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Original Article

Feasibility of transcatheter closure of multiple defects within the oval fossa

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Abstract *Background*: Multiple perforations in the floor of the oval fossa may be an obstacle for transcatheter closure. Thus, we analyzed the interventions in 33 patients with more than one interatrial communication in comparison with 370 procedures with a single defect. *Methods and Results*: A diagnostic catheterization, which included a balloon-sizing maneuver, was performed. We implanted a total of 46 occluders, made up of 42 Amplatzers and 4 CardioSEALs. In 20 patients, the defects were closed with a single occluder, namely 18 Amplatzer and 2 CardioSEAL devices. Complete closure was achieved in 15 patients, while a tiny residual shunt remained in 5 patients. In 13 patients, two devices were implanted, without any residual shunt being found immediately after implantation. In 3 patients, the occluders did not touch each other. In 10 patients, their rims overlapped. In comparison with the control group, the group with multiple defects did not differ in the distribution of age, gender, and indications for device closure. The mean time of the procedure, and the time required for fluoroscopy, however, were significant longer ($P < 0.001$). These times ranged from 45 to 250 minutes with a median of 140 minutes, and from 0.0 to 39.2 minutes, with a median of 12.0 minutes, respectively. Also, the association with an atrial septal aneurysm was significantly more frequent (61 vs. 17%; $P < 0.001$). The times taken during insertion of double devices were also significantly longer than those needed for insertion of a single device ($P < 0.001$). *Conclusions*: Transcatheter closure of multiple defects within the oval fossa is feasible with currently available occluders, albeit than, in selected cases it is necessary to implant two devices.

Keywords: congenital heart disease; interatrial septal defects; interventional catheterisation

THE INTERVENTIONAL CLOSURE OF CENTRALLY located defects within the oval fossa, and patency of the oval foramen, is currently evolving into standard therapy at some centers.[1] Multiple communications, however, may be an obstacle for transcatheter closure.[2] Thus, we analyzed our results of the closure of such defects by the implantation of one or two devices, and compared them with a group of 370 patients with single defects treated during the same time period at our institution.

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Methods

Patients

Between May 1997 and April 2000, we undertook cardiac catheterization in 50 patients with multiple defects within the oval fossa, assessing the options for possible interventional closure. Indications for treatment were right ventricular volume overload in 27, and presumed paradoxical embolism in 23 patients. In 29 patients, a transesophageal echocardiography prior to intervention was suggestive of two or more defects. In 12 patients, the presence of more than one defect was discovered by transesophageal echocardiography during the diagnostic catheterization, and in 9 patients additional defects were demonstrated during balloon-sizing after the effective occlusion of one defect. An atrial septal

aneurysm was present in 33 patients. All patients had given their informed written consent for the interventional procedure, which included the option of the implantation of more than one device should it be necessary. All procedures were undertaken in accordance with institutional guidelines, and were approved by the institutional ethics committee.

Diagnostic catheterization

A diagnostic catheterization, which included a balloon-sizing maneuver, was performed as described previously.[1,3] The presence of at least one additional defect (Fig. 1A) was proved with color Doppler by occlusion of one defect, a residual shunt being demonstrated through a second defect at a different site in the floor of the oval fossa (Fig. 1B and C). If an occlusion with a single occluder seemed not to be possible, two defects were occluded with sizing balloons, introduced via two sheaths through the femoral vein, in order to estimate both stretched diameters. Furthermore, the minimum distance between the defects that were under consideration to carry the occluders was accurately measured by the use of multi-plane transesophageal echocardiography (Vingmed, Horton, Norway). This permitted assessment of the likely spatial relationships of the occluders to each other after implantation. If more than two defects were present, the distances between those further communications, and those which had been sized, was determined to verify whether the rims of the occluders would close the defects. To facilitate the selection of the occluders, a flow sheet (Table 1) was established on the basis of the following:

- Whenever possible the defects should be stented rather than only covered.
- If defects lay so close to each other that a second device could not be implanted, but the two could be covered with one device, the defects should be covered on both their left and right atrial sides.
- If an Amplatzer occluder or a Cardioseal device could be used, the Amplatzer was preferred, because of its higher rates of occlusion.[1,4]

Intervention

A total number of 29 Amplatzer Septal Occluders, 13 Amplatzer Persistent Foramen Ovale Occluders (AGA Medical Corp., Golden Valley, MN, USA) and 4 CardioSEAL devices (Nitinol Medical Technologies Inc., Boston, MA, USA) were implanted. The occluders were deployed as described previously.[1,5] In the case of the implantation of two devices, first the larger and then the smaller one was deployed. After implantation (Fig. 1D and Fig. 2), color and contrast echocardiography during Valsalva's maneuver was performed to exclude residual shunts. Patients received antibiotic prophylaxis for 24 hours, with the first dose being administered during intervention. Continuous infusion of heparin, at a rate of 400 Units per kg per day, was started for 48 hours, and acetylsalicylate, at a dose of 3—5 mg/kg per day, was administered for 6 months beginning the day after occlusion. Endocarditis prophylaxis was likewise recommended for 6 months whenever necessary.

