

Retrospective Study

Percutaneous closure of secundum type atrial septal defects: More than 5-year follow-up

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septal defect (ASD) closure in adults.

METHODS: All patients who underwent percutaneous closure of an ASD in the St. Antonius Hospital, Nieuwegein, The Netherlands, between February 1998 and December 2006 were included. Percutaneous closure took place under general anaesthesia and transesophageal echocardiographic monitoring. Transthoracic echocardiography (TTE) was performed 24 h post-procedure to visualize the device position and to look for residual shunting using color Doppler. All complications were registered. All patients were invited for an outpatient visit and contrast TTE more than 5-years after closure. Efficacy was based on the presence of a residual right-to-left shunt (RLS), graded as minimal, moderate or severe. The presence of a residual left-to-right shunt (LRS) was diagnosed using color Doppler, and was not graded. Descriptive statistics were used for patients' characteristics. Univariate analysis was used to identify predictors for residual shunting.

RESULTS: In total, 104 patients (mean age 45.5 ± 17.1 years) underwent percutaneous ASD closure using an Amplatzer device (ASO) in 76 patients and a Cardioseal/Starflex device (CS/SF) in 28 patients. The mean follow-up was 6.4 ± 3.4 years. Device migration occurred in 4 patients of whom two cases occurred during the index hospitalization (1 ASO, 1 CS/SF). The other 2 cases of device migration occurred during the first 6 mo of follow-up (2 CS/SF). The recurrent thrombo-embolic event rate was similar in both groups: 0.4% per follow-up year. More than 12 mo post-ASD closure and latest follow-up, new-onset supraventricular tachyarrhythmia's occurred in 3.9% and 0% for the ASO and CS/SF group, respectively. The RLS rate at latest follow-up was 17.4% (minimal 10.9%, moderate 2.2%, severe 4.3%) and 45.5% (minimal 27.3%, moderate 18.2%, severe 0%) for the ASO- and CS/SF groups, respectively. There was no residual LRS in both

Abstract

AIM: To investigate long-term efficacy of two different devices more than five years after percutaneous atrial

groups.

CONCLUSION: Percutaneous ASD closure has good long-term safety and efficacy profiles. The residual RLS rate seems to be high more than 5 years after closure, especially in the CS/SF. Residual LRS was not observed.

Key words: Percutaneous intervention; Atrial septal defect; Closure device; Right-to-left interatrial shunt; Left-to-right interatrial shunt; Echocardiography

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Core tip: Several atrial septal defect (ASD) closing devices have been proven safe and effective for percutaneous ASD closure. We evaluated long-term (*i.e.*, more than 5-year of follow-up) efficacy of two different devices used in adults. Percutaneous ASD closure seems to be relatively safe using the Amplatzer device. Though, the right-to-left shunt (RLS) rate is high, a residual left-to-right shunt was absent at latest follow up. The Cardioseal/Starflex device appears to be associated with a higher complication- and residual RLS rate. The importance of a residual RLS is unclear. Therefore, long-term follow up might be necessary.

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INTRODUCTION

An atrial septal defect (ASD) is a common cardiac defect and accounts for one third of all congenital heart diseases detected in adults^[1,2]. The diagnosis in adults is often made when complications of the shunt occur, such as pulmonary hypertension, heart failure, arrhythmias, or paradoxical embolism. Most of these complications might be prevented by closure.

Since the first description of the transcatheter closure device for an ASD in 1976 by King *et al*^[3], percutaneous ASD closure has been practiced and described extensively. Other studies evaluated various ASD closure devices and showed good mid-term (up to 2 years) safety and efficacy profiles^[4-7]. However, long-term (*i.e.*, more than 5-year after closure) safety and efficacy data on percutaneous closure devices has not been available yet. We report long-term efficacy and safety of two types of ASD closure devices.

MATERIALS AND METHODS

Population

All patients who underwent a percutaneous closure of

an ASD in the St. Antonius Hospital, Nieuwegein, The Netherlands, between February 1998 and December 2006 were included in this study. All patients were invited for an outpatient visit and transthoracic echocardiography (TTE).

Closing procedure

As reported earlier, percutaneous closure took place under general anaesthesia and transesophageal echocardiographic (TEE) monitoring according to standard techniques^[4]. TTE was performed 24 h post-procedure to visualize the device position and to look for residual shunting using color Doppler.

