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Echocardiography-guided percutaneous closure of oval-shaped secundum atrial septal defects

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Abstract

Background An atrial septal defect (ASD) is considered oval-shaped when its shortest diameter is less than 75% of the longest diameter. Research on percutaneous closure of oval-shaped ASDs is limited, with no known reports of non-fluoroscopic closure for this population.

Objective To assess the effectiveness of non-fluoroscopic percutaneous closure for oval-shaped ASDs.

Methods This single-center retrospective study evaluates patients undergoing non-fluoroscopic percutaneous closure of oval-shaped ASDs, defined by the shortest to longest diameter ratio < 0.75, a circular index of 1.33, or ultrasound visualization of an oval shape. Device size was chosen to be 0–4 mm larger than the defect's longest diameter, based on transthoracic and transesophageal ultrasound measurements.

Results We identified 78 patients (33.3% children, 20.5% males) with a mean age of 27.4 ± 16.3 years and a mean weight of 46.8 ± 19.8 kg. The mean longest diameter and mean shortest diameter of ASDs were 23.3 ± 6.8 mm and 15.8 ± 5 mm, respectively. The mean ratio of the shortest to longest diameter was 0.7 ± 0.1. Percutaneous closure was not attempted in 7/78 (9%) patients. Three out of 71 (4.2%) procedures were fluoroscopy-guided upfront due to technical difficulties, and 5/71 (7%) were converted to fluoroscopy-guided closure. Overall procedural success rate was 98.6% (70/71) including 63/71 (88.7%) performed with zero fluoroscopy. Mean device size was 26.5 ± 7.1 mm. Mean procedural time was 45.3 ± 22.6 min. Eleven intraprocedural complications occurred including 6 arrhythmias, 3 pericardial effusions, and 2 device dislodgements.

Conclusion Transcatheter closure of oval-shaped ASD is safe and feasible. Echocardiography is adequate for adequate operative guidance.

Keywords Atrial septal defect, Oval-shaped, Percutaneous, Non-fluoroscopy

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Introduction

Atrial septal defect (ASD) is one of the most prevalent congenital heart disorders that affects one in every 1000 live newborns. Percutaneous closure is one of the chosen methods for ASD closure, specifically secundum ASD, as it poses a lower risk of complications and mortality compared to surgical closure [1]. However, an accurate size assessment of the defect and a thorough understanding of the defect's morphology are critical for successful device closure of ASD. ASD provides a variety of shapes including circular, oval, crescent, and complex morphology [2, 3]. The size of the device should be considered in accordance with the different diameters of the defect when applying device closure for non-circular ASD. The adversity in the device closure of an oval-shaped ASD is that the circular device could be much larger than the shortest diameter of the ASD, thus leading to deformity in the remaining rims [4, 5]. To provide more reliable guidance for percutaneous closure of ASDs with an oval morphology, we present our single-center experience of echocardiography-guided closure of those defects.

Methods

Study design and population

We conducted a retrospective clinical data review of pediatric and adult patients with oval-shaped secundum ASDs from July 2018 until May 2023 at our institution. Our local ethical committee approved this research protocol.

Preprocedural preparation

For the decision of percutaneous closure, a transthoracic echocardiogram (TTE) was first performed. If the defect was not visualized due to a poor ultrasound window, a transesophageal echocardiogram (TEE) was done. The eligibility criteria for percutaneous closure were oval-shaped secundum ASD with evidence of right ventricular overload, no significant and irreversible pulmonary arterial hypertension, no significant arrhythmia, no serious comorbidities, and the operator presumption of appropriate rims for device implantation. We defined an ASD as oval-shaped when the ratio of the shortest diameter to the longest diameter is below 0.75, or circular index 1.33 [2, 3], or "en-face" view visualization of oval shape on TEE [2, 3, 5]. Most interventions were performed using the zero-fluoroscopy echocardiography-guided only method.

Device selection, procedural technique, and evaluation

For device size selection, the longest two-dimensional diameter measured on TTE and TEE at end-systole was used. We generally select a device 0–4 mm larger than the defect's longest diameter, adjusting based on septal rim flexibility. If implantation fails or a larger device is needed, we increase the size by 20–25%. For oval-shaped ASDs, we estimate device size using $\sqrt{axb}$. rather than a specific formula.

