ORIGINAL ARTICLE

JOURNAL OF
CARDIAC SURGERY WILEY

Percardiac closure of large apical ventricular septal defects in infants: Novel modifications and mid-term results

Geoffrey J. Changwe MD[1] | **Li Hongxin MD**[2] | **Hai-Zhou Zhang MD**[3] |
Guo Wenbin MD[3] | **Fei Liang MD**[3] | **Xing-Xu Cao MD**[1] | **Shan-Liang Chen MD**[2]

[1]Shandong Provincial Qianfoshan Hospital, Shandong University, Jinan, China

[2]Department of Cardiovascular Surgery, The First Affiliated Hospital of Shandong First Medical University, Jinan, China

[3]Department of Cardiovascular Surgery, Shandong Provincial Hospital Affiliated to Shandong First Medical University, Jinan, China

Correspondence
Li Hongxin, MD, Department of Cardiovascular Surgery, The First Affiliated Hospital of Shandong First Medical University, No. 16766, Jingshi Rd, 250014 Jinan, China.
Email: hongxinli@hotmail.com

Abstract

Background/Aim: Both open heart surgery and percutaneous approaches retain several limitations in closing large apical muscular ventricular septal defects (AmVSD) in infants. We present probe-assisted percardiac device closure (PDC), an exclusively transoesophageal-echocardiography guided technique, as an alternative with midterm results.

Methods: Thirty-six infants with large AmVSDs (single or multiple-holed) underwent PDC in our department. Mean AmVSD for single and multiple-holed measured 7.2 ± 2.4 mm and 6.3 ± 3.4 mm, respectively. Subjects presented with a spectrum of cardiopulmonary sequelae and growth retardation, either alone or combined. Some were ventilator dependent and re-do cases. In addition, AmVSDs were categorized: cylindrical, tunnel and cave-like shaped as per color Doppler interrogation. Pursuant to cardiac access and deployment technique, subjects were apportioned: group A; inferior median sternotomy (perventricular), B; right mini-thoracotomy (peratrial) and C; complete median sternotomy (perventricular). Under exclusive echocardiography, the Z- or J probe-assisted delivery system was utilized to access AmVSDs and implant device(s) via aforementioned techniques.

Results: Forty-two muscular ventricular septal devices (8.4 ± 2.6 mm) were implanted in 36 subjects uneventfully. Seventeen "complex," and 10 cylindrical or straight tunnel-shapedAmVSDs (including 2 re-do patients) suited perventricular and peratrial techniques respectively. Comparatively, group B exhibited shorter procedural indices than A ($p < .01$). Five of 15 multiple-holed AmVSDs (four Swiss cheese) required two or three devices for a satisfactory occlusion. Nevertheless, post occlusion insignificant residual shunts(≤ 2 mm) seldom achieved spontaneous closure, and at 36-month follow-up complete closure was 67%. Residual shunt persisted amongst multiple-holed. All patients improved during follow up.

Abbreviations: AmVSD, apical muscular ventricular septal defect; CPB, cardiopulmonary bypass; ICMT, intracardiac manipulation time; LV, left ventricle/ventricular; PADS, probe-assisted delivery system; PDC, percardiac device closure; RS, residual shunt; RV, right ventricle/ventricular; TEE, transoesophageal echocardiography/echocardiographic.

Conclusion: PDC is feasible, safe and effective alternative technique for AmVSD in infants.

KEYWORDS

apical muscular ventricular septal defect, device closure, infant, percardiac, transoesophageal-echocardiography

1 | INTRODUCTION

Infants with large apical ventricular septal defects (AmVSD) may present with symptoms including recurrent lower respiratory infection, pulmonary hypertension, growth retardation, and heart failure, either alone or combined. Unrepaired large AmVSD like other hemodynamically significant congenital heart defects can be a source of persistent morbidity and early mortality.[1]

Currently, no universal technique exists to effectively close large AmVSDs in infants due to morphological variability and defect access challenge. Closure can be performed either surgically or percutaneously. However, clinically compromised infants may not suit either technique. Conventional surgery retains cardiopulmonary bypass (CPB) associated complications and closure failure, while percutaneous retains vessel limitation and complications.[2,3] The perventricular technique proved effective in perimembranous and non-apical muscular ventricular septal defect occlusions.[4] Its application in AmVSD occlusion has been limited.[5] Our empirical experience proves AmVSD access and morphological variation as major obstacles.

We hereby present percardiac device closure (PDC), a dual-technique remedy for large AmVSD in infants under exclusively transoesophageal echocardiography (TEE) guidance, as an alternative technique and evaluate safety, efficacy, and midterm results.

2 | METHODS

2.1 | Cohort's clinical details

From August 2011 to June 2020, 36 infants with moderate to severely compromised clinical baselines and anthropometric parameter underwent PDC of AmVSD in our department. Subjects presented with signs and symptoms including recurrent lower respiratory infections, heart failure, moderate to severe pulmonary hypertension, and growth retardation. Notably, 2 (6%) subjects were re-do and 5 (14%) were ventilator dependent. In addition, 28 (78%) subjects presented with more than or equal to two active symptoms, and 9 (25%) had severe associated cardiac lesions requiring repair on CPB after AmVSD closure. All subjects underwent pertinent screening procedures. Of the cohort, 22 (61%) were girls with mean age and weight: 6.9 ± 3.5 months and 6.3 ± 1.9 kg, respectively. The mean maximum diameter for single and multiple-holed AmVSDs were 7.2 ± 2.4 mm and 6.3 ± 3.4 mm, respectively. Demography and clinical symptoms are shown in (Table 1).

TABLE 1 Patient demography and associated clinical symptoms

Variable	Total	Group A	Group B	Group C
Patient number	36	17	10	9
Age (months)	6.9 ± 3.4 (1-12)	6.6 ± 3.0 (1–11)	6.0 ± 3.7 (1.4–11)	8.7 ± 3.2 (3–12)
Gender (F/M)	22/14	11/6	7/3	4/5
Weight (kg)	6.3 ± 1.9 (2.7–10)	6.1 ± 1.8	6.0 ± 2.4	7.0 ± 1.8
Pre-op symptom				
PH	30	16	8	6
RLRI	27	13	8	6
Heart failure	23	11	6	6
Growth retardation	16	9	4	3
Ventilator dependent	5	3	2	0
Associated cardiac defects				
Perimembranous VSD	8	3[a]	0	5
Other anomalies	7	3[a]	0	4

Note: Anomalies surgically corrected in group C (perimembranous VSD, n = 5; tetralogy of Fallot, n = 1; stenosis of left pulmonary artery, n = 1; doubly committed subarterial VSD, n = 1; and mitral prolapse, n = 1).
Abbreviations: PH, pulmonary hypertension; RLRI, recurrent lower respiratory infection; VSD, ventricular septal defect.
[a]Simultaneously occluded in group A (patent ductus arteriosus, n = 2; atrial septal defect, n = 1; perimembranous VSD, n = 3).

