Percutaneous Catheter Closure of Atrial Septal Defect. Short-Term and Mid-Term Results

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Introduction. Percutaneous closure of atrial septal defects (ASD) is becoming more frequent.

Patients and method. From October 1997 to October 2002, 209 patients, age 0.4-70 (mean 19.5) years, were catheterized to close an ASD or patent foramen ovale (PFO). Transesophageal echocardiography was performed simultaneously in all patients. Two hundred and six patients had ASD (25 multiple ASDs) and 3 had PFO. Three devices were used, the Amplatzer Atrial Septal Occluder (ASO), CardioSeal (CS), and Starflex (SF).

Results. Device implantation was achieved in 181 patients (87%) but had to be abandoned in 28 patients, generally because the ASD was too large. One hundred and seventy-four ASOs were implanted in 172 patients with ASD (2 ASOs were implanted in 2 patients with double ASD) and CS/SF in 9 patients (3 patients with PFO and 6 with ASD). The procedure was effective in 166/172 (96%) ASO implantations and in 8/9 (89%) CS/SF implantations. The procedure was unsuccessful in 7 patients and the device had to be removed (6 ASO and 1 SF). The occlusion rate with ASO was 88% after 24 hours, 91% after 1 month, 95% after 1 year, 97% after 2 years, and 100% after 4 and 5 years. All defects treated with SF/CS were closed successfully after 24 hours. In one case the ASO device was embolized to the aorta. In the first month after ASO implantation, supraventricular tachycardia appeared in 2 patients and transient left ventricular failure in 2 patients. No late complications were observed.

Conclusion. Percutaneous catheter closure of selected types of ASD using the Amplatzer Atrial Septal Occluder, CardioSeal, or Starflex should be offered to patients as non-surgical alternative. The type of device used depends on the defect size and morphology as well as the surgeon's experience. The presence of multiple defects does not exclude the possibility of a successful percutaneous catheter closure.

Key words: *Interventional cardiology. Atrial septal defect. Transcatheter closure.*

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Cierre percutáneo de la comunicación interauricular. Resultados a corto y medio plazo

Introducción. El cierre percutáneo de la comunicación interauricular (CIA) es una alternativa de tratamiento cada vez más utilizada.

Pacientes y método. Entre octubre de 1997 y de 2002 se realizó cateterismo cardíaco, con la intención de cierre de una comunicación interatrial (CIA) o foramen oval permeable (FOP), en 209 pacientes con edades comprendidas entre 0,4 y 70 años (media, 19,5 años). En todos los casos se realizó ecocardiografía transesofágica (ETE) simultánea. En 206 casos existía CIA (25 con defectos múltiples) y en tres un FOP. Se utilizaron 3 dispositivos: Amplatzer Atrial Septal Occluder (ASO), CardioSeal (CS) y Starflex (SF).

Resultados. Se aceptó para cierre percutáneo a 181 pacientes (87%). Se rechazaron 28 casos, en su gran mayoría por el excesivo tamaño del defecto. En 172 pacientes con CIA se utilizaron 174 ASO (en 2 casos con 2 defectos alejados se implantaron 2 ASO) y en 9 pacientes (seis con CIA y tres con FOP) los dispositivos CS/SF. El implante percutáneo del ASO fue efectivo en 166/172 (96%) pacientes, y el de CS/SF en 8/9 (89%) pacientes. En 6 casos de ASO y uno de SF el cierre no se pudo realizar por posicionamiento incorrecto del dispositivo. El porcentaje de cierre completo de la CIA con ASO fue del 88% después de 24 h, del 91% al mes, del 95% a un año, del 97% a los 2 años y del 100% a los 4 y 5 años de su implante. Todos los defectos tratados con dispositivos CS/SF se cerraron completamente después de 24 h. Como complicaciones destaca un caso de embolización de ASO en la aorta, extrayéndose el dispositivo con cirugía, 2 casos con episodios de taquicardia supraventricular

ABBREVIATIONS

RA: right atrium.
LA: left atrium.
ASO: Amplatzer Atrial Septal Occluder.
CS: CardioSeal.
SF: Starflex.
ASD: atrial septal defect.
TEE: transesophageal echocardiography.
TTE: transthoracic echocardiography.
PFO: patent foramen ovale.
TIA: transient ischemic attack.

y otros dos con insuficiencia cardíaca izquierda transitoria durante el primer mes tras la colocación de un ASO.