For ASD closure using echocardiography guidance alone, without fluoroscopy, the procedure commences with a pre-procedural echocardiographic assessment to evaluate the size, shape, rims, and estimated device size. We typically puncture the right femoral vein and insert a 4–6 F sheath, depending on the patient's body weight. Heparin is administered at a dose of 50–100 IU/kg BW. During the procedure, echocardiography guides each step, starting with the 4–6 F multipurpose end hole (MPA2) catheter passing through the inferior vena cava into the right atrium, crossing the septum into the left atrium, and then into the left upper pulmonary vein (LUPV). The echocardiography precisely displays the catheter's position. If the intraprocedural view is suboptimal, the procedure is temporarily paused until an optimal view is regained [6–8].

Using echocardiography guidance, the Amplatzer exchange wire is advanced into the MPA2 catheter towards the LUPV. The MPA2 catheter is then withdrawn, and the delivery sheath is introduced under echocardiographic guidance to the LUPV. The device is subsequently advanced and deployed in the interatrial septum region. Upon completion, echocardiography re-evaluates the device's position and performs a wiggle test. If the device is stable and the operator is satisfied with the echocardiography assessment, the device is released. The residual shunt and any complications after device implantation were evaluated by follow-up TTE on the following day and 6 months after the procedures [6–8].

Statistical analysis

Categorical data were expressed as counts and percentages while continuous variables were expressed as means ± standard deviations. The statistical analyses were performed using SPSS 26.0. To compare the results of both groups, the T-test was used for numerical data while Fischer's exact test was used for categorical data due to the small sample size. P value < 0.05 was considered statistically significant.

Results

Patients

We identified 78 patients who met the inclusion criteria from our database. Of the enrolled oval-shaped patients, 52 patients were adults, and 26 patients were children (see Table 1). Seven patients from the study were excluded from attempting closure at the outset. These exclusions were due to either the unsuitability of device closure or severe pulmonary hypertension, as confirmed

by hemodynamic assessment in patients with suspicion of pulmonary hypertension based on history taking, physical examination, chest X-ray, and echocardiography, which contraindicates ASD closure (see Fig. 1). Based on the measurement of echocardiographic images, the mean longest diameter (a) and shortest diameter (b) were 23.3 ± 6.8 mm and 15.8 ± 5 mm, respectively. The mean ratio of the shortest diameter to the longest diameter was 0.7 ± 0.1. Other baseline characteristics of the patients are detailed in Table 1.

Procedure

Most of our procedures were performed by zero-fluoroscopy technique that was conducted in 41 adults and 22 children. All procedures employed TEE, adhering to the standard protocol at our center. However, two patients were guided exclusively by TTE due to the unavailability of a small-sized TEE probe for patients weighing less than 10 kg at the time of the procedure. Five procedures, all involving adult patients, were subsequently converted to the fluoroscopy technique. Only three patients (two adults and one child) underwent fluoroscopy guidance from the outset due to technical difficulties. The average device size was 26.5 ± 7.1 mm, with significantly larger device size in adults (28.3 ± 7 mm) than in children (22.5 ± 5.7 mm). The device types used were Cera™ ASD Occluder (Lifetech, China), MemoPart™ ASD Occluder (Lepu, China), and AMPLATZER™ Septal Occluder (Abbott, USA), see Table 2 for more details. The mean procedural time was 45.26 ± 22.57 min. There was a good correlation between the maximal defect sizing and the device size selection ($r = 0.823$, $p < 0.001$). According to our linear regression analysis, the device size selection for oval-shaped secundum ASD is [Device size = 2.476 + (1.055 x ASD longest diameter)]; $r^2 = 0.820$ (see Fig. 2b).

