TECHNIQUE

Transcatheter closure of secundum atrial septal defects with the atrial septal defect occlusion system (ASDOS): initial experience in children

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Abstract

Objective—To report initial experiences with transcatheter occlusion of atrial septal defects using a new occlusion device.

Subjects—10 children aged 1.1 to 14.9 years.

Inclusion criteria—Patients with a body weight above 10 kg, normal pulmonary resistance and an indication for surgical closure of a secundum atrial septal defect, a residual tissue rim of interatrial septum surrounding the defect of more than 5 mm, and a maximum defect diameter of 20 mm.

Methods—The defects were closed by a transcatheter device (ASDOS) consisting of two umbrellas which are introduced over a guidewire loop. Both umbrellas consist of a central body and five arms formed from preshaped nitinol wire covered with a thin polyurethane patch. The central body of the distal umbrella contains a thread, the proximal umbrella contains a bolt. The two umbrellas are connected by screwing the bolt on the thread using a screwdriver catheter.

Results—The implantation was performed under echocardiographic guidance; in six of 10 patients, transoesophageal echocardiography was necessary. The “stretched” diameter of the defect evaluated during balloon sizing ranged from 10 to 20 mm, and the pulmonary to systemic blood flow ratio from 1.5:1 to 2.8:1. Transcatheter closure was successfully performed in 9/10 patients using devices with a diameter of 25 mm to 40 mm. No severe complications occurred. However, in one patient with a pre-existing prolonged PR interval brief periods of second and third degree atrioventricular block occurred after the implantation but normalised within 3 d. During a follow up period of 21 to 29 weeks no device embolisation, thromboembolic complications, fractures of the implanted device, atrial perforations, pericardial effusions, obstructions of systemic or pulmonary veins, atrioventricular valve dysfunction, or other complications occurred.

Conclusions—The new device is a promising transcatheter approach for the

occlusion of secundum atrial septal defects in children. However, further evaluation and long term data are needed before this transcatheter technique can be recommended.

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Keywords: secundum atrial septal defect; interventional cardiology; congenital heart disease; transcatheter occlusion

Surgical closure of atrial septal defects has a negligible mortality, but is associated with morbidity, discomfort, and pain. As an alternative to surgery, several attempts have been made to occlude secundum atrial septal defects by transcatheter techniques.^{1–6} Although various techniques have been investigated, none has achieved general acceptance.^{1–6} We report our initial experience with the transcatheter occlusion of atrial septal defects in children using a new device (ASDOS: Atrial Septal Defect Occlusion System, Dr Ing Osypka Corp, Germany), which is based on the technique originally described by Babic *et al*,⁶ which has now been refined for clinical application.

Methods

PATIENTS

In this communication we report our initial experience with the transcatheter closure of secundum atrial septal defects in 10 children aged 1.1 to 14.9 years (table 1) using the ASDOS device. Only patients with a body weight above 10 kg, normal pulmonary resistance, and an indication for surgical closure of a secundum atrial septal defect were included into this study. Patients with atrial septal defects other than secundum defects, patients with secundum atrial septal defect and a tissue rim of interatrial septum surrounding the defect of less than 5 mm and with a defect diameter above 20 mm were excluded from this study. For preinterventional imaging, transthoracic echocardiography was performed to measure the maximum diameter of the defect and the minimum septal tissue rim surrounding the defect.^{7,8} Additionally, the “length” of the interatrial septum was mea-

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Table 1 Patient data and echocardiographic findings

No	Age (years)	Weight (kg)	Follow up (weeks)	Echocardiographic measurements		
				RVID/LVID (mm)	Defect diameter TT/TEE*	Septal length
1	9.1	41.0	29	19/46	16/17	50
2	5.3	16.5	28	19/28	14/—	43
3	10.7	32.5	25	27/38	15/20	48
4	1.1	12.5	25	18/28	8/—	28
5	3.7	15.0	24	18/29	17/—	34
6	10.0	30.5	23	20/38	14/14	44
7	14.4	49.8	22	26/39	14/—	43
8	14.9	52.1	21	27/40	12/—	45
9	7.8	21.4	21	16/35	17/17	44
10	2.9	15.9	—*	22/30	11/—	37

*Implantation abandoned and device retrieved
RVID, diastolic right ventricular internal diameter (M mode); LVID, diastolic left ventricular internal diameter (M mode); defect diameter, largest diameter of the defect in the cross-sectional echocardiogram; TT, transthoracic echocardiogram; TEE, transoesophageal echocardiogram; septal length, distance between mitral insertion and right upper pulmonary vein in the apical four chamber view.