Conclusión. El cierre percutáneo en los pacientes portadores de CIA o FOP es una atractiva alternativa al tratamiento quirúrgico. La elección del implante depende de la anatomía del defecto y la experiencia del médico. La existencia de múltiples defectos no excluye la posibilidad de su cierre percutáneo eficaz.

Palabras clave: *Cardiología intervencionista. Comunicación interauricular. Cierre percutáneo.*

INTRODUCTION

An atrial septal defect (ASD) is, due to its frequency, the fourth most common congenital heart disease, appearing in 3.78 of every 10 000 live newborns.[1] The diagnosis of an ASD, with signs of right ventricular volume overload, is an indication for its closure. Surgical treatment is safe and efficient, but entails the complications associated with thoracotomy, as well as the possibility of bleeding, arrhythmia, post-pericardiotomy syndrome, and residual short circuits.[2,3] Since the first study published on nonsurgical ASD closure,[4] various occlusion methods have been used, usually in the form of a double umbrella framework or squares with branches covered with polyester patches (Clamshell, ASDOS, Angel Wings, Sideris device). Although the initial results were promising, on long-term followup there was an incidence of breakage of the metallic branches or damage of the atrium walls which required surgical repair.[6] These problems were the result of devices that were too rigid to support the mechanical force caused by cardiac motion. As a result, a new generation of devices emerged, with articulated elastic branches, such as CardioSeal (CS) and Starflex (SF). Since the first published paper by Masura et al[7] in 1997 numerous studies have been published, including in Spain,[8,9] that have analyzed the results of using the new system with 2 Nitinol disks called the Amplatzer Atrial Septal Occluder (ASO). The aim of this study is to present our experience with percutaneous closure of ASDs.

PATIENTS AND METHODS

We studied 209 patients who between October, 1997, and October, 2002, underwent cardiac catheterization for percutaneous closure of an ASD (Figure 1). The patients were aged between 0.4 years and 70 years (mean, 19.5 years) and weighed between 3.5 kg and 96 kg (mean, 49 kg). The procedure was initially indicated according to the diagnosis determined by transthoracic echocardiography (TTE) imaging in the children in the study and transesophageal echocardiography (TEE) imaging in the adults. The diagnosis was confirmed during cardiac catheterization with simultaneous TTE. The stretch diameter of the defect was measured with a calibrated balloon, locating the interatrial defect as precisely as possible. In most cases the procedure was indicated in patients with a left-right short circuit and with echocardiographic tracings showing right ventricular volume overload. A stretch diameter of less than 38 mm with the edges of the septum facing toward the mitral valve, coronary sinus, and left superior pulmonary vein were required for inclusion, with a minimum edge length of 6 mm, except in the case of the aortic edge. The procedure was also indicated in patients with transient cerebrovascular attacks (TIA), with ASD and non-significant left-right short circuit or with a patent foramen oval (PFO) with right-left short circuit evident during performance of the Valsalva maneuver.

