Percutaneous-perventricular device closure of ventricular septal defect: mid-term follow-up.

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Research article

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Abstract

Background: This report presents updated data and mid-term follow-up information to a former study introducing the novel technique of percutaneous-perventricular device closure of doubly committed subarterial ventricular septal defect.

Methods: Thirty-eight patients were added to the former series. There are totally 54 patients who had isolated doubly committed subarterial ventricular septal defects underwent percutaneous-perventricular device closure. Closure outcomes and possible complications were measured in the hospital and during the 2.5 years follow-up.

Results: Closure was successful in 53 patients (98.1%). There was no mortality, residual shunt, new valve regurgitation or arrhythmia either perioperatively or during the entire follow-up period. Only one patient who developed pericardial effusion and tamponade in the former series. The mean hospital stay was 3.2±0.6 days (range, 3.0 to 6.0 days), one unsuccessful cases needed blood transfusion (1.9%).

Conclusions: The percutaneous-perventricular device closure of isolated doubly committed subarterial ventricular septal defects appeared to be efficacious. Close monitoring for bleeding is very necessary postoperatively especially in younger patients. This technique is generally safe in selected group of patients with acceptable mid-term outcomes. Keywords: Ventricular septal defect; Device closure; Minimally invasive surgery

Background

Doubly committed subarterial ventricular septal defect (VSD) is a unique type of VSD accounting for about 5-7% of all VSDs [1], which has been a contraindication for percutaneous transcatheter device closure due to the challenging geometry consisting of the upper edge of the defect and the aortic valve. Perventricular device closure of VSD without cardiopulmonary bypass (CPB) under transesophageal echocardiography (TEE) guidance has been widely practiced in China [2-3], and also gained some experience in Europe [4]. This technique has also been introduced recently in the treatment of doubly committed subarterial VSD with encouraging initial results and excellent cosmetic outcome [5-7]. Comparing with a mini-thoracotomy in this technique, we have advanced a novel and more minimally invasive method by combining perventricular device closure and the percutaneous approach [8]. We successfully closed doubly committed subarterial VSDs through a pinhole-size puncture on the chest. The short-term result has been introduced elsewhere [8], and we present an update of the patient series and its mid-term follow-up result.

Methods

In our previous report [9], patients were enrolled from January to May 2015, totally 16 patients (9 male) were included. In this update, from January 2015 to January 2019 patients presented with isolated doubly committed subarterial VSDs diagnosed by transthoracic echocardiography (TTE) were added to this observation. The inclusion and exclusion criteria were consistent with the previous study [8]. This technique and updating study were approved by the hospital ethics committee. Again, individual informed consent was obtained from the adult patients and both parents of all the pediatric patients[8]. Alternative treatment options would be given to patients or their parents before decision making. All patients underwent 12-lead electrocardiography (ECG) before the surgery and detailed TEE under general anaesthesia before the procedure by the same echocardiographer. The following data were recorded: the maximum diameter of the defect as assessed by multiple views the presences of any aortic or pulmonary regurgitation the presence of any major coronary branch crossing the infundibulum of RV and any preoperative arrhythmia [8].

The general principles have been described elsewhere and in the previous study [8-9]. However, an improvement in terms of technical detail was made in the updated population. In the previously described method, after retrieving the cable of the first eccentric device, the delivery sheath would be kept inside the right ventricle (RV). That is to say, the tip of the sheath was kept in the RV cavity. In the revised method, instead of keeping the depth of the sheath carefully, the sheath would be advanced prophylactically into the pulmonary artery for 2-3 cm after removing the cable. When the second device was ready, the sheath would be pulled back to the RV in order to deploy the right disc of the device against the RV free wall.

The patient has only one small hole after the operation [8]. All patients would be closely monitored in the intensive care unit for 24 hours. In the previous study, TTE was conducted every hour by a tailored probe which was secured on the chest of each patient to ensure continuous monitoring of pericardial effusion from the same view [8]. In the updated patients, continuous TTE was replaced by intermittent check every 4 hours. Patients also received TTE examination and 12-lead ECG on the second postoperative day, the day before discharge and during the follow-up period [8]. The position and stability of the device, residual shunt, aortic or pulmonary regurgitation, tricuspid regurgitation, RV outflow tract patency, as well as any arrhythmia were carefully checked during the examinations [8].

