Feasibility of Transcatheter Closure of Secundum Atrial Septal Defect in Low Weight Infants Under 2-Year-Old from a 3-year Retrospective Cohort Study

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We aimed to evaluate the feasibility of interventional treatment of atrial septal defect (ASD) in low weight infants under 2-year-old. Seven hundred and ninety-three secundum ASD patients were divided into 2 groups: 665 were above 2-year-old and 128 were under 2-year-old. The basic conditions before the operation, postoperative complications within 24 hours, and adverse outcomes during a three-year follow-up were compared between the 2 groups using multivariate analysis. There were significant differences in age, weight, and the diameter of the ASD between the 2 groups ($p < 0.001$). The immediate success rate of the procedure was 96.7%. There were no significant differences in the success rate of the procedure, the incidence of residual shunt, arrhythmia, procedure-related arrhythmia, and occluder shedding between 2 groups ($p > 0.05$). Similarly, we found no association between age ≤2-year-old and any adverse outcomes postprocedure within 24 hours, including procedure failure (OR = 0.35; 95% CI: 0.04 to 2.93), residual shunt (OR = 1.07; 95% CI: 0.54 to 2.14), arrhythmia (OR = 0.68; 95% CI: 0.32 to 1.43), or procedure-related arrhythmia (OR = 0.34; 95% CI: 0.04 to 2.87). In the follow-up data, we found no association between age ≤2-year-old and arrhythmia (HR = 0.95; 95% CI: 0.50 to 1.80) and procedure-related arrhythmia (HR = 0.96;95% CI:0.25 to 3.64). Kaplan-Meier survival curves indicated no significant difference in the occurrence of arrhythmia between the 2 groups (log-rank test: p = 0.776). In conclusion, percutaneous ASD closure in young and low weight infants has a high success and low complication rate, along with reliable effects.
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The incidence of atrial septal defect (ASD) in all live births is about 56/10,000. It is generally believed that ASD ≤3 mm in diameter in infants under 3 years old will close naturally 100% within 1.5 years, 80% within 1.5 years for 3-8 mm defects, while only a few ≥8 mm defects can be closed naturally.[1−3] The natural closure age of ASD ranged from 7-month to 6-year-old, with a median of 1.6-year-old. According to the consensus of Chinese experts in 2011,[4] the indications of interventional occlusion of ASD are: an age greater than 3-year-old, a secondary orifice ASD of at least 5 mm, an increased right heart volume load, and a left-to-right shunt of at least 36 mm. The expert consensus [5] stated patients with indications of interventional occlusion should receive intervention if greater than 2-year-old in 2015. It was also pointed out that an increase in right heart load, such as ASD (≥10 mm) and right heart enlargement are adverse factors for the natural closure of ASD. Dzceink et al[6] found this point in 2006. Many patients suffer from recurrent respiratory tract infections caused by an abnormal increase in right heart load and pulmonary blood flow in infancy. Early intervention can reduce complications, such as pulmonary infection and growth retardation. Some studies[7] have shown that the younger the patients are, the lighter the degree of myocardial remodeling, which is caused by the increasing right heart load. The recovery of right heart function and structure is more ideal at an earlier age, Therefore, early treatment of ASD is conducive to the patients. We aimed to evaluate the feasibility of interventional treatment of ASD in low weight infants under 2-year-old.

Methods

Seven hundred and ninety three consecutive patients were from January 2011 to December 2016 in the Guangdong Cardiovascular Institute and the first people's hospital

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of chenzhou that met the diagnostic criteria for ASD were included.[4] All patients diagnosed with Secundum ASD were into 2 groups by age(665 patients >2-year-old in the control group, 128 patients in the experimental group ≤2-year-old.).

Informed consent for interventional procedure was obtained from all patients or guardians. The hospital investigational review board approved the study. Patients with ASD that were of hemodynamic significance, defects that were small but were accompanied with a serious risk of blood clot, and ASD with a diameter greater than the selected occluder were included. Patients with endocarditis, bleeding disorders, contraindication to aspirin (except those taking other anti-platelet agents for 6 months continuously), severe pulmonary hypertension, severe infection, ostium primum ASD, coronary sinus type ASD, pulmonary vein ectopic drainage, and those requiring surgical treatment for other heart defects were excluded.[5]