Figure 1 Photograph of the left and right atrial umbrella of the ASDOS device. The arms of the device are shown; these are made out of curved nitinol and covered by a thin microperforated polyurethane patch.

Figure 2 Schematic drawing of the ASDOS components. The two umbrellas (fig 1) are introduced through an 11F sheath over a guidewire with a conus. The central body of the left atrial umbrella contains a thread and the right atrial umbrella contains a bolt. The left atrial umbrella is manipulated by a pusher, which is a 22G metallic cannula, and by the conus on the guidewire; the right atrial umbrella by the screwdriver catheter. The umbrellas are connected by pulling on the guidewire to insert the thread into the bolt and then screwing the bolt on the thread using the screwdriver catheter.

sured in the apical four chamber view from the septal insertion of the mitral valve to the origin of the right upper pulmonary vein, as an estimate for the largest device which could be implanted into the atria.³

STUDY PROTOCOL AND INFORMED CONSENT
After in vitro testing of mechanical stability and fatigue and of biocompatibility, and after in vivo tests of the device in pigs with artificially created atrial septal defects (University of Aarhus, Denmark), the device was released for a limited clinical trial according to a study protocol approved by the authorised human subjects committee and by the local governmental authorities. The study protocol was designed according to the declaration of Helsinki in its revised Tokyo form. Informed consent was obtained from the parents before implantation.

DESCRIPTION OF THE DEVICE
The ASDOS device (fig 1) consists of two umbrellas which are introduced into the left and right atrium over a guidewire loop from the femoral vein, through the atrial septal defect to the femoral artery, according to the technique originally described by Babic *et al.*⁶ Both umbrellas consist of a central body and five arms, which are made of preshaped nitinol wire and covered by thin polyurethane patches. The central body of the distal (left atrial) umbrella contains a thread, the proximal (right atrial) umbrella contains a bolt (figs 1 and 2). The two umbrellas are inserted into the left and right atria separately and connected by screwing the bolt on the thread using a screwdriver catheter (figs 3 and 4).

METHOD OF IMPLANTATION
During cardiac catheterisation, anomalous drainage of the pulmonary veins was excluded

Figure 3 The two umbrellas are delivered on the two sides of the atrial septal defect. Embolisation of the left atrial umbrella into the mitral valve is prevented by pulling on the guidewire. The right atrial umbrella is controlled by use of the screwdriver catheter.

Figure 4 Same patient as in fig 3; the umbrellas are connected by screwing the bolt of the right atrial umbrella on the thread of the left atrial umbrella. Note the increase in the tip to tip diameter of the two umbrellas before (fig 3) and after connecting them.

Figure 5 Echocardiogram during positioning of the device. The echocardiogram (subxiphoidal view) shows the interatrial septum and the device; two arms of the left atrial umbrella have passed through the defect into the right atrium (arrow). The echocardiographic appearance of the device is characterised by fewer artefacts than with other devices, and the nitinol arms are clearly depicted by echocardiography.

and the pulmonary to systemic flow ratio calculated. The stretched diameter of the defect was assessed by balloon sizing,⁷⁹ using either a 6F open ended modified Berman catheter (special request, Arrows) with a maximum balloon diameter of 16 mm, or an occlusion balloon (Boston Scientific) with a maximum diameter of 25 mm. The balloon catheter was inserted into the left atrium and slowly inflated; transthoracic or transoesophageal colour coded Doppler echocardiography was used to evaluate the smallest balloon diameter at which the left to right shunt ceased.

