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Percutaneous *versus* Surgical Closure of Atrial Septal Defects in Children and Adolescents

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Abstract

Background: There is a scarcity of data comparing percutaneous and surgical closure of the secundum atrial septal defect (ASD).

Objectives: Assessment of safety and efficacy of both methods of treatment in a referral center affiliated with the Ministry of Health.

Methods: Observational, prospective, non-randomized study of two cohorts of children and adolescents younger than 14 years, treated by catheterization or surgery. Data was collected prospectively in the percutaneous group (A) and retrospectively in the surgical group (B).

Results: A total of 75 patients (pts) were enrolled in group A from April 2009 to October 2011 and 105 pts were treated in group B from January 2006 to January 2011. Age was older and weight was higher in group B and the ASD diameter was similar in both groups. Technical success was achieved in all procedures and there were no deaths. Complications (most minor) occurred in 68% of group B and 4% of A (p < 0.001). Rates of total occlusion or non-significant residual shunts were similar in both groups. Median hospitalization time was 1.2 days in group A and 8.4 days in group B (p < 0.001).

Conclusion: Both treatment modalities are safe and effective, showing excellent outcomes. However, the percutaneous treatment has lower morbidity and shorter in-hospital stay length. These observations support the concept that percutaneous treatment of atrial septal defects should be regarded as the method of choice to manage selected patients with this condition (Arq Bras Cardiol. 2013;100(4):354-361).

Keywords: Heart Defects, Congenital; Heart Septal Defects, Atrial / surgery; Catheterization.

Introduction

The secundum atrial septal defect (ASD) results from a deficiency in the embryological development of the septum primum in the interatrial septum (IAS). This anomaly corresponds to 6-10% of all congenital heart defects, and is more prevalent in females, with a ratio of 2:1[1,2].

ASD treatment is indicated in cases when pulmonary flow (Qp) exceeds systemic flow (Qs) by > 50% (Qp:Qs > 1.5:1), indicating hemodynamic defect characterized by increased right ventricular dimensions on echocardiography[1,2]. Currently, most patients with this condition can be safely and effectively treated by percutaneous intervention. Due to its low relative prevalence and institutional preference for surgical or percutaneous closure, there are no randomized trials in the literature comparing both techniques. In nonrandomized studies and in a meta-analysis, the surgical approach showed more frequent and significant complication rates[3-9].

For these reasons, interventional catheterization has been used as a therapeutic modality of choice for ASD occlusion in most centers worldwide. In Brazil, there is still some resistance on the part of the medical community, specialized in indicating percutaneous treatment for ASD, especially in children. Moreover, this procedure is not covered by the Brazilian Unified Health System (SUS), which makes its assessment on a large scale difficult. Even with these limitations, several groups in Brazil have been using this technique in the supplementary health system for over 15 years with consistent and reproducible results using different prostheses[5,10-16].

This study aims to compare the safety and efficacy between the percutaneous and surgical closure of ASD in children and adolescents treated in a center of excellence connected with the Ministry of Health (MH) in Brazil.

Methods

Observational, prospective, non-randomized study of two cohorts of children and adolescents younger than 14 years with ASD, consecutively treated through interventional catheterization or conventional cardiac surgery. The age

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of cohort of 14 years was arbitrarily set due to institutional criteria, which treats patients older than that age in an adult cardiology ward. The patients in the percutaneous group were treated during the triennium 2009-2011 as part of a project approved and funded by the Brazilian MH to evaluate and incorporate new technology in one of its centers of excellence[17]. The costs of prostheses and hospitalizations were covered by MH Project.

In this group, data were collected prospectively and the results were compared with those observed after treatment by conventional surgery in the same hospital, during a contemporary period of the last five years (2006 to 2011). In the surgical group, data were collected retrospectively by analyzing patients' records. After approval of the project by the MH and its start in 2009, patients were allocated to one of the two groups according to the preference of the attending physician. Before 2009, the treatment offered to patients in the hospital care philanthropic project was exclusively surgical.

The study was approved by the research ethics committee of the Hospital. Parents or guardians signed an informed consent form before all procedures. In the surgical group, the standard institutional consent form was used, not requiring specific consent for the study as it consisted of collecting data from medical records.

