JSHD
Journal of Structural Heart Disease

Original Scientific Article

Journal of Structural Heart Disease, December 2019, Volume 5, Issue 6:237-247
DOI: https://doi.org/10.12945/j.jshd.2019.001.19

Received: January 05, 2019
Accepted: February 19, 2019
Published online: December 2019

Endovascular VSD Closure with Lifetech KONAR-Multifunctional Occluder - Novel Device

Jesus Damsky Barbosa, MD[1*], José Alonso, MD[2], Liliana Ferrín, [3], Marcelo Rivarola, MD[4], Victorio Lucini, MD[5], Julio Biancolini, MD[6], Adelia Marques Vitorino, MD[6], Rosa Ramírez[7], Judith Ackerman[8], Ines Martinez[8], Fernanda Biancolini[8], Ana María Susana de Dios[8,9]

[1] Pediatric Cardiology, "Pedro de Elizalde" Childrens Hospital, CABA, , Argentina

[2] Pediatric Cardiology and Catheterization Laboratory, High Complexity Hospital "Juan Domingo Peron", Formosa, Argentina

[3] Pediatric Cardiology and Catheterization Laboratory, Institute of Cardiology of Corrientes, Corrientes, Argentina

[4] Pediatric Cardiology and Catheterization Laboratory, Universitary Austral Hospital, Pilar Centro, Buenos Aires, Argentina

[5] Catheterization Laboratory, "Pedro de Elizalde" Childrens Hospital, CABA, Argentina

[6] Pediatric Cardiology and Catheterization Laboratory, "Pedro de Elizalde" Childrens Hospital, CABA, Argentina

[7] Pediatric Nursing Catheterization Laboratory, "Pedro de Elizalde" Childrens Hospital, Buenos Aires, Argentina

[8] Pediatric Cardiology and Echocardiography Laboratory, "Pedro de Elizalde" Childrens Hospital, Buenos Aires, Argentina

[9] Pediatric Cardiology, "Trinidad Mitre" Institution, Buenos Aires, Argentina

Abstract

The aim of this publication is to report the short and mid-term results of the closure of perimembranous and muscular Ventricular Septal Defect (VSDs) with the novel device, Konar-Multifunctional Occluder (MFO).

Introduction: The endovascular closure of Ventricular Septal Defect (VSD) is a well-established procedure. The Konar Multifunctional occluder (MFO) allows closure of large VSDs in an antegrade or retrograde way.

Materials and Method: Since October 2017, the VSD closures were performed in 17 patients with MFO device, including 3 patients weighing less than 5 kg with Associated Complex Congenital Heart Diseases. The Transthoracic Echocardiography (TTE) measurements were as follow: Left orifice: mean of 7.71 mm ±SD (4 to 12.3 mm); Right orifice: mean of 4.69 mm ±SD (2.8 to 7.8 mm); Length: mean of 5.75 mm ±SD (3 to 9.7 mm).

Results: From the scope of 17 patients, 16 procedures were successful and only 1 failed. The mean follow-up was 5.3 months (1 to 11 month). There were no major complications such as complete AV block, hemolysis, etc. No residual shunt was showed in the mid-term follow-up. 2 patients less than 5 kg died afterwards: 1 due to sepsis and the other one after the reoperation of severe restenosis of the pulmonary veins.

Conclusions: VSD closure with the Konar-MF occluder is feasible for both congenital and residual postoperative VSDs. It offers a vast variety of options by allowing different approaches to the VSD occlusion, (antegrade, retrograde and even through the foramen ovale), that had greatly simplified the procedure, giving the device a very substantial advantage, including the closure of large defects in low weight patients.

Key Words

Konar-MFO • MFO • VSD closure • ADO II

Introduction

Ventricular Septal Defects (VSDs) is the second most frequent congenital heart disease. The incidence of VSD is between 1.5 and 3.5/1000 in live birth and 4.5 to 7/1000 in premature babies1. The perimembranous VSD makes 70% of the VSD2 cases.

Fax +1 203 785 3346
E-Mail: jshd@scienceinternational.org
http://structuralheartdisease.org/

ISSN 2326-4004

Accessible online at:
http://structuralheartdisease.org/

* Corresponding Author:
Damsky Barbosa Jesus, MD
Head of Pediatric Cardiology Unit
"Pedro de Elizalde" Childrens Hospital
40 Montes de Oca Av., C1270AAN CABA, Argentina
Tel.: +549 11 5803 8203; E-Mail: jdamskyb@gmail.com

Table 1. Different types of MFO catalog numbers with the corresponding delivery sheaths.

Catalog Number		D Disc Diameter (mm)	D2 Waist Diameter LV Side (mm)	D1 Waist Diameter RV Side (mm)	L Waist Length (mm)	Recommended Delivery Sheath (Fr)
	LT-MFO-5-3	10	5	3	4	4F-5F
	LT-MFO-6-4	10	6	4	4	
	LT-MFO-7-5	12	7	5	4	
	LT-MFO-8-6	12	8	6	4	
 with membrane	LT-MFO-9-7	14	9	7	4	6F
	LT-MFO-10-8	14	10	8	4	
	LT-MFO-12-10	16	12	10	4	7F
	LT-MFO-14-12	18	14	12	4	

Although surgical intervention is considered the gold standard for VSD [3-6], VSDs can successfully be closed by catheterization in patients with favorable anatomies and precise indications. Despite this, different complications have arisen where the complete AV block [7, 8], remains the most fearsome, and therefore, it is necessary to be extremely careful with the indication of this procedure, the choice of the device, and even with the vascular access selection.

Different devices have proven to successfully close different types of VSDs, depending on the size, location, and presence or absence of prolapse of the aortic sigmoid. Several devices have been used in VSD closure, such as the PDA Nit-Occlud® coil, Flipper® PDA [9, 10] coil, AMPLATZER™ [11, 12] devices for muscular VSD and Ductus ADO II devices [13, 14].

Regarding vascular access, the arteriovenous loop for the perimembranous VSDs that requires puncture of the femoral artery and the femoral vein was already described by Lock et al [15]. In mid-ventricular and apical VSDs, the arteriovenous loop is performed through the right jugular vein. However, the retrograde approach from the femoral artery can be done by using devices with symmetrical discs that allow easy access and rapid treatment of the VSD [3, 12].

The new Lifetech KONAR-MF™ Multifunctional Occluder (MFO) was developed to allow the occlusions of small to large defects that can be placed through both vascular approaches, anterograde and retrograde.

