A Word of Caution

Risk of Device Erosion After Percutaneous Treatment of Atrial Septal Defect in Patients With Dilated Aortic Root

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The US Food and Drug Administration has alerted providers and patients that the catheter-delivered Amplatzer atrial septal occluder (AGA Medical, Golden Valley, MN) from St. Jude Medical poses a small risk of potentially life-threatening complications. According to the agency, the device can erode the surrounding tissue over time and may cause cardiac tamponade or other complications that require immediate surgery. The agency estimates the risk of such emergencies at 1 to 3 per 1000 implanted patients and notes that >230,000 Amplatzer atrial septal occluder devices have been implanted around the world. The device rubbing against the wall of the heart can erode the tissue and create a hole. It can also lead to further scraping or erosion through tissue in the upper chambers (atria) of the heart, primarily in the top of the atria near the aorta. This scraping may also cause separate or simultaneous holes in the aortic root. The US Food and Drug Administration does not recommend device removal for patients who have the Amplatzer atrial septal occluder unless physicians determine that removal is appropriate for their particular patients.

We describe the case of a 42-year-old man who first presented after experiencing a small cerebrovascular accident. Transesophageal echocardiography (TEE) demonstrated the presence of a moderate-sized atrial septal defect (ASD) 1.4 cm in diameter and a deficient superior (aortic) rim (Figure, A and Movie I in the online-only Data Supplement). The patient also had a bicuspid aortic valve (Figure, B and Movie I in the online-only Data Supplement) with minimal aortic regurgitation and mild aortic noncoronary sinus dilation (4.2 cm). Aortic rim deficiency is not a generalized contraindication for device ASD closure, and given that all the other septal rims were of adequate size and because of the only mild aortopathy, the defect was closed under TEE guidance with the use of an Amplatzer atrial septal occluder 20-mm device. After device deployment, there was no residual blood flow across the aorta, creating no form of pressure (Figure, C and Movie II in the online-only Data Supplement). Six months later, a repeat TEE showed enlargement of the aorta at the noncoronary sinus level (4.6 cm) without deterioration of the valvular function. The 2 anterior disks of the device, however, were displaced vertically onto the enlarging noncoronary sinus, appearing to apply pressure on the wall of the aorta. The footprints of the disks, imaged from the inside of the aorta by TEE, were encroaching 2.3 mm inside the aortic wall (Figure, D and Movie III in the online-only Data Supplement). This was confirmed by computed tomographic angiography (Figure, E). The ASD was completely closed, and there was no pericardial fluid. The patient remained asymptomatic. On the basis of TEE and computed tomographic angiography findings, we decided to proceed to cardiac surgery. On operation, both disks of the device appeared to have eroded the roof of the left atrium, as well as the adventitia and media of the aortic wall at the level of the noncoronary sinus, sparing only the intima (Figure, F). The device was explanted, and the ASD was closed with a pericardial patch. A Vascutek vascular graft (Terumo Ltd, Ann Arbor, MI) was used to replace the noncoronary sinus sparing the aortic valve (modified aortic root remodeling procedure). The patient made a full recovery.

This is a word of caution to avoid percutaneous treatment of big ASDs in patients with concomitant dilated aortic root, especially if this is combined with bicuspid aortic valve.

Disclosures
None.

References

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Figure. A, The preimplantation transesophageal echocardiography (TEE) showed a big atrial septal defect (ASD). B, A 2-dimensional TEE also showed a bicuspid aortic valve with mild aortic regurgitation. C, TEE performed immediately after implantation showed that the device position was ideal without residual shunt and any form of pressure to the aorta (AO). D, At 6 months after implantation, the footprints of the disks, imaged from the inside of the aorta by TEE, were encroaching inside the aortic wall. E, Computed tomographic angiography confirmed that the 2 anterior disks of the device pressed the aortic wall (black arrow-head). F, Intraoperatively, both disks of the device appeared to have eroded the roof of the left atrium (LA), as well as the adventitia and media of the aortic wall at the level of the noncoronary sinus, sparing only the intima (black arrows). RA indicates right atrium.
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**Movie Legend**

**Movie 1:** 2D TOE showed a big ASD and a bicuspid aortic valve. Best viewed with Windows Media Player.

**Movie 2:** 2D TOE immediately post-implant showed an ideal position of Amplatzer device (the two anterior disks of the device splayed across the aorta without any pressure on it). Best viewed with Windows Media Player.

**Movie 3:** 3D TOE 6 months post-implant revealed the footprints of the two anterior disks of the device that encroached inside the aortic wall. Best viewed with Windows Media Player.