REVIEW

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Unveiling the Efficacy and Safety Divide Between Fluoroscopy and Non-fluoroscopy Approaches in Transcatheter Atrial Septal Occluder Procedures: A Systematic Review and Meta-analysis

Kino Kino, Heka Widya Putri

Department of Cardiology, Faculty of Medicine Andalas University; Rumah Sakit Umum Pusat Dr. M. Djamil Kota Padang Sumatera Barat, Padang, Indonesia

Abstract

This study compares the effectiveness of fluoroscopy versus non-fluoroscopy procedures during percutaneous closure of atrial septal defects (ASD) in children. The clinical concern surrounding radiation exposure in children and medical staff is well recognized. A systematic review and meta-analysis were conducted using PubMed, ScienceDirect, and Cochrane databases, including studies up to February 2024. Prospective studies were assessed for risk of bias and effect sizes were calculated using standard mean differences (MD) and log risk ratios. Out of 18 studies, five were included in qualitative analysis and four in the meta-analysis. Findings indicated significantly higher success rates in the non-fluoroscopy group compared to the fluoroscopy group [odds ratio (OR) =3.40, $P < 0.001$], shorter procedure times (MD =12.59), and a lower risk of postoperative complications (OR =3.22). Non-fluoroscopy-guided ASD closure appears to be a more effective and safer approach in pediatric patients.

Keywords: Atrial septal defect, procedures, fluoroscopy, pediatric

INTRODUCTION

Atrial septal defect (ASD) is a congenital heart anomaly with the secundum type of ASD comprising the majority of clinically significant cases. While a patent foramen ovale (PFO) may be present in up to 25% of the population, true ASDs have a lower incidence of approximately 1.6 per 1,000 live births. Differentiation between PFO and ASD is crucial in both diagnosis and management.[1,2] Treatment modalities include open cardiac surgery and percutaneous device closure, with the latter being preferred because of its minimally invasive nature and proven efficacy.[3,4]

Fluoroscopy in combination with echocardiography is the traditional method for device guidance during ASD closure. However, this exposes patients and healthcare personnel to ionizing radiation, posing long-term health risks, especially in children.[4,5] This concern is particularly significant for children given their heightened sensitivity to radiation and the potential for long-term side effects over their extensive expected lifespan.[3,6]

With the aim of reducing radiation exposure, some centers have explored using echocardiography alone, either transesophageal echocardiography (TEE) or transthoracic echocardiography (TTE) to guide device closure.[7,8] Despite growing interest,

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Address for Correspondence: Asst. Heka Widya Putri, Department of Cardiology, Faculty of Medicine Andalas University; Rumah Sakit Umum Pusat Dr. M. Djamil Kota Padang Sumatera Barat, Padang, Indonesia
E-mail: heka.wd@gmail.com
ORCID ID: orcid.org/0009-0002-8823-9165

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non-fluoroscopy-guided closure has not been widely adopted, partly due to the lack of robust comparative evidence. This study aims to systematically compare the safety, effectiveness, and procedural outcomes of fluoroscopy-guided versus non-fluoroscopy-guided transcatheter ASD closure in pediatric patients. We hypothesized that non-fluoroscopy techniques would yield comparable or superior outcomes with reduced complication rates and procedural time.

METHODS

Study Criteria

This systematic review and meta-analysis adhered to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and was not registered in PROSPERO. A comprehensive search of PubMed, Cochrane Library, ScienceDirect, Scopus, and Web of Science was conducted through February 2024. We used specific inclusion criteria to identify relevant articles, focusing on primary outcomes such as success rate, mean procedure time, and complication rate. The selection of studies was limited to those published in English. Articles in other languages, duplicates, review articles, and publications not relevant to the topic were not included. No restrictions were placed on the publication year of the selected studies.

Participants Criteria

This study cohort included patients preoperatively diagnosed with isolated type II ASD that required surgery without concomitant heart disease. The patient's medical history, clinical symptoms, chest X-ray, electrocardiogram, and echocardiogram were used to diagnose this condition. Patients were excluded if they exhibited symptoms of an infectious disease, severe pulmonary hypertension, or any other condition that would contraindicate surgery.

