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Original Research Article

Transcatheter closure of ventricular septal defect from retrograde transarterial approach: immediate and long-term outcome

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ABSTRACT

Background: Ventricular septal defect (VSD) is a commonly encountered congenital heart defect. The aim of this study was to analyze five years' experience with patients who had undergone transcatheter closure of VSD using retrograde transarterial approach.
Methods: It was a retrospective study conducted from December 2014 to December 2019. Cases planned for VSD closure in retrograde approach were included. A total of 147 cases fulfilled the criteria after left ventricular angiography and procedure was performed without forming arteriovenous loop. Follow up was planned at 1, 3, 6, 12 months and yearly thereafter.
Results: The mean age of the patients was 5.94±4.67 years and mean weight was 17.93±8.26 kg. Perimembranous VSD was present in 70.06% cases and the size of the VSD was 5.5±1.8 mm. Amplatzer duct occluder II was the commonest device used (55.24%). Mean device size was 6.2±1.8 (5-8 mm). Complete occlusion was achieved immediately in 94.56% cases, and after one month in 99.36% cases. Four (2.78%) cases were postponed for malpositioning and encroachment of aortic valve. One patient (2.22%) had tiny residual VSD up to 3 years follow up. Bacterial endocarditis was noticed in one patient (0.80%) at one year follow up. No evidence of complete heart block was encountered in follow up period of six to 60 months.
Conclusions: This study recommends that retrograde transarterial approach for closure of moderate to small VSD is safe, effective, and minimally invasive, can be performed in short time with less radiation hazard and less trauma to conducting tissues.

Keywords: Closure, Outcome, Retrograde approach, Ventricular septal defect

INTRODUCTION

Ventricular septal defect (VSD) is one of the commonest birth defects related to significant morbidity and mortality.[1] Along with surgical closure, transcatheter device closure of VSD by antegrade approach using arteriovenous loop is an established procedure of VSD device closure.[2] This approach of device closure is cumbersome and time-consuming and needs multiple steps and expensive accessories throughout the procedure.[3] Forming an arteriovenous loop by crossing VSD is technically challenging and exposure to radiation is very high. Fluoroscopy cannot provide landmark on where the VSD is located and mostly crossing VSD depends on skill and expertise of the operator. Moreover, right ventricular trabeculation, aneurysmal tricuspid valve, flow interference in beating heart, proximity of the defect to tricuspid and aortic valve as well as conducting system make antegrade approach even more difficult.[4,5] So, several modifications in approach, device design is in evolution since first report by Lock et al. in 1988.[6] Retrograde, transarterial approach can reduce the number

of procedure steps and time, fluoroscopy time and radiation exposure.

This study was intended to analyze the immediate and long-term outcome of the cases who had undergone percutaneous device closure from retrograde arterial approach without forming arteriovenous loop.

METHODS

From December 2014 to December 2019, a total of 182 cases were admitted to Lab Aid Cardiac Hospital with an intention of device closure of ventricular septal defect (VSD). Retrospective analysis of the cases was done after taking written, informed consent of the parents and patients, as required. The medical ethical committee of the hospital approved the study. Out of 182 cases, 33 cases were referred for surgical closure after diagnostic catheterization, two cases were kept in follow up for small size. Device closure was attempted in 147 cases and in four cases devices were taken out for malposition. All of the cases had previous diagnostic work up and isolated perimembranous (PM) VSD, doubly committed VSD, sub aortic VSD, muscular VSD, VSD with aneurismal tissue, fenestrated VSD and post-operative residual VSD were included initially for trial of device closure. Associated cardiac defects like atrial septal defect (ASD) and patent ductus arteriosus (PDA) were also included which could be intervened in thesame setting. For sub aortic and double committed VSDs, minimum 1 mm distance of the aortic valve from VSD margin was mandatory. Patients whose age was $\geq$24 months and weight $\geq$8 kg were qualified for the procedure for untreated cases. But the age of four patients of postoperative residual VSD were ten months to two years and were accepted with special consideration. Patient with the evidence of right or non-coronary cusp (RCC, NCC) prolapse and aortic regurgitation (AR), infundibular stenosis, malaligned VSD were excluded. Any patient with VSD size more than 70% of the aortic diameter were excluded from this approach of closure. For muscular VSDs, up to 8 mm diameter on left ventricular side were included. Any patient with pulmonary artery pressure more than half of systemic pressure were excluded. The cases whose VSDs demand classical approach of device closure and closure by forming arteriovenous loop were excluded. Only femoral artery (right or left) was cannulated in every case and 5 French or 6 French introducing sheaths were used. Femoral venous cannulation set was kept ready for complicated cases. Doubly committed and sub aortic VSDs were accepted on trial basis. All parameters were checked thoroughly in "GE vivid I (up to 2016) and EPIQ 7C Phillips" echocardiography machine one day before intervention. Chest X-ray (CXR) and 12 lead Electrocardiography (ECG) was performed along with necessary blood works. All cases under five years were performed under deep sedation with cocktail medications: injection Ketamine 1 mg/kg bodyweight, Injection midazolum 0.1 mg/kg bodyweight and Injection phenobarbitone 10 mg/kg loading dose. Rest of the cases were performed under conscious sedation. Fluoroscopy and transthoracic echocardiography guide were taken during the procedure. All patients were kept in observation for 24 hours and discharged thereafter with advice of Aspirin 5 mg/kg body weight for 3 months. Follow up schedule was at 1, 3, 6, 12 months and yearly thereafter. In each follow up CXR, ECG and echocardiography were performed, in 6 months follow up Holter ECG was advised.

