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HYBRID INTERVENTIONAL PROCEDURES IN CONGENITAL HEART DISEASE

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Abstract

The evolution of congenital cardiac surgery has seen significant innovative advances in collaborative efforts between congenital cardiac surgeons and interventionalists to provide the least invasive intervention with the greatest hemodynamic benefit for patients with congenital heart disease. This review looks at how this collaborative approach has evolved and is being applied to treat a number of congenital conditions across the age ranges.

Introduction

The last three decades have seen tremendous progress in the treatment of children born with complex congenital heart disease (CHD). Advances in both surgical and interventional procedures to palliate potentially fatal anomalies have contributed to the current survival rate of over 85% for CHD patients into adulthood.¹ However, both surgery and transcatheter approaches have drawbacks. The invasive nature of surgery and cardiopulmonary bypass makes for a long recovery period with potential developmental implications when done at a very young age. Transcatheter approaches may be limited by access, patient size, and related issues. It is often not physically possible to deliver the required devices intravascularly through relatively large delivery sheaths that are difficult to negotiate around the curves of the heart. Therefore, it is not surprising that surgeons and interventionalists have increasingly started working together to maximize the potentials and minimize the limitations of their respective approaches. It is in this setting that the “hybrid” approach to CHD has evolved. This type of collaboration provides the interventionalist and surgeon with direct access to the heart and may help patients avoid the need for cardiopulmonary bypass. Today, there are multiple procedures that may be performed by a hybrid approach to treat both common and not so common congenital cardiac abnormalities. This review will discuss many of these procedures in detail.

Hybrid Procedure for Hypoplastic Left Heart Syndrome

The first complete hybrid palliative approach to hypoplastic left heart syndrome (HLHS) was described in 1993 by Gibbs et al. with surgical banding of the branch pulmonary arteries (PA) and percutaneous stenting of the arterial duct.² This was accompanied by either surgical or percutaneous decompression of the left atrium by opening the septum. There was concern about long-term mortality, and subsequent reports confirmed these initial concerns with no survivors beyond 30 months from all eight patients palliated with this approach.³ The major complication leading to death in five of the eight patients was pulmonary overcirculation

and resulting right ventricular (RV) failure. Additional experience with the hybrid approach was not described again until 2002, when a group from Giessen reported specific preprocedural targets for the tightness of the PA band with the goal of achieving distal PA pressures less than 50% of systemic pressures, as confirmed by Doppler velocities of at least 4 m/s across the bands and a reduction in systemic oxygen saturations to approximately 80%.⁴ Of the 11 patients, 10 survived to a stage II procedure, and there was one intraoperative death. Overall survival through stage II was 82%, a rate that was confirmed by a larger cohort of 58 patients by the same group.⁵

This method evolved into the first truly hybrid approach to the management of HLHS, which was described by the group in Columbus in 2005. In this model, the surgeon and interventionalist work side-by-side to band the PAs and stent the arterial duct through the PA, with further transcatheter intervention to the atrial septum performed as a separate procedure if necessary.⁶ This group subsequently published their extended experience of 40 neonates with this approach, including 15 patients through stage III palliation with 83% survival.⁷ Since this time, the hybrid approach to HLHS has evolved into a recognized management strategy. Recent retrospective comparison of the hybrid approach with the Norwood procedure demonstrated comparable outcomes through stage II palliation in 75 patients.⁸ However, the hybrid cohort with 85% survival through comprehensive stage II palliation had a higher need for reintervention on the PAs and overall smaller PAs.

