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# Early and Mid-Term Follow-up Results of Device Closure of Secundum Atrial Septal Defects Using Transesophageal Echocardiogram Guidance: A Comparison of Percutaneous Versus Peratrial Approaches

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## Abstract

**Background:** Percutaneous closure of secundum atrial septal defects (ASDs) under only transesophageal echocardiogram (TEE) guidance is less invasive and avoids exposure to radiation, but the treatment of choice is controversial. **Methods:** One hundred and forty-four patients with a secundum ASD were included in this study. The patients received percutaneous device closure (PCDC/TEE) (n = 74) or peratrial device closure (PDC/TEE) (n = 70). A double-disk ASD occluder was used in both groups. The treatment was performed under only TEE guidance in both groups. Physical exams, electrocardiography, and echocardiography were performed immediately after device release, and at discharge, 3, 6, 12 months, and at yearly intervals after the procedure. **Results:** In ASD with a maximum diameter less than 20 mm, the successful closure rate was 100% for all PCDC/TEE and PDC/TEE. When the ASD diameter was between 20 mm and 25 mm, the success rate was 84% for PCDC/TEE and 100% for PDC/TEE. The average intracardiac manipulation time was  $19.4 \pm 6.4$  minutes for PCDC/TEE and  $5.7 \pm 7.0$  minutes for PDC/TEE ( $p < 0.001$ ). The average procedure time was  $23.1 \pm 6.8$  minutes for PCDC/TEE and  $51.1 \pm 8.2$  minutes for PDC/TEE ( $p < 0.001$ ). The postoperative hospital stay was  $3 \pm 1$  days for PCDC/TEE and  $5 \pm 1$  days for PDC/TEE ( $p < 0.001$ ). For the mean follow-up of  $520 \pm 256$  days, there no cardiac deaths or significant residual shunts were documented in either group. **Conclusions:** In patients with an ASD less than 25 mm, PCDC/TEE is a safe and effective method of ASD closure. Additionally, PCDC/TEE is less traumatic, provides better cosmetic results, and decreases hospital stays. However, when the ASD diameter is greater than 20 mm and the aortic rim of ASD is less than 3 mm, the peratrial approach may be a better choice.

## Keywords

transesophageal echocardiogram; percutaneous; peratrial; device closure; atrial septal defect; early and mid-term

## Introduction

Atrial septal defect (ASD) is one of the most common congenital heart defects, accounting for 25–30% of all congenital heart defects in adults. Secundum ASD is the most common form of ASD in both adults and children, affecting approximately 10.3 individuals per 10,000 live births [1]. Patients with such defects, if left untreated, may experience various complications, including right ventricular (RV) failure, atrial arrhythmias, and systemic embolization. Despite the high success rate and low complication rates of surgical closure of ASD, transcatheter closure using devices is currently considered the preferred method for treating secundum ASD [2,3].

Since the pioneering work of King and Mills *et al.* in 1974 [4,5], percutaneous closure has proven to be a safe and effective method for treating secundum ASDs [6–8]. Although percutaneous device closure (PCDC) could avoid cardiopulmonary bypass (CPB), it has to be operated with fluoroscopy and angiogram. Both physicians and patients are exposed to X-ray radiation, which may lead to unnecessary physical harm. Additionally, this approach necessitates large and expensive X-ray equipment [9,10]. In recent years, many cardiac centers have begun performing minimally invasive transcatheter closure, especially in some large cardiac centers in China. This technique combines percutaneous closure with open surgery [11,12]. Using this technique, device closure of secundum ASD patients was performed through right mini thoracotomy without CPB and fluoroscopy guidance under transesophageal echocardiography (TEE). However, it is more invasive than PCDC and carries surgical risks such as major bleeding, infection, pleural effusion, pericardial effusion, and hydrothorax

