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Original Article

Short Term Outcomes of Transcatheter Ventricular Septal Defect Device Closure at Tertiary Cardiac Care Center

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ABSTRACT

Objective: To determine post procedural immediate and short-term outcomes of transcatheter Ventricular Septal Defect (VSD) device closure.

Study Design: Longitudinal Cross-sectional study.

Place and Duration of Study: Pediatric Cardiology Unit at Tertiary Cardiac Care Centre, Rawalpindi, Pakistan, from Feb to Oct 2022.

Methodology: Total of 62 patients fulfilling inclusion and exclusion criteria who underwent transcatheter VSD device closure were retrospectively identified from our institutional database by non-probability consecutive sampling technique. Preprocedural evaluation [Transthoracic Echocardiography (TTE) & Electrocardiography(ECG)], procedural details and immediate post procedure outcomes were documented. Follow-up evaluations were done at 6 and 12 months. It included clinical examination, TTE and 12 lead ECG. New onset and status of old complications were documented in each visit. SPSS version 24.00 was used to analyze data. Chi-square test was used to find association between study variables. *p-<0.05* was considered significant.

Results: Sixty-two patients were followed up for upto 1 year after VSD device closure. Mean VSD size on Echo was 4.61±2.52mm. Successful closure was obtained in 54(87.0%) of cases out of 62. Complications documented during and immediately after procedure were transient arrythmias in 22(35.5%), residual leaks in 9(14.6%) which reduced to 3(4.8%) on 12 months follow up, device redeployment in 3(4.8%), complete heart block (cAVB) in 1(1.6%), device embolization in 1(1.6%), hemolysis in 2(3.2%), contrast related complications in 1(1.6%), aortic regurgitation (AR) in 4(6.4%). Death occurred in 1(1.6%) patient secondary to contrast related complications.

Conclusion: Transcatheter VSD closure is a promising and safe treatment modality with high success rate. Complications can be minimized by careful selection and assessment of patients and device size & type.

Keywords: Outcome, Transcatheter, Ventricular Septal Defect device closure.

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INTRODUCTION

Ventricular Septal Defect (VSD) is one of the most commonly encountered Congenital Heart Defect (CHD) accounting for about 30% of total CHDs. Management of VSDs depends upon the symptoms, the probability of spontaneous closure and expected long term complications. First transcatheter VSD device closure was reported in late 80s.[1] With profound advancement in catheter based interventions, transcatheter VSD closure has proved to be a safe and attractive alternative to surgery.[2-4]

Device closure of small and moderate size VSDs is indicated in symptomatic patients, asymptomatic patients with pulmonary to systemic blood flow ratio (Qp: Qs) >1.5:1, left atrium and ventricular enlargement on echocardiography, previous episode of infective endocarditis and doubly committed subarterial VSD. Other social indications are psychosocial impact, inherent problems related to stigmata of having heart defect, employment/medical fitness for specific jobs, health insurance and professional sports participation. Advantages of device closure include avoidance of median sternotomy scar/cardiopulmonary bypass and shorter hospital stay and recovery period.

Although mortality associated with VSD device closure is very low,[5] but it is no doubt a technically challenging procedure and some studies suggest a higher complication rate than surgery.[6] Potential complications related to device or technique are complete heart block,[7] aortic/ tricuspid valve damage, femoral

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artery thrombosis, residual leak, and hemolysis. No follow up study has been done so far in our institute explaining the outcome of the procedure. AFIC/NIHD is doing the maximum number of VSD device closures in the country. This study was aimed to share our experience in closing different anatomical variants of VSDs focusing on immediate and short term follow up outcome and complications so as to improve our understanding about the efficacy and safety of the procedure and various types of devices.

METHODOLOGY

It was a Longitudinal Cross-sectional study conducted at Pediatric Cardiology Department, Tertiary Cardiac Care Centre, Rawalpindi Pakistan, from Febraury to October 2022 after approval from Institutional Ethical Review Board under letter no. (IERB#9/2/R&D/2022/154).