Follow-up and complications

Follow-up information was obtained at the outpatient clinic or by a telephone interview. All complications were documented, and divided into major and minor as described by Khairy *et al*^[8]. Major complications included procedure related events such as haemorrhage requiring blood transfusion, occurrence of cardiac tamponade, need for procedure-related surgical intervention, massive fatal pulmonary emboli, occurrence of new thrombo-embolic events and death^[8].

New-onset supraventricular tachycardia's were diagnosed by routine ECG when patients visited the outpatient clinic or when patients visited the emergency department because of symptoms.

Efficacy

The efficacy of the ASD closure was based on the presence of residual shunting using contrast TTE (cTTE) with Valsalva manoeuvre, and color Doppler. A residual right-to-left shunt (RLS) was present if microbubbles appeared in the left atrium. Opacification of the left ventricle and shunt grade were classified as minimal (maximum of 30 micro-bubbles in left ventricle), moderate (between 30 and 100 bubbles in left ventricle), and large (> 100 micro-bubbles in the left ventricle). This division was based on the maximum number of microbubbles counted in one still frame, as previously reported^[9]. The presence of a left-to-right shunt (LRS) was based color Doppler imaging at the atrial septum. The LRS was not graded.

Statistical analysis

Descriptive statistics were used for patients' characteristics. Continuous variables with normal distribution are presented as mean \pm SD or median with range if normal distribution was absent. Univariate analysis was used to identify predictors for residual shunting. All statistical analyses were performed using SPSS software (version 22.0 for Windows).

RESULTS

Study population

Percutaneous ASD closure was performed in 104

Table 1 Baseline characteristics

Number	104
Age (yr)	45.5 ± 17.1
Female, <i>n</i> (%)	78 (75.0)
Weight (kg)	73.1 ± 15.1
Risk factors and co-morbidities (%)	
Arterial hypertension	18.4
Hypercholesterolemia	3.9
Diabetes	1.9
Smoking	18.4
CAD	4.9
History of SVT	26.2
Antithrombotic treatment, <i>n</i> (%)	
None	59 (56.7)
Aspirin	20 (19.2)
Dipyridamol	1 (1.0)
Oral anticoagulants	21 (20.2)
Unknown	3 (2.9)
Indication for closure, <i>n</i> (%)	
RV volume overload	72 (69.2)
Cryptogenic TIA/stroke	21 (20.2)
Asymptomatic	11 (10.6)
RVSP + CVP (mmHg) ¹	34.6 ± 10.5
ASD diameter (mm) ²	18.3 ± 6.3
Follow up (yr)	6.4 ± 3.4

Data are presented as mean ± SD. ¹On transthoracic echocardiography; ²On transesophageal echocardiography. CAD: Coronary artery disease; SVT: Supraventricular arrhythmia; TIA: Transient ischemic attack; RVSP: Right ventricular systolic pressure; CVP: Central venous pressure; ASD: Atrial septal defect.

consecutive patients (75% women; mean age, 45.5 ± 17.1 years). Baseline characteristics, risk factors, co-morbidity and indication for closure are summarized in Table 1.

Less than 12-mo follow-up: Safety and efficacy

Device implantation was initially uneventful in 102 patients (98.1%). In 76 patients (73.1%) an Amplatzer (ASO), and in 28 patients (26.9%) a Cardioseal/Starflex (CS/SF) was used for closure. In total, 4 major complications occurred within the first 6 mo. Two patients (1.9%, 1 ASO, 1 CS/SF) suffered from embolization of the device during the index hospitalization and two (1.9%, 2 CS/SF) within the first 6 mo after closure. All underwent surgical device extraction; the ASD was closed using a patch during the same operation. All patients recovered well. Procedural characteristics are shown in Table 2.

Between 6- and 12 mo, another two patients (1.9%, 2 CS/SF) underwent surgical extraction of the device and the ASD was closed with a patch during the same operation. One patient had a large residual shunt, which could not be closed with a second device. The other patient needed rhythm surgery, therefore, device extraction was performed.