A complete transthoracic ultrasound (TTE) was performed in all patients. The atrial septum was scanned in 4-chamber, short-axis, and subcostal diatrial views to assess the defects and rims.[8] Distance from the margin of the defect to the coronary sinus, atrioventricular valves, and the right upper pulmonary vein was also measured. TTE was performed continuously throughout the procedure to monitor device deployment. The immediate closure results and device position were assessed by TTE after releasing the device. Measuring the width of the color jet as it exited the atrial septum was used to assess the severity of the residual shunt.[9–11]

Several devices were included: an ASD occluder from Beijing Huayi Shengjie Technology Co., LTD., an ASD occluder from Lifetech Scientific, a Boat Fit ASD occluder from Beijing Dragon Flying Institute Memory Alloy, and an Amplatzer septal occluder from AGA Medical Corp., Golden Valley, Minnesota.

Routine left and right cardiac catheterization was performed in all patients. We selected the appropriate occluder with either the conventional release or pulmonary vein release method.[12]

For adults and most children over 12 years old, we used lidocaine for local infiltration anesthesia at the femoral vein puncture site. Other children use general anesthesia in this study

Aspirin was orally administered for 6 months after the procedure at a dose of 3 to 5 mg/kg/day. Clopidogrel was used for G6PD deficiency. Follow-up care included a physical examination, electrocardiography, chest x-ray, and an echocardiography study at 24 h, and then 1, 3, 6, 12, and 36 months after the procedure. Complications included: headache, residual shunt, fistula formation, shedding of the occluder, arrhythmias (atrioventricular blocks and premature atrial and ventricular contractions), cardiac erosion (aortic about room fistula, cleft mitral valve), thrombosis, and embolism.

All data analyses were performed using Stata, version 13.1. Continuous variables with non-normal distributions were presented as medians (ranges) while categorical variables were presented as frequencies (percentage). Baseline and procedure characteristics were compared between 2 cohorts. Continuous and categorical variables were compared using Kruskal-Wallis tests, chi-square, or Fisher's exact tests. Univariate analyses were performed to compare adverse outcomes 24 hours post-procedure between the 2 groups. Multivariate logistic analyses were then conducted to adjust for confounders, including weight ≤15 kg, a large ASD (≥25 mm), and insufficient rims (<5 mm). Kaplan-Meier analyses were utilized to assess the difference in the cumulative proportion of adverse outcomes between the 2 cohorts. Cox proportional hazard models were performed to calculate the relative risks of residual shunt and arrhythmia. In multivariate Cox regression models, the hazard ratios were adjusted for potential confounding variables including weight ≤15 kg, a large ASD (≥25 mm), and insufficient rims (<5 mm). All tests were 2-tailed, and a p value <0.05 was deemed statistically significant.

Results

The characteristics of 793 patients are shown in Table 1. Six hundred and sixty-five patients and 128 patients were

Table 1
Baseline characteristics of the study groups

Characteristics	Age(years)>2 (n = 665)	Age(years) ≤2 (n = 128)	p value
Age, month [median (range)]	57 (25-664)	19 (7-24)	<0.001
Male/female	277(41.65%)/388(58.35%)	55(42.97%)/73 (57.03%)	0.782
Weight ≤ 15 kg	300 (45.11%)	126 (98.44%)	<0.001
Weight ≤ 10 kg	21 (3.16%)	73 (57.03%)	<0.001
Pulmonary arterial systolic pressure, mm Hg [median (range)]	28 (6-72)	29 (14-53)	0.274
Pulmonary arterial diastolic pressure, mm Hg [median (range)]	9 (-12-28)	8 (-4-35)	0.314
Mean pulmonary arterial pressure, mm Hg [median (range)]	17 (3-45)	15 (6-40)	0.107
Pulmonary arterial systolic pressure ≥ 30 mm Hg	273 (41.05%)	61 (47.66%)	0.152
Insufficient rims (<5mm)	553 (83.03%)	98 (76.56%)	0.081
ASD, mm [median (range)]	14 (3-37)	11 (4-30)	<0.001
Big ASD (≥ 25mm)	47 (7.07%)	1 (0.78%)	0.004
Large ASD (≥ 35mm)	3 (0.45)	0	1.000
Multiple ASD	69 (10.38%)	16 (12.5%)	0.477
Combined PS	3 (0.45%)	0	1.000
Combined VSD	4 (0.6%)	0	1.000
Combined PDA	3 (0.45%)	0	1.000