Outcome

During the procedures, there were several complications such as arrhythmias, pericardial effusions, dislodgements, and residual shunts. All arrhythmias were deemed benign and resolved spontaneously, likely triggered by wire/catheter maneuvers during the procedure, except for one patient who required atropine and cardiopulmonary resuscitation (CPR) for approximately one minute. Mild effusions were observed, attributable to certain larger defect size, post-procedure. They were also given diuretics post-procedure. None of the effusions necessitated pericardiocentesis. Device dislodgement occurred in two patients: one underwent a successful re-attempt at ASD closure, while the other required device retrieval with a subsequent surgical referral. The intraprocedural success rate was 70 out of 71 cases (98.6%). On evaluation, sixty-three patients (88.7%) became asymptomatic while some patients experienced dyspnea, hematoma, edema, and back pain (see Table 2).

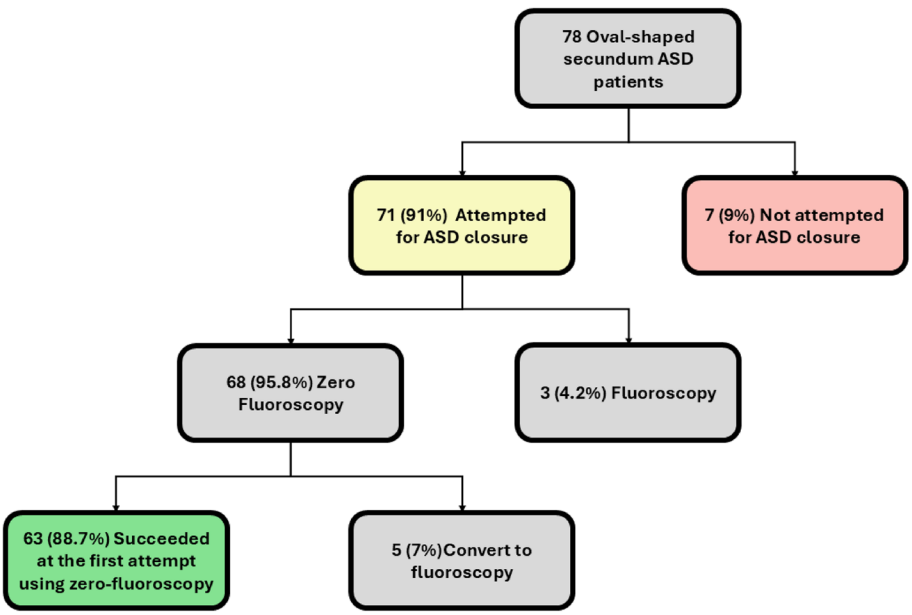

Fig. 1 Flowchart of the patients included in our study. A total of 63 patients (88.7%) successfully underwent closure of oval-shaped secundum ASD using a fully zero-fluoroscopy technique

Table 1 Baseline demographic and clinical characteristics

Demographics	Overall (*n* = 78)	Adults (*n* = 52)	Children (*n* = 26)	*P* value
No. of patients, n (%)	78 (100)	52 (66.7)	26 (33.3)	
Male gender, n (%)	16 (20.5)	8 (10.3)	8 (10.3)	0.141
Weight (kg), mean ± SD	46.8 ± 19.8	56.4 ± 13.7	30.5 ± 18	**< 0.001**
Age (years), mean ± SD	27.4 ± 16.3	36.1 ± 12.3	9.6 ± 5.1	**< 0.001**
Symptoms at first onset				
Asymptomatic, n (%)	17 (21.8)	9 (11.5)	8 (10.3)	
Murmur, n (%)	2 (2.6)	--	2 (2.6)	
Failure to thrive, n (%)	5 (6.4)	--	5 (6.4)	
Recurrent respiratory tract infection, n (%)	3 (3.8)	--	3 (3.8)	
Shortness of breath, n (%)	38 (48.7)	33 (42.3)	5 (6.4)	
Palpitation, n (%)	9 (11.5)	7 (9)	2 (2.6)	
Chest discomfort, n (%)	7 (9)	5 (6.4)	2 (2.6)	
Laboratory examination				
Hemoglobin, mean ± SD	13.1 ± 1.8	13.2 ± 1.8	13 ± 1.8	0.560
Hematocrit, mean ± SD	39.2 ± 4.8	39.5 ± 4.7	38.7 ± 4.9	0.455
Leukocyte, mean ± SD	8099.2 ± 2290.2	7562.3 ± 2119.1	9173.1 ± 2279.2	**0.003**
Thrombocyte, mean ± SD	294423.1 ± 78899.8	283903.8 ± 67853.1	315461.5 ± 95345.8	0.140
ASD diameter				
Shortest (mm), mean ± SD	15.8 ± 5	17.1 ± 5.4	13.2 ± 2.7	**< 0.001**
Longest (mm), mean ± SD	23.3 ± 6.8	24.8 ± 7.1	20.2 ± 4.9	**0.004**
Circular index, mean ± SD	1.5 ± 0.3	1.5 ± 0.3	1.5 ± 0.2	0.476
Shortest to longest diameter ratio, mean ± SD	0.7 ± 0.1	0.7 ± 0.1	0.7 ± 0.1	0.242
Inadequate rims, n (%)	42 (53.8)	31 (39.7)	11 (14.1)	0.159
Aortic rim, n (%)	35 (44.9)	28 (35.9)	7 (9)	
Posterior rim, n (%)	14 (17.9)	10 (12.8)	4 (5.1)	
Mitral rim, n (%)	2 (2.6)	1 (1.3)	1 (1.3)	
Inferior vena cava rim, n (%)	10 (12.8)	6 (7.7)	4 (5.1)	
Superior vena cava rim, n (%)	1 (1.3)	--	1 (1.3)	

