Transcatheter Closure of Large Atrial Septal Defects
Feasibility and Safety in a Large Adult and Pediatric Population

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Background—Data are needed on the safety and efficacy of device closure of large atrial septal defects.

Methods and Results—Between 1998 and 2013, 336 patients (161 children <15 years) with large, isolated, secundum atrial septal defects (balloon-stretched diameter ≥34 mm in adults or echocardiographic diameter >15 mm/m2 in children) were managed using the Amplatzer device, at the Marie Lannelongue Hospital. Transthoracic echocardiographic guidance was used starting in 2005 (n=219; 65.2%). Balloon-stretched diameter was >40 mm in 36 adults; mean values were 37.6±3.3 mm in other adults and 26.3±6.3 mm/m2 in children. Amplatzer closure was successful in 311 (92.6%; 95% confidence interval, 89%–95%) patients. Superior and posterior rim deficiencies were more common in failed than in successful procedures (superior, 24.0% versus 4.8%; P=0.002; and posterior, 32.0% versus 4.2%; P<0.001). Device migration occurred in 4 adults (2 cases each of surgical and transcatheter retrieval); in the 21 remaining failures, the device was unreleased and withdrawn. After a median follow-up of 10.0 years (2.5–17 years), all patients were alive with no history of late complications.

Conclusions—Closure of large atrial septal defects using the Amplatzer device is safe and effective in both adults and children. Superior and posterior rim deficiencies are associated with procedural failure. Closure can be performed under transthoracic echocardiographic guidance in experienced centers. Early device migration is rare and can be safely managed by device extraction. Long-term follow-up showed no deaths or major late complications in our population of 311 patients. (Circ Cardiovasc Interv. 2014;7:00-00.)

Key Words: catheterization • echocardiography • heart septal defects • pediatrics

Atrial septal defect (ASD) is a common congenital heart defect with a reported incidence of 10/1000 live births.1 Untreated ASD can cause right ventricular overload with right heart failure, atrial arrhythmias, systemic embolism, pulmonary hypertension, and premature death.2,3 During the past 15 years, transcatheter closure of isolated secundum ASD has become the preferred treatment strategy in most cases.4,5 High-volume institutions have reported strong evidence of good long-term outcomes using this strategy.6,7 However, with large ASDs, the challenges of percutaneous treatment usually result in a preference for surgical closure. Few studies provide information on the safety and efficacy of transcatheter closure of large ASDs in adults and pediatric patients. Concern about deploying large devices has been exacerbated by recent reports of severe complications such as aortic erosion, cardiac perforation, atrioventricular block, or device-related aortic regurgitation.8,9 The Amplatzer Septal Occluder (ASO, Saint Jude Medical, St Paul, MN) is the most widely used device for percutaneous ASD closure worldwide. However, there is a paucity of data on transcather closure of large ASDs, especially using the 40-mm ASO.10 We hypothesized that percutaneous closure of large ASDs was feasible and safe.

Here, we tested our hypothesis by evaluating early and long-term outcomes of adults and children with large ASDs managed using the ASO.

Methods

Study Design

We conducted a prospective single-center study at the Marie Lannelongue Hospital in Paris, France. Among 1441 ASDs managed between 1998 and 2013 by transcatheter closure using the ASO, 336 (23.3%) were isolated, large, secundum ASDs and were included in the study. Children were defined as patients <15 years. Large ASD was defined as a balloon-stretched diameter ≥34 mm in adults or an echocardiographic diameter ≥15 mm/m2 in children.11,12 Data were collected with special attention to echocardiographic data, implantation characteristics, and early outcome. Our institutional review
WHAT IS KNOWN

- Transcatheter closure of isolated secundum atrial septal defects is the preferred treatment strategy in most cases.
- Large atrial septal defects constitute a challenging subgroup usually leading to surgical closure.
- There is a paucity of data on transcatheter closure of large atrial septal defects with major concerns because of reports of severe complications.

WHAT THE STUDY ADDS

- Closure of large, isolated, secundum atrial septal defects using a septal occluder is safe and effective, in both adults and pediatric patients.
- In experienced hands, the procedure can be performed routinely under transthoracic echocardiography guidance.
- Superior and posterior septal rim deficiencies are associated with procedural failure.
- Early device migration is rare and can be managed safely with percutaneous or surgical extraction.

board approved the study, and all patients or legal guardians gave their informed consent to study inclusion.

