TECHNICAL CONSIDERATIONS FOR VENTRICULAR SEPTAL DEFECT DEVICE CLOSURE USING COCOON OCCLUDERS AT TERTIARY CARE CENTER IN PAKISTAN

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ABSTRACT

Objective: Transcatheter device closure of ventricular septal defect (VSD) is now a day's safe and feasible alternative to surgery in most of cases. Ventricular septal defect device closure with cocoon occluders is technically very suitable due to device geometry and compliance. We are presenting our experience with these occluders in our centre.

Study Design: Retrospective cross-sectional study.

Place and Duration of Study: Armed Forces Institute of Cardiology, Rawalpindi, from Jan 2020 to Apr 2021.

Methodology: We analysed the Cath data and video clips of 13 patients who underwent transcatheter closure of ventricular septal defect with Cocoon occluders at our tertiary care centre. The median patient age was 14 years 6 months, and the median patient weight was 28.2kg. Average ventricular septal defect size was 5.36 mm, Average contrast used was 60ml with fluoro time 15.3 minutes, Male to female ratio was 10:8, Two types of devices (perimembranous and muscular) were used. Minimum device size was 6/4 while maximum 10/7. Three ventricular septal defect devices were used for PDA.

Results: All devices were successfully implanted in all patients. The follow-up period was 12 months, and no mortality was noted. In one patients ventricular septal defect cocoon device was used for PDA closure. No complication was observed in all the patients. No immediate residual leak was detected in all patients with perimembranous ventricular septal defect. There was no device embolization and No heart blocks were noted following device closures.

Conclusion: Cocoon devices can be used safely and effectively for ventricular septal defect. Selection of cases is of ultimate importance for optimal results. Although this is one year follow up. Later follow up will elaborate more on the long term results and suitability of these devices.

Keywords: A trial septal defect, Cocoon devices, Patent ductus arteriosis, Ventricular septal defect.

INTRODUCTION

Among all congenital heart defects Ventricular septal defect (VSD) is the leading cardiac malformation[1,2]. Operative treatment of VSD has been undertaken for the last many years with fairly reasonable results with least complications and was considered treatment of choice. But still operative option of closing the VSD carries risks of bypass surgery along with scar formation sometimes complicated by keloid at skin site[3]. Alternatively transcatheter VSD closure by occlusders is becoming more favourable with least complications over the time. VSD is used to be managed with Amplatzer devices to start with catheter based VSD device closure has been done with multiple brands Transcatheter closure of VSD is being done for the last many years with favourable results. Device being used for these defects are of various shapes and brands with continual innovations based on growing operater experiences[4-7]. VSD device closure is being done in our country with various kinds of devices (Amplatzer, Lipu, Pfmcoil, MFO and Occlutech). Presently Cocoon devices (vascular innovations Co, Nonthaburi, Thailand) for VSD sare becoming popular for use in various types of VSD subtypes[8-13]. These devices are relatively softer and compliant compared to Amplatzer device and safe for conduction system. We are using these devices in Pakistan for more than an year for VSD, we are publishing our initial experience of using these devices at our tertiary care center[14].

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METHODOLOGY

Eighteen patients who underwent transcatheter VSD closure with Cocoon devices at our tertiary care institute. Patients were enrolled retrospectively (table-I). There were 7 males and 6 females. The median age was 5.8 years, ranging from 7 months to 48 years, and the median weight was 20.3kg (range 7-59.9kg). Diagnosis and detailed evaluation of anatomical classification and size were performed with transthoracic echocardiography (TTE) before the procedure. All patients had a significant systolic murmur on chest auscultation and VSDs on TTE. Evidence of significant volume overload such as clinical symptoms, cardiomegaly on chest radiography, or left ventricular dilatation on echocardiography was resolved prior to closure. Patients with elevated pulmonary artery pressure, aortic valve regurgitation associated with VSD, or a

defect too large for the device were not candidates for transcatheter closure.