The purpose of this study is to report the short- and mid-term results of perimembranous and muscular VSDs closure with the use of the new MFO.

Materials and Method

The experience with the new MFO for endovascular closure of VSDs began in October 2017.

Device design

The MFO is a self-expanding occluder consisting of a layer nitinol wire mesh with 144 wires of 0.002" nitinol cables. It has two discs joined by a waist, which is formed by a truncated cone. The base of this cone is attached to the left disc and from the vertex, which is umbilicated, hangs an arm that joins it to the right disc. This arm allows articulation to the right disc. The length of the waist is 4 mm and stretches up to 7 mm.

The left disc or "high-pressure disc" is attached to the base of the truncated cone of the waist, and the right or "low-pressure disc" is attached to the waist arm. Each disc contains a 2.4 mm long hub with a screw so that the device can be positioned retrogradely or anterogradely. Both discs of the device are of equal size. It is a symmetric device.

The base of the cone or "D2" has a diameter of 2 mm greater than the vertex. adding 2 mm on each side to "D2" we obtain the diameter of the left disc or

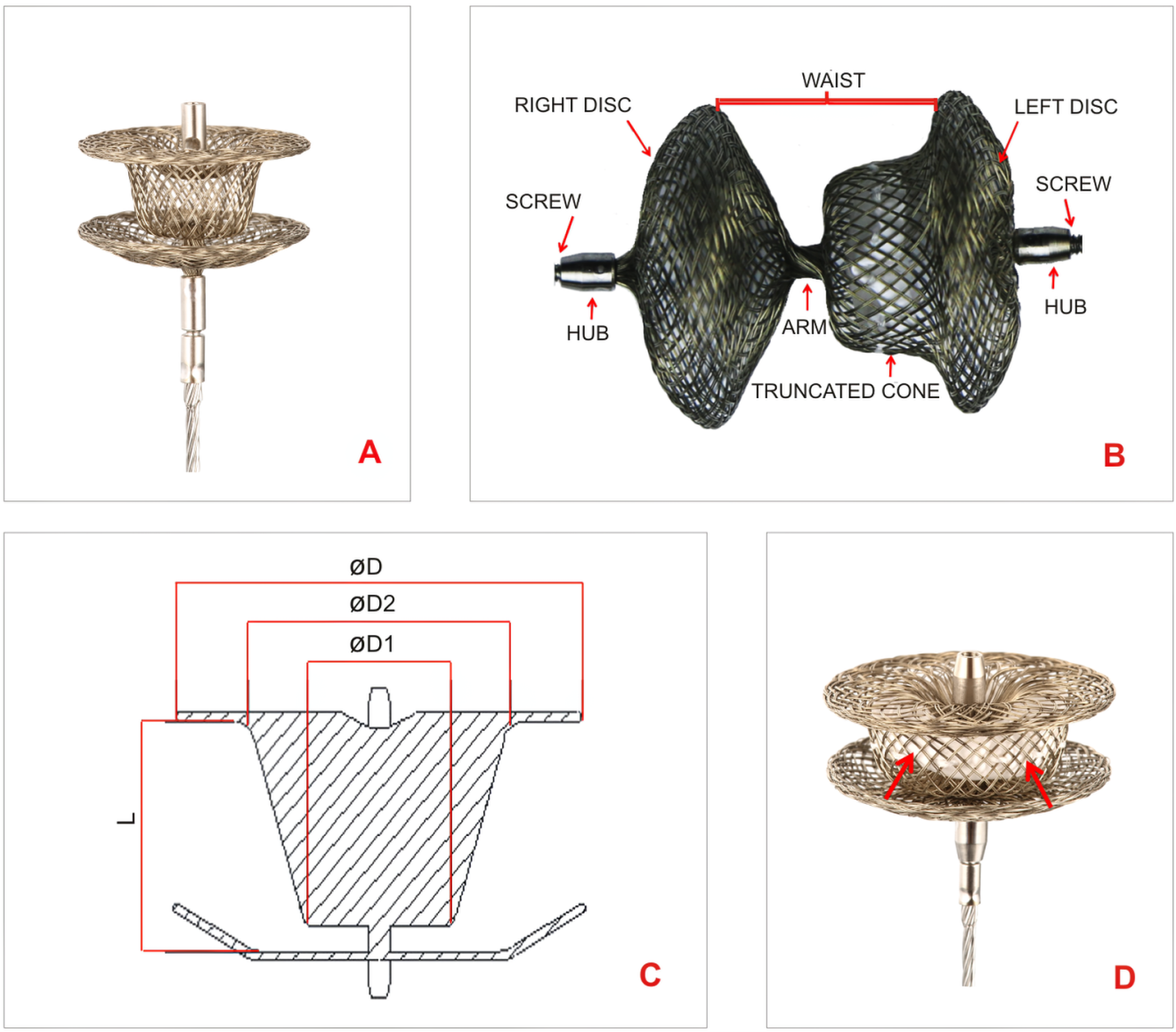

Figure 1. Konar-MFO. ***Panel A.*** The device. ***Panel B.*** The design. ***Panel C.*** Device Components Denomination: ***(Panel D)*** Disc diameter, ***(Panel D1):*** Waist Diameter Right Ventricular side ***(Panel D2):*** Waist Diameter Left Ventricular side. ***Panel D.*** The arrows show the PTFE.

"D", except for the 5-3, 7-5 and 9-7 devices where 2.5 mm must be added on each side.

Devices whose disc diameters "D" is ≥ 14 mm have a PTFE membrane inside (Figure 1).

The delivery system consists of a sheath and a cable (Figure 2). The cable has a thickness of 3 fr and a length of 1,5 m. On one side it has a screw to hold the device and on the other a handle that allows the device delivery maneuver with a counter-clockwise rotation. The delivery sheaths diameter depends on the diameter of the device (Table 1).

All procedures were performed under general anesthesia and patients were anticoagulated with Heparin 100 IU / kg and repeated 50 IU / kg every hour. 7500 IU were used in adults and afterward added 2500 IU more.