Patient Population

Controversy still exists as to which patients should be offered this approach. Without randomized controlled trials, it is not possible to compare the longer-term outcomes of the hybrid approach with standard stage I surgery, especially with the much lower level of experience with the hybrid technique compared to Norwood. These trials are ongoing and the results are keenly anticipated. However, there have been certain infant populations—birth weight less than 2.5 kg, severe RV dysfunction, intact or restrictive atrial septum, prematurity, associated severe noncardiac genetic abnormalities, intracerebral hemorrhage, and postnatal collapse with a pH less than 7—identified as high risk for surgical

palliation,^{9,10} with surgical stage I mortality rates over 60%. In these cases, the hybrid approach may be an alternative to cardiopulmonary bypass. Yet multiple small case series showed that survival to a stage II procedure is only 44% to 50% in this high-risk group, even with an initial hybrid approach.^{11,12} Other potential benefits of the hybrid approach in HLHS, such as improved neurodevelopmental function by avoiding prolonged cardiopulmonary bypass and deep hypothermic circulatory arrest in neonatal life, or using it as a less-invasive strategy to assess potential growth of left heart structures in cases of borderline left ventricular size, have been investigated but with inconclusive results.^{6,13}

Technical Considerations

Because of the steep technical learning curve of the hybrid approach to HLHS, there are numerous potential challenges. A successful approach must focus on providing balanced pulmonary blood flow and alleviating any obstruction across the aorta and atrial septum. One of the potential intraprocedural and interstage risks with the hybrid approach is obstruction to the retrograde aortic arch with ductal stenting. In cases of HLHS with aortic atresia, both the coronary and cerebral circulations are dependent on retrograde aortic flow. The incidence of an interstage retrograde aortic arch obstruction has been reported at 24%.¹⁴ If flow obstruction is recognized prior to hybrid stage I palliation, a traditional surgical approach should be considered. However, alternative approaches have been described, including a prophylactic main PA to innominate artery shunt (a “reverse Blalock-Taussig shunt”) during stage I palliation,¹⁵ although this has fallen out of favor due to poor results. Use of an open-cell self-expanding stent is preferred by many centers since obstruction of the aortic arch is less likely with an open-cell design and also easier to treat. The use of balloon-expandable stents is usually reserved for ductal stenosis (Figure 1). Recent follow-up evaluation of the ductal stent in 37 neonates demonstrated the need for multiple stents in 30% of the cohort,¹⁶ and 13% required reintervention following the initial stent placement. Therefore, careful monitoring is important to ensure that systemic and cerebral blood flow remain unobstructed. Indeed, recent data have suggested that cerebral perfusion may be impaired in patients undergoing a hybrid procedure when compared to those undergoing Norwood.¹⁷

Transcatheter fenestration of the septum may present challenges

due to bowing of a thickened septum into the right atrium with a hypoplastic left atrium. Creation of an adequate opening may require initial transeptal or radiofrequency perforation (if intact), followed by static balloon and/or cutting balloon atrial septoplasty or stenting of the thickened atrial septum (Figure 2). However, repeat interventions may be necessary in up to 20% of patients, and major adverse events have been reported in 9% of cases.¹⁸

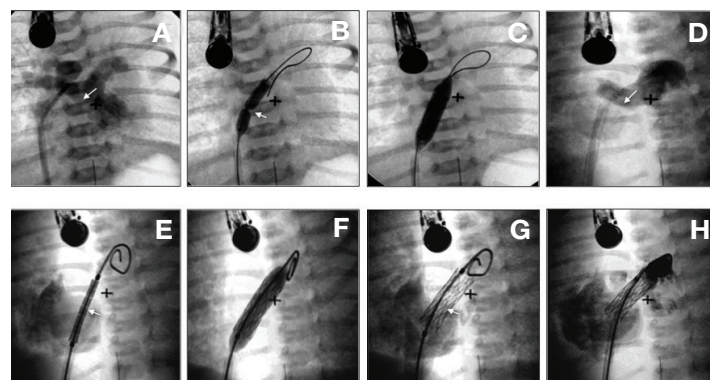


Figure 2. Balloon dilation and stenting of the interatrial septum in the setting of hypoplastic left heart syndrome. (A) Initial angiogram demonstrates a small left atrium with dilated pulmonary veins and a severely restricted atrial septum (white arrow). (B) Balloon dilatation of this area confirms the tiny communication with resolution of the waist following further dilatation with a cutting balloon (C). The communication, however, remains restrictive (D – white arrow) and thus a balloon expandable stent is placed across the atrial septum (E–G) with creation of unrestrictive flow from the left atrium on angiography (H).