2.2 | Diagnosis and definition of AmVSD

Transthoracic echocardiography was used to diagnose AmVSD, and defined as a defect on the ventricular septum distal to moderator band. AmVSDs were then classified morphologically as single or multiple-holed, and the latter defined by presence of more than or equal to 2 (≥ 4: Swiss-cheese) defects on the left ventricular (LV) side. And further classified by location as anterior, middle and posterior.

2.3 | Inclusion criteria

For inclusion in this study, subject(s) must have: (1) a single AmVSD measuring at least 4.0 mm from the right ventricular (RV) side, with history of recurrent lower respiratory tract infection, heart failure, and growth retardation, either alone or combined; (2) multiple-holed AmVSD with the largest hole more than or equal to 3 mm in diameter; (3) asymptomatic AmVSDs, but gradually eliciting LV overload or significant pulmonary hypertension, and failure to close spontaneously following two consecutive echocardiographic check-ups at 3-month interval; (4) AmVSD with the

size of ≥ 3 mm coexisting with nonapical defects requiring early simultaneous occlusion, or with severe malformations (as main indications) requiring surgical correction.

The Hospital Ethics Committee approved this study, and was conducted in accordance with the tenets of the Helsinki declaration, with informed written consent obtained from care-giver.

2.4 | AmVSD configurational categorization and distribution

Based on the shape of color Doppler shunt, AmVSD were categorized: cylindrical-, tunnel-, and cave-like shaped (Figure 1). Group A had "complex- AmVSDs," thus; large AmVSDs with inadequate rims at the anterior or posterior wall, tortuous tunnel-shaped, cave-like, multiple-holed, and anteriorly located. In this group, the heart was accessed via inferior mini-midline sternotomy and deployed via perventricular. Group B had single AmVSDs with adequate circumferential rims, mainly cylindrical and straight tunnel-shaped, either middle or posteriorly located. The heart was accessed via right parasternal mini-thoracotomy and occlusion via peratrial. Group C composed of AmVSDs coexisting with severe
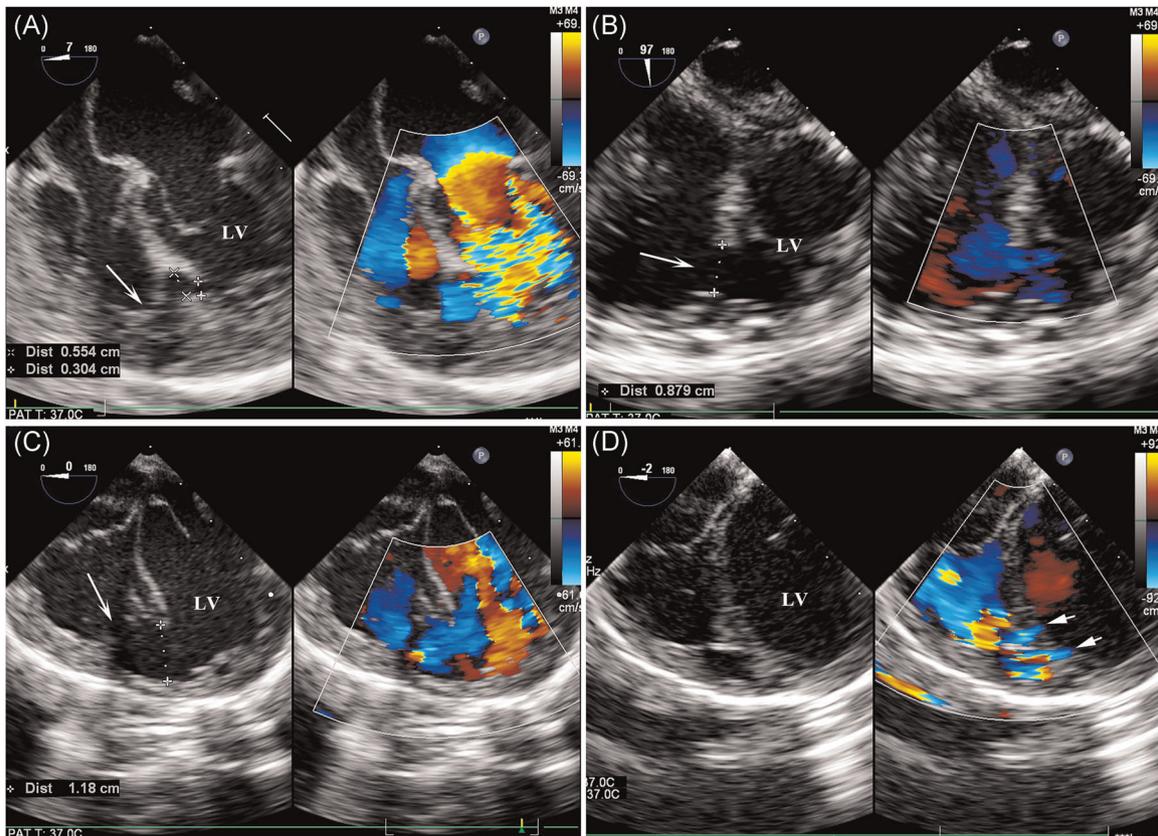

FIGURE 1 Transoesophageal echocardiography images depicting configurations and morphology of apical muscular ventricular septal defect (AmVSD). (A) tunnel-shaped; (B) cylindrical-shaped; (C) cave-like shaped; and (D) multiple-holed cave-like AmVSD. (arrow, exit of AmVSD; arrowhead, multiple-holed entry; LV, left ventricle)

malformations, therefore, cardiac access and occlusion were performed via complete sternotomy and perventricular.