For the implantation of the ASDOS device, a guidewire "loop" from the femoral vein through the atrial septal defect to the femoral artery was established (figs 3 and 4). This was achieved by inserting a balloon tipped, open ended catheter (Berman 7F, Arrows) into the femoral vein, crossing the atrial septal defect

and the mitral valve, advancing it into the ascending aorta using a preshaped 0.035 inch guidewire (THSF, Cook), entering the descending aorta, and performing a catch manoeuvre from the arterial side using a 4F snare catheter (4F cobra catheter, Cordis) and a 0.018 inch guidewire (TSF 180 cm, Cook) as sling. A 0.014 inch nitinol guidewire with a 0.035 inch conus in its middle (400 cm ASDOS guidewire, Osypka) was inserted into the venous catheter and was pulled out of the arterial sheath with the snare catheter. This "guidewire loop" was immediately covered by a 4F modified right Amplatz catheter (Cordis, special request), which was inserted into the femoral artery over the nitinol wire to protect the aortic and mitral valve leaflets. The conus on the guidewire was placed in the left atrium. Heparin 200 U/kg and cefuroxime 50 mg/kg were given intravenously.

Over this loop a preshaped 11F long sheath was inserted into the femoral vein and advanced into the left atrium. Over the guidewire the distal (left atrial) and proximal (right atrial) umbrellas were inserted over the guidewire through this long sheath. The left atrial umbrella was advanced using a "pusher" (metallic 22G canula with rounded tip) and retrieved by the conus on the guidewire railway (fig 2), the right atrial umbrella was controlled by the "screwdriver" catheter. After delivery of the distal umbrella into the left atrium the long sheath was withdrawn into the lower right atrium and the right atrial umbrella delivered (fig 3). For definitive implantation, the two umbrellas were brought on tension using the screwdriver catheter and the conus on the nitinol loop (fig 4).

Echocardiography was used for adequate positioning of the device, and to confirm cessation of left to right shunting (fig 5). To connect the two umbrellas, the bolt was advanced into the thread and the screwdriver catheter rotated clockwise so that the bolt was firmly screwed onto the thread (fig 2). The tip to tip diameter of the left atrial umbrella was measured after insertion into the left atrium through the long sheath and after screwing both umbrellas together (figs 3 and 4). After echocardiographic confirmation of complete closure of the atrial septal defect, normal flow within the systemic and pulmonary veins, competence of the atrioventricular valves, and an adequate position of the umbrellas on both sides of the atrial septum, the implanted device was released from the guidewire loop by pulling the nitinol wire into the (arterial) 4F catheter and pulling this catheter out of the patient (fig 6).

POSTIMPLANTATION TREATMENT

After the procedure heparin 600 IU/kg/d was given intravenously, reduced to 400 IU/kg on the second day, and to 200 IU/kg on the third day. The antithrombin III levels were held above 90%, and cefuroxime 50 mg/kg was given in two doses after 6 and 12 h. The children were discharged three days after the procedure with aspirin 2 to 3 mg/kg daily for six months.

Figure 6 The implanted device after releasing it from the guidewire. The configuration of the two umbrellas, reminiscent of a flower, is shown in an LAO projection (top). The corresponding transoesophageal echocardiogram shows the interatrial septum with the device which occludes the defect completely (bottom).

FOLLOW UP INVESTIGATIONS

After implantation of the device, clinical investigation, standard electrocardiograms, echocardiography, chest x ray, and Holter monitoring were performed before discharge, and after two weeks, one month, two months, and six months.

Results

During a three month period, transcatheter occlusion of secundum atrial septal defects was attempted in 10 patients. The age of the patients ranged from 1.1 to 14.9 years (table 1), and body weight ranged from 12.0 to 52.1 kg. The diameter of the secundum atrial septal defect was from 8 to 16 mm in the "native" cross sectional echocardiogram, with the "stretched" diameter ranging from 10 to 20 mm. The pulmonary to systemic blood flow ratio was from 1.5:1 to 2.8:1 (table 2). In none of the patients was anomalous drainage of pulmonary veins or pulmonary hypertension observed. In one patient, mild Ebstein's disease of the tricuspid valve was an associated finding (table 2). General anaesthesia was per-

formed in six of 10 patients to allow transoesophageal echocardiography for adequate positioning of the device.

Transcatheter occlusion of the atrial septal defect was successfully performed in nine patients, the size of the implanted devices ranging from 25 to 40 mm; six of the nine implanted devices had a diameter of 40 mm (table 2). The tip to tip diameter of the left atrial umbrella, which was measured after delivery into the left atrium (fig 3) and after screwing both umbrellas together (fig 4), increased during the implantation by 12% to 42% (mean 24.3%) (table 2). The screening times ranged from 17 to 39 min, and the procedural times from 132 to 194 min.

