

Analysis and comparison of failure causes of minimally invasive surgical closure of ventricular septal defects in children

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ABSTRACT

Objectives The aims of the present study were to explore the causes of minimally invasive surgical ventricular septal defect (VSD) closure failure under transesophageal echocardiography guidance and thus to improve the success rate of surgical VSD closure.

Methods From January 2015 to December 2019, 522 children with VSD underwent minimally invasive surgical closure. Nineteen procedures (3.64%) were unsuccessful. The failure causes, VSD locations and surgical incision approaches were retrospectively analyzed.

Results Among the 19 patients (3.64%) with unsuccessful outcomes, 18 were switched to cardiopulmonary bypass (CPB) surgery, and 1 was closed successfully using an occlusion device a year later. The causes of failure included occlusion device shedding or shifting (n=6), failure of the guidewire (or the sheath) to pass through a small defect (n=5), device-related valve regurgitation (n=4), significant residual shunt (n=2), ventricular fibrillation (n=1), and continuous sharp blood pressure decreases (n=1). Patients with high VSD had a slightly higher failure rate than those with perimembranous VSD (p=0.049), and its key reason is the high proportion of occlusion device shedding or shifting (p=0.001). No significant difference in the failure rate was found between patients with different surgical incision approaches.

Conclusions Minimally invasive surgery has a high success rate for perimembranous VSDs. Occlusion device shedding or shifting is the most common cause of failure. The shedding or shifting risk of eccentric occlusion devices being used only for high VSDs is much greater than that of concentric occlusion devices being used for perimembranous VSDs, which increases the risk of conversion to CPB surgery for high VSDs.

INTRODUCTION

Ventricular septal defect (VSD) is a common congenital heart disease, and its treatment includes cardiopulmonary bypass (CPB) surgery and minimally invasive surgery. Minimally invasive surgery for transthoracic VSD closure under transesophageal echocardiography (TEE) guidance has attracted the attention of many scholars because of its

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Minimally invasive surgery for transthoracic ventricular septal defect (VSD) closure under transesophageal echocardiography guidance has achieved good clinical effects and has been rapidly popularized and used.
- ⇒ The failure rate of minimally invasive surgery is still high, approximately 5%.

WHAT THIS STUDY ADDS

- ⇒ The most common cause of failure was occlusion device shedding or shifting, including intraoperative shedding or shifting and postoperative delayed shifting.
- ⇒ The use of an eccentric occlusion device for high VSDs is the highest risk factor for minimally invasive surgical failure.
- ⇒ The incision approach for minimally invasive surgery does not affect the failure rate.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Awareness of the risk factors and the different causes of minimally invasive surgical VSD closure failure should be considered.
- ⇒ Surgeons should be aware that the shedding or shifting risk of eccentric occlusion devices being used only for high VSDs is much greater than that of concentric occlusion devices being used for perimembranous VSDs.

advantages of no CPB, no radiation injury, no restriction on weight or vascular access, less need for blood transfusion, minimal trauma, and quick recovery.¹⁻⁶ This approach has achieved good clinical effects and has been rapidly popularized and used. Two different surgical incision approaches, left intercostal incision (≤ 1 cm) and sternotomy incision (2-3 cm), have been adopted in our hospital according to different needs. High VSDs are closed with an eccentric occlusion device, and perimembranous VSDs are closed with a concentric occlusion device. The present



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study aimed to summarize the causes of failure cases among pediatric patients with minimally invasive surgical VSD closure during the past 5 years at our hospital to share our clinical experience of selecting an optimal VSD closure approach with the goal of increasing the success rate of VSD closure.

