Double-Umbrella Closure of Atrial Defects

Initial Clinical Applications

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Forty patients were catheterized for closure of atrial septal defects with the Rashkind patent ductus arteriosus umbrella device, a modified Rashkind umbrella device, and the newly designed Lock Clamshell Occluder. Patients weighed 8 kg or more (a requirement for transvenous access with the 11F delivery sheath) and had defects suitable for closure based on two-dimensional echocardiography. The new device was at least 1.6 times the diameter of the atrial septal defect as determined by balloon sizing at catheterization. Patients were followed up by telephone, clinical examination, and echocardiography at 6 months. We attempted closure in 34 patients, with atrial septal defects ranging in diameter from 3 to 22 mm; device sizes ranged from 17 to 33 mm. Initial device position immediately after release was correct in all patients. A cerebral embolus occurred in one elderly patient before device placement—the patient died 1 week later. Two instances of early device embolization occurred, and devices were retrieved by catheter without complication. Follow-up of 31 patients discharged with devices in place, for a total of 31 patient-years, has yielded no umbrella-related complications. Adequate imaging studies in 19 patients 6.5 months after device placement revealed no atrial shunt in 12; residual flow through separate, previously unrecognized atrial septal defects occurred in two; and small residual leaks (<3 mm) around devices were present in five patients. This initial success indicates that double-umbrella closure of atrial septal defects will aid in the treatment of intracardiac defects. (Circulation 1990;82:751–758)

Transcatheter techniques for closure of atrial defects have been available for more than two decades, yet the approach has not achieved widespread usage. The double-disk device of King and Mills,1 used first in 1976, was successful in several patients. No significant morbidity was noted during a follow-up period of 10 years. The very large catheter size that was required (23F) by this device limited its applicability.

The more recent single-umbrella device of Rashkind2 could be delivered through a 15F system (allowing use in children weighing 20 kg or more). This device relied on barbed hooks to ensure attachment to the left side of the atrial septum. Once engaged, these hooks are very difficult to disengage from the atrial endomyocardium. Thus, the first place that the first hook engages will determine the location of all the other hooks, and poorly centered devices have been common in experimental studies and early clinical trials.3,4

Our laboratory recently modified the double-umbrella patent ductus arteriosus (PDA) technique of the late Dr. William Rashkind to close a variety of intracardiac defects, including atrial septal defects4 and ventricular septal defects.5 Based on this preliminary experience, we developed a device with lengthened arms and a hinge allowing them to fold back against themselves, creating a double umbrella with a "clamshell" configuration (Figure 1). Preliminary animal data were encouraging.3

We have now used the Rashkind PDA umbrella, a modified PDA umbrella, a prototype clamshell occluder, and the Lock Clamshell Occluder (USCI Angiographics, Tewksbury, Mass.) to attempt closure of 34 atrial defects. We have reviewed this experience to assess the technique, short-term results, and limitations of double-umbrella closure of atrial septal defects.

Methods

Patient Selection

Patients were considered for double-umbrella closure of atrial defects if each of the following criteria were met: 1) closure of the defect was clinically indicated; 2) the risks and benefits of double-
umbrella closure of the atrial defect were, in the judgment of the patient's cardiologist and cardiovascular surgeon, preferable to the risks and benefits of surgery; 3) the echocardiographic or angiographic diameter of the defect was no more than 50% the stated diameter of the largest available umbrella, and the defect appeared single; 4) at least 4 mm separated the defect edges from important cardiac structures, for example, atrioventricular valves, venae cavae, and pulmonary veins, as estimated by echocardiography; and 5) patients were large enough (weighting more than 8 kg) to allow femoral vein access to the atrial defect with an 11F sheath.

Patients who met the above criteria were offered the option of transcatheter double-umbrella closure; those who consented underwent cardiac catheterization to further determine their suitability for transcatheter closure.

All umbrellas were implanted under research protocols approved by the Committee on Clinical Investigation and the Food and Drug Administration. Informed consent was obtained with forms approved by the Committee on Clinical Investigation at the Children's Hospital, Boston.

**Cardiac Catheterization**

The hemodynamic effects of the lesion were determined by routine pressure and oximetry measurements and by balloon occlusion when indicated. Test occlusion of the atrial defects with contrast-filled balloons not only predicted the hemodynamic effects of closure, but also estimated how far the defect could be displaced during gentle traction (Figure 2).

