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EDITORIAL COMMENT

Bigger Is Feasible With a Short Retroaortic Rim But Is it Always Better?*

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Patent foramen ovale (PFO) closure is performed routinely around the world. Two devices have received approval in North America: the Amplatzer PFO Occluder (Abbott Structural Heart) and the Gore Cardioform (W.L. Gore). The most common indication for closure is the prevention of recurrent paradoxical emboli after a cryptogenic stroke. Other indications for closure include decompression illness and platypnea orthodeoxia. Multiple observational, retrospective, and prospective randomized trials have confirmed its efficacy and safety with low periprocedural complications. The 2 complications most feared among operators are device embolization and device erosion. Device embolization can often be treated by percutaneous retrieval. Device erosion, however, is a potentially life-threatening complication requiring urgent surgical intervention.

To mitigate the risk of device embolization, larger devices are used for "better" anchoring. However, larger devices are more likely associated with higher erosion risk. The exact conditions leading to device erosion have yet to be determined. Common reasons cited in the literature and discussed among operators include a larger device size, device interference with the atrial free wall, and deficient retroaortic rims. The incidence of device erosion is very low. It is reported to occur in 0.018% of cases.[1]

The PC,[2] RESPECT Extended,[3,4] and CLOSE[5] trials are 3 landmark trials that compared PFO closure with the Amplatzer PFO Occluder vs medical treatment after a cryptogenic stroke. The mean age in these trials ranged from 42.9 to 45.7 years, all-cause mortality was below 2.0%, recurrent embolic events (stroke/transient ischemic attack) ranged from 3.0% to 3.6%, and the onset of new atrial fibrillation ranged from 1.4% to 4.6%. The length of the retroaortic rim was not routinely measured or reported, and the PFO device most used is the 25-mm PFO Amplatzer Occluder device.

In this issue of *JACC: Advances*, Stefanescu Schmidt et al[6] examines whether a short retroaortic rim defined as <9 mm is safe as it pertains to the risk of device erosion. The study is a single-center, retrospective analysis of 324 patients who underwent PFO closure with the Amplatzer PFO Occluder device between 2006 and 2017. Of the 324 patients, 197 patients had a deficient retroaortic rim. The mean age of the patients is 49.8 years. Preprocedural transesophageal echocardiograms were reanalyzed, and the distance from the aorta to the PFO was measured. Long-term outcomes were analyzed using a government administrative database. The median follow-up period was 7 years. Three-quarters of patients had their PFO closed for a cryptogenic stroke. The procedures were primarily done using fluoroscopic guidance alone, and the 35-mm Amplatzer PFO Occluder device was mostly used. There were 18 deaths in the entire study population (5.6%), and new-onset atrial fibrillation was reported to have occurred in 11% of the study population. The rate of recurrent stroke or transient ischemic attack was 5.6%. The authors report no cases of device embolization or erosion requiring cardiac surgery over the study period. The article concludes that a short retroaortic rim does not confer an increased risk of device erosion. The authors acknowledge that this outcome is

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realized within the limitations of an administrative database and for a complication with a very low event rate.

The authors are to be congratulated for a well-written manuscript. The hypothesis tested is clinically relevant. The outcomes from the manuscript will contribute to the totality of the current data and will impact how procedures are done. The study's primary purpose was to assess the safety and efficacy of PFO closure in patients with a deficient retroaortic rim using the Amplatzer PFO device. The article is unique because it challenges the original recommendation made by the manufacturer and largely ignored by the interventional community. The recommendation stated that no device should be implanted if the retroaortic rim is <9 mm. They have demonstrated this approach to be feasible; however, there are several issues of concern about the statement that it is safe.

First, the article differs in 2 noteworthy procedural aspects compared to landmark PFO trials and the general PFO closure practice. Most implants were performed using fluoroscopic imaging only, and most PFOs were closed with the 35-mm device.

The Amplatzer TM PFO Occluder device comes in multiple sizes (18 mm, 25 mm, and 35 mm). The most used size is the 25-mm device. Larger sizes are recommended in specific anatomical situations, such as prominent atrial septal aneurysms and large PFOs, to mitigate the risk of device embolization. Generally, transesophageal echocardiography or intracardiac echocardiography imaging is used to determine anatomical PFO characteristics so that the smallest device is deployed to close the interatrial communication. It is commonly accepted that a smaller device has a lower risk of device erosion. Smaller devices are also less likely to interfere with the electric circuitry within the atria and cause atrial fibrillation. In addition, intraprocedural imaging is recommended to evaluate device stability, distance to the atrial wall, retroaortic rim distance, and residual leaks. When only fluoroscopy is used, these anatomical details are not appreciated. The use of fluoroscopy alone to guide PFO closure is well documented in the literature,[7] and it is growing in popularity within the interventional community. However, if fluoroscopy-guided PFO closure results in the use of larger devices to mitigate the risk of embolization, then the increased risk of device erosion and new-onset atrial fibrillation may be an unexpected consequence. The manuscript reports no cases of device erosion requiring cardiac surgery. However, the numerically higher rate of unexplained all-cause mortality in this relatively young population and the higher rate of new-onset atrial fibrillation raise concern as to whether the liberal use of the larger 35-mm PFO device may be a contributing factor.

Second, the complication of device erosion is a rare event. It is reported to occur in 1/5,000 cases. The study's sample size is 324 patients, of which 197 had a short retroaortic rim. There were no reported cases of device erosion requiring surgical intervention. Statistically, given the small sample size, this is not surprising. Also, long-term outcomes of the study population were obtained using a government administrative database. The government administrative database mandated that patient confidentiality be maintained. Therefore, individual medical records were not available for review. There are 18 unexplained deaths in a relatively young population of 324 patients, giving a 5.6% mortality rate over the study period. The cause of the individual deaths could not be verified. More details relative to the baseline characteristics of patients who died would be needed to contextualize the findings better. Therefore, sudden cardiac death related to device erosion cannot be excluded.

Lastly, with the advancement of technology, access to the left atrium through the interatrial septum has become more important. Percutaneous procedures that address mitral valve pathology, left atrial appendage occlusion, and left atrial/ventricular arrhythmias have become the standard of care in 2022. There is a push to create PFO closure techniques that leave a smaller footprint on the atrial septum to facilitate access to the left atrium. Large PFO devices make access to the left atrium more challenging and may limit future transcatheter left-sided interventions.

Overall, Stefanescu Schmidt et al[6] have demonstrated that PFO closure in patients with a short (<9 mm) retroaortic rim is feasible using large devices under fluoroscopic guidance. To determine whether this practice is safe will require a much larger patient cohort and a more comprehensive database. Also, if limiting intraprocedural imaging results in larger PFO devices being used to overcompensate for the risk of device embolization, then this approach may limit future percutaneous interventions that require left atrial access. When it

comes to the interatrial septum, bigger may be feasible but may not always be better!

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