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Transcatheter closure of perimembranous ventricular septal defects by using the amplatzer ductal occluder type I

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***Abstract*---**Background: - A ventricular septal defect is a hole or a defect in the septum that divides the 2 lower chambers of the heart, resulting in communication between the left and right ventricular cavities. Objectives: -To evaluate the efficacy and safety of percutaneous transcatheter closure of perimembranous VSD by using Amplatzer Ductal Occluder type I. Method: This is a prospective study. Total numbers of 216 patients with perimembranous VSD were enrolled for transcatheter closure of the defect by using Amplatzer Ductal Occluder type I (ADO I). The inclusion criteria of the study were: the VSD diameter ranged from 4mm to 12 mm, the VSD distance (rim) at least 2mm from atrioventricular and semilunar valves, and the systolic pulmonary atrial pressure ranged (20-75 mm Hg) with mean pulmonary atrial pressure (40 mm Hg). The patients with malalignment type of VSD were excluded from the study. Results: total number of patients was 216 of them 118 (54.6%) were females and 98 (45.4%) were males with mean age (10.9yr ± 8.75) and mean weight (21 kg ± 22.5). The types of perimembranous ventricular septal defects were perimembranous-muscular ventricular septal defects 112 (51.9%), perimembranous-inlet ventricular septal defects 88 (40.7%) and perimembranous-outlet ventricular septal defects 16 (7.4%). The success rate was 204 (94.4%) and failure was 12 (5.6%). Conclusions:

The Amplatzer Ductal Occluder type I is suitable and effective in occlusion of perimembranous VSD in different locations with or without aneurysm and has a high rate of complete closure with no significant adverse effects. More than one device may be used to close defect in one patient. Successful and safe closure of perimembranous ventricular septal defects also was achieved in very young children and those with complex anatomy.

***Keywords*---**transcatheter closure, perimembranous ventricular septal defect, amplatzer ductal occluder type I.

Introduction

A ventricular septal defect (VSD) is a hole or a defect in the septum that divides the 2 lower chambers of the heart, resulting in communication between the ventricular cavities. A VSD may occur as a primary anomaly, with or without additional major associated cardiac defects. It may also occur as a single component of a wide variety of intracardiac anomalies, including tetralogy of Fallot (TOF), complete atrioventricular (AV) canal defects, transposition of great arteries, and corrected transpositions [(1)]. Isolated ventricular septal defect (VSD) is the most commonly recognized form of cardiac malformation and constitutes over 20% of all congenital cardiac disease [(1)]. Recent echocardiographic studies demonstrated an incidence of VSD in newborns to be 5 to 50 per 1,000 [(2- 4)]. The lower prevalence in adults with congenital heart disease is due to spontaneous closure of many defects. VSDs are slightly more common in females: Approximately 56% female, 44% male [(5)]. Cardiac catheterization is rarely necessary for patients with uncomplicated VSD and without evidence for pulmonary vascular obstructive disease. In patients suspected of having pulmonary vascular obstructive disease, cardiac catheterization is essential to accurately measure pulmonary vascular resistance to determine whether the patient is a candidate for closure of the VSD [(6)]. In the anterior aspect, the tricuspid-valve attachment divides the area of membranous septum into an interventricular component (between the LV and the RV) and an AV component (between the LV and the RA) [(7)]. Prolapse of one of the aortic valve cusps may occur with outlet or perimembranous VSDs. Patients with outlet defects usually have deficiency of muscular or fibrous support below the aortic valve with herniation of the right coronary leaflet through the VSD [(8)]. The prevalence of this complication is highest in patients with an outlet VSD but occurs with some perimembranous VSDs as well. The associated aortic valve insufficiency increases with age [(9)]. The relationship of the atrioventricular conduction pathways to the defect is important to surgical repair. In perimembranous defects, the bundle of His lies in a subendocardial position as it courses along the posterior-inferior margin of the defect. In inlet defects, the bundle of His passes anterosuperiorly to the defect [(10)]. The aim of study to evaluate the efficacy and safety of percutaneous transcatheter closure of perimembranous VSD by using Amplatzer Ductal Occluder type I.

