

Original Article



Echocardiographic Classification of Perimembranous Ventricular Septal Defect Guides Selection of the Occluder Design for Their Transcatheter Device Closure

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Conflict of Interest

The authors have no financial conflicts of interest.

Author Contributions

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ABSTRACT

BACKGROUND: Perimembranous ventricular septal defects (VSDs) has proximate relation to the aortic and tricuspid valves as well as the conduction tissues. Transcatheter closure utilizes various off-label device designs.

METHODS: Perimembranous VSD without aortic margin were classified as group A, with thick aortic margin as group B, with membranous septal aneurysm as group C and defects restricted by tricuspid valve attachments as group D. The proposed ideal design was asymmetric device in group A; duct occluder I (ADOI) and muscular ventricular septal occluder (MVSO) in group B; thin profile duct occluder II (ADOII) in group C and ADOI in group D. Device was 0–2 mm larger than the defect.

RESULTS: Eighty patients with VSD measuring 6.83 ± 2.87 mm underwent successful closure. Device was retrieved before release in one group A and one group C patient due to aortic regurgitation. Asymmetric device was used in 16 group A defects. Among group B defects, ADOI was used in 5, ADOII in 5, MVSO in one and asymmetric device in 3. Group C defects were closed with ADOI in 7, ADOII in 10 and asymmetric device in 3. Three patients with multiple exits had 2 ADOII devices. Group D defects were closed using ADOI in 20 and ADOII in 10 patients. There was no late aortic regurgitation or heart block on a follow-up exceeding 7 years.

CONCLUSIONS: This echocardiographic classification helps device selection in every single patient. While asymmetric device is uniquely suited for group A defects, different designs are appropriate in the other groups.

Keywords: Echocardiography; Heart septal defects; Devices

INTRODUCTION

Ventricular septal defect (VSD) is the commonest form of congenital heart disease, accounting for 40% of them.¹⁾ Perimembranous defects are located in close vicinity of anteroseptal tricuspid commissure and below the commissure between the non coronary and right coronary cusps of the aortic valve.²⁾ The proximity to the atrioventricular nodal

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conduction tissue also explains the increased frequency of heart block in patients after transcatheter closure using the earlier asymmetric devices.³⁾ Modified off-label devices that reduce the radial force on the margins and remove the clamp force unlike the asymmetric device are increasingly used for device closure of perimembranous defects and they have shown comparable results with surgery.⁴⁾ Increasing procedural success using these devices have encouraged cardiac surgeons to employ these devices through minimally invasive incisions without resorting to extracorporeal circulation.⁵⁾ Such periventricular device closures show similar procedural outcomes compared to conventional surgery.⁶⁾

Tissue tags from the edges of the membranous septum or accessory chordal attachments from tricuspid valve may lead to aneurysm formation around the defect.²⁾ The precise margins of the defects in relation to the aortic and tricuspid valves decide the suitability of these defects for device closure. While significant inlet extension towards the septal tricuspid annulus increases the risk of heart block, proximity to aortic annulus increases the risk of distortion of the aortic valve leaflet mobility.⁷⁾ On the basis of the relation of the VSD margins with these 2 valves and presence of septal aneurysm, 4 different morphological forms of defects are described on echocardiography.⁸⁾ In the first form named group A, the superior VSD margin is coalescent with the aortic annulus with no clear separation. In the second form named group B, a well-developed ventriculo-infundibular fold separates the defect from the aortic valve forming a muscular aortic margin. While tissue tags from membranous septum form an aneurysm in the third form named group C, accessory tricuspid leaflets form an aneurysm in the fourth form named group D.⁸⁾ These last 2 forms may have more than one exit on the right ventricular end separated by membranous tissue or tricuspid chords.

The initial asymmetric membranous device designed for perimembranous defects in 1998 was withdrawn due to high incidence of conduction disturbances caused by high radial stress and clamp force.⁹⁾ The devices without clamp force like the Amplatzer muscular VSD occluder (Abbott Medical, Plymouth, MN, USA) and the Amplatzer duct occluder I (ADOI; Abbott Medical) and devices made of thinner nitinol wires like Amplatzer duct occluder II (ADOII; Abbott Medical) were later considered for off-label closure of perimembranous VSD.¹⁰⁾¹¹⁾ With the availability of these different device designs, echocardiographic analysis of the VSD became crucial for selecting the appropriate device. We analyzed our experience with transcatheter closure of consecutive patients with perimembranous VSD and retrospectively correlated the choice of device with their echocardiographic anatomy.

METHODS

All consecutive patients who underwent device closure of perimembranous VSD between 2007 and 2013 from a tertiary pediatric cardiac care hospital were included in this retrospective analysis. Institutional ethics committee permitted this retrospective analysis. The regulatory authority for use of different drugs and implantable devices in the country permitted use of all the different designs of the occluders used in the study for closure of perimembranous defects. Informed consent was obtained from patients for transcatheter closure after explanations about alternative surgical choices and publication of anonymized images for publication.

