Transcatheter interventions in patients with congenital heart disease (CHD) have paved the way for the development of the field of interventional cardiology. In 1966, Rashkind and Miller described balloon enlargement of an atrial septal communication in 3 infants to facilitate intracardiac mixing in the setting of transposition of the great arteries. Charles Mullins, another great pioneer in the field of congenital interventions, later reflected “The initial response to this report varied between admiration and horror but, in either case, the procedure stirred the imagination of the ‘invasive’ cardiologists.”

Abstract: Percutaneous therapies for congenital heart disease have evolved rapidly in the past 3 decades. This has occurred despite limited investment from industry and support from regulatory bodies resulting in a lack of specific device development. Indeed, many devices remain off-label with a best-fit approach often required, spurring an innovative culture within the subspecialty, which had arguably laid the foundation for many of the current and evolving structural heart interventions. Challenges remain, not least encouraging device design focused on smaller infants and the inevitable consequences of somatic growth. Data collection tools are emerging but remain behind adult cardiology and cardiac surgery and leading to partial blindness as to the longer-term consequences of our interventions. Tail coating on the back of developments in other fields of adult intervention will soon fail to meet the expanding needs for more precise interventions and biological materials. Increasing collaboration with surgical colleagues will require development of dedicated equipment for hybrid interventions aimed at minimizing the longer-term consequences of scar to the heart. Therefore, great challenges remain to ensure that children and adults with congenital heart disease continue to benefit from an exponential growth in minimally invasive interventions and technology. This can only be achieved through a concerted collaborative approach from physicians, industry, academia, and regulatory bodies supporting great innovators to continue the philosophy of thinking beyond the limits that has been the foundation of our specialty for the past 50 years.

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Key Words: adult congenital cardiology heart pulmonary valve
throughout the entire cardioiology world and set the stage for all future intracardiac interventional procedures—the true beginning of pediatric and adult interventional cardiology. Further innovations were not far behind. The following year, Porstmann et al.10 published their initial experience with transcatheter occlusion of the persistent arterial duct, whereas less than a decade later King et al.4 would go on to perform transcatheter atrial septal defect (ASD) closure in 5 patients with startling success, considering the limitations of the technology then available (Figure 1). Fast forward through 2 decades of developments in balloon angioplasty, including fetal interventions and stenting, to September 12, 2000, when Bonhoeffer et al.9 performed the first percutaneous pulmonary valve replacement in a 12-year-old male with a dysfunctional right ventricle to pulmonary artery (PA) conduit. This was almost 2 years before the first contemporary report of transcatheter aortic valve replacement by Cribier et al.8 These breakthroughs are all the more impressive considering the limited attention that congenital heart interventions have received from mainstream bodies responsible for financial support and device development. That said, recent advances particularly in stent placement in newborn infants have benefited from technological advances in stent design for coronary artery and peripheral vascular disease. Indeed, initial reports of outcomes after stenting of the arterial duct were disappointing with high mortality rates.7 However, the excellent outcomes seen more recently suggest that this improvement is at least in part because of the development of more appropriate stents and wires.8,9 It is unclear whether this trend will continue as we push to the very boundaries of congenital interventions. For example, transcatheter patent ductus arteriosus (PDA) occlusion has now been reported in infants weighing <1 kg,10 despite the fact there is no Food and Drug Administration approved device designed specifically for transcatheter PDA occlusion in premature neonates. Great progress has been made, but challenges remain. This review will outline some of the current approaches used in congenital interventions and challenges that exist with developing our field for the future.

Fetal Cardiac Interventions

The concept that flow impacts vessel or chamber growth is well established in the evolution of congenital heart lesions. With improving diagnostic capabilities and availability of fetal cardiac screening, over 50% of significant congenital heart lesions can be identified in the antenatal period.11 This may provide an opportunity to alter blood flow and therefore arrest or reverse progressive subsequent chamber or vessel hypoplasia in selected conditions. The first report of transcatheter fetal intervention, published in 1991, described attempted balloon aortic valvuloplasty in 2 fetuses, with neither surviving to term.12 Since this time, fetal interventions have been performed on the pulmonary valve in fetuses with hypoplastic right heart and on the atrial septum in fetuses with hypoplastic left heart syndrome with an intact or highly restrictive atrial septum with reasonable success, and guidelines for fetal interventions have been published.13 A single-center cohort of 100 cases of fetal balloon aortic valvuloplasty demonstrated fetal demise in 11% and biventricular circulation in 43% of the live born cohort.14 Although the majority of children achieving a biventricular circulation required further interventions, these are encouraging results, diverting patients away from palliation with a univentricular heart (Figure 2). The optimal approach to maintaining patency of the fetal atrial septum is less clear-cut with the potential for recurrent restriction in the absence of an atrial stent, which may be more technically challenging.15 Future challenges with fetal interventions may include creating centers of excellence, as a significant learning curve exists and may not be tolerated as demand for optimal outcomes becomes the norm.16