Data are expressed either as mean ± SD or as median (range). The institutional review board approved this study and waived the need for consent from patients or parents.

Characteristics of Devices

The Cocoon VSD device is manufactured with intent to close by catheter various types of hemodynamically significant VSDs. It is a self-expandable, double discdevice made from Nitinol wire mesh coated with platinum using nano fusion technology. The two discs are linked together by a connecting waist corresponding to the size of the VSDs. In order to increase closing ability, the discs and the waist are filled with polypropylene fabric, securely sewn to the wires using polyester thread. Cocoon VSD occluders are available in three different designs to match the types and location of the VSDs to close: membranous type (fig-1), muscular type (fig-2) and Aneurysmal VSD device (fig-3). It is made from Nitinol wires coated with platinum using nanofusion technology. The distance between the two discs is different among the three types of VSD occluders: 4 mm, 7mm, and 10mm. Both side discs are 6mm or 6.5mm larger than the waist. The Cocoon duct occluder has the same profile as the Amplatzer duct occluder.

Device Implantation and Follow-Up

These procedures were done under general anaesthesia and under transthoracic and transesophageal echocardiography (TEE) guidance. Anticoagulation was done with heparin 100 u/kg to avoid femoral artery thrombosis. Pre-procedure selection of exact device size was based on echocardiography in various views preferably in diastolic phase and again confirmed during procedure in multiple LV angiographic views. The device size was based on all echo and angiographic images keeping the largest size in consideration. Final selection of device size was waist size 1-2mm larger than the selected.

Closure of VSD With Cocoon Device

All types of VSDs closures were performed considering the same prerequisites with special attention to device selection Similar procedures were applied for every kind of VSD closure. With the help of Right Judkin (JR) and cut pigtail assisted by Terumo® guide wire VSDs were crossed in retrograde fashion from the aorta (fig-4a). Guide wire was snared from various sites (LPA, RPA, Innominate vein, SVS and IVC) ensuring terumo wire not entangled in tricuspid valve chordae or any other cardiac structure and withdrawn through the femoral venous sheath (fig-2). The catheter was advanced over the guide wire to the inferior vena cava. The selected size of delivery sheath corresponding to device size was passed over the guide wire from the femoral vein to the ascending aorta in a

Figure-1: Membranous VSD.

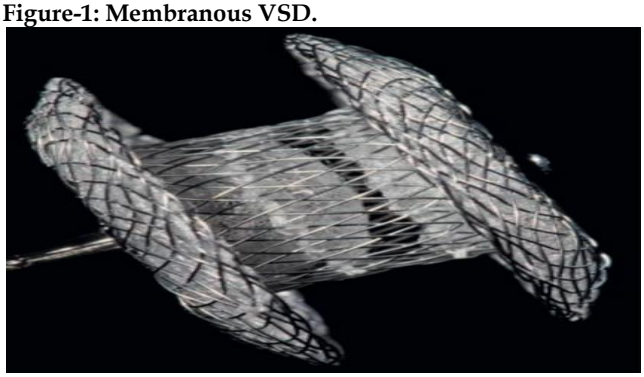

Figure-2: Muscular VSD device.

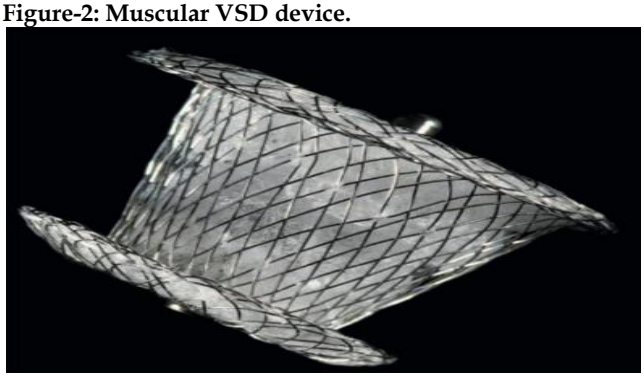

Figure-3: Aneurysmal VSD device

kissing technique in which catheter and dilator of sheath ends were kept close to each other with the help of artery forceps clamped at external ends of sheath and catheter keeping both ends firm while advancing the sheath and pulling the catheter till dilator of sheath was in descending aorta. At this point dilator was pulled in to the sheath in order to avoid trauma to aorta with pointed end of dilator. Thenhard end of

