

Editorial Comment

Transcatheter Closure of Atrial Septal Defect: Are We There Yet?*

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Surgical closure of ostium secundum atrial septal defects (ASDs) can be performed successfully with low (<1%) mortality. However, the morbidity associated with general anesthesia, thoracotomy, cardiopulmonary bypass, postoperative monitoring in the intensive care unit and several days of hospital stay is considerable. The expense associated with this morbidity, operative scar and psychologic trauma to the patient and parents are additional disadvantages of surgical treatment. For these reasons, several groups of cardiologists, for the past two and one-half decades, have been investigating transcatheter methods to close the ASDs. The pioneering works of King and colleagues (1-3) and Rashkind and colleagues (4-6) have paved the way in these efforts. King designed paired, opposed, Dacron-covered, stainless steel umbrellas collapsed into a capsule attached to the tip of the catheter that were implanted across the atrial septum through a 23F sheath. Because of the large delivery sheath, requiring cutdown, and complexity of the procedure, King neither continued the investigation nor did other cardiologists adopt this method. Rashkind designed a single, foam-covered umbrella with miniature hooks with an elaborate centering mechanism and applied it to animal models and human subjects (4-6). The device and delivery system, although less bulky than King's device, still required a 16F sheath for device implantation. Because of the difficulties associated with implantation of the hooked device, Rashkind introduced a double-disk system, similar to his patent ductus arteriosus occluding device (6). This double-disk device was later modified by Lock et al. (7); this device is without hooks but with a bend in the arms of the device and uses spring tension to allow arms of the device to fold against each other and has been named the Clamshell device. This device requires an 11F sheath for implantation. Although the initial clinical trials with the device were encouraging, development of fractures of the arms of the device and embolization (8,9) forced the investigators and the Food and Drug Administration to

withdraw the device (in 1991) from further clinical trials. A buttoned double-disk device that can be implanted through an 8F sheath was developed by Sideris et al. (10). Single institutional (11-15) and multi-institutional (16-18) clinical trials began. At the time of last review (19), nearly 800 devices had been implanted and, at present >1,000 ASDs have been closed with the buttoned device (Sideris EB, personal communication, November 1997).

Over the past few years, a large variety of other devices have suddenly emerged. These include the monodisk device of Pavčnick et al. (20), Das-Angel Wing self-centering device (21), the atrial septal defect occluding system (ASDOS) (22,23), the Amplatzer septal occluder (24) and the redesigned Clamshell (the CardioSeal device) (25). Clinical trials within or outside the United States have just begun with the majority of these devices.

In this issue of the Journal, Thanopoulos et al. (26) present preliminary results of their experience with the Amplatzer septal occluder. The device consists of two self-expandable round disks connected to each other with a 4-mm wide waist (Fig. 1 in Thanopoulos et al. [26]), made of 0.004- to 0.005-in. Nitinol wire mesh and filled with Dacron fabric (24,26). Eighteen of the 22 patients evaluated met echocardiographic criteria for device closure, and of these 18 patients with intent to close, 16 (89%) underwent successful device implantation; in the remaining 2, closure was not attempted because of the large, stretched diameter of the ASD. Misplacement of the device occurred in one patient (6%), but the disks of the device were withdrawn into the delivery sheath and device redeployed successfully. Complete occlusion of the defect by angiography and color Doppler echocardiography was demonstrated in 13 patients (81%). The follow-up duration was short, 1 to 3 months. Residual shunt was present in only one patient (6%) at 3-month follow-up. As I began writing this editorial in late November 1997, I was under the impression that the report by Thanopoulos et al. (26) was the first clinical report, but before I completed this editorial, my attention was drawn to the report by Masura et al. (27) in the December 1997 issue of *Catheterization and Cardiovascular Diagnosis*. They also report their preliminary experience with the Amplatzer. Their results in 30 patients are similar to those reported by Thanopoulos et al. (26).

The advantages of the Amplatzer device appear to be small delivery sheath, ease with which the method of implantation is learned and the ability to retrieve and reposition the device (without damaging it) before release. However, the high success rate may, in part, be related to relatively small-sized defects that were occluded. It remains to be seen whether such results are maintained when more variable-sized defects are closed and when the method is applied to larger groups of patients than are presented the report by Thanopoulos et al. (26).

The authors state that the waist of the device, stenting the defect, is the major support for device retention, but I suspect that the disks on either side of the septum also play a role in

*Editorials published in *Journal of the American College of Cardiology* reflect the views of the authors and do not necessarily represent the views of JACC or the American College of Cardiology.

