

## Comparison of Outcomes of Transcatheter and Surgical Procedure in Perimembranous Ventricular Septal Defect Patients with Tricuspid Regurgitation

**Dear Editor,**

Surgery has long been considered as an optimal treatment strategy to treat ventricular septal defect (VSD) complicated with moderate or severe tricuspid regurgitation (TR).<sup>1-3</sup> Effects of non-surgical intervention, such as interventional closure, are not well-established yet.<sup>4-7</sup> This study aimed to compare the effects of TR and clinical outcomes in VSD patients, treated either with transcatheter closure procedure or surgery procedure. We hypothesised that transcatheter closure procedure was non-inferior to surgical procedure.

**Materials and Methods**

This study was a prospective, randomised, single-centre study in China. Overall, 43 patients with VSD and moderate or severe TR were prospectively recruited from January 2009 to February 2011. Inclusion criteria for surgery or transcatheter closure treatments were: 1) age >3 years old or weight >10 kg; 2) a perimembranous VSD with diameter of greater than 3 mm and less than 14 mm by transthoracic echocardiography; 3) the defect located at 9 - 11 o'clock positions counterclockwise in the short axis parasternal view; 4) complicated with moderate or severe TR; 5) a distance greater than 2 mm from the perimembranous VSD to the aortic valve and 3 mm from the perimembranous VSD to the tricuspid valve (TV); 6) left to right shunt; and 7) pulmonary pressure <40 mmHg estimated by colour Doppler echocardiography. All patients had standard echocardiography examinations before and after the procedures.

*Transcatheter Closure Procedure*

Right and left heart catheterisation, as well as ascending aortography was routinely performed to exclude aortic valve prolapse and regurgitation. Left ventriculography and echocardiography allowed the proper selection of the Shanghai pmVSD occluder (LEPU Medical Technology Co, Ltd, Beijing, China) (Fig. 1A). The established delivery cable was used to send the occluder into the left chamber along the long sheath. Based on x-ray examination, the occluder was released to the left chamber side. The occluder was then drawn back to allow the attachment of its left chamber side to the VSD. To fix the delivery cable, the

long sheath was drawn back to the right chamber and the right chamber side of the plugging device was opened. The occluder was stabilised by exerting an appropriate force. Left ventriculography was performed again to observe the plugging effect of VSD and to evaluate whether the occluder affected the aortic valve (Figs. 1B and 1C).

*Surgical Operation Procedure*

Operations for VSDs were performed through a midline sternotomy incision. Bicaval cannulation with cannulation of the superior vena cava enabled the exposure of the defects through the right atrium. An oblique incision anterior to the terminal sulcus and parallel to the atrioventricular groove was made from the appendage inferiorly toward the inferior vena cava. Two stay sutures were placed on the posterior margin of the incision, by taking care to avoid the sinus

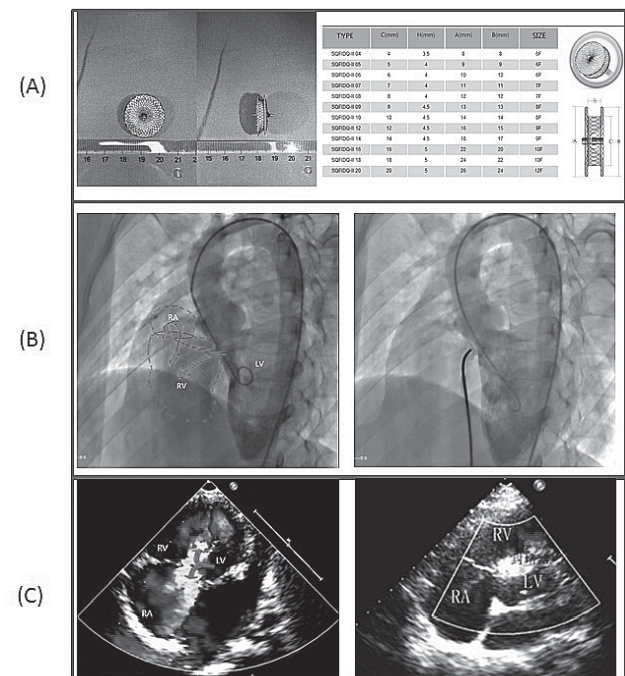


Fig. 1. A is an image of a perimembranous ventricular septal defect (VSD) occluder (Shanghai Shape Memory Alloy Co. Ltd). B shows ventriculographic images before and after an interventional closure procedure. C shows Doppler echocardiographic images before and after an interventional closure procedure.

