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Article Review

Outcomes of True Zero-Fluoroscopy Catheter Ablation for Atrial Fibrillation Care: A Systematic Review and Meta-analysis

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Abstract

***Introduction**: Atrial fibrillation (AF) represents the most common arrhythmia. Current guidelines recommending catheter ablation as first-line rhythm control and definitive treatment for AF which resistant or unresponsive to antiarrhythmic drugs. However, there is concerning issue of fluoroscopy radiation regarding conventional catheter ablation. Zero-fluoroscopy (ZF) emerged as novel technique to fully eliminated fluoroscopy with uncertainty of efficacy and safety. Previous review was insufficient, as they grouped fluoroless ablation under the ZF category.*

***Method**: Scopus, Pubmed, ScienceDirect, and CENTRAL were used to identify relevant studies prior to December 21, 2024. Studies directly comparing TZF vs NZF were included. Quality assessment was carried out using the RoB 2.0 and ROBINS-I tool. Meta-analysis was conducted using R-Studio.*

***Results**: There were one randomized controlled trial (RCT) and seven non-randomized cohorts (1.131 patients) included. The success of pulmonary vein isolation (PVI) with TZF and NZF was comparable, with follow-up visits showing equivalent AF recurrence rates at 6 months (RR = 1.00; 95% CI = 0.90-1.11; p = 0.99) and 12 months (RR = 0.57; 95% CI = 0.13 – 2.57; p = 0.47). ZF showed a significantly shorter procedural time duration (MD = -8.94; 95% CI = -13.56 – (-4.32); p < 0.01). Safety evaluation of ZF demonstrated comparable results for cardiac tamponade (RR = 1.77; 95% CI = 0.37 – 8.37; p = 0.47) and other adverse events risk.*

***Conclusion**: TZF technique in catheter ablation for AF is a revolutionary, effective, and safe innovation. TZF has potential to become the standard approach in AF catheter ablation.*

***Keywords:** Atrial Fibrillation; Catheter Ablation; Efficacy; Safety; Zero fluoroscopy.*

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1. INTRODUCTION

Over the past decade, the American Heart Association (AHA) and the European Society of Cardiology (ESC) have identified atrial fibrillation (AF) as a priority due to its status as the most prevalent arrhythmia, affecting more than 37 million people worldwide[1, 2]. AF is associated with a high risk of stroke, heart failure, and sudden death[1]. Approximately 20% of all strokes are related to AF, meaning that patients with AF have two to five times higher risk of stroke and heart failure compared to the general population[3]. Data from World Health Organization (WHO) also notes that deaths from stroke often triggered by AF and exceed 6 million cases annually. The growing burden of AF and[1, 2] its complications highlights the urgent need for effective and safe management strategies.

According ESC 2024 guidelines, the first-line rhythm control therapy for AF is catheter ablation in accordance with patient consent, and strongly advised for paroxysmal or persistent AF that is resistant to antiarrhythmic drugs[4–6]. However, traditional catheter ablation techniques rely on X-rays for real-time imaging to navigate the catheter within the heart, exposing patients and operators to ionizing radiation. Cumulative exposure in the long term may increase the risk of cancer and tissue damage, particularly dangerous in pregnant women and children [7–9]. In line with the principle of as low as reasonably achievable (ALARA), a minimal or even zero-fluoroscopy (ZF) technique has been developed to minimize or eliminate radiation exposure[10].

The ZF approach need advanced technology and operator expertise, involving a 3-dimensional electroanatomical mapping (3D-EAM) system and intracardiac echocardiography (ICE)[10]. Systems such as CARTO, Ensite NavX, and Rhytmia, employ magnetic fields or electrical impedance to reconstruct cardiac anatomy and track catheter position in real time[11, 12]. Combined with ICE, these tools enable precise localization and ablation of AF foci, particularly in the pulmonary veins, without the need for X-ray imaging[13].

Although ZF demonstrated potential to eliminate radiation exposure, concerns remain regarding its effectiveness and safety in ablation techniques that require high precision. Without fluoroscopy, catheter navigation relies heavily on 3D-EAM and IC, which may limit visualization[10, 12, 13]. Inaccurate mapping or excessive ablation depth into myocardium or epicardium carries a high risk of pericardial effusion and even cardiac tamponade[14]. Furthermore, studies reported inconsistent recurrence rates in both groups, one study showing lower and another reported higher recurrence rate in ZF[15–18]. These findings are leading to some experts questioning whether ZF can match the accuracy of fluoroscopy-guided techniques.

