Subject Area:

Retrograde transcatheter closure of perimembranous aneurysmal ventricular septal defects using amplatzer vascular plug II

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Abstract

Introduction

Retrograde transcatheter closure of perimembranous aneurysmal ventricular septal defects (pmVSD) can be a better option for transcatheter closure of ventricular septal defect with device placement into ventricular septal aneurysm with fewer complications. Also, a retrograde approach might decrease procedure time and radiation exposure time.

Aim

The purpose of this study was to report off-label experience using Amplatzer Vascular Plug II (AVPII) for the trans catheter closure of perimembranous aneurysmal VSD. Comparison of haemodynamic effects of ketamine and sevofluorane as in induction of anesthesia.

Materials and methods

Our series consists of a fifteen child with pmVSD. The mean age was 4.9 years (range: 1.2–10 years), mean left ventricular end-diastolic dimension 38.3 mm. Maximum and minimum defect sizes were 4 and 8 mm by transthoracic echocardiography (mean defect size: 5.2 mm). The procedure was performed under general anesthesia with left heart catheterization for retrograde closure of the defect. The study was done on 15 children from 2016 to 2018 for retrograde transcatheter closure of aneurysmal perimembrance VSDs using an Amplatzer vascular plug II Baseline characteristics of the study patients are set in Table I. All the children who had aneurysmal perimembrance outlet ventricular septal defect with left to right shunt were included for assessment of closure. The children eligiable underwent clinical evaluation that also included electrocardiogram (ECG), and standard echocardiography assessment.

Results

All participants who met the inclusion criteria were sent to the catheterization laboratory. Following left ventricular angiogram, three patients were excluded as technically nonfeasible. Failure to cannulate the defect in one patient and deficient aneurysmal tissue during left ventricular angiography in two cases. The device was successfully deployed in 12 children with the retrograde technique. In two patients antegrade approach was used using the ADO I device due to deficient aneurysmal tissue. The complete VSD closure rate was 84% immediately, 92% at 24 h, and 92% at the last follow-up. Atrioventricular conduction system was not affected by the procedure in any patients. Arterial complication developed in two patients. There was no device embolization; no aortic regurge developed in any patient. According to children had ketamine in induction of anesthesia HR recorded (122±16) beats /min but the children had sevofuran in indnction of anestherin re corded (108±12) beats/min but not significant different howevere the (MBP) inth children had ketamin had (68±14) mm Hg but the children had sevofluran in induction (60±8) mm Hg but not significant different.

Conclusions

Retrograde transcatheter closure of pmVSDs using AVPII is a safe and effective alternative method which allow closure of a wider range of VSDs due to availability of wide ranges of AVPII sizes of up to 22 mm in diameter. The retrograde approach can also simply the procedure with less fluoroscopy time and anesthesia time.

Keywords: Perimembranous, septal aneurysm, transcatheter

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Access this article online

Quick Response Code:

Website:
www.jmsr.eg.net

DOI:
10.4103/JMISR.JMISR_63_19

INTRODUCTION

Ventricular septal defects (VSDs) are one of the most common forms of congenital heart defects accounting for about 20% of defects in isolation [1].

Yilmaz and colleagues have reported that perimembranous aneurysmal VSD (pmVSD) was found in 20% of perimembranous VSDs[2] that can progress in infancy to a functionally smaller defect with aneurysmal formation [3], which reduces the VSD size and allows transcatheter closure with fewer complications.

Introduction of amplatzer family of devices has markedly widened the scope of transcatheter closure of these defects [4], especially device closure of pmVSDs which has been complicated with unpredicted episodes of conduction block [5,6] in 20–30% of cases due to the proximity of conduction fibers to the margins of the defect. The mechanism of conduction block is likely related to local myocardial inflammation as the most common cause due to the self-expanding Nitinol devices that exert expansive force on the margins of the defect. An alternate method of device placement has been described, in which the occluder device is implanted into the ventricular septum aneurysm [7,8]. In this position, the device is remote from the conduction system and aortic valve. Retrograde transcatheter device closure of VSD has been described in some studies [9–11] when the antegrade approach had failed using the venous route. This approach is simple as it avoids the circuitous route of antegrade approach by femoral vein with the use of large stiff delivery sheaths, which may cause hemodynamic instability while crossing the tricuspid valve, the defect or the aortic valve, and also shortens the total procedure time, decrease radiation exposure to the patient and operators, and decrease the procedure cost, which represents an important issue in developing countries.

