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

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

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(2 cases each of surgical and transcatheter retrieval); in the 21 remaining failures, the device was unreleased and withdrawn.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
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 percutaneus 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.16 Symptoms were not among the inclusion criteria. Of the 336 patients, 175 were adults (median age, 40.0 [16.0–82.0] 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 Electric 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.17 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 posterosuperior 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, posterosuperior, 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 mm2/m2 in the children.

Device Characteristics

ASD 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%) patients, 0.9 to 1 in 52 (32.3%) patients, 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 valvar 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. 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, \( >200000 \) ASOs have been implanted worldwide including 46000 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></th>
<th>Children (n=161)</th>
<th>Adults (n=175)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TEE Guidance</td>
<td>TTE Guidance</td>
</tr>
<tr>
<td>No. of patients</td>
<td>58</td>
<td>103</td>
</tr>
<tr>
<td>Age, y</td>
<td>6.0 (2.0–15.0)</td>
<td>8.0 (2.0–15.0)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>20.0 (10.0–65.0)</td>
<td>23.0 (11.0–70.0)</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>
</tr>
</tbody>
</table>

Deficient rims
- Aortic: 29 (50.0%) vs. 55 (53.4%); \( P = 0.74 \) vs. 18 (30.5%); \( P = 0.49 \)
- Posterior: 8 (13.8%) vs. 11 (10.7%); \( P = 0.61 \) vs. 4 (6.8%); \( P = 0.14 \)
- Anteroinferior: 2 (3.5%) vs. 6 (5.8%); \( P = 0.71 \) vs. 7 (11.9%); \( P = 0.002 \)
- Posterosuperior: 8 (13.8%) vs. 11 (10.7%); \( P = 0.61 \) vs. 4 (6.8%); \( P = 0.43 \)
- Inferior: 7 (12.1%) vs. 8 (7.8%); \( P = 0.40 \) vs. 2 (3.4%); \( P = 1.00 \)
- Superior: 8 (13.8%) vs. 11 (10.7%); \( P = 0.61 \) vs. 4 (6.8%); \( P = 0.43 \)

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 |

ASO/LA length ratio (%) | 88.4 (57.1–137.4) | 87.8 (57.6–139.5) | 0.97 | na | na | na |

Procedural success/especially 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 and ≥30 mm in adults or ≥15 mm/m² in children. 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. 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 2. Characteristics of Failed Procedures in Adults

<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>Deficient Rims</th>
<th>Echo Guidance</th>
<th>ASO, mm</th>
<th>Reason for Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>18</td>
<td>21</td>
<td>33</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>TEE 34</td>
<td>ASO migration (LA)</td>
</tr>
<tr>
<td>2</td>
<td>47</td>
<td>28</td>
<td>34</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>TEE 34</td>
<td>ASO migration (RV)</td>
</tr>
<tr>
<td>3</td>
<td>69</td>
<td>33</td>
<td>38</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 38</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>4</td>
<td>48</td>
<td>25</td>
<td>36</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 36</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>5</td>
<td>57</td>
<td>29</td>
<td>36</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 36</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>6</td>
<td>23</td>
<td>24</td>
<td>34</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 34</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>7</td>
<td>18</td>
<td>22</td>
<td>36</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>TEE 36</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>8</td>
<td>20</td>
<td>35</td>
<td>40</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 36</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>9</td>
<td>18</td>
<td>24</td>
<td>38</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 38</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>10</td>
<td>49</td>
<td>25</td>
<td>&gt;40</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>TEE 40</td>
<td>Unstable ASO</td>
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<tr>
<td>11</td>
<td>52</td>
<td>23</td>
<td>34</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>TEE 36</td>
<td>ASO migration (RA)</td>
</tr>
<tr>
<td>12</td>
<td>17</td>
<td>30</td>
<td>38</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>TEE 36</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>13</td>
<td>40</td>
<td>30</td>
<td>40</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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<td>Unstable ASO</td>
</tr>
<tr>
<td>14</td>
<td>31</td>
<td>32</td>
<td>&gt;40</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 40</td>
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</tr>
<tr>
<td>15</td>
<td>48</td>
<td>32</td>
<td>38</td>
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<td>Yes</td>
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<td>Yes</td>
<td>TEE 36</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>16</td>
<td>33</td>
<td>25</td>
<td>32</td>
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<td>No</td>
<td>TEE 36</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>17</td>
<td>53</td>
<td>30</td>
<td>40</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>TEE 36</td>
<td>Unstable ASO</td>
</tr>
<tr>
<td>18</td>
<td>64</td>
<td>26</td>
<td>40</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>TEE 40</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.

Table 3. Characteristics of Failed Procedures in Children

<table>
<thead>
<tr>
<th>Patients</th>
<th>Age, y</th>
<th>Weight, kg</th>
<th>TTE Diameter, mm/m²</th>
<th>Balloon-Stretched Diameter, mm/m²</th>
<th>Aneurysmal Septum</th>
<th>PAH</th>
<th>Deficient Rims</th>
<th>Echo Guidance</th>
<th>ASO/LA Length, %</th>
<th>Reason for Failure</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>9</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</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>16</td>
<td>16.7</td>
<td>22.7</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 24</td>
<td>&gt;100</td>
</tr>
<tr>
<td>3</td>
<td>6</td>
<td>18</td>
<td>26.4</td>
<td>34.3</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 22</td>
<td>&gt;100</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>16</td>
<td>21.7</td>
<td>28.9</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 22</td>
<td>&gt;100</td>
</tr>
<tr>
<td>5</td>
<td>11</td>
<td>44</td>
<td>28.2</td>
<td>16.9</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 18</td>
<td>&lt;80</td>
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<tr>
<td>6</td>
<td>6</td>
<td>11</td>
<td>25.6</td>
<td>37.6</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>TEE 34</td>
<td>&gt;100</td>
</tr>
<tr>
<td>7</td>
<td>7</td>
<td>16</td>
<td>15.5</td>
<td>26.8</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>TEE 34</td>
<td>&gt;100</td>
</tr>
</tbody>
</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; Sup, superior; TEE, transesophageal echocardiography; and TTE, transthoracic echocardiography.
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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>154</td>
<td>7</td>
<td>...</td>
</tr>
<tr>
<td>Deficient aortic rim, n (%)</td>
<td>79 (51.3%)</td>
<td>5 (71.4%)</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 (28.6%)</td>
<td>0.13</td>
</tr>
<tr>
<td>Deficient inferior rim, n (%)</td>
<td>18 (11.7%)</td>
<td>1 (14.3%)</td>
<td>0.59</td>
</tr>
<tr>
<td>In adults (n=175)</td>
<td>157</td>
<td>18</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>
<td>1.00</td>
</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>15 (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>

Factors Associated With Procedural Failure

Large ASDs (>38 mm) and septal 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 as a source of procedural difficulties. In our experience, aortic rim 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.
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.

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Disclosures
None.

References


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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

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