Indonesian Journal of Cardiology
Indonesian J Cardiol 2026:47:42-50
pISSN; 2830-3105 / eISSN: 2964-7304
doi: 10.3070/ijc.1985

Original Article

Non - Fluoroscopic Transesophageal Echocardiography Guided Transcatheter Closure of Atrial Septal Defects: Single Centre Experience in The North of Sumatra Island, Indonesia

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Abstract

Background: Non-fluoroscopic, transesophageal-guided percutaneous closure of Atrial Septal Defect (ASD) can be a first-line strategy to reduce radiation exposure and its cumulative effec. We report our experience as the first center located far from the capital city of Indonesia that routinely performs transcatheter closure of ASD under the guidance of Transesophageal Echocardiography (TEE) without fluoroscopy.

Methods: We collected data of patients whose ASD was successfully closed percutaneously from May 2020 to August 2024. For a total of 116 patients of secundum ASD that are suitable for device closure, we routinely intend to do non-fluoroscopy transcatheter ASD closure guided by TEE.

Results: The zero-fluoroscopy technique was successfully performed in 111 patients. The ASD diameter is 10-40 mm, and the mean size of the occluding device is 9-42 mm. The mean procedural times are 55.81 ± 22.7 minutes. The success rate is 95% with only one case of pericardial effusion. Five cases were excluded as they were finally assisted by fluoroscopy due to the limitation of the echocardiographic view.

Conclusions: A thorough transcatheter ASD closure technique guided by TEE can routinely be performed without fluoroscopy.

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(Indonesian J Cardiol, 2026;47:42-50)

Keywords: Atrial septal defect, GUCH, Echocardiography, Transcatheter closure, non-fluoroscopic.

Introduction

The non-fluoroscopic technique of transcatheter closure of Atrial Septal Defect (ASD) was developed by Ewert in 2000 in order to avoid radiation exposure in children.[1] Transcatheter ASD device closure with Transesophageal Echocardiography (TEE) guidance alone was proved to be as effective and safe as ASD closure with fluoroscopy guidance in children.[2] In Indonesia, this technique was first successfully performed in pregnant woman by team of National Heart Centre Harapan Kita Jakarta in 2018.[3] Being located quite far from Jakarta, capital city of Indonesia, in a separated island, Heart Centre of Adam Malik General Hospital Medan has been routinely performing this non-fluoroscopic technique since May 2020. As an established heart centre located on the island of Sumatra, Indonesia, we report our experience with this technique.

Methods

This study is a descriptive observational study that cross-sectionally analyses registry data of our centre. Our registry is an updated, institution-based, and confidential registry maintained by the Paediatric Cardiology and Congenital Heart Disease Division of the Cardiology Department at Adam Malik General Hospital. This registry has been running since 2020. All ASD patients who are recorded for ASD device closure will be included in this study as the target population. We intend to apply non-fluoroscopic ASD device closure initially; therefore, we exclude patients for whom this approach can't be performed. Registry data collection and statistical analysis are being performed by two distinct individuals, each of whom is independent and blind to the operator of the procedure. TEE was performed to ensure the suitability of all rims that are adequate for transcatheter closure.[4]

Indication and Contraindication

Initially, patients were clinically diagnosed with secundum ASD and confirmed by TTE. Pediatric ASD patients who are interested in having contraindications complicating Pulmonary Hypertension (PH) will proceed to Right Heart Catheterization (RHC) to calculate the flow ratio and pulmonary resistance. For the majority of our patients are Grown Up with Congenital Heart Disease (GUCH) we practiced most of the recommendations from European Society of Cardiology (ESC) Guidelines 2020 for the Management of Adult Congenital Heart Disease of as well as Indonesian Heart Association Guidelines for Adult with Congenital Heart Disease 2020.[5-6] Patient diagnosed with secundum ASD with clinically significant left to right shunt with signs of Right Ventricle (RV) volume overload will be admitted to the hospital to have RHC as a method to confirm Pulmonary Arterial Hypertension (PAH) (Pulmonary Vascular Resistance [PVR]>3WU). ASD with an increased flow ratio (Qp/Qs > 1.5) will be closed, with the option to perform balloon testing to weigh the benefit versus the risk of closure in a patient with PVR < 3 WU and Left Ventricle (LV) disease. In a patient with low PVR and without LV disease, ASD should be closed with a Class I Recommendation. In a patient with PVR 3-5 WU, ASD can be closed with Class IIa Recommendation. Meanwhile, patients with PVR>5WU will be recommended to have months of PAH treatment before closure with a fenestrated device, only when PVR falls below 5 WU after PAH treatment and the flow ratio >1.5.[5-6]

