Transcatheter closure of atrial septal defects has been a dream of pediatric cardiologists for the past 25 years. The study by Rome and coworkers in this issue of *Circulation,* the latest advance in a 20-year sequence, suggests that the dream is now almost a reality. To understand the true significance of the present study, a brief review of past work in this area is important.

In 1976, King and Mills reported the first transcatheter closure of a secundum atrial septal defect in humans with a double-umbrella device. Mills and coworkers has evolved from a dumbbell-shaped double-disk prosthesis to a single-disk, hook-fastened occluder. The most recent of the Rashkind-type devices consists of six stainless steel ribs; three of the stainless steel ribs terminate with a small barbed hook, which support a disk of polyurethane foam. The Rashkind Atrial Septal Defect Occluder (USCI Angiographics, Tewksbury, Mass.) is manufactured in three sizes (25, 30, and 35 mm in diameter) and is recommended for use in patients with an isolated secundum atrial septal defect 18 mm or less in diameter. The delivery system for the Rashkind device uses a 16F delivery sheath. Clinical experience with the Rashkind Atrial Septal Defect Occluder is limited. Rashkind has published his experience with the single-disk occluder in 23 children and adults. Satisfactory closure was achieved in 14 children (61%), but in nine, the closure was considered unsatisfactory. Six of these nine children underwent surgical repair of atrial septal defect; in four, repair was required because of malpositioned devices. At the University of Michigan, we have attempted transcatheter closure of atrial septal defect with a 25-mm Rashkind Atrial Septal Defect Occluder in three children (age, 3–8 years; weight, 11.1–22 kg). Satisfactory closure was obtained in one child, an 8-year-old boy with an atrial septal defect 13 mm in diameter. The remaining two children required emergency surgical repair after transcatheter closure of atrial septal defect because of improper seating or hook detachment.

Because the results with the Rashkind Atrial Septal Defect Occluder have been mixed, with approximately half of all attempts being unsuccessful and because the device relied on barbed hooks to ensure attachment to the atrial septum and, therefore, makes subsequent, nonsurgical, catheter retrieval impossible, a new device was developed by Lock and coworkers. Lock's initial experience involved the use of a modified 33-mm Rashkind Patent Ductus Arteriosus Occluder (USCI Angiographics). Based on this initial experience, the new device as described in the present study by Rome et al. was developed. This new device is a modified double-umbrella Rashkind Patent Ductus Arteriosus Occluder that has now been named the Lock Clamshell Occluder (USCI Angiographics); the arms of the device function similarly to a clamshell in that they are hinged and fold back against themselves. The Clamshell Occluder has two major advantages over the previous Rashkind Atrial Septal Defect Occluder: 1) Because the Clamshell Occluder has no barbed hooks, its position can be adjusted, and the device can, if necessary, be nonsurgically retrieved; and 2) the delivery system requires an 11F sheath, rather than a 16F introducer sheath, making its use more appropriate in children.

However, despite the excellent results reported by Rome and coworkers, the Clamshell Occluder does have limitations: The Clamshell Occluder cannot be used when the atrial septal defect's stretched diameter is larger than 22 mm or when there is less than a 4-mm separation between the defect's edges and other important cardiac structures. Because of these two limitations the current Clamshell Occluder only will be applicable to approximately two thirds of the patients with atrial defects. In the study by Rome et al. most defects that were closed appeared to be small (mean stretched diameter of 11 mm); thus, it is not known if the rate of complete and successful

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closure in moderate-sized atrial septal defects will be as high as reported in the present study. Also because the Clamshell Occluder requires an 11F delivery system, it cannot be used in children weighing less than 8 kg. Sideris and coworkers recently described a new transcatheter atrial septal defect occluder that requires only an 8F delivery system. If these preliminary results by Sideris et al in animals are documented in human clinical trials, transcatheter closure of atrial septal defects may be possible in all children regardless of size. Although the present study by Rome and coworkers describes excellent short-term follow-up of the Clamshell Occluder, long-term outcome is unknown. Last, device embolization was the only major complication observed by Rome and coworkers that was directly associated with placement of the Clamshell Occluder. Even though embolization occurred in only two patients, both of whom had elevated right atrial pressures, methods that may eliminate this complication will require further study.

In summary, during the past 20 years, pediatric cardiologists have made remarkable progress toward developing a nonsurgical method of closing atrial septal defects. Based on the present study of Rome and coworkers, we now appear to be within reach of effective techniques for transcatheter closure of most atrial septal defects. Hopefully, with further modification and experience, transcatheter closure will become the standard of care for most children and adults with isolated secundum atrial septal defects. Although the Clamshell Occluder appears to be applicable to only a small group of subjects (children and adults with a small-to-moderately sized, isolated secundum atrial defect), there are other potential uses of this device that I believe will make it applicable to a much larger group of individuals. These other applications may include the closure of patent foramina ovale in adults with unexplained embolic strokes; the closure of posttraumatic, postinfarction, or residual postoperative ventricular septal defects; and the closure of many other types of complex intracardiac defects. Thus, I believe the work of Rome et al represents a landmark achievement that will ultimately result in the Clamshell Occluder becoming an important interventional tool used by both pediatric and adult cardiologists.

References

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