INVESTIGACIÓN CLÍNICA

Transcatheter closure of secundum atrial septal defects and fenestrated Fontan using the Amplatzer septal occluder. Initial prospective study

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Summary

Objective: To evaluate the safety and efficacy of transcatheter closure of secundum atrial septal defects and fenestrated Fontan with the Amplatzer septal occluder. **Methods:** Fifteen consecutive patients, with a significant interatrial communications, were considered for the procedure; four patients with defects that were too large or with deficient margins were excluded after initial transesophageal echocardiography. **Results:** Eleven procedures were performed in 11 patients (10 atrial septal defects and 1 fenestrated Fontan) aged 9 to 38 years, mean 17.7 ± 9 years; body weight 30 to 87 kg, mean 51.4 ± 16. The stretched balloon diameter of the defects ranged from 8 to 28 mm, mean 18.8 ± 6.9; the diameter of the devices ranged from 10 to 30 mm, mean 20.8 ± 6. Immediate total occlusion rate was 18.1%, rising to 63.6% after 24 hours. Total occlusion rate at one month reached 100%. Severe transient sinus bradycardia in one (9%) was the only complications. At follow-up (10 to 26 months, mean 13.2 ± 5.0) all patients remain asymptomatic with no residual shunt. **Conclusions:** The Amplatzer septal occluder is very efficient and offered interventional interatrial communications closure in 100% of our group of consecutive patients with excellent intermediate results.

Resumen

Cierre transcateterismo de defectos septales atriales y Fontan fenestrado mediante el dispositivo de Amplatzer. Estudio prospectivo inicial

Objetivo: Evaluar la seguridad y eficacia del cierre transcateterismo de defectos septales atriales y Fontan fenestrado mediante el dispositivo de Amplatzer.
Método: Quince enfermos consecutivos con comunicaciones interauriculares significativas fueron considerados inicialmente; se excluyeron 4 de ellos por defectos demasiado grandes o con bordes deficientes después de ecocardiografía transesofágica inicial. **Resultados**: Se realizaron 11 procedimientos en 11 enfermos (10 con defectos septales auriculares y uno con Fontan fenestrado), el rango de edad fue de 9 a 38 años, media 17.9 ± 9 años; peso de 30 a 87 kg, media 51.4 ± 16. El diámetro de balón ajustado al defecto varió de 8 a 28 mm, media 18.8 ± 6.9; el diámetro de los dispositivos varió de 10 a 30 mm, media 20.8 ± 6. La oclusión total inmediata ocurrió en el 18.1%, subiendo a 63.6% a las 24 horas. La oclusión total en el 100% de los enfermos se obtuvo al mes de seguimiento. **Complicaciones:** Se produjo severa bradicardia sinusal

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transitoria en un enfermo (9%). El seguimiento varió de 10 a 26 meses, media 13.2 ± 5.0. Todos los enfermos se encuentran asintomáticos sin corto circuito residual. **Conclusiones:** El oclusor Amplatzer es muy eficiente y ofrece el cierre de las comunicaciones interauriculares en el 100% de nuestro grupo de enfermos consecutivos con excelentes resultados a mediano plazo. (Arch Cardiol Mex 2003; 73:185-189).

Key words: Atrial septal defect. Amplatzer occluder. Fenestrated Fontan.
Palabras clave: Defecto septal auricular. Oclusor de Amplatzer. Fontan fenestrado.

Introduction

In 1976, King and Mills were the first to report the successful transcatheter closure of atrial septal defects using a double disc device introduced through a very large transvenous sheath.[1] The pioneering work of Rashkind[2] and Lock and colleagues[3] provided additional evidence that similar techniques could be used effectively and with relative safety. Many of the ideas that governed these early designs have been incorporated into the Amplatzer device that is now available for clinical use, offering an alternative to surgical repair in up to probably 50% of patients with a secundum defect. The Amplatzer device has the lowest incidence of residual atrial shunting and embolization. Its easy retrievability before release makes repositioning after suboptimal deployment straightforward.[4] Potential disadvantages are its large bulk, the capacity for incomplete endothelization with thrombus formation, and the theorical risk of nickel toxicity.[5]

We report our initial experience and mid term outcome with Amplatzer occluder for closure of atrial septal defect (ASD) and a patient with a fenestrated Fontan procedure, with reference to its safety and efficacy.