METHODS

Patients

We collected the data of patients who underwent minimally invasive surgical VSD closure at our hospital between January 2015 and December 2019. Nineteen cases of failure were identified among 522 patients. The inclusion criteria for a minimally invasive surgical VSD closure were as follows: perimembranous VSD and high VSD; no obvious reduction in VSD size, slow weight gain, or loud heart murmurs; no or mild tricuspid regurgitation without valvular heart disease; and no or mild aortic valve prolapse and aortic regurgitation with a perfect closed point. The exclusion criteria were as follows: non-restrictive VSD, malalignment-type VSD, valve abnormality that required surgical repair, severe pulmonary hypertension and other heart diseases, and other surgical contraindications.

Patients' age, weight, sex, VSD location, surgical incision approach, and specific cause for failure were all collected. A perimembranous VSD was defined to be located in the 09:00–11:00 positions in the parasternal short-axis view, and the distance between the VSD upper rim and the aortic valve was larger than 2 mm. A high VSD was defined to be located in the 11:00–13:00 positions in the parasternal short-axis view, and the distance between the VSD and the aortic valve was less than 2 mm. The surgical incision approach was selected at the discretion of the chief surgeon. A sternotomy incision was made in the lower part of the sternum, which was approximately 2–3 cm in length. A left intercostal incision was generally made on the left second–fourth intercostal space of the sternum, and the length was ≤ 1 cm. Informed consent was obtained from the guardians of all patients before the procedure. The following situations are thought to lead to failure of minimally invasive surgical VSD closure: (1) the procedure was either discontinued with removal of the device or converted to CPB surgery; and (2) reoperation was performed due to the occlusion device during follow-up.

Surgical procedures

Transthoracic echocardiography was performed 1–2 days before surgery to determine whether TEE-guided VSD closure was feasible. After the patient was anesthetized in the operating room, TEE was used to evaluate the VSD and select the appropriate occlusion device (Shanghai Shape Memory Alloy Co.). A concentric occlusion device was used for perimembranous VSDs, and the size of the concentric occlusion device selected was 0.5–1.5 mm larger than the maximum VSD diameter. An eccentric

occlusion device was used for high VSDs, and the size of the eccentric occlusion device selected was approximately 2 mm larger than the maximum VSD diameter. Then, a surgical incision (a sternotomy incision or an intercostal incision) was made; the pericardium was opened; and the heart was exposed. The whole surgical procedure, including the location of the position of the puncture on the anterior wall of the right ventricle, insertion of the guidewire and the sheath, and implantation of the occlusion device, were all carried out under real-time TEE guidance. During the operation, the patients' vital signs were closely monitored which included heart rate, rhythm, blood pressure, and oxygen saturation. After the device was released, TEE was used to evaluate the position of the occlusion device, presence of residual VSD shunt, device-related valve regurgitation, and presence of pericardial effusion. If the patient's vital signs were significantly abnormal or the device was not in the appropriate position, the procedure was either discontinued with removal of the device or converted to CPB surgery.

Follow-up

Follow-up examinations, including transthoracic echocardiography, electrocardiogram, X-rays, and blood tests, were performed to assess heart function, heart rhythm, occlusion device placement, residual shunting, valve regurgitation, infective endocarditis, and thrombus and pericardial effusion.

Statistical analysis

The data of age, weight and follow-up time are expressed as the median \pm interquartile range (IQR). The chi-square test or Fisher's exact test was used for pairwise comparisons between counting data groups by IBM SPSS Statistics V.23.0 software. The Kwiatkowski-Phillips-Schmidt-Shin (KPSS) test⁷ was applied to further compared the annual failure rates of minimally invasive surgical VSD closure over the 5-year period and was realized by using R software V.4.1.0 'urca' package. The null hypothesis of the KPSS test is a stationary series or a trend stationary series, while the alternative hypothesis is that there is a unit root. When the t-test value is far smaller than the critical value of 1%; that is, the p-test value is also far less than 1%, and the sequence has no significant instability. Therefore, this sequence is considered stable. A p value less than 0.05 was considered indicative of the statistical significance of each test.

