



Open surgical repair for the removal of an Amplatzer™ device

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Abstract: Although Amplatzer™ Septal Occluder devices are generally safe for the treatment of atrial septal defects (ASDs), there is a risk that the device will erode through aortic tissue. Herein, we present the case of a 33-year-old woman who required open surgical repair to remove an Amplatzer™ Septal Occluder device because a fistula had formed through the right atrium and noncoronary sinus within her native aortic root.

Keywords: Amplatzer™ Septal Occluder; aortic root; fistula

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Introduction

Transcatheter closure of atrial septal defects (ASDs) using the Amplatzer™ Septal Occluder device (St. Jude Medical, Plymouth, MN) has been demonstrated to be safe and effective since the device was approved by the U.S. Food and Drug Administration (FDA) in 2001. However, several complications have been associated with the use of this device, including perforation, device migration, embolization, thrombosis, infection of the atrial wall, and tissue erosion. A case of cardiac erosion was published in 2002 (1). Erosion rates have since been reported to range from 0.043% to 0.3% (2).

The FDA issued a warning in 2013 about safety issues encountered with the Amplatzer™ device after receiving more than 100 reports of device-associated erosion (3). The device is made of a self-expanding nitinol metal mesh. If the device is sized improperly, the mesh can rub against the cardiac wall and erode the tissue of the atrium and the adjacent aortic root, potentially leading to cardiac tamponade.

Herein, we report the case of a patient who required open surgical repair for the removal of an Amplatzer™ Septal Occluder device that was eroding into the aortic root.

Case presentation

The patient was a 33-year-old woman who had undergone ASD repair with an Amplatzer™ device 9 years prior at age 24.

Patient selection and workup

A preoperative transesophageal echocardiogram showed erosion consistent with a fistula from the noncoronary sinus of the aortic root to the right atrium. From preoperative computed tomography (CT) imaging, it was evident that the previously placed Amplatzer™ device had eroded into the noncoronary sinus of the aortic root at two distinct locations. This finding was confirmed with 3-dimensional CT reconstruction images (*Figure 1*). An illustration is provided to show the fistulas and the direction of blood flow through these defects (*Figure 2*).

Procedure

A median sternotomy was performed, and cardiopulmonary bypass was initiated using bicaval cannulation. A left ventricular sump was placed via the right superior pulmonary vein. The heart was arrested with antegrade and

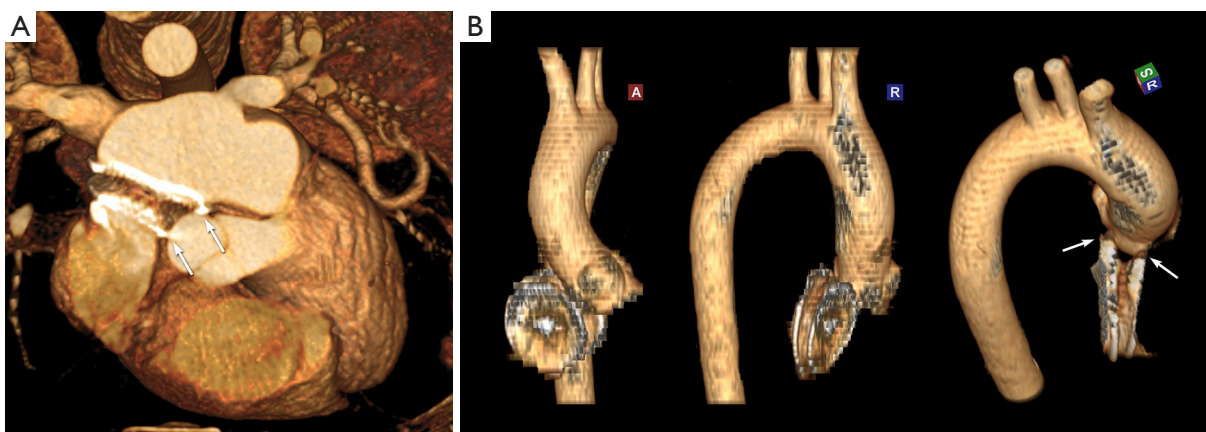


Figure 1 Three-dimensional computed tomographic reconstructions of the heart (A) and the aorta (B) showing erosion of the Amplatzer Septal Occluder device into the noncoronary sinus in 2 distinct places (arrows). This 33-year-old woman required open surgical repair for removal of the device. Used with permission of Baylor College of Medicine.

