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Evaluation of the results of percutaneous closure by means of the Amplatzer device in pediatric patients with intra-auricular communication (IAC)

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Abstract

Objective: *To describe the results of percutaneous closure by means of the Amplatzer Septal Occluder (ASO) device in pediatric patients with intra-auricular communication (IAC).* **Materials and Methods:** *Descriptive transversal study in patients submitted to percutaneous closure of IAC from March 2005 to March 2013. Patients aged < 16 years, weight > 6 kg, IAC type ostium segundum, and patent foramen ovale, with border separations borders > 5 mm, and absence of coexisting pathology were included in the study. We excluded from the study children with severe pulmonary blood pressure/arterial hypertension. Descriptive statistics with the SPSS v. 20.0 statistical software package.* **Results:** *We included in the study 28 patients, feminine gender (n = 19, 68%), median age = 8 years (range, 4-14), weight 30.7 kg (range, 15-69). New York Heart Association (NYHA) functional class I (n = 21, 75%), II (n = 7, 25%). Median IAC size, 15.50 mm (range, 5-25), and a median ASO size of 17.54 mm (range, 8-28). After ASO placement, 100% presented NYHA I at one month, cardiac murmur (n = 2, 7.1%), cessation of cardiac murmur at month 6 (n = 28, 100%), without evidence of arrhythmias at one month 100%, residual short circuit at 24 hours (n = 4, 14%), complete occlusion at month 6 (n = 28, 100%), normalization size of VD, and cessation of tricuspid insufficiency 100% at one year. Complications included minimal bleeding during the procedure (n = 2, 7%), transitory cephalea (n = 5, 18%), and dysautonomia (n = 1, 4%).* **Conclusion:** *Percutaneous closure of IAC of children fitted with the ASO device is safe and exhibits good results.* (Gac Med Mex. 2015;151:436-42)

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Introduction

Congenital heart defects are the most common malformations at birth, with a prevalence of 8 cases for every 1000 live births and newborns' overall survival of about 85%[1-4]. Intra-auricular communication (IAC), also known as atrial septal defect (ASD), which is defined as abnormal communication between both atria, is 2 to 3 times more common in females than in males[2,5]. Infants and children with ASD are usually asymptomatic or exhibit cyanosis during crying. At physical examination,

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body habitus is usually thin (weight below the 10th percentile), with grade II to III/IV systolic murmur heard at the superior sternal border, with a fixed split second heart sound[6-7].

Communication closure is indicated when the Qp/Qs ratio higher than 1.5 with right cavities' volume overload[8].

Therapeutic cardiac catheterization allows for this condition to be successfully treated with low morbidity[9-11]. ASD was first described by King and Mills in 1976. The technique became popular thanks to the works by Lock J, et al. in the Boston Children's Hospital using Rashkind's device modified to close different cardiac defects[12].

Doctor Kurt Amplatz, radiology professor in Minnesota, designed the Amplatzer septal occluder 20 (ASO20), built with a nitinol mesh with elasticity properties, thermal memory material and self-centering possibility[13-16].

The advantages of this therapeutic option with the Amplatzer device are clear: it doesn't require sternotomy, avoids the need for extracorporeal circulation and blood transfusions and reduces associated morbidity, length of hospitalization and daily activities disruption for the child and the family[15,17,18].

The purpose of this study was to describe short and mid-term results of percutaneous closure with the Amplatzer device in pediatric patients with congenital heart disease of the ASD type.

Material and methods

This was a cross-sectional, descriptive study conducted at the IMSS CMNO High Specialty Medical Unit Pediatrics Hospital, a reference hospital for the West of the country; it included patients undergoing ASD percutaneous closure with an Amplatzer device from March 2005 to March 2013.

Selection criteria

Patients younger than 16 years, weighing more than 6 kg, echocardiographically diagnosed with ASD and admitted to the hospital's Cardiology Department Hemodynamics Center to have a percutaneous closure with Amplatzer practiced were included. Patients with clinical and echocardiographic evidence of severe pulmonary arterial hypertension and with incomplete medical records, or children whose parents did not sign the informed consent for the placement of the device were excluded.

Criteria for Amplatzer device placement

Patients with ostium secundum (OS)- and oval foramen-type ASD with presence of separation borders with neighboring structures larger than 5 mm and with adequate consistence were defined as candidates; anatomical planes and structures of the aorta (anterosuperior ridge), right and left atrioventricular plane (anteroinferior ridge), superior vena cava (posteroposterior ridge) and inferior vena cava (anteroinferior ridge), as well as pulmonary veins and coronary sinus debouchment were assessed; measurements were made with transesophageal echocardiography, and the absence of coexisting conditions requiring surgical procedures was determined.

Study development

For the collection of the required data from physical and electronic patient files, a previously designed report form, structured according to the study variables, was used. This instrument was intended to collect the most relevant information for subsequent statistical analysis and to establish conclusions and recommendations.