terumo wire was gently pulled out of catheter ensuring no blood loss during this maneuver. RV end of the selected device was screwed on the delivery cable and carefully passed through the delivery sheath. The distal disc was partially opened in the descending and gently withdrawn in to aorta till the device approaches aortic valve. Here cable is gently rotated to make its way through aortic valve, if there was some resistance the device was drawn little more in to the sheath which helped to cross the valve and immediately opened the whole LV disc after crossing the valve. The cable and sheath was gently withdrawn at the desired position of septum confirming position with the help of LV angiograms. The RV disc was released at proper site while confirming by LV angiograms (fig-4b & 4c). After confirmation of device (position, tricuspid valve and aortic valve analysis for regurgiatation, residual flow along the device, stability of the device) by angiograms and transthoracic echocardiograms, the device was released (fig-4d).

Following device closure anticoagulation was continued with IV heparin 50 units/kg 6 hourly for the next 24 hours. During this time the patients were continuously monitored for oxygen saturation, ECG for arrythmias, checking for puncture site, 4 hourly echocardiograms (for device stability, embolization, pericardialeffusion, residualleakage, aortic and tricuspid valve leakge) were done in all patients till discharged next day. Acetylsalicylic acid (5mg/kg/day) was advised for 6 months. Two week, after 3 months and 6 months after the procedure, echocardiogram and electrocardiography were routinely carried out at an outpatient clinic.

RESULTS

All 18 patients showed successful implantation of these devices. The cases were followed up after 6 months and no complication was noted in terms of mortality, device embolization, residual flow, arrhythmia and anemia. We used membranous and muscular devices, no aneurysmal device has been used so far. A device was successfully implanted in all patients.

Muscular devices were best suited for mid-muscular defects due to length and tortuosity of the defects. One device was used for DCSAVSD. Most of the devices used were for membranous defects and 3 devices were used for muscular defects. The mean fluoro time was 15.3min (range 6-39min). Mean contrast used was 60ml. Average weight was 28.2 Kg while average age was 14 years 6 months. Average VSD size was 5.36 min. No patients experienced major procedural complications, residual leak in one patient settled next day of procedure and no conduction abnormalities was

Figure-4a: Membranous VSD.

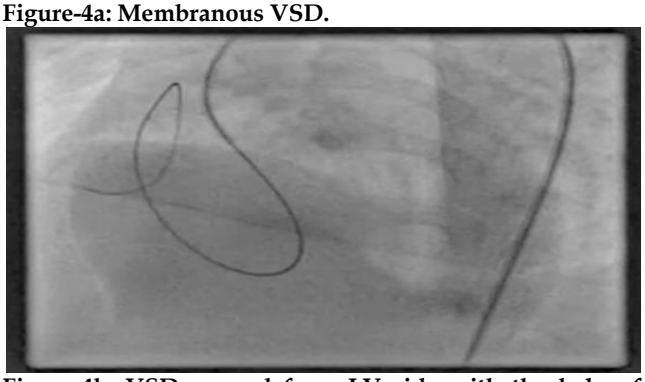

Figure-4b: VSD crossed from LV side with the help of terumo wire which is now in RA.

