Transcatheter Closure of Congenital Perimembranous Ventricular Septal Defect in Children Using Symmetric Occluders: An 8-Year Multiinstitutional Experience

Lei Wang, MD, PhD,* Sancheng Cao, MD, Jun Li, MD,* Lifang Yang, MD,* Yin Liu, MD, Jun Ren, MD, PhD, Qiaomei Ma, MD, Haijian Xing, MD, Dan Li, MD, Danqiu Tian, MD, Yi Wan, MD, PhD, Shiqiang Yu, MD, PhD, Tao Chen, MD, Xiuling Yang, MD, and Jian Yang, MD, PhD

Department of Cardiology, Xi'an Children Hospital, Departments of Ultrasound Diagnosis and Anesthesiology, Xijing Hospital, Department of Health Statistics, and Xijing Cardiovascular Hospital, Fourth Military Medical University, Xi'an, People's Republic of China, Department of Cardiology, Affiliated Hospital of Qinghai Medical University, Xi Ning, People's Republic of China; and College of Health Sciences, University of Wyoming, Laramie, Wyoming

Background. **Perimembranous ventricular septal defects (pmVSDs) are one of the most common forms of congenital cardiac malformation in children. Results of transcatheter pmVSD closure remain debatable, prompting the need for further evaluation with regard to the safety and efficacy of this procedure. The aim of the study was to analyze the safety, efficacy, and long-term follow-up data associated with transcatheter closure of pmVSDs in children using symmetric occluders.**

Methods. **From December 2002 to October 2011, 525 children with pmVSDs between 2 and 12 years of age underwent transcatheter closure at three major heart centers in northwest China with symmetric pmVSD occluders. All patients were followed up until October 2011 with electrocardiogram and transthoracic echocardiography. Adverse events were recorded and evaluated.**

Results. **There were 252 male and 273 female patients with an average weight of 21.5 kg. The mean age at the time of transcatheter closure was 5.6 years, and the average ratio of pulmonic to systemic blood flow was 2.5. Transcatheter intervention was successfully performed in 502 patients (95.6%). The median device size implanted was 6.5 mm (range, 4 to 18 mm). During a median 45-month follow-up period, no mortality occurred. A total of three major adverse events (0.6%) were reported; two were valve-related. Meanwhile, 104 minor adverse events were detected during the entire follow-up period. All individuals experiencing major adverse events were younger than 3 years of age. The incidence of major adverse events in patients younger than 3 years old was significantly higher than that of patients older than 3 years old (3.75% versus 0.00%; Fisher's exact test $p = 0.004$).**

Conclusions. **Data from the current study suggest that transcatheter pmVSD closure using symmetric occluders displayed an excellent success rate and long-term follow-up results. The transcatheter approach provides a less-invasive alternative to open surgery and displays some promise in the treatment of pmVSDs in certain patient populations.**

(Ann Thorac Surg 2012;94:592–8)
© 2012 by The Society of Thoracic Surgeons

Perimembranous ventricular septal defects (pmVSDs) are one of the most common forms of congenital cardiac malformations in children, accounting for up to 40% of all cardiac anomalies [1–4]. During the past decade, transcatheter techniques for closure of pmVSDs using the Amplatzer pmVSD occluder (AGA Medical, Golden Valley, MN) have been developed [5, 6]. Unfortunately, at the present time this technique is not well implemented worldwide because of an unacceptably high rate of postprocedural and late-onset heart block [7, 8]. Based on the design of the Amplatzer pmVSD device, modified double-disk symmetric devices were introduced in China in 2003, aiming to decrease the high rate of heart block and improve clinical outcomes [9]. However, reports of the indication of transcatheter pmVSD closure using symmetric occluders and its long-term follow-up results in children were rare [10]. In our series, we report on the experience of transcatheter closure of congenital pmVSDs in children with a multicenter regional cohort study, discussing the long-term safety and efficacy of the symmetric occluders.

Patients and Methods

Patients

From December 2002 to October 2011, 2,546 children between 2 and 12 years of age with congenital pmVSDs were enrolled in three major medical centers in north-

Accepted for publication March 26, 2012.

*These authors are equal contributors.

Address correspondence to Dr J Yang, Xijing Cardiovascular Hospital, 15 Chang Le West Rd, Xincheng District, Xi'an 710032, People's Republic of China; e-mail: yangjian1212@hotmail.com.

