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ORIGINAL ARTICLE

Transcatheter closure of atrial septal defects type 2 in children under three years of age

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Abstract

Background: Atrial septal defect (ASD) type 2, according to current standards, is closed percutaneously usually after the child has reached the age of four to five years. There are limited data regarding such treatment in younger infants.

Aim: We sought to evaluate the feasibility, safety, and efficacy of percutaneous ASD closure in children under three years of age.

Methods: The research group consisted of 157 children less than three years old with haemodynamically significant ASD, who underwent effective transcatheter ASD closure in a single tertiary centre between 1999 and 2014. The mean procedural age of the treated children was 2.2 years and mean weight was 12.5 kg. In all cases nitinol wire mesh devices were applied (mostly Amplatzer Septal Occluders). ASD was closed using standard technique (except a few cases wherein the left disc of the implant was inserted initially into the right pulmonary vein to prevent oblique position of the device). Procedure-related complications were divided into major and minor ones.

Results: Atrial septal defect was closed in 149 children: 97 with a single ASD and 52 with double/multiple ASD. The procedure was abandoned in eight patients (three with single and five with double/multiple ASD). No death or implant embolisation occurred during the procedure or follow-up, and there was one case of major postprocedural complications. Normalisation of the right ventricular diameter occurred in all patients during one-year follow-up. In the majority of children acceleration of physical development and resolution of accompanying morbidity were observed in follow-up.

Conclusions: Percutaneous ASD closure can be performed safely in children under three years of age with low risk of peri- or postprocedural complications.

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

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INTRODUCTION

Atrial septal defect (ASD) comprises 5.9% to 22% of all congenital heart defects. In neonates and infants left-to-right shunt is limited by higher pulmonary vascular resistance (PVR) and impaired right ventricular (RV) susceptibility. With a decrease in PVR the shunt increases; however, most patients remain asymptomatic. Small ASDs can close spontaneously whereas large ones, as a rule, do not (they may even increase in size). Due to an extension of the right atrium (RA), development of arrhythmias is frequent (usually in adulthood), the most serious of which are atrial fibrillation or atrial flutter. Late effects of significant ASD are atrioventricular valve insufficiency (especially the tricuspid valve), sinus node dysfunction, congestion, and even premature cardiac death. In particular cases ASD leads to irreversible pulmonary vascular disease (Eisenmenger syndrome). Recurrent upper respiratory tract infection, unsatisfactory weight gain or heart failure exacerbation in early childhood are other manifestations of ASD, and the reason behind them remains unclear. Percutaneous ASD closure, according to current standards, is typically performed after the child has reached the age of four to five years [1–6]. In younger patients with heart failure symptoms the intervention should be undertaken in advance. The indication for ASD closure is a significant left-to-right shunt (pulmonary to systemic flow ratio > 1.5) manifested by enlargement of the RA and RV; however, the majority of ASD treatment recommendations

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have arisen when the surgery (with extracorporeal circulation) was the only possible method of treatment. New transcatheter (TC) techniques of ASD closure have proven to be as effective as surgery, but with lower complication rate, and they are nowadays considered to be the treatment of choice [7, 8]. The aim of the study was to evaluate the feasibility, safety, and efficacy of percutaneous secundum ASD closure in children less than three years old in a single tertiary centre. To the best of our knowledge, it is the largest analysed group of young children in whom ASD was closed percutaneously [9–21].

METHODS

Patients

Overall, 157 children (110 girls) under three years of age with significant secundum ASD, who were referred for TC of ASD between September 1999 and April 2014, were enrolled in the study. The morphology of ASD, right heart cavities, as well as other miscellaneous heart defects, were assessed by transthoracic echocardiography (TTE). Transoesophageal echocardiography (TEE) was performed before the procedure for confirmation of the diagnosis and TC guidance. The procedure was successful in 149 (94.9%) children, who were included in subsequent analysis. There were 97 patients with a single and 52 patients with double/multiple ASD. The patients were 0.5 to 3.0 years old (mean age 2.2 ± 0.6 years) and their mean weight was 12.6 ± 2.5 kg (range 6.5–20 kg). The analysed population included 145 children with normal karyotype and four with trisomy 21 (Down syndrome). Accompanying heart defects were diagnosed in 32 patients and included valvular stenosis of the pulmonary artery — gradient above 40 mmHg (n = 8), insignificant pulmonary valve stenosis — gradient below 40 mmHg (n = 8), insignificant patent ductus arteriosus (n = 4) and ventricular septal defect (n = 4), left superior vena cava (n = 1), and coarctation of the aorta (n = 1). RV dilation was present in all but two children, who underwent surgical correction of complex cyanotic heart defect in the neonatal period with bidirectional shunt through ASD. Informed consent was signed by all guardians.