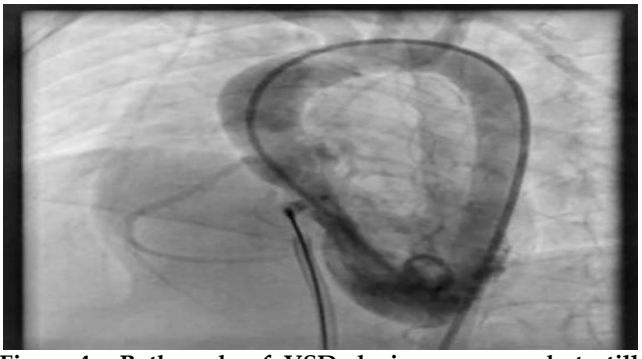

Figure-4c: Both ends of VSD device are open but still attached to delivery cable showing complete closure on LV angiogram.

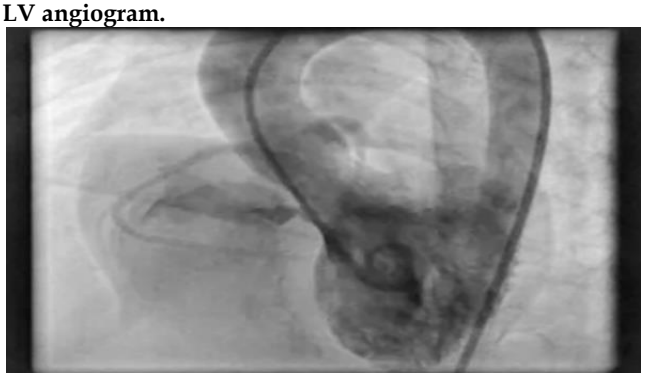

Figure-4d: LV angiogram showing moderate size PMVSD.

observed. No device implantation resulted in aortic regurgitation. In 5 patients VSD device was used to occlude tubular PDAs which resulted in satisfactory PDA closure with no residual leak.

DISCUSSION

VSD device closure with cocoon devices showed optimal results so far. No conduction abnormalities and device related aortic regurgitation has been observed patients. Following the initial transcatheter closures of VSD by Lock *et al*[13], mostly Amplatzer occluder devices[14] have been used worldwide. surgery has been the best treatment of large VSD for the last many years, Catheter related device closure has many benefits like avoiding cardiopulmonary bypass side effects, avoiding scar and keloid formation, reassuring psychologically, limited time in hospital, Limited ICU burden, speedy recovery[15]. Transcatheter closure of muscular VSD is favourite since long[16,17.] and multiple device types have been used[18]. In a meta-analysis study there have been found no differences surgical versus transcatheter closure muscular VSD[18]. Transcatheter perimembranous VSD closure is always tricky requiring good imaging for case selection, avoiding proximity to aortic valve and conduction system, associated aortic regurgitation and aneurysm formation. Selection criteria for catheter closure is same for surgical closure. Large left to right shunt and LA and LV dilatation along with frequent chest infections and tachypnea were considerations in case selection.

Most of the Complications of device closure are immediate post procedure. Expectedly the known hazards of VSD device closure are incompetence of varying degree at right AV and aortic, device migration, conduction abnormalities, residual leakage, pericardial effusion, thrombosis at puncture site, RVOT obstruction in cases of DCSAVSD device closure, contrast related side effects like fever, hypersensitivity reaction and trauma to cardiac structures during AV loop formation and sheath manipulation. All these complications are avoided with meticulous case selection and carefull procedural steps. AV blocks need close monitoring[19,20].

Since we have used membranous and muscular VSD devices so far and limited number of patients are implanted, more experience and volume will guide accuracy of device to be used for a particular lesion in terms of length, location, course of defect and proximity of aortic valve. We have not used these devices till now for postoperative residual significant shunts but seems to be suitable when tried in later cases. Although Amplatzer devices have been used in large volume in the past but these devices have no variability in terms of types, shapes and compatibility to adjacent structures. Cocoon devices are also found suitable for aneurysmal defects when these devices fill the aneurysm and fit with its flexible waist. Now its need of the hour to have variable devices suited for various types of VSDs. Although MFO occluder is becoming popular for VSD closure but sometimes its looks lengthy device compared to defect and seems dwindling in right or left ventricle a potential threat for thrombus formation[21,22].