2.5 | Pre-procedure evaluation

After administration of general anesthesia, intubation and anticoagulation (heparin 100 IU/kg) as per protocol, preprocedural TEE (Philips IE33, Philips Healthcare, Best, The Netherlands) was performed to re-evaluate AmVSD dimensions.

2.6 | Device selection

Two types of muscular ventricular septal occluders (Starway Medical Technology, Inc., Beijing, China) with waist-height measuring 5 and 7 mm were utilized. AmVSD size and morphology determined device selection. Regarding single tunnel or cylindrical defects, a device measuring 1–2 mm larger than LV-side diameter was chosen. Cave-like took-up a device measuring up to 2 mm larger than the LV-side diameter was selected. For multiple-holed AmVSDs, we up-sized the device at least 2 to 3 mm larger than the largest LV-side hole to occlude the largest hole and squeeze or cover the small one (s), while, tunnel lengthy or septal thickness dictated waist-height.

2.7 | The probe-assisted delivery system

The probe-assisted delivery system (PADS) consist of a J- or Z-shaped hollow probe (metallic) about 20 cm long with a blunt tip-end (ZL 2010 1 0169667.6), with auxiliary components (Starway Medical Technology, Inc., Beijing, China) components (Figure 2A).
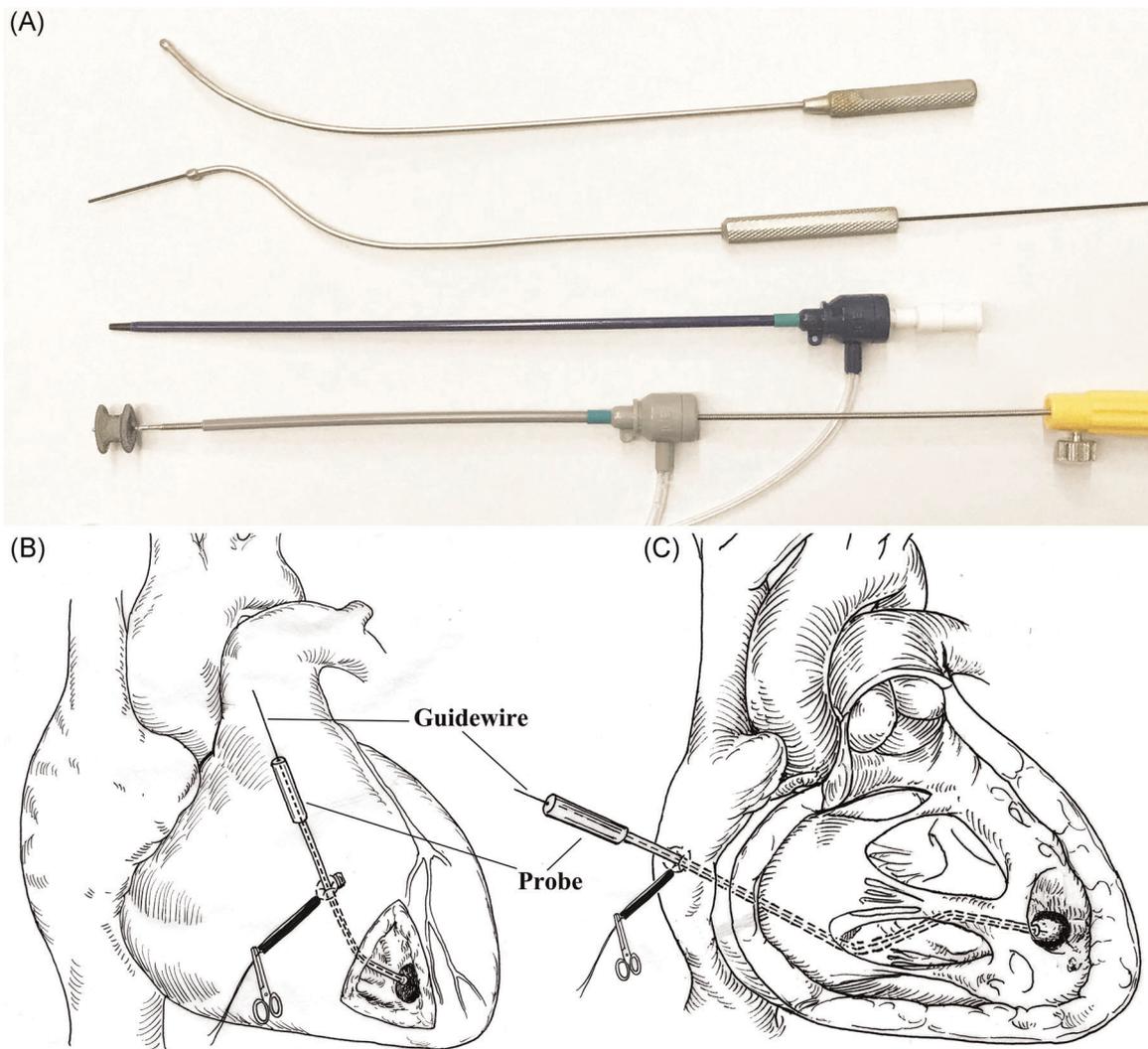

FIGURE 2 Composition and application of probe-assisted delivery system. (A) From top J- and Z-shaped probes, dilator inside delivery sheath, loading sheath and cable with device. (B) The J-probe was introduced into right ventricle and advanced through the defect into the left ventricle. (C) The Z-probe was inserted into the right atrium, passed through tricuspid valve and advanced into the left ventricle

2.8 | Procedure

2.8.1 | Group A

A 2–3 cm partial inferior midline sternotomy is made. After pericardiotomy, a search for an appropriate site for purse-string placement is conducted under TEE guidance. Maneuver involves tapping of RV-free wall with a peanut sponge on forceps, while observing puncture-defect alignment. Once established, two opposite purse-string sutures (5-0 polypropylene, Ethicon, Inc.) are placed on RV-free wall, the region between the atrio-ventricular groove and left anterior descending coronary artery (Figure 2B). Deployment stages are shown in Figure 3. Regarding multiple-holed AmVSD, if chosen device does not adequately squeeze or cover the peripheral holes upon initial attempt, using the probe, a second device is deployed to occlude a relatively larger residual hole.