Inclusion criteria

Patients were included if there was significant left ventricular volume overload (defined by left ventricular internal end diastolic dimension on parasternal M-mode Z score > 2) and/or left ventricle (LV) looking visibly significantly dilated in apical 4 chamber view.¹²⁾ Associated cardiac condition that can be dealt non-invasively by catheter interventions like valvar pulmonary stenosis, coarctation of aorta was also included.

Exclusion criteria

Patients less than 1 year of age, weight during the procedure less than 5 kg were excluded. Associated conditions that cannot be dealt in catheterization laboratory, significant right or non-coronary cusp prolapse and distortion, significant aortic regurgitation were also excluded. Postoperative residual VSD were not included in the analysis.

Echocardiographic classification

Once the echocardiographic anatomical relations of a VSD suggests that it is perimembranous in location due to its intrinsic relation to the anteroseptal tricuspid commissure and the aortic annulus, they are further subdivided into one of the 4 types previously described.⁸⁾

Type A: VSD with absent aortic rim. The superior margin of the defect is flush with the aortic annulus with no significant separation (**Figure 1**).

Type B: VSD with good well-formed aortic margin formed by the ventriculo-infundibular fold (**Figure 2**).

Type C: VSD restricted by septal aneurysm formed by fibrous tissue ingrowth from the edges of the VSD (**Figure 3**).

Type D: VSD restricted by septal aneurysm formed by part of tricuspid valve leaflets, either septal or anterior caused by the chordal attachments to the apical edge of the VSD (**Figure 4**). The superior margin of the VSD is always separated from the aortic annulus in the types B, C and D, in view of the anatomical definition used in this classification.

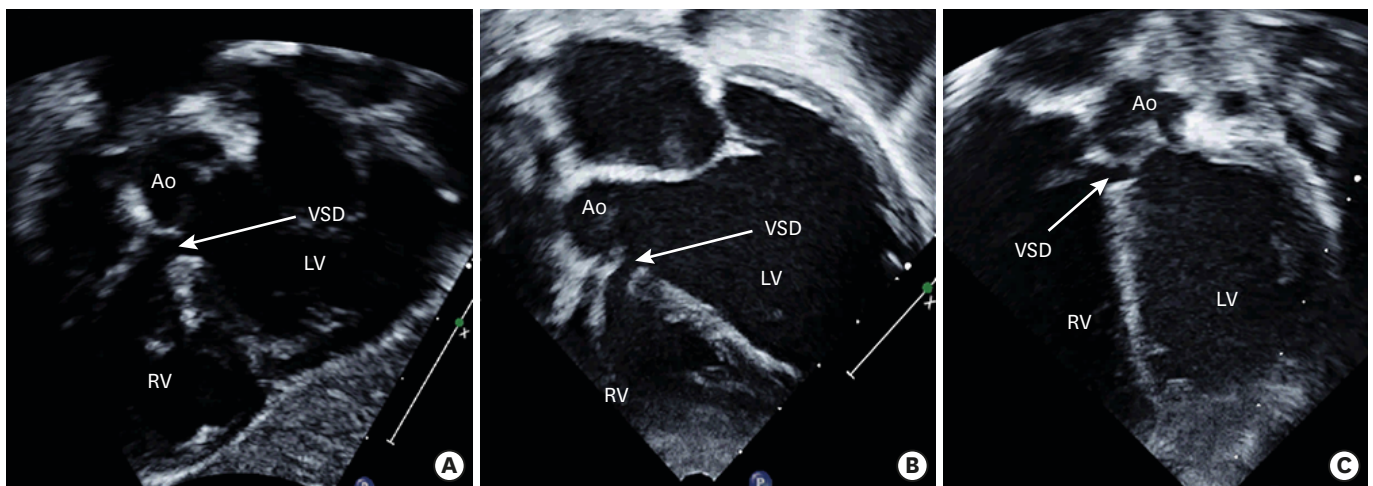


Figure 1. Type A VSD. Perimembranous VSD shown in subxiphoid short axis view (A) between LV and RV with Ao valve leaflets flush with the superior margin of the defect. Subxiphoid long axis view (B) and apical 5 chamber view (C) also show the absent aortic margin. VSD: ventricular septal defect, LV: left ventricle, RV: right ventricle, Ao: aortic.

