

Percutaneous Closure of Ventricular Septal Defects in 116 Patients

Experience with different devices

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إغلاق ثقب الحاجز البطيني عبر الجلد في 116 مريضاً تجربة استخدام وسائل إغلاق مختلفة

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ABSTRACT: Objectives: This study aimed to review the experience with percutaneous closure of ventricular septal defects (VSDs) at the National Heart Center (NHC) in Muscat, Oman. **Methods:** This retrospective study was conducted from November 2008 to December 2017. Patients' electronic medical records were reviewed to identify their clinical, imaging and interventional data before and after the procedure and on the last follow-up. **Results:** A total of 116 patients, the majority of which were female (58%), underwent 118 percutaneous procedures for VSD closure at a median age of 3.54 years (range: 0.25–33 years) and a median weight of 12 kg (range: 3.5–78 kg). The mean diameter of the VSDs as determined by transoesophageal echocardiogram was 5.6 ± 1.9 mm (n = 105). The commonest type of VSD was perimembranous (n = 75, 63.5%). Devices were successfully placed during 111 (94.1%) procedures in 109 (94.0%) patients, with the commonest device being an Amplatzer™ duct occluder I (St. Jude Medical, Little Canada, Minnesota, USA; n = 39, 35.1%). There was no mortality. Early major cardiac complications occurred in six patients (5.5%) with device embolisation being the commonest (n = 4, 3.7%). The median follow-up period was 19 months (range: 1–84 months) in 89 (81.7%) of the patients. One patient (0.9%) required a permanent pacemaker for a complete heart block. **Conclusion:** This study has demonstrated a good rate of VSD closure with low morbidity and no mortality using the percutaneous approach with different devices. Long-term follow-up is needed to specifically evaluate the function of adjacent structures and the long-term effects on conduction systems.

Keywords: Ventricular Septal Defect; Percutaneous Coronary Intervention; Amplatzer Occluder Device; Vascular Closure Device; Heart Block; Oman.

المخلص: الهدف: هدفت هذه الدراسة الى إستعراض تجربة إغلاق ثقب الحاجز البطيني عبر الجلد في المركز الوطني للقلب بمسقط، عُمان. **الطريقة:** أجريت هذه الدراسة الأستغاديّة من نوفمبر 2008 إلى ديسمبر 2017. تمت مراجعة السجلات الطبية الإلكترونيّة للمرضى لتحديد البيانات السريرية والتصويرية والتدخلية قبل وبعد العملية وأثناء آخر متابعة للمريض. **النتائج:** خضع ما مجموعه 116 مريضاً لـ 118 عملية عبر الجلد لإغلاق ثقب الحاجز البطيني وكان غالبيتهم من الإناث (58%) بمتوسط عمر 3.54 سنة (المدى: 0.25–33 سنة) ومتوسط وزن 12 كجم (المدى: 3.5–78 كجم). كان متوسط قطر ثقب الحاجز البطيني حسبما حدده مخطط صدى القلب عبر المرئ هو 5.6 ± 1.9 مم (عدد: 105) وكان الثقب حول الغشاء هو أكثر أنواع ثقب الحاجز البطيني شيوعاً (عدد: 75، 63.5%). تم وضع وسائل الإغلاق بنجاح خلال 111 (94.1%) عملية لـ 109 (94.0%) مريضاً وكان أكثر وسائل الإغلاق شيوعاً هي سدادة مجرى من نوع أمبلاتزر (سانت جود، ليتل كندا، مينيسوتا، الولايات المتحدة الأمريكية، عدد: 39، 35.1%). لم يكن هناك وفيات. حدثت مضاعفات قلبية عظمى مبكرة في ستة مرضى (5.5%) وكان إنصمام السدادة هو الأكثر شيوعاً (عدد = 4، 3.7%). بلغ متوسط فترة المتابعة 19 شهراً (المدى: 1–84 شهراً) في 89 (81.7%) مريضاً. احتاج مريض واحد (0.9%) إلى ناظمة قلبية دائمة بسبب إحصار قلبي تام. **الخلاصة:** أظهرت هذه الدراسة معدلاً جيداً لإغلاق ثقب الحاجز البطيني بواسطة مسك عبر الجلد باستخدام وسائل إغلاق مختلفة مع مراضة منخفضة وعدم حدوث وفيات، هناك حاجة إلى متابعة طويلة الأجل لتقييم وظيفة التراكيب المجاورة والتأثيرات طويلة المدى على أنظمة التوصيل الكهربائي للقلب بشكل خاص.