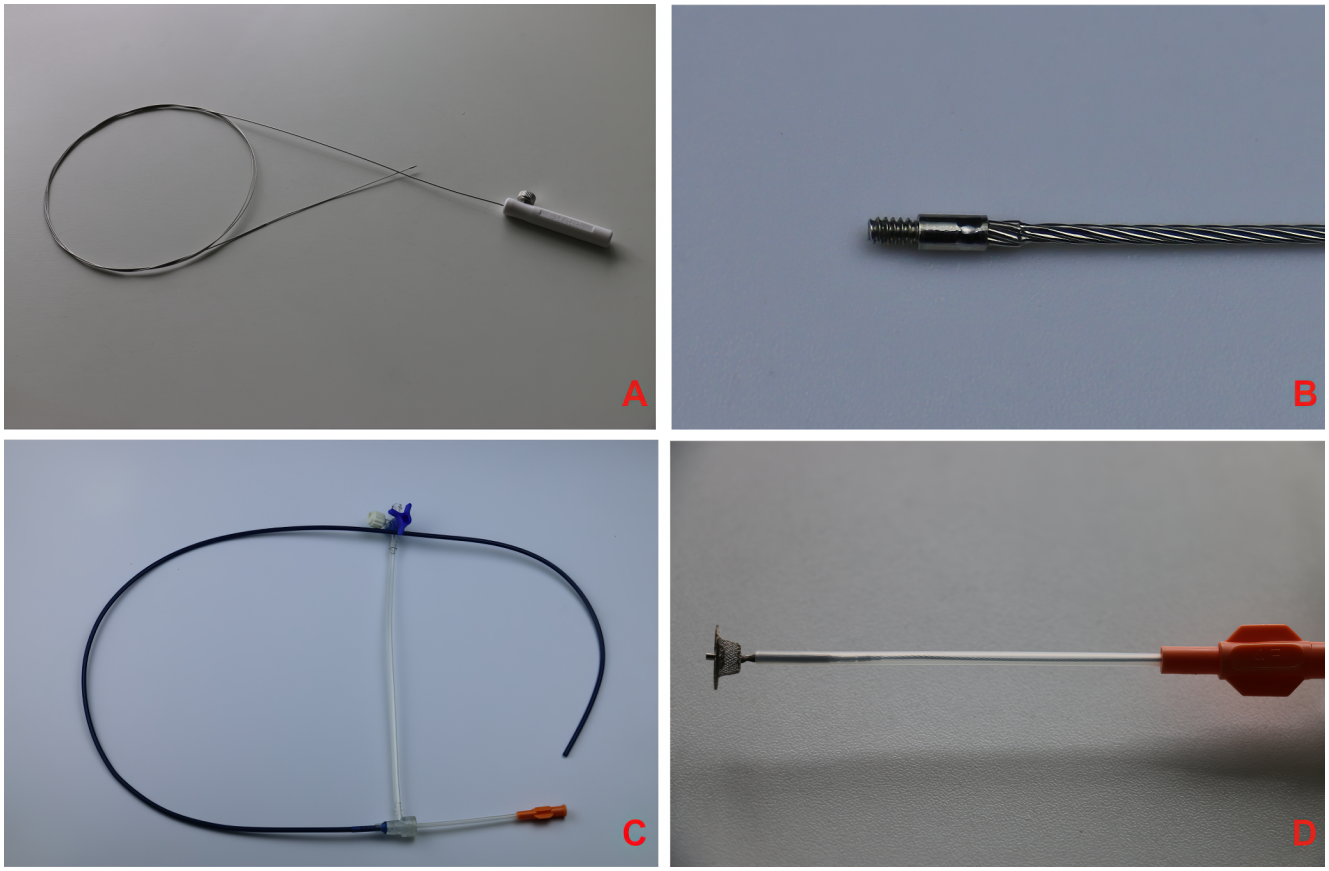

Figure 2. Delivery System. ***Panel A.*** The cable has, on one side a screw to hold the device and on the other side, the handle. ***Panel B.*** The screw that holds the device. ***Panel C.*** The sheath. ***Panel D.*** The loader with the device.

Protocol design

Inclusion criteria

1. Patient > 2.5 kg
2. Perimembranous VSD with aneurism
3. Muscular VSDs with adequate rims
4. Pulmonary/Systemic flow (QP/QS) > 1.5:1
5. Clinical and/or echocardiographic signs of volume overload
6. Pulmonary resistance (PR) ≤7UW
7. History of endocarditis

Exclusion criteria

1. Perimembranous VSDs without aneurysm
2. Muscular VSDs with inadequate rims
3. Not perimembranous or muscular VSD type
4. PR > 7 UW
5. Associate congenital heart disease of exclusively surgical resolution

All previous measurements for the patient selection were made with transthoracic echocardiography (TTE), included the right orifice, the left orifice, and the VSD length.

During the procedure, the patients over 5 Kg, were measured with transesophageal echocardiography (TEE) and under 5kg by transthoracic echocardiography (TTE).

Patients with perimembranous and high muscular VSDs performed 24 hours Holter before the procedure as well as an electrocardiogram (EKG) for those with the prior disorder.

The choice of the appropriate device is related to the TTE measurements of the VSD orifices, the size of the waist and the high-pressure disc of the device. The waist diameter, suggested by the device Company, is 2 mm greater than the maximum diameter of

