

TRANSCATHETER DEVICE CLOSURE OF PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECT FROM RIGHT VENTRICULAR APPROACH WITHOUT ARTERIO-VEINOUS LOOP

Amjad Mehmood, Khurram Akhtar, Syeda Sadia Hina Kazmi, Mehboob Sultan, Nadim Sadiq, Aziz Ahmed, Hajira Akbar, Maad Ullah, Hafsa Inam

Armed Forces Institute of Cardiology/National Institute of Heart Diseases (AFIC/NIHD)/National University of Medical Sciences (NUMS) Rawalpindi Pakistan

ABSTRACT

Objective: To evaluate the safety and efficacy of transcatheter closure for Perimembranous Ventricleseptal defect (pm VSD) without arteriovenous (AV) loop. The most common congenital heart defect is PMVSD. Transcatheter closure of PMVSD without AV loop is a recently described technique with limited results for follow-up.

Study Design: Retrospective analytical study.

Place and Duration of Study: Paediatric Cardiology, Armed Forces Institute of Cardiology and National Institute of Heart Diseases, Rawalpindi Pakistan, from Jan 2015 to Oct 2018.

Method and Methods: Total of 30 patients with PMVSD were enrolled in this retrospective analytical study and treated percutaneously with VSD occluders.

Results: All patients were followed up to date. According to colour Doppler transthoracic echocardiography the mean \pm SD end-diastolic PMVSD size was 4.87 ± 1.32 mm. Placement of the device was successful in all patients (100%) and the mean \pm SD device size 7 ± 1.58 mm. During follow-up, No major adverse events were reported.

Conclusions: In experienced hands, transcatheter PMVSD closure without AV loop can be performed safely and successfully with low morbidity and mortality. Short-term results are favorable, and the transcatheter approach provides a less-invasive alternative that may become the first choice in selected pmVSD patients.

Keywords: Arteriovenous loop, Transcatheter, Ventricular septal defect.

This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

INTRODUCTION

The most common congenital heart defect encountered in pediatric cardiology clinic is VSD¹. VSD may occur in isolation or it may be part of other cardiac anomalies or clinical syndromes². Prevalence of VSD is about 25 to 30 per cent. There are three main types of VSD namely, muscular, doubly committed and perimembranous, with perimembranous type the most common accounting for about 80 percent of the cases³. The natural course and clinical presentations of VSD are mostly dependent on VSD size. Children with large VSD may present early with clinical symptoms of tachypnea, feeding difficulties, failure to thrive, cardiac failure and even with pulmonary hypertension. These patients are diagnosed early. Children with small

VSD may be diagnosed incidentally during clinical examination. Small VSD may close spontaneously with time and other may require intervention⁴. Large VSD if left untreated may result in complications like ventricular dysfunction, aortic regurgitation and arrhythmias⁵.

Management of this congenital defect has changed drastically in the last 5 decades Different modalities are used for VSD closure with each having advantages and disadvantages. Surgical closure of VSD has good short and long term outcome and at young age surgical VSD closure is still the best option. Long term survival after VSD closure is about 80 percent. Complications of surgical closure include arrhythmia, chylothorax, aortic regurgitation and various degree heart blocks. Mortality from surgical closure at later stage is mostly due to cardiac causes like heart failure, sudden death and reoperation⁶. Transcatheter Closure of VSD is innovative step in the

Correspondence: Dr Amjad Mahmood, Paeds Cardiologist, Armed Forces Institute of Cardiology Rawalpindi Pakistan
Email: amjpaedcard@yahoo.com

curative management for this defect. Moreover transcatheter VSD Closure without arteriovenous loop is even more cost effective, timesaving, technically feasible and safe procedure.

Previously transcatheter closure of perimembranous VSD (PMVSD), which involves the membranous and the adjacent septum have been limited to small series with scarce results⁷⁻⁹. However most of the studies focused on the closure of muscular septum, accounting for about 70% of cases. Conventional treatment for PMVSD is considered to be open heart surgery with associated morbidity and mortality. From the advent of transcatheter VSD closure in 1988¹⁰, this approach for VSD closure has been logical and scar free alternative to surgical closure which is even more favourable for young females for social and cosmetic reasons. Based on our local data in Pakistan, closures of PMVSD is done surgically with no reports of transcatheter occlusion¹¹. This study was carried out to evaluate the safety and efficacy of transcatheter closure of PMVSD Without AV loop and to its short term outcome.

