

# Percutaneous device closure of atrial septal defect with totally transthoracic echocardiography guide, without x-ray machine

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### Abstract

The present study investigated the feasibility of totally transthoracic echocardiography-guided percutaneous device occlusion of atrial septal defects (ASDs) without using x-ray equipment.

Between September and December 2014, we performed totally transthoracic echocardiography-guided percutaneous device occlusion for 20 patients with secundum ASD without using x-ray equipment. We carried out percutaneous femoral vein puncture, used a specialized delivery sheath during operation, and closed the ASD by releasing an occluder.

All 20 patients experienced successful occlusion and smoothly went through the perioperative period. The average procedure time ranged from 30 to 40 minutes ( $32.4 \pm 3.5$  minutes), and the size of the implanted occluder ranged from 20 to 38 mm ( $25.4 \pm 5.8$  mm). No occluder displacements, residual fistula, or thrombus-related complications after the procedure. There was no clinical death, no arrhythmia, no hemolysis, no infection, or embolism during patients' hospitalization and the follow-up period.

Totally transthoracic echocardiography-guided percutaneous device occlusion of ASDs without the use of x-ray equipment may be safe and feasible.

**Abbreviations:** ASD = atrial septal defect, CHD = congenital heart diseases, ECG = electrocardiogram, TEE = transesophageal echocardiography, TTE = transthoracic echocardiography.

Keywords: cardiac intervention, CHD, septal defects

## 1. Introduction

Atrial septal defect (ASD) is a common congenital heart disease, about 8% to 10% of all congenital heart diseases (CHDs) and 30% to 40% adults with CHDs are diagnosed to have ASDs. The traditional treatment is direct-vision intracardiac repair under cardiopulmonary bypass, which can obtain satisfactory operative result and leads to the relatively large incision, postoperative

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pain.<sup>[1,2]</sup> Recently, techniques for percutaneous device occlusion and minimally invasive transthoracic device occlusion have improved markedly and have achieved satisfactory outcomes in some patients with ASD, which have gradually become another standard treatment for most secundum ASDs.<sup>[3–6]</sup> But the former need x-ray radiation and the latter still need a surgical minimal incision. In order to overcome the above shortcomings of the 3 methods, we performed totally transthoracic echocardiographyguided percutaneous device occlusion for 20 patients with secundum ASD without using x-ray equipment and here report good outcomes from the new procedure.

# 2. Materials and methods

The present study was approved by the ethics committee of Fujian Medical University, China, and adhered to the tenets of the Declaration of Helsinki. Additionally, the written informed consent was obtained from the patients or the parents of the patients.

In total, 20 patients were enrolled from our institution between the period of September and December 2014. The patients ranged in age from 15 to 48 y, weighed from 34 to 56 kg, and the diameter of ASD was from 16 to 30 mm. All 20 patients were diagnosed by echocardiography with a secundum ASD. The special criteria which included in our group: secundum ASD with presence of adequate rims (distance from the edge of the defect to the superior vena cava, inferior vena cava, coronary sinus, and pulmonary vein  $\geq 5$  mm) and the max diameter of the ASD was 30 mm. Other indications for the ASD closure included hemodynamically significant left to right shunts and (or) significant chamber enlargement, and (or) mild to moderate pulmonary hypertension, with presence of clinical symptoms. The exclusion criteria which included elevated nonreactive pulmonary vascular resistance, associated other congenital heart

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disease needing surgical intervention, uncontrolled congestive heart failure, inability to obtain informed consent.

All patients had mild pulmonary hypertension without other associated cardiac malformations. Routine examinations including a standard electrocardiogram, a chest x-ray, and blood tests were conducted. All the patients were symptomatic, which included palpitations, shortness of breath, exercise intolerance, and insignificant chest pain. The chest x-ray film showed pulmonary congestion, and the echocardiography showed hemodynamically significant left to right shunts and (or) significant chamber enlargement.