الكلمات المفتاحية: ثقب الحاجز البطيني؛ تدخل عبر الجلد؛ وسيلة إغلاق أمبلاتزر؛ إحصار القلب؛ عُمان.

ADVANCES IN KNOWLEDGE

- The results of this study revealed that percutaneous closure of ventricular septal defects (VSDs) can be performed safely with limited complications.
- This study may serve as a reference point for future research on this subject.

APPLICATION TO PATIENT CARE

- This study provides evidence that percutaneous VSD closure is safe and effective with low risk of complete heart block.

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VENTRICULAR SEPTAL DEFECT (VSD) IS THE most common type of congenital heart disease with an incidence of 3–3.5 per 1,000 live births; almost 80% of these VSDs are perimembranous.^{1–3} Closure is indicated when the VSD is haemodynamically significant to prevent future complications, including ventricular dysfunction, arrhythmias and pulmonary arterial hypertension.⁴ Surgical approaches traditionally have been the mainstay of therapy in closing VSDs.^{2,3,5,6} Surgical approaches, however, have been associated with morbidity and mortality, patient discomfort, sternotomy and scarring.^{5–8} The transcatheter approach gained cardiologists' special interest over the last decade due to its encouraging results.^{9–12} This study aimed to review experiences with percutaneous VSD closure at the National Heart Center (NHC) of Oman.

Methods

This retrospective study included all patients who underwent percutaneous VSD device closure at the NHC from November 2008 to December 2017. Medical records were reviewed for clinical evaluation data and findings from electrocardiograms, transthoracic electrocardiograms (TTEs) and transoesophageal echocardiograms (TEEs) before and after the intervention and on the last follow-up. The catheterisation database was reviewed to identify patients who underwent attempted transcatheter VSD closure. Angiograms and cardiac catheterisation reports were analysed to determine haemodynamics and procedural characteristics. All cardiac catheterisations were done under general anaesthesia by a transfemoral approach under TEE guidance. Follow-ups were done at one, three and six months post-procedure and then yearly. A successful procedure was defined as one in which a stable device was successfully positioned across the defect with no complications to adjacent structures and no significant residual shunt. Adverse events and complications were assessed intraoperatively, before discharge and on subsequent follow-up visits. Technical details of the procedure were followed according to a previously established protocol.¹³

Statistical Package for the Social Sciences (SPSS), Version 25.0 (IBM, Corp., Armonk, New York, USA) was used to analyse the data, which were described as mean \pm standard deviation. Median and range were used to describe continuous variables and categorical data were expressed as frequencies with percentages. An association analysis of procedure results and risk factors was done. Dependent outcome variables were analysed to determine whether procedures were successful, the incident of total early complications and

the occurrence of device embolisation. Independent variables included in the analysis were patients' age at the procedure, weight and gender. Also included in the analysis was the defect diameter as measured on TTE and whether patients were diagnosed with ventricular septal aneurysm. Univariate analysis was performed using binary logistic regression. Multivariable analysis to study risk factors for the occurrence of dependent variables was performed using multiple logistic regression. Odds ratios (OR) and their 95% confidence intervals were calculated for the independent variables. Differences were considered statistically significant at $P < 0.05$.

The study was approved by The Royal Hospital's Institutional Review Board.

Results

A total of 116 patients, of which 67 (58%) were female, underwent 118 percutaneous procedures (two patients underwent two device placements) for VSD closure at a median age of 3.54 years (range: 0.25–33 years) and had a median weight of 12 kg (range: 3.5–78 kg) [Table 1]. Nine patients were over 18 years of age with a mean age of 24.5 ± 3.4 years and a mean weight of 66 ± 8 kg. Perimembranous VSD was commonest ($n = 75$; 63.5%).