RESULTS

Among the 522 patients who underwent minimally invasive surgical VSD closure, a total of 19 cases of unsuccessful closure were identified in this study. The failed cases included nine men and ten women aged 10–129 (30 \pm 33) months and weighing 7–63 (13 \pm 6) kg. **Table 1** shows the failure causes and follow-up treatment of 19 children with unsuccessful VSD closure. Occlusion device shedding or shifting, failure of the guidewire (or the sheath) to pass through a small defect and device-related

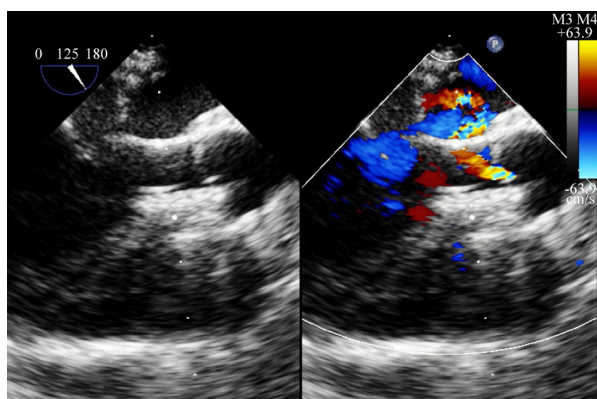
Table 1 Summary of the failure causes and follow-up treatment of 19 children with unsuccessful ventricular septal defect closure

Failure causes	Patients, n (%)	Failure rate, n/N (%)	Conversion to CPB surgery	Minimally invasive surgery
Occlusion device shedding or shifting	6 (31.58)	6/522 (1.15)		
Intraoperative shedding or shifting	4		4*	
Postoperative delayed shifting	2		2†	
Failure of the guidewire (or the sheath) to pass through a small defect	5 (26.32)	5/522 (0.96)		
Failure of the guidewire to pass through a small defect	4		4*	
Failure of the sheath to pass through a small defect	1		1*	
Device-related valve regurgitation	4 (21.05)	4/522 (0.77)		
Obvious aortic regurgitation	2		2*	
Obvious tricuspid regurgitation	2		2*	
Significant residual shunt	2 (10.53)	2/522 (0.38)	2*	
Ventricular fibrillation during the operation	1 (5.26)	1/522 (0.19)	1*	
Continuous and sharp fall of blood pressure during the operation	1 (5.26)	1/522 (0.19)		1
Total	19 (100)	19/522 (3.64)	18	1

*Intraoperative conversion.
 †Postoperative conversion.
 CPB, cardiopulmonary bypass; N, total patients (N=522).

valve regurgitation (figure 1) were common causes of failed VSD closure. Of the 19 children with failed closure, 18 underwent CPB surgery, and 1 was closed successfully using an occlusion device a year later. Two cases of intraoperative shedding and two cases intraoperative shifting were found by intraoperative TEE and warranted immediate conversion to CPB surgery. Two cases of postoperative delayed shifting (figure 2A) were found by transthoracic echocardiography on the second day and warranted immediate CPB surgery.

The failure rate of high VSD closure (6.77%) was slightly significantly higher than that of perimembranous VSD closure (2.57%) ($p=0.049$). No significant difference in the failure rate of VSD closure was found between patient with surgical sternotomy incision and left intercostal incision (table 2).


Figure 1 Device-related aortic valve regurgitation was caused by the use of an eccentric occlusion device for a high ventricular septal defect.