**Closure Technique**

We first passed a 0.035-in. Teflon-coated guide wire across the defect and advanced a 7F balloon-tipped end-hole flotation catheter over the wire across the defect. The balloon was filled with a maximum of 1.5 ml dilute contrast medium, corresponding to a diameter of 13–14 mm, and withdrawn to size the defect. In some atrial defects, a larger inflated balloon size could be advanced through the defect than could be withdrawn, presumably because the apple-shaped flotation balloons would catch on the inferior atrial septal edge (Figure 3).

If this balloon could not close the defect, a larger 9F occlusion balloon catheter (Medi-tech, Watertown, Mass.) was used. Defects with stretched diameters larger than 10 mm were considered too large for the 17 mm umbrella, and defects larger than 22 mm were considered too large for the 33-mm device.

For defects considered suitable for closure, the skin, inguinal fascia, and vein were predilated with a 12F dilator, and an 11F long sheath and dilator were advanced over the 0.035-in. guide wire positioned in a left pulmonary vein to cross the defect. During removal of the dilator from the long sheath, saline was infused between the guide wire and sheath through a side-arm adapter to maintain a constant volume in the sheath, thus preventing air from entering the sheath.

The nominal umbrella diameter (i.e., the diagonal length of two arms) was chosen to be at least 1.6 times larger than the stretched diameter of the defect. The distal arms were opened in the mid–left
atrium and then retracted against the septum until the arms were seen to bend. While maintaining this device position, the sheath was then retracted, allowing the proximal (right atrial) arms to open. Once all eight arms were deployed, the control wire was readvanced to let the umbrella assume a neutral position.

Before umbrella release, we tested the arm positioning in three ways: 1) the fluoroscopic angle was changed to maximally separate the right from the left atrial arms (generally a shallow left anterior oblique view with cranial angulation), and the control wire was then advanced and retracted 1–2 mm under fluoroscopic visualization to be certain that the arms separated as predicted; 2) the umbrella was inspected with transthoracic echocardiography, generally a subxiphoid view, to be certain that the septum moved with the umbrella and to attempt to be certain that all eight arms were correctly positioned; and 3) contrast medium was injected through the side arm of the long sheath, positioned 5–10 mm below the umbrella, to outline the right atrial side of the septum.

These maneuvers required 1–3 minutes. Once we were satisfied that the umbrella appeared adequately positioned, the pin-pin mechanism was activated with the wire in a neutral position, releasing the umbrella.

**Patient Management and Follow-up**

All patients were fully heparinized (100 units/kg) at the beginning of the procedure, and each received intravenous cephazolin (50 mg/kg) 1 hour before and 12 hours after closure. A chest roentgenogram obtained 4–6 hours after umbrella release confirmed intracardiac umbrella position. Patients were discharged 1–3 days after closure.

Patients were observed clinically for evidence of umbrella dislodgment. Auscultation and color flow Doppler echocardiography or catheterization were used to assess residual flow across the defect at a 6-month postclosure procedure. Information was obtained by telephone to assess the incidence of strokes, endocarditis, embolic events, late deaths, or symptomatic arrhythmias.

**Results**

**Patient Selection**

We brought 40 patients to the catheterization laboratory to consider closure of 40 interatrial
defects. The anatomy of the defects varied (Table 1), but most were secundum atrial septal defects or patent foramina ovale in patients with significant, associated cardiac disease. In six patients, we did not attempt closure. In the first, a 17-mm PDA umbrella was placed in a 9-mm atrial septal defect (before the Lock Clamshell umbrella was available); the device was unstable and not released. Two patients had atrial defects with stretched measurements greater than 70% the diameter of the largest available umbrella. Another patient, with right-to-left atrial shunting, was found to have a second defect by balloon occlusion angiography (Figure 4). The fifth patient had multiple atrial defects and partial anomalous pulmonary venous connection unsuspected before catheterization. Last, in an 8-kg infant with pulmonary atresia and intact ventricular septum, we could not advance the 11F sheath and dilator securely across the atrial septum into the left atrium.

Cardiac Catheterization

Of the 40 catheterized patients, 27 had a right-to-left atrial shunt producing cyanosis, and 11 had a left-to-right shunt. Two patients (with prior stroke or brain abscess and a patent foramen ovale) had no measurable increase or evidence of cyanosis, although one of these required long-term oxygen therapy to reduce the degree of cyanosis. Fourteen patients had pressure gradients up to 10 mm Hg across their atrial defects.