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A previous systematic review evaluated ZF ablation in AF. However, it included low-fluoroscopy or fluoroless procedures within the ZF group, meaning the comparison was not strictly between pure ZF and conventional fluoroscopy-guided ablation[19]. Even low-dose fluoroscopy carries health risks[20, 21]. Ideally, ZF should refer only to techniques that completely eliminate fluoroscopy exposure. Therefore, we conducted a systematic review and meta-analysis comparing pure ZF (true zero fluoroscopy) with non-zero fluoroscopy (NZF), including both high- and low-dose fluoroscopy approaches.

2. METHOD

This systematic review and meta-analysis were conducted according to Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guideline 2020[22]. This study was registered under the identifier: CRD420261367316.

Inclusion and Exclusion Criteria

Inclusion criteria were as follow: (1) randomized controlled trial (RCT) or non-randomized cohort directly compared ZF and NZF in radiofrequency catheter ablation in AF population (persistent or paroxysmal) proved by electrocardiography (ECG) test; (2) ZF modality used were ZF with pure zero fluoroscopy, proved by average fluoroscopy dose was either 0 mGy/cm^2, 0 mSv, or average fluoroscopy time was 0 minutes in the study, meanwhile NZF is the modality with average fluoroscopy dose or time above 0; (3) studies published in English. Exclusion criteria were: review articles, case reports, case series, letters to editor, and observational studies not directly compared ZF and NZF.

Data Search and Extraction

A systematic search of studies was conducted in four databases, PubMed, Scopus, Cochrane Central Register of Controlled Trials (CENTRAL), and ScienceDirect from December 21 to December 24, 2024. The search on Scopus and CENTRAL was conducted using the keywords: (“zero fluoroscopy” OR “non fluoros*”) AND (“ablation” OR ‘isolation’) AND (“atrial fibrillation”). The search on PubMed was conducted using the keywords: (“zero fluoroscopy” OR “non fluoros*”) AND (‘ablation’ or “isolation”) AND (“atrial fibrillation” [MESH]). Searches on ScienceDirect were conducted using the keywords: (“zero fluoroscopy” OR “non fluoroscopy”) AND (‘ablation’ OR “isolation”) AND (“atrial fibrillation” OR “AF”). From the study data obtained, title, abstract, and full text screening were performed by 2 authors independently (EMK and NES) with any conflicts arising to be resolved by a third party (CDT).

From the studies included, following data were then extracted: (1) first author, (2) study design, (3) mean age of patients and total number of patients in each group (ZF and NZF), (4) total number of patients converted to NZF, (5) type of ZF modality, (6)

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mean radiation dose in the NZF group, and (6) outcomes. The primary outcomes were ZF effectivity in terms of the success rate of pulmonary vein isolation (PVI), recurrence rate of AF, and average procedural time. The average procedural time is calculated from the moment the catheter is inserted through the femoral vein, through mapping, until the ablation energy is fully administered. The secondary outcome was the safety of ZF.

Study Quality Assessment

In this study, we used 2 study quality assessment tools. For RCT, we used A Revised Tool for Assessing Risk of Bias in Randomised Trials (RoB2), while nonrandomized cohort studies evaluate with Risk of bias in Non-randomized studies-of Interventions (ROBINS-I). Two authors independently assess the studies quality (NES and EMK), with conflicts resolved by a third party (CDT).

Statistical Analysis and Result Synthesis

R Studio version 4.4.1 (Posit PBC, Boston, USA) was used for statistical analysis. I^2 statistics will be used to evaluate heterogeneity, that were defined as low (25%), moderate (26 50%), and high (>50%). For outcomes with high variability that precluded meta-analysis, a qualitative was performed by assessing the direction of effect with albatross plot visualization and combining p-values to determine the signification.

Certainty of evidence will be assessed using the GRADE framework. Two authors (NES and CDT) will independently assess the certainty of evidence, with any conflicts resolved through a third party (II)

3. RESULT

General Information, Study Characteristic and Quality

A total of 419 studies were identified by initial database search. After duplication removal, 192 studies remained for title and abstract screening. Subsequently, 28 studies passed screening and underwent full-text screening. At the end, 8 studies met the inclusion and exclusion criteria were include and will be analyzed in this study. The PRISMA flowchart process is available in Figure 1.