By analyzing the specific causes among failed cases, we found the key reason for the high failure rate of high VSD is the occlusion device shedding or shifting ($p=0.001$), and the remaining sepecific failure reasons were insignificant (table 3). High VSDs were more likely to cause

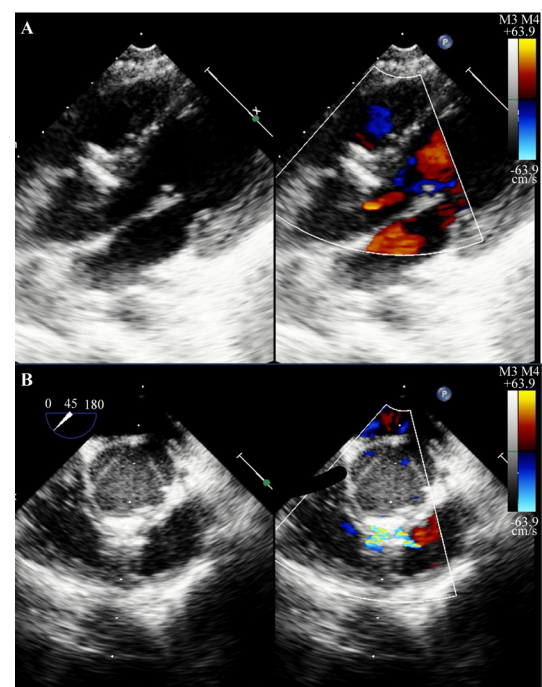

Figure 2 Delayed shifting of the eccentric occlusion device was found after high ventricular septal defect closure surgery (A). A slight residual shunt within the occlusion device and a normal position of the occlusion device in this patient were found by intraoperative transesophageal echocardiography (B).

Table 2 Comparisons of the failure rate of minimally invasive surgical VSD closure between different VSD locations and surgical incision approaches

Groups	Total patients (n=522)	Success		Failure		P value
		Patients (n=503)	Percentage (%)	Patients (n=19)	Percentage (%)	
VSD location						
Perimembranous VSD	389	379	97.43	10	2.57	0.049
High VSD	133	124	93.23	9	6.77	
Surgical incision approach						
Sternotomy incision	263	252	95.82	11	4.18	0.505
Left intercostal incision	259	251	96.91	8	3.09	

VSD, ventricular septal defect.

occlusion device shedding or shifting than perimembranous VSDs. In detail, 5 cases of occlusion device shedding or shifting were noted among patients with high VSDs, including 3 cases of intraoperative shedding or shifting and 2 cases of delayed shifting. Intraoperative shedding or shifting occurred in three cases with VSD sizes of 4, 4 and 6 mm. Delayed shifting occurred in two cases with VSD sizes of 3 and 7 mm. In one case with a VSD size of 7 mm, no residual shunting and the normal position of the occlusion device were found during the operation. In another case with a VSD size of 3 mm, a slight residual shunt within the occlusion device with a size of approximately 1 mm and a flow rate of approximately 2 m/s was found during the operation; however, the position of the occlusion device was normal and stable (figure 2B); thus, the device was released.

No significant difference was found in the annual failure rates of VSD closure via minimally invasive surgery guided by TEE over the 5-year period from 2015 to 2019 (t-statistic=0.11, $p<0.01$). Data comparisons of the annual failure rates are shown in table 4.

All patients were followed up for a mean period of 48 (25–70) months after the operation. Short-term complications, including pericardial effusion and pleural effusion, resolved within 4 months. No other complications were found during follow-up.

DISCUSSION

In this study, 522 children underwent minimally invasive surgical VSD closure, and 19 cases (3.64%) of failure occurred. The failure rate was low compared with that

Table 3 Comparisons of surgical factors between patients with perimembranous VSD and high VSD

Variables	Perimembranous VSD (n=389)	High VSD (n=133)	P value
Occlusion device shedding or shifting			
Yes	1 (0.26%)	5 (3.76%)	0.005
No	388 (99.74%)	128 (96.24%)	
Failure of the guidewire (or the sheath) to pass through a small defect			
Yes	4 (1.03%)	1 (0.75%)	1.00
No	385 (98.97%)	132 (99.25%)	
Device-related valve regurgitation			
Yes	3 (0.77%)	1 (0.75%)	1.00
No	386 (99.23%)	132 (99.25%)	
Significant residual shunt			
Yes	1 (0.26%)	1 (0.75%)	0.45
No	388 (99.74%)	132 (99.25%)	
Ventricular fibrillation			
Yes	1 (0.26%)	0 (0%)	1.00
No	388 (99.74%)	133 (100.00%)	
Continuous and sharp blood pressure decreases			
Yes	0 (0%)	1 (0.75%)	0.23
No	389 (100.00%)	132 (99.25%)	

VSD, ventricular septal defect.