Sometimes when device is very close to aortic valve which endangers future aortic valve regurgitation due to metallic proximity and intendation of valve leaflets most commonly right coronary cusp with each cardiac cycle. When defect is close to valve leaflet echocardiography assessment is important to avoid regurgitation. In 5 chamber view focusing on defect if valve leaflet and defect is visible in same view then possibly device will tend to touch the valve and future outcome is not sure. For this reason MFO device will be suitable as its very thin, soft and not bulky which probably will not not cause valve incompetence. While if the defect is clearly visible and leaflets are not visible then this possibly safe to use cocccon or any other device and will not harm leaflets. Further more stability of the device is preplanned by size of holding rim (crista) especially upper rim which should be minimum 3mm. Absence of rim will not hold the device and tends to embolise. Another issue is device manipulation in aorta especially through aortic valve when doing procedure in retrograde manner. While loaded device is in aorta, the distal disc is partially opened in the descending aorta and gently withdrawn till the device approaches aortic valve. Here cable is gently rotated to make its way through aortic valve, if there is some resistance the device is drawn little more in to the sheath making it onion shape which helped to cross the valve and immediately opened the whole LV disc after crossing the valve. Any casual maneuver at this stage may damage the aortic valve and cause valve regurgitation. Another issue is wire crossing and snaring for AV loop. Most of the time wire is crossed with catheter positioning into VSD, but sometimes wire is crossed with loop in LV and taken to LPA. This loop is undone when the snared wire is gently pulled keeping both ends tight with the help of artery forceps. Conventionally wire is snared from RPA or LPA keeping in view caliber of vessel and diameter of open snare but sometimes wire is taken into Innominate vein, SVC

or IVC and snared. In this scenario care is taken not to entangle wire in tricuspid valve apparatus.

Although the incidence of heart blocks in VSD device closure is 0.3% reported by Zhao *et al*[23] but we did not observe any heart block in our cases. Only while AV loop formation and maneuvering the catheter in LV, there is brief episode of arrythmia which is settled when traction is loosened from LV.

CONCLUSION

Although relatively new in the market, Cocoon devices can be used safely and effectively for VSD closure. So far we have not have observed any complication due to these devices, still we need more experience to reveal credibility of these device but definitely the waist size variations are compliant with the varying sizes and shapes of VSDs.

