Transcatheter ventricular septal defect closure via femoral vein alone under transthoracic echocardiography guidance without fluoroscopy: preliminary experience

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Abstract

Objective. Transcatheter closure of congenital ventricular septal defects under echocardiography guidance could avoid potential radiation damage from fluoroscopy probes. However, mini-surgical incision, transesophageal echocardiography combined with tracheal intubation, and limited artery access further complicate the procedure. Therefore, we aimed to describe our preliminary experiences in percutaneous VSD closure via the femoral vein only under transthoracic echocardiography (TTE) guidance. **Methods.** Between December 2018 and November 2021, 19 patients underwent transcatheter VSD closure via femoral vein alone under the guidance of TTE in our hospital. The morphology, location, diameter of VSD, and procedural outcomes were thoroughly reviewed. Symmetric, asymmetric, or eccentric occlusion device was chosen for closure based on the VSD characteristics. **Results.** There were 16 perimembranous VSD and 3 intracristal VSD patients in this cohort. The range of diameter of the VSD was from 3.8 to 7.4 mm. Fifteen symmetrical occluders were implanted in 13 perimembranous and 2 intracristal VSD patients. Two eccentric occluders were implanted in 1 perimembranous and 1 intracristal VSD patient since the rim to the aortic valve distance was <2 mm. Moreover, 2 asymmetrical occluders were used in 2 perimembranous multi-hole VSDs. Immediate procedure and 16.1±9.9 months' follow-up outcomes showed no device dislodgement and embolism, no new-onset aortic valve regurgitation, and no atrioventricular heart block. **Conclusions.** Transcatheter perimembranous and intracristal VSD closure via femoral vein alone under the TTE guidance is feasible and safe in eligible patients. The new type of multipurpose specialized catheter will facilitate this procedure.

INTRODUCTION

Ventricular septal defect (VSD) is one of the most common forms of congenital heart

disease (CHD), affecting 1 in every 240 babies born in the US. The transcatheter closure (TCC) device has been found less traumatic with better outcomes compared to conventional surgical intervention in the management of VSD. Furthermore, long-term follow-up studies have confirmed the improved safety and efficacy of the TCC procedure in both pediatric and adult patients, thus making percutaneous VSD closure widely practiced in clinical settings[1-3].

Because of the substantial health hazards in pediatric patients and medical staff from the traditional fluoroscopy-guided TCC procedure[4-6], the echocardiography-guided VSD closure approach has been increasing in CHD management in China[7-10]. Moreover, mini-sternotomy or mini-thoracotomy for VSD correction brings additional cosmetic issues. The application of transesophageal echocardiography (TEE)

combined with tracheal intubation in VSD patients under general anesthesia further complicates the procedure with increased risk. Furthermore, retrograde closure of the ventricular septal valve via the femoral artery only without an arteriovenous loop remains a technical challenge in VSD with mild aortic cusp prolapse[11, 12].

Therefore, we report the multi-modal therapeutic advantages of the percutaneous VSD closure via femoral vein only under the guidance of transthoracic echocardiography (TTE) in the eligible patient.

MATERIALS AND METHODS

Subject selection

A total of 19 patients with VSD who had successfully undergone TCC procedure via a femoral vein under the guidance of TTE at our hospital between December 2018 and November 2021 were retrospectively reviewed and recruited to this study. The study protocol was approved by the institutional ethics committee of the First Affiliated Hospital of Guangxi Medical University. The requirement for patient consent was waived because of the retrospective nature of the study.

The enrolled patients fully met the following selection criteria: 1) age [?] 2 years old; 2) bodyweight [?] 10 kg; 3) diagnosed with either perimembranous or intracristal VSD, and 4) VSD diameter [?]3mm. While cases were excluded, if 1) diagnosed with either doubly committed subarterial defects or inlet muscular septal defect (inlet VSD); 2) chronically comorbid with cardiac lesions requiring correction during the procedure; 3) diagnosed with a moderate-to-severe grade of aortic valve regurgitation; 4) presence of severe pulmonary hypertension; 5) having acute infective endocarditis, and 6) comorbid with hemorrhagic diseases, that are not suitable for antiplatelet therapy.