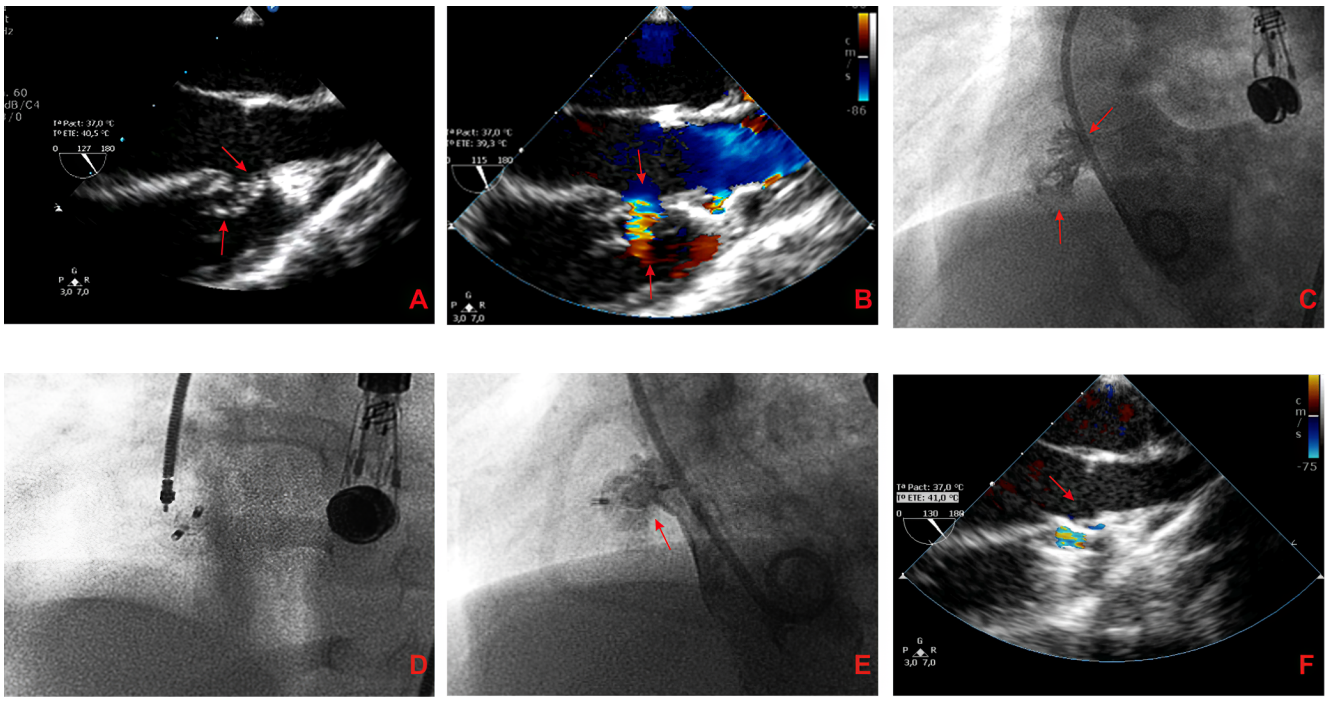

Figure 3. Perimembranous VSD. ***Panel A.*** TEE 120 degrees view. The arrows show the VSD. ***Panel B.*** TEE 120 degrees with Doppler color where the arrow shows the flow of the color through the VSD. ***Panel C.*** Left Ventricular Angiography (4 chambers): the arrow shows the VSD. ***Panel D.*** Retrograde approach positioning of the device. ***Panel E.*** Left Ventricle Angiography (4 chambers): the arrow shows the correct position of the device. ***Panel F.*** TEE 120 degrees view that shows the trivial residual shunt.

the right orifice of the defect. The left disk has a main role in the perimembranous and high muscular VSDs, due to the risk of AV block. In the case of perimembranous VSD with more than one right orifice, the device will need to be placed inside the aneurysm to avoid the conducting system and to occlude all the right orifices. This is achieved with a retrograde approach (Figure 3).

In muscular VSDs, the device has to inevitably lay over the interventricular septum; special care has to be taken in high muscular VSDs due to the direct relationship with the conduct system (Figure 4).

Follow up

- 24 hs: Thoracic X-Ray, EKG and TTE.
- 1 month: EKG and TTE.
- 3 months: EKG, TTE, and 24hs Holter.
- 6 months: EKG and TTE.
- 1 year: Thoracic X-Ray, EKG, TTE and 24hs Holter.

Statistics Analysis

T-Test or Student Test was used in the statistical analysis. Statistical significance is $p < 0.05$.

Results

17 procedures performed on 17 patients: 14 patients > 10 kg and 3 patients <5 kg.

> 10 kg

Sex: 9 males, 5 females; *Age*: median 12.67 years (1.11 to 37 years); and *Weight*: mean 39,96 kg ±SD (12 to 89 kg).

2 patients had complete right bundle branch block prior to the procedure, both postoperative.

VSD type

- Perimembranous VSD with aneurysm: 4 patients. 2 of them had 2 right orifices.

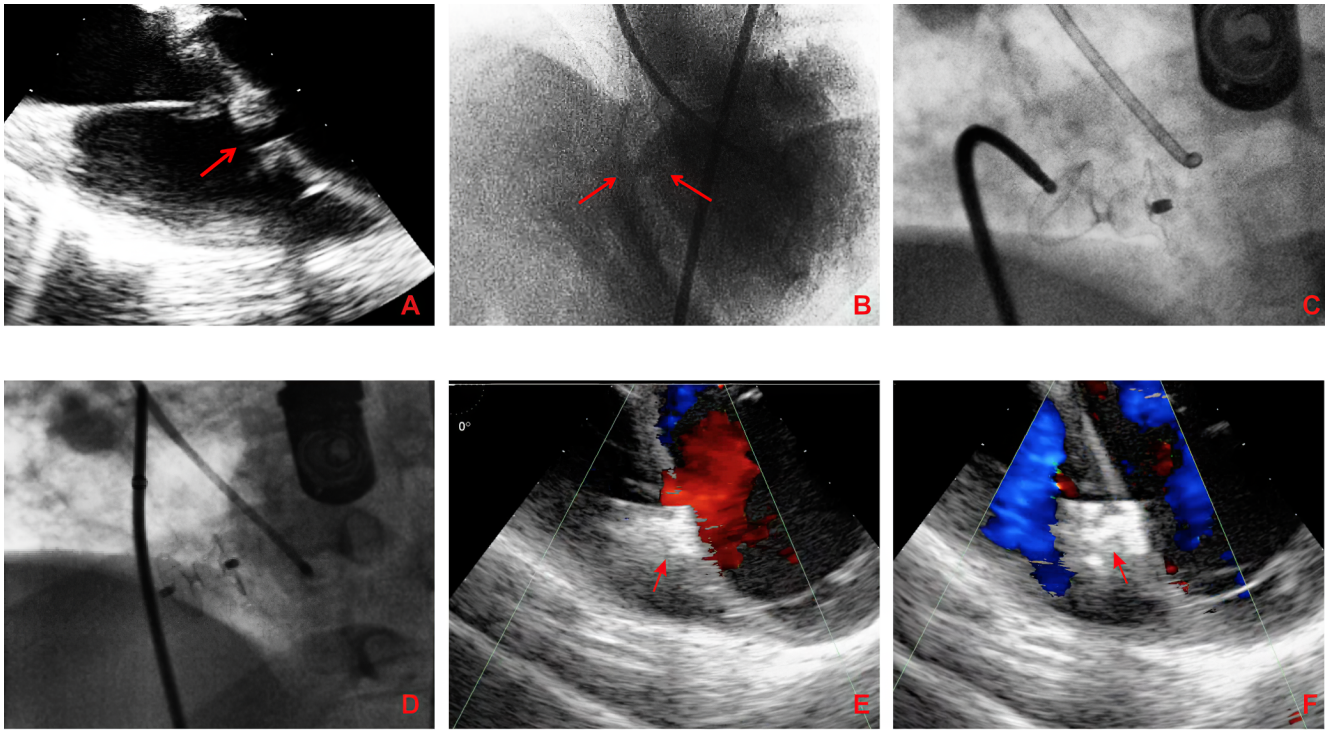

Figure 4. Muscular VSD. ***Panel A.*** TEE 0-degree view. The arrow shows the Muscular VSD. ***Panel B.*** Left Ventricle Angiography (4 chambers): The Muscular VSD is shown by the arrows. ***Panel C.*** MFO Anterograde approach positioning. ***Panel D.*** Left Ventricle Angiography (4 chambers): The device is correctly in place. ***Panels E and F.*** TEE shows no residual shunt.