CONFLICT OF INTEREST

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

REFERENCES

1. Lee SM, Song JY, Choi JY, Lee SY, Paik JS, Chang SI et al. Transcatheter closure of perimembranous ventricular septal defect using Amplatzer ductal occluder. Catheter Cardiovasc Interv 2013; 82(7): 1141-46.
2. Diab KA, Cao QL, Hijazi ZM. Device closure of congenital ventricular septal defects. Congenit Heart Dis 2007; 2(2): 92-103.
3. Butera G, Chessa M, Carminati M. Percutaneous closure of ventricular septal defects. Cardiol Young 2007; 17(3): 243-253.
4. Janorkar S, Goh T, Wilkinson J. Transcatheter closure of ventricular septal defects using the Rashkind device: initial experience. Catheter Cardiovasc Interv 1999; 46(1): 43-48.
5. Balzer D. Current status of percutaneous closure of ventricular septal defects. Pediatr Ther 2012; 2: 112.
6. Holzer R, Balzer D, Cao QL, Lock K, Hijazi ZM. Amplatzer Muscular Ventricular Septal Defect Investigators. Device closure of muscular ventricular septal defects using the Amplatzer muscular ventricular septal defect occluder: immediate and mid-term results of a US. registry. J Am Coll Cardiol 2004; 43(7): 1257-63.
7. Fu YC. Transcatheter device closure of muscular ventricular septal defect. Pediatr Neonatol 2011; 52(1): 3-4.
8. Pedra CA, Pedra SR, Esteves CA, Sergio C, Sergio L.N, Braga M.D et al. Percutaneous closure of perimembranous ventricular septal defects with the Amplatzer device: technical and morphological considerations. Catheter Cardiovasc Interv 2004; 61(3): 403-10.
9. Zuo J, Xie J, Yi W, Zhang J, Jun L, Dhingua Y et al. Results of transcatheter closure of perimembranous ventricular septal defect. Am J Cardiol 2010; 106(7): 1034-1037.
10. Holzer R, de Giovanni J, Walsh KP. Transcatheter closure of perimembranous ventricular septal defects using the amplatzer membranous VSD occluder: immediate and midterm results of an international registry. Catheter Cardiovasc Interv 2006; 68: 620-28.
11. Ghosh S, Sridhar A, Sivaprakasam M. Complete heart block following transcatheter closure of perimembranous VSD using amplatzer duct occluder II. Catheter Cardiovasc Interv 2017; 92(5): 921-24.
12. Ghaderian M, Merajie M, Mortezaeian H, Aarabi M, Mohammad Y, Shah Mohammadi A, et al. Efficacy and safety of using amplatzer ductal occluder for transcatheter closure of perimembranous ventricular septal defect in pediatrics. Iran J Pediatr 2015; 25(2): e386.
13. Lock JE, Block PC, McKay RG, Baim DS, Keane JF. Transcatheter closure of ventricular septal defects. Circulation 1988; 78: 361-68.
14. Hijazi ZM, Hakim F, Haweleh AA, Madani A, Tarawna W. Catheter closure of perimembranous ventricular septal defects using the new Amplatzer membranous VSD occluder: initial clinical experience. Catheter Cardiovasc Interv 2002; 56(4): 508-15.
15. Yang L, Tai BC, Khin LW, Quek SC. A systematic review on the efficacy and safety of transcatheter device closure of ventricular septal defects (VSD). J Interv Cardiol 2014; 27(3): 260-72.
16. Hijazi ZM, Hakim F, Al-Fadley F, Abdelhamid J, Cao QL. Transcatheter closure of single muscular ventricular septal defects using the amplatzer muscular VSD occluder: initial results and technical considerations. Catheter Cardiovasc Interv 2000; 49(2): 167-72.
17. Kitagawa T, Durham LA, Mosca RS, Bove EL. Techniques and results in the management of multiple ventricular septal defects. J Thorac Cardiovasc Surg 1998; 115(4): 848-56.
18. Saurav A, Kaushik M, Mahesh Alla V, Michael D, White MD, Aryan N et al. Comparison of percutaneous device closure versus surgical closure of peri-membranous ventricular septal defects: A systematic review and meta-analysis. Catheter Cardiovasc Interv2015; 86(6): 1048-56.
19. Moodie DS. Technology Insight: transcatheter closure of ventricular septal defects. Nat Clin Pract Cardiovasc Med 2005; 2(1): 592-96.
20. Santhanam H, Yang L, Chen Z, Tai BC, Rajgor DD, Quek SC, et al. A meta-analysis of transcatheter device closure of perimembranous ventricular septal defect. Int J Cardiol 2018; 254(1): 75-83.
21. Yang R, Kong XQ, Sheng YH, Zhou L, Yong YH, Sun W et al. Risk factors and outcomes of post-procedure heart blocks after transcatheter device closure of perimembranous ventricular septal defect. JACC Cardiovasc Interv 2012; 5(4): 422-27.
22. Li P, Zhao XX, Zheng X, Qin YW. Arrhythmias after transcatheter closure of perimembranous ventricular septal defects with a modified double-disk occluder: early and long-term results. Heart Vessels 2012; 27: 405-10.
23. Zhao LJ, Han B, Zhang JJ, Yi YC, Jiang DD, Lyu JL, et al. Post-procedural outcomes and risk factors for arrhythmias following transcatheter closure of congenital perimembranous ventricular septal defect: a single-center retrospective study. Chin Med J (Engl) 2017; 130(5): 516-521.