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Feasibility, Safety and Long-Term Follow-Up of Transcatheter Closure of Secundum Atrial Septal Defects with Deficient Rims

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Key Words
Deficient rims · Atrial septal defect · Complications · Follow-up period · Left-to-right shunt

Abstract
Objective: The aim of this work was to evaluate the feasibility and safety of transcatheter closure procedures for the treatment of atrial septal defects (ASDs) with insufficient rims. ***Methods:*** A total of 507 secondary ASDs were divided into two groups based on whether they had deficient rims or not (152 vs. 355 cases, respectively). Any complications, including residual shunt, heart arrhythmia, occluder translocation, etc., were followed up for 1–3 years. ***Results:*** There were no differences in gender, weight, exposure time, ECG states, pulmonary pressure, the intervention success rate, occurrence of residual shunt, the operation time and occurrence of residual shunt during follow-up between the two groups ($p > 0.05$). However, the occurrence of rhythm disorders was significantly different between the two groups; ASDs with deficient rims were at an elevated risk ($p < 0.05$). Specifically, there was a significantly higher incidence in the occurrence of arrhythmia in the deficient rims group at 24 h postoperation, but no differences in arrhythmia incidence at any of the other follow-up time points (1, 3, 6, 12 and 36 months; $p > 0.05$). ***Conclusions:*** Patients with deficient rims experience a high success rate of ASD intervention and low rate of complications when the procedures are performed by experienced operators.
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Introduction

Atrial septal defects (ASDs) are among the most common congenital heart diseases, with an incidence of 56 per 10,000 live births [1]. Hemodynamic changes occur due to a septal defect (the right and left heart chambers are no longer separated), and the blood can be shunted from left to right causing dangerous increases in the pulmonary circulatory blood volume. Common results of left-to-right shunting are frequent pulmonary infections and right ventricular dysfunction. Since King et al. [2] and King and Mills [3] reported the first cases of ASD intervention in 1974, the treatment of these defects has improved with accumulating experience, although challenges to the repair of ASDs remain, specifically a certain range of edge problems (e.g. insufficient rims). The goal of our study was to review the relevant data for a group of patients that underwent ASD interventional treatment

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and to compare the outcomes for patients with sufficient versus insufficient rims. We assessed occluder selection, the mode of operation, and the type and rate of postoperative complications to determine how the presentation of the defect edges affects the feasibility and success of ASD interventional treatment.

Methods

Study Subjects and Inclusion and Exclusion Criteria

Patients treated from January 2011 to April 2014 in the Guangdong Cardiovascular Institute who met the diagnostic criteria for ASD were included in this study [4]. We selected 507 consecutive patients (278 females, 229 males) with secundum ASD. Informed consent for intervention operations was obtained from all patients or guardians. The hospital investigational review board approved the study. Patients with ASDs that were of hemodynamic significance, defects that were small but were accompanied by a serious risk of blood clot, and ASDs with a diameter greater than the selected occluder were included in this study. Patients with endocarditis, bleeding disorders, contraindication to aspirin (except those taking other antiplatelet agents for 6 months continuously), severe pulmonary hypertension, severe infection, and those requiring surgical treatment for other heart defects were excluded from the study [5].

Transthoracic Echocardiography

A complete transthoracic echocardiography (TTE) study was performed in all 507 patients (152 patients with a small atrial septal rim and 355 patients with sufficient rims) just prior to cardiac catheterization, as part of the closure protocol. The atrial septum was scanned in 4-chamber, short-axis and subcostal biatrial views to assess the defects and rims. The superior and inferior vena cava rims were measured in the subcostal biatrial view, which clearly displayed the superior vena cava and inferior vena cava in the same image. Anterior and posterior rims were measured in the short-axis plane, displaying the aortic root [6]. The 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 result 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. This was classified as trivial if the width was <1 mm in diameter, small if the width was between 1 and 2 mm, moderate if the width was between 2 and 4 mm, and large if the width was ≥4 mm [7–9].

