International Journal of Cardiovascular and Thoracic Surgery
2023; 9(1): 5-8
http://www.sciencepublishinggroup.com/j/ijcts
doi: 10.11648/j.ijcts.20230901.12
ISSN: 2575-4866 (Print); ISSN: 2575-4882 (Online)

Transcatheter Closure of Ventricular Septal Defects (VSD): Preliminary Results in Children Weighing 5kg or Less

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To cite this article:

Mirza Mohd Kamran, Shaad Abqari, Azam Haseen, Mayank Yadav. Transcatheter Closure of Ventricular Septal Defects (VSD): Preliminary Results in Children Weighing 5kg or Less. *International Journal of Cardiovascular and Thoracic Surgery.* Vol. 9, No. 1, 2023, pp. 5-8.
doi: 10.11648/j.ijcts.20230901.12

Received: December 9, 2022; **Accepted**: December 30, 2022; **Published**: May 22, 2023

Abstract: *Aim:* This study aims to evaluate feasibility and complications of device closure of ventricular septal defect (VSD) in children weighing 5kg. *Methods:* Between March 2018 and March 2021, total 15 patients with Ventricular Septal Defect (VSD) weighing 5Kg or less were taken to Cath lab for percutaneous VSD closure out of which 13 (86%) had successful transcatheter closure and 2 (14%) cases were unsuccessful and subsequently send for surgical closure. All of these13 patients under went transcatheter closure of VSD using either a Amplatzer duct occluder1, Amplatzer duct Occluder 2 or Amplatzer Muscular VSD Occluder. A retrospective review of the results and related complications was done. *Results:* Among these 15 patients, 7 were females, 6 were male and the mean age was 8.5 (4-16month. The mean weight in this study was 4.46Kg (2.3-5Kg). Mean VSD size was 4.5 (3-10mm), 9 patients had VSD sizes between 3to5mm, 3 had between5-10 mm and 1 with more than 10mm. Among types of VSD, 9 cases were having Perimembranous, 1 was upper muscular, 1was mid while 1was lower muscular and only 1 had outlet muscular VSD. Amplatzer Duct Occluder (ADOI) was used in 2 cases, 9 were closed with Amplatzer Duct Occluder (ADO2) and 2 were selected for closure with Amplatzer Muscular VSD Occluder. Transthoracic Echocardiography (TTE) in immediate post intervention period revealed all these devices in situ with no or minimal residual flow which subsided within 24 hours period. As far as complications are concerned, we had one device embolization noted in our study. Tricuspid regurgitation (TR) was noted at the time of discharge in 4 patients but subsided after 48 hours while trivial aortic regurgitation was noted (AR) only in one case which is under close follow up and not increasing in severity after 6 months follow-up. *Conclusions*: Transcatheter closure of VSD in children 5kg or less is feasible and safe alternative to surgical VSD closure.

Keywords: Ventricular Septal Defect, Transcatheter Closure, Weight<5kgs, Interventions

1. Introduction

Surgical closure of VSD was first described by Lillehi [1] et in the year 1954 and after that it was continued to be regarded as the gold standard treatment.

However over the past 10 years transcatheter device closure has emerged as safe alternative especially in case of muscular VSDs [2], though no significant number of peri membranous VSD are being closed percutaneously. [3-5]. The side effects of cardiopulmonary bypass prolong ICU and hospital stay and psychological trauma of scar can be avoided [6], but device closure is also not a absolute risk free procedure as it has its own associated complications and drawback such as radiation exposure, risk of arrhythmias, interference with aortic (AVs) and tricuspid valves, and quite frequent significant residual shunting. When encountering in small infants or patients with poor vascular access, catheter closure is a challenge [7] especially so in patients with big Gerbode defects. With the availability of new safer devices, difficult and larger defects are now being attempted to be

closed in the Cath lab. The present study was undertaken to look at the profile and spectrum of cases and their short term out comes to provide the insight on the feasibility of the procedure. In this study we share our experience of closure of VSD in small children weighing less than 5kgs.

2. Materials and Methods

The present study was under taken in Pediatric Cardiac evaluation and cardiac surgery unit at Jawaharlal Nehru Medical College and Hospital at Aligarh Muslim University, Aligarh. The Unit is a newly established tertiary referral center and receives patients from adjoining districts. Relevant data were obtained retrospectively from the case file sand the catheterization records and data were analyzed between March 2018 and March 2021, total 15 patients with Ventricular Septal Defect (VSD) weighing 5Kg or less were taken to Cath lab for percutaneous VSD closure out of which 13 (86%) had successful transcatheter closure and 2 (14%) cases were unsuccessful and subsequently send for surgical closure.