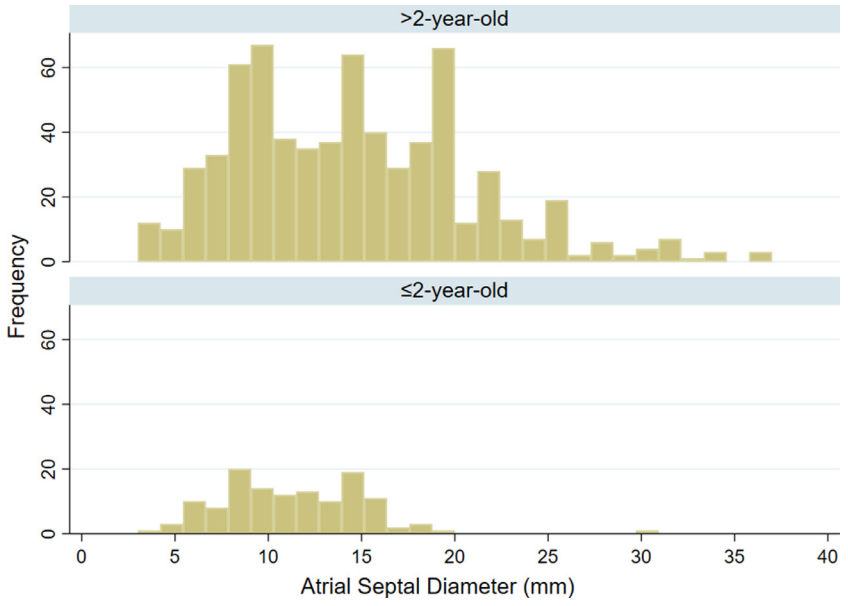

Figure 1. Distributions of atrial septal largest diameter between study groups.

assigned to the control and experimental group, respectively. The median weight of the control group was 16 kg (range: 9 to 1 kg). The median weight of the experimental group was 10 kg (range: 6.1 to 20 kg). There were significant differences in age, weight, and the diameter of the ASD between the 2 groups ($p < 0.001$). No significant differences in gender, pulmonary systolic pressure, pulmonary diastolic pressure, mean pulmonary artery pressure, or the number of cases of deficient margins between the 2 groups ($p > 0.05$).Distributions of atrial septal largest diameter between study groups are shown in Figure 1 ($p < 0.001$).

There were no significant differences in the operative time, exposure time, electrocardiogram, or the pulmonary systemic circulation blood flow ratio between the 2 groups ($p > 0.05$). The type of occluder p value was equal to 0.025, which was mainly related to the different proportion of occluders used by Dragon Boat Feidu and Shengjie of Huay, as shown in Table 2.

Overall, the immediate success rate of the procedure was 96.7%. There were no significant differences in the success rate of the procedure or the incidence of residual shunt, arrhythmia, procedure-related arrhythmia, or occluder shedding ($p > 0.05$). No complications, such as atrioventricular passage, hemorrhage, or thromboembolism occurred in either group. There were 4 cases that experienced shedding of the occluder in the control group and 1 in the experimental group, as shown in Table 3. After applying multivariable logistic analysis, we found no association between an age ≤2-year-old and any adverse outcomes postprocedure within 24 hours, including procedure failure (OR = 0.35; 95%CI: 0.04 to 2.93), residual shunt (OR = 1.07; 95%CI: 0.54 to 2.14), arrhythmia (OR = 0.68; 95%CI: 0.32 to 1.43), and procedure-related arrhythmia (OR = 0.34; 95%CI: 0.04 to 2.87), as shown in Table 4.

The number of adverse complications following three-year follow-up are shown in Table 5. The most common adverse outcome was arrhythmia, a smaller proportion of which was related to the procedure. We also found no association between an age ≤2-year-old and arrhythmia (OR = 0.95; 95%CI: 0.50 to 1.80) or procedure-related arrhythmia (OR = 0.96; 95%CI: 0.25 to 3.64) in the multivariate Cox proportional hazard models in Table 6. The Kaplan-Meier survival curve indicated no significant differences in the cumulative arrhythmia-free rate of ASD patients between the 2 groups at a 36-month follow-up by log-rank test (p = 0.776) (Figure 2).