Procedure

The exact size and morphology of the defect was evaluated by TEE. Sufficient ASD rims (at least 5 mm) were necessary to attempt the TC; the exception was the aortic rim, which could be residual or absent. However, if a residual aortic rim was accompanied by another floppy rim, the patient was disqualified from the procedure due to high risk of failure. In all children the ratio of the applied implant diameter (expressed in mm) to body weight (expressed in kg) was determined. Generally, when the ratio is > 1.0, occluder was considered as a big one.

In the analysed group of patients this parameter ranged from 0.47 to 2.27 (mean 1.0 ± 0.3; > 1.0 — 65 patients, 1.0 — 18 patients, < 1.0 — 66 patients).

Three types of implants were used, all made of nitinol wire mesh: Amplatzer Septal Occluder (St. Jude Medical, Inc., Minneapolis, MN, USA; now Abbott), Amplatzer Multi-Fenestrated Septal Occluder — "Cribriform," and Cardi-O-Fix ASD Occluder (Starway Medical Technology, Inc., Beijing, China), which was used in relatively heavier, most often older patients (who needed an application of a larger delivery system). All procedures were performed under general anaesthesia with endotracheal intubation, cefazolin and heparin (100 IU/kg) were given to all patients. Diagnostic right heart catheterisation was done in all patients before the procedure. In two patients after complex cyanotic heart defect surgery with bidirectional shunt through ASD a balloon ASD occlusion test was carried out for 15 min, during which oxygen saturation, and venous and arterial pressures were monitored. In cases with increased oxygen saturation (pulse oximeter) without increase in venous pressure the test was considered to be positive. In 50 of 149 patients (33.5%) the balloon "stop flow" calibration of ASD was performed (St. Jude Medical, Inc., Minneapolis, MN, USA; now Abbott) in order to choose the appropriate implant size. In patients with centrally located defect and stable atrial septum implants of diameter 20% to 30% greater than that specified in TEE were used. TC was usually performed according to standard protocol, except in a few cases wherein the left atrial disc of the device was initially inserted into, and opened in the right upper pulmonary vein to prevent oblique position of the device; thereafter, the right atrial disc was opened in the RA. After pulling the entire system, the left atrial disk was ejected to the left atrium. After the procedure proper position of the device in all patients was confirmed by TEE. Before the implant was released, a so-called "Minnesota wiggle" manoeuvre (consisting in pushing and pulling the delivery system) was performed to ensure stable position of the implant in ASD.

Follow-up

Subsequent control examinations after the procedure, including electrocardiography (ECG) and TTE, were performed after one day, three, six, and 12 months and thereafter yearly in our outpatient clinic. All patients were given acetylsalicylic acid (ASA) for six months (3–5 mg/kg). Complications related to the procedure were divided into minor and major ones. Minor complications included embolisation of the device with successful transcatheter removal, transient arrhythmias requiring treatment (pharmacotherapy or cardioversion), ECG changes (ST-T changes), insignificant valve dysfunction, haematoma or other complications at the place of venous access, venous thrombosis, and respiratory infections in the postoperative period. Major complications comprised cerebral embolism, endocarditis, arrhythmias requiring pacemaker implantation or long-term antiarrhythmic therapy, device embolisation requiring urgent surgery, tissue erosion surrounding the implant, pericardial tamponade requiring intervention, or death. The follow-up period ranged from 0.1 to 14.7 years (mean 6.0 ± 3.5 years). Fourteen (10.7%) patients were lost to follow-up.

