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Surgical Removal of Occluder Devices: Complications and Pitfalls

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ABSTRACT

Interventional closures of atrial septal defects (ASDs) and paravalvular leaks represent attractive treatment options to prevent surgical procedures. Nevertheless, a small number of complications or pitfalls remain after interventional closure of ASDs or paravalvular leaks that require surgical therapy. We report on 3 cases in which surgery was necessary after attempts to close a paravalvular leak. A mechanical valve prosthesis in the mitral position was explanted from a 73-year-old man because of increasing hemolysis and restriction of the motion of one leaflet by the occluder device. A 21-year-old woman with 3 previous surgeries for truncus arteriosus communis type 1 developed paravalvular leakage after replacements of the pulmonary and aortic valves. Although aortic insufficiency was reduced to grade I by placing 2 Amplatzer occluders, significant hemolysis developed. A 24-year-old woman had previously undergone 3 cardiac surgeries (commissurotomy at the age of 5 years for aortic stenosis, followed by aortic valve replacements at 13 and 14 years of age). The patient developed severe hemolysis after interventional closure. A redo aortic valve replacement was performed for the fourth time. As in the previous 2 cases, the surgery for this challenging case and the postoperative course went well. We also present 6 cases in which the occluder was explanted because of dislocation, thrombus formation, irritation of the aortic root, or systemic allergic reaction to the percutaneous occluder after initial closure of the ASD. The intra- and postoperative courses were uneventful in all cases. In summary, surgery for complications or pitfalls after interventional closure of paravalvular leaks or ASDs is challenging and carries a high risk in cases of paravalvular leaks. Nevertheless, the outcomes of the presented cases were uneventful. In the future, the development of a more suitable device technology may improve the results of interventional procedures, especially in cases of paravalvular leaks.

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INTRODUCTION

As an alternative to surgical treatment, the percutaneous transcatheter closure technique is typically used in the management of congenital heart defects, including atrial or ventricular septal defect, patent ductus arteriosus, and ruptured sinus of Valsalva [Schaeffler 2007; Lasorda 2008]. In addition, the practice of transcatheter closure of paravalvular leaks was initiated in 1987 by using the double-umbrella device developed by Rashkind and Cuaso [Hourihan 1992]. These procedures are not free of potential problems, however. Reported complications include cerebral embolism, cardiac perforation, malpositioning of the device with a residual shunt, vascular trauma, thrombus formation on the device, and interference with atrioventricular valve function [Rigby 1999]. This report describes 9 patients who required surgical treatment for interventional complications after closure of a paravalvular leak or an atrial septal defect (ASD). Current challenges and indications for this evolving technology are discussed.

CASE REPORTS

Case 1

A 73-year-old man was referred for grade III mitral regurgitation due to a persistent paravalvular leak. At the age of 53 years, the patient had a bioprosthesis implanted in the mitral position, which was replaced by a mechanical prosthesis at the age of 66 years because of valve degeneration. A relevant paravalvular leak diagnosed 6 years after the last valve exchange prompted 2 attempts of interventional closure with the Amplatzer PDA Occluder (AGA Medical, Plymouth, MN, USA). The patient experienced increasing hemolysis, and his clinical status progressively declined over the subsequent 2 years. A fluoroscopy examination revealed mitral insufficiency caused by restriction of leaflet motion by one of the occluder devices.

Intraoperative findings confirmed the results of the imaging study (Figure 1). The third replacement of the mechanical prosthesis and the postoperative course were uneventful.

Case 2

A 21-year-old woman had undergone 3 previous surgeries for a truncus arteriosus communis type 1. Banding of the pulmonary artery at the age of 1 year was followed by a placement of an extracardial conduit and closure of a ventricular