Out of 8 studies, 1 study was RCT, 3 were non-randomized retrospective cohort, and 4 were non-randomized prospective cohort conducted internationally, with total 1.331 patients. The ZF approach involved 3D-EAM and ICE-guided pulmonary vein access via transeptal route. One patient in ZF group was converted to the NZF group to confirm proper sheath placement in the left femoral vein after the patient reported persistent pain despite repeated local anesthetic injections, thus this patient was excluded from the final analysis[18]. Detail characteristics of each

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study are presented in Table 1. After quality assessment, five studies had a low risk of bias, 1 study had a moderate risk of bias, and 2 studies had a high risk of bias as shown in Figure 2.

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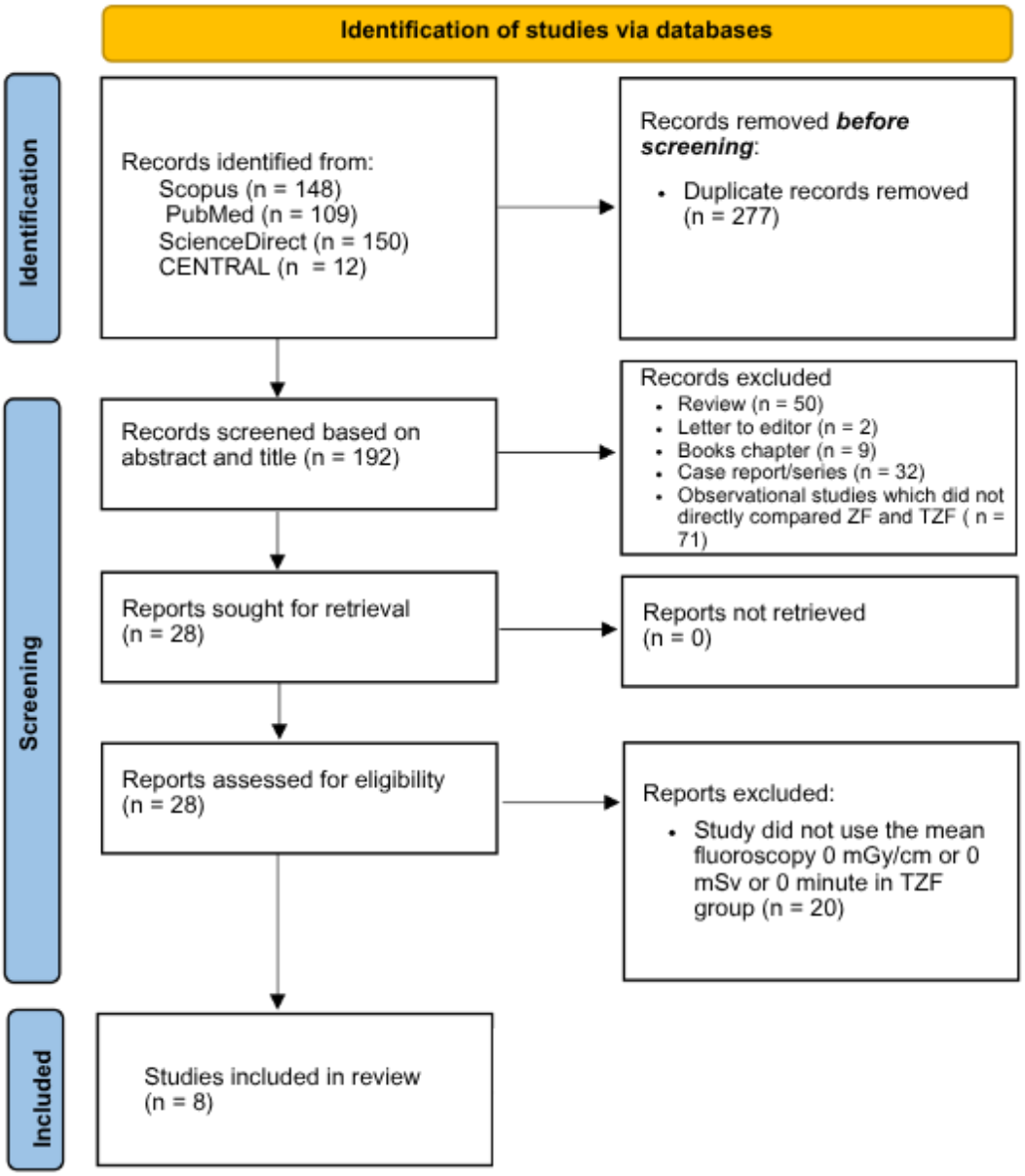