Devices were successfully placed in 109 (94.0%) patients during 111 (94.1%) procedures. The mean diameter of the defects from the right ventricular side was 5.7 ± 2.1 mm ($n = 109$) as determined by TTE and 5.6 ± 1.9 mm ($n = 105$) as determined by TEE [Table 2]. Mild tricuspid valve regurgitation was present prior to closure in 34 (31.2%) patients and was determined to be moderate in three (2.8%) cases. Aortic valve regurgitation was mild in three (2.8%) patients. In total, 56 (51.4%) cases had aneurysmal tissues from the right ventricle side. Procedures were abandoned in seven patients (five males and two females) at a median age of 1.7 years (range: 0.58–22 years) and a median weight of eight kg (range: 4–60 kg). Abandonment was due to various reasons including haemodynamic instability and hypotension in three patients, worsening aortic regurgitation in one patient, improper orientation and compaction of the device across the defects in two patients and incidental finding of an interrupted inferior vena cava in one patient. In this last patient, the procedure was attempted via a jugular venous approach, which was unsuccessful.

Analysis of risk factors using univariate analysis revealed that only a larger diameter of the VSD, as determined by TTE, was a significant predictor of procedure failure; successful procedures involved VSDs with a mean diameter of five mm (range: 2.5–

14 mm) while unsuccessful procedures had a mean diameter of eight mm (range: 5–14 mm; $P < 0.01$). Multivariable analysis also showed that a larger VSD diameter was a significant predictor for procedure failure (OR: 1.60, 95% CI: 1.11–2.30; $P = 0.01$) [Table 3].

All closures were performed through a trans-femoral approach. Arterio-venous looping was done in 104 (93.7%) procedures, whereas in six (5.4%) procedures the closure was done by a retrograde approach from the femoral artery. In one patient (0.9%), the device was deployed directly from a right ventricular approach. The most common devices used were the Amplatzer™ duct occluder I (St. Jude Medical, Little Canada, Minnesota, USA; ADOI) in 39 (35.1%) procedures and the Amplatzer™ duct occluder II (St. Jude Medical; ADOII) in 26 (23.4%) [Table 2]. The mean duration of stay in hospital was 2.0 ± 1.6 days. No procedure-related deaths were recorded. Immediate complete closure was achieved in 52 (46.8%) procedures, which increased to 69 (62.2%) at

day one post-procedure and to 79 out of 89 patients (88.8%) at last follow-up.

Procedure or device-related complications occurred in 10 (9.2%) patients. Of these cases, early major cardiac complications within 12 hours of the procedure occurred in six patients (5.5%); device embolisation occurred in four patients (3.7%). Severe tricuspid valve regurgitation occurred in one patient (0.9%); the sixth patient in the series developed severe tricuspid valve stenosis (0.9%). Five patients required surgical retrieval of devices (4.6%). In one patient, the device was retrieved by a snare

Table 1: Characteristics of the study population (N = 118 procedures)*

Characteristic	n (%)		P value
	Total procedures	Unsuccessful procedures	
Median age in years (range)	3.54 (0.25–33)	1.7 (0.58–22)	0.48
Median weight in kg (range)	12 (3.5–78)	8 (4–60)	0.49
Gender			0.13
Male	49	5	
Female	67	2	
Age in years			
≤1	20 (16.9)	2 (1.7)	
1–13	81 (68.6)	4 (3.4)	
13–18	8 (6.8)	0 (0)	
≥18	9 (7.6)	1 (0.8)	
VSD Type			
Perimembranous	75 (63.5)	6 (5.1)	
High muscular	23 (19.5)	0 (0)	
Mid muscular	9 (7.6)	0 (0)	
Residual post-surgery	7 (5.9)	0 (0)	
Inlet	3 (2.7)	1 (0.8)	
Residual post-device	1 (0.8)	0 (0)	

VSD = ventricular septal device.

