

# Comparative study of the transcatheter and transthoracic device closure treatments for atrial septal defect

## A Chinese single-institution experience

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### Abstract

The purpose of this study was to compare patient populations, safety, feasibility, complications, and total costs of the transcatheter and transthoracic device closure treatments for secundum atrial septal defect.

From January 2014 to December 2014, we enrolled 155 patients with secundum atrial septal defects in our hospital. The patients were divided into 2 groups: the 70 patients in group A underwent transcatheter device closure, and the 85 patients in group B underwent transthoracic intraoperative device closure with a right lateral mini-thoracotomy.

In group A, the total occlusion rate was 94.3% immediately after the operation, 100% at 3 months, and 100% at 12 months of follow-up; the group A results were not statistically different from the group B results (94.1%, 98.8%, 98.8%, respectively). There was a statistically significant difference in the minor complication rate ( $P < 0.05$ ), and there were no reported deaths. There was a greater indicated scope using the transthoracic closure device to treat atrial septal defects. In our comparative study, the patients in group B had longer intensive care unit stays and hospital stays than group A ( $P < 0.05$ ).

Both of the device closure treatment options for secundum atrial septal defect are safe and feasible. The transcatheter device closure approach has the advantages of more cosmetic results, less trauma, and a shorter hospital stay than the transthoracic approach. On the contrary, the transthoracic closure device is an economical alternative choice, particularly for patients who are not eligible for the transcatheter closure device.

**Abbreviations:** ASD = atrial septal defect, CHD = congenital heart disease, ICU = intensive care unit, TTE = transthoracic echocardiography.

**Keywords:** cardiac intervention, CHD, septal defects, surgery, transcatheter

## 1. Introduction

Atrial septal defects (ASDs) are documented in 2 of 1000 live births, approximately 13% of all cases of congenital heart diseases (CHDs).<sup>[1]</sup> Although surgical closure for secundum ASD can be

reliably achieved with no mortality and minimal morbidity,<sup>[2]</sup> it requires the utilization of cardiopulmonary bypass and surgical incision, results in postoperative pain and a prolonged hospital stay, which can cause patients physical and psychological trauma. In 1976, King et al<sup>[3]</sup> attempted the first transcatheter closure of a secundum ASD in human beings. Transcatheter closure with the Amplatzer septal defect occluder (AGA Medical, Corporation, Plymouth, MN) has gradually become another standard treatment for most secundum ASDs.<sup>[4,5]</sup> In recent years, another kind of hybrid technology that includes an intraoperative transthoracic closure device for ASD has been developed and implemented, especially in China. Similar to the success of transcatheter closure of ASDs, this approach has also achieved high technical success and good acute outcomes.<sup>[6–9]</sup> The device closure approaches have nearly replaced open heart repair, especially in cases of isolated secundum ASD. The results using these 2 different device closures for ASD have been reported in earlier published studies.<sup>[4–9]</sup> To the best of our knowledge, there has rare been a report comparing the transcatheter and transthoracic devices for ASD treatment. We report on our single institutional experience with these 2 alternative therapeutic modalities for ASD closure.

## 2. Methods

The present study was approved by the ethics committee of our university and adhered to the Declaration of Helsinki. In addition, written informed consent was obtained from the patients or the patient's relatives.

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*Authorship:* QC, HC designed the study, collected the clinical data, performed the statistical analysis, participated in the operation, and drafted the manuscript. Z-Y C, G-C Z, L-W C, FX, and J-J H participated in the operation and revised the article. All authors read and approved the final manuscript.

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Figure 1. The occlusion device.

### 2.1. Device

The Amplatzer ASD device was used in group A, and a standard transcatheter closure approach was adopted. In group B, the intraoperative ASD occluder was modified from the Amplatzer atrial septal occluder, which was manufactured by Dong Guan Ke Wei Medical Apparatus Co. Ltd of China (Fig. 1). In previous reports, we have introduced this domestic device.<sup>[10]</sup> The device consists of an occluder made from an alloy of nickel and titanium, a metal delivered sheath, and a pushing rod. The double disc occluder has a 10-cm thread in the right disc, facilitating its withdrawal into the 40-cm long and 3 to 6 diameter sheath.

