Cardiology in the Young

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Transcatheter closure of ventricular septal defects: preliminary results in children weighing 10 kg or less

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Abstract

Introduction: Ventricular septal defect is one of the commonest heart defect in children and closure of this defect with devices has seen a rapid progression over a period of time. The availability of new and safer devices has made the transcatheter closure of ventricular septal defect a suitable option even in young children. *Aim:* The study was done to evaluate the feasibility and complications of device closure of ventricular septal defect in children weighing 10 kg or less with different types of devices. *Methods:* The present study was undertaken in a newly established dedicated Paediatric Cardiac Unit at a Tertiary Care Hospital. Relevant data were obtained retrospectively from the case files and the catheterisation records and data were analysed for first 50 patients with ventricular septal defect weighing 10 kg or less between March 2018 and March 2021. *Results:* Among these 50 patients selected, device closure was successfully done in 45 (90%) cases while 5 (10%) attempts were unsuccessful for various reasons. The mean weight in this study was 7.46 ± 1.89 kg (2.3–10 kg), 21 (42%) cases were females while 29 (58%) were males; mean age was 19.4 ± 11.88 months (4–48 months). Right heart catheterisation study showed 21 (42%) patients with normal pulmonary artery pressures (no pulmonary artery hypertension). Among 29 patients with pulmonary arterial hypertension, 13 patients (22%) were having mild pulmonary arterial hypertension, 4 (8%) were with moderate pulmonary arterial hypertension, and 12 (24%) were with severe pulmonary arterial hypertension. Mean Qp/Qs was 2.73 ± 0.72 (2.5–4.5) and mean pulmonary vascular resistance was 1.5 ± 1.04 (0.6–4.6 WU). Amplatzer Duct Occluder (ADOI) was used in 15 (30%) cases, 27 (52%) cases were closed with Amplatzer Duct Occluder (ADOII), and the 3 (6%) cases closure was done with Amplatzer muscular ventricular septal defect occluder. *Conclusions:* Transcatheter closure of ventricular septal defect in children 10 kg or less is feasible and safe alternative to surgical ventricular septal defect closure. The immediate and short-term outcomes have proven this method to be safe and valid.

Surgical closure of ventricular septal defect was first described by Lillehei et al. in 1954[1] and it continued to be regarded as the gold standard treatment. However, over the past 10 years, percutaneous trans-catheter device closure has emerged as a safer alternative especially in case of muscular ventricular septal defects[2], though now significant number of perimembranous defects are also 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 has its own associated complications such as radiation exposure, risk of arrhythmias, interference with aortic and tricuspid valves, and quite frequent significant residual shunting. When encountering small infants or patients with poor vascular access, catheter closure can be a challenge[7] especially so in those with bigger defects. With the availability of newer safer devices, difficult and larger defects are now being attempted to be closed in the cardiac catheterisation lab. The present study was undertaken to look at the profile and spectrum of cases and their short-term outcomes and to provide insight on the feasibility of the procedure in small children weighing less than 10 kg.

Materials and methods

The present study was undertaken in a newly established Paediatric Cardiac Unit in a tertiary referral centre. Relevant data were obtained retrospectively from the case files and the catheterisation records and data were analysed. Between March 2018 and March 2021, a total of 50 patients with ventricular septal defect weighing 10 kg or less were taken up for percutaneous ventricular septal defect closure (Table 1). All patients were admitted at least 1 day prior to the procedure for clinical, laboratory (pre-cath profile), chest X-ray, ECG and transthoracic echocardiograph assessment. Echocardiographic evaluation included defining the size and the anatomy of the defect while dimensions of left atrial and ventricle were also recorded. Mean

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pulmonary artery pressure > 25 mm Hg was considered as pulmonary arterial hypertension. For the purpose of further classification, the pulmonary arterial pressure was compared with systemic arterial pressure. Mild pulmonary arterial hypertension was defined if pulmonary artery pressure was less than 50% of systemic pressure, moderate pulmonary hypertension was defined if pulmonary artery pressure was more than 50% but less than 66.6%, and finally severe pulmonary hypertension was defined if pulmonary artery pressure is more than 66.6% of systemic pressure. Along with this, pulmonary vascular resistance was also documented in all patients in Woods units.