Method

This is a prospective study was done in the Ibn Al-Bitar cardiac center in a period from September 2013 to October 2015. Total numbers of 216 patients with perimembranous VSD were enrolled for transcatheter closure of the defect by using Amplatzer Ductal Occluder type I (ADO I). The inclusion criteria of the study were: the VSD diameter ranged from 4mm to 12 mm, the VSD distance (rim) at least 2mm from atrioventricular and semilunar valves, and the systolic pulmonary atrial pressure ranged (20-75 mm Hg) with mean pulmonary atrial pressure (40 mm Hg). The patients with malalignment type of VSD were excluded from the study. The protocol of our work were: An informed consent was obtained from all patients, the procedures were done under general anesthesia and by guidance of transcatheter thoracic echocardiography (TTE), and right and left heart catheterization with aortogram and left ventricle angiography with left anterior oblique (LAO) 70° with cranial angulation 20° for infracristal defects and with LAO 80° with cranial angulation 40° for supracristal defects. For planning the interventional approach, echocardiographic assessment of the size, number, and location of the VSDs is of crucial importance. The short axis view is important in delineating the location of the PM VSD. The four-chamber view at the level of the atrioventricular valves demonstrates the inlet defects. Patients were screened by conventional transthoracic two- dimensional echocardiography with multiple subcostal, apical and parasternal views. Procedure was undertaken under general anesthesia those who is less than (17 years) of age and in few cases under local anesthesia. Access is obtained in the femoral artery and the femoral vein. Routine right and left heart catheterization is performed to evaluate the pulmonary and systemic pressure and asses the degree of shunting. The patients were heparinized to achieve an activated clotting time of more than (200 seconds) at the time of device implantation. The entire device assembly is withdrawn back to the septum with further retraction of the sheath to expand the waist inside the septum after echocardiography and left ventriculography confirm good device position. The device is released by counterclockwise rotation of the cable using the pinvise. Once the device is released, the cable should be brought inside the sheath immediately to prevent any injury from the sharp end of the cable. Repeat echocardiography and left ventriculography are performed to assess the final result in terms of closure and residual shunt and to assess the function of the tricuspid, mitral, and aortic valve. All patients were discharged on the day after the procedure and prescribed aspirin (3–5 mg/kg) daily for six months. Before discharge a transthoracic echocardiogram were recorded. The follow-up two dimensional and color doppler echocardiographic studies done at 1month, 3 months, 6 months and 12 months after the closure and in each visit looking for residual shunt, AR, TR, and complete heart block.

Results

Cross sectional study of 216, (54.6%) of patients are males and (45.4%) of them are females, (51.9%) of patients with PM-muscular VSD, (69.4%) of patients with absent aneurysm, (80.6%) of patient are indication of closure of PM-VSD due to Changes on CXR or echo, (94.4%) of patients with Success rate. As show in table 1.

Table 1: distribution of variables including in current study in patients with RCC

variables		frequency	percentage
Gender	*male*	98	45.4
	female	118	54.6
types of PM-VSD.	PM-muscular VSD	112	51.9
	PM-inlet VSD	88	40.7
	PM-outlet VSD	16	7.4
Aneurysm	*Presence*	66	30.6
	Absent	150	69.4
indication of closure of PM-VSD	*Changes on CXR or echo*	174	80.6
	Symptomatic	38	17.6
	Previous SBE	4	1.8
Rate	*Success rate*	204	94.4
	Failure rate	12	5.6

As show in table 2; there is significant association between The presence and absence of aneurysm in the types of PM-VSD. (84.4%) of PM-inlet VSD are Absence of aneurysm and (53.6%) of PM- muscular VSD are Absence of aneurysm.

Table (2): - The presence and absence of aneurysm in the types of PM-VSD

Aneurysm	PM- muscular VSD	PM-inlet VSD	PM-outlet VSD
Absence of aneurysm	60 (53.6%)	74 (84.4%)	16 (100%)
Presence of aneurysm	52 (46.4%)	14 (15.6%)	0 (0%)

P-value = 0.0001 (≤0.05 significant).

As show in table 3, there is significant association between The presence and absence of prolapse in the types of PM-VSD. (78.4%) of patients with PM- inlet VSD are Absence of prolapse, (58%) of patients with PM-muscular VSD are Absence of prolapse.