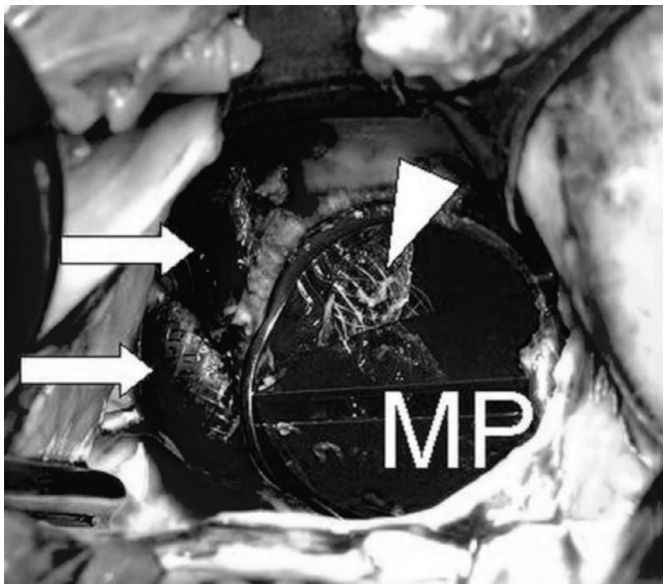

Figure 1. Intraoperative findings of an obstructed leaflet of the prosthetic valve in mitral position (MP) in the patient in case 1. Two occluder devices are placed into the paravalvular leak (arrows). One occluder protrudes into valve hinges and arrests the leaflet (arrowhead).

septal defect 4 years later. Replacements of the pulmonary and aortic valves by mechanical prostheses were necessary at the age of 13 years. Paravalvular leakage of the aortic valve diagnosed at the age of 20 years was treated by intervention with 2 Amplatzer PDA Occluder devices (Figure 2). Although the aortic insufficiency was reduced to grade I, significant hemolysis developed. Six months later, the patient was referred to surgery for valve replacement. Intraoperatively, the 2 devices were correctly placed in one paravalvular leak, and another leak was present opposite of the first and was not treated. This fourth major cardiac surgery to replace the aortic valve was uneventful, as was the postoperative course.

Case 3

This 24-year-old woman had previously undergone 3 cardiac surgeries. A commissurotomy at the age of 5 years for aortic stenosis was followed by aortic valve replacements at 13 and 14 years of age, the latter for prosthesis dysfunction. A paravalvular leak diagnosed at the age of 24 years prompted interventional closure. The patient developed severe hemolysis immediately after the intervention. The fourth redo aortic valve replacement was performed 1 week later. As in the previous 2 patients, surgery for this challenging case and the postoperative course both went well.

Case 4

A 60-year-old woman underwent interventional closure of an ASD. Six years later, the patient was referred to our institution because of thrombus formation (3.3 × 1.5 cm) in the right atrium that prolapsed into the tricuspid valve. Intraoperative observations confirmed the preoperative transesophageal echocardiography findings. Both the thrombus and the Amplatzer device were removed with the aid of a heart–lung machine. The ASD was closed with a pericardial patch. The postoperative course was uneventful.

Case 5

A 7-year-old girl underwent interventional closure of an ASD II with the Angel Wings system (Microvena Corporation, White Bear Lake, MN, USA). Unfortunately, the occluder could not be placed correctly. Consequently, the dislocated occluder was removed during open heart surgery, and the ASD was treated by direct closure on the same day. The recovery after surgery was uneventful.

Case 6

A 72-year-old woman with a persistent foramen ovale developed a paradoxical cerebral embolism. Initially, the persistent foramen ovale was closed with an Amplatzer device. Thereafter, a dislocation of the occluder occurred. With the aid of a heart–lung machine, the dislocated device was removed, the foramen ovale was closed by direct suture, and an aortocoronary bypass was placed for concomitant single-vessel disease (75% stenosis of the right coronary artery). The course after surgery was without adverse events.

Case 7

A 42-year-old woman underwent an uneventful closure of a patent foramen ovale (PFO) with a 35-mm Amplatzer device. Two years later, an echocardiography examination revealed a recurrent ASD and a dislocation of the Amplatzer device with mechanical irritation of the aortic root. The dislocated Amplatzer device was explanted with the aid of a heart–lung machine, and the ASD was closed with a pericardial patch. The postoperative course was uneventful.