### 2.2. Patients

We reviewed the charts of 155 patients with ASD who were admitted to our hospital between January 2014 and December 2014 and they were divided into 2 groups according to which closure approach the patient chose. A total of 16 other patients who had undergone preliminary surgical treatment were excluded from this study during this same period. There were 70 patients in group A and 85 patients in group B. All of the patients' clinical data are summarized in Table 1. There were no differences in gender, age, and body weight distribution between the 2 groups. All of the patients had a confirmed diagnosis of ASD and were sufficiently assessed by pre-operative transthoracic echocardiography (TTE). Routine clinical examinations were performed, which included a standard lead electrocardiogram, a

chest X-ray examination, and routine blood and biochemical tests. Arrhythmias (which included sinus bradycardia, atrial fibrillation, and atrial flutter) were detected in 5 patients in the 2 groups. In all of the patients, the chest X-ray showed evidence of pulmonary hypertension. Out of all of the patients, 56 had mild–moderate pulmonary hypertension. Patients with severe pulmonary hypertension who required drug therapy were excluded from this study. In both groups, 15 patients suffered from palpitations, shortness of breath, chest tightness, and decreased exercise tolerance.

The criteria for inclusion in group A: secundum ASD with presence of adequate rims ( $\geq 5$ mm) and a maximum ASD diameter of 32mm. In group B, in addition to the inclusion criteria for group A, the patients had a secundum ASD with an inferior vena cava rim deficiency and/or maximum ASD diameter of 44mm. In the 2 groups, the other indications for the ASD closure included hemodynamically significant left to right shunts and (or) significant chamber enlargement and (or) mild to moderate to severe pulmonary hypertension, despite medical therapy, with presence of symptoms like shortness of breath or exercise intolerance. The exclusion criteria included elevated nonreactive pulmonary vascular resistance, other associated CHD that required surgical intervention, uncontrolled congestive heart failure, any evidence of local or generalized sepsis or any infection that could not be successfully treated before device placement, malignancy with a life expectancy of less than 2 years, and the inability to obtain informed consent.<sup>[11]</sup>

### 2.3. Hybrid protocol

In group A, the procedure was performed in the catheter lab under local anesthesia utilizing TTE monitoring and X-ray guidance. The cardiac catheterization was performed through the femoral vein, and the defect was passed and quantified with a sizing balloon. The ASD diameter was assessed by echocardiography and angiography, and the selected occluder was 1 to 2 mm larger than the measurement obtained by the 2 assessments. The technique employed for the device implantation has been detailed in previous reports.<sup>[12,13]</sup>

In group B, TTE was used to assess the ASD pre- and intraoperation, in particular, the defect size and the circumferential margins adjacent to the defect. The occluder was chosen to allow for a margin of 4 to 6 mm in excess of the maximum ASD diameter. The surgery was performed under general anesthesia. A right anterior sub-mammary mini-thoracotomy (approximately 3–5 cm in length) was made through the fourth intercostal space. Through this incision, a “purse-string” suture approximately 15 mm in diameter was stitched in the right atrium. The occluder was drawn into the delivery sheath, and then an incision was opened in the “purse-string” suture and the delivery sheath was inserted (Fig. 2). Under continuous TTE guidance, the sheath was advanced through the ASD into the left atrium. Then, the left and the right disc were deployed in turn by pushing the rod to close the ASD (Figures 3 and 4).<sup>[10,14,15]</sup>

### 2.4. Statistical analysis

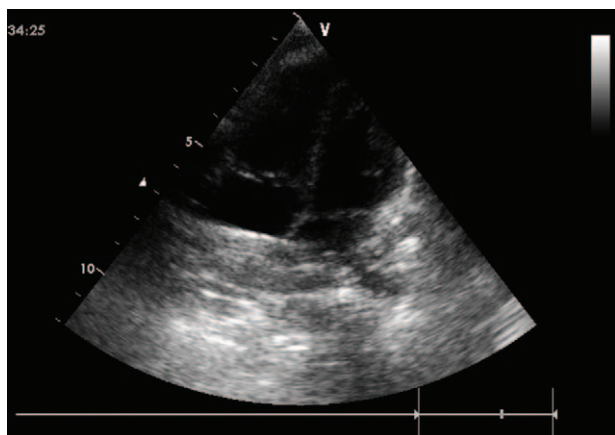
Continuous data are presented as the mean  $\pm$  standard deviation and range. Clinical parameters between the 2 groups were compared with the independent samples *t* test. Nominal variables were compared between 2 groups using Fisher's exact test. A *P* value less than 0.05 was defined as statistically significant.