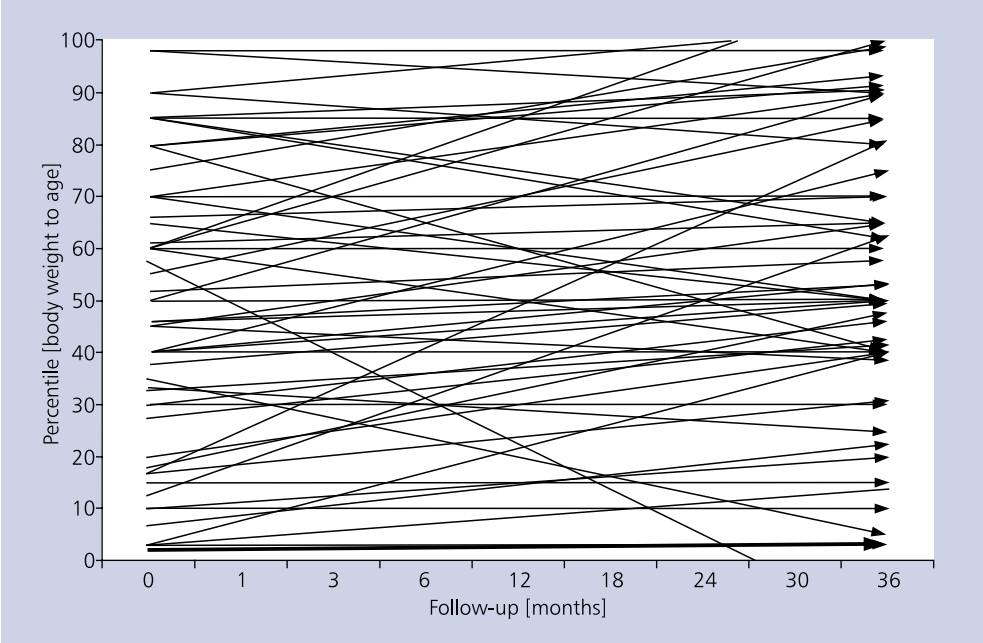

Figure 1. The trend of channel change on a percentile grid (body weight to age) over the observation period of 36 months

Statistical analysis

The database was created in Microsoft Excel 97 — 2003. Average values and standard deviations of individual parameters were calculated. Comparison of right and left ventricular proportions was carried out using the Fisher exact test and, when necessary, Student t test. Differences were considered statistically significant when $p < 0.05$.

RESULTS

Transcatheter ASD closure was abandoned in eight patients (three with single and five with double/multiple ASD) because of oblique position of the implant in a relatively large or unfavourable defect. ASD was sucesfully closed in 149 patients. There were no periprocedural complications. No early or late embolisations were observed. Complications during the follow-up period are discussed below. In all patients (except for two children after complex cyanotic heart defect surgery with bidirectional shunt through ASD) the indication for ASD closure was RV dilatation with left-to-right shunt at the level of the atrial septum. Other indications included slow weight gain (below the 25th percentile; n = 38), significant pulmonary valve stenosis (n = 8), increased sweating and easy fatigue (n = 31), frequent respiratory infections (n = 27), or strong parental request (n = 43). Mean ASD diameter on TEE was 10.3 ± 3.2 mm (single ASD group) and 11.6 ± 3.0 mm (double/multiple ASD group). There were eight children with multiperforated atrial septal aneurysm. Mean implant size to body weight ratio was 1.0 ± 0.3 (range 0.4–2.3). In the double/multiple ASD group, weight gain before the procedure was worse than in the single ASD group (position on a centile chart below the 25th percentile: multiple ASD 19/52 patients [36.5%] vs. single ASD 19/97 patients [19.6%], $p < 0.05$). In children with bidirectional shunt through ASD (n = 2) the balloon occlusion test proved to be positive. Mean fluoroscopy time was 4.5 ± 3.6 min.

Out of 60 patients in whom body weight analysis was possible, in six, 12, 18, 24, 30, and 36 months after the procedure, the trend lines of the centile channel were determined (Fig. 1). In the analysed group there was an increase in the percentile channel (body weight to age) in 33 (55%) patients and a decrease in the percentile channel in 11 (18.3%) patients. In 16 (26.7%) patients the percentile channel during the observation period did not change. Patients with the greatest drop in the percentile channel had comorbidities, such as bronchial asthma, frequent respiratory infections, and gastroenterological problems. Table 1 presents ASD morphology details in the single and multiple ASD groups. In both groups the significant RV dimension and proportions of left to right ventricle decreased during one-year follow-up (Figs. 2, 3).

Types of occluders

In 145 (97.3%) patients Amplatzer Septal Occluders and in two (1.4%) patients with multiperforated interatrial septum aneurysm Amplatzer Multi-Fenestrated Septal Occluders — "Cribriform" (18 and 25 mm) were used. In the remaining two patients (1.4%; 2.6 and 3 years old; with body weight 15 and 18 kg, respectively) Cardi-O-Fix devices (10 and 14 mm) were used; in both, a 7-F delivery sheath was applied.