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Table 1. Atrial Septal Closure Devices

Device	Delivery Sheath Size	Clinical Trial Status
King and Mills interlocking umbrellas	23F	Inactive
Rashkind hooked device	16F	Inactive
Rashkind double-disk device	11F	Inactive
Lock Clamshell device	11F	Inactive
Sideris buttoned device	8F/9F	Phase II trials
Das Angel Wing device	11F	Phase II trials
Sideris centering buttoned device	11F	Clinical trials outside the U.S.
ASDOS	11F	Clinical trials outside the U.S.
Amplatzer	7F/8F	Phase I trials
CardioSeal	11F	Phase I trials

ASDOS = Atrial septal defect occluding system.

the device stability, and the investigators may have to pay greater attention to the size of the disks as well.

The bulkiness of the device, as seen on the cineradiographic and echocardiographic frames, is of some concern, although no adverse effects related to this were observed. The device's metallic frame is completely exposed within the heart, which may increase thrombogenicity and is of concern, but neither Thoropoulos et al. nor Masura et al. observed such problems. Finally, one has to wait for follow-up studies to see whether "stress" fractures develop with time.

The procedures of echocardiographic selection, catheterization and cineangiography to exclude other anomalies (particularly anomalous pulmonary venous return) and balloon sizing of the ASD (28-30) appear to be very similar with all transcatheter-deployed devices. The sizing of the delivery sheath used for device deployment varies with the device (Table 1); the Amplatzer appears to require a smaller delivery sheath than the other devices. Retrieval of the device before release is possible with most devices but appears to be much simpler with the Amplatzer and without damaging the device. Transcatheter device retrieval after its release, should it be required, was not addressed by Thonopoulos et al. (26) or by Masura et al. (27), and I suspect that it may be difficult. Similarly, surgical retrieval may be problematic. The authors state that their device, along with the Das-Angel Wing and Pavčnik Monodisk, are the only devices with a self-centering mechanism. To this should be added the centering buttoned

device (31), which also has self-centering characteristics but requires an 11F sheath for device delivery.

When one compares the preliminary results of this device with similar preliminary experiences with other devices (Table 2), the results, in terms of percent implantation feasibility in patients with intent to close, success of implantation, device dislodgment frequency and effective occlusion rates are comparable. Late follow-up results are not available for the Amplatzer, and when they are available, they should be scrutinized and compared with those of other new devices as well as with those of the buttoned device, which has the largest clinical experience to date (19; Sideris EB, personal communication, November 1997). The majority of devices are either not in use or are under clinical investigation within or outside the United States (Table 1).

All these devices are only useful for closing small- to medium-sized ASDs with adequate septal rims and do not address ASDs that have small and inadequate rims and ostium primum defects. For this reason, a significant proportion of these defects cannot be closed with the devices that are currently under clinical trial and therefore require operation. Preliminary data from Sideris et al. (33) suggest that such defects with inadequate rims can be occluded by a balloon-based buttoned device. The device consists of a detachable latex balloon occluder attached to a button loop and a loading wire in a manner similar to the buttoned device (17) and a counteroccluder. The deflated balloon, after delivery into the left atrium, is filled with sufficient diluted contrast material to make it slightly larger than the stretched diameter of the ASD and is wedged against the defect. A counteroccluder is then delivered into the right atrium and buttoned across the defect. The balloon gradually deflates over the next 60 days, by which time the flattened balloon is endothelialized, thus closing the defect. Preliminary results of the method in animal models and in human subjects (33) is encouraging. Similar innovative designs to close large defects with small margins should be developed in the future.

In summary, a large variety of devices have been developed to occlude ASDs. Most of the devices have either been withdrawn or are under clinical investigation (Table 1). The results with the newest of the devices, the Amplatzer, described in Thanopoulos et al. (26) are encouraging and are comparable with preliminary experiences with other devices. Experience with larger groups of patients and longer follow-up

Table 2. Comparison of Preliminary Results

Device (ref no.)	No. of Subjects Taken to Cath Lab With Intent to Close	No. (%) of Subjects in Whom Device Was Implanted	No. (%) of Subjects in Whom Device Dislodgment/Embolization/Misplacement Occurred	No. (%) of Subjects with Effective Occlusion*
Clamshell (32)	40	34 (85%)	2 (6%)	12 (63%)†
Buttoned (17)	200	180 (90%)	12 (7%)	154 (92%)
Amplatzer (27)	18	16 (89%)	1 (6%)	13 (81%)

*Effective occlusion defined as no or trivial residual shunt. †Nineteen of 32 subjects had adequate imaging studies; 12 (63%) of these had no residual shunt. Cath Lab = catheterization laboratory.

are needed before making any definitive conclusions. Future research should focus on innovative methods to nonsurgically close large defects with deficient septal rims.

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