Table 2
Procedure characteristics of study groups

Characteristics	Age(years) >2 (n = 665)	Age (years)≤2 (n = 128)	p value
Operation time, min [median (range)]	43 (6-180)	45 (10-120)	0.130
Fluoroscopic time, min [median (range)]	6 (2-29)	6 (3-25)	0.192
Device used			
Longzhoufeidu	158 (23.94%)	20 (15.75%)	0.025
Lifetech	430 (65.15%)	83 (65.35%)	
Shengjie	45 (6.82%)	17 (13.39%)	
AGA	27 (4.09%)	7 (5.51%)	
ECG normal	96 (14.44%)	12 (9.38%)	0.126
Qp/Qs ratio [median (range)]	1.88 (1.2-12)	1.73 (1.14-5.7)	0.065

Table 3
Outcomes and complications within 24 hours post procedure

Outcomes	Age(years) >2 (n = 665)	Age(years) ≤2 (n = 128)	p value
Procedure failure	25 (3.76%)	1 (0.78%)	0.103
Residual shunt	65 (9.77%)	13 (10.16%)	0.894
Arrhythmia	90 (13.53%)	10 (7.81%)	0.074
Procedure-related arrhythmia	15 (2.26%)	1 (0.78%)	0.491
Shedding of occluder	4 (0.6%)	1(0.008%)	1.000
Aortic about room fistula	0	0	-
Hemolysis	0	0	-
Thrombosis embolism	0	0	-
headache	0	0	-

Table 4
Logistic analyses of association between an age ≤2-year-old and post-procedure outcomes within 24 hours

Outcomes	OR*	95%CI	p value
Procedure failure	0.35	0.04-2.93	0.331
Residual shunt	1.07	0.54-2.14	0.842
Arrhythmia	0.68	0.32-1.43	0.307
Procedure-related arrhythmia	0.34	0.04-2.87	0.322

CI = confidence interval; OR = odds ratio.
* Adjusted for weight ≤15 kg, big ASD and insufficient rims; age>2 years was used as reference.

Table 5
Cumulative cases with adverse outcomes in 3-year follow-up

Outcomes	n (%)
Residual shunt	0
Arrhythmia	86 (11.21%)
Procedure-related arrhythmia	21 (2.65%)
Shedding of occlude	1 (0.13%)
Aortic about room fistula	0
Hemolysis	0
Thrombosis embolism	0
Headache	0
Abnormal color doppler echocardiography	0

Occluder detachment occurred in 5 cases (4 cases in the > 2-year-old group and 1 case in the ≤2-year-old group) within half an hour of the operation. For one of these cases, the patient was a 22-month-old male, who presented with a margin deficiency. This patient with an ASD of 16 mm in diameter was treated with an occluder that was 24 mm in diameter. The margin of superior vena cava was 3.7 mm, and soft rims were present. While the left atrial occluder tray slid to the right atrium, immediate thoracotomy and repair of the ASD occluder, including removal, was implemented. The second case was an 87-month-old female patient with porous ASD who as treated by a Boat Fit ASD occluder 10 mm in diameter, which was released and then dropped off to the right atrium. The occluder was removed by trap and then replaced with a HeartTMASD occluder from Lifetech Scientific, which was a 16 mm ASD occluder. Because of atrial arrhythmia, the occluder was abandoned and replaced by surgical repair. The third case was a 14-year-old male patient with a superior vena cava edge of 3 mm, right pulmonary vein edge of 5 mm, aortic edge of 2 mm and the ASD of 28 mm in diameter. One minute after occlusion, the occluder detached into the right atrium. Surgical removal of the occluder and ASD repair was performed. Another case was a 24-year-old female with a normal edge and an ASD diameter of 37 mm, which was repaired with an occluder 42-mm in diameter. The defect was too large, and the left atrial disc was easily pulled to the right atrium. The patient then declined interventional occlusion and ASD repair surgery was implemented. In addition, three patients presented with a

Table 6
Univariate and multivariate Cox proportional hazard analyses of age ≤ 2 years for adverse outcomes

Outcomes	Univariate analysis		Multivariate analysis	
	HR (95%CI)	p value	HR* (95%CI)	p value
Arrhythmia	0.81 (0.44-1.50)	0.511	0.95 (0.50-1.80)	0.864
Procedure-related arrhythmia	0.86 (0.25-2.94)	0.816	0.96 (0.25-3.64)	0.946

CI = confidence interval; HR = hazard ratio.
* Adjusted for weight ≤15 kg, a large ASD, and insufficient rims; age >2-year-old was used as a reference.

