Congenital Heart Disease

Transcatheter Closure of Perimembranous Ventricular Septal Defects

Early and Long-Term Results

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Objectives	We sought to analyze safety, efficacy, and follow-up results of percutaneous closure of perimembranous ventricular septal defects (pmVSD).
Background	Results of pmVSD transcatheter closure have been reported in the literature; however, follow-up data are still limited.
Methods	Between January 1999 and June 2006, 104 patients underwent percutaneous closure of a pmVSD at our institution. An Amplatzer VSD device (muscular or eccentric) (AGA Medical Corp., Golden Valley, Minnesota) was used in all subjects.
Results	The mean age at closure was 14 years (range 0.6 to 63 years). The attempt to place a device was successful in 100 patients (96.2%). The median device size used was 8 mm (range 4 to 16 mm). No deaths occurred. Total occlusion rate was 47% at completion of the procedure, rising to 84% at discharge and 99% during the follow-up. A total of 13 early complications occurred (11.5%), but in all but 2 subjects (1.9%) these were transient. The median follow-up was 38.5 months. The most significant complication was complete atrioventricular block (cAVB), which required pacemaker implantation in 6 subjects (5.7%; 2 in the early phase and 4 during the follow-up). Cox proportional hazards regression analysis showed that the only variable significantly associated with the occurrence of this complication was age at the time of the procedure (p = 0.028; relative risk 0.25). All subjects experiencing this problem were <6 years old.
Conclusions	In the current era and in experienced hands, pmVSD closure can be performed safely and successfully. The major concern is the occurrence of cAVB; therefore, very careful monitoring of rhythm is mandatory during follow-up. (J Am Coll Cardiol 2007;50:1189–95) © 2007 by the American College of Cardiology Foundation

Surgical closure of a perimembranous ventricular septal defect (pmVSD) is now a routine procedure. It has minimal mortality, although it is still associated with the potential risks of complete atrioventricular block (cAVB), postpericardiotomy syndrome, wound infection, neurologic sequelae after cardiopulmonary bypass, and chylothorax (1–6).

In the last decade, percutaneous techniques to close cardiac defects have been developed. Closure of atrial septal defects, patent ductus arteriosus, and muscular ventricular septal defects using transcatheter devices has been widely reported (6–14). More recently, percutaneous techniques and devices have been developed specifically for the closure of pmVSD. The initial experience in humans appears encouraging (15,16), but there are no data from large series of patients with an adequate follow-up.

Here, we report our early and mid-term follow-up results of percutaneous closure of pmVSD in 104 subjects.

Methods

Between January 1999 and June 2006, we prospectively collected data on 104 patients who underwent transcatheter closure of a pmVSD at our institution. The patients' general characteristics are reported in Table 1. Patients were assessed by a standard echocardiographic protocol: all patients underwent transthoracic echocardiography (TTE) that was performed with a Vingmed 800 (Vingmed Sound, Horten, Norway) and a System Five performance ultrasound system (Vingmed Sound) using a transducer appropriate to each patient's size and body weight.

**Abbreviations
and Acronyms**

cAVB = complete
atrioventricular block

MVSD-O = muscular
ventricular septal defect
occluder

pmVSD = perimembranous
ventricular septal defect

PMVSD-O =
perimembranous
ventricular septal defect
occluder

TEE = transesophageal
echocardiography

TTE = transthoracic
echocardiography

Inclusion and exclusion criteria. The criteria for inclusion in this study were clinical and/or echo-cardiographic evidence of a significant left-to-right shunt through a pmVSD.

A left-to-right shunt was considered to be significant when the following were found: 1) cardiomegaly on chest X-ray; 2) left atrial enlargement, defined as a left atrial to aortic ratio >1.5; 3) left ventricular enlargement (left ventricular volume overload), defined as a left ventricular end-diastolic diameter >+2 standard deviations (SD) above the mean for the patient's age; and 4) symptoms including frequent respiratory infections and/or failure to thrive and New York Heart Association functional class II or greater. Frequent respiratory infections were defined as more than 6 events/year (17). Failure to thrive was defined according to Hamil et al. (18).

We intended that patients should weigh at least 6 kg to be eligible for percutaneous closure of a pmVSD. However, the ideal weight for percutaneous treatment was considered to be above 8 to 10 kg.