Clinical and echographic parameters of the control evaluations performed at the moment the device was placed, at 24 h post-placement, at one month, at six months and at one year were assessed.

Procedures and study development

All procedures were carried out under general inhaled anesthesia, which was applied by a pediatric anesthesiologist; balanced or intravenous general anesthesia (ketamine, fentanyl and a neuromuscular blocking agent) was used. For the ASD closure, a transesophageal guide was used, with a multiplanar probe connected to a Philips echocardiography equipment model 2136669, OmniPlane II and OmniPlane III transductor. A transesophageal echocardiogram was performed during the procedure. ASOs with selected sizes were used, according to the diameter and type of defect. The method employed was based on adjusting the diameter of the defect to the waist of the balloon, obtained by transesophageal echocardiography and fluoroscopy.

All patients were administered antibiotic therapy (amoxicillin 50 mg/kg/body weight) during the procedure and two additional doses every 8 h. After recovery in an area adjacent to the Hemodynamics Center, the

Table 1. Clinical and demographic characteristics of pediatric patients with ASD managed with Amplatzer device implantation

Characteristics	Study group (n = 28)
Gender	
Female, n (%)	19 (68)
Male, n (%)	9 (32)
Age, median (range)	8.5 (4-14)
4-7 years, n (%)	11 (39)
8-11 years, n (%)	11 (39)
12-14 years, n (%)	6 (22)
Weight, median (range)	30.75 (15-69)
15-24 kg, n (%)	8 (29)
25-34 kg, n (%)	11 (39)
35-44 kg, n (%)	3 (11)
45-55 kg, n (%)	4 (14)
> 55 kg, n (%)	2 (7)

Table 2. Clinical evolution initial characteristics in CMNO Pediatrics Hospital ASD-carrier patients with Amplatzer device implanted

Characteristics	Frequency (n = 28)
Type of ASD	
Foramen ovale, n (%)	13 (46)
OS, n (%)	15 (54)
Functional class	
Class I, n (%)	21 (75)
Class II, n (%)	7 (25)
Presence of murmur, n (%)	25 (89)
Murmur grade	
Grade I, n (%)	12 (48)
Grade II, n (%)	13 (52)
Murmur location	
Systolic, n (%)	25 (100)
Diastolic, n (%)	0 (0)
Rhythm disorder, n (%)	1 (4)
Conduction disorder	
CRBBB, n (%)	4 (14)
IRBBB, n (%)	6 (21)
None, n (%)	18 (65)

patients were transferred to the hospitalization area for routine clinical observation until complete recovery, for a maximum period of 24 h, according to each patient's assessment.

At the moment of discharge, prophylaxis for bacterial endocarditis was indicated for 6 months, in addition to acetylsalicylic acid (2-5 mg/kg/d at a maximum dose of 100 mg) for the same period of time and with the recommendation to avoid contact sports for one month.

Sample size calculation

No sample size calculation was made, since all patients with the Amplatzer device who met the selection criteria were included. A non-random sampling of consecutive cases during the study period was performed.

Statistical analysis

Qualitative variables were analyzed using frequencies and percentages, and quantitative variables, with medians and ranges (minimum and maximum). An electronic database was managed with the Microsoft Office 2010 Excel program, and the SPSS software, version 2.0 for Windows, was used for the data analysis.

Ethical considerations

The study complied with the international research principles established in the Declaration of Helsinki of 1975. The parents or legal guardians of the children were asked to sign the informed consent form for the placement of the device. The protocol was approved the hospital's 1302 Local Research and Ethics Committee, with registration number R-2013-1302-41.

Results

Here, we present an analysis of the results obtained in the study conducted at the CMNO UMAE Pediatrics Hospital over the period encompassed between March 2005 and March 2013. A total of 32 patients diagnosed with ASD undergoing percutaneous closure of the defect were identified, out of which 4 were excluded, thus leaving 28 eligible patients.

Table 1 shows the population's characteristics: predominance of the female gender is observed (68% of cases), especially among schoolchildren aged up to 11 years, which represent most part of the population; median weight was 30.75 kg.

Table 2 shows that 75% of the patients had NYHA functional class I and 89% had murmur (grade II: 52% vs. grade I: 48%), with systolic location in 100%; 4% had rhythm disturbances and 35%, conduction disorders; out of these, 14% had complete right bundle-branch block (CRBBB), and 21%, incomplete (IRBBB).