Within the first 12-mo, recurrent thrombo-embolic events occurred in 1 patient (0.9%, 1 CS/SF). This 58-year-old patient suffered a transient ischemic attack (TIA). Because of a history of supraventricular

Table 2 Procedural characteristics *n* (%)

Devices	
Amplatzer	76 (73.1)
Diameter, mm ¹	25 (12-38)
Cardioseal/starflex	28 (26.9)
Diameter, mm ¹	33 (20-40)
General anaesthesia	104 (100)
TEE guiding	104 (100)
In-hospital complications	
Device embolization	2 (1.9)
New-onset SVT	3 (2.9)
Allergic reaction	1 (1.0)
Fever	1 (1.0)
Groin hematoma	1 (1.0)
Tamponade	1 (1.0)
Shunt by TTE ²	
Color Doppler	9 (11.4)
Hospital stay, d ¹	2 (2-7)

¹Data presented as median (range); ²Data available in 79 patients. TEE: Transesophageal echocardiography; SVT: Supraventricular tachycardia; TTE: Transthoracic echocardiography.

tachyarrhythmia's (SVT) the patient was already using oral anticoagulation. cTTE showed no residual RLS.

New-onset SVT's occurred in 6.6% of the ASO group and in 17.9% of the CS/SF group.

More than 12-mo follow-up: Efficacy and complications

Contrast TTE was performed in 57 patients (54.8%, 46 ASO and 11 CF/SF). Median follow-up time for the ASO group was 6.6 years (5.0-11.1 years) and the CS/SF group 9.9 years (6.3-13.4 years). Though, cTTE could only be performed in 57 patients, follow-up information was available in a total of 81 patients.

Long-term follow-up data could not be retrieved (interview or cTTE) in 23 patients of which 6 were surgically closed, 4 died (no device related cause was suspected) and 13 were lost to follow-up.

Contrast TTE showed a RLS shunt in eight patients (17.4%) who received an ASO. Of these, five patients (10.9%) had a minimal, one patient (2.2%) a moderate and two patients (4.3%) a severe residual shunt. Five patients who received a CS/SF device (45.5%) had a residual RLS of which three patients (27.3%) had a minimal and two patients (18.2%) a moderate residual RLS. When minimal shunts were excluded, the closure rate was 93.5% for ASO and 81.8% for the CS/SF device, respectively. There was no recurrent RLS at latest follow up. Our analyses showed no significant differences in the diameters of the ASD or the device used between the patients with or without a residual shunt. Secondly, no predictors for a right-to-left shunt at long-term follow-up could be found using univariate analysis.

Recurrent thrombo-embolic events after more than 12 mo of follow-up occurred in two patients (1.9%, 2 ASO). One 40-year-old patient suffered a cerebrovascular accident 2.5 years after ASD closure, while on aspirin because of coronary artery disease.

Table 3 Five years follow-up

	Amplatzer	Cardioseal/STARflex
5 yr follow-up available, <i>n</i> (%)	58 (76.3)	23 (82.1)
New-onset SVT		
0-1 yr	5 (6.6)	5 (17.9)
> 1 yr	3 (3.9)	0
Reoccurrence TIA/stroke		
0-1 yr	0	1 (3.6)
> 1 yr	2 (2.6)	0
TTE > 5 yr FU available, <i>n</i>	46	11
RLS		
No shunt	38 (82.6)	6 (54.5)
Minimal	5 (10.9)	3 (27.3)
Moderate	1 (2.2)	2 (18.2)
Severe	2 (4.3)	0
LRS	0	0
Follow up (yr)	6.6 (5.0-11.1)	9.9 (6.3-13.4)

SVT: Supraventricular arrhythmia; TIA: Transient ischaemic attack; TTE: Transthoracic echocardiography; FU: Follow-up; RLS: Right-to-left shunt; LRS: Left-to-right shunt.

Although there was no history of SVT or device thrombus, oral anticoagulation was initiated after this event. At long-term follow up, a minimal residual RLS was found. The other patient (48-year-old) was known with a history of multiple TIA's prior to closure and was therefore treated with Aspirin. Despite closure of the ASD and optimal medical treatment, the patient suffered from another TIA more than 5 years after ASD closure. At the long-term follow-up visit no residual shunt or thrombus formation on the device was found. This patient had no history of SVT. In total, 3 patients suffered a recurrent neurological event during a mean follow up of 6.4 years (0.5% per year follow up).