Only subjects with a rim of at least 1 mm separating the aortic valve from the pmVSD were included. We excluded patients with an infundibular defect, patients with pmVSD and prolapse of an aortic cusp, and patients with pmVSD and malalignment.

Patients or parents of the children gave their informed written consent to the procedure.

Devices and delivery systems used. Two different Amplatzer devices (AGA Medical Corp., Golden Valley, Minnesota) were used: the muscular ventricular septal defect occluder (MVSD-O) and the perimembranous ventricular septal defect occluder (PMVSD-O) (14–17). These devices have a woven mesh of 72 nitinol wires with shape memory. They are made of a 0.004- to 0.005-inch nitinol wire with a polyester mesh inside. These devices and their delivery systems have been previously described (14). We used the muscular VSD device in our early experience before the membranous device was available and when a "subaortic rim" of at least 5 mm was present. Finally, we used the muscular VSD device in some cases with an associated aneurysm of the ventricular septum.

Procedure. Percutaneous closure of a VSD was performed under general anesthesia with orotracheal intubation. Patients were given 100 IU/kg heparin and antibiotics intravenously. The procedure was performed under fluoroscopic and transesophageal echocardiographic (TEE) control. Access was through the right femoral vein and left femoral artery.

Standard right and left cardiac catheterization, standard left ventriculography, and angiography of the ascending aorta were performed in all cases. The size of the VSD and its relation to the aorta were confirmed. The diameter of the VSD was measured on the left ventricular side and was calculated by integrating data from TEE and angiographic measurements. A device 1 to 2 mm larger than the measured VSD diameter was chosen.

The VSD was crossed from the left ventricle using a right coronary artery catheter (Cordis Corp., Miami, Florida) or an Amplatzer right coronary catheter (Cordis Corp.) and an exchange floppy Terumo guidewire (Terumo Europe, Leuven, Belgium) was advanced into the pulmonary artery or the superior or inferior vena cava. The wire was then snared (EV3, Plymouth, Minnesota) to establish an arteriovenous circuit.

Technical details regarding closure procedures for pmVSD have been previously reported in detail (14).

Early in our experience, we closed some cases of pmVSD with a >5 mm rim toward the aortic valve using a retrograde aortic approach and an MVSD-O. In those cases, the VSD was crossed from the left ventricle and the wire was placed in the apex of the right ventricle. The long sheath was advanced from the aorta, through the VSD into the right ventricular apex. The device was advanced in the long sheath, and then the distal disc was opened in the right ventricle and withdrawn to the septum. The proximal disc was then opened, taking care to avoid any entrapment of the aortic valve with the disc of the device. Finally, the correct position was confirmed and the device released.

VSD analysis. The diameter of the VSD was measured by TTE and TEE using 2-dimensional imaging and color flow Doppler on long- and short-axis views. The vertical diameter was measured during left ventricular angiography using the views described.

A ventricular septal aneurysm was present in 35 patients (32%). In these cases, VSD size was also measured on the left ventricular side. Associated lesions were encountered in 5 subjects. Multiple defects were treated in 2 patients. Postsurgical residual VSDs in a perimembranous position were treated in 5 subjects.

Residual shunts and valve regurgitation. A residual shunt was considered to be present when color Doppler flow mapping showed a left-to-right shunt across the interven-

Table 1	General Characteristics	
n	104	
Gender (F/M)	58/46	
Age (yrs)	Median 14 (range 0.6 to 63)	
Age groups		
<10 yrs	66 patients	
10–20 yrs	15 patients	
>20 yrs	23 patients	
Weight (kg)	Median 26.5 (range 6.5 to 96)	

tricular septum. A shunt was defined trivial (<1 mm color jet width), small (1 to 2 mm color jet width), moderate (2 to 4 mm color jet width), or large (>4 mm color jet width) (19). Valve regurgitation was evaluated by color Doppler flow imaging in a standard way.

Seven subjects had trivial aortic regurgitation. Seven had trivial to mild tricuspid regurgitation. Finally, 10 subjects had trivial to mild mitral regurgitation related to mitral annulus dilatation due to volume overload of the left ventricle.

Follow-up. All subjects underwent clinical examination, electrocardiography, chest X-rays, 24-h electrocardiographic Holter monitoring, and TTE before discharge, at 1, 6, and 12 months after the procedure, and yearly thereafter. Before discharge, urinalysis was performed to exclude hemolysis. Platelet antiaggregation therapy with 5 mg/kg/day aspirin orally and endocarditis prophylaxis were prescribed for 6 months.