Minimal invasive ASD with device closure will be conducted when ASD rims are categorized as suitable for transcatheter closure. At our centre, when rims are identified, we adopt a non-fluoroscopic approach as our first-line method.

Preparations and Pre-Medications

We intended to conduct this technique over all secundum ASD with sufficient rims (≥5 mm from the defect to the superior or inferior vena cava, right upper or lower Pulmonary Vein (PV), coronary sinus, mitral or tricuspid valve), ASD without any other heart conditions requiring surgical correction, ASD>40mm, or the diameter of the left side of occluder not larger than the overall length of the atrial septum. All patients gave informed consent to be sedated and intubated, and then underwent this procedure without fluoroscopy.

We applied this technique to patients with deficient rims only when the other rims were adequate. Although it would be challenging, for example, on even posterior rims that are deficient, as long as the opposite rims are supporting and the other rims are well enough, we still proceed with this technique. For aortic rim deficiency or even no aortic rim at all, this technique was also planned in the first place, only if the surrounding rims were adequate. If two or more sides of the rims were not deemed sufficient, or if the patient's safety was at risk, even when only one rim was insufficient, we excluded them and proceeded directly to surgical closure. Another challenging condition was malalignment of ASDs and oval form of ASDs (ratio of the shortest diameter to the longest diameter = 0.75) or floppy

rims.[7-8] We still proceed with the procedure for those challenging cases. Regarding the possibility of erosions, we follow patients with these challenging conditions by performing TTE hours after closure. Some preparations are also needed within the protocols. To minimize the risk of infection, we administered a single intravenous loading dose of antibiotics, followed by two subsequent doses, for prophylaxis. After ASD was totally occluded, we then gave furosemide 40 mg iv (1 mg/kg) to reduce the chances of surging of the left atrial pressure. Unfractionated heparin (100 IU/kg) was given shortly after the guiding stiff wire reached the PV.

Technical Aspects and Bail-put Considerations

Procedural success depends on accurate measurement of working length, defined as the distance from the third intercostal space at the right mid-clavicular line to the right femoral venous puncture site (or the left if right femoral vein puncture fails). This measurement serves as a critical safety parameter, preventing excessive catheter advancement and cardiac perforation.[8]

The procedure was performed in a routine operating room under TEE guidance without fluoroscopy. All patients underwent general anaesthesia with intubation. TEE was used to perform a comprehensive post-intubation study, assessing all aspects of ASD anatomy (location, size, presence of additional defects, and adequacy of the various rims).[4] The procedure is stepwise described in Figure 1.

If any difficulty was encountered with the echo field of view, we switched to fluoroscopy. Of the 116 patients, five patients were helped by fluoroscopy. We infrequently perform balloon sizing; among 116 patients, only 1 was helped by this procedure, performed under fluoroscopy.

Device embolism is the most frequent complication of percutaneous transcatheter closure of ASD, which could be lethal. Snaring will be the first move to manage the embolism while the device is dislodged during the procedure. If possible and safe, we will attempt to resolve the defect by restarting the procedure and, if needed, adding techniques (e.g., balloon sizing) or repeating the examination of all rims to obtain the precise device size. If the embolism occurs at a high-risk site and cannot be snared, or if it is snared but fails to be captured, the patient will be referred for surgery. All procedures were performed in a catheterization laboratory, with a cardiopulmonary bypass unit on standby in the operating room adjacent to the catheterization laboratory. Thus, a patient could be converted to open heart surgery immediately in order to retrieve the device and repair the ASD.[4]

