

Device closure of ventricular septal defect: Initial experience in Nepal



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ABSTRACT

Background: Device closure is an attractive alternative in the management of Ventricular Septal defect (VSD). **Aims and Objectives:** The aim of the study was to assess the safety and early outcome of VSD device closure at Shahid Gangalal National Heart Centre, Nepal. **Materials and Methods:** The study was single center, retrospective study. All the VSD cases that were attempted for VSD device closure during December 2016 to February 2019 were included. Catheterization laboratory records for VSD type and size, Device type and size were retrospectively reviewed. Hospital records were reviewed for in-hospital complications. **Results:** Sixty-one VSD cases were attempted for device closure. VSD was successfully closed in 55 (90.1%) patients. The mean age of the patient was 11.1 years. Twenty-nine (52.7%) were female and 26 (47.3%) were male. Perimembranous VSD was present in 49 (89 %) and muscular VSD in 6 (11 %) patients. The size of VSD ranged between 2 and 12 mm (Mean 5.4 mm). The VSD was closed with Amplatzer duct occluder I, Amplatzer duct occluder II, Amplatzer muscular VSD occluder and Memopart PDA device in 24 (43.7%), 26 (47.3%), 4 (7.2%) and one patient (1.8%) patients respectively. The postoperative complications were insignificant residual leak across device in 2(3.6%) patients, mild pericardial effusion in one (1.8%) patient. None of the patient had new onset tricuspid regurgitation, aortic regurgitation and complete heart block. One patient developed Right bundle branch block, one developed Left bundle branch block, and one developed junctional rhythm. There was no mortality. **Conclusion:** VSD device closure can be safe and effective if patients are selected properly.

Key words: Amplatzer duct occluder I; Amplatzer duct occluder II; Amplatzer muscular VSD occluder; Ventricular Septal defect

INTRODUCTION

Ventricular septal defect (VSD) is a common congenital heart defect in both children and adults.¹ It occurs in 50% of all children with congenital heart disease² and in 20% as an isolated lesion.³ In addition to congenital VSDs, VSDs can be acquired and result from trauma or following a myocardial infarction.

VSDs are openings in the ventricular septum and may occur anywhere in the septum. They are classified according to their location.^{1,4} Approximately 70-80% of defects are perimembranous in location. Another 5-20% are muscular in nature.^{5,6} Outlet VSDs account for 5-7% of all VSDs. Inlet VSDs constitute another 5-8% of VSDs.⁴ Surgical closure of muscular and perimembranous VSD has a low mortality and morbidity and has been

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the standard treatment for patients with pulmonary flow overload and heart failure.⁷ VSD device closure has been shown to be a viable alternative whenever possible.⁸ There are very report of VSD device closure of outlet VSD. Whereas inlet VSDs are not amenable to device closure since there is no supporting tissue between the margins of the defect and the atrioventricular valve tissue.⁴ Acquired VSDs complicated by myocardial infarction occur in 0.2% of patients in the thrombolytic era and are associated with a very high mortality rate.⁹ VSD post MI can be managed with device closure. Traumatic VSDs have only rarely been reported and reports of percutaneous closure are scarce.^{10,11}

There are multiple studies around the world about the safety and efficacy of VSD device closure. Till date there is no study from Nepal about the safety and efficacy of VSD device closure. This study aims to study the safety and efficacy of VSD device closure in Nepal.

MATERIALS AND METHODS

This study was a single center, retrospective cross sectional study conducted at Shahid Gangalal National Heart Centre, Kathmandu, Nepal. All the VSD cases with who were attempted for VSD device closure during December 2016 to February 2019 were retrospectively reviewed. Catheterization laboratory records for age, gender, VSD type, VSD size, Device type, device size, procedural approach were retrospectively reviewed. Hospital records were reviewed for in-hospital complications. This study was approved from Institutional review committee of National Heart Centre, Kathmandu, Nepal. All the variables were entered into the Statistical Package for Social Sciences software, version 14 (SPSS Inc) for data analysis. Descriptive statistics were computed and presented as means for continuous variables categorical variables were reported in percentages.

Procedure

Device closure of perimembranous VSD was performed under conscious sedation and under local anesthesia. Access was through the femoral vein and artery. Heparin (100 IU/kg) and intravenous antibiotic were administrated. The procedure was performed under fluoroscopic control. Left ventricular angiography was performed at 60° to 20° left anterior oblique projection/cranial to profile the perimembranous and angiography of ascending aorta to profile the aortic valves. Left ventriculography combine with intraprocedural transthoracic echocardiogram (TTE) were used to obtain the location, size of VSD, and its relationship with adjacent aortic valves. The diameter of VSD was measured at largest diastolic phase on the

left ventricular side and was calculated by integrating data from the TTE and angiography measurement. The device was selected 1 to 2 mm larger than the measured VSD diameter.

