

TECHNICAL OVERVIEW OF PERCUTANEOUS TRANS-CATHETER DEVICE OCCLUSION OF VENTRICULAR SEPTAL DEFECTS WITH VARIOUS BRANDS OF SEPTAL OCCLUDERS. EXPERIENCE AT AFIC-NIHD RAWALPINDI.

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ABSTRACT

Objective: To review our current trans-catheter practices and challenges involved during occlusion of ventricular septal defects (VSDs) and ventricular septal ruptures (VSRs) and share our experience using the varied specialized devices accessible in the market employing several approaches and techniques and the attendant pros and cons attached with each device.

Study Design: Descriptive cross-sectional study.

Place and Duration of Study: At Armed Forces Institute of Cardiology/National Institute of Heart Diseases (AFIC/NIHD), two years retrospective analysis from data gathered on VSD closures on children and adults from Sep 2017 to Sep 2019, including ventricular septal ruptures in patients with acute myocardial infarctions.

Methodology: It is a retrospective descriptive cross-sectional study. The retrospective analysis of all trans-catheter VSD occlusions that were carried out over last 2 years in AFIC/NIHD deploying various brands of VSD closure. We collected 339 cases of percutaneous trans-catheter device occlusion of VSDs from paediatric catheterization data base.

Results: Total no of cases with attempted percutaneous Trans-Catheter Ventricular Septal device Closures were 339 and procedure considered successful in 317 (93.5%) and only 22 (6.5%) cases were not successful. Three (0.8%) cases had transient intravascular hemolysis, while in one case the device had to be explanted.

Conclusion: Trans-catheter occlusion of VSDs is now possible with a variety of devices available. Often at times, in a given situation, more than one device type can produce a similar preferred outcome. Device cost shall however be a major factor in our choice of device selection during VSD occlusions. The success rate compares to surgical patch plasty with minimum morbidity and mortality.

Keywords: Trans catheter VSD occlusion, Ventricular septal defect.

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INTRODUCTION

Surgical closure of VSD is considered to be the gold standard method for closing VSDs but is associated with some morbidity, pain, post surgical scar and incidences of heart block¹. For small VSDs transcatheter VSD device occlusion is a safe and an attractive alternative to VSD surgical patch closure and thus avoids the need for cardiopulmonary bypass². However the long term results and complications are still awaited. Percutaneous trans catheter device occlusion of VSDs is a refined and a composite interventional procedure in structural heart intervention^{3,4}.

Often at times it is accomplished with more than one operators at hand. Requires skills at multiple levels and at times has an element of fortuitousness additional to the procedure⁵. Because of the intricacy of the procedure, the possible various locations involved, each location with its attendant points of consideration, numerous VSD device occluders with variety of pros and cons are available in the market. Only when cognizant with the armamentarium available and the type of subject involved, the dexterity of the operator team with that particular occluder, can a successful outcome be accomplished in each individual case. We present a short experience of two years in our clinical setup and the type of devices available to us and our consideration during deployment⁶.

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METHODOLOGY

It is a retrospective descriptive cross-sectional study. The retrospective analysis of all trans-catheter VSD occlusions that were carried out over last 2 years (i.e. September 2017 to August 2019) in AFIC/NIHD deploying various brands of VSD closure. We collected 339 cases of percutaneous transcatheter device occlusion of VSDs from paediatric cardiac catheterization data base.

The procedures were collected based on ECHO reviews or opinions for cath occlusions. Only those patients who were presented with restricted VSD but without aortic regurgitation and weight more than six kilogram with minimum age one year were included. Few cases were ventricular septal ruptures (VSR) who presented acutely and were in decompensated stage and had to undergo immediate occlusion were also included. Patients who had large VSDs, restrictive VSD with AR were excluded. Cath procedures were performed on Siemen’s single plane equipment. Informed consent was taken before all the procedures.

Data collection was carried out and analysis was performed using SPSS version 23.

RESULTS

All the VSD device data was retrieved retrospectively from Paeds cardiology catheterization

no of cases were 339, details of Percutaneous Trans-Catheter Ventricular Septal device Closures used (table-I). Out of 339 mostly cases were successfully done i.e. 317 (93.5%), only 22 (6.5%) cases were not successful.

Device occlusion was achieved in nearly 339 cases. Only in a few cases 22 (6.5%) the procedure abandoned when it was realized that the device size or shape was unsuitable for the defect. We had few cases who developed first degree heart

Table-I: Details of percutaneous trans-catheter ventricular septal closures.