Device and delivery system

As the procedure was performed by using retrograde approach, we used devices which can be delivered through small size delivery systems. Amplatzer duct occluder II (ADO II, Abbott vascular solution, USA) was used. It is a sell expanding nitinol mesh device with two retention discs. The central waist is designed to fill the defect and two retention discs are designed to deploy on two side of defects. Though it is meant for PDA, its off-label use in closing VSD is well accepted. We also used Lifetech^{TM} MF- Konar (Lifetech Scientific, Schenzen company limited, China) VSD device. It is a self expanding device composed of nitinol wire mesh. It has two discs joined by a waist which is a truncated cone. Left disc or high-pressure disc is attached to the base of the truncated clone and right or low-pressure base attached to waist. Both discs are of equal size and have screw on both sides. Another device used was the Cook detachable coil of 5x4 mm (Cook Medical) in cases where VSD diameter was $\leq$3 mm. Recommended delivery system of ADOII and MF-Konar were used in some cases. We used Judkins right coronary guiding catheter (Medtronic, Minneapolis, MN, USA) as delivery catheter in most of the cases.

Procedure

LV Angiography was performed to analyze VSD, its proximity to aortic valve, presence of aneurysmal tissue if any, fenestration number and feasibility to close etc. Aortogram was performed to see any valve cusp prolapsing or AR. After making the decision to close, VSD was crossed with JR 4 catheter from LV side with the help of 0.035 terumoguide wire and stationed in main pulmonary artery or right ventricular (RV) apex, exchanged with 260 cm Teflon coated exchange wire later. Delivery system/ catheter forwarded over the wire to RV apex. Catheter or delivery sheath was not forwarded to pulmonary artery intentionally to avoid kinking. Device loaded to the delivery cable and forwarded to RV apex, RV disc released and whole system pulled back to VSD margins on RV side, later LV disc was released, and dye injected through delivery catheter to check perfect positioning, encroachment of valves etc. Transthoracic echocardiography guide was taken to look for residual VSD, condition of aortic, tricuspid valve and possibility of LV or RV out flow tract obstruction. ECG and hemodynamics were checked

continuously. Finally, devices were released by unscrewing. LV angiogram and aortogram were performedat the end to look for any residual VSD and neo-aortic valve regurgitation.

Follow up

Follow up at one and 6 months were attended by all 143 patients. Follow up data of 124 cases (88.71%) were available after first one year. Five patients were lost from follow up. Range of follow up was from 6-60months with median 28 months. No mortality was noticed in follow up. No major adverse event was recorded. One patient had endocarditis after one year of implantation and was treated successfully.

CXR, ECG, echocardiography was performed in each follow up. Residual tiny VSD was present in one patient only up to 3 years follow up.

Holter ECG performed routinely in all cases after 6 month and was normal. No patient had reported with complete heart block.

Statistical analysis

Continuous variables were expressed as mean, median and standard deviation. Categorical variables were expressed as number and percentage. As the study is on single- arm, single centre study, comparison was not made. Data were analyzed in MS Excel.

RESULTS

Total one hundred and eighty-two cases were accepted for trial of VSD Device closure (Figure 1).

