BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (http://bmjopen.bmj.com).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

BMJ Open

Safety and efficacy of steerable versus non-steerable sheaths for catheter ablation of atrial fibrillation-An updated systematic review and meta-analysis

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-068350
Article Type:	Original research
Date Submitted by the Author:	15-Sep-2022
Complete List of Authors:	Jin, Xinyao; Hangzhou Red Cross Hospital, Zhou, Yuqing; The First College of Clinical Medicine, Zhejiang Chinese Medical University, Hangzhou, Zhejiang, China. Wu, Yuanhong; Hangzhou Red Cross Hospital Xie, Mingbin; Hangzhou Red Cross Hospital
Keywords:	Pacing & electrophysiology < CARDIOLOGY, Adult cardiology < CARDIOLOGY, Audit < CARDIOLOGY

SCHOLARONE™
Manuscripts

BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

Safety and efficacy of steerable versus non-steerable sheaths for catheter ablation of atrial fibrillation-An updated systematic review and meta-analysis

Xinyao Jin[1]; Yuqing Zhou[2]; Yuanhong Wu[1] ; Mingbin Xie[1]

Summary

Background With the development of radiofrequency ablation technology in recent years, more and more patients with atrial fibrillation have been treated with radiofrequency ablation. Steerable sheaths have been widely used in radiofrequency ablation of atrial fibrillation. The aim of this meta-analysis was to compare the efficacy and safety of atrial fibrillation ablation using steerable and non-steerable sheaths.

Methods From inception to March 2022, we conducted a comprehensive, systematic search of the databases Pubmed, MEDLINE, EMBASE, web of science and the Cochrane Library to finalize the study. The effects were calculated using pooled odds ratio (OR) and mean difference (MD) for categorical and continuous data. And we also estimated the 95% confidence interval (CI).

Results Five studies of radiofrequency ablation of AF were selected, three prospective and two retrospective, involving 282 steerable and 236 non-steerable sheath ablation patients. The rate of recurrence of AF or atrial arrhythmias was 27.3% versus 43.6% (OR: 0.50, 95% CI: 0.35 to 0.73, Z = 3.59, P = 0.00003) and acute PVs (8.7% vs 17.4%, OR: 0.47, 95% CI: 0.23 to 0.95, Z = 2.10, P = 0.04); In the steerable sheath group and the non-steerable sheath group, the total ablation time (P = 0.25), fluoroscopy time (P = 0.26) and total operative time (P = 0.35) were not significantly different.

Conclusion The steerable sheath for AF ablation could effectively reduce the AF recurrence rate and the incidence of acute PVs.

Key word atrial fibrillation, catheter ablation, steerable sheath, non-steerable sheath, Meta-analysis

1 Introduction

Since Haissagurer et al. Reported that the rapid impulse issued by the ectopic excitation center in the pulmonary vein triggered and driven AF through the electrical connection with the atrium[1]. Ablation of the electrical connection site was the radical treatment of AF, which laid the theoretical basis for the treatment of AF by pulmonary vein vestibular electrical isolation(PVI). With the development of technology, radiofrequency ablation is widely used in the treatment of atrial fibrillation, which greatly reduces the recurrence of atrial fibrillation, effectively prevents the

Xinyao Jin and Yuqing Zhou contributed equally to this work.

Corresponding author：Xie Mingbin ORCID：0000-0002-1875-2505
hz_xiemingbin@163.com
1 Department of Cardiology, Affiliated Hangzhou Chest Hospital, Zhejiang University School of Medicine (HangZhou Red Cross Hospital), Hangzhou, Zhejiang, China.
2 The First College of Clinical Medicine, Zhejiang Chinese Medical University, Hangzhou, Zhejiang, China.

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

occurrence of heart failure and embolism events, prolongs patients' life and improves their quality of life. [2-4]. In clinical practice, pulmonary vein reconnection still occurs in large numbers after the first ablation due to non-continuous ablation line, focal non-transmural lesions and tissue edema caused by ablation head displacement, which greatly increases the recurrence rate of atrial fibrillation[5-7]. Therefore, stable, repeatable and reliable attachment to the ablation target during the ablation process has become one of the keys to the success of ablation[8-12], which goes beyond the use of traditional fixed curve sheaths. In prior practice, steerable sheaths have been widely used in radiofrequency ablation of AF and improved catheter navigation, catheter stability, and LA wall contact, so as to provide stable transmural ablation lesions and reduce reconnection of pulmonary veins to reduce AF recurrence[9]. However, we know that the Comparison of steerable and non-steerable sheaths in radiofrequency ablation of atrial fibrillation has not been systematically evaluated and analyzed. Therefore, our meta-analysis is to compare the outcomes and safety of RF ablation of AF using steerable and non-steerable sheaths, in order to provide reliable evidence for clinical practice.

2 Method

2.1 Search strategy

We conducted and reported this systematic review according to the PRISMA guideline criteria. This systematic review was conducted pursuant to a forward-looking agreement and was not registered with any external entity. Two researchers (Jin and Zhou) searched 3 databases: Pubmed, MEDLINE, EMBASE, web of science, the Cochrane Library. It was limited to English literature, and there are no specific date, sex and age restrictions. The coverage dates for this review began from each database's inception and ended on 22 March 2022. The search strategy consisted of four core components, which were linked using the AND operator: 1) clinical trials(e.g., therapeutic studies, human cohort trials); 2) atrial fibrillation(e.g. paroxysmal atrial fibrillation and persistent atrial fibrillation); 3) sheath(e.g., steerable sheaths, navigable vascular sheaths, non-steerable sheaths, fixed curve sheaths); 4) Radiofrequency ablation(e.g., pulmonary vein isolation, pulmonary vein vestibule isolation and circumferential pulmonary vein isolation). MESH and keywords were identified for each of the 4 keywords to complete the search and were reviewed by an independent expert (consultant) from an external institution. In addition, We manually reviewed the reference lists of previously included trials and retrieved key articles to further complete the relevant study.