- Muscular VSD: 8 patients (5 high-muscular and 3 mid-ventricular VSDs). 1 patient had a Ductus Arteriosus associated that was also closed in the same procedure.
- 2 postoperative VSDs: 1 patient had a Perimembranous VSD surgically repaired who suffered from endocarditis and presented with a residual shunt, and 1 patient had Tetralogy of Fallot surgically repaired with a residual VSD and Subtricuspid left ventricle-right atrium shunt.
- 2 postoperative VSDs: 1 patient had a Perimembranous VSD surgically repaired who suffered from endocarditis and presented with a residual shunt; The other patient had Tetralogy of Fallot surgically repaired with a residual VSD and subtricuspid left ventricle-right atrium shunt.

VSD echocardiographic measurements:

- Left orifice: mean 6.92 mm ±SD 2.83.
- Right orifice: mean 4.54 mm ±SD 1.50. 2 patients had more than one right orifice.
- Length: mean 4.82 mm ±SD 3.72.

Hemodynamic data:

- QP/QS: mean 1.65/1 (1.3/1 to 2.2/1).
- Pulmonary pressure: mean 24/11 (20/10 to 40/16).

The device most frequently used was 7-5. The devices employed were: 5-3: 3 devices, 6-4: 2 devices, 7-5: 4 devices, 8-6: 3 devices, 9-7: 1 device and 10-8 1 device.

The mean of the right waist was 5.07mm ±SD 1.52; the mean of the left waist was 7.07mm ±SD 1.52, and the mean length of the waist was 4 mm.

Endovascular VSD closure was successful in 13 out of 14 patients with trivial to no residual shunt. The failed procedure was on a patient who had a high muscular VSD and persisted with severe residual shunt after the implantation of the device. There was an attempt to close the VSD with a bigger device, but the patient presented a transient AV block during the procedure so the decision was taken to surgically close the defect.

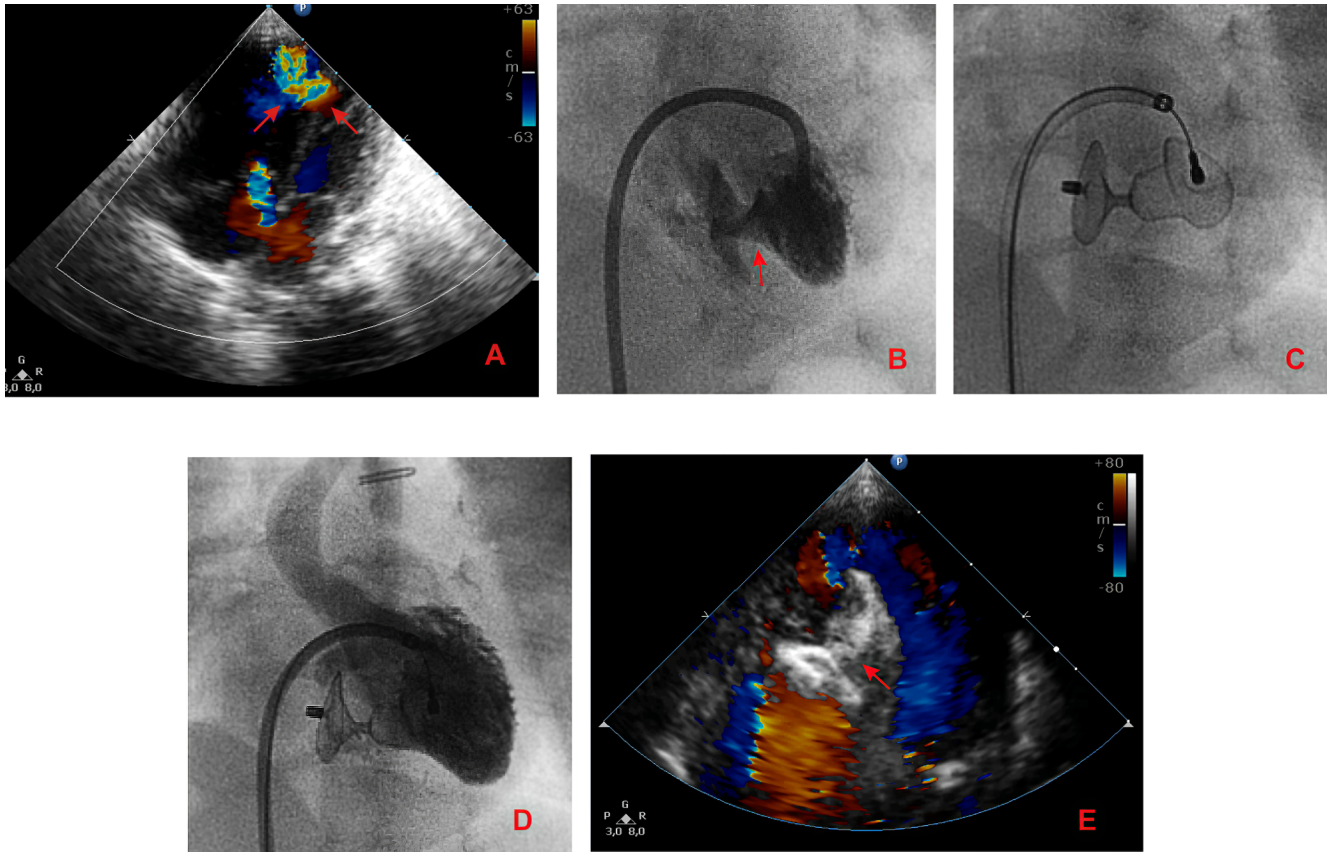

Figure 5. Mid-Muscular VSD. ***Panel A.*** TEE: 4 chambers view shows the Mid-ventricular VSD. ***Panel B.*** Left Ventricular Angiogram: the arrow shows the VSD ***Panel C.*** MFO totally positioned crossing the mitral valve. ***Panel D.*** Left Ventricular Angiogram: a trivial residual shunt can be observed. ***Panel E.*** TEE: 4 chambers view: the arrow shows the trivial residual shunt.

