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EDITORIAL COMMENT

Outcomes After Device Closure of Atrial Septal Defect in Children

The Present Is Good, Is the Future Brighter?*

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Since the pioneering work of King and Mills in 1974, percutaneous closure with several devices has proven to be safe and effective when compared with surgical atrial septal defect (ASD) closure (1,2). In the current era, more than 80% of secundum ASDs are treated percutaneously. In the United States, 2 devices are approved by the U.S. Food and Drug Administration for ASD closure: the Amplatzer Septal Occluder (ASO, St Jude Medical, Inc., Saint Paul, Minnesota) and the Gore CARDIOFORM Septal Occluder (GSO, W.L. Gore & Associates, Flagstaff, Arizona). The latter replaced the Gore HELEX Septal Occluder (HSO) after several design modifications, including simplification of the delivery mechanism. The GSO, available in diameters of 15 to 30 mm in 5-mm increments, can only close small-to-moderate ASDs. The ASO is the only available device in the United States to close large ASDs. A third device from the Gore family, the Gore CARDIOFORM ASD Occluder, designed to close larger defects, is currently in clinical trials in the United States. Several other devices are available around the world.

Acute and mid-term outcomes have been shown to be excellent with clinical success rates of more than 90% in the pivotal trials for both the ASO and the Gore HELEX Septal Occluder, with clinical success defined as either no residual shunt or a clinically insignificant leak, no need for a repeat procedure to treat the ASD, and absence of a major complication (1,2). Although most ASDs are amenable to device closure, limitations exist related to absolute size of the defect; size of the defect in relationship to total septal length in small patients; and rim deficiency, particularly of the inferior-posterior rim in continuity with the inferior vena cava. Device-related complications are uncommon, and include device embolization, conduction abnormalities including heart block and atrial arrhythmias, and cardiac erosion. Erosion, which has been observed only with the ASO, is rare with a reported incidence ranging from 0.043% to 0.3%, but potentially lethal (3-5).

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In this issue of *JACC: Cardiovascular Interventions*, Jalal et al. (6) report outcomes of ASD closure with the ASO in a large cohort of pediatric patients up to age 18 years with a median follow-up of 3.5 years. A total of 1,395 children were identified, 1,326 were included in the study because of missing data in 69 patients. Acute outcomes were excellent with a procedural success rate of 95.3% and procedural complication rate of 1.8%. Longer-term outcomes at a median of 3.5 years were also excellent with 1.04% rate of major late complications, including no death or erosion. They report a higher rate of periprocedural and late complications in smaller patients (≤15 kg) and in patients with large ASDs.

Examining Table 4 in Jalal et al. (6), the acute complications that were significantly more common in smaller children were pericardial effusion, conduction abnormalities, and mitral regurgitation. The only late complication more commonly seen in patients ≤15 kg was pulmonary hypertension, which seems to be related to other comorbidities or patient selection at the outset rather than a complication of percutaneous closure. Acute complications have also

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been shown to be more common in smaller patients by other investigators (7,8).

Overall their complication rates are generally lower than what has been reported in other series of ASD closure with the ASO. The study design is retrospective and includes data from 9 different French institutions. Demographic, echocardiographic, and procedural data were collected from computerized medical records from each institution. Follow-up data were obtained from medical records review and telephone calls to primary care physicians. There is no description of the follow-up protocol, or what proportion of the follow-up information was derived from evaluation by a cardiologist.

Procedural success, defined as successful implantation of the device without embolization or malposition leading to pulmonary venous obstruction or atrioventricular valve damage, was 95.3%. Complete description of rim deficiency was reported to be available in 85.4% of the patients in this retrospective dataset. Notably 13.6% of their patients had a deficient inferior rim, but failure of implantation was only 4.7%. Only transthoracic and transesophageal echocardiogram were used for guidance during closure. Intracardiac ultrasound, which often provides the best imaging of the inferior-posterior rim, was not used in this study.

Pericardial effusions were noted in 6 patients, all described as "mild" with no hemodynamic instability or signs of erosion, and all resolved spontaneously with medical treatment; details of the medical treatment are not reported. Various degrees of heart block were seen in 5 patients; 3 resolved spontaneously or with steroid therapy, 1 required ASO removal 2 days after deployment, and 1 has persistent, asymptomatic second-degree atrioventricular block.

From the study cohort of 1,326 patients, 1,264 patients had successful ASD closure. Follow-up data were available in 1,158 patients and 106 patients were lost to follow-up. Assuming the 69 patients not included because of missing data at the outset had the defect closed, the actual rate of patients with an implanted device who were lost to follow-up could be as high as 13.1%. The most common long-term complications were migraine headaches and arrhythmia. All arrhythmias believed to be device-related were atrial arrhythmias; late-onset atrioventricular block was not observed. No cases of cardiac erosion were observed.

Other series with more rigorous study design have found slightly higher complication rates. A prospective, nonrandomized, multicenter post-approval study evaluated ASD closure with the ASO in 1,000 patients followed for 2 years (9). Closure rate at 2 years was 97.5%. Hemodynamic compromise occurred in 0.65% of patients, including confirmed cardiac erosion in 3 of 928 patients (0.3%). An additional 31 patients had pericardial effusions with 1 of 31 requiring pericardiocentesis; all of these were adjudicated as not related to erosion. The total adverse event rate was 6.56%, including atrial arrhythmias (1.3%) and 6 device embolizations (0.6%), 1 diagnosed 12 days after implantation with hemodynamic compromise. There were no deaths.

Continued access data with 5 years of follow-up for the Gore HELEX Septal Occluder reported a clinical success rate of 96.2% and 3.0% rate of major complications related to the device (1.5% embolization within 24 h, 1.5% wire fractures with elective device removal) (10). No patient experienced hemodynamic compromise, cardiac erosions, or other catastrophic events. One patient has been reported with mitral valve perforation because of a wire frame fracture who underwent surgical device removal and mitral valve repair because of significant although asymptomatic mitral regurgitation (11). Outcomes for the GSO in 173 patients followed for at least 12 months showed complete closure in 95.4% and no clinically significant leaks (12). There were no serious events during a median follow-up of 20 months. No wire frame fractures leading to device instability or damage to an intracardiac structure have been reported with this device.

A recent case-control study sought to better understand the mechanism and potential risk factors for cardiac erosion with the ASO (13). All 125 erosions reported to St Jude's Medical between 2002 and 2014 were age- and sex-matched with a control ASO closure case with no erosion. On multivariate analysis deficiency of any rim (or of the aortic rim), device size >5 mm larger than the static ASD diameter, and patient weight/device size ratio were significantly associated with erosion. Nearly all erosion cases had a deficient aortic rim (94%), in contrast to 24% of the control subjects.

Erosion remains rare, and to date no risk factors have been identified with a strong enough association to warrant contraindication. Awareness when counseling families of the characteristics of patients who have had erosions (absent rims), and efforts not to oversize the device are important. At present ASDs with a stop-flow diameter up to 17 mm can typically be successfully closed with a GSO. Larger

defects require an ASO. Preliminary results with the investigational Gore CARDIOFORM ASD occluder, ranging in diameter from 27 to 48 mm, showed success in closing much larger defects than possible with previous Gore devices (14). Although the full safety profile of this device will take some time to elucidate, mechanistically it is similar to the other Gore devices, and is an important addition to the current options for percutaneous secundum ASD closure.

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