Table (3): - The presence and absence of prolapse in the types of PM-VSD

Type of VSD	Absence of prolapse	Prolapse of RCC	Prolapse of NCC	Prolapse of both (RCC & NCC)
PM-muscular VSD	65 (58%)	17 (15.2%)	18 (16.1%)	12 (10.7%)
PM- inlet VSD	69 (78.4%)	5 (5.7%)	6 (6.8%)	8 (9.1%)
PM-outlet VSD	2 (12.5%)	8 (50%)	2 (12.5%)	4 (25%)

P-value = 0.0001 (≤0.05 significant).

As show in table 4; 79.2% of patients have absence of associated lesion.

Table (4): - The presence and absence and types of associated lesions in the types of PM-VSD

Type of associated lesion	Frequency	Percentage	Fate
Absence of associated	171	79.2%	-

lesion			
RVOT	16	7.4%	Beta-blockers, regress on follow- up
PFO	14	6.5%	Follow-up
Subaortic ridge	12	5.6%	Captured by device with no LVOT gradient or new onset AR
PDA	3	1.4%	Successful trans catheter closure

The mean age, weight, size on ECHO, angiography and LVEDD show in table 5.

Table (5): - The ranges and means of different parameters in patients with PM-VSD

Parameter	Range	Mean ± standard deviation
Age	9 mo - 44 yr	10.9 ± 8.75 yrs
Weight	5 - 95 kg	21 ± 22.5 kg
Size of VSD by echo	4 - 12 mm	7.8 ± 2 mm
Size of VSD by LV angiography	4 - 12 mm	7.8 ± 2 mm
LVEDD	28 - 64 mm	44 ± 9 mm
Fluoroscopic time	9 - 50 min	20 ± 10.25 min
Procedure time	23 - 120 min	56 ± 24.25 min

As show in table 6; the frequency of closure failure of percutaneous trans catheter closure of different types of PM-VSD by using ADO I.

Table (6): - The frequency of closure failure of percutaneous trans catheter closure of different types of PM-VSD by using ADO I

Type of PM- VSD	Frequency of closure failure	Cause
PM-inlet VSD	6	7 cases (large defect with insufficient rims). 5 cases (new onset AR due to aortic valve contact).
PM-outlet VSD	3	
PM-muscular VSD	3	

As show in fig 1; 136 (63%) of patients with absent of problems.