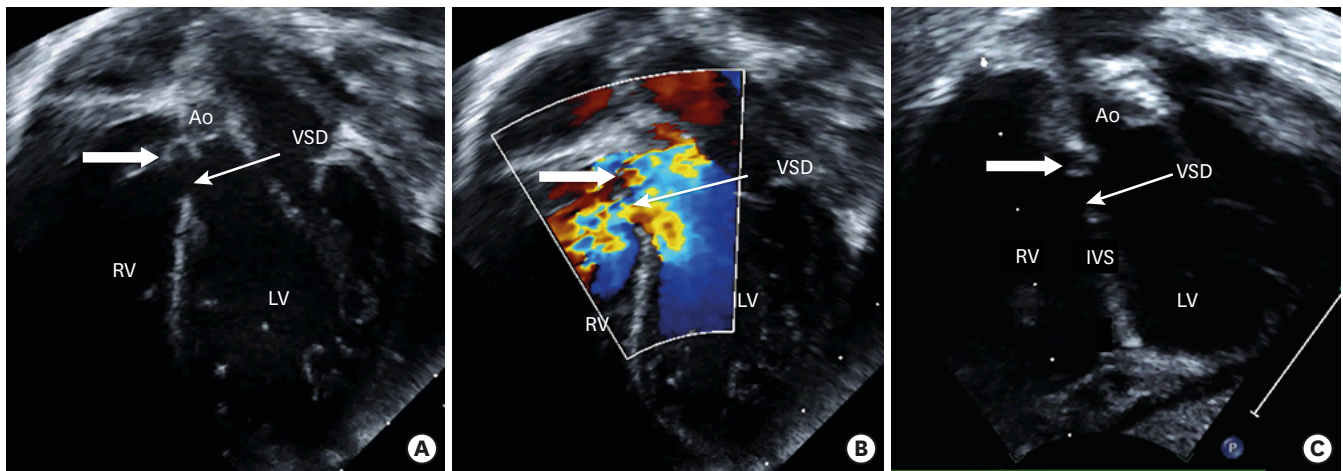


Figure 2. Type B VSD. Apical 5 chamber view (A) with color flow imaging (B) show perimembranous VSD between LV and RV separated from Ao valve by a thick muscular margin (block arrow). Subxiphoid short axis view (C) also shows a thick muscular margin separating the defect from aortic valve. VSD: ventricular septal defect, LV: left ventricle, RV: right ventricle, Ao: aortic, IVS: interventricular septum.

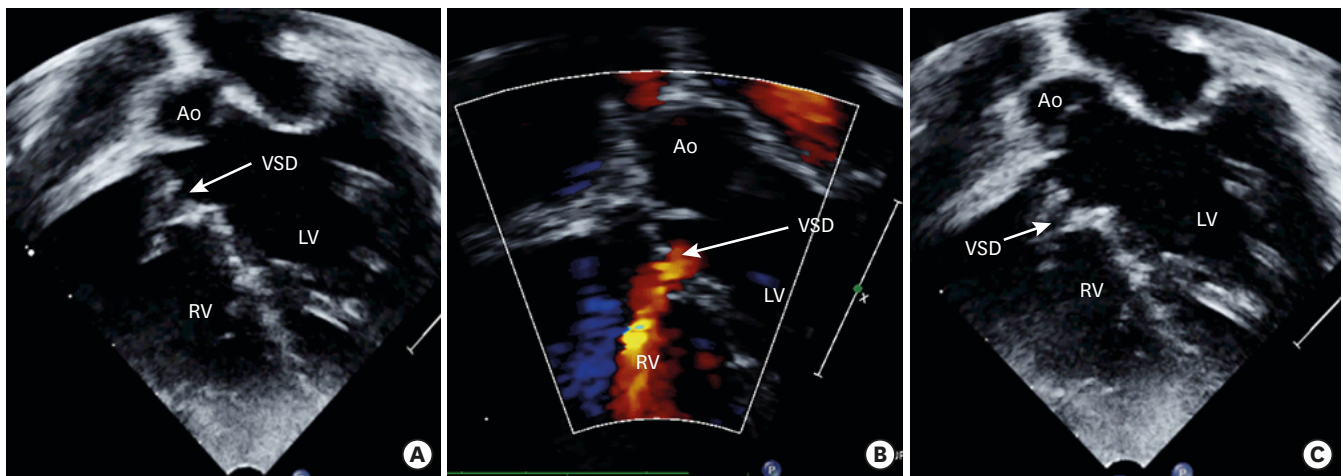


Figure 3. Type C VSD. A membranous septal aneurysm formed by tissue ingrowth from edges of the VSD between LV and RV is shown in apical 5 chamber view (A). The separation of the edges of the VSD from Ao annulus by the aneurysmal tissue is demonstrated in color flow imaging (B). A modified subxiphoid view (C) also shows this aneurysmal tissue separate from septal tricuspid leaflet. VSD: ventricular septal defect, LV: left ventricle, RV: right ventricle, Ao: aortic.

