Original Article

Clinical Efficacy and Safety of the Percutaneous Treatment of Secundum Atrial Septal Defect with the Amplatzer Occluder

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Objective

To assess the clinical efficacy and safety of the Amplatzer occluder for percutaneous closure of secundum atrial septal defect.

Methods

Forty-nine patients underwent the procedure guided by transesophageal echocardiography (TEE) while under general anesthesia, afterwards being clinically followed up for 12 months.

Results

The defect presented as a single orifice in 91.8% of the cases. The means of the longitudinal and transverse diameters were 14.3±5.0 mm and 14.4±4.9 mm, respectively. The means of the stretched diameters and prostheses were 19.3±5.1 mm and 20.3±4.9 mm, respectively. Technical success occurred in 97.9% of the cases. Immediate residual flow was observed in 54.1% of the patients, being minimum or small in 45.8% and moderate in 8.3%. After 24 hours, residual flow was observed in 25% of the patients (P = 0.0002). At the end of 13.1±1.3 months, the incidence of the overall residual flow decreased to 14.6%, only 4.1% being moderate. A significant reduction in the right ventricular diastolic diameter was observed in the different phases of clinical follow-up (P < 0.001).

Conclusion

Implantation of the Amplatzer prosthesis proved to be effective and safe, constituting an option for the treatment of the secundum atrial septal defect in selected cases.

Keywords

congenital heart diseases, atrial septal defect, interventional catheterization, Amplatzer occluder

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Received for publication: 07/01/2003
Accepted for publication: 07/29/2004
English version by Stela Maris Costalonga

Atrial septal defect (ASD) was first described by Rokitansky [1] in 1875, but its clinical data were only compiled in 1941 by Bedford et al [2]. Its prevalence is 3.78 patients per 10,000 live births [3] with a predominance in the female sex at the proportion of 1.5 to 3.5:1 [4,5].

Since 1948, when the first atrial septorhaphy was performed by Murray [6], the surgical treatment with the aid of extracorporeal circulation has been considered the first-choice procedure for closure of atrial septal defects with low morbidity and reduced mortality (0.5% to 1%) in specialized centers [7-9].

The percutaneous treatment appeared 3 decades ago as an alternative to surgical treatment. It was performed for the first time in 1976 by King et al [10], who used a prosthesis of their own conception. Later, in 1983, Rashkind [11] began to investigate the single umbrella, which was fixed to the septum by means of small hooks. At the end of the 1980s, Lock et al [12] developed the clamshell double umbrella, which, however, during clinical follow-up, showed fractures in its rods, its investigation being interrupted by the FDA. In the 1990s, several devices were developed with the configuration of umbrellas or occluders, which had some problems, such as an elevated incidence of residual flow, displacement or embolization of the device, and heart perforation, which required surgical correction [13-18].

Sharafuddin et al [19] published the results of an experimental study with a new prosthetic conception in one single self-centered and self-expanding component, called the Amplatzer occluder, which was investigated in several international centers, and, among us, by Fontes et al [20], with good immediate results.

We report the experience in our institution with that device up to mid 2001, focusing on the immediate results and considering clinical follow-up for one year after implantation.

Methods

Between January 2000 and July 2001, 49 (80.3%) of 61 patients recruited in the sector of congenital heart diseases of the Instituto Dante Pazzanese de Cardiologia (IDPC) with secundum atrial septal defect were selected for this study. They underwent transthoracic (TTE) and transesophageal (TEE) echocardiography and met the following inclusion criteria: patients of both sexes and of any age group, weighing more than 15 kg; with left-to-

right blood flow through the atrial septal defect; with dilated right ventricle (RV) with signs of volumetric overload. In addition, the defect should have the following characteristics: greater diameter ≤ 30 mm, both in the longitudinal and transverse directions; distance of at least 5 to 7 mm between its rims and the atrioventricular valves, the origin of the coronary sinus (CS) and the inferior vena cava (IVC), in its inferior portion, maintaining the same distance between its superior portion and the emergence of the right superior pulmonary vein (RSPV) and the superior vena cava (SVC). The antero-superior rim (related to the aorta in the transverse plane) could be deficient (< 5mm) or absent.