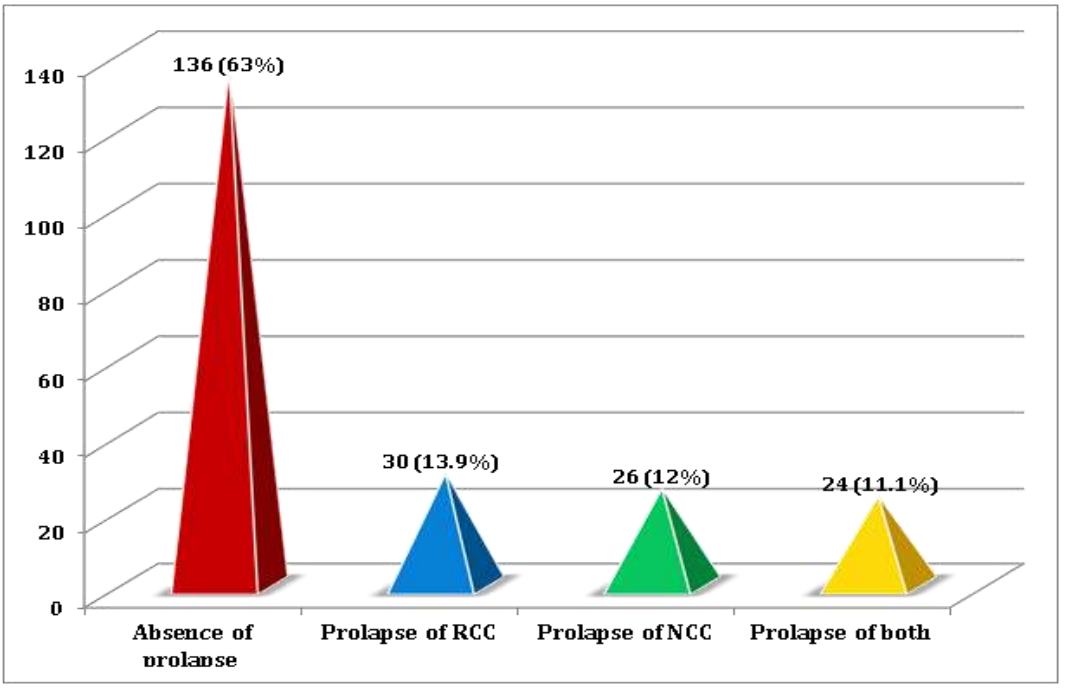

Figure (1): - Three-dimensional pyramid chart shows the frequency and percentage of absence or presence of different types of prolapse.

Discussion

In study was done in Iran by Mehdi et. al [11] included 28 patients with mean age 4.7 ± 6.3 yrs, mean weight 14.7 ± 10 and the mean defect size of the right ventricular side was 4.5 ± 1.6 mm. The ADOs were successfully implanted in all patients 100% compared with our study 204 (94.4%). The VSD occlusion rate was 65.7% at completion of the procedure, rising up to 79.5% at discharge and 96.4% during follow-up. Small residual shunts were seen at completion of the procedure, but they disappeared during follow-up in all but one patient. In another study was done in Iran by Mehdi Ghaderian, Mahmood Merajie, Hodjjat Mortezaeian and et. al [12] comprised 110 patients with mean age 4.3 ± 5.6 yr and mean body weight 14.9 ± 10.8 kg. The VSD occlusion rate was 72.8% at the completion of the procedure and rose up to 99% during the follow- up compared with our study (94.4%). The most serious significant complication was complete atrioventricular block, which was seen in 2 patients compared with our study one case complicated. In another study was done in China by Jun Liu, Zhen Wang, Lei Gao and etal [13] in 890 patients, defect diameter of the PMVSDs was 5.21 ± 8.15 mm, the technical success rate was 871 (97.9%) compared with our study 204 (94.4%), The incidence of serious complication was10 (1.12%) including five cases of third-degree atrioventricular block, two of severe tricuspid valve regurgitation, one of cerebral infarction in the basal ganglia area, and two of femoral artery thrombosis compared with our study the incidence of serious complication was1 (0.5%) was hemopericardium. In another study also was done in China by Jian Yang, Lifang Yang, YiWan and etal [14] in 848 patients with median age 9 yrs (2–73yrs) and with median body weight 30.5 kg (10–88 kg) with indications of closure were

symptomatic 337 (40.5%), hemodynamic changes 462 (55.5%), asymptomatic 23 (2.8%) and previous SBE 10 (1.2%). The size of VSD by echo 5.1 mm (1.3 -15.5 mm) and LVEDD 1.9 ± 1.6, fluoroscopic time was 12.5 min (4 -149 min) as compared with our study was 20 (9 - 50 min), procedure time was 41.2 min (22 – 342 min) as compared with our study was 56 (23-120 min), placement of the device was successful in 832 patients (98.1%) compared with our study 204 (94.4%), the adverse events occurred in 103 patients (12.4%) as compared with our study 1 patient (0.5%). In another study was done in USA by Yun-Ching Fu, John Bass, Zahid Amin and etal [15] in 38 patients with median age was 7.7 years (range, 1.2 - 54.4 yrs) and median weight was 25 kg (range, 8.3 - 110 kg), the attempt to place a device was successful in 32 (91%) compared with our study 204 (94.4%), The median fluoroscopic time was 36 min (14 - 191 min) as compared with our study was 20 (9 - 50 min) , and the median total procedure time was 121 min (67 - 276 min) as compared with our study was 56 (23-120 min). Three patients (8.6%) had serious adverse events of complete heart block, peri-hepatic bleeding, and rupture of tricuspid valve chordae tendineae as compared with our study was only one complication.