Follow up

The mean follow-up was 5.75 months (1 to 10 months). No complete AV block, hemolysis or mayor complications were observed throughout the follow-up.

< 5 kg

Patients <5 kg had another congenital heart disease associated with severe hemodynamic repercussions. All 3 patients presented with heart failure and pulmonary edema.

The mid-ventricular muscular VSDs were the type of defect.

The associated congenital heart diseases were as follow:

Case 1

1-month-old, 3 kg. Suffered from severe Aortic stenosis and severe Aortic coarctation associated with patent Ductus Arteriosus and a muscular VSD. Aortic valvuloplasty and balloon angioplasty were performed and, 4 days later, the Aortic arch was surgically repaired and the Ductus closed. A week later, the patient remained with heart failure and pulmonary edema, so endovascular occlusion of the VSD was successfully done (Figure 5).

Case 2

3-month-old, 3 kg. Presented with transposition of great arteries and a muscular VSD. After being surgically repaired with arterial switch technique, the patient persisted with residual VSD and severe heart

Table 2. Shows the hemodynamic data, VSD measurements, the devices used and the immediate results.

Case	Left To Right Shunt	Pulmonary Hypertension	Left Orifice	Right Orifice	Length	MFO	Residual Shunt
1	Severe	Severe	8 MM	8 MM	4 MM	10/8	No
2	Severe	Severe	5 MM	7 MM	3 MM	8-6	Mild
3	Severe	Moderate	5 MM	5 MM	3 MM	6-4	No

failure reason why endovascular occlusion of the VSD was performed.

Case 3

5-month-old, 5 kg. The anomaly associated was an obstructed infradiaphragmatic pulmonary venous return. After the surgical repair, the severe pulmonary hypertension persisted so Nitric Oxide was required. After 10 days, the pulmonary pressure decreased and endovascular VSD occlusion was performed. During the Pulmonary vein re-stenosis surgery, the patient died.

Table 2 shows the hemodynamic data, the VSD measurements, the devices used and the immediate result.

Follow up

Case 1

Good clinical condition with Aortic re-coarctation waiting for a new angioplasty.

Case 2

The patients died 15 days after the procedure due to sepsis.

Case 3

The patient developed a progressive severe Pulmonary Vein Stenosis and died during the surgery.

Discussion

VSD closure has historically been surgical [3-6]. After Lock [15] performed the first VSD occlusion by catheterization, different devices and vascular approaches have been proposed.

VSD closure was historically treated through surgery [3-6]. After Lock[15] performed the first VSD occlusion by catheterization, different devices and vascular approaches, such as Nit-Occlud® PDA coil, Flipper® PDA [9, 10] coil and AMPLATZER™ [11, 12] devices for muscular VSD and Ductus ADO II devices [13,14]. have been used to perform the closure.

Few complications were reported, being complete AV block the most feared [7, 8, 17-19].

The endovascular occlusion of perimembranous defects with the MFO device has the same feasibility as other known devices. The MFO great versatility in the vascular access, allow the possibility of closing defects of larger sizes with lower profile sheaths that can be placed through both vascular approaches, anterograde and retrograde, expanding the spectrum of patients who can benefit from the alternative closure by catheterization, among others.

In the short term follow-up, we did not observe in the cohort patients the complete AV block, however, it is a complication that can appear at any time that requires [19] a close follow-up.

In the vascular access, we usually use the antegrade approach for mid-ventricular and apical muscular defects, leaving the retrograde maneuver for the perimembranous and high muscular VSDs. Depending on the circumstances, avoiding the arteriovenous loop can simplify the procedure and reduce the risks associated with this technique. Moreover, avoiding arterial puncture represents a great advantage, especially in small patients. The MFO's great versatility, due to the double hub with screw-in both sides, allows the occlusion of the VSD in an antegrade or retrograde way according to convenience. In complex cases where the placement of the device is challenging, we suggest the use of the antegrade approach.

When using the retrograde approach, the right disc has to be completely open on the right side of the VSD so when it is pulled gently towards the left side, the full occlusion of the right orifice is performed. Later on, the waist and left disc are deployed within the aneurysm, with no differences regarding residual shunt between both approaches.

The patent foramen ovale (PFO) allows reaching through the mitral valve, the left ventricle and catheterizing mid-ventricular and apical VSDs from the cavity. Caution must be placed during the procedure in order to avoid injuries to the mitral valve. The guides must be covered with the catheter at all times and the placement of the sheath through the mitral valve must be done carefully.

Smaller devices contain compact mesh, compare to the larger ones. The PTFE membrane is needed inside the larger occluders to facilitate the closure.

The MFO devices come in different sizes, where the greater diameter of the waist goes from 5 to 14mm and the disc from 10 to 18 mm, enabling the closure of VSDs from 3 mm to 12 mm. To select the adequate device size, the Company suggests that the right waist should exceed the maximum right diameter of the VSD by at least 2 mm. Occasionally the right disc, contributes to the occlusion avoiding the oversize of the device.

In our analysis, the cohort of patients showed that when comparing the right waist of the device with the echocardiographic measurement of the right orifice of the VSD, the mean of the diameters was almost equal. The same result was showed when comparing the left waist of the device with the left diameter of the defect. The result of the analysis of the cohort of patients showed, that the size of the discs had a significant difference with the left waist, which established a linear relationship between the left diameter of the VSD and the size of the discs. The discs device was 4 mm larger than the left orifice of the VSD, concluding that the required size of the disc using the diameter of the left orifice of the VSD should have an additional 4 mm.

Another relevant observation during the analysis for the closure of the perimembranous defects was that the size of the device was ruled by the diameter of the aneurysm, as it had to be placed inside to avoid the AV block, to perform the complete occlusion of the right orifices, sometimes more than one.

The perimembranous VSDs without aneurysm is difficult to be treated with MFO [15-19] since the symmetrical discs might injure the Aortic sigmoids. Eccentric devices can be used for these types of defects where the left disc does not reach the aortic sigmoid valve [22].

Base on our experience, the alternative treatment was able to be offered to patients with very low weight, greater than 2,500 kg [7, 26-28], serious life risk, and did not comply with any requirement needed for other treatments. This group of patients manifests heart failure and acute pulmonary edema due to large defects, greater than 5 mm. Babies with a severe left to right shunt are often symptomatic with failure to thrive and can die from heart failure and respiratory compromise if the medical treatment is insufficient and the closure is delayed. Only patients with mid-ventricular and apical VSD can benefit from MFO for endovascular closure. Patients with high muscular and perimembranous VSDs, especially in patients under 1 year of age, will not be recommended for closure due to the high risk for complete AV block [12]. The low-profile and flexibility of the delivery system is well tolerated by the venous system that allows the crossing through the foramen ovale to LV avoiding the puncture of the arterial, common complication in young children. This is the main reason why Nageswara [26] and Zartner [27] already proposed avoiding arterial puncture in young children.