The indication for ASD repair was the presence of increased right chambers on echocardiography[18,19], which also assessed the size of the defect through transthoracic or transesophageal approach. The criteria for inclusion in the percutaneous group were the presence of secundum ASD favorable for percutaneous closure evaluated by transesophageal echocardiography, age younger than 14 years and absence of associated heart diseases requiring surgical correction. The surgical group included patients with secundum ASD (favorable or unfavorable for percutaneous approach) with no other significant defects associated with age and younger than 14 years, referred for surgery at the discretion of the attending physician. Exclusion criteria for both groups were weight < 8 kg (reflecting the standard practice of treating ASD in patients whose weight is > 8-10kg) and unfavorable hemodynamic calculations for defect closure.

Patients in the percutaneous group with two ASDs and distant from each other that needed more than a device for occlusion were excluded due to the economic implications of the implant of more than one prosthesis. Patients with two adjacent ASDs that could be occluded with only one prosthesis; patients with two distant ASDs, but in whom the smallest defect was < 4 mm (therefore with no clinical impact); those with cribriform IAS with multiple small defects that could be occluded with only one prosthesis and simple additional defects that could be treated by catheterization (e.g., patent ductus arteriosus or vascular malformation) were not excluded. Patients with large ASDs that required large devices for the size of the patient with risk of interference with atrioventricular valve function, pulmonary venous or coronary sinus drainage were excluded. Patients with deficiency of more than one border (usually contralateral) around the defect, usually accompanied by thin and distensible IAS, were also excluded from the percutaneous group and included in the surgical group. Patients not treated by conventional surgical techniques, such as thoracoscopy, were excluded.

The patients were catheterized following the routinely used technique[5,9,20,21]. All procedures were performed under general anesthesia with assisted mechanical ventilation. The right or left femoral vein was the preferred venous access route. In a patient with left isomerism and absence of the hepatic portion of the inferior vena cava, transhepatic access was used. After venipuncture, heparin was administered at a dose of 50-100 U/kg, as well as prophylactic antibiotics (Cefuroxime 30-50 mg/kg, three doses). Two-dimensional, and in some cases, three-dimensional transesophageal echocardiography (TEE) was used to estimate the native and stretched (when necessary) diameter of the defect and to aid in the positioning and release of the chosen prosthesis. The following prostheses were used: Amplatzer ASO and cribriform (AGA Medical Corp., Golden Valley, Minnesota, USA)[4,22], Figulla ASD and PFO (Occlutech GmbH, Jena, Germany)[23], Atriasept / Intrasept Cardia (Cardia Inc., Eagan, USA)[24], Helex Septal Occluder (WL Gore & Associates, Newark, USA)[25,26] and Cera (Lifetech Scientific Co., Shenzhen, China). All of them are registered with the National Health Surveillance Agency (Anvisa).

When the borders of the defect were considered thick enough for adequate prosthesis anchorage, the stretched diameter technique was not used and the choice of prosthesis waist diameter was estimated to be 20 to 30% larger than the original ASD one measured at TEE. When necessary, the "stop flow" technique was employed to determine the stretched diameter, thus selecting prosthesis of which waist was of 1-2 mm larger than the stretched one.

The self-centering prostheses (Amplatzer ASO, Figulla ASD, Cardia and Cera) with central waist were used in most cases. The prostheses Helex, Figulla PFO, Cardia Intrasept Double-Rounded or Amplatzer cribriform that were not self-centering were selected in the presence of multifenestrated IAS, being implemented through the most central orifice. The Helex prosthesis was also occasionally used in single and central defects < 10-12 mm. When there were two ASDs, self-centering prostheses were used implanted in the largest defect (usually anteroposterior) with additional ASD closure (usually posteroinferior) due to coverage of the discs around the central waist. Two surgeons performed the percutaneous procedures or supervised training residents in all cases.

Surgical treatment was performed by standard techniques with cardiopulmonary bypass (CPB). The technique used was the direct suture of the orifice or the interposition of bovine pericardium flap or homologue tissue, according to the size of the defect and the surgeon's preference. Three surgical teams performed the procedures, one of which was responsible for over 90% of cases.