Table 4 Comparisons of the annual failure rates of minimal invasive surgical ventricular septal defect closure over the 5-year period from 2015 to 2019

Year	Total patients (n=522)	Success		Failure		t-statistic	P value
		Patients (n=503)	Percentage (%)	Patients (n=19)	Percentage (%)		
2015	81	79	97.53	2	2.47	0.11	<0.01
2016	109	105	96.33	4	3.67		
2017	104	98	94.23	6	5.77		
2018	101	97	96.04	4	3.96		
2019	127	124	97.64	3	2.36		
Total	522	503	96.36	19	3.64		

in other studies.^{3-5 8-12} In the 5 years from 2015 to 2019, the annual failure rate was similar and not significantly different likely due to our team having substantial experience in surgical VSD closure in children. Transthoracic minimally invasive surgical VSD closure has been carried out for more than 10 years in our hospital. Moreover, the ultraminimal left intercostal incision was improved on the basis of the sternotomy incision approach in nearly 1000 patients.^{1 6 13} Therefore, the learning curve of the ultraminimal left intercostal incision approach for VSD closure is shallow. For surgical VSD closure, both cardiac surgeons and TEE doctors must accumulate early experience, have skillful manipulatory techniques, and work cooperatively.^{6 12 14}

No significant difference in the failure rate was found between the ultraminimal left intercostal incision approach and sternotomy incision approach. However, the use of the ultraminimal left intercostal incision (≤ 1 cm) prevents the need for a sternal incision and leads to minimal scarring. Therefore, promoting the application of this procedure in VSD closure is worthwhile.¹⁵

Compared with those in previous literature,¹² the proportion of occlusion device shedding or shifting, which are the most common cause of procedure failure, was higher in this study cohort. The rate of VSD closure failure varies because of different VSD locations. The key reason for the high failure rate of high VSD is the occlusion device shedding or shifting, which likely due the use of eccentric occlusion devices for high VSD. The unique design of the eccentric occlusion device is suitable for high VSD, because its left disc exceeds the connecting waist by 0 mm in its superior aspect and by 4 mm in its inferior aspect (mark), while its right disc is 2 mm larger than the waist. This design can prevent aortic valve trauma caused by the placement of an ordinary occlusion device. Pointing the superior part of the left disc toward the aortic valve can prevent impairment of aortic valve function and contribute to the success the closure of high VSD.¹ However, due to the bare upper edge of the left disc, the rate of device shedding or shifting is much higher compared with a concentric occlusion device. In this study, the sizes of the high VSDs causing shedding or shifting of the eccentric occlusion device ranged from 3 mm to 7 mm. It seems that the size of the defect is not the

main cause but the use of an eccentric occluder matters. Therefore, our team recommends that the push-pull test should be carried out after the occlusion device is released. After the test, the occlusion device should be released only in the absence of residual shunting at the upper edge of the occlusion device, and the position of the occlusion device is stable to prevent intraoperative and postoperative delayed shedding or shifting.