METHODOLOGY

From 02 Jan 2015 to 10 Oct 2018 Total 30 patients with PMVSD were enrolled for attempted transcatheter closure without AV Loop using the VSD occluders available at our centre. VSD occluder (shsma; Lipu Medical) and Occlutech VSD occluder were used in the study. In all PMVSD patients, transcatheter closure was indicated for large left to right shunt with pulmonary artery pressure not more than half systemic. Detailed Echocardiogram was done in each patient prior to the procedure. Estimation of VSD size and pulmonary artery pressure was carried out. All patients were routinely screened by conventional two-dimensional and colour Doppler transthoracic echocardiography (TTE). The following inclusion criteria were used in this study: (i) congenital PMVSD as shown by echocardiography; (ii) body weight >10 kg and age >2 years; (iii) maximum VSD diameter 20 mm by TTE; (iv) defect located at the 9 to 11 o'clock positions of an analog clock in the short-axis parasternal view by

TTE; (v) a distance of 1mm from the PMVSD to the aortic valve; (vi) left-to-right shunt; and (vii) calculated pulmonary vascular resistance <8 Wood units. The exclusion criteria are as follows: (i) defects associated with other cardiac lesions requiring a surgical approach; body-weight <10kg and age <2 years; irreversible pulmonary vascular disease with calculated pulmonary vascular resistance >8 Wood units; (ii) Aortic regurgitation; (iii) Aortic valve prolapse; and right-to-left shunt.

Before intervention, an informed written consent was obtained from patients' Guardian/parents. Physical examination, a chest X-ray, 12-

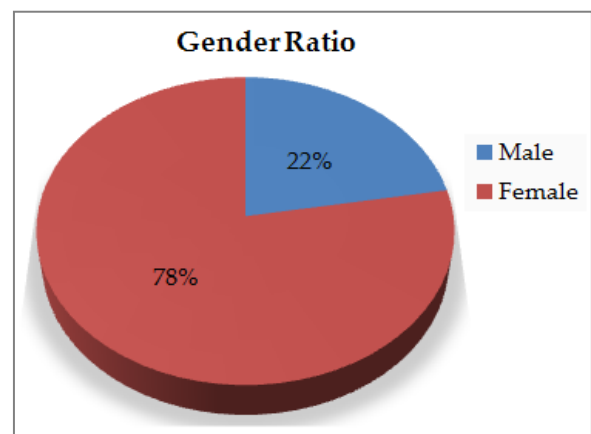


Figure-1: Gender ratio of patients who underwent percutaneous closure of VSD.

lead electrocardiogram (ECG), and TTE were routinely performed to verify complete occlusion and to identify any new-onset aortic valve regurgitation. After the intervention, patients were transferred to the general wards. Continuous ECG monitoring was used during the first 24 hours after the procedure. Post procedural Aspirin (5 mg/kg) is given to all patients for 6 months.

The catheterization procedure was performed under general anaesthesia. Heparin (100 IU/kg) and antibiotics were administered intravenously during the procedure. Access was through the right femoral vein and artery. Angiography in the left ventricle at a 45/20 left anterior oblique projection/cranial was used to profile the PMVSD (fig-1). Location, size of the PMVSD, and

its relationship with the aortic valve were assessed. Each PMVSD was categorized by shape as tubular, window-like, aneurysmal, or conical. The diameter of the PMVSD was measured at the largest diastolic phase, and an occluder was selected based on this measurement. The defect was then passed from the right ventricle by a 5 Fr Judkins right catheter (fig-2). After crossing the VSD, the catheter was replaced by super stiff exchange wire (fig-3). A long sheath (6-12 Fr) was advanced to the left ventricle over this wire and positioned beneath the aortic valve preferably in the left ventricle apex. Through the long sheath, the pm VSD occluder was deployed under fluoroscopic control and echocardiographic guidance. Angiography in the left ventricle and ascending aorta was performed again to confirm adequate device implantation (fig-4 & 5).