2.2 Study selection

The title and abstract of the study were independently selected by two researchers (Jin and Zhou). The disagreement was decided by the third examiner (Xie). All studies considered to meet the screening criteria for title and abstract were reviewed in full by 2 independent reviewers (Jin and Zhou) using the same criteria. The participation of the third reviewer (Xie) in the discussion was used to resolve the inconsistency. Articles were filtrated and identified according to the following inclusion criteria: 1) all AF catheter ablation relevant clinical studies were original articles published in English; 2) Full text and complete data could be provided(if the data is incomplete, complete data can be provided after contacting the author); 3) Case-control study (including prospective cohort study or retrospective cohort study design); 4) The primary end points of the study were recurrence of atrial fibrillation and atrial arrhythmias, and surgical complications. 5) The secondary end points were acute pulmonary vein reconnection (PVs), ablation time, fluoroscopy time and total procedure time. 6) The object of study was human being, but not animal or tissue. The exclusion criteria were

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

as follows: 1) case reports, conference abstracts, and animal experiments; 2) Studies reporting incomplete or irrelevant data; 3) Studies that didn't use steerable sheath; 4) Studies using methods other than radiofrequency ablation (such as cryoablation and pulse ablation).

2.3 Data Extraction, Results, and Quality Assessment

The standardized protocol and reporting forms was used to extract data on study characteristics (year of publication, study design, authors, year of publication), study questions (sample size, AF type, sheath type, duration, baseline characteristics) and results (outcomes, key findings). Two paired reviewers ((Jin and Zhou) independently extracted this information from each study and resolved any disagreements through discussion. The primary end points were the rate of recurrence of AF and atrial tachyarrhythmias after surgery and intraoperative complications during follow-up. Secondary endpoints included PVs acute reconnection, ablation time, fluoroscopy time, and total procedure time. Risk bias was assessed independently by two reviewers (Jin and Zhou) using the Newcastle Ottawa scale(NOS) for the quality of the selected studies. Any disagreement was then resolved through the participation and discussion of the third reviewer (Xie).

2.4 Statistical analysis

All extracted data were summarized and analyzed by using Review Manager version 5.3 software (Copenhagen: Nordic Cochrane Centre, Cochrane Collaboration, 2014). We used odds ratio (OR) and respective 95% confidence intervals (95% CI) to compare differences for dichotomous variables and calculated weighted mean difference (WMD) or standard mean difference (SMD) and respective 95% confidence intervals (95% CI) to analyze continuous variables. A Cochrane's Q p-value < 0.05 was considered significant. With a 95% confidence interval, the statistic I2 was interpreted as follows: $\geqslant$ 50% reflectd high heterogeneity between studies, and $<$ 50% indicated low heterogeneity. In the case of low heterogeneity, we used the fixed effects model; When heterogeneity was significant, a random effects model was used. Study possible publication bias was assessed by funnel plot.

3 Results

3.1 Study and Data Selection

The results of the detailed search process were shown in Fig. 1. 333 potentially relevant records were obtained in our search strategy, of which 175 were excluded as duplicates. Of the remaining, 149 studies were excluded after title and abstract reviewed. After detailed assessment of the full text, further 4 studies were excluded due to the following: 2 uncontrolled trials, 1 using VIZIGO bi-directional sheath, 1 reporting duplicate date. In the end, we selected 5 studies in this meta-analysis.

3.2 Study Characteristics and Quality Assessment of Included Studies

From the selected studies, there were 518 subjects, of which 282 (54.4%) in the steerable sheath group and 236 (45.6%) in the non-steerable group. The characteristics of the 5 studies were summarized in Table 1. The incidence of paroxysmal AF was 69%, and the Christopher Piorkowski et al.[13-14], Kim Rajappan et al.[15], Marc W. Deyell et al.[16] and Masaharu Masuda et al.[17] included all subtypes of AF. Steering sheaths used in selected studies included non-steerable transseptal sheath (Mullins; Cook Inc., Bloomington, IN, USA) , aconventional non-steerable sheath (Swartz SL0, St Jude Medical), controlled steerable sheath (Agilis, St. Jude Medical, St. Paul, MN, USA). The follow-up in the 3 studies was 6 months after the first surgery, but 12 $\pm$ 2 months in the study by Masaharu Masuda et al.[17], 3 months in the study by Marc W. Deyell et al.[16]. There were no significant differences between the two groups in terms of mean age, proportion of males,

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

hypertension ratio, duration of AF, mean left atrial (LA) diameter, and proportion of underlying cardiac disease.

3.3 Main clinical outcomes

The primary end point of the included study was the time to recurrence of AF with a duration ⩾ 30s on holter in 3-12 months after radiofrequency ablation. Christopher Piorkowsk et al.[13-14], Kim Rajappan et al.[15], Marc W. Deyell et al.[16] and Masaharu Masuda et al.[17] reported statistically significant differences in AF and atrial tachyarrhythmias recurrence rates after AF ablation procedures. The frequency of AF and atrial tachyarrhythmias recurrence was favorable for steerable sheath compared to non-steerable sheath groups (27.3% versus 42.8%, OR: 0.52, 95% CI: 0.36 to 0.76, Z = 3.41, P = 0.0006; Fig. 2A). The fixed-effects model was chosen because heterogeneity was not significant ($\chi 2 = 4.04$, df = 4, I2 = 1%, P = 0.4).

This study showed no statistically significant difference in complication rates between the test and control groups (4.9% versus 4.4%, OR: 1.03, 95% CI: 0.42 to 2.56, Z = 0.07, P = 0.94, Fig. 2B) and the fixed effects model was selected ($\chi 2 = 0.97$, df = 3, I2 = 0%, P = 0.81). The hematomas in the groin and femoral vein were the most common complications during and after surgery. One patient in the steerable sheath group reported by Christopher Piorkowsk et al.[13] had a peri-interventional stroke with minimal residuals during follow-up; One patient had a pseudoaneurysm at the femoral access site that had to be surgically resolved; In the non-steerable sheath group, 2 patients had cardiac tamponade requiring pericardiocentesis and 1 patient had phrenic nerve palsy, which resolved during follow-up.