*Procedures were carried out in 116 patients; there were seven unsuccessful procedures.

Table 2: Procedural data and devices used for percutaneous closure of ventricular septal defects (N = 111 procedures)*

Variable	n (%)	Mean ± SD
Procedure		
VSD diameter (RV) via TTE in mm	109 (98.2)	5.7 ± 2.1
VSD diameter (LV) via TEE in mm	46 (41.4)	8.6 ± 2.5
VSD diameter (RV) via TEE in mm	105 (94.6)	5.6 ± 1.9
VSD diameter via angiogram in mm	103 (92.8)	5.7 ± 2
MPA pressure in mmHg	79 (71.2)	21 ± 8
LVEDp in mmHg	93 (83.8)	10 ± 3.5
Qp:Qs	87 (78.4)	2 ± 1:1
VSD Device		
ADOI	39 (35.1)	
ADOII	26 (23.4)	
AMVSD	16 (14.4)	
APMVSD	14 (12.6)	
Pfm Coil	8 (7.2)	
CDO	7 (6.3)	
ASO	1 (1.0)	
Device size (LV) in mm		8.7 ± 2.5
Device size (RV) in mm		6.7 ± 2.2

SD = standard deviation; VSD = ventricular septal defect; RV = right ventricle; TTE = transthoracic echocardiography; LV = left ventricle; TEE = transoesophageal echocardiography; MPA = main pulmonary artery; LVEDp = left ventricular end diastolic pressure; Qp = pulmonary flow; Qs = systemic flow; ADO = Amplatzer™ duct occluder (St. Jude Medical, Little Canada, Minnesota, USA); AMVSD = Amplatzer™ muscular ventricular septal defect occluder (St. Jude Medical); APMVSD = Amplatzer™ perimembranous ventricular septal defect occluder (St. Jude Medical); CDO = cocoon duct occluder; ASO = Amplatzer™ atrial septal occluder (St. Jude Medical).

*Procedures were carried out in 109 patients. Procedures were abandoned in seven patients due to haemodynamic instability and hypotension in three patients, worsening aortic regurgitation in one patient, improper orientation and compaction of the device across the defects in two patients and incidental finding of an interrupted inferior vena cava in one patient (procedure was attempted via a jugular venous approach but was unsuccessful).

Table 3: Univariate and multivariate analysis of risk factors for successful percutaneous closure of ventricular septal defect (N = 118)

Variable	Univariate		P value	Multivariate		P value
	Procedure success			OR	95% CI	
	Yes	No				
	111	7				
Median age in years (range)	4 (0.25–33)	1.7 (0.58–21.6)	0.48	1.01	0.67–1.52	0.10
Age less than one year			0.41	1.72	0.17–17.70	0.65
Yes	18	2				
No	93	5				
Median weight in kg (range)	13 (3.5–78)	8 (4–60)	0.49	1.02	0.86–1.22	0.81
Weight less than 10 kg			0.26	6.33	0.38–105.1	0.20
Yes	40	4				
No	71	3				
Gender			0.13	0.30	0.05–1.80	0.19
Male	45	5				
Female	66	2				
VSD aneurysm present			0.28	a0.68	0.10–4.68	0.69
Yes	56	2				
No	55	5				
Median VSD size via TTE in mm (range)	5 (2.5–14)	8 (5–14)	<0.01	1.60	1.11–2.30	0.01

OR = odds ratio; CI = confidence interval; VSD = ventricular septal defect; TTE = transthoracic electrocardiogram.

