ORIGINAL ARTICLE

Safety and Efficacy of VSD Closure Using Single Disc vs Double Disc Devices

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Abstract

Background: ***Ventricular septal defect is the most frequent congenital heart disease, with the peri-membranous ventricular septal defect (Pm-VSD) being the most frequent subtype.***

Aim: ***To assess the success rate and complications of device closure of symptomatic, hemodynamically significant Pm-VSDs using single-disc and double-disc devices.***

Patients and methods: ***This investigation was a cross-sectional comparative investigation performed on twenty cases with pm VSD at Cardiology Department, Faculty of Medicine, Al-Azhar University at the duration from June 2023 to January 2024.***

Results: ***There was no significant distinction in ventricular septal defect size or angiography before closure between single and double disc cases, with a p-value more than 0.05. Nevertheless, there was a significant distinction in looping, fluoroscopy time, and technique. In the single disc group, all cases (100%) underwent an antegrade technique. There was a significant difference in RS, with a higher number of cases in the double disc group (10 cases 90%) than the single disc group, p-value less than 0.05. No immediate complications occurred in both groups. All cases presented with sinus rhythm before closure, no case developed complete heart block, only one patient developed RBBB post procedure in the double disc group.***

Conclusion: ***Trans-catheter closure of ventricular septal defects is safe and efficient in selected cases. Both single- and double-disc devices are equally effective and safe.***

Keywords: Safety; Efficacy; VSD closure; Single disc; Double disc

1. Introduction

Ventricular septal defect (VSD) is the most frequent congenital heart disease (CHD), with the peri-membranous ventricular septal defect (Pm-VSD) being the most frequent subtype.[1]

Although spontaneous closure rates are great, surgical repair could be necessary throughout early infancy in the event of severe pulmonary hypertension or failure to thrive in spite of optimal medical management.[2]

An unknown percentage of cases with small residual defects develop cardiac problems later in life, and they subsequently become candidates for closure.[3]

In comparison to operation, the percutaneous approach has the potential to decrease costs, facilitate speedier recovery, decrease death, and shorten hospital stays. Additionally, it avoids sternotomy.[4]

Interventional PM-VSD closure has become more acceptable as a result of advancements in cardiac imaging modalities and techniques, which have made it possible to use a variety of occlusion systems. However, it continues to be technically challenging.[5]

As a result of the close proximity to the valvular system and conductive tissues, as well as the highly heterogeneous anatomical morphology, trans-catheter closure of peri-membranous ventricular septal defect remains a complex operation that poses technical challenges and significant complications risk.

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The aim of this investigation was to assess the success rate and complications of device closure of symptomatic, hemodynamically significant PM-VSDs utilizing single disc {Amplatzer duct occluder I (ADOI)} and double disc {Amplatzer duct occluder II (ADOII) and multifunctional occcluder(MFO)} devices.

2. Patients and methods

This investigation was a cross-sectional comparative investigation performed on twenty cases with pm VSD at Cardiology Department, Faculty of Medicine, Al-Azhar University at the period from June 2023 to January 2024.

Ethical aspects

This investigation has been permitted by the Ethical Committee of Al-Azhar University and an informed consent was acquired from all enrolled participants or their parents. The investigation protocol has been designed in agreement with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans.

Inclusion criteria: Symptomatic, hemodynamically significant pm-VSDs for percutaneous trans-catheter closure.

Exclusion criteria: Eisenmenger syndrome, large ventricular septal defect, rheumatic heart disease, other related congenital heart diseases, and related cardiomyopathy.

Methods

All patients were subjected to the following:

Physical examination

Detailed history: This was taken from all subjects'

laboratory analyses involving serum electrolytes, INR, complete blood count, and renal and liver function tests.

Resting 12-Leads (ECG): Carried out to detect: Heart rhythm and rate, any evidence, and heart block.

Resting conventional Trans-Thoracic echocardiography: to acquire sufficient images in various standard views, all cases have been examined while at rest in the left lateral decubitus position.

The following measurements were taken.

Assessment of VSD with regard to size, shape of the defect, presence of other VSD, assessment of the subaortic rim in parasternal long axis views and apical-5-chamber, assessment of nearby valves like the tricuspid valve and the aortic valve, assessment of left ventricular diameters and volumes by the modified Simpson method, and assessment of left atrial diameters.