Inclusion criteria

Patients were selected on the basis of following criterias: haemodynamically significant ventricular septal defect, refractory heart failure with medications, repeated respiratory infection, failure to thrive and evidence of left-heart volume overload which was considered as per (LA/LV size z score ≥2) left atrial enlargement, defined as a left atricle-to-aortic diameter ratio >1.5 on the parasternal long axis (PLAX) examination; left ventricle overload and enlargement, defined as left ventricle end-diastolic z-score on echocardiogram, indexed to body surface area ≥2.0 and Qp/Qs > 2.0. Any patient with ≤10 kg with ventricular septal defect was considered amenable for closure if at least 3 mm tissue rim separating the defect from the aortic or tricuspid valve was present, and there was no or minimal aortic regurgitation.

Exclusion criteria

Malaligned ventricular septal defect especially those with inlet extension, ventricular septal defect with aortic valve prolapse with more than mild AR, ventricular septal defect with any other associated heart defect that needs surgical closure otherwise were referred for surgery.

Imaging

Pre-procedural echocardiography assessment was done diligently in all the patients, and echoes parameters assessed the location and size of the defect specially their proximity to aortic and tricuspid valve and the presence of any regurgitation in any of these valves. Ventricular septal defect amenable to device therapy was only in which there was an aortic margin of at least 3 mm. Left heart volume overload was assessed on M-mode which included the assessment of left atrium and left ventricular size in parasternal long-axis view. Left article was considered overloaded when left article/aorta ratio was more than 1.5. Left ventricular enlargement was documented when end-diastolic ventricular diameter z score was more than 2 for body surface area.

Preparation of patients

All patients were admitted at least 24 hours prior to the procedure date. Meticulous history and clinical examination were performed as per unit protocol. Blood investigations in the form of complete blood count and C-reactive protein were done to rule out any active infection. Baseline renal function (blood urea, serum electrolytes, and serum creatinine) were documented in all patients. Coagulation parameters (prothrombin time, activated partial thromboplastin time) and serology (HIV, Hepatitis B, and C) were also done in all cases. Chest X-ray was performed in all cases to look for pulmonary plethora and also 12-lead electrocardiograms were done to check baseline rhythm before taking them in catheterisation lab. All the parents were informed about the procedure. Its complications and written and informed consent were taken from them before the procedure.

Procedure

The procedure was performed under conscious sedation in 47 patients while 3 patients were given general anaesthesia where the ventricular septal defect was approached via right internal jugular vein route. A single dose of intravenous antibiotic was administered 30 minutes prior to the procedure. The right femoral vein and right femoral artery access were taken percutaneous in all 50 cases while in 3 cases additional right internal jugular vein was also taken. All patients were given heparin 100 U/kg immediately after inserting the short sheath, and activated clotting time was kept above 200 seconds with repeated dose of heparin if needed. LV angiogram was done in left anterior oblique-30/cranial-20 and left anterior oblique-60/cranial-30 to define the ventricular septal defect as per unit policy. Right heart catheterisation was performed, and basal oximetric data was recorded. The ratio of pulmonary to systemic blood flow (Qp/Qs) was calculated (Qp/Qs > 2.0 was considered significant). Selection of device was done based on the measurement of echo and angiography. The ventricular septal defect was crossed from the LV side (retrogradely) in all cases. After crossing with Terumo Guide Wire M 0.035" 260Cm J Angled Tip (RF * GA35263M) arterio-venous (AV) loop was formed in 24 cases which includes all cases done with Amplatzer Septal Occuluder (ADO I), cases done via right internal jugular vein and one case with larger muscular ventricular septal defect done with Amplatzer muscular device which required bigger sheath to avoid any injury to femoral artery while in 26 cases ventricular septal defect devices were attempted in retrograde fashion without forming AV loop. For devices done from venous side after making AV loop, a long delivery sheath (AGA Medical Corporation, Golden Valley, MN, USA) was taken over this wire and its tip was kept inside the left ventricular cavity. Choice of the device was carefully made based on both echocardiographic and angiographic assessments of the defect. On echo, the defect was measured both on the left and right ventricular side, and the device size was decided based on the largest measured dimension. The device chosen was 1–2 mm larger than the largest defect diameter measured on the right ventricular side. Normally if there is a septal aneurysm and the defect is taking a conical shape, the choice would be ADO I, while smaller defects were closed with ADOII, for larger defects muscular device was used. Carefully the device was deployed across the defect by gradual unsheathing while checking its placement by transthoracic echo and fluoroscopy. Particular care was taken to safeguard the mitral valve apparatus. Mitral regurgitation was also meticulously checked secondarily to entrapment of chordal apparatus after device delivery from LV apex. For procedures that were performed from the left ventricular side, the defect was crossed with the same catheter and wire assembly and the diagnostic Judkins Right catheter was replaced with a guiding Judkins Right and the device was placed across the defect under echo and fluoroscopic guidance.