Hybrid Approach to Ventricular Septal Defect Closure

In 1998, Amin and colleagues described a perventricular approach for closure of membranous and muscular ventricular septal defects (VSD) in both an animal model and subsequently a human infant.^{19,20} The benefits of this approach were direct access to the heart following surgical sternotomy for direct placement of a closure device across the VSD, without the need for cardiopulmonary bypass or ionizing radiation. Initial complication rates were low, with complete closure of all muscular defects. There was residual flow seen in membranous defect closure in three of five animals and, unfortunately, one developed aortic regurgitation. Further studies confirmed these outcomes both in isolated VSDs and in conjunction with other congenital cardiac lesions^{21,22} and also in a few adult patients with postinfarction VSD who were high risk for surgery because of hemodynamic compromise.²³

Patient Population

Like most hybrid interventions, there has not been a definitive group of patients described who may benefit from this approach. While it has been primarily performed in small infants who were too small for traditional transcatheter closure, there have been reports of the approach being used in adult patients as well, namely in postinfarction VSDs and iatrogenic postoperative VSDs.^{23,24} In general, this approach should be considered for patients in whom cardiopulmonary bypass should be avoided or shortened. Such patients include those with hemodynamic instability (such as in postinfarction VSD) who may not survive traditional open-heart surgery, or complex cardiac anatomy, where shortening the length of bypass or avoiding it altogether in one stage of repair in a small

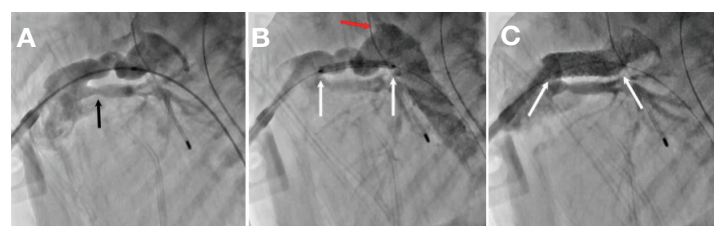


Figure 1. Hybrid stage I palliation for hypoplastic left heart syndrome. (A) In a hybrid setting and after the LPA and RPA bands (black arrow) have been placed via a small median sternotomy off cardiopulmonary bypass, an angiogram is performed through a short sheath placed directly into the main pulmonary artery above the valve after a guide wire has been placed through the PDA into the descending aorta. (B) A balloon expandable stent (white arrows) was chosen because the PDA was tortuous and displayed some narrowing. The red arrow represents retrograde flow to the aortic arch. (C) A final angiogram is performed after deployment to demonstrate the stent covering the entire length of the PDA (white arrows). LPA: left pulmonary artery; RPA: right pulmonary artery; PDA: patent ductus arteriosus.

infant may be beneficial in the long run. It also has been used in patients when either transcatheter or surgical closure failed or was thought to be technically challenging because of anatomy.

Direct comparison of periventricular VSD closure with surgery has not been carried out to date. However, in our experience avoidance of cardiopulmonary bypass and its ensuing effects has most often translated into immediate postprocedural extubation, without the need for inotropic support, and early hospital discharge. Longer-term evaluation of the impact of these rigid devices on ventricular function are anticipated, however anecdotal experience has not indicated any deleterious effects to date.

Technique

The approach to periventricular VSD closure is demonstrated in Figure 3. It is critical to have good intraprocedural imaging with either transesophageal or transthoracic/epicardial echocardiography, as the location for sheath insertion and device positioning hinges solely on this mode of imaging. The heart is approached via a median sternotomy or a subxyphoid incision without sternotomy. Under echocardiographic guidance, the best position for RV sheath insertion is chosen, paying careful attention to the relationship of the VSD to the apex of the heart, the tricuspid