All patients were followed up until and the median follow-up period was 30 months. Clinical examination, Holter or electro-cardiographic monitoring, chest roentgenogram, and TTE were performed at 1, 6, 12 months after the procedure and yearly thereafter. Adverse events were ascertained at each assessment on the basis of clinical evaluation. Thrombi, valve regurgitation, and residual shunts were looked for using TTE. Complications were prospectively recorded and divided into major and minor adverse events.

Events were graded as major or minor adverse events. Major adverse events included but were not limited to death during or after the procedure because of complications of the procedure, complete heart block requiring pacemaker implantation, thromboembolism, and new-onset valvular regurgitation requiring surgical repair. Minor adverse events included but were not limited to groin haematoma, blood loss requiring transfusion, device embolization with transcatheter removal, any cardiac arrhythmia that required medication, new or increased valvular regurgitation less than two grades, haemolysis requiring medication, fever $>38.5^{\circ}\text{C}$, rash, and loss of peripheral pulse. These minor adverse events required medical intervention but were not life

threatening; they had no long-term sequelae and did not require long-term therapy.

All the data was analyzed using SPSS Version 23. Frequency and percentages were calculated for qualitative variables like gender and VSD occluder devices and mean \pm SD were calculated for quantitative variables like age, VSD



Figure-2(a): LV-angiogram in LAO 45 Cran 20 view showing moderate sized perimembranous VSD.

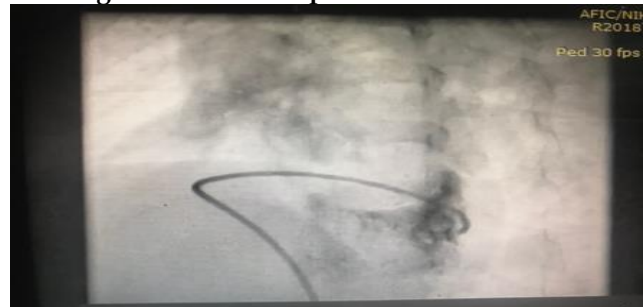


Figure-2(b): 5 FJR crossed from RV side to LV without forming AV Loop. Check angiogram showing catheter just below the mitral valve.



Figure-2(c) :Amplatzer super stiff wire parked in LV apex.

size and VSD occluder size etc.

RESULTS

Among all 30 patients in which we attempted transcatheter closure of PMVSD, all patients (100%) were successfully treated by

transcatheter intervention. There were 7 male and 23 female patients as shown in figure-1.

According to colour Doppler TTE before intervention, the mean \pm SD end-diastolic PMVSD size was 4.87 ± 1.32 mm as shown in

femoral pulse for few hours which settled with IV heparin.

DISCUSSION

Perimembranous ventricular septal defect is



Figure-2(d): VSD device in place showing proper position of LV and RV side of double disc device.



Figure-2(e) :Final position of device confirmed on LV angiogram.

table-I.

Complications And Troubleshootings

- Aortic regurgitation requiring surgical repair or replacement,

the most common congenital cardiac defect¹². ... Open surgery and the transcatheter technique can achieve reasonably good results in closing aPMVSD^{13,14}.

Transcatheter closure has the advantages of

Table: Patient's data (quantitative variables) undergoing intervention.

Variables	Minimum	Maximum	Mean	Std. Deviation
Age (years)	2.00	18.00	7.1111	4.64878
VSD Size (mm)	3.50	7.00	4.8667	1.31719
Device Size	5	10	7.00	1.581
Flouroscopy time(min)	5	24	11.56	5.897
Procedure time(min)	15	35	24.44	6.346
Contrast used (mm)	40	120	81.67	28.723

- Device embolizations requiring surgical removal
- Infective endocarditis.
- Complete atrioventricular block
- Pacemaker implantation
- Residual shunt
- Tricuspid valvular regurgitation
- Death

During median follow-up, 2 adverse events (6%) were reported in patients who underwent attempted VSD closure. One child developed arrhythmia while the sheath was in left ventricle which settled subsequently. The other had weak

reduced psychological impact, less pain, and discomfort due to the procedure, shorter hospital stay, no need for admission to an intensive care unit, faster time to normal activities⁷.