During long-term follow-up, new-onset SVT occurred in 3 patients (3.9%) who received an ASO and in none of the patients who received a CS/SF device.

Long-term residual shunt rate, recurrent thrombo-embolic event rate and new-onset SVT rate are presented in Table 3. Figure 1 shows the percentage of patients with residual right-to-left shunt at more than 5-year follow-up after percutaneous ASD closure.

A flow-chart showing the results of this study during follow-up is presented in Figure 2.

DISCUSSION

Percutaneous ASD closure has relatively good long-term safety- and efficacy profiles, especially using the ASO device. A high residual RLS was present in CS/SF. Residual LRS was not observed in either the ASO- or the CS/SF group.

Complications

Device embolization and dislocation is a well-known complication after percutaneous ASD closure^[10,11]. The CS/SF is related to a relatively high embolization rate

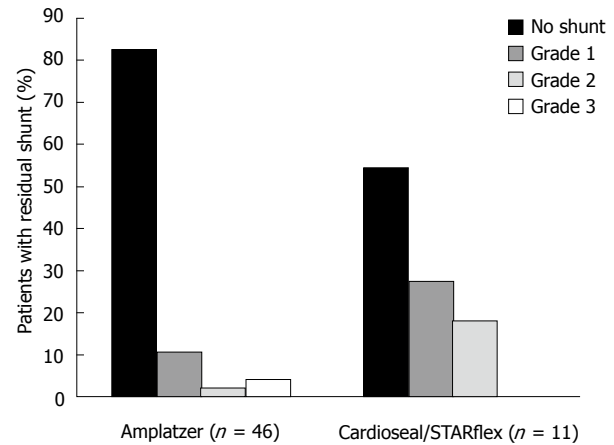


Figure 1 Percentage of patients with residual right-to-left shunt at more than 5-year follow-up after percutaneous atrial septal defect closure.

compared to the ASO^[12]. In literature, embolization of the CS/SF has been described between 1.4% and 2.5% and for the ASO between 0.1% and 2.4%^[7,10,13,14]. In all studies, embolization occurred during the procedure or the index hospitalization. Kefer *et al.*^[15] and Masura *et al.*^[16], described 112 and 151 patients with a mean follow-up of 5 and 6.5 years, respectively, and showed no device embolization using the ASO device.

In our study 4 major complications (3.8%) occurred within the first six months after closure. Device migration occurred in 10.7% of the patients with a CS/SF device and in 1.3% using an ASO device. All devices were surgically extracted and the ASD was closed with a patch. Compared to the literature our CS/SF subgroup had a higher complication rate, while the ASO subgroup was similar. Hence, the CS/SF devices are no longer available for ASD closure. However, long-term follow-up of patients who received a CS/SF device is recommended.

Because device embolization occurred more often in patients with a Cardioseal/Starflex device, we analysed potential reasons/risk factors only for this device. Post *et al.*^[15] showed that the initial ASD and the device diameter were significantly higher in the patients in whom the device was embolized. However, due to the small sample size of this study it is difficult to make any conclusions.

Recurrent thrombo-embolic events

Kefer *et al.*^[15] described a recurrent stroke rate of 0% after percutaneous ASD closure with similar devices and follow-up time as in our study. Masura *et al.*^[16] described no thrombo-embolisms during the entire follow-up period. One patient (0.6% per follow-up year) with an ASO device in the study of Spies *et al.*^[7] suffered a thrombo-embolic event, which could not be related to a residual shunt or device related thrombus formation.

In our study, the recurrent thrombo-embolic event rate during long-term follow-up was 0.4% per