3.4 Secondary Clinical Outcomes

Christopher Piorkowski et al.[13] reported fewer acute pulmonary vein reconnections in the steerable sheath group compared to the non-steerable sheath group (11.1% in the steerable sheath versus 20.0% in the non-steerable). The results were similar to those reported by Marc W. Deyell et al.[16] and Masaharu Masuda et al.[17] The description of acute reconnection of PV was not addressed in the study by Kim Rajappan et al.[15] In the pooled analysis of five studies, The steerable sheath group was superior to the non-steerable sheath group in reducing the risk of PV reconnection (8.7% versus 17.4%, OR: 0.47, 95% CI: 0.23 to 0.95, Z = 2.1, P = 0.04, I2 = 0%; Fig. 3A).

In all studies, there was no statistically significant difference in ablation time in the steerable sheath group compared to the non-steerable sheath group. After pooled analysis, the steerable sheath group was no better than the non-steerable sheath group in reducing ablation time (WMD = − 3.6, 95% CI: − 9.77 to 2.57, Z = 1.14, P = 0.25, I2 = 72%; Fig. 3B); Total procedure time did not differ between two groups (WMD = − 3.11, 95% CI: − 9.63 to 3.42, Z = 0.93, P = 0.35, I2 = 26%; Fig. 3C).Christopher Piorkowski et al.[13] reported shorter fluoroscopy time in the steerable sheath group compared to the non-steerable sheath group (33 ± 14 minutes in the steerable sheath versus 45 ± 17 minutes in the non-steerable, P < 0.001). Other studies reported no significant difference in fluoroscopy time between the two groups. In pooled analysis, the steerable sheath group was no better than the non-steerable sheath group in reducing fluoroscopy time (WMD = − 3.32, 95% CI: − 9.10 to 2.47, Z = 1.12, P = 0.26, I2 = 90%; Fig. 3D).

Risk of bias in included studies

For the analysis of AF recurrence rate, the funnel plot was symmetric, so we think there was no significant publication bias (Fig. 4).

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

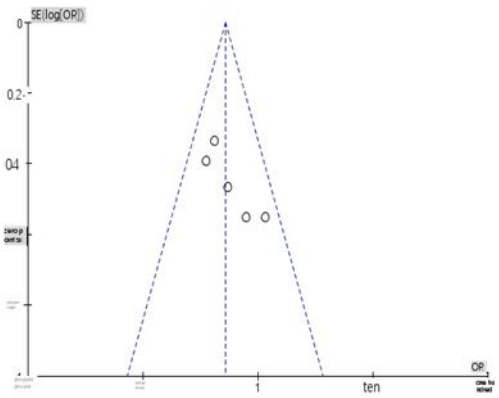


Figure 4 Funnel plot of comparison: SS/FS, outcomes: AF recurrence rate

4. Discussion

This meta-analysis showed that there was no significant difference in clinical complications between AF ablation with steerable sheaths and non-steerable sheaths, suggesting that both steerable and non-steerable sheaths are safe and effective for AF ablation. However, in reducing the incidence of atrial fibrillation, rapid atrial arrhythmia and pulmonary vein connection, Steerable sheaths have significant advantages over fixed curved sheaths.

Radiofrequency catheter ablation (RFCA) has developed as the recommended treatment for atrial fibrillation, and circumferential pulmonary vein antrum isolation is considered to be the cornerstone for the treatment of paroxysmal and persistent atrial fibrillation[1-4]. However, similar to other long left atrial ablation lines, continuous and transmural ablation of these lesions is often difficult to achieve. Therefore, in clinical practice, due to the following reasons:1) Incomplete isolation of pulmonary veins; 2) Distant pulmonary vein isolation; 3) The occurrence of pulmonary vein reconnection lead to the occurrence of atrial fibrillation and atrial arrhythmia in a large number of patients, which greatly reduces the success rate of radiofrequency ablation[6,18,19]. Therefore, the duration and transmural lesions of PVI(pulmonary vein isolation) are critical to reduce AF recurrence. But during actual manipulation, It is a major challenge for the interventionalist to attempt a complex 3D ablation line in the pulmonary vein vestibule in an organ which moves with the respiratory rate, requiring a stable catheter and adequate tissue contact in order to achieve the desired ablation goal (transmural ablation with long duration). In recent years, steerable transseptal sheaths and fixed curve sheaths have been widely used in clinical radiofrequency ablation. The steerable sheath is convenient to enter and contact the ablation target, which is conducive to the continuity, maintenance and transmurality of the ablation target, and has been paid more and more attention and used in clinical practice[8-12]. Studies have shown that steerable sheaths used for AF ablation are more effective and have comparable safety to conventional fixed curve sheaths[13-17]. However, the steerable sheath has a higher price than the fixed curve sheath, which requires patients to bear more equipment costs and becomes the concern of clinical surgeons. Therefore, we need a meta-analysis to evaluate and clarify the clinical impact of radiofrequency ablation under steerable sheath navigation, so as to provide a basis for clinical practice.

The advantage of using the steerable sheath for navigation may be due to the fact that the ablation tip is passively steered relative to the sheath itself and is only pushed and retracted within the sheath based on electrogram, fluorogram, and three-dimensional tactile information, which greatly improves the stability and steerability of the ablation tip[9]. It also allows the head ablation control

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

in the millimeter range at the preset ablation target, which greatly reduces the occurrence of leakage points during ablation (eventually leading to acute reconnection of pulmonary veins). In addition, precise navigation of the ablation head provides the basis for reliable pacer and voltage mapping to find gaps in the complex 3-D PV anatomy to improve achievement of complete PVI[20]. Second, the pressure that could be applied through the tip of the ablation catheter was higher, which makes it possible to achieve transmural ablation of thicker regions of the left atrium (usually anterior to the left and right sided PVs)[21,22]. This is also confirmed by Masaharu Masuda et al.[17], when using the steerable sheath, the CF of the ipsilateral pulmonary vein vestibule was higher than that by using the fixed curve sheath. In the same area, CF value was only 5g when using fixed sheath, but almost doubled when using steerable sheath. The stability of the target may also reduce tissue edema caused by catheter instability due to heart beating. Moreover, more stable transmural ablation reduces the incidence of acute PV reconnection, as confirmed by this meta-analysis.