Table 1

Comparison of clinical data in both groups.

|                     | Group A         | Group B         | <i>P</i> |
|---------------------|-----------------|-----------------|----------|
| Number of patients  | 70              | 85              |          |
| Male/female         | 31/39           | 40/45           |          |
| Age, y              | 18.2 $\pm$ 6.5  | 19.1 $\pm$ 5.3  | >0.05    |
| Body weight, kg     | 35.6 $\pm$ 19.1 | 36.1 $\pm$ 20.2 | >0.05    |
| ASD size, mm        | 18.9 $\pm$ 5.3  | 25.6 $\pm$ 8.8  | <0.05    |
| operative time, min | 35.5 $\pm$ 9.6  | 40.2 $\pm$ 8.5  | <0.05    |
| ICU stay, h         | 0               | 26.6 $\pm$ 11.2 |          |
| Hospital stay, d    | 2.2 $\pm$ 1.1   | 5.1 $\pm$ 1.2   | <0.05    |
| Follow-up, y        | 1.2 $\pm$ 0.8   | 1.3 $\pm$ 1.1   | >0.05    |

ASD = atrial septal defect, ICU = intensive care unit.



**Figure 2.** The sheath positioned from the right atrial free wall into the left atrial cavity across the ASD.



**Figure 4.** Final image shown after both discs were deployed.

**3. Results**

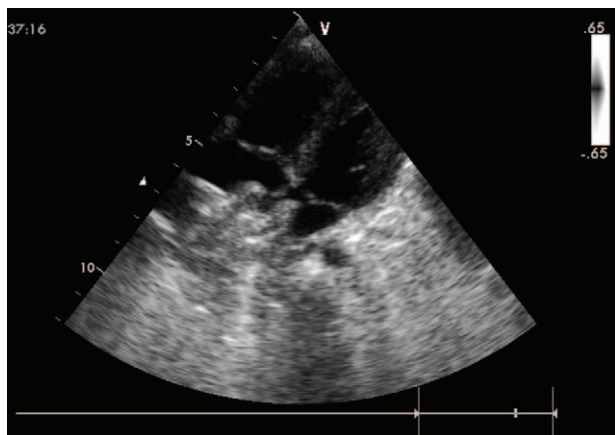
In both groups, delivery of the occluder was successful in 153 patients, and the other 2 patients were converted to surgical closure. In group A, the diameter of the ASDs ranged from 10 to 30 mm ( $20.1 \pm 5.3$  mm), and the size of the implanted occluder ranged from 12 to 32 mm ( $26.5 \pm 6.8$  mm). The corresponding data in group B were 14 to 42 mm diameter ( $28.1 \pm 6.3$  mm) and 20 to 46 mm occluder size ( $34.5 \pm 6.2$  mm). The successful ASD closure rate was 94.3% immediately after the operation, 100% at 3 months, and 100% at 12 months of follow-up in group A, which was not statistically different from the results in group B (94.1%, 98.8%, 98.8%, respectively). Tables 1 and 2 also depict the clinical data comparison of all the patients in both groups. In group B, the patients had small residual shunts, and shunts were detected at the junction of the occluder and the deficient rim. At the 3-month and 1-year follow-up, only 1 out of the 85 patients in group B still had small residual shunts, and there was no evidence of hemodynamic effects.

Two patients underwent emergent surgery to retrieve the occluder and patch closure due to occluder dislodgement. The patient in group A had a 30 mm ASD and received a 34 mm occluder, and a deficient inferior vena cava rim was confirmed during the operation. The other patient in group B had a 38 mm ASD and received a 46 mm occlude; the rim around the ASD had been deemed sufficient during

the preoperative preparation (in contrast to the aforementioned patient in group A). After the occluder was initially released and the incision was closed, occluder dislodgement was detected by TTE examination. The patients then underwent thoracoscope-assisted patch closure as a remedial measure.

Neither group had any serious complications or mortality, such as cerebral embolism, cardiac perforation, atrioventricular valve distortion, endocarditis, repeat procedure, or atrioventricular block requiring pacemaker implantation. The incidence of minor complications in group B was significantly higher than in group A ( $P < 0.05$ ). In group A, minor complications were encountered in 16 patients, including hematoma at the access site and transient cardiac arrhythmia in the course of the device deployment. Temporary atrial premature beats, sinus bradycardia, and tachycardia were observed in these patients, which were easily treated by medicine or spontaneous recovery. The patients with hematoma at the access site did not require medical intervention. In group B, transient cardiac arrhythmias occurred during occluder deployment in 25 patients, and no intervention was needed except close observation. A total of 2 patients experienced surgical wound complications, including the fat liquefaction of the incision and resuturing. Another 5 patients developed pericardial effusion or hydrothorax that required medical drainage tube placement. Another 5 patients developed pulmonary infections and received antibiotic treatment.

In group A, all of the patients were monitored in the common ward postoperatively, and the mean total duration of the hospital stay was 2.5 days. In group B, all of the patients were monitored in the ICU for 6 to 36 hours and thereafter were transferred to the common ward; the mean total duration of the hospital stay was 5.6 days, which was significantly longer than group A ( $P < 0.05$ ).



