TRANSCATHETER OCCLUSION OF ANEURYSMAL SUBAORTIC VENTRICULAR SEPTAL DEFECTS BY MEANS OF NIT-OCCLUD (PFM) DETACHABLE COILS-PRIMARY EXPERIENCE IN A TERTIARY CENTER

Khurram Akhtar, Syed Asif Akbar Shah, Amjad Mehmood, Khaled Rifat Abdel Megud, Aziz Ahmed*, Nadeem Sadiq, Mehboob Sultan, Hajira Akbar, Adiba Akhtar Khalil, Kamal Saleem**

Armed Forces Institute of Cardiology (AFIC)/National Institute of Heart Diseases (NIHD)/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Beni Suef University Cairo, Egypt, **Combined Military Hospital Sargodha/National University of Medical Sciences (NUMS) Pakistan

ABSTRACT

Objective: To share a single centre experience of transcatheter device closure of subaortic aneurysmal ventricular septal defects with Nit-Occlud (PFM) detachable Coils at a tertiary cardiac center in Pakistan.
Study Design: A retrospective case series study.
Place and Duration of Study: AFIC/NIHD Rawalpindi Pakistan, from Jun 2018 to Oct 2018.
Material and Methods: A retrospective analysis of all consecutive patients had percutaneous occlusion of aneurysmal sub aortic perimembranous VSD with Nit-Occlud (PFM) detachable Coils was carried out to assess its immediate and short term efficacy and safety.
Results: 12 patients (pts) had aneurysmal per-membranous (PM) VSD were enrolled. In 11 patients successful VSD closure was performed. Mean age of patients was 8 ± 5.7 years. Mean procedural time was 52.69 ± 12 mins. Total fluoroscopy time was 15 ± 8.5 min. Contrast had meant of 54 ± 19.6 ml. 5 were males and 7 patients were females (M:F, 0.8:1). 4 pt's (36.3%) had mild to moderate residual shunts. Closure rate was 81.8% after 1 and 4 months. Onept's had immediate device retrieval, 2 (18.1%) had transient IV hemolysis and 2 (18.1%) had persistent severe IV hemolysis. None of our patients had heart blocks, device embolisation or infective endocarditis during a mean follow-up period of 2 months (range1 to 4 months).
Conclusion: In selected cases VSD closure with Nit-Occlud detachable Coils is safe and feasible with a minimal risk of side effects like heart block. Close monitoring is needed for intravascular hemolysis in patients having residual shunts in the immediate post procedure period.

Keywords: Aneurysmal sub aortic perimembranous,Device embolisation, Heart block,Intravascular hemolysis, Nit-Occlud (PFM) detachable Coils, Percutaneous occlusion, Ventricular septal defect.

INTRODUCTION

Ventricular septaldefect (VSD) is the commonest amongst CHDs (20 to 25%) excluding bicuspid aortic valve. Peri membranous defects are the most prevalent among the VSDs (80%)[1-5]. Surgical closure of VSDs had been the mainstay of management since Gibbon, Lillehei, and Kirklin advent bypass technique in the 1950s to successfully close ASDs[6] till Rashkind reported percutaneous closure VSD's in an animal model in the early 1970s[7]. Lock *et al* first attempted this in human's in 1988[8]. Variable success since then have been reported with the use of devices which were originally designed for closure of other intracardiac defects (Rashkind umbrella device, Lock clamshell, Cardioseal, coils, Sideris buttoned device, Amplatzer etc)[9]. Complications include conduction disturbances[10], device embolization, aortic regurgitation, tricuspid regurgitation, hemolysis, residual shunts[9]and rarely infective endocarditis[11-13].

Although success and complication rate of both methods is comparable percutaneous closure of VSDs is relatively less invasive, has quick recovery and shorter hospital stay[14-16]. Even incidence of the most serious complication i-e complete AV block has not been higher in percutaneous closure as compared to surgery[16].