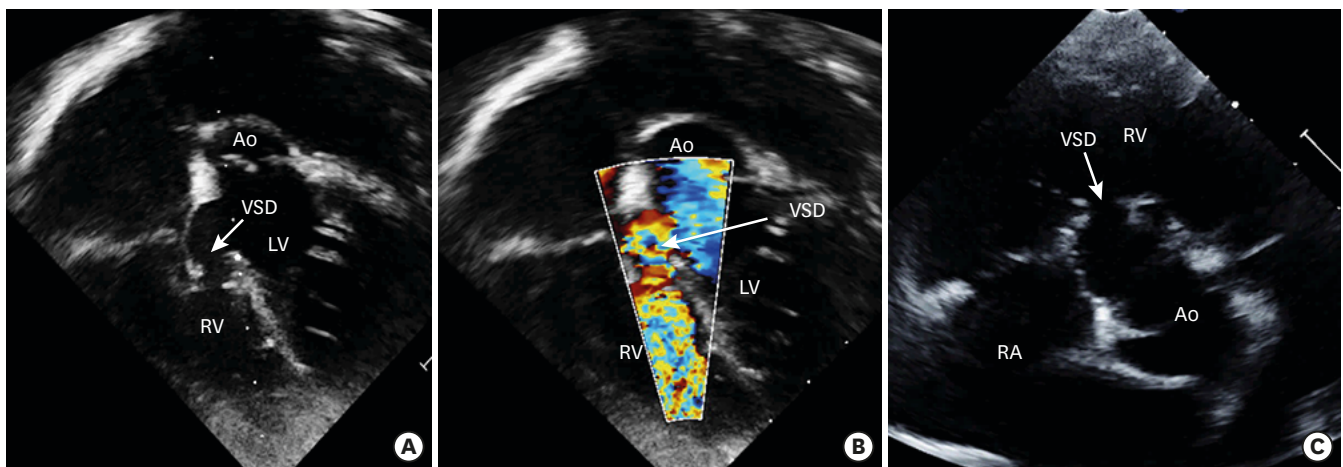


Figure 4. Type D VSD. The chordal septal attachments of the tricuspid valve to the edges of the VSD between LV and RV is shown in apical 5 chamber view (A). Color flow imaging (B) shows its separation from the Ao annulus. Parasternal short axis view (C) also shows the tricuspid valve leaflet attachments restricting the defect. VSD: ventricular septal defect, LV: left ventricle, RV: right ventricle, Ao: aortic.

Echocardiographic analysis

A detailed analysis of the VSD was carried by Philips Epic 7C echocardiographic machine (Philips, Best, Netherlands). The VSD was analyzed in subcostal short axis, apical 5 chamber, parasternal short and long axis views. Subcostal short axis view was used to analyze its relation to tricuspid and aortic valve and measure the size of the defect. Apical 5-chamber view was used to image the defect and the septal aneurysm if present. Parasternal long axis view was used to analyze the presence of aortic cusp prolapse or distortion, aortic regurgitation and measure the size of LV on M-mode before calculating the Z-score.¹²⁾ The aortic margin of the defect defined as the shortest distance from the right ventricular exit of the VSD to the aortic leaflet hinge point was best measured on parasternal long axis or apical views. The parasternal short axis view showed the size of VSD at LV side, exit point, its relation to the aortic and the tricuspid valve leaflets. After analyzing the VSD in all views, a comprehensive idea of the location of the VSD in relation to the aortic and tricuspid valves and size of the VSD was made before planning the device closure. The narrowest exit point of the VSD was measured in subxiphoid, apical and parasternal views and recorded as the size of the defect. In non-circular defects with different measurements of the right ventricular exit orifice in the 3 views, the largest among them is used as the diameter of the defect. A device 0–2 mm larger than this diameter is chosen for closure.

Rationale in selection of device

Type A VSD do not have any aortic margin and its superior edge is flush with the aortic annulus. These defects need an occluder, which does not have any protrusion on the left ventricular side towards the aortic valve leaflets. Asymmetric membranous device ideally suits this anatomy (**Figure 5**). Type B defects have good muscular margins around them, permitting closure with devices that have a thick waist. These defects can be closed either by ADOI device or muscular VSD occluder depending on their size, the latter device preferred in larger defects to provide stability as they have retention skirts on either side (**Figure 6**). Both these devices have a 7 mm profile that best suits the thick muscular edges of the type B defect. Type C VSD with membranous septal aneurysm is best closed by retrograde transaortic delivery of ADOII devices due to the simplicity of avoiding arteriovenous circuit formation (**Figure 7**). Moreover these thin low profile devices with minimal separation (< 4 mm) between the discs are ideally suited for the thin edges of these defects within the membranous septal aneurysm. Type D defects that are formed by septal chordal attachments of tricuspid leaflets with aneurysm formation are best treated by ADOI device as there is no right ventricular retention skirt to cause a protrusion in the right ventricular inflow. The asymmetric membranous VSD device has a high clamp force and more radial strength risking the conduction tissues more than the other devices. They need positioning to align the flat aortic margin flush with the aortic annulus and the protruding left ventricular margin towards the ventricular apex (**Figure 8**). If there are multiple right ventricular exits of a defect, an additional device was used to close a residual defect before releasing the first device off the cable. In these circumstances, a low profile ADO II device was often preferred.