Sufficient occlusion of the defect was achieved in nine of 10 patients after release of the device. In two patients the defect was completely occluded during the first attempt to position the device; in all other patients careful repositioning of the device under echocardiographic guidance was necessary. In two patients a significant shunt persisted after implantation of the device, but before releasing it from the guidewire railway. In one patient the initial device chosen was too small (30 mm) and was retrieved. The right atrial umbrella was retrieved using the screwdriver catheter and the left atrial umbrella by pulling on the venous end of the nitinol wire. After implantation of a 40 mm device complete occlusion of the defect was achieved (table 2). In the other patient the attempt at transcatheter closure was unsuccessful, because the left atrial umbrella passed through the superior aspect of the defect despite several attempts to reposition the device. The device was retrieved and further attempts of transcatheter closure of the defect were abandoned. In two additional patients a minimal residual shunt at the rim of the device was observed while the device was on the guidewire railway; this disappeared immediately after the release of the device. While complete occlusion was achieved without residual shunt immediately after release of the device, during the follow up period of 21 to 29 weeks a "trivial" residual shunt was observed in one patient by colour Doppler echocardiography one and two months after the implantation. However, it could not be differentiated with certainty from an unusual flow pattern around the device.¹⁰

COMPLICATIONS

No deaths or severe complications necessitating surgery or causing significant morbidity occurred during this initial trial. Neither during implantation nor during a follow up period of 21 to 29 weeks were there any device embolisations, thromboembolic complications, fractures of the implanted device, atrial perforations, pericardial effusions, obstructions of systemic or pulmonary veins, atrioventricular valve dysfunction or other complications. However, in two patients transitory rhythm disturbances were noted immediately after the implantation of the ASDOS device. In one patient with pre-existing intermittent junctional rhythm, a predominant

Table 2 Implantation data

No	Q _p :Q _s	pPA (mm Hg)	Stretched diameter (mm)	Implanted device (mm)	Change of device diameter	Comments
1	1.8:1	18/9 (13)	17	40	12%	—
2	2.0:1	27/15 (18)	15	40	17%	30 mm device retrieved
3	2.8:1	20/9 (13)	20	40	37%	—
4	1.5:1	19/9 (12)	10	25	25%	—
5	1.5:1	22/11 (14)	14	30	21%	Mild Ebstein's disease of the tricuspid valve Transitory junctional rhythm
6	2.0:1	26/12 (16)	12	30	42%	—
7	1.9:1	18/7 (11)	17	40	15%	—
8	2.2:1	15/5 (9)	17	40	23%	—
9	2.6:1	23/11 (15)	19	40	27%	Transient disturbance of AV conductance
10	2.5:1	24/7 (15)	13	35	24%	35 mm device retrieved and further attempts were abandoned

Q_p:Q_s, pulmonary to systemic blood flow ratio; pPA, pulmonary pressure (systolic/diastolic, (mean)); stretched diameter, defect diameter as assessed by balloon sizing; implanted device, diameter of the implanted device after implantation; change of device diameter, increase of the tip to tip diameter of the device during the implantation.

junctional rhythm was observed within the first 2 d after the implantation (table 2), which normalised to a stable sinus rhythm with 2 d. In the other patient with a pre-existing prolongation of the PR interval to 170 ms, brief periods of second and third degree atrioventricular block occurred within the first 3 d after the implantation. Because there was a stable escape rhythm with narrow QRS complexes no specific treatment was needed and atrioventricular conduction normalised within 3 d. Repeated Holter monitoring and standard electrocardiograms showed normal AV conduction with a PR interval of 140 ms during follow up (21 weeks). In another patient, bleeding from the puncture site was noted 10 h after the procedure, which ceased when heparin dosage was reduced from 600 to 300 IU/kg/d. No transfusions were necessary in any patient.

