Transcatheter closure of secundum-type atrial septal defect (ASD II) is an increasingly widespread alternative to surgical closure (1). The Amplatzer septal occluder (ASO) is currently one of the most frequently used devices for transcatheter closure of ASD II (2). Immediate-, short-, and intermediate-term results of percutaneous closure of ASD II using ASO are promising (2–4). However, long-term data after ASO implantation are lacking. Therefore, the purpose of the present study was to evaluate a long-term outcome of transcatheter closure of ASD II using ASO in a single institution.

**METHODS**

**Patient population.** From September 1995 to January 2000, 151 patients having isolated ASD II underwent transcatheter closure using ASO. All 151 patients were followed up until September 2004. All patients were included in our previous study analyzing morphological characteristics of isolated ASD II (5). At the time of implantation, the mean patient age was 11.9 ± 11.6 years and weight 36.0 ± 20.9 kg. The study was part of a clinical trial approved by an authorized ethics committee. An informed written consent has been obtained from all patients or their parents.

**The occluder.** The Amplatzer septal occluder and delivery system (AGA Medical, Golden Valley, Minnesota) have been described in detail previously (2,6).

**Selection of patients suitable for transcatheter closure.** The selection of patients suitable for a transcatheter closure using ASO was based on the measurement of the maximal defect diameter and morphological characteristics of the defect. In fact, ASD II characteristics of all patients included in the present study were reported in detail previously (5).

**Preimplantation protocol.** A physical examination, a standard 12-lead electrocardiogram (ECG), chest radiograph, transthoracic echocardiography (TTE), and transesophageal echocardiography (TEE) were performed in all patients.

**Implantation procedure.** The protocol for ASO implantation has been reported in detail previously (2).

**Follow-up protocol.** Immediately after the ASO release, a precise TEE examination was performed. The shape of the occluder was evaluated. Thrombus formation on the device was sought. A detailed color Doppler interrogation of the interatrial septum was performed to detect and quantify any residual shunts. A color Doppler signal width <2 mm was considered as a small residual shunt, 2 to 4 mm as a moderate shunt, and >4 mm as a significant residual shunt. Relationships between the occluder and both atrioventricular valves were evaluated. Drainage of the caval veins, right pulmonary veins, and coronary sinus were evaluated for obstruction.

At 24-h follow-up, ECG, chest radiograph, and TTE were performed. Both chest radiograph and TTE allowed evaluation of the ASO shape. Thrombi on both discs of the ASO were searched for using TTE. Residual shunts were sought and quantified using the same color Doppler criteria as during TEE examination. A relationship of both atrioventricular valves toward the occluder was assessed. Drainage of the caval veins, right pulmonary veins, and coronary sinus were evaluated for obstruction.

Thereafter, follow-up ECG and TTE were performed at 1 month, 3 months, 12 months, and then annually after the
The present study demonstrates an excellent outcome of percutaneous ASD II closure using ASO during a follow-up period ranging up to 9 years.

**Safety of ASD II closure using ASO.** Complications of percutaneous ASD II closure using ASO reported in the literature were rare and were early in the vast majority of patients (4,7). Exceptionally, reported complications were late (7–10). No deaths or significant complications were experienced in the present study. Therefore, this study confirms safety of percutaneous ASD II closure using ASO both early and during long-term follow-up.

The cardiac perforation is a rare, life-threatening complication of transcatheter closure of ASD II and was not experienced in the present study. A procedure-related cardiac perforation is an avoidable complication of ASO implantation (7). In contrast, a cardiac perforation occurring six months after ASO implantation causing hemodynamic collapse remained unexplained and is, therefore, more worrisome (8). An aorta-to-right-atrial fistula is an additional rare complication caused by erosion into the aorta by the right atrial disc of ASO (9). It was detected three months after ASO implantation in a defect with a deficient superior anterior rim. A 26-mm device was implanted in a defect with a stretch defect diameter of 26 mm. Selecting a device 2 to 4 mm larger than the stretch defect diameter might prevent the development of fistula in this defect morphology.

Device embolizations and malpositions are well known early complications of percutaneous ASD II closure (7,11). An early device embolization or malposition are avoidable complications of percutaneous ASD II closure using ASO and were not experienced in this study. Delayed ASO embolization, occurring one week after implantation, was also reported (10). The defect was oval in shape in the reported patient, and, therefore, undersized ASO was implanted.

The incidence of thrombus formation on ASD II closure devices, particularly on ASO, is low (12,13). Thrombi develop on devices both early and late during follow-up. Neither thrombus formation nor systemic thromboembolism were detected in our group of patients either immediately after implantation or during follow-up. However, TEE was performed only immediately after the device implantation in the present study, and, therefore, small, clinically silent thrombi may not be detected in our group of patients during follow-up.

