Late erosion of an Amplatzer septal occluder device 6 years after placement

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Cardiac perforation is a rare complication after transcatheter closure of an atrial septal defect (ASD) or patent foramen ovale (PFO). Erosion usually occurs within the first days after device placement. We report a case of device erosion 6 years after device closure of a PFO.

CLINICAL SUMMARY

A 46-year-old man underwent transcatheter closure of a PFO at our institution after a stroke-like event. The stretched diameter of the PFO was 9 to 10 mm. A 14-mm Amplatzer septal occluder device (AGA Medical Corporation, Golden Valley, Minn) was placed. Immediately after placement, a trivial degree of left-to-right shunt was seen through the center of the device by intracardiac echocardiography; agitated saline injection revealed a trivial right-to-left shunt. The procedure was uncomplicated, and the patient was dismissed from the hospital the following day. Predismissal transthoracic echocardiogram (TTE) showed good position and stability of the device with no apparent shunt.

Ten days later, the patient returned with intermittent palpitations. Electrocardiogram revealed atrial fibrillation with rapid ventricular response. He was given intravenous diltiazem and promptly returned to sinus rhythm. TTE again documented good position of the occluder device with no recurrent atrial shunt or pericardial effusion. He was observed in the hospital overnight and dismissed on a regimen of oral diltiazem for 1 month. He had no recurrence of atrial fibrillation.

Six years later, he came to the emergency department with progressive pleuritic chest pain. He had had similar chest pains 1 month prior, which were not extensively investigated, but resolved spontaneously. In the emergency department he was hypotensive with mild jugular venous distention. TTE documented moderate pericardial effusion with tamponade. Pericardiocentesis removed 325 mL of bloody fluid. Transesophageal echocardiography did not show any evidence of shunt around the device. The device was again noted to not straddle the aortic root. Transesophageal echocardiographic

imaging was unable to document erosion of the occluder device through the atrial wall or aorta, but in retrospect it did not appear properly aligned with the superior limbus of septum secundum (Figure 1).

Hemopericardium recurred, and urgent mediastinal exploration was performed. Blood, clot, and fibrinous material were evacuated from the pericardial space. The left atrial disk of the occluder device was noted to have eroded through the dome of the left atrium, with approximately 4 to 5 mm of the disk visible from outside the left atrium (Figure 2). Intermittent, active bleeding was noted externally at the site of left atrial erosion. After initiation of cardiopulmonary bypass and administration of cardioplegic solution, the right atrium was opened and the device was excised. The atrial septum was repaired with bovine pericardium and the left atrial erosion defect was debrided and sutured closed. He was dismissed 5 days later but was readmitted 12 days later with a sternal wound infection that responded to debridement and intravenous antibiotic therapy.

DISCUSSION

Erosion is a rare but serious risk of closure of ASDs and PFOs using Amplatzer septal occluder devices. The rate of erosion of Amplatzer ASD and PFO occluder devices is estimated to be approximately 0.1% but carries a high risk of mortality.^{1,2} Erosion most often occurs at the anterosuperior wall of the right or left atrium, resulting in pericardial effusion, frequently with cardiac tamponade. Erosion may involve the ascending aorta, which may result in a fistulous atrial-aortic communication and associated heart failure.

FIGURE 1. Short-axis view of the atrial septum showing malalignment of the septal occluder device (arrow) with the superior limbus of the fossa ovalis. RA, Right atrium; LA, left atrium; Ao, aorta; L, limbus.

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Disclosures: Authors have nothing to disclose with regard to commercial support. Received for publication Dec 15, 2010; accepted for publication March 1, 2011; available ahead of print April 4, 2011.

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J Thorac Cardiovasc Surg 2011;142:221-2
0022-5223/\$36.00

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doi:10.1016/j.jtcvs.2011.03.006

FIGURE 2. Intraoperative photograph of the left atrial disk of the septal occluder device (arrows) as it protrudes through the dome of the left atrium.

The risk of erosion into the aorta has prompted recommendation against device oversizing and straddling over the aortic root.² This recommendation has since been disputed by expert opinion regarding the mechanism of device-related erosions.³ Thus, opinions of some experienced operators concerning erosions by the Amplatzer septal occluder have been at odds with manufacturer recommendations.⁴ This reported left atrial wall erosion may have resulted from migration of the device through the superior rim of the atrial septum and through the dome of the left atrium. This speculation raises questions of unique individual susceptibility to device erosion through the atrial wall.

Most reported cases of erosion occur within 72 hours of device placement.^{1,2} The latest reported erosion after PFO closure occurred 16 months after device placement.⁵ Erosion after ASD closure has been documented 3 years after device placement.²

We present the latest known case of device erosion after placement of a relatively small (14 mm) Amplatzer septal occluder device, 6 years after placement. This case illustrates the importance of recognizing the ongoing, albeit low, risk of device erosion long after initial ASD/PFO closure. A history of ASD/PFO device closure should prompt appropriate investigation in patients who have chest pain, shortness of breath, new-onset heart failure symptoms, or other symptoms suggestive of a cardiac etiology.

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COMMENTARY

Continued controversy regarding adverse events after Amplatzer septal device closure: Mass hysteria or tip of the iceberg?

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In this issue of the *Journal*, Taggart and coauthors¹ have reported their experience with late erosion of an Amplatzer septal occluder device (AGA Medical Corporation, Plymouth,

Minn), resulting in cardiac tamponade and necessitating subsequent emergency surgery.¹ Findings at surgery were perforation of the left side of the disk through the dome of the left atrium. This case report contains several interesting pieces of history including arrhythmia 10 days after Amplatzer device placement and chest pain 1 month before the patient's subsequent presentation with tamponade. They point out that 6 years is longer than the hazard function for erosion is commonly thought to have still been in effect. The longest previously reported interval between insertion and erosion of an Amplatzer device was 3 years. It seems that the complication pattern of this device is still being defined.

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J Thorac Cardiovasc Surg 2011;142:222-3

0022-5223/\$36.00

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doi:10.1016/j.jtcvs.2011.04.014