During the follow-up, interviews, clinical examinations and echocardiograms were obtained within 48 hours, and 1, 6, and 12 months after implantation. Chest X-ray and Holter monitoring were performed 1 month and 12 months after implantation. Mean follow-up time was 16 months, with a range from 3 to 34 months.

Statistical evaluation

The patients with multiple defects treated by transcatheter occlusion were compared with results of a group of 370 patients with single defects treated during the same period at our institution.

The Mann-Whitney U test was used to detect differences in age, procedural times, and fluoroscopic times. The chi-squared test was used to analyze whether significant differences exist in the distribution of gender, in the frequency of atrial septal aneurysms, and in the indications for catheterization. The latter compared presumed paradoxical embolism versus right ventricular volume overload. A separate analysis was performed within the patients having multiple defects closed by single as opposed to double devices to compare procedural times, fluoroscopic times (Mann-Whitney U test), and the occurrence of residual shunts (chi-squared test). Statistical significance was taken at a value of $P < 0.05$.

Results

After balloon sizing, interventional closure was not considered possible in 17 patients, either because the multiple communications were found to extend over the whole surface of the oval fossa, or because large defects had no suitable rims. These patients underwent surgical correction.

In 20 patients, the defects were closed with a single occluder, employing 18 Amplatzer devices and 2 CardioSEAL occluders. Complete closure was achieved in 15 patients, while a tiny residual shunt

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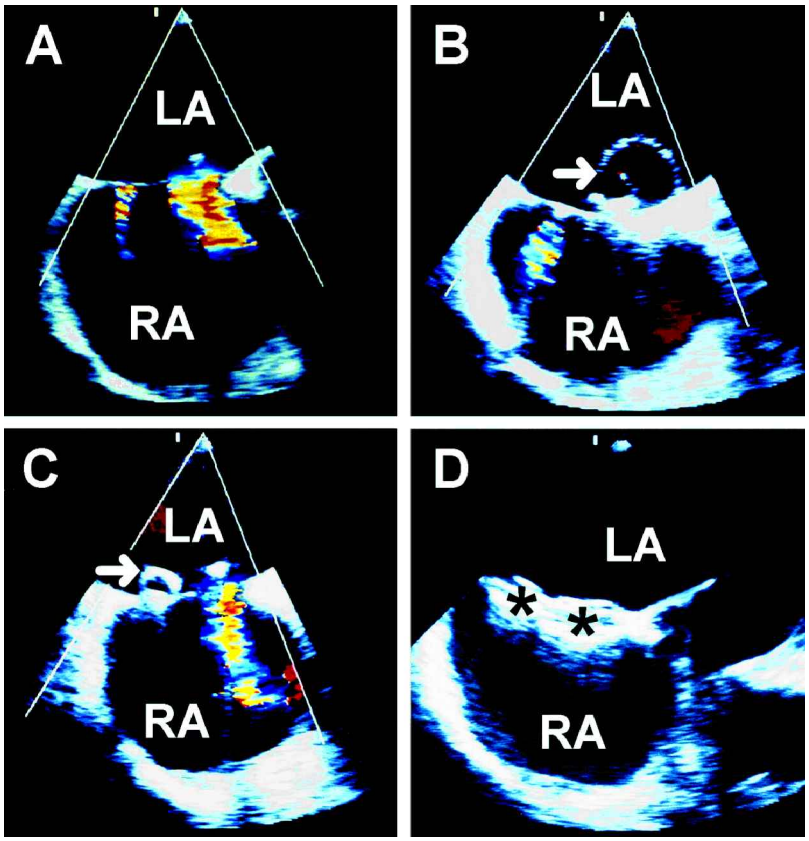

Figure 1:
Transesophageal echocardiographic views of the implantation of two Amplatzer Septal Occluders in two defects within the oval fossa : (A) native atrial septal defects; (B) sizing of the larger, and (C) the smaller, defect with balloons; (D) competent closure of both defects with two implanted occluders. LA = left atrium, RA = right atrium, arrow = sizing balloon, asterix = Amplatzer Septal Occluder.

remained in 5 patients. These patients are scheduled for the implantation of a second device if spontaneous closure does not occur within 12 months. In 13 patients, two devices were implanted, in the absence of any residual shunt immediately after implantation. In 3 patients, the occluders did not touch each other. In the remaining 10, their rims overlapped, albeit that the configuration of the devices was not altered (Fig. 2). Mean procedural time ranged from 45 to 250 minutes with a median of 140 minutes. Fluoroscopic time ranged from 0.0 to 39.2 minutes, with a median of 12.0 minutes. During the follow-up, repeated Holter monitoring showed sinus rhythm, while echocardiographic examinations revealed a stable position of all devices and excluded any formation of thrombus, either related to the devices or in the atriums. No vascular complications occurred. In 19 patients with presumed paradoxical embolism, an ischemic cerebral event has not reoccurred to date. There was one unrelated death in one patient after 4 months. Otherwise the follow-up period was uneventful.