The Nitinol coil system (Nit-OccludLê) developed by PFM specially for transcatheter

Correspondence: Dr Syed Asif Akbar Shah, Dept of Paediatric, Armed Forces Institute of Cardiology Rawalpindi Pakistan
Email: saashah16@hotmail.com

occlusion of perimembranous defects with aneurysmal septum and cone-shaped muscular VSD defects is available since 2010. The device consists of a nitinol coil fitted with polyester fibres. Its offers minimal complication rate due to its unique flexible design. Nitinol wire have demonstrated to be elastic, adaptable and better malleable to cardiac structures especially when deployment entails the risk of causing a heart block or aortic leaflet damage. We report our very first experience in deploying Nit-Occlud (PFM, Cologne, Germany) devices for the purpose of occluding subaortic aneurysmal ventricular septal defects at a tertiary cardiac center in Pakistan.

MATERIAL AND METHODS

The PFM device has a 0.25mm primary windings and secondary coil loops. The primary windings are made over a straight core wire, creating an extremely adaptable straight tension spring with an internal diameter of 0.25mm and an outer diameter of 0.96 mm. A 0.04mm flat wire is introduced into the lumen of the primary windings. The spring is wound around a feature with an hour glass contour and is shock - heat treated. This procedure forms two disks with a 2mm small central part. The distal disk is larger and much firmer than the proximal disk. The proximal disk is reversed so that the device has a cone in cone shape.

Procedure was performed under general anaesthesia for children younger than 12 years. For older children and adults' local anaesthesia was used. Both arterial and venous femoral access was obtained. A basic angiogram in 25 degree cranial and 25 degree left anterior oblique (LAO) position with a Pigtail catheter was done to clearly delineate the VSD. Judkins right heart or a cut pigtail catheter from the left ventricular side was advanced across the VSD over 0.035-inch Terumo exchange wire in the right ventricle and then pulmonary artery or right SVC. Terumo wire was then snared out via RFV to form an AV loop and allowing us a stable rail road for advancement of 7to 8 F long sheath (Mullen Cook) across the VSD and aortic valve in the ascending aorta.

Evaluation for size, shape, location, physiology, pressure restrictiveness, shunt volume of the ventricular septal defects (with special attention to nearby structures, chordae and size of the aortic rim) chamber size, cardiac function and associated defects was performed by 2D echocardiography using Philips IE 33 with a 5MHz transducer using standard imaging views. Presence of any degree of aortic insufficiency with or without prolapse, involvement of aortic cusps with element of aortic right cusp prolapse and any subsequent grade of aortic valve insufficiency (AI) was also documented. Where the echocardiographic window was not optimal (in some adults cases) TEE study was performed.

Our size selection for a certain size of the defect was based on the following approximate assumption; we simply doubled the maximal size of the defect at the LV end at end diastole to correspond to the device size for the LA disk, for e.g. Nit- Occlud device with a diameter of 16 mm was suitable for a subaortic perimembranous VSD with a maximum diameter of 8mm from the LV end. Nit-Occlud has rounded edges and has a disk-like geometry. The central portion is flexible with better adaptation to the VSD anatomy as shown in Figure after successful closure of the defect.

Our collection of patients was primarily aimed at pursuing the subaorticperimembranous VSDs with or without any grade of AI.

RESULTS

In total 12 cases were performed. Our patients mean age was 8 years with SD 5.7. Mean procedural time was 52.69 mins with SD of 12. Total fluoroscopy time 15 ± 8.5 min. Mean of 54 ml of contrast was used with a SD of 19.6ml. Ten cases were done in general anaesthesia and 2 cases were done in local anaesthesia. 5 were males and 7 patients were females. One patient weighing 3kg, had his PDA occluded by PFM device too. We had no absent pulses following the procedure. Size 5 F and 6F were used for

venous access. And size 4F, 5F and 6F were used for the arterial access. In 2 patients we were able to cross the VSD from the RV side and did not need to create a AV loop for the procedure. In 1 patient we had to retrieve the VSD device as we could not achieve a satisfactory deployment and occlusion of the defect. The device was snared and replaced with a PDA occlude. Four patients had intravascular hemolysis secondary to residual shunts across the device. In two patients, the hemolysis was brief and resolved the next day with hydration and mere observation. In two patients the device had to be pulled out following a persistent fall in hemoglobin and intravascular hemolysis. One of these had his device removed surgically following a 5-day wait, and the other patient had his device removed by transcatheter approach following a wait of 7 days. A VSD muscular device was then used instead. Immediately post procedure, we did not encounter any patient with heart block or arrhythmia, aortic or tricuspid valve regurgitation and infective endocarditis.