After deployment, the device stability and possible residual shunt (RS) are assessed. Upon satisfactory assessment, the stay-in suture is removed or kept in-situ if the device is deemed unstable. The pericardium is opposed appropriately, drainage tubes inserted, and chest closed in a standard fashion.

2.8.2 | Group B

An incision of 1.5–2 cm is made in the fourth intercostal space, pericardium incised and cradled. Two parallel purse-string sutures (5-0 polypropylene) are placed on the right atrium. The purse-string circle is punctured, and the Z-shaped hollow probe introduced into the right atrium (Figure 2C). Subsequent steps of peratrial device closure of an AmVSD are shown in (Figure 4). After implantation and satisfactory evaluation as in group A, the stay-in suture is removed, and cardiac window is closed without a drainage tube.

2.8.3 | Group C

After full midline-sternotomy and administration of standard dosage of anticoagulation (heparin 3 mg/kg), the J-probe and auxiliary components are sequentially utilized, and device deployed as in group A. After AmVSD occlusion on the beating heart, CPB is instituted to repair associated malformations while retaining stay-in suture on device. After CPB disconnection, assessment TEE is performed as in
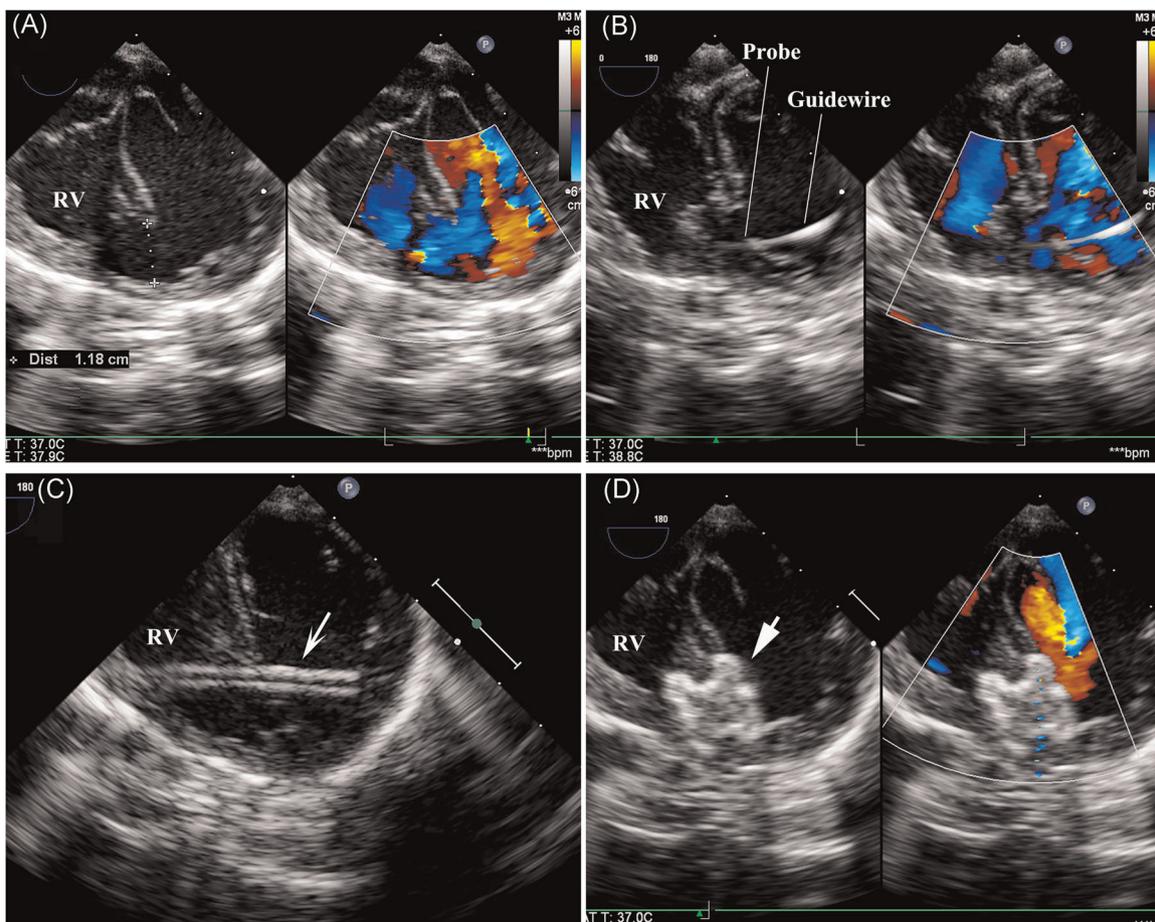