Table 4: Details of early complications after percutaneous closure of ventricular septal defect

No.	Age in months	Gender	Weight in kg	VSD type	VSD size in mm	Device type (size)	Adverse event	Outcome
1	20	M	8.9	PMVSD	9	ADOI (10/8)	Embolisation	Surgical retrieval
2	6	M	12	PMVSD	9	ADOI (12/10)	Embolisation	Surgical retrieval
3	14	F	7.4	PMVSD	6	APMVSD (8)	Embolisation	Catheter retrieval; same device used
4	13	M	11.2	PMVSD	4	Pfm coil (8/6)	Embolisation	Catheter retrieval
5	5	F	3.5	PMVSD	4	ADOII (5/4)	Severe TR and severe residual shunt	Surgical removal and repair
6	36	F	11.7	MM	11	AMVSD (12)	Severe TS	Surgical removal
7	11	M	5.3	PMVSD	5	PFM coil (10/6)	Haemolysis and severe residual shunt	Second device placed (ADOII)
8	10	F	5.7	PMVSD	7.5	APMVSD (10)	Haemolysis	Improved
9	6	F	4.2	HM	9	AMVSD (12)	Transient second-degree block	Improved but CHB 21 months later
10	12	M	39	HM	7	ADOI (12/10)	Urinary bladder-injury	Required surgical exploration of urinary bladder

VSD = ventricular septal defect; PMVSD = perimembranous ventricular septal defect; ADO = Amplatzer™ duct occluder (St. Jude Medical, Little Canada, Minnesota, USA); APMVSD = Amplatzer™ membranous ventricular septal defect occlude (St. Jude Medical); TR = tricuspid regurgitation; MM = mid-muscular ventricular septal defect; AMVSD = Amplatzer™ muscular ventricular septal defect occlude (St. Jude Medical); TS = Tricuspid stenosis; HM = high muscular ventricular septal defect; CHB = complete heart block.

Table 5: Univariate and multivariate analysis of risk factors for early complications of percutaneous closures of ventricular septal defects (N = 111)

Variable	Univariate		P value	Multivariate		P value
	Early complications			OR	95% CI	
	Yes	No				
	10	101				
Median age in years (range)	1.38 (0.33–13.67)	4.42 (0.25–33)	0.11	0.91	0.58–1.42	0.67
Age less than one year old			0.06	0.39	0.06–2.73	0.35
Yes	4	15				
No	6	86				
Median weight in kg (range)	8.15 (3.5–39)	14 (3.5–78)	0.14	1.01	0.85–1.18	0.96
Weight less than 10 kg			0.10	1.54	0.17–13.87	0.70
Yes	6	34				
No	4	67				
Gender			0.53	0.66	0.14–3.03	0.59
Male	5	40				
Female	5	61				
VSD aneurysm present			0.53	2.31	0.45–11.84	0.32
Yes	6	50				
No	4	51				
Median VSD size via TTE in mm (range)	6 (3.6–12)	5 (2.5–14)	0.17	1.29	0.95–1.75	0.11

OR = odds ratio; CI = confidence interval; VSD = ventricular septal defect; TTE = transthoracic electrocardiogram.

Table 6: Univariate and multivariate analysis of risk factors for device embolisation (N = 111)

Variable	Univariate		P value	Multivariate		P value
	Embolisation present			OR	95% CI	
	Yes	No				
	4	107				
Median age in years (range)	1.71 (1.08–4.17)	4.33 (0.25–33.08)	0.23	0.05	0.01–5.29	0.21
Age less than one year old			0.100	1.38	0.18–14.70	0.100
Yes	0	19				
No	4	88				
Median weight in kg (range)	10.05 (7.4–12)	13.50(3.5–78)	0.30	0.61	0.11–3.37	0.57
Weight less than 10 kg			0.54	0.16	0.00–184.29	0.61
Yes	2	38				
No	2	69				
Gender			0.19	0.17	0.03–9.48	0.40
Male	3	42				
Female	1	65				
VSD aneurysm present			0.34	11.18	0.19–647.12	0.24
Yes	3	53				
No	1	54				
Median VSD size via TTE in mm (range)	6 (3.6–12)	5 (2.5–14)	0.23	1.42	0.77–2.66	0.26