Figure 1. King–Mills cardiac umbrella used for the first experimental atrial septal defect closure: left atrial umbrella (A), right atrial umbrella (B), locking catheter and cone (C), and an outer catheter (D).

Nonstandard Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>3D</td>
<td>3-dimensional</td>
</tr>
<tr>
<td>ASD</td>
<td>atrial septal defect</td>
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<tr>
<td>CHD</td>
<td>congenital heart disease</td>
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<tr>
<td>PA</td>
<td>pulmonary artery</td>
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<tr>
<td>PDA</td>
<td>patent ductus arteriosus</td>
</tr>
<tr>
<td>RVOT</td>
<td>right ventricular outflow tract</td>
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<tr>
<td>VSD</td>
<td>ventricular septal defect</td>
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such as Japan have reaped the benefits of complete follow-up data sets. It is essential that such registries become the standard for new and preexisting device assessment over the next decade. Device stiffness has also been implicated, and newer devices have focused on less rigid designs. However, with increasing need to access the left atrium for structural interventions in later life, the optimal solution is likely to involve a bioresorbable material to act as a scaffold for native tissue overgrowth and occlusion. Clinical experience with partially bioresorbable occluders exists; however, technical concerns (12% implantation failure) and early and late complication rates of 9% and 12%, respectively, have limited widespread acceptance. Clinical trials evaluating completely bioresorbable occluders are ongoing; however, the optimal mechanical and degradation properties for a suitable biomaterial for transcatheter ASD closure have yet to be fully elucidated. It is unclear whether parallel efforts to expand device design to overcome the challenges of transcatheter closure of ASDs with deficient poster-inferior rims will evolve because financial investment is likely to yield a poor return considering the low incidence of such defects.

The great paradox of CHD therapy is the need to provide polar opposite interventions on the heart. Although great efforts have been ongoing for decades to create the ideal ASD closure device, other groups have been attempting to create ASDs in infants requiring egress of blood from the left atrium, through nonthermal, mechanical tissue fractionation using high-intensity ultrasound pulses or histotripsy. Transition from animal studies to human application has been slow; however, the potential benefits of avoiding balloon intervention particularly in fetal life warrant continued development.

**Ventricular Septal Defects**

Transcatheter ventricular septal defect (VSD) closure was first described in 1987, and the procedure has evolved with the development of numerous devices and approaches for device delivery, including hybrid perventricular approach (Figure 3), avoiding the need for cardiopulmonary bypass.

Challenges for minimally invasive device closure remain because the majority of VSDs exist in anatomically challenging locations within the ventricular septum and are usually clinically relevant soon after birth, when navigating stiff delivery sheaths around the heart may lead to hemodynamic instability. Transcatheter closure of perimembranous defects has been thwarted by concerns over device related complete heart block with rates of ≈5% seen in a large European registry. Identifying favorable anatomic variances, including aneurysmal tissue within the VSD, along with newer device designs, has helped reduce rates of heart block; however, this remains the main concern for aggressively pursuing device development for transcatheter VSD closure in smaller infants. The proximity of the defect to the aortic valve remains a technical challenge, with the need for greater device stability potentially occurring at the expense of possible device impingement on the aortic valve. Approaches to circumvent the need for an arteriovenous loop for device delivery with potential consequent valve distortion have included transseptal or retrograde arterial approaches. Ultimately, investment in device design is necessary to develop lower profile delivery systems and device characteristics that will ensure device stability with closure rates similar to surgery and minimal trauma to the conduction system. Less invasive approaches are also in development with perventricular closure performed with laparoscopic guidance through the chest wall.