Echocardiographic assessment

Comprehensive TTE procedure was performed using the iE33 ultrasound system, where the frequency range of S5-1 probe was 1-5 MHz, and that for S8-3 probe was 3 -8 MHz (Philips Medical Systems, USA) by an experienced echocardiologist (Dr. Ji Wu) before the TCC of VSD. The VSD morphology, diameter, location, the distance from the rim of the VSD to the aortic valve, aortic prolapse/regurgitation, and other cardiac abnormalities were thoroughly assessed. The orifice on the right ventricular side was measured in the case of multi-hole perimembranous VSD with an aneurysm. Information about additional echocardiography parameters was retrieved from the hospital's echocardiography database. In the parasternal short-axis views, distances between the VSD far point and pulmonary annular and tricuspid septal annular were expressed as D_{fp} and D_{ft}, respectively, while the distance between VSD near point and tricuspid septal annular was expressed as D_{nt}(**Figure 1**).

Device description

VSD Heart occluder was designed and manufactured by Shenzhen LifeTech Scientific corporation. It was a self-expandable device with two discs with a 3-mm long connecting waist. The diameter of the waist corresponded to the size of the VSD occluder. Three types of occluder were mainly used, such as the symmetrically and asymmetrically concentric, and eccentric. The flanges of the 2 ventricular discs were 2-mm wide in the symmetry type. The flange of the device was 4 mm wider than the waist on the left ventricular side and 2 mm wider than the waist on the right side in the asymmetrical concentric type. In the eccentric type, the superior part of the left ventricular disc facing the aortic valve was 0.5 mm, and the opposite part was 5 mm.

Procedure

We performed the procedure in a routine operation room. The patient was placed in a supine position with general anesthesia. A laryngeal mask was placed to facilitate airway management. Dr. Ji Wu used a GE ultrasound machine (Vivid E95, GE Healthcare, USA) for procedure guidance. Heparin was administered at the dose of 100 IU/kg after the right femoral vein was punctured and a 5F arterial sheath was inserted. In the subxiphoid view, 5F Judkins right JR 4.0 (JR4) catheter (Cordis Corporation, USA) was introduced

along a 0.035-in angled hydrophilic guidewire (Terumo Radifocus Guide Wire, M Standard Type) into the right atrial. After rotating the tip of JR4 towards the tricuspid valve, the guidewire was pushed into the right ventricle, and subsequently, JR4 was advanced through it. Successful placement of the catheter in the right ventricle outflow tract was verified in the short-axis view. The direction of JR4 was then adjusted to align with the ventricular septum and slowly pulled it back until the tip of the catheter dropped into VSD gap. Four-chamber or long-axis view was used to monitor the catheter in the left ventricle. After the guidewire was pushed forward, JR4 was manipulated in the four-chamber view and confirmed to locate in the left ventricle apex. JR4 was subsequently retracted after the hydrophilic guidewire was removed and substituted by a standard exchange J-Tip guidewire (Cordis Corporation, USA). The long delivery sheath was advanced over the guidewire to the left ventricle under echocardiographic monitoring. Sheath length placed via the right femoral vein was estimated based on the counterpart of JR4 implanted in advance. After the dilator of the sheath was withdrawn, an occluder 1-2 mm longer than the longest diameter of VSD was delivered along the sheath. Different types of occluder were selected in accordance with the morphology of VSD. The apical four-chamber or five-chamber view could always reliably monitor the VSD occluder deployment. Before the occluder was unscrewed, the correct position of the device, the presence of residual shunt, and aortic regurgitation were identified by multiple echocardiographic views. If the position was appropriate as per TTE images, the occluder was detached (**Figure 2**). Otherwise, either the occluder type was changed or switched to surgical intervention.

Postoperative management and follow-up

A dose of 3–5 mg/kg oral aspirin was given 6 h after the procedure and continued for 6 consecutive months. All patients underwent continuous ECG for 2 days postoperatively in case of any severe cardiac arrhythmia. TTE using 12-lead ECG was performed before the discharge and at 1-, 3-, 6- and 12-month post-operation and yearly thereafter, as well.