Division into Experimental and Control Groups

In this retrospective study, patients were divided into two groups: (1) those with ASDs with insufficient rims (experimental group) and (2) those with sufficient rims (control group). The experimental group included patients with deficient rims of the right pulmonary vein, superior vena cava and inferior vena cava, or atrioventricular valve, of which at least one rim was 5 mm or less [3]. Patients in which all rims were more than 5 mm were allocated to the control group. We placed 152 cases (30.0%) in the deficient rims group and 355 cases (70.0%) in the sufficient rims group. There were 106 patients (69.7%) with a single deficient rim and 46 cases with two or more deficient rims (30.3%). Cases in which the edge length was greater than or equal to 3.0 mm accounted for 79.6% of the patients.

Devices

The following devices were used to treat patients with secundum ASDs based on the case presentation: a Boat Fit ASD occluder of Beijing Dragon Flying Institute Memory Alloy, an ASD occluder, a Cera™ ASD occluder, and a Heart™ ASD occluder of Lifetech Scientific. The Amplatzer septal occluder (AGA Medical Corp., Golden Valley, Minn., USA) was specifically used to treat patients with deficient rims.

Implantation Procedure

Routine right heart catheterization and measurements of right atrial pressure, right ventricular pressure, pulmonary artery pressure in the superior vena cava and inferior vena cava, and the pulmonary artery and left atrium pulmonary vein blood oxygen saturation were recorded. We then calculated the circulation/pulmonary blood flow and resistance ratio. We established the transport track of the femoral vein and inferior vena cava from the right atrium to the left atrium and to the pulmonary veins. We then selected the appropriate occluder for use with either the conventional release or pulmonary vein release method. The device was deployed by the femoral vein route in the long delivery of the sheath, under the supervision of X-ray and TTE. The left plate was released first (in the left atria), then the operator returned to the system so that the waist card was in the housing to finally release the right plate (in the right atria). When the position was confirmed, the device was completely released.

Medication and Follow-Up

Aspirin was orally administered for 6 months after surgery at a dose of 3–5 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 closure procedure. Transthoracic echocardiography was performed to evaluate the device position and potential residual shunts. 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.

Statistical Analysis

SPSS 19.0 for Windows (SPSS Inc., Chicago, Ill., USA) was used for the statistical analysis. $p < 0.05$ was considered statistically significant. For inspection methods normal continuous data between the groups were compared using two independent samples and a t test (homogeneity of variance) or corrected t test (ANOVA missing). Nonnormally distributed data was compared using a Wilcoxon rank sum test. Discrete data were compared with a t test or Fisher's exact test. All hypothesis testing used a two-tailed test. Parametric data are expressed as the mean ± SD. Nonparametric analysis was performed using the Pearson χ^2 test or Fisher's exact test. An independent samples t test was used to compare means.

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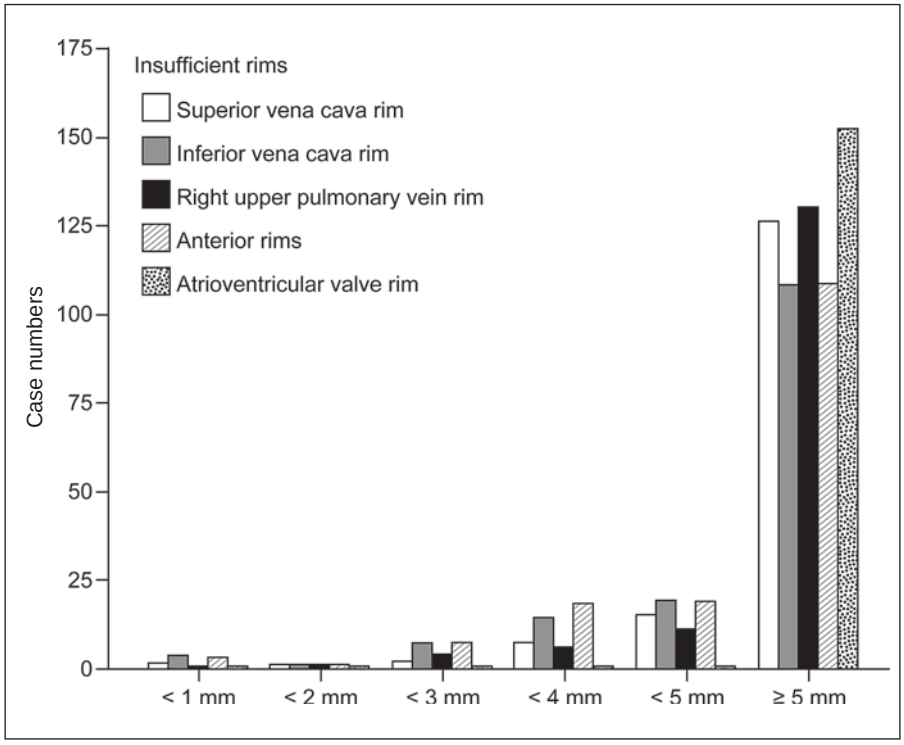

