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Percutaneous transcatheter closure of perimembranous ventricular septal defects in one working group, long-term follow up

Abstract

Our goal in this work was to evaluate the safety and efficacy of percutaneous transcatheter closure of ventricular septal defects (VSD), mostly perimembranous types (VSDpm) and long-term results. The VSD is the most common congenital heart disease. Transcatheter percutaneous closure have been a novel technique.

Material and methods: Between December 2004 and December 2013, 300 patients with medical record of VSD were admitted to our study, previously admitted to the cath lab at our center for percutaneous treatment of their VSD with various types of devices. All patients were followed until December 2013, 1 to 109 months. VSD type treated: perimembranous (VSDpm) 93.85 % and muscular (VSDM) 6.14%. The VSD measures before the procedure by echocardiography or at cardiac cath ventriculography were 2 - 18 mm. Successful implantation of the device was 91.4 % in all attempted cases.

The type of device used was Amplatzer 73.30 % and the Nit Occlud Coil 26.69 %. Complications were mostly minor, major complications were 2.49% including the late follow-up. They were complete AV block in 2 cases, 0.99 %; 2 cases need late surgery in the follow up secondary to the VSD closure procedure, 0.99 % and 1 case that required removal of the device in surgery because of Hemolysis 0.5 %.

Conclusions: Percutaneous closure of VSD in experienced hands can be performed safely and successfully with low morbidity and mortality. Long-term results are good; percutaneous closure of VSD is less invasive and could be taken as a reasonable proven alternative in the treatment of perimembranous ventricular septal defects as well.

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Federico Borges,[1] Angelo Sparano,[1] Yudith Robles,[1] Manfred Hermanni,[1] Carlos Garcia,[1] Rosa Zabala,[1] Guillermo Villoria,[2] Manuel Acuñ,[1] Hugo Castro,[1] Roshec Bravo,[1] Ericson Ramirez,[1] Carlos Troconis[3]

[1]Division of Pediatric Cardiology, Caracas Children's Hospital, Venezuela
[2]Division of Cardiology, CMDLT, Venezuela
[3]Division of Cardiovascular Surgery, UCQNE, Venezuela

Correspondence: Federico Borges, Chief of the Division of Pediatric Cardiology, Hospital de Niños J. M. de los Rios, Caracas, Venezuela, Email cardiologoinf@gmail.com

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Abbreviations: VSD, ventricular septal defects; VSDpm, perimembranous ventricular septal defects; Cardiac Cath; cardiac catheterization laboratory; AD, amplatzer devices; NOCD, nit occlude coil devices, VSDM, muscular ventricular septal defect; CAVB, complete atrioventricular blockage

Introduction

The Ventricular septal defects (VSD) are the most common congenital heart defect, being the perimembranous VSD (VSDpm) the highest within its variants, 70 %.[1,2] Percutaneous transcatheter closure of VSD has been only worldwide approved for muscular VSD (VSDM),[3] since in the gold standard treatment for the perimembranous VSD is surgical closure with the use of extracorporeal circulation.[4-7,8,9-11,12-17,18-21] Aside that due to the high rate of complications reported on initial experiences for percutaneous procedures to close VSDpm, such as complete atrioventricular blockage (CAVB).[22,23]

The standard surgical closure has also risks and complications as CAVB in 1.1% of the cases,[5,12,24-27] the post pericardiectomy syndrome, residual shunts beside of being a more invasive procedure.[5,8] On the other side, the interventional modality is an alternative for the VSD closure, tested as a method of first choice in closing VSDM and implemented as an alternative treatment in perimembranous VSD since the first reports of percutaneous VSD closure in 1988.[14,15,28-40]

These works have demonstrated that percutaneous alternative is a successful choice with low morbidity and mortality during the procedure as well as at long-term follow up. Most literature reports are of few cases, larger numbers are from multicenter reports where results also show high morbidity and mortality in the perimembranous VSD closure.[14,15,28-41] This work is a single working group including all VSD types, mostly perimembranous VSD with a long-term follow up.

Background: the Service of Cardiovascular Surgery at the Caracas Children's Hospital lacking of surgical capacity regarding to the large list of patients in need and the Division of Cardiology of that center acting as a referral unit for a government's public pediatric cardiac facility, as a way to address the high demand made this unique opportunity to develops such accumulated skills for this report.