Patients with the following characteristics were excluded from the study: secundum atrial septal defect with clinical signs of right-to-left blood flow (sat 0_2 < 94%); fixed pulmonary arterial hypertension and other heart associated defects requiring surgical correction. The same criterion was used for patients with defects of the ostium primum type, venous sinus, intracavitary thrombi, and thrombosis of the IVC.

After clinical evaluation, patients suspected of having secundum atrial septal defect underwent conventional electrocardiography and chest radiological study in the frontal position, aiming at calculating the cardiothoracic index (CTI). Then, they were referred for TTE and TEE to confirm the diagnosis, and constituted the selection of favorable cases for percutaneous closure. In addition to confirmation of the diagnosis, TTE aimed at measuring the right ventricular diastolic diameter (RVDD) in the left parasternal position, and its value was normalized according to age, weight, and height, and expressed as a percentage (% RVDD) [21].

Then, the patients underwent cardiac catheterization while under balanced general anesthesia. Complete manometric recording was obtained, and blood samples were collected for oximetry, aiming at calculating the pulmonary (PF) and systemic flows (SF), the pulmonary (PR) and systemic (SR) resistances, as well as their relations according to the Fick method.

For visualization of the atrial septal defect, angiography in the RSPV was performed in the left anterior oblique view (40º) with cranial angulation (40º). The diagnostic study was completed with left ventricular angiography in the left anterior oblique view (70º) with cranial angulation (30º).

The Amplatzer occluder (Aga Medical Corporation, Golden Valley, MN, USA) was described in 1997 by Sharafuddin et al [19]. The metal used in its fabrication is a metallic alloy composed of nickel (55%) and titanium (45%), named nitinol, with a thickness of 0.004 – 0.0075 inches. The major advantage of nitinol is its exceptional resistance and high capacity to absorb energy, which makes it capable of dissipating tension 4 times more rapidly than stainless steel does [22]. The prosthesis is formed by 2 retention disks linked by one waist in a single body. The disks are available in sizes with unit variation from 4 to 20 mm, and, from that measure upwards, at every 2 mm up to 40 mm in diameter. The prosthesis is filled with polyester fiber that is highly thrombogenic.

The procedure of implantation was additionally monitored by TEE aiming at: 1) assessment of the measurement of the stretched diameter (SD) of the defect; 2) monitoring of opening and positioning of the prosthesis in the interatrial septum; 3) documentation of the occlusion of the defect; and 4) identification and quantification of the immediate residual flow when present.

The technique of implantation of the Amplatzer occluder was reported in the study by Fontes et al [20]. The choice of the diameter of the prosthesis was based on the relation between the diameter of its waist and the SD measured, which should be approximately 1:1.

The residual flow was quantified according to the classification by Boutin et al [23]. Systemic anticoagulation was performed via the arterial route, by injecting 50 IU/kg of sodium heparin, followed by the intravenous administration of cefazolin sodium at the dosage of 30 mg/kg before the procedure and repeated at 6-hour intervals 3 times more.

On the following day, 24 hours after the procedure, electrocardiography, chest radiography, and TTE were performed in addition to clinical assessment, aiming at evaluating cardiac auscultation, the electrocardiographic pattern, cardiac area (CTI), RVDD, and % RVDD, and also at detecting and quantifying residual flow.

Once the ideal position of the device on the interatrial septum and absence of severe residual flow were confirmed, the patient was discharged from the hospital and was prescribed acetylsalicylic acid at the dosage of 5 to 10 mg/kg/day. Prophylactic antibiotic therapy was recommended for infective endocarditis for 6 months in all patients and indefinitely for those with persistent residual flow [24].

The patients were followed up on an outpatient care basis at one, 3, and 12 months after the procedure, when, in addition to the clinical examination, the following tests were performed: electrocardiography, chest radiography, and TTE. In the third month after implantation, all patients underwent TEE, and, in case residual flow persisted, that examination was repeated in the 12th month.