All patients were admitted at least 1 day prior to the procedure for clinical, laboratory (pre-Cath profile), chest X-ray, ECG and echocardiograph assessment. Echocardiographic evaluation revealed the size & anatomy of the VSD and estimation of the pulmonary artery pressure (PAP) and dimensions of Left atrial and ventricle. Patients were screened for feasibility of device closure and also presence of any other associated defect.

2.1. Inclusion Criteria

Patients were selected as per the surgical indications for isolated VSD: hemodynamically significant VSD, refractory heart failure with medications and repeated respiratory infection. Failure to thrive, evidence of left heart volume overload which was considered as per (LA/LVsizezscore≥2) and Qp/Qs>2.0. Any patient with ≤5kg with VSD amenable for device closure and meeting the above criteria were taken up for the study.

2.2. Exclusion Criteria

Malaligned VSD especially those with inlet extension, VSD with aortic valve prolapse with any degree of AR, VSD with any other associated heart defect that needs surgical closure otherwise.

2.3. Procedures

All the parents were informed about the procedure; its complications and written consent were taken from each of them before the procedure. The procedure was performed under conscious sedation in 12 patients and onlyin1 patient under general anesthesia (GA) where the VSD was approached via right internal jugular (RIJV) route. A single dose of intra venous antibiotic was administered 30 minutes prior to procedure. The Right femoral vein (RFV) and right femoral artery (RFA) access was taken per cutaneous in all 13 cases while in only 1 case additional Right Internal Jugular Vein (RIJV) was also taken in addition with RFV and RFA. Right heart catheterization was performed and basal systemic and pulmonary arterial pressures were taken and ratio of pulmonary to systemic blood flow (Qp/Qs) were calculated. Qp/Qs>2.0 were considered significant and was considered for closure. LV angiogram was done in LAO-30/CRA-20 and LAO-60/CRA-30 to define the VSD as unit policy. Selection of device was done based on the measurement on echoandangiography. VSD was crossed from the Side (retrogradely) in all 13cases. After crossing with Terumo Guide Wire M0.035”260 cm J angled tip (RF*GA35263M) AV loop was formed in 5 cases while in 8 cases VSD devices were deployed in retrograde fashion without forming AV loop. Device was delivered as per the standard technique under fluoroscopic and echo guidance (TTE and also TEE in one case). Post procedure, the patients were monitored in the intensive cardiac care unit for 24hrs. A close monitoring was done for device embolization. Patients were discharged after 48 hours of observation. All cases were followed at 1month, 3months, 6months and 1 year post procedure and every year thereafter as per policy of the Unit. Improvement in functional class and weight gain was noted. The patients were evaluated clinically for any evidence of worsening. At follow up echocardiography the position of the device was confirmed and residual shunt if any was noted. The presence of AR, TR was looked for and TR gradient was recorded along with LA and LV dimensions.

Table 1. *Demographic and Procedure details of patients.*

Sn	Age (months)/Sex	Weight (Kg)	Type of VSD	Size of VSD (mm)	PAH	Qp/Qs	Route of Deployment	Type of Device	Result
1	7/M	5	PM	3	No	3.2	RFA	5x4mm-ADO-II	Successful
2	7/M	4.2	PM	3	No	2.8	RFA	5x4mm-ADO-II	Successful
3	8/F	3.5	OM	3	No	3.4	RFA	5x4mm-ADO-II	Successful
4	6/F	4	PM	3	Mild	3.0	RFA	6x4mm-ADO-II	Successful
5	6/M	5	PM	4	Mild	3.9	RFA	6x4mm–ADO-II	Successful
6	6/M	5	PM	6	No	4.2	RFV	8x6mm–ADO-I	Successful
7	4/F	4.8	PM	6	Severe	4.0	RFV	8x6mm–ADO-I	Successful
8	16/F	5	LM	6	Severe	3.0	RIJV	8mm–MUSCULAR	Successful
9	12/F.	4.8	MM	10	Severe	6.5	RFV	12mm-MUSCULAR	Successful
10	10/M	5	PM	3	Mild	2.8	RFA	5x6mmADO-II	Successful
11	13/F	4.5	PM	5	Severe	4.2	RFV	6X4mmADO-II	Successful
12	16/F	5	UM	3	No	2.6	RFA	5x4mmADO-II	Successful

Sn	Age (months)/Sex	Weight (Kg)	Type of VSD	Size of VSD (mm)	PAH	Qp/Qs	Route of Deployment	Type of Device	Result
13	4/M	2.3	PM	4	Severe	4	RFA	6X4mmADO-II	Successful
14	7/M	4.7	PM	4	Mild	2.6	RFA	6X4mmembolized	Surgery
15	6/F	3.8	PM	4	Severe	3.0	RFA	6X4ADOII, iatrogenic AR	Surgery