Statistics

The data for nominal variables were expressed as percentages and continuous variables were expressed by mean ±SD and/or median (range). SPSS 16.0 for Windows (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. The data not applicable to comparable analysis were descriptively reported.

Results

Thirty-eight patients were added to the update, so totally 54 patients (26 male) were included according to the selection criteria [8]. The mean age was 5.0±6.6 years (range, 0.6 to 30.0 years) and the mean body weight was 18.7±12.8 kg (range, 7.8 to 55.0 kg) in the series. The mean VSD diameter measured by preoperative TTE was 4.4±1.4 mm (range, 2.0 to 5.5 mm) and 4.4±1.1 mm (range, 3.0 to 7.0 mm) by TEE after general anesthesia（table 1）. Before the procedure, ten patients (18.5%) had trivial aortic regurgitation without aortic valve prolapse and 5 patient (9.3%) had trivial tricuspid regurgitation. One patient was found with trivial pulmonary regurgitation (1.9%) preoperatively.

Table 1. Characteristics of Study Patients

Sex (male/female)	26/28
Mean age at time of procedure (years)	5.0 ± 6.6 (range, 0.6–30.0)
Mean body weight (kg)	18.7 ± 12.8 (range, 7.8–55.0)
Mean VSD diameter by TTE (mm)	4.4± 1.4 (range, 2.0–5.5)
Mean VSD diameter by TEE (mm)	4.4 ±1.1 (range, 3.0–7.0)
Mean eccentric occluder diameter (mm)	7.1 ±1.3 (range, 5.0–10.0)
Preoperative arrhythmia	
Atrioventricular block	0 (0%)
Right bundle branch block	0 (0%)
Other arrhythmia	0 (0%)
Preoperative valve regurgitation	
Aortic regurgitation	10 trivial (18.5%)
Pulmonary regurgitation	1 (1.9%)
Tricuspid regurgitation	5 trivial (9.3%)

Outcomes of percutaneous perventricular device closure, fifty-three patients completed the percutaneous perventricular device closure successfully (53/54, 98.1%). The mean size of the device for VSD closure was 7.1±1.3 mm (range, 5.0 to 10.0 mm), and the device size of diameter for the RV tunnel was 5.0 mm or 6.0 mm. No death, residual shunt, device dislocation or obstruction of the RV outflow tract was observed in the updated patients (Table 1). 54

patients for 3 months, 49 patients for 6 months, 41 for 1 year, 32 for 2 years, 24 for 3 years, and 13 for 4 years. The follow-up rate was 100 % (Table 2).

Table 2. Follow-Up Outcomes of Percutaneous Perventricular Device Closure

In-Hospital / Follow-Up	Death	Residual Shun	RVOT Obstruction	Valve Regurgitation n/n (%)		
	n/n（%）	n/n（%）	n/n（%）	AR	PR	TR
After procedure in the OR	0/54 (0%)	4/54 (7.4%)	0/54 (0%)	1/54 (1.9%)	0/54 (0%)	0/54 (0%)
Discharge	0/54 (0%)	0/54 (0%)	0/54 (0%)	0/54 (0%)	0/54 (0%)	1/54 (2%)
3 months	0/54 (0%)	0/54 (0%)	0/54 (0%)	1/54 (1.9%)	0/54 (0%)	0/54 (0%)
6 months	0/49 (0%)	0/49 (0%)	0/49 (0%)	1/49 (2.0%)	0/49 (0%)	0/49 (0%)
1 years	0/41 (0%)	0/41 (0%)	0/41 (0%)	1/41 (2.4%)	0/41 (0%)	0/41 (0%)
2 years	0/32 (0%)	0/32 (0%)	0/32 (0%)	1/32 (3.0%)	0/32 (0%)	0/32 (0%)
3 years	0/24 (0%)	0/24 (0%)	0/24 (0%)	0/24 (0%)	0/24 (0%)	0/24 (0%)
4 years	0/13 (0%)	0/13 (0%)	0/13 (0%)	0/13 (0%)	0/13 (0%)	0/13 (0%)