Results

Forty-nine patients were selected for percutaneous occlusion of secundum atrial septal defect with the Amplatzer occluder, 29 (59.2%) of whom were women. The demographic data are shown in table I. Regarding the NYHA functional class, 44.9% were in functional class I, and 55.1% were in functional class II. On physical examination, all patients had a cardiac auscultation compatible with atrial septal defect, and, on chest X-ray, 85.7% had a CTI > 0.50.

On echocardiography (TTE and TEE), the atrial septal defect appeared as a single orifice in 91.8% (45/49) of the patients, as 2 orifices in 2.0% (1/49), and multifenestrated in 6.2% (3/49). The anterosuperior rim was deficient (< 5 mm) or absent in 40.6%. Paradoxical septal movement was observed in 65.9% (31/47) of the patients. Regarding the morphology of the defects with one single orifice, 71.2% had a circular shape and 28.8% had an elliptical shape. The means of the longitudinal (LD) and transverse (TD) diameters of the orifices were 14.3±5.0 mm (7.0 to 28.0) and 14.4±4.9 mm (6.0 to 26.3), respectively, and the means of the RVDD and %RVDD assessed on echocardiography were 26.5±6.0 (15.0 to 40.0) and 134.1±25.6% (86.0 to 178.0), respectively.

Through cardiac catheterization, the following relations were also assessed: QP/QS = 2.0±1.9 (1.2 – 3.5) and PR/SR = 0.06± 0.03 (0.01 – 0.14). The mean stretched diameter assessed with the measuring balloon was 19.3±5.1 mm (8.0 – 36 mm), and a good linear correlation was observed between the measurements

Table I – Demographic data of patients undergoing percutaneous closure of secundum atrial septal defect with the Amplatzer occluder

Variables	Variation*	Mean	Standard deviation	Median
Age (years)	3.4 a 56.2	19.8	15.8	13.3
Weight (kg)	16.5 a 90.0	44.3	19.6	41.0
Height (m)	1.0 a 1.8	1.4	0.2	1.5
Body surface (m^2)	0.7 a 2.1	1.3	0.4	1.3
Body mass index (kg/m^2)	13.8 a 31.2	20.5	4.5	19.3

* minimum and maximum

of the SD and of the TD ($r = 0.769 – P < 0.001$) and of the LD ($r = 0.743 – P < 0.001$).

Forty-nine prostheses were implanted with technical success in 48 patients, because one patient had 2 defects occluded with 2 devices of different sizes [25]. The only failure occurred in one adult female patient, whose defect had a thin and compliant posteroinferior rim and a poorly developed anterosuperior rim, which resulted in displacement of both disks to the RA. The diameters of the devices selected ranged from 9 to 36 mm, the most used being those of 19, 20, and 24 mm, which were used in 7 procedures each. The mean diameter of the occluders used was 20.3±4.9 mm. The relation between the SD and the diameter of the occluder was almost 1:1.

In the 3 cases with multifenestrated atrial septal defects (ASDs), we always used a single device with a diameter at least 2 mm greater than the SD, aiming at covering the total area of all orifices. No additional difficulty was observed in the implantation of the device in one case associated with aneurysm of the fossa ovalis. Replacement of the Amplatzer occluder by another of greater diameter was required in 2 patients due to deficiency or absence of the anterosuperior rim.

Right after definitive deployment of the device, color Doppler TEE showed that 54.1% of the patients had residual flow, which was classified as minimum in 11 patients, small in 11, and moderate in 4.

The mean time of fluoroscopy was 17.6±11.7 min (2.7 – 63.1 min) and that of the procedure was 73.8±30.9 min (30 – 180 min).

The only immediate complication observed in the catheterization room was the appearance of paroxysmal supraventricular tachycardia in 6.1% of the patients, which was reverted to sinus rhythm after venous injection of adenosine.

During in-hospital evolution, the electrocardiography showed a temporary alternation to junctional rhythm in 4.1% of the patients, and also a reduction in the incidence of the right bundle-branch conduction disorder (RBBCD) from 72.9% to 66.7% ($P < 0.01$). The CTI > 0.50, present in 85.7% of the patients before the procedure, decreased to 68.4% ($P = 0.016$). On echocardiography, a decrease was observed in the mean RVDD from 26.5±6.0 mm to 24.7±6.2 mm, and also in the mean %RVDD from 134.1±25.6% to 124.3±24.5%, and both differences were significant ($P < 0.001$).