Discussion

The transcatheter closure of secundum atrial septal defects is a promising approach. In this initial series we were able to close nine of 10 defects (ranging from 10 mm to 20 mm) using devices with a diameter of 25 mm to 40 mm. However, because of problems observed with the “buttoned device”³ and with the first generation “clamshell” device,⁴ the potential disadvantages and main risks of these transcatheter techniques have to be discussed. Transcatheter closure of atrial septal defects depends on an adequate rim of septal tissue surrounding the defect, as the device has to cover the defect and bear on an adequate amount of septal tissue for both sufficient occlusion of the defect and firm attachment of the device to the atrial septum. The latter also seems to be important for endothelialisation of the device.^{11 12} Balloon sizing to determine the “stretched” defect diameter seems to be mandatory to deal with multiple and irregular shaped defects and to take account of the varying thickness of the septal tissue surrounding

the defect.^{7 8} Despite this, in one patient implantation had to be abandoned because the left atrial umbrella passed through the superior aspect of the defect, indicating that the superior septal tissue was too flacid.

During the implantation of the ASDOS device, tension is developed between the two umbrellas so that the septal tissue is compressed between them, resulting in firm attachment of the device. Despite this, we believe that the diameter of the device should be double the defect diameter for a safe implantation. During implantation of the ASDOS device, stretching of the interatrial septum can occur, as the tips of the two umbrellas move apart when they are connected (figs 3 and 4). This increase of the tip to tip diameter during the implantation ranged in our series from 12% to 42% (mean 24.3%). Stretching of the atrial septum during implantation of the ASDOS device might be even more extensive than during balloon sizing, as two or more arms of the device can be caught within a trabeculation on the surface of the septal rim surrounding the defect. Additionally, “folding” of the septal tissue can occur, due to the tension between the opposite arms of both umbrellas (fig 6). In two patients we observed trivial shunting at the rim of the device, which was attributed to this mechanism and disappeared immediately after release of the device.

Although the ASDOS device is not self-centring,⁵ positioning of the device within the defect can be achieved by use of the guidewire loop and the individually preshaped pusher (fig 2). Careful repositioning of the device under echocardiographic guidance was necessary in most patients to achieve adequate positioning. Transthoracic or subxiphoidal echocardiographic guidance proved to be adequate in small children (fig 5), while in older children transoesophageal echocardiography had to be performed (fig 6). Echocardiographic guidance seems to be better than fluoroscopy, as it allows the precise assessment of the defect, its dimensions, the position of the device within the defect, and its relation to adjacent structures.^{7 9 13} When compared with other devices,^{3 9} the echocardiographic appearance of the ASDOS device is characterised by fewer artefacts (fig 5). This is particularly important for assessing whether arms of the device have passed through the defect.

It also seems mandatory that the device selected is smaller than the interatrial septum, so that interference with adjacent structures is avoided. Perforation of the atria due to the tension between the two umbrellas is a matter of concern when the device selected is too large.¹⁴ As an estimate for the size of the atrial septum, we measured the “septal length” in the apical four chamber view.⁷ Whether this measure is adequate for the selection of the largest device possible cannot be decided from these data. Thus careful echocardiographic imaging of the implanted device and its relation to adjacent structures is mandatory during the procedure.¹⁵ In one of our patients (table 2), the device was obviously positioned

in close proximity to the atrioventricular node, resulting in a transient impairment of AV conduction. Although AV conduction normalised within a few days, compression of the AV node between the umbrellas is a matter of concern when large devices are implanted, though during this initial trial relatively large defects were occluded (table 2). For the implantation of large devices, the ability to retrieve the device if necessary is an important feature. In two patients the device had to be retrieved, and thus was possible without complications. Both umbrellas were intact after extraction.

Potential complications such as fractures or embolisations of the device, thromboembolic complications, pericardial effusions due to perforation, tricuspid or mitral regurgitation, or alterations of venous return were not observed in this initial series. However, the transient deterioration of atrioventricular conduction in one patient is a matter of concern, as discussed above, although it resolved completely. Another potential complication is laceration of the mitral and aortic leaflets by the guidewire loop, so care must be taken to cover the guidewire with a catheter during the procedure to protect the aortic and mitral valve leaflets.

Despite our limited experiences and a short follow up period it can be concluded that this new device seems to be a promising transcatheter technique for the occlusion of secundum atrial septal defects in children. In the design of the device, the use of curved arms made from memory metal seems to be a major advantage, as this should guarantee the shape of the device even in case of arm fracture. However, because complications have occurred with other devices, further evaluation and long term data seem to be necessary

before this new technique can be generally recommended.

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