Other possible complications include thromboembolic events, progression of PH, and new valvular abnormalities such as mitral or tricuspid regurgitation, aortic regurgitation, or erosion that causes pericardial effusion and arrhythmia. If complications are mild, we will observe for several hours to determine whether they improve or worsen. Worsening into more severe complications will lead to open heart surgery to manage the complication and take the device out, following defect closure.[17]

Devices

As previously described, the defect was sized based on the maximum defect diameter. The diameter for each patient was selected in accordance with the TEE result, with a diameter 2 to 4 mm in excess of the maximum defect diameter.4 Another option for sizing, the occluding device size was determined by 20% of the defect size. If the oval size were the same, we could use the same device size as the defect size. The Left Atrium (LA) septal diameter was measured precisely. What to avoid is so that the disk wouldn't close the PV, touch the tricuspid, or erode the aorta. We consider placing the disk slightly over the aorta in cases with a zero to minimal aortic rim. The largest device size successfully done in our centre is 42mm.

Device selection at our center was the MemoPart™ ASD occluder. The MemoPart ASD occluder was a self-expanding double-disc device made of nitinol mesh, stainless steel bushing(s), suture line, and polyester fabric membrane. The other device, Occlutech ASD, was made of Titanium oxide-covered nitinol with a spunbonded PET patch for faster endothelialisation, and there is a unique ball connection between the pusher and occluder. This made the Occlutech ASD more rigid. We had two cases using this device that were complicated by Cobra deformity (Table 1). The other device was Amplatzer™ Septal Occluders (ASO). This retrievable device became the device of choice for most interventional cardiologists for decades. In one case, we performed the procedure using a fenestrated device because there was a simultaneously high mean LA pressure on the RHC.

Education, Follow-up, and Long-term Medication

If the high flow condition was accompanied by PH (mean PAP >20 mmHg), we also treat the patient with a pulmonary vasodilator agent (PDE5 inhibitors) alongside the afterload reducing agent,

such as Angiotensin-Converting Enzyme (ACE) inhibitors or beta-blockers, and a diuretic if there were still signs of pulmonary congestion due to lung overflow. Aspirin (3-5mg/kg) was given for a period of six months of period.[4]

After a successful procedure, appropriate patient education and follow-up are also essential parts of the treatment. We gave instructions on how to care of the oral hygiene and prevent the development of caries. PH treatments needed to be continued as the physical fitness improved, as long as the PH signs and symptoms were also diminished.

Results

From May 2020 to August 2024, 111 secundum ASDs were closed under the guidance of TEE. Five were excluded due to the need of fluoroscopy to help complete the procedure. There were 21 (19%) male patients and 90 (81%) female patients (Table 1). Our first case was a 64-year-old lady with a 24 mm defect. The patients' mean age was 37 ± 14.3 years, and their mean body weight was 53 ± 26.3 kg. The sizes of the secundum ASDs ranged from 10 to 40 mm, and there were descriptions of rim size in Table 1. Five patients had complex ASD with posterior rim deficiency. Four of them had minimal, thin, and floppy, and one of them had no posterior rim at all. From all five cases, anterior rims are long enough to support the device, ranging from 12-20mm. The mean size of the device was 28 ± 7.5 mm (ranging from 6–36 mm). The mean procedural time IS 55.8 ± 22.7 minutes.

Discussion

It has been reported that radiation exposure during percutaneous coronary interventions decreased significantly (by 36%) between 2008 and 2018 in Germany. However, physicians and patients remain exposed to low-dose fluoroscopy, further stimulating substantial interest in radiation-free cardiac interventions. At a high-volume medical centre in Italy, the proportion of zero-fluoroscopy procedures increased from 8.5% in 2017 to 22.9% in 2021, fully demonstrating this developmental trend.[9]

To contribute academically, our study findings consistently recommend a non-fluoroscopic technique as the first option for transcatheter ASD