Fig. 1. The exact deficient rim length of the experimental group.

Results

Baseline Characteristics

The characteristics of the 507 total cases, divided between the experimental and control groups, are listed in table 1. Of these, 152 patients had deficient rims (30.0%) and 355 patients had sufficient rims (70.0%). For patients with deficient rims, 106 cases (69.7%) presented with a single deficient rim, while 46 cases (30.3%) presented with two or more deficient rims (30.3%). However, the limited edge length was greater than or equal to 3.0 mm in most patients (79.6%). On the basis of the length of the deficient rims, 152 patients were divided into subgroups (<1.0 mm; ≥1.0, <2.0 mm; ≥2.0, <3.0 mm; ≥3.0, <4.0 mm; ≥ 4.0, <5.0 mm, and ≥5.0 mm) as shown in figure 1. There were no cases of deficient rims on atrioventricular valves.

Comparison of Basic Data

There were no differences in gender distribution, body weight, exposure time, ECG results or pulmonary artery pressure between the two groups (deficient vs. sufficient rims; $p > 0.05$). However, the ASD maximum diameter was statistically different between the two groups ($p = 0.00$). There was a significant difference in the pulmonic to systemic blood flow rates between the two groups; this

Table 1. Basic characteristics of all cases (n = 507)

Age, years	48 (32, 92) [7–591]
Male/female	229 (45.2)/278 (54.8)
Weight, kg	15.0 (12.0, 21.0) [7.5–81.0]
>15 kg	239 (47.1)
≤15 kg	268 (52.9)
Sinus rhythm	506 (99.8)
Atrial rhythm	1 (0.2)
Right ventricular dilatation	497 (98.0)
Pulmonary arterial systolic pressure ≥30 mm Hg	180 (35.5)
Big ASD (≥25 mm)	30 (5.9)
Large ASD (≥35 mm)	4 (0.8)
Multiple ASD	42 (8.3)
Combined pulmonary stenosis	3 (0.6)
Combined ventricular septal defect	3 (0.6)
Combined patent ductus arteriosus	1 (0.2)
Combined partial anomalous pulmonary venous drainage	1 (0.2)
Combined dual atrioventricular nodal pathway	1 (0.2)

Values are presented as the mean (95% CI) [range], or n (%).

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Table 2. Comparison of basic data between the two groups

	Male/ female	Age, months	Weight, kg	Operation time, min	Fluoroscopic time, min	Qp/Qs	ECG normal	ASD, mm	PAH, mm Hg
Deficient rims group (n = 152)									
	72/80	47 (31, 86) [8–492]	15.0 (11.1–20.0) [7.5–62.0]	45 (40, 52) [20–135]	6.0 (5.0, 8.0) [2.0–25.0]	1.98 (1.54, 2.63) [0.65–6.30]	150/2	16.0 (12.0, 20.0) [4.0–37.0]	27 (24, 32) [6–54]
Sufficient rims group (n = 355)									
	157/198	48 (32, 95) [7–591]	15.0 (12.0, 22.5) [7.5–81.0]	40 (35, 50) [5–180]	6.0 (5.0, 8.2) [2.0–30.0]	1.78 (1.42, 2.40) [1.00–6.70]	354/1	12.0 (9.0, 17.2) [3.7–40.0]	27 (23, 31) [11–72]
Z/χ^2	0.43	–1.08	–1.49	–2.23	–0.06	–2.31	1.94	–5.27	–1.66
p	0.52	0.27	0.14	0.02*	0.95	0.02*	0.22	<0.001*	0.1

Values are presented as the mean (95% CI) [range], or n. PAH = Pulmonary arterial hypertension. * $p < 0.05$.

