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.

References

1. Amin Z, Hijazi ZM, Bass JL, Cheatham JP, Hellenbrand W, Kleinman CS. PFO closure complications from the AGA registry. *Catheter Cardiovasc Interv.* 2008; 72:74-9.
2. Amin Z, Hijazi ZM, Bass JL, Cheatham JP, Hellenbrand WE, Kleinman CS. Erosion of Amplatzer septal occluder device after closure of secundum atrial septal defects: review of registry of complications and recommendations to minimize future risk. *Catheter Cardiovasc Interv.* 2004;63:496-502.
3. El-Said HG, Moore JW. Erosion by the Amplatzer septal occluder: experienced operator opinions at odds with manufacturer recommendations? *Catheter Cardiovasc Interv.* 2009;73:925-30.
4. AGA Medical Corporation Website; US Products. Available at: <http://www.amplatzer.com/USProducts/ASDDevices/tabid/179/Default.aspx>. Accessed September 7, 2010.
5. Cecconi M, Quarti A, Bianchini F, Bucari S, Costantini C, Giovagnoni A, et al. Late cardiac perforation after transcatheter closure of patent foramen ovale. *Ann Thorac Surg.* 2006;81:e29-30.

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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In 2009, we² published the results of an exhaustive review of the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database regarding the incidence of reported adverse events after Amplatzer device placement. In this review, we found an increasing number of events reported over a 5.5-year period, equivalent estimated mortality for device placement compared with Society of Thoracic Surgeons database surgical closure data, and a much higher need for operation and operative mortality *per adverse event* for device closure compared with surgical closure. After publication of these data, we were contacted by representatives of AGA Medical Association, and their concerns regarding possible interpretations of our results led to a clarification letter in a subsequent issue.³ Since that time we have been also contacted by the FDA, where an updated data mining project is supposed to be ongoing to further observe the trends in reported complications.

Although AGA Medical has made honest attempts at good faith reporting of ongoing results, we continue to believe that a mandatory user registry, identical to what surgeons use for ventricular assist devices, would be useful. The current case report indicates that the long-term complication profile of this device is still unknown. A closer look at the present report also reveals other interesting points that echo the MAUDE registry findings. The fact that the patient presented with new-onset arrhythmia 10 days after device placement is not insignificant inasmuch as arrhythmia was listed as an independent complication of device placement and also was found as a warning sign of device embolization, particularly into the right ventricle.² New-onset arrhythmias in a patient with an Amplatzer device should be taken seriously, including an urgent echocardiographic assessment.

The development of chest pain 1 month before the tamponade episode may also be of relevance. The actual mechanism of the erosion of this device has been hotly debated, but it seems that a gradually progressing erosion process is a real possibility despite the manufacturer's recommendations. Taggart and associates¹ point out that "most reported cases occur within 72 hours of placement," but our MAUDE data show that 24 of 51 known perforations occurred greater than 24 hours from placement, with 8 occurring at 1 to 6 months, 2 at 6 months to 1 year, and at 3 greater than 1 year. The sites of erosion included various combinations of atrium and/or aorta in the FDA reports, and the left atrium was the common site of atrial level perforation. Until the mechanism of erosion and its relationship to sizing and time after placement is better understood, we cannot speculate on individual patient susceptibility.

The increasing number of reported adverse events with the Amplatzer device may simply reflect an increase in the number of devices placed. It is also possible that the known events are just the "tip of the iceberg" with a constant hazard function for erosion that exists over the lifetime of the patient. The only way to get real answers to these important issues is to actively collect short-term outcome data and to continue active surveillance of these devices.

References

1. Taggart NW, Dearani JA, Hagler DJ. Later erosion of an Amplatzer septal occluder device 6 years after placement. *J Thorac Cardiovasc Surg.* 2011;142:221-2.
2. DiBardino DJ, McElhinney DB, Kaza AK, Mayer JE Jr. Analysis of the US Food and Drug Administration Manufacturer and User Facility Device Experience database for adverse events involving Amplatzer septal occluder devices and comparison with the Society of Thoracic Surgery congenital cardiac surgery database. *J Thorac Cardiovasc Surg.* 2009;137:1334-41.
3. DiBardino DJ. Clarification of statements made regarding investigation into Amplatzer device complication incidence and comparison with the Society of Thoracic Surgery database. *J Thorac Cardiovasc Surg.* 2009;138:784-5.

A technique for implanting outflow cannulas for Berlin Heart EXCOR ventricular assist device in small pediatric patients

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The Berlin Heart EXCOR (Berlin, Germany) ventricular assist device has been used with increasing frequency in younger pediatric patients. The smallest available blood pump has a 10-mL volume, and the smallest outflow cannula tip is 3 mm in diameter. The cannula has a 90-degree angulation with a flanged tip for sewing to the ascending aorta or main pulmonary artery. There is a short, grooved extension from the flange in this design. During a typical cannula insertion, a side-biting clamp is placed on the aorta and the cannula is anastomosed to a matching arteriotomy while the patient