The postoperative residual VSDs range has been reported between 5 and 25% [30] if reoperation is decided, complications can arise [31]. When residual VSDs are greater than 3 mm and associated with QP / QS over 1.5 / 1, they need to be closed [32, 33]. Base on the information mention before, the endovascular treatment is a suitable option. In our experience, two patients had a residual postoperative VSD and required endovascular closure with no complications in the follow-up. Both patients had post-surgical complete right bundle branch block, so they underwent Holter prior to the procedure that did not show any other type of severe arrhythmia that contraindicated the device occlusion, and they did not present complete AV block during follow-up.

Base on our experience, successful closure was achieved in 92.8% of the cases, without major complications and minimal or no residual shunt. The failed procedure was due to the appearance of transient complete AV block during a reposition maneuver of the device that caused to refer the closure to surgery.

Regarding the group of patients under 5 kg who had severe cardiac diseases, (TCGA with mid-ventricular VSD, critical aortic stenosis with severe aortic coarctation, Total anomalous pulmonary venous connection (TAPVC), the decision was taken to repair the most severe emergent pathology that was putting the patient's life at risk through VSD with the MFO, due to the versatility of the device.

One of the main strengths of this novel device is the presence of a double hub that allows an anterograde or retrograde approach, as well as the low-profile delivery system that allows the closing of large VSDs in low-weigh patients under 5 Kg.

One of the disadvantages of the device in perimembranous VSDs with prolapse of the aortic sigmoid is the symmetrical diameter of the discs that can compromise the function of the aortic valve. As well the length of the right hub (7mm) can injure the tricuspid valve during the device implantation.

This is the first publication of the novel device "MFO" for endovascular VSD closure that is in full development with satisfactory short and mid-term results.

Conclusion

The device increase the possibility of closure of different types of VSD since it allows choosing the antegrade or retrograde approach as well as the closing of a great variety of sizes of VSD and the occlusion of large defects in low-weight patients.

The learning curve of the device, will let us know more details about MFO including the success rate of VSD closure.

Acknowledgments

The author would like to thank Yafeng Luo, regional business manager of Lifetech; Shuanglan He, business manager of Lifetech; and Javier Varde, Lifetech business manager in Argentina, for the collaboration and support to make MFO happen in Argentina.

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

References

1. Mc Daniel NL, Gutgesell HP. Ventricular Septal Defects. Moss and Adams' Heart Disease in Infants, Children, and Adolescents: Including the Fetus and Young Adults, 7th Edition. Chapter 32.
2. Hoffman JI, Kaplan S. The incidence of congenital heart disease. J Am Coll Cardiol. 2002;39:1890-1900. DOI: 10.1016/S0735-1097(02)01886-7
3. Mavroudis C, Backer CL, Jacobs JP. Ventricular septal defect. Pediatric Cardiothoracic Surgery 3rd Mosby, p298-320.
4. Wollenek G, Wyse R, Sullivan I, Elliot M, de Leval M, Stark J. Closure of muscular ventricular septal defects through a left ventriculotomy. Eur J Cardiothorac Surg. 1996;10:595-598. DOI: 10.1016/S1010-7940(96)80371-X
5. Bol-Raap G, Weerheim J, Kappetein AP, Witsenburg M, Bogers AJ. Follow-up after surgical closure of congenital ventricular septal defects. Eur J Cardiothorac Surg. 2003;24:511-515. DOI: 10.1016/S1010-7940(03)00430-5
6. Vázquez F, Mirabal R, González O, González A, Rodríguez O, et al. Resultados del tratamiento quirúrgico de la comunicación interventricular en pacientes pediátricos. Anales de Cirugía Cardíaca y Vascular. 12:28-33.
7. Carminati M, Butera G, Chessa M, De Giovanni J, Fisher G, Gewillig M, et. al. Transcatheter closure of congenital ventricular septal defects: results of the European Registry. European Heart Journal. 2007;28:2361-2368. DOI: 10.1093/eurheartj/ehm314
8. Zhu XY, Liu YH, Hou CJ, Han XM, Sheng XT, Zhang DZ, et al. Risk factors for early arrhythmias post transcatheter closure of perimembranous ventricular septal defects. Zhonghua Xin Xue Guan Bing Za Zhi. 2007;35:633-636. PMID: 17961429
9. Nogi S, Haneda N, Tomita H and Yasuda K. Transcatheter Coil Occlusion of Perimembranous Ventricular Septal Defects. Cardiovascular Interventions. 2008;72:683-690. DOI: 10.1002/ccd.21703
10. Michel-Behnke I, Le TP, Waldecker B, Akintuerk H, Valeske K, Schranz D. Percutaneous closure of congenital and acquired ventricular septal defects. Considerations on selection of the occlusion device. J Interv Cardiol. 2005;18:89-99. DOI: 10.1111/j.1540-8183.2005.04051.x
11. Hijazi ZM, Hakim F, Al-Fadley F, Abdelhamid J, Cao Q-L. Transcatheter Closure of Single Muscular Ventricular Septal Defects Using the Amplatzer Muscular VSD Occluder: Initial Results and Technical Considerations. Catheterization and Cardiovascular Interventions. 2000;49:167-172. DOI: 10.1002/(SICI)1522-726X(200002)49:2<167::AID-CCD11>3.0.CO;2-S
12. Jameel AA, Arfi AM, Arif H, Amjad K, Omar GM. Retrograde Approach for Device Closure of Muscular Ventricular Septal Defects in Children and Adolescents, Using the Amplatzer Muscular Ventricular Sep-