Table 3. Outcomes and complications occurring within the first 24 h postprocedure

	Success/ failure	Device used (Lifetech/ Longzhoufeidu/AGA)	Residual shunt	Arrhythmia	Shedding of occluder	Aortic about room fistula	Hemolysis	Thrombosis embolism
Deficient rims group (n = 152)	144/8	122/29/1	10	11	1	–	–	–
Sufficient rims group (n = 355)	345/10	231/122/3	18	3	1	–	–	–
Z/χ^2	0.43	11.89	0.46	16.19	–	–	–	–
p	0.19	–	0.31	<0.001*	–	–	–	–

* $p < 0.05$.

Table 4. Comparison of the occurrence of residual shunt at each follow-up point

	24 h postprocedure		1 month postprocedure	
	residual shunt	no residual shunt	residual shunt	no residual shunt
Deficient rims group	10 (6.6)	142 (93.4)	3 (2.0)	149 (98)
Sufficient rims group	18 (5.1)	337 (94.9)	1 (0.3)	354 (99.7)
χ^2	0.37		3.88	
p	0.54		0.49	

Values are presented as n (%).

Table 5. Comparison of residual shunt occurrence for patients with multi- versus non-multihole ASDs

	Residual shunt	No residual shunt
Multihole ASD	10 (35.7)	32 (6.7)
Non-multihole ASD	18 (64.3)	447 (93.3)
χ^2	29.35	
p	<0.001	

Values are presented as n (%).

ratio was slightly higher in the deficient rims groups ($p = 0.02$; table 2).

Comparison of the Immediate Outcomes and Complications between Groups Postsurgery

The immediate procedure success rate was 96.4%, and there were no significant differences in the operation success rate or the occurrence of a residual shunt between the two groups ($p > 0.05$). However, there was a significant difference in the incidence of arrhythmia between the two

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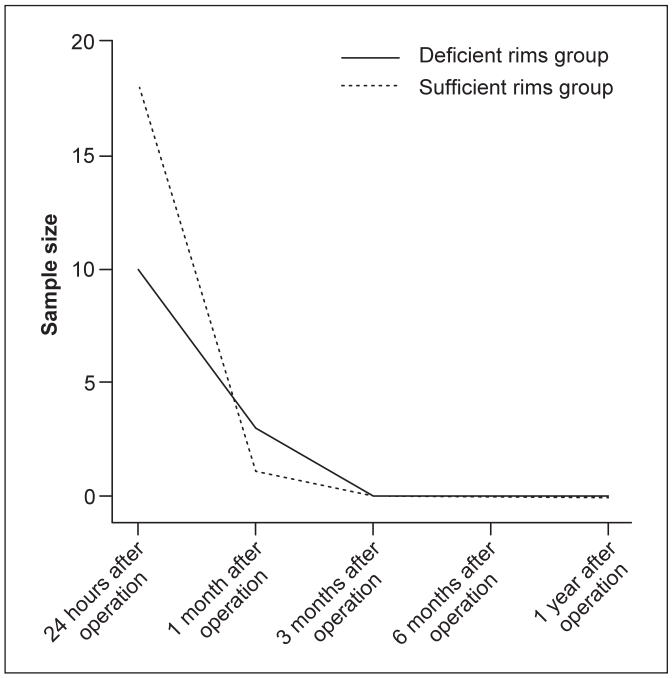

Fig. 2. Trends in the occurrence of residual shunts over time for both the deficient and sufficient rims groups.

groups ($p < 0.05$), and 2 patients experienced dislocation of the device (table 3).

Comparisons in the Occurrence of Residual Shunts during Follow-Up

Less than 50% of patients completed follow-up due to its extended length (3 years). Follow-up compliance was not compared between the two groups (sufficient vs. deficient rims). There were no significant differences in the occurrence of residual shunt between the two groups at 24 h and 1 month after the closure procedure ($p > 0.05$). There were no cases of residual shunt in either group at 3, 6 or 12 months after the closure procedure (table 4). However, the multihole ASD residual shunt incidence was lower than for non-multihole ASDs ($p < 0.05$; table 5). The incidence of residual shunts over time is plotted for both groups in figure 2.