A sample size of 60 was calculated by taking 4% prevalence of VSD and using 5.4% proportion of cases with exposure using WHO calculator at 95% Confidence Interval and 5% margin of error.[8] However we collected data from 62 patients.

Inclusion Criteria: Patients between 1-30 years of both gender who underwent transcatheter VSD device closure were included in the study who fulfilled the following criteria: weight >8 kg, symptomatic with H/O recurrent respiratory tract infections or failure to thrive, pulmonary to systemic blood flow ratio (Qp:Qs) >1.5:1 on echocardiography, left sided volume overload with Left Atrial (LA) enlargement defined as LA to aorta diameter ratio >1.5 on echocardiography parasternal long axis view and doubly committed subarterial VSD with or without any of the above criteria.

Exclusion Criteria: Children with VSD and less than 8 kg body weight, large VSD defined as >75% of aortic annulus diameter on echocardiography in infants, VSD associated with right aortic cusp prolapse, aortic regurgitation>Grade-I, mid RV bands or severe pulmonary hypertension (pulmonary vascular resistance >8 wood units/m^2), patients with VSD and associated CHD not amenable to transcatheter repair and VSD device closures done for residual defects after surgical repair and ischemic Ventricular Septal Rupture (VSR).

Patients who underwent trans-catheter VSD device closure were selected retrospectively by non-probability consecutive sampling, identified from our institutional database. Informed written consent was taken from those parents/patients who came for their follow up visit during this time period. Pre-procedural evaluation (TTE & ECG), procedural details and immediate post-procedure outcomes were documented.

Preprocedural and post procedural echocardiographic assessment was done using Siemens Acuson SC2000 Prime (4MHz transducer) or Philips iE 33(5 Mhz transducer).

Follow-up evaluations were done at 6 and 12 months. Prospective follow up data collection was done for patients coming for their 6 months and 12 months follow up visit. It included clinical examination, transthoracic echocardiography and 12 lead ECG. New onset and status of old complications were documented in each visit.

Categorical variables were summarized as frequencies and percentages and continuous variables as mean with standard deviation. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS Statistics), version 24.00. Chi-square test was used to find association between study variables. $p<0.05$ considered statistically significant.

RESULTS

Total 62 patients were followed up for upto 1 year following VSD device closure. Mean age was 8.8±6.9 years. Out of total 40(64.5%) were males and 22(35.5%) were females. All patients had sinus rhythm on preprocedural ECG assessment. Most common VSD location addressed by transcatheter closure was perimembranous VSD noted in 24(38.7%) patient followed by doubly committed VSD in 13(21%) and PM VSD with aneurysm 10(16.1%). Mean VSD diameter on Echo was 4.66±2.52mm (Table-I).

Table-I: Demographic and Diagnostic Characteristics of the Study sample (n= 62)

Variables	Frequency(%), Mean±SD
Sex	
Male	40(64.5)
Female	22(35.5)
Age (years)	8.8±6.9
VSD Location	
Perimembranous VSD	24 (38.7)
Doubly committed	13 (21)
Perimembranous VSD with aneurysm	10 (16)
Outlet muscular	11 (17.7)
Mid muscular	3 (4.8)
Inlet Muscular	1(1.6)
VSD diameter on Echo (mm)	4.66 ±2.52
VSD diameter Angiogram (mm)	4.81±2.65

** VSD = Ventricular Septal Defect*

Complications at the time of procedure and immediate post procedure are mentioned in Table-II.