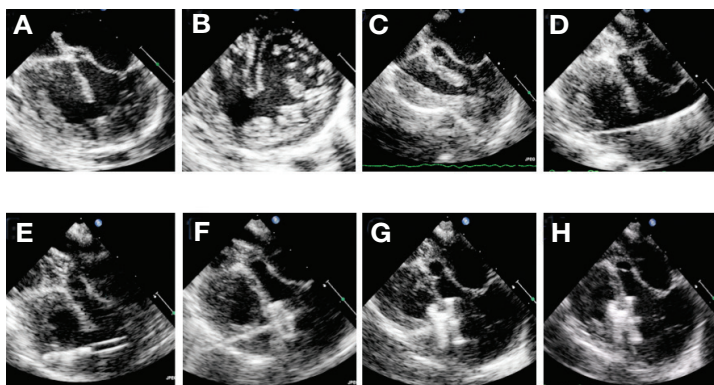


Figure 3. Periventricular closure of a large muscular ventricular septal defect. The defect is imaged in two different planes (A, B) with the site of proposed ventricular puncture indicated by digital pressure on the right ventricular wall (C). Once the wire is across the defect (D), the sheath is advanced into the left ventricle and the device advanced through the sheath (E). Initially the left ventricular device is deployed (F) followed by the right ventricular disk (G), with the device sitting in a good position across the defect following release (H).

valve, and the mitral valve apparatus. Once the puncture site is chosen, the surgeon places a purse-string suture at the desired location. Through this suture, an 18-gauge needle is introduced into the RV, through which a 0.035" hydrophilic wire is inserted. The wire is manipulated across the VSD into the LV, and a short delivery sheath is inserted over the wire once the puncture needle is removed. Measuring the distance from the RV free wall to the posterior wall of the left ventricle may be valuable, particularly in very small infants, to ensure that the sheath is not advanced too far for fear of perforating the LV wall. The appropriately sized device is then chosen, in general 1 to 2 mm larger than the maximum defect size (measured in at least two planes using color Doppler). Once the device is loaded into the delivery sheath and advanced, the left-sided disk is deployed in the mid-LV cavity under echocardiographic guidance as the sheath is withdrawn over the delivery cable. The entire assembly is then withdrawn gently until the LV disc is flush against the septum and defect. Further retraction of the sheath then deploys the waist inside the septum. The RV disk is then deployed in the usual fashion. Careful

evaluation for residual shunting and presence of worsening tricuspid or mitral regurgitation should be performed in multiple planes both prior to and after release of the device. At the end of the case, the surgeon will achieve hemostasis by tightening the previously placed purse-string suture as the delivery sheath is withdrawn. Surgical closure of the incision is then performed. Potential complications include complete heart block, injury to the aortic valve, cardiac perforation, device embolization, and hemolysis.²⁵ However, the technique avoids peripheral vascular complications that can be seen with transcatheter VSD closure.

Pulmonic Valve Implantation

Over the last decade, transcatheter pulmonic valve replacement (tPVR) has been developed and improved upon. There are currently two available valves for percutaneous replacement in the pulmonic position. The Melody valve (Medtronic Inc., Minneapolis, MN) was the first FDA-approved percutaneous heart valve. The SAPIEN valve (Edwards Lifesciences Corp., Irvine, CA) was designed for use in the aortic position for patients who are high risk for traditional surgical aortic valve replacement, although it has also been assessed in clinical trials in the pulmonic position.²⁶ Unfortunately as with many transcatheter procedures, a large delivery sheath (22 Fr for Melody valve, 22 or 24 Fr for SAPIEN valve) prohibits the use of this technology in smaller patients or patients with vascular access issues, and higher complication rates have been reported in patients weighing less than 30 kg.²⁷

The first reports of hybrid pulmonic valve replacement were described in 2011 in the setting of failed transcatheter valve implantation in a teenager and adult with CHD.^{28,29} There has been one report of the hybrid approach being used "ad hoc" in a small patient (12 kg) with multiple past surgeries and severe pulmonic insufficiency in the setting of a patched RV outflow tract (RVOT).³⁰

