Minimally invasive transthoracic device closure of isolated ventricular septal defects without cardiopulmonary bypass: Long-term follow-up results

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Objective: Minimally invasive transthoracic device closure (MITDC) of ventricular septal defects (VSD) under transesophageal echocardiography guidance is increasingly and successfully being performed with excellent results. We retrospectively reviewed 458 patients who received this treatment in our center and summarized the 6-year follow-up results.

Methods: From March 2007 to March 2013, 458 patients (mean age, 11.41 ± 6.73 months; body weight, 9.82 ± 5.88 kg) underwent MITDC. Patients were strictly followed up according to a standard protocol by 2 specially appointed doctors. Meanwhile, 283 cases with an isolated VSD who underwent traditional surgical repair during this period were also reviewed and several characteristics were compared between the 2 groups.

Results: A total of 441 cases were successfully closed (96.29%), and the other 17 patients were converted to surgical closure. There were no deaths or major complications. Concentric devices were used in 313 cases (70.98%), eccentric devices in 113 cases (25.62%), and special devices in 15 cases (3.40%). The mean intracardiac deployment time was 18.35 ± 17.13 minutes (3-48 minutes). Most of the patients were discharged within 5 days after surgery. Follow-up in 426 patients (96.60%) ranged from 6 to 78 months (47.31 ± 19.69 months) and revealed no severe complications. Fewer minor complications, such as device-related trace to mild tricuspid regurgitation, residual shunt, and right bundle branch block, occurred with MITDC than surgical closure.

Conclusions: MITDC of a VSD on a beating heart is a safe and effective alternative to conventional treatments. The 6-year clinical outcomes are promising. Modification of occluders and the delivery set play an important role in good outcomes. (J Thorac Cardiovasc Surg 2015;149:257-65)

See related commentary on pages 265-6.

Ventricular septal defect (VSD) is the most common congenital heart defect. Both surgical and percutaneous device closure of VSDs have drawbacks and limitations. In 2007, Xing and colleagues[1] reported successful minimally invasive transthoracic device closure (MITDC) of 11 perimembranous VSDs with a newly designed delivery system under transesophageal echocardiography (TEE) guidance. Since then, MITDC of VSDs under TEE guidance has been increasingly and successfully performed with excellent preliminary and midterm results in China and in some European countries.[2-13]

We retrospectively reviewed 458 patients with a VSD who received this treatment and 283 patients with a VSD who underwent traditional surgical repair from 2007 to 2013 at our center. The 6-year clinical follow-up results were summarized and compared between the 2 groups.

PATIENTS AND METHODS

Patients

Patients were selected according to the surgical indications for an isolated VSD: refractory heart failure with medication; repeated respiratory infection (>6 times per year); tardiness of body development; evidence of left heart volume overload (heart enlargement observed on chest radiographs, left atrium/aorta ratio >1.5 on echocardiography, left ventricular end diastolic diameter >2 standard deviations on echocardiography); and a history of previous endocarditis. Exclusion criteria for MITDC were nonrestrictive or malaligned VSD; those with inlet extension of the VSD; VSD with significant aortic prolapse; a newborn infant or young infant with large VSD and severe pulmonary hypertension; those who could not be followed up; and patients or their guardians who refused to accept this new treatment.

Between March 2007 and March 2013, 458 patients with a VSD underwent off-pump MITDC. The study was approved by the institutional review board. Individual informed consent was obtained from the patients' guardians. During the same period, a total of 283 patients with an isolated VSD underwent surgical closure with cardiopulmonary bypass (CPB), including 197 patients not fit for MITDC, 69 patients whose guardians refused to accept this new

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Abbreviations and Acronyms

cAVB = complete atrioventricular block
CPB = cardiopulmonary bypass
ECG = electrocardiography
IVS = interventricular septum
MITDC = minimally invasive transthoracic device closure
PDA = patent ductus arteriosus
TEE = transesophageal echocardiography
TR = tricuspid regurgitation
TTE = transthoracic echocardiography
VSD = ventricular septal defect

treatment, and 17 patients converted to heart surgery from failed MITDC. The patients' general characteristics are listed in Table 1.

Devices and Delivery Sets

The occluder was modified from the Amplatzer (AGA Medical Corporation, Plymouth, Minn) atrial septal defect and membranous VSD occluder, made by Lifetech Scientific (Shenzhen) Co Ltd (Shenzhen, China) and Shanghai Shape Memory Alloy Co Ltd (Shanghai, China). The size of the device corresponds to the waist dimension of the device. Five types of occluders were supplied in this cohort: a perimembranous VSD concentric occluder (concentric), a perimembranous VSD eccentric occluder (eccentric), a muscular VSD occluder (muscular), a patent ductus arteriosus (PDA) occluder, and a special occluder (saddlelike) for subarterial VSD (Figure 1). The device is available in sizes ranging from 4 to 16 mm in 1-mm increments (Figure 2). The waist height of each type of occluder ranged from 3 mm to 7 mm in 1-mm increments (Figure 3).

