

# Open-Chest Device Closure for the Minimally Invasive Management of Atrial Septal Defect in Young Children

Hao Zhang,<sup>1</sup> Shou-jun Li,<sup>1</sup> Yong-qing Li,<sup>2</sup> Hao Wang,<sup>2</sup> Sheng-shou Hu<sup>1</sup>

<sup>1</sup>Center for Pediatric Surgery and <sup>2</sup>Department of Echocardiography, Cardiovascular Institute and Fu Wai Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China



Dr. Zhang

## ABSTRACT

**Background.** We integrated a catheter-based device and minimally invasive surgical techniques for the treatment of atrial septal defect for children younger than 2 years old.

**Methods.** Forty-three patients were divided into 3 groups: group A underwent open-chest device closure with a right lateral thoracotomy (n = 12), group B underwent open-heart repair with a right lateral thoracotomy and cardiopulmonary bypass (n = 11), and group C underwent open-heart repair with a median thoracotomy and cardiopulmonary bypass (n = 20).

**Results.** Group A had the lowest weight ( $9.25 \pm 1.3$  kg) and smallest defect size ( $10.25 \pm 3.9$  mm). In group A, 2 patients had to be transitioned to open-heart repair after unsuccessful occlusion. Compared with the open-heart groups, the device group had a shorter total operation time ( $111 \pm 39$  minutes), required the minimum amount of blood products ( $39 \pm 38$  mL), and had a smaller amount of pleural drainage in the first 12 hours after the procedure ( $29 \pm 12$  mL). All patients were discharged. The right ventricular end-diastolic diameter reduced significantly after the repair; furthermore, there was no difference in the size of reduction. However, the device group had the highest medical costs ( $30,639 \pm 3831$  Chinese yuan). During the follow-up, there were no occluder-related complications observed in Group A, and there were no residual shunts or arrhythmia observed in the groups.

**Conclusions.** The open-chest device closure was safely performed as a supplement for percutaneous treatment for young children.

## INTRODUCTION

Secundum type atrial septal defect (ASD) is a very common congenital heart defect. Although young children with ASD are usually asymptomatic and could wait for elective surgical or catheter-based closure after 3 years, a specific subgroup with large ASD suffer from frequent respiratory infection and/or heart failure. Therefore, early closure could be beneficial for such a subgroup [Lammers 2005]. Due to various reasons, the regular percutaneous occlusion approach sometimes cannot be utilized for children younger than 2 years old, and these patients are generally referred to the surgical department.

Open-heart repair with midline sternotomy and cardiopulmonary bypass (CPB) has been considered the gold standard for the management of ASD. Recently, more cosmetically appealing incisions have been advocated to reduce the physical and psychological trauma for the children. However, the utilization of CPB is still necessary in either a standard midline or lateral thoracotomy. To avoid the potential adverse effects of CPB on young children, we integrated a catheter-based device and minimally invasive surgical approach to close ASD and compared the results and costs with conventional surgical approaches.

## PATIENTS

The procedure of open-chest peratrial device closure for ASD was approved by the Ethics Committee of Beijing Fu Wai Hospital in April 2005. Between May 2005 and May 2006, 43 consecutive patients younger than 2 years old were enrolled in the study. All the children had a history of heart failure and/or frequent respiratory infection. The size, location, and margin of ASD were evaluated by the same echocardiographic team. All families were fully informed about the following 3 different approaches preoperatively. According to the type of ASD and the family's decision, the patients were divided into 3 groups: group A underwent open-chest device closure with a right lateral thoracotomy (n = 12), group B underwent open-heart repair with a right lateral thoracotomy and CPB (n = 11), and group C underwent open-heart repair with a median thoracotomy and CPB (n = 20).

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Correspondence: Sheng-Shou Hu, MD, Chief, Department of Cardiac Surgery, President, Cardiovascular Institute and Fu Wai Heart Hospital, Professor, Peking Union Medical College, 167 Beilishilu, Beijing 100037, P. R. of China; telephone and fax: 86-10-88396050 (e-mail: drzhanghao@yahoo.com).