**Figure 3.** The disc of an occluder was deployed in the atrial cavity.

**Table 2**  
The minor complication in both groups.

| Minor complication                  | Group A | Group B |
|-------------------------------------|---------|---------|
| Hematoma at access site             | 1       | 0       |
| Trauma to femoral artery            | 0       | 0       |
| Transient arrhythmias               | 15      | 25      |
| Pericardial effusion or hydrothorax | 0       | 5       |
| Pulmonary infection                 | 0       | 5       |
| Surgical incision                   | 0       | 2       |

The total follow-up period ranged from 1 to 2 years. During the follow-up period, there were no thromboembolic events, no aortic erosions, no other major complications, and no progression to moderate–severe pulmonary hypertension in either group. To date, none of the patients in either group have developed complete heart block or/and mitral regurgitation.

#### 4. Discussion

Surgical closure of ASD through a midline incision is associated with excellent results with a mortality rate of nearly zero percent,<sup>[16]</sup> and it was considered the gold standard for ASD closure in the past. With the development of various devices, there are 2 modalities, including transcatheter and intraoperative device closure device implantation, which have gained popularity in overcoming some of the disadvantages of surgical repair. The procedure of transcatheter closure of ASD leaves no scar, results in no postoperative pain, does not require general anesthesia, and involves a very short hospital stay. Intraoperative transthoracic device closure, on the contrary, is a cost-effective, cosmetic, and less-invasive operation appropriate for most secundum ASDs. The results of ASD surgical and device closure have been compared in earlier published studies.<sup>[17–20]</sup> In our review of the literature, we did not find any reports that compared ASD closure with transcatheter and transthoracic devices. The aimed of our work was to compare the safety, feasibility, and total cost of the 2 alternative modalities.

There are many articles focused on transcatheter closure of large secundum ASDs. Romanelli et al<sup>[21]</sup> reported their experience assessing the feasibility of transcatheter closure of very large ASDs. Their successful close rate was 100% in the moderately large ASD group (20–29 mm), 92% in the very large group (30–39 mm) but only 17% in the extremely large group ( $\geq 40$  mm). They also concluded that the presence or absence of an aortic rim of the septum did not influence procedural success.<sup>[21]</sup> Huang et al<sup>[22]</sup> reviewed their experience using the device to close large, secundum-type ASDs in children. Their results confirmed that transcatheter closure was feasible and that complication rates were low. They also showed that a deficient retroaortic rim did not influence successful device implantation rate and that a large device may be needed in such a procedure.<sup>[22]</sup> Lopez et al<sup>[23]</sup> reported on a series of 33 adult patients with a large secundum ASD who underwent attempted transcatheter device closure using the 40 mm occluder. The study concluded that this approach was safe and effective in most patients with a large ASD up to a diameter of 39 mm. They emphasized that the procedure may fail or the device may embolize due to the large ASD size.<sup>[23]</sup> Fraisse and Trivedi<sup>[24]</sup> summarized their finding that patients with large ASD ( $>38$  mm) defects with deficient rims are usually not offered transcatheter closure but are referred for surgical closure in their paper. Guo et al<sup>[25]</sup> compared transcatheter with intraoperative device closure in the treatment of large secundum ASDs ( $\geq 30$  mm). Their result showed a similar success rate, but the intraoperative closure group had more periprocedural complications and longer hospital stays. The long-term follow-up in both group was encouraging.<sup>[25]</sup> Hongxin et al<sup>[26]</sup> reported their short and mid-term results using an intraoperative device closure in large secundum ASDs (20–37 mm, and about half of patients had one short rim). Their experience showed that intraoperative device closure was a safe and feasible technique for closing large ASDs, and this approach had the advantages of cost savings, cosmetic results, and less trauma.<sup>[26]</sup>

Our results confirmed that the 2 approaches provide nearly the same success rate, safety, and efficacy. Group A had fewer complications, no ICU stay, shorter hospital stays, and less trauma

than group B. For patients with moderate ASD, transcatheter closure should be used as the first choice. However, for patients with a larger ASD, especially when combined with 1 short rim, another treatment selection may be prudent. Although the above reports approved of transcatheter closure of large secundum ASDs, most of the large ASD cases were less than 40 mm, which means that the transcatheter closure of large secundum ASDs is still challenging. In our opinion, transthoracic device closure can be used to treat larger defects than transcatheter device closure. In our previous experience and reports by Hongxin et al,<sup>[26]</sup> patients with large secundum ASDs, even more than 40 mm, can be treated using transthoracic device closure; we even have experience using a 48 mm occluder via this approach.<sup>[27]</sup> In our study, 5 transcatheter device closures failed and were then referred to surgery and underwent transthoracic device closure.