Table 3. Echocardiographic transesophageal characteristics in CMNO Pediatrics Hospital ASD-carrier patients prior to Amplatzer device implantation (March 2005-March 2013)

	Frequency (n = 28)
RV size	
Normal, n (%)	15 (54)
Dilated, n (%)	13 (46)
Margins	
Sufficient, n (%)	26 (93)
Insufficient, n (%)	2 (7)
Pulmonary artery pressure	
Normal, n (%)	27 (96)
Mild pulmonary hypertension, n (%)	1 (4)
Mitral valve insufficiency	
Yes, n (%)	0 (0)
No, n (%)	28 (0)
Tricuspid insufficiency	
Yes, n (%)	2 (7)
No, n (%)	26 (93)

As shown in table 3, 54% of the patients had a right ventricle (RV) with normal characteristics, with sufficient margins in 93% of cases, normal pulmonary artery pressure in 96% and data consistent with tricuspid insufficiency in 3%.

Table 4 shows that 100% of patients had functional class I one month after the device was placed, 7.1% continued with heart murmur at one-month follow-up, with murmur dissapearing in 100% of patients at 6-month follow-up, and 100% remained free of cardiac arrhythmias throughout the follow-up.

Table 5 shows the patients' echocardiographic evolution: 14% remained with short circuit 24 h after the device was placed and 4% at one month. At 6 months, the closure was successful in 100% of patients. RV dimensions were normalized in 100% of the patients at 12-month follow-up, with no data consistent with tricuspid insufficiency in 100% of the patients.

Table 6 shows that 7% of patients had bleeding at the moment of the procedure, which constitutes a minor complication. No complications were reported 24 h after the procedure. There were no hematomas, tamponade, hypotension or cardiorespiratory arrest.

Figure 1 shows the device when it is inserted, at the moment of its release, and the correct location in the atrial septum.

Discussion

Treatment of congenital defects using the endovascular route is an old ambition of cardiologists. Currently, ASD percutaneous closure is a commonly used technique in many centers of our country and the rest of the world. The evolution of materials has enabled the emergence of last-generation devices, with ASO standing out.

In the present work, safety and efficacy of the ASO device have been assessed and, among our results, the higher proportion of female sex patients (2/3 parts vs. 1/3 of male patients) should be highlighted. This is characteristic in ASD patients: the literature reports that this heart condition is 2-3 times more common in females than in males. Median weight is also consistent with the multi-center MAGIC trial[2,5,19].

Table 4. Clinical evolution of CMNO Pediatrics Hospital ASD-carrier patients with Amplatzer device implanted (March 2005-March 2013)

Variable	Before	1 month	6 months	12 months
Functional class				
I	21 (75)	28 (100)	28 (100)	28 (100)
II	7 (25)			
Cardiac murmur				
No	3 (11%)	26 (92.9%)	28 (100%)	28 (100%)
Yes	25 (89%)	2 (7.1%)		
Murmur grade				
Grade I	12 (43%)	2 (7.1%)		
Grade II	13 (46%)			
Arrhythmia				
No	27 (96)	28 (100)	28 (100)	28 (100)
Yes	1 (4)			

Table 5. Echocardiographic evolution of CMNO Pediatrics Hospital ASD-carrier patients with Amplatzer device implanted (March 2005-March 2013)

	Before	24 h	1 month	6 months	12 months
Short circuit					
Yes, n (%)	28 (100)	4 (14)	1 (4)	0 (0)	0 (0)
No, n (%)	0 (0)	24 (86)	27 (96)	28 (100)	28 (100)
RV dimensions					
Dilated, n (%)	13 (54)				0 (0)
Normal, n (%)	15 (46)				28 (100)
Mitral insufficiency					
Yes, n (%)	0 (0)				0 (0)
No, n (%)	28 (100)				28 (100)
Tricuspid insufficiency					
Yes, n (%)	2 (7)				0 (0)
No, n (%)	26 (93)				28 (100)

With regard to the type of ASD, in our study it was clear that the highest proportion of patients had OS-type ASD, which accounted for more than half of cases, in comparison with foramen-type ASD; these are similar figures to those reported in the literature, where OS-type ASD represents approximately 75% of cases[2,5,20,21].

With regard to initial clinical and electrocardiographic findings in our patients, most of them were in NYHA functional class I and only a small proportion had

Table 6. Distribution of studied patients according to clinical complication during the procedure and the first 24 h after percutaneous closure of septal defect with an Amplatzer device

Clinical event	Procedure	First 24 h
Bleeding, n (%)	2 (7)	0
Transient headache, n (%)	0 (0)	5 (18)
Dysautonomia	0 (0)	1 (4)