**Patent Ductus Arteriosus**

Transcatheter PDA occlusion has become the most established congenital heart intervention since its initial description in 1967. A myriad of devices exist both inside and outside the United States, reflecting morphological heterogeneity. Debate remains as to the clinical benefit and cost-effectiveness of closure of the
very small, clinically silent PDA with published guidelines listing this as a IIb indication. However, this is persisting ambiguity regarding the risk:benefit of this approach. At the other end of the evolving scale is the challenge of transcatheter PDA closure in extremely low birth weight infants where the clinical need is clearer; however, technical challenges remain.

Balloon Valvuloplasty and Angioplasty

Balloon valvuloplasty remains the treatment of choice for congenital pulmonary valve stenosis with excellent outcomes and low reintervention rates. Higher balloon:annulus ratios have been associated with higher rates of clinically significant pulmonary regurgitation. Debate remains on the longer-term outcomes of balloon aortic valvuloplasty compared with surgery in neonates and children (Table). Less favorable outcomes for valvuloplasty may be seen with unicuspid valve morphology. An algorithm-based approach to mitigate against aortic regurgitation, which is progressive and more likely to lead to longer-term aortic valve replacement, has also been reported.

In patients with branch PA stenoses, one of the few randomized control trials performed in the setting of transcatheter interventions demonstrated that cutting balloon angioplasty led to a greater increase in vessel lumen diameter with similar complication profile when compared with high-pressure balloon angioplasty in patients that did not respond to lower-pressure balloon angioplasty.

Stenting

Stenting has evolved into the treatment of choice for major vessel stenotic lesions in appropriately sized patients with CHD. A recent large nonrandomized series comparing balloon angioplasty, stenting, and surgery for treatment of coarctation of the aorta in patients >10 kg demonstrated shorter hospitalization and fewer complications in the stented cohort compared with the surgical cohort. The benefits of stenting over surgical arterioplasty for PA stenosis have also been reported with significantly higher reintervention rates seen in the surgical group. Challenges remain with 9% of subjects in a recent registry review of almost 1200 patients undergoing PA stenting, experiencing death, or major adverse event. Those weighing <4 kg or with a univentricular circulation were more likely to have a serious complication. Stents remain the source of difficult treatment decisions, limited by stent diameter that will ultimately be outstripped by somatic growth. Numerous approaches have been reported to deal with somatic outgrowth, including high-pressure balloon--induced fracturing of small diameter stents or novel stent designs, consisting of 2 stent halves connected by resorbable sutures. More recent evaluation of stent type and design in an animal model suggests that stainless steel coronary and renal open cell stents may be more amenable to unzipping than nitinol or biliary stents. Such studies evaluating subtle differences in stent design for future interventions are a vital part of the coordinated approach required to organize efforts to optimize outcomes.

Covered stents have been used in higher-risk patients with coarctation of the aorta to prevent against serious aortic wall trauma, although a randomized trial evaluating bare metal and covered stents for severe native coarctation of the aorta did not demonstrate any benefit of covered stents in this setting. The use of covered stents has also been described in the setting of prestenting of calcified right ventricular to PA conduits as a precursor to transcatheter pulmonary valve replacement, although predictors for risk of conduit damage during balloon dilation or bare metal stenting have yet to be identified. The variety of CHD lesions treated with stents has evolved over the past decade. Stenting of the arterial duct has reemerged...
particularly since the description of the hybrid approach to hypoplastic left heart syndrome.52 Some centers primarily using this approach for palliation of hypoplastic left heart syndrome have described excellent outcomes with unadjusted survival rates of 84% at 1 year,53 surpassing standard Norwood surgical result of many contemporary series. Recent registry data would also suggest that procedure outcomes are less affected by volume of procedures with comparable results seen with low- and high-volume centers.54 No randomized trial data, however, have been published, and in the majority of centers, the hybrid approach is restricted for higher-risk cohorts.55 The potential benefit of this approach in promoting a biventricular circulation in patients with borderline left heart size at birth, or indeed in delaying complex surgery in neonates with multiple-level left heart obstruction, warrants its continued inclusion as part of a progressive complete CHD program.