Table 1. Single and double/multiple atrial septal defect (ASD) morphology and location determined by transoesophageal echocardiography

Morphology of the defect	Number of patients with single ASD	Number of patients with double/multiple ASD
Aortic rim below 5 mm/residual	30/97 (31)	13/52 (25.1)
Posterior rim below 5 mm	15/97 (15.5)	8/52 (15.4)
Centrally located defect	52/97 (53.5)	25/52 (48.0)
Multiperforated aneurysm	None	6/52 (11.5)

Data are shown as number (percentage)

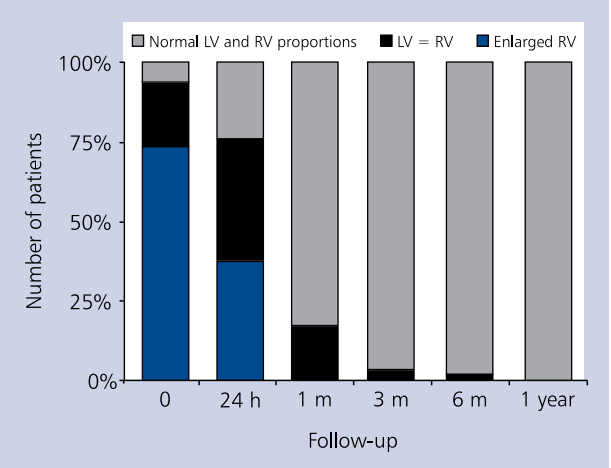

Figure 2. Changes in the proportion of heart cavities after the closure of a single atrial septal defect type II depending on the length of the follow-up period; LV — left ventricle; RV — right ventricle

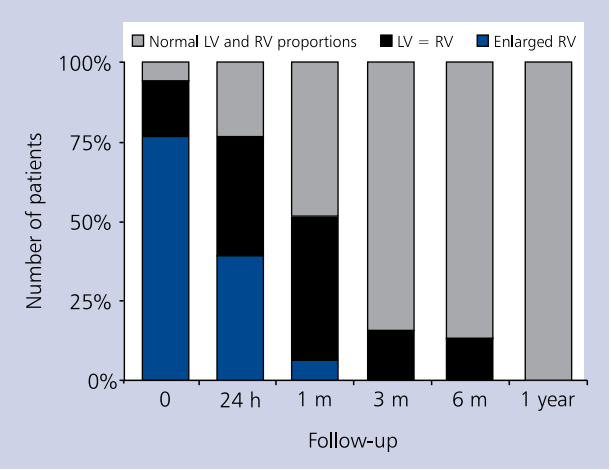

Figure 3. Changes in the proportion of heart cavities after the closure of a double/multiple atrial septal defect type II depending on the length of the follow-up period; LV — left ventricle; RV — right ventricle

In the group of patients with a single ASD the diameter of occluders ranged from 5 to 24 mm (mean 12.3 ± 3.3 mm) and in the group of patients with double/multiple ASD it ranged from 6 to 25 mm (mean 12.4 ± 3.3 mm) — not statistically significant. In two patients with bidirectional shunt, 5- and 9-mm Amplatzer Septal Occluders were delivered.

Other interventions performed simultaneously with the ASD closure

In eight (5.4%) children with significant pulmonary stenosis, pulmonary balloon valvuloplasty prior to transcatheter ASD closure was performed (six patients with a single ASD) with gradient reduction from 56.0 to 20.4 ± 4.8 mmHg. In one infant with ASD and aortic recoarctation, successful balloon angioplasty was done with gradient reduction from 35 to 12 mmHg.

Complications

Major complications during the procedure or follow-up occurred in one patient, who developed supraventricular tachycardia requiring long-term antiarrhythmic therapy for two years after the procedure (n = 1). Minor periprocedural complications included respiratory tract infection (n = 5), anaemia requiring transfusion of the erythrocyte mass (n = 1), and a small amount (2–3 mm) of fluid in the pericardium (n = 1). Mild arrhythmias and conduction disturbances were found during the procedure in five patients: supraventricular tachycardia (n = 2; one patient needed adenosine bolus, in the other patient it resolved spontaneously), transient single ventricular and supraventricular extrasystoles (n = 2) and second-degree atrioventricular blocks (Mobitz types I and II), which resolved after steroid administration. In long-term observation, minor complications (mild mitral valve insufficiency) occurred in two patients.