Dislodgement or embolization of an occluder is a catastrophic complication of a device closure procedure. Especially when it occurs during the release of the occluder, emergency surgical repair is the only remedy. In our study, 2 patients in both groups experienced such a complication and required emergency surgery. Some reports have also mentioned transcatheter closure of large secundum ASDs and reported good results. However, Fraisse and Trivedi<sup>[24]</sup> noted which ASD dimension was too large for this approach. It remains very challenging to use transcatheter closure devices in patients with large ASDs ( $>38$  mm) and/or defects with deficient rims. In our country, hybrid operating rooms are not very popular, only a few are distributed in large medical centers. Transcatheter closure procedures are usually performed in the cardiac catheterization laboratory. If an occluder dislodgement occurs, the patient must be transferred to the operating room for surgical repair, which may take time and increase the embolization risk. However, it was easy to convert to a regular open-heart procedure if the intraoperative transthoracic device closure failed without additional incisions, which may ensure the safety of the procedure. Thus, in our opinion, if the ASD diameter is greater than 30 mm, choosing the transthoracic closure approach is obviously more sensible.

Although we had an occluder dislodgement failure in group B, there were more cases of large ASDs ( $>30$  mm) in group B than in group A ( $P < 0.05$ ). In group B, especially in patients with a large ASD, we usually sutured the “left atrium - occluder - the right atrium” through the junction of the Waterston’s groove to fix the occluder in position. In the case of the failed case in group B, we did not use this suture technique, which may have led to the occluder dislodgement. Our suture technology significantly expanded the indications for the device closure and accordingly improved the success rate of the device closure of ASD. Although this approach still left approximately 3 to 5-mm incision scars, they were more safe and successful than the transcatheter approach and involved relatively less surgical trauma than a surgical repair. Our approach was more accepted by those special patients with large ASDs in our country. The other merits to this approach including its short delivery sheath were advanced to the ASD directly, so it was easier to guide the sheath across the defect and adjust the device to anchor properly, and the procedure time could be significantly shortened. Second, the surgeon was more easily able to maneuver the rod to check its stability by a push-pull maneuver. Third, the device could be easily recycled through the thread.

We also agreed with that using transesophageal echocardiography to guide device closure treatments for ASD was more accurate than using transthoracic echocardiography. But to manipulate the esophageal probe may lead to esophageal lesions.

Meanwhile, another study also confirmed the safety and efficacy of transthoracic echocardiographic guidance of ASD device closure.<sup>[28]</sup> In our previous papers,<sup>[10,27]</sup> we also reported our mature experience about using transthoracic echocardiography as the only guiding tool. With the help of the experienced sinologist, the different acoustic view by TTE can provide a satisfactory visualization to guide our operation, which may make the transthoracic procedure more simple.

From an economic point of view, another important finding in our study was cheap price of the domestic occluder (about 800 vs 2000 USD for Amplatzer ASD device). Relatively higher medical costs have always limited the popularity of the percutaneous approach in Third World nations. Because of this reason, the cost-effectiveness of intraoperative approach is another reason it should be the treatment of choice to effectively treat secundum ASD patients.

In our opinion, for patients with ASD < 30 mm, both the transthoracic and transcatheter device closure can obtain satisfactory clinical results, but the transcatheter approach has more advantages. For patients with large ASD > 30 mm, although the transcatheter approach can successfully occlude some patients, we still recommended the transthoracic approach. For those patients with peripheral vascular disease or who are unwilling to undergo radiation exposure, in facilities that lack the technical expertise or equipment, and for those ASD patients with an inferior vena cava rim deficiency, the transthoracic approach is the best choice.

As in any retrospective study, there was bias associated with data collection and enrolling patients in the 2 groups, which were not randomized. As a result of the 70 cases in group A and the 85 patients in group B, our experience was limited and longer term follow-up is needed. This study was limited to 1 institution, and other institutions may find different results. The other limitation was that this study was conducted in a low-income country, and there might be different cost-effectiveness results in high-income countries.

In conclusion, our study demonstrated that transthoracic device closure and transcatheter device closure were both safe and efficacious modalities to treat patients with secundum ASD. The transcatheter approach had the advantage of less trauma, no scar, no postoperative pain, and shorter ICU stay time and hospital stay time. Compared with the transcatheter approach, the transthoracic approach had the advantage of cost saving, shorter operative time, and broader indications.

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