Table 1. Patients' Characteristics and Clinical Data of VSD Patients with Tricuspid Regurgitation

Clinical Data	Surgery Group (n = 22)	Interventional Group (n = 21)	P Value <sup>†</sup>
Age (y)	16 ± 8	16 ± 9	0.80
Male, n (%)	13 (59)	12 (60)	0.50
Body weight (kg)	36 ± 10	38 ± 11	0.90
Body mass index (kg/m <sup>2</sup> )	21 ± 1	21 ± 2	0.50
Echocardiography before procedure			
VSD diameter (mm)	7.4 ± 2.5	6.7 ± 1.9	0.50
Diameter of LV (cm)	4.9 ± 0.6	5.0 ± 0.5	0.90
Indexed diameter of LV* (cm/kg)	0.14 ± 0.03	0.14 ± 0.03	0.50
Moderate tricuspid regurgitation, n (%)	16 (73)	17 (81)	0.40
Severe tricuspid regurgitation, n (%)	6 (27)	4 (19)	0.40

LV: Left ventricle; VSD: Ventricular septal defect

\*Ratio of diameter of LV and body weight.

<sup>†</sup> $P < 0.05$  indicates a statistically significant difference.

node. The TV ring was exposed by everting the anterior margin of the atriotomy. Dacron patch was used to sew up the VSD directly or to repair the defect, respectively. A tricuspid water-thrashing test was then conducted to observe TR. Tricuspid valvuloplasty was performed if severe TR was present.

## Results

All 43 patients were treated, of which 22 had surgical treatment and 21 had transcatheter treatment. Baseline clinical data are summarised in Table 1. Before operation, there were no statistical differences between the surgery group and interventional closure group in baseline conditions ( $P$  values  $> 0.05$ ). In the surgery group, the success rate was 100% without severe complications occurrence. There was 1 secondary complication involving low residual shunt, but it did not require treatment. In the interventional closure group, the success rate was 100%. There was 1 secondary complication, which involved mild aortic regurgitation but did not require special treatment. The postoperative follow-up was 3 to 12 months (i.e. mean duration follow-up of 10 months). The survival rate was 100%, and no complications occurred.

Table 2 summarised the data after closure operation. There was a significantly decreased length, area, volume, flow rate and differential pressure after both surgery and transcatheter closure groups. After closure operation, no statistical difference was found in the degrees of TR between the 2 groups. Second, in comparison with the surgical group, the transcatheter closure group had lower white blood cell (WBC), creatine kinase (CK-MB), cardiac troponin I (cTnI), myoglobin (MYO), and drug score. The interventional

closure group had less operation time ( $39.8 \pm 12.8$  vs  $63.6 \pm 9.3$  minutes,  $P < 0.0001$ ), but higher operation cost ( $2.3 \pm 0.3$  vs  $1.9 \pm 0.1 \times 1000$  ¥,  $P < 0.0001$ ), and comparable hospital stay and complications ( $P > 0.05$ ).

## Discussion

Our study showed that interventional closure procedure was technically feasible to close the perimembranous VSDs and then eliminated the occurrence of TR comparing to surgical closure procedure. Interventional closure procedure better protected myocardium and reduced myocardial injury and the operation time. Furthermore, compared with the surgical closure procedure, interventional closure procedure had the following advantages. First, the interventional closure group had shorter operation times. Second, the interventional closure group required smaller amounts of vasoactive drugs, had lower occurrence of postoperative inflammatory reactions, and showed lower incidence of myocardial injury. Third, there was no statistical difference in complication after operation than the surgical closure group.

### *Advantages of Transcatheter Closure of Perimembranous VSD Using Symmetrical Occluder*

Compared with the asymmetric Amplatzer occluder, the symmetric Shanghai Shape Memory pmVSD occluder in this study (Lepu Medical Technology Co., Ltd., Beijing, China) (Fig. 1), had demonstrated to reduce the risk of atrioventricular block and residual shunt<sup>4,8,9</sup> due to: 1) its easier deployment, 2) reduction of pressure from occlude to interventricular septum, thus reducing damage of conduction system, and 3) occluder fringe of less than 2 mm so that the

Table 2. Patients' Tricuspid Regurgitation Features Before and After Operation, and Myocardial Injury Indices and Hospital Stay in Surgery Group and Interventional Closure Group