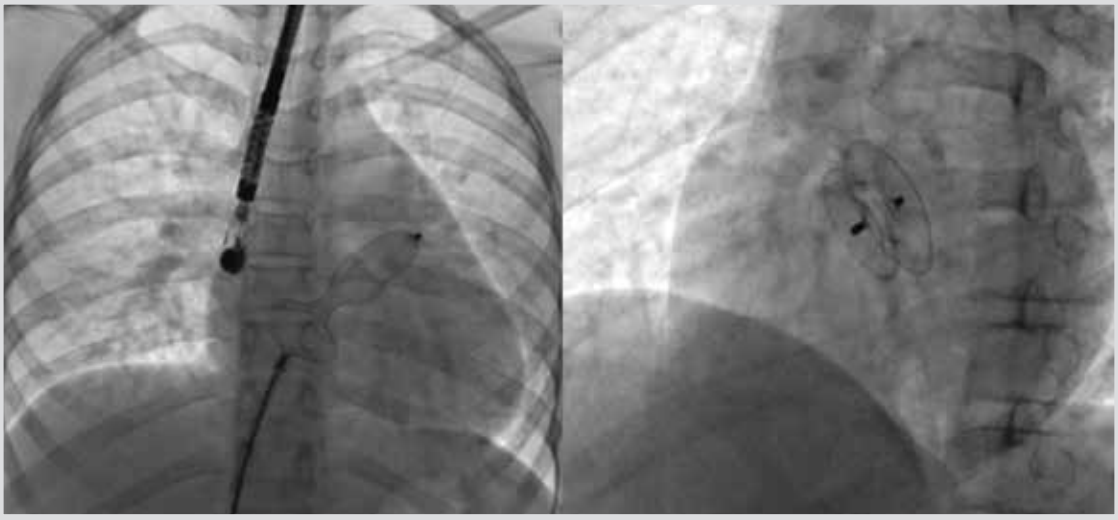

Figure 1. *Images of the moment of the Amplatzer device release and of a correctly positioned device in the atrial septum.*

NYHA functional class II, almost all with mild grade I or II systolic murmur present. Noteworthy, 3 patients had no murmur: two had fixed split of the second cardiac sound and one tachyarrhythmia, and the ASD diagnosis was made with trans-thoracic echocardiogram. With regard to the conduction disorders found, a small proportion had a right bundle-branch block. All this is consistent with the description of clinical and electrocardiographic findings reported by other authors[2,5,7,8,20,21].

Within the initial echocardiographic findings, RV dilation was observed in little less than half the patients, with sufficient margins practically in all patients; there was only one case of mild pulmonary hypertension (pulmonary artery systolic pressure of 40 mmHg) and findings consistent with tricuspid insufficiency in 7% of the cases.

In our study, different device sizes were used, but the most widely employed was number 20 (6 cases). The election of the device adequate size in based on measurements made with transesophageal echocardiography (TEE) and balloon catheter occlusion. In general, a device is used with a waist slightly larger (1 or 2 mm) than the defect diameter[14,22].

Of the 29 devices attempted to be inserted, 28 were successfully placed and only one patient had an unsuccessful placement attempt; this patient, with a large-diameter ASD and unfavorable anatomy, had a previous surgery for large vessels transposition and later underwent surgery to correct the defect. One patient required balloon catheter support due to a fenestrated ASD; this support was used at the moment of alignment of the device with the inter-atrial septum and a vertical position was obtained in relation to the septum.

With regard to clinical and echocardiographic findings after the Amplatzer device implantation, favorable changes were shown. Clinical improvement was observed in all patients, who showed a NYHA I functional class, as well as RV dimensions normalization and absence of tricuspid insufficiency at 1-year follow-up.

Complete closure without short circuit was found in most patients at the moment of the procedure; in a small proportion there was a short circuit in the immediate trans-thoracic echocardiogram. During the echocardiographic follow-up, one patient had a leak one month after the device was placed, but there was complete closure in all patients at 6-month follow-up. This is consistent with Munayer-Calderón, et al. findings, who report 92.5% complete occlusion at the moment of intervention and 100% occlusion at 6 months, but is lower than the figures obtained by Zabala Argüelles, et al. or by the MAGIC multi-center trial, with reports of 96-100% immediate occlusion. At echocardiographic follow-up, one patient had a separation of the left disk surface[8,15,19].

All complications occurring to intervened patients in our study were minor, and the following should be highlighted: two patients with bleeding from the puncture zone, similar to what Parra-Bravo, et al. and Roel reported, and 5 patients with transient headache and one with dysautonomia occurring after the device was placed, similar to findings by Munayer-Calderón, et al., who reported headache in 9.5% of patients[8,23-25].

Finally, in 75% of patients, hospital length of stay lasted 48 h, which is, on average, similar to figures reported in the literature.

The experience obtained in the present investigation indicates that this procedure has a low rate of minor complications and that there is complete closure of the defect without further complications.

Conclusions

In our series of cases, with 28 successfully implanted devices, mid-term results are encouraging; in 18% of the cases there were minor complications, which resolved favorably during the follow-up.

An improvement was observed in clinical and echocardiographic evolution during the follow-up, as well as a complete occlusion in all patients.

In conclusion, this procedure can be considered a good alternative for the treatment of ASD.

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Conflicts of interest

The study has no conflicts of interest.

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