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EDITORIAL

The Race to Close Perimembranous Ventricular Septal Defects (PVSD): Proceed with Caution

THOMAS J. FORBES, M.D., F.A.C.C., F.S.C.A.I.

From the Children's Hospital of Michigan, Detroit Medical Center (DMC); Wayne State University, Detroit, Michigan

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Over a decade after the first successful transcatheter closure of a muscular ventricular septal defect (VSD) back in 1987,[1] the race began to develop a suitable device for transcatheter closure of perimembranous ventricular septal defects (PVSD). With the development of braided Nitinol technology, the first-generation devices showed early promise, although due to early and late device complications associated with complete atrioventricular block, the trip was delayed considerably. However, over the past 7 years, considerable progress has been made regarding device development.

Due to the chordal attachments of the atrioventricular valves, the curvilinear relationship of the inflow–outflow septum, and in the majority of cases, close relationship to the aortic valve and the AV node conduction system, the ventricular septum is the most complex anatomical structure interventionalists have to deal with in the heart. By far, the most common location of a congenital VSD is within the perimembranous septum, as supported by the current article in this issue of JOIC, where 90% of all VSD closure procedures were done in PVSDs. By definition, a perimembranous VSD is located just underneath the aortic valve (many times impinging on the annulus of the aortic valve) with the conduction system traversing just posterior-inferior to the defect itself. Due to this, transcatheter closure of PVSDs has been, by far, the hardest "nut to crack." From earlier experiences, it became abundantly clear that use of "off label" devices made for treatment of other intracardiac defects (atrial septal defects, patent ductus arteriousus) were not suitable for closure of PVSDs. Difficulties encountered with impingement on aortic valve leaflets, causing insufficiency, were observed with the symmetric devices, and development of early and late atrio-ventricular block has been observed with the first generation of asymmetrical devices.[2,3] Part of the issue in the development of AV block, particularly late-onset AV block, relates to the material used in making the device. Nitinol alloy provides the foundation for all current VSD occluder devices. One of the properties of Nitinol is that it continues to expand, gradually over time, to its nominal size. Therefore constant, and sometimes increasing, pressure is put on the edges of the perimembranous septum, which, in combination with the "abrasive" properties of the device, could cause irreparable damage to the AV conduction system. Newer-generation devices have been developed that puts less tension on the perimembranous septum, with early results showing promise that development of AV block will be minimized. One device, the Product For Medicine (PFM) PVSD-Li device, has not encountered complete AV block to date.[4]

The authors in the current issue of the *Journal of Interventional Cardiology* who wrote "A systematic review of the efficacy and safety of transcatheter device closure of VSD's" are to be commended for their efforts.[5] This is a considerable undertaking, and although there are limitations in their approach that they mention in their manuscript, they point to the

Address for reprints: Thomas J. Forbes, Professor, Pediatrics-Wayne State University; Co-Director, Cardiac Catheterization Lab, Children's Hospital of Michigan; Co-Director, Great Lakes Structural Heart Institute, Detroit Medical Center (DMC), 3901 Beaubien, Detroit, MI 48201. Fax: 313-993-0894; e-mail: tforbes@dmc.org

challenges encountered in closing PVSDs. In just focusing over the past decade, 6 devices have been developed in an attempt to overcome the challenges. The greatest challenge remains in closing PVSDs in infants <6 kg. By far, the largest number of PVSDs that are in need of surgical intervention are infants who are in persistent heart failure weighing <6 kg. From the STS database, over the past 5 years, between 210 and 235 patients >8 kg undergo surgical repair of their PVSD every year in the United States. In contrast, more than 10× that number undergo surgical closure of PVSDs in infants <8 kg in the United States. Unfortunately, over 98% of the patients reported in the papers analyzed for this report were >8 kg in weight. Clearly this remains a challenge in the area of transcatheter closure of PVSDs.

So initial progress was made regarding transcatheter closure of PVSDs, but unexpected complications slowed the process down. The surgeons, with their excellent outcomes, have set the bar high. Challenges remain for the interventionalist to be sure, but recent progress has lended encouragement that the majority of children, and a greater number of infants, born with hemodynamically significant PVSDs will be able to reliably undergo transcatheter device closure of their defect.

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