Post-procedure care

Post-procedure, the patients were kept in ICU for observation. Cardiac rhythm was monitored for the next 24 hours. Echocardiography and 12-lead ECG were done on all patients on next 2 consecutive days. Patients were discharged from

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Table 1. Baseline characteristics of the patients

S. no	Age (months)	Sex	Weight (kg)	Type of ventricular septal defect
1	48	F	10	PM
2	48	F	10	UM
3	24	M	8	MM
4	36	F	10	UM
5	7	M	6	PM
6	7	M	5.4	PM
7	8	F	3.5	OM
8	24	M	9	PM
9	6	F	4	PM
10	6	M	5	PM
11	41	F	10	PM
12	40	M	9.5	PM
13	30	F	8.8	PM
14	12	F	8	PM
15	24	F	6	LM
16	6	M	5.9	PM
17	12	M	8.5	PM
18	19	M	6.8	PM
19	24	M	9.3	OM
20	17	M	8.6	PM
21	4	F	4.8	PM
22	24	M	7	UM
23	12	M	6	PM
24	36	M	9.7	PM
25	17	M	8.4	PM
26	16	F	7.7	PM
27	12	F	6.7	PM
28	24	M	8.4	PM
29	48	M	10	PM
30	24	F	9	PM
31	16	F	5.3	LM
32	21	F	8.7	UM
33	12.	F	5.6	MM
34	19	M	7.5	PM
35	12	M	6.5	UM
36	9	M	7.3	PM
37	16	F	7.9	PM
38	24	M	9	PM
39	10	M	5.7	PM
40	13	F	6	PM
41	12	M	8	UM
42	36	M	10	PM
43	16	F	6	UM
44	12	M	6.5	PM
45	4	M	2.3	PM
46	7	M	4.7	PM
47	18	F	8.5	PM
48	16	F	6.8	OM
49	30	F	8.6	MM
50	18	M	8.0	PM

F = female; LM = lower muscular; M = male; MM = mid muscular; OM = outlet muscular; PM = perimembranous; RFA = right femoral artery; RFV = right femoral vein; RIJV = right internal jugular vein; UM = upper muscular
Mean weight 7.46 ± 1.89 kg (2.3–10 kg); mean age 19.4 ± 11.88 months (4–48 months).

intensive care on the following day and subsequently to home the next day. All the patients were started on oral aspirin (5 mg/kg/day – single dose after food) and advised to continue that for a total of 3 months.

Follow up

All the patients were called for follow-up after 7 days of discharge from the hospital and subsequently at 1 month, 3 months, 6 months, and at 12 months intervals as per the unit protocol. In this study, we aimed to study the immediate outcome of the device closure, and long-term follow-up is ongoing. On each follow-up visit, the patients were evaluated clinically for any evidence of worsening, improvement in functional class, and weight gain. At follow-up echocardiography, the position of the device was confirmed and residual shunt if any was noted. The presence of aortic regurgitation and tricuspid regurgitation was looked for and TR gradient was recorded along with left article and left ventricle dimensions. All the patients had 12-lead ECG done on follow-up for the assessment of rhythm.