Methods

A review of all patients records diagnosed with VSD were taken down and treated by the working team of the cardiac cath Lab of the Division of Cardiology at Children's Hospital J.M. Los Rios, Caracas, Venezuela, between December 2004 and December 2013.

The team knowing the complications reported in the literature for device closure of perimembranous VSD, decided from the beginning to follow 3 rules of thumb on its attempt of percutaneous closure, to avoid CAVB, namely: no oversizing the device in relation to the size of the VSD, utilization when present of the aneurysmal formation of de septum placing the device within the aneurysm to prevent the bundle of Hiss and not to close those VSD that has had transient CAVB (TCAVB).

Material / devices

The devices used were of the Amplatzer brand, St. Jude Medical industry formerly AGA Medical: the membranous VSD asymmetric

device, the muscular VSD device, the VSD MI, the ASD occluder, the PDA occluder, the ADOII and Nit – Occlude Brand, Coil Spiral Sistem, pfm Industry: NIT- Occlude VSD Le, NIT- Occlude PDA.

All steps of the technique, selected patients and pathologies are described, namely:

Ways of approach: two (2) options were used, the first one the Quick Way (QW) in which the catheter is passed from left ventricle (LV) to the right ventricle (RV) and the first disc of the device is deployed on the RV then the second disc on the LV.

The second one as the Artery-Venous Loop (ASA from Spanish for loop) method in which the VSD is passed from the left to the right ventricle, advancing the guide wire to the vena cava or to the pulmonary artery, then the guide wire is retrieved and exteriorized from the patient through out the femoral vein, establishing this manner an arterio-venous loop or ASA, the device's carriage catheter is advanced from the venous side into the left cavities, the LV if an Amplatzer is to be used, especially for the AVSDm or into the aorta if is a Nit - Occlude Spiral System, the first disc of the device is deployed in left side followed by the second disc in the RV side (Table 1).

Table 1 Patients studied and their characteristics by year

Year	Total
2004	2
2005	14
2006	15
2007	31
2008	74
2009	57
2010	12
2011	37
2012	41
2013	17
Total	**300**

Total patients (p) with VSD, 300 cases.

By Gender: female dominance 53 %.

Age: range 5 months to 56 years.

Weight: range 4.4 - 77 kg.

VSD type: described in 293 patients, 275 membranous, 93.85 % and 18 muscular, 6.14 %.

Hemodynamic data denoting indications for the VSD closure (Score):

- Symptoms such as fatigue, failure to thrive; need the use of medication for CHF;
- Echocardiographic findings: Qp/Qs ratio, AI/Ao ratio, radiologic findings: cardiomegaly, high pulmonary flow or pulmonary venous congestion.
- Assigning one (1) point to each finding/value up to a total of 5.
- Another features were taken in consideration: as finding of a sinus of Valsalva prolapse (SVP) or rupture of a Valsalva sinus (RVS) or a Gerbode defect Table (2-8).

Other associated cardiac anomalies: 54 patients, 18 %; 14 ASD, 4.6 %; 10 PDA, 3.3 %, 1 of them with severe pulmonary hypertension and Situs inversus totalis; 9 combination of ASD and PDA, one of them with Down syndrome and another with severe pulmonary hypertension (PHT); 7 with pulmonary valve stenosis, 2.3%; 2 with coarctation of the aorta, 0.6 %; 2 with moderate to severe tricuspid regurgitation, 0.6%; 1 with permeable foramen ovale (PFO); 1 aortic insufficiency; 1 with mitral parachute valve; 1 with suspected pulmonary hemangioma as finding during the catheterization; 1 adult female with post myocardial infart VSD and 1 adult male with double valve replacement (mitral and aortic).

Table 2 The percentage of patients with indication was 91.14 %[25,58]

Score	Total
Hemodynamic Repercussion	
1	48
2	48
3	64
4	57
5	28
0	26
Total	**271**
With hemodynamic repercussion (HR)	245
VSD CLOSURE INDICATED	**247**
Another Indication without HR	2

VSD sizes: Measured by transthoracic echocardiography (TTE), transesophageal echocardiography (TEE) [31] or by catheterization. Range: 2 to 18 mm of diameter.