Statistical analysis

Normally distributed continuous variables are presented as mean ± standard deviation (SD) and non-normally distributed variables as median (interquartile range (IQR)). Categorical variables are expressed as numbers and proportions. The Kolmogorov–Smirnov test was conducted for the normality measurement. SPSS version 23.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

RESULTS

Study population and TTE measurements

Nineteen patients were treated with a TCC procedure for VSD management via a femoral vein under the guidance of TTE between March 2018 and December 2021. Diagnostically, there were 16 perimembranous VSDs and 3 intracristal VSDs. The range of diameter of the VSD was from 3.8 to 7.4 mm. However, 1 perimembranous and 3 intracristal VSDs had a distance [?] 2 mm between the rim and aortic valve. The ranges of D_{nt}, D_{ft} , and D_{fp} were 4.0 - 9.5mm, 8.7 - 24.2mm, and 4.0 - 18.6 mm, respectively (**Table 1**).

Procedure and follow-up outcomes

The average procedure time was 109+-50.8mins. Fifteen symmetric occluders were implanted in 13 perimembranous and 2 intracristal VSD patients following the abovementioned TCC procedure. Furthermore,2 eccentric occluders were implanted in 1 perimembranous and 1 intracristal VSD patient, respectively. Two asymmetric occluders were used in 2 perimembranous patients due to their muti-hole VSD morphology. The size range of the occluder was from 5 to 10 mm. Notably, one patient with the muti-hole VSD had 2 mm residential leaks after the occluder was deployed (**Table 2**).

During a median of 16.1+-9.9 months' follow-up, all the patients exhibited sinus

rhythm and no signs of atrioventricular heart block. Although 2 patients had an onset of the right bundle branch block, however, no new onset of aortic valve regurgitation, device embolism, or other postoperative adverse events were observed. Residential leaks were sustained.

DISCUSSION

We have described our preliminary experiences in the management of percutaneous VSD closure via femoral vein only under the TTE guidance without fluoroscopy, which we believe to be the first case study on the TCC procedure involving multiple types of occluder based on the VSD diameter and morphology variations.

Since Lock and colleagues[13] first reported the transcatheter perimembranous VSD closure in 1988, percutaneous device closure has been an alternative treatment to perimembranous VSD. To avoid the potential damage from the radiation of radioisotopes to doctors and patients, Chinese surgeons specifically performed minimally invasive perventricular device closure under the TEE guidance alone without fluoroscopy assistance. Operative effects, such as surgical trauma, general anesthesia, endotracheal intubation, and inevitable scar weaken echocardiography-based therapeutic strategy. Unlike the whole instrument-tracking images from fluoroscopy, echocardiography images are segmental; therefore, an arterio-venous loop is difficult to establish using a snare. A single vessel is routinely employed in such instances[14, 15]. Wang et al. have demonstrated the feasibility and safety of the retrograde approach through the femoral artery under TTE guidance alone. Nonetheless, the concern about this strategy is particularly centered at the arterial injury in small children owing to large delivery systems[16]. The chance of damage to the aortic valve further increases when the catheter and sheath are advanced into the left ventricle. Therefore, we performed the procedure through an antegrade approach by real-time echocardiography monitoring. A stable sheath location was acquired by pushing it into the left ventricle apex along the guidewire. Thus, no arterio-venous loop was needed, and procedural injury to the artery and aortic valve were avoided.

Sub-arterial VSD has a superior rim of <2 mm under the aortic valves. Thus, a symmetric occluder may protrude to influence the aortic valve. The eccentric occluder has been designed especially for this kind of VSD with a flange of the LV disc facing the aortic valve of 0-0.5 mm rim, and employment should be antegrade due to its eccentricity. Lower partial median sternotomy or mini-thoracotomy are usually performed to facilitate this procedure via perventricular access[17-19]. We used an eccentric occluder in two sub-arterial VSD patients through the femoral vein. One VSD was perimembranous, and the other was infracristal with mild prolapse of the aortic valve. Employment of the occluder with simultaneous TTE monitoring greatly helped judge whether the occluder affected the aortic valve; if so, the direction of the occluder could be adjusted, or the occluder type could be changed. Otherwise, conventional surgical intervention could be recommended.