Literature Search and Study Selection

We conducted a comprehensive search until February 2024 using PubMed, MEDLINE, Cochrane Library, Scopus, Web of Science, and ScienceDirect, following the PRISMA guidelines. The search terms utilized were "[fluoroscopy odds ratio (OR) fluoroscopic]" and "(atrial septal)" and "(device closure OR transcatheter OR echocardiography OR radiation-free)". After removing duplicates and review articles, the remaining research titles and abstracts were independently examined to determine eligibility. The full texts of selected studies were then evaluated against the inclusion and exclusion criteria.

Statistical Analysis

Effect sizes were calculated using the Mantel-Haenszel method. Because a fixed-effects model was initially employed given the clear clinical heterogeneity among the studies, a random-effects model was ultimately used for pooled estimates. Heterogeneity was assessed using the I^2 statistic and τ^2. Funnel plots were generated to assess publication bias. Data extraction included study characteristics, participant demographics, intervention details, and outcomes. Quality and risk of bias was assessed using the Cochrane Risk of Bias Tool for RCTs and ROBINS-I for non-randomized studies. The quality assessment results of the individual studies are presented in the Table 1.

RESULTS

Out of 98 identified records, eighteen full-text articles were assessed for eligibility, and four studies comprising a total of 1,143 pediatric patients were included in the meta-analysis. The studies were conducted in diverse settings, including China, Switzerland, and Germany. The methodological characteristics and comparative outcomes of these studies are summarized in Table 2. Non-fluoroscopy techniques showed significantly higher procedural success [relative risk (RR): 3.40] [95% confidence interval (CI): 1.92-6.01], $P < 0.001$), shorter procedure durations [mean difference (MD) =-12.59 minutes (95% CI: -16.8 to -8.3)], and higher intraoperative and postoperative complications [OR =3.22 (95% CI: 1.85-5.62)]. Heterogeneity was moderate (I^2 =56%). The method used to choose the studies for this review is visually represented in Figure 1 following the standard PRISMA flow diagram.

DISCUSSION

Four studies involving 1,143 children who underwent transcatheter ASD closure were conducted in China, Switzerland, and Germany. The studies assessed various parameters, including the success rate, procedure duration, and intraoperative and postoperative complications. These findings indicate that non-fluoroscopy methods are more effective than fluoroscopy, with a higher success rate and shorter procedure durations.[9] However, only four studies were included, and one reported an extremely wide CI [Kong et al.[10] RR =33.53 (2.06-545.50)], reflecting low precision. The pooled success rate supports the efficacy of non-fluoroscopy methods, although some studies showed only marginal differences 96% vs. 97%).[11]

Table 1. Risk of bias

Study ID	Experimental	Comparator	Outcome	D1	D2	D3	D4	D5	Overall
Ackermann et al.[11]	Eptinezumab	Placebo	Monthly migraine days	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Kong et al.[10]	Eptinezumab	Placebo	Monthly migraine days	Some concerns	Low risk	Low risk	Some concerns	Low risk	Some concerns
Xu et al.[4]	Eptinezumab	Placebo	Monthly migraine days	Low risk	Low risk	Low risk	Low risk	Low risk	High risk
Ewert et al.[12]	Eptinezumab	Placebo	Monthly migraine days	Some concerns	Low risk	Low risk	High risk	Low risk	

D1: Randomisation process, D2: Deviations from the intended interventions, D3: Missing outcome data, D4: Measurement of the outcome, D5: Selection of the reported result