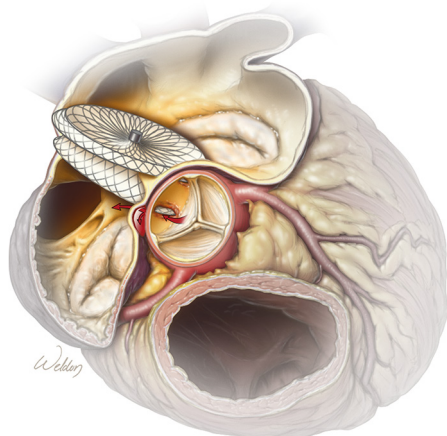


Figure 2 An illustration showing the location of the Amplatzer™ Septal Occluder device and the sites of erosion into the noncoronary sinus, which created 2 fistulas. The direction of blood flow through these defects is shown. Used with permission of Baylor College of Medicine.

retrograde cardioplegia. A right atriotomy was made, and upon entry to the right atrium, the Amplatzer™ device was found to be adherent to both the atrial wall and the septum (Figure 3). Careful, sharp dissection with a scalpel was used to separate the device from the surrounding structures (Figure 4). During this dissection process, the fistula into the aortic root was identified (Figure 5). In order to remove the device from the surrounding structures, almost the entire atrial septum had to be removed. The fistula was debrided

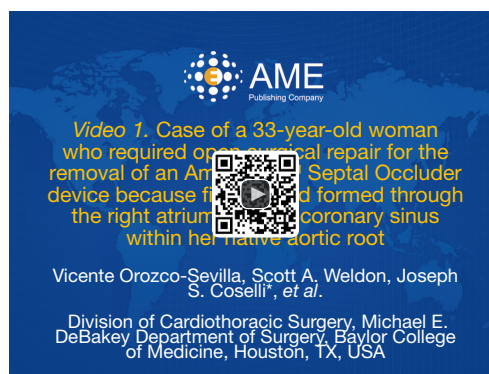


Figure 3 Case of a 33-year-old woman who required open surgical repair for the removal of an Amplatzer™ Septal Occluder device because fistulas had formed through the right atrium and noncoronary sinus within her native aortic root (4). Used with permission of Baylor College of Medicine.

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back to the healthy tissue and repaired with a piece of bovine pericardium, which was secured into place with a running 4-0 Prolene suture. After the first fistula was closed, the second opening into the aortic root was identified, and it was noted that there was damage to the noncoronary sinus that was not amenable to simple repair. The aortic root was opened and exposed via transection at the sinotubular junction. The aortic tissue of the noncoronary sinus was completely resected. The sinus was reconstructed using a piece of bovine pericardium. After the noncoronary sinus of the aortic root was repaired, the residual ASD was repaired using a piece of autologous

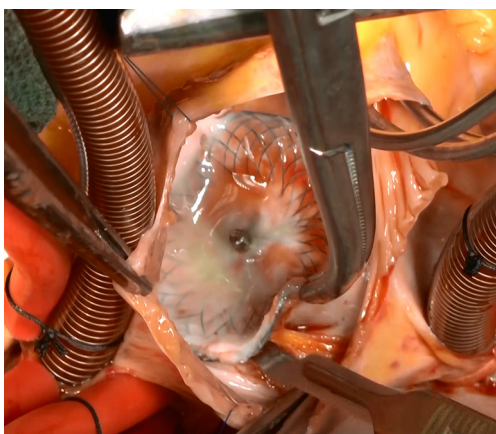


Figure 4 Photograph showing careful, sharp dissection with a scalpel to begin separating the Amplatzer™ device from the surrounding structures. Used with permission of Baylor College of Medicine.