Patient Characteristics

All 336 included patients had left-to-right interatrial shunting with right ventricular dilatation and paradoxical interventricular septal motion. Symptoms were not among the inclusion criteria. Of the 336 patients, 175 were adults (median age, 40.0 [16.0–89.0] years; median weight, 66.0 [32.0–110.0] kg) and 161 were children (median age, 7.0 [2.0–15.0] years; median weight, 22.0 [10.0–70.0] kg). Male/female ratio was 0.58. All patients but 19 adults were in sinus rhythm.

Echocardiography Protocol

Transesophageal echocardiography (TEE) and transthoracic echocardiography (TTE) were performed using Philips iE33 or General Electrics Vivid 7 echocardiography machines. TTE was performed routinely before ASD closure. Right ventricular size and function were assessed according to the American Society of Echocardiography guidelines.13 Right ventricular systolic pressure was estimated using the Bernoulli equation in patients with tricuspid regurgitation. An experienced cardiologist carefully evaluated the anatomic ASD features. The largest ASD diameter on any view was recorded as ASD size. Left atrial (LA) length was the distance from the anterior mitral valve leaflet to the posterior LA wall on the subcostal view. When not measured, LA length was estimated as 0.597+0.404 log body surface area.18 Special attention was given to anteroinferior and posteroseptal rims on the 4-chambers view, aortic and posterior rims on the short-axis left parasternal view, and inferior and superior rims on the subcostal view. Rims <5 mm in length were considered deficient. Anteroinferior, posteroseptal, aortic, posterior, inferior, and superior rims were deficient in 16 (4.8%), 21 (6.2%), 151 (44.9%), 21 (6.2%), 37 (10.9%), and 21 (6.2%) patients respectively. All patients underwent full TTE evaluations 6 hours and 2 days after ASD closure.

ASD Assessment in the Catheterization Laboratory

Right heart catheterization consistently showed substantial left-to-right interatrial shunting, with a mean Qp/Qs ratio of 2.9±0.5; 45 (13.4%) patients had pulmonary arterial hypertension (defined as mean pulmonary arterial pressure >25 mmHg), including 9 (2.7%) adults with mean pulmonary arterial pressure >35 mmHg. Balloon-stretched diameter exceeded 40 mm in 36 adults; mean value was 37.6±3.3 mm in the remaining 139 adults and 26.3±6.3 mm/m² in the children.

Device Characteristics

ASO diameter in adults was 34 mm in 49 (28.0%) patients, 36 mm in 61 (34.9%), 38 mm in 29 (16.5%), and 40 mm in 36 (20.6%) patients. In children, ASO/LA length ratio was <0.8 in 42 (26.1%) patients, 0.8 to 0.9 in 47 (29.2%), 0.9 to 1 in 52 (32.3%), and >1 in 38 (23.6%) patients.

Procedural Characteristics

The procedure was performed as previously described.7,9,20 In our institution, ASD closure was done under general anesthesia with orotracheal intubation and TEE guidance from 1998 to 2005. Starting in 2005, TTE guidance was used in all patients, regardless of age or ASD characteristics. TTE-guided procedures were performed under deep sedation in spontaneously breathing children <12 years and under local anesthesia in other patients. In our study, 207 (61.6%) patients (all managed before 2005) had general anesthesia and 219 (65.2%) patients (all patients since 2005) had TTE guidance. In patients with pulmonary arterial hypertension, criteria for ASD closure were pulmonary vascular resistance <15 WU²/m², persistent left-to-right interatrial shunt (Qp/Qs ratio >1.5), and symptom onset within the past 6 months.21 ASD sizing was based on the fluoroscopic assessment of balloon stretching. A 27-mm or 33-mm Medi-Tech Equalizer balloon (Boston Scientific, Natick, MA, USA) was fully inflated in the left atrium and then pulled back against the septum. With progressive balloon deflation, a slight deformity of the balloon was seen just before its popping through the septum, giving the balloon-stretched diameter of the ASD.

Procedural success was defined as the presence of all 3 following criteria: successful ASO delivery without periprocedural complications; well-positioned ASO as assessed by TTE after 6 and 48 hours; and well-positioned ASO as assessed by TTE after 6 and 48 hours. An unpaired Student t test when appropriate. Successful and failed procedures were also compared according to rim deficiencies using the χ² test. P values <0.05 were considered statistically significant.
Results
Among the 1441 patients with isolated secundum ASD who underwent transcatheter closure at the Marie Lannelongue Hospital from 1998 to 2013, 336 (23.3%) had large ASDs.