Regarding the residual flow during the in-hospital phase, the percentage of complete occlusion increased to 75% of the cases, being observed in 12 patients and classified as minimum in one, mild in 8, and moderate in 3 patients. The only complication observed during that period was occlusion of the femoral artery in one patient caused by embolization of fragments of the measuring balloon, which required surgical thrombectomy.

All 48 patients were clinically assessed, the mean follow-up being 13.1±1.3 months. Regarding the evolution of the NYHA functional class, by the end of the observation period, 93.7% of the patients were in functional class I.

The evolution data of the electrocardiogram are shown in table II. Reversion to sinus rhythm was observed in patients with junctional rhythm right after implantation at one and 3 months. A decrease in the incidence of isolated RBBCD from 73.5% to 45.8% ($P < 0.001$) was noted at the end of the observation period.

The CTI > 0.50, present in 85.7% of the patients before the procedure, progressively decreased in all intervals reaching 21.3% at the end of 12 months (fig. 1).

The evolution of the residual flow, considering its percentage and magnitude, is shown in figures 2 and 3, respectively. Clinical success was observed in 95.8% (46/48) of the patients at the end of the evaluation, the 2 cases of moderate residual flow excluded. The multivariate analysis performed to assess the possible correlation of age group, sex, the QP/QS relation, and SD with residual flow at the end of the third month showed statistical significance only for the QP/QS relation ($P = 0.0348$).

The paradoxical septal movement detected on TTE, previously in 65.9% (31/47) of the patients, decreased to 10.6% (5/47) at the end of 12 months ($P < 0.001$).

Table II – Electrocardiographic data of 48 patients undergoing percutaneous closure in different periods of observation

Variables Time	Sinus rhythm %	Mean SÂQRS Circular	SÂQRS SD Circular	RAO %	RVO %	RBBCD %	RBBCD + LASDB %
Pre	93.9	66.8º	0.7º	32.7	20.4	73.5	8.2
24 hours	91.7	65.2º	0.7º	27.1	20.8	66.7	8.3
1 month	93.8	61.2º	0.6º	18.8	16.7	56.3	4.2
3 months	95.8	59.4º	0.6º	10.4	6.3	47.9	4.2
12 months	95.8	54.9º	0.5º	0	2.0	45.8	2.0

SÂQRS- electrical axis; RAO- right atrial overload; RVO- right ventricular overload; RBBCD- right bundle-branch conduction disorder; LASDB- left anterosuperior divisional block.

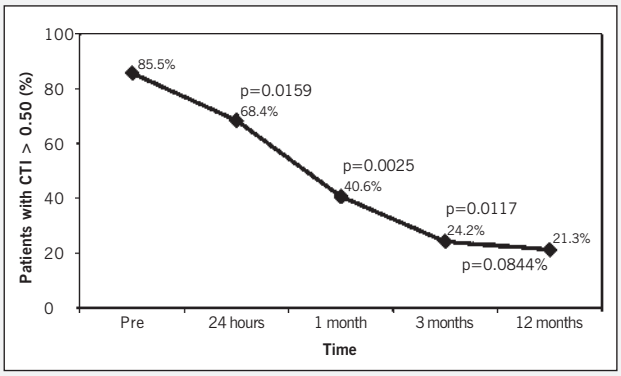

Fig. 1 - Evolution of the patients with cardiothoracic index (CTI) > 0.50. A progressive and significant reduction in the measurements of CTI is observed until the third month after the procedure.

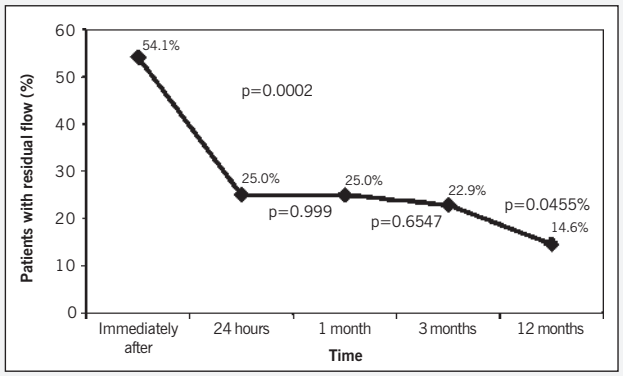

Fig. 3 - Evolution of the residual flow. Note the significant reduction in its incidence in the first 24 hours and 3 months after implantation of the occluder.