The study by Kim Rajappan et al.[15] further showed that the use of the steerable sheath for right inferior pulmonary vein ablation could reduce CT registration time as well as ablation time. This may be due to the fact that the right lower pulmonary vein is relatively more difficult to place and attach by using the fixed curved sheath, while the steerable sheath can use the inverted U technique to quickly attach to PVs, which can build 3D models flexibly. This also greatly reduces the impact of the learning curve and manipulation experience of young interventionalists on RF ablation.

Access with a larger transseptal sheath and ablation with more catheter tip pressure often raise safety concerns for the interventionalist during the procedure. In complications, there is no higher overall complication rate with steerable sheath. However, thicker sheaths have a direct correlation to single complications such as femoral vein injury and hematoma.

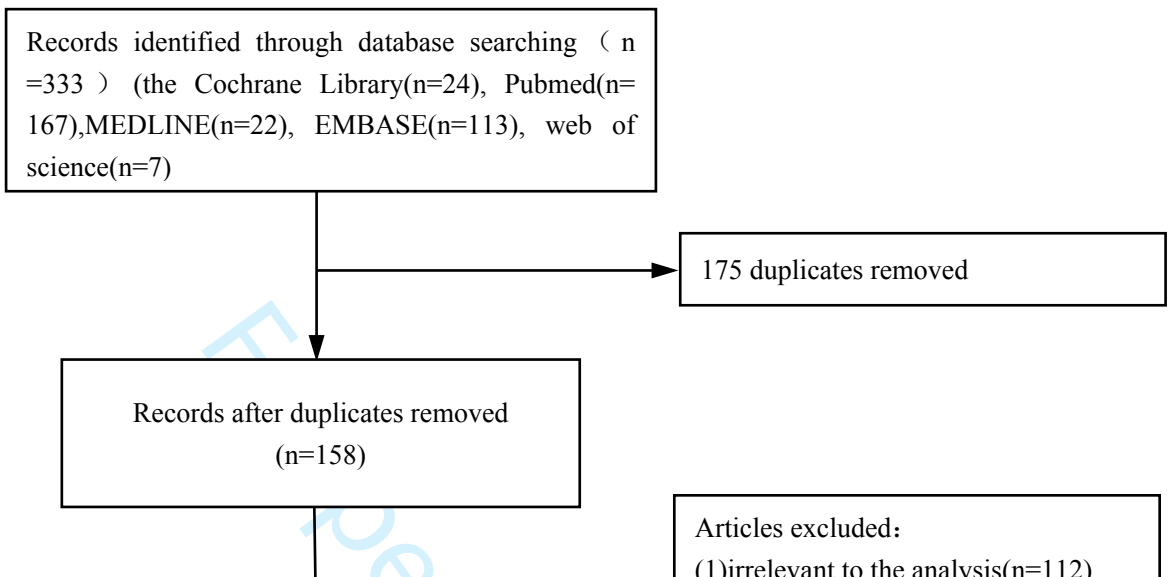
Limitations There are some limitations to this study. First, all included studies are partly retrospective or non-randomized observational cohort studies. Secondly, in these studies, the force-time index or other ablation index are not mentioned. This data is reproducible in some clinical ablation treatments and is gaining increasing acceptance. If available, it will provide a firmer basis for clinical selection of steerable sheath. Finally, our sample size was small, with a minimum follow-up of 3 months and a maximum follow-up of 12 months. Therefore, the effect of selective sheath on AF recurrence in long-term follow-up is uncertain. To confirm the findings in our study, we need more randomized studies with larger sample sizes and longer follow-up.

Conclusion Compared with traditional fixed sheath, catheter ablation of AF with steerable sheath has better efficacy, which can effectively reduce the recurrence rate of atrial fibrillation and the occurrence of acute PVs. However, it can not shorten the procedure time and reduce complications.

For Peer Review Only

Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Figure 1 The flowchart of the literature search process



Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

Table 1 Baseline characteristics of included studies

First author (year)	Study design	Sample size		Age		Male		PAF	AF duration		LA size		Hypertension		Structural heart disease		Follow-up (month)
		SS	FS	SS	FS	SS	FS	(n)	SS	FS	SS	FS	SS	FS	SS	FS	
Christopher Piorkowski MD 2011[13]	Prospective observational	63	60	57±9	62±9	44 (70)	35 (58)	64%	46	55	43 ± 6	40±6	42 (67)	40 (67)	16(25.4)	22(36.7)	6
Christopher Piorkowski M.D.2008[14]	Retrospective observational	83	83	55 ±9	55 ± 9	61 (73)	61 (73)	80%	52	54	36 ± 13	38±8	34 (41)	34 (41)	13(15.7)	13(15.7)	6
Kim Rajappan2009[15]	Prospective observational	27	27	57±10	54±10	19	20	50%	53±31	61±41	41±6	44±8	NA	NA	10(37)	7(26)	6
Marc W. Deyell2020[16]	Retrospective observational	52	33	56.6±13.1	61.2±11.7	36	20	69.40%	NA	NA	41.8 ±6.4	40.3 ±7.2	21 (40.38)	16 (48.48)	NA	NA	3
Masaharu Masuda2016[17]	Prospective observational	57	33	67 ± 11	66± 11	39 (68)	24 (73)	67%	29 ± 36	25± 26	40 ± 7	38± 6	33 (58)	22 (67)	NA	NA	12±2