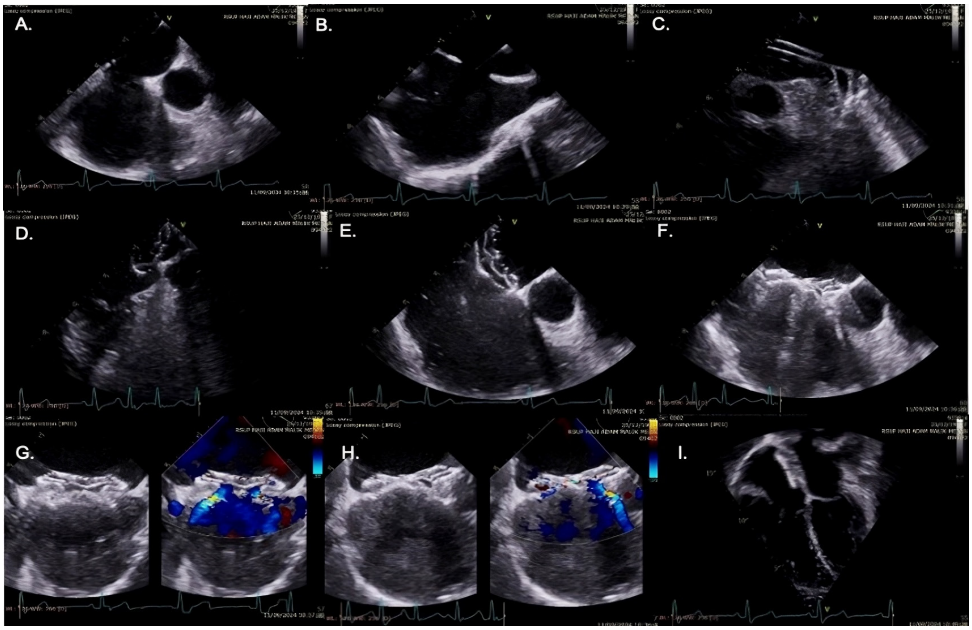

Figure 1. A-B: After ASD size and rim measurement by TEE, the procedure is started by advancing a Multipurpose Catheter (MP) across the defect to reach the left PV. C: A stiff wire is inserted following the MP to guide the delivery sheath to the left PV. D: After the device is inserted through the introducer into the delivery sheath, we push the LA disk out mostly into the PV. E: Then we dragged the delivery sheath and tried to position the LA disk align with the rims. This approach was very well done by viewing the aorta and posterior rim (30°-40°). F-G: The RA disk was deployed and captured all of the appropriate rims. H: Only a central and minimal shunt was seen. I: Device is seen on TTE 4 chamber view.

Table 1. Baseline demographic data of secundum ASD patients.

Parameter	N
Female (n)	90 (81.1)
Age (yrs)	37 ± 14.3
Weight (kg)	53 ± 26.3
Body Surface Area (m^2)	1.71 ± 2.09
Defect Size (mm)	28 ± 7.55
Procedural Time (mins)	55.8 ± 22.7

Table 2. Measurements of ASD rims .

Rims	Mean (SD)
Aortic (mm)	6 (4.025)
Mitral (mm)	12.69 (5.587)
Posterior (mm)	12.14 (6.012)
Superior (mm)	7.72 (4.349)
Inferior Vena Cava (mm)	13.35 (6.746)
Superior Vena Cava (mm)	12.20 (5.927)

The successful rate was 95%, and only one successful closure was complicated by a manageable pericardial effusion. From two cases of embolization, one case had no aortic rim and a floppy Inferior Vena Cava (IVC) rim. Another case had malalignment, and the aortic rim was floppy and thin.

Table 3. Rate of performance of non-fluoroscopy transcatheter ASD closure technique in Heart Centre of Adam Malik General Hospital.

Parameter	n = 111 (%)
Succeed	105 (94.6%)
Succeed with self-limited complication	1 (0.9%)
*pericardial effusion, erosion of RA and RV	
Not successful	5 (4.5%)
Device emboli (2)	
Deformity of the device, not recoil (2)	
Inadequate device size (1)	

device closure. The main issue in this technique was the operator's performance in tracking the guidewire and sheath in the 2D view of TEE. Visualization of the tip of the catheter, wires, and deployment of the device is critical for the safety and efficacy of device closure of ASD. Thus, an operator skilled in transcatheter intervention and an experienced echocardiographer were mandatory.[3]

Radiation exposure was the second issue that would benefit from this procedure compared with conservative fluoroscopy. This made an advantage for some populations who were at risk of some conditions (ASD with pregnancy) and other comorbidities (worsening of heart failure or PH).[3,10] Most of the studies underwent this procedure on children. Our centre would gave an unique perspective of how 98% of ASD patients were adults.