Comparisons in the Occurrence of Arrhythmias during Follow-Up

There were 14 cases of arrhythmias within 24 h of completion of the closure procedure, including 6 cases of I°AVB, 2 cases of frequent ventricular prematurity, 5 cases of early or nonparoxysmal atrial tachycardia, and 1 case of II°AVB. There was 1 case of nonparoxysmal atrial tachycardia and 1 case of I°AVB before the procedure. There was a significantly higher incidence in arrhythmia in the insufficient rims group at 24 h postsurgery ($p < 0.05$), but there were no significant differences between the two groups at any other time point ($p > 0.05$). These results are presented in tables 6 and 7. The incidence of arrhythmias over time is plotted for both groups in figure 3.

Comparison of Occluder and Operation Mode Selection

The 'conventional release method' or 'pulmonary vein release method' was used for interventional occlusion. There was a statistically significant difference in procedure selection between the two groups ($p < 0.001$); the pulmonary vein release method was more frequently used to treat defects with insufficient rims (table 8). There may also be a statistically significant trend in the relationship between the size of the occluder used and the septal defect diameter ($p = 0.06$).

Other Complications

Occluder detachment occurred in 3 cases within 30 min of the operation. For 1 of these cases, the patient was a male aged 1 year and 10 months, who presented with a marginal deficiency. This patient's ASD was 16 mm in diameter and he was treated with an occluder that was 24 mm in diameter. The margin of the superior vena cava was 3.7 mm with soft rims. The left atrial occluder tray slid to the right atrium, and an immediate thoracotomy and ASD repair was required, including occluder removal. The other case was a 14-year-old male patient with a superior vena cava edge of 3 mm, a right pulmonary vein edge of 5 mm, an ASD of 28 mm and an aortic edge of 2 mm. Atrial septal occluder detachment fell into the right ventricular 1 min after transcatheter closure of atrial septal. The patient required surgical removal of the occluder and ASD repair. The final case was a 24-year-old female with a normal edge and an ASD diameter of 37 mm, which was repaired with a 42-mm diameter occluder. The defect was too large and the left atrial disc was easily pulled to the right atrium, resulting in an unsuccessful interventional occlusion and ASD repair surgery. This patient presented with a headache 1 month postsurgery and an ASD of 28 mm. The occluder used was 38 mm in diameter, and echocardiography showed no residual shunt or thrombosis, while electroencephalogram, cranial CT and MRI were normal. There were no further complications, such as atrial fistula, hemolysis or embolism, and the etiology of her headache was unknown.

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Table 6. Comparison of the occurrence of arrhythmias (yes/no) at each follow-up point

	24 h postprocedure		1 month postprocedure		3 months postprocedure		6 months postprocedure		12 months postprocedure	
	yes	no	yes	no	yes	no	yes	no	yes	no
Deficient rims group (n = 152)	11 (7.2)	141 (92.8)	6 (3.9)	146 (96.1)	4 (2.6)	148 (97.4)	4 (2.6)	148 (97.4)	4 (2.6)	148 (97.4)
Sufficient rims group (n = 355)	3 (0.8)	352 (99.2)	5 (1.5)	350 (98.6)	4 (1.1)	351 (98.9)	2 (0.6)	353 (99.4)	2 (0.6)	353 (99.4)
χ^2	16.19		3.23		1.55		3.89		3.89	
p	0		0.09		0.25		0.07		0.07	

Values are presented as n (%).

Table 7. Type of arrhythmias occurring in the experimental versus control groups

	Atrial premature beat, atrial tachycardia or AV junctional escape beat	AV block (I°/II°)	Ventricular premature beat
Deficient rims group (n = 152)	4	7/2	1
Sufficient rims group (n = 355)	6	1/2	1
χ^2	0.88	7.38	0.38
p	0.46	0.01*	0.51

* $p < 0.05$.

Discussion

ASD is one of the most common congenital heart diseases, but it can be repaired by interventional treatment, which has the advantages of limited trauma, no scarring, no effects on appearance or recovery, relative safety, and yet can achieve the same results as more traditional surgical treatments [10]. With accumulating experience performing this treatment, along with improvements in the operation technique, even defects with small margins or rims can be successfully repaired using interventional treatment. In this study, patients were followed for up to 36 months, and we compared the selected operation mode and postoperative complications in patients with normal rims to those with one or more insufficient rims. In this way, the feasibility of the ASD interventional treatment for patients with deficient rims was evaluated objectively.