Right ventricular outflow tract (RVOT) stenting in symptomatic infants with tetralogy of Fallot has also evolved to compete with surgical palliation in recent years,56,57 following concerns over mortality rates of 6% to 7% after early surgical repair or palliation.58 Positive effects on PA growth have been demonstrated,59 supporting the beneficial impact of increased flow on vessel growth; however, the presence of a metal stent within the RVOT has consequences for complete surgical repair.60 Stenting across the pulmonary annulus commits the patient to a transannular patch and the long-term impacts of chronic pulmonary regurgitation (Figure 4). Efforts to preserve pulmonary valve function in this setting continue to provide a huge challenge to all involved in care of these patients. Whether advances in transcatheter ablation techniques and equipment may resurrect attempts to remodel subpulmonic muscle bundles and promote growth of the pulmonary annulus, thus augmenting efforts to preserve pulmonary valve function, remains to be seen.61

Many of the challenges relating to patient size and stenting could be overcome by a bioresorbable option. Indeed, in a recent needs analysis survey among congenital interventionalists, 41% of respondents chose an appropriate bioresorbable scaffold as the device they would like to have access to, with 27% indicating that this would have the greatest impact on improving the morbidity of their patients.62 Experience with currently available coronary scaffolds in CHD lesions has been disappointing with restenosis rates suggesting lack of appropriate radial strength63 and again reflects the need for investment in a scaffold appropriate for CHD practice. This

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Comment</th>
<th>Concerns</th>
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<tbody>
<tr>
<td>ASD</td>
<td>Transcatheter closure possible in &gt;80% cases</td>
<td>0.2% incidence of erosion with certain devices</td>
</tr>
<tr>
<td>VSD</td>
<td>Muscular defects and aneurismatic membranous defects</td>
<td>5% incidence of heart block with membranous defects</td>
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<td>PDA</td>
<td>Standard therapy. Evolving in very small infants</td>
<td>Concerns about device protrusion in smaller infants</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Excellent initial and longer-term outcomes</td>
<td>Poorer response seen with very dysplastic valves</td>
</tr>
<tr>
<td>Aortic</td>
<td>Outcomes similar to surgery in neonates and infants</td>
<td>Progressive aortic regurgitation leading to need for AVR</td>
</tr>
<tr>
<td>Pulmonary arteries</td>
<td>Stenting likely to provide a more sustained relief of stenosis</td>
<td>Restenosis (ballooning). Somatic outgrowth (stenting)</td>
</tr>
<tr>
<td>Aortic arch</td>
<td>Stenting effective therapy in older children</td>
<td>Aneurysm formation with ballooning</td>
</tr>
<tr>
<td>RVOT</td>
<td>Provides good palliation for symptomatic ToF patients</td>
<td>May increase the need for transannular patch repair</td>
</tr>
<tr>
<td>PDA</td>
<td>Use of a native connection from the aorta to the pulmonary arteries to provide pulmonary blood flow</td>
<td>Significant variation in ductal morphology</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Excellent outcomes (conduits). Evolving—native RVOT</td>
<td>Endocarditis rates with Melody valve</td>
</tr>
<tr>
<td>Tricuspid</td>
<td>Option for valve in valve in congenital patients</td>
<td>Native valve replacement continues to prove a challenge</td>
</tr>
<tr>
<td>Mitral</td>
<td>Growth option with stented tissue valve in children</td>
<td>Longer-term outcomes are lacking</td>
</tr>
<tr>
<td>Aortic</td>
<td>Evolving need in patients with bicuspid aortic valve disease</td>
<td>Unclear as to the optimal age to consider this a viable alternative to surgery</td>
</tr>
<tr>
<td>HLHS</td>
<td>Excellent outcomes reported in experienced centers</td>
<td>Unclear whether this should be reserved for higher-risk cohorts</td>
</tr>
<tr>
<td>VSD</td>
<td>Good outcomes in small cohorts</td>
<td>Large clinical experience lacking—limited numbers</td>
</tr>
<tr>
<td>Others</td>
<td>Pulmonary valve and pulmonary artery interventions are evolving</td>
<td>Collaboration with surgical team essential for optimal outcomes</td>
</tr>
</tbody>
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ASD indicates atrial septal defect; AVR, aortic valve replacement; HLHS, hypoplastic left heart syndrome; PDA, patent ductus arteriosus; RVOT, right ventricular outflow tract; ToF, tetralogy of fallot; and VSD, ventricular septal defect.
may include development of a hybrid polymer/biocorrodible material that will provide adequate radial strength at a low enough profile to allow vessel remodeling and promote normal vessel growth.