FIGURE 3 The steps of perventricular device closure of apical ventricular septal defect (AmVSD). (A) TEE was performed to evaluate AmVSD size, morphology and configuration. (B) After purse string circle puncture, the J-probe was introduced and advanced towards AmVSD with open-tip end well aligned with defect. Then a flexible guide wire was introduced and advanced into left ventricle through the hollow probe. (C) The delivery sheath (arrow) was fed on guidewire and advanced into left ventricle. (D) A proper device (arrowhead) attached to a stay-in suture was introduced into the delivery sheath and deployed. TEE, transoesophageal echocardiography
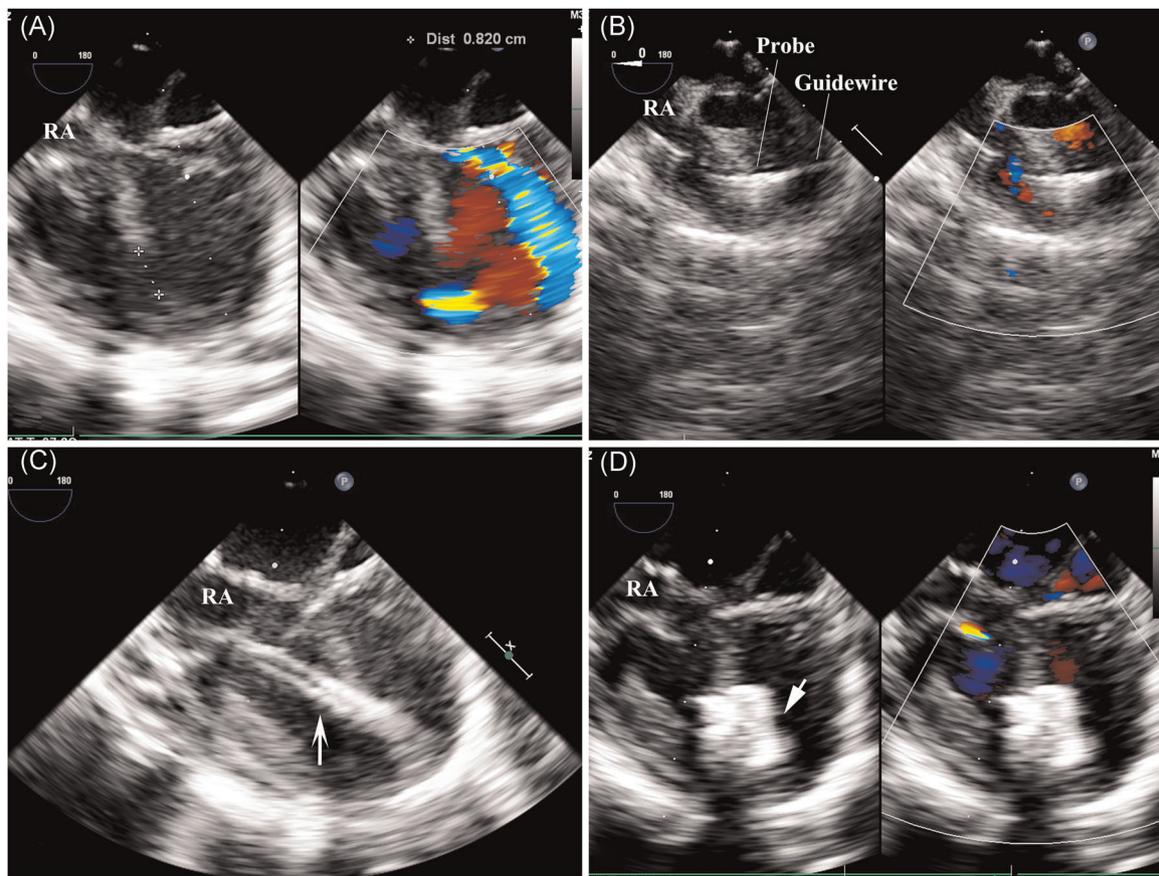
FIGURE 4 The steps of peratrial device closure of apical ventricular septal defect (AmVSD). (A) A cylindrical-shaped AmVSD was measured. (B) The Z-probe and guidewire were introduced into right atrium, passed through tricuspid valve and advanced into left ventricle via AmVSD. (C) The delivery sheath (arrow) was passed across the AmVSD and into the left ventricle. (D) A proper device (arrowhead) was deployed

previous groups and doubtful device stability warrants stay-in suture retention. Chest is closed in standard fashion with drainage tubes.

2.9 | Patient follow-up

We performed once-off chest radiography, and periodical echocardiography and electrocardiography before dismissal, and further at 1, 3, 6, and 12 month(s) and yearly thereafter. RS color jet width dimension was graded: trivial (< 1 mm), small (1–2 mm), moderate (2-4 mm), and large (> 4 mm).[3] In this study, RS less than or equal to 2 mm was deemed insignificant. About 75% of the patients were discharged home 4 to 7 days post operation on aspirin (3–4 mg/kg per day for 3 months).

2.10 | Statistical analysis

Data are expressed as mean ± standard deviation or median and range for continuous variables or frequency or percentage for categorical variables. Intracardiac manipulation time (ICMT) is defined as the time interval (for AmVSD occlusion only) between the hollow-probe

introduction and device delivery sheath withdrawal from the heart. Comparison of pertinent variables (ICMT, procedure, and intubation times) are between group A and B, and verified using the independent samples t-test. Statistical comparisons of proportions were analyzed using Fisher's Exact Probability Test and χ^2 test (Stata10.0 software; StataCorp LP, College Station, TX) and p-value (< .05) deemed significant.

