Clinical Use of the Amplatzer Device in the Management of Intracardiac Defects: A Single-Center Experience

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Abstract

Device therapy is a viable alternative to open heart surgery in the management of intracardiac defects. The Amplatzer septal occluder (ASO) is one such device that has been adapted to close a wide variety of cardiac defects with few complications and a high success rate. This is a retrospective review of all the patients who received the ASO between 2012 and 2016 at the University of Kentucky. In total, 169 patients underwent percutaneous closure of a septal defect with Amplatzer during the timeframe studied, and of those, 91% received the device for an atrial septal defect or patent foramen ovale. Patients presented with stroke, transient ischemic attack, migraine, dyspnea or other symptoms and were diagnosed by transesophageal echocardiography and cardiac catheterization. All Amplatzer devices achieved successful closure without requiring a second procedure. Four patients sustained complications of the procedure, with two experiencing tamponade, one with hematoma, and one with cellulitis. The Amplatzer device was not directly implicated in the three fatalities that occurred within 30 days of the septal occlusion procedure. The ASO has performed very well at our institution and we expect it to serve additional functions as the field of transcatheter cardiology develops.

Keywords
- cardiac device
- repair
- percutaneous
- cardiac catheterization
- symptomatic
- ultrasound

The Amplatzer septal occluder (ASO) was developed by interventional radiologist Kurt Amplatz in 1997 at the University of Minnesota.[1] A sturdy, but collapsible wire mesh composed of nitinol, a nickel, and titanium alloy, the ASO's initial indication was for atrial septal defects up to 21 mm in size.[2] The ASO prototype has today been modified to suit an additional number of cardiac defects including ventricular septal defect, arteriovenous malformation, patent ductus arteriosus, and arteriovenous fistula.[3,4] Currently, the ASO can be used in both adults and children, with children faring slightly better,[5] due to earlier intervention. However, a more recent study has shown that due to improvements in technique and device innovation, both groups have similar numbers of documented complications (including residual shunts and device embolization), both immediately following the procedure and at follow-up appointments years later.[6] Review of the literature demonstrates a lack of single or multicenter studies with a sample size of greater than 100 patients in the recent 5 years exploring the safety and efficacy of the most recent Amplatzer devices. Therefore, this report aims to review our experience at the University of Kentucky with the ASO.

Methods and Materials

Patient Demographics

With Institutional Review Board approval, we reviewed records of 169 patients who underwent placement of an

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ASO between 2012 and 2016 at the University of Kentucky. Of these 169 patients, 89 were female and 80 were male. The mean age was 50 ± 16 years, with a range of 5 to 82 years and median of 52 years.

These patients were referred for device placement from both inpatient and outpatient settings, and each patient presented with symptoms such as stroke, transient ischemic attack (TIA), migraine, and/or dyspnea. Diagnostic confirmation of their defects was performed by transesophageal echocardiography and cardiac catheterization.

The procedure was performed in the catheterization laboratory. Confirmation of placement and shunt detection was performed by an agitated saline test. Variations in device size were reported, and the types of defects closed included atrial septal defect, patent foramen ovale, ventricular septal defect, and Gerbode-type defect. For every patient, outpatient follow-up appointments included a clinical examination and echocardiogram.

Results

One-hundred and sixty-nine patients underwent percutaneous closure of a cardiac defect at University of Kentucky Medical Center. The procedures performed included closure of 53 atrial septal defects, 98 patent foramen ovales, 6 ventricular septal defects, 4 unspecified patent foramen ovale/atrial septal defects, 2 pulmonary arteriovenous malformations, 1 patent ductus arteriosus, 1 aortic perivalvular leak, 1 fistula between aortic sinus of Valsalva and right atrium, 1 interatrial septostomy, 1 multivalve periprosthetic leak, and 1 Gerbode-type defect.

Echocardiographic and Catheterization Data

Of the 169 patients, 29 had defect size documented, which ranged from 6 mm to 25 mm, with an average of 14.2 mm.