S. No.	VSD Device Closures	No. of cases
1.	VSD device	266
2.	ASD Device	19
3.	PDA Device	54
4.	Total VSD closures	339

blocks and some cases had a transient 3rd degree heart block. No case with permanent 3rd degree heart block was recorded in our series. We had 3 (0.8%) cases who had transient intravascular hemolysis. In 2 (0.6%) cases, the hemolysis eventually subsided spontaneously while in 1 (0.3%) case the device had to be explanted. No case of device embolization.

DISCUSSION

PFM Nit Occlud Spiral Coil system

Very suitable devices for aneurysmal perimembranous restrictive VSDs but can also be

Table-II: Details of PFM Nit Occlud Spiral Coil system and recommended implantation catheters size.

Nit-Occlud® Lê VSD				
REF ⇅	Coil diameter ⇅	Implantation catheter ⇅	Implantation catheter length ⇅	PU ⇅
149086	8 x 6 mm	6 F	105 cm	1
149106	10 x 6 mm	6 F	105 cm	1
149126	12 x 6 mm	6 F	105 cm	1
149128	12 x 8 mm	7 F	105 cm	1
149148	14 x 8 mm	7 F	105 cm	1
149168	16 x 8 mm	7 F	105 cm	1

database (September 2017 to August 2019). Total

safely deployed in VSDs at muscular regions^{3,7}.

These are springy structures and therefore better adjustable to cardiac structures. Made of Nitinol, these devices have excellent shape memory. The Nit-Occlud device is made from 0.25mm wire and has primary windings and a secondary coil loops⁸. The coil design with securely attached polyester fibers results in a rapid, effective and safe VSD occlusion³. Pre-mounted in 6F and 7F

technical issue that we learnt during the course of our deployments with such devices was that the operator had to be patient enough to allow the device to fall in the left ventricular cavity spontaneously once the LV side coils had been configured and unsheathed in the ascending aorta, and thus allowing the whole device to fall en-block, rather than to pull the LV sided helical

Table-III: Device sizes and recommended mullen sheath.

Nit-Occlud® PDA-R						
REF ⇅	Disc ⇅	Introducer sheath ⇅	Length ⇅	Introducer length ⇅	Stent ⇅	PU ⇅
160102	8 mm	6 F	6.5 mm	90 cm	4 mm	1
160103	10 mm	6 F	7 mm	90 cm	5.5 mm	1
160104	12 mm	6 F	8.5 mm	90 cm	7 mm	1
160105	14 mm	7 F	9.5 mm	90 cm	8.5 mm	1
160106	16 mm	8 F	11 mm	90 cm	10 mm	1
160107	18 mm	8 F	12 mm	90 cm	11.5 mm	1
160108	20 mm	10 F	13.5 mm	90 cm	13 mm	1

delivery catheter it can be safely deployed to occlude VSDs close to the aortic valves and sometimes may actually support the prolapsing right coronary cusp^{3,9}. Can produce a post occlusion temporary heart block. If the choice and size of the device has been assessed correctly, this device has very low risk of embolization. A coil with a distal diameter at least twice the minimal diameter of the vsd on the right ventricular side is appropriate and should be selected. Thus for an 8 mm defect (at the RV end) we would choose a PFM VSD occluder of 16/8 mm. The device is most suitable for aneurysmal defects and a properly selected device can block more than one orifices if present within an aneurysm. The device mechanism is finest if it is snugly located within the aneurysm with closely opposed helical springs and with no residual leak on post deployment echocardiographic analysis and on an LV angiograms taken in LAO 25 and cranial 25 degrees¹⁰⁻¹². The 14 × 8 mm and 16 × 8 mm devices have an augmented axial stiffness, which increases the adaptation to the septum and the fixation of the coil in bigger defects³. One

structure across the aortic valve and in the process end up with an unwound and straightened structure rather than the helical and closely wound wire structure of the device. This we learnt was best achieved by application of a



Figure-1: PFM Nit occlud spiral coil system.

steady tug applied both to the Mullen sheath, the device cable and the implantation catheter at the junction of the aortic valve and allowing it to fall itself within the LV cavity. It is advisable not form the distal disk of Nit-Occlud by unsheathing the device in the LV cavity for fear of entanglement in the chordae of mitral leaflets¹¹.

Once the LV sided loop structure have been unfolded and distal disk formed, the whole assembly has to be pulled across the defect so that the LV sided wires are tightly in opposition with the ventricular septum, and while still applying a constant tug on the whole Mullen

had to be explanted and the patient sent for surgery. In another patient we had to keep the patient admitted and with IV blood transfusions to keep the HB above 10 g/dl^{10,12}.

