Cardiac Perforation by Atrial Septal Defect Closure Devices
A Potentially Catastrophic and Still Unclear Event

We read with interest the safety review paper by Moore et al. (1) aimed at outlining the available information on the safety of atrial septal defect (ASD) closure devices (Amplatzer septal occluder [ASO], St. Jude Medical, St. Paul, Minnesota, and Helex septal occluder, W.L. Gore, Flagstaff, Arizona) with a focus on cardiac perforation.

In this endeavor, the authors of that paper quoted the analysis by DiBardino et al. (2), which presented 51 cardiac perforations reported to the Manufacturer and MAUDE (User Facility Device Experience) database, with a concerning overall mortality of 19.6% and evidence that ruptures may occur as late as 3 years after deployment.

Similarly, Moore et al. (1) reported a MAUDE database analysis by the U.S. Food and Drug Administration showing how erosion contributes to 15% of medical device reports, with an overall 16.2% mortality in 80 patients who required device removal. Again, the time to erosion reported in the 13 deaths ranged from 1 day to 2.2 years (3).

Cardiac perforation is a rare complication of ASD closure devices, not encountered in the pivotal or post-market approval studies, which is particularly troubling in view of the potential for late occurrence, the few convincing data on risk factors, and the impending catastrophic outcome.

Although not quoted by Moore et al. (1), we reported the longest time frame (5 years) ever recorded for an ASO-related cardiac perforation, which occurred during an intense isometric exertion in a 54-year-old patient (4).

Although anecdotal, our observation might have 2-fold importance. On the one hand, the potential for an even more delayed adverse event should not be underestimated. Indeed, this late occurrence might suggest a more cautious revision of the follow-up imaging schedule after device implantation (1).

On the other hand, the occurrence of the event during an intense isometric exertion raises the question whether dynamic changes in the anatomic relationship between the device and surrounding cardiac structures, particularly during Valsalva maneuvers or other pressurizing conditions, might play a role in the determinism of the complication. This issue could be of the utmost importance in people exposed to strenuous physical activity.

This hypothesis might suggest 2 precautionary initiatives: 1) the introduction of stress echocardiography in the routine assessment of patients after ASD closure device implantation to evaluate the appropriateness of the device positioning under dynamic conditions; and 2) greater restriction imposed during intense physical activity in ASD closure devices holders until this issue is finally elucidated.

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Reply
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We thank Dr. Santini and colleagues for their interest in our paper (1). Santini and colleagues discuss a hypothetical cause of erosion based on an anecdotal report stemming from 1 patient who had a device-related cardiac perforation following a period of intense isometric exercise. We did not reference the report by Santini et al. (2), but we acknowledge that a period of intense exercise could potentially bring about hemodynamic changes that may alter the relationship between the device and surrounding structures and, thereby, increase the risk for erosion. However, this hypothesis is based on a single case report. As alluded to in our review, erosions are rare, with the overall incidence of erosions ranging from 0.1% to 0.3% and with mortality from erosion being around 0.05%,