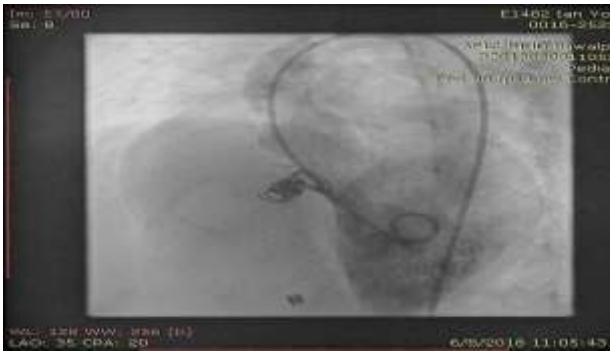

Figure: Post successful deployment of Nit Occuldpfm detachable coil, contrast injection in LV via pigtail catheter showing stable position of coils with no residual VSD.

Data Analysis

We expressed continuous variables as ranges and mean ± standard deviation. Qualitative variables were expressed as percentages. All statistical analyses were performed using SPSS version 20.0; IBM SPSS Software for Predictive Analytics; SPSS, Chicago, IL, United States of America), a *p*-value <0.05 was considered statistically significant.

DISCUSSION

Percutaneous VSD device closure is effective and safe. Successful closure can be achieved in 91.9 to 99% cases[8], 17-24 using various devices[9,17,19,25-27]. Consistent with this, we achieved a successful device implantation in 91.6%. 7 out of 12 (58.3%) patients had complete immediate closure and 4 (33%) had mild to moderate residual leak. We have documented a closure rate of 81.8% at 4 months follow up.

36.3% of our pt's experienced adverse events in early post procedure period whereas none during the follow-up as compared to total 20.5% and serious events in 1.9% of patients in a recently published data of VSD closure with the Nit-Occlude Lê VSD-Coil in 110 patients[22].

Intravascular hemolysis is a relatively common complication following coil occlusion of VSD's in the immediate post procedure period because of residual shunt across the device, causing mechanical fragmentation of red blood cells[28,29]. Hemolysis which occurs in 0.7-15% of cases[10,28] is usually transient, resolves with conservative management but some may need blood transfusion[19,20,22] or might need surgical retrieval of the device in case of massive or persistent hemolysis[17]. In our study four patients experienced hemolysis and two needed blood transfusion because of progressive fall in Hb who ultimately needed retrieval of the device followed by surgical patch closure in one and percutaneous device closure with muscular VSD device in the other one. In the remaining two it was resolved spontaneously in couple of days with improved hydration, although residual shunt persisted on TTE.

Cardiac arrhythmias are not uncommon after device closure of pMVSD due to the defect proximity to the conduction system. Complete heart block has been reported in 0.23–6.4% in several studies[17-20,24,30] which usually occurs immediately after the procedure due to device oversizing, squeezing effect of the device, direct compression or can present late due to fibrous tissue formation secondary to inflammation[19,31].

Adverse hemodynamic outcome may result from commonly occurring right or left BBB. A relatively rare complete LBBB which can potentially cause chamber enlargement or heart failure in some, may resolve with or without steroid therapy[19,24,32,34]. In the current study none of pt's had either complete heart block or BBB in the immediate post procedure follow up period.

Post procedure aortic and tricuspid valve regurgitation are other known complications which usually results from device impingement on valvular leaflets, damage to the aortic valve leaflets or interference with chordae tendinae during device deployment leading to AR or TR respectively[34,17,35]. In one study TR was seen in 5.4% of cases[35] and surgical intervention was required in severe or progressive AR[17,20] or TR[24]. This highlights the importance of monitoring with trans thoracic echo in the pre, intra, and post procedure period. Inner experience one pt had mild to moderate AR following coil occlusion caused by impingement of device on aortic leaflets along with residual shunt resulting in IV hemolysis needing device retrieval. One of our pt's had transient AR in the immediate post procedural period but resolved later. None of our pt's had TR .

Other serious complications like Infective endocarditis and device embolisation are so far reported once by Amal M11 and Haas NA22 respectively but luckily none of our patients had device embolisation or infective endocarditis.