Table 2. Systematic review table

First author, year	Study design	Origin	Baseline						
			Participants	Age (years)		n		ASD diameter (mm)	
				Fluoroscopy	Non-fluoroscopy	Fluoroscopy	Non-fluoroscopy	Fluoroscopy	Non-fluoroscopy
Ackermann et al.[11]	Retrospective, observational, single-center	University Children's Hospital Zurich, Switzerland	Children undergoing transcatheter ASD closure between 2002 and 2016	6.1 (3.8-10.6)	5.7 (4.1-9.6)	141 female and 97 male (n=238)	103 female and 56 male (n=159)	13.5	12.3
Xu et al.[4]	Retrospective study	Children's Hospital, Zhejiang University School of Medicine, China	Children who underwent percutaneous ASD closure at the hospital between November 2014 and January 2017	62.5 (38.8) months (5.2 years)	71.7 (40.7) months	66 men and 97 female (n=163)	54 men and 76 female (n=130)	9.3 (3.9)	9.9 (4.2)
Kong et al.[10]	Prospective randomized multicenter trial	Fuwai Hospital, Beijing; People's Hospital of Xinjiang Uygur Autonomous Region, Urumqi; Henan Provincial People's Hospital, Zhengzhou, China	Patients presenting with ASD at 3 centers, from July 2018 to September 2019	11 (3-63)	12.5 (2-65)	48	52	10 (5-28)	10 (5-27.9)
Ewert et al.[12]	Retrospective study	Berlin, Germany	All patients with either an ASD of the secundum type or a persistent foramen ovale after presumed paradoxical embolism who were considered suitable for transcatheter closure from July 1998 to May 1999	34 (1-78)	18 (2-66)	131	22	11 (4-26)	9 (6-26)

Table 2. Continued

Comparison	Outcome									
	Successful rate		Median procedure time (min)		Intraprocedural complications (n)		Post-operative complications (n)		Postoperative hospital stay (days)	
	Fluoroscopy	Non-fluoroscopy	Fluoroscopy	Non-fluoroscopy	Fluoroscopy	Non-fluoroscopy	Fluoroscopy	Non-fluoroscopy	Fluoroscopy	Non-fluoroscopy
Ackermann et al.[11] intraprocedural fluoroscopy ± TEE guidance; group 2: TEE guidance alone	96% (n=238)	97% (n=154)	60	34	8	1	8	4	-	-
Xu et al.[4]	100%	100%	28.6 (10.9)	21.5 (14.6)	1	0	21	1	2.9 (0.6)	3.2 (0.6)
Kong et al.[10]	33 (68.75%)	52 (100%)	34	28	8	0	0	0	-	-
Ewert et al.[12]	128/131	22/22	100	88	-	-	-	-	-	-

ASD: Atrial septal defect, PAN: Percutaneous and non-fluoroscopic, TEE: Transoesophageal echocardiography