Table 3 Reported types of the VSD

Perimembranous	275
Musculars	18
With septal aneurysm formation	195 70.90 %
Sinus of valsalva prolapse (SVP)	33 12 %
Aneurysm and sinus of valsalva prolapse (SVP)	18 6.5 %
Fenestrated membranous VSD	19 6.9 %

Note: in 3 patients the aneurysms were incomplete. 7 patients had multiple VSD with combination of muscular and membranous on 3 patients.

Table 4 Reported location of the perimembranous VSD: n 268

Sub Tricuspid (STr)	141 52.61 %
Sub Aortic (SAo)	59 22.01 %
Basal Medium (BM)	23 8.58%
Sub Pulmonar (Sp)	1 0.37 %;
Not defined (ND)	11 4.10 %.
Membranous muscular (Mm)	24 8.96 %
Postero Basal (Pb)	9 3.36 %
Total	268

Table 5 Combination of some features that subsequently influenced on the results

Features	n	Closed
Septal aneurysm formation	195	146
SVP:	33	15
• Aneurysm + SVP	18	13
• SVP without aneurysm	15	2

Gerbode defects a communication of the left ventricular (LV) to right atrium (RA) in 5 patients 1.6%.

Ruptured sinus of valsalva aneurysm (RSVA) with an aortic to RV shunt, secondary to a thin pars membranous with VSD, 4 patients, 1.3%, in 1 patient it ruptured into both ventricles (Figure 1a- Figure 6b).

Other associated conditions: 1patient with vasovagal syncope, 1 with a pulmonary artery banding (PAB) previously done for multiple muscular VSD.

Table 6 Causes of Failure

Causes of Failure	34
Trasient complete AV block (TCAVB)	7
Prolapses of sinus of valsalva	5
Defect too big for the available devices	1
Aorta overriding the VSD	1
Technical complications	12
Tricusp regurgitation	1
Coronary spasm induced by the catheter	1
Aortic insufficiency	1
Defect too small to cross it	1
Ruptured sinus of valsalva aneurysm to both ventricles	1
Postero basal defect without aneurysm formation	1
Non precised difficult anatomy	1
Cardiac arrest and CPR during the procedure	1

Table 7 In the presence of TCAVB, 3 cases were aborted and 7 failed (10 patients), 3.3%; 4.68% of the aborted and 20.58% of failed[21]

Aborted	64
Trasient complete AV block (TCAVB)	3
Blind pouch aneurysm	7
Right coronary spasm induced by the catheter	2
Severe pulmonary hypertention (PHT)	12
Post Surgical residual VSD too small	2
Ruptured sinus of valsalva aneurysm (RSVA)	7
Too big to the available devices	1
Too small to be close	8
Too big postero basal defect	1
Aortic overriding the VSD	7
No VSD	1
Size of the device non available at Cath Lab	1
Anesthesia related bronchospasm	1
Too small ruptured sinus of valsalva (RSV)	1
Non precised difficult Anatomy	1
Suprahepatic Inferior vena cava agenesis	5
Cardiac arrest and CPR during the procedure	1
Other	3

Table 8 Attempts to VSD closures by year and relationship in percentage of success

Year	n	Attempted	Closed	Failed	Aborted	% Succes excluding aborted
2004	1	1	1	0	0	100
2005	15	15	11	4	0	73
2006	15	11	8	3	4	72
2007	31	26	20	6	5	76
2008	74	72	50	12	12	80
2009	57	43	40	3	4	93
2010	12	8	7	1	4	87
2011	37	28	26	2	9	93
2012	41	30	28	2	11	93
2013	17	12	12	0	5	100
Total	300	246	202	34		82

Another associated risk factors: 2 Jehovah witness, who do not accept blood transfusions.

Associated Syndromes: 16 patients with Down syndrome, 5.3 %; 1 with Alagille syndrome and 1 with Noonan syndrome.

Results

Procedure time: reflected as heparin average time (in between heparin given at VSD diagnosis and measurements by TEE and catheterization until complete the VSD closure) was 50 minutes and the average fluoroscopy time was 33 minutes. In relation with the used techniques, with the loop "ASA" method on 180 patients, 82.56 %; the average heparin time was 53 minutes and fluoroscopy 34 minutes, with the QW method on 38 patients, 17.43 %; the heparin time was 33 minutes and fluoroscopy time 20 minutes.