AIM

The purpose of this study was to report our off-label experience using Amplatzer Vascular Plug II (AGA Medical Corp., Golden Valley, Minnesota, USA) for retrograde closure of pmVSD.

MATERIALS AND METHODS

The study was done on fifteen children from 2016 to 2018 for retrograde transcatheter closure of pmVSDs using an AVPII. Baseline characteristics of the study patients are set in Table 1. All the children who had aneurysmal perimembranous outlet VSD with left to right shunt were included for assessment of closure. The children eligible underwent a clinical evaluation that also included an ECG and standard echocardiography assessment.

Inclusion and exclusion criteria

In all pmVSD patients, transcatheter closure was indicated for hemodynamic symptomatic or other medical reasons. All patients were evaluated by transthoracic echocardiography (TTE) with GE Vivid 5 (GE Healthcare, USA).

Exclusion criteria

Defects associated with other cardiac lesions requiring a surgical approach:

(1) Inlet and doubly committed VSD.
(2) pmVSD with a bidirectional or predominant right to left shunt through the VSD on color Doppler (irreversible pulmonary hypertension).
(3) More than mild aortic regurgitation.
(4) Aortic valve prolapsed.

Inclusion criteria

(1) Symptoms and signs of heart failure.
(2) Failure to thrive.
(3) Frequent respiratory infection (defined as >6 events in 12 months).
(4) The cardiothoracic ratio of more than 0.5 with increased pulmonary vascularity on chest radiography.
(5) History of infective endocarditis.
(6) Age more than 1 year.

Device

AVPII is nitinol braided in two layers in the smaller devices and three layers in devices bigger than 10 mm. It is available in diameters starting at 3 mm, ranging from 4 to 22 mm in 2 mm increments. It is available in lengths ranging from 6 to 18 mm and is deployed through 5–9-Fr guiding catheters.

Device implantation

The catheterization procedure was performed under general anesthesia with tracheal intubation. Heparin (100 IU/kg) was administered intravenously during the procedure. Approximately 30 min before device implantation prophylactic antibiotics were administered, and an additional dose was given 8 h later. Based on the quality of the image, TTE was selected to guide deployment. Access is through the right or left femoral artery puncture. Angiography in the left ventricle (LV) at a 55°/20° left anterior oblique projection/cranial was used to profile the pmVSD. Location, size of the pmVSD, and its relationship with the aortic valve were assessed. Each pmVSD was categorized by its shape as tubular, window-like, and aneurismal type. The diameter of the pmVSD was measured at the largest diastolic phase, and an occluder size was selected based on this measurement (Fig 1).

Device selection

The waist diameter of the chosen AVPII was approximately equal to the right ventricular (RV) outlet of the aneurysm or greater by 1–2 mm in single RV outlet. In fenestrated aneurysmal defect device diameter was selected according to the LV inlet diameter of VSD as a device used to close the inlet of the defect.