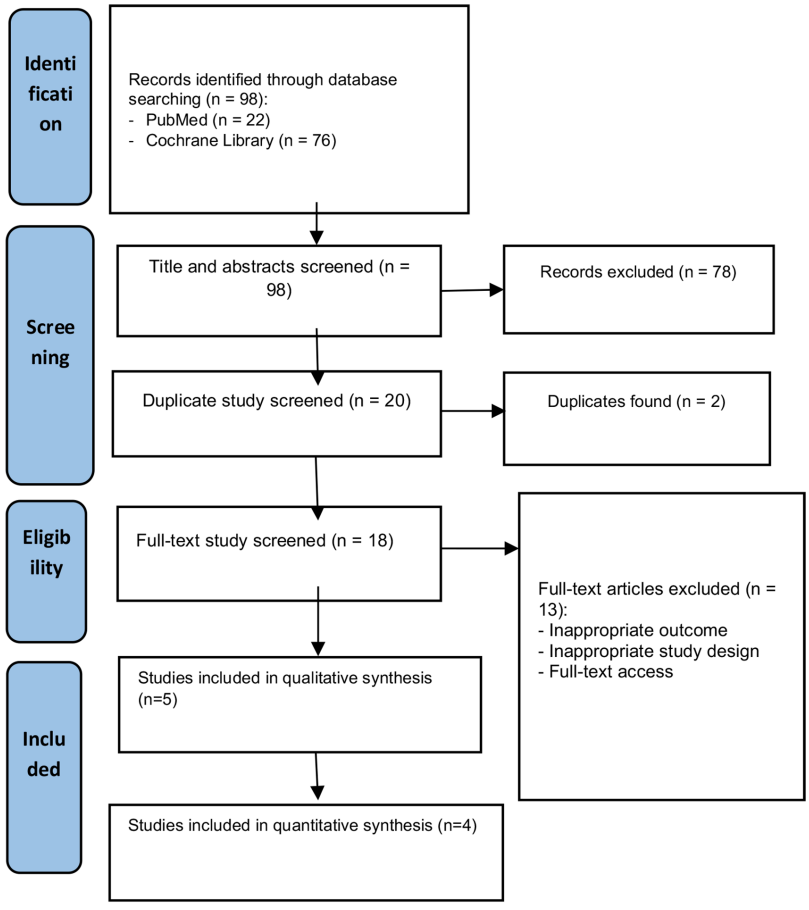

Figure 1. Diagram flow of literature search strategy for this systematic review

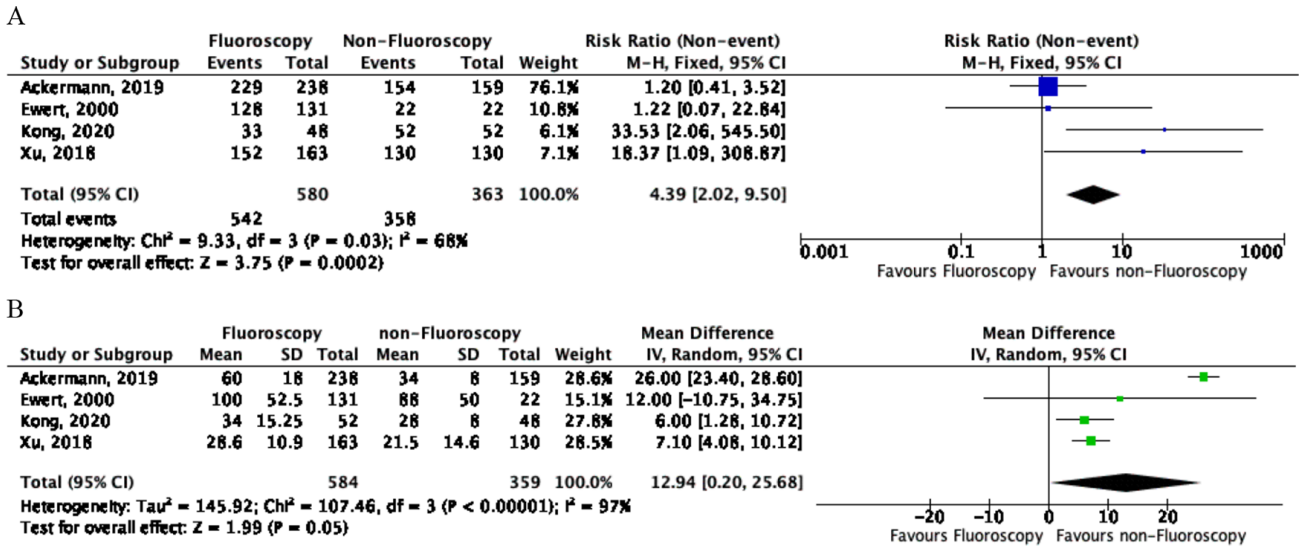

Figure 2. Forest plot of successful event (A) and procedure duration (B) between fluoroscopy *versus* non-fluoroscopy group