Previously Installed Devices

From the 169 patients, 3 had prior atrial septal defect occlusion with a Gore Helex septal occluder, and 1 had a prior ASO in place. All devices had significant shunting of blood between the atria, and another Amplatzer occluder was installed to close the defect.

In the patient population studied, defect closure was attempted and ultimately unsuccessful with a total of 10 Gore Helex septal occluders and 0 ASOs. When the occluder did not produce a satisfactory closure, the occluder was withdrawn and an Amplatzer occluder was then inserted and successfully closed the defect.

Device Size

The most common size of Amplatzer atrial septal occluder used was 18 mm (102 patients), but sizes ranged from 10 mm to 30 mm. In addition, ventricular septal defect closure devices used ranged from 4 mm to 18 mm. Finally, four patients received either an Amplatzer duct occluder or Amplatzer vascular plug each.

Efficacy

All 169 patients had successful closure of their defect with any residual shunt being both clinically insignificant and temporary; all residual shunts were found to have closed within a year as determined via echo bubble study. Of the 60 patients with consistently documented follow-up during the year after their procedure, 57 (95%) were found to have subjectively increased functional improvement and 3 were found to have no subjective change in presenting symptoms.

Morbidity and Mortality

Within 30 days of the procedure, 16 patients, or 9.47% of the studied population, reported palpitations. Seven patients (4.14%) reported angina, and 2 patients (1.18%) reported headache. All Amplatzer devices achieved successful closure without requiring a second procedure, resulting in a reintervention rate of 0%.

Four patients experienced major complications of the procedure. Two experienced tamponade, one developed a hematoma at the insertion site, and one developed cellulitis and an abscess at the insertion site (►**Table 1**).

For both patients with tamponade, transseptal puncture resulted in a small tear approximated at the superior vena cava. Emergent pericardiocentesis corrected tamponade in one patient with no long-term sequelae. The other patient was also managed with pericardiocentesis, but later developed pericarditis, which was treated appropriately and she

Table 1 Mortality and major complications among each category of defect

	Mortality	Major complications
PFO	Hemorrhagic stroke, pulmonary embolism	Tamponade
ASD	N/A	Tamponade, cellulitis and abscess, hematoma
VSD	Ventricular septal rupture	N/A
Unspecified PFO/ASD	N/A	N/A
Pulmonary AVM	N/A	N/A
Other	N/A	N/A

Abbreviations: ASD, atrial septal defect; AVM, arteriovenous malformation; PFO, patent foramen ovale; VSD, ventricular septal defect.

was discharged in stable condition. One pediatric patient developed fever and headache, which resolved shortly thereafter. One patient developed groin cellulitis and abscess following their catheterization procedure, which required antibiotic therapy, surgical incision, and drainage.

Three patients died within 30 days of the procedure. One patient presented with a stroke and pulmonary embolism, and was taken emergently to the catheterization laboratory after being started on heparin. Days after the procedure, that patient experienced conversion to hemorrhagic stroke with subsequent tonsillar herniation. One patient presented with a ventricular septal rupture secondary to myocardial infarction (MI), and received a 24-mm ASO in the VSD. Despite successful closure of the defect, the ischemic biventricular cardiac failure continued secondary to the MI, and 28 days later the patient died. The third patient was taken to the catheterization laboratory with a massive thrombus straddling the right and left atria through an atrial septal defect; after the clot was partially extracted and the septum closed, a fragment of the clot formed a saddle pulmonary embolism, which was ruled to be the cause of death for that patient.