The immediate closure result and device position was assessed by TTE after releasing the device. The width of the color jet as it exited the atrial septum was used as a measure of the severity of any residual shunt. The residual shunt was classified as trivial if the width was <1 mm in diameter, small if the width was between 1 and 2 mm, moderate if the width was between 2 and 4 mm, and large if the width was ≥4 mm [11]. In this study, we only identified small residual shunts, and the immediate closure rate was 94.5%, while the closure rate after 1 month was 99.2%. We found no significant differences in the occurrence or type of residual shunt between patients with sufficient rims and patients with deficient rims ($p > 0.05$). There were 42 cases of multihole ASDs, which we determined to be the main contributor to the occurrence of a residual shunt; the difference in shunt occurrence was statistically significant between the multihole and nonporous ASD groups ($p < 0.001$). In this study, despite using an occluder for a double-hole ASD, there was an increased incidence of residual shunt. However, over time the residual shunt will gradually reduce until it disappears. There were no cases of residual shunt in either group (sufficient vs. deficient rims) at 3, 6 or 12 months postsurgery. This may be related to the occluder implantation after peripheral occluder endothelialization. Xie et al. [12] found that in an ASD animal model there are gross anatomical changes that occur 1–6 months after the procedure; the occluder and the atrial septal tissue fit more

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Table 8. Comparison of the method of operation selection between the two groups

	Difference between D1 and D, mm	Pulmonary venous release
Deficient rims group (n = 152)	5.0 (4.0, 6.0) [0.0–12.0]	87 (57.2)
Sufficient rims group (n = 355)	4.3 (4.0, 6.0) [0.0–16.0]	48 (13.5)
Z/χ^2	1.3	104.1
p	0.06*	<0.001*

Values are presented as the mean (95% CI) [range], or n (%). D1 = ASD diameter; D = occluder waist diameter. * $p < 0.05$.

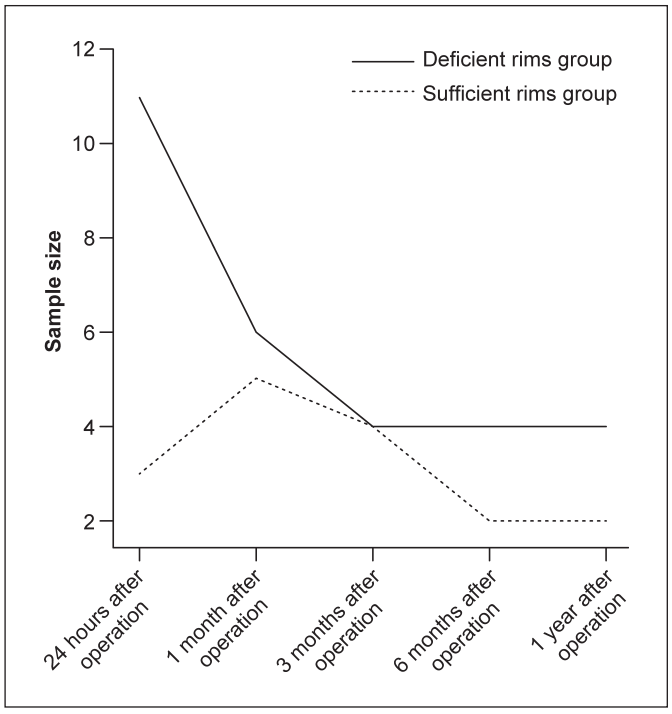

Fig. 3. Trends in the occurrence of arrhythmias over time in both the deficient and sufficient rims groups.

closely with time, and the surface occluder becomes completely coated with a layer of white translucent endothelial tissue. Therefore, in children with porous ASDs, the occluder should be placed as close as possible to the central shunt. Hemodynamic changes do not often occur when there is a small residual shunt that cannot be resolved by other treatments. Regular follow-up after discharge is often sufficient for these patients [13].