Closure

We attempted closure in 34 defects ranging in diameter from 3 to 22 mm (mean, 11 mm). In these patients, we used the original Rashkind PDA umbrella in 12, including patients 2, 5, 7, and 8 reported previously, a modified 33-mm PDA umbrella in two, a prototype clamshell occluder in three, and the Lock Clamshell Occluder in 17 (33 mm in seven, 28 mm in six, 23 mm in two, and 17 mm in two). All of the defects (Table 1) were closed with the clamshell devices; there were no other significant differences among the patients receiving the original Rashkind PDA, the modified Rashkind, the prototype clamshell, or the Lock Clamshell Occluder. In all 34 patients, the defect was straddled by the first umbrella, and each umbrella appeared securely placed. After release, right atrial angiography or echocardiography confirmed stable umbrella positioning (Figure 5); the catheters were removed; and hemostasis was achieved with pressure alone. Because we had previously been able to dislodge a correctly positioned umbrella (in animals) with cath-

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**Figure 3.** Angiogram depicting a contrast-filled Berman balloon catheter being pulled from the left to right atrium across a secundum atrial septal defect. Inferior aspect of the balloon is asymmetrically indented as it catches on the inferior rim of the atrial septal defect (arrow). A Lock Clamshell Occluder is held on the patient's chest for size comparison.
Table I. Patient Characteristics

<table>
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<th>Defect</th>
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<th>Associated diagnoses</th>
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<th>Device implanted (n)</th>
<th>Age (yr)</th>
<th>Weight (kg)</th>
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<td>Single ventricle</td>
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<td>Total patients</td>
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<td>34</td>
<td>20</td>
<td>0.9–82†</td>
<td>46</td>
</tr>
</tbody>
</table>

*Two patients’ status after attempted surgical repair of ASDs (see text).
†Five patients <6 years of age, devices implanted in four.
‡Ten patients <25 kg in weight, devices implanted in eight.

ASD, atrial septal defect; SVC, superior vena cava; TOF, tetralogy of Fallot; PAH, pulmonary arterial hypertension; IVC, inferior vena cava.

eter manipulation,3 we did not attempt to obtain repeated hemodynamic measurements in the immediate postclosure period. Right atrial angiography and color flow Doppler echocardiography demonstrated transatrial flow through the Dacron patches of the umbrella immediately after umbrella release, but smaller defects that were closed with the original Rashkind PDA device often demonstrated complete closure within minutes of placement.

One major complication of the procedure occurred. A 70-year-old cyanotic patient with multiple prior strokes and pulmonary emboli developed acute hemodynamic instability and obtundation immediately after placement of the Mullins sheath across the atrial defect, before device loading. A presumptive diagnosis of cerebral embolus was made. The device was delivered without further incident, but the patient died from complications of the cerebrovascular accident 1 week later. Permission for postmortem examination was denied. We speculated that placement of the large sheath dislodged an iliac vein thrombus. We now require iliofemoral vein imaging before catheterization in any patient with cyanosis and a history of embolic events.

In two of five instances in which umbrellas were composed of stainless steel 0.07-in. in diameter was used. Postclosure angiography demonstrated that the hinges flexed with each cardiac cycle, allowing the inferior arms to separate by several millimeters with each heartbeat. Several hours after being returned to the cardiac floor, the patient noticed (in retrospect) some increased cyanosis. At routine predischarge chest roentgenography, the umbrella was noted to have dislodged and was found at the bifurcation of the iliac arteries. The umbrella was retrieved with a forceps snare and was delivered to the femoral artery, and the artery was exposed surgically for umbrella retrieval and vascular repair. The patient was discharged several days later and underwent uneventful surgical closure of the atrial defect at a later time. The second case of device embolization also occurred in a cyanotic patient. At catheterization several years after surgical closure of atrial septal defect, the patient was found to have a patch incompletely baffling inferior vena cava blood to the left atrium through the atrial defect. At catheterization, the communication between the inferior vena cava pathway and the right atrium was enlarged by balloon dilation, and a 33-mm prototype clavimsh shell device was delivered across the 20-mm defect. Follow-up echocardiography 2 hours after catheterization demonstrated device embolization. The device was found at the iliac bifurcation by fluoroscopy; it was retrieved as described above without complication. Review of fluoroscopic tapes in this patient demonstrated that the atrial defect lacked a posterior septal rim and was probably of the sinus venosus type.
During the follow-up period, 31 patients were discharged from the hospital with implanted umbrellas, which were followed for 3–48 months (mean follow-up, 13 months) for a total of 31 patient-years. Since the Lock Clamshell Occluder was first implanted in February 1989, the follow-up in these patients has ranged from 3 to 12 months. During that time, no umbrella-related complications have been noted. One woman had a transient increase in preexistent ocular migraine attacks, and two patients after undergoing Fontan procedures have had arrhythmias (progressive atrioventricular block after umbrella placement into a lower superior vena cava–left atrial junction in one and episodic atrial flutter after umbrella placement into a coronary sinus septal defect in the other) that may be related to their underlying cardiac disorder.