**Transcatheter Valve Replacement**

Transcatheter pulmonary valve replacement has evolved over 15 years to become the approach of choice in patients with suitable RVOT morphology. Clinical trials evaluating 2 dominant valve systems have demonstrated excellent initial restoration of pulmonary valve function in patients with dysfunctional right ventricle–PA conduits, with 92% freedom from need for surgical explantation at a mean follow-up of 5 years. However, RVOT morphology varies widely, and ≈75% of patients with a dilated, dysfunctional RVOT are not candidates for balloon-expandable valve systems in their current format. Hybrid plication of the RVOT has been described to facilitate delivery of a balloon-expandable valve system in dilated outflows (Figure 5); however, growing experience with a self-expanding system is likely to supersede the need for alteration of the RVOT to facilitate fitting of a balloon-expandable valve.

The evolving field of transcatheter valve replacement has brought with it a new set of considerations for the interventionalist. Compression of surrounding structures, including the coronary arteries, distortion of the aorta with potential for aortopulmonary fistulae, and endocarditis with reported rates of up to 8% with the Melody valve (Medtronic Inc, Minneapolis, MN), has all evolved in the consciousness of the interventional community as this procedure has grown. It is disappointing, however, that despite its introduction relatively recently, there is still a lack of procedure-specific registry infrastructure within the CHD community to facilitate ongoing assessment of outcomes from larger cohorts. Highly restrictive and expensive pathways for approval of new devices particularly in the United States have occurred at the expense of longer-term surveillance once these devices have been introduced. Regulatory bodies and industry must collaborate and come to a responsible common ground for ensuring that longer-term surveillance receives as much investment as short-term safety and efficacy.

Transcatheter valve replacement in CHD patients has evolved beyond the pulmonary valve. Transcatheter aortic valve replacement, now a commonplace therapy for acquired calcific aortic valve stenosis, will likely extend to treatment of aortic valve dysfunction secondary to congenital bicuspid aortic valve disease. Reports also exist outlining its use in children with severe aortic valve dysfunction on the background of serious congenital heart defects, mostly as rescue therapy. In a recent registry of transcatheter tricuspid valve-in-valve replacement in over 150 patients, almost 60% of the cohort had CHD, reflecting clinically relevant numbers of CHD patients who may benefit from evolving transcatheter tricuspid valve therapies. Of particular interest is the growing experience of hybrid mitral valve replacement with the Melody valve, which facilitates avoidance of vitamin K antagonist anticoagulation with potential for valve growth because the valve is dilated via the transseptal approach over time. The issue of how to deal with somatic growth remains unique to the CHD population. Although the properties of the Melody valve that facilitates valve function at a variety of diameters are attractive in the short term, ultimately harnessing advances in tissue engineering to

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**Figure 4.** Series of transthoracic images outlining placement of subvalvar right ventricular outflow tract (RVOT) stent in a neonate with symptomatic tetralogy of Fallot. A, Preprocedural transthoracic echocardiogram (TTE) demonstrating subvalvar muscular RVOT obstruction; B, intraprocedural TTE guiding stent placement across the RVOT; C, subcostal view after stent placement demonstrating satisfactory position within the RVOT; and D, parasternal short-axis TTE demonstrating the distal stent tip below the pulmonary valve annulus (white arrow).
Hybrid Interventions and Development of Catheter Laboratories and Imaging Systems

Hybrid palliation and treatment of CHD lesions have evolved beyond ductal stenting in hypoplastic left heart syndrome to include periventricular VSD closure, intraoperative PA stenting, vascular cutdowns for neonatal interventions, and transcatheter pulmonary valve replacement. Indeed, the limits of this approach are bound less and less by anatomic challenges, placing major emphasis on the need for collaboration between surgeon and interventionalist and developing an environment that is conducive to both teams working comfortably and efficiently in the same area. Although most large CHD treatment centers now include a hybrid catheterization laboratory, to date guidelines on appropriate layout for such a space and staffing requirements are lacking, as is consensus on appropriate lesions that may be treated in this way and strategies to do so. As the boundaries of reducing procedural mortality are tested, the consequences of smaller hemodynamic alterations become greater. Use of exit angiography has been shown to elucidate unexpected residual anatomic distortions in 56% of patients undergoing surgical correction of CHD lesions leading to a change in therapeutic management in 50% of this cohort. Therefore, as the field develops, boundaries as to what constitutes a cardiac theater and a cardiac catheterization laboratory should disappear, and ideally each should be able to provide the needs of both.