AR = aortic regurgitation; OR = operating room; PR = pulmonary regurgitation; RVOT = right ventricular outflow tract; TR = tricuspid regurgitation;

No new findings were observed in the updated patients in terms of postoperative new aortic, pulmonary or tricuspid valve problems or any new onset of arrhythmia (Table 1). From TTE clinical follow-up, there was no acceleration of blood flow in the RVOT (Fig.1).

Preoperative aortic regurgitation 9 patients had disappeared during the follow-up period, one case which remained stable during the follow-up periods. Device-related aortic regurgitation was not found. Thrombosis, hemolysis, infective endocarditis or conduction abnormalities were not encountered. Other than the attempt in which bleeding occurred in one patient due to undesired dislodgement of the delivery sheath [8]. This case was regarded as unsuccessful. In another two updated cases, a small amount of pericardial effusion was found several hours in the ICU (maximal depth: 8mm and 1.0 cm respectively). A single-lumen central venous catheter was used to drain the pericardial cavity and the effusion did not increase.

The postoperative recovery was smooth. The mean postoperative hospital stay was 3.2±2.5 days (range, 2.0 to 6.0 days). The second unsuccessful case received blood transfusion in the previous report [8].

Fig 1. Red arrow indicates the concentric device was deployed in the right ventricular outflow tract.

Discussion

The application of perventricular device closure has brought selected patients with doubly committed subarterial VSD to a minimally invasive era with reasonable outcomes [6-7]. One more step forward, we have introduced the so called percutaneous-perventricular device closure technique in our previous publication combining percutaneous transcatheter device closure and perventricular device closure, which has dramatically downsized the surgical site from a small incision to a pinhole [8]. Based on a relatively small series, the successful rate was high and only one case failed due to pericardial effusion in the operating room. In the follow-up period, no other major problems were found. However, only 16 patients were included in that series, and the follow-up period was only one year. In order to investigate the effectiveness and especially safety of this novel technique, we have updated the sample size and continued focusing on outcomes during a longer period of time.

Not surprisingly, taking the complete and successful rate of VSD closure into consideration, the effectiveness of this technique was stable. All the VSD devices have been successfully placed without any residual shunting or device dislocation. These devices did not cause any new valve or rhythm problem even in a longer follow-up period. This was quite consistent with those studies using perventricular technique alone [5-7, 10]. Acute pericardial effusion was found in one case due to dislodgement of the sheath from the RV in the previous report [8], and this event was explained as “accident” by us then. In our old technique protocol, after releasing the VSD device, the tip of sheath should be kept right in the RV outflow tract without compromising the first device or dislodging out of the heart. This is actually difficult and very demanding due to the small distance between the device and the RV free wall. Technical improvements have been made in the update to avoid this pitfall. By parking the sheath in the pulmonary artery temporarily before deploying the second hemostatic device, a reasonable length of sheath could be kept safely in the heart, no more dislodgement was found in any of the 38 updated patients.

At the same time, pericardial effusion was noticed in two other added patients in the Intensive Care Unit after their uneventful surgery. The effusion was drained and caused no

further adverse result, but still drawn our attention. These two patients were aged 7 and 8 months respectively, so we assume that their RV free wall was thin in the puncture region. The hemostatic device (Shanghai Shape Memory Alloy Material Co. Ltd, Shanghai, China) has a 5 mm high waist, which might be greater than the myocardium. Delayed bleeding or oozing could come from the less packed “sandwich”. This complication implied that careful monitoring for the pericardial effusion might still be needed after an uncomplicated surgery, especially in younger patients less than one year old. Besides, internal mammary artery injury happened in a patient aged one in the updated series. This might be due to variant course of the artery which was more close to the edge of the sternum. Anyhow, we still believe that the puncture point should be located adjacent to the left border of the sternum.