CI: Confidence interval

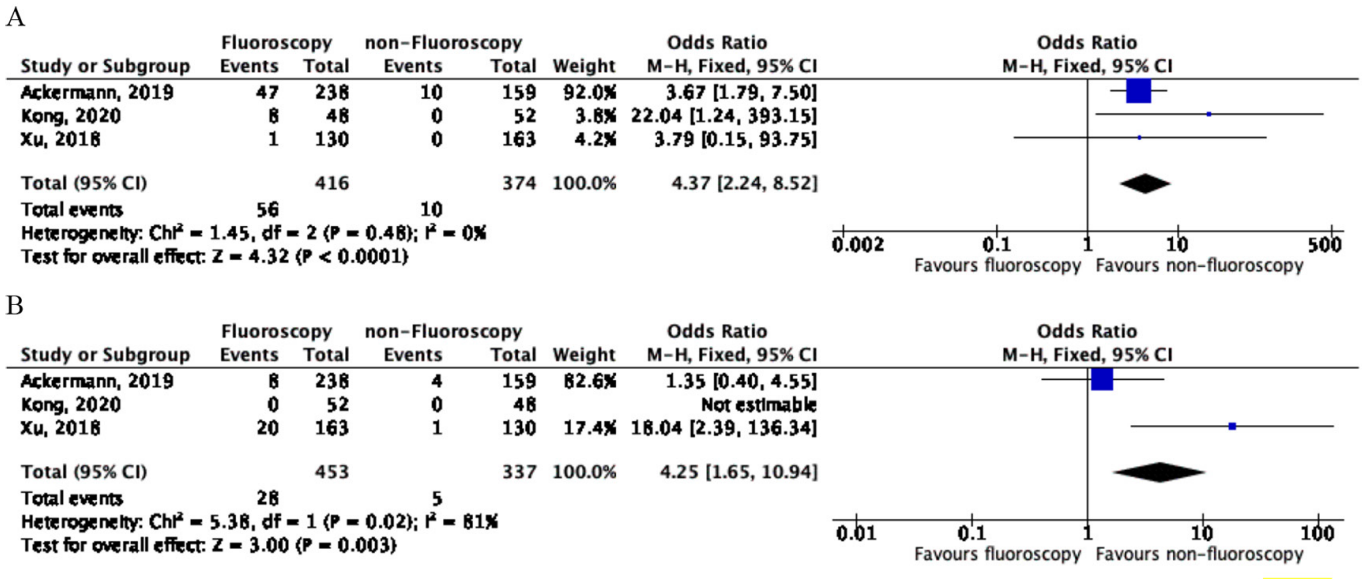

Figure 3. Forest plot of intraprocedural complication (A) and postoperative complications (B) between fluoroscopy *versus* non-fluoroscopy group

CI: Confidence interval

Operative success was determined based on specific criteria: successful passage of the guidewire through ASD into the left atrium (LA), successful entry of the delivery sheath into the LA guided by the guidewire without descending into the right atrium after removal of the guidewire, successful removal of the guidewire from the patient. The definition of procedural success was not standardized across studies, potentially contributing to heterogeneity. Moreover, while the pooled analysis favors non-fluoroscopy, results must be interpreted with caution due to variations in patient selection, imaging modalities (TEE vs. TTE), operator experience, and device types.[12]

The study with the largest number of participants reported a high success rate for transcatheter ASD device closures across both examined groups. Specifically, 229 out of 238 cases (96%) in the fluoroscopy group and 154 out of 159 cases (97%) in the non-fluoroscopy group achieved successful closure ($P = 0.736$). For the nine unsuccessful cases in the fluoroscopy group,

surgery was performed successfully. In the non-fluoroscopy group, secondary fluoroscopy guidance was employed, leading to successful interventional ASD device closure in four out of five of their initially unsuccessful cases (Figure 2A).

The MD of 12.59 indicates that, on average, there is a 12.59 minute difference in procedure time between fluoroscopy-guided and non-fluoroscopy-guided procedures for transcatheter ASD closure. The average duration of procedures for percutaneous ASD closure under fluoroscopic guidance has been documented to vary between 40 and 110 minutes, with variations in how studies define total procedure time.[4,9] Xu et al.[4] showed that the non-fluoroscopy group had a shorter duration [21.5 (14.6) min] than the fluoroscopy group [28.6 (10.9) min], when evaluated from heparinization to removal of the delivery system ($P < 0.001$), with a difference of 7 min (~25%). Procedure durations for fluoroscopy and non-fluoroscopy are summarized in Figure 2B.