Procedural closure

The parents of the kids signed informed written consent following receiving a thorough explanation of procedural details, advantages, and potential complications. The same operators conducted all surgeries in the catheterization laboratory under general anesthesia with TEE and fluoroscopic guidance. One femoral vein (FV) and one 5F ipsilateral arterial line have been obtained. Subsequently, all cases have been administered intravenous (IV) heparin at a rate of fifty to one hundred international units per kilogram, with a limit of five thousand international units. In addition, prophylactic antibiotic treatment has been administered at the start of the surgery utilizing intravenous cefazolin (thirty milligrams per kilogram, maximum two thousand milligrams). To profile the defect, left ventriculography has been carried out with a pigtail catheter at a 55-60° left anterior oblique to 20° cranial projection. This has been combined with intraoperative TEE to precisely identify Pm-VSD shape, location, size, depth, and its correlation with the adjacent tricuspid and aortic valves.

Ante-grade approach:

All single-disc devices have been implanted using this antegrade approach. Utilizing a 5-F manually cut pigtail catheter and a 0.035-inch J tip Terumo glide wire combination, the ventricular septal defect was retrogradely crossed from the left ventricle side. The catheter has been advanced into either branch of the PA, or preferably into the inferior or superior vena cava, after crossing the ventricular septal defect. An arterio-venous loop has been created by snaring and exteriorizing a Terumo wire through the femoral vein. An appropriate six, seven, or eight F delivery system has been advanced from the femoral vein across the ventricular septal defect over this wire until the sheath apex reaches the ascending aorta. The dilator has been subsequently removed from the venous line, and the guide wire and the end-hole catheter have been removed from the arterial line. A saline solution was used to load the selected device, which was then advanced to the apex of the delivery sheath without rotation under fluoroscopy after the long sheath had been flushed. The distal disk has been partially opened in the ascending aorta and subsequently gently drawn back through the AV into the left ventricle. Subsequently, the delivery sheath was gradually retracted until the distal disc was fully deployed on the left ventricular side of the ventricular septal defect. The waist of the device has been deployed in a ventricular septal defect by retracting the sheath and pulling the entire assembly (delivery sheath and delivery cable) back into the defect. The sheath has been retracted to deploy the proximal disc following the confirmation of the position by angiography and TEE. Following complete deployment of the occluder, TEE has been conducted in conjunction with left ventricle angiography to confirm the

device's shape and position, residual shunt, and the absence of interference with the AV cusps. It was challenging to anticipate the evolution of the delivery cable after the device had been released, as it was generating some regurgitation as it passed across the TV. After confirming that the device was in a good position and that there were no AV disturbances, the cable was turned counterclockwise to release the device. To prevent angiography, catheter manipulation in the left ventricle, and accidental mobilization of the device, the final outcome has been solely evaluated using TEE.

Retrograde Approach:

All double disc devices were implanted using this retrograde approach. A delivery sheath has been introduced from the FA and advanced over an exchange wire, via the ventricular septal defect, after crossing the defect from the left ventricular side, utilizing the same approach as above. The delivery sheath has been used to load the chosen device, which has then been advanced to its tip in the right ventricle. The delivery catheter has been gradually withdrawn into the right ventricle, near the defect, with the assistance of TEE guidance. Upon confirmation of the position, the distal disk has been gradually advanced out of the catheter, and the entire system has been drawn back as a single unit against the septum. TEE verified the absence of tricuspid regurgitation (TR) associated with RD at this stage. The catheter has been subsequently retracted to facilitate the opening of the proximal disk and waist against the septum on the left side with gentle tension. The device's position and stability, proximity to AV, and presence of significant TR have been subsequently evaluated utilizing TEE in multiple views. It was mandatory to administer a hand injection into the ascending aorta via a guiding catheter prior to detaching the device to confirm the absence of LD interference with AV. The device was subsequently released through a counterclockwise cable rotation, and the final outcome was evaluated by TEE.

All cases were examined clinically, with CXR performed to detect early complications, twelve-lead EKG carried out to confirm sinus rhythm and detect heart block, and echocardiography carried out to identify aortic insufficiency, pericardial effusion, tricuspid valve stenosis, left ventricle outflow tract obstruction, left ventricle function, & shunting degree through device.

All cases have been discharged from the hospital twenty-four hours following the operation, and endocarditis prophylaxis has been given for the 1st six months in every case.

Follow-up protocol

After three months new onset adverse events have been monitored on basis of clinical assessment, ECG, echocardiography. TEE included change in LV function and dimensions, change in AR, TR and RS.