Deployment of the device

The defect was passed using a 0.035-inch hydrophilic Terumo wire and then a 6 Fr Right Judkins or Amplatzer Right catheter was introduced over the Terumo wire and then exchanged with a super-stiff exchangeable wire. The guiding catheter advanced to the RV over the wire where the wire was removed and the

Table 1: Clinical and Demographic of patients in the study

Patient no.	Sex	Age (years)	Ratio LA:AO left atrial to aortic diameter ratio	TR	EPAP	LVEDD (mm)	LVESD (mm)	MSA
1	Male	8	1.07	25	30	43	28	+
2	Male	8.7	1.4	31	35	47	30	+
3	Female	1.4	1.75	43	48	34	20	+
4	Female	1.8	1.3	20	25	31	22	+
5	Male	2.5	1.5	23	28	36	22	+
6	Female	4.2	1.5	18	23	37	26	+
7	Male	7	1.1	15	20	43	28	+
8	Male	8.2	1.4	30	30	46	32	+
9	Female	2	1.75	20	35	34	20	+
10	Female	2.2	1.3	28	33	35	22	+
11	Female	3	1.15	15	23	33	19	+
12	Female	4	1.5	28	33	37	25	+
13	Female	2	1.25	30	35	33	20	-
14	Male	10	1.1	16	21	39	27	-
15	Female	9	1.04	25	30	43	23	-

LVEDD, left ventricular end-diastolic dimension; LVESD, left ventricular end-systolic dimension; MSA, membranous septal aneurysm. TR, tricuspid regurge; EPAP, estimated pulmonary artery pressure

guiding catheter was loaded with the device. The right retention disk of AVPII was deployed, and the assembly is withdrawn so that the disk was aligned with the septum guided by TTE (Fig 2). The waist and left retention disk were then sequentially deployed within the left side of the aneurysm. Once a stable position and no interference with aortic and tricuspid valves were confirmed with TTE in apical five-chamber and parasternal short axis and subcostal views; LV injection was done in the left anterior oblique view to visualize accurate closure with no residual flow across te device, then the delivery system was detached and removed together with the guiding catheter (Fig 3). Left ventriculography showed minimal intradevice residual shunting in two patients. TTE revealed both retention disks to be flat and in an appropriate position without interference with the aortic valve. Aorta root injection was performed after closure to verify any new-onset aortic valve regurgitation. Continuous ECG monitoring was used during the first 24 h after the procedure. The patient received Aspirin (5 mg/kg daily) for the first 6 months in all patients.

Follow-up evaluation
All patients were evaluated before discharge with physical examinations, ECGs, and echocardiograms. Also, all patients were referred for follow-up, which occurred at a median time of 6 months.

Echocardiography follow-up
Immediate postprocedural echocardiogram was done to all patients. Despite trivial to small residual VSD shunting in two patients, there was an acute reduction in LV size in all patients and tricuspid regurge.

Late complications and analysis
Two patients developed femoral artery thrombosis documented by duplex that required anticoagulant therapy with continuous intravenous heparin infusion for 3 days and then continued on subcutaneous Clexane for 1 week, where signs and symptoms improved and duplex document recanalization of the thrombus.

RESULTS
All participants who met the inclusion criteria were sent to the catheterization laboratory with the intention to treat the defect percutaneously. Fifteen patients (nine women, 60% and six men, 40%) were eligible for the procedure [Table 1].

Their ages ranged from 1.4 to 10 years (mean: 4.5 ± 2.9 years). All patients have pmVSD by transthoracic echo with VSD diameter (RV end) with TTE mean of 5.3 ± 1.3 mm. In eight (66.7%) patients, there were single RV outlet VSD while in four (33.3%) patients number 1, 2, 5, and 8; fenestrated ventricular septal aneurysm (VSR) was also seen. In patient number 1 there was fenestrated ventricular septum aneurysm with two RV outlet defects 5 and 3 mm during LV angiography, and AVPII size 10 was used to close inlet of the defect; also patient number 2 has two RV outlet VSD (6 and 3 mm) during LV angiography where AVPII size 12 was selected for closure of LV outlet of defect. Failure for retrograde closure using AVPII was in two patients. In patient number 14 there was a failure to cross the defect with Terumo wire due to the small size of the defect (3 mm in diameter) with prolongation of the procedural time. In patient number 13 and 15, there were deficient aneurysmal septal tissues during LV angiography, so antegrade procedural with a venous circuit using Amplatzer Duct Occlude I size 8/6 in patient number 15 and device size 6/4 in patient number 13.

