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EDITORIAL COMMENT

Interventions in Complex Congenital Heart Disease

The Exciting Potential of Magnetic Resonance Imaging*

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The electrocardiogram (ECG) and fluoroscopy were essential in the development of pediatric cardiology as a subspecialty by providing a means to study congenital heart disease. Surgical repair for congenital heart disease was first performed by Robert Gross in 1938 to ligate a patent ductus (1), and in 1944 the Blalock-Taussig operation for creation of a surgical pulmonary arterial-shunt for the treatment of tetralogy of Fallot was performed (2). As transcatheter valve replacement is now established, more than 70 years later, as a less invasive alternative to open heart surgery in adults, the potential to explore transcatheter approaches to single-ventricle shunt surgeries in children is attractive. While pediatric catheterization laboratories became common in the 1950s, the development of devices specifically for pediatric use has lagged behind devices for adult heart disease, and the off-label use of approved devices in the pediatric cardiac patients has been fraught with concerns over safety.

In this issue of *JACC: Cardiovascular Interventions*, Ratnayaka et al. (3) report the use of magnetic resonance imaging (MRI) and its exquisite soft-tissue detail, ability to image in complex imaging planes, and real-time interactivity to guide the transcatheter placement of a cavopulmonary shunt in animals, as could be envisioned in single ventricle pediatric patients. In this study, Covered Cheatham-Platinum stents (CCPS) (Numed Inc, Hopkinton, New York) were used to create the shunt with 100% success, and

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a total procedure time of slightly more than 1 h on average. Several groups have used MRI fused with x-ray imaging (4–8) to combine the soft tissue detail of MRI with the high temporal frame rate of fluoroscopy to guide percutaneous procedures, such as septal defect closures, pericardial access, and transendocardial injections. However, the potential misregistration of the 2 imaging modalities combined with the inability to account for cardiac and respiratory motion would be insufficient to guide a needle puncture from the superior vena cava to the main pulmonary artery while avoiding critical structures, such as the aorta. Because congenital heart patients often undergo numerous catheterization procedures, MRI-guided procedures are particularly appealing due to the lack of ionization radiation, which is of higher concern in pediatric patients. A final advantage of MRI is the ability to assess the patency of the procedure by measuring flow during and after the procedure non-invasively using velocity encoding techniques (9) rather than placing flow wires or using ultrasound.

In a separate set of experiments, Ratnayaka et al. (3) developed a novel, custom-built device with a longer length with MRI-visible markings to further reduce stent deployment times by 3-fold relative to the commercial product tested. Currently, the CCPS is not approved by the U.S. Food and Drug Administration for coarctation of the aorta in patients and is only available under a Continued Access protocol

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after enrollment concluded in the COAST II (Covered Cheatham-Platinum Stents Placement for Prevention or Treatment of Aortic Wall Injury Associated with Coarctation of the Aorta) trial (10). Thus, the design of a specific device for this MRI-guided procedure would be a prudent approach if it enhances outcomes and reduces procedure times.

This study also used a custom, active MRI exchange guidewire rather than passive devices. Passive guidewire devices that are doped with iron oxides often distort the surrounding anatomy and looping of the guidewire may be difficult to ascertain (11). While passive devices or "off-the-shelf" guidewires may be adequate for diagnostic catheterizations, they are likely to be insufficient in providing tip localization to guide complex device placement. As the FDA has already approved an active MRI guidewire, the development of a family of exchangeable guidewires should be less onerous to obtain approval and critical to the future adoption of MRI-guided pediatric procedures.

Over and above the hurdle of developing MRI safe devices for these procedures is the need to train interventionalists to learn new navigation techniques afforded by MRI to visualize anatomy in nonstandard imaging planes relative to fluoroscopic procedures. In addition, the laboratory that performed these procedures is a highly specialized one and at this juncture is only replicated in a handful of centers around the globe. The success of the shunt creation was only assessed in the acute phase. However, long-term biocompatibility will be a pre-requisite for approval of MRI-specific devices. The current study used farm pigs, which are much larger than the average pediatric patient undergoing multiple revision surgeries. It is often challenging to create compact MRI active devices that contain both the device components and the active electronics without substantial increases to the device diameter. Fortunately, the authors have used passive markers on the proposed new stent to create MRI visibility. Thus, the use of larger animals for proof of principle is not a concern for sizing the components. However, altered hemodynamics in a single ventricle situation with anatomical differences will be difficult to recreate in an animal model regardless of animal size. In this study, the authors have made incredible strides in device development and MRI interface guidance systems for a practical approach to a challenging minimally invasive procedure. The final challenge will be to convince device manufacturers and pediatric cardiologists to become early adopters of MRI-guided procedures to transform the almost 7 decades of experience with Glenn and hemi-Fontan procedures to a less invasive approach.

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