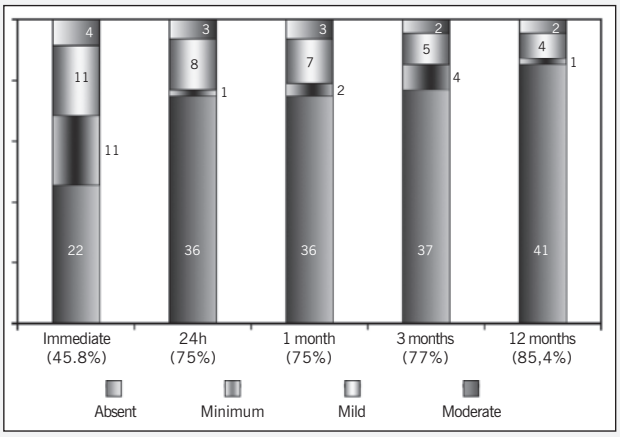

Fig. 2 - Graph of the residual flow considering its magnitude during the different periods of observation.

The measurements of RVDD (mm) obtained before implantation of the Amplatzer prosthesis and during its clinical evolution are summarized in table III. A significant reduction in RV dimensions (RVDD) occurred in the different phases of observation as compared with the values before occlusion of the defect ($P < 0.001$).

Considering the normalized values (% RVDD), we observed that 87.5% (42/48) of the patients had increased values before the procedure, while at the end of 12 months that figure decreased to 42.2% (19/45) of the patients ($P < 0.001$). A statistically significant difference in that variable was observed between the means obtained during the different periods of observation, as compared with those obtained before the procedure ($P < 0.001$). Normalization of the RV dimensions was evidenced between the third and 12th months of evolution.

When the patients were divided into 2 groups according to QP/QS relation ≥ 2 and QP/QS < 2, we observed that the evolution of the %RVDD evidenced significantly lower means (P=0.004) in patients whose relation was < 2 (fig. 4). Normalization of the %RVDD was achieved around the third month of evolution in the group with QP/QS < 2, while in those whose QP/QS > 2, normalization was achieved only 12 months after the procedure.

The same tendency was detected for the diameters of the occluders ≥ 20 mm and < 20 mm. The means of the %RVDD decreased in parallel in both groups, being significantly lower for the patients whose prosthesis diameters were < 20 mm (P=0.034). That variable reached normality in the third month of evolution in patients implanted with prostheses whose diameters were < 20 mm, while in those receiving occluders whose diameters were ≥ 20 mm, that result was not achieved until the end of the period of clinical evolution.

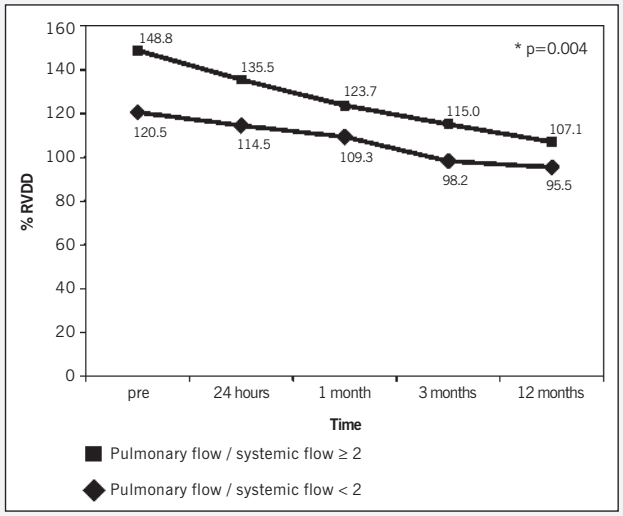

Fig. 4 - Evolution of the means of the right ventricular diastolic diameters corrected for age, weight, and height (% RVDD) in the 2 groups according to the pulmonary flow/ systemic flow relation. Normalization of the measurements was observed in the third month of follow-up when that relation was < 2; the same did not happen when that relation was ≥ 2.