Figure 1. PRISMA Flowchart

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Table 1. Study Characteristic

Author (Year)	Study Design	Mean Age TZF (year)	TZF total patient	Mean Age NZF (tahun)	NZF total patient	TZF patient that was converted to NZF	TZF Type	AF Characteristic	Fluoroscopy Dose ± SD in NZF (mGy/cm2)
Bulava et al. (2015)[23]	RCT	61.6 ± 9.9	40	60.2 ± 11.1	40	1	CARTO dan ICE	Paroxysmal AF	3062 ± 1585
Lyan et al. (2018)[24]	Non-randomized retrospective cohort	59.7±11.3	245	60.8±10.6	236	0	CARTO dan ICE	Paroxysmal AF	16352.7 ± 13714.1
Zhang et al. (2020)[25]	Non-randomized prospective cohort	58.1 ± 11.3	27	62 ± 9.6	30	0	CARTO dan ICE	Paroxysmal AF	70.5 ± 13.5
Zei et al. (2020)[26]	Non-randomized prospective cohort	62 ± 8.4	100	63 ± 8.9	60	0	CARTO dan ICE	Paroxysmal dan persisten AF	1250 ± 514.86
Gul et al. (2021)[27]	Non-randomized retrospective cohort	61.9 ± 10.6	116	62.6 ± 10.6	131	0	CARTO dan ICE	Paroxysmal dan persisten AF	Tidak tersedia
Hang et al. (2021)[28]	Non-randomized	59.7 ± 8.7	55	58.5 ± 10.0	55	0	CARTO dan ICE	Paroxysmal AF	109.1 ± 57.9

	prospective cohort								
Zhou et al. (2023)[29]	Non-randomized retrospective cohort	62.31±10.8	48	60.31±9.28	49	0	CARTO dan ICE	Paroxysmal dan persisten AF	77.1 ± 44.3
Torma et al. (2024)[30]	Non-randomized prospective cohort	68 (57.5; 73)	50	69.5 (58; 72.3)	50	0	CARTO dan ICE	Paroxysmal dan persisten AF	4.8 ± 1.05

ZF: zero-fluoroscopy; NZF: non-zero fluoroscopy; SD: standard deviation; AF: atrial fibrilasi; ICE: intracardiac echocardiography

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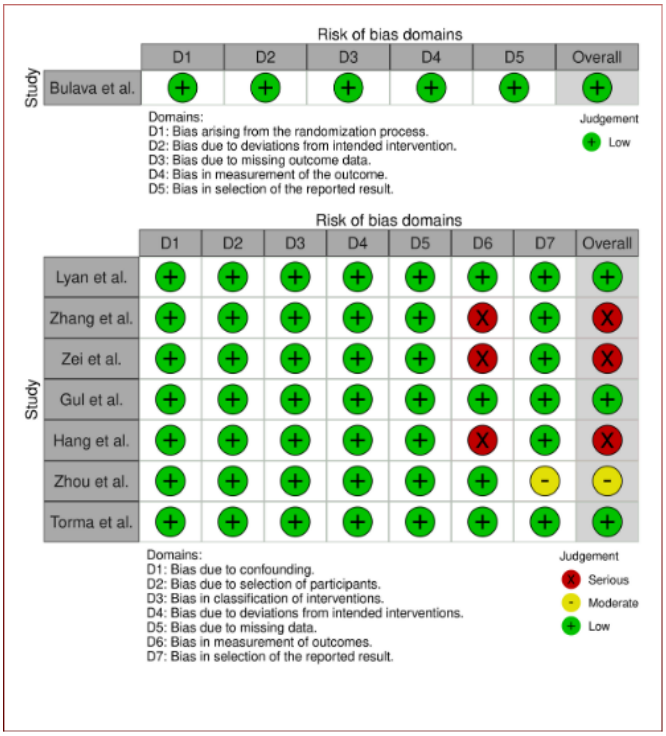

Figure 2. Risk of Bias

Zhang et al., Zei et al., and Hang et al. reported a high risk in domain 6 because they reported the procedural time from when the patient entered the catheter lab to when they left, which could cause assessment bias. However, this risk did not affect the results because it was not included in the analysis. Zhou et al. reported a moderate risk in domain 7 because they did not report safety indicators.