Konar-MF VSD Occluder

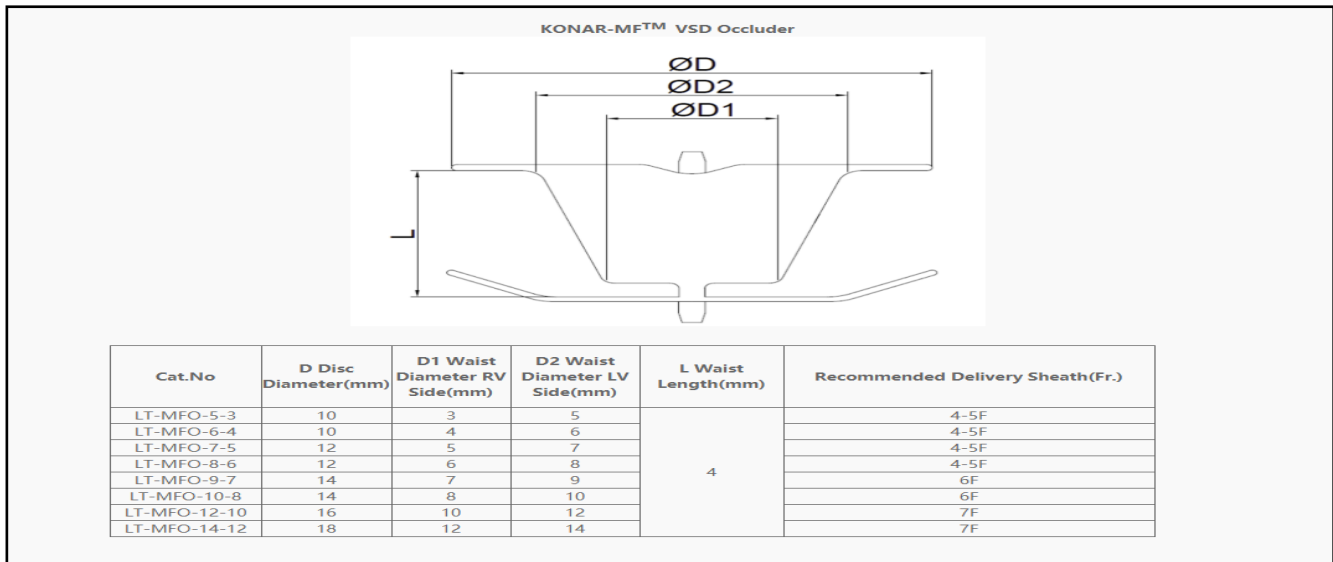


Figure-2: Konar-MF VSD Occluder sizes and recommed delivery sheath.

sheath and the delivery cable, the right sided loops have to be let go for proper deployment. An excessively moving wire structure within an aneurysm implies that the device has not been suitably applied and the whole body may actually be on the LV side of the aneurysm rather than across the defect! The device can be used for doubly committed VSDs with VSD occluded with Angiographic C arm in RAO 30 degrees and in true lateral projections. The device is so manufactured, that a small tip of the helical spring protrudes out of its implantation catheter. If this protuberant part is pulled accidentally into the catheter, it is not possible to push it out. This could be overcome by actually stripping that radio opaque marker at the distal end of the implantation catheter and thus exposing the wire end. Nit-Occlud can be deployed through small introducer sheaths of 6F and 7F and thus permits its use in small infants. There were 03 cases with post procedural intravascular hemoglobinuria. This occurred because these patients had residual flow across the devices. In one patient the device

The standard transcatheter ventricular septal defects (VSD) closure procedure is accomplished by first establishing an arteriovenous (AV) loop circuit and is called an antegrade approach or the transvenous approach. The directly retrograde

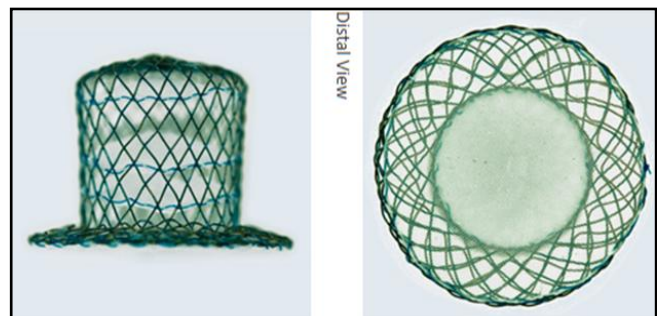


Figure-3: a) Lateral View of PDA-R. b) Distal view of PDA-R.