In all cases, prior to catheterization, physical examination, echocardiogram, chest radiograph, and TTE were performed. In 6 patients, percutaneous closure of a residual ASD was indicated following a surgical procedure (in 2 patients following anatomical correction of the transposition of large arteries, and in the other 4 after surgical closure of an ASD). In another 5 patients the other interventions were performed simultaneously in the setting of coexisting lesions: pulmonary valvu-
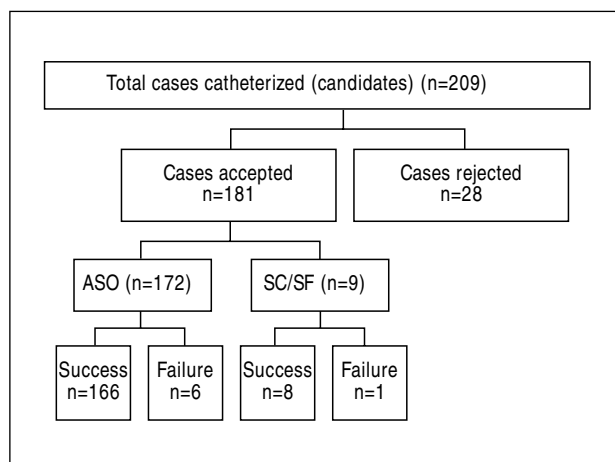

Fig. 1. Graph of the patients studied.
ASO indicates Amplatzer Atrial Septal Occluder; CS, CardioSeal; SF, Starflex.

loplasty for severe pulmonary valve stenosis in 4 patients, and in another patient closure of persistent ductus arteriosus.

In those patients with ischemic cardiopathy, complex cardiac defects, or abnormal drainage of the pulmonary veins the procedure was not indicated.

The diameter of the device was the same or greater than the stretch diameter of the defect which, in turn, was greater than the diameter of the ASD as seen on TEE (ratio 1.4:1).

Devices

The ASO (AGA Medical Corporation, Golden Valley, Minn.) (Figure 2) is a device with 2 discs made of fine Nitinol wire mesh with a thermal memory and auto-centering capability. Both discs are joined by a 4 mm waist. In the devices 4 mm to 10 mm in diameter, the left atrial and right atrial discs are 12 mm and 8 mm larger, respectively, than the waist. In the 11 mm to 40 mm diameter devices, the left atrium disc is 14 mm larger and the right atrial disc is 10 mm larger than the waist. Three polyester patches, located in the discs and in the waist of the device, cause coagulation and the obstruction of the defect. The device is introduced loaded and with a delivery guide via a 6F to 12F sheath which is placed in the left atrium via the ASD. One advantage of the ASO is the possibility of recovering and repositioning the device, multiple times if necessary, before deploying the device.

In 9 patients CardioSeal and Starflex devices were used (Figure 3) (Nitinol Medical Technologies, Inc., Boston, Mass.) Both consist of a double umbrella framework with 4 nitinol arms that are covered with a square polyester patch. The Starflex type has a system of self-centering threads that connect the arms of both umbrellas.

Procedure protocol

In the pediatric patients all procedures were performed under general anesthesia and intubation, and in some of the adult patients, procedures were performed with only sedation and local anesthetic. Antibiotic prophylaxis (cephazoline) was administered and the right femoral vein was punctured. TEE was performed and the diameter of the defect was measured in different projections, analyzing the borders (anterior, posterior, inferior, and superior) and the total length of the septal defect. Diagnostic cardiac catheterization was then performed and the pressures of both atria, the right ventricle, and the pulmonary artery were measured. In patients older than 40 years of age, coronary angiography was performed.