So far, arrhythmias were reported only early after ASO implantation (7,14). Similarly, we noted an increase in supraventricular and ventricular ectopy immediately and 24-h after the procedure and not later during follow-up.

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**Table 1.** Time Course of Residual Atrial Shunt Disappearance After Amplatzer Septal Occluder Implantation in All 151 Patients in the Study

<table>
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<th>Follow-Up</th>
<th>Residual Shunts: Moderate + Small (%)</th>
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<tbody>
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<td>Immediate</td>
<td>31: 6 + 25 (20.5)</td>
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<tr>
<td>1 day</td>
<td>13: 4 + 9 (8.6)</td>
</tr>
<tr>
<td>1 month</td>
<td>7: 3 + 4 (4.6)</td>
</tr>
<tr>
<td>3 months</td>
<td>2: 2 + 0 (1.3)</td>
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**Abbreviations and Acronyms**
- ASD II = secundum-type atrial septal defect
- ASO = Amplatzer septal occluder
- TEE = transesophageal echocardiography
- TTE = transthoracic echocardiography

implantation. The same TTE examination protocol was used throughout a follow-up period as performed 24 h after the procedure. In addition, complications related to the ASO implantation were noted at each follow-up visit. Aspirin, 5 mg/kg daily, and infective endocarditis prophylaxis were recommended for 6 months after the procedure in all patients.

**Statistics.** The data are expressed as mean ± SD or as median and ranges as appropriate.

**RESULTS**

From September 1995 to January 2000, 154 patients were taken to the catheterization laboratory with an intent-to-treat. Transcatheter closure was attempted in 151 patients, and implantation of the occluder was successful in all of them.

The mean maximal defect diameter measured by TEE was 12.9 ± 4.4 mm. The mean stretched defect diameter was 15.9 ± 4.8 mm. Altogether, 152 occluders have been implanted. Two occluders were implanted in a single patient having two widely separated defects. The mean size of the implanted ASO was 16.1 ± 5.3.

Follow-up evaluation was complete at each of the intervals. There were no deaths, cardiac perforations, device embolizations or malpositions, thrombus formations or thromboembolisms, significant arrhythmias, infective endocarditis prophylaxis were recommended for 6 months after the procedure in all patients.

Deformation of implanted occluder or occluder integrity problems were not detected during follow-up in any patient.

**DISCUSSION**

The present study demonstrates an excellent outcome of percutaneous ASD II closure using ASO during a follow-up period ranging up to 9 years.

The mitral valve and tricuspid valve were not encroached by the occluder in any patient in the study. The caval veins, right pulmonary veins, and coronary sinus drained freely in all patients during the follow-up period.

Satisfactory images of implanted devices were obtained in all patients in the study. Deformation of implanted occluder or occluder integrity problems were not detected during follow-up in any patient.

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Infective endocarditis on ASO was not experienced in our study. However, an infective endocarditis on an ASO was reported in a single patient almost two months after implantation, underscoring the need for antibiotic prophylaxis until a complete endothelialization occurs (6,15).

The function of both atrioventricular valves and drainage of the caval veins, right pulmonary veins, and coronary sinus were undisturbed both immediately after ASO implantation and during follow-up. Careful patient selection and precise evaluation after device positioning is necessary to prevent a compromise of structures surrounding the device.

So far, device integrity problems or deformations of implanted occluders were not reported after ASO implantation and were also not observed in this study. In contrast, a large ASO profile obtained immediately after implantation decreases significantly during follow-up, resulting in a much lower device profile (16).

The reported incidence of late events after ASO implantation is low. Therefore, a small sample size may not be representative of the incidence of rare events; this can only be resolved by a large, multi-centered registry.

Effectiveness of ASD II closure using ASO. The present study confirmed effectiveness of percutaneous ASD II closure using ASO. Our group of 151 patients was selected from a group of 190 consecutive children having isolated ASD II (5). Thus, 79.4% of patients with isolated ASD II underwent successful implantation of ASO. Similarly, Fischer et al. (4) reported successful ASO implantation in 200 of 236 consecutive patients (84.7%). An immediate complete closure was demonstrated by TEE in 120 of 151 patients (91.3%). The closure rate increased steadily during follow-up, resulting in a six-month period after ASO implantation to achieve a high closure rate.

Conclusions. The present study proved that percutaneous closure of ASD II using ASO is safe and effective during a follow-up period of up to 9.0 years. A precise selection of suitable patients based on ASD II size and morphology, a selection of ASO of appropriate size, attention to technical details during implantation, and consideration for infective endocarditis prophylaxis and low-dose aspirin during a six-month period after ASO implantation are crucial to prevent complications and to achieve a high closure rate.

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REFERENCES