The 'cobra-like' configuration of the ASO device is a rare but known complication of percutaneous treatment of atrial septal defects that occurs in 0-3% of published series.[15] It is, in fact, the extreme variant of a series of distortions deriving from a change in position of the device's nitinol wires. This deformity can happen in either the RA or the LA disc.[16] These distortions range from a slight bulge to the 'cobra-like' formation. Some reasons are implied by a manufacturing defect, the excessively distal release of the device, which can push the LA disc into the free wall of the left atrium, the left atrial appendage, or the PV orifice, and by deformation of these structures or difficulties in positioning the device within the sheath. Difficulty loading the device, twisting the device while advancing it through a smaller sheath, or kinking the delivery catheter can also be reasons. In two of our cases (Figure 2), deformities were

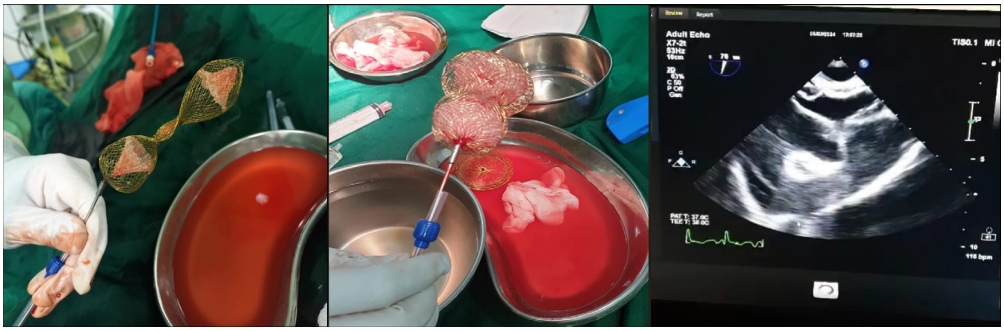

Figure 2. Device deformities causing unsuccessful procedure, from left to right: Cobra deformity, LA disc bulging, and fixed deformity as seen through TEE.

happening with the same brand. The greater length of wire between the disc margin and the centre of the device compromises its memory of shape.[16] We have tried to do clockwise or the back-and-forward movement within the sheath, which may have favoured relocation of the wires, leading to recovery of the usual configuration, but still couldn't fix the deformities. For the patient's safety, we postponed the procedure.

Our study consists mostly of adults. We have only eight patients under 17 years old, with a 6-year-old as the youngest. We consider this a special circumstance arising from the limitation of working in a general hospital, where admission to the Paediatric Department for patients under 18 years is obligatory. The authors of this study are cardiologists working at the Heart Centre within the general hospital, where most of the paediatric patients under 18 are referred to the Paediatric Department to ensure that children are managed by a paediatrician as their primary physician. A paediatrician can possibly consult a cardiologist at Heart Centre, but usually they will have the procedures under a paediatrician (cardiology consultant). Although we, as Cardiologists (interventional paediatric consultants), are technically permitted and legally authorized to perform transcatheter ASD device closure, practical regulations for this shared competency across age groups and subsets are still being developed for general hospitals in Indonesia. Additionally, at Adam Malik General Hospital, the Paediatric Department is located in a separate building and under a different managerial unit from our Heart Centre. This situation is similar to that in other hospitals in Indonesia, except at the National Heart Centre in Jakarta, where all patients with congenital heart disease of any age are managed by Cardiologists because it is a specialized hospital.