Material and methods

All patients with a clinically significant ASD in whom cardiac surgery was indicated were invited to participate in the trial. Initial selection was based on in transthoracic and transesophageal echocardiography (TOE). ASD with a diameter of 31 mm or less with suitable septal rim of at least 5 mm from the right pulmonary veins, coronary sinus, superior cava vein, inferior cava vein, and mitral valve were considered suitable. A patient with a fenestrated Fontan and low oxygen saturation was also included. Informed consent was obtained from all patients or their parents.

Technique. All the procedures were performed under general anesthesia. Cardiac catheterization was performed using general endotracheal anesthesia, systemic heparinization and antimicrobial prophylaxis with intravenous **cephazolin** (25 mg/kg). Detailed assessment of the size and mor-

Table I. Demographic echocardiographic and hemodynamic data.

N	Ident. Years	Age	S kg	W. m	H. Date	Implant Mm	TOE D diameter Mm	Balloon	Qp/Qs mmg	PA P zer size	Amplatzer oclussion at	Complete	Complica up	Follow	S
1.	PCC	19	M	49	1.56	09/11/00	11	13	2.6	30/12/20	17	24 h	N	26	A
2.	BTN	13	F	34	1.46	14/06/01	10	18	2.1	27/05/09	18	24 h	N	19	A
3.	JGC	12	M	30	1.50	04/07/01	8	9	2.0	17/07/13	10	Immediat	N	18	A
4.	GCE	9	F	43	1.39	21/01/02	21	24	2.1	22/07/15	26	24 h	N	12	A
5.	VHM	15	F	58	1.58	22/01/02	27	31	1.8	35/10/25	32	24 h	N	12	A
6.	SDP	19	M	87	1.88	06/02/02	20	23	2.2	45/08/18	26	2 m	N	11	A
7.	CGA	38	M	70	1.60	19/02/02	21	24	1.7	40/30/20	26	2 m	N	11	A
8.	RPJ	15	M	63	1.63	21/02/02	18	22	1.9	35/25/20	24	Immediat	N	11	A
9.	LVG	26	F	50	1.55	21/02/02	20	28	2.0	30/15/25	30	1 m	N	11	A
10.	XOM	36	F	55	1.60	27/02/02	16	18	1.9	25/11/18	20	1 m	N	11	A
11.	DBJ	14	M	51	1.74	08/03/02	11	11	0.5*	16/13/14	13	24 h	N	10	A
	Mean	17.7		51.4	1.59		15.5	18.8	2.0	29/13/18	20.8			13.2	

- *Fontan Fenestration occluded, no considered for Qp/Qs mean
- Ident = Identification, S = Sex, W = Weight, H = Height, TOE D = Transesophageal echocardiography Diameter, Pulmonary artery pressures, S = Clinical Status, A = Asymptomatic

phology of the ASD and its rim, was performed by TOE. Once a complete saturation and hemodynamic study had been carried out, pulmonary arteriography was performed in anteroposterior view to exclude anomalous pulmonary venous drainage. A right upper pulmonary vein angiography in the four chamber view was performed to visualize the atrial septum. The ASD was sized with a sizing balloon catheter. The stretched diameter of the ASD was defined as the diameter of the balloon that can be withdrawn across the ASD with mild resistance and slight deformity monitored by **TOE**. The technique used for the implantation of the Amplatzer device has been described elsewhere.[6,7] **TOE** sector scanner to monitor device placement was performed in all patients.

Follow-up. All patients underwent clinical examination, electrocardiography, chest radiography, and transthoracic echocardiography prior to discharge. The same procedures were performed at periods of 1, 2, 3, 6, 10, 12 months after implantation. All patients received aspirin 100 mg/day for 3 months and were followed at least for 10 months.

Data collection and analysis. All data were collected on a set data sheet, collated by a single coordinator, and entered into a common database for analysis. Descriptive statistical data are presented as mean (SD).