The most commonly used is AVPII size 8 in five (41.7%) patients followed by size 6 in three (33.3%) patients,

size 10 (in two patient 16.7%) and device size 12 in one patient (8.3%) in Table 2. Our mean fluoroscopic time was 26.8 ± 3.7 min. Fine residual leaks were observed in two patients by angiography and TTE immediately after the device closure with trivial residual leakage observed in one patient after 24 h and in follow-up period by TTE after 3 months. The complete VSD closure rate was 84% immediately after the procedure, 92% at 24 h and 92% at the last follow-up. The mean LV end-diastolic dimension of the patients was 38 ± 5.4 mm before VSD closure and 32 ± 5.9 mm after closure ($P = 0.0001$), mean LA dimension 26 ± 4.4 mm before closure and 21 ± 3.5 mm after ($P = 0.0001$).

A reduction of pre-existing TR was seen in all children after VSD closure, with a mean TR of 24.7 ± 8 and 8.9 ± 1.7 mmHg after closure ($P = 0.003$) as it was converted to a normotensive (normal calculated RV systolic pressure) TR.

There was no incidence of left bundle branch block, P-Q prolongation, or CHB during the follow-up evaluation. There was no evidence of aortic regurgitation in any of the cases by echocardiogram. Arterial complication developed in two (16.7%) patients in the form of femoral artery thrombosis that was treated with intravenous heparin infusion and relief of symptoms and signs in the follow-up period. There was no device embolization nor aortic regurge develop in any patient.

DISCUSSION

AVPII device received FDA approval for use in September 2007 for a various procedure with numerous published reports describing their utility for vascular occlusion procedures, including peripheral vasculature [12], pulmonary AVMs [13,14], aortopulmonary collaterals [15], and patent ductus arteriosus [16,17].

Our study group is limited to those with VSDs with aneurysmal septal tissue to deploy the device within the aneurysm as pmVSD, as MSA is devoid of any component of the conduction system [18,19] apart from aortic valve and conduction tissue for less complications as reported mostly in complete heart block [8,11].

In the current case series, the retrograde technique was implemented successfully in 12 patients except in three patients. In one patient out of these three patients, there was failure to cannulate the defect with a prolonged procedural time which is also reported by Jameel *et al.* [20].

In or direct retrograde approach, the delivery system is advanced over the long exchangeable wire without creating an AV loop and passing the defect from the LV side and avoids fewer steps compared with the antegrade technique. The authors accept that transcatheter VSD closure is considered one of the interventional procedures with a high level of difficulty [21].

In a large case series reported by experienced centers indicate considerably prolonged fluoroscopy and procedure times in

some cases. For example, the maximum procedure time was 300 and 342 min in the European registry[22] involving 403 cases and in a single-center Chinese study[23] conducted on 848 cases.

This technique seems to reduce the fluoroscopy time and radiation exposure of the operator and the patient, and cost of the procedure as the long delivery sheath is replaced by a guiding catheter and there is no need for snare as in the retrograde approach there is direct device deployment without the need for an arteriovenous circuit.

While the small diameter of the arterial vessels in infants poses an obstacle for the selection of the retrograde approach, in our study using the guiding catheter changes as delivery systems for AVPII device allowed the use of transarterial implantation technique without possessing this obstacle.

Recently, with this technique, the Amplatzer muscular occlude device [20,24] and ADO II device[25] have been implanted successfully in adolescents and children with congenital VSD.

