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Early and Late Complications Associated With Transcatheter Occlusion of Secundum Atrial Septal Defect

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OBJECTIVES The goal of this study was to report the early and late complications experienced in atrial septal defect (ASD) transcatheter closure.

BACKGROUND Atrial septal defect transcatheter occlusion techniques have become an alternative to surgical procedures. A number of different devices are available for transcatheter ASD closure. The type and rate of complications are different for different devices.

METHODS Between December 1996 and January 2001, 417 patients (mean age: 26.6 ± 19 years) underwent transcatheter occlusion of secundum type ASD. Complications were categorized into major and minor. Two different devices were used: the CardioSEAL/STARFlex in 159 patients and the Amplatzer septal occluder in 258 patients.

RESULTS Thirty-four patients experienced 36 complications during the hospitalization (8.6%, 95% confidence interval: 6.1% to 11.1%). Ten patients underwent elective surgical repair because of device malposition (three patients) or device embolization (seven patients). Twenty-four patients experienced 25 minor complications: unsatisfactory device position or embolization. Devices were retrieved using a gooseneck snare and/or a basket; 11 patients experienced arrhythmic problems. Other complications were: pericardial effusion, thrombus formation on the left atrial disc, right iliac vein dissection, groin hematoma, hemorrhage in the retropharynx and sizing balloon rupture. Two patients had late complications: peripheral embolization in the left leg one year after implantation of an Amplatzer device and sudden death 1.5 year later.

CONCLUSIONS Our series of patients with ASD by transcatheter occlusion shows that the procedure is safe and effective in the vast majority of cases. To further reduce the complications rate, the criteria of device selection according to ASD morphology and some technical tips during implantation are discussed. (J Am Coll Cardiol 2002;39:1061–5) © 2002 by the American College of Cardiology Foundation

The secundum type atrial septal defect (ASD) is the fourth most common congenital heart defect with an incidence of 3.78 per 10,000 live births (1), corresponding to 5.9% of diagnosed congenital heart disease in children (2). The ASD can now be treated by transcatheter occlusion technique. We report the early and late complications experienced in ASD transcatheter closure.

METHODS

Patients. Between December 1996 and January 2001, 417 patients (mean age: 26.6 ± 19 years) underwent transcatheter occlusion of secundum type ASD (Table 1). Of 417 patients, 34 experienced complications due to the procedure. Complications were categorized into major and minor (3). Major complications included all events leading to one of the following: 1) death; 2) life-threatening hemodynamic decompensation requiring immediate therapy; 3) need for surgical intervention; and 4) significant permanent anatomic or functional lesion resulting from catheterization. Minor complications were defined as events that were transient and resolved with specific treatment.

Devices and implantation technique. Two different devices were used: the CardioSEAL/STARFlex (CS/SF) (from 1996) in 159 patients and the Amplatzer septal occluder (ASO) (from 1999) in 258 patients.

The CS/SF (Nitinol Medical Technical Inc., Boston, Massachusetts) is a second-generation double umbrella device that was developed from the Clamshell occluder. It consists of a metallic framework covered, in umbrella-like fashion, by knitted polyester fabric. The device is available in five different sizes, 17, 23, 28, 33 and 40 mm, which can be delivered through an 11F long sheath. The CardioSEAL has been recently modified (StarFLEX) by the addition of a flexible self-centering mechanism, and it can be inserted on a front loading system of a 10F.

The ASO is constructed from 0.004-in. to 0.0075-in. nitinol wires that are tightly woven into two flat buttons (discs) with a 4-mm connecting waist that dictates the device diameter. The device is available from 4-mm to 38-mm. There are a total of three Dacron polyester patches sewn securely with polyester thread into each disc and the connecting waist to increase the thrombogenicity of the

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Abbreviations and Acronyms
ASD = atrial septal defect
ASO = Amplatzer septal occluder
CS/SF = CardioSEAL/STARFlex
TEE = transesophageal echocardiography

device. The device is delivered through a 6F up to 12F long sheath.

