VIA MEDICA

ORIGINAL ARTICLE

Cardiology Journal
2014, Vol. 21, No. 3, pp. 279–283
DOI: 10.5603/CJ.a2013.0120

ISSN 1897–5593

Transcatheter closure of atrial septal defect in children up to 10 kg of body weight with Amplatzer device

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Abstract

Background: *Transcatheter closure of atrial septal defect (ASD) in older children and adults is currently considered the first-choice therapeutic option. This approach remains challenging in younger children. The aim of the study was to evaluate feasibility, safety and midterm efficacy of percutaneous ASD closure in symptomatic infants ≤ 10 kg body weight in our institution.*

Methods: *There were 28 children up to 10 kg of body weight, who were qualified for transcatheter closure of ASD. All patients but one showed overload of right atrium and right ventricle. Mean weight of patients who underwent transcatheter closure was 9.2 ± 0.88 kg and age 1.59 ± 0.58 years, respectively. Transcatheter closure of ASD was conducted using Amplatzer occluders (ASO).*

Results: *The devices were implanted successfully in 26/28 patients (93%). In 2 (7%) children the device repeatedly straddled the septum in relatively big ASD and the procedure was abandoned. Mean ASD diameter in patients, who underwent transcatheter closure, was 9.08 ± 2.9 mm (transthoracic echocardiography) and mean implant size/weight ratio was 1.07 ± 0.31. In the child with right-left shunt through ASD normalization of saturation occurred. Mean fluoroscopy time was 4.16 min. In 3 children minor complications occurred: transient arrhythmias (n = 1), fever after procedure (n = 2). The follow-up time was 6.1 (range 1.2–11) years. At follow-up, clinical condition and/or growth improved in all patients except 4 children with coexisting comorbidity. No arrhythmia nor conduction disturbances were observed during follow-up.*

Conclusions: *In selected patients weighing less or equal to 10 kg, percutaneous closure of ASD is a safe and effective procedure.* (Cardiol J 2014; 21, 3: 279–283)

Key words: atrial septal defect, transcatheter closure, small children

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Received: 02.06.2013 Accepted: 25.07.2013

Introduction

Atrial septal defect of type II (ASD) is one of the most common congenital heart defects occurring in children and makes 8–10% of all congenital heart defects. 75% ASD cases are placed in the region of fossa ovalis. The size of the defect can range from a small fenestration to a complete lack of the septum. The major element of the defect is most often a left-right shunt. Although ASD closure is recommended in the childhood, the diagnosis is often set in adult patients in the third or fourth decade of life when heart insufficiency or rhythm disorders are manifested.

However, it happens that the symptoms of hemodynamically significant ASD, such as recurring infections of the upper airways, impaired child development (small weight growth), decreased effort tolerance, or cardiac insufficiency occur even in small children. In some cases, the unclosed defect can lead to irreversible, progressive disease — pulmonary hypertension (Eisenmenger syndrome).

The procedure of ASD closure is made according to a plan respecting standards usually when a child is 4 years old [1–3], however in younger patients with clinical symptoms of heart defects, the intervention date should be hastened. Hemodynamically significant left to right shunt with pulmonary/systemic flow ratio — Qp/Qs > 1.5 is a classical indication for ASD closure. In clinical practice, symptoms of right atrium (RA) and right ventricle (RV) volume overload in echocardiography is an indication for ASD closure. Percutaneous ASD closure is presently considered to be a therapeutic option of the first choice. These procedures are a challenge in younger children. For practical purposes, any defect of 8 mm or larger with evidence of significant left to right shunt should be closed when identified, even in very young patients, because such a defect will likely never close spontaneously and may in fact even get larger [4, 5].

The aim of this study was to analyze the results, efficacy and safety of the percutaneous closure of symptomatic ASD in children with body mass up to 10 kg. Present reports on this subject are scarce [6–15]. The group of children described in this study is one of the most numerous we have found in the literature available.

Methods

Description of the study group

The procedure of percutaneous ASD closure has been performed in our Center since October 1997. Since then, we have made 1180 procedures. From April 2002 to December 2011, 28 children were qualified for this type of intervention (22 girls and 6 boys) with body mass up to 10 kg.