Statistical methods. Data are expressed as a frequency or percentage for nominal variables and as the mean $\pm$ SD for continuous variables. The Statistix package version 8 (Analytical Software, Tallahassee, Florida) was used for the statistical computations.

The following dependent outcome variables were analyzed: total complications, cAVB, device embolization, and vascular complications. The following independent variables were included in the analysis: age at procedure, weight at procedure, gender, defect type (congenital, residual postsurgery), device type (muscular Amplatzer device, eccentric Amplatzer device), device diameter, associated procedures (yes or no), multiple defects (yes or no), ventricular septal aneurysm (yes or no), device diameter/defect diameter measured on TTE, and device diameter/patient's weight.

Univariate analysis was performed using the chi-square test, Fisher exact test, unpaired Student *t* test, Wilcoxon rank sum test, 1-way analysis of variance, and the Kruskall-Wallis test as appropriate.

Multivariable analysis to study risk factors for the occurrence of early complications was performed using multiple logistic regression analysis. The regression model diagnostic was performed by obtaining the standardized residuals and the Cook's D and examining them with Wilk-Shapiro and Rankit plot tests. Independent variables with a p value of <0.2 in the univariate analysis were included in the multivariable model. Odds ratios and their 95% confidence intervals (CI) were calculated for independent variables included in the multivariable model (20).

Multivariable analysis using Cox proportional hazard regression analysis was performed to study the role of independent variables on the occurrence of cAVB in the early period and during the follow-up. The proportional hazards assumption was evaluated using the goodness-of-fit approach (21).

All tests were 2-sided. A probability value of p < 0.05 was considered to be statistically significant.

Table 2	Procedural Data and Devices Used
Fluoroscopic time (min)	29 $\pm$ 14 (range 5 to 72)
Procedure time (min)	100 $\pm$ 33 (range 45 to 200)
Qp/Qs	2 $\pm$ 0.6 (range 1.3 to 5)
Qp/Qs groups	
Qp/Qs <2	47 patients
Qp/Qs ≥2	57 patients
Systolic PA pressure (mm Hg)	27 $\pm$ 6
Mean PA pressure (mm Hg)	16 $\pm$ 5
VSD diameter on TTE (mm)	7.2 $\pm$ 2.4 (range 3 to 16)
Mean size of the device used (mm)	9.2 $\pm$ 2.8 (range 4 to 16)
Device diameter/VSD diameter on TTE (%)	131 $\pm$ 27 (range 100 to 228)
Type of device used	
MVSD-O	14 patients
PMVSD-O	84 patients
Multiple devices	2 patients

MVSD-O = muscular ventricular septal defect occluder; PA = pulmonary artery; PMVSD-O, perimembranous ventricular septal defect occluder; Qp/Qs = pulmonary to systemic flow ratio; TTE = transthoracic echocardiography; VSD = ventricular septal defect.

Results

Procedural data. Data are reported in Table 2. During the period of the study, all subjects with the inclusion criteria were sent to the catheterization laboratory with the intention to treat the defect percutaneously. In 100 of 104 patients the defect was successfully closed (96.2%). In 4 subjects the procedure was aborted. Technical problems occurred in 2 patients (two 8-year-old girls with malaligned pmVSD and prolapse of the aortic cusp): In one girl it was impossible to obtain a stable position of the long sheath, and in the other the device could not be positioned and was retrieved before unscrewing it. These subjects were treated very early in our experience and it is possible that there was an error in their selection or a lack in operator experience. In 2 patients (a 5-year-old girl and a 6-year-old boy), cAVB developed during maneuvers of the catheter or Terumo guidewire. The procedure was stopped in both subjects and they both recovered sinus rhythm within 1 to 2 h. They underwent uneventful surgical VSD closure.

Complex procedures. Complex procedures (combined procedures, multiple pmVSD, postsurgical residual VSD) were performed in 12 patients (11.5%). Five subjects underwent combined procedures: pulmonary valve dilatation in 1 subject, atrial septal defect closure in 1, patent ductus arteriosus closure in 1, atrial septal defect and small patent ductus arteriosus closure in 1, and aortic coarctation stenting in 1. Two subjects were treated for multiple pmVSD within an aneurysm of the ventricular septum. Finally, 5 patients underwent percutaneous closure of a postsurgical residual VSD (pmVSD closure in 4, residual post-Fallot in 1). These patients had undergone surgery a median of 2 years (range 1 to 5 years) before the percutaneous procedure.