Immediate Postprocedural Outcome
The procedure was successful in 311 (92.6%; 95% confidence interval, 89%–95%) patients, with only 2 trivial residual interatrial shunts. ASD characteristics and procedural outcomes according to echocardiographic guidance in children and in adults are summarized in Table 1. Characteristics of failed procedures in adults and children are reported in Tables 2 and 3, respectively.

The procedure failed in 18 (10.3%) of the 175 adults. The ASO was deployed but not delivered in 14 then considered unstable and withdrawn, without incident. ASO migration occurred in the remaining 4 patients, of whom 2 were managed by transcatheter ASO retrieval and surgical ASD closure and 2 by same-stage surgical ASO retrieval and ASD closure. ASO closure failed in 7 (4.3%) of the 161 children, because the ASD was considered too large to be closed with a transcatheter device in 5 patients, and ASO was considered unstable and withdrawn in 2 patients. The ASO was retrieved before being delivered to avoid cardiac deformation or device-related atrioventricular valve regurgitation. No other major or minor complications occurred during the procedure or within the first 48 postprocedural hours.

Superior and posterior rim deficiencies were significantly more common in patients with failed rather than successful closure (superior, 24.0% versus 4.8%; \( P=0.002 \) and posterior, 32.0% versus 4.2%; \( P<0.001 \)). Deficiencies of the aortic, anteroinferior, and inferior rims were not associated with procedural failure (Table 4).

Long-Term Outcomes
No patient was lost to follow-up. Median follow-up was 10.0 years (range, 2.5–17 years). All patients were alive and asymptomatic at the time of this writing. None experienced late complications; more specifically, no cases of late cardiac perforation or ASO migration were recorded. No regurgitation through the aortic, mitral, or other valves developed in any patient. There were no instances of ASO-related endocarditis, thromboembolism, conduction disorders, or ventricular arrhythmias. After ASD closure, 20 women had 28 uneventful pregnancies; more specifically, no intra- or postpartum thromboembolic events occurred. All patients had normal left ventricular systolic function at the last visit. Of 19 (47.4%) adults with preclosure atrial arrhythmias, 9 returned to sinus rhythm and 10 remained in atrial fibrillation; atrial fibrillation developed in 2 other adults. All cases of atrial fibrillation were controlled effectively by pharmacological treatment.

Discussion
Since the Food and Drug Administration licensed the ASO in 2001, >200 000 ASOs have been implanted worldwide including 46 000 in the United States. However, data on large ASDs managed using the ASO are scarce. Ours is the largest study of transcatheter closure of large secundum ASD. Our main

Table 1. Atrial Septal Defect Characteristics and Procedural Outcomes According to Echocardiographic Guidance Technique

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>TEE Guidance</th>
<th>TTE Guidance</th>
<th>( P ) Value</th>
<th>TEE Guidance</th>
<th>TTE Guidance</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children (n=161)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Adults (n=175)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>58</td>
<td>103</td>
<td>...</td>
<td>59</td>
<td>116</td>
<td>...</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>6.0 (2.0–15.0)</td>
<td>8.0 (2.0–15.0)</td>
<td>0.03</td>
<td>39.0 (17.0–89.0)</td>
<td>39.0 (16.0–86.0)</td>
<td>0.51</td>
</tr>
<tr>
<td>TTE ASD diameter (mm/m² in children, mm in adults)</td>
<td>15 (8–41)</td>
<td>17 (11–40)</td>
<td>0.009</td>
<td>24 (15–35)</td>
<td>28 (15–39)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Deficient rims

- Aortic
- Posterior
- Anteroinferior
- Posterosuperior
- Inferior
- Superior

Balloon-stretched diameter (mm/m² in children, mm in adults) | 21 (12–37) | 24 (13–40) | <0.001 | 36.0 (28.0–45.0) | 38.0 (28.0–45.0) | <0.001 |

ASO, mm | 19 (8–30) | 20 (12–36) | 0.09 | 36.0 (34.0–40.0) | 36.0 (34.0–40.0) | 0.42 |

Procedural success/excessively large ASO or instability/ASO migration | 54/4/0 | 100/3/0 | 0.25 | 50/7/2 | 107/7/2 | 0.30 |

ASD indicates atrial septal defect; ASO, Amplatzer Septal Occluder; LA, left atrial; na, not applicable; and TEE, transesophageal echocardiography.
finding is that ASO closure of large ASDs is feasible and safe in both adults and children.