Different devices have been used to close PMVSD¹⁵, among which the Amplatzer PMVSD occluder and similar devices have been shown to cause few complications and yield good results¹⁶. In our set up we used SHSMA and Occlutech devices for VSD closure.

However, long-term follow-up results are lacking with transcatheter device closure as compared to open heart surgery⁷. This study was

designed to evaluate the safety and efficacy of transcatheter closure of PMVSD without AV loop and its intermediate and long-term clinical outcomes.

Adverse events rate was low and no permanent cAVBs was experienced. Careful monitoring of the heart rhythm remains mandatory throughout follow-up due to the severe impact of and the characteristically late onset of cAVB.

Valvular regurgitation was another major consideration catheter closure of PMVSD. Impingement of the occluder on the valve leaflets may cause instant aortic or tricuspid regurgitation by interfering with the chordae tendineae¹⁷. Thus, Transthoracic echocardiography (TTE) and angiography are crucial for confirming correct device deployment. We experienced no case of valve regurgitation. The mechanism may be associated with improper placement of the occluder on the tricuspid septal leaflets, migration of the occluder, shape memory of nithinol wires, or rupture of the chordae tendineae¹⁸.

Perimembranous ventricular septal defect involves the entire membranous septum and adjacent structures and may have many variations. The aortic valve, tricuspid chordae tendineae, atrioventricular node, conduction bundle are all closely related to the PMVSD. Complications of transcatheter PMVSD closure in our study were negligible.

Most adverse events took place in the early stage of the procedure, and only minor events were observed during the follow-up period after discharge. This outcome is quite different from previous reports^{7,19}. The most common complications associated with transcatheter PMVSD closure were heart rhythm disturbances and late appearance of femoral pulse. Other common adverse events included kinking of sheath during device placement which settled with little pull back of sheath with device.

To avoid complications the inclusion/exclusion criteria for transcatheter PMVSD closure should be strict. Severe aortic valve prolapse, a large VSD with pulmonary hypertension,

abnormal tricuspid chordae tendineae origination, and small infants with low body weight should be referred for open surgery and excluded from transcatheter intervention. In our center, more PMVSD patients were referred directly for surgery after TTE screening during the same study period. It is likely due to this strict screening that the success rate of transcatheter PMVSD closure in our group was remarkable.

Second, passing the guide-wire and catheter across the defect is a crucial step in transcatheter PMVSD closure⁹. Different types of guide catheters can be useful in passing through the PMVSD, such as the right Judkins, and partly cut pigtail catheter. Once the guide-wire passes the defect, the route of catheter and guide wire should be properly monitored. Kinking of the sheath should be carefully watched before introducing the device.

Before releasing the device, angiography of the ascending aorta is recommended to determine whether aortic valve insufficiency is present. If new-onset aortic valvular regurgitation is identified, either asymmetric devices or abandonment of the procedure should be considered to prevent severe complications.

CONCLUSION

This study has proved that transcatheter device closure without AV loop is an effective method in treating PMVSD patients with excellent results avoiding many complications in experienced hands. The success rate was high, and the long-term follow-up result was favorable. Adverse events were rare and were generally manageable. The transcatheter approach provides a less-invasive alternative to open surgery and may become the treatment of choice for selected patients with PMVSD.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

REFERENCES

1. Rahmath MR, Numan M, Dilawar M. Medium to long-term echo follow-up after ventricular septal defect device closure. *Asian Cardiovascular and Thoracic Annals* 2016; 24(5): 422-7.