Closure method

Femoral arterial and venous access after local anesthesia and controlled conscious sedation with ketamine was obtained in patients where arteriovenous loop formation was needed to deploy asymmetric membranous device or ADOI device and transvenous delivery of muscular VSD device. Femoral arterial access alone was found suitable for retrograde deployment of ADOII or the muscular VSD occluder. After initial hemodynamic assessment by recording pulmonary artery and aortic pressures in all patients and collection of samples

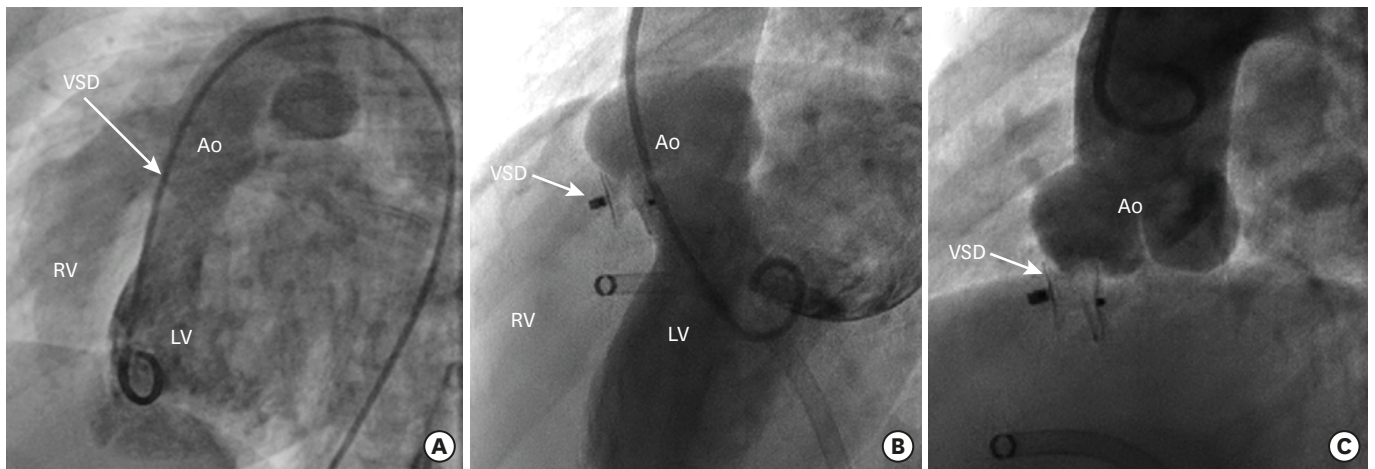


Figure 5. Asymmetric device in type A defect. Left ventriculogram in steep left anterior oblique projection (A) shows the VSD flush with the Ao valve. Closure with an asymmetric device with a flat aortic margin that is flush with aortic valve (B) is confirmed on aortic root angiogram (C). VSD: ventricular septal defect, LV: left ventricle, RV: right ventricle, Ao: aortic.

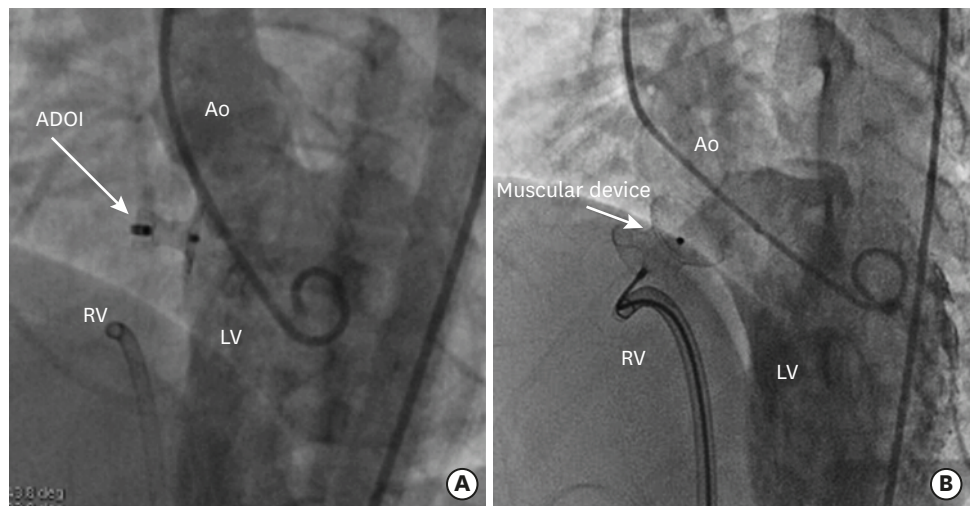


Figure 6. Device closure of type B VSD. Defects with good Ao margins between the LV and RV is closed (A) with ADOI. Muscular device with double retention skirts provide stability in larger defects (B). VSD: ventricular septal defect, LV: left ventricle, RV: right ventricle, Ao: aortic, ADOI: duct occlude I.