STATISTICS

Data have been examined utilizing Statistics Package for Social Sciences (SPSS) version 25. Qualitative data have been expressed as frequency and percentage. Continuous quantitative data have been expressed as median and Interquartile range (Median with IQR).

Median: The middle number is determined by arranging all data points and selecting the one in the middle (or, if there are two middle numbers, by calculating the mean of the two numbers).

IQR (inter-quartile range) is a measure of statistical dispersion, which is the spread of the data. It is defined as the difference between the 75th and 25th percentiles of the data.

Probability (P-value)

A p-value less than 0.05 has been considered significant.

A p-value less than 0.001 has been considered highly significant.

A p-value more than 0.05 has been considered insignificant.

PATIENTS

Single disc devices have been inserted in 9 cases with a median age of 6 years (IQR, 5-9.5) and weight of 23 kilograms (IQR, 17–32). Double disc devices have been inserted in 11 cases with a median age of 5 years (IQR, 3-10) and weight of 18 kilograms (IQR, 12.5–33). The baseline characteristics, interventional & echocardiographic variables of the cases are presented in Table 1.

3. Results

The duration of monitoring in our investigation was 3 months in all cases. Early residual shunts were more common in double disc group (90.9%) when compared by single disc group (44.4%) (P-value=0.024). At 3 months follow up, incidence of residual shunts is equal in both groups (p-value=0.82). One case in double disc group developed new onset RBBB with no case in both groups developed complete heart block. Significant valvular insufficiency was not observed at early or 3 months follow up.

Table 1. comparison of studied groups (single disc and double disc) as regard demographic data, TTE and interventional parameters in all studied cases.

DEMOGRAPHIC DATA		SINGLE DISC (N= 9)	DOUBLE DISC (N= 11)	STAT. TEST	P-VALUE
AGE (Y)	Median (IQR)	6 (5 – 9.5)	5 (3 – 10)	U= 40	0.47 NS
GENDER	Males	5 55.6%	3 27.3%	X^2= 1.7	0.2 NS
	Females	4 44.4%	8 72.7%		
WEIGHT (KG)	Median (IQR)	23 (17 – 32)	18 (12.5 – 33)	U= 38	0.36 NS
HEIGHT(CM)	Median (IQR)	120 (116 – 135)	110 (90 – 129)	U= 36	0.304 NS
BSA(M^2)	Median (IQR)	0.8 (0.8 – 1.1)	0.7 (0.6 – 1.1)	U= 38	0.38 NS

TTE FINDING					
VSD SIZE	Median (IQR)	3.3 (3 – 4)	4 (3 – 4.5)	U= 38	0.36 NS
SAR	Median (IQR)	5 (4 – 5)	5 (3.5 – 5)	U= 45	0.69 NS
AR		0	1	X^2= 0.86	0.35 NS
TR		9 100%	11 100%	-------	-------
TV ANEURYSM		8 88.9%	45.5%	X^2= 4.1	0.043 S
TECHNIQUES UTILIZED, N (%)					
LOOPING		9 100%	0 0.0%	X2= 20	<0.001 HS
TECHNIQUE	Antegrade	9 100%	0 0.0%	X2= 20	<0.001 HS
	Retrograde	0 0.0%	11 100.0%		
FLUOROSCOPY TIME	Median (IQR)	40 (35 – 49)	20 (17 – 22)	U= 0	<0.001 HS
DEVICE EMBOLIZATION, N (%)		0 0.0%	1 9.1%	X^2= 0.86	0.35 NS
RESIDUAL SHUNT IN THE 1ST 24 HOURS, N (%)		4 44.4%	10 90.9%	X^2= 5.1	0.024 S
RESIDUAL SHUNT AT 3 MONTHS, N (%)		2 22.2%	2 18.2%	X^2= 0.05	0.82 NS

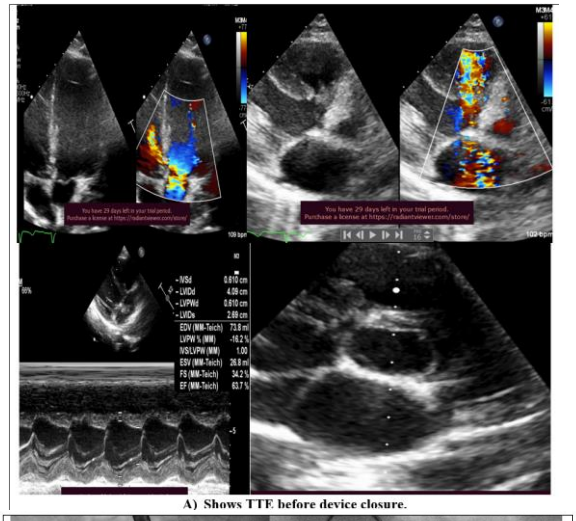
Table 2. Major & minor complications.