After combined intravenous-inhalation anesthesia, the patient was placed in a 30-degree right chest elevated position. The location, size, and margin of the ASD were identified using transthoracic echocardiography. The size of the occluder was chosen based on the results of echocardiography. The occluder was soaked in heparin saline and then was placed in a small delivery sheath. After systemic heparinization (1 mg/kg), the surgeon carried out right femoral vein puncture. A venous sheath was inserted, and a multifunctional catheter was advanced into the right atrium via the inferior vena cava under the guidance of echocardiography (Fig. 1). A guidewire was inserted into the left atrium, and the multifunctional catheter was withdrawn (Figs. 2 and 3). A delivery sheath was inserted along the guidewire into the left atrium, and the inner core and the guidewire were withdrawn (Fig. 4). Then, an occluder was delivered carefully through the sheath. Under the real-time guidance of transthoracic echocardiography, the left atrial disc was opened (Fig. 5). The delivery sheath was then rotated to make the left atrial disc parallel to the atrial septum. The left atrial disc was pulled back, and the right atrial disc was opened (Fig. 6). After the occluder clamped the margin of the ASD, the occluder's immobility and the possible presence of a residual shunt were evaluated using transthoracic echcardiography, as were the structures and functions of the superior vena cava, the inferior vena cava, the coronary sinus openings, the mitral valve, and the tricuspid valve. The delivery sheath then was withdrawn. The patient was sent to the intensive care unit after operation, and extubation was carried out. Anticoagulation via oral administration of dipyridamole or aspirin was carried out for 3 months after operation.

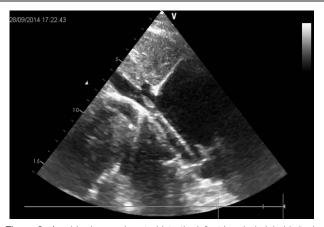


Figure 2. A guidewire was inserted into the left atrium (subxiphoid view).

#### 3. Results

Successful occlusion was achieved in all 20 patients (clinical data of patients were showed in Table 1), among whom the operative time ranged from 30 to 40 minutes  $(32.4 \pm 3.5 \text{ minutes})$  and the occluder size ranged from 20 to 38 mm ( $25.4 \pm 5.8$  mm). There were no complications related to occluder dislocation, residual fistula, complete atrioventricular block, or thrombosis-related conditions. There was no clinical death, no arrhythmia, no hemolysis, no infection, or embolism during patients' hospitalization. During 6 months-1 year follow-up period, out-patient was by functional, echocardiographic, and ECG assessment. Symptoms had been either resolved totally or improved significantly. The complete closure rate was 100%. None of the patients spared the complication associated with the device. Table 2 shows changes in the size and the function of the heart before and after ASD closure in the follow-up period. At 3 months and at 1 year's follow-up after ASD closure, the anatomic parameters of the right heart were significantly reduced compared with the preoperative data. Meanwhile, the pulmonary artery pressure had corresponding decreased significantly.

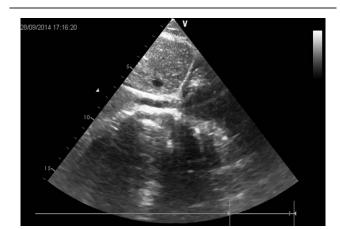


Figure 1. A multifunctional catheter was advanced into the right atrium via the inferior vena cava under the guidance of echocardiography.



Figure 3. A guidewire was inserted into the left atrium (parasternal short-axis view).

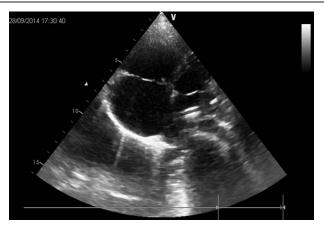


Figure 4. A delivery sheath was inserted into the left atrium.

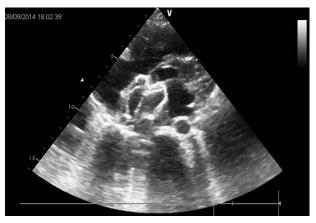


Figure 6. The right atrial disc was opened.

# 4. Discussion

Atrial septal defect is a common congenital heart disease. Traditional direct-vision intracardiac repair with or without cardiac arrest under cardiopulmonary bypass has achieved satisfactory outcomes. However, extracorporeal circulation may damage the human body, including systemic inflammatory response, multiple organ damage, and myocardial ischemiareperfusion injury. Moreover, all incisions, including the midsternal incision, the small lower sternal incision, and the curved right chest incision may result in relatively large surgery scars.<sup>[1,2]</sup> Transcatheter device occlusion has improved significantly in recent years and has achieved satisfactory outcomes, which contains no scar, no postoperatieve pain, no general anesthesia and very short hospital stay. However, both doctors and patients are exposed to x-ray radiation, which may lead to the unnecessary exposure to physical damage. This method also requires large and expensive x-ray equipment.<sup>[3,4]</sup> Recently, many cardiac centers have initiated minimally invasive transthoracic occlusion, especially in some big heart center in China. This technique combines percutaneous occlusion and open surgery. Although the procedure is a cost-effective, cosmetic and lessinvasive, it still requires an incision about 3 to 4 cm in length.<sup>[5,6]</sup>

To minimize the procedure's invasiveness further, integrated the advantages and disadvantages of the existing various