Results

Among the 50 selected patients, device closure was successfully done in 45 (90%) cases while 5 (10%) were sent for surgery for various reasons. The mean weight in this study was 7.46 ± 1.89 kg (2.3–10 kg). 21 (42%) cases were females, while 29 (58%) were males; the mean age was 19.4 ± 11.88 months (4–48 months). Among types of ventricular septal defect, 35 (70%) cases were having perimembranous, 7 (14%) were upper muscular, 3 (6%) were mid muscular while 2 (4%) were lower muscular, and 3 (6%) had outlet muscular ventricular septal defect (one outlet muscular sub arterial and two outlet muscular subpulmonic) (Table 1). Right heart catheterisation study showed 21 (42%) patients with normal pulmonary artery pressure (no pulmonary arterial hypertension). Among 29 patients with pulmonary arterial hypertension, 13 (22%) patients were with mild pulmonary arterial hypertension, 4 (8%) were with moderate pulmonary arterial hypertension, and 12 (24%) were with severe pulmonary arterial hypertension. Mean Qp/Qs was 2.73 ± 0.72 (2.5–4.5), and mean pulmonary vascular resistance was

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Table 2. Cardiac catheterisation data and type of the device used (successful cases)

S. no	Type of ventricular septal defect	Size of ventricular septal defect (mm) on LV side	Size of ventricular septal defect (mm) on RV side	PAH	Qp/Qs	PVR (Woods unit)	Route of deployment	Type of device
1	PM	5	4	No	2.1	1	RFA	6×4mm-ADO-II
2	UM	6	6	Mild	2.2	1.4	RFV	10×8mm-ADO-I
3	MM	6	6.5	Severe	3.4	2	RIJV	8mm-MUSCULAR
4	UM	8	7	Mild	2.2	1.3	RFV	10×8mm-ADO-I
5	PM	3	3	No	2.0	1	RFA	5×4mm-ADO-II
6	PM	4	3	No	2.8	0.8	RFA	5×4mm-ADO-II
7	OM	4	3	No	2.4	0.7	RFA	5×4mm-ADO-II
8	PM	6	5	Mild	2.8	1	RFV	8×6mm –ADO-I
9	PM	5	3	Mild	2.0	0.9	RFA	6×4mm-ADO-II
10	PM	6	4	Mild	2.1	1	RFA	6×4mm –ADO-II
11	PM	8	6	No	2.6	0.6	RFV	10×8mm-ADO-I
12	PM	6	5	Moderate	3.4	1.8	RFV	8×6mm –ADO-I
13	PM	6	5	Moderate	2.8	1.6	RFV	8×6mm ADO-I
14	PM	4	4	No	2.6	0.9	RFA	6×4mm-ADO-II
15	LM	12	12	Severe	3.5	3	RIJV	14mm-MUSCULAR
16	PM	8	6	No	2.2	2	RFV	8×6mm –ADO-I
17	PM	6	5	Mild	3.0	1	RFV	8×6mm –ADO-I
18	PM	6	4	No	2.1	0.8	RFA	6×6mm-ADO-II
19	OM	6	4	No	2.6	0.9	RFA	6×4mm-ADO-II
20	PM	3	3	No	2.1	1	RFA	5×4mm-ADO-II
21	PM	8	6	Severe	3.0	2.8	RFV	8×6mm-ADO-I
22	UM	8	8	Severe	4.4	3.4	RFV	10×8mm-ADO-I
23	PM	4	3	No	2.0	1	RFA	5×4mm-ADO-II
24	PM	10	8	Mild	2.6	0.8	RFV	10×8mm-ADO-I
25	PM	4	4	No	2.0	0.6	RFA	6×4mm-ADO-II
26	PM	4	3	No	2.1	0.7	RFA	5×4mm –ADO-II
27	PM	5	4	No	2.0	0.5	RFA	6×4mm –ADO-II
28	PM	4	4	Mild	2.0	1	RFA	6×4mm –ADO-II
29	PM	12	10	Mild	2.1	1	RFV	12×10mm ADO I
30	PM	6	5	Mild	2.2	1.1	RFV	8×6mm –ADO-I
31	LM	6	6	Severe	4.0	4	RIJV	8mm –MUSCULAR
32	UM	4	4	Mild	3.0	1	RFA	6×4mm –ADO-II
33	MM	12	10	Severe	4.5	3.8	RFV	12mm –Muscular
34	PM	5	4	No	2.2	1	RFA	6×4mm-ADO-II
35	UM	4	4	No	2.1	0.5	RFA	6×4mm-ADO-II
36	PM	6	3.4	No	2.1	0.6	RFA	6×4mm-ADO-II
37	PM	6	6	Severe	4.0	3	RFV	8×6mm ADO-I
38	PM	8	8	Severe	3.5	0.8	RFV	12×10mm ADO-I
39	PM	4	3	Mild	2.8	1	RFA	5×6mm ADO-II
40	PM	5	5	Severe	4.2	3	RFV	6×4mm ADO-II
41	UM	4	4	Moderate	2.8	1.8	RFA	6×4mm ADO-II
42	PM	12	12	Severe	3.6	4.6	RFV	14×12mm –ADO-I