Although TEE offers clear images in transcatheter congenital heart intervention and is suggested in echocardiography guidance alone, TTE has its advantage in avoiding endotracheal intubation and TEE probe insertion-associated complications. So TTE guidance is considered an alternative strategy to atrial septal defect (ASD) or patent ductus arteriosus (PDA) closure, or balloon pulmonary valvuloplasty[20-22]. Wang and his colleagues have suggested the feasibility, safety, and effectiveness in percutaneous perimembranous VSD closure under the TTE guidance alone[15]. We had a clear impression of VSD from echocardiography images during preoperative echo assessment. Once got a clear vision in several sections when the patients were lying in a supine position, TTE guidance would be implemented in the subsequent procedure. Patients were always kept under general anesthesia while ventilating with a laryngeal mask. Thereafter a quieter state was acquired when the TTE probe moved on the patient's chest. In case of the images during the procedure were uninterpretable or TCC was difficult to execute, conversion to surgery was easy to achieve.

A guidewire could smoothly advance into the right ventricle via artery along the left-to-right blood flow direction. However, antegrade advancement of the guidewire from right to left ventricle needed transvenous guidance of catheter. As there was no specifically designed catheter for trans-femoral vein VSD occlusion, we chose JR4 or modified cut pigtail catheter to guide the guidewire passing through the VSD. Measurement of proper diameter of VSD was significant to the success of this strategy. The tip of the catheter was difficult to insert into a small VSD gap. It seemed that perimembranous VSD with a diameter of less than 3 mm was not appropriate for transvenous occlusion in our study. Additionally, the location of VSD influenced the establishment of the guidewire trajectory. When VSD was close to the septal leaflet of the tricuspid valve, the catheter was easily pulled out to the right atrial before its tip fell into the VSD. Our data showed that

over 8 mm of D_{ft} facilitated the catheter manipulation to insert into the left ventricle. While VSD was double committed sub-arterial, the guidewire trajectory was difficult to cross into the left ventricle along the catheter due to the perpendicular angle between the VSD location and direction of guidewire advancement. So, we did not include double committed subarterial VSD cases in this study. The shortest distance between the VSD far point and the pulmonary annular was 4 mm. Importantly, these results may serve as the reference values to be used in preoperative echocardiography assessment.

Limitations

There were certain limitations to this study, which should be carefully considered in the interpretation of results. First, this study could include only 19 patients. Hence, to understand the anatomical characteristics of VSD for the identification of patients suitable for transvenous occlusion, further study should include a large cohort of VSD patients. Second, a specialized catheter should be designed so that a wide spectrum of VSD can be closed via venous access alone. And third, although the TTE images were not clear for every patient, we speculate that TTE can provide clear images in pediatric patients; therefore, it is a qualified imaging modality in echocardiographic guidance.

CONCLUSION

Transcatheter VSD closure via femoral vein alone under the TTE guidance without fluoroscopy is a feasible and safe procedure. This approach could avoid tracheal intubation, fluoroscopy damage, artery invasion, and scars from the surgical incision. More patients will be benefitted from this procedure with further experience and the development of multipurpose specialized catheters.

Conflict of interest

None declared.

Data Availability Statement

The data that support the findings of this article are available on reasonable request from the corresponding author[J.W].

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References

1. Bergmann M, Germann CP, Nordmeyer J, Peters B, Berger F, Schubert S (2021) Short- and Long-term Outcome After Interventional VSD Closure: A Single-Center Experience in Pediatric and Adult Patients. Pediatr Cardiol 42(1):78-88

2. Kozlik-Feldmann R, Lorber A, Sievert H, Ewert P, Jux C, Muller GC, Dalla Pozza R, Yigitbasi M, Schranz D, Lindinger A, Galal O, Meinertz T (2021) Long-term outcome of perimembranous VSD closure using the Nit-Occlud(R) Le VSD coil system. Clin Res Cardiol 110(3):382-390

3. Li P, Zhao XX, Zheng X, Qin YW (2012) Arrhythmias after transcatheter closure of perimembranous ventricular septal defects with a modified double-disk occluder: early and long-term results. Heart Vessels 27(4):405-410

4. Cohen S, Liu A, Gurvitz M, Guo L, Therrien J, Laprise C, Kaufman JS, Abrahamowicz M, Marelli AJ (2018) Exposure to Low-Dose Ionizing Radiation From Cardiac Procedures and Malignancy Risk in Adults With Congenital Heart Disease. Circulation 137(13):1334-1345