Technique

Since this procedure is evolving, there is not an "established" protocol. However, the general consensus is that the pulmonary annulus can be accessed through direct surgical sheath placement in the RV free wall or the RVOT (Figures 4, 5). As with tPVR, the conduit or native RVOT often requires pretesting prior to valve implantation. Coronary artery proximity should always be

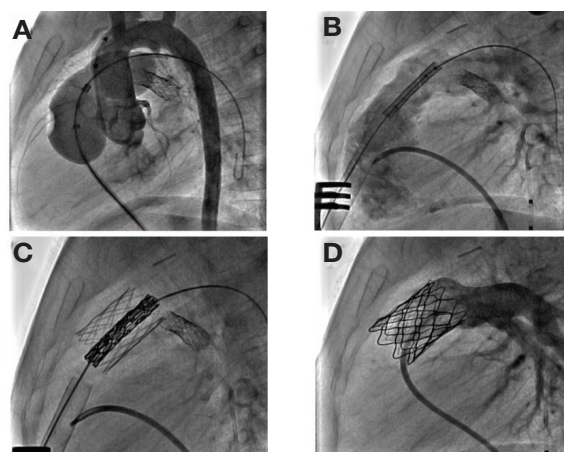


Figure 4. Periventricular pulmonic valve implantation (lateral fluoroscopy images). (A) Balloon inflation in the right ventricular outflow tract with simultaneous aortic root angiography to test for coronary artery compression. (B) Positioning of bare metal stent in the right ventricular outflow tract for "pretesting." (C) Positioning of the Melody valve inside the pretested right ventricular outflow tract. (D) Following Melody valve deployment, pulmonary angiography demonstrates no pulmonic insufficiency.

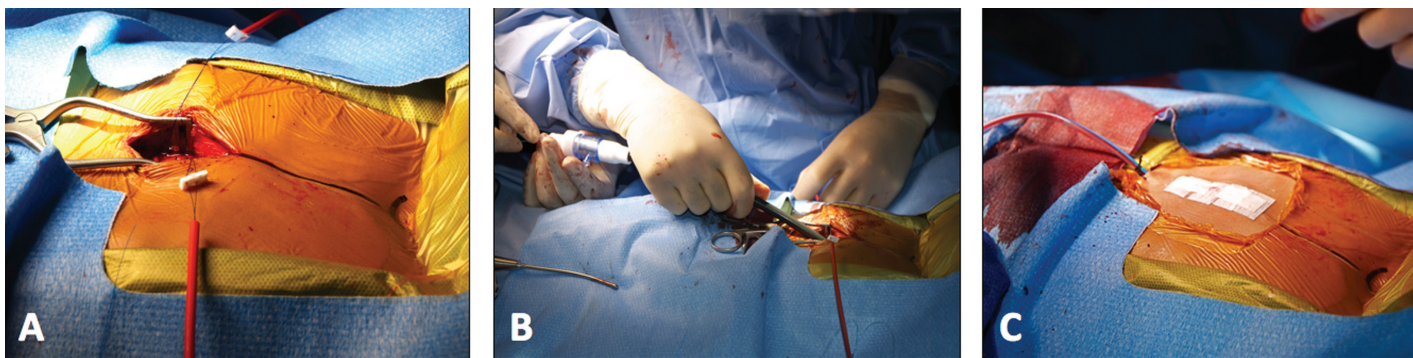


Figure 5. Subxyphoid access for perventricular pulmonic valve implantation. (A) The size and location of the surgical incision. (B) The 22-Fr valve delivery sheath being inserted through the incision. (C) Final appearance of the chest wall after closure.

assessed, as the reported rates of compression are approximately 5%.³¹ This can be achieved through a percutaneous approach on the day of the hybrid procedure, prior to the procedure as stenting typically requires a smaller sheath than valve implantation, or through the surgical hybrid sheath in conjunction with valve implantation. The appropriate valve size is chosen based on noninvasive and angiographic imaging. The valve is then inserted through its appropriate delivery sheath and implanted within the previously placed stent. Since the sheath is inserted directly into the main PA, the uncertainty of the curves of the right heart as exists in the traditional transcatheter approach is neutralized. Once correct positioning has been verified, the sheath is removed and the puncture site is closed with a purse-string suture as previously described. The chest wall incision is then surgically closed (Figure 5).