The criteria for using each device in our center changed during time; from 1996 to 1999 only the CS/SF has been used. After 1999, when the ASO became available, we preferred to close an ASD bigger then 18 mm only with the new device.

In all patients, implantation was carried out under general anesthesia. Before starting the catheterization, transesophageal echocardiographic examination was undertaken using a multiplane probe. Standard catheterization of the right heart was then performed through the right femoral vein, taking recordings of pressures and blood samples to calculate Qp/Qs ratio. Angiographic visualization of the defects was achieved by injection of a contrast material in the left atrium or the right upper pulmonary vein in the left anterior oblique view with cranial angulation. Heparin (100 IU/kg) and antibiotic prophylaxis were given routinely. Meditech or Numed balloons were used to establish the stretched diameter of the defect. Implantation was performed under fluoroscopic and echocardiographic control. After positioning a long sheath in the left atrium, the device was attached to its delivery wire and advanced within the sheath until the distal disc was deployed in the left atrial cavity. Both the sheath and delivery system were then slowly withdrawn towards the atrial septum. The proper position of the distal disc is confirmed on transesophageal echocardiography (TEE), and then the proximal disc was opened on the right side of the atrial septum by withdrawing the sheath. Interference of the device with the caval or pulmonary veins or with the atrioventricular valves was checked echocardiographically once deployment was complete. If all findings were satisfactory, the device was released.

Protocol for follow-up. All patients underwent clinical examination, electrocardiography, chest radiography in two

Table 1. Patient Overview

	Name	Age (yrs)	Gender	Weight (kg)	Height (cm)	Implantation Date	ASD TTE (mm)	ASD TEE (mm)	ASD Balloon (mm)	Qp:Qs	Device Size (mm)	Device Type	Procedure Time (min)	Fluoro Time (min)
1	BM	8.7	M	43	137	12/1996	13	15	16	2	33	CS/SF	70	27
2	ME	14.4	F	50	170	3/1997	13	13	14	2	28/33	CS/SF	160	66
3	CC	17.8	F	56	165	7/1997	15	17	20	3	40	CS/SF	100	30
4	TF	35.4	F	63	160	7/1997	15	15	20	3.7	40	CS/SF	80	26
5	CD	8.9	M	25	150	12/1997	6	5	7	1.4	17	CS/SF	180	49
6	DPA	22.3	F	81	163	2/1998	17	16	23	2	40	CS/SF	80	30
7	BS	10.5	F	33	147	3/1998	16	14	17	3.1	33/40	CS/SF	130	48
8	MB	27	F	58	167	2/1998	14	15	17	1.8	33/40	CS/SF	85	29
9	FE	6.8	F	26	112	9/1998	12	15	20	1.6	20	ASO	57	16
10	ZO	51	M	77	175	11/1998	15	18	20	2.2	40	CS/SF	55	12
11	CA	37.2	M	73.8	185	12/1998	10	21	24	1.53	33/40–26	CS/SF	120	63
12	SA	13	M	52	155	2/1999	12	16	18	1.8	18	ASO	55	11
13	CF	34.4	F	55.5	162	2/1999	14	12	18	3.7	18	ASO	80	18
14	GA	35	F	61	165	4/1999	12	16	19	1.6	19	ASO	59	13
15	RMG	43	F	79	160	5/1999	19	22	26	2	26	ASO	100	27
16	MB	5.7	F	19.7	122	7/1999	19	20	22	4.67	22	ASO	55	22
17	ZL	56	F	68	164	2/2000	19	20	27	2	28	ASO	50	18
18	TE	15.2	F	56	170	2/2000	15	18	20	2.5	20	ASO	65	19
19	ZV	13.5	M	45	159	3/2000	19	21	24	1.8	24	ASO	70	20
20	BL	67.7	F	65	155	3/2000	15	17	24	1.5	24	ASO	50	18
21	EA	5.8	M	15	107	5/2000	11	15	19	1.5	19	ASO	75	14
22	GV	28.6	F	60	166	6/2000	20	30	30	1.6	30	ASO	60	10
23	MA	12.4	M	51	140	6/2000	19	29	30	3	30	ASO	75	16
24	MV	18.2	F	63	1.6	6/2000	11	8	15	2	28/33	CS/SF	110	62
25	FC	68	F	78	155	7/2000		18	20	1.8	22	ASO	90	16
26	FA	35	M	93	162	8/2000	16	20	26	2.2	26	ASO	120	6
27	UL	55	F	53	157	9/2000	10	13	13		13	ASO	90	18
28	MM	4.8	M	14	89	9/2000	13	15	18	1.7	18	ASO	75	10
29	EA	18	F	68	169	10/2000	20	23	28	2.5	28	ASO	84	21
30	AS	22.7	F	45	154	11/2000	18	22	24	2.6	24	ASO	60	13
31	FMT	36	F	45	1.65	12/2000	19	25	30	2.8	30	ASO	54	18
32	CA	37.2	F	71.50	170	12/2000	8	11	13	1.9	23	CS/SF	60	25
33	CD	60	F	60	160	1/2001	17	19	32	1.6	34	ASO	103	37
34	AC	29	M	78	172	1/2001	13	14	19	2.3	18	ASO	55	18