PM-Perimembranous, UM-Upper Muscular, MM-Middle Muscular, LM-Lower Muscular, OM-Outlet Muscular, RFA-Rightfemoralartery, RFV-Rightfemoralvein, RIJV-Rightinternaljugularvein
MeanAge-8.5months; MeanWeight-4.46Kg; MeanVSDsize-4.5mm; Mean Qp/Qs-3.66

3. Results

Among these 15 patients, 8 were females, 7 were male and the mean age was 8.5 (4-16months). The mean weight in this study was 4.46 Kg (2.3-5Kg). Mean VSD size was 4.5 (3-10mm), 11 patients had VSD sizes between 3to5mm, 3 had between 5-10mm and 1 with more than 10mm. Among types of VSD, 11 cases were having Perimembranous, 1 was upper muscular, 1with mid while 1 was lower muscular and only 1 had outlet muscular VSD. Amplatzer Duct Occluder (ADOI) was used in 2 cases, 9 was closed with Amplatzer Duct Occluder (ADO2), 2 were selected for closure with Amplatzer Muscular VSD Occluder and 2 were referred for surgical closure. As far as complications are concerned, we had one device embolization noted in our study Tricuspid regurgitation TR was noted at the time of discharge and in 2 patients but subsided after 48 hours in both patients while aortic regurgitation was noted (TRIVIAL) only in one case which is under close follow up and not increasing in severity after 6months follow-up.

Unsuccessful Attempted Cases:

Table 2 gives a brief description of cases where the transcatheter closure was not successful due to various reasons.

Case1: 7 months/4.7 kg male kid having 3mm peri membranous VSD with no PAH (Qp/Qs3.0) where ADOII 6/4 were implanted after forming an AV loop through RFV. Device get embolized immediately into deep LPA (Left pulmonary artery. Attempts were made to retrieve the device but could not be done, hence child was sent to OR (Operation Room) to remove the device and surgical VSD closure was done.

Case2:

Our second unsuccessful attempted case was 6months female child with weight of 3.8kg having 4mm outlet muscular VSD with no PAH (Qp/Qs2.8), it was decided to close this defect with 6/4ADOII from retrograde approach, but after deployment of the device it was noted that LV disc of device had captured one of the cusp of aortic valve and which was causing significant AR, though redeployment was done but with the same results so it was decided no to release the device to avoid any further damage to aortic valve and subsequently child was referred for surgical closure.

Table 2. *Details for unsuccessful attempted cases.*

S/NO.	Age (months) / Sex	Weight	VSD size	Route of deployment	REASON
1	7/M	4.7Kg	3mm	RFV	6-4 ADO II got embolised immediately after deployment into LPA, retrieval tried but was unsuccessful and child was sent to surgery.
2	6/F	3.8Kg	4mm	RFA	Presence of iatrogenic AR was noted after device deployment, hence device taken out and surgical VSD closure was done

4. Discussion

With the better understanding of anatomy and also availability of advance and less traumatic hardware especially the Occluder, device closure of VSD even in small infants (<5Kg) looks promising and safe alternative to surgery.

In this particular study we are sharing our initial results for device closure of VSD in babies less than 5 kg. Results are really encouraging with low complications rate. The most common defect in our study was peri membranous VSD and majority of it was closed with ADOII. Results were comparable as shown by Vijaylakshmi et al in their study [8]. Tane et al. [9] were the first group to use ADOII in VSD closure as it was designed to close Patent Ductus Arteriosus (PDA) and not VSD, because of its soft design and low profile it was considered as less traumatic and more suitable for VSD closure also and currently its off-label use is getting popular for closure of other defects than PDA. Recent years has witnessed the more regular use of this device for VSD. Before Tane et al no one has used this device before to close VSD. Few similar uses can be seen in Delaware et al. [10]

The closure of outlet muscular defect was done with ADOII device, again with above obvious reason. Kanaan et al in their study has reported a success rate of 93.5% with closure with this Device [11].

In our study we were able to close actual large muscular defects, especially with severe PAH whom we close it with a 14 mm Amplatzer muscular device.

Device closure of peri membranous VSD is gaining popularity with less morbidity and comparable results to surgery. A recent meta-analysis from 54 publications with 6762 patients had showed nearly 98% success rate with the residual shunt (15.9%) and rhythm abnormalities (10.3%) as the most common complications. [12]. Few other papers are available with 412 cases with goo results, Amplatzer devices are being considered safest among all these studies. [13-15].

5. Study Limitations

Not enough data available to compare and discuss. No long term follow up is available. Needs further follow up for better consolidations of results.

6. Conclusions

Transcatheter closure of ventricular septal defect has emerged as safe and less traumatic alternative to surgical closure for Ventricular Septal Defect (VSD) closure especially in infants weighing less than 5 kg. The procedure had a low rate of complications even with the initial experience at a newly established catheterization laboratory.

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