Transcatheter Closure of Atrial Septal Defects Without Fluoroscopy
Feasibility of a New Method

Peter Ewert, MD; Felix Berger, MD; Ingo Daehnert, MD; John van Wees, MD; Matthias Gittermann, MD; Hashim Abdul-Khalilq, MD; Peter E. Lange, MD, PhD

Background—In an effort to reduce x-ray exposure, we developed a technique for transcatheter closure of atrial septal defects under echocardiographic guidance without fluoroscopy. To assess the efficiency of this procedure for routine use, we compared our initial results with those for the conventional procedure.

Methods and Results—Twenty-two randomly selected patients (median age 18 years; range 2 to 66 years) with atrial septal defects (n = 13) or patent foramen ovale (n = 9) underwent cardiac catheterization for possible interventional defect closure with echocardiography as the only imaging tool. Median stretched diameter was 9 mm (range 6 to 26 mm); median left-to-right shunt over the atrial septal defects was Qp/Qs = 1.8 (range 1.5 to 2.6). An Amplatzer septal occluder was successfully implanted in 19 defects without fluoroscopy and in 3 with the help of radiography. After 1 month, complete defect closure was documented in all patients. Compared with the conventional procedure of a control group of 131 patients, procedure times were not significantly different (88 versus 100 minutes; P = 0.09). However, the study group received significantly higher doses of propofol for sedation (9.9 versus 5.6 mg/kg body weight; P = 0.002) owing to extended transesophageal echocardiography.

Conclusions—In the majority of patients in whom transcatheter closure of interatrial communications with the Amplatzer septal occluder is possible, the procedure can be safely performed under echocardiographic guidance without fluoroscopy. (Circulation. 2000;101:847-849.)

Key Words: heart septal defects • catheterization • echocardiography

The increased diagnostic accuracy of 2D and color Doppler echocardiography enables surgical closure of atrial septal defects without routine preoperative cardiac catheterization.1,2 However, with the introduction of new transcatheter methods for interventional defect closure,3-5 cardiac catheterization in patients with atrial septal defects has experienced a renaissance. In an effort to reduce the x-ray exposure, we recently developed a technique for diagnostic catheterization, balloon sizing, and transcatheter closure of atrial septal defects with the Amplatzer septal occluder under echocardiographic guidance without fluoroscopy.6 To assess the efficiency of this procedure for routine use, we compared the initial results in 22 consecutive patients with our standard procedure in 131 patients.

Methods

Patients
From July 1998 to May 1999, of all patients with either an atrial septal defect of the secundum type or a persistent foramen ovale after presumed paradoxical embolism who were considered suitable for transcatheter closure on the basis of an outpatient echocardiographic study (diameter not larger than 32 mm and ≥7 mm rim to adjacent anatomic structures), 34 patients were assigned to the working group of echocardiographic guidance by random selection based on a day of the week. After balloon sizing without fluoroscopy, 6 defects were estimated as too large for interventional closure, 4 had insufficient septal rim to adjacent anatomic structures, and 2 showed perforated septal aneurysms that were unsuitable for device placement. These patients were excluded from this study. In the remaining 22 patients (study group), a closure of the defects was attempted with echocardiography as the only imaging tool. The study group was compared with a control group of 131 patients whose atrial septal defects were conventionally closed with an Amplatzer septal occluder by the use of fluoroscopy. The patients of the control group fulfilled the same criteria for interventional defect closure as those of the study group. Demographic data of both groups are presented in the Table. All procedures were in accordance with institutional guidelines and were approved by the institutional review committee. There was informed consent from the patients of the study group or from their parents, respectively, to perform the procedure without fluoroscopy.

Procedures
In the study group, diagnostic catheterization, balloon sizing maneuver, and transcatheter closure of the atrial septal defects were performed without fluoroscopy, as previously described. The interventional procedures took place in the catheterization laboratory, so that fluoroscopy...
was available at any time should it be needed. There were no restrictions on the operator to prevent him from switching to fluoroscopic guidance at any time during the procedure. In the control group, fluoroscopy and echocardiography were used together.

In both groups, the patients were spontaneously breathing under sedation with propofol. Patient interviews, clinical examinations, and echocardiograms were obtained within 48 hours and 1, 6, and 12 months after implantation. Chest radiographs and Holter monitoring were performed within 48 hours and after 1 and 12 months. The mean follow-up period was 5 months (range 1 to 10 months) in the study group and 12 months (range 1 to 23 months) in the control group.

Statistical Evaluation
The Mann-Whitney U test was used to detect differences between the 2 groups with regard to the distribution of age, body weight, size of the defects, shunt volume, procedure time, and dose of propofol administered during the procedure. The χ² test was used to detect differences in the distribution of defect types and in closure rates. Statistical significance was defined as a value of P<0.05.

Results
Comparison of the study and control groups revealed no statistical differences with regard to age, body weight, defect type or size, shunt volume, procedure time, or complete closure rate (Table; Figure). However, the doses of propofol used in the study group were significantly higher than in the control group (Table).