Figure 5. The left atrial disc was opened.

methods, we have performed totally transthoracic echocardiography-guided percutaneous device occlusion of ASDs without using x-ray equipment in the operating room. This technique results in a puncture wound only in the right inguinal area, which is similar to the traditional transcatheter device closure method. Due to the lack of enough experience, we selected patients with secundum ASDs with sufficient defect margins so we could perform occlusion easily. In addition, we selected more older patients for facilitating delivery sheath placement. Additionally, this new technique can simplify the procedure and be easy to implement. The average operation time was no more than 40 minutes, which made most of surgeons accept this new procedure. The procedure used in the present study should be performed by surgeons who are familiar with open-heart surgery and minimally invasive transthoracic device occlusion, especially if they have experience with major-vessel intervention. This process needs certain learning curve for operators. Without x-ray positioning, the surgeon's spatial thinking and real-time communication with the sonologist are especially important during guidewire placement into the left atrium, to finish the key point of this procedure.

Transthoracic echocardiography played an important role during the operation and should be carried out by an experienced sonologist.<sup>[7,8]</sup> We also found some other papers which supported our opinion. Those authors reported transthoracic

# Table 1

Clinical data of patients undergoing totally transthoracic echocardiography guided percutaneous device occlusion of ASD.

| Item                        |                |
|-----------------------------|----------------|
| Sex, M:F                    | 8:12           |
| Age, y                      | 25.5±9.5       |
| Weight, kg                  | 55.6±10.1      |
| Echocardiographic parameter |                |
| ASD diameter, mm            | 21.2±3.5       |
| QP/QS amount                | 1.8±0.5        |
| Clinical data               |                |
| Occluder size, mm           | $25.4 \pm 5.8$ |
| Operative time, min         | $32.4 \pm 3.5$ |
| Hospital stay, days         | 2.2±1.3        |
| Follow-up, mo               | $8.5 \pm 2.4$  |
|                             |                |

ASD = atrial septal defect, QP/QS = pulmonary-to-systemic blood flow.

Table 2

Changes in right heart size before and after atrial septal defect closure.

| Item   | Preoperation    | 3 months after procedure | 1 year after procedure |
|--|-----------------|--------------------------|------------------------|
| End-systolic length of the right atrium, mm              | $56.8 \pm 8.5$  | $48.2 \pm 6.5^*$         | $45.3 \pm 7.3^{*}$     |
| End-systolic width of the right atrium, mm               | $52.3 \pm 7.5$  | $45.3 \pm 6.4^{*}$       | $42.6 \pm 7.1^{*}$     |
| End-diastolic length of the right ventricle, mm          | $63.4 \pm 12.1$ | $55.1 \pm 10.2^{*}$      | $52.3 \pm 9.4^{*}$     |
| End-diastolic width of the right ventricle, mm           | 46.8±10.3       | 43.3±8.5                 | $42.7 \pm 7.5$         |
| Mean pulmonary artery pressure, mm hg                    | 42±12           | $24.3 \pm 5.2^{*}$       | $22.5 \pm 3.3^{*}$     |
| Three-dimensional right ventricular ejection fraction, % | $58.5 \pm 4.7$  | $45.3 \pm 5.2^{*}$       | $44.5 \pm 3.6^{*}$     |
| Left ventricular ejection fraction, %                    | $55.3 \pm 5.8$  | $56.4 \pm 6.6$           | 57.1±5.6               |

\* Different from preoperative (P < 0.05).

echocardiographic guidance of transcatheter atrial septal defect closure. Kardon and his colleagues reported a series of 64 patients for ASD closure using TTE-guidance. In their study, 56 patients had successful result, 12 patients were referred for surgical closure, and 5 patients with multiple ASDs or poor transthoracic acoustic windows were guided by transesophageal echocardiography.<sup>[9]</sup> Li et al<sup>[10]</sup> summarized that TTE was a reliable and useful tool for device closure ASD, which included measurement of ASD diameter, guidance the occluder deployment and evaluation of residual shunts. They also emphasized that transcatheter ASD closure guided by TTE was effective and safe in patients with ASD <or=20mm. So TTE can be used as a primary and reliable tool for the measurement of ASD and guidance during device closure by skilled and professional hands. In our previous experience, we used TTE to guide transthoracic device closure of ASDs and obtained satisfactory clinical effect.<sup>[5]</sup> With our increasing experience, we have gained important insights that have helped to improve TTE guidance and to prepare for our new procedure. With the help of the experienced sinologist, the apical 4 chamber view, the parasternal long axis view, and the subxiphoid acoustic window can provide a satisfactory visualization to complete our operation, and the diameter of defect was measured in each of these views and a maximum diameter determined. So we confirmed TTE was an effective guided tool in our study.