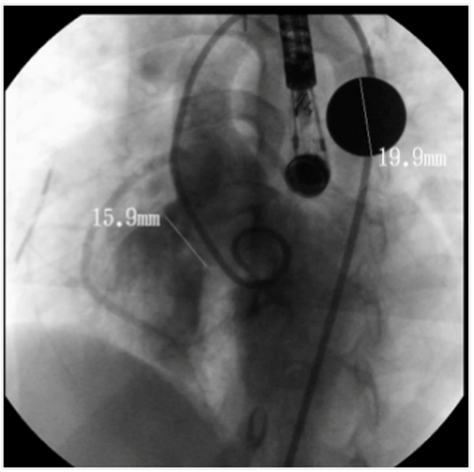

Figure 1a Large perimembranous VSD.

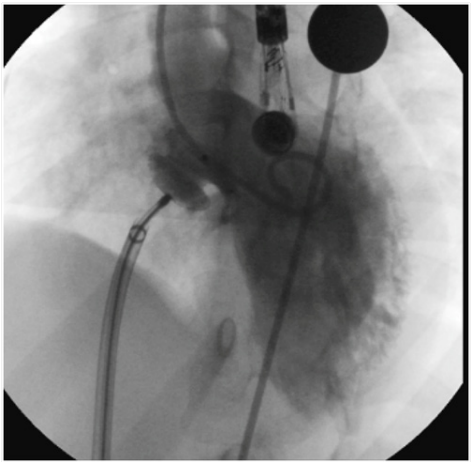

Figure 1b Closed with Amplatzer asymmetric membranous VSD closure devise, "ASA" loop approach.

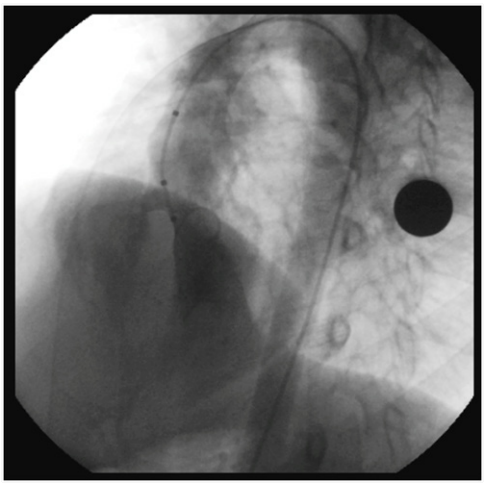

Figure 2a Perimembranous VSD with aneurysm formation.

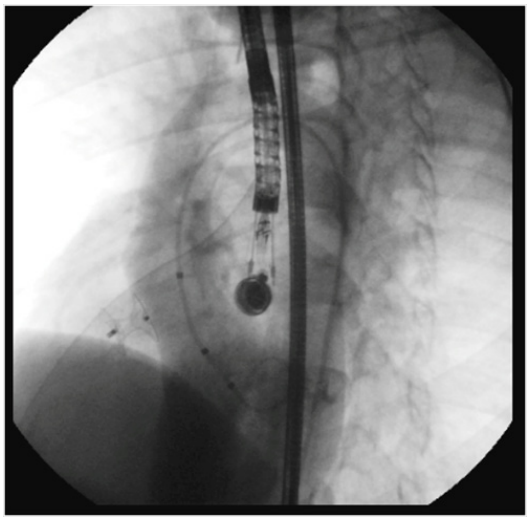

Figure 2b Closed with an Amplatzer Muscular VSD device by "ASA" loop approach.

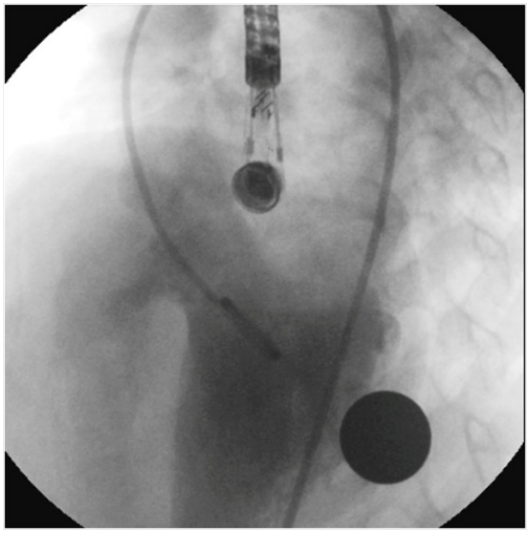

Figure 3a Perimembranous VSD with aneurysm formation.