Complications. EARLY POSTPROCEDURAL COMPLICATIONS. No deaths occurred. A total of 13 significant complications occurred in 12 patients (11.5%). These were

device embolization (n = 2), vascular complications (n = 4), and rhythm abnormalities (n = 7). However, in all but 2 subjects (1.9%) who needed implantation of a pacemaker, these were transient complications and the patients had no sequelae.

Univariate analysis showed that no variable predicted the occurrence of early complications. Only 2 variables showed a trend toward significance (device diameter/patient weight: no complication 0.38 ± 0.27 vs. complication 0.52 ± 0.4; p = 0.07). In the multivariable model, device type (p = 0.15) was also included. However, no risk factors were found.

DEVICE EMBOLIZATION. This complication occurred in 2 patients (1.9%). In both cases, the device was recaptured—in the right pulmonary artery in one the descending aorta in the other—using a goose-neck snare and a Mullins long sheath. In these cases a larger device was chosen and successfully implanted. The occurrence of device embolization was not related to any of the independent variables studied.

VASCULAR COMPLICATIONS. Femoral arterial thrombosis occurred in 3 patients (2.9%). In a 4-year-old girl (18 kg), vascular surgery of the femoral artery was needed for safe removal of a 10-F arterial sheath used to recapture an 8-mm PMVSD-O device that had embolized in the descending aorta. In two 1-year-old girls (7.5 and 7 kg), thrombolysis with recombinant tissue plasminogen activator was successful. In addition, a 40-year-old woman developed a femoral arterovenous fistula needing vascular surgery. The occurrence of vascular complications was not related to any of the independent variables studied.

ARRHYTHMIC COMPLICATIONS. Significant arrhythmias occurred in 7 patients with a pmVSD (6.7%). Ventricular fibrillation requiring external electrical cardioversion occurred in a 64-year-old woman during maneuvers of the long sheath. Complete atrioventricular block occurred during the procedure in 2 subjects in whom the procedure was aborted (already described). Complete atrioventricular block occurred soon after device release in 2 subjects with a pmVSD. In 1 child (a 2-year-old boy, 10-mm PMVSD-O) the block was transient, whereas in the second (a 3.4-year-old girl) it persisted for some hours after implantation of a 10-mm PMVSD-O. The girl was sent for surgery and recovered stable sinus rhythm after surgical closure and device removal.

Complete atrioventricular block developed 24 h after implantation of a 12-mm PMVSD-O in a 2-year-old boy. A permanent pacemaker was implanted into this child who has recovered stable sinus rhythm during follow-up. A 3.4-year-old boy treated with an 8-mm PMVSD-O developed cAVB 5 days after the procedure. He had a heart rate of 50 beats/min and was asymptomatic. We decided to treat him with corticoid therapy (1 mg/kg) for 2 weeks. The cAVB disappeared completely.

Finally, stable cAVB appeared 7 days after procedure in a 4-year-old boy who developed vomiting and paleness and had a heart rate of 40 beats/min. He underwent pacemaker implantation.

TRANSIENT MINOR COMPLICATIONS. Transient atrial fibrillation occurred in a 5-year-old boy; no treatment was needed. A transient right bundle branch block occurred in 1 subject, and a transient left bundle branch block occurred in 2 other patients. Two subjects developed moderate groin hematoma. Transient mild hemolysis was recorded in 2 subjects but resolved spontaneously within 48 h after the procedure. Transient left brachial palsy occurred in a 40-year-old man.

Valve regurgitation and residual shunts. Preoperative aortic, tricuspid, or mitral valve regurgitation remained unchanged after the procedure. No significant new regurgitation of valves occurred. A trivial intraprosthetic residual shunt was present in 49 subjects (47%) at the end of the procedure. At discharge, 17 patients (16%) had a tiny residual shunt and none had signs of hemolysis. The TTE at 1, 6, 12, 24, 36, and 48 months showed a trivial residual shunt in 1 patient (1%) due to a small fenestration within an aneurysm. There were no significant differences in the occurrence of residual shunting between the 2 devices used.

Hospital stay. All subjects in whom the percutaneous procedure was uneventful stayed in hospital for 2 days after the procedure. In cases with minor arrhythmic abnormalities, even transient bundle branch blocks, the hospital stay was prolonged to 72 h. The mean hospital stay was 4 ± 1 day.