Twenty-two patients have undergone follow-up studies for evaluation of atrial septal defect closure (color flow Doppler echocardiography examination in 18, angiography in two, and both in two patients) at a mean of 6.5 months after device implantation. In three patients, studies were inadequate to assess the atrial septum. Among the remaining 19 patients, no atrial shunting was detected in 12. Two patients had complete closure of the defect but had residual color flow through additional previously unrecognized tiny atrial defects (1–2 mm). Residual leaks around the device were present in five patients. The ratio of device size to defect diameter was larger in patients whose defects were completely closed (4.3±2.2) compared with those with incomplete defect closure (1.8±0.8, p<0.01 by Student’s t test). Of the five patients with residual leaks around the devices, four had umbrellas less than 1.8 times the stretched defect diameter, and one (after undergoing Fontan proce-
FIGURE 5. Angiogram demonstrating the appropriately positioned device straddling the atrial septum. Contrast medium was injected through a pigtail catheter in the right atrium after deployment of a 28-mm Lock Clamshell Occluder.

dure) had a leak around a device ocluding a supra-annular tricuspid valve patch leak.

Discussion

This experience demonstrates that, after a 15-year evolution, transcatheter occlusion of atrial septal defects was achieved in 32 of 34 highly selected patients, with one episode of major morbidity in a high-risk patient. The clinical course at short-term follow-up of the remaining patients has been benign. Success appears to be related, at least in part, to the use of a double-umbrella system that uses spring tension for septal attachment.

A safe and effective atrial septal occluder may alter the management of patients other than children with secundum atrial septal defects or residual atrial leaks after the Fontan operation. The percutaneous method of mitral valve dilation has now been widely applied to adults with rheumatic mitral stenosis. The marked improvements in transvalvular gradient have been accompanied by a small, but significant, incidence of atrial level shunts. Such defects appear ideal for transcatheter closure. Similarly, improvements in echocardiographic accuracy have revealed an elevated incidence of patent foramina ovale in young adults with unexplained embolic stroke. If this apparent relation is causative (e.g., the strokes are due to paradoxical embolism at the atrial level), transcatheter closure of these defects may reduce or eliminate the incidence of subsequent strokes.

Despite such promising application of transcatheter atrial septal defect closure, this study highlights certain limitations of the technique. Patients with atrial defects lacking a complete septal rim (sinus venosus defects) and those with additional defects distal from the main atrial defect are likely to be poor candidates for transcatheter device closure. Accurate assessment of atrial septal anatomy is vital for appropriate patient selection for successful closure of atrial defects. High-resolution two-dimensional echocardiographic examination with color flow Doppler appears to be the best technique for making this assessment. We used standard echocardiography to identify “ideal” patients: patients with large (>20 mm) defects or defects that were multiple or elongated were rejected before catheterization. However, in two patients, residual atrial shunts were present because of previously unrecognized secondary small atrial defects, and in one patient, device migration occurred, probably secondary to absence of septal rim. In each of these three instances, echocardiographic assessment of the interatrial septum was limited because of patient size. The level of diagnostic precision needed may well require transesoph-
ageal echocardiography in older individuals\textsuperscript{10,11} for patient selection. Last, follow-up of the whole patient group has been brief, and the numbers are small.

Nonetheless, the initial technical success and the apparent lack of late clinical sequelae suggest that double-umbrella closure of atrial defects will contribute significantly to the management of various types of intracardiac defects.

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**References**


**KEY WORDS** • atrial septal defect • occlusion • catheterization
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