**Table 1. Clinical characteristic data of patient groups.**

Variable	PCDC/TEE (n = 74)	PDC/TEE (n = 70)	<i>p</i> value
Sex (F/M)	18:56	21:49	0.460
Weight (kg)	56.2 ± 18.2*	54.9 ± 16.7	0.660
Median age (years)	33.2 ± 16.8*	31.2 ± 15.6	0.450
Age (years)			0.591
≤10 (n)	13	10	
≥11 (n)	61	60	
PASP (mmHg)			0.898
<40 (n)	59	55	
40–70 (n)	12	11	
>70 (n)	3	4	
Diameter of ASD (mm)			0.626
5 ≤ D < 20 mm (n)	49	49	
20 ≤ D ≤ 25 mm (n)	25	21	
Aortic rim			0.558
<3 mm (n)	22	24	
≥3 mm (n)	52	46	

\**p* > 0.05. PCDC, patients received percutaneous device closure; TEE, transesophageal echocardiogram; PDC, peratrial device closure; F, Female; M, Male; PASP, pulmonary arterial systolic pressure; ASD, atrial septal defect.

[11–13]. Percutaneous closure of a secundum ASD guided by transesophageal echocardiography avoids X-ray exposure and the need for large and expensive X-ray equipment, and avoids thoracic incisions, resulting in less trauma and a more aesthetic outcome.

This study retrospectively compares the safety and efficacy of PCDC/TEE versus PDC/TEE in treating secondary atrial septal defects in a single-center non-randomized controlled setting.

## Patients and Methods

### Patients' Clinical Details

From August 2020 to July 2023, 74 secondary ASD patients underwent PCDC/TEE at our institution. These patients were allocated to the PCDC/TEE group. During the same period, 480 consecutive secondary ASD patients underwent PDC/TEE via a right anterior mini thoracotomy. Among them, 70 matched control patients were determined based on patient age and ASD size. These patients were assigned to the PDC/TEE group.

The inclusion criteria for device closure included: (1) Patient's age greater than 2.5 years old, (2) an isolated secundum ASD (measured by TTE) and anatomically adequate for device therapies, (3) hemodynamically significant left-to-right shunt. Exclusion criteria were: (1) Patient's age less than 2.5 years, (2) primary atrial septal defect, (3) patients with multiple defects, (4) associated congenital heart anomalies requiring surgical correction, (5) severe pulmonary arterial hypertension, atrial-level right-to-left shunt, (6) recent myocardial infarction, (7) unsta-

ble angina and decompensated congestive heart failure patients, as well as those with right and/or left ventricular decompensation, ejection fraction <30%, (8) history of recurrent pulmonary infections, (9) any type of severe infection <1 month before surgery, (10) intracardiac thrombus, (11) unable to obtain informed consent, (12) contraindications to antiplatelet therapy.

Upon admission, routine examinations were performed, including standard electrocardiography (ECG), chest X-ray, and transthoracic echocardiography. Blood tests were conducted to rule out coagulation disorders.

Informed consent regarding PDC/TEE or PCDC/TEE was obtained from the patients and/or their guardians. This study was approved by our hospital's ethics committee and conducted in accordance with the principles of the Helsinki Declaration. Baseline characteristics data for both groups are presented in Table 1.

### Transesophageal Echocardiography (TEE) and Device Selection

A PHILIPS IE33 echocardiography instrument (SZ022B0409, Philips Healthcare (Suzhou) Co., Ltd., Suzhou, China) with a 2.0 to 7.0 MHz frequency conversion probe was used.

The PCDC/TEE group underwent the procedure under sedation and local anesthesia, whereas the PDC/TEE group underwent it under general anesthesia. All patients were placed in a supine position, and TEE was performed at the initiation of the procedure to assess the position and size of the ASD as well as the suitability for device closure.

The device selection was determined according to the maximum diameter of the defect by TEE and the age of the

patients. In the PCDC/TEE group, the closure device was oversized by 6–8 mm compared to the maximum diameter of the defect. However, if the patient was less than 10 years old, the device selected was 4–6 mm larger than the defect. The device selection in PDC/TEE group has been described in the previous reports, the size of the device chosen exceeded the maximum diameter of the defect by 4–6 mm; if the patient was less than 10 years old, the device chosen was 2–4 mm larger than the maximum diameter.

### Procedure

A double-disk septal occluder (Starway Medical Technology, Inc. Beijing, China), based on the Amplatzer septal occluder, was utilized to close the ASD.