3 | RESULTS

Forty-eight devices (including six non-AmVSD devices) were successfully implanted in all 36 infants (100%). Twenty-six subjects (72%) from groups A and C had AmVSD accessed using the J-probe and the remaining otherwise. In relation to apical septal plane, 31 (86%) and 5 (14%) subjects had AmVSDs located anteriorly (or medially; Figure 5A–D), and posteriorly (Figure 5E–H) respectively. Fifteen (42%) patients exhibited multiple-holed AmVSDs (Swiss-cheese, $n = 4$; Figure 5I–L) of which 8, 5, and 2 were tunnel-, cave-like-, and cylindrical-shaped, respectively. The mean AmVSD LV-side and RV-side diameter for group A and B measured 7.6 ± 2.6 mm and 6.5 ± 2.2 mm, respectively. The mean device size for AmVSD was 8.4 ± 2.6 (5–14) mm, with waist-height −5 or 7 mm (Table 2).
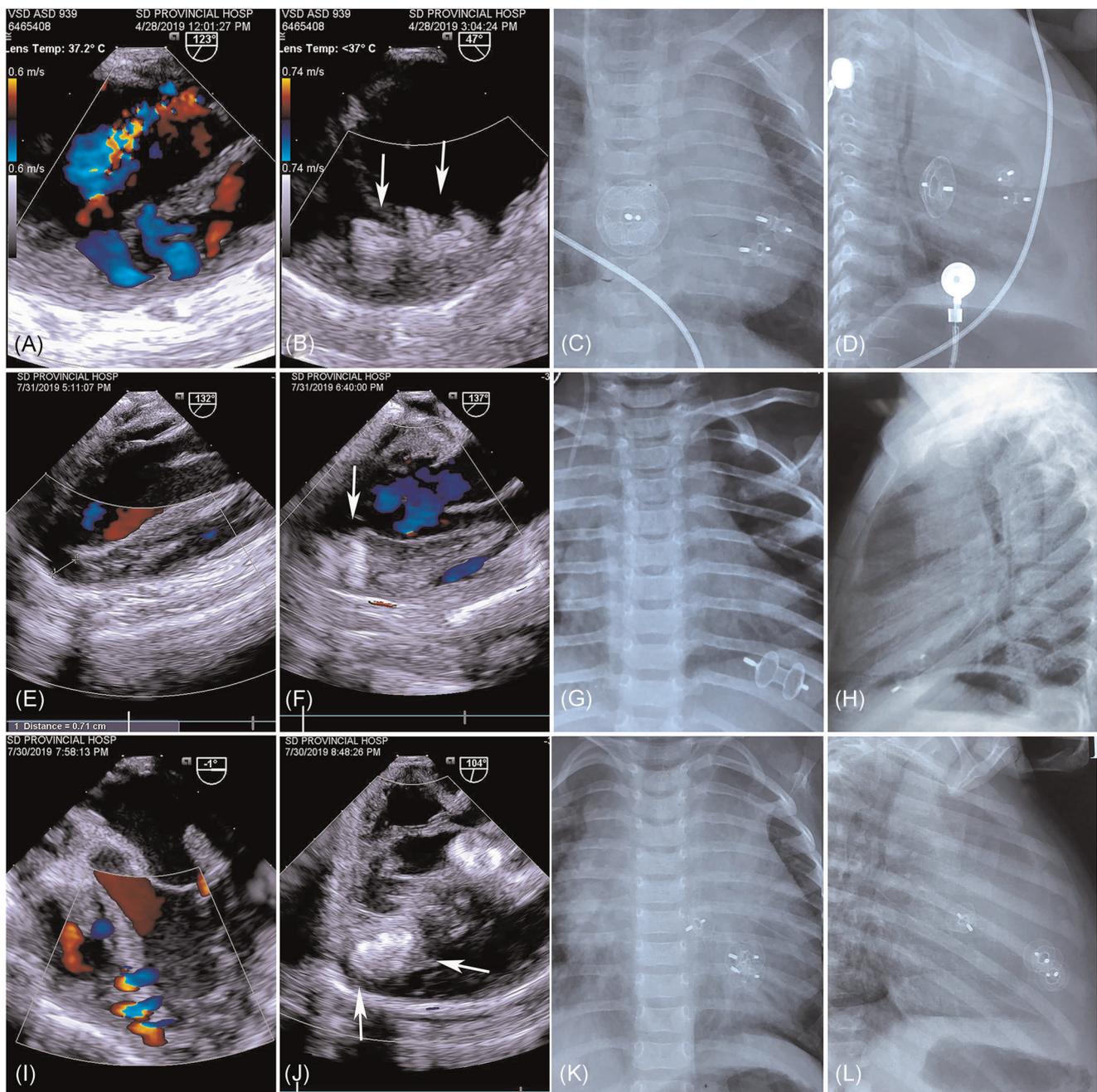
FIGURE 5 Echocardiographic illustrations of apical muscular ventricular septal defects (AmVSDs) and device confirmatory x-ray. (A)–(D) two anteriorly located multiple-holed AmVSDs with corresponding devices (arrows) and one interatrial septal occluder. (E)–(H) a posteriorly located single AmVSD with corresponding device (arrow). (I)–(L) Three centrally located holes of Swiss-cheese AmVSD with corresponding two devices & one perimembranous located VSD device

Six patients (17%) with extra non-apical septal lesions received one extra device each. Five (33%) of 15-multiple-holed AmVSDs, among them three Swiss-cheese and two tunnel-shaped received two or three devices for satisfactory occlusion. Of the cohort, 2(6%) patients were re-do cases following unsuccessful repair of AmVSD via complete sternotomy. We employed peratrial approach due to the anticipated difficulties using perventricular approach.

Overall mean ICMT exclusively for AmVSD was 18 ± 14 (range, 4–58) minutes, whereas group A and B recorded 20 ± 15 (4–53) and

9 ± 3 (4–16) min ($p < .05$) respectively. The procedural time was shorter in group B than A ($p < .01$). The overall median intubation time for group A and B was 17 h, while, group A and B were 31 (3–110) h and 7 (3–48) h ($p < .05$), respectively. Only nine subjects (25%) from group C received blood transfusion due to CPB.

Twenty-seven (75%) patients exhibited insignificant RS immediately after device release, and the rate reduced to 42%, 35%, and 33% at 3-, 6-, and 36-month follow-up. At 3-month follow-up, the RS for cylindrical-, tunnel-, and cave-like AmVSDs were 33%, 38%,

TABLE 2 Patient clinical outcome

Variable	Total (n = 36)	Group A (n = 17)	Group B (n = 10)	Group C (n = 9)	p-value
AmVSD size (mm)					N/A
LV-side	7.0 ± 2.9 (3.0–13)	7.9 ± 2.8	7.3 ± 2.2	5.3 ± 3.0	
RV-side	6.0 ± 2.3 (3.0–11)	6.8 ± 2.3	6.1 ± 1.8	4.4 ± 1.8	
AmVSD configuration					N/A
Cylindrical	10	0	8	1	
Tunnel	16	7	2 (Straight)	6	
Cave-like	11	9	0	2	
Multiple-holed	15	8	1	6	N/A
Device size (mm)	8.4 ± 2.6 (5-14)	9.5 ± 2.8	8.0 ± 2.0	6.9 ± 1.4	.106
ICMT (min)	18 ± 14 (4–58)	20 ± 15	9 ± 3	23 ± 16	.012
Procedure time (min)	70 ± 23 (40–132)	80 ± 23 (53–132)	54 ± 10 (40–71)	–	<.001
Intubation time (h)	17 (3–110)	31 (3–110)	7 (3–48)	–	0.048
LVEDD (cm)					
Pre-operation	2.90 ± 0.46 (1.80–3.67)*	2.94 ± 0.39 (2.40–3.67)	2.81 ± 0.54 (1.80–3.50)	–	* 0.002
1 month postoperation	2.52 ± 0.39 (1.70–3.61)*	2.59 ± 0.40 (2.00–3.61)	2.40 ± 0.33 (1.70–2.83)	–	

Note: p value between group A and B.

Abbreviations: AmVSD, apical ventricular septal defect; ICMT, intracardiac manipulation time; LV, left ventricle; LVEDD, left ventricular end-diastolic dimension.

and 55%, respectively. All patients, except two, had RS less than 2 mm. RS predominantly occurred in cave-like (6/11, p > .05) and multiple-hole (12/15, p < .0001) AmVSDs at 3-month follow-up. After 3 -month of follow-up, RS persisted at about 35%. The RS rate in multiple-holed defects remained unchanged (Table 3).