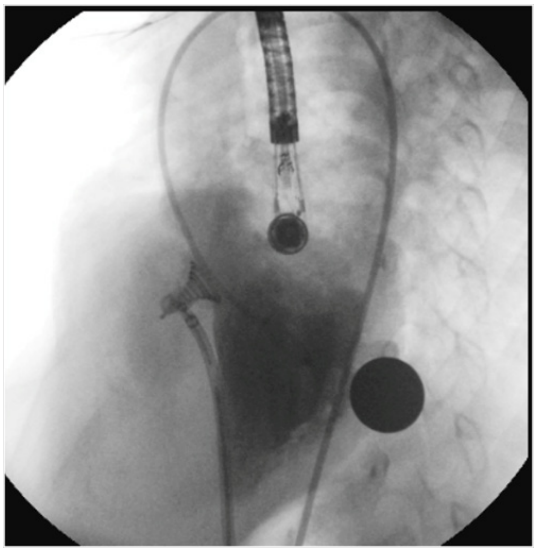

Figure 3b Closed with a NIT- Occlud VSD Le, "ASA" loop approach.

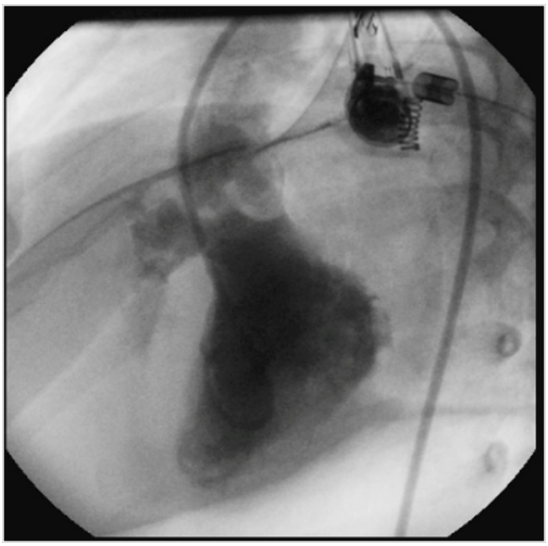

Figure 4a Membranous VSD with fenestrated aneurysm formation.

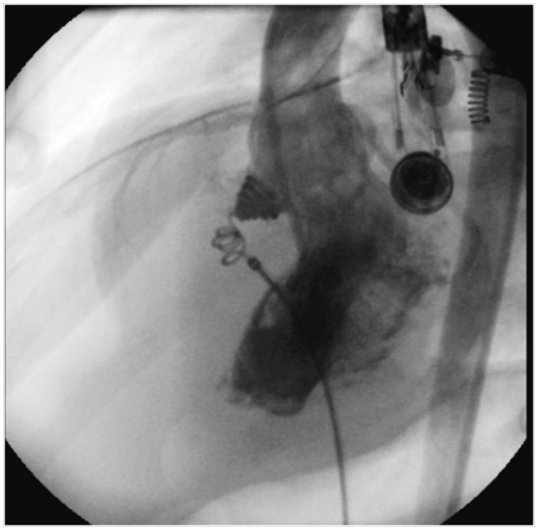

Figure 4b Closed with a Nit-Occlud PDA device, "ASA" loop approach.

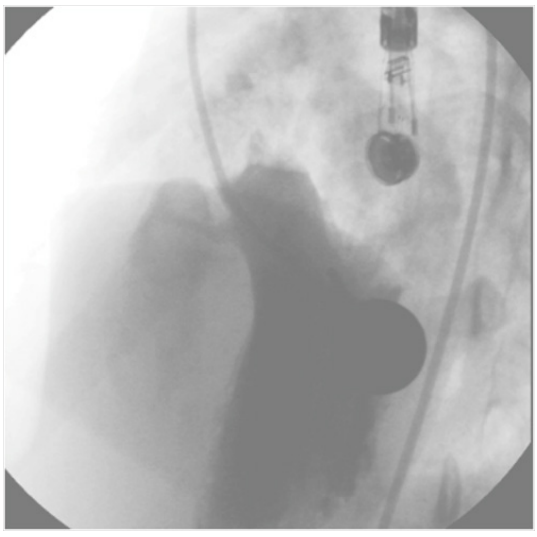

Figure 5a Muscular-membranous VSD.