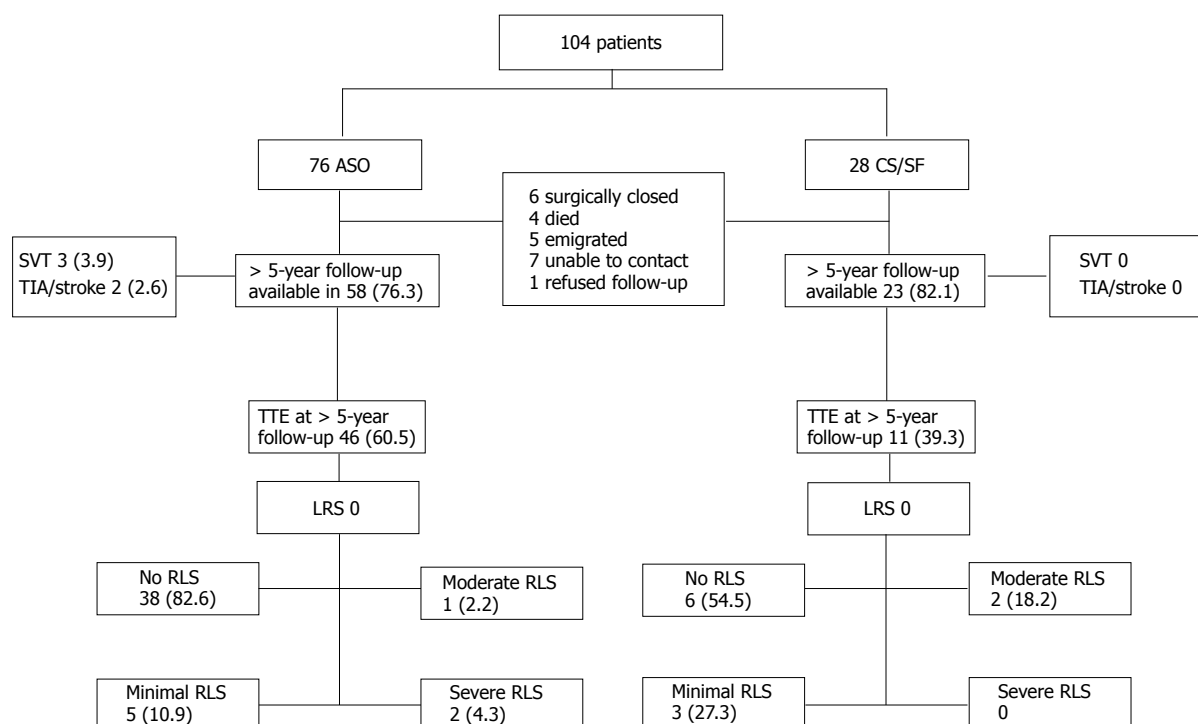


Figure 2 Flow-chart showing the results of this study during follow-up. Data is presented as number of patients (%). ASO: Amplatzer; CS/SF: Cardioseal/Starflex; SVT: Supraventricular arrhythmia; TIA: Transient ischemic attack; TTE: Transthoracic echocardiography; LRS: Left-to-right shunt; RLS: Right-to-left shunt.

follow-up year for both devices, which is similar when compared to the literature. As described above, all patients were treated with anti-platelet therapy or oral anticoagulation and a minimal residual RLS was found in only one patient.

Arrhythmias

arrhythmias early after ASO or other devices implantation are common and extensively described^[10,17,18]. Masura *et al*^[16] also mentioned SVT's at early follow-up, but none during long-term follow-up. Chessa *et al*^[10] noted that arrhythmias are the second most common complication in their study (2.6%) early after the procedure using both the ASO and the CS/SF. Tomar *et al*^[19] described peri-procedural arrhythmias but none were seen during long-term follow-up (median 56 mo). At 2-year follow-up, Spies *et al*^[18] found an annual incidence of new-onset atrial fibrillation of 4.1%. Butera *et al*^[13] described 274 patients (153 ASO, 121 CS/SF) and showed no arrhythmias at follow-up (respectively 16- and 24-mo).

In our study, 3.9% of the patients with an ASO device had new-onset SVT without any abnormalities during cTTE at long-term follow up.

Residual shunting

Residual LRS rates for the ASO has previously been described in several studies and ranged between 0%-12.5% at long-term follow up^[13-16,19,20]. Kefer *et al*^[15] described a residual LRS rate of 4%. However, only 2 patients (1.8%) with a residual LRS had received an ASO. At 3-year follow-up, Masura *et al*^[16]

showed no residual shunt using color-Doppler. Butera *et al*^[20] described 165 patients with a residual LRS rate of 2% in patients suffering multiple ASD's. At 24-mo follow-up, a non-significant difference between the ASO and CS/SF was found (respectively 0% vs 4.4%). In a study by Nugent *et al*^[14], 72 patients received a CS/SF device with a total residual LRS of 12.5% between 12- and 24-mo of follow-up.