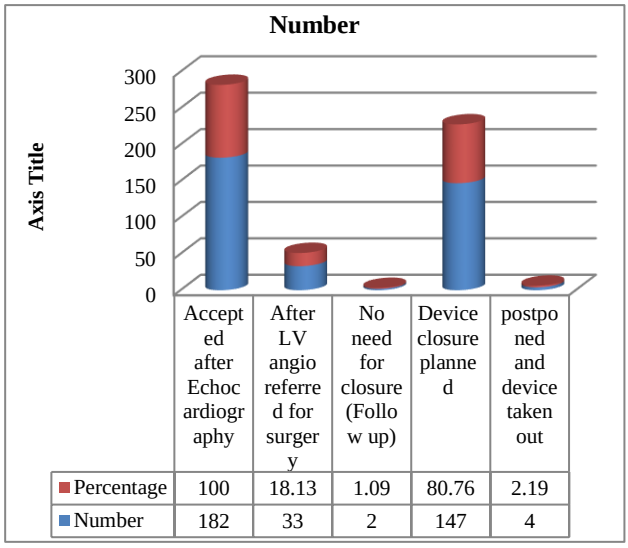

Figure 1: Summary of patient accepted for VSD device closure initially (n=182).

After diagnostic catheterization 33 (18.13%) cases were found not suitable for the procedure due to close proximity to aortic valve, large size or significant infundibular muscle band. Two cases were found very small on RV side and kept on follow up.

In one hundred forty-seven (80.76%) cases, device closure attempted and in four (2.19%) cases devices were taken out before release for causing aortic regurgitation and/or RVOT obstruction.

Table 1: Demographic data (n=147).

Variables	Mean±SD/ N (%)	Range/ratio
Age (years)	5.94±4.67	10 M to 35 Y
Weight (kg)	17.93±8.26	8 kg to 49 kg
Sex		
Female	73 (46.65)	1.01 : 1
Male	74 (50.34)	
Type of VSD		
Perimembranous (PM)	103 (70.06)	
Muscular	6 (4.08)	
Doubly committed	8 (5.44)	
Sub aortic	9 (6.12)	
Fenestrated	4 (2.72)	
PM VSD with aneurismal tissue	13(8.84)	
Post- operative residual VSD	4 (2.72)	
Size of VSD (mm)	5.5±1.8	3-7.5
Associated heart defect		
ASD secundum	15 (10.20)	
Mild PS	10 (6.80)	
PDA	5 (3.40)	
Additional Muscular VSD	3 (2.04)	
Trivial AR	5 (3.40)	

Table 1 showed demographic data. Mean age was 5.94±4.67 years and ranged from 10 months to 35 years. Four cases in this study were less than 24months who had residual VSD after surgical closure. Mean weight was 17.93±8.26 kg and range was 8-49 kg, male and female ratio was 1.01:1.

Among VSD types, PM VSD was 70.06%, PM VSD with aneurysm was 8.84%, muscular VSD 4.08%, doubly committed VSD 5.44%, sub Aortic VSD 6.12%, fenestrated VSD 2.72% and post-operative residual VSD 2.72%.

Mean VSD size was 5.8±1.8 mm (range 3-7.5mm). ASD was the most common association (10.20%) followed by mild PS (6.80%), PDA (3.40%), trivial AR (3.40%).

Table 2: Types of devices used (n=143).

Symptoms	Size	No (%)		Mean± SD
Amplatzer duct occlude II	6×4 5×3	75 4	79 (55.24)	6.2±0.75
MF-Konar	8×6 7×5 6×4 5×3	12 10 37 2	61 (42.66)	
Cook detachable coil	5×4	3 (2.09)		

Table 3: Cath lab data and immediate outcome (n=147).

S. no.	Variables	No. (%) Mean±SD
1	Complete occlusion	139 (94.56)
2	Postponed after trial & referred to surgery	4 (2.72)
3	Residual Shunt	4 (2.72)
4	Neo AR	2 (1.36)
5	Procedure time (min)	31.61±13.39
6	Fluoroscopy time (min)	9.29±3.73
7	Combined intervention	
	ASD device closure	6 (4.08)
	PDA device closure	5 (3.40)
8	Access site hematoma	2 (1.36)
9	Transient arrhythmia (V. tachy, V. Ectopics, SVT)	8 (5.44)
10	Procedure success rate	
	Immediate occlusion	139/147 (94.50)

Table 2 showed types of devices used. ADOII was used in 79 (55.24%) cases, MF-Konar in 61 (42.66%) cases and Cook coil in 3 (2.04%) cases. Mean device size was 6.2±0.75 mm.