CONCLUSION

Our preliminary experience with Nit-Occlud devices has been inspiring with fairly safe and effective results. However we need to acquire more experience in handling and implantation of this device for both restrictive PM VSDs and also be well acquainted of appropriate patient selection, short-comings and attendant complications to reduce complications risk. The device holds tremendous potential if used for aneurysmal peri membranous VSDs in our setup as the largest chunk of congenital defects are small restrictive PMVSDs for whom serious surgical procedures are not warranted.

LIMITATION OF STUDY

This is a retrospective study done on a very small sample size of a single centre with a short follow-up period.

CONFLICT OF INTEREST

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

REFERENCES

1. Fyler DC: Nadas' Pediatric Cardiology. Hanly & Belfus, Inc., Philadelphia, PA. 1992.
2. SyamasundarRao P: Diagnosis and management of acyanotic heart disease: part II left-to-right shunt lesions. Indian J Pediatr 2005; 72(6): 503–12.
3. McDaniel NL, Gutgesell P: Ventricular septal defects. In: Allen HD, Driscoll DJ, Shaddy RE, Felts TF. Eds. Moss & Adams' Heart Disease in Infants, Children, and Adolescents: Including the Fetus and Young Adult. 7th ed. Philadelphia, PA: Wolters Kluwer/Lippincott Williams & Wilkins; 2008; 667–82.
4. Rao PS: Congenital heart defects – A review. In: Rao PS, ed. Congenital Heart Disease Selected Aspects. InTech, ISBN 978-953-307-472-6, Rijeka, Croatia, 2011; 3–44.
5. Lewis DA, Loffredo CA, Corre-Villasenor A, Wilson PD, Martin GR. Descriptive epidemiology of membranous and muscular ventricular septal defects, the Baltimore- Washington infant study. Cardiol Young 1996; 6: 281-90
6. Rao PS, Harris AD: Recent advances in managing septal defects: atrial septal defects [version 1; referees: 2 approved]. F1000 Res. 2017; 6: 2042.
7. Rashkind WJ: Experimental transvenous closure of atrial and ventricular septal defects. Circulation 1975; 52: II–8.
8. Lock JE, Block PC, McKay RG.: Transcatheter closure of ventricular septal defects. Circulation 1988; 78(2): 361–8.
9. Arora R, Trehan V, Kumar A, Kalra GS, Nigam M. Transcatheter closure of congenital ventricular septal defects: Experience with various devices. J IntervCardiol 2003;16:83-91.
10. Odemis E, Saygi M, Guzeltas A, Tanidir IC, Ergul Y, Ozyilmaz I, Bakir I. Transcatheter closure of perimembranous ventricular septal defects using Nit- OccludLe VSD coil: early and mid term results. Pediatr Cardiol 2014; 35: 817-23.
11. Amal M El-Sisi, Yasser M Menaissy Samia A Bekheet. Infective endocarditis following coil occlusion of perimembranous ventricular septal defect with the Nit OccludLe device. Annals of Pediatric Cardiology 2016; 9: 59-61.
12. Scheuerman O, Bruckheimer E, Marcus N, Hoffer V, Garty BZ. Endocarditis after closure of ventricular septal defect by transcatheter device. Pediatrics 2006; 117: e1256-8.
13. Kassis I, Shachor-Meyouhas Y, Khatib I, Khoury A, Le TP, Lorber A. Kingella endocarditis after closure of ventricular septal defect with a transcatheter device. Pediatr Infect Dis J 2012; 31: 105-6.
14. Chungsomprasong P, Durongpisitkul K, Vijarnsorn C, Soongswang J, Lê TP. The results of transcatheter closure of VSD using Amplatzer® device and Nit OccludLê coil. Catheter CardiovascInterv 2011; 78: 1032-40.