Bold values are significant *p*-values

Discussion

The importance of defining oval-shaped secundum atrial septal defect

Since transcatheter device closure is less intrusive and has a success rate that is comparable to surgical repair, it is frequently utilized for secundum ASDs [9, 10]. Despite this, some secundum ASDs have unfavorable anatomy and are not all appropriate for device closure [11–14]. Previously, the defect diameter/septal length ratio served as the basis for the indication for percutaneous treatment [15, 16]. However, as institutional expertise has grown across the globe, describing the morphology of the defect is now thought to be crucial for successful transcatheter closure. One morphological variant of ASD that may require device-sizing adjustment is the oval-shaped ASD. Therefore, the closure process may be more difficult [2, 3, 5].

Earlier studies suggested a different method for identifying oval-shaped ASD. When the shortest diameter is less than 75% of the longest diameter, an ASD is described by Song et al. [2] as oval-shaped. Seo et al. [5] employed a circular index with a maximum/minimum diameter threshold of 1.5. However, to identify the oval-shaped ASD in their more recent work, Hascoet et al. [3] used a visual examination of the 3D 'en-face' image. Our study used the most recent visualization methodology to identify oval-shaped ASD. The mean longest diameter and the mean shortest diameter were, respectively, 23.3 ± 6.8 mm and 15.8 ± 5 mm, whereas the quantification result supported the positive results from the visualization approach. The average difference between the longest and shortest diameters, expressed as a circular index, was 1.52 ± 0.30.

When the expected diameter of the ASD was the smallest, a device would be difficult to deploy in an oval-shaped ASD and might get knocked into one of the atrial chambers. Due to persistent stresses, the device tends to shift toward the aortic-mitral plane (direction of blood