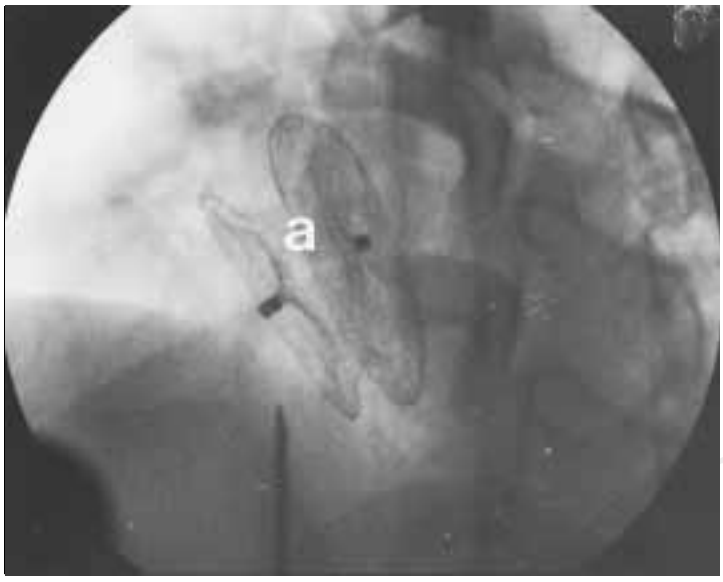

Fig. 1. Four chamber view. The Amplatzer device (a) was deployed at the atrial septal defect.

Results

Four patients showed very large defects: more than 31 mm, larger than the largest available Amplatzer device or inadequate rim on the TOE and were considered unsuitable for closure with the device; we did not attempt to introduce the device in these patients and they were excluded of the protocol; thus, 11 implants were performed in 11 patients during the study period from November 2000 to March 2002. *Table I* depicts the demographic, hemodynamic, and echocardiographic data for the 11 patients. There were 10 patients with fossa ovalis ASD *(Fig. 1)* and one patient with a fenestrated Fontan procedure *(Figs. 2a y 2b)*. They ranged in age from 9 to 38 years, mean 17.7 ± 9.6, and weight from 30 to 87 kg, mean 51.4 ± 16. Procedural time ranged from 45 to 190 minutes, mean 99 ± 35, fluoroscopy time was not assessed. The defects ranged in size from 8 to 27 mm, mean 15.5 ± 5.9 by **TOE**, and from 9 to 31 mm, mean 18.8 ± 6.9 by stretched balloon. The Amplatzer device size ranged from 10 to 32 mm, mean 20.8 ± 6.

Complications: One patient (patient 2) showed severe transient sinus bradycardia (36 per minute). In patient 5, the 34-size Amplatzer device was incorrectly deployed, interfering with the anterior leaflet of the mitral valve motion and was retrieved and exchanged for a 32 size-Amplatzer. These two complications were considered minor complications.

There were 100 successful implants. Total occlusion rate immediately after the procedure was 18.1%, after 24 hours, 36.3%; one month, 54.5%; rising to 100% at 2 months. The patient with a 8 mm fenestrated Fontan increased his oxygen saturation from 75 to 93% after fenestration occlusion, with no change in the atrial pressure. All patients were followed for at least 10 months, remained well with no complications or new symptoms. The follow up ranged from 10 to 26 months, mean 13.2 ± 5.0.

Discussion

Following the initial successful report of non-surgical transcatheter closure of ASD[1] various devices were introduced; however, short- and mid-term follow up of several these devices have raised concerns about fatigue fractures of metal struts[8] and displacement of the device or perforation of the atrial wall necessitating surgical removal.[9,10] The Amplatzer septal occluder employs the concept of closing the ASD by stenting the

defect with its conjoint waist. The device is therefore truly self-centering and achieves fixation and stability by stenting the defect, the stability is provided by the two atrial discs. The device was designed to be easily retrievable **once** it is released from the delivery wire, thereby allowing removal in the event of malpositioning. This was easily demonstrable in case 5 where a too large device was implanted incorrectly over the septal mitral valve. This retrievability has the advantage of avoiding emergency surgery in problematic cases. The overall technique appears simpler than with the other existing devices and therefore has a shorter learning curve. Careful patient selection is important. Selection of the correct size of device depends on accurate assessment of the stretched diameter of the ASD, as the device is matched to the size of the stretched ASD diameter. This is currently done using a balloon catheter filled with diluted contrast. During the sizing process, care must be taken not to undersize oval defects, as resistance from the minor diameter may be felt as the balloon is withdrawn across the defect. This error may be minimized by using TOE to visualize the defect during balloon inflation. TOE is also used to correct positioning and stability of the ASO device before it is released and immediately after implantation.