DISCUSSION

According to the presented results, TC of ASD is effective and feasible in children under three years of age. Amplatzer occluders were used in the vast majority of analysed cases. Literature reports on transcatheter ASD closure in young children are mostly limited to short case series [8–21]. Moreover, the risk-benefit ratio of this procedure in young patients has not been clearly defined.

This study analysed a population of 157 children under three years of age referred for transcatheter ASD closure, which is one of the largest groups in the world treated in this way in a single tertiary centre.

In our clinical practice ASDs are closed percutaneously in children and adults in equal proportions [5]. TC of ASD is a well-established and safe method of treatment used in children and adults for many years in cardiac centres around the world. It is the method of choice in the treatment of secundum ASD with appropriate morphology [6]. There is compelling evidence that percutaneous closure is more beneficial in comparison to surgical treatment in terms of complications, frequency, and length of hospital stay [7, 8].

Despite the consensus that closure of significant ASD is necessary from the clinical point of view, discrepancies exist regarding the best timing due to a theoretical possibility of spontaneous closure as the child grows. Over the past few decades, many analyses of spontaneous ASD closure have been made [22, 23]. Small defects usually have a greater tendency to close, while larger ones tend to enlarge. However, there are single cases of spontaneous closure of a large ASD in young children [24, 25]. The fact that small defects are characterised by spontaneous closure or reduction in dimensions was taken into account in the qualification of patients for our study. In the literature, however, evidence exists that initially small, haemodynamically non-significant ASD has the potential to increase with the child's growth even beyond the capabilities of the transcatheter method [26].

Considering available publications, it can be proposed that there is no clear benefit from closing ASD < 8 mm in asymptomatic children under three years of age. These conclusions were taken into account when referring children for ASD transcatheter closure in our study. ASD closure is performed according to the applicable guidelines [1–6], usually after the child has reached the age of four years. However, the timing of the intervention should be brought forward in younger patients with clinical symptoms of heart failure. Based on our analysis, acceleration of physical development, normalisation of cardiac indicators, and resolution of accompanying morbidity can be asserted in the majority of children under three years of age undergoing ASD closure. Our preliminary experience indicates that the method can also be effective and highly beneficial in patients with a complex cyanotic heart defect with bidirectional shunt through small ASD, as in other reports [27].

The majority of complications were mild and usually of self-limiting nature. Embolisations of implants — nowadays rare — are presumably related to the operators' learning curve. Available analyses show that residual shunt after percutaneous ASD closure is present in approximately 10% of cases and usually resolves spontaneously in the early postprocedural period. This was confirmed also by our results. The formation of thrombi on the occluder (not observed in the analysed group) despite the standard antiaggregation treatment (ASA 3–5 mg/kg for half a year) is described in about 2% to 3% of cases, mainly in short-term follow-up. Perforation of the atrial wall (also referred to as erosion) and late implant embolisation occur sporadically (0.1%–0.3%), according to the United States Food and Drug Administration. As shown in the registry of Amin et al. [28], patients with residual aortic rim or lack thereof are particularly predisposed to such complications. In the presented material no cases of embolisation, erosion, or thrombus formation on the occluder were found in follow-up.

Transcatheter closing of ASD in children under three years of age helps to avoid an increase in the size of large ASD and the use of larger implants in older patients.

Inconveniences related to the procedure include (i) small size of vessels; (ii) the problem with ASD calibration with the balloon catheter (intended by manufacturers for use in adults); (iii) small atrial septum and more difficult manipulations of catheters in the heart; (iv) lack of cooperation with the patient (general anaesthesia and longer sedation time required); (v) often an oblique position of the implant in the ASD after opening of the left atrial disc.

In conclusion, percutaneous closure of ASD is a safe and effective procedure in children under three years of age. Subjective improvement in children's clinical state (better exercise tolerance) is observed after the procedure. Moreover, more than half of the analysed patients showed improved anthropometric parameters (weight gain) and experienced fewer episodes of respiratory tract infections. The proportions of the heart chambers normalised in all patients in follow-up. In two patients with complex cyanotic congenital heart defect with a bidirectional shunt through the ASD, normalisation of blood oxygen saturation as well as improvement in development occurred after the procedure. Technical difficulties encountered during percutaneous ASD closure can be solved with special implantation techniques in the majority of cases.

Conflict of interest: *none declared*

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WHAT IS NEW?

To the best of our knowledge, it is the largest analysed group of young children in whom atrial septal defect (ASD) was closed percutaneously. Our data confirm the usefulness and efficacy of transcatheter closure of ASD in this group of patients.