The PCDC/TEE procedure was monitored under biatrial view of TEE. After percutaneous puncture of the femoral vein, a 5 F (1 F catheter diameter approximately equal to 0.33 mm) or 6 F right heart catheter was manipulated through the ASD into the left atrium under TEE guidance. Subsequently, a 260 cm exchange guidewire was introduced into the left atrium via catheterization. Depending on the patient's age, an 8–14 F long delivery sheath was passed over the guidewire and advanced into the left atrium. The tip of the delivery sheath was positioned to align as closely as possible with the plane of the atrial septal defect (Fig. 1A). The delivery cable with the occluder is inserted into the delivery sheath. The operator secures the delivery sheath and advances the delivery cable to deploy the left atrial disc. By gently pulling on the left atrial disc with the delivery cable, the atrial septum is engaged (Fig. 1B), which can be sensed by the operator through the delivery cable and observed via TEE imaging. By applying gentle tension to the delivery sheath while keeping the delivery cable fixed, the sheath can be withdrawn, and the right atrial disc can be deployed (Fig. 1C,D). Proper manipulation of the fully deployed occluder is done using the delivery cable to ensure secure positioning. Subsequent TEE examination is performed to assess for any residual hemodynamic shunting, potential obstruction of venous return, or damage to the atrioventricular valve. Once the optimal position is achieved, the occluder is released.

The PDC/TEE delivery system only included a short plastic sheath with a sidearm and a delivery cable (Fig. 2). Details of the procedure have been described in previous reports. In brief, following induction of general anesthesia, a 2.5–3 cm incision is made at the right sternal border in the right anterior third or fourth intercostal space. A delivery sheath is inserted into the right atrium and secured with purse-string sutures. Under guidance of TEE, the delivery sheath is advanced through the ASD into the left atrium, and the delivery cable with the occluder is pushed into the sheath and deployed to expand the left atrial disc within the left atrium, ensuring the left atrial disc remains parallel to the atrial septum (Fig. 1E). The delivery cable is then se-

cured, and the delivery sheath is withdrawn to position the waist and the right atrial discs, followed by withdrawal of the delivery sheath and cable after confirming optimal positioning and stability of the occluder via TEE (Fig. 1F–H). Sutures are used to close the puncture site on the right atrium. This small thoracotomy incision is closed without placement of a drainage tube.

After release, TEE was performed for further demonstration of the device position, shape and residual shunts in two groups. After release, TEE examination is performed on both groups of patients to further confirm the position, shape, and residual shunting of the device.