of oximetry in selected cases, left ventricular angiogram was done with a pigtail catheter. Left ventriculogram, fluoroscopic landmarks and simultaneous transthoracic echocardiogram guided the closure in most patients unless inadequate transthoracic images warranted a brief transesophageal study before device release. Closure of the VSD was done using various devices according to the standard established practice techniques.³⁾¹⁰⁾¹¹⁾ In most patients, especially in Type A defects, where asymmetric devices were chosen, the delivery sheath was positioned in the LV to open the left disc of the device before deployment across the VSD. In few instances where ADOI device was used; the left disc was deployed in the ascending aorta to bring the partially open disc through the aortic annulus to the level of the VSD.

Follow-up

After the initial patient enrolment for device closure and completion of the procedure, these patients were followed 3 monthly for the first year followed by yearly clinical examinations with electrocardiogram and echocardiogram for late occurrences of conduction disturbances

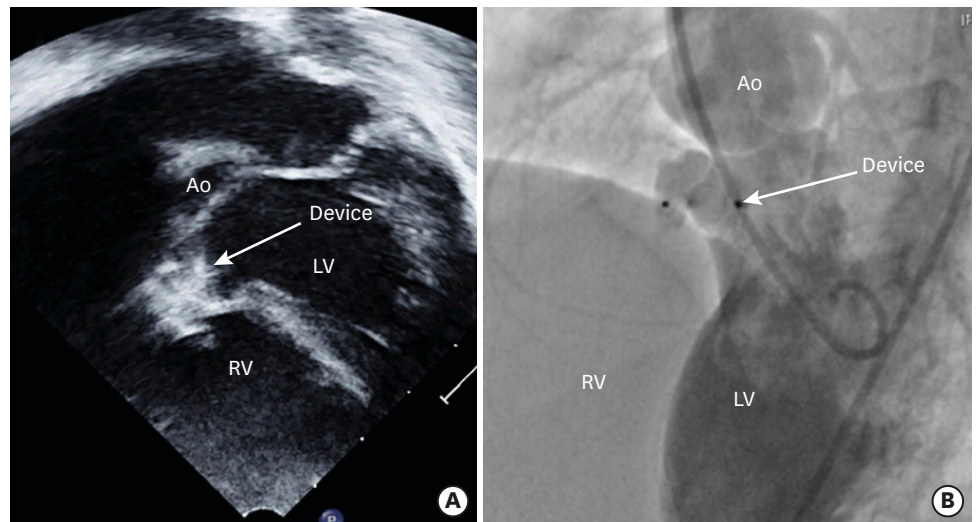


Figure 7. Device closure in type C VSD. ADOII with 2 retention skirts closes a defect between LV and RV in the apical view (A). Left ventriculogram (B) confirms the position of the device well away from Ao valve leaflets. VSD: ventricular septal defect, LV: left ventricle, RV: right ventricle, Ao: aortic, ADOII: duct occlude II.

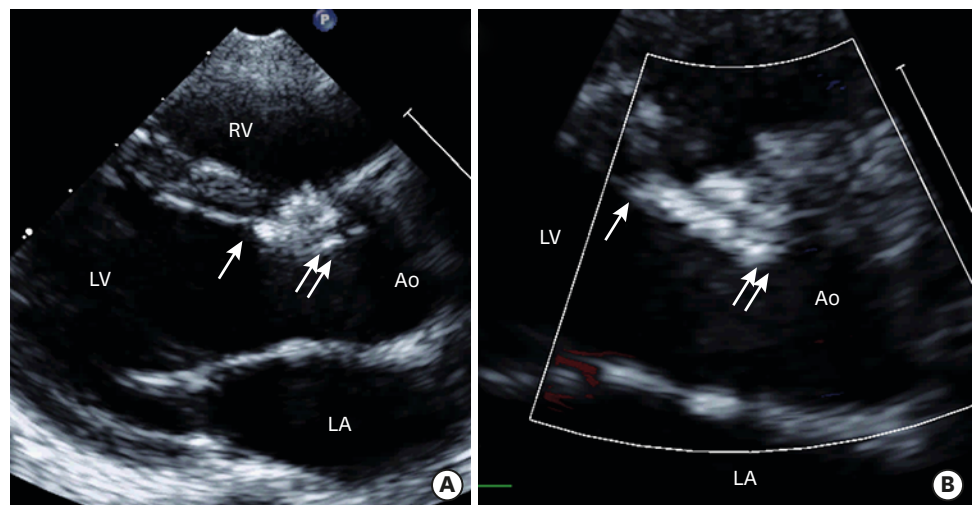


Figure 8. Orientation of asymmetric device. Asymmetric device is positioned in the defect between the LV and RV with the flat aortic margin (double arrow) abutting the Ao valve leaflets and the long protruding left ventricular edge (single arrow) facing the ventricular apex in this parasternal long axis view (A). A magnified view (B) with color flow mapping confirms absence of aortic regurgitation in a diastolic frame. LV: left ventricle, RV: right ventricle, Ao: aortic, LA: left atrium.