Citation: Borges F, Sparano A, Robles Y, et al. Percutaneous transcatheter closure of perimembranous ventricular septal defects in one working group, long-term follow up. *J Pediatr Neonatal Care.* 2016;5(1):11–12. DOI: 10.15406/jpnc.2016.05.00168

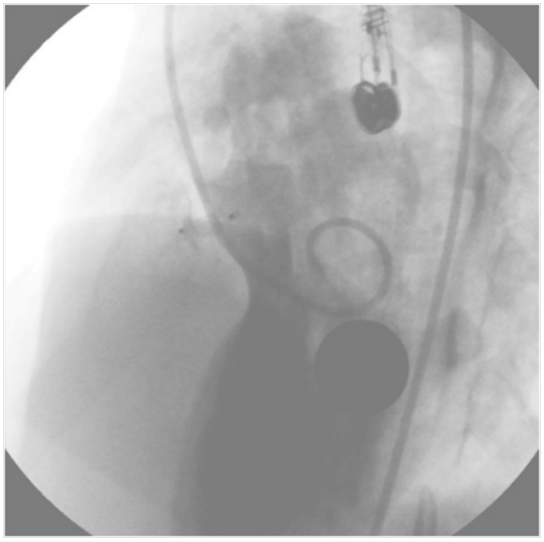

Figure 5b Closed with an Amplatzer ADO II, "Fast way" approach, retrograde.

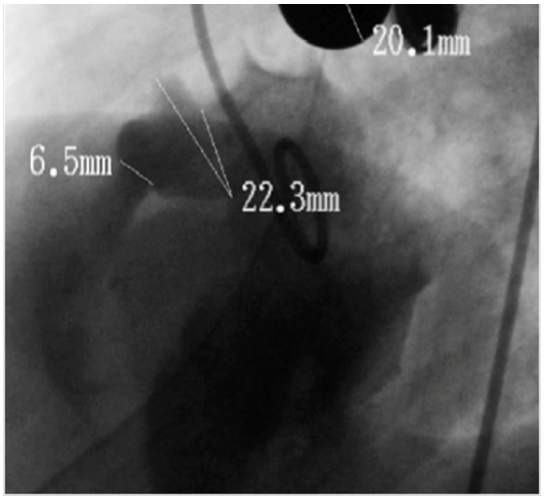

Figure 6a Large membranous VSD with aneurysm formation.

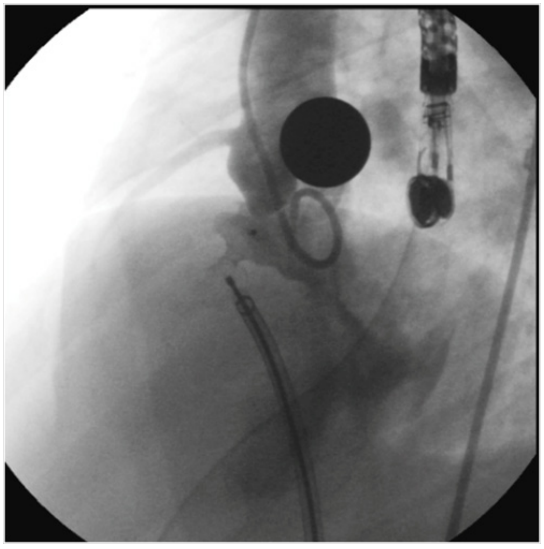

Figure 6b Closed with an Muscular Amplatzer device inside the aneurysm, "ASA" loop approach.

Procedure time and Devices: with Amplatzer the average time was 50 minutes (QW 33 minutes vs loop "ASA" way 56 minutes); with Nit Occlud device all cases were done by the loop "ASA" way and the average time was 37 minutes.

Outcomes definitions: all closed VSD were considered successes, as failure were all those attempts made to close it, crossing the VSD with catheters without achieving the closure and aborted for those that for some reason or features it was not attempted to cross the VSD with the catheter Table (6&7).