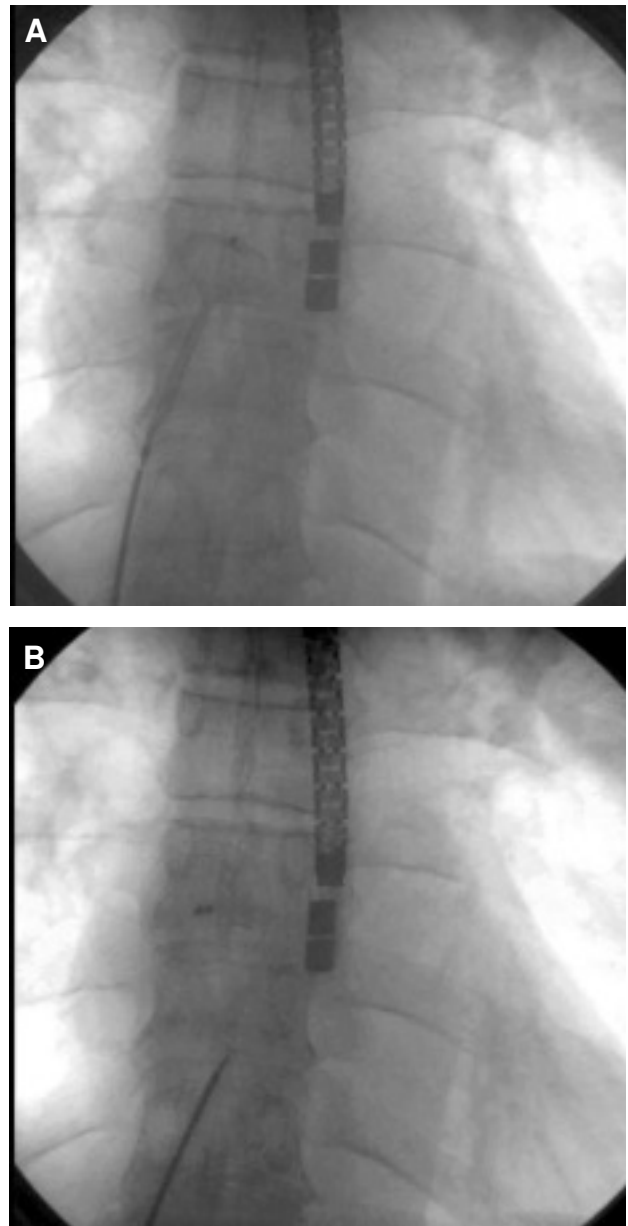Following the intravenous administration of heparin (100 U/kg) the stretch diameter of the defect was mea-

Fig. 2. Implantation of an Amplatzer Atrial Septal Occluder (ASO). A: The disc on the left atrial side is open. The right disc is inside the sheath still connected to the deployment system. B: The device in the correct position after deployment.

sured with occlusion catheters, either OBW by Meditech (20, 27 or 33 mm) or AGA Medical Corporation (24 or 34 mm). Introduction into the left atrium was accomplished coaxially via catheter exchange with a guide wire located in the left superior pulmonary vein. The balloon was filled in the left atrium with contrast material diluted with physiological serum until it reached a volume greater than the diameter of the defect, and was slowly removed under TEE-color Doppler control until the short circuit disappeared entirely. The balloon was then slowly deflated and drawn toward the right atrium until the jump

of the balloon to the right atrium was noted. The stretch diameter was that of the balloon when the balloon passed from the left to the right atrium, occluding the ASD. Once the balloon was outside the patient, the diameter of the balloon was tested by inflating it with the same amount in millimeters of contrast solution, assuming the stretch diameter to be that of the orifice through which the balloon passed with a certain degree of difficulty, according to the template recommended by the manufacturer. The closure device (ASO) was chosen so that its diameter was the same or 1 to 4 mm greater than the stretch diameter of the defect. When the Starflex device was used, the ratio was 2:1 with respect to the ASD or sufficiently large to block the entire aneurysm wall. The distal disk of the ASO was opened in the left atrium and, later, the proximal disk was opened in the right atrium. When implantation was incorrect on TEE, the device was removed within the vein and the maneuver was repeated as many times as necessary. Device stability was controlled by means of the Minnesota maneuver (push and drawing of the device toward both atria without deployment).[10] Antibiotic prophylaxis was administered for 24 hours, heparin was administered at a dose of 400 U/kg/24 hours for 48 hours, and acetylsalicylic acid was administered at an antiaggregate dose (2 to 5 mg/kg) for 6 months (for the last patients this was also administered for 24 hours prior to the procedure). Intense sport activity was discouraged for a month following the procedure and bacterial endocarditis prophylaxis was recommended for 6 months (or until complete closure of the ASD was achieved). At followup at 1, 3, and 12 months and every year thereafter, a physical examination, electrocardiogram, chest radiography, and TTE were performed.