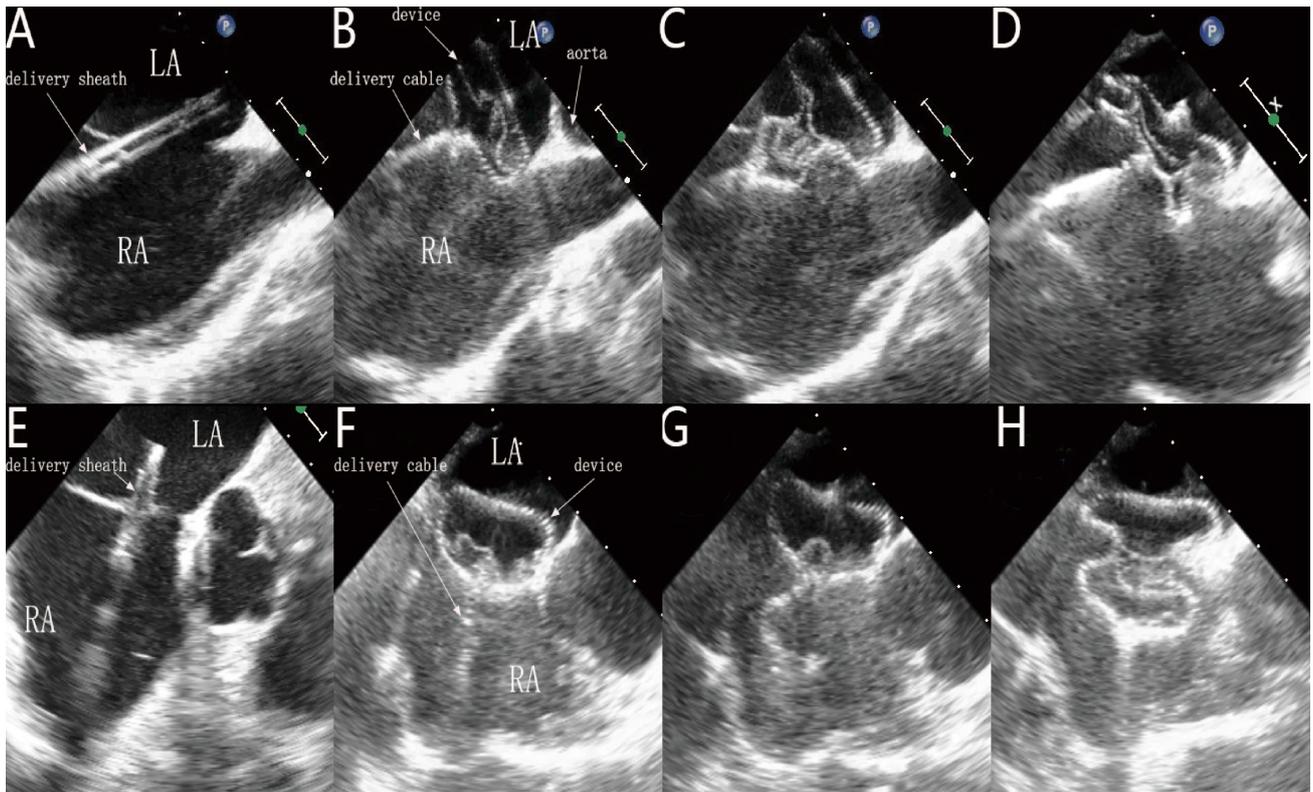
### Patient Follow-Up

During the procedure, a suitable antibiotic dose was given, followed by two additional doses given at 8-hour intervals afterwards. Aspirin (3–4 mg/kg/day) (XB01AC, Bayer Healthcare Co., Ltd., Beijing, China) was consistently taken for a period of 6 months.

Twenty-four hours after the procedure, an electrocardiogram and a TTE were performed. Follow-up evaluations were done 3 months, 6 months, 12 months and yearly after discharge. All visits involved routine physical examinations, electrocardiograms, and TTEs. The parameters that were evaluated during the follow-up included maximal defect diameter measured by TTE, device size, intracardiac manipulation time, procedure time, postoperative hospital stay, and residual shunting. Routine physical examination, TTE and electrocardiograms were used to identify potential complications: major bleeding, infection, pleural effusion, pericardial effusion, arrhythmias, the complete closure rate after device release, cardiac deaths and other potential related complications. Furthermore, when complications arose, the management and outcomes of these complications were also included in the follow-up. Attention was also given to residual shunting, arrhythmias, and valve dysfunction. Residual shunting was categorized as trivial (jet width  $\leq 1$  mm), small (jet width  $\leq 2$  mm), moderate (jet width 2–4 mm), or large (jet width  $\geq 4$  mm) [14].

### Statistical Analysis

Analysis was conducted using SPSS 26.0 (SPSS Inc., Chicago, IL, USA). Results were reported as mean  $\pm$  standard deviation. Intracardiac operation time was defined as the duration from the introduction of the delivery sheath into the right atrium to the withdrawal of the delivery sheath and guidewire from the right atrium. Intracardiac operation time, procedure time, defect and device size were compared between the 2 groups with the independent samples *t* test. Statistical comparisons of proportions were analyzed using a chi-square test. A probability value of less than 0.05 was defined as statistically significant.



**Fig. 1. TEE images of the procedure of PDC/TEE and PCDC/TEE.** The procedure of PCDC/TEE(A–D). The procedure of PDC/TEE(E–H). A: the tip of the delivery sheath was adjusted to be as perpendicular as possible to the plane of the atrial septal defects; B: the left atrial disc was deployed; C–D: the sheath was withdrawn and the right atrial disc was deployed. E: the sheath was advanced through the ASD into the left atrium and positioned parallel to the atrial septum; F–H: the right disc was deployed and the sheath was withdrawn. LA = left atrium, RA = right atrium.

