Title

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Journal

Catheterization and Cardiovascular Interventions, 89(1)

ISSN

1522-1946

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Publication Date

2017

DOI

10.1002/ccd.26891

Catheterization and Cardiovascular Interventions 89:112–113 (2017)

Editorial Comment

Addressing the Needs of Treating Congenital Heart Disease: The Influence of Deficient Retro-Aortic Rim on Technical Success and Early Adverse Events Following Device Closure of Secundum Atrial Septal Defects: An Analysis of the IMPACT Registry®

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Key Points

- For secundum ASD, a deficient retro-aortic rim is common (40% of cases)
- However, the deficient retro-aortic rim had no effect on ASD device placement success or immediate outcome
- The IMPACT Registry does not track long-term outcome, so there is no information provided about long-term complications, such as erosion.

The accompanying article [1] from the IMPACT registry describes the immediate results for closure of atrial septal defects stratified by whether there was an adequate retro-aortic rim of 5 mm versus those who had insufficient tissue with less than 5 mm for the devices to grasp. Of the 1,564 subjects with adequate data to analyze, the prevalence of a deficient aortic rim was 40%, which is higher than previously reported.

The study is noteworthy for several reasons. It represents a coordinated effort by 77 institutions to combine their data so that a better understanding of treatment of congenital heart disease can be obtained. A variety of devices was used in this registry with the Amplatzer atrial septal occluder (ASO) accounting for 70% of devices, and the Gore devices in 25% of cases (Helex 20% and Cardioform 5%).

It is reassuring to know that there was no effect of a deficient aortic rim in terms of success of the procedure, time required, or immediate complications such as embolization or need for surgery. ASD devices splay out over the aortic bump in the atrial septum. There has been concern that having a deficient aortic rim would either make it more difficult for the device to stay in place or might predispose to the device sticking into the wall of the atrium or aorta which could lead to erosion. Unfortunately, the IMPACT registry does not provide follow-up data so this study was not designed to answer the question of factors that might predispose to erosion. However, there is an ongoing FDA mandated post-market approval study for the Amplatzer device to understand the prevalence of erosion and factors that may predispose to it in the current era. In this context, it is important to note that there have been no reports of erosion with the Gore Helex or Cardioform devices. Unfortunately, the Gore Cardioform device is limited to ASDs that are 17 mm or less in diameter.

The patients that were included in this analysis were predominantly children and technical failure occurred in 5.8% of procedures, but there was no difference in the rate of technical failure between subjects with deficient retro-aortic rim (6.7%) and those with larger retro-aortic rim (5.2%, $P = 0.19$). Embolization of a device occurred in 29 cases, of which 76% were successfully treated by transcatheter intervention. The remaining six cases underwent cardiac surgery. Major early adverse events occurred in 1.2% of cases with no difference between subjects with or without a deficient retro-aortic rim. It is useful to note that as the children got older and larger, the complication rate decreased. Not unexpectedly, larger septal defects were associated with a lower technical success.

Conflict of interest: Nothing to report.

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Received 22 November 2016; Revision accepted 22 November 2016

DOI: 10.1002/ccd.26891
Published online 9 January 2017 in Wiley Online Library (wileyonlinelibrary.com)

Although not statistically significant, the risk of embolization for the Helex device was slightly higher than for the ASO device (3.0% vs. 1.6%). This slight increase in technical failure is presumably due to the fact that the Helex device is more complex to deploy. However, the Helex device has been supplanted by the Gore Septal Occluder (GSO), which is beautifully engineered, simpler, and stronger. Despite the infrequent use of the GSO device in the current report, its use is gaining traction and it is reassuring that there was no greater incidence of device complication or technical failure.

There are still several open questions about percutaneous ASD closure. The most important issue is what is the optimal device to use? The Gore Septal Occluder appears to be better tolerated with no evidence of erosion but is only useful for ASDs less than 17 mm in diameter. What is the current risk of erosion with the Amplatzer device? Can it be redesigned with softer and more flexible nitinol wires to decrease the risk of erosion and yet maintain its integrity and effectiveness? What is the best technique for sizing ASDs? Is the Doppler "stop flow" method preferable or is more complete stretching of the septal defect more reliable?

The optimal strategy for treating a patient with an atrial septal defect still remains a challenge, with or without a deficient retro-aortic rim. This report from the IMPACT registry is reassuring in that it demonstrates that a deficient retro-aortic rim was prevalent but was not associated with increased risk of technical failure or early adverse events. It is a demonstration of the utility of combining individual center data into a national registry to address issues of common interest in the care of patients with congenital heart disease.

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