After the interventional treatment of ASDs, 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% [14, 15]. When there is a left-to-right shunt, preoperative right ventricular overload can occur, while a right ventricular volume load drop can occur postoperatively. Furthermore, the amplitude of the ECG P-wave amplitude can decrease, the P wave duration can be shortened, and myocardial troponin may be released, while closure of the atrial wall can cause mechanical damage and edema of the inner wall of the atrium, all of which are associated with early atrial tachycardia [16]. This does not often occur immediately, but will occur a month after the closure procedure as the myocardial edema subsides and the heart rate slows to facilitate recovery. The PR interval and the duration of the P wave was lengthened in the follow-up period, which indicated that the atrial conduction delay was prolonged, so it was necessary to extend the follow-up time, which was favorable for the discovery of potential atrioventricular block [14].

Arrhythmia can often be treated with minimally invasive hormone therapy and nutritional myocardial drugs. In the first days after surgery, 71.4% of all the arrhythmias disappeared, which was evident at the 1-month follow-up. Two patients with delayed third-degree atrioventricular block (III°AVB) returned to normal within 6 months of the closure procedure. However, there were no significant changes in the long-term follow-up of 3 patients with III°AVB, even at 1 year postoperation. Vecht et al. [17] also examined the incidence of arrhythmia after ASD intervention and showed that the incidence rate of arrhythmia decreases with time. The results of this study are consistent with the results of our meta-analysis. A III°AVB is a rare complication of ASD interventional therapy, which can occur when an edge of the occluder rests on the sinoatrial node, causing mechanical friction, physical oppression, and local inflammatory reactions and edema, which is often followed by fibrosis and scar formation [18]. Unfortunately, this can occur anywhere from several days to several years after intervention. Another cause of III°AVB is the use of an occluder with a diameter that is too large

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to repair the defect. Studies have shown that increasing occluder size is an independent risk factor for III°AVB [19]. These theories provide the basis for the treatment of atrioventricular blocks that do not resolve after hormone therapy. During the early stages of III°AVB, glucocorticoid and nutritional myocardial drugs may be effective to improve the AV block, but there is no evidence that these drugs can reverse the conduction block [20]. For those patients in which III°AVB does not resolve with drug therapy, the occluder is usually removed within a week. For some patients, recovery of a normal sinus rhythm occurs naturally without the need to install a permanent pacemaker. However, the timing of the surgery is essential to restoring a sinus rhythm. Once identified, treatments for an AVB should begin immediately, which include surgery and the appropriate application of hormones that can improve myocardial edema and relieve the inflammatory reaction to return to a stable hemodynamic state. A heart rate greater than 50 beats/min requires clinical observation and close follow-up.

In this study, two cases of occluder detachment occurred. During the interventional treatment of ASD, occluder detachment results in an embolism rate of about 1.4%, while 0.4% of these cases will require further surgery [21]. Occluder detachment is most common in patients with insufficient rims or extremely large ASD diameters. One recovery approach would be to reenter the heart through the femoral vein to snare the detached occluder. The other option would be to perform thoracic surgery to remove the occluder. In our study, both cases of detached occluders were treated with thoracic surgery, and their postoperative recovery was satisfactory. The adverse outcomes for this study were limited. Other than occluder detachment and arrhythmia, we had only 1 case with unexplained headache, with no evidence of thrombosis or epilepsy, which required additional follow-up.

Intervention for ASD is often most successful during childhood, but working with children can ultimately pose more challenges. However, our study confirmed that even with deficient or marginal rims, interventional treatment was largely successful (only small residual shunts occurred, which were mostly resolved by the 1-month follow-up appointment) and was accompanied by a relatively low complication rate. One reason why this procedure was so successful in our study population is that most patients only had a single deficient rim (69.7%), which was typically ≥3 mm (79.6%). Therefore, the apparent success rate in a population with a greater number of deficient rims with smaller edges might be different. However, another reason for our success is that echocardiography assessment of the edge prior to surgery proved accurate and we are well practiced at performing the pulmonary vein release method. Therefore, it is feasible to maintain this high success rate when selecting appropriate cases for pulmonary vein release (some may require conventional techniques), using skilled operators to place the catheter, and bearing in mind the edge and size of the defect when selecting the treatment course, occluder size and follow-up care.

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Conflict of Interest

The authors declare that they have no conflicts of interest.

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