Different from the child population, we should consider the ASD size, device size, occurrence of PH, and diastolic dysfunction that can lead to higher left atrial pressure, which can worsen after ASD closure. When we compare our study to findings from the application of this technique on the child population, there are obvious differences in children, such as shorter procedural times, smaller ASD device closure, and lower rates of complications (embolization and erosion or pericardial effusion).[13] The device deformities, e.g., cobra head deformity itself, are often reported in adult patients who are related to larger device size and delivery sheath variances, and multiple attempts of placing the device on some deficient rims of ASD. Both children and adults undergoing non-fluoroscopic ASD device closure are guided by TEE, which is superior in image resolution because the probe is positioned adjacent to the left atrial posterior wall, placing the interatrial septum within the optimal imaging range.[9]

Another major concern in ASD closure is the risk of post-procedural elevation in LA pressure, particularly in older adults with diastolic dysfunction. Holzer et al. suggest performing a test occlusion; if the mean LA pressure increases by more than 3 mmHg, the use of a fenestrated occluder may be warranted.[17] We don't apply these approaches; otherwise, we follow the Indonesian and ESC guidelines on GUCH. We also continue heart failure medications that can control LA pressure, as well as PH medications.

Considering the advantages of this technique, Percutaneous and Non-Fluoroscopic (PAN) procedures use echocardiographic guidance as an alternative to conventional fluoroscopy. This eliminates radiation exposure while maintaining procedural efficacy. Implementation of the PAN

procedure follows a comprehensive, systematic framework designed to ensure procedural safety and efficacy across varying levels of complexity. The overall approach can be structured into four sequential phases: patient selection, preoperative assessment, intraoperative team coordination, and postoperative evaluation.[9]

TEE can be used to monitor the occlusion device's release, particularly to confirm correct placement, verify complete release, confirm the absence of residual shunt, and assess the condition of the atrial valve. In our procedures, once the occlusion device was confirmed to be correctly placed, we released the device in full to assess its effect of the device.[13]

Some disadvantages are evident compared with conventional (fluoroscopic) ASD device closure. This non-fluoroscopic technique may be controversial in terms of procedural time. The main factors associated with procedure time include: the process to reach the PVs, because there may be some difficulty in tracking the tip of the catheter and/ or guidewire with TEE, and the course of device deployment, as the angle between the sheath and atrial septum may not be good enough, so that redeployment may be needed. Although longer procedural times were required in certain cases, especially in the early stages of the study, procedural time decreased markedly as operators gained experience.[4] Another possible disadvantage of this technique is that it is performed under general anaesthesia, necessitating a period of strict observation after the procedure.[9] These disadvantages related to longer procedural time can be mitigated over time as the operator and teammate are already in line with one another through their learning curve. This study provides insight into the safety of this technique. Another issue is that we should widen our possibilities to use another choice of ASD closure device to help the success rate for each device, which should have its own superiority and infirmity.[15]

This is a registry-based study. To address our study limitation, we plan to continue monitoring and to complete follow-up of patients' clinical conditions to provide further analysis of factors associated with symptom improvement. As a heart center located relatively far from the capital city of Indonesia, this established registry is useful of describing the application of this technique in the early era of non-fluoroscopic approaches to structural heart disease management (Figure 3).