Feasibility and Safety

In our study, transcatheter closure of large ASDs proved safe and effective in both adults and children, with a 92.6% procedural success rate. There is no consensus about the definition of large ASD. In recent studies, large ASD was usually defined as an echocardiographic diameter of 20 to 36 mm in adults\textsuperscript{7,16,22–25} and very or extremely large ASD as a TTE diameter ≥30 mm in adults or ≥15 mm/m\textsuperscript{2} in children.\textsuperscript{15,16} In a 2001 study of 44 adults with large ASDs, we found that ASO closure was safe and effective, with less morbidity compared with surgical closure.\textsuperscript{7} Here, we focused on large ASDs in adults and children, given the therapeutic challenges raised by these defects and the dearth of information on short- and long-term outcomes in large patient populations. A 92% success rate was reported recently in 13 adults with large ASDs, contrasting with a significantly lower 17% success rate in 6 patients with extremely large ASDs (≥40 mm).\textsuperscript{15} In another study, the success rate was close to 90% in patients with large ASDs.\textsuperscript{24,26} A 2005 report describes the short-term outcomes of 33 patients with extremely large ASDs managed using the 40-mm ASO.\textsuperscript{13} The data came from an international registry that included the manufacturer’s database. The success rate was 84.8%; of the 5 failures, 2 were because of early ASO migration, 2 to ASO instability, and 1 to left atrium perforation by the sheath. In our study, we had a higher success rate, no major complications, and only 4 ASO migrations.

Surgical closure carries mortality rates of <1% in children and 1.2% to 3.3% in adults\textsuperscript{27–29} and induces morbidity related to the auriculotomy, extracorporeal circulation, sternotomy

### Table 2. Characteristics of Failed Procedures in Adults

<table>
<thead>
<tr>
<th>Patients</th>
<th>Age, y</th>
<th>Weight, kg</th>
<th>TTE Diameter, mm/m\textsuperscript{2}</th>
<th>Balloon-Stretched Diameter, mm/m\textsuperscript{2}</th>
<th>Aneurysmal Septum</th>
<th>PAH</th>
<th>Deficient Rims</th>
<th>Echo Guidance</th>
<th>ASO, mm</th>
<th>Reason for Failure</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>18</td>
<td>36</td>
<td>18.5</td>
<td>21.9</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>TEE 24</td>
<td>80–90 Unstable ASO</td>
</tr>
<tr>
<td>2</td>
<td>47</td>
<td>28</td>
<td>24.4</td>
<td>26.2</td>
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<td>No</td>
<td>No</td>
<td>No</td>
<td>TEE 24</td>
<td>&gt;100 ASD too large</td>
</tr>
<tr>
<td>3</td>
<td>69</td>
<td>33</td>
<td>20.7</td>
<td>22.3</td>
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<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>TEE 22</td>
<td>&gt;100 ASD too large</td>
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<tr>
<td>4</td>
<td>67</td>
<td>26</td>
<td>26.4</td>
<td>26.4</td>
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<td>No</td>
<td>No</td>
<td>No</td>
<td>TEE 18</td>
<td>&lt;80 Unstable ASO</td>
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<tr>
<td>5</td>
<td>32</td>
<td>33</td>
<td>27.6</td>
<td>27.6</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>TEE 18</td>
<td>ASO migration (LA)</td>
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<tr>
<td>6</td>
<td>25</td>
<td>28</td>
<td>26.8</td>
<td>26.8</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>TEE 24</td>
<td>&gt;100 ASD too large</td>
</tr>
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</table>

### Table 3. Characteristics of Failed Procedures in Children

<table>
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<th>Patients</th>
<th>Age, y</th>
<th>Weight, kg</th>
<th>TTE Diameter, mm/m\textsuperscript{2}</th>
<th>Balloon-Stretched Diameter, mm/m\textsuperscript{2}</th>
<th>Aneurysmal Septum</th>
<th>PAH</th>
<th>Deficient Rims</th>
<th>Echo Guidance</th>
<th>ASO, mm</th>
<th>Reason for Failure</th>
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<tbody>
<tr>
<td>1</td>
<td>9</td>
<td>36</td>
<td>18.5</td>
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<td>No</td>
<td>TEE 24</td>
<td>80–90 Unstable ASO</td>
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</tr>
<tr>
<td>2</td>
<td>16</td>
<td>16</td>
<td>18.7</td>
<td>22.7</td>
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<td>Yes</td>
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<tr>
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<td>26</td>
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<td>No</td>
<td>Yes</td>
<td>No</td>
<td>&gt;100 ASD too large</td>
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</table>