Discussion

Percutaneous closure with the ASO has been proven to be a highly successful procedure, with lower rates of post-procedure complications and a shorter hospital stay when compared with open surgery. Hospital stay was decreased by almost 3 days with ASO use versus open repair, which may lead to better outcomes both medically and financially.[5] In addition, the complication rate for the ASO post-procedure was 7.2% as compared with surgical repair, which was 24%, but mortality rates among both device and surgical groups remained equal.[5]

At the University of Kentucky, we experienced four major post-procedure complications as described above, constituting 2.4% of the study population. Two were believed to be due to transseptal puncture, and two were infections at the site of catheter insertion; none appeared to be related to the Amplatzer device itself. The Amplatzer device was not directly implicated in the three deaths that occurred within 30 days of the septal occlusion procedure. No cases of device embolization, thromboembolism, atrioventricular nodal block, significant arrhythmias or perforation of vessels, and myocardium were noted, although these have been reported in previous studies at other institutions.[7–10] All study patients underwent successful closure of their defects with a procedure failure rate of 0% as it pertains to the ASO. Minor complications, as mentioned above, did occur, but resolved spontaneously without further effect. These numbers, pertaining to complications and procedure failure rate, fall appropriately on the trajectory of rates from previous single center studies.

Although there are a few single center studies discussing the use of ASO in defect closure, we compared our rates of morbidity and success with three other institutions specifically those in Canada, Brazil, and India who have also demonstrated the reliability of the ASO.[11–13] All three studies focused on closure of an ASD through percutaneous methods using an ASO and found similar procedural and post-procedural complication rates. The 2002 study of 117 patients in Montreal, Canada, demonstrated a procedure failure rate of 11% and complications including two arteriovenous fistulas, one life-threatening air embolism, and two hematomas. The 2007 study of 101 patients in Brazil showed a procedure failure rate of 7% and complications including three hematomas and one supraventricular tachycardia which had to be reverted using adenosine. The most recent study of 543 patients in 2011 in India revealed a procedure failure rate of 2.3% and complications including three patients who developed pulmonary edema, one pericardial effusion, and one loss of femoral pulse due to wall edema. Thus, major post-procedural complications accounted for ~4.3%, 4.0%, and 0.95% of the study population, respectively. Minor complications including residual shunts, headaches, and mild arrhythmias were also noted, but these resolved in all cases within 1 year. These statistics are highly comparable to the numbers obtained at our institution.

With regard to functional improvement among the 169 patients at our institution, all 169 patients had complete closure of shunt within 1 year. All those presenting with atrial and ventricular enlargement due to an ASD or VSD saw reversal of enlargement on follow-up echocardiography. Of the 169 patients, 60 were found to have consistent follow-up regarding their feelings of improvement and quality of life. Of the 60 patients, 57 were found to have marked improvement in presenting symptoms such as dyspnea on exertion, migraines, and residual stroke/TIA effects. Three patients were observed to report no significant changes in presenting symptoms. Notably, one of these was due to residual effects after stroke; however, the patient had a co-diagnosis of multiple sclerosis, which may have played a role in symptoms. Another patient reported no change in dyspnea, but was noted to have co-diagnosis of atrial fibrillation possibly contributing to persisting dyspnea. A final patient reported more pronounced leg pain and weakness, which was determined due to worsening of concurrent leg claudication from vascular disease. Clearly, the septal occlusion procedure with Amplatzer has improved immensely in a 15-year time period in terms of complication and success rates.

Conclusion

Overall, percutaneous cardiac repair with the ASO is a feasible procedure that is not only effective but has also been shown to be durable in the long term. Our study supports this assertion: at our institution, the initial success rate and long-term objective efficacy of the occlusion procedure were both 100%, while the success rate in terms of subjective symptomatic relief in the 60 patients with 1-year follow-ups was 95%. Cardiac repair with the ASO has a reliable safety profile and ease of operation that makes it the procedure of choice when it comes to atrial septal defect correction. Nevertheless, it is important to keep in mind the potential complications that have been reported with this device and continue to monitor patients accordingly. As

the field of transcatheter cardiology grows, it is expected that the ASO will serve new functions and will act as a catalyst in the birth of pioneering technologies.

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