In all patients (apart from one child with borderline hypoplastic RV and tricuspid incompetence) overload of right cardiac cavities was found. All the interventions were performed in the Cathlab of Congenital Heart Diseases and Pediatric Cardiology Ward, Silesian Centre of Heart Diseases in Zabrze. The implant Amplatzer Atrial Septal Occluder (ASO) by AGA Medical Corp (USA) was used in all the procedures.

The intervention was successfully performed in 26 children at the age of 0.5–2.8 years, mean 1.59 ± 0.58 years. In 2 cases the percutaneous closure was canceled due to persistent slanting opening of the implant in the big ASD. Children's body mass was 6.5–10 kg (mean 9.2 ± 0.88 kg). In 18 children single ASD was present, while in 10 patients multiple defects were found. There were 6 patients with multiperforated aneurysm of interatrial septum and 4 patients with small additional fenestration located close to the main defect. One patient (with borderline RV hypoplasia) had previous surgery of complex cyanotic heart defect (RVOT reconstruction, right-sided Blalock-Tausig anastomosis and PDA ligation).

Additional heart defects occurred in 3 patients; as mentioned above, one patient had pulmonary valve atresia with intact ventricular septum, the second had a small ventricular septal defect and the third had pulmonary valve stenosis. This patient had pulmonary balloon valvuloplasty performed before ASD closure during the same procedure. General qualification criteria for the intervention were significant symptoms of left-right shunt through ASD with overload of RA and RV. One patient (with hypoplastic RV) had right-left shunt with central cyanosis (saturation 79%).

The interview in the study group showed the following symptoms: body mass deficiency (below or equal 25 centiles) — 19 children, sweating, fatigability while eating — 7 children, recurring infections of respiratory tract — 6 children (in one, recurring obturative bronchitis and nephropathy were found). One child's history revealed premature birth with hypotrophy (birth body mass 870 g) and some other disorders. Moreover, one child was diagnosed with fetal alcohol syndrome and another with Down syndrome. The important factor enhancing the qualification of children for transcatheter ASD closure were insistent parents' requests for an intervention.

The intervention was cancelled when ASD was not hemodynamically significant, anatomy

was unfavorable (lack of posterior or posterior-inferior septal rim — 2 children) or defects were multiple of unfavorable localization or ASD was accompanied by other cardiac defects requiring surgical correction.

Procedural details

All the interventions of transcatheter ASD closure in children up to 10 kg were performed in the hemodynamic laboratory in general anesthesia with endotracheal intubation and antibiotic cover. Standard application of heparin 100 μ/kg before the procedure and cefazolinum in 3 doses every 8 h were used. Then, constant infusion of heparin 300 μ/kg/24 h was administered under activated partial thromboplastic time control. The ASD closure was performed under fluoroscopic and transesophageal echocardiography (TEE) guidance according to the defined guidelines [16]. Necessary condition for transcatheter ASD closure was the presence of atrial septal rims (at least 5 mm) in order to obtain a stable implant position. The exception was aortal rim which could be deficient. However, if it was accompanied additionally by other deficient or floppy rim, a patient was disqualified from transcatheter treatment and was directed to surgical correction.

The size of the defect in all the procedures was evaluated in two parallel projections.

The implant size was selected either on the basis of the defect stretch diameter or with reference to defect diameter defined by TEE (it was equal or 2–3 mm bigger than the biggest measurement in this examination). Catheter calibration was omitted in 4 children with multi-fenestrated aneurysm of interatrial septum (size of the implant was equal to the entrance of aneurysm) and in 11 children with centrally located defect with good surrounding rims. During the intervention, the occluder was loaded onto a special delivery system and was transported through a long sheath introduced from femoral vein to the right and left atrium through the defect. Then, the left-atrial disc was opened, the implant was pulled to atrial septum obtaining support and then right-atrial disc was deployed. After occluder insertion, before its release, a precise evaluation of the implant position was made using TEE. In some cases the "Minnesota wiggle" maneuver was used by pushing and then pulling the device in order to make sure that the implant is located properly in the atrial septum. The device was released in all the cases by unscrewing from the leading system after echocardiography and fluoroscopy which confirmed its proper position. When the occluder's position was not satisfactory, a reposition was made by retracting one or 2 discs into the sheath and deploying them again.