5. Johnson JN, Hornik CP, Li JS, Benjamin DK, Jr., Yoshizumi TT, Reiman RE, Frush DP, Hill KD (2014) Cumulative radiation exposure and cancer risk estimation in children with heart disease. Circulation 130(2):161-167

6. Modan B, Keinan L, Blumstein T, Sadetzki S (2000) Cancer following cardiac catheterization in childhood. International journal of epidemiology 29(3):424-428

7. Chen Q, Hong ZN, Zhang GC, Chen LW, Zhang QL, Lin ZW, Cao H (2018) Intraoperative Device Closure of Isolated Ventricular Septal Defects: Experience on 1,090 Cases. Ann Thorac Surg 105(6):1797-1802

8. Song S, Fan T, Li B, Liang W, Dong H, Wu K, Liu L (2017) Minimally Invasive Peratrial Device Closure of Perimembranous Ventricular Septal Defect Through a Right Infraaxillary Route: Clinical Experience and Preliminary Results. Ann Thorac Surg 103(1):199-204

9. Xing Q, Pan S, An Q, Zhang Z, Li J, Li F, Wu Q, Zhuang Z (2010) Minimally invasive perventricular device closure of perimembranous ventricular septal defect without cardiopulmonary bypass: multicenter experience and mid-term follow-up. J Thorac Cardiovasc Surg 139(6):1409-1415

10. Zeng XJ, Sun SQ, Chen XF, Ma XJ, Luo YH, Lim YP, Tao L (2008) Device closure of perimembranous ventricular septal defects with a minimally invasive technique in 12 patients. Ann Thorac Surg 85(1):192-194

11. Lin HC, Lin MT, Chen CA, Hsu JY, Lin SM, Wu MH, Wang JK (2021) Safety and efficacy of transcatheter closure of outlet-type ventricular septal defects in children and adults with Amplatzer Duct Occluder II. J Formos Med Assoc 120(1 Pt 1):180-188

12. Yang P, Wu Z, Liu Z, Zhang J, Zhou H, Ji X, Yi Q, Li M (2021) Unplanned Surgery After Transcatheter Closure of Ventricular Septal Defect in Children: Causes and Risk Factors. Frontiers in pediatrics 9:772138

13. Lock JE, Block PC, McKay RG, Baim DS, Keane JF (1988) Transcatheter closure of ventricular septal defects. Circulation 78(2):361-368

14. Bu H, Yang Y, Wu Q, Jin W, Zhao T (2019) Echocardiography-guided percutaneous closure of perimembranous ventricular septal defects without arterial access and fluoroscopy. BMC Pediatr 19(1):302

15. Wang S, Ouyang W, Liu Y, Zhang F, Guo G, Zhao G, Pan X (2018) Transcatheter perimembranous ventricular septal defect closure under transthoracic echocardiographic guidance without fluoroscopy. J Thorac Dis 10(9):5222-5231

16. Arora R, Trehan V, Kumar A, Kalra GS, Nigam M (2003) Transcatheter closure of congenital ventricular septal defects: experience with various devices. Journal of interventional cardiology 16(1):83-91

17. Hongxin L, Wenbin G, Liang F, Zhang HZ, Zhu M, Zhang WL (2015) Perventricular device closure of a doubly committed juxtaarterial ventricular septal defect through a left parasternal approach: midterm follow-up results. J Cardiothorac Surg 10:175

18. Lin K, Zhu D, Tao K, Gan C, Tang H, Feng Y, An Q (2013) Hybrid perventricular device closure of doubly committed subarterial ventricular septal defects: mid-term results. Catheter Cardiovasc Interv 82(3):E225-232

19. Pan S, Xing Q, Cao Q, Wang P, Duan S, Wu Q, Hou K (2012) Perventricular device closure of doubly committed subarterial ventral septal defect through left anterior minithoracotomy on beating hearts. Ann Thorac Surg 94(6):2070-2075