In comparison with the patients having solitary defects, those with multiple defects did not differ in the distribution of age, gender and indications for device closure (Table 2). The association with an atrial septal aneurysm, in contrast, was significantly more frequent in those with multiple defects, being found in 20 of 33 as opposed to 61 of 370 (Table 2). The procedural and the fluoroscopic times were significantly longer in the patients with multiple defects (Table 2). This was due to the time taken to implant two devices (Table 3). Multiple devices resulted in doubling of fluoroscopic time, and to prolongation of the procedure for more than one hour. In contrast to the use of single devices, however, complete closure of the defects could be achieved in every patient (Table 3).

Discussion

Atrial defects within the oval fossa are usually single. In some patients, however, more than one may be present.[1,2,5] This creates but minor problems if surgical closure is performed. For transcatheter closure, it is a challenge.[6] This is because complete closure must be the ultimate goal if the interventional procedure is to become a real alternative to standard surgical therapy.[1] If intervention is performed to prevent paradoxical embolism, complete occlusion of all interatrial communications is essential so as to justify the procedure.[7,8] With the techniques as presented here, these aims can be achieved by deployment of an occluder that

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Table 1. Suggestions for the choice of devices for transcatheter closure of two atrial septal perforations. In the left columns the diameters of the defects can be chosen, then in the horizontal row dependent on the distance of the perforations, a recommendation for the choice of the occluder(s) can be found.

Diameter of		Distance between Perforations (mm)						
1. Perforation	2. Perforation	1	2	3	4	5	6mm	7 or more
(1-2 mm)	1-2mm	APO 25mm					2 ASO 4mm	
3-4mm	1-2mm	APO 25mm				APO 35mm		
	3-4mm	APO 35mm						
5-7mm	1-2mm	ASO		APO 35mm				
	3-4mm	APO 25	APO 35 mm					
5mm	5mm	APO 35mm				2 ASO, one size smaller than perforations	2 ASO	
6mm	5mm	APO 35mm			CS 33mm			
7mm	5mm	APO 35mm		CS 33mm				
8mm	1-2mm	ASO		APO 35mm				
	3-4mm	APO 35mm			CS 33mm			
	5mm	APO 35mm	CS 33mm					
	6mm	CS 33mm			CS 40mm			
	7mm	CS 33mm		CS 40mm				
	8mm	CS 33mm	CS 40mm					
9mm	1-2mm	ASO		APO 35mm	CS 33mm			
	3mm	ASO	CS 33mm					
	4mm	APO 35mm	CS 33mm					
	5mm	CS 33mm			CS 40mm			
	6mm	CS 33mm		CS 40mm				
	7mm	CS 33mm	CS 40mm					
	8mm	CS 40mm						
	9mm	CS 40mm						
10mm	1-2mm	ASO		CS 33mm				
	3mm	ASO	CS 33mm					
	4mm	CS 33mm			CS 40mm			
	5mm	CS 33mm		CS 40mm				
	6mm	CS 33mm	CS 40mm					
	7mm	CS 40mm						
	8mm	CS 40mm						
	9mm	CS 40mm						
> 10mm	1-2mm	ASO						
	3mm	ASO						

Note: This diagram represents only suggestions. For any individual case, the spatial relationships to adjacent anatomical structures, the morphology of the defects, or the presence of a persistent foramen ovale may favour the implantation of other devices as recommended in this table. Combinations of defects, which are not listed may also be treated with an Amplatzer or a Cardioseal occluder in selected cases. ASO = Amplatzer ASD Occluder; APO = Amplatzer PFO Occluder; CS = Cardioseal occluder