After the percutaneous procedure, patients were transferred to the intensive care unit (ICU) when the weight was < 10 kg or routine recovery room. After the surgical procedure, patients recovered in the ICU as usual. An echocardiogram was performed at the time of hospital discharge and at 1, 6 and 12 months after the percutaneous procedure and at discharge and between six months and one year after surgery. Aspirin (5.3 mg / kg / day) was administered for six months to patients who received prostheses.

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Technical success was defined as successful prosthesis implantation. Effectiveness was assessed by total occlusion rates or presence of residual flow with no hemodynamic impact (< 4 mm) before hospital discharge and/or during follow-up. Safety was assessed by the occurrence of combined major and minor complications and adverse events during hospitalization.

Complications were classified into major and minor, with some modifications, as shown in previous publications[4]. Major complications were the occurrence of death, cerebral embolism, cardiac perforation with tamponade, endocarditis, need for reintervention (surgical or percutaneous), arrhythmias requiring permanent pacemaker or long-term antiarrhythmic drugs, pleural or pericardial effusion requiring surgical drainage and surgical intervention due to device embolization. Minor complications included prosthesis embolization with percutaneous removal, cardiac arrhythmia not requiring prolonged treatment, hematoma at the venous access site, retroperitoneal hematoma not requiring intervention and pericardial effusion with clinical treatment. Additionally, anemia requiring blood products, non-cardiac infection, hemodynamic disturbances requiring inotropic support and varied respiratory complications (pulmonary edema, laryngitis) were also considered minor complications.

Statistical analysis was performed using Sigmastat software, release 2011. Data are shown as absolute values and frequency, and mean and standard deviation or median and range according to the sample distribution. The Chi-square or Fisher's test was used to compare frequencies and the Student's *t* test or Mann-Whitney test was used to compare the means or medians. P values ≤ 0.05 were considered statistically significant.

Results

From April/2009 to October/2011, 75 patients were prospectively allocated in the percutaneous group (group A). The surgical treatment group (group B) consisted of 105 patients treated between January 2006 and January/2011. The age and weight of patients in the percutaneous group were significantly higher than in the surgical group (94.7 ± 45.8 *versus* 57.1 ± 39.8 months and 27.9 ± 15.2 *versus* 18.6 ± 11.1 kg). Other demographic variables, shown in Table 1, were similar in both groups. The stretched diameter measured by balloon sizing was used in the percutaneous intervention group in 19 patients (25%). The presence of multiple defects or multifenestrated septum was 18% and 14% in Groups A and B, respectively. The mean pulmonary artery pressure was normal in both groups.

Technical success was observed in all procedures. In percutaneous procedures, the Amplatzer ASO device was used in 45 cases (60%), CERA in 17 (23%) and Helex in eight (11%). The five remaining patients received Figulla PFO, Cardia Atriasept Double-Rounded PFO, Cardia Intrasept Double-Rounded, Cardia Atriasept and Amplatzer cribriform devices. Three patients (4%) patients had simple additional heart defects that were successfully treated during the same procedure (two PDAs and a pulmonary arteriovenous fistula). In the surgical group, 50 patients (48%) had their defect repaired through minithoracotomy access, 45 (43%) through classical thoracotomy and 10 patients (9%) through other incisions. Seventy defects (66%) were repaired by direct suture

and 35 (34%) by interposition of homologous or heterologous graft. One patient had mild pulmonary valve stenosis that was corrected in the same procedure (commissurotomy). Table 2 shows the procedural data in both groups.

Major and minor complications occurred in 70 patients (67%) in the surgical group and in three patients (4%) from the percutaneous group (p < 0.001). Major complications in the surgical group occurred in 17 patients and minor in 53. There were no deaths. Data related to complications are shown in Table 3.

In group A there were three transient atrioventricular blocks after device implantation. Corticoids were needed in two of them. One patient required prosthesis removal (Helex), which changed its position after locking migrating downward to the coronary sinus. After a three-month period another procedure was performed, in which new prostheses were implanted (Amplatzer) without complications. The other two showed subsequent stabilization, with no need for device exchange. Patients returned to sinus rhythm after approximately 10 minutes. None of the patients required the use of pacemakers or needed ICU admission. There were no other major or minor complications in the percutaneous treatment group. Of this group, three patients were referred to the ICU due to weight < 10 kg for a mean period of 12 hours.

