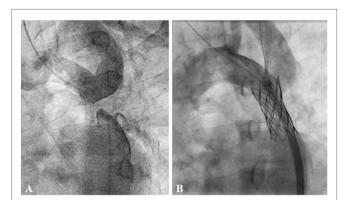


FIGURE 10 | Pre- (A) and post-procedural (B) angiography of the covered CP stent implantation in the interrupted descending aorta: Courtesy of Nageswara Rao Konati.

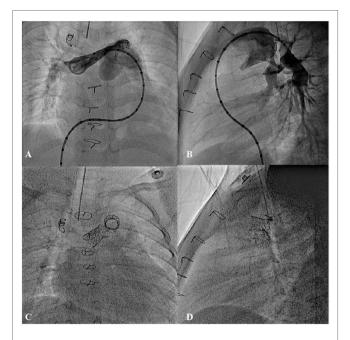


FIGURE 11 | Bilateral pulmonary artery stenting in post Rastelli type operation for type I truncus arteriosus with severe bilateral proximal pulmonary branches stenosis. (A,B) Pre-procedure and (C,D) Post-stent implantation.

or catheter intervention. However, stenosis within the lung parenchyma can only be treated by endovascular approach, usually during catheterization or, less often, during hybrid surgery (88). Recurrent stenosis after surgery may occur in 35–40% of patients due to scar formation, distortion of the reconstructed vessels, or external compression (89, 90). In small children or patients with complex anatomy, primary BA may be used in severe main or branch pulmonary artery stenosis (22). However, in branch pulmonary artery stenoses, standard BA may have success rates of 50–60% with a recurrence rate of 15% and complication rate of 6–12% (88, 90–92). High-pressure and cutting balloons improved

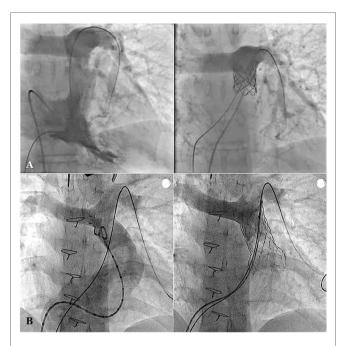


FIGURE 12 | Pre- and post-procedural angiography of the Melody valve implantation in post right ventricular outflow tract patch repaired pulmonary atresia with intact ventricular septum with severe pulmonary insufficiency (A) and Venus P-valve implantation in post transannular patch repaired tetralogy of Fallot with severe pulmonary regurgitation (B).

the success rates, especially in younger patients with resistant lesions (93, 94). However, with continuous improvement of the stent technology, in most patients, stenting has become a treatment of choice for branch pulmonary artery stenosis. Stents can be implanted effectively in patients with surgery-related stenosis, bifurcation stenosis, multi-level obstruction, or stenosis from the pressure effect of the adjacent structures (22, 95) (**Figure 11**). In growing children, however, they will require further dilation until the vessels reach adult diameter. In recurrent or complex stenoses, they usually need several attempts for pulmonary artery branch rehabilitation.

PERCUTANEOUS PULMONARY VALVE IMPLANTATION

In order to accomplish complete bi-ventricular repair in various CHDs, such as tetralogy of Fallot, double outlet right ventricle, truncus arteriosus, or transposition of the great artery with ventricular septal defect, RVOT reconstruction with or without conduit replacement has been the mainstay of surgical treatment for decades. However, most of these reconstructed RVOTs will eventually develop dysfunction, and multiple surgical reinterventions may be needed during the lifetime of the patients (96, 97). Currently, percutaneous pulmonary valve implantation (PPVI) is considered an effective alternative treatment for conduit dysfunction (97) (**Figure 12A**). However, with limitations of the available valve diameters and the size of delivery systems, current

exclusions of PPVI are dysfunctional large native RVOTs and body weight <30 kg (22, 97). To overcome the RVOT limitation, modifying the percutaneous valve into a self-expandable platform has shown feasibility to implant these valves into large native RVOTs up to 32 mm in diameter (15) (**Figure 12B**). In the near future, with continuous improvement of the valve design, PPVI will become a standard treatment in most dysfunctional post-surgical RVOTs. However, longevity of these valves is yet to be determined.

CONCLUSION

Although interventional cardiologists have been able to treat many congenital heart defects without surgery, there are still

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numerous defects which need the surgeons. Furthermore, there is an increasing trend toward collaboration involving both the interventionist and the surgeons, with the aim of improving the patient outcomes.

AUTHOR CONTRIBUTIONS

WP: drafting and writing the work. SQ: revising it critically for important intellectual content; final approval of the version to be published. They both agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Conflict of Interest Statement: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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