transarterial VSD closure without using AV loop might be better option as shortens the procedure time and decreases radiation exposure. The Konar-MF occluder device manufactured by Lifetech Scientific is ideal for this purpose^{2,11}. Uses small sized sheaths and therefore can permit

deployment in small infants. The device has double-sided screw for retrograde and antegrade approach. Partnered with 4-7Fr delivery sheath and can be easily deployed in small infants. It is so designed that it can be used for a variety of VSds and especially safe for perimembranous defects with or without aneurysms, muscular VSds and fenestrated VSds. The two discs are connected together by a wire and its soft woven mesh provides high conformability to septal defects. For retrograde implantation, the device requires two arterial lines access. Since the LV disc is essentially a PDA occluder attached via a thin stalk to an RV disc, we utilized a 7/5 MFO device to close a 3mm PDA in an 8 months old 8kg infant, using the retrograde approach and a 4 F Mullen sheath with a successful outcome^{11,13}.

PDA ADO I device

We have also used the regular ADO I device (SHSMA- Lipu) for closure of perimembranous defects. The device has a good retention disc on the LV side and thus can be used to occlude both perimembranous and doubly committed VSds. However this device does not enjoy a primary position for choice selection as a VSD occluder^{12,14}.

PFM PDA -R

The Nit-Occlud® PDA-R is an occlusion system developed by pfm medical ag specifically for closing fairly large PDAs. The implant is knitted from a single nitinol wire. This gives the distal disc a very low profile with no connecting hubs. The rim of the disc is reinforced to facilitate implantation and to avoid pull through. The polyester fabric facing the aorta promotes accelerated endothelialisation²⁻⁴. membranes (depending on the size) are sewn into the implant and one membrane is sewn at the aortic face to ensure immediate closure in the catheter lab and to promote endothelialisation. It has a unique release mechanism and has soft and tension free release¹⁵⁻¹⁷.

We employed this device especially for occluding VSds at the doubly committed area. This premise was based on the assumption that

while it has a longer shank (making it safer with respect to device embolization) as compared to any other device in the market, it does not have a retention disk on the RV side and thus causes least obstruction at the right ventricular outflow tract. The technique employed for VSD occlusion at (DCSA) this position is accomplished in different views than from the usual LAO 25 and Cranial 25 degrees used for occlusion of perimembranous defects. Angiograms are taken in true 90 degrees and in RAO 30 degrees. Once the defect size and location has been assessed, the defect is crossed using a cut pigtail made like a hockey stick. The reason we use a cut end is that the catheter is less able to slip back into the aorta (pushed by the LV stroke output) when compared to a Judkins right heart catheter¹⁶.

By means of a straight-tip wire like the exchange length Treumo wire, the defect is negotiated in LAO 90 and then the wire snared either from the left pulmonary artery or the SVC/IVS. Having made a railroad the Mullen sheath is then passed over the exchange wire and finally parked in the ascending aorta. PDA-R retention disc is then opened in the ascending aorta and pulled into the LV cavity across the valve. The whole procedure is ideally carried out in the LAO 90 degree. The device snaps to a new untagged horizontal position on release from the RV end with its stent projecting in the right ventricular outflow tract^{3,17}.

Muscular VSD Occluders

The original Amplatzer muscular VSD is ideal for catheter closure of muscular VSds (and later clones i.e. Shsma Lipu, Occlutech, Lifetech Scientific, Cocoon). The device can be implanted via the antegrade approach after first establishing an arteriovenous railroad. Our center has a large clinical data on safety and efficacy of VSD occlusions including ventricular septal ruptures using Chinese-made Shanghai Shape Memory Alloy (SHSMA) occluders in patients with congenital heart defects with waist lengths 7mm. This self-expandable double disc device made from Nitinol wire mesh has also been used for

duct closures and AV fistulas. The device is available in many different sizes and allows the operator to close defects located in the apical, posterior, anterior and midmuscular portions of the VSD. We have not used hubless muscular VSD occluders. The device has the added advantage of being cost effective too^{13,18-20}.

ASD for VSRs and VSDs

We have been using ASD devices for post-acute myocardial infarction- ventricular septal rupture occlusions. The procedural success was however guided not by the technical difficulty and complexity involved in the execution of the procedure but by the frailty of patients being offered intervention in a semiconscious, mentally obtunded uncooperative patient with feeble vital signs and poor renal functions^{13,20}.