Table 4: Postponed cases after trial of VSD device closure (n=4).

S. no.	Variables	Encroachment of Aortic valve /AR	RVOT obstruction
1	Sub aortic VSD	+	-
2	Doubly committed VSD	+	-
3	Doubly committed VSD	-	+
4	Sub Aortic VSD	+	-

Table 3 showed cath lab data and immediate result. Complete occlusion was achieved in 94.56% cases. Device was removed from implanted site for complications in 2.72% cases, residual shunt was seen in 2.72% cases.

Procedure time was 31.61±13.39 minute and fluoroscopy time was 9.29±3.73 min. Combined procedure of ASD device closure was performed in six (4.08%) cases and PDA device closure in five (3.40%) cases. Access site hematoma was noticed in two (1.36%) cases and transient arrhythmia in the form of ventricular tachycardia (VT), ventricular ectopic, supra ventricular tachycardia (SVT) in eight (5.59%) cases.

Table 4 showed summary of cases whose device were taken out after implantation. Case 1 had subaortic VSD and caused severe AR due to encroachment of valve, case 2 and 3 had doubly committed VSD caused AR and RVOT obstruction, 4th case had sub aortic VSD caused moderate AR.

Table 5: Complications and ongoing follow up.

Variables	n=143 1 month	n=143 6 month	n=124 1 year	n=45 3 year	n=25 5 year
	N (%)	N (%)	N (%)	N (%)	N (%)
Complete occlusion	142 (99.36)	142 (99.36)	123 (99.19)	44 (97.78)	25 (100)
Embolization of device	0	0	0	0	0
Device malposition towards LVOT	2 (1.39)	2 (1.39)	2 (1.61)	1 (2.22)	0
Complete heart block	0	0	0	0	0
Right or left bundle brunch block	0	0	0	0	0
Bacterial endocarditis	0	0	1 (0.80)	0	0
Residual shunt	1 (0.69)	1 (0.69)	1 (0.80)	1 (2.22)	0
Death	0	0	0	0	0

Table 5 showed complications in follow up period. All patients (143) completed follow up of 6 month, 5 patients were lost from follow up at 1 year while 124 cases attended. In third year 45cases and in fifth year 25 cases

had attended follow up. Rest are in the process of follow up. Residual tiny VSD in one case of coil occlusion performed in 2016 was persisting at last follow up of three years (2.22%). In two cases (1.39%) device was misplaced towards left ventricular out flow tract (LVOT) and was causing mild obstruction which would not necessitate any intervention, one (2.22%) of them had completed 3 year follow up. Complete atrioventricular block (CAVB) was not encountered in any cases. One patient (0.80%) had bacterial endocarditis in one year follow up and was treated successfully.

DISCUSSION

Ventricular septal defect is the most common congenital heart defect in children. The incidence of VSD varies from 1.5 to 3.5 per thousand term infants and 4.5 to 7 per thousand premature infants.[6] Perimembranous (PM) VSD accounts for 70-80% of all case.[7,8]

Rest 20% are muscular VSDs of inlet, trabecular or infundibular type.[8] Large non-restrictive VSDs lead to congestive heart failure and severe pulmonary hypertension very early. If left untreated they lead to Eisenmenger syndrome at very early stage.[9,10] Surgical closure of VSD has long been established. Till today, surgery is the only option for large complicated VSDs.[11]Approach of device closure forming arterial venous loop often had chance of complications like complete heart block, injury to valves (tricuspid and aortic valves) and even heart perforation.[7]Amplatzer muscular VSD occluder (AGA Medical, Plymouth, MN, USA) was the first specially designed device for muscular VSD available since 1998.[12,13] Later, Amplatzer membranous occluder for PM VSD was first implanted in 2002.[14,15]Amplatzer duct occluder devices (ADO) are designed for ductus arteriosus. ADO II is a modification of ADO I produce by AGA medical corporation.