and aortic valve regurgitation. Residual flow across the defect, tricuspid regurgitation, aortic valve dysfunction, ventricular function were monitored in these patients on follow-up. Patients who did not attend the follow-up appointments were advised to send electrocardiogram and echocardiogram recorded in their neighbourhood cardiology clinics with emphasis on residual flows and valvar dysfunction.

RESULTS

During the 6-year study period from October 2007 to September 2013, a total of 116 patients underwent device closure of VSD of whom 82 patients (70.7%) with perimembranous VSD

were included in the study (**Supplementary Table 1**). Muscular defects and postoperative residual defects formed the rest of the patients. The patients were aged 1–40 years with a mean of 9.61 ± 8.28 years. The weight of the patients during the procedure ranged from 5.6–79 kg with a mean of 26.18 ± 18.67 kg. The only patient weighing less than 8 kg in the cohort was a 1.2 year old child with 6 mm perimembranous VSD and significant discrete postsubclavian coarctation of aorta who was sick and unfit for surgery. Additional procedures were done in 5 patients (6.1%). Two patients had device closure of patent ductus arteriosus, one patient had atrial septal defect device closure, one had right pulmonary artery stent angioplasty and the last patient underwent balloon angioplasty for discrete coarctation of aorta.

Echocardiographic classification

According to the echocardiographic classifications, type A VSD constituted 20.73% (17 patients), type B VSD was 17.07% (14 cases), type C VSD was 25.6% (21 patients) and type D VSD comprised of 36.6% (30 patients). The mean size of the VSD was 6.83 ± 2.87 mm. Eighty patients (97.6%) had successful closure of the VSD. In 2 patients (2.4%) with one each in groups A and C, the VSD device was taken out before release in view of contact of the left ventricular retention skirt of the device with the aortic valve leaflets leading to mild aortic regurgitation.

Devices used in the study

Asymmetric perimembranous VSD device was used in 22 cases, ADOI device was used in 32 patients and ADOII device was used in 25 patients. Muscular VSD device was used in one patient. Three patients with type C VSD and multiple fenestrations received 2 ADOII devices each for closing the additional fenestrations. One asymmetric device was retrieved in a type A VSD and one ADOI device was retrieved in a type C VSD due to occurrence of aortic regurgitation.

Devices used in the individual groups

Among the 17 type A defects, 16 had a successful closure. One device was retrieved due to aortic regurgitation. The mean VSD diameter was 8.03 ± 3.04 mm. All patients with type A VSD had closure with asymmetric device. The size of the device was 2 mm larger than the VSD. All 14 patients with type B VSD had a successful closure. The mean VSD diameter was 7.07 ± 3.62 mm. The type B VSD were closed with ADOI in 5 patients, ADOII in 5 patients, muscular VSD device in one and asymmetric device in the rest. Asymmetric device was used before 2009, when the off-label uses of the other devices were not reported.⁹⁾¹⁰⁾ One out of the 21 type C VSD had a failed procedure as there was contact of the left ventricular retention skirt of the ADOI device with the aortic valve leaflets resulting in mild aortic regurgitation and was withdrawn. Other patients had a successful closure. The mean defect size was 6.39 ± 1.82 mm. ADOI device was used in 7 patients, ADOII device was used in 10 patients and 3 patients were closed with asymmetric device before 2009. Three patients with multiple right ventricular exits needed 2 ADOII devices sequentially deployed one after the other. Type D VSD constituted the majority of patients; device closure was successful in all of them. The defect measured 6.29 ± 1.9 mm. ADOI was used in 20 patients and ADOII was used in 10 patients.

Follow up

Eighty patients who had successful procedure were followed up after the device closure for a median duration of 7.9 years (range 5–12 years). Follow-up data was complete in all patients. There was complete closure of the defect without residual flows in all patients. There was no new onset aortic regurgitation or additional valvar disturbances on follow-up. The electrocardiogram on follow-up showed normal atrioventricular nodal conduction in all the patients. There were no episodes of infective endocarditis or hemolysis.

