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(2 cases each of surgical and transcatheter retrieval); in the 21 remaining failures, the device was unreleased and withdrawn.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;7:837-843.)

Key Words: catheterization • echocardiography • heart septal defects • pediatrics
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.18 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 0.88. 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 using Philips iE33 or General Electrics Vivid 7 echocardiography machines. TTE was 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.

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.

Procedure Characteristics

The procedure was performed as previously described.7,19,20 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 WU·m⁻², 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, with no ASO migration; and hospital discharge on postprocedure day 2. Cardiac erosion, pericardial effusion, air embolus, ASO-related valvular regurgitation, thromboembolism, pulmonary edema, stroke, atrioventricular block, ventricular arrhythmias, and hemolysis were considered major complications. At hospital discharge, patients were prescribed oral antiplatelet therapy for 6 months.

Follow-Up

ECG was monitored for 24 hours. A physical examination, 12-lead ECG, and TTE were performed 6 and 48 hours after procedure. A physical examination and TTE were done 1 week, 3 months, and 1 year after procedure. The referring cardiologists provided subsequent follow-up. Long-term outcomes were assessed by telephone interviews of all patients and all referring cardiologists to obtain information on cardiac status, data at the last visit, and any delayed complications.

Statistical Analysis

Analyses were performed using PASW Statistics 18 software (SPSS Inc, Chicago, IL.). Categorical variables were described as numbers and percentages. Continuous variables were tested for normality with the χ² goodness-of-fit test, and variables with normal distribution were expressed as mean±SD, whereas those with non-normal distribution were expressed as median (min–max). Data on TEE-guided and TTE-guided procedures were compared in both the pediatric and the adult groups, using the nonparametric Mann–Whitney test or using 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. ASD 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 atriocentric 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.6 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

|                     | Children (n=161) | Adults (n=175) | P Value
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TEE Guidance</td>
<td>TTE Guidance</td>
<td></td>
</tr>
<tr>
<td>No. of patients</td>
<td>58</td>
<td>103</td>
<td>...</td>
</tr>
<tr>
<td>Age, y</td>
<td>6.0 (2.0–15.0)</td>
<td>8.0 (2.0–15.0)</td>
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</tr>
<tr>
<td>Weight, kg</td>
<td>20.0 (10.0–65.0)</td>
<td>23.0 (11.0–70.0)</td>
<td>&lt;0.001</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>
</tr>
</tbody>
</table>

Deficient rims
- Aortic
  - No. patients: 29 (50.0%)
  - TTE: 55 (53.4%)
  - P Value: 0.74
- Posterior
  - No. patients: 8 (13.8%)
  - TTE: 11 (10.7%)
  - P Value: 0.61
- Anteroinferior
  - No. patients: 2 (3.5%)
  - TTE: 6 (5.8%)
  - P Value: 0.71
- Posterosuperior
  - No. patients: 8 (13.8%)
  - TTE: 11 (10.7%)
  - P Value: 0.61
- Inferior
  - No. patients: 7 (12.1%)
  - TTE: 8 (7.8%)
  - P Value: 0.40
- Superior
  - No. patients: 8 (13.8%)
  - TTE: 11 (10.7%)
  - P Value: 0.61
- Balloon-stretched diameter (mm/m² in children, mm in adults)
  - No. patients: 21 (12–37)
  - TTE: 24 (13–40)
  - P Value: <0.001

ASO, mm
- No. patients: 19 (8–30)
- TTE: 20 (12–36)
- P Value: 0.09
- 34 mm ASO/36 mm ASO/38 mm
  - No. patients: 17
  - TTE: 22/12/8
  - P Value: 39/17/28
  - ASO/40 mm ASD
  - ASO/40 mm ASD
  - ASO/40 mm ASD
  - ASO/40 mm ASD
  - ASO/40 mm ASD

ASO/LA length ratio (%)
- No. patients: 88.4 (57.1–137.4)
- TTE: 87.8 (57.6–139.5)
- P Value: 0.97
- Procedural success/cessarily large
  - No. patients: 54/4/0
  - TTE: 100/3/0
  - P Value: 0.25
  - ASO or instability/ASO migration
  - No. patients: 50/7/2
  - TTE: 107/7/2
  - P Value: 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 and ≥30 mm in adults or ≥15 mm/m² in children. A 2001 study of 44 adults with large ASDs found that ASO closure was safe and effective, with less morbidity compared with surgical closure. 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). In another study, the success rate was close to 90% in patients with large ASDs. A 2005 report describes the short-term outcomes of 33 patients with extremely large ASDs managed using the 40-mm ASO. 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 and induces morbidity related to the auriculotomy, extracorporeal circulation, sternotomy