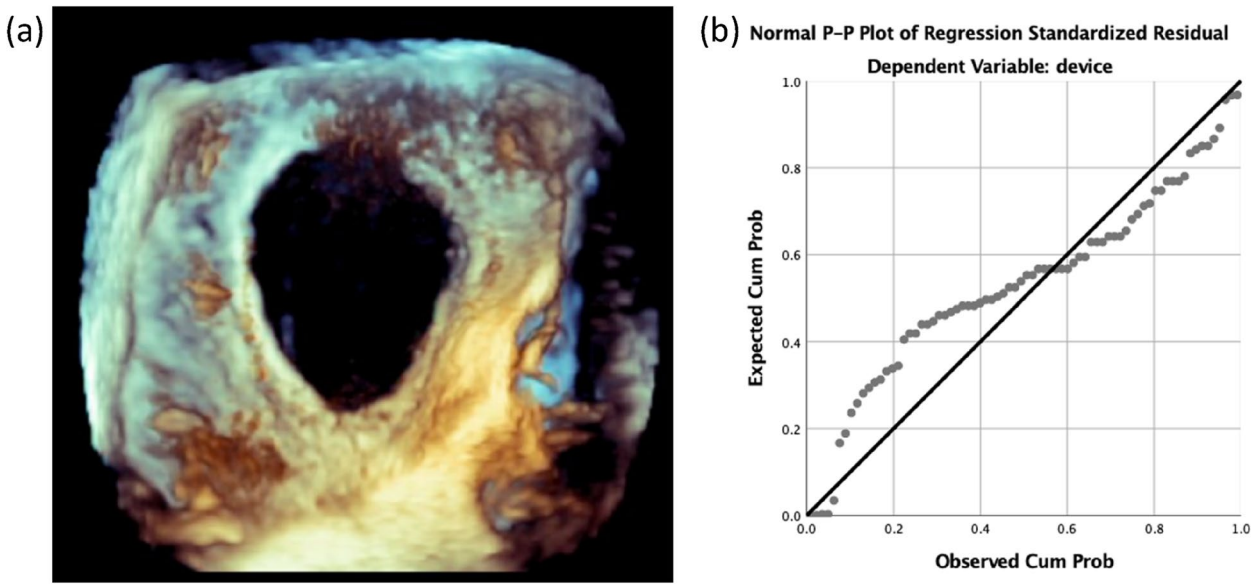

Fig. 2 Oval-shaped secundum atrial septal defect (ASD). **a** "en-face" view visualization of oval shape secundum ASD on TEE. **b** Positive correlation between the maximal defect sizing and the device size selection ($r = 0.823$, $p < 0.001$). By our linear regression analysis, the device size selection of oval-shaped secundum ASD is [Device size = 2.476 + (1.055 x ASD longest diameter)]; $r^2 = 0.820$

flow): the gravity, the device's weight, movement of the interatrial septum, and drag and friction drag, which are influenced by the thickness of the device (friction drag is directly proportional to the area of the item in the fluid and the square of the blood velocity) [2, 3, 14].

Larger devices, on the other hand, are more likely to develop mushroom deformities, encroach on cardiac structures, and cause potentially life-threatening problems including cardiac erosions. Due to these dangers, it was advised against using devices with a diameter greater than 1.5 ASD to prevent oversizing. Care must be taken not to obstruct the valve or venous return when the device is oversized. Device size is receiving more attention as trans-catheter device closure expertise grows rather than just success [14].

Zero-fluoroscopy method in oval-shaped secundum atrial septal defect closure

For a more precise size and form characterization of the ASD, three-dimensional imaging of the atrial septum and ASD is essential. The operator can see the number, size, and rim size with multiplanar reconstruction and an en-face view by using TEE as preprocedural and intraprocedural imaging in the closure of an ASD device (see Fig. 2a). The operator may be able to inspect both the position of the device and the location of the catheter during the intervention [3, 6, 17, 18].

All ASD closure at our institution would be done first with zero-fluoroscopy methods [6], and if during the procedure, the operator deemed that the zero-fluoroscopy method is not clear and could be harmful to the patient, the approach would be changed to the fluoroscopy guidance. Our study demonstrated that zero-fluoroscopy oval-shaped secundum ASD closure could produce satisfactory results that are on par with those obtained using the accepted fluoroscopy technique.

Fluoroscopy may have some long-term, delayed side effects, especially in children and newborns. The reports of skin injuries, which can be unpleasant and incapacitating and include redness, necrosis, and ulceration, have increased over time. The risk of acquiring neoplasms, radiation-induced cataracts, and hair loss has also increased [18–21]. Our study demonstrated that the zero-fluoroscopy method is sufficient for successful defect closure even though Song et al.'s [2] computed tomography technology provides low-dose radiation in defining oval ASD.