Table-II: Minor and Major Per and Post Procedural Complications (n =62)

Variables	Frequency(%)
Minor Complications	
Residual leak immediately after the procedure	9(14.6)
Transient conduction abnormalities (bradycardia/bundle branch block/VT)	22(35.5)
Arterial thrombosis/temporary loss of peripheral pulsations	4(6.4)
Hemolysis resolved with conservative management	1(1.6)
Mild aortic regurgitation	7(11.3)
Device recapture and redeployment	3(4.8)
Transient complete heart block during device retrieval	1(1.6)
Mild Tricuspid regurgitation	2(3.3)
Major Complications	
cAVB requiring surgery	1(1.6)
Hemolysis requiring surgical removal of device	1(1.6)
Device embolization	1(1.6)
Infective endocarditis	0
Valvular regurgitation requiring surgery	1(1.6)
Tricuspid stenosis requiring reintervention	1(1.6)
Moderate Aortic regurgitation requiring surgery	1(1.6)
Death (Contrast associated complication)	1(1.6)

** cAVB: Complete Atrioventricular Block*

Most commonly used device was Lifetech VSD MFO in 37(59.7%) patients followed by SHSMA Muscular VSD 11(17.7%), Cocoon VSD device 5(8.1%), PFM NitOccl-ud VSD coil 4(6.5%), and Amplatzer Muscular VSD device 3(4.8%). PFM PDA-R device and ADO II were used in 1 (1.6%) patient each. For perimembranous defects, most commonly used device used was MFO 45(72.5%). Most of the doubly committed defects were closed with MFO (84%), rest of the two doubly committed defects were closed by PFM PDA-R and SHSMA VSD device. Mean fluoroscopy time was 18±13.22 mins. Most commonly used LV angiogram view for perimembranous defects was LAO 45 Cr 25 23(37.5%) followed by LAO 25 Cr25 21(33.3%). AV loop was formed in 22(35.5%) cases. Succcessful closure was obtained in 54(87%) cases (Table-IV).

No patient had cardiac arrest during the procedure. Follow up statistics of residual leaks, aortic regur-gitation and conduction abnormalities are mentioned in Table-III. Only 1(1.6%) lost to follow up. Minor ECG changes (partial RBBB) were seen in 4 (6.4%) study subjects immediately post procedure. Incidence and pattern of minor ECG changes remained same on 6 months and 12 months follow up. Table IV described the relation of various complications with type of device used for VSD closure.

DISCUSSION

Transcatheter VSD device closure is an attractive treatment option for small and moderate size VSDs but even with growing expertise, every new case poses a new challenge.

Procedural success mainly depends upon selection and preprocedural echocardiographic assess-ment of the patient, expertise of the operator and

Table-III: Complications Immediate Post Procedure, 6 months and 12 months follow up (n=62)

Complications	Immediate post procedure n(%)	6 months follow up n(%)	12 months follow up n(%)
AR			
Mild	3 (4.8)	2(3.2)	2(3.2)
Moderate	1(1.6)	2(3.2)	1(1.6)
Severe	-	-	1(1.6)
Residual Shunt	9(14.6)	5(8)	3(4.8)
CHB	1(1.6)	-	-

**AR: Aortic Regurgitation, CHB: Complete Heart Block*

Table-IV: Outcome Association with Different Device Types (n=62)

Device	MFO	SHSMA Muscular VSD	Cocoon Muscular VSD	Nit Occlude PFM Coil	ADO-II	Amplatzer Muscular VSD Device	PFM PDA-R	*p*-value
No of patients (n=62)	37(59.7)	11(17.7)	5(8.1)	4(6.5)	1(1.6)	3(4.8)	1(1.6)	-
Success rate %	83%	100%	100%	75%	100%	66%	100%	-
AR at 6 & 12 months (n=4)	2(50)	0	0	1(25)	0	0	1(25)	0.11
CAVB (n=1)	1(100)	0	0	0	0	0	0	0.09
Residual shunt post procedure (n=9)	5(55.55)	1(11.11)	0	2(22.22)	0	1(11.11)	0	0.49
Hemolysis (n=2)	0	0	0	2(100)	0	0	0	0.01
Contrast complication (n=1)	0	0	1(25)	0	0	0	0	0.22