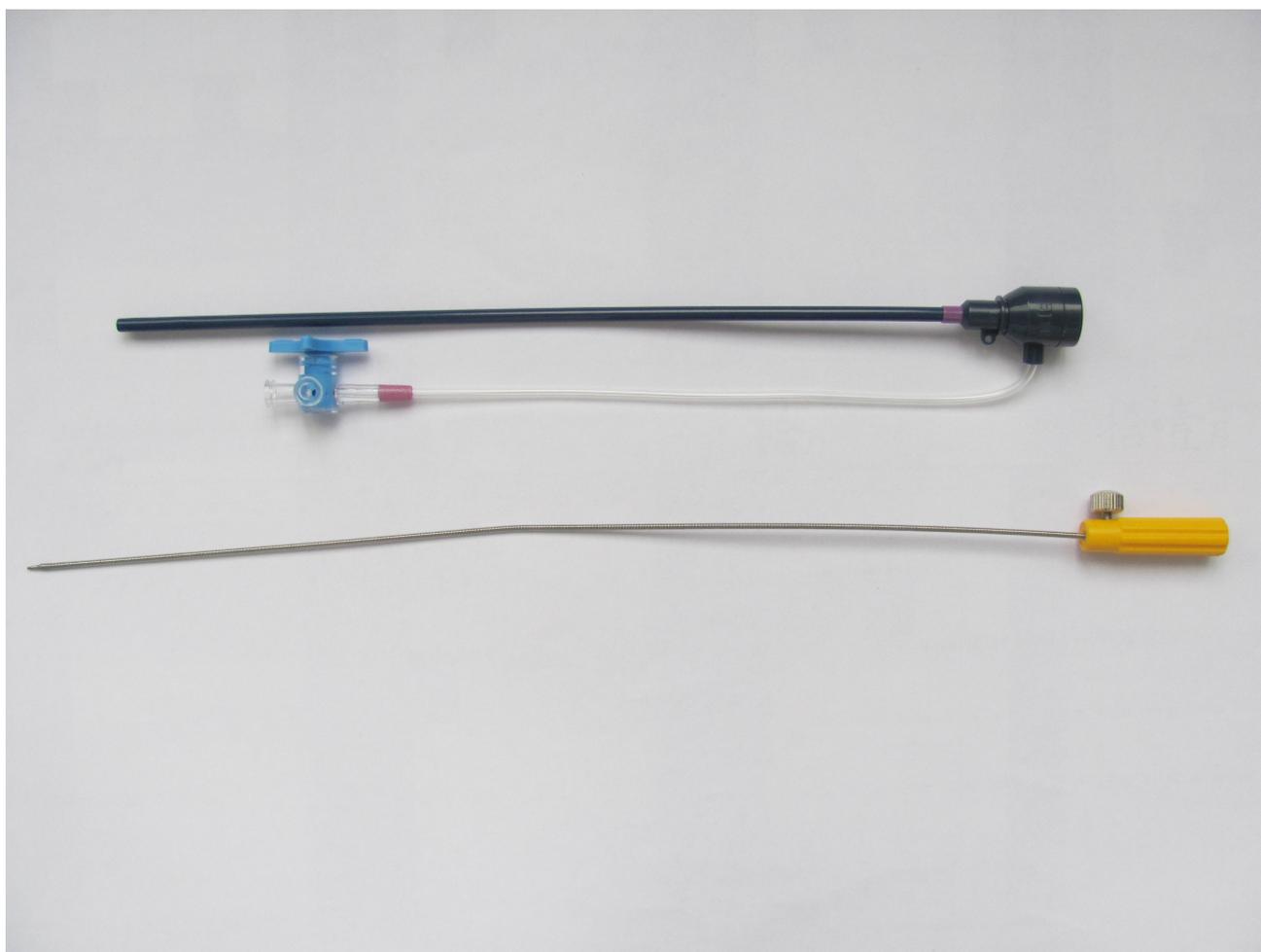
## Results

### Intraoperative Results

The procedural defects measured by TEE were  $16.7 \pm 4.7$  mm in the PCDC/TEE group and  $16.7 \pm 4.8$  mm in the PDC/TEE group ( $p = 0.880$ ), and the implanted occluders were  $22.6 \pm 5.2$  mm in PCDC/TEE group and  $21.2 \pm 5.7$  mm in PDC/TEE group ( $p = 0.131$ ). The intracardiac manipulation time was  $19.4 \pm 6.4$  minutes for PCDC/TEE and  $5.7 \pm 7.0$  minutes for PDC/TEE ( $p < 0.001$ ); the procedure time was  $23.1 \pm 6.8$  minutes for PCDC/TEE and  $51.1 \pm 8.2$  minutes for PDC/TEE ( $p < 0.001$ ). When the maximum diameter of ASD was  $<20$  mm, the success rate of both groups was 100%. When the ASD diameter was between 20 mm and 25 mm, the success rate was 84% in the PCDC/TEE group and 100% in the PDC/TEE group. 4 patients experienced recurrence after PCDC/TEE but were treated successfully with PDC/TEE. The common reasons for failure were that the aorta rim of ASD was deficient for the left disk placing (Table 2).

### Postoperative and Follow-Up Results

After the procedure, the TEE found residual shunts in 10/70 (14%) patients in the PDC/TEE group and 13/70 (18%) patients in the PCDC/TEE group ( $p = 0.443$ ); the postoperative hospital stay was  $5 \pm 1$  days for PDC/TEE and  $3 \pm 1$  days for PCDC/TEE ( $p < 0.001$ ). In the PDC/TEE group requiring diuretics, 4 patients were recorded to have pleural effusion, while no pleural effusion was observed in the PCDC/TEE group ( $p = 0.128$ ). Among untreated patients in the PDC/TEE group, 2 were recorded to have pericardial effusion, whereas no pericardial effusion was documented in the PCDC/TEE group. 7 patients in the PDC/TEE group were documented to have transient arrhythmias during the perioperative period, with no permanent arrhythmias observed. Among them, 2 patients were documented to have first-degree atrioventricular block (AVB) and frequent ventricular premature beats, respectively. One patient was documented to have atrial flutter, and two patients were documented to have atrial fibrillation (AF). All of these were transient and did not require treatment. In the PCDC/TEE group, six patients were documented to have arrhythmias during the perioperative period, including two with atrial fibrillation, one with atrial tachy-