ASD = atrial septal defect; ASO = Amplatzer septal occluder; CS/SF = CardioSEAL/STARFlex; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography.

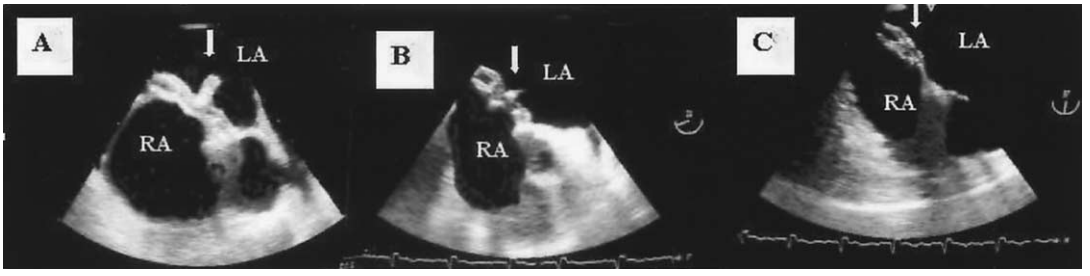

Figure 1. Transesophageal echocardiography follow-up of a patient with thrombus in the left Amplatzer septal occluder (ASO) disc. **(A)** Thrombus **(arrow)** in the left ASO disc immediately after device implantation. **(B)** Thrombus reduction **(arrow)** after three months anticoagulant therapy. **(C)** Left ASO disc thrombus free **(arrow)** after six months anticoagulant therapy. LA = left atrium; RA = right atrium.

projections and transthoracic echocardiography before discharge. The same procedures were performed at 1, 6 and 12 months after the implantation. Aspirin, at a dose of 5 mg kg daily, was recommended from six months after implantation.

RESULTS

The overall incidence of complications was 8.6% (95% confidence interval: 6.1% to 11.1%) (36/417). Thirty-four patients experienced 36 complications during the hospitalization: 11 major and 25 minor. This incidence includes the learning curve for each device. The embolization/malposition was the most common complication (3.5%), accounting for almost half of the events (16 complications in 15 patients; 47% of all complications).