In group B, ten patients had cardiac arrhythmias including three with ectopic junctional tachycardia, three with atrial fibrillation, two with 1st degree AV blocks, one with sinus bradycardia and one with low junctional rhythm. Nine patients required therapeutic intervention, with a temporary pacemaker being implanted in five and/or drug treatment in seven and/or electrical cardioversion in two. Pulmonary edema requiring diuretics occurred in six patients. Five patients had pleural or pericardial effusion postoperatively and three required surgical drainage. Infectious fever occurred in eight patients: two with surgical wound infection, three with urinary tract infection, one with acute gastroenteritis, one with bronchopneumonia and another undetermined case. Anemia requiring postoperative transfusion was observed in 33 patients (30%). Twenty patients (18%) required vasoactive drugs such as adrenaline and/or milrinone for hemodynamic stabilization. All patients required ICU admission with a mean time of hospitalization of 1.6 ± 1.3 days.

The patients were hospitalized for a mean of 1.2 days (1-3 days) after the percutaneous procedure and 8.4 days (5-100 days) after surgical intervention (p < 0.001). The patient with prolonged hospitalization (100 days) was 22 months old, weighed 9.8 kg and had several complications such as arrhythmia, need for vasoactive drugs, pleural effusion requiring surgical drainage and infection.

The defect occlusion rate was similar in both groups. In group A, ten patients (13%) had residual flow on echocardiography at discharge. Of these ten patients, two had small additional ASDs (2 and 4 mm) distant from the larger ASD occluded by the prosthesis, purposely left uncovered due to lack of hemodynamic significance of the defects. All patients in Group A were reassessed at a median follow up of 12 months (3-30 months). During this period, the right ventricle returned to normal size for age in spite of the persistence of residual flow by additional ASDs. The remaining eight patients had minor or small immediate residual flow (< 2 mm) that disappeared during the same follow-up period.

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Table 1 – Demographic data of patients and characteristics of atrial septal defect (ASD)

	Group A (75 pts)	Group B (105 pts)	p
Age (months)	94.7 ± 45.8	57.1 ± 39.8	< 0.001
Weight (kg)	27.9 ± 15.2	18.8 ± 11.1	< 0.001
Male sex	31 pts (41%)	43 pts (41%)	NS
Genetic syndromes	3 pts (4%)	9 pts (8%)	NS
ASD single diameter (mm)	12.5 ± 4.5	14.1 ± 6.6	NS
Multiple ASD /MF	14 pts (18%)	15 pts (14%)	NS

ASD: atrial septal defect; multiple ASD: septum with two orifices; ASD single diameter: original diameter of single ASD (non-stretched); MF: multifenestrated septum; kg: kilograms; pts: patients.

Table 2 – Procedural data: techniques and prostheses used

	Group A (N = 75 pts)	Group B (N = 105 pts)
ASO CIA	45 (60%)	-
CERA CIA	17 (23%)	-
Helex	8 (11%)	-
Other prostheses	5 (7%)	-
Simple additional lesions	3 (4%)	1 (1%)
Mini-thoracotomy	-	50 (48%)
Classic thoracotomy	-	45 (43%)
Direct suture	-	70 (66%)
CPB time (min)	-	32.0 ± 11.5

ASO CIA: Amplatzer prosthesis; CPB: cardiopulmonary bypass; CERA CIA: CERA prosthesis; pts: patients.

Table 3 - Major and minor procedure complications

	Group A (N = 75 pts)	Group B (N = 105 pts)	p
Total complications	3 (4%)	70 (68%)	< 0.001
Major complications	0	4 (4%)	NS
Need for reintervention	-	1 (1%)	
Pleural/pericardial effusion with surgical drainage	-	3 (3%)	
Minor complications	3 (4%)	66 (63%)	< 0.001
Arrhythmias	3 (4%)	10 (9.5%)	
Pleural/pericardial effusion without surgical drainage	-	2 (2%)	
Noncardiac infections	-	8 (7%)	
Anemia that required blood products	-	33 (30%)	
Inotropic support	-	20 (18%)	
Diverse respiratory pictures	-	10 (9.5%)	
Median hospitalization time (days)	1.2	8.4	< 0.001

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No patient required additional procedures for residual flow management in group A and there were no complications in the follow-up period. In group B, four patients (4%) had residual flow after surgery, which required surgical intervention in one of them due to flap dehiscence. The flow was considered unimportant in three of them (< 2 mm). During a median follow-up of 24 months (6-60 months) in 70 patients, none showed residual flow or complications.