**Fig. 2. Direct delivery system.** The PDC/TEE delivery system included a short plastic sheath with a sidearm and a delivery cable.

cardia, one with atrial flutter, and two with frequent ventricular premature beats ( $p = 0.777$ ). Most were transient and did not require treatment, except for one case of persistent atrial fibrillation requiring amiodarone treatment. Both groups of patients had no other complications (Table 2).

All patients in both groups underwent TEE and ECG follow-up ranging from 86 to 740 days (median 726 days). No other complications were observed during this period.

In follow-up patients among the patients followed up, the complete closure rate was 82% at immediately after device release, 90% at discharge, 96% at the 3-month, 98% at the 6-month, 100% at 12-month, and 100% at the 2-year in the PCDC/TEE group and the complete closure rate was 86% at immediately after device release, 94% at discharge, 97% at the 3-month, 98% at the 6-month, 100% at 12-month and at the 2-year in the PCDC/TEE group (Table 3).

## Discussion

Our current research indicates that the PCDC/TEE method is a safe and effective treatment for ASD [15].

PCDC requires fluoroscopy and its associated side effects. Previous reports have found an association between ionizing radiation and an increased incidence of malignant tumors. This effect is increased in children [16]. In PCDC, children often need to be exposed to radiation multiple times. And cath lab staff, including interventional cardiologists, is consistently exposed to ionizing radiation, which poses inherent health risks [17]. Increased use of PCDC/TEE can eliminate exposure to ionizing radiation, reduce the use of hospital resources, and potentially save money. Additionally, it is safer, as the procedure is performed in a standard operating room, allowing for immediate conversion to surgical closure if device closure fails.