Case 8

An ASD was closed with an Amplatzer occluder in a 42-year-old woman. The device was in the correct position shortly after the intervention, but after the patient

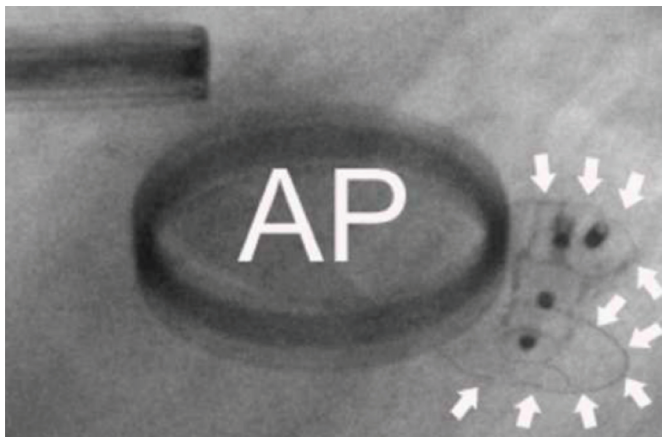

Figure 2. Interventional closure of a paravalvular leak in the patient in case 2. Two occluder devices are correctly placed (arrows). AP indicates aortic prosthesis.

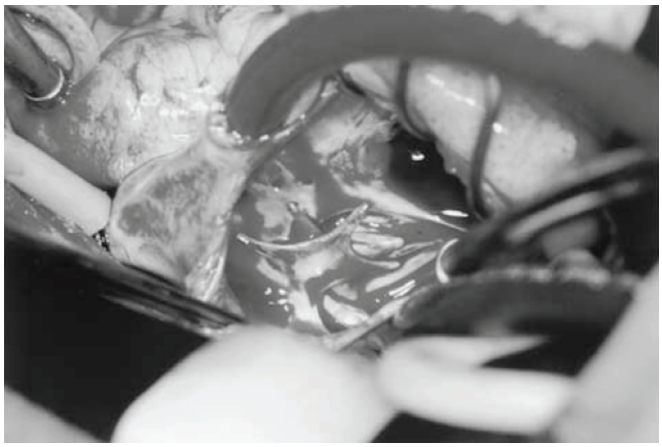

Figure 3. Intraoperative view of the patent foramen ovale occluder.

experienced a severe coughing attack, a transesophageal echocardiographic evaluation revealed that the device had dislocated into the left ventricular outflow tract. During open heart surgery, the dislocated device was removed through the ASD and through the mitral valve. The septal defect was closed with a Dacron patch. After surgery, the patient recovered well without experiencing any adverse events.

Case 9

A 37-year-old woman with a PFO was admitted to our institution for transcatheter occlusion of her PFO. She had experienced an episode of paradoxical cerebral embolism 1 year previously, and anticoagulation therapy with phenprocoumon had been initiated. Despite anticoagulation therapy, the patient had a transient ischemic attack 6 months before admission.

The patient had slight exertional dyspnea (New York Heart Association class I-II) but had no body weight change or fever at the time of admission. Transvenous occlusion of the PFO was performed with a PFO Star device (Cardia, Eagan, MN, USA) by means of a 30-mm umbrella under transesophageal echocardiographic guidance. The postinterventional studies showed that the position of the device was satisfactory, and there was no residual shunt. Two months after the PFO occlusion, the patient began experiencing dyspnea, a temperature of 38°C, and dependent edema. Endocarditis or infection of the device was suspected, and she was referred back to our institution. A laboratory examination revealed a white blood cell count of 8800/μL (51.9% granulocytes, 31.4% lymphocytes, 9.8% monocytes, 5.7% eosinophils, and 1.2% basophils), a hemoglobin concentration of 14.5 g/dL, a hematocrit of 43.2%, a platelet count of 256,000/dL, and a C-reactive protein concentration of 0.8 mg/dL; other biochemical indices were within reference intervals. Echocardiography with color Doppler scanning showed no residual shunt, no findings suggestive of intracardiac vegetation, and good cardiac function. Blood cultures were performed several times, but each culture showed no growth. The patient's history was significant for allergic reactions to some medications and an episode of allergic asthma. With the patient's high levels of immunoglobulin E (144 U/mL; normal range, 0-100 U/mL) and eosinophilic cationic protein (29 μg/L; normal range, 2.3-12.0 μg/L), we assumed she was having a hypersensitivity reaction to the PFO occluder. Skin patch testing was performed with nitinol, the primary component of the device, and the results were positive in both the early and late phases.

Because the high-grade fever and edema persisted, the patient agreed to explantation of the device. Four months after transcatheter PFO occlusion, the device was removed surgically, and the PFO was closed with an autologous pericardial patch during extracorporeal cardiopulmonary bypass. An intraoperative examination showed that the device appeared to be functioning properly (Figure 3). A pathologic examination of the device showed nonspecific inflammation with no evidence of infection. The patient recovered uneventfully and is doing well 1 year postoperatively.

