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ORIGINAL ARTICLE

Minimally Invasive Perventricular Device Closure of Ventricular Septal Defect: a Comparative Study in 80 Patients

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Key words: transesophageal echocardiography; minimally invasive; ventricular septal defect

Objective To evaluate the efficacy of minimally invasive perventricular device closure of ventricular septal defect (VSD).

Methods Between September 2011 and February 2013, we collected 40 patients who underwent perventricular closure *via* a small lower sternal incision (minimally invasive group), aged 15.5 ± 3.5 years (12 months to 32 years) with a body weight of 24.2 ± 7.5 kg (10.8-58.0 kg). The mean size of VSD was 5.6 ± 0.5 mm (2-14 mm). Another 40 patients were included as the surgical group, receiving the conventional surgical repair of VSD. The device of the minimally invasive group was released under the guidance of transesophageal echocardiography. Success rate, cardiac indicators, and clinical outcomes of the 2 groups were compared.

Results The patients in the surgical group and those in the minimally invasive group showed similar results in success rate (both 97.5%). The procedure time, intensive care unit stay, hospital stay, and postoperative recovery time in the minimally invasive group were significantly shorter than those in the surgical group (58 ± 21 minutes *versus* 145 ± 26 minutes, 2 ± 1 days *versus* 8 ± 3 days, 5 ± 1 days *versus* 16 ± 6 days, 3 ± 1 days *versus* 90 ± 20 days, all $P < 0.05$). The minimally invasive group had a higher incidence of conduction anomalies (17.5% *versus* 2.5%, $P < 0.05$). In the follow-up period of 3-12 months, there was no new residual shunt, noticeable aortic regurgitation, significant arrhythmias, or device failure except for new complications in the surgical group.

Conclusions The success rate of minimally invasive perventricular device closure of VSD under transesophageal echocardiography guidance is similar to that of conventional surgical repair, but the short-term outcomes of the minimally invasive approach is much better. Long-term follow-up is necessary to confirm the effectiveness of this technique.

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In recent years, the treatment of ventricular septal defect (VSD) has become more and more successful with cardiopulmonary bypass and percutaneous transluminal closure device, and has developed into

a safe and effective method.¹⁻⁴ Along with the advances of technology, minimally invasive perventricular device closure of VSD has been widely and successfully conducted in some institutions in China.⁵⁻⁷ From September 2011 to February 2013, we collected 40 patients who underwent perventricular closure of VSD *via* a substernal small incision, and another 40 patients who underwent the conventional surgical repair, aiming to compare the effect

of minimally invasive periventricular device closure and that of the conventional surgical repair, and to evaluate the efficacy of minimally invasive periventricular device closure.

PATIENTS AND METHODS

Patient inclusion

From September 2011 to February 2013, all patients in the First Clinical Hospital of Lanzhou University fulfilling the following inclusion criteria were selected: (1) aged more than 1 year and less than 32 years; (2) body weight between 10 kg and 58 kg; (3) having isolated large VSD (2-14 mm) with left-to-right shunt but no significant pulmonary arterial hypertension. Patients with concomitant diseases were excluded from the study except the cases with small patent ductus arteriosus or atrial septal defect.

Altogether 40 patients underwent periventricular closure (minimally invasive group), and another 40 patients receiving the conventional surgical repair of VSD were included as the surgical group.

VSD closure procedure

VSD closure procedures were performed with the patients under general anesthesia in supine position, with single-lumen tracheal intubation. Transesophageal echocardiography (TEE) was performed to measure the exact size and location of VSD. After incision (3-5 cm) at the lower sternum, the pericardium was suspended and the right ventricular free wall was exposed, a purse string suture was placed on the right ventricular free wall. A guide wire was inserted through the ventricular septal defect to the left ventricle under TEE guidance, over which a modified delivery sheath was introduced to establish the delivery pathway. The device was advanced inside the short delivery sheath, and the left ventricular disk was deployed under TEE guidance by retracting the sheath. Once the left ventricular disk was confirmed by TEE, the right ventricular disk was deployed until the device was completely opened. If no atrioventricular or aortic valvular disturbance or residual shunt was detected, the sheath was pulled out of the right ventricle. TEE was performed again to detect and evaluate the residual interventricular shunt and observe the aortic valve bypass. The pericardium was partially closed, a chest tube was placed in the mediastinum, the sternum and chest wall was closed in the routine manner. After the operation, the patients were transferred to and observed in intensive care unit.

Statistical analysis

Statistical analysis was performed with StatsDirect software.

Data are expressed as means $\pm$ SD (range). Clinical parameters between the 2 groups were compared with independent samples *t*-test. Nominal variables of the 2 groups were compared using Fisher's exact test. Complications were analyzed by Chi-square test. $P<0.05$ was considered statistically significant.

RESULTS

Clinical outcomes

The surgical group and the minimally invasive group did not show significant differences in success rate, cardiothoracic ratio, left ventricular ejection fraction, left ventricular end-diastolic diameter, left ventricular end-systolic diameter, left ventricular end-systolic volume, left ventricular end-diastolic volume, and left ventricular end-diastolic pressure (all $P>0.05$, Table 1).

In the minimally invasive group, the VSDs were successfully occluded in all patients but 1 (97.5%), who required immediate surgical conversion after the operation failed. TEE analysis revealed 5 cases of residual shunt (<2 mm), 6 arrhythmia, 7 conduction block, and 2 aortic and tricuspid incompetence (Table 2). There was no incidence of device embolization or occluder shift. The whole process took 58 ± 21 minutes, the deployment of the device was finished in 35 ± 15 minutes. The chest tube was removed 1-2 days after the operation. All the patients in this group were discharged no later than 7 days (Table 3). TEE images displayed normal cardiac function and proper position of the device without affecting the surrounding tissues.