Reports suggested that the accuracy of transthoracic echocardiography was lower than that of transesophageal echocardiography. The most important reason was that TEE images were clearer because the TEE probe was adjacent to the left atrium.<sup>[11]</sup> Ko and his colleagues compared TTE, cardiac CT, TEE in the evaluation of secundum ASD for closure with an Amplatzer septal occluder in pediatric patients. Their result showed the long axis of a large ASD can be underestimated at TTE. Meanwhile, Cardiac CT seems comparable with TEE in the assessment of ASD and is helpful in noninvasive evaluation for ASD device closure.<sup>[12]</sup> However, after performing minimally invasive transthoracic device occlusion, we found that in the general population, transthoracic echocardiography can achieve satisfactory imaging that is comparable to that from transesophageal echocardiography.<sup>[5]</sup>

Many paper reported their experience about the safety and efficacy of transthoracic echocardiographic guidance of ASD device closure. Although they used transthoracic echocardiographic in combination with fluoroscopy to guide transcatheter ASD closure.<sup>[13–15]</sup> They confirmed both the median procedure time and the median fluoroscopy time was significantly shorter in TTE group. Xie Shaobo and his colleagues discussed percutaneous trans-jugular vein closure of ASD with steerable introducer under echocardiographic guidance. Their method showed some

merits as follows: without fluoroscopy, easy operation, mild damage, and wider indication.<sup>[16]</sup> Pan XB and his colleagues reported their experience of percutaneous ASD closure with TTE guidance as the only imaging tool. Their method avoided fluoroscopy, endotracheal intubation, and probe insertion and was associated with a satisfactory procedural success rate and lower costs.<sup>[17]</sup> They measured the distance from the right parasternal third intercostal space to the puncture site, this is the "working length" for catheter insertion. Then they used different echocardiography view (apical 4-chamber or parasternal shortaxis view) to detect the location of the catheter. Our approach is similar to their methods, which also proved we can finish such procedure without fluoroscopy guidance.

The key technical points of the procedure are the following: (1) during the placement of the multifunctional catheter, the inferior vena cava, and the right atrium should be detected using the transthoracic echocardiographically identified subxiphoid acoustic window to guide catheter placement into the right atrium. The catheter can be rotated to make the catheter tip point toward the atrial septal defect. Meanwhile, a guidewire should be inserted into the left atrium. Because the guidewire may circle within the right atrium or enter the superior vena cava, repeated positioning may be necessary. (2) The guidewire and delivery sheath should be gently deployed, and real-time echocardiography should be applied for positioning. Although the guidewire tip is soft, it still can damage the large blood vessels and atria. (3) After release of the left atrial disc, surgeons should pay attention to observe whether the left atrial disc and the atrial septum are parallel. If there is a certain angle between the left atrial disc and the atrial septum, the occluder may easily get stuck in the atrial septal defect transversely when it is pulled back. In such a situation, the direction can be adjusted by gradually rotating the delivery sheath in a clockwise direction to make the left atrial disc parallel to the atrial septum. The left atrial disc should be pulled up to the atrial septum thereafter.

Our study has various shortcomings. First, the number of enrolled cases is small, and we cannot rule out selection bias. Thus, we shall further study patient selection, surgical procedures, and perioperative monitoring, and we will continue to explore its indications and contraindications. The surgeon who performs this kind of procedure should have sufficient clinical experience and good spatial orientation. This procedure requires cooperation among many departments and has a steep learning curve. In our initial experience, it should only be carried out in selected patients with sufficient defect margins by experienced sonologists. If the delivery sheath is made of materials that can be observed more easily via echocardiography, the establishment of the delivery pathway should become simpler. We do not want to claim that this procedure can be replaced the traditional method, but it can be used as an alternative way. In short, this technique has certain advantages compared with previous techniques and can be further promoted because it avoids fluoroscopy and is performed by surgeons. As a result of the 20 successful cases, our experience is still limited, and longer follow-ups and larger sample size are needed in future research.

In conclusion, we believe that total transthoracic echocardiography-guided percutaneous device occlusion of atrial septal defects without the use of x-ray equipment is safe and feasible. It can avoid extracorporeal circulation, is minimally invasive, and has aesthetically beneficial outcomes. This procedure can be guided by transthoracic echocardiography and does not require large radiation equipment. In the worst case, even if the occlusion fails, the intervention can be converted to open surgery. Hence, we recommend totally transthoracic echocardiography-guided percutaneous device occlusion without using x-ray equipment for the treatment of patients with atrial septal defects.

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