Conclusion

The Amplatzer Ductal Occluder type I is suitable and effective in occlusion of perimembranous VSD in different locations with or without aneurysm and has a high rate of complete closure with no significant adverse effects. More than one device may be used to close defect in one patient. Successful and safe closure of perimembranous ventricular septal defects also was achieved in very young children and those with complex anatomy.

References

1. Mavroudis C, Baker CL, Idriss FS. Ventricular septal defect. In: Mavroudis C, Baker CL, eds.Pediatric cardiac surgery, 2nd ed. St Louis: Mosby, 1994:201–24.
2. Tikanoja T. Effect of technical development on the apparent incidence of congenital heart disease. Pediatr Cardiol 1995; 16:100-101.
3. Roguin N, Du Z-D, Barak M, et al. High prevalence of muscular ventricular septal defect in neonates. J Am Coll Cardiol 1995; 26:1545-1548.
4. Ooshima A, Fukushige J, Ueda K. Incidence of structural cardiac disorders in neonates: An evaluation by color Doppler echocardiography and the results of a 1-year follow-up. Cardiology 1995; 86:402-406.
5. Hoffman JLE, Rudolph AM. The natural history of ventricular septal defects in infancy. Am J Cardiol 1965;16:634-653.
6. Graham TP Jr, Jarmakani JM, Canent RV Jr, et al. Left heart volume estimations in infancy and childhood: Reevaluation of methodology and normal values. Circulation 1991; 43:895-904.
7. Van Praagh R, Geva T, Kreutzer J. Ventricular septal defects: how shall we describe, name and classify them. J Am Coll Cardiol. 1989 Nov 1. 14(5):1298-9.
8. Van Praagh R, McNamara JJ. Anatomic types of ventricular septal with aortic insufficiency. Am Heart J 1968; 75:604-619.
9. Eroglu AG, Ã–ztunÃ§ F, Saltik L et al. Aortic valve prolapse and aortic

regurgitation in patients with ventricular septal defect. Pediatr Cardiol 2003;24:36-39.
10. Anderson RH, Wilcox BR. The surgical anatomy of ventricular septal defect. J Cardiac Surg 1992;7:17-34.
11. Mehdi Ghaderian, Mahmood Merajie, Hodjjat Mortezaeian, Moghadam Aarabi, Yoosef Mohammad and Akbar Shah Mohammadi. Efficacy and Safety of Using Amplatzer Ductal Occluder for Transcatheter Closure of Perimembranous Ventricular Septal Defect in Pediatrics. Iran J Pediatr. 2015; 25(2): e386.
12. Mehdi Ghaderian, Mahmood Merajie, Hodjjat Mortezaeian, Mohammad Yoosef Aarabi Moghadam and Akbar Shah Mohammadi. Mid-term Follow-up of the Transcatheter Closure of Perimembranous Ventricular Septal Defects in Children Using the Amplatzer. J Teh Univ Heart Ctr 10(4) October 27 2015.
13. Jun Liu, Zhen Wang, Lei Gao, Hui-Lian Tan, Qinghou Zheng and Mi-Lin Zhang. A Large Institutional Study on Outcomes and Complications after Transcatheter Closure of a Perimembranous-Type Ventricular Septal Defect in 890 Cases. Acta Cardiol Sin 2013; 29:271-276.
14. Jian Yang, Lifang Yang, YiWan, Jian Zuo, Jun Zhang, Wensheng Chen, Jun Li, Lijun Sun, Shiqiang Yu, Jincheng Liu, Tao Chen, Weixun Duan, Lize Xiong, and Dinghua Yi. Transcatheter device closure of perimembranous ventricular septal defects: mid-term outcomes. European Heart Journal (2010) 31, 2238–2245.
15. Yun-Ching Fu, MD, PHD, John Bass, MD, FACC, Zahid Amin, MD, FACC, Wolfgang Radtke, MD, FACC, John P. Cheatham, MD, FACC, William E. Hellenbrand, MD, FACC, David Balzer, MD, FACC, Qi-Ling Cao, MD and Ziyad M. Hijazi, MD, MPH, FACC. Transcatheter Closure of Perimembranous Ventricular Septal Defects Using the New Amplatzer Membranous VSD Occluder. Journal of the American College of Cardiology Vol. 47, No. 2, 2006.