CONCLUSION

At this point in time, trans-catheter occlusion of VSDs is now possible with a variety of devices available. Often at times, in a given situation, more than one device type can produce a similar preferred outcome. As more data, steadily builds up, we shall be better cognizant regarding the correct choice of device and with its associated attendant pros and cons. Device cost shall however be a major factor in our choice of device selection during VSD occlusions. The success rate compares to surgical patch plasty with minimum morbidity and mortality.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

REFERENCES

1. Garay F, Sandhu S, Cao QL, Hijazi ZM. Device closure of congenital (perimembranous and muscular) and acquired ventricular septal defects using the amplatzer devices: Percutaneous and perventricular techniques. *Heart Views* 2006; 7: 44-54
2. Pfmmedical-productcatalogue-occluder-nit_occludr_pda.

- (Device ref).
3. Vasssen TPL, Freudenthal F, Grabitz RG, Sievert H. Nit OCclud p259-263. Catheter based devices for the treatment of non-coronary cardiovascular disease in adults and children. PS Rao, Morton J Kern. 2003 Lippincott Williams & Wilkins Philadelphia PA 19106 USA LWW.com.
4. lifetechmed.com-en-product_p1.konarmf%E2%84%A2%20vsd%20occluder-index.-aspx
5. Pfmmedical- productcatalogue-occluder-nit_occludr_pda. (Device ref).
6. Sun WF, Dong ZF, Gong K.. Transcatheter Closure with Use of the SHSMA Occluder in 180 Patients with Congenital Heart Defects. *Tex Heart Inst J.* 2010; 37(5): 531-537.
7. en.lepumedical.com-productList_details.html-productID=Occluders1
8. lifetechmed.com-en.product-p1,cera-282.aspx
9. accessdata.fda.gov-cdrh_docs_pdf4-P040040c.pdf From Amplatzer Website
10. Akhtar K, Shah SAA, Mehmood A, Rifat K, Sadiq N, Sultan M et al. Transcatheter occlusion of aneurysmal subaortic ventricular septal defects by means of Nit Occlud (PFM) detachable coils-primary experience in a tertiary center. *Pak Armed Forces Med J* 2019; 69 (1): S48-S52.
11. Amin Z, Gu X, Berry JM. Perventricular closure of ventricular septal defects without cardiopulmonary bypass. *Ann Thorac Surg* 1999; 68: 149-154
12. Amin Z, Berry JM, Foker JE. Intraoperative closure of muscular ventricular septal defect in a canine model and applicability of the technique in a baby. *J Thorac Cardiovasc Surg* 1998; 115:1347-76.
13. Tofeig M, Patel RG, Walsh KP. Transcatheter closure of a midmuscular ventricular septal defect with an amplatzer VSD occlusion device. *Heart* 1999; 81: 438-40.
14. Pesonen E, Thilen U, Sandstorm S et al. Transcatheter closure of post-infarction ventricular septal defect with Amplatzer Septal Occluder Device. *Scand Cardiovasc J* 2000; 34: 446-48.
15. Benton JP, Barker KS. Transcatheter closure of ventricular septal defects; a nonsurgical approach to the care of the patient with acute ventricular septal rupture. *Heart Lung* 1992; 21 : 356-364
16. Lock JE, Block PC, McKay RG. Transcatheter closure of ventricular septal defects. *Circulation* 1988; 78(8): 361-68.
17. Latif HA, alwi M, Khanhavel G. transcathetr closure of multiple muscular ventricular septal defects using Gianturco coils. *Ann Thorac Surg* 1999; 68(5): 1400-01.
18. Saurav A, Kaushik M, Mahesh Alla V. Comparison of percutaneous device closure versus surgical closure of perimembranous ventricular septal defects: A systematic review and metaanalysis. *Catheter Cardiovasc Interv* 2015; 86(6): 1048-56. 17.
19. Arminati M, Butera G, Chessa M, De GJ, Fisher G, Gewillig M. Transcatheter closure of congenital ventricular septal defects: results of the european registry. *Eur Heart J* 2007; 28(8): 2361-68.
20. Wei Y, Wang X, Zhang S, Hou L, Wang Y, Xu Y. Retraction note: Transcatheter closure of perimembranous ventricular septal defects (vsd) with vsd occluder: early and mid-term results. *Heart Vessels* 2012; 27: 398-404.