The intervention's result (implant stability, residual shunt) was evaluated by TEE during the procedure and afterwards — transthoracic echocardiography (TTE) was used. After the procedure aspirin in dosage 3–5 mg/kg during 6 months was applied.

Control examinations (ECG and TTE) were performed in the 1st, 3rd, 6th, 12th months after the procedure and then annually.

The study was approved by the local bioethical committee and all parents gave their informed consent.

Results

The intervention was effective in 26/28 patients (93%). In 2 children the procedure was abandoned due to a relatively big defect and oblique position of the implant in its lumen. Their age was 1.3 and 1.5 years. The ASD diameter in TEE in the patients who underwent successful closure ranged from 4 mm to 16 mm, mean 9.08 ± 2.9 mm. In 11/26 children (42.3%) the defect diameter ("stretch") was estimated by balloon sizing and was 11.36 ± 3.8 mm. In all the procedures ASO implants (AGA Med. Corp. USA) of the diameter from 5 to 16 (mean 10.42 ± 2.73) mm were used by application of 6 F or 7 F introducer. Body mass [kg] to implant diameter [mm] ratio ranged from 0.5 to 1.56, mean 1.07 ± 0.31. In 13/26 children (50%) it was equal or exceeded the value of 1.2. There was no ASO embolization in any case, nor during or after the procedure. Mean fluoroscopy time was 4.2 (from 1.0 to 11.0) min, mean procedure time was 48 (from 20 to 90) min depending mainly on the time of TEE examination. The implantation was effective at the first deployment in 24/26 patients. In 1 patient, only third reposition was effective (oblique implant position in ASD). In this case the method included using a dilatator inserted from the opposing femoral vein in order to stabilize the upper part of left-atrium disc on the left side of interatrial septum, the implant was inserted into the upper right pulmonary vein and the left-atrial disc was opened there together with simultaneous opening of the right atrial disc with a proper pulling movement of the delivery system. Unfortunately, these maneuvers were unsuccessful in 2 (7%) children qualified to transcatheter ASD closure. The procedure was interrupted due to unfavorable anatomy of the defect (the implant was deployed

incorrectly on the atrial septum several times) and the patients were referred to cardiosurgical treatment.

One child had a short episode of supraventricular tachycardia in the postoperative period, which disappeared spontaneously. One child, despite effective closure of the defect at the first trial, removed the tracheal tube during the intervention and it was impossible to evaluate the implant position near aortal valve. A correct position of the occluder was confirmed by TTE. One child simultaneously to ASD closure had successful pulmonary balloon valvuloplasty (gradient decreased from 70 to 23 mm Hg). Two children got infection in the post-procedural period. One had 3-day fever with the temperature 38°C, another had upper respiratory tract infection. Both were given antibiotic cover — the first one — cefazolin, the other — cefuroxime.

The follow-up period was 6.1 (from 1.2 to 11) years. During this period residual atrial shunt was found in 10 (38.4%) patients directly after the intervention, in 8 (30.8%) patients 24 h after the procedure, in 5 (19.2%) patients within 1 month after the procedure, in 2 (7.7%) patients within 3 months after the procedure and in 1 (3.85%) a very trivial one, 12 months after the procedure. In all children who had transcatheter ASD closure (except for one with RV hypoplasty) decreased dimensions of RA and RV were found in echocardiography already 3 months after the intervention. In a child with RV and tricuspid valve hypoplasty with right-left shunt through ASD, an increased right cardiac cavity, improved normalization of blood saturation and enhanced physical development were observed after the intervention.

Better appetite, regression or decrease of cardiac failure, lower susceptibility to upper airways infections were observed in all the children. Moreover, much better weight growth was observed and as a consequence the age/weight index went up on the centile nets (Fig. 1).

This index decreased in 1 child with a non-cardiac morbidity. The child had other coexisting allergic and nephrologic diseases. Weaker development persisted in 3 children (below 10 percentile), 1 child with fetal alcohol syndrome, the other with very low birth weight and another with Down syndrome. No rhythm nor conduction disorders were observed in any of the patients.