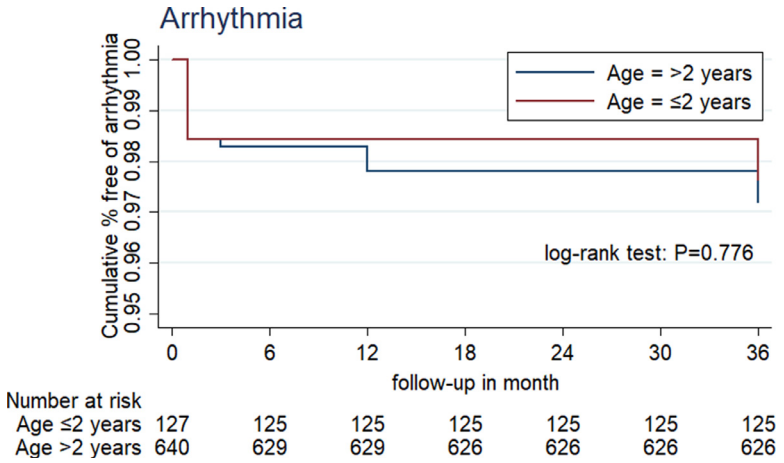

Figure 2. Kaplan-Meier survival curve of cumulative % free of arrhythmia in ASD patients between study groups.

headache. One 24-year-old woman had a headache 1 month after interventional occlusion, the other two 12 to 14-year-olds had a headache about half a year after interventional occlusion. Echocardiography showed no residual shunt or thrombosis, while the results of electroencephalogram, cranial CT, and MRI were normal. There were further no complications, such as atrial fistula, hemolysis, or embolism. The etiology of her headache was unknown. The symptoms of headache, however, disappeared after surgical removal of the occluder.

Discussion

Zhang Zhiwei's team has carried out the interventional therapy of congenital heart disease since 1990. The first domestic occluder was successfully put into clinical use in 2000. In China, the total number of patients with ASD is huge. Transcatheter closure for congenital heart disease has made several big leaps forward during its development in China.[13,14]

From 1998 to 2009, We successfully performed ASD occlusion[15] in 12 under 2-year- old infants. From 2011 to 2016, all patients with secundum ASD were occluded in our center. Among the 128 patients, 98.4% of the patients weighed less than 15 kg. And more than half of the patients weighted less than 10 kg, of which the minimum weight was 7 kg and the minimum age was 7 months, while 11 cases were younger than 1-year-old. Among the 665 cases, 45.1% of the patients weighted less than 15 kg and 3.1% weighed less than 10 kg. The overall ASD closure success rate (including follow-up period) is excellent in our study. Procedure times, radiography screening times, and interventional success rates are similar or comparable to previous results reported in children ≥10 kg in weight or adults.[16–18] Whereas previous series showed higher complication rates,[19–23] our results show a low complication rate. Compared with secundum ASD patients older than 2-year-old, secundum ASD interventional occlusion in low-weight patients was feasible and safe; the success rate of it interventional occlusion in young low-weight patients was similar to that of the control group.

The edge of ASD in infants is flat, thin, and easily damaged. This is especially problematic for large ASD; the earliest balloon measurement of the diameter of the ASD may tear the edge of the defect, resulting in a large edgeless ASD, which causes these children to lose the opportunity for interventional treatment. The right ventricular space of infants is often small, such that the incidence of potential complications of balloon occlusion of the tricuspid orifice and vena cava is significantly higher than in adults. The success rate of transcatheter closure of ASD is high (98%). An important factor is that using transthoracic echocardiography to observe and measure the maximum diameter of the ASD and choosing the appropriate occluder not only avoid the complications associated with balloon measurement, but also significantly improve the success rate of interventional occlusion, shorten the operation time, and reduce the complications caused by prolonged anesthesia. Therefore, ASD interventional occlusion in infants requires skilled catheterists doctors.

All cases have been followed up for at least 3 years, some up to 8 years. In this experimental group, children were younger, had larger defects, larger shunt volumes, no significant increase in pulmonary artery pressure, right atrium enlargement, tricuspid regurgitation, and increased right heart volume load as found by color Doppler echocardiography. All these conditions were significantly improved after 3 to 6 months of follow-up after interventional occlusion, and nearly all patients were reexamined at 6 months after the procedure, indicating that the left-right heart ratio had returned to normal. Therefore, we believe that: (1) it is more appropriate to intervene at 2-year-old for patients with ASDs ≥10 mm or defects ≤10 mm with increased right ventricular volume load or with atrial septal enlargement. (2) Percutaneous ASD occlusion is generally not advocated for in infants under 1 year of age, unless combined with other cardiac malformations that need to and can be treated by interventional therapy. If the ASD is larger, it is estimated that the possibility of natural closure is not high. (3) We believe that a defect ≤10 mm that does not show an increased in right ventricular volume load by echocardiography, electrocardiogram, and X-ray chest radiography and patients without atrial septal enlargement can be followed up.