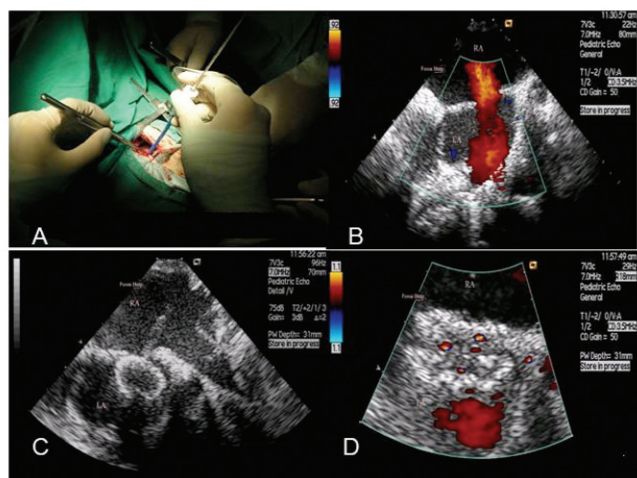


Figure 1. Open-chest peratrial device closure of atrial septal defect. A, Sheath puncture through the atrium via a mini-right lateral thoracotomy. B-D, Occlusion of the defect with real-time transesophageal echocardiography.

## METHODS

### Open-Chest Peratrial Device Closure

After incubation and general anesthesia, an echocardiographic probe was inserted in the esophagus. The patient was placed on the left side and elevated 60 to 80°, and a cosmetic skin incision was made between the anterior and posterior axillary folds as described by our group previously [Liu 2000]. Through the fourth intercostal space, the pericardium was opened to expose part of the right atrium. After the heparinization, a purse-string suture was placed in the surface of the right atrium, and then the sheath was inserted through the small incision inside the purse string. Guided by transesophageal echocardiography (TEE), the sheath passed through the defect, and the left atrial disk was deployed and pulled gently against the atrial septum. The right atrial disk was then deployed, and a to-and-fro motion of the sheath was performed to ensure a secure position across the defect. Finally the device (Starway; Beijing Starway Medical Corp, Beijing, China) was released after the confirmation of an appropriate position and nonresidual shunt by TEE (Figure 1). Once the sheath was withdrawn, the purse string was tied and the chest was closed, with a tube left for the drainage. Aspirin (5 mg/kg) was administered daily, starting the day after the procedure.

### Open-Heart Repair with CPB

Either a midline or right lateral incision was utilized separately in the open-heart procedure. As described previously, in group B, the chest was opened through the fourth intercostal space. The pericardium was opened and extended to offer adequate exposure to the aorta and vena cava. In group C, a standard midline sternotomy was performed. The heart-lung machine was prepared according to institutional protocol. Regular 200 to 300 mL of purified

red blood cells were prefilled to keep the appropriate hematocrit level during CPB. In both groups B and C, ASD was repaired by suture alone in 1 patient, pericardial patch in 11, and Dacron patch in 19.

### Collection of Perioperative Data

All patients were referred to the surgical department without cardiac catheterization and angiography. The following data from transthoracic echocardiography was collected preoperatively and postoperatively: systolic pulmonary artery pressure, right ventricular end-diastolic diameter, diameter of ASD, and occurrence of a residual shunt. The cardiothoracic ratio was recorded from the chest x-ray before the operation.

The following data were defined and collected. The skin-to-skin time between the cutting and closure of skin incision was defined by the total operation time, and the length of CPB or peratrial puncture to device release was defined by the defect closure time. The blood products were defined as the requirements for purified red blood cell in the operation room, and the blood loss was defined as the amount of pleural drainage during the first 12 hours after the procedure. Costs were defined as the sum of patient care-related medical costs between admission and discharge. Data on the patient's age, sex, weight, length of postoperative ventilator support, and length of intensive care unit stay were collected separately.

### Follow-up

All patients underwent clinical examination, chest x-ray, electrocardiography, and transthoracic echocardiography at 1 week, 3 months, and 6 months after the procedure. Anticoagulation therapy with aspirin, 5 mg/kg per day by mouth, was prescribed for 3 months in group A.

### Statistical Analysis

All numerical data are expressed as the mean  $\pm$  SD. The diameter change of right ventricular end-diastolic diameter was analyzed by the paired *t* test. Sex difference was analyzed by the chi-square test. One-way analysis of variance was performed to compare the numerical data between the 3 groups. Data were considered statistically significant if  $P < .05$ .