In the context of cardiac catheterization, this will for the foreseeable future encompass the presence of an imaging system. Significant advances have been made with newer imaging platforms focusing on radiation dose reduction, imaging quality, and also advanced imaging modalities, fusing preprocedural imaging with live acquisition images, or creating 3-dimensional (3D) images through rotational angiography. The use of echocardiography-acquired images can be superimposed onto fluoroscopy images to guide complex closure procedures. In a contemporary series of 114 3D rotational studies in CHD patients, rotational angiography with multiplanar reconstruction was judged to be superior to the diagnostic quality of fixed plane angiography. Additional benefits include assessment of nearby structures, including the airways that may impact the interventional approach. Ultimately, however, these imaging modalities are represented on a 2D screen. Holography provides images created in real time from volumetric data, which float in the air during the procedure, in front of the operator and could provide an intuitive and interactive 3D display for the interventionalist. Early experience in a clinical setting has been reported; however, it is unclear as yet how this will translate into guiding interventional outcomes in a meaningful way.

Guidelines, Registries, Standardized Clinical Pathways, and Risk Adjustment Models

Standardizing approaches, collecting data on outcomes, and identifying risk are the foundations of any quality management system. Guidelines for interventions in adult CHD patients were included in a 2008 document, with guidelines for interventions in pediatric patients published in 2011. There are minor variances in suggested timings of intervention, but these documents provide a framework to guide clinical decision-making. The response to a particular intervention however is not always uniform reflecting a unique
set of circumstances presented by each patient. Although guidelines for balloon aortic valvuloplasty exist, patient response may vary greatly. In smaller patients, attempts to achieve an optimal result with abolition of gradients may lead to significant aortic regurgitation. Introduction of a standardized clinical assessment and management plan is this setting has been reported, and although challenging to validate, this approach may remove some of the variability.

Figure 6. Series of images outlining double hybrid Melody valve placement in an 8.8-kg infant with severe postoperative pulmonary and left atrioventricular valve regurgitation after surgical repair of tetralogy of Fallot with complete atrioventricular septal defect. Severe leak of both valves compromised forward flow through the heart with low cardiac output. A, Parasternal long-axis view with color Doppler on transthoracic echocardiogram (TTE) demonstrating severe pulmonary regurgitation after transannular patch repair. An intraoperative stent was placed in the right pulmonary artery; (B) apical 4-chamber view with anterior angulation demonstrates a Melody valve in the pulmonary position. This was placed after main pulmonary artery plication via a percutaneous approach; (C) color Doppler TTE image in the parasternal short-axis view indicates no pulmonary incompetence after valve implantation; (D) apical 4-chamber view on TTE demonstrates severe left atrioventricular valve regurgitation; (E) similar view after hybrid Melody placement; and (F) chest x-ray demonstrating both Melody valves in place. These hybrid interventions facilitated full recovery from low cardiac output after initial operative repair.

Figure 7. Cartoon illustrating possible future strategies for the surgical management of newborns with congenital heart disease (CHD). If CHD is diagnosed prenatally, fetal cells may be harvested and induced pluripotent stem cells (iPS) generated; as an alternative, umbilical cord stem cells can be isolated at the time of birth. When diagnosis of CHD is made after birth or in babies who require a palliative surgical operation soon after birth, stem cells may be isolated from surgical cardiac leftovers. All these types of cells will allow the generation of a tissue-engineered graft endowed with growth and remodeling potential, necessary for the definitive correction of cardiac defects (Taken from Avolio et al99; Illustration Credit: Ben Smith).
in decision-making that exists among operators on any given day and justify the outcome of a particular intervention as assessed by referring colleagues.