Another difficult problem of ASD occlusion in young and low weight infants is femoral vein puncture. The smaller the body weight, the smaller the blood vessel, and the more difficult the puncture is to perform. The success of vascular puncture accounts for half the success of the procedure. The puncture technique we currently used is the Seldinger puncture. Based on our experience, we usually recommend intervention when the patient's weight is above 10 kg.

In our study, 26 had a failed occlusion (25 cases in control group and 1 case in experimental group). There was no significant difference ($p \geq 0.05$). The causes of failure were mainly related to an insufficient margin of ASD, excessive defects, complicated pulmonary hypertension, serious arrhythmia during operation, and the detachment of the occluder.

There was only a small incidence of residual shunt, which was about 10% in both groups 24 hours after the operation ($p \geq 0.05$). No cases of residual shunt in the 2 groups 3 years after the closure procedure. This may be related to the occluder implantation after peripheral occluder endothelialization. Zhang Zhiwei's team found that in an ASD animal model where the animal was implanted with a atrial septal occluder, 1 to 6 months later, gross anatomy showed the occluder and the atrial septal tissue fitted closely, and the surface of the occluder was completely covered with a layer of white translucent endothelial tissue.[24] Therefore, the porous ASD of children should be as close as possible to the central shunt. Hemodynamic changes were not affected by a small amount of residual shunt, which could not be treated with special treatment and was regularly followed up after discharge.[25]

After the interventional therapy of ASD, atrial arrhythmias are relatively common, including atrial tachycardia and premature atrial beating; the incidence rates for these arrhythmias range from 5.2% to 16.0%.[26,27] When there is a left to right shunt, preoperative right ventricular overload can occur, while a right ventricular volume load drop can occur postoperatively. Atrial wall edema caused by mechanical injury of atrial wall can be caused by the occluder.[28] The arrhythmias found on the first day after operation disappeared in 82.3% of the patients at the 1-month follow up, after treatment with hormone and nutritious myocardium. One month later, 5 cases of Ⅱ° AVB, disappeared in 6 months follow-up after hormone therapy. This is different from postoperative arrhythmias caused by the surgical repair of ASD, which may be associated with surgical scars and often need to be treated by radiofrequency ablation.

In this study, 5 cases of occluder detachment occurred (0.5%). The need for surgical treatment accounted for 0.4% of cases,[29] which occurs with margin deficiency or a large ASD, which is detected intraoperatively or soon during the post-treatment follow up. One surgical approach to gain access is via the femoral vein pathway to retrieve the detached occluder. Another involves a thoracic surgical operation to remove the occluder. Five cases in this group were treated with the latter, and the postoperative recovery was satisfactory. There were 2 cases of unexplained headache, no evidence of thrombosis, epilepsy, or need for further follow-up. The symptoms of headache disappeared after removing the occluder by thoracotomy and removing the occluder in 12-year-old 13-year-old patients. No other serious complications occurred.

To sum up, this procedure is safe, reliable and good feasibility in young and low weight infants. However, it is necessary to carefully consider the indications for it, select appropriate cases, and a skilled catheter operator perform the procedure. It is more advantageous for children to choose the smallest occluder possible. Generally, the appropriate size is the maximum diameter of the ASD plus 3 mm. A small amount of residual shunt when the edge of occluder is less than 3 mm is allowed immediately after operation and will likely resolve during follow up.

Author's contributions

Chunhui Cao:Conceptualization, Methodology, Software, Writing - Original Draft, Writing - Review & Editing; Ren Li:Conceptualization, Visualization, Investigation, Software; Jun Huang:Conceptualization, Visualization, Software,Investigation; Yaqin Zhao:Conceptualization, Visualization, Investigation; Zhonghua Wang:Methodology, Resources, Visualization; Yumei Xie: Resources, Methodology, Visualization; Shushui Wang:Resources, Methodology, Visualization; Rong Zhou:Project administration; Dongxin Lin:Formal analysis, Software,Methodology; Lingxia Fan: Resources, Software; Xianglong Wei: Supervision, Validation; Zhiwei Zhang:Supervision, Funding acquisition, Resources, Writing - Review & Editing.

Disclosures

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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