Table III – Measurements of the right ventricular diastolic diameter (mm) before and after implantation of the Amplatzer occluder

Time	N of patients	Variation*	Mean	Standard deviation	Median
Pre	48	15.0 a 40.0	26.6	6.1	26.0
24 hours	47	13.5 a 40.0	24.7	6.2	24.0
1 month	45	13.0 a 36.0	22.7	5.3	22.0
3 months	45	13.0 a 33.0	20.9	4.8	20.0
12 months	45	11.0 a 33.0	19.9	4.5	20.0

* minimum and maximum

In models with the covariables, only the QP/QS relation (for RVDD, P=0.020; for %RVDD, P=0.003) and age (for RVDD, P < 0.001) showed influence on right ventricular regression.

Regarding the late complications, episodes of paroxysmal supraventricular tachycardia were observed in 4.2% (2/48) of the cases. Only one patient developed mutable atrial pacemaker after 12 months, and a small pericardial effusion was detected in another patient (TTE). The patient with complete atrioventricular block before the procedure did not require implantation of a definitive pacemaker until the end of clinical follow-up.

Discussion

Safety and efficacy of a prosthesis for occlusion of secundum atrial septal defects are directly related to the simplicity of the technique of implantation in association with the facility of repositioning and rescue, low index of residual flow, and minimum incidence of complications. In addition, other important characteristics of the device are as follows: biocompatibility of the materials, adequate profile, and absence of fractures and structural deformities during late evolution.

The results obtained in this study with 48 patients undergoing percutaneous occlusion of secundum atrial septal defect with the Amplatzer occluder were excellent in all aspects. The technical and clinical success rates were 98% and 96%, respectively, with low morbidity and no mortality.

Due to its versatility, the Amplatzer septal occluder was used in a great variety of defects, such as those with SD > 20 mm, multiple defects, associated with an atrial septal aneurysm, and those with an anterosuperior margin < 5 mm (41%). That device was also effective regardless of the geometrical form of the defect (circular or elliptical), which enlarges its indications in comparison with those of the previously developed devices [26].

In special situations, such as multiple defects with a distance between the orifices ≥ 7 mm, the use of distinct prostheses is recommended for occlusion. Prostheses with diameters 2 to 4 mm greater than the SD are recommended in defects ≥ 20 and < 30 mm, aiming at a better position and lower incidence of residual flow [27]. The use of devices with diameters ≥ 30 mm occurred only in 4.2% of the patients, in whom the so-called implantation angle in regard to the atrial septum was modified, partially releasing the distal occluder disk in the RSPV. The set was rapidly pulled to the LA and the remaining components were expanded in the usual sequence [27]. The deficient rims, particularly the anterosuperior rim, which is an important predictor of embolization of the device and genesis of residual flow [28,29], were not limiting factors for the Amplatzer occluder due to its occluding mechanism, in which the retention disks fix to the deficient rim.

Immediate complications were observed in a reduced number of patients, among which, alternation to junctional rhythm stands out in 4.1% of the cases, probably related to the compression exerted by the waist of the prosthesis on the conduction system located in the atrial septum [30,31]. In our experience, no case of displacement or immediate embolization of the occluder was observed. This was attributed to the careful selection of patients, to the mechanism of fixation of the occluder on the defect, and to the adequate choice of the diameter of the occluder in regard to the stretched diameter. The incidence of that complication requiring rescue ranged from 1.1% to 2.2% in the literature, being lower than that observed with other prostheses [32,33].

The immediate residual flow observed in 54.1% (26/48) of the patients might have been related to insufficient thrombosis or thrombosis not totally stabilized by the device itself. That hypothesis was confirmed by the fact that in 45.8% (22/48) of the patients, the residual flow was minimum or mild, and of those, 18.7% (9/48) were located in the central portion or occurred through the occluder.