Follow-up. Follow-up data were available for all patients. The median duration of follow-up was 38.5 months (range 3 to 72 months). No deaths or cases of endocarditis occurred. Patients with failure to thrive had complete recovery of growth (from 10th percentile up to 50th percentile during follow-up). Subjects with frequent respiratory infections had no significant recurrences. Left ventricular dimensions returned to normal in all subjects but one (a 7-year-old girl whose left ventricular end-diastolic diameter was 44 mm). The New York Heart Association functional class was I in all subjects.

During the entire follow-up period, 4 subjects developed cAVB. Two out of 4 experienced syncope (a 4-year-old boy and a 1.2-year-old girl both treated with an 8-mm PMVSD-O) due to paroxysmal cAVB, 4 and 20 months after the procedure, respectively. Another patient (a 2.7-year-old boy treated with a 12-mm PMVSD-O) developed asymptomatic cAVB with a heart rate of 40 beats/min 12 months after closure of the defect. The patient who had the transient cAVB successfully treated with corticosteroids developed stable cAVB 8 months after procedure. An endocardial ventricular pacemaker was implanted into all of these subjects.

Analysis of risk factors for the occurrence of cAVB. A total of 9 patients experienced cAVB during the period of the study. This rhythm abnormality occurred early in 5 patients, whereas in 4 it was a late event. Pacemaker

implantation was needed in 40% (2 of 5) of the cases of early cAVB; however, in 2 of these subjects the procedure was aborted, the device removed, and the patients sent to surgery. A pacemaker was implanted in 100% (4 of 4) of the cases of late cAVB.

Univariate analysis showed that the following variables were significantly associated with the occurrence of cAVB: age at procedure (no cAVB 14.7 ± 15.6 [95% CI 11.5 to 15.6] years vs. cAVB 2.7 ± 1 [95% CI 1.6 to 3.7] years; p < 0.0001), weight (no cAVB 36.2 ± 23.3 [95% CI 32 to 41] kg vs. cAVB 15.8 ± 5.7 [95% CI 9.7 to 22] kg; p < 0.0001), and device diameter/patient's weight ratio (no cAVB 0.39 ± 0.29 vs. cAVB 0.66 ± 0.31; p = 0.03). The occurrence of cAVB was not associated with either the ratio of the device measure to VSD diameter measured on TTE (no cAVB 135 ± 27% vs. cAVB 121 ± 18%; p = 0.9) or the presence of aneurysm of the ventricular septum (2 of 33 with aneurysm vs. 4 of 65 without aneurysm; p = 0.98).

Multivariable analysis using Cox proportional hazard regression analysis showed that age was significantly associated with the occurrence of cAVB (p = 0.028; relative risk 0.25).

Discussion

Perimembranous ventricular septal defects are the most common congenital heart defects (1). Subjects with volume overload of the left chamber due to a VSD require closure of the defect to prevent ventricular dilatation and dysfunction, arrhythmias, aortic regurgitation, pulmonary arterial hypertension, endocarditis, or a double-chambered right ventricle (22).

Surgery is the gold standard for pmVSD closure; however, although it is generally a safe procedure it does have some potential risks, including cAVB in 1% to 5% of the patients (1–4,6), significant residual VSD in 1% to 5% (1–4), the necessity for reoperation in 2% (1,4), and even death in 0.5% (1–4). Furthermore, infections, tachyarrhythmias, and neurologic complications may occur (1,4).

Interventional pediatric cardiologists have made efforts in the last decade to develop a percutaneous approach for the closure of pmVSD (15,16,23–25). However, only the recent introduction of the Amplatzer muscular and pmVSD occluders has increased the number of subjects in whom percutaneous closure is feasible (15,16,26–33).

At the beginning of our experience, we used the MVSD-O in 10 selected patients who had a distance of at least 5 mm between the superior rim of the defect and the aortic valve. The device was successfully deployed in all cases by using a retrograde approach. Similar good results on the use of muscular VSD devices for properly selected perimembranous defects were reported by Arora et al. (26). When the PMVSD-O became available, the indications for percutaneous closure were expanded also to cases with only 1 to 2 mm between the defect and the aortic valve (15,16). Studies in the literature reported that the rate of successful

closure was between 90% and 100% (15,16,26–33). Consistent with this, in our series of 104 patients the rate of successful implantation was 96.2%.