COMPLICATIONS	SINGLE DISC (N= 9)	DOUBLE DISC (N= 11)
MAJOR COMPLICATIONS		
VALVE INJURY	0	0
CAVB	0	0
LBBB	0	0
DEVICE EMBOLIZATION	0	1
THROMBOEMBOLISM	0	0
VENTRICULAR PERFORATION	0	0
MINOR COMPLICATIONS		
TRANSIENT LOSS OF PULSE	0	0
NEW ONSET AORTIC REGURGITATION	0	0
RBBB	0	1
INCREASE IN DEGREE OF TRICUSPID REGURGITATION	1 (from mild TR to moderate TR)	5 (from trivial TR to mild TR)
VASCULAR COMPLICATION	0	0

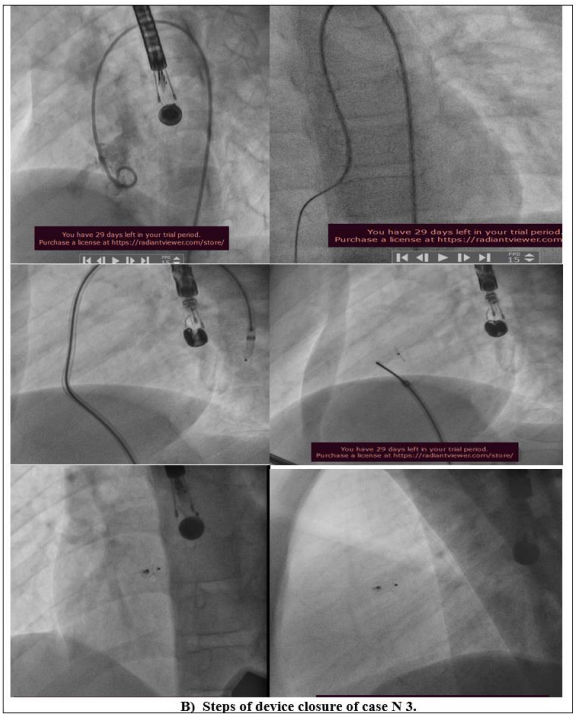
CASE PRESENTATION

Case One

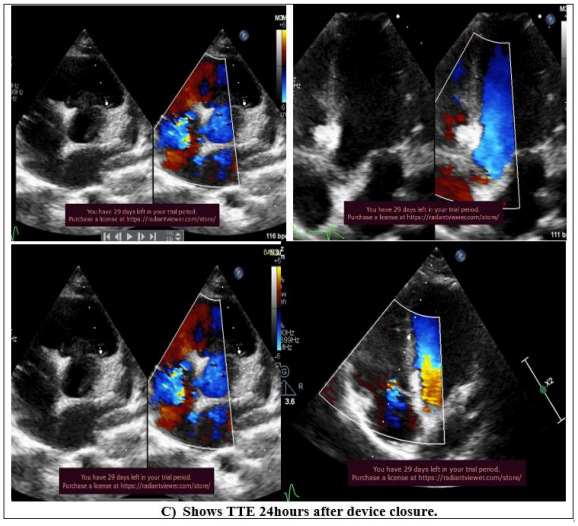
11ys. Old girl with history of accidently discovered VSD during survey in preschool medical workup. and flow with SAR 4mm. Normal MV structure with mild MR. Device closure under GA Physical examination: Unremarkable general and local examination apart from holosystolic harsh murmur over the pericardium. Basic labs: Within normal range. CXR: Revealed cardiomegaly with lung plethora. ECG: Sinus rhythm with RBBB. TTE: Shows Pm-VSD measuring 3mm with trial of closure by septal leaflet aneurysm, causing mild TR. Dilated left side of the heart. Normal AV structure using fluoroscopy and TEE guidance: Accurate sizing of the VSD done by LV angiography in LAO 30°, cranial 30° projection, VSD size was 2.5 mm, so dust occluder 6-4 device was chosen. Crossing of the VSD by manually cut pigtail over hydrophilic terumo wire, wire snared from PA to form complete AV loop. Long sheath introduced over the wire from venous side till descending aorta. Duct occluder 6-4 loaded, delivered antegradely, positioned in the VSD under fluoroscopy and TEE guidance then released after assessment of aortic valve, tricuspid valve, device stability and residual flow. During procedure case developed recurrent attacks of arrhythmia but completely disappeared after the procedure. The total fluoroscopy time was 82 minutes with total amount of contrast 40ml. Challenging during procedure was mainly due to forming complete AV loop. Follow up after 24hour: Physical examination, CXR, ECG and TTE done with no complication, RS, or embolization. Follow up after 3 months: ECG, TTE done with no complications or RS with improvement of left ventricular dimensions.