The defect was crossed in a retrograde fashion from the left ventricle using Judkins right catheter and an exchange floppy guide wire was advanced into the pulmonary artery or the superior or inferior vena cava. The wire was then snared to establish an arteriovenous circuit through femoral vein approach on the same side. An appropriate size of dilator and long sheath was advanced to the left ventricle through the arteriovenous circuit and positioned beneath the aortic valve. The device screwed on the delivery cable was passed through the delivery sheath. The distal disc was opened in the aorta or left ventricle, and the whole system was withdrawn. The right ventricular disc was opened in the right ventricle after confirming that the left ventricular disc was in the correct position.

In case where ADO II was used the VSD was crossed in a retrograde fashion from the aorta using a Terumo® guide wire. A Judkins right catheter was crossed across the VSD. ADO II device was loaded in the loader. The distal disc RV disc was opened in right ventricle, and the whole system was withdrawn. The proximal (LV ventricular) disc was opened in the left ventricle.

The VSD can also be crossed in an ante grade fashion from the RV using a Judkins right catheter with Terumo® guide wire which were advanced through the defect and into the ascending aorta or LV apex. The Terumo wire was then replaced with a super stiff guidewire. An appropriate size delivery system was advanced through the VSD from the femoral vein and into the ascending aorta or LV apex. The dilator and guide wire were removed, and the chosen ADO I or similar device was loaded and advanced to the appropriate position. Under echocardiographic guidance, the device was partially opened in the ascending aorta, and then gently pulled back through the valve into the left ventricle. The retention skirt was pulled into the defect, and the rest of the device deployed by pulling back the delivery sheath.

After verification of device position, the aortic and tricuspid valves by TTE and angiography, the device was released. Patients were transferred to general wards; continuous ECG monitoring was used for 24 h after the procedure. Clinical examination, chest X-ray, TTE, and ECG were done before the hospital discharge. In-hospital complication was recorded.

RESULTS

During the study period sixty-one cases were attempted for device closure. VSD was successfully closed in 55 (90.1%) patients. Among the six attempted case one was post myocardial infarction case. The procedure was abandoned as its anatomy was not suitable for device closure. In the remaining five cases which were all perimembranous VSD, procedure was abandoned due to development of AR in four case and unstable device in one case. The mean age of the patient was 11.1 years. Twenty-nine 29 (52.7%) were female and 26 (47.3%) were male as shown in Table 1. Perimembranous VSD in 49 (89 %) and muscular VSD in 6 (11 %) patients as shown in Table 1. The size of VSD ranged between 2 to 12 mm with the mean 5.4 mm. The VSD was closed with Amplatzer duct occluder I, Amplatzer duct occluder II, Amplatzer muscular VSD occluder and Memopart PDA device in 24 (43.7%), 26 (47.3%), 4 (7.2 %) and one patient (1.8%) patients respectively as shown in Table 2. Ante grade technique was used in 5 cases. In all other cases retrograde technique was used to cross the VSD.

The postoperative complications were insignificant residual leak across device in 2(3.6%) patients, mild pericardial effusion in one (1.8%) patient. None of the patient had new onset tricuspid regurgitation, aortic regurgitation and complete heart block. One patient developed Right bundle branch block, one developed Left bundle branch block, and one developed junctional rhythm. Patient recovered with steroid therapy. All these bundle branch block and

junctional rhythm occurred in perimembranous VSD cases. There was no mortality.

DISCUSSION

This study highlights the initial experience on VSD device closure in the country. Our success rate of 90% with low complication rates is encouraging though VSD device closure is much more complicated procedure than device closure of atrial septal defects and patent ductus arteriosus. Advancements in catheter techniques and devices are leading into the era of device closure of VSDs. The benefits of avoiding bypass are intuitive, and the relative ease of placement makes this procedure ultimately attractive.¹²

Our success rate of 90% and few complications is comparable to international studies. Carminati et al¹³ reviewed 12 studies published until 2006 and the results of the European VSD registry reported technical procedural success rates of 87-100% with major complication rates of 0-15% and the need for pacemaker implantation in 0-8% of patients. The investigators also reported on 430 patients collected on an intention to-treat basis from 23 tertiary referral centers as part of a registry. The patients included 119 muscular, 250 membranous, 16 multiple, and 45 post-operative residual VSDs. The overall procedural success was 95.3%. There were early complications in 55 patients (12.7%) with significant complications in 28 patients (6.5%). One death was reported (0.2%), vascular complications in 0.7% patients, hemolysis in 1.2% patients, infection in 0.5% patients, device embolization in 0.9% patients and early complete heart block (CHB) in 2.8% patients. Complete closure of the VSD was achieved in 65% of patients by discharge and in 83% at a median follow up time of 2 yrs. The majority of the residual shunts were trivial or mild and only 3 patients (0.7%) were subsequently referred for surgery.