**MFO: Lifetech Multifunction Occluder, ADO:Amplatzer Duct Occluder, VSD: Ventricular Septal Defect*

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Success rate %	83%	100%	100%	75%	100%	66%	100%	-
AR at 6 & 12 months (n=4)	2(50)	0	0	1(25)	0	0	1(25)	0.11
CAVB (n=1)	1(100)	0	0	0	0	0	0	0.09
Residual shunt post procedure (n=9)	5(55.55)	1(11.11)	0	2(22.22)	0	1(11.11)	0	0.49
Hemolysis (n=2)	0	0	0	2(100)	0	0	0	0.01
Contrast complication (n=1)	0	0	1(25)	0	0	0	0	0.22

**MFO: Lifetech Multifunction Occluder, ADO:Amplatzer Duct Occluder, VSD: Ventricular Septal Defect*

appropriate choice of device size and type for that particular defect. Our study revealed an immediate procedural success rate of 87% which is comparable to successful outcome described in other studies.[9-13]

During deployment of device while closing peri-membranous and doubly committed VSDs, operator must be careful not to damage aortic valve cusp. A distance of >2mm is acceptable but depends on the device type and expected device position.[14]

Newer studies reported very low rate of significant AR (<0.5%) post perimembranous VSD device closure after the introduction of softer and low profile devices. Other than the aortic valve, the tricuspid valve should also be monitored during and after the procedure. [14]

Our study revealed 4.8% and 1.6% incidence of mild and moderate AR respectively in the immediate post procedure time compared with 2.3% incidence in a study by Sadiq *et al.*[13]

AR severity increased in two cases, one in a doubly committed defect closed with PFM PDA-R device and other with a PFM coil deployed inappropriately in LVOT. It was removed surgically. Mild AR with MFO devices didn't increase over 1 year follow up.

Most common VSD location whose device closure was associated with post procedure AR was doubly committed 3(23.0) out of 13 procedures which is lesser than described in a study by Huang *et al.* who described occurrence of mild AR in 42% patients in immediate post procedure time out of which 33% remained unchanged.[15]

A 10mm VSD defect in perimembranous area with aneurysmal tissue and multiple exit jets in 4.5 years old boy was closed with 12/10 Lifetech MFO device (Figure-1a), a small residual leak was observed. Echo done 4 hours after the procedure revealed right sided disc of MFO in RA with dilated RA, engorged IVC and tricuspid stenosis. Device was retrieved and defect was then closed with a larger size device 14/12 MFO. Post procedure mild TR was observed. We concluded that before device release, it is important to be sure that RV disc is not compromising septal leaflet of tricuspid valve.

One patient with doubly committed VSD had device embolization after 24 hrs (Figure-1b) and 2 patients were referred to surgeon because of failure of device to stay in the defect before release. We concluded that the true absence of conal septum with valve leaflet forming the superior margin in these particular cases led to failure of device closure.

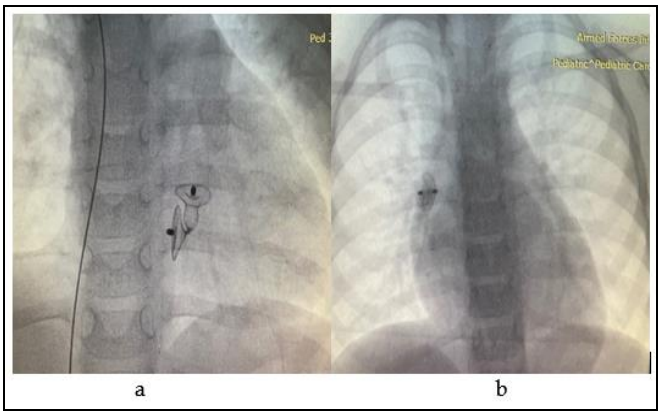

Figure-1(a): MFO RV Disc Deployed Above Septal Leaflet of Tricuspid Valve, 1(b): Device Embolization to Right Pulmonary Artery

All the vascular complications following VSD device closure were managed with heparin 100IU/kg bolus followed by heparin infusion ranging from 20-30 IU/kg/hr.