catheter. An early significant residual shunt occurred in two (1.8%) patients. Pre-existing mild tricuspid valve regurgitation did not change post-procedure. However, moderate regurgitation was detected in two (1.8%) patients. Early aortic valve regurgitation was mild in two (2%) patients, although the condition was pre-existing; another patient also had an early mild aortic valve regurgitation before the procedure which improved. Complete heart block (CHB) was detected in only one patient (0.9%), a symptomatic six-month-old girl weighing 4.2 kg with an 11-mm long anterior muscular VSD. A 12-mm Amplatzer™ (St. Jude Medical) muscular VSD (AMVSD) occluder was used. However, after releasing the device, a transient 2:1 atrioventricular block was noted. The block improved and the patient was discharged two days later. She presented 21 months later with a recurrence of CHB with a heart rate of 56 beats/minute for which a permanent pacemaker was placed. Her follow-ups prior to the presentation were completely normal [Table 4]. Follow-up was possible in 89 (81.7%) patients with a median follow-up period of 19 months (range: 1–84 months). All patients improved clinically.

The assessment of risk factors for the occurrence of early complications and device embolisation using univariate and multivariate logistic regression analyses showed no statistically significant association with independent predictors [Tables 5 and 6].

Discussion

Percutaneous closure of VSDs has gained popularity in the last few years. The procedure has many advantages, but it is not without challenges. In this study, different types of VSDs were closed, but the perimembranous type was the most common (63.5%). The reported success rate of the procedure in the literature is high; Butera *et al.* and Holzer *et al.* reported successful closure rates of approximately 96% and 93%, respectively.^{14,15} The current study found a comparable successful closure rate of 94.1%.

The percutaneous approach for VSD closure is challenging in small patients and there are no clear guidelines about the best approaches to use or what devices to select. Choosing the correct procedure to use in addressing VSDs depends on many factors. Infants with low body weight are often referred for surgery. Diab *et al.* reported a series of infants less than one year of age; the smallest infant undergoing a purely percutaneous approach was 3.8 kg.¹⁶ Narin *et al.* reported successful percutaneous closure in 12 infants less than 12 months of age using this approach in infants as small as three kg, although one patient in their series developed CHB six months post-procedure.¹⁷ In the

current study, the youngest patient was a symptomatic male aged three months old and weighing 3.5 kg. This patient had a large (eight mm) residual mid muscular post-surgical VSD closed using a 10 mm AMVSD occluder uneventfully. The researchers have observed a trend of early complications in younger patients; however, the number of complications among these younger patients was not statistically significant ($P = 0.06$). Holzer *et al.* reported that patients “with a weight below 10 kg had a significantly higher incidence of adverse events than patients with a weight above 10 kg (58.3% versus 25.0%, $P = 0.0285$)”.¹⁵ Therefore, interventionists should be extremely careful in smaller infants in selecting the types of devices and sizes to use when dealing with VSDs. Moreover, current devices should be improved to reduce complications in this group.

Appropriate device selection is of fundamental importance to achieve safe closure when dealing with VSDs.¹⁸ The current researchers primarily select devices based on VSD morphology with preferences for ductal devices for VSDs in membranous/upper muscular locations and muscular VSD devices for muscular VSDs. ADOII, with its softer profile, should be used for VSDs close to the aortic valve. It has been observed that 51.4% of the defects had aneurysmal tissues from the right ventricle. In the majority of cases, the researchers aim to deploy the device within the aneurysm if it is large enough to avoid encroaching on the aortic valve. Furthermore, the researchers use devices with a smaller right ventricular disc such as duct occluders to avoid entrapment of the tricuspid valve. However, the number of fenestrations and the strength of the aneurysm are limiting factors. The current study, though, did not show the presence of an aneurysm to be a predictor for procedure success or for the occurrence of complications.

Early complications were observed in 10 (9.2%) patients but fortunately, no deaths occurred. Six (5.5%) patients required surgical removal of the devices and repair of the defects with no sequelae. In the current study, there was a relatively small number of patients with large defects. The rate of early complications was comparable to other published literature. Butera *et al.* reported 13 early significant complications in 12 patients (11.5%); two of these complications were related to device embolisation.¹⁹ In the current study, no variables were observed which predicted early complications in the analysis model, but valvular regurgitation or stenosis were found to be more concerning complications with device closures.