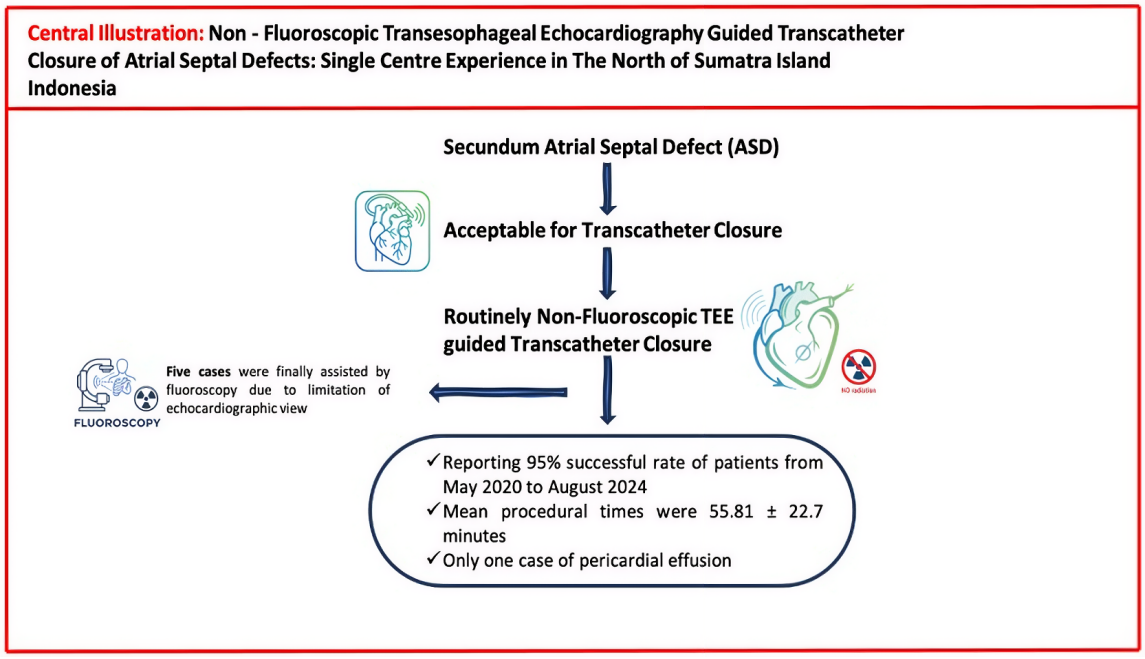

Figure 3. Central illustration of the study.

Conclusion

Non-fluoroscopy transcatheter closure of secundum ASD can routinely be performed. With some adjustments, operators who are already accustomed to the TEE view and this thorough procedure can be protected from the harm of radiation.

List of Abbreviations

ACE	Angiotensin-Converting Enzyme
ASD	Atrial Septal Defect
ASO	Amplatzer Septal Occluders
ESC	European Society of Cardiology
GUCH	Grown Up with Congenital Heart Disease
IRB	Institutional Review Board
IU	International Units
IVC	Inferior Vena Cava
LA	Left Atrium / Left Atrial
LV	Left Ventricle
MP	Multipurpose Catheter
PAH	Pulmonary Arterial Hypertension
PAN	Percutaneous and Non-Fluoroscopic
PAP	Pulmonary Arterial Pressure
PDE5	Phosphodiesterase type 5
PH	Pulmonary Hypertension
PV	Pulmonary Vein
PVR	Pulmonary Vascular Resistance
Qp/Qs	Flow ratio (Pulmonary-to-Systemic Flow Ratio)
RHC	Right Heart Catheterization
RV	Right Ventricle
TEE	Transesophageal Echocardiography
TTE	Transthoracic Echocardiography
WU	Wood Units

Ethical Clearance

The study was conducted in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and the Helsinki Declaration of 1975, as revised in 2013, where applicable. Institutional Review Board (IRB) approval was obtained from Adam Malik Hospital. All patients have given informed consent for their inclusion in the study, where applicable.

Publication Approval

All patients have given informed consent for their inclusion in the study, where applicable.

Authors Contributions

Ali Nafiah Nasution & Bertha Gabriela Napitupulu (Pediatric Cardiology and Congenital Heart Disease Division) and Tengku Winda Ardini & Joy Wulansari Purba (Echocardiography and Cardiovascular Imaging (Non Invasive Cardiology) Division) accomplished for substantial contribution to the conception and design of the study and the analysis of clinical data, drafting the manuscript and final approval of the version to be published. All of those four people together with Cut Aryfa Andra (The Head Faculty of Cardiology and Vascular Medicine Study Program), Anggia Chairuddin Lubis as (The Head of Cardiology and Vascular Medicine Department) and Abdullah Afif Siregar (Professor on Pediatric Cardiology and Congenital Heart Disease Division) contributed to give final approval of the version to be published.

Acknowledgments

None.

Conflict of Interest

All authors have disclosed any conflicts of interest relevant to this work.

Availability of Data and Materials

Not applicable.

Funding

This paper received no specific grant from any funding agency, commercial or not-for-profit sectors.

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Not applicable.

Generative AI and AI-Assisted Technologies in the Writing Process

Authors acknowledge that artificial intelligence (AI) tools were only used to assist in language editing and did not generate or alter the scientific content, analyses, or conclusions presented in this manuscript.

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