<table>
<thead>
<tr>
<th>Patients</th>
<th>Age, y</th>
<th>TTE Diameter, mm</th>
<th>Balloon-Stretched Diameter, mm</th>
<th>Aneurysmal Septum</th>
<th>PAH</th>
<th>Aortic</th>
<th>Post</th>
<th>Antinf</th>
<th>Postsup</th>
<th>Inf</th>
<th>Sup</th>
<th>Echo Guidance</th>
<th>ASO, mm</th>
<th>Reason for Failure</th>
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</tr>
<tr>
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</tr>
<tr>
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<tr>
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<tr>
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<td>No</td>
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<tr>
<td>17</td>
<td>53</td>
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<td>40</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>TEE 40</td>
<td></td>
<td>ASO migration (RV)</td>
</tr>
</tbody>
</table>

Antinf indicates anteroinferior; 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.
or as a relative contraindication to percutaneous ASD closure or ASO instability. Aortic rim deficiency has been described as a risk factor for ASO migration.16,34–36 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,16 and patients with extremely large defects are also good candidates for surgery, with low post-surgical morbidity and mortality rates.31,34 Other high-volume institutions should compare transcatheter and surgical closure in adults with extremely large ASDs.

### 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.13,16 However, serious delayed complications have been reported in 1.2% to 2.5% of cases after ASD closure using the ASO.31,42 They included device migration/malposition, infection, severe arrhythmias, thromboembolism, device-related valvular regurgitation, and cardiac erosion/perforation.5,9–11,13,44 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.5,6,35 Whether device closure of ASD carries a risk of progressive aortic insufficiency remains controversial.12,45 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.44

### Limitations

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

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Table 4. Impact of Rim Deficiencies on Procedural Success in Patients With Large Atrial Septal Defects Managed Using Transcatheter Closure With the Amplatzer Septal Occluder

<table>
<thead>
<tr>
<th></th>
<th>Successful Closure</th>
<th>Failed Closure</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>In children (n=161)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deficient aortic rim, n (%)</td>
<td>79 (51.3%)</td>
<td>7 (48.7%)</td>
<td>0.45</td>
</tr>
<tr>
<td>Deficient superior rim, n (%)</td>
<td>15 (9.7%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Deficient anteroinferior rim, n (%)</td>
<td>8 (5.2%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Deficient posterior rim, n (%)</td>
<td>13 (8.4%)</td>
<td>2 (13.3%)</td>
<td>0.13</td>
</tr>
<tr>
<td>Deficient inferior rim, n (%)</td>
<td>18 (11.7%)</td>
<td>1 (6.3%)</td>
<td>0.59</td>
</tr>
<tr>
<td>In adults (n=175)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deficient aortic rim, n (%)</td>
<td>57 (36.3%)</td>
<td>10 (55.6%)</td>
<td>0.13</td>
</tr>
<tr>
<td>Deficient superior rim, n (%)</td>
<td>0 (0%)</td>
<td>6 (33.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Deficient anteroinferior rim, n (%)</td>
<td>8 (5.1%)</td>
<td>0 (0%)</td>
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</tr>
<tr>
<td>Deficient posterior rim, n (%)</td>
<td>0 (0%)</td>
<td>6 (33.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Deficient inferior rim, n (%)</td>
<td>17 (10.8%)</td>
<td>1 (5.6%)</td>
<td>0.70</td>
</tr>
<tr>
<td>In adults and children (n=336)</td>
<td>311</td>
<td>25</td>
<td>...</td>
</tr>
<tr>
<td>Deficient aortic rim, n (%)</td>
<td>136 (43.7%)</td>
<td>15 (60.0%)</td>
<td>0.14</td>
</tr>
<tr>
<td>Deficient superior rim, n (%)</td>
<td>15 (4.8%)</td>
<td>6 (24.0%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Deficient anteroinferior rim, n (%)</td>
<td>16 (5.1%)</td>
<td>0 (0%)</td>
<td>0.62</td>
</tr>
<tr>
<td>Deficient posterior rim, n (%)</td>
<td>13 (4.2%)</td>
<td>8 (32.0%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Deficient inferior rim, n (%)</td>
<td>35 (11.2%)</td>
<td>2 (8.0%)</td>
<td>1.00</td>
</tr>
</tbody>
</table>
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
We gratefully acknowledge Antoinette Wolfe for linguistic revision.

Disclosures
None.

References


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

Alban-Elouen Baruteau, Jérôme Petit, Virginie Lambert, Marielle Gouton, Dominique Piot, Philippe Brenot, Claude-Yves Angel, Lucile Houyel, Emmanuel Le Bret, Régine Roussin, Mohamedou Ly, André Capderou and Emre Belli

_Circ Cardiovasc Interv._ 2014;7:837-843; originally published online November 25, 2014; doi: 10.1161/CIRCINTERVENTIONS.113.001254

_Circulation: Cardiovascular Interventions_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-7640. Online ISSN: 1941-7632

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