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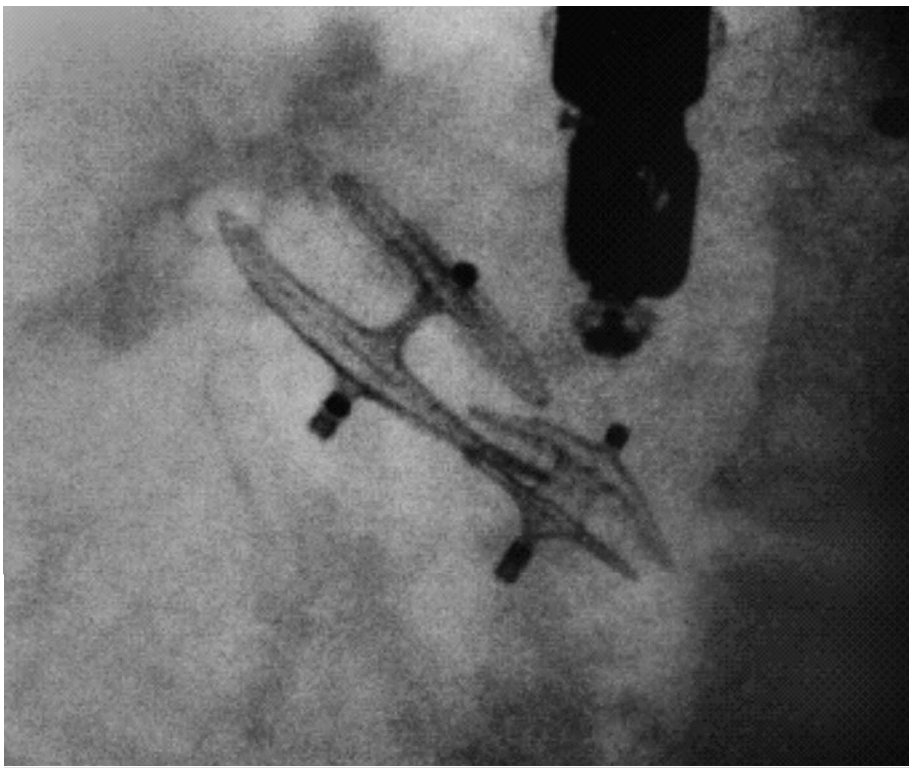

Fig. 2:
X-ray view in 45° left oblique projection with 10° cranial angulation of two deployed Amplatzer devices: an atrial septal occluder of 4 mm stent diameter and a 25 mm persistent foramen ovale occluder. In the right upper half of the figure the transesophageal probe is visible.

Table 2. Comparison of patients with multiple (n = 33) as opposed to solitary defects (n = 370)

	Multiple defects		Solitary defects		
	Median	Range	Median	Range	*P* value
Age (y)	47	(2 –78)	40	(0.7 – 78)	0.64 (n.s.)
Gender (f/m)	18/15		220/150		0.58 (n.s.)
Indication for closure*	19/14		182/188		0.36 (n.s.)
Atrial septal aneurysm	20		61		< 0.001
Fluoroscopic time (min)	12.0	(0.0 –39.2)	7.1	(0.0 –64.3)	< 0.001
Procedural time (min)	140	(45 –250)	90	(20 – 360)	< 0.001

* = presumed paradoxical embolism vs. right ventricular volume overload

Table 3. Comparison of insertion of single (n = 20) as opposed to two devices (n = 13)

	Single device		Two devices		
	Median	Range	Median	Range	*P* value
Fluoroscopic time (min)	9.9	(2.5 – 39.2)	18.2	(0.0 – 28.4)	< 0.001
Procedural time (min)	108	(45 – 240)	170	(125 – 250)	0.001
Residual shunts*	5		0		0.05

* = after one month

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covers additional defects in the immediate vicinity or, if the distance between the defects is too wide, by the consecutive implantation of two occluders.

The success of these methods, however, depends on meticulous sizing, for which transesophageal echocardiographic guidance is mandatory. It also needs an exact prediction for the position of the device. In the case of an Amplatzer Septal occluder, this prediction is possible because the widths of both circular rims are known, and because the self-expanding, and thereby self-centering, connecting stents secure the location and prevent displacement. The short rims of 7 to 8 mm are advantageous because they permit the implantation of two occluders relatively close to each other without interference. The Amplatzer PFO Occluder, and the CardioSEAL device, with the thin connecting rod between the left and right atrial discs, can be used if the defects lie within a septal aneurysm, which was found in just over three-fifths of the patients. The wider 'rims' in relation to the rod of these devices allow concomitant closure of additional defects that are further apart than 8 mm, as well as giving an additional splinting effect to the aneurysm. Overlapping of rims, as occurred in 10 patients (Fig. 2), does not seem to cause kinking, angulation, displacement or residual shunting, either with the use of the Amplatzer or the CardioSEAL devices.

On the basis of our experience, use of two devices was superior in providing complete closure in comparison to use of single devices ($P = 0.05$). The implantation of two devices, therefore, might be considered if complete closure of multiple defects with a single device remains in doubt. Although this means extended fluoroscopic and procedural times, we are confident that, with increasing experience, these times can be reduced, as has already occurred in one patient in whom the procedure was performed under echocardiographic guidance without resort to fluoroscopy. Although the costs for closure using two devices are considerably increased when compared with implantation of a single device, this option emerges in selected cases as an alternative to surgery for the closure of more than one defect of the oval fossa.

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