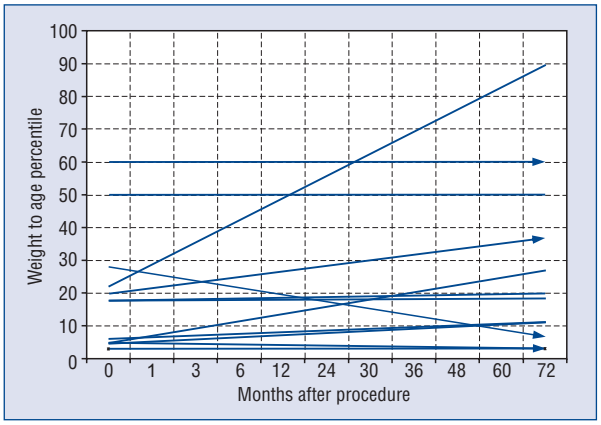

Figure 1. Body weight (in percentiles) before (0) and after (1–72 months) transcatheter atrial septal defect (ASD) closure in 15 children with weight up to 10 kg during procedure and at least 6-year follow-up.

Discussion

According to the presented results, transcatheter ASD closure is a feasible and effective method even in the youngest group of children, i.e. with the body weight up to 10 kg, even in infants. To perform this procedure we applied Amplatzer occluders. The advantages of this device are: the biggest experience with the use of them and the smallest delivery systems necessary for implantation. The latter is of great importance in small children whose vessel size is tiny.

Generally, there is a consensus that significant ASD should be closed, but there are different opinions when to do it. The reason for this is a theoretical chance of spontaneous closure of the defects as the child grows. It is also the main reason for postponing the intervention, usually according to the majority of experts' opinions, to the age from 3 to 5 years [1–4].

On the other hand, it should be stressed that published data demonstrated tendency to increase diameter of big ASD with time in observation periods in children. This fact can sometimes be an obstacle to further non-surgical treatment. Therefore, there is an agreement that small defects tend to close spontaneously, while the bigger ones — to increase [5].

Present reports on transcatheter ASD closure in small children are scarce and only a few refer to the group with a body weight below 10 kg [6–15]. The population described in this study is one of the biggest groups treated by this method in the world.

On the basis of the results, a thesis can be formulated that most of these children show the improvement of physical development, cardiac indices normalization and regression or significant decrease of accompanying morbidity. Our expe-

riences contradict those published recently by a group of researchers from Houston, who stated that better results can be achieved in children whose implant size and body weight ratio is smaller than 1.2 (in our material such a group consisted of 50% patients) [6]. This can be a result of the older age of children in their study [6]. Moreover, our initial experience indicates that the method can be effective and clinically favorable in patients with a complex defect with right-left shunt through the ASD. According to our assumptions, early closure of ASD II in small children should result, together with a child's growth, in a decrease of the implant diameter and septum length ratio and should improve the heart hemodynamics in the future (in cases of larger defects closure in older children or adults, "stenting" of the whole atrial septum with a nitinol plug often takes place).

Transcatheter ASD closure in small children requires an experienced operator due to potential technical problems. An intervention cardiologist can encounter problems related to small vessel dimensions, or with defect calibration with a balloon catheter during ASD closure in children with a weight up to 10 kg. These balloons are generally dedicated by producers for adult patients — but this method was unnecessary and omitted in majority of our children. Moreover, small heart dimensions, relatively small atrial septum, make catheter maneuvers difficult. Furthermore, available delivery catheters (with 45 degrees ending of the long sheath) do not make the procedure easier, often causing oblique position of the implant in relation to the septum. In such a situation, some of the techniques that we applied in our patients can be helpful.

Limitations of the study

Our study has its limitations. At first it was a retrospective analysis and there existed a lack of specific symptoms of left to right shunt in this heterogeneous population. Documented gain weight and relief of symptoms after ASD closure suggest that the defect had played a prominent role in the clinical state, although this could not be fully demonstrated. The number of patients was too small to correctly evaluate the risk for minor or major complications.

Conclusions

The results presented above show that safety, efficacy and medium-length results of transcatheter ASD closure performed in small children are high and very promising. It can be the reason for changing the binding directives, i.e. move the indications to transcatheter ASD closure to children of an earlier age.

Acknowledgements

These investigations were realized according to the DoctoRIS scholarship program.

Conflict of interest: none declared

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