Failure of the guidewire (or the sheath) to pass through a small defect is the second most common reason for failure, mainly due to the small and variable shunt orifice caused by the proliferation of fibrous tissue on the right ventricular side of the defect. To avoid repair surgery for small defects under CPB, some surgeons have tried minimally invasive surgical VSD closure before repair. Under this condition, whether the guidewire can pass through the VSD is closely related to the proficiency of the doctors and their close cooperation. In particular, accurate positioning can increase the success rate of small defect closure.¹⁵ If the success rate of VSD closure is not very high, a sternotomy incision, which is made in the lower part of the sternum, is recommended. When minimally invasive surgery is converted to CPB surgery, the operation can be completed by extending the original incision.^{13 15}

A third cause of failure is obvious interference with the movement of adjacent valves after releasing the VSD occlusion device. If obvious tricuspid regurgitation, that is, mild to moderate and above, or aggravated aortic regurgitation is found after releasing the occlusion device, our team believes that the occlusion device interferes with the movement of adjacent valves. If the valve regurgitation still does not improve after the occlusion device is adjusted again, it should be switched to CPB surgery. Therefore, TEE should be used to accurately evaluate the VSD location and the distance from the defect to the tricuspid valve and aortic valve before surgery. At the same time, the whole closure process should be carefully and dynamically monitored in real time to prevent valve damage. If obvious valve regurgitation is noted during the closure process, the closure operation should be suspended, adjusted, or even abandoned.

Residual shunts were the most common short-term complication of minimally invasive surgical VSD closure.

A mild residual shunt has been shown to self-heal during follow-up exams. However, at present, no unified and reliable standard is available for the acceptable level of residual shunting after occlusion device release. Our team has found through practical experience that in perimembranous VSDs, a small residual shunt with a size of <2mm can self-heal. A significant residual shunt (>2mm with high-speed flow >2.5 m/s) adjacent to the occlusion device most likely requires replacement with a larger occlusion device or conversion to CPB surgery.^{15 16} For a high VSD occluded with an eccentric occlusion device, the literature indicates that a residual shunt with a size <1.5mm and flow rate of <1.5 m/s can be self-healing.¹⁷ However, our team recommends that a residual shunt of any size adjacent to the occlusion device is likely to need replacement with a larger occlusion device or conversion to CPB surgery to prevent postoperative delayed shedding or shifting of the occlusion device.

Transient decreases in blood pressure during minimally invasive surgery are common. However, an inability to perform complete closure due to continuous and sharp decreases in blood pressure has rarely been reported. In this study, a 12-month-old female patient weighing 8.1 kg had a subaortic valve VSD measuring 4.3mm. During surgical VSD closure via a left intercostal incision, a continuous and sharp decrease in blood pressure occurred when the sheath passed through the defect. Because her guardians refused to allow repair of the VSD under CPB, the closure operation was stopped after two attempts. One year later, minimally invasive surgical VSD closure was performed again with the same incision approach. The child underwent successful VSD closure without any obvious decrease in blood pressure during the operation. The reason for the continuous and sharp decrease in blood pressure during closure surgery is still unclear. A multicenter study with a large sample size is necessary to determine the reason. An overweight patient developed ventricular fibrillation during closure surgery, which is considered to be related to excessive cardiac traction. This complication has been reported in another article.⁶

In conclusion, in this study, minimally invasive surgery had a higher success rate for perimembranous VSD treatment, and the location of VSDs is an important predictive factor. Occlusion device shedding or shifting is the most common cause of failure. The use of an eccentric occlusion device for high VSDs increases the risk of occlusion device shedding or shifting, which leads to conversion to CPB surgery. Failure of the guidewire (or the sheath) to pass through a small defect and device-related valve regurgitation are also common causes of failed VSD closure. In addition, significant residual shunt, serious arrhythmia and continuous and sharp blood pressure decreases during the operation also occurred. The incision approach for minimally invasive surgery does not affect the failure rate, and the surgical incision can be selected according to different needs. However, this study was limited by its single-center design, and some

questions encountered in the practice of closure surgery still cannot be answered. In the future, our team will continue to increase the sample size and conduct a multicenter study to provide more reliable information to serve as a clinical reference for improving the success rate of surgical VSD closure.

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Patient consent for publication Not applicable.

Ethics approval This study was approved by the ethics board of the Children's Hospital, Zhejiang University School of Medicine, on June 24, 2021 (approval number: 2021-IRB-144).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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