Table 2: Echo versus Angiography for defect sizing

Patient no.	VSD (size) (echo) (mm)	VSD size (angio) (mm)	AVPII	Fluoroscopy time (min)
1	7	5 and 3	10	40
2	8	6 and 3	12	35
3	4	5	6	22
4	5	4	6	26
5	4	4&2	8	23
6	6	6	8	25
7	5	6	8	28
8	6	5&3	10	30
9	5	5	6	23
10	6	7	8	26
11	4	5	6	25
12	4	6	8	28

AVPII, Amplatzer vascular plug II; VSD, ventricular septal defect
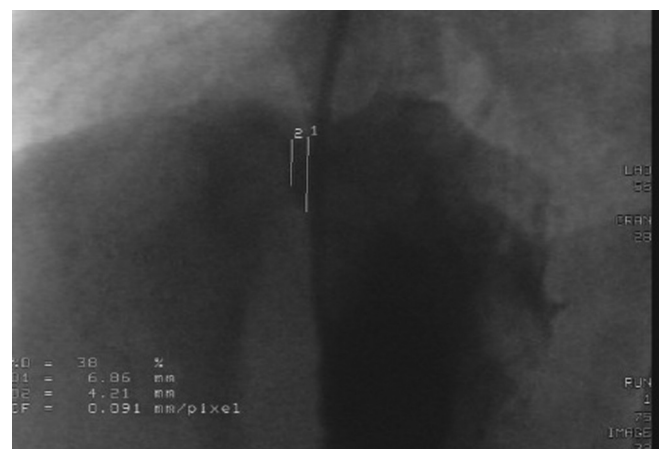
Figure 1: Sizing of aneurysmal VSD defect (LV inlet & RV outlet) diameters in left ventricular angiograms in long-axial oblique projections for device selection

Table 3: Comparesion with previous studies

Reference (nu)	Case number	Implantation technique		Fluoroscopy time		
		Antegrade	Retrograde	Mean	Median	Range
Our series	15	2	12	27.6	26	18-40
Koniti	13	0	13	18.8	NA	8.2-45
Jameel	7	0	7	33.8	NA	13.7-74.3
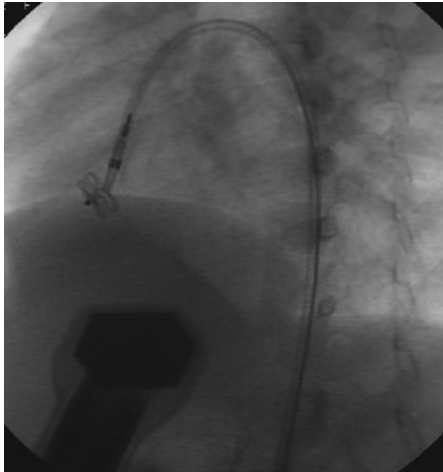
Figure 2: Device deployment guided by trans thoracic echocardiography

When comparing our study to two pediatric series [Table 3] that employed a technique similar to ours, our timings were somewhat longer than the figures in the study by Koneti *et al*.[25] and shorter than that reported in the study by Jameel *et al*. [20].

The retrograde implantation technique was easily employed in the majority of our cases, as the fluoroscopy time ranges from 18 to 40 min with a mean of 27.6 min.

Pooling data from the literature, Butera *et al*.[26] calculated the mean rate of successful closure at 96.3%, while in our study, we had a comparable VSD closure rate of 92%. None of our patients developed CHB during the procedure or follow-up period compared to Carminati *et al*.[22] who noticed a 2.5% occurrence of acute (within 48 h) and late-onset (at 5 and 12 months postprocedure) complete heart block in Amplatzer device closure of pmVSD [27]. None of our patients developed CHB during the procedure or follow-up so far.

CONCLUSION

The results of the present study suggest that the retrograde approach may be implemented successfully in pmVSD closure without creating AV loop in children patients. However, the morphological features of the defect, including aneurysmal septal aneurysm, is important in selecting patients for transcatheter closure using AVPII. This technique is simple and easy, without the need for arteriovenous loop, which in turn reduces the fluoroscopy time; also, AVPII appears to be cheaper than the devices compared using this technique. However, usage in a larger

Figure 3: A left ventricular angiogram (long-axial oblique projection) obtained after release of the device with absence of residual shunt

series of pmVSDs and a longer period of follow-up is needed to detect the development of late conduction abnormalities. Using of ketamine in induction of anesthesia in children under cardiac surgery maintains haumodynamic stallity and easily available.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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