(*Continued*)

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Table 2. (*Continued*)

S. no	Type of ventricular septal defect	Size of ventricular septal defect (mm) on LV side	Size of ventricular septal defect (mm) on RV side	PAH	Qp/Qs	PVR (Woods unit)	Route of deployment	Type of device
43	UM	3	3	No	2.6	0.8	RFA	5×4mm ADO-II
44	PM	3.5	3.5	Moderate	3.5	1.2	RFV	6×4mm ADO-II
45	PM	4	4	Severe	3.0	2.6	RFA	6×4mm ADO-II

ADOI = Amplatzer duct occluder I; ADO II = Amplatzer duct occlude; LM = lower muscular; MM = middle muscular; OM = outlet muscular; PM = perimembranous; RFA = right femoral artery; RFV = right femoral vein; RIJV = right internal jugular vein; UM = upper muscular.
Mean Qp/Qs 2.73 ± 0.72 (2.5–4.5) and mean pulmonary vascular resistance 1.5 ± 1.04 (0.6–4.6WU).

1.5 ± 1.04 (0.6–4.6WU) (Table 2). As far as route for device deployment is concerned, 27 (54%) devices were deployed in retrograde fashion via femoral artery through 5F Guiding JR (ADO-II), including the smallest kid of our study (case number 45). In 15 (38%) cases, we have deployed devices in antegrade fashion via right femoral vein, and in 3 (6.6%) cases with mid muscular and lower muscular ventricular septal defect, we have used right internal jugular vein to deploy the devices. We have intentionally tried to minimise the formation of AV loop to avoid any injury to tricuspid valve and also other vital structures. AV loop formation was limited to only those cases where the plan was to put ADOI so that a larger disc to be placed on LV side and also in those cases where a larger sheath was required to avoid any injury to the artery. Amplatzer Duct Occluder (ADOI) was used in 15 (30%) cases, 27 (52%) were closed with Amplatzer Duct Occluder (ADOII) and the 3(6%) cases were selected for closure with Amplatzer muscular ventricular septal defect occluder. Transthoracic Echocardiography (TTE) in immediate post-intervention period revealed devices *in situ* in 45 (90%) cases while in 1 (2%) case immediate device embolisation occurred into left pulmonary artery which is discussed in detail under the unsuccessful cases which was eventually sent for surgery. No residual flow was noted in 40 (88%) cases while in 5 (12%) minimal residual flow (intra-device) was noted at the time discharge but no residual was present on follow-up (1 month). No patient had any evidence of neo-Aortic Regurgitation or Tricuspid regurgitation however, in eight patients, there was a decrease in the amount of tricuspid regurgiation at 1-month follow-up.