Our study showed no residual LRS for both devices at more than 5-year of follow-up. However, the prevalence of a RLS is relatively high. Earlier, Luermans *et al*^[12] described a residual LRS rate of 14% 3.4 years after closure in 29 patients who received a CS/SF device.

In our study, the RLS rate for the ASO was 17.4% and 45.5% for the CS/SF device more than five years after closure. When excluding the minimal shunts, the ASO had a RLS rate of 6.5% and the CS/SF of 18.2%. The importance of this relatively high rate of RLS is unclear, as the reason for closure was mainly related to the presence of a LRS. Therefore, the fact that we did not notice residual LRS is an important observation. Moreover, to assess the clinical importance of the presence of a RLS, long-term follow-up might be necessary.

The difference in RLS rate after percutaneous ASD closure might be due to the different closing mechanisms; the ASO has a "stent-like" mechanism and consists of Nitinol metal with rounded disks with a polyester fabric sewn inside the meshed disks. The CS/SF device has a "double patch" mechanism and

the fabric is directly exposed to blood^[13,21]. The latter might delay the endothelialisation of the devices, which is important for complete closure of the ASD. Why endothelialisation happens in some patients better than others is unclear.

Limitations

Firstly, it is a single-centre design with a small sample-size. Secondly, we used cTTE at follow-up for residual shunt classification while the gold standard is contrast TEE. Though, we did not use contrast TEE, literature describes mostly studies where only color Doppler is used for the assessment of residual shunts. Thirdly, an independent core lab did not review the TTE's. Fourthly, the long-term follow up data was available in about 80% of patients; this might lead to an under- or overestimation.

Percutaneous closure of a secundum-type atrial septal defect seems to be safe using the ASO. Though, the RLS rate is relatively high, a residual LRS is absent more than 5-year after closure. The CS/SF appears to be associated with a relatively high complication- and residual RLS rate. Because of the unclear importance of a RLS after percutaneous ASD closure, long-term follow-up might be necessary.

COMMENTS

Background

An atrial septal defect (ASD) is a common cardiac defect and accounts for one third of all congenital heart diseases detected in adults. The diagnosis in adults is often made when complications of the shunt occur, such as pulmonary hypertension, heart failure, arrhythmias, or paradoxical embolism. Most of these complications might be prevented by closure.

Research frontiers

Since the first description of transcatheter device closure of an ASD in 1976, percutaneous closure of an ASD has been practiced and described extensively. Other studies showed the efficacy and safety of percutaneous closure of ASD's with different devices, mainly during mid-term follow up. Little is known about follow-up more than 5 years after percutaneous ASD closure in adults. We report the efficacy of ASD device closure at more than 5 years follow-up (long-term follow-up).

Innovations and breakthroughs

Previous studies showed that a percutaneous closed ASD using a Cardioseal/Starflex (CS/SF) is associated with a high residual right-to-left shunt (RLS) at mid-term follow-up. This study confirmed that a high residual RLS is still present during long-term follow-up. However, no left-to-right shunt (LRS) was present. Percutaneous closure using an Amplatzer device (ASO) has proven to be efficient at mid-term follow-up. During long-term follow-up no LRS was found. However, a relatively high RLS was present. The importance of RLS at follow-up is unclear. The safety for both devices is similar when compared to literature.

Applications

During long-term follow-up, percutaneous closure of ASD's seems to be safe using different devices, especially using the ASO device. A high residual RLS is present in CS/SF, however there was no residual LRS observed using both the ASO- and the CS/SF device.

Terminology

An ASD is an opening in the septum between the right- and left atrium. It is a congenital heart disease and therefore present at birth. An ASD can cause symptoms due to heart failure, arrhythmia's, paradoxical embolism and pulmonary hypertension. Percutaneous closure of an ASD is a relatively simple procedure where a Nitinol device is placed in the opening between the right- and left atrium. Transthoracic ultrasound of the heart is used to check whether

there is a residual opening in the atrial septum.

Peer-review

The paper by Dr. Snijder *et al* reports the experience in percutaneous closure of atrial septal defects in 104 patients using two devices. Interestingly, in a long-term follow-up a residual left-to-right shunt is absent, although the rate of a residual right-to-left shunt is relatively high.

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