Pulmonal Vein Isolation Success

PVI success was generally associated as the main indicator short term AF ablation succession. Out of 8 studies, 5 indicated a PVI success rate. Five studies revealed consistent results with 100% OVI success rate for all patients without cardiac arrest during the course of procedure, in both TZF and NSF, indicating its equal short-term efficacy[15, 18, 31–33].

Recurrence Rate

AF recurrence is the primary outcome used to determine the long-term success of AF ablation. Seven studies reported recurrence rates[15–18, 31, 32]. Gul et al. (2021) reported comparable recurrence rate at 3-months follow up (17/116 vs 25/131; $p<0.05$). Two studies reported recurrence at 6-months follow up. Our meta-analysis (Figure 3.A.) showed comparable rates between group (RR = 1.00; 95% CI: 0.90 – 1.11; p = 0.99; I^2 = 0%)[15, 16]. Three studies reported 12-months follow-up then we performed meta-analysis (Figure 3.B). The result also showed comparable recurrence rate[17, 18, 32]. Although the funnel plot was asymmetry (Figure 4), Egger's regression test

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revealed no significant publication or small-sample bias (intercept: 2.99; p = 0.46). Lyan et al. (2018) reported comparable recurrence rate at 15-months follow-up (62/245 vs 61/245; p > 0.05).

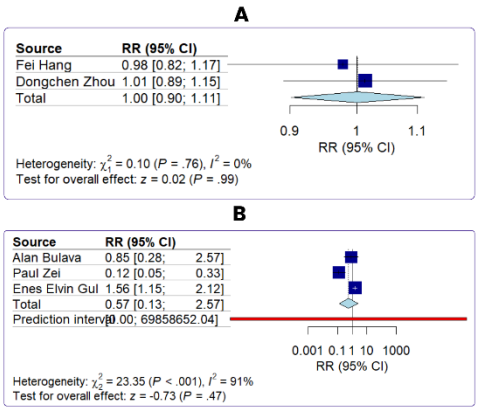

Figure 3. Forest-plot of Recurrence Rate. (A) 6-months Follow-up; (B) 12-Months Follow-up.

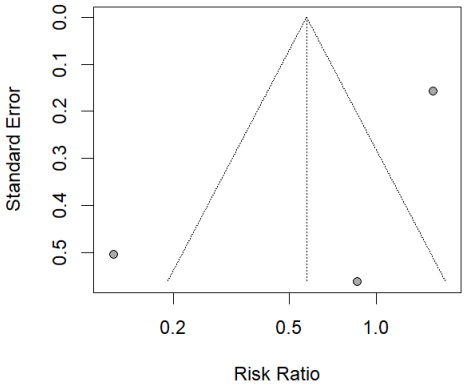

Figure 4. Funnel Plot of 12-months Follow-up Recurrence Rate

Procedural Time

Procedural time was defined as the average duration time of the procedure, measured from the catheter insertion to femoral vein, mapping, until the completion of ablation energy delivery. Four studies reported procedural time[17, 18, 31, 32]. The meta-analysis result (Figure 5.A.) showed that the procedural time was significantly lower in TZF than NZF (MD = -5.9; 95% CI = (-9.2) – (-2.61); p < 0.001). This result was robust based on leave-one-out analysis (Figure 5.B).

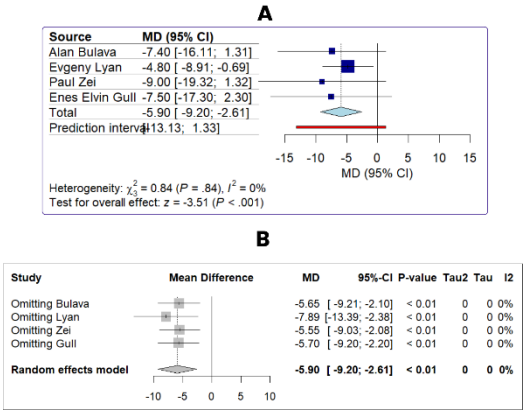

Figure 5. (A) Forest-plot of Procedural Time; (B) Sensitivity analysis using leave-one-out technique.

Safety Profile

Two study reported cardiac tamponade adverse events[17, 31]. The meta-analysis showed no significant difference between ZF and NZF (RR = 1.77; 95% CI = 0.37 – 8.37; p = 0.47).