### Table: Comparison of Study Group (n=22) and Control Group (n=131)

<table>
<thead>
<tr>
<th></th>
<th>Study Group</th>
<th>Control Group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>Median</td>
<td>Range</td>
<td>Median</td>
</tr>
<tr>
<td>Body weight, kg</td>
<td>18 (2–66)</td>
<td>34 (1–78)</td>
<td>57 (13–118)</td>
</tr>
<tr>
<td>PFO vs ASD</td>
<td>9/13</td>
<td>54/77</td>
<td>0.98 (NS)</td>
</tr>
<tr>
<td>Defect size, mm</td>
<td>9 (6–26)</td>
<td>11 (4–26)</td>
<td>3.33 (NS)</td>
</tr>
<tr>
<td>Shunt (Qp/Qs)</td>
<td>1.5 (1.0–2.6)</td>
<td>1.4 (1.0–2.6)</td>
<td>0.33 (NS)</td>
</tr>
<tr>
<td>Procedure time, min</td>
<td>88 (35–135)</td>
<td>100 (45–150)</td>
<td>0.09 (NS)</td>
</tr>
<tr>
<td>Propofol, mg/kg BW</td>
<td>9.9 (3.2–19.2)</td>
<td>5.6 (2.6–21.2)</td>
<td>0.002</td>
</tr>
<tr>
<td>Residual shunts*</td>
<td>0/22</td>
<td>3/131</td>
<td>0.47 (NS)</td>
</tr>
</tbody>
</table>

PFO indicates patent foramen ovale; ASD, atrial septal defect; and BW, body weight.

*After 1 month.

In 19 of the 22 patients studied, diagnostic catheterization, performance of the sizing maneuver, and defect closure were possible with echocardiography as the only imaging tool. Fluoroscopy was used in 3 patients. In 1 of them, the left atrial disc configured incompletely; in the second, the operator felt uncomfortable because of a small atrial septal aneurysm; and in the third, it seemed appropriate to use fluoroscopy for the first use of the Amplatzer PFO occluder.

In 1 patient, atrial flutter occurred during the diagnostic catheterization. Sinus rhythm was established by cardioversion before the release of the occluder. Otherwise, the procedures of the study group were uneventful, and in particular, the use of fluoroscopy was not necessary for a potentially hazardous situation in any patient in the study group.

On follow-up, echocardiograms and chest radiographs showed no displacement of the occluders. Holter ECG revealed sinus rhythm in all patients.

Discussion
With the extensive use of echocardiography for patient selection and intervention and the development of new occluder systems, the transcatheter closure of atrial septal defects has become a standard technique in some centers.\(^7\) With increasing operator experience and the development of easy-to-handle devices, x-ray exposure is minimized to several minutes, particularly if transesophageal echocardiography is used.\(^8,9\) However, to avoid completely the use of fluoroscopy, the technique of device placement itself must be as safe as possible under echocardiographic guidance, as must the diagnostic catheterization and the reliable sizing of the defect. We concur that the need for invasive hemodynamic measurements before a transcatheter closure may certainly be questioned in patients with uncomplicated atrial septal defects.\(^1,2\) Indeed, in no patient in the study group did the results of the right heart catheterization lead to a decision not to intervene. However, at the present stage of transcatheter defect closure, we believe that oximetric shunt estimation and pressure recordings are justified, and they are still routinely performed at our institution.

The noninvasive estimation of the defect diameter with echocardiography or MRI produced reasonable results.\(^10–12\) However, their accuracy is limited and only useful for patient...
selection. The determination of the balloon-stretched defect diameter, thus far performed under fluoroscopy, remains indispensable. In the present study, echocardiography alone proved to be suitable to guide the sizing catheter and to determine the defect diameter regardless of the size or shape in all 22 patients, mainly because the saline-filled balloon is clearly visible with echocardiography.

The successful closure of 19 of 22 interatrial communications without fluoroscopy proves that the transcatheter procedure is possible under echocardiographic guidance alone in many patients. Moreover, we must emphasize that in the 3 patients in whom the operator decided to use fluoroscopy to implant the device, there were only minor causes for concern. We are confident that with further practice, these situations can be handled under echocardiographic guidance as well.

The median procedure time of 88 minutes confirms the result of our preliminary study6 and is comparable to the time needed for our standard practice8 and with the results of other investigators.3,13 The considerably higher doses of propofol used in the study group reflect the longer time for which the transesophageal echocardiographic probe must be inserted. Nevertheless, hypoventilation and hypoxemia were not clinical problems. However, if the procedure is performed under general anesthesia, as some centers do, this factor may play a minor role.

Our study was limited to some extent because we have only treated 22 patients thus far, and the largest septal defect measured was only 26 mm in diameter. Whether the procedure is suitable for larger defects remains to be determined. However, for a successful intervention under echocardiographic guidance, the rotation-symmetrical shape and the self-centering capabilities of the Amplatzer septal occluder are fundamental. These features are responsible for the high occlusion rates,3,9,14 regardless of which imaging modalities were preferred for the intervention.

The basic question whether the procedure without fluoroscopy should be further refined by more widespread use in other experienced centers has to be discussed. We are convinced, however, that good transesophageal echocardiographic views and easy-to-handle devices justify the transcatheter closure of atrial septal defects without the routine use of fluoroscopy.

Acknowledgment
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References
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