Unsuccessful attempts

Case 1: 7 months/4.7 kg male kid having 3 mm perimembranous ventricular septal defect with no pulmonary arterial hypertension (Qp/Qs 3.0) where ADO II 6/4 was implanted after forming an AV loop through right femoral vein. The device got embolised immediately into deep left pulmonary artery. Attempts were made to retrieve the device but it was not successful. Hence child was sent for surgical ventricular septal defect closure. The reason behind this failure was under-sizing of the device (as per feedbacks from the surgical team).

Case 2: 18 months/8.5 kg female child with 5 mm perimembranous ventricular septal defect with moderate pulmonary arterial hypertension (Qp/Qs 3.8), planned for device closure with 8/6 ADOI from the venous side but after the formation of AV loop and during advancement of 6F AMPLATZER™ 180° Delivery System from right ventricle through ventricular septal defect into left ventricle, the child developed severe bradycardia which improved after removing the delivery system. No further attempt was made to cross the defect and subsequently, the child was sent for surgery.

Case 3: 16 months female child with weight of 6.8 kg having 4 mm outlet muscular ventricular septal defect with no pulmonary arterial hypertension (Qp/Qs 2.8), it was decided to close this defect with 6/4 ADO II from retrograde approach, but after deployment of the device it was noted that left ventricle disc of device was causing significant AR so the child was referred to surgical closure.

Case 4: This was 30-month-old male kid with 8.6 kg weight who was having a large mid muscular (14 mm) ventricular septal defect and severe pulmonary arterial hypertension (reversible, Qp/Qs 4.8). We have planned to close the defect from antegrade approach with 16 mm Amplatzer muscular ventricular septal defect but the device never attained the stable position though another attempt was made from RIJV approach using 18 mm muscular ventricular septal defect device, but after multiple attempts it was not taking a stable position hence it was decided to close the defect surgically.

Case 5: 18 months male child with the weight of 8 kg with 4 mm PM ventricular septal defect with moderate pulmonary arterial hypertension, Qp/Qs 3.8 taken up in Cath lab with a plan to close the defect with 5/5 ADO II but there was significant residual shunt. Another attempt was made with ADO I 8-6 device but it was causing significant impingement of aortic valve therefore no further attempts were made and child had undergone surgical ventricular septal defect closure.

The above cases with unsuccessful attempts have highlighted the fact that case selection and meticulous pre-procedure imaging are of paramount importance. Two patients had an issue with undersizing, one with proximity to aortic valve; one had the rhythm issue (severe bradycardia) which was noted after forming an arterio venous loop and advancing long sheath across perimembranous ventricular septal defect that resulted in stretching (shear pressure) of atrio ventricular node. In smaller kids with perimembranous ventricular septal defect which requires formation of arterio-venous loop surgical closure is better option to avoid these rythm related complications. While in another last case the device never achieved the stable position.

Discussion

Transcatheter device closure of ventricular septal defect has increasingly become a popular alternative to surgery; however, both the procedures are not free from adverse effects like systemic inflammatory reactions from cardio pulmonary bye pass, intra-operative cardiac arrest and blood products transfusion for cardiac surgery can cause significant morbidity in children. Likewise, thin peripheral vessels in low-weight infants and radiation exposure for trans-catheter intervention are major deterrents. In very small

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children, catheters are difficult to manipulate, leading to increasing cardiac catheterisation time and hence the radiation, trauma while manipulations causing significant aortic or tricuspid insufficiency or sometimes injury to the conduction system leading to various degrees of heart blocks.

In this study, we aimed to study the immediate outcome of percutaneous ventricular septal defect closure in a selected group of patients and its feasibility especially in small children by weight. The most common defect in our study was perimembranous ventricular septal defect and in large number of patients, it was closed with ADO II septal occluder without any rhythm issues, This could be due to the design of the ADO II device which is soft in nature with no polyester material that does not apply a direct force on conduction system as shown by Vijaylakshmi et al in their study.[8] Rest of the defects were closed with ADO I device and all the defects were having some degree of aneurysm; this device was designed for PDA closure but subsequently now utilised for closing ventricular septal defects. The first case report that described that ADO could be used for ventricular septal defect closure was by Tan et al.[9] further Dilawar et al.[10] reported three cases which were closed with ADO I.