The most significant alteration in residual flow occurred right after the first 24 hours, when its incidence drastically decreased to 25% (12/48) of the cases, being mainly attributed to the thrombogenic action exerted by the polyester fibers located inside the prosthesis. That was confirmed by the fact that of the 9 patients with immediate residual flow through the central part of the prosthesis, 8 showed complete occlusion on TTE before hospital discharge.

At the end of the 12th month of evolution, the overall residual flow significantly decreased from 22.9% (11/48), in the third month, to 14.5% (7/48) of the patients (P < 0.045). Of those, only 4.1% (2/48) were of a moderate degree, one of whom had received the implantation of the occluder with the greatest diameter of our case series (36 mm), and the other had multiple fenestrations.

Considering the percentage of complete closure of the defect around 12 months, which corresponded to 85.4% (41/48), we observed that the result obtained is comparable to those already reported in the literature with the Amplatzer device. Walsh et al [34] and Chan et al [35] reported complete closure after one year in more than 90% of the patients. It is important to emphasize that this report reflects the initial learning curve at our institution.

The progressive decline in the incidence of right atrial and ventricular overloads and in the persistence of RBBCD, and the displacement of the mean SÂQRS from 66.8º±7º to 54.9º±5º at 12 months were important indirect data to show the improvement in the hemodynamic conditions measured on electrocardiography. This explains why the electromechanical alterations due to the important decrease or abolition of the volumetric overload imposed to the right heart are directly related to the better conduction of the electrical stimulus originating from the sinoatrial node to the bundles in the atrial cavities and ventricles. These findings were corroborated by Veldtman et al [36] using the CardioSEAL prosthesis and by Dhillon et al [37] using the Amplatzer occluder.

Regarding the radiological alterations, a significant decrease in patients with CTI > 0.50 has been shown as early as 24 hours after occlusion of the defect, which demonstrates directly the rapid involution of the right chambers right after closure of the atrial septal defect with the device.

The right ventricular dimensions expressed by RVDD and %RVDD significantly decreased right after the first 24 hours (P < 0.001), due to the sudden decrease in the volumetric overload of the right chambers and their rapid adaptation to the new hemodynamic conditions. Normalization of those measures occurred gradually between the third and 12th months after the procedure.

It is also important to emphasize the relation found between the QP/QS and the %RVDD. The patients with QP/QS < 2 had significantly lower %RVDD values in all periods of observation as compared with those whose QP/QS was ≥ 2. Normalization of

the RV dimensions was reached in the third month among patients whose QP/QS was < 2. In patients whose QP/QS was ≥ 2, normalization only occurred after 12 months (P=0.004).

The same was observed when the relation between the diameter of the occluder used and the %RVDD was assessed. Normalization of the %RVDD in the group implanted with the smaller occluders (< 20 mm) occurred around the third month, while in the cases with larger occluders (≥ 20 mm), the RV dimensions normalized only after 12 months (P=0.034).

Considering those results, we can state that in patients with a high QP/QS, great blood flow directed in the left-to-right direction, and defects of marked dimensions, normalization of the %RVDD should occur in a more prolonged interval, probably due to the greater distension of the right ventricle observed in these situations.

Due to the low incidence of residual flow observed at the end of one year, one could not investigate whether the reduction in those measures occurred similarly in cases with complete closure of the defect and in those with persistent residual flow.

In our experience, late complications occurred in few patients, paroxysmal supraventricular tachyarrhythmia being the most frequent (4.2%). Detection on routine TTE of pericardial effusion of small proportions in only one patient after 3 months of evolution has not been totally elucidated, because the procedure was uneventful and no fluid was evidenced in the pericardial space at any time.

Another advantage of the Amplatzer occluder was the lack of immediate perforation or late erosion of the atrial wall due to the round profile of the occluding disks [38].

In conclusion, the results obtained in this study highlight the efficacy of the Amplatzer occluder for occluding secundum atrial septal defects, translated by the high percentage of technical success (97.8%) and the rapid and significant involution of the residual flow in the first 24 hours and between the third and 12th months of evolution. A significant reduction in the echocardiographic dimensions of the right ventricle was observed between the third and 12th months of evolution. The safety of that device was identified by the lack of displacement or embolization, and by the low incidence of arrhythmias.

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