Sizing VSD and Device: For the Nit – Occlud technique, the recommended device number should be 4 mm larger than the measured VSD size.[37] That way we avoid oversize the device in relation to the VSD.

Contrarily in the Amplatz technique we used the same number of the device in relation to the VSD size.

The devices were of equal size for the corresponding device number in 26%, of equal size or less in 63%, adding the oversized by 1 mm 80% and by 2 mm 89%; based on the rule of not overdo the device respect the VSD size to avoid the CAVB complication as well as to use a smaller device within the aneurysm formation in which the percentage was 37%.

Access method and success: by the "ASA" loop way the successful rate in 157 patients was 87%. While with the QW in 37 patients was 97 %.

Devices and success: Amplatzer 162 patients, 91.35% success. Nit - Occlude 59p, 93.22 % success. With the Amplatzer types: VSDm, 88p, 88.63 % success; VSDMuscular, 32p, 93.75 % success; ADOII 28p, 96.42 %; PDA device 2p, 100 % success; Septal Occluder ASD device, 3p, 66 % success; VSD Post MI device, 2 failed attempts. With the Nit - Occlud types: VSD Le, 39p, 100 % success and with the Nit - Occlud PDA 20p, 90 % success.

Follow-up time: Between 1 month and 109 months.

Early and Late Complications[30,22]

Residual shunt (RS): Detected immediately in the catheterization, 44p. 21.7 % of the 202 cases closed with devices.

Residual shunt immediately and device: Amplatzer VSDm 8%. Nit - Occlud VSD Le 26 % expected for the type of design. It is more frequent in devices not designed for VSD closure.

Hemolysis: began within a few hours after catheterization, which in our experience was the transient most frequent complication. Found on 5 cases of the 202 closed, 2.48 %. Within those closed with Amplatz devices it was observe on 3 patient, 1.85 %, 2 times in the same patient with a muscular Amplatz device, both removed in the first week and one with an Amplatz muscular VSD that stop in a week with medical treatment; 1 Amplatz VSDm who despite improvement in 7 days went to surgery for device removal and VSD closure.

On the other side, within those closed with the Nit - Occlud it was seen on 2 p, 3.4%; one with a Nit - Occlud VSD Le ended in the first week adding a second type of coil, PDA Nit Occlud. On the other patient closed with a Nit - Occlud PDA (not designed for VSD closure) the hemolysis subsided spontaneously within 2 days.[42]

Early migration: happen on 6 patients of the total recorded 289 cases, 2 %; In 2 Amplatz, 0.69 % and 4 Nit Occlud 1.38 %. On three of them the device tilted into the aneurysm, i.e.: 2 Nit – Occlud and 1 Amplatz. Likewise on two of the 6 patients the migration was seen without the device being released.

Aortic insufficiency: although it was observed during the procedure without the device been release on 2 cases of the 202 closed, 0.99%; the devices were retrieved.

RV dysfunction: 2p, from 202 closed 0.99%.

Tricuspid regurgitation: 5 patients, 3 during the procedure (1.48%) of which one was retrieved immediately, one solved by delay surgery and the third one with medical treatment. Two appeared on the late follow up (0.99%) without hemodynamic repercussion.

Residual shunt on the follow up: Of the 44p with early RS, 38% disappeared spontaneously within 24 hours; additionally 9% on the first week, 43% disappeared spontaneously in its follow-up (1 month to 7 years). On 6.8% persisted during the follow up without clinical repercussion and only one patient needed surgical retrieval and VSD closure 7 years later. Residual shunt and the used device with Amplatzer: 24p, 14.81% and with Nit - Occlud: 20P, 33.89 %.

Late migration of the device: in one patient (0.5 %) the *NIT VSD Le* device migrated 7 years after implanted.

Transient arrhythmias early or late: on 14 patients, 6.93 %, i.e.: Transient AVB 10, 1 alternating Sinus and Nodal rhythm, 1 VT, one transient 1st degree AV block, 1 premature SVT.

Permanent CAVB on the follow up requiring a pacemaker placement:[22] on two patients 0.99 % of the closed ones. Amplatz devices were used on both.

Permanent bundle branch of Hiss block: found on 6 patients, 2.97 %; 4 RBBB and 2 hemiblock of the posterior subdivision of the left bundle branch late on the follow up, all without hemodinamic repercussion.