The feasibility of TEE-guided ASD occlusion has also been confirmed [18], transesophageal echocardiography has several advantages. TEE can display the position, size, and surrounding rims of the ASD, which fluoroscopy cannot. Additionally, TEE can be used to observe hemodynamic shunting before and after closure. However, because TEE provides a narrow field of view, it cannot display the left upper pulmonary vein and atrial septum in a single view.

**Table 2. The immediate, short-term and middle-term clinical outcomes of successful patients in the two groups.**

Variable	PCDC/TEE Group (n = 70)	PDC/TEE Group (n = 70)	p value
Median diameter of ASD (mm)	16.7 ± 4.7	16.7 ± 4.8	0.880
Device size (mm)	22.6 ± 5.2	21.2 ± 5.7	0.131
D value	5.9 ± 1.5	4.4 ± 1.7	<0.001
ICMT (min)	19.4 ± 6.4	5.7 ± 7.0	<0.001
Procedure time(min)	23.1 ± 6.8	51.1 ± 8.2	<0.001
Postoperative hospital stay (days)	3 ± 1	5 ± 1	<0.001
Residual shunting, n (%)	13 (18)	10 (14)	0.493
Trivial, n (%)	6 (7)	4 (6)	
Small, n (%)	5 (7)	3 (4)	
Moderate, n (%)	2 (3)	1 (1)	
Large, n (%)	0 (0)	0 (0)	
Major bleeding, n (%)	0 (0)	0 (0)	–
Infection, n (%)	0 (0)	0 (0)	–
Pleural effusion, n (%)	0 (0)	4 (6)	0.128
Arrhythmias, n (%)	6 (9)	7 (10)	0.777
Pericardial effusion, n (%)	0 (0)	2 (3)	0.496
Cardiac deaths, n (%)	0 (0)	0 (0)	–

D value: difference between the device size and the maximum diameter of ASD. ICMT, intracardiac manipulation time; PCDC, percutaneous device closure; TEE, transesophageal echocardiogram; PDC, peratrial device closure.

**Table 3. The shunt closure rates between PCDC/TEE group and PDC/TEE group.**

Variable	PCDC/TEE Group (n)	PDC/TEE Group (n)	p value
RS at immediately after device release (%)	13/70 (18)	10/70 (14)	0.493
RS at discharge (%)	7/70 (10)	4/70 (6)	0.345
RS at 3-month (%)	3/70 (4)	2/70 (3)	1.000
RS at 6-month (%)	1/63 (2)	1/64 (2)	0.484
RS at 12-month (%)	0/50 (0)	0/54 (0)	–

RS, residual shunting.

In our study, the maximum diameter closed using PCDC/TEE was 25 mm. Treating large ASDs (>25 mm) is challenging, limiting the application of PCDC/TEE. From the analysis above, it can be seen that the defect diameter and aortic margin are two important factors for surgical success. In patients undergoing PCDC/TEE, the overall success rate was 94.6%; it was 100% when the defect diameter was less than 20 mm and 84% when the defect size was between 20 mm and 25 mm. The 4 PCDC/TEE failure cases had ASD diameters of 20 mm, 23 mm, 24 mm, and 25 mm, respectively, and aortic margins of 0 mm, 1 mm, 2.5 mm, and 2.8 mm, respectively. Common reasons for failure were insufficient aortic margins, and difficulty in placing the left atrial disc during deployment. We believe that when the ASD diameter is less than 20 mm, the aortic margin does not determine success. However, when the ASD diameter is 20–25 mm, a longer aortic margin is needed. In the current study, if the aortic margin was greater than 3 mm, the closure rate was 100%. Difficulty in positioning the delivery sheath tip perpendicular to the plane of a larger ASD may result in less secure placement of the left atrial disc

(Fig. 1A). However, all 4 patients who experienced failure with PCDC/TEE subsequently achieved successful closure with PDC/TEE.