Challenges and techniques in oval-shaped secundum ASD closure

Various technical adjustments were implemented to address complex anatomical challenges. These modifications involved altering the deployment maneuvers, such as adjusting the orientation of the left atrial disk of the device within the left atrium or changing the deployment sequence by initially positioning the central core of the device slightly within the left atrium before securing it to the septum. In cases where standard methods were unsuccessful, alternative approaches included positioning the left disk within the left or right upper lobe pulmonary

Table 2 Procedural details in patients undergoing ASD closure

Procedural variable	Overall (*n* = 71)	Adults (*n* = 48)	Children (*n* = 23)	*P* value
Imaging modality				
Zero-fluoroscopy, n (%)	63 (88.7)	41 (57.7)	22 (31)	
Convert to fluoroscopy, n (%)	5 (7)	5 (7)	--	
Fluoroscopy, n (%)	3 (4.2)	2 (2.8)	1 (1.4)	
Implanted device size (mm), mean ± SD	26.5 ± 7.1	28.3 ± 7	22.5 ± 5.7	**0.001**
Estimated device size $\sqrt{axb}$(mm), mean ± SD	18.6 ± 4.8	19.7 ± 5.1	16.4 ± 3.5	**0.007**
Device oversize[a] (%), mean ± SD	1.2 ± 0.1	1.2 ± 0.1	1.1 ± 0.2	0.128
Device oversize[b] (%), mean ± SD	1.8 ± 0.3	1.8 ± 0.4	1.7 ± 0.2	0.245
Device type				
Cera™ ASD Occluder (Lifetech, China), n (%)	51 (71.8)	33 (46.5)	18 (25.4)	
Memopart™ ASD Occluder (Lepu, China), n (%)	13 (18.3)	10 (14.1)	3 (4.2)	
AMPLATZER™ Septal Occluder (Abbott, USA), n (%)	7 (9.9)	5 (7)	2 (2.8)	
Complications	14 (19.7)	11 (15.5)	3 (4.2)	0.525
Residual shunt, n (%)	2 (2.8)	1 (1.4)	1 (1.4)	
Arrhythmia, n (%)	6 (8.5)	4 (5.6)	2 (2.8)	
Sinus bradycardia, n (%)	3 (4.2)	1 (1.4)	2 (2.8)	
Paroxysmal atrial tachycardia, n (%)	1 (1.4)	1 (1.4)	--	
Junctional rhythm, n (%)	1 (1.4)	1 (1.4)	--	
Ventricular tachycardia, n (%)	1 (1.4)	1 (1.4)	--	
Pericardial effusion, n (%)	3 (4.2)	3 (4.2)	--	
Mild, n (%)	3 (4.2)	3 (4.2)	--	
Moderate, n (%)	--	--	--	
Severe, n (%)	--	--	--	
Dislodgement, n (%)	2 (2.8)	1 (1.4)	1 (1.4)	
Death, n (%)	--	--	--	
Procedural success rate, n (%)	70 (98.6)	48 (67.6)	22 (31)	0.324
Current symptoms				
Asymptomatic, n (%)	63 (88.7)	39 (54.9)	24 (33.8)	
Dyspnea, n (%)	3 (4.2)	3 (4.2)	--	
Edema, n (%)	1 (1.4)	--	1 (1.4)	
Hematoma, n (%)	3 (4.2)	2 (2.8)	1 (1.4)	
Back pain, n (%)	1 (1.4)	1 (1.4)	--	

[a] according to the largest ASD diameter

[b] according to the shorted ASD diameter

vein. Additional adaptations in implantation techniques encompassed the utilization of customized or steerable delivery sheaths and employing balloon-assisted closure methods [22].

Balloon sizing has been regarded as a crucial component of transcatheter closure of oval-shaped secundum ASD about the morphology of the condition. Inflation of the balloon would have the effect of changing the defect's shape so that it matched the balloon's comparatively circular shape [6]. Our experience, however, has shown that excepting individuals with extremely big defects, percutaneous closure may be accomplished without balloon assistance with the correct size and definition of the morphology of ASD. For oval-shaped ASD, Song et al. [2] demonstrated effective device closure using an ASD device. The mean device upsizing in the ovoid group was remarkably smaller than in the circular group, which was interesting and consistent with Zanchetta's theory [11]. According to their findings, the circular group's device was 3.7 mm longer than the longest diameter of the defect, while the ovoid group's device was 1.8 mm longer. However, this depends on the defect's shortest to longest diameter ratio.