2. Mavroudis C. Ventricular septal defect. In Atlas of Pediatric Cardiac Surgery 2015 (pp. 99-115). Springer London.
3. Kung GC, Wong PC. Ventricular Septal Defects. In Transesophageal Echocardiography for Congenital Heart Disease 2014 (pp. 241-252). Springer London.
4. Baro L, Paul T, Chaliha MS, Gogoi A, Katakai RP, Dowerah P. Clinical Spectrum of Ventricular Septal Defect in Children in A Tertiary Care Hospital. *Cough* 2016; 30: 48: 68.
5. Jortveit J, Leirgul E, Eskedal L, Greve G, Fomina T, Døhlen G, et al. Mortality and complications in 3495 children with isolated ventricular septal defects. *Archives of disease in childhood* 2016; 101(9): 808-13.
6. Menting ME, Cuypers JA, Opić P, Utens EM, Witsenburg M, van den Bosch AE, van Domburg RT, et al. The unnatural history of the ventricular septal defect: outcome up to 40 years after surgical closure. *J Am Coll Cardiol* 2015; 65(18): 1941-51.
7. Thanopoulos BD, Rigby ML, Karanasios E, Stefanadis C, Blom N, Ottenkamp J, Zarayelyan A. Transcatheter closure of perimembranous ventricular septal defects in infants and children using the Amplatzer perimembranous ventricular septal defect occluder. *Am J Cardiol* 2007; 99: 984-89.
8. Xunmin C, Shisen J, Jianbin G, Haidong W, Lijun W. Comparison of results and complications of surgical and Amplatzer device closure of perimembranous ventricular septal defects. *Int J Cardiol* 2007; 120: 28-31.
9. Qin Y, Chen J, Zhao X, Liao D, Mu R, Wang S, Wu H, Guo H. Transcatheter closure of perimembranous ventricular septal defect using a modified double-disk occluder. *Am J Cardiol* 2008; 101: 1781-86.
10. Lock JE, Block PC, McKay RG, Baim DS, Keane JF. Transcatheter closure of ventricular septal defects. *Circulation* 1988; 78: 361-368.
11. Shah SM, Ullah I, Khan MG, Ullah N, Malik A, Khan RA. Frequency of Complete Heart Block After Surgical Closure of Perimembranous Ventricular Septal Defect. *J Postgrad Med Inst* 2016; 29(4).
12. Butera G, Chessa M, Carminati M. Percutaneous closure of ventricular septal defects. *Cardiol Young* 2007; 17: 243-53.
13. Zheng Q, Zuo J, Yang J, Wang H, Yu S, Yi D. A comparative study: early results and complications of percutaneous and surgical closure of ventricular septal defect. *Cardiology* 2009; 238-43.
14. Backer CL. Ventricular septal defect closure: what is the role for transcatheter closure? *Cardiology* 2009; 114: 235-37.
15. Gu X, Han YM, Titus JL, Amin Z, Berry JM, Kong H, et al. Transcatheter closure of membranous ventricular septal defects with a new nitinol prosthesis in a natural swine model. *Catheter Cardiovasc Interv* 2000; 50: 502-09.
16. Hijazi ZM, Hakim F, Al-Fadley F, Abdelhamid J, Cao QL. Transcatheter closure of single muscular ventricular septal defects using the amplatzer muscular VSD occluder: initial results and technical considerations. *Catheter Cardiovasc Interv* 2000; 49: 167-72.
17. Sullivan ID. Transcatheter closure of perimembranous ventricular septal defect: is the risk of heart block too high a price? *Heart* 2007; 93: 284-86.
18. Szkutnik M, Qureshi SA, Kusa J, Rosenthal E, Bialkowski J. Use of the Amplatzer muscular ventricular septal defect occluder for closure of perimembranous ventricular septal defects. *Heart* 2007; 93: 355-58.
19. Chessa M, Butera G, Negura D, Bussadori C, Giamberti A, Fesslova V, Carminati M. Transcatheter closure of congenital ventricular septal defects in adult: mid-term results and complications. *Int J Cardiol* 2009; 133: 70-3.
20. Butera G, Carminati M, Chessa M, Piazza L, Micheletti A, Negura DG, et al. Transcatheter closure of perimembranous ventricular septal defects: early and long-term results. *J Am Coll Cardiol* 2007; 50: 1189-95.