Several studies on VSD device closures in China¹⁴⁻¹⁷ with Amplatzer devices or the Chinese occluders were reported. Majority of the patients were perimembranous VSDs patients. They reported a procedural success of 94.9% to 99.8% with an overall success rate of 98.6%. The amount of residual shunt >2 mm during follow up ranged from 0% to 4.7%. Adverse events were reported to occur in 2.5% to 19.3% of patients with major complications ranged from 0.6% to 10.9%. CHB occurred in 0.1% to 7.6% of patients with the vast majority being transient or responded to steroid therapy. Pacemakers were implanted in 5/2079 patients (0.2%) in these studies.

Holzer et al¹⁸ reported the results of a large international registry of perimembranous VSD closure using the

Table 1: Demographics (successful cases) N=55

Clinical characteristics	N (%)
Male	26 (47.3)
Female	29 (52.7)
Perimembranous VSD	49 (89)
Muscular VSD	6 (11)

Table 2: Device types and size n=55

Device type and size	N (%)
ADO I	
6×8	3
8×10	8
10×12	13
ADO II	
4×6	6
5×4	8
6×4	8
6×6	4
Muscular VSD device	
6	1
12	1
14	2
Memopart	
10×12	1

Amplatzer Perimembranous VSD device. One hundred patients were enrolled with procedural success in 93 (93%). Immediately after the procedure, complete closure was present in 58.1% of patients with <2 mm shunt in 98.7%. Transient CHB was noted in 2 patients and an additional 2 experienced CHB requiring pacemaker implantation. Therefore, a total of 4% of patients experienced CHB with 2% and required pacemaker implantation.

Device closure of subarterial VSD is considered difficult to accomplish due to its proximity to the aortic valve with possible impingement and subsequent development/worsening aortic regurgitation; therefore, surgical closure is recommended in most cases. Device closure of sub arterial VSD with Amplatzer Duct Occluder is technically feasible and safe in patients older than 7 years of age. However, development or worsening of aortic regurgitation necessitates long-term follow-up.¹⁹ Placement failure was experienced by 5.1% of patients as a result of proximity to the aortic valve and acute insufficiency, chordae of the tricuspid valve, and inability to pass the delivery sheath.²⁰ In contrast to perimembranous VSD, where device closure could cause atrioventricular block, the location of sub arterial VSD is far away from the conduction system atrioventricular block could be avoided.¹⁹

Muscular VSDs present a particular challenge to surgical closure. Various surgical techniques have been attempted, including right atrial, right ventricular, and left ventricular approaches. The first two provided poor visualization of the defects due to the heavy trabeculations of the RV. The latter, although provides better exposure, has been associated with significant ventricular dysfunction.^{21,22} In addition, the various surgical options are associated with high morbidity and a significant incidence of residual shunts.²³ Device closure has been contemplated as a better alternative. The complications encountered in device closure of muscular VSD using an AVSDO are transient arrhythmias that occurred during or soon after the procedure.^{24,25} In this study we have a very good success rate in device closure of muscular VSD.

Post infarct VSDs (PIVSD) have a particularly poor prognosis with mortality rates for medically treated patients of 94% at 30 days post infarct and 97% at 1 year post infarct.⁹ Survival following surgical repair is likewise quite poor with mortality rates of 47% at 30 days and 53% at 1 year post infarct.⁹ Device closure of PIVSD compares favorably with surgical VSD closure and therefore trans-catheter VSD closure has emerged as a reasonable alternative to surgical management in these patients.⁴ We have yet to do device closure of PIVSD in our center.

Retrospective in nature, single center study, non-randomized study, with relatively small patient's population

without long term follow up are the major limitations of this study.

CONCLUSION

In our experience, we have an excellent success rate of VSD device closure rate with low incidence of serious adverse event. Device closure of VSD is a valuable option in carefully selected patients. It can avoid cardiopulmonary bypass, surgical risk and a surgical scar.

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CMA- Concept and design of the study, manuscript preparation, statistically analyzed and interpreted, Critical revision of the manuscript; **MS-** Concept and design of the study, critical revision of manuscript and review of the study; **SCS-** Reviewed the literature, helped in preparing first draft of manuscript; **AB-** Reviewed the literature, helped in preparing first draft of manuscript, collected data; **SD-** Reviewed the literature, helped in preparing first draft of manuscript; **KPA-** Collected data, statistically analyzed and interpreted, helped in preparing first draft of manuscript; **PS-** Reviewed the literature, helped in preparing first draft of manuscript; **SA-** Collected data and reviewed the literature; **US-** Collected data, statistically analyzed and interpreted, helped in preparing first draft of manuscript.

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