DISCUSSION

Transcatheter closure of perimembranous VSD is now increasingly adopted as an alternative for surgery in patients carefully selected based on echocardiography.^{10,11} The last decade has witnessed the sea change in adoption of percutaneous device closure of these defects with recent reports of off-label use of various device designs.¹³ While earlier implantations using asymmetric device were associated with 5% incidence of complete heart block, recent systematic reviews and meta-analysis showed similar incidence of procedural success and conduction disturbances when compared with surgical closure.^{3,14} The high radial stress and clamp force of the asymmetric device was earlier linked with the conduction complications and oversizing of the defect was another key factor.⁸ Off-label use of ADOI and ADOII devices showed a low incidence of complications compared to the earlier designs.^{9,10}

Perimembranous VSD show various morphological differences due to varying proximity to the aortic valve annulus and varying tricuspid chordal attachments to the margins of the VSD, apart from differences in the size of the defect and the number of exit orifices.¹ Echocardiogram plays a crucial role in identifying these variations and subgrouping the defects depending on the morphology.⁷ Adoption of simple transthoracic echocardiographic views is mandatory for universal use of these classifications.⁷ Such morphological classifications should also have an impact on the choice of device design as there are no dedicated device design unique for closure of all forms of perimembranous VSD.

While early reports of heart block resulted in withdrawal of asymmetric device design by St. Jude Medical from American and European centers, a very recent systematic reevaluation of the withdrawn asymmetric design has shown promise especially in superiorly located defects with deficient aortic margin in the absence of significant aortic valve prolapse and after excluding very large defects.¹⁵ These asymmetric designs are available in Eastern world from vendors other than St. Jude Medicals and are continued to be used in large volume centers with good procedural success and reduced incidence of heart block.¹⁶ The encouraging results with these designs have led to increasing use of periventricular use of these devices by cardiothoracic surgeons without employing cardiopulmonary bypass with outcomes comparable to conventional surgery.¹⁷

The current proposed classification guided the selection of the device based on the transthoracic echocardiogram. In our series of 82 patients, 80 patients (97.6%) had successful device closure. The selection of the device based on the echocardiogram was found to be appropriate in all. We proposed that the type A VSD with absent aortic margin would ideally need an asymmetric device to avoid impinging on the aortic valve leaflets. A similar recent study reporting use of various device designs barring the asymmetric design in perimembranous VSD quoted instances of aortic regurgitation after use of ADOI and ADOII devices in 3 out of 50 patients.¹⁸ Since we liberally used asymmetric design that was available from the vendors from Eastern world other than St. Jude Medical in these patients, there were no aortic regurgitation on follow-up in our cohort. The type B defects with good aortic margin would be amenable for closure with ADOI or muscular VSD device, the latter being preferred in large defects where device stability was crucial. We used a 12 mm muscular VSD occluder in one patient who had a 12 mm defect as the additional 4 mm retention skirt of this device provided stability without oversizing. All other type B defects were smaller than 10 mm and were closed with ADOI or ADOII devices. Before 2009, 3 type B defects and 3 type C defects were closed with asymmetric device. Once off-label use of ADOI and ADOII devices were reported, we switched to these devices in non type A defects.

There were 2 procedural failures. In a type A defect with subtle right aortic cusp prolapse, despite a stable device position of an asymmetric device, there was mild aortic regurgitation. In another type C defect, there was mild aortic regurgitation following ADOI device. These devices were retrieved before release and patients were sent for surgery. Our experience showed that proper case selection of the perimembranous VSD based on focused echocardiographic imaging helped to select the appropriate type of device. The proposed classification of the VSD for the purpose of device closure was a helpful tool in this regard.⁸⁾

Being a retrospective analysis, this single center study involved only 82 patients over a very wide age and weight range. Even though our proposal to use a specific device design for a given morphology was followed in majority of patients, asymmetric devices were used in patients with non type A morphology before 2009, even when there were adequate aortic margins. Performance of all procedures by the same operator removed the bias of device selection in every patient. Follow-up exceeding 7 years of this study that stopped further enrolment after 2013 collected data on late occurrences of heart block and aortic regurgitation following device closures. In spite of withdrawal of asymmetric device by St. Jude Medical many years ago, similar designs made by Eastern world vendors permitted their continuous use. As enrolment stopped in 2013, new device designs like Multifunctional VSD occluders were not included in this study. The data on procedural time and fluoroscopic time were not recorded in the database before 2009 and they could not be analyzed.

In conclusion, absence of dedicated devices for closure of perimembranous VSD forces utilization of different off-label designs. Morphological classification of VSD by echocardiography depending on aortic margin, septal aneurysm, number of defects and size allows to customize the design of the device in every patient. While asymmetric design is uniquely suited for defects with deficient aortic margin, different designs are appropriate in the other types of defects. Avoiding an oversizing more than 2 mm in every patient avoids late occurrences of heart block and aortic regurgitation on follow-up. Transcatheter closure of perimembranous VSD can be performed safely and successfully in experienced centers if cases are carefully selected by echocardiogram. Transthoracic echocardiographic analysis of VSD is the key for selecting the correct design and size of the VSD.

SUPPLEMENTARY MATERIAL

Supplementary Table 1

Demographic and hemodynamic data

[Click here to view](#)

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