Other procedural complications were reported to be comparable between the two groups. Bulava et al. observed no procedural complications in either group[18]. Lyan et al. also reported no complications other than cardiac tamponade in both groups[31]. Zei et al. identified one case of thigh hematoma in the NZF group, while Zhang et al. reported no additional procedural complications[32, 34]. Gul et al. found comparable rates of left leg hematoma between

groups (1/116 vs 4/131; p = 0.2), and Torma et al. similarly reported no procedural complications in either group[17, 33]. Overall, the ZF approach appears safe and does not increase the risk of significant complications. Although complications such as cardiac tamponade, pericardial effusion, and minor procedural events remain inherent risks of AF ablation, there is no significant evidence that ZF carries a higher risk compared with NZF.

Certainty of evidence

Across quantitative outcomes, our certainty of evidence yielded a low quality. The evidence was downgraded due to only included observational studies and limited number of patients (Table 2).

4. DISCUSSION

This systematic review and meta-analysis evaluated the efficacy and safety of true zero-fluoroscopy (TZF) catheter ablation compared with non-zero fluoroscopy (NZF) in patients with atrial fibrillation (AF). By strictly including studies that applied pure zero fluoroscopy, it provides a more precise evaluation of radiation-free ablation strategies, and overall, TZF demonstrated non-inferior procedural success and long-term rhythm outcomes, with a significantly shorter procedural time and a comparable safety profile.

Our result showed that PVI success was comparable between ZF and NZF, confirming that fluoroscopy is not essential for achieving procedural success. Despite ZF providing operator to have limited visualization, the combination 3D-EAM and ICE appeared sufficient to guide catheter insertion, right atrial mapping, transseptal puncture, and precise ablation within the pulmonary veins. These processes can be done without X-ray imaging[35, 36]. Therefore, when performed appropriately, ZF can achieve equivalent short-term efficacy, although operator expertise in anatomical mapping remains a critical factor[37].

Regarding recurrence rates, pooled analyses at multiple follow-up intervals (6 and 12 months) demonstrated no significant difference between groups. These findings suggest that atrial substrate characteristics, particularly the extent of fibrosis, independently predict post-ablation recurrence, indicating that long-term rhythm outcomes are driven more by tissue properties than by procedural guidance alone[38]. The absence of significant publication bias further strengthens the validity of these results, supporting that eliminating fluoroscopy does not compromise long-term effectiveness.

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Table 2. Certainty of Evidences

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Usual Care	**Risk with TZF**				
Recurrence rate at 6-months	857 per 1,000	**857 per 1,000** (771 to 951)	**RR 1.00** (0.90 to 1.11)	174 (2 non-randomised studies)	⊕⊕◯◯ Low	TZF was comparable to NZF in early-reccurence outcome
Reccurence rate at 12-months	327 per 1,000	**186 per 1,000** (42 to 839)	**RR 0.57** (0.13 to 2.57)	478 (3 non-randomised studies)	⊕⊕◯◯ Low	TZF was comparable to NZF in late-reccurence outcome
Procedural Time		MD **5.9 Minutes fewer** (9.2 fewer to 2.61 fewer)	-	967 (4 non-randomised studies)	⊕⊕◯◯ Low	TZF resulted in significantly lower mean procedural time compared to NZF

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

Interestingly, ZF was associated with significantly shorter procedural time. While NZF requires additional time for fluoroscopic positioning and adjustment, ZF relies directly on continuous 3D-EAM and ICE visualization[6, 33, 36, 39]. Shorter procedural duration may implied in: (1) eliminating occupational radiation exposure in patient and operator; (2) reduce anesthesia-related risks such as hypotension, hypoventilation, and apnea in patients[40]; (3) decrease operator fatigue[10, 39].

TZF showed comparable risk of cardiac tamponade and other procedural complications[17, 18, 31–34]. These findings indicate that that ICE-guided visualization is adequate to maintain procedural safety without fluoroscopy. There is no evidence suggesting that TZF increases major or minor complication risks compared with NZF.

This study has several strengths, including multicenter international data and the strict inclusion of true zero-fluoroscopy techniques. However, there are limitations to be acknowledged. First, most included studies were observational. Second, we were unable to stratify outcomes based on AF type (paroxysmal and persistent) and operator experience, which became the confounding factors and may influence the recurrence and procedural time.

5. CONCLUSION

TZF catheter ablation for atrial fibrillation (AF) demonstrating non-inferiority to NZF in efficacy without compromising safety; with advancements in operator experience and technology, TZF has potential to become the standard replacement for conventional ablation methods, offering significant benefits for both patients and operators.

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