20. Pan XB, Ou-Yang WB, Pang KJ, Zhang FW, Wang SZ, Liu Y, Zhang DW, Guo GL, Tian PS, Hu SS (2015) Percutaneous Closure of Atrial Septal Defects Under Transthoracic Echocardiography Guidance Without Fluoroscopy or Intubation in Children. J Interv Cardiol 28(4):390-395

21. Trehan V, Mukhopadhyay S, Nigam A, Yusuf J, Mehta V, Gupta MD, Girish MP, Tyagi S (2005) Mitral valvuloplasty by inoue balloon under transthoracic echocardiographic guidance. Journal of the American Society of Echocardiography : official publication of the American Society of Echocardiography 18(9):964-969

22. Ye Z, Li Z, Yi H, Zhu Y, Sun Y, Li P, Ma N (2020) Percutaneous device closure of pediatirc patent ductus arteriosus through femoral artery guidance by transthoracic echocardiography without radiation and

contrast agents. J Cardiothorac Surg 15(1):107

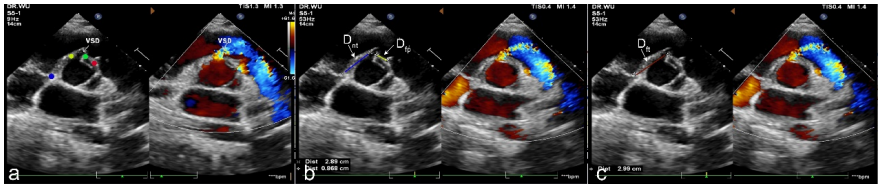

Figure 1: Echocardiography evaluation before device closure of VSD. **a** The VSD near point (yellow point) and far point (green point), the tricuspid septal annular (blue point), and pulmonary annular (red point) were shown in short-axis view. **b** Dnt and Dfp were measured in short-axis view. **c** Dft was measured in short-axis view. VSD= ventricular septal defect, Dnt= the distance between VSD near point and tricuspid septal annular, Dfp= the distance between VSD far point and pulmonary annular, Dft= the distance between VSD far point and tricuspid septal annular.