15. Zheng Q, Zhao Z, Zuo J.: A comparative study: Early results and complications of percutaneous and surgical closure of ventricular septal defect. Cardiology 2009; 114(4): 238–43.
16. Saurav A, Kaushik M, Mahesh Alla V. Comparison of percutaneous device closure versus surgical closure of peri-membranous ventricular septal defects: A systematic review and meta-analysis. Catheter CardiovascInterv 2015; 86(6): 1048–56.
17. 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; 28:2361–8.
18. Wei Y, Wang X, Zhang S, Hou L, Wang Y, Xu Y. Retraction note: transcatheter closure of perimembranous ventricular septal defects (vsd) with vsdoccluder: early and mid-term results. Heart Vessels 2012; 27:398–404.
19. Butera G, Carminati M, Chessa M, Piazza L, Micheletti A, Negura DG. Transcatheter closure of perimembranous ventricular septal defects: early and long-t erm results. J Am CollCardiol 2007; 50:1189-95.
20. Yang J, Yang L, Wan Y, Zuo J, Zhang J, Chen W. Transcatheter device closure of perimembranous ventricular septal defects: mid-term outcomes. Eur Heart J. 2010; 31:2238–45.
21. Chungsomprasong P, Durongpisitkul K, Vijarnsorn C, Soongswang J, Lê TP.The results of transcatheter closure of vsd using amplatzerdevice and nit occlud le coil. Catheter Cardiovasc Intervent 2011; 78:1032–40.
22. Haas NA, Kock L, Bertram H, Boekenkamp R, Wolf DD, Ditkivskyy I. Interventional vsd-closure with the nit-occlud, lê vsd-coil in 110 patients: early and midterm results of the eureveco-registry. Pediatr Cardiol 2017; 38: 215–27.
23. Qin Y, Chen J, Zhao X, Liao D, Mu R, Wang S. Transcatheter closure of perimembranous ventricular septal defect using a modified double-disk occluder. Am J Cardiol 2008; 101:1781–6.
24. Liu J, Wang Z, Gao L, Tan HL, Zheng Q, Zhang ML. A large institutional study on outcomes and complications after transcatheter closure of a perimembranous-type ventricular septal defect in 890 cases.Acta Cardiol Sin2013; 29:271–6.
25. Mandal KD, Su D and Pang Y. Long-Term Outcome of Transcatheter Device Closure of Perimembranous Ventricular Septal Defects. Front. Pediatr 2018; 6:128.
26. Nogi S, Haneda N, Tomita H: Transcatheter coil occlusion of perimembranous ventricular septal defects. Catheter Cardiovasc Interv 2008; 72(5): 683–90.
27. Nguyen HL, Phan QT, Dinh LH, Tran HB, Won H, Thottian JJ, et al.Nit-Occlud Lê VSD coil versus Duct Occluders for percutaneous perimembranous ventricular septal defect closure. Congenit Heart Dis 2018;13(4):584-593.
28. Spence MS, Thomson JD, Weber N, Qureshi SA. Transient renal failure due to hemolysis following transcatheter closure of a muscular VSD using an Amplatzer muscular VSD oc- cluder. Catheter CardiovascInterv 2006;67:663–7.
29. Joseph G, Mandalay A, Zacharias TU, George B. Severe intravascular hemolysis after transcatheter closure of a large patent ductusarteriosus using the Amplatzer duct occluder: successful resolution by intradevice coil deployment. Catheter Cardiovasc Interv 2002; 55:245–9.
30. Bai Y, Liu J, Qin YW, Wu H, Zhao XX. Percutaneous closure of perimembranous ventricular septal defect with modified double-disk occluder: what is the outcome at 10-year follow-up.Con-genital Heart Dis 2016; 11:45–51.
31. Walsh MA, Bialkowski J, Szkutnik M. Atrioventricular block after trans-catheter closure of perimembranous ventricular septal defects.Heart 2006; 92:1295–7.
32. Yang R, Kong XQ, Sheng YH, Zhou L, Xu D, Yong YH,. Risk factors and outcomes of post-procedure heart blocks after transcatheter device closure of perimembranous ventricular septal defect. JaccCardiovascIntervent2012; 5:422–7.
33. Kloecker L, Emmel M, Sreeram N. Late complete left bundle branch block after transcatheter closure of a muscular ventricular septal defect. Cardiol Young2010; 20:560–1.
34. Kenny D, Tometzki A, Martin R. Significant aortic regurgitation associated with transcatheter closure of perimembranous ventricular septal defects with a deficient aortic rim. Catheter CardiovascIntervent2007; 70:445–9.
35. Zuo J, Xie J, Yi W, Yang J, Zhang J, Li J. Results of transcatheter closure of perimembranous ventricular septal defect. Am J Cardiol 2010; 106: 1034–7.