Tricuspid, mitral and aortic valve impingement have also been described in the literature. Holzer *et al.* reported an early new or increasing tricuspid and

aortic valve regurgitation at a rate of 9.2% for each complication; however, almost all of these patients' complications were found to have improved on last follow-up.¹⁵ In the current series, the tricuspid valve was most commonly involved ($n = 2$, 1.8%). These complications were mainly related to the relatively larger right sided disc. Both patients underwent surgical retrieval of the devices and uneventful VSD patch closure. This finding emphasises again the need to carefully evaluate both semilunar and atrioventricular valves prior to device release. However, not all device-related valvular complications can be detected prior to release due to the reconfiguration of the device once the tension of the delivery cable has been released.¹⁵

CHB is a known significant concerning complication post-perimembranous-VSD closure. In the current study, the rate was low (0.9%). Holzer *et al.* and Arora *et al.* observed rates of 2%, 1.9%, respectively.^{15,20} The proposed mechanism for intraprocedural heart block occurring may be direct mechanical injury by the device, while post-procedural occurrences may be due to local inflammation, oedema and fibrosis triggered by ventricular retention discs.^{17,18} The patient who developed CHB in the current study was small with low body weight and a relatively larger device with two discs. The current researchers believe that the use of ductal devices with just one disc (e.g. ADOI) is a major reason for the low incidence of CHB in this study; however, further studies are needed to confirm this phenomenon. Importantly, it is challenging to completely avoid heart block given the anatomic predisposition toward such defects, especially in patients with perimembranous VSD or in cases where the device is relatively large with large retention discs. Regular follow-up is needed as heart block can manifest as a late complication following a procedure even when the immediate post-procedural recovery is uneventful.

This study was subject to certain limitations. It was retrospective and limited by the potential for missing data. In addition, the group was not homogenous as it included both paediatric and adult patients so findings cannot be generalised to one particular age group. Furthermore, this study is a single-centre study so findings may not be generalisable to larger populations. Midterm and follow-up data, however, were reported.

Conclusion

This study has demonstrated a good closure rate of VSDs with low morbidity and no mortality using the percutaneous approach with different devices. Long-term follow-up is needed to specifically evaluate the

function of adjacent structures and the long-term effects of devices on the conduction system.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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References

1. Hoffman JI, Kaplan S. The incidence of congenital heart disease. *J Am Coll Cardiol* 2002; 39:1890–900. [https://doi.org/10.1016/S0735-1097\(02\)01886-7](https://doi.org/10.1016/S0735-1097(02)01886-7).
2. Warnes CA, Williams RG, Bashore TM, Child JS, Connolly HM, Dearani JA, et al. ACC/AHA 2008 guidelines for the management of adults with congenital heart disease: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to develop guidelines on the management of adults with congenital heart disease). *Circulation* 2008; 118:e714–833. <https://doi.org/10.1016/j.jacc.2008.10.001>.
3. Baumgartner H, Bonhoeffer P, De Groot NM, de Haan F, Deanfield JE, Galie N, et al. ESC Guidelines for the management of grown-up congenital heart disease (new version 2010). *Eur Heart J* 2010; 31:2915–57. <https://doi.org/10.1093/eurheartj/ehq249>.
4. Kidd L, Driscoll DJ, Gersony WM, Hayes CJ, Keane JF, O'Fallon WM, et al. Second natural history study of congenital heart defects. Results of treatment of patients with ventricular septal defects. *Circulation* 1993; 87: I38–51.
5. Monro JL, Alexiou C, Salmon AP, Keeton BR. Reoperations and survival after primary repair of congenital heart defects in children. *J Thorac Cardiovasc Surg* 2003; 126:511–20. [https://doi.org/10.1016/s0022-5223\(03\)00115-6](https://doi.org/10.1016/s0022-5223(03)00115-6).
6. Bol-Raap G, Weerheim J, Kappetein AP, Witsenburg M, Bogers AJ. Follow-up after surgical closure of congenital ventricular septal defect. *Eur J Cardiothorac Surg* 2003; 24:511–15. [https://doi.org/10.1016/s1010-7940\(03\)00430-5](https://doi.org/10.1016/s1010-7940(03)00430-5).
7. Andersen HØ, de Leval MR, Tsang VT, Elliott MJ, Anderson RH, Cook AC. Is complete heart block after surgical closure of ventricular septum defects still an issue? *Ann Thorac Surg* 2006; 82:948–56. <https://doi.org/10.1016/j.athoracsur.2006.04.030>.
8. Nygren A, Sunnegårdh J, Berggren H. Preoperative evaluation and surgery in isolated ventricular septal defects: A 21 year perspective. *Heart* 2000; 83:198–204. <https://doi.org/10.1136/heart.83.2.198>.
9. Lock JE, Block PC, McKay RG, Baim DS, Keane JF. Transcatheter closure of ventricular septal defects. *Circulation* 1988; 78:361–8. <https://doi.org/10.1161/01.cir.78.2.361>.
10. Bass JL, Kalra GS, Arora R, Masura J, Gavora P, Thanopoulos BD, et al. Initial human experience with the Amplatzer perimembranous ventricular septal occluder device. *Catheter Cardiovasc Interv* 2003; 58:238–45. <https://doi.org/10.1002/ccd.10406>.
11. Walavalkar V, Maiya S, Pujar S, Ramachandra P, Siddaiah S, Spronck B, et al. Percutaneous device closure of congenital isolated ventricular septal defects: A single-center retrospective database study amongst 412 cases. *Pediatr Cardiol* 2020; 41:591–8. <https://doi.org/10.1007/s00246-020-02315-0>.