An OR of 4.37 indicates a statistically significant association between fluoroscopy guidance and intraprocedural complications in transcatheter ASD closure. This means that patients undergoing fluoroscopy-guided procedures have approximately 4.37 times higher odds of experiencing intraprocedural complications than those undergoing non-fluoroscopy-guided procedures. The CI indicated that this association was relatively precise, ranging from 2.24 to 8.52. Ackermann et al.[11] found intraprocedural complications in 8 cases (3.3%) in the fluoroscopy group, including temporary cardiac rhythm abnormalities, such as transient atrioventricular (AV) dissociation, transient AV block, or non-sustained supraventricular tachycardia, in six cases, and intraprocedural device embolization in two cases. In the non-fluoroscopy group, a male patient underwent Amplatzer septal occluder device embolization due to a defective retroaortic ASD rim. A plot comparing intraprocedural and postoperative complication rates between fluoroscopy and non-fluoroscopy is presented in Figure 3A. This meta-analysis indicates that fluoroscopy-guided transcatheter ASD closure is significantly more likely to result in intraprocedural complications than non-fluoroscopy-guided treatments.

The OR of 3.22, calculated using the Mantel-Haenszel method with fixed effects, indicates that patients undergoing fluoroscopy-guided ASD closure have a 3.22 times higher likelihood of experiencing postoperative complications than those undergoing non-fluoroscopy-guided closure procedures. Major adverse events were categorized as any complications arising within 1 month of the procedures, related to either the devices used or the procedure itself. These complications included but were not limited to death, the necessity of urgent surgery, severe cardiac tamponade requiring drainage or surgical repair, cardiac perforation, hemorrhage, and strokes.[10]

Ewert et al.[12] 12 found that non-fluoroscopy procedures using TEE (88 min) were numerically shorter than with fluoroscopy (100 min); while the success rates differed between the groups, this variation was not considered statistically significant ($P = 0.09$). Several reasons could account for this observed difference. First, TEE provides clear imaging, enabling precise assessment of ASD characteristics such as location, size, and shape, helping to select the most suitable closure device on the first attempt. Second, TEE allows real-time visualization of various components such as steel wires, sheaths, and occlusion devices, facilitating the assessment of residual shunting and the impact of the occlusion device on surrounding structures such as AV valves, pulmonary veins, vena cava, and coronary sinus opening. This capability significantly decreases the procedural time. Third, conventional X-ray equipment may not accurately depict cardiac anatomy, requiring equipment rotation and repeated TEE examinations, thus lengthening procedure duration. In summary, this meta-analysis suggests that fluoroscopy-guided procedures take longer than non-fluoroscopy-guided procedures, with an estimated MD ranging from 1.34 to 23.83 min.

In the study by Xu et al.[4] postoperative fever (temperature above 38 °C) was less common in the non-fluoroscopy group (TEE) than in the fluoroscopy group, with 1 of 130 patients compared to 15 of 163 patients (0.8 versus 9.2%, $P < 0.001$). The rates of other complications were not significantly different between the groups (as shown in Figure 3B). Additionally, no patients in either group experienced postoperative residual shunts, shedding or displacement of the occlusion device, or pericardial effusion.

Our findings support the use of non-fluoroscopy-guided ASD closure, which resulted in improved outcomes and reduced radiation risk. The evidence, while promising, is based on a limited number of studies. The results may not generalize to all populations due to variation in imaging technologies and operator experience. Sensitivity analysis confirmed the robustness of our findings. However, no funnel plot asymmetry was observed, suggesting minimal publication bias.

Study Limitations

The generalizability of these findings is limited by the inclusion of only four studies, which also exhibit moderate heterogeneity among their study populations. Furthermore, a significant drawback is the absence of long-term follow-up data, preventing a comprehensive understanding of long-term outcomes. Lastly, the fact that this analysis was not registered in PROSPERO could raise concerns regarding potential reporting biases.

CONCLUSION

Non-fluoroscopy-guided ASD closure is a promising alternative to fluoroscopy, offering comparable or superior clinical outcomes with lower radiation risk. Larger multicenter studies with standardized definitions and long-term follow-up are needed to confirm these findings.

Footnotes

Authorship Contributions

Surgical and Medical Practices: H.W.P., Concept: K.K., H.W.P., Design: H.W.P., Data Collection or Processing: K.K., Analysis or Interpretation: H.W.P., Literature Search: K.K., Writing: K.K.

Conflict of Interest: No conflict of interest was declared by the authors.

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