Comparing with valve problem or arrhythmia, obstruction of RV outflow tract might be more technique specific and of interest in the follow-up. We have expanded the study population and observed every patient for three years. There was not a single case presented with RV outflow tract obstruction in the whole follow-up period, not even in infants. No obvious flow acceleration was noticed in any echocardiographic exam. We did not measure geometric numbers of the RV outflow tract in any patient before the surgery. However, it’s understandable that patients with VSD, especially a doubly committed subarterial one, would have a wider or larger infundibular region. This characteristic might allow a more crowded outflow tract without flow acceleration.

Conclusions

In summary, with larger size of study population and longer follow-up period of time, the percutaneous-perventricular device closure of doubly committed subarterial VSDs still appeared to be an extremely minimally invasive and efficacious technique. Although with technique improvement, the most common complication is still bleeding. Close monitoring is very necessary postoperatively no matter how uncomplicated the procedure is, special attention should be paid to younger patients. Other than that, this technique is generally safe with acceptable mid-term outcomes.

Declarations

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Abbreviations

VSD = ventricular septal defect;

CPB = cardiopulmonary bypass;

ECG = electrocardiography;

TEE = transesophageal echocardiography

TTE = transthoracic echocardiography;

AR = aortic regurgitation;

AVB = atrioventricular block;

OR = operating room;

PR = pulmonary regurgitation;

RVOT = right ventricular outflow tract;

TR = tricuspid regurgitation;

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Contributions

Long Wang and Ke Lin proposed this study. Long Wang and Lin Xie collected and interpreted the data. Long Wang, Weiqiang Ruan, Changping Gan and Tao Li analyzed the data. All authors read and approved the final manuscript.

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Ethics declarations

Ethics approval and consent to participate

The study accords with the ethics of the West China Hospital of Sichuan University.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Additional information

Not applicable.

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Figures

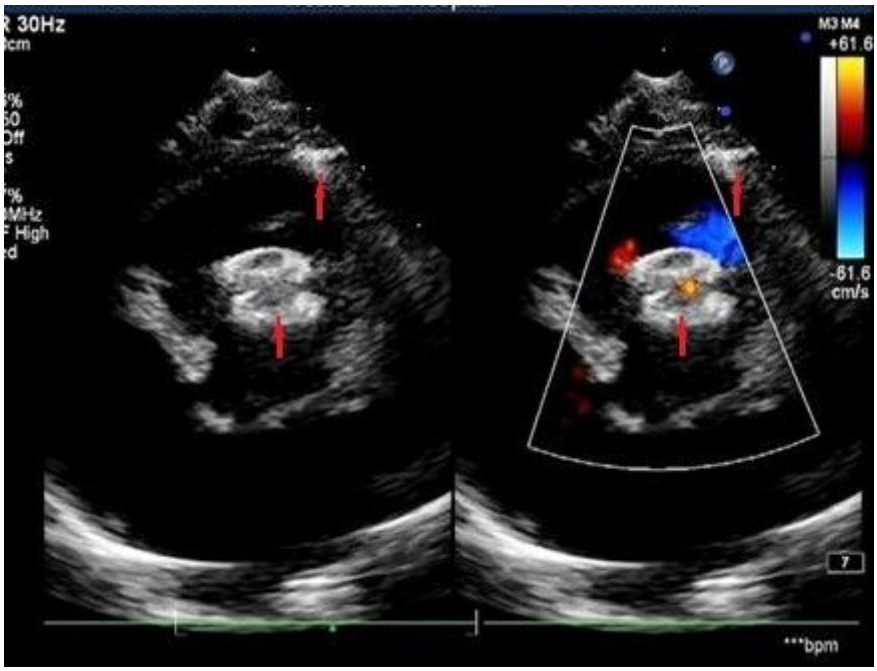

Figure 1

Red arrow indicates the concentric device was deployed in the right ventricular outflow tract.