The device size was chosen according to the position and diameter of the VSD, and the thickness of the interventricular septum (IVS). We recommended a device with a waist size 1 to 2 mm larger than the diameter of the VSD and a waist height corresponding to the thickness of the IVS; a concentric occluder for a perimembranous VSD with a margin more than 2 mm from the aortic valve; an eccentric occluder for a perimembranous VSD with a margin less than 2 mm from the aortic valve; a muscular or PDA occluder for muscular VSD; a saddlelike occluder for subarterial VSD with less than mild aortic prolapse and regurgitation.

The entire delivery set was modified by Dr Quansheng Xing,[5] including a trocar (Terumo Corporation, Tokyo, Japan), a flexible guidewire (SCW Medicath Ltd, Shenzhen, China), and a dilator, a delivery sheath, a delivery cable, and a loading sheath (Lifetech Scientific [Shenzhen] Co Ltd and Shanghai Shape Memory Alloy Co Ltd). The total length of the delivery set ranged from 20 to 30 cm. The size of the delivery sheath selected depended on the device size (5F, 7F, or 9F).

Procedure

MITDC was performed under general anesthesia and TEE guidance in the operating room. The position, shape, size of the VSD and adjacent structures, especially its relationship with the aortic valve, were reassessed with TEE before operating and then the appropriate device and delivery system were selected. Access was through a small subxiphoid incision or the third left intercostal space beside the sternum for subarterial VSDs (Figure 4). A small pericardiotomy was performed and the pericardium was cradled to expose the free wall of the right ventricle. The detailed implanting steps of this technique were basically the same as described previously (Figure 5).[5,7,9] If severe, arrhythmialike, frequent premature ventricular contractions, left bundle branch block, complete atrioventricular block (cAVB), failure to pass the guidewire through the VSD or implant the occluder, anything more than mild residual shunt, new aortic insufficiency, or more than mild tricuspid regurgitation (TR) was identified, the patients were converted to conventional repair with CPB. All patients with successful device closure were monitored in the intensive care unit until extubation, and urinalysis was performed daily for 3 days to exclude hemolysis. Anticoagulation therapy with aspirin (3 mg/kg/d by mouth) was prescribed for 3 to 6 months. A total of 283 patients with isolated VSDs underwent conventional intracardiac surgery with CPB as routine.

Follow-up

Electrocardiography (ECG), transthoracic echocardiography (TTE), and chest radiography were performed before discharge. If needed, 24-hour electrocardiographic Holter monitoring was performed. Outpatient follow-up was at 1 month, 3 months, 6 months, 1 year, and annually and included clinical examination, ECG, TTE, and chest radiography. All patients were strictly followed up with the same standard protocol by 2 doctors who were specially appointed. Several characteristics (eg, operating time, complications, blood transfusion, hospital stay time, cost of hospitalization, and postoperative complications) were compared between the 2 groups.

Data Analysis

All continuous variables are expressed as means ± standard deviation with a range, and nominal variables are presented as frequencies and percentages. Analysis of continuous variables was done with the Student *t* test and analysis of categorical variables was performed with the χ^2 test. SPSS 18.0 for Windows (SPSS Inc, Chicago, Ill) was used for statistical analysis.

RESULTS

Procedure Data and Early Postoperative Results

In the device closure group, VSDs were successfully closed in 441 patients (96.29%), and the other 17 patients were converted to surgical closure, including 5 patients with moderate aortic insufficiency, 4 patients with residual shunts more than 2 mm wide or blood flow velocity more than 3.0 m/s on TEE, 2 patients with severe arrhythmia occurring immediately after the guidewire was passed through the defect or occluder was deployed, 2 patients with right ventricle outflow tract obstruction with a pressure gradient more than 20 mm Hg, 2 patients in whom the guidewire failed to cross the defect, and 2 patients with abnormal occluder plasticity. A subxiphoid approach was used in 358 patients (81.18%) and incision through the third left intercostal space beside the sternum was used in 83 patients (18.82%). A concentric device was used in 313 patients (70.98%), an eccentric device in 113 patients (25.62%), and others in 15 patients (3.40%); the others included 8 muscular devices, 5 saddlelike devices, and 3 PDA devices (1 patient with a central muscular VSD and an apical muscular VSD was closed with a muscular device and a PDA device, respectively). The mean size of the device used was 6.53 ± 5.25 mm (range, 4-12 mm). It was necessary to open more than 1 device for a given patient in 49 cases (11.11%). In a 3-month-old baby girl, who weighed 5 kg, a series of 6 occluders were used to close a

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