Most tricky one was the closure of outlet muscular ventricular septal defect. We have excluded the sub-arterial doubly committed outlet ventricular septal defect which does not have any tissue between the upper margin of the defect and semi-lunar valve. These defects are very prone to aortic cusp prolapse and the development of AR. The closure of outlet muscular defect was done with ADO II device, again with the above obvious reason. ADO II has low-profile retention discs that can sit better in the defect without disturbing the aortic as well as tricuspid valve. Kanaan et al in their study have reported a success rate of 93.5% with closure with ADO II.[11] The closure of the defect also protect against the aortic valve prolapse which has a high incidence in outlet ventricular septal defect. There was no immediate complication but long-term follow-up is required for the final outcome.

As for the muscular ventricular septal defects, most of them are relatively far from the AV valve, so they are amenable for device closure. Also there are less chances of conduction abnormalities with the device deployment. Besides some of the muscular ventricular septal defects, especially those in the apical or anterior region of the ventricular septum, direct surgical repair with CPB and cardioplegic arrest can present significant difficulties. In our study, we were able to close quite larger muscular defects, especially in a 2-year-old with severe pulmonary arterial hypertension whom we closed it with a 14 mm Amplatzer muscular device.

Device closure of perimembranous ventricular septal defect 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%) are the common complications.[12] Percutaneous ventricular septal defect closure is still not currently approved in many countries because of the risk of the development of heart block.[13–15] Post operative complete heart block following surgical closure of ventricular septal defect usually appears immediately after the operation and therefore corrective measures can be taken early while in cases of device closure heart block can occur at any time from a few minutes to years even after successful and uncomplicated procedures[12–17] and may require permanent pacing.[18–21] In this aspect, ADO II device is gaining popularity because of its profile and soft nature even in children with less than 1 year of age as studied by Narin N et al.[4] ADOII device utilises a small delivery sheath and can be deployed with lesser manipulation through angulation with overall less procedure time.[22]

The development of AR is another complication especially in defects which have smaller subaortic rim and sometimes it can appear post-release of the device. Here also, ADO II is a preferable choice of device. Zhao et al. have mentioned that ADOII has little effect on the aortic valve[23] while other authors have emphasised about the ability of this device to adapt to different shapes and to fit into the defect without disturbing the valve.[23,24] Tricuspid regurgitation can develop post device deployment but in majority of cases, it is related to injury to valve apparatus while forming the AV loop or when passing the sheath from venous side. TR has decreased in some patients post-deployment because of closing of shunt which was causing it through indirect gerbode's effect.

The most suitable device for ventricular septal defect which is not very large (>5mm) and perimembranous in location is ADOII because of its feasibility to deliver retrogradely without forming the AV loop. The softer profile of this device also decreases the chances of injury to adjacent structures and has less shearing force over the septum, so the development of heart block is also less, and ease of delivery with a smaller sheath or even guiding catheter decreases the overall procedure time.

With new improved and even customised devices for each patient, this procedure is likely to gain more acceptance.

Study limitations

Limitations of the present study are the single centre study with a lack of long-term follow-up. More studies with a larger number of patients and a long-term follow-up are required to analyse the safety and efficacy of transcatheter closure of ventricular septal defect in this age group.

Conclusions

Although surgical repair of ventricular septal defects is a safe, widely accepted procedure but it is associated with morbidity, discomfort, and a scar. As an alternative to surgery transcatheter closure of ventricular septal defect with different devices is a good alternative with acceptable results. With the current availability of devices for ventricular septal defect closure, transcatheter closure of ventricular septal defect can be considered as safe and efficacious in children weighing 10 kg or less with good mid-term outcomes though a long-term follow-up is still needed. The procedure had a low rate of complications even with the initial experience at a newly established catheterisation laboratory.

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