RESULTS

The procedure was performed in 181 patients (86.7% of the total of 209 patients) (Figure 1). Twenty-eight patients were rejected: 22 due to excessive defect diameter, 3 due to the coexistence of 2 septal defects distant from each other, 2 patients due to the coexistence of coronary artery disease, and 1 patient due to a partial abnormality in drainage of the pulmonary veins.

The mean diameter of the ASD measured by TEE was 13.2 mm±5.5 mm, and the mean stretch diameter was 18.9 mm±6.2 mm (43% larger). Two defects were found in 25 patients, and 2 devices were implanted in only 2 cases with 2 defects that were distant from each other. In 3 patients a septal aneurysm was found, and in 70 patients the aortic border was deficient. The existence of a TIA indicated the closure of the ASD in 3 patients. In 5 patients a double interventionist procedure was performed: effective pulmonary balloon valvuloplasty and consecutive implantation of an ASO in

4 cases, and percutaneous closure of a ductus with a 5PDA5 coil and closure of the ASD in another.

One hundred and seventy-four ASO devices were implanted in 172 patients (2 ASO devices were implanted in 2 patients). The mean diameter of the device used was 19 mm±7.2 mm (range, 5 to 40 mm). Mean scope time was 11.1 minutes (range, 1.6 to 50 minutes).

In 7 patients closure of the ASD was not achieved (6 cases using the ASO and 1 the CS), and the device was removed due to incorrect positioning in spite of various attempts. The only immediate embolization of an ASO was produced by a 16-mm device: the device embolized to the left ventricle and abdominal aorta within a few minutes. A Dotter basket was introduced into the aorta via puncture of the left femoral artery and the implant was lifted out by means of the basket via the abdominal aorta to near the aortic arch. The patient was referred to surgery, where the defect was closed and the embolized device was removed. The Dotter basket and the introducers were removed in the intensive care unit. One adolescent patient aged 18 years presented with an episode of supraventricular tachycardia the day after closure of the ASD with a 28 mm ASO; the tachycardia resolved after intravenous administration of verapamil. Another 19-year-old adolescent experienced atrial fibrillation with rapid ventricular response (approximately 200 beats/minute) 3 weeks after implantation; pharmacological treatment was not effective and the patient only recovered sinus rhythm after electrical cardioversion. No other types of arrhythmia were detected after implantation of the ASO. In 2 patients (63 years and 8 years of age with 17-mm and 20-mm ASO devices, respectively) we observed transient heart failure during the 2 days after percutaneous closure of the ASA that was treated with continuous intravenous infusion of dopamine. In the first patient we believe the cause was poor adaptation of the left ventricle to volumetric overload, and in the other patient the cause was unknown, although, (we wish to highlight this fact) this was the only patient in our sample with significant psychomotor difficulties.

Other devices used

In 1 patient who had a multi-perforated aneurysm of the ASD we used only one 33-mm CardioSeal device, and in 5 patients with central defects (2 patients had an additional defect) we attempted percutaneous closure with 28-mm and 33-mm Starflex devices. In another 3 patients with TIA and PFO we used two 23-mm Starflex devices and one 23-mm CardioSeal device. We were unable to achieve complete closure of the defects in only 1 patient with ASD; we were not able to position the Starflex adequately and it was removed; the patient was referred for conventional surgery. The

mean fluoroscopy time was 19 minutes (range, 10-45 min), and there were no complications noted.

In most of the patients a small mosaic of left to right flow was observed in the central portion of the ASO right after it was placed. Total occlusion was confirmed by TTE with color Doppler imaging in 88% of patients 24 hours after the procedure, in 91% of patients at 1 month, in 95% of patients at 1 year, in 97% of patients 2 years after implantation, and in 100% of patients at 4 and 5 years after implantation.