There is no single best way to choose a device for an oval-shaped ASD. Indeed, there are some difficulties in choosing the device for oval ASD, as has been described

in many previous studies [2, 4, 6, 14]. One study by Zanchetta et al. [11] made a formulation to determine the device size in oval-shaped ASD as they found that the device might be smaller than the longest diameter of the defect. They predict the size by measuring the FOA (fossa ovalis area)= $\pi\ ab/4$, so the diameter would be d = $\sqrt{FOAx4/\pi}$ or d = $\sqrt{axb}$ (a = maximal diameter, b = minimal diameter). Although our study did not use this formulation to determine the device size (see Fig. 2b), the results of all the procedures are still very satisfying with 98.6% good results with a very low rate of complications (19.7%). During this pilot study, we also developed a formula to determine the device size for patients with oval-shaped secundum ASD. The formula is Device size = 2.476 + (1.055 x ASD longest diameter). This formula can be applied regardless of whether fluoroscopy or zero-fluoroscopy (echocardiography-guided only) techniques are used.

Currently, two different closure philosophies have been proposed based on defect size and anatomy, utilizing either self-centering or non-self-centering devices. The former approach is suitable for larger ASDs due to its "stenting" closure mechanism, albeit potentially impacting local anatomy and physiology due to the inherent stiffness of the device. In contrast, the latter approach focuses on ensuring complete ASD "coverage", offering lower risks of anatomical and functional interference and thus predicting fewer long-term complications. The GORE Cardioform ASD Occluder device (WL Gore & Associates, Flagstaff, AZ) is highlighted for its softness and anatomical compliance, with Santoro et al. [23] recommending its implantation under both fluoroscopy and echocardiographic guidance. While our institution did not utilize the GORE Cardioform ASD Occluder device, we employed a similarly soft device, the Cera™ ASD Occluder (Lifetech, China), without encountering issues during fully guided echocardiography throughout both intra- and periprocedural phases for oval-shaped secundum ASDs.

Haddad et al. (2023) [24] introduced an innovative ASD closure technique known as the FAST (Fast Atrial Sheath Traction) method. This approach involves rapidly unsheathing the device in the middle of the left atrium, allowing it to clamp the ASD from both sides simultaneously. The FAST technique was primarily utilized in patients with absent aortic rims or an ASD size-to-body weight ratio exceeding 0.9. At our institution, we occasionally employed a similar approach in complex ASD cases, not limited to oval-shaped secundum ASDs. Here, we swiftly deployed the device into the pulmonary vein-left atrium, followed by immediate traction to open the rear (right disc), thereby achieving a clamping effect. This method was typically reserved for cases where conventional techniques were ineffective.

Limitation

This study does not include sex- and gender-based analyses. Additionally, due to the limited number of subjects in the fluoroscopy group, a comparative analysis between fluoroscopy and zero-fluoroscopy secundum oval-shaped ASD closure was not conducted.

Conclusion

Transcatheter closure of oval-shaped secundum atrial septal defect was proven safe and successful in this pilot study. Additionally, our work has shown that echocardiography is adequate for pre- and intra-operative guidance for effective defect repair.

Clinical perspectives

- The success rate with the zero-fluoroscopy technique as initial guidance for oval-shaped secundum ASD was 88.7%.
- Defining the oval anatomy is crucial alongside defining the ASD size and related rims for procedural success.

Abbreviations

ASD	Atrial septal defect
BW	Body weight
FAST	Fast atrial sheath traction
LUPV	Left upper pulmonary vein
TEE	Transesophageal echocardiography
TTE	Transthoracic echocardiography

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Patient consent statement

The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Authors' contributions

SNS, KM, PR wrote the main manuscript text. BM and CC collected and analyzed the data. BM designed the figures. All authors reviewed the manuscript.

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Availability of data and materials

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Data availability

Data is provided within the manuscript

Declarations

Ethics approval and consent to participate
The studies involving humans were approved by the Institutional Review Board of the National Cardiovascular Center Harapan Kita. The studies were conducted per the local legislation and institutional requirements.

Competing interests
The authors declare no competing interests.

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