A) Shows TTE before device closure.



B) Steps of device closure of case N 3.



C) Shows TTE 24hours after device closure.

Figure 1. Shows case One

4. Discussion

The present investigation enrolled two well-matched groups in baseline data to eliminate the impact of any confounding factor that could influence the final result. However, there was a statistically insignificant distinction among the examined groups in terms of baseline characteristics.

Regarding angiography findings, the present investigation revealed that all cases in single disc group underwent antegrade technique and looping, however in double disc group all cases underwent retrograde technique.

Regarding follow-up:

Residual shunt (RS) was significantly greater in double disc group than single disc group in early follow up (90.9% vs 40.4% respectively) but the incidence is equal in both groups at 3 months follow up (22% vs 18% respectively). Fluoroscopy time was significantly shorter in double disc group compared to single disc group. No immediate complications were found in either group.

Significant valvular insufficiency was not observed at early or 3-month follow-up.

One case in the double disc group developed a new onset of RBBB, and no case in either group developed complete heart block.

The above results showed no clear difference in outcomes between single and double-disc groups as regard both safety and efficacy.

El-Sisi et al.,[6] compared single disc and double disc devices for ventricular septal defect closure in 30 kids, found no significant difference in weight and median age. Single disc cases had larger VSD sizes and longer Fluoroscopy time, and the device type matched TTE information in 84% of cases. Monitoring ranged from 2 to 24 months, with a mean LVEDD z-score of 1.1 before VSD closure. Complete closure rates were 87, 90, and 94% at the first, 24-hour, and last follow-up, respectively. No cases developed heart block or other complications. The study concluded that single disc and double disc are equally effective and safe in PM-VSD closure.

The outcome of a single disc was reported by Haddad et al.,[7] who enrolled 7 cases in the ADOI group. At six months of monitoring, no cases have residual shunt, and 2 (28.5%) cases have trivial aortic regurgitation. Fluoroscopy time was 30.7 ± 17.8 min in the single disc group. One single disc (12 ×10) accidentally embolized to the aorta following release and was surgically recaptured from the iliac artery in a case with 15 years 15-year-old. There was no operation-related death. One complete atrioventricular block was identified eighteen months following single disc implantation, and permanent pacing was required.

The efficacy of double disc in VSD closure was confirmed by Wang et al.,[8] who assessed long-term efficiency and safety of double disc for the closure of ventricular septal defects in an investigation of 188 cases. The investigation demonstrated a success rate of 98.9% percent. There were no instances of complete atrioventricular block, infective endocarditis, or mortality throughout the median 77-month monitoring duration. A cerebrovascular accident occurred in a single case who was transferred to the neurology department the day following the operation, resulting in one significant adverse event (0.5 percent). The most prevalent minor adverse event was the residual shunt rate, which was 44.6 percent. The rate of cardiac conduction block was 4.3 percent. Particularly, intermittent LBBB has been observed in one peri-membranous ventricular septal defect case throughout the 28-month monitoring. The degree of insufficiency remained stable throughout the monitoring period, and three cases (1.6 percent) developed new-onset mild tricuspid insufficiency. There was no new-onset aortic insufficiency.

As well, Wongwaitaweewong et al.,[9] retrospective review of 49 cases who had trans-catheter ventricular septal defect closure utilizing a double disc found 100% success, with most implantations performed retrograde. The double disc has been successfully implanted in 55% of cases that failed other devices. No major complications occurred, and the device was safe and efficient for VSD closures with defects smaller than 6 mm.

4. Conclusion

Both the single and double devices were comparable in safety and efficiency.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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