Surgeries related on the follow up: 14patients that still remain with VSD were sent for surgical closure, i.e.: 4p due to catheterization technical failure; 7p failed for unrelated catheterization causes, 2p because having a large residual VSD and one with a AV canal type of VSD.

Surgeries related to catheterization complications: 3p, 1%. One patient with hemolysis have surgery for device retrieval and closure of the VSD in the first week post implant; the one Nit - Occlud VSD Le mentioned above that migrated into the aneurysm and persisted with a residual shunt at 7 years of follow up and one closed with an Amplatz VSDm that required a tricuspid valve replacement on late follow up.

Cases with no indications for device closure at the catheterization/ echocardiographic evaluation that were sent for surgical closure: 27patients, 9%. (*)

Discussion

For the catheterization technique, the mammary catheter was the most used to cross the VSD because we found that shortens the time. The QW method reduces the heparin and fluoroscopy times in contradiction to the reported by others and shorter than the "ASA" loop way. We also observed that with the "ASA" loop the time of the procedure with the Nit - Occlud was shorter than with the Amplatzer, 37 vs 56 minutes.

Total success is 81.85 % or roughly higher in pure membranous VSD, 84.10 %, When removing the aborted cases and the transient AV block (TCAVB) in the procedure, the overall success rises to 91.4 %. The learning curve took about 4 years (135 cases) from witch the success rose up to above 90 %.

A raise on the percentage of success was enhanced with a better selection of cases, excluding those where a device closure were not indicated and the aborted ones without trying it. After been taken to the cath lab for hemodynamic evaluation the choice of cases with the TEE is the key to success, you can reduce the learning curve if clearly understand the criteria of exclusion and determined the device closure or not. Within the membranous VSD, those with aneurysmal formation have a substantial effectiveness. Less effective are the closure of subaortic location with prolapsed aortic sinus of Valsalva without aneurysm formation. The most frequent causes of failure were mistakenly selection of cases on the establishment of the plan followed by the existence of TCAVB and the prolapse of the Valsalva's sinus which all together were 38 %. While for those aborted, the VSD with severe pulmonary hypertension (PHT) were the main cause, 18%.

Other Aborted reasons such as a very small defect, Valsalva sinus prolapse, overriding aorta and IVC agenesis, 42 %, also were not validated before the catheterization.

Regarding the used devices, there was not significant difference in the success rate between Amplatz and Nit - Occlud; but in cases of outlining the devices needs for closing perimembranous VSD, such as Nit - Occlud VSD Le and Amplatz VSDm, by the ASA loop method there was a consistency in favor of the NIT Occlud, 100 % vs 89%, however the Nit Occlud being used only in those VSD with aneurysm formation improved the chances of success, additionally in the membranous VSD without aneurysm with higher risk of failure, the only one device that can be used is the Amplatzer VSDm, while in another aspect the Amplatz VSD Muscular only has a high success rate when use in the membranous VSD with aneurysm formation and on those muscular approaching it by both methods.

If we add the 0.99% of those closed cases with CAVB that needed a pacemaker implantation and the 3.3% of aborted and failed TAVB, make a total of 4,29%, which resembles the percentage of CAVB of perimembranous VSD in the European register,[22] Hence ending the procedure on those cases with TCAVB could avoid permanent CAVB, furthermore following the rule of thumb of using only devices of the same or smaller size than the size of the VSD or deploying it inside the aneurysm formation. The hemolysis found related to the VSD devices have had the incidence quite similar for both Amplatz and Nit-Occlud.

The complications inherent to catheterization that had to be solved were: 3 by surgery for retrieval and/or closure, i.e. one patient that required a late follow up tricuspid valve replacement (TVR) 0.5 %; one more with hemolysis that required surgery within the first week, 0.5 % and another due to a large residual shunt and thrombocytopenia went to surgery 0.5 %.[43-58]

Conclusion

Percutaneous closure of perimembranous VSD revealed a high chance of success with a low risk of morbidity and mortality. We recommend it as a rational procedure of choice for perimembranous VSD closure when indicated.

Additionally, this technique could well be applied when the surgical closure is not conceivable, as on low income countries where have humans and finances resources limitations.

Acknowledgments

None.

Conflicts of Interset

None.

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