DISCUSSION

Transcatheter closure of ASDs with occluder devices is increasingly common. Furthermore, Amplatzer occluder devices have been popularly accepted as a promising alternative to open heart surgery in cases of paravalvular leak in order to avoid redo surgery.

Initial case reports have confirmed the feasibility of this interventional closure technique of paravalvular leaks for selected patients, but these reports have also revealed a variety of challenges [Pate 2006]. For instance, residual leaks were observed in 10 of 11 sites of device deployment in a series of 12 patients [Shapira 2007]. Hemolysis may persist, even if the regurgitation is reduced (see cases 2 and 3). Thus, the event-free survival rate (freedom from reoperation, reintervention, and significant residual shunt) was as low as 48% in a series of 24 patients [Hein 2006]. Common reasons for the failure of this demanding intervention are poor imaging and an unsuitable anatomy, such as crescent-shaped or multiple leaks and severe calcification. Additional limitations result from inadequate device configuration, because the occluders in use were originally designed for atrial and ventricular septal defects or patent ducts. Consequently, surgery still remains the criterion standard of treatment for paravalvular leaks while the technology of interventional closure is being advanced.

The 3 cases with paravalvular leaks presented here are unusual because of the multiple previous surgeries. These cases were technically challenging and of high risk, and avoiding a fourth cardiac surgery for reoperative valve exchange by means of a catheter-based intervention would have been preferable. We therefore advocate a multidisciplinary approach that includes interventional cardiologists and surgeons. Depending on the level of hemolysis, the severity of the regurgitation, and the anatomy of the paravalvular leak, the risk of surgery must be weighed against the likelihood of success of intervention. Surgical backup is also provided for every intervention in the event of interventional complications.

ASD is a common cardiac condition, accounting for approximately 10% of all congenital heart defects. Percutaneous closure has become a well-established alternative to surgical closure.

The pivotal study in the United States that led to Food and Drug Administration approval of the Amplatzer device proved that patients who underwent surgical closure had a 24% incidence of minor and major complications, compared with only 7.2% in the group of patients who underwent percutaneous closure [Du 2002]. Nowadays, there are a number of different devices available for transcatheter closure of ASDs, all of which have demonstrated advantages and disadvantages. The type and rate of complications are different for different devices. Embolization and malposition are the most common complications. Once the device embolizes, 2 different options are possible: (1) retrieve the device by a gooseneck snare or a basket catheter or (2) refer the patient to the surgeon. The last option is indicated when the size of the device is among the largest; the surgeon will retrieve the device and close the ASD at the same time. Embolization occurs, first of all, in the pulmonary circulation. Embolization in the left side of the heart or in the systemic circulation is a rare but feared complication. Nevertheless, surgical removal of occluder devices is much easier and carries less risk in ASD patients who have had no previous operations than in patients with paravalvular leaks, who often have undergone several previous cardiac operations; therefore, the surgical procedure for removal of the dislocated device can be performed under standard conditions in ASD patients. Even a completely endoscopic removal of a dislocated Amplatzer device for closure of an ASD has recently been described [Bonatti 2008].

A study of 1000 patients who underwent percutaneous closure with a device found the incidence of thrombus formation (as described in case 4) to be 1.2% in patients with ASD and 2.5% in patients with a PFO [Krumsdorf 2004]. Postprocedure atrial fibrillation and persistent atrial septal aneurysm seem to be predictors of thrombus formation.

The systemic allergic reaction to the PFO occluder described in case 9 might not be common, but the potential risk of nickel toxicity should not be ignored. The value of preoperative skin patch testing for metals in all patients is controversial, but testing is likely justified in patients with a history of allergic reactions. Regardless of the results of such testing, however, the risks and benefits of therapeutic options with metal-containing intracardial or endovascular devices in such patients must be considered carefully.

In summary, the complications and pitfalls after transcatheter closure of paravalvular leaks or ASDs can be surgically treated with excellent results and low morbidity. Cases involving multiple previous surgeries and complications after interventional treatment of paravalvular leaks are challenging and are often of high risk. Nevertheless, the outcomes of our cases were uneventful. Future studies, perhaps with a more suitable device technology, may address a hybrid approach so that outcomes can be improved, even for the most complex cases of paravalvular leakage.

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