A common morphologic variation is the presence of an aneurysm of the ventricular septum. We found this variant in 32% of our patients. Usually, we tried to close the true anatomic hole with the most appropriate device, as judged from case to case. Sometimes, when the redundant tissue of the aneurysm was relatively small, the device could cover the hole and the aneurysm; in cases of very large aneurysms, the device was implanted within the aneurysm itself, with the aim of closing the true anatomic hole and not placing the device at the "entrance" on the left ventricular side, to avoid an oversized device.

A total of 13 significant early complications occurred in 12 patients (11.5%). However, in all but 2 cases (1.9%), early complications were transient and the patients had no sequelae. Statistical analysis showed that no variable predicted the occurrence of early complications. The rate of major complications reported in the literature ranges between 0% and 8.6% (15,16,26–33). No significant valve regurgitation occurred in our series, and the incidence of residual shunting, which was 16% at discharge, decreased to 1% during the follow-up. In all cases, the residual shunts were graded as trivial.

The only serious concern of percutaneous pmVSD closure is the occurrence of cAVB. This complication required pacemaker implantation in 6 subjects with pmVSD (5.7%) in our series. The cAVB rates reported in the literature vary between 0% and 5.7% (15,16,26–33). However, it is noteworthy that most published studies reported only early postprocedural results. In our series, the median follow-up was 38.5 months and cAVB was a late event in 4 out of the 6 subjects requiring pacemaker implantation. Although some authors have emphasized that an oversized device is a risk factor for the occurrence of cAVB, in particular in subjects with pmVSD, this was not confirmed by our data. Some authors (34,35) have suggested that a course of steroids should be used in an effort to avoid pacemaker implantation. We used this approach successfully in 1 subject; however, some months later he again developed stable cAVB. Furthermore, although this therapy could be useful in an acute setting, we believe it is unlikely to be useful for late events occurring during the follow-up. Multivariable analysis using Cox proportional hazard regression analysis showed that age was significantly associated with the occurrence of cAVB (p = 0.028; relative risk 0.25). It is notable that cAVB occurred only in subjects who were less than 6 years old at the time the percutaneous procedure was performed. Complete atrioventricular block can occur even in patients undergoing surgical pmVSD closure; indeed, this complication develops in about 1% to 5% of subjects so treated (1–4,6). However, compared with surgery in which cAVB usually appears early after the operation, in patients treated percutaneously the occurrence of cAVB is quite unpredictable and it is usually a late problem. This compli-

cation is related to the proximity of the conduction system to the margins of the pmVSD. Therefore, both surgery and device implantation may interfere with atrioventricular conduction. Various mechanisms may be involved. The device may cause direct compression trauma or provoke an inflammatory reaction or scar formation in the conduction tissue. However, there are no direct data about the mechanisms involved in the occurrence of cAVB after percutaneous closure of a pmVSD.

Clinical implications. The percutaneous approach for the treatment of congenital heart diseases is appreciated by patients and their parents because it has less psychologic impact (given the absence of a skin scar), the time spent in hospital is shorter, the procedure causes less pain and discomfort, and there is no need for admission to an intensive care unit. In the current era, percutaneous pmVSD closure provides a valuable alternative to surgery. However, the decision to perform percutaneous closure of pmVSD in young subjects must be carefully weighed given the challenging nature of this technique and the risk of cAVB. Because of the late occurrence of cAVB, very careful monitoring of rhythm and atrioventricular conduction is mandatory during the follow-up. In fact, cAVB may occur in completely asymptomatic subjects. Our rhythm-monitoring protocol after procedure included 24-h electrocardiographic Holter recordings at 2 and 6 weeks, 3, 6, 12, 18, and 24 months, and then yearly.

Study limitations. First of all, only in very experienced hands can these techniques be carried out safely and complications managed in the proper way. Furthermore, highly specialized surgical back-up must always be available. Secondly, although the techniques of percutaneous pmVSD closure appear to be safe in the medium-term follow-up, it is not known whether they are safe in the very long term, whereas the long-term safety and efficacy of surgery are well documented.

Conclusions

Percutaneous pmVSD closure is associated with excellent success and closure rates, no mortality, and low morbidity. Nowadays, pmVSD percutaneous closure is a valuable alternative to surgery. Longer follow-up data and improvements in device characteristics are needed to reduce the risk of cAVB.

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