© 2012 by The Society of Thoracic Surgeons
Published by Elsevier Inc

0003-4975/$36.00
doi:10.1016/j.athoracsur.2012.03.067

Table 1. Baseline Characteristics

Variable	Result (median with range)
Patients (n)	525
Sex (F/M) (n/%)	273 (52.0%)/252 (48.0%)
Age (y)	5.6 (2–12)
Weight (kg)	21.5 (9.5–67.0)
Indications	
Symptoms (frequent respiratory infections, edema, NYHA functional class II or greater)	136 (25.9%)
Hemodynamic changes (cardiomegaly on chest radiograph, left atrial or left ventricular enlargement verified by echocardiography)	385 (73.3%)
Previous SBE	4 (0.8%)
Echocardiography	
Subaortic rim (mm)	3.2 (1.0–18.3)
Subtricuspid rim (mm)	5.3 (2.0–21.0)
VSD size (mm)	4.4 (2.3–10.3)
Heart function (NYHA grade)	
I	477 (90.9%)
II	45 (8.6%)
III	3 (0.5%)
IV	0
LVEDD (mean ± SD, Z score)	2.1 ± 1.6

LVEDD = left ventricular end-diastolic dimension; NYHA = New York Heart Association; SBE = subacute bacterial endocarditis; SD = standard deviation; VSD = ventricular septal defect.

west China (Xi'an Children Hospital and Xijing Hospital, Xi'an, and Affiliated Hospital of Qinghai Medical University, Xi Ning). All patients underwent routine examination including chest radiograph, standard 12-lead electrocardiogram, and transthoracic echocardiography (TTE). Transthoracic echocardiography was used for patient selection of transcatheter pmVSD closure. After TTE screening, 525 children were included in this study based on the inclusion and exclusion criteria. There were 252 male patients and 273 female patients with an average weight of 21.5 kg. The average ratio of pulmonic to systemic blood flow was 2.5 (range, 1.7 to 6.8). Demographic and diagnostic data are summarized in Table 1. The median hospital stay was 3.4 days (range, 1 to 18 days).

Echocardiographic Assessment

The echocardiography inclusion criteria were (1) a congenital pmVSD with the defect located at the 9 to 11 o'clock positions of an analog clock in the short-axis parasternal view with left-to-right shunt; (2) a pmVSD diameter of greater than 2 mm and less than 10 mm; (3) a distance of greater than 1 mm from the pmVSD to the aortic valve; (4) mild aortic valve prolapse and no pathologic aortic regurgitation; (5) no active infective endocarditis; and (6) no main tricuspid chordae tendineae located around the rim of the pmVSD. The distance between the pmVSD and aortic valve as well as the presence of abnormal tricuspid main chordae tendineae was examined in each patient before intervention (Fig 1). After TTE screening, 525 patients were selected for the attempted transcatheter closure using symmetric occluders and were enrolled in the study (Fig 2). Before intervention, an informed written consent was obtained from the patients' parents. The ethics committee of each hospital approved the study, and it was registered with ClinicalTrials.gov (number NCT00890799) and carried out in accordance with the Declaration of Helsinki (1996) and all relevant Chinese laws.

Device

The Shanghai pmVSD occluder (LEPU Medical Technology Co, Ltd, Beijing, China) was used in the study. The device was made of 0.005-inch nitinol wire mesh and fabric inside, and the diameter of both disks was 4 mm larger than that of the waist. The thickness of the waist of the Shanghai pmVSD occluder was 3 mm (Fig 3). The symmetric occluder was approved in 2003 by the State Food and Drug Administration, P.R. China, and it received the Conformité Européenne mark in 2008 [9, 11].

Device Implantation

The catheterization procedure was performed under basal anesthesia without tracheal intubation for all patients. Heparin (100 IU/kg) and antibiotics were admin-

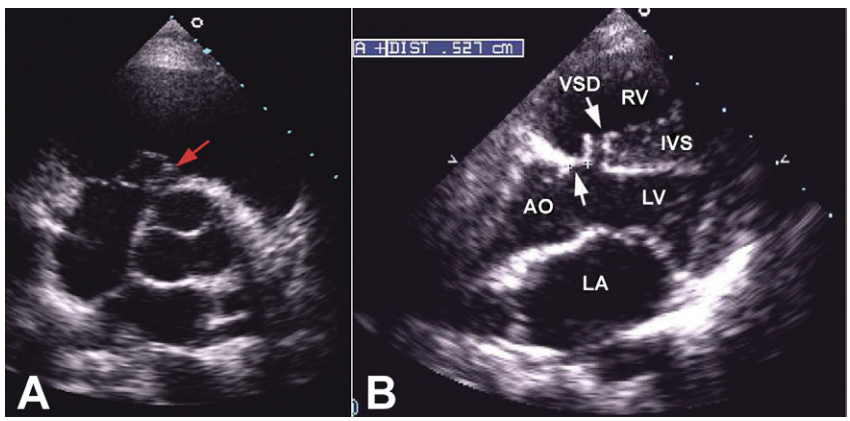

Fig 1. Routine transthoracic echocardiography screening. (A) Presence of abnormal tricuspid main chordae tendineae (red arrow). (B) Distance between the perimembranous ventricular septal defect (VSD) and aortic valve was measured in each patient. (AO = aorta; IVS = interventricular septum; LA = left atrium; LV = left ventricle; RV = right ventricle.)

Download English Version:

https://daneshyari.com/en/article/2876028

Download Persian Version:

https://daneshyari.com/article/2876028

Daneshyari.com