Participation in a procedural registry for congenital interventional centers has become commonplace but only recently. These registries include procedure-specific registries as seen with the Congenital Cardiovascular Interventional Study Consortium, or broader registries such as Congenital Cardiac Catheterization Project on Outcomes, which uses prospective CHD data across many pediatric institutions or Improving Pediatric and Adult Congenital Treatment, which forms part of a National Cardiovascular Data Registry. For the first time since the inception of this specialty, meaningful pooled data are now available to assist in counseling patients and parents about the outcomes of interventions in patient subgroups, including the increased risks seen with interventions in children <2 kg, and the outcomes of interventions in adult patients performed in pediatric hospitals. These registries are also providing information for risk-adjusted scoring systems such as Catheterization for Congenital Heart Disease Adjustment for Risk Method and Catheterization Risk Score for Pediatrics facilitating a preprocedural risk score for a specific intervention in low- and high-risk patients. Finally, these registries are evolving to assess quality metrics in participating centers, providing benchmark goals for radiation doses for specific procedures among other outcome variables.

**Evolving and Future Approaches**

Congenital interventionalists continue to innovate inside and outside the realm of CHD. In patients with pulmonary arterial hypertension, transcatheter creation of an aortopulmonary connection by fluoroscopically guided needle perforation of the descending aorta at the site of apposition to the left PA creates a tract for deployment of a covered stent between these vessels, thus decompressing the suprasystemic right ventricle with good symptomatic relief in survivors. Efforts are ongoing to provide a viable transcatheter alternative to the completion of a total cavopulmonary shunt, avoiding the need for further surgery and cardiopulmonary bypass on an already compromised circulation. Indeed, magnetic resonance imaging–guided creation of a superior cavopulmonary shunt has been described in a porcine model, and one may wonder whether future palliation of some single ventricle conditions may obviate the need for surgery at all and whether we will be performing these interventions without the need for ionizing radiation.

Ultimately, a shift in mindset is required to consider not only the anatomic aspects on an intervention, but also the physiological impact, assessing how changes in flow may mediate not only vessel growth but also vessel function. As mortality and early morbidity are become less relevant benchmarks, the choice between a surgical and transcatheter option for a particular defect should also encompass longer-term physiological effects of an intervention. For example, minor flow disturbances may mediate low-grade inflammation in the setting of repaired coarctation of the aorta. This may lead to arterial remodeling and affect the emergence of systolic hypertension in young adulthood. These variances in flow can be measured by magnetic resonance imaging. As the debate continues as to whether surgery or stenting is the optimal approach for treatment of coarctation, efforts should be made to include these longer-term consequences of a particular therapy. The introduction of bioresorbable materials may shift the balance in favor of an interventional approach if return of normal vascular function after absorption can be demonstrated, as has been seen after adult coronary stenting. The major limitation in answering these questions is the lack of investment in supporting the research. Limited returns will not inspire industry to invest, and, therefore, increased funds need to be made available at government level, such as through the Office of Orphan Products Development via the Food and Drug Administration. Collaboration that has driven the success of clinical registries should be supported in the research environment, with industry, researchers, government bodies, academic institutions, and philanthropy working together to achieve common goals. The need for such joined thinking and investment is clear when we focus on the major goals ahead. As the field of transcatheter valve replacement continues to expand and some attention may be directed to limiting valve degeneration, limited focus will be given to the need for growth, as this is not a concern for adult valve replacement. However, in children, recurrent surgery is commonplace to replace valves because of somatic outgrowth with 50% of patients in 1 series requiring homograft replacement in the pulmonary position by 10 years. Harnessing the broader medical interest in tissue engineering to patients with CHD, who may benefit most from this technology, is paramount. The basic concept is to create living material made by cellularized grafts that, once implanted into the heart, grows and remodels in parallel with the recipient organ (Figure 7). Delivering this cellularized graft or valve, harnessed to a bioresorbable scaffold, via a minimally invasive approach, opens up the potential of a 1-stage, nonsurgical curative procedure for these patients.

**Conclusions**

The field of congenital interventional cardiology has contributed significantly to the development of interventional cardiology as a whole. Greater focus on collaboration and standardization of approaches with continued development of outcome registries is key to consolidating current practice. Future possibilities for minimally invasive therapeutic approaches are vast; however, concerted efforts are required to ease pathways for device development and introduction to the market, without compromise in safety or efficacy.

**Disclosures**

Z.M. Hijazi acts a consultant for Occlutech International AB. The other author reports no conflicts.

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