All patients showed improvement in symptoms and heart function. The LV end-diastolic dimension at 1-month follow-up (p = .002) decreased. No death (early/late) or major device related complication was recorded, except one post occlusion hemoglobinuria due to hemolysis, which disappeared after 7 days.

4 | DISCUSSION

4.1 | Available techniques and limitations

Complete closure of large AmVSDs in infants poses anatomical, technical, and defect access challenges. Available closure techniques retain several disadvantages and associated complications.[6] Technically, it is difficult to access and effectively repair defects distal to moderator band via right atrium.[7] As a result, intra-atrial surgical closure is often associated with significant RS. Alternative surgical techniques have the potential to cause ventricular dysfunction, apical aneurysm and ventricular arrhythmias.[8,9]

Percutaneous technique as an alternative retain several advantages. However, percutaneous technique in infants retain vascular limitation, and associated complications.[10] There is an acute turn at the AmVSD between left and right ventricle which cause difficulty in defect crossing for the guidewire and delivery sheath in percutaneous. In addition, the small apical space and coarsy trabeculations make

double-device deployment in multiple-holed AmVSD almost impossible. The inability to apply stay-in suture risks device safety.[11,12] Percutaneous demand expensive gadgets and long learning curve.

4.2 | PDC genesis, technical advantages, and concern

In 1998, perventricular technique (focused on perimembranous VSD) was introduced and realized early this century.[4] Despite passing over two-decades since its inception, the technique has not been widely applied in AmVSD occlusion.[5,13] In 2014, Hongxin et al.[11] introduced a novel technique, thus peratrial technique. The idea of PDC stems from these two techniques. The advantages of PDC technique includes:

1. Both the J and Z-probes, which are short, steerable and with good echocardiographic visualization, are designed to overcome defect access challenges through different access windows using exclusively TEE guidance.
2. The avascular nature of PDC avoids arterio-venous guidewire loop establishment, eliminates vessel injury, and body weight limitations. The direct passage of instrument(s) through AmVSD prevents injury to valvular leaflets, and chordae (trabeculae) entrapment by guide-wire, which sometimes occur in percutaneous.
3. The use of stay-in suture offers enhanced device safety both during and post implantation, otherwise not feasible in percutaneous technique.
4. The basic nature of PADS components renders PDC not only cost effective, but retains a short learning curve for surgeons, and feasible in low resource set-up nations.

TABLE 3 Residual shunt follow-up after percardiac device closure of apical muscular ventricular septal defects

	IADR (n = 36)	At discharge (n = 36)	1 Mon (n = 36)	3 Months (n = 36)	6 Months (n = 34)	12 Months (n = 30)	24 Months (n = 23)	36 Months (n = 18)
Group A and C (n = 26)	21	15	15	14	11	9	8	5
Group B (n = 10)	6	4	1	1	1	1	1	1
AmVSD configuration								
Cylindrical (n = 9)	7	5	3	3	3	3	3	1
Tunnel-shaped (n = 16)	13	7	6	6	5	4	3	2
Cave-like (n = 11)	7	7	7	6	4	3	3	3
Multiple-holed (n = 15), (%)	15/15 (100)	12/15 (80)	12/15 (80)	12/15 (80)	11/14 (79)	10/11 (91)	6/8 (75)	5/6 (83)
Complete closure (%)	9/36 (25)	17/36 (47)	20/36 (56)	21/36 (58)	22/34 (65)	20/30 (67)	14/23 (61)	12/18 (67)
Follow-up median (months)	30 (3–84)							

Abbreviations: AmVSD, apical muscular ventricular septal defect; IADR, immediate after device release.

In PDC, two obligations of great concern: (1) The puncture site in the perventricular approach should not be too close to the AmVSD so as to offer optimal space for device deployment. (2) The fragility of apical muscle demands utmost patience and care when advancing deployment instruments to avoid perforation of LV free wall.

Contrary to published reports, to our knowledge, we present the largest cohort exclusively focusing on occlusion of large AmVSD in infants.[13,14]

4.3 | Perventricular versus peratrial route

The inferior partial sternotomy in perventricular technique is associated with postoperative pain and hemorrhage, may form unpleasant scar, and pectus carinatum deformity. A pericardial drainage tube is required. Nevertheless, the short distance between AmVSD and access point proves perventricular effective in easy defect crossing and device positioning, and therefore, suitable in occluding all kinds of AmVSDs. It is especially suitable for complex AmVSDs such as tortuous tunnel-shaped, cave-like and multiple-holed. Regarding the anteriorly located AmVSD, due to the elevated plane of the ventricular septum, passage of "Z" probe (in peratrial) through the defect is difficult. Therefore, perventricular approach is a better option.

Comparatively, peratrial approach is cosmetically pleasant, less traumatic, and painful, require no drainage tubes, as well as offers short postoperative hospital stay and RV is kept intact. In addition, besides exhibiting short ICMT, intubation, and procedure times, peratrial suits redo cases, as the technique avoids previous midline scars and adhesions. However, its application was hampered by variation in morphological architecture of AmVSDs. The peratrial route forms an acute angle to the AmVSD, which hinder access of small, tortuous tunnel-shaped, cave-like and anterior AmVSDs, and device positioning in large AmVSD. Additionally, failure to retain a stay-in suture decreases post implantation device safety. Henceforth, peratrial is only reserved for patients with good occlusion anatomy and high success rate.

4.4 | AmVSD configuration and role in RS

The initial strategy was to occlude the LV-side of an AmVSD, it being smoother than RV-side would improve device stability, defect sealing, and prevent RS. However, the strategy was hampered by variation in AmVSD morphology. An in-depth analysis of AmVSD configuration highlighted below proved pivotal in choosing different access window and predict the RS after occlusion.

4.4.1 | Cylindrical-shaped

Because of satisfactory AmVSD LV-side rims, location and the desire to keep RV intact, peratrial approach proved effective enough to accomplish occlusion with satisfactory results. In this series, the outcomes characterized fewer incidences of insignificant RS 3/9 at 3-month follow-up.

4.4.2 | Tunnel-shaped

This category composed of single and multiple-holed AmVSD. Single AmVSDs were usually long and tortuous. Sometimes the defects of the LV-side and the RV-side were in unequal plane. The double discs of the device could not cover the defect symmetrically, therefore causing RS.