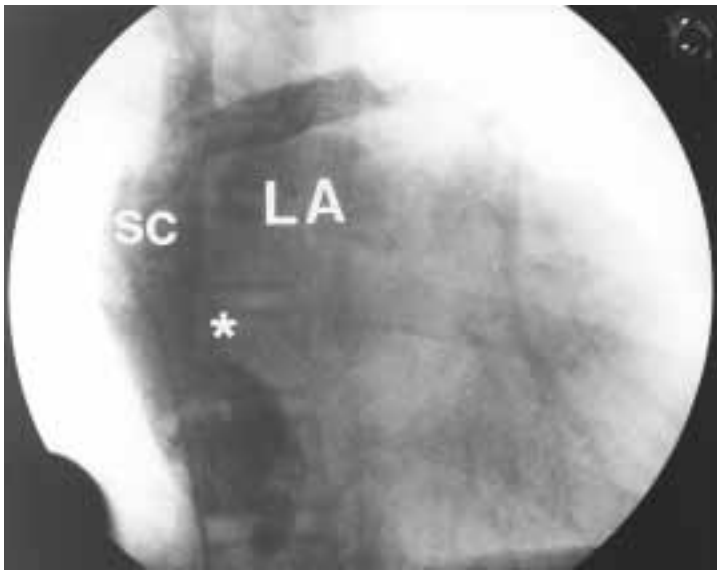

Fig. 2a. Patient with a fenestrated Fontan operation. Frontal view, angiogram in the superior caval vein (SC). The contrast passes through the fenestration (white asterisk) to the left atrium (LA).

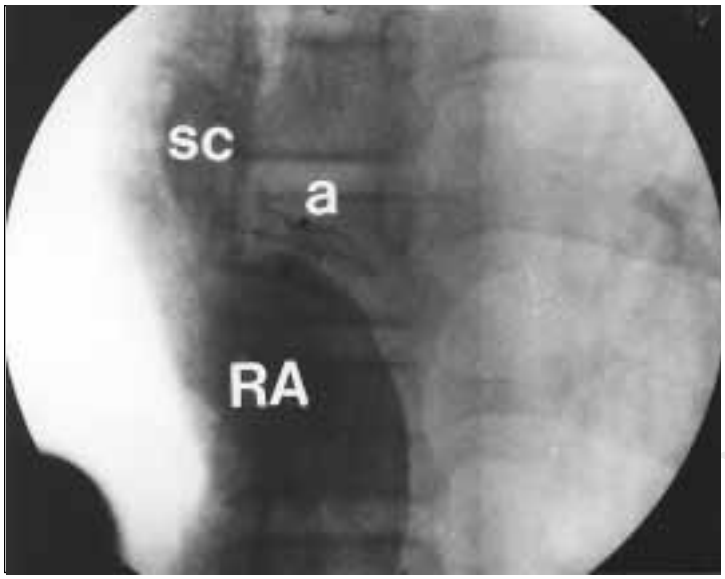

Fig. 2b, same patient and view. The Amplatzer occluder (a), closed the fenestration. SC: Superior caval vein, RA: Right atrium.

Supraventricular tachycardia, severe bradycardia, transient atrioventricular block and occasionally atrial flutter or atrial fibrillation may occur during device implantation or also during the sizing process.[11,12] These events can usually be terminated by further manipulation of the catheter within the atria, breaking a re-entrant tachycardia. An electrode catheter may be used instead of a standard catheter so that overdrive pacing may be employed to terminate the tachycardia. Very rarely, synchronized countershock is necessary.

Our early experience with ASO, as well as that of others,[12,13] suggests that safe closure of an ASD of up to 32 mm in diameter is feasible if located in a suitable position. The ASO is also suitable for fenestration closure after a Fontan procedure.[14] In addition, at least four new devices have now been used for closure of ASDs and Fontan fenestration and are being tested in clinical trials. These are CardioSEAL, the modification of the initial Clam-shell device, various generations of the Sideris buttoned device, and the Angel-Wings device. It has been estimated that about 50% of ASDs in the fossa ovalis might be suitable for transcatheter closure;[15] however, the proportion of defects suitable for ASO closure may increase. The ASO device has an early high occlusion rate even when compared with cardiac surgery.[16] It was 100% effective in our limited experience with no major complications in the mid-term. The ASO is now completing international registry follow-up and it is likely to be

approved for general release for closure of atrial septal defects.

Conclusions

The Amplatzer septal occluder was very efficient and offered interventional closure of ASD and in one case of fenestrated Fontan in 100% of our initial group of consecutive patients with excellent intermediate results. Further experience in Fontan fenestrated cases, with larger devices and long-term results are required to reach conclusive results.

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