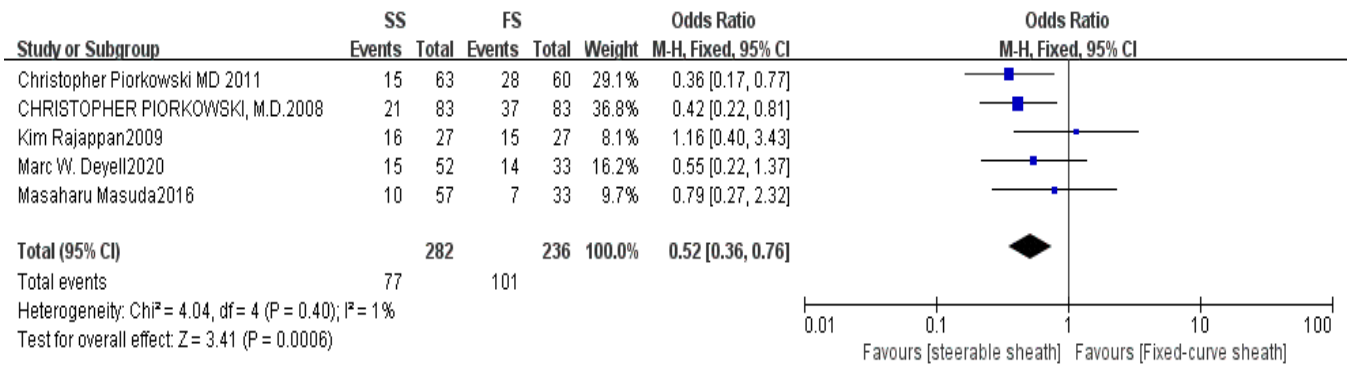
SS steerable sheath, FS Fixed-curve sheath, PAF paroxysmal atrial fibrillation, AF atrial fibrillation, LA left atrium, N/A not available/applicable;

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

http://bmjopen.bmj.com/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

(A) **Recurrence of atrial fibrillation and atrial arrhythmias**



(B) **Complications**

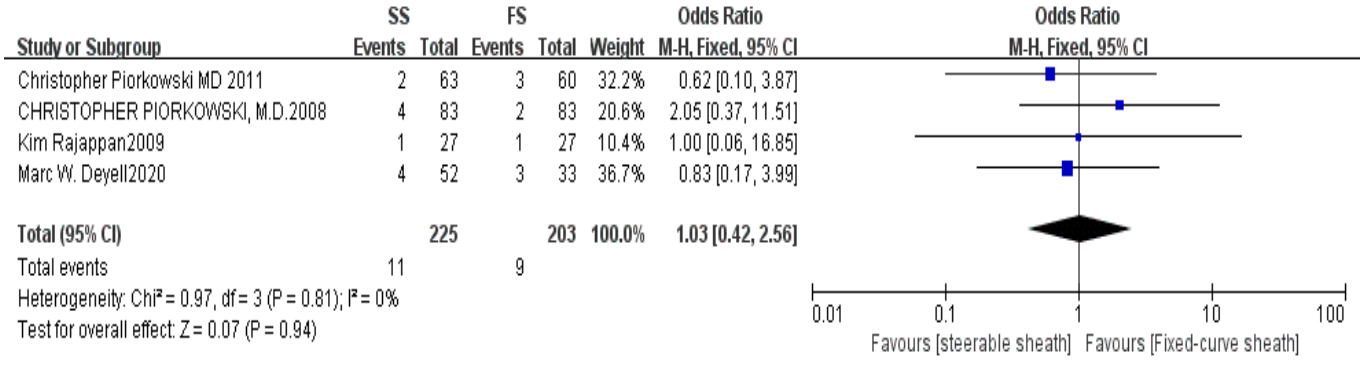
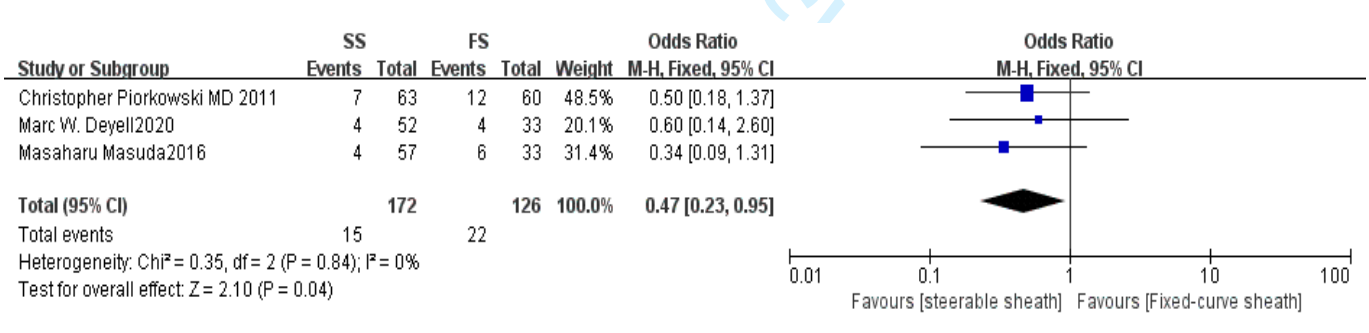
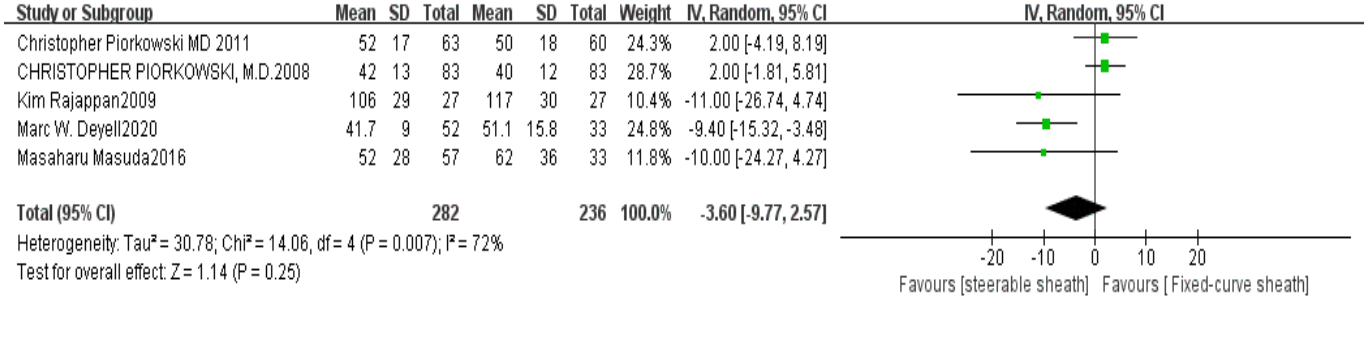


Figure 2 Forest plot of the primary outcomes. (A) Recurrence of atrial fibrillation and atrial arrhythmias and (B) Complications. CI, confidence interval; SS, steerable; FS, fixed-curve sheath; M--H, Mantel--Haenszel