The safety and effectiveness of utilizing PDC/TEE have been demonstrated [12,13,19,20]. Compared to PCDC and PCDC/TEE, the advantages of PDC/TEE include: (1) ease of handling instruments, (2) applicability to large diameter or complex ASDs that cannot be closed percutaneously, (3) instrument stability, (4) PDC/TEE is not limited to infants (the percutaneous approach is not applicable in infants whose femoral arteries cannot accommodate sheaths large enough to deliver larger closure devices). Specifically, because the delivery cable is perpendicular to the atrial septum after device deployment (Fig. 1H), surgeons can better assess the stability of the device through push-pull maneuvers.

Although the intracardiac time was longer for PDC/TEE than for the PCDC/TEE group, the operation time was shorter for the PDC/TEE group. All patients undergoing PDC/TEE required tracheal intubation and general anesthesia with ventilation, while patients undergoing

PCDC/TEE did not require this. Compared to the PDC/TEE group, the hospital stay for the PCDC/TEE group was significantly shorter (Table 2).

The mortality rate for both groups was zero, consistent with previous research findings indicating a low mortality rate for device closure of ASDs [21]. Compared to PCDC/TEE, PDC/TEE was more invasive and associated with more surgery-related complications, such as pleural effusion (6%), pericardial effusion (3%), wound infections, and bleeding. To date, arrhythmias have only been reported early post-implantation, are mostly transient, and do not require treatment [3,22–24]. The incidence of thrombus formation during the device closure process is low, consistent with previous relevant research findings [3,12]. During the follow-up period, we did not observe thrombus formation or systemic embolic events in our patient group. Aside from pleural and pericardial effusions, and arrhythmias, no other significant complications were observed during follow-up, which also demonstrates the safety of PCDC/TEE. This may also relate to the small sample size and short follow-up duration of our study. Therefore, we will continue to regularly follow our patient cohort and are prepared to report any related complications.

Additionally, residual shunting is a common complication of ASD closure devices [3]. It is generally considered that mild or tiny residual shunts detected immediately after device release can be ignored, as they usually resolve during the follow-up process. In our study, we observed that the shunt closure rate improved over time.

### Study Limitations

The first limitation of this study is that it is a single-center, non-randomized study comparing PCDC/TEE and PDC/TEE. Conducting randomized studies for ASD closure is challenging due to numerous logistical and ethical reasons, leading to potential biases in comparing these two surgical approaches. The second limitation is the small sample size of the study, comprising only 70 patients, which limits the conclusions regarding complication rates and closure success rates. Additionally, these patients were only followed up for 2 years, making the long-term prognosis for any group of patients unclear. Despite these limitations, the current study highlights the safety and efficacy of both surgical approaches and lays the groundwork for future randomized trials in larger patient populations.

### Conclusions

For the patients whose diameter of secundum ASD is less than 25 mm, PCDC/TEE is safe and efficacious. However, when the ASD diameter was greater than 20 mm and the aortic rim was less than 3 mm, the peratrial approach may provide an increased rate of closure.

### Abbreviations

TEE, transesophageal echocardiogram; PCDC/TEE, Percutaneous device closure only under transesophageal echocardiograph guidance; PDC, Peratrial device closure; ASDs, atrial septal defects; TTE, transthoracic echocardiography.

### Availability of Data and Materials

The data presented in this study are available on request from the corresponding author.

### Author Contributions

(I) Conception and design: JinS, JC, MZ, TZ. (II) Administrative support: TZ. (III) Provision of study materials or patients: JinS, JC, TZ, ZW. (IV) Collection and assembly of data: JinS, JC, JS, XM, LW. (V) Data analysis and interpretation: JinS, JC, ZW, TZ. (VI) Manuscript writing: All authors. (VII) Final approval of manuscript: All authors. All authors contributed to editorial changes in the manuscript. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

### Ethics Approval and Consent to Participate

The study was approved by Shandong Provincial Hospital Ethics Committee for Medical Technology and Clinical Applications (JSYY: NO.2024-001). The patient has signed the informed consent.

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Not Applicable.

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## Conflict of Interest

The authors declares no conflict of interest. TZ serves as editorial board member of this journal. TZ declares that he was not involved in the processing of this article and has no access to information regarding its processing.

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