	Surgery Group (n = 22)		Interventional Group (n = 21)	
	Preoperative	Postoperative	Preoperative	Postoperative
Tricuspid regurgitation features using echocardiography				
Length (cm)	3.39 ± 0.80	0.51 ± 0.32*	3.26 ± 0.84	0.57 ± 0.22*
Area (cm <sup>2</sup> )	3.66 ± 1.09	0.43 ± 0.27*	3.25 ± 0.89	0.56 ± 0.17*
Volume (mL)	3.47 ± 1.08	0.29 ± 0.20*	3.10 ± 0.89	0.40 ± 0.15*
Flow rate (m/s)	2.45 ± 0.42	0.65 ± 0.40*	2.48 ± 0.45	0.57 ± 0.27*
Differential pressure (mmHg)	24.00 ± 8.37	2.31 ± 1.89*	25.50 ± 8.13	1.60 ± 1.27*
Myocardial injury indices and hospital stay after operation				
WBC (×10 <sup>9</sup> /L)		16.0 ± 3.0		10.2 ± 2.7*
CRP (mg/L)		90.8 ± 81.4		25.8 ± 17.5*
CK-MB (ng/mL)		10.3 ± 5.1		3.4 ± 1.3*
cTnI (ng/mL)		7.5 ± 5.8		1.5 ± 0.6*
MYO (ng/mL)		879.2 ± 547.4		129.2 ± 35.3*
Drug score		7.5 ± 3.6		5.5 ± 2.4*
Operation time (minutes)		63.6 ± 9.3		39.8 ± 12.8*
Operation cost (× ¥1000)		1.9 ± 0.1		2.3 ± 0.3*
Hospital stay (days)		7.6 ± 0.8		7.7 ± 0.9
Complications (n)		1		1

CK-MB: Creatine kinase-MB; cTnI: Cardiac troponin I; CRP: C-reactive protein; MYO: Myoglobin; WBC: White blood cell

\*Indicates a statistically significant,  $P < 0.05$ .

occluder does not contact the aortic valve, thus avoiding any damage to the aorta.

#### *Interventional Closure Procedure May Cause Some Complications*

In our study, we found 1 case with slight aortic valve regurgitation postoperation. This finding indicated that VSD closure operation could cause aortic valve regurgitation, similar to other reports.<sup>9</sup> However, this aortic regurgitation was minimal and did not require treatment. Another common complication was tricuspid damage.<sup>10</sup> However, in our study, no tricuspid damage related to interventional treatment was observed. Conduction block and other severe arrhythmias after VSD closure are of big concern to cardiologists because the defect is adjacent to the conduction tissues. In this study, no case of severe atrioventricular block occurrence was observed in the intervention group.

In this study, the cost of intervention was higher than surgery. The higher costs were from the occluder (i.e. about 13,000 yuan, approximately USD 2093.60) and a remote electrocardiogram (ECG) monitoring for 6 to 7 days in hospital. In terms of the number of days in hospitalisation,

both groups had similar duration (i.e. about 7 days). This was because the patients in the catheter intervention group needed to be monitored for 6 to 7 days to detect possible arrhythmia, based on consensus from our intervention experts.

#### **Conclusion**

We have demonstrated that the TR outcomes and clinical outcomes of interventional closure procedure in patients with VSD complicated with moderate or severe TR were not inferior to surgical treatment.

#### *Acknowledgement*

The authors would like to thank Duke-NUS/SingHealth Academic Medicine Research Institute and the medical editing assistance of Taara Madhavan (Associate, Clinical Sciences, Duke-NUS Medical School). This work was supported in part by the Medical Scientific Research Foundation of Hubei Province, China (JX6B90) and Medical Scientific Research Foundation of Wuhan City, China (WX13C7).

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Xiao Ke Shang, <sup>1</sup>MD, Liang Zhong, <sup>3,4</sup>PHD, Rong Lu, <sup>1</sup>MD, Gang Cheng Zhang, <sup>1</sup>MD, Mei Liu, <sup>2</sup>MD, Qun Shan Shen, <sup>1</sup>MD, Xin Zhou, <sup>1</sup>MD, Chang Yu Qin, <sup>1</sup>MD, Hong Mei Zhou, <sup>1</sup>MD

<sup>1</sup>Department of Intervention, Wuhan Asia Heart Hospital, China

<sup>2</sup>Department of Intensive Care Unit, Wuhan No.1 Hospital, China

<sup>3</sup>National Heart Research Institute of Singapore, National Heart Centre Singapore, Singapore

<sup>4</sup>Duke-NUS Medical School, Singapore

Address for Correspondence: Dr Liang Zhong, National Heart Centre Singapore, 5 Hospital Drive, Singapore 169609.

Email: zhong.liang@nhcs.com.sg