### Demographic Characteristics of the Patients

	Group A	Group B	Group C
Age, mo	14 $\pm$ 4.9	18 $\pm$ 5.6	16.8 $\pm$ 6.5
Weight, kg	9.25 $\pm$ 1.3	10.11 $\pm$ 2.3	10.31 $\pm$ 2.46
Male sex, %	58.3	55.6	52.4
Defect size, mm	10.25 $\pm$ 3.9	13.81 $\pm$ 3.1	17.1 $\pm$ 6.4
Systolic pulmonary artery pressure, mmHg	38.7 $\pm$ 5.5	38.4 $\pm$ 4.8	44.6 $\pm$ 8.8
Right ventricular end-diastolic diameter, mm	16.8 $\pm$ 5.5	17.9 $\pm$ 2.8	18.9 $\pm$ 3.7
Cardiothoracic ratio	0.584 $\pm$ 0.19	0.577 $\pm$ 0.19	0.582 $\pm$ 0.09

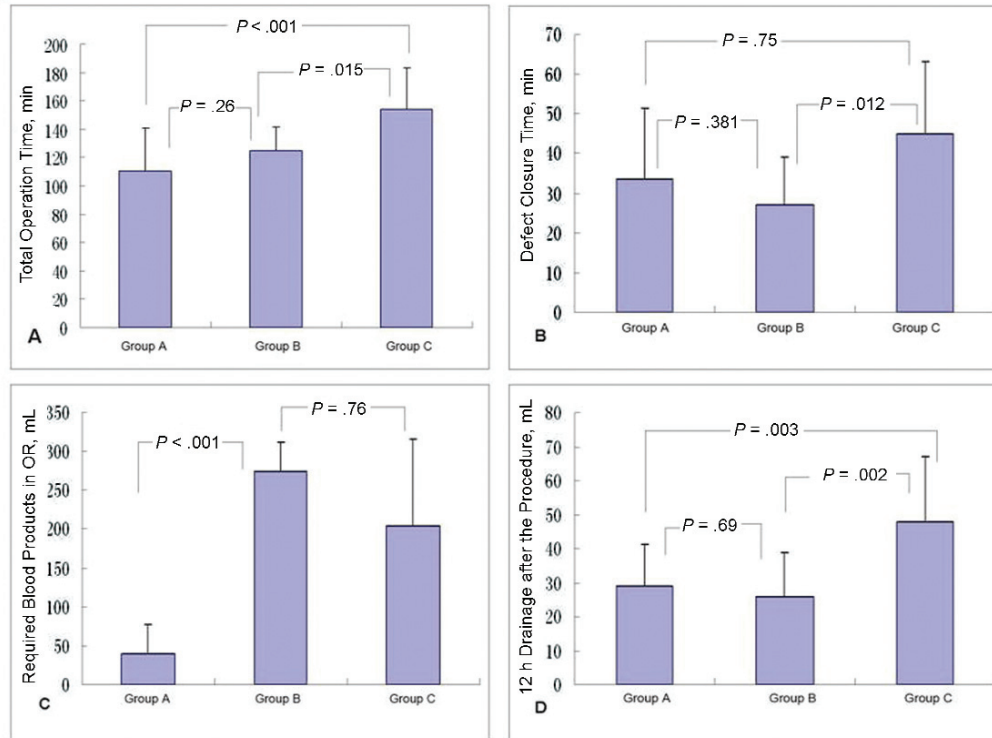


Figure 2. Comparisons of clinical outcomes. A, The total operation time. B, The defect closure time. C, Amount of blood products required in the operation room. D, The amount of pleural drainage in the first 12 hours after the procedure.

## RESULTS

### Patient Characteristics

The demographic data of the patients are reported in the Table. There were no differences in age, sex, cardiothoracic ratio, systolic pulmonary artery pressure, and right ventricular end-diastolic diameter between the 3 groups. However, compared with the conventional surgical repair group (group C), the device group (group A) had a lower body weight and smaller defect size ( $P = .047$  and  $.002$ , respectively), but there were no differences between groups A and B ( $P = .421$  and  $.08$ , respectively).

### Clinical Outcomes

Of the 12 patients in group A, 2 patients had to be transitioned to conventional surgical repair after unsuccessful occlusion, and these 2 patients' data were excluded from the study. There was no difference in length of postoperative ventilator support and length of pediatric intensive care unit stay. Compared with traditional surgical repair, groups A and B had a shorter defect closure time; furthermore, group A had the shortest total operation time. The amount of pleural drainage was highest in group C, and there was no difference between the other groups. The requirement of blood products was not different between the surgical repair groups with CPB; however, the device closure group needed the least amount of blood products in the operation room (Figure 2). Except for the occurrence of postoperative pneumonia in 1

patient in group C, there were no complications in any of the groups. Residual atrial shunt was not observed in any group before discharge. All patients were discharged.