DISCUSSION

In recent years various devices have been used for the percutaneous closure of an ASD.[11] The complicated implantation method associated with certain devices has been linked to a significant incidence of complications.[6,12] The ASO was used in our hospital for the first time in 1997.[10] Its advantages are ease of implantation, the possibility of repositioning the device until after the deployment of the proximal disk (a property specific to the ASO device) which results in a decrease in complications due to increased efficacy in closure.[7-10,13-15] Nevertheless, as is the case with other implants, the precise selection of patients with defects in the central or anterosuperior portions of the septum is necessary and selecting those with good edges in the direction of the mitral valve, coronary sinus, venas cava, and the pulmonary veins. We want to highlight an important point: the necessity of the left atrial disc diameter being smaller than the diameter of the septum.

In 86.7% of the patients initially selected (181 of 209 patients) closure was achieved. This percentage could have been higher, but the devices larger than 26 mm have only been available since 1999. The ASO implant was effective in 96.5% of patients (166 of 172 patients) and, in the case of the CS/SF, in 88.9% of patients (8 of 9) (Figure 3). The cause of embolization in 1 implant in the left ventricle and aorta is not clear, but it seems that the assessment of the defect may not have been exact, and the device chosen may have been too small and, although initially stable, was displaced during the Minnesota maneuver. Berger et al[13] reported a similar complication; they removed the ASO via the femoral artery.

The presence of a residual short circuit is usually related to the presence of an additional defect. The probable success of closure of 2 defects with an ASO is greater when the additional defect is small and the distance between the defects is less than 7 mm.[16] When there are 2 coexistent defects at a distance from each other, 2 devices can be used.[17] When multiple perforations of the fossa ovale are present, with or without an additional aneurysm, use of the CardioSeal device may be indicated, which is beneficial in this situation
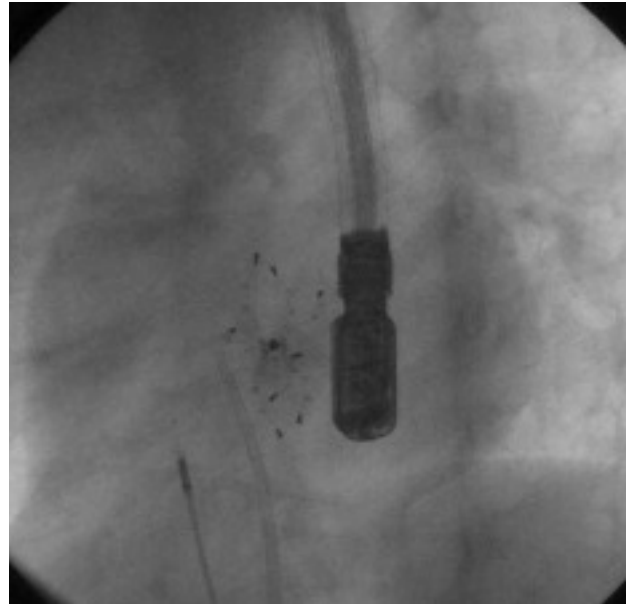

Fig. 3. The Starflex device (SF) in the correct position after deployment.

as it can close small defects and, at the same time, stabilize the septum.[11] In central defects that are not very big, the Starflex device is another alternative for closure due to the fact that it is flatter and has a lower metallic element content than the ASO.[18] In our view, the usefulness of these devices for percutaneous closure of ASD is limited by it being a more difficult procedure due to poor visualization of the devices on TEE monitoring, although the 2 devices (CS and SF) appear to be very useful for percutaneous closure of a PFO.

Pulmonary valve stenosis can be dilated with a balloon before closure of the ASD with a device (used during the same procedure).[19] We performed this double treatment in 4 patients.

In a certain patients with patent foramen ovale and neurological accidents of unknown origin surgical closure of ASD has been proposed.[20] Percutaneous closure has started to be a treatment option[21] as confirmed by our experience in 3 cases.

CONCLUSIONS

The possibility of percutaneous closure of a symptomatic ASD or a PFO must be offered as a desirable alternative to surgery. Analysis of the morphology of the septum and the septal defect or defects affects the choice device used. The presence of multiple interatrial communications does not preclude the possibility of their percutaneous closure using 1 or 2 devices.

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