4.4.3 | Cave-like

If chosen device was too big, small "cave" risked compromising complete unfolding of the device's right disc and cause RS. Some cave-like defects lacked device anchorage rim on the free wall. In such a scenario, the chosen device was pulled into the "cave" chamber and positioned across trabeculae within RV. The intra-trabeculae device positioning caused inadequate sealing with subsequent RS.

4.4.4 | Multiple-holed

Regarding this category, RS was found only in 3/21 (14%) patients with single AmVSD at 3-month follow-up. RS mainly occurred in multiple-holed AmVSD (80%). Morphologically, some multiple-holed had scattered multiple entry defects with thick interventricular muscle or trabeculae between them. In such a scenario, a single device was not adequate enough to occlude the largest hole and squeeze the peripheral small holes. To achieve satisfactory occlusion, more than one device was required.

During the follow-up, multiple-holed AmVSD seldom achieved spontaneous occlusion due to lacking in support structures such as fibrous tissue formation and prolapsing leaflets. Follow-up closure rate revealed an unreported correlation of persistent RS to AmVSD morphology. Despite the scarcity of comparative literature focused on exclusive management of AmVSD, it must be acknowledged that RS is pretty common in both surgical repair and device closure.

4.5 | Occlusion of AmVSDs in patients undergoing CPB

Our empirical observation is that AmVSD occlusion must be performed before initiation of CPB. This approach maintains intracardiac hemodynamic pressure and exact chamber geometry, thus, making guide-wire passage and device deployment easier. However, if the CPB is initiated, either alone or with subsequent cardiac arrest before AmVSD occlusion, the opposite is true. The application of two or three anchoring stitches to the device before anomaly repair guarantees stability. Empirically, device deployment to the AmVSD in a collapsed heart is not a good idea because it's difficult to both identify the real AmVSD and safely pass deployment instruments into the LV.

4.6 | Study limitations

Being a debutant technique and not prospective in nature, more patients and technique adoption is required to eliminate confounded bias and validate technique. Because patients are not randomly assigned, comparison of pertinent data between A and B may be bias. Comparatively, incisions in PDC remain a shortcoming. Because of migratory nature of population, only 18 patients were followed-up for more than 3 years.

5 | CONCLUSIONS

PDC of AmVSDs is feasible, efficacious and safe, regardless of patient's body weight. RS rate is highly related to AmVSD morphology, and during the late follow-up period, RS remained unchanged among multiple-holed AmVSDs. While perventricular route befitted "complex" AmVSD, peratrial exhibited shorter procedure time, better cosmetic outcome and less invasive.

CONFLICT OF INTERESTS
The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS
Geoffrey J. Changwe: drafting/concept/critical revision. **Li Hongxin**: concept/design/critical revision/approval/funding. **Hai-Zhou Zhang**: concept/interpretation. **Guo Wenbin**: design/imaging. **Fei Liang**: data collection. **Xing-Xu Cao**: data collection. **Shan-Liang Chen**: data analysis.

DATA AVAILABILITY STATEMENT
Data available on request.

ORCID
Geoffrey J. Changwe https://orcid.org/0000-0001-6663-6202
Li Hongxin http://orcid.org/0000-0003-4940-1414

REFERENCES
1. Özdemir Şahan Y, Kılıçoğlu E, Ülger, Tutar Z. Evaluation of children with congenital heart disease hospitalized with the diagnosis of lower respiratory tract infection. *J Pediatr Res*. 2018;30:32-36.
2. Stellin G, Padalino M, Milanesi O, et al. Surgical closure of apical ventricular septal defects through a right ventricular apical infundibulotomy. *Ann Thorac Surg*. 2000;69:597-601.
3. Carminati M, Butera G, Chessa M, et al. Transcatheter closure of congenital ventricular septal defects: results of the European Registry. *Eur Heart J*. 2007;28:2361-2368.
4. Amin Z, Gu X, BerryJM, Titus JL, Gidding SS, Rocchini AP. Periventricular closure of ventricular septal defects without cardiopulmonary bypass. *Ann Thorac Surg*. 1999;68:149-153.
5. Fouilloux V, Bonello B, Gran C, Fraisse A, Mace L, Kreitmann B. Perventricular closure of muscular ventricular septal defects in

infants with echocardiographic guidance only. *World J Pediatric Congenit Heart Surg.* 2012;34:446-451.

6. Van Praagh S, Mayer JE, Berman NB, Flanagan MF, Geva T, Van Praagh R. Apical ventricular septal defects: follow-up concerning anatomic and surgical considerations. *Ann Thorac Surg.* 2002;73:48-56.

7. Myhre U, Duncan BW, Mee RBB, et al. Apical right ventriculotomy for closure of apical ventricular septal defects. *Ann Thorac Surg.* 2004;78: 204-208.

8. Perez-Negueruela C, Carretero J, Mayol J, Caffarena JM. Surgical closure of multiple large apical ventricular septal defects: how we do it. *Cardiol Young.* 2017;27:588-591.

9. Ootaki Y, Yamaguchi M, Yoshimura N, Oka S, Yoshida M, Hasegawa T. Surgical management of trabecular ventricular septal defects: the sandwich technique. *J Thorac Cardiovasc Surg.* 2003;125:508-512.

10. Thanopoulos BD, Rigby ML. Outcome of transcatheter closure of muscular ventricular septal defects with the Amplatzer ventricular septal defect occluder. *Heart.* 2005;91:513-516.

11. Hongxin L, Zhang N, Wenbin G, et al. Peratrial device closure of perimembranous ventricular septal defects through a right parasternal approach. *Ann Thorac Surg.* 2014;98:668-674.

12. Garcia-Valentin A, Congiu S, Mayol J, et al. Device migration in hybrid technique for apical muscular ventricular septal defects closure. *Interact Cardiovasc Thorac Surg.* 2007;156:780-782.

13. Bacha EA, Cao Q-L, Starr JP, Waight D, Ebeid MR, Hijazi ZM. Perventricular device closure of muscular ventricular septal defects on the beating heart: technique and results. *J Thorac Cardiovasc Surg.* 2003;126:1718-1723.

14. Tsang VT, Hsia T-Y, Yates RW, Anderson RH. Surgical repair of supposedly multiple defects within the apical part of the muscular ventricular septum. *Ann Thorac Surg.* 2002;73:58-62.