Residual high velocity shunt and exposure of the blood flow 22 to the devices are the main factors leading to intravascular hemolysis post device closure.

A study stated that range of hemolysis after transcatheter VSD device closure is between 0.7-15%.[17]

In a spanish study on closure of VSD with NitOcclud Le VSD coil revealed significant residual shunt in 3.8% patients and 1.9% had significant hemolysis requiring surgical explantation.[18] In a recent study, the incidence of post-procedural hemolysis was 1.6%, all managed conservatively with hydration and alkalinization.[19] In our study, observed results revealed that hemolysis was exclusively seen with VSD closures with PFM Nit occlude coil. In both cases, hemolysis resolved within 1 week with conservative management.

Maximum recommended contrast volume to be used in pediatric catheterization procedure is 6ml/kg. There are very few studies describing contrast related adverse events in pediatric cardiac catheterization procedures. A study by Senthilnathan *et al.* reported acute neurological changes and transient nephropathy in only 0.09% cases with no mortality.[20]

Contrary to that, we experienced death of 1 patient secondary to contrast induced malignant hyperthermia, acute encephalopathy and renal dysfunction.

The most frequent complication after transcatheter VSD device closure is the presence of a residual shunt through the existing defect or an additional defect.[21,22] Luckily, most of the residual shunts after device closure closed within 1 year after the procedure either spontaneously or by device induced endothelial proliferation and fibrosis.[21]

In general, significant shunts of >2mm with an audible murmur should be revised either by using larger devices if feasible or surgery. Studies showed that >90% closure rates on follow-up and rarely surgery is required to address the problem of a residual shunt.[23,24]

Our study revealed an incidence of residual leaks as 14.6% in the immediate post procedure time which was reduced to 8% and 4.8% on follow up at 6 and 12 months respectively.

These results are comparable to a local study conducted by Sadiq *et al*.[13] which showed a 20.5% residual leaks in immediate post procedure time, persisted only in 2.3% on follow up at 1 year.

A meta-analysis,[25] of transcatheter perimembranous VSD device closure revealed residual shunt as the most common complication (15.9%), valvular defects (4.1%) and cAVB (1.1%). Our study revealed 1(1.6%) incidence of cAVB.

Hence only 1 patient, 7 years old with perimembranous VSD along with aneurysm was treated with Lifetech MFO 10/8 developed cAVB 4 days after the procedure. She initially responded to steroids but ultimately device had to be explanted surgically due to intermittent cAVB. Although placement of LV disc in aneurysm is considered safe for conduction abnormalities as described in an article by Song,[14] but here we concluded that even a softer device like MFO with LV disc deployed in aneurysm if oversized can lead to complete heart block.

Our study has not only highlighted the immediate post procedure outcomes and complications but also encompassed the short term follow up of the patients. Progression of complications like AR is described along with the resolution of residual shunts and ECG changes in various patients. We were able to identify various factors leading to complications in this particular procedure and future strategies have been formulated to reduce the incidence.

LIMITATIONS OF STUDY

Intermediate- and long-term follow up is required for a better understanding of outcomes and complications of transcatheter VSD device closure. A larger cohort of patients would have been a better representative of overall safety and efficacy of the procedure.

CONCLUSION

Transcatheter VSD closure is a promising and safe treatment modality. Immediate successful closure rate is 87% with minimal complications.

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Conflict of interest: None

Authors' Contribution

Following authors have made substantial contributions to the manuscript:

SI, SR & KA: Manuscript writing, data Collection, approval of the final version to be published.

AM & HA: Critical review, approval of the final version to be published.

AA & AS: Critical review, data analysis, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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