Seven patients had device embolization that needed surgical retrieval. In four patients the device was a CS/SF (Patients 1, 3, 4, 10); the other three patients had an ASO implanted (Patients 19, 23, 29). Three more patients underwent elective surgical repair because of malposition of the device (Patients 6, 13, 16). In four patients the device was delivered but, because of an unsatisfactory position (Patients 2, 7, 24) or embolization (Patient 8), it was retrieved using a gooseneck snare and/or a basket; a second device was successfully implanted. The embolized/malpositioned CS/SF were 40-mm in five cases, 33-mm in four cases and 28-mm in two cases. Embolization of the ASO occurred with devices approximately or bigger than 24-mm. Malposition occurred with 19-mm and 22-mm devices, and, in one of those, it was related to accidental detachment of the device inside the delivery sheath. Several maneuvers had been performed in order to find the proper position for the deployment of the distal disc unscrewing the device from its delivery cable. One patient (Patient 11) experienced both malposition (CS/SF 33-mm) and embolization in the right ventricle at the second attempt (CS/SF 40-mm) 6 h after implantation. The ASD was closed with an ASO 26-mm. One patient (Patient 24) had a malposition of his device (CS/SF 28-mm); using a gooseneck snare, the device was pulled back into a 14F introducer up to the common femoral vein where it was surgically retrieved. The ASD was then closed using a CS/SF 33-mm. Arrhythmias are the next most common complication (2.6%). Eleven patients experienced arrhythmic problems: atrial fibrillation requiring electrical cardioversion (Patients 13, 14, 15, 18, 23, 31), atrial fibrillation with spontaneous resolution (Patients 11, 22) and supraventricular tachycardia with spontaneous resolution (Patients 12, 26). In Patient 23 during electrical cardioversion the device embolized a few minutes after implantation; at the TEE control, no residual shunt was detected before cardioversion. Patient 9 had a complete atrioventricular block immediately after device implantation. The device (ASO 18-mm) was then removed with a complete sinus rhythm recovery 3 h later. He underwent successful closure with a 14-mm ASO one year later. Electrical cardioversion was effective in five cases. In the remaining patients, sinus rhythm returned spontaneously. None of these patients experienced palpitations before the procedure, and the electrocardiogram was normal for all of them.

Pericardial effusion was experienced by two patients (Patients 17 and 27). Patient 17 was treated medically and showed complete resolution of the effusion 20 days later; the preprocedure echocardiogram on this patient did not show pericardial effusion. The mechanism of this complication in that patient is not clear.

Patient 27 had a perforation due to the guidewire and needed surgical drainage of the effusion in the cath lab. This patient underwent complete ASD closure.

Patient 20 had a thrombus formation on the left atrial disc immediately after delivery; she was fully heparinized. She was treated with anticoagulant therapy for six months with complete resolution at the TEE control (Fig. 1). There was right iliac vein dissection (Patient 5) treated by implantation of two stents, groin hematoma (Patient 25) requiring surgical revision, hemorrhage in the retropharynx (Patient 28).

In Patient 33 the sizing balloon ruptured (MediTech 33-mm) and was retained along the long wire. The ruptured balloon was retrieved with a basket catheter from the right femoral vein. Two patients had late complications. Patient 30 was reported to have experienced peripheral embolization in the left leg one year after implantation of an Amplatzer device. She required surgical retrieval of the distal peripheral embolus followed by anticoagulation treatment for one month. Patient 34 died suddenly 1.5 years

Table 2. Complications Reported by Different Authors

Reference	Device	Total Patients	# of Major Complications	Device Embolization	Surgery	CV	PM	PE	Other
Walsh et al. (4)	Sideris	33	1		1	0		1	
	ASO	39	1	1	1	0			
Sievert et al. (5)	ASDOS	154	11	2	11	0		5	2 infectious endocarditis, 2 thrombus formation
Carminati et al. (6)	CS	79	3	3	2	0			
	SF	38	1	1	1	0			
Berger et al. (7)	ASO	61	1	1	1	0			
Chan et al. (8)	ASO	100	0			0			1 transient ST elevation, 1 transient AB block, 1 presumed deep vein thrombosis, 1 presumed TIA
Waight et al. (9)	ASO	77	3	2		0	1		
Hijazi et al. (10)	ASO	18	1	1		0			

AB = atrioventricular block; ASO = Amplatzer septal occluder; CS = CardioSEAL; CV = electrical cardioversion; PE = pericardial effusion; PM = pacemaker; SF = STARFlex; TIA = transient ischemic attack.

later. No post mortem data are available, and we do not know whether the event is related to the device implanted.