Antinf indicates anteroinferior; ASD, atrial septal defect; ASO, Amplatzer Septal Occluder; Inf, inferior; LA, left atrium; PAH, pulmonary arterial hypertension; Post, posterior; Postsup, posterosuperior; RA, right atrium; RV, right ventricle; Sup, superior; TEE, transesophageal echocardiography; and TTE, transthoracic echocardiography.
Factors Associated With Procedural Failure

Large ASDs (>38 mm) and septic rim deficiencies remain challenging to treat and are usually managed by surgery. Large ASDs are often associated with rim deficiencies. In our study, superior and posterior rim deficiencies were associated with procedural failure related to excessive ASD size or ASO instability. Aortic rim deficiency has been described as a relative contraindication to percutaneous ASD closure or ASO instability. Aortic rim deficiency has been described as risk factors for ASO migration. We found no association between inferior rim deficiency and procedural failure. Thus, a large ASD with aortic or inferior rim deficiency may remain a good indication for attempting transcatheter closure. In experienced centers, transcatheter closure may be suitable for extremely large defects with deficient rims, particularly in adults, in whom we consider that deployment of a 40-mm ASO should always be attempted. This point is debated, however, and patients with extremely large defects are also good candidates for surgery, with low postsurgical morbidity and mortality rates. Other high-volume institutions should compare transcatheter and surgical closure in adults with extremely large ASDs. In children, extreme caution should be used when the ASO/LA length ratio is >1, given the risk of cardiac deformation and interference with adjacent structures.

TTE Guidance of Large ASD Closure

In our series, no major complications occurred in any of the 219 patients who underwent TTE-guided closure. The success rate was high in our large unselected population of adults and children. The procedural failure and ASO migration rates were low and not significantly different between the TTE- and TEE-guidance groups.

TEE or intracardiac echocardiography are widely used to guide ASO implantation. Data demonstrating the feasibility of TTE-guided transcatheter ASD closure come only from case reports and small case-series studies, chiefly of patients with small central defects, and mostly in children whose echogenicity is better than in adults.

A prospective randomized single-center trial in 40 children recently demonstrated that, in selected pediatric patients, TTE was as efficient and safe as TEE for guiding ASO closure of ASDs. An additional safety benefit is the decreased fluoroscopy exposure with TTE. Since 2005 we have been using routine TTE guidance for ASD closure, regardless of patient age and ASD anatomy. Benefits include a shorter procedure time; and elimination of potential complications related to intubation, general anesthesia or TEE, although these are rare.

Poor echogenicity and deficient rims did not constitute a technical limitation in any of our patients, probably because of the high level of operator experience. Our results show that, in experienced surgical centers, TTE guidance of transcatheter ASD closure is safe in both adults and children, even those with extremely large, isolated, secundum ASD with or without deficient rims.

Limitations

We focused on severe early and delayed complications. Complete data on supraventricular arrhythmias were not collected.

Long-Term Outcomes After Large ASD Closure

After a median follow-up of 10.0 years, no late severe complications had occurred in any of our 311 patients who underwent successful ASD closure, in keeping with previous data from smaller case series. However, serious delayed complications have been reported in 1.2% to 2.5% of cases after ASD closure using the ASO. They included device migration/malposition, infection, severe arrhythmias, thromboembolism, device-related valvular regurgitation, and cardiac erosion/perforation. Device erosion has been reported in 0.1% of cases, chiefly in patients with aortic rim deficiency and is probably ascribable to the use of an oversized device. Whether device closure of ASD carries a risk of progressive aortic insufficiency remains controversial. In our case series of large ASDs, neither device erosion nor delayed aortic regurgitation occurred, and no other long-term complications developed. Supraventricular arrhythmias resolved in 47.4% of patients and persistent or newly developed atrial fibrillation was well controlled medically, in keeping with previous reports.
Given the large number of patients coming from all parts of the country, detailed follow-up of cardiac rhythm with regular 24-hour ECG Holter monitoring would not have been feasible in all patients.

Conclusions

Transcatheter closure of large, isolated, secundum ASDs using the ASO is safe and effective, in both adults and pediatric patients. Superior and posterior septal rim deficiencies are associated with procedural failure. In experienced centers, the procedure can be routinely performed under fluoroscopic and TTE guidance, even in patients with rim deficiencies. Early ASO migration is rare and can be managed safely with percutaneous or surgical extraction. No late complications occurred.

Acknowledgments

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Disclosures

None.

References

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