(A) **Acute Pulmonary Vein Reconnection**



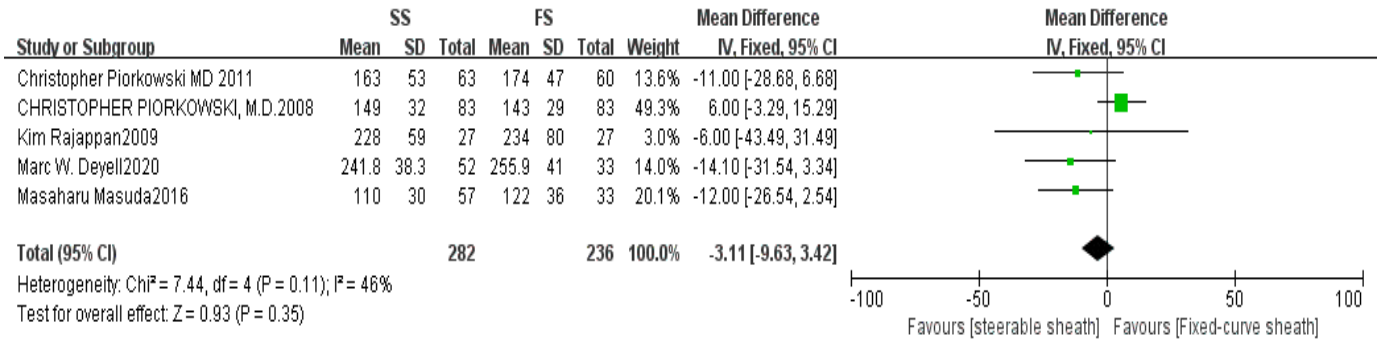
(B) **Ablation Time**



For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

(C) **Total Procedure Time**



(D) **Fluoroscopy Time**

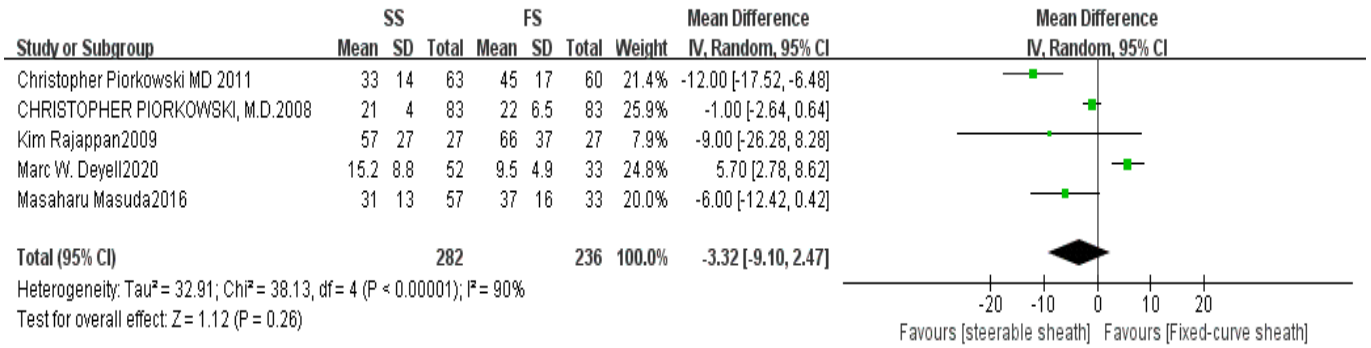


Figure 3 Forest plot of the secondary outcomes. (A) acute pulmonary vein reconnection;(B) ablation time;(C) total procedure time;(D) fluoroscopy time. CI, confidence interval; SS, steerable; FS, fixed-curve sheath; M--H, Mantel--Haenszel

Author contribution Xinyao Jin and Mingbin Xie designed the meta-analysis and selected studies. Yuqing Zhou and Yuanhong Wu collected and analyzed the data statistically. All authors contributed to the writing of this manuscript.

Data availability statement No new data were generated or analysed in support of this research.

Funding There were no sources of funding for this systematic review and meta-analysis.

Conflict of interest The authors declare no competing interests.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

References

[1] Haïssaguerre M, Jaïs P, Shah DC, Takahashi A, Hocini M, QuiniouG, et al. Spontaneous initiation of atrial fibrillation by ectopic beats originating in the pulmonary veins. N Engl J Med. 1998;339:659-666.

[2] Packer D L, Mark D B, Robb R A , et al. Effect of Catheter Ablation vs Antiarrhythmic Drug Therapy on Mortality, Stroke, Bleeding, and Cardiac Arrest Among Patients With Atrial Fibrillation: The CABANA Randomized Clinical Trial. JAMA. 2019 Apr 2;321(13):1261-1274.

[3] C Blomström-Lundqvist, Gizurarson S, J Schwieler, et al. Effect of Catheter Ablation vs Antiarrhythmic Medication on Quality of Life in Patients With Atrial Fibrillation: The CAPTAF Randomized Clinical Trial. JAMA. 2019 Mar 19;321(11):1059-1068.

[4] Marrouche N F, Brachmann J, Andresen D, et al. Catheter Ablation for Atrial Fibrillation with Heart Failure. N Engl J Med. 2018 Feb 1;378(5):417-427.

[5] Ouyang F, Tilz R , Chun J , et al. Long-Term Results of Catheter Ablation in Paroxysmal Atrial Fibrillation Lessons From a 5-Year Follow-Up. Circulation. 2010 Dec 7;122(23):2368-2377.

[6] Shah S, Barakat AF, Saliba WI, Abdur Rehman K, Tarakji KG, Rickard J, et al. Recurrent atrial fibrillation after initial long-term ablation success: electrophysiological findings and outcomes of repeat ablation procedures. Circ Arrhythm Electrophysiol. 2018;11(4):e005785.

[7] Macle L, Khairy P, Weerasooriya R, et al. Adenosine-guided pulmonary vein isolation for the treatment of paroxysmal atrial fibrillation: an international, multicentre, randomised superiority tria. Lancet, 2015:672-679.

[8] Hiner E, Shah DP. Choice of Steerable Sheath Impacts Contact Force Stability During Pulmonary Vein Isolation. J Innov Card Rhythm Manag. 2021 Dec 15;12(12):4790-4795.