12. Bentham JR, Gujral A, Adwani S, Archer N, Wilson N. Does the technique of interventional closure of perimembranous ventricular septal defect reduce the incidence of heart block? *Cardiol Young* 2011; 21:271–80. <https://doi.org/10.1017/S1047951110002039>.
13. Diab KA, Cao QL, Hijazi ZM. Device closure of congenital ventricular septal defects. *Congenit Heart Dis* 2007; 2:92–103. <https://doi.org/10.1111/j.1747-0803.2007.00080.x>.
14. Butera G, Chessa M, Carminati M. Percutaneous closure of ventricular septal defects. *Cardiol Young* 2007; 17:243–53. <https://doi.org/10.1017/S1047951107000431>.
15. Holzer R, de Giovanni J, Walsh KP, Tometzki A, Goh T, Hakim F, et al. 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; 68:620–8. <https://doi.org/10.1002/ccd.20659>.
16. Diab KA, Cao QL, Mora BN, Hijazi ZM. Device closure of muscular ventricular septal defects in infants less than one year of age using the Amplatzer devices: Feasibility and outcome. *Catheter Cardiovasc Interv* 2007; 70:90–7. <https://doi.org/10.1002/ccd.21142>.
17. Narin N, Pamukcu O, Tuncay A, Baykan A, Sunkak S, Tasci O, et al. Percutaneous ventricular septal defect closure in patients under 1 year of age. *Pediatr Cardiol* 2018; 39:1009–15. <https://doi.org/10.1007/s00246-018-1852-5>.
18. Santhanam H, Yang L, Chen Z, Tai BC, Rajgor DD, Quek SC. A meta-analysis of transcatheter device closure of perimembranous ventricular septal defect. *Int J Cardiol* 2018; 254:75–83. <https://doi.org/10.1016/j.ijcard.2017.12.011>.
19. Butera G, Carminati M, Chessa M, Piazza L, Micheletti A, Negura DG, et al. Transcatheter closure of perimembranous ventricular septal defects: Early and long-term results. *J Am Coll Cardiol* 2007; 50:1189–95. <https://doi.org/10.1016/j.jacc.2007.03.068>.
20. Arora R, Trehan V, Kumar A, Kalra GS, Nigam M. Transcatheter closure of congenital ventricular septal defects: Experience with various devices. *J Interv Cardiol* 2003; 16:83–91. <https://doi.org/10.1046/j.1540-8183.2003.08006.x>.