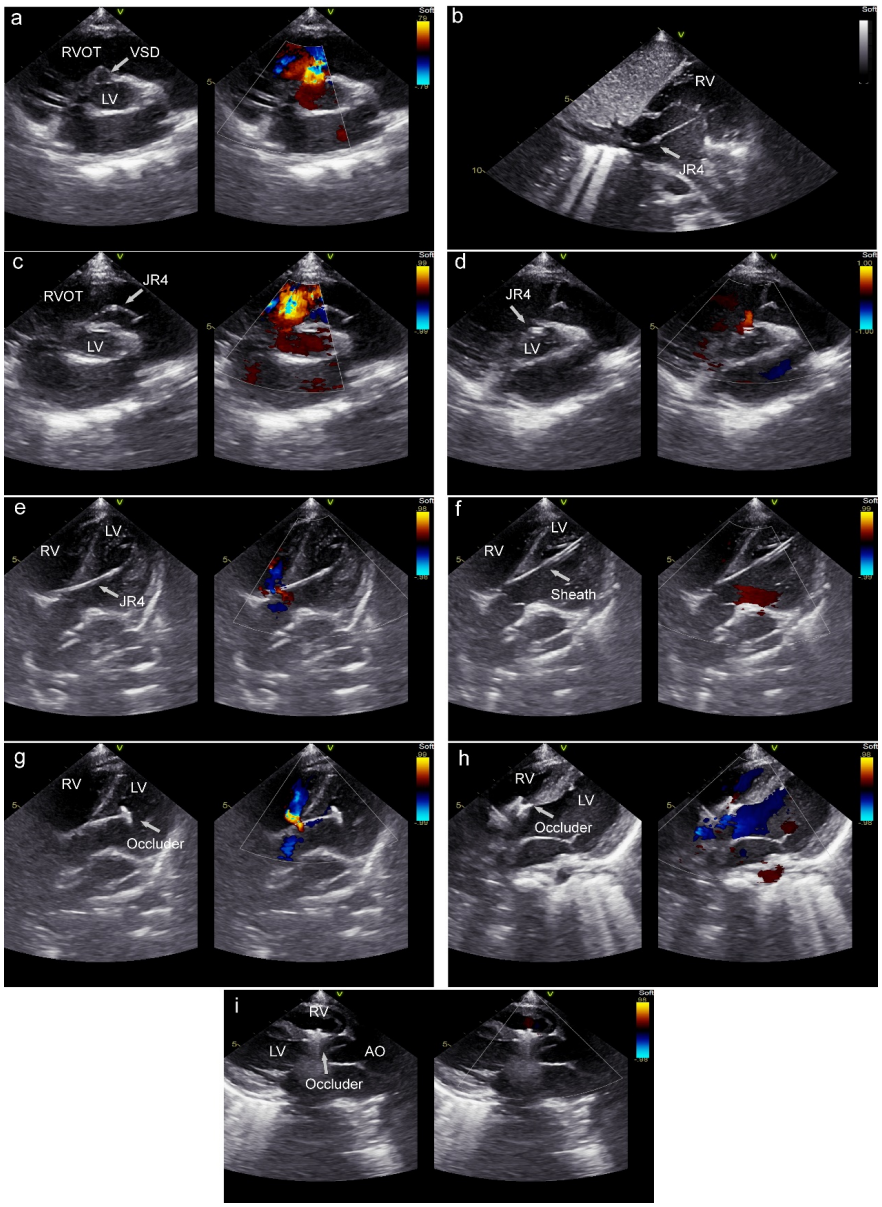

Figure 2: Transcatheter VSD closure via femoral vein alone under the TTE guidance. **a** TTE view of intracristal VSD.**b** A 0.035-in angled hydrophilic guidewire crossed through tricuspid valve under JR4 guidance in subxiphoid view. **c** JR4 in right ventricle outflow tract. **d** The tip of JR4 dropped into VSD gap in short axis view. **e** JR4 was placed in the left ventricle apex. **f** The long delivery sheath was advanced over the exchange guide wire into the left apex in the four-chamber view.**g** Deployment of VSD occluder under TTE monitoring. **h**Assessment of position and aortic regurgitation in five chamber view.**i** No aortic valve regurgitation was detected in the long axis view of the aorta. VSD= ventricular septal defect, TTE= transcatheter echocardiography, JR= Judkins right coronary catheter.

Table 1. Baseline Characteristics of Patients

Total number,(n)	19
Age,median (IQR), kg	5.1(3.1-6.9)

Total number,(n)	19
Gender(male),n(%)	5(26.3)
Height, mean (SD), cm	109.5(19.6)
Weight, median (IQR), kg	17.0(14.4-20.3)
BSA, median (IQR),m^2	0.7(0.6-0.8)
TTE	
Perimenbranous, n(%)	16 (84.2)
Intracristal, n(%)	3(15.8)
Diameter, mean (SD), mm	5.4 (1.1)
Distance to aortic valve,mean (SD), mm	2.7(1.8)
D_{nt}, mean (SD), mm	6.5 (2.0)
D_{fp}, mean (SD), mm	11.5 (3.8)
D_{ft}, mean (SD), mm	13.1 (3.5)
Aortic regurgitation,n(%)	1(5.3)
ECG	
Sinus rhythm,n(%)	19(100)
RBBB	0
LBBB	0
II° or III° AVB	0

BSA= body surface area; IQR= interquartile range

SD= standard deviation;

TTE=transthoracic echocardiography;

D_{nt}=the distance between VSD near point and tricuspid septal annular;

D_{fp}=the distance between VSD far point and pulmonary annular;

D_{ft}= the distance between VSD far point and tricuspid septal annular;

ECG=electrocardiogram;

RBBB= right bundle branch block; LBBB= left bundle branch block;

AVB= atrioventricular block

Table 2. Results of Procedure

Variables	Values
Procedure time, mean (SD), min	104.8 (50.8)
Device type	
symmetry,n(%)	15(78.9)
asymmetry,n(%)	2 (10.5)
eccentricity,n(%)	2 (10.5)
Device size,median (IQR),mm	7.0 (6.0-8.0)
Device related AR,n(%)	0
Device related TR,n(%)	0
Residual shuts,n(%)	1,(5.3)
Device dislodgement or embolism, n(%)	0
Pericardial effusion, n(%)	0

SD= standard deviation; IQR= interquartile range;

AR=aortic regurgitation; TR=tricuspid regurgitation