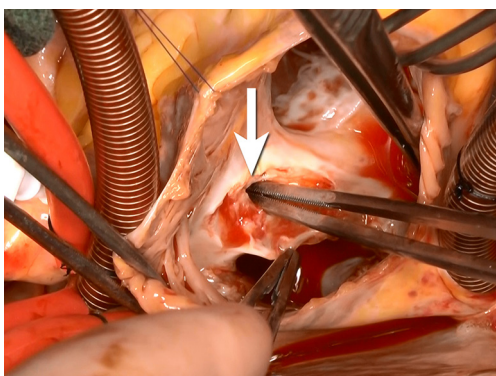


Figure 5 Photograph taken after the adherent Amplatzer™ Septal Occluder device was removed, revealing a fistula into the aortic root (arrow). Used with permission of Baylor College of Medicine.

pericardium. The residual defect of the superior portion of the right atrium was closed with a separate piece of bovine pericardium (Figure 6). The right atriotomy was then closed in a running fashion, and the aorta was reapproximated and closed with a running Prolene suture, which incorporated the free edge of the reconstructed noncoronary sinus. An intraoperative echocardiogram showed a completely competent aortic valve without residual fistulization.

Postoperative management

The patient recovered well and was discharged home on postoperative day 6 without any complications. An

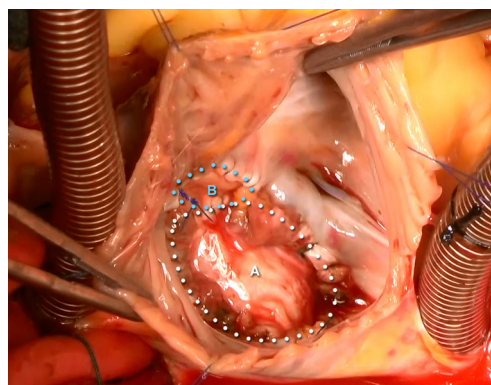


Figure 6 Photograph showing the completed repair. After the aortic sinus was repaired, a piece of autologous pericardium (A) was used to repair the residual atrial septal defect. A separate piece of bovine pericardium (B) was used to repair the residual defect in the superior portion of the right atrium. Used with permission of Baylor College of Medicine.

echocardiogram obtained 7 months after the repair showed no residual defects, and the patient was still doing well 16 months after the repair.

Discussion

The Amplatzer™ Septal Occluder is the most commonly used device for transcatheter closure of ASDs because it is simple to deploy, can be used for a large range of defect sizes, and has a high occlusion rate compared with other transcatheter devices (5). However, in 2012, the FDA Circulatory System Devices Panel convened an advisory committee to review the safety of ASD closure devices from all manufacturers because of accounts of such devices causing erosions (2). A multicenter cohort registry on congenital cases of ASD was used to compare the outcomes of 688 patients who underwent ASD closure with 1 of 3 devices (6). The study showed that cardiac erosion was an uncommon event (0.5% of patients, n=3) and occurred only after the use of the Amplatzer™ Septal Occluder device, which was used in most patients (n=566).

McElhinney *et al.* (2) compared the case details for all the patients reported to have developed an erosion after Amplatzer™ device implantation to those for patients who underwent ASD closure with the same device but did not develop an erosion. They found that the erosions were associated with deficient aortic or superior vena cava rims (less than 5 mm in any view), a larger absolute size of the

Amplatzer™ Septal Occluder devices, a larger difference between the balloon-sized diameter and native ASD diameter, and a smaller patient weight:device size ratio. In a multivariable analysis, the factors found to be associated with cardiac erosion were deficiency of any rim, balloon-sized diameter more than 5 mm larger than the native ASD diameter, and patient weight:device ratio. Multiple stakeholder organizations, including the American Heart Association and the American College of Cardiology, have agreed that deficient aortic rim should be classified as a high-risk feature for ASD closures (2).

A multi-institutional study from the European Congenital Heart Surgeons Association reviewed the records of 56 patients who underwent surgery to address complications after transcatheter closure of an ASD (7). Of the 56 patients, 9 required surgical intervention to address aortic or atrial perforation or erosion. The most frequent indication for surgery was device embolization (n=29). The mortality rate associated with surgically addressing the device-related complications was significantly higher than that associated with primary surgical closure of the ASD. The use of transcatheter techniques has also been reported for the treatment of an aorta-to-right atrium fistula caused by Amplatzer™ device erosion of the tissue; the report describes a means to close the fistula without removing the device (8).

In conclusion, careful preoperative assessment and imaging are essential before proceeding with transcatheter insertion of an ASD closure device, and proper follow-up is critical for detecting potential complications, including erosions. As the above case illustrates, when erosion with fistula formation does occur, surgical removal of the Amplatzer™ Septal Occluder device and fistula repair can be performed with good outcomes.

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