Flexibility of articulation allows this device to fit safely in PM VSDs.[16] Off label use of this device reduces the risk of feared complication of atrioventricular block which occur in 3% to 20% of the cases closed with membranous occluder. [17–19]

So, ADO II was used in this series to close perimembraneous VSD to eliminate the risk of complete atrioventricular block. With this device, up to 6.5 mm size defects can be closed with a minimum distance of 3 mm from its upper margin to aortic valve.[20] Life tech ™ Koner –MF was also used in many centers and a multicenter study showed excellent outcome after closure of PM & muscular VSDs.[21] Considering the advantages of using latest flexible, soft devices with considerable small size delivery system or catheter, transarterial retrograde approach of closing small perimembranous VSDs was started in our center since 2012.

Retrograde approach of VSD closure with cook detachable coils was practiced since 2008.[22] We simplified pm VSD closure technique by using transthoracicecho guide and using deep sedation rather than general anesthesia.[23]

Initially 182 patients were accepted after echocardiography and finally after diagnostic catheterization 147 cases were selected for final implantation of device (Figure 1).

Mean age of the patient in this study was 5.94±4.67 year (Table 1) which was almost similar to a study conducted by Butera el al[3]. Mean weight of the patients were 17.93±8.26 kg. Whoever had VSD with distance minimum of 1 to 2 mm from aortic valve for doubly committed or sub aortic VSD and size less than 70 % of the aortic diameter (Table1) were selected for device closure. PM VSD were 70.06%. In the study group there were sub aortic, doubly committed, fenestrated and post-operative residual VSDs also. Doubly committed (DC) VSDs were closed with devices by per ventricular approach successfully.[24] We accepted the cases for trial mainly to fulfill parents desire as they were refusing surgery and in some cases it was successful. Sub aortic VSD's were also closed with ADO device in a Chinese study.[25] In our series we closed small DC and sub aortic VSDs with ADOII or MF- Konar in children who were more than 5 years of age and had minimum 1 mm distance from the aortic valve. After implantation, proximity to aortic valve, any evidence of encroachment of aortic valve was checked by transthoracic echocardiography. In this series, ADOII was the commonest device used followed by MF-Konar and PDA coil (Table 2).[1,16,17,21,22,24]

Fluoroscopy time and procedure time was less, 31.61±13.39 and 9.29±3.73, 8±5 mm respectively (Table 4). This will reduce ionizing radiation to children who are sensitive to radiation exposure and may develop toxicity. Immediate occlusion out of 143 device implanted cases was 94.50%, four (2.78%) cases had residual shunt in Cath lab, Neo AR was observed in two (1.36%) cases (Table 3). Four cases were postponed for inducing significant AR and right ventricular outflow tract obstruction. Two of them were doubly committed and two sub-aortic VSD and devices were not deployed rather taken out (Table 4). These four cases were referred to surgery. Five years follow up was completed in 25 cases, three years in 45 cases, one year in 124 cases and 6 months in all 143 cases (Table 5). No major complications like CAVB were noticed in any of the cases. Immediate and long-term result correlates with other studies .[1,2,16–18,21]

Outcome experience with M VSD-O was good as described by Arora et al.[26] Studies suggested that outcome of device closure with PM VSD-O is also up to 90-100%.[27,28] But in spite of good occlusion, possibility of complete AV block remains very high in follow up. In surgical closure cases, through it is safe but chances of CAVB is 1-5%, residual VSD 1-5%, necessity for redo

surgery is 2% and death is 0.5%.[29–32] So, comparing to convention method of device closure and surgical closure immediate outcome is excellent with retrograde technique. In follow up out of 143 cases, 142 (99.31%) had complete occlusion and there was only one tiny residual VSD in a case of coil occlusion case persisted till 3 years follow up. In two cases there was slight device malposition below aortic valve, but no intervention required. Aneurysmal and fenestrated VSDs in this study were closed successfully with a single device. Result is similar to other studies.[33] However, for multiple fenestrated VSDs, surgical closure is a good option if not managed by devices.[34] Now a days, many center are also doing VSD device closure through transaxillary and single transvenous approach with good results.[35,36] In this series, trans-arterial approach, avoidance of loop formation and direct release of soft textured devices led to less trauma, inflammation to conducting tissue and saved tricuspid valve and aortic valves from any damage.

Limitations of this study were the large VSD and patient with severe pulmonary hypertension were not included, as they need thorough diagnostic catheterization, conventional method of arteriovenous loop formation. Only small and moderate VSDs can be closed by this technique.

CONCLUSION

In conclusion, trans-arterial retrograde approach was proved as safe, effective technique of VSD closure which can protect patient from radiation hazard and major complications in long term.

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