### Medical Costs

The cost for group A was  $30,639 \pm 3831$  Chinese yuan (1 US dollar  $\approx$  8 Chinese yuan), and it was much higher than in the other 2 groups ( $P < .001$ ). There was no difference in the costs between group B and C ( $20,672 \pm 2988$  versus  $22,367 \pm 4746$ ;  $P = .31$ ).

### Follow-up

There was no device-related complication observed in group A during the follow-up. In all 3 groups, the size of the right ventricle dramatically decreased 1 week after the defect closure ( $5.16 \pm 2.91$ ,  $4.77 \pm 1.64$ , and  $6.05 \pm 2.57$  mm for groups A, B, and C, respectively;  $P > .05$ ), and there were no differences in the time-related change of right ventricular end-diastolic diameter. There were no residual atrial shunts, atrial arrhythmia, or thrombus formation observed in the groups during follow-up.

## DISCUSSION

With the developments of various devices since 1976, percutaneous transcatheter occlusions of ASD gradually become the first choice for select patients [Thanopoluos 1998]. However, due to patient weight and limited vascular access, percuta-

neous approach sometimes could not be utilized for young children. Some families refused to allow their children to undergo prolonged x-ray exposure during the percutaneous closure. We have developed a cosmetic incision for the treatment of various congenital heart diseases. Previous changes to the type of incision have never changed the essential component of this type of cardiac surgery—open-heart repair with the aid of CPB. Considering the above facts, we integrated the use of a catheter-based device with a surgical approach to occlude the defects and avoid the use of CPB, and thus develop a new minimally invasive surgical management of ASD for young children as a supplement for percutaneous treatment.

We applied the same criteria with cardiologists to allow us to choose “suitable” ASD for the device closure, and the open-chest approach offered an operative field and allowed the cardiac surgeons to do better with traditional surgical techniques. Sometimes we sutured the rim of the occluder with the atrium to prevent malposition in cases of ASD with a poor rim.

In the device group, because of the avoidance of CPB, we could limit the length of incision between 4 to 5 cm. Hence the operation time could be significantly shortened. In our series, the skin-to-skin time could be limited to 1 hour by an experienced surgeon. Liang and his colleagues occluded defects via a 3-cm anterior minithoracotomy [Liang 2006]. However, we preferred to use a right lateral incision because it was easy to extend for conversion to a regular open-heart procedure.

The significant benefit offered by the open-chest device closure is the avoidance of CPB, thus maximally reducing the requirement of blood products. Blood transfusions remain a risk of cardiac surgery that have important health consequences [Karski 2003]. In our study, all the blood products in the surgical repair groups were required with CPB. Although CPB was avoided during the procedure, patients in the device group still needed to receive quick transfusions of 10 to 20 mL blood intravenously several times because the motion of the sheath could result in a change of blood pressure. However, with accumulated experience of the surgeons, the last 4 patients of the series did not require the transfusion of any blood products. Thus, with an experienced operator, the open-chest device closure could be a no-blood-required procedure compared with the conventional surgical approach with CPB.

We still experienced a learning curve with the device closure. First, surgeons needed to learn to be familiar with a device that they have never used before. Second, they had to become accustomed to guidance by echocardiography instead of using their own vision to close the defect. In our earlier

series, the occluder was shed from the sheath in the right atrium during the puncture in 1 patient. Due to the open-chest approach, regular CPB was set up rapidly and the patients received consequent open-heart repair.

Relatively higher medical costs are always a real challenge in popularizing a percutaneous approach in a developing country [Vida 2006]. In this study, although we chose a domestically made device to maximally reduce the costs, the device group still had the highest costs. The major contributor to higher cost in the device group was the cost of the device, which accounted for about 44% of all the medical costs. In the surgical repair groups, the major contributor was the CPB hardware; furthermore, the amount of hardware cost accounted for only about 20% of the total costs. In the future, we will experience the same challenge to improve the cost-effectiveness offered by a catheter-based device in our country.

In conclusion, the open-chest device closure offers another alternative approach for minimally invasive management of ASD in young children. It does not require x-ray exposure and has no vascular limit for utilizing the device, thus avoiding CPB and reducing the amount of blood products required. A 1-stop platform is also offered by the open-chest approach to correct combined congenital defects in an off-pump fashion with rapid transition to regular open-heart repair.

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