[9] Joseph J, Wong KC, Ginks MR, Bashir Y, Betts TR, Rajappan K. Steerable sheath technology in the ablation of atrial fibrillation. Recent Pat Cardiovasc Drug Discov. 2013 Dec;8(3):171-177.

[10] Ullah W, Hunter RJ, McLean A, Dhinoja M, Earley MJ, Sporton S, Schilling RJ. Impact of steerable sheaths on contact forces and reconnection sites in ablation for persistent atrial fibrillation. J Cardiovasc Electrophysiol. 2015 Mar;26(3):266-273.

[11] Reichlin T, Michaud GF. Our approach to maximizing the durability of pulmonary vein isolation during a paroxysmal atrial fibrillation ablation procedure. J Cardiovasc Electrophysiol. 2012 Nov;23(11):1272-1276.

[12] Brunelli M, Raffa S, Große A, Wauters K, Menoni S, Schreiber M, Geller JC. Influence of the anatomic characteristics of the pulmonary vein ostium, the learning curve, and the use of a steerable sheath on success of pulmonary vein isolation with a novel multielectrode ablation catheter. Europace. 2012 Mar;14(3):331-340.

[13] Piorkowski C, Eitel C, Rolf S, et al. Steerable versus nonsteerable sheath technology in atrial fibrillation ablation: a prospective, randomized study. Circulation Arrhythmia & Electrophysiology, 2011, 4(2):157-165.

[14]PMD Christopher, KMD Hans, GMD Jin-Hong, et al. Steerable Sheath Catheter Navigation for Ablation of Atrial Fibrillation: A Case Control Study. Pacing and Clinical Electrophysiology, 2008, 31(7):863-873.

[15] Kim R, Victoria B, Laura R, et al. A randomized trial to compare atrial fibrillation ablation using a steerable vs. a non-steerable sheath. Europace, 2009(5):571-575.

[16] Deyell M W, Wen G, Laksman Z, et al. The impact of steerable sheaths on unblinded contact force during catheter ablation for atrial fibrillation. J Interv Card Electrophysiol. 2020 Apr;57(3):417-424.

[17] Masuda M, Fujita M, Iida O, et al. Steerable versus non-steerable sheaths during pulmonary vein isolation: impact of left atrial enlargement on the catheter–tissue contact force. J Interv Card Electrophysiol, 2016, 47(1):1-9.

[18] Neuzil P, Reddy VY, Kautzner J, Petru J,Wichterle D, Shah D, et al. Electrical reconnection after pulmonary vein isolation is contingent on contact force during initial treatment: results from the EFFICAS I

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

study. Circ Arrhythm Electrophysiol. 2013;6:327–333.
[19] Sotomi Y, Kikkawa T, Inoue K, Tanaka K, Toyoshima Y, Oka T, et al. Regional difference of optimal contact force to prevent acute pulmonary vein reconnection during radiofrequency catheter ablation for atrial fibrillation. J Cardiovasc Electrophysiol. 2014;25:941–947.
[20] Ali A, Sakes A, Arkenbout EA, Henselmans P, van Starkenburg R, Szili-Torok T, Breedveld P. Catheter steering in interventional cardiology: Mechanical analysis and novel solution. Proc Inst Mech Eng H. 2019 Dec;233(12):1207-1218.
[21] Kautzner J, Neuzil P, Lambert H, Peichl P, Petru J, Cihak R, et al.EFFICAS II: optimization of catheter contact force improves out-come ofpulmonary vein isolation for paroxysmal atrial fibrillation.Europace. 2015;17:1229–1235.
[22] Schluermann F, Krauss T, Biermann J, Hartmann M, Trolese L, Pache G, et al. In vivo contact force measurements and correlation with left atrial anatomy during catheter ablation ofatrial fibrillation. Europace. 2015;17:1526–1532.

For peer review only

Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	1-2
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	1-2
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	2-3
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	2
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	2-3
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	3
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	3
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	8
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	3
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	3
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	3
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	3
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	3
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	3
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	3
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	3
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	3
Certainty	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	3

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
assessment			
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	7
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	7
Study characteristics	17	Cite each included study and present its characteristics.	3
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	4
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	4、9-10
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	4、9-10
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	4、9-10
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	4、9-10
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	4、9-10
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	4、9-10
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	4、9-10
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	5-6
	23b	Discuss any limitations of the evidence included in the review.	5-6
	23c	Discuss any limitations of the review processes used.	5-6
	23d	Discuss implications of the results for practice, policy, and future research.	5-6
OTHER INFORMATION			
Registration and protocol	24a	Registration does not apply .	2
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	2
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	2
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	10
Competing interests	26	Declare any competing interests of review authors.	10
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	10

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

For peer review only

1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . cted by copyright, including for uses related to text and data mining, AI training, and similar technologies.

PRISMA 2020 Checklist

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

For peer review only

1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . cted by copyright, including for uses related to text and data mining, AI training, and similar technologies.

BMJ Open

Safety and efficacy of steerable versus non-steerable sheaths for catheter ablation of atrial fibrillation systematic review and meta-analysis

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-068350.R1
Article Type:	Original research
Date Submitted by the Author:	28-Jul-2023
Complete List of Authors:	Jin, Xinyao; Hangzhou Red Cross Hospital, Zhou, Yuqing; Zhejiang Chinese Medical University First Clinical Medical College Wu, Yuanhong; Hangzhou Red Cross Hospital Xie, Mingbin; Hangzhou Red Cross Hospital
Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Evidence based practice, Cardiovascular medicine
Keywords:	Pacing & electrophysiology < CARDIOLOGY, Adult cardiology < CARDIOLOGY, Audit < CARDIOLOGY

SCHOLARONE™
Manuscripts

BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

Safety and efficacy of steerable versus non-steerable sheaths for catheter ablation of atrial fibrillation systematic review and meta-analysis

Xinyao Jin[1]; Yuqing Zhou[2]; Yuanhong Wu[1] ; Mingbin Xie[1*]

Department of Cardiology, Affiliated Hangzhou Chest Hospital, Zhejiang University School of Medicine (HangZhou Red Cross Hospital), Hangzhou, Zhejiang, China.
2 The First College of Clinical Medicine, Zhejiang Chinese Medical University, Hangzhou, Zhejiang, China.
*Corresponding author：Xie Mingbin ORCID：0000-0002-1875-2505
e-mail:hz_xiemingbin@163.com
Xinyao Jin and Yuqing Zhou contributed equally to this work.