Discussion

In this non-randomized study with two contemporary cohorts of pediatric patients (younger than 14 years) treated in the same center, percutaneous closure of ASD in children and adolescents showed to be safer than and as effective as conventional surgical treatment. A contemporary surgical treatment cohort was used for comparison purposes, as there has been no change in surgical techniques in the last ten years, thus making the comparison adequate.

It is unlikely that younger age and lower weight observed in the surgical group had an impact on the incidence and severity of complications found, as the mean age of patients in this group was almost five years (with mean weight of almost 20 kg), which does not constitute a usual risk factor in contemporary pediatric cardiac surgery, especially in the case of a technically simple surgery with a short time of CPB. It is more likely that the increased incidence and severity of complications were simply associated with the invasive nature of cardiac surgery, requiring CPB and thoracotomy. The younger age of the surgical group reflects the conduct of our team to operate earlier on children, before the age of 4-5 years, to allow a ministernotomy (made more difficult in older children), used in nearly half of this series.

In contrast, the oldest age observed in the percutaneous group (mean of almost 8 years) reflects the conduct of our group to give preference to treatment at a moment in which the procedure is technically easier and allows the use of prostheses without the risk of major interference with adjacent cardiac structures. Although this time is debatable in the literature, it seems that the ideal age for the percutaneous approach is between 3 and 10 years or in children weighing more than 15 kg. Moreover, the procedure can and should be used in younger children weighing less than 10 kg when there are chromosomal syndromes or significant diseases associated with other systems, such as bronchopulmonary dysplasia of prematurity, perennial asthma, kidney failure, severe scoliosis, among others. In these patients, the procedure is safe and effective[27].

As a common complication, arrhythmias were observed in both groups, in agreement with the literature. The increased incidence and severity of these arrhythmias in the surgical group is probably associated with the performance of atriotomy and surgical manipulation of the IAS during the procedure. Moreover, the scar created by the atriotomy can function as a histological substrate for arrhythmogenic foci and / or reentry phenomenon, even at these patients' later life. Moreover, the use of prostheses may result in blocks of varying degrees in children, albeit transient, as observed in three patients in this series.

In one of these, the blockade was due to the lack of self-centering mechanism of the device used (Helex), causing it to shift into the coronary sinus, probably temporarily traumatizing the region of the atrioventricular node, which required removal of the device and, subsequently, a new procedure. Three months after the implant of a self-centering prosthesis, this inferior migration was minimized and prevented the blockade. In one study[28], the percutaneous closure of ASD in young children resulted in rates of approximately 4% of blockades. However, large-sized prostheses were used in that study. This observation, together with those derived from this study, show the importance of patient selection for the percutaneous procedure, especially regarding the ideal age for the procedure and careful selection of the size and type of device for the underlying anatomy.

The occurrence of pleural or pericardial effusion requiring drainage and more prolonged hospitalization is relatively common after surgical correction of the ASD, as seen in three patients in this study. The cause of this complication remains mostly unknown.

Even when it does not require draining, the effusion increases postoperative morbidity as it requires higher doses of diuretics for treatment. The highest incidence of infection after surgery in this study reflects the more invasive nature of this approach, with the need for more prolonged intubation, use of urinary catheter and central venous and arterial catheters, immunosuppression secondary to the presence of CPB and surgical wound. Additionally, there was a significant number (30%) of patients that required postoperative blood transfusion in the surgical group. If we also consider the use of blood during CPB, these patients are multitransfused, which increases morbidity. The need for vasoactive drugs to maintain hemodynamic conditions in almost 20% of patients and longer length of hospital stay also demonstrate the higher morbidity of the surgical procedure.

The low morbidity rate observed in the group treated percutaneously reflects the group's experience in this procedure, especially with regard to patient selection and the less invasive characteristic of the procedure. We speculate that these findings would allow the adoption of a semiambulatorial scheme for the treatment of patients with ASD during hospitalization without the need for laboratory tests and hospital discharge after a brief observation period of 24 hours.