DISCUSSION

In the last 50 years cardiac catheterization has changed its primary role from a diagnostic investigation to that of a therapeutic procedure. Most recently, ASD transcatheter occlusion techniques have become an alternative to surgical procedure using cardiopulmonary bypass. A number of different devices are available for transcatheter ASD closure, all of them with demonstrated advantages and disadvantages. The type and rate of complications are different among different devices (4–10) (Table 2). In our experience the embolization/malposition was the most common complication. Devices usually embolize in the main pulmonary artery (89% in our group). Once the device embolizes, two different options are possible: 1) retrieve the device by a gooseneck snare or a basket catheter, 2) refer the patient to the surgeon. The last option is indicated when the size of the device is among the largest; the surgeon will retrieve the device and close the ASD at the same time. If we decide to attempt the retrieval, an introducer of at least 12F to 14F size is inserted to accommodate the device captured by a gooseneck snare or a basket catheter. Such an attempt can be carried out with CS/SF. An embolized/malpositioned ASO, in our experience, is irretrievable. Among the five cases with the CS/SF 40-mm device, at least four had a satisfactory position after release; nevertheless, they embolized within 24 h. Therefore, we became convinced that arms are too weak to grab the septal margins and hold the device in place with sufficient stability. The 40-mm device was then abandoned in our practice, and the ASO device became the first choice for closing defects larger than 18 mm. Our personal guidelines are:

1) for ASD larger than 18 mm, use ASO device;
2) where several maneuvers are needed for positioning ASO, remember to screw the cable on the device again to avoid accidental detachment; and
3) once the ASO has detached from its cable, it becomes difficult to retrieve.

Arrhythmias are the next most common complication. For patients who experienced atrial fibrillation or supraventricular tachycardia after ASO device implantation, a possible explanation could be the stretching of the interatrial septum by the central waist of the device.

Thrombus formation in the left atrial disk immediately after the procedure was experienced in a 67-year-old patient suffering from systemic hypertension and with evidence of spontaneous contrast on echocardiogram. To avoid this complication, it is now our policy to start oral antiaggregation therapy one day before the procedure in all patients. We do not start anticoagulation therapy because we do not have criteria to define the high-risk patients that need it. The rupture of the sizing balloon is an unpredictable event because it seems to be related to the balloon itself. This complication was managed by locating the balloon outlined by some contrast material along the long wire and by retrieving it using a basket catheter.

The other complications (right iliac vein dissection, groin hematoma, retropharynx hemorrhage) were related to human mismanagement during the procedure. The major complication reported in Patient 34, that is, sudden death, is quite worrisome and needs further investigations in other large series. We cannot understand how a device implanted 1.5 year before could cause sudden death. It is, however, our responsibility to report it because there are no other known reasons to explain this event in a young man of good health of 34 years of age. Peripheral embolization in Patient 19 was clearly related to the presence of thrombi in the device as detected at the TTE. A nonhypercoagulable state was found. The patient had experienced severe gastrointestinal tract infectious disease. This complication is very important because it tells us that endothelization of the device is not completed after six months, and some predisposing factors, such as an infection, can favor thrombus formation on the device beyond the period of antiaggregation treatment.

Conclusions. Our series of patients with ASD treated with transcatheter occlusion shows that the procedure is safe, with a low rate of early and late complications. However, some aspects need further and longer investigations, especially the possibility of late thrombus formation on the device, systemic embolization and, the most worrisome event, sudden death.

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