tal Defect Occluder. Pediatric Cardiology. 2006;27:720-728. DOI: 10.1007/s00246-006-1365-5
13. Koneti NR, Sreeram N, Penumatsa RR, Arramraj SK, Karunakar V, Trieschmann U. Transcatheter Retrograde Closure of Perimembranous Ventricular Septal Defects in Children with the Amplatzer Duct Occluder II Device. J Am Coll Cardiol. 2012;60:2421-2422. DOI: 10.1016/j.jacc.2012.08.1004
14. Borges F, Sparano A, Robles Y, Urbano E, Hermanni M, Zabala R, et. al. Percutaneous Transcatheter Closure of Perimembranous Ventricular Septal Defects in One Working group, Long-Term Follow up. J Pediatr Neonatal Care. 2016;5:168. DOI: 10.15406/jpnc.2016.05.00168
15. Lock J, Block P, McKay R, Baim D, Keane JF. Transcatheter Closure of Ventricular Septal Defects. Circulation. 1988;78:361-368. DOI: 10.1161/01.CIR.78.2.361
16. Lillehei CW, Cohen M, Warden HE, Varco RL. The results of direct vision closure of ventricular septal defects in eight patients by means of controlled cross circulation. Urg Gynecol Obstet. 1955;101:446-466. PMID: 13256320
17. Ghosh S, Sridhar A, Sivaprakasam M. Complete heart block following transcatheter closure of perimembranous VSD using amplatzer duct occluder II. Catheter Cardiovasc Interv. 2017;1-4. DOI: 10.1002/ccd.27177
18. Narin N, Pamukcu O, Tuncay A, Baykan A, Sunkak S, Tasci O, et. al. Percutaneous Ventricular Septal Defect Closure in Patients Under 1 Year of Age. Pediatr Cardiol. 2018;39:1009-1015. DOI: 10.1007/s00246-018-1852-5
19. Predescu D, Chaturvedi RR, Friedberg MK, Benson LN, Ozawa A, Lee K-J. Complete heart block associated with device closure of perimembranous ventricular septal defects. J Thorac Cardiovasc Surg. 2008;336:1223-1228. DOI: 10.1016/j.jtcvs.2008.02.037
20. Tan CA, Levi DS, Moore JW. Percutaneous closure of perimembranous ventricular septal defect associated with a ventricular septal aneurysm using the Amplatzer ductal occluder. Catheter Cardiovasc Interv. 2005;66:427-431. DOI: 10.1002/ccd.20499
21. Esteves CA, Solarewicz LA, Cassar R, Neves JR, Esteves V, Arrieta R. Occlusion of the perimembranous ventricular septal defect using Cera device. Catheter Cardiovasc Interv. 2012;80:182-187. DOI: 10.1002/ccd.24371
22. Hijazi Z, Hakim F, Haweleh AA, Madani A, Tarawna H, Hiari A, et al. Catheter closure of perimembranous ventricular septal defects using the new Amplatzer membranous VSD occluder: Initial clinical experience. Catheter Cardiovasc Interv. 2002;56:508-515. DOI: 10.1002/ccd.10292
23. Bass JL, Kalra GS, Arora R, Masura J, Gavora P, Thanopoulos BD, et al. Initial human experience with the Amplatzer perimembranous ventricular septal occluder device. Catheter Cardiovasc Interv. 2003;58:238-245. DOI: 10.1002/ccd.10406
24. Pedra CA, Pedra SRF, Esteves CA, Pontes SC, Braga SL, Arrieta SR, et al. Percutaneous closure of perimembranous ventricular septal defects with the Amplatzer device: Technical and morphological considerations. Catheter Cardiovasc Interv. 2004;61:403-410. DOI: 10.1002/ccd.10797
25. Yun-Ching Fu, Bass J, Amin Z, Radtke W, Cheatham JP, Hellenbrand WE, et al. Transcatheter Closure of Perimembranous Ventricular Septal Defects Using the New Amplatzer Membranous VSD Occluder. Results of the U.S. Phase I Trial. J Am Coll Cardiol. 2006;47:319-325. DOI: 10.1016/j.jacc.2005.09.028
26. Diab KA, Cao QL, Mora BN, Hijazi ZM. Device Closure of Muscular Ventricular Septal Defects in Infants Less Than One Year of Age Using the Amplatzer Devices: Feasibility and Outcome. Catheterization and Cardiovascular Interventions. 2007;70:90-97. DOI: 10.1002/ccd.21142
27. Koneti NR, Verma S, Bakhru S, Vadlamudi J, Kathare P, Penumatsa RR, et al. Transcatheter Transseptal Antegrade Closure of Muscular Ventricular Septal Defects in Young Children. Catheterization and Cardiovascular Interventions. 2013;82:E500-E506. DOI: 10.1002/ccd.25020
28. Zartner P, Christians C, Stelter J, Hraska V, Schneider M. Transvascular Closure of Single and Multiple Muscular Ventricular Septal Defects in Neonates and Infants < 20 kg. Catheterization and Cardiovascular Interventions. 2014;83:564-570. DOI: 10.1002/ccd.25177
29. Dua JS, Carminati M, Lucente M, Piazza L, Chessa M, Negura D, et al. Transcatheter Closure of Postsurgical Residual Ventricular Septal Defects: Early and Mid-Term Results. Catheterization and Cardiovascular Interventions. 2010;75:246-255. DOI: 10.1002/ccd.22262
30. Zhang B, Liang J, Zheng X, Jiang G, Yang Z, Zhang L, et al. Transcatheter Closure of Postoperative Residual Ventricular Septal Defects Using Amplatzer-Type Perimembranous VSD Occluders. J Invasive Cardiol. 2013;25:402-405. PMID: 23913605
31. Serraf A, Lacour-Gayet F, Bruniaux J, Ouaknine R, Losay J, Petit J, et al. Surgical management of isolated multiple ventricular septal defects. Logical approach in 130 cases. J Thorac Cardiovasc Surg. 1992;103:437-442. DOI: 10.1016/S0022-5223(19)34982-7
32. Yang SG, Novello R, Nicolson S, Steven J, Gaynor JW, Spray TL, et al. Evaluation of ventricular septal defect repair using intraoperative transesophageal echocardiography: frequency and significance of residual defects in infants and children. Echocardiography. 2000;17:681-684. DOI: 10.1046/j.1540-8175.2000.00681.x
33. Dodge-Khatami A, Knirsch W, Tomaske M, Prêtre R, Bettex D, Rousson V, et al. Spontaneous Closure of Small Residual Ventricular Septal Defects After Surgical Repair. Ann Thorac Surg. 2007;83:902-6. DOI: 10.1016/j.athoracsur.2006.09.086

Cite this article as: Damsky Barbosa J, Alonso J, Ferrín L, Rivarola M, Lucini V, Biancolini J, Marques Vitorino A, Ramírez R, Ackerman J, Martinez I, Biancolini F, de Dios AMS. Endovascular VSD Closure with Lifetech KONAR-Multifunctional Occluder - Novel Device. Structural Heart Disease. 2019;5(6):237-247. DOI: https://doi.org/10.12945/j.jshd.2019.001.19