In the few case reports published on this procedure, there have not been any procedural complications reported. Potential complications include valve or stent embolization (particularly when advancing the valve through the pre-existing stent), PA perforation, conduit rupture, coronary artery compression, and obstruction of either PA by the stent or device. The advantage of the hybrid approach is that some of these issues may be dealt with directly as the sternum is open. While these complications have not been reported with the hybrid technique to date, they were seen in as many as 12% of early tPVR patients.³²

Other Procedures

The field of congenital cardiac repair is quickly developing with vast advancements being made in both transcatheter and surgical techniques. There are therefore a few other concepts that may be considered to be in the “hybrid” realm that are worth mentioning.

Intraoperative Angiography

Intraoperative angiography can identify the exact location and extent of any residual stenoses or vessel distortion, and the benefits of this approach after surgical or hybrid procedures have been reported.^{33,34} Most reports to date commenting on intraoperative angiography in patients with CHD have been selective as to which types of cases this imaging modality is used. Suggested pathologies where angiography may be of benefit include tetralogy of Fallot repair, PA reconstruction, cavopulmonary anastomosis, transposition of the great arteries to assess coronary artery patency, and after complex aortic arch procedures, including Norwood surgery for HLHS. Further experience with this type of intraoperative imaging may expand its potential applications and

provide more integration between interventional cardiology and cardiac surgery.

Hybrid procedures in Adults with Congenital Heart Disease

Specifically when CHD is not diagnosed until adulthood, certain complications may arise that may make surgical correction more difficult or dangerous. Therefore, despite the fact that hybrid approaches to CHD were developed mostly to accommodate smaller patients, there have been some opportunities to use hybrid approaches in adult congenital patients as well.³⁵ Such is the case for patent ductus arteriosus (PDA). When diagnosed in childhood, PDA can be treated by either a surgical ligation or endovascularly using one of several closure devices or coils. When diagnosed later in life, surgery has significantly more risk and therefore a transcatheter route of closure is preferred. Since PDAs may dilate significantly over time, device closure may not be possible in adults and therefore endovascular stent graft exclusion of the PDA has been performed. In the case of a small adult patient in whom the femoral vessels were not large enough to accommodate stent graft insertion, there is a report of a laparotomy and end-to-side anastomosis of a Dacron graft to the abdominal aorta performed to form a conduit for stent graft implantation.³⁶ In another report, the dilated PDA was closed by patch repair from the PA side accompanied by a multiple valve surgery, after which the aorta-side entry of the aneurysmal PDA was covered with an endovascular stent graft.³⁷ There have been reports of hybrid approaches to coarctation of the aorta stenting, specifically in settings where the coarctation is diagnosed late in life in conjunction with other cardiac abnormalities,³⁸ or when an aberrant right subclavian artery was present; in these cases, hybrid vascular surgery to reimplant the head and neck vessels has allowed covered stent implantation.³⁹ Other areas of potential use of the hybrid approach include temporary balloon occlusion of either large collaterals or previously placed shunts during cardiopulmonary bypass to prevent flooding of the surgical field,⁴⁰ repair of paravalvular leaks,⁴¹ and hybrid repair of pulmonary venous baffle obstruction after atrial switch.⁴²

Summary

The use of the hybrid approach to treat patients with congenital heart disease may be a large part of the future of this exciting medical specialty. This type of innovation, through cooperation between surgeons and interventionalists, aims at improving longer-term outcomes for patients with congenital heart disease. Further endeavors to provide the best physiological palliation with

the least-invasive means possible represents the future of medicine and will continue to challenge future generations of congenital cardiologists and cardiac surgeons.

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Keywords: congenital heart disease, hypoplastic left heart syndrome, hybrid vascular surgery

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