In the surgical group, 1 patient died of acute infection. Complications included 2 residual shunt (<2 mm), 1 atrioventricular block, 1 tricuspid incompetence, 2 bleeding, 1 arrhythmia and 8 other complications (Table 2). The procedure duration, intensive care unit stay, hospital stay, and postoperative recovery time were significantly shorter in the minimally invasive group than in the surgical group (all $P<0.05$), but the equipment and total costs were significantly higher in the minimally invasive group than in the surgical group (both $P<0.05$) (Table 3). All the 40 patients in the surgical group needed blood products (800 ± 120 ml) (Table 3), among them 22 cases used whole blood.

Follow-up results

Up to the submission of this article, all the included patients have undergone more than 3 months of follow-up. In the minimally invasive group, the short-term outcomes were acceptable. One patient has persistent incomplete right bundle branch block, another has developed intra-procedural heart block, requiring permanent pacemaker to maintain

normal cardiac function. In addition, one patient has persistent closure-related trace and mild aortic regurgitation. There were no other new complications. In the surgical group, four patients suffered major new complications, one died of severe gastroenteritis, one had incision infection,

one pericardial effusion, one heart failure; three patients had persistent arrhythmia, one has persistent conduction anomalies. There were no other complications. TEE analysis showed good systolic and diastolic function, displaying no residual interventricular shunt or tricuspid regurgitation.

Table 1. The comparison of clinical indicators of the minimally invasive group and surgical group[§]

Group	Sex (female: male)	Age (year)	Weight (kg)	Success rate (%)	Size of VSD (mm)	Cardiothoracic ratio
Minimally invasive group (n=40)	18:12	15.0±3.0	24.2±5.5	97.5	5.0±0.3	0.46±0.05
Surgical group (n=40)	16:14	15.5±3.5	24.2±7.5	97.5	6.8±0.4	0.43±0.05
P value	> 0.05	> 0.05	> 0.05	> 0.05	< 0.05	> 0.05
Group	LVEDP (mmHg)	LVEDD (mm)	LVESD (mm)	LVEF (%)	LVEDV (ml)	LVESV (ml)
Minimally invasive group (n=40)	7.3±2.9	40.2±8.6	28.0±6.0	51±3	85±6	34±4
Surgical group (n=40)	7.6±2.8	40.8±7.4	26.0±5.0	49±3	83±8	32±3
P value	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

§: Plus-minus values are means±SD.

VSD: ventricular septal defect; LVEDP: left ventricular end-diastolic pressure; LVEDD: left ventricular end-diastolic diameter; LVESD: left ventricular end-systolic diameter; LVEF: left ventricular ejection fraction; LVEDV: left ventricular end-diastolic volume; LVESV: left ventricular end-systolic volume.

Table 2. Procedure-related complications of the minimally invasive group and surgical group (n)

Group	Residual shunt	Bleeding	Aortic and tricuspid regurgitation	Arrhythmia	Conduction anomalies	Other complications	New complications in follow-up
Minimally invasive group (n=40)	5	0	2	6	7	0	0
Surgical group (n=40)	2	2	1	1	1	8	5
P value	>0.05	>0.05	>0.05	<0.05	<0.05	<0.05	<0.05

Table 3. The comparison of clinical outcomes of the minimally invasive group and surgical group[§]

Group	Incision location	Extracorporeal circulation (minutes)	Blood products (ml)	Operation time (minutes)	Intensive care unit stay (day)
Minimally invasive group (n=40)	Lower-middle sternum	0	0	58±21	2±1
Surgical group (n=40)	Center of the chest	85±15	800±120	145±26	8±3
P value		<0.05	<0.05	<0.05	<0.05
Group	Extubation time (day)	Total hospital stay (day)	Postoperative recovery time (day)	Equipment cost (10 000 yuan)	Total cost (10 000 yuan)
Minimally invasive group (n=40)	2±1	5±1	3±1	3.5±1.0	4.5±1.5
Surgical group (n=40)	4±1	16±6	90±20	0.5±0.2	3.0±0.5
P value	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05

§: Plus-minus values are means±SD.

DISCUSSION

Since the minimally invasive perventricular device closure of VSD was successfully applied in animal models,⁸⁻¹⁰ this technology has been constantly reported in clinical settings.¹¹⁻¹³ The results of this study reflect some advantages of minimally invasive perventricular device closure of VSD in comparison with the conventional surgical repair. One advantage is that it can avoid the use of cardiopulmonary bypass. It could also shorten recovery time and reduce the incidence of complications. Other advantages of periventricular closure have been reported, including simple operation, effectiveness, and safety,^{5, 14} acceptable short-term follow-up outcomes¹⁵ and satisfactory esthetic effect.¹⁶ In addition, this technology has more accurate device positioning because the whole process could be monitored and guided by TEE, which can ensure the safety of the procedure. Once a patient is considered not suitable for this procedure or the device closure fails, the surgeons can immediately convert to traditional surgical repair. More importantly, this technology could be applied for periatrial closure of atrial septal defect¹⁷⁻¹⁹ and patent ductus arteriosus,^{20,21} even those close to the aortic valve. However, this new technology still has its own drawbacks and limitations. For instance, the residual leakage rate and procedure cost are high, the follow-up time is short and the incidence of complete heart block is unacceptable.²² Further studies with larger cohorts and longer-term follow-up are necessary to evaluate the long-term results of minimally invasive perventricular device closure of VSD.

This comparative study has its limitations, namely small sample size, short follow-up, and lack of randomization. Despite these shortcomings, this study demonstrates the feasibility and advantages of minimally invasive perventricular device closure of VSD over traditional surgical repair. Certainly, long-term follow-up is also necessary to confirm the validity of this new technique.

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