This conduct would result in significant saving of resources and availability of hospital beds to other patients with more complex heart diseases that require intensive treatment and surgical repair only. Although we observed low rates of complications in this study, some considerations must be made. The occurrence of erosion is a rare, but well documented complication in the percutaneous treatment of ASD[29]. The mechanisms involved in its physiopathology are not entirely known, but it seems that the overestimation of the device dimensions in ASDs with deficient anterosuperior borders is a predisposing factor.

Interestingly, this complication is rarely found in children. In a previous study in adults, our group found this complication in a patient with an ASD at a higher location in the septum[30]. Device embolization is another complication that can be

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found during the learning curve and/or defects in patients with borderline characteristics for the implant. Although prosthesis rescue at the cath lab is usually possible, surgical intervention may be required depending on the position where the prosthesis is located.

We observed a high rate of ASD occlusion in both groups in this study. Rates higher than 95-98% in the percutaneous group are found in literature depending on the type of prosthesis used, defect size and phase of the learning curve. Due to the study planning and the relatively low number of patients, it was not possible to compare the performance of each prosthesis individually. While acknowledging that there was a relatively short follow-up time of patients treated percutaneously in this study, there is evidence from the literature showing that the safety and efficacy persist after more than 10 years of follow-up[31]. Although the occurrence of residual flow is rare in patients treated by surgical technique, when it occurs, it may require further intervention due to suture dehiscence and persistence of large diameters of the original defect, as observed in one patient in our series. The lack of follow-up of all patients in the surgical group reflects the retrospective nature of data collection with loss of information.

The outcomes in this study are in agreement with those reported in the literature on non-randomized observational studies and a meta-analysis recently published by Butera et al[3]. In this review of 13 original nonrandomized studies with over 3,000 patients, one death was observed in the surgical group (incidence of 0.08%; 95% confidence interval (95%CI): 0 - 0.23%) and none in the percutaneous group. The analysis of general complications after the procedures showed rates of 31% (95% CI: 21-41%) for surgical patients and 6.6% (95%CI: 3.9 to 9.2%) for patients treated percutaneously. The adjusted odds ratio related to the likelihood of overall complications was 5.4 (95%CI: 2.96 to 9.84, p < 0.0001) in favor of percutaneous treatment. The rates of major complications were 6.8% (95%CI: 4 to 9.5%) in the surgical group and 1.9% (95% CI: 0.9 to 2.9%) in the percutaneous group. The adjusted odds ratio for major complications was 3.81 (95%CI: 2.7 to 5.36, p = 0.006), again favoring the percutaneous treatment. These authors concluded that the percutaneous treatment is associated with less likelihood of complications when compared to the surgical approach.

There are also other advantages of percutaneous treatment that were not explored in this study, including faster RV function recovery determined through echocardiography and biochemical markers[32-34] and perhaps a better neurocognitive performance of patients undergoing intervention when compared to those who underwent surgical repair[35].

The major limitations of the present study are the lack of follow-up in all patients in the surgical group, the relatively short follow-up of patients undergoing percutaneous treatment and its nonrandomized design. There are no similar studies in the literature and it is extremely unlikely they will be carried out. Currently, the percutaneous approach is so well established, standardized and disseminated in major world centers, that recruitment of patients for the surgical group after randomization would be difficult to explain to parents or guardians.

As observed in almost all the literature on the treatment of congenital heart disease, progress achieved in the management of patients is derived from prospective observational cohort studies with analysis of risk factors for adverse outcomes. When these risk factors are recognized and controlled, there is improvement of results. Regarding the study shown here, although it was not randomized and thus introduced patient selection biases, its strong point is the fact that it was carried out with two cohorts of patients treated almost contemporarily in a single excellence center, by experienced and relatively homogeneous teams, using well-established and standardized surgical and percutaneous techniques, already past their learning curves. In conclusion, the experience shown here probably reflects one of the best clinical practices found in the country.

Based on data shown here and the evidence in the literature regarding the safety and efficacy of this procedure, we believe that the percutaneous closure of ASD should be considered the treatment modality of choice for the treatment of selected patients with this condition. In our opinion, this modality is well-developed enough in Brazil to be submitted to a cost-effectiveness assessment in order to be incorporated into SUS and can be used in large scale in the population.

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