Abstract

Objectives With the development of radiofrequency ablation technology. In recent years, more and more patients with atrial fibrillation(AF) have been treated with radiofrequency ablation. Steerable sheaths have been widely used in radiofrequency ablation of AF. The aim of this meta-analysis was to compare the efficacy and safety of AF ablation using steerable(SS) and non-steerable sheaths(NSS).

Methods From the beginning to March 2022, we conducted a comprehensive, systematic search of the databases Pubmed, MEDLINE, EMBASE, web of science and the Cochrane Library to finish the study. For categorical and continuous data, We used odds ratios (OR) and mean difference (MD) to calculate the effect. And we also estimated the 95% Confidence Interval (CI).

Results Five studies of radiofrequency ablation of AF were selected, three prospective and two retrospective, involving 282 SS and 236 NSS ablation patients. The rate of recurrence of AF or atrial arrhythmias was 27.3% versus 43.6% (OR: 0.50, 95% CI: 0.35 to 0.73, Z = 3.59, P = 0.00003) and acute pulmonary vein reconnection (PVs) (8.7% vs 17.4%, OR: 0.47, 95% CI: 0.23 to 0.95, Z = 2.10, P = 0.04); In the SS group and the NSS group, the total ablation time (P = 0.25), fluoroscopy time (P = 0.26) and total operative time (P = 0.35) were not significantly different.

Conclusions Compared with the use of NSS, the use of SS for radiofrequency ablation of AF can effectively reduce the recurrence rate of AF and the occurrence of acute PVs events. However, there is no advantage in shortening the total radiofrequency time, fluoroscopy time, total surgical time, and reducing complications.

Key words AF, catheter ablation, steerable sheath, non-steerable sheath, Meta-analysis

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

STRENGTHS AND LIMITATIONS OF THIS STUDY

1. Rigorous search strategy including grey literature and non-indexed trials.
2.Quality of evidence assessment using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework.
3. There is notable heterogeneity and the small number of studies limits the analyses that can be conducted to account for heterogeneity in the absence of patient-level data.
4. The included studies are retrospective and non-randomized observational Cohort study, lacking large sample, multi center Randomized controlled trial.
5.There are many clinical studies on controllable and fixed sheaths, but there is a lack of systematic analysis. We provides a homogenous evaluation of evidence by assessing the effectiveness, safety and efficiency of NSS guided AF ablation .

Introduction

Discription of the Condtion

Since Haissagurer et al. Reported that the rapid impulse issued by the ectopic excitation center in the pulmonary vein triggered and driven AF through the electrical connection with the atrium[1]. Ablation of the electrical connection site was the radical treatment of AF, which laid the theoretical basis for the treatment of AF by pulmonary vein vestibular electrical isolation(PVI). With the development of technology, radiofrequency ablation is widely used in the treatment of AF, which greatly reduces the recurrence of AF, effectively prevents the occurrence of heart failure and embolism events, prolongs patients' life and improves their quality of life. [2-4]. In clinical practice, pulmonary vein reconnection still occurs in large numbers after the first ablation due to non-continuous ablation line, focal non-transmural lesions and tissue edema caused by ablation head displacement, which greatly increases the recurrence rate of AF[5-7]. Therefore, stable, repeatable and reliable attachment to the ablation target during the ablation process has become one of the keys to the success of ablation[8-12], which goes beyond the use of traditional fixed curve sheaths. In prior practice, SS have been widely used in radiofrequency ablation of AF and improved catheter navigation, catheter stability, and LA wall contact, so as to provide stable transmural ablation lesions and reduce reconnection of pulmonary veins to reduce AF recurrence[9]. However, we know that the Comparison of SS and NSS in radiofrequency ablation of AF has not been systematically evaluated and analyzed. Therefore, our meta-analysis is to compare the outcomes and safety of RF ablation of AF using SS and NSS, in order to provide reliable evidence for clinical practice.

Method

Search strategy

We conducted and reported this systematic review according to the PRISMA guideline criteria. This systematic review was conducted pursuant to a forward-looking agreement and was not registered with any external entity. Two researchers (Jin and Zhou) searched 3 databases: Pubmed, MEDLINE, EMBASE, web of science, the Cochrane Library. It was limited to English literature, and there are no specific date, sex and age restrictions. The coverage dates for this review began from each database's inception and ended on 22 March 2022. The search strategy consisted of four core components, which were linked using the AND operator: 1) clinical trials(e.g., therapeutic studies, human cohort trials); 2) AF(e.g. paroxysmal AF and persistent AF); 3) sheath(e.g., SS, navigable vascular sheaths, NSS, fixed curve sheaths); 4) Radiofrequency ablation(e.g., pulmonary vein

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

isolation, pulmonary vein vestibule isolation and circumferential pulmonary vein isolation). MESH and keywords were identified for each of the 4 keywords to complete the search and were reviewed by an independent expert (consultant) from an external institution. In addition, We manually reviewed the reference lists of previously included trials and retrieved key articles to further complete the relevant study.

Study selection

The title and abstract of the study were independently selected by two researchers (Jin and Zhou). The disagreement was decided by the third examiner (Xie). All studies considered to meet the screening criteria for title and abstract were reviewed in full by 2 independent reviewers (Jin and Zhou) using the same criteria. The participation of the third reviewer (Xie) in the discussion was used to resolve the inconsistency. Articles were filtrated and identified according to the following inclusion criteria: 1) All AF catheter ablation relevant clinical studies were original articles published in English; 2) Full text and complete data could be provided(if the data is incomplete, complete data can be provided after contacting the author); 3) Case-control study (including prospective cohort study or retrospective cohort study design); 4) The primary end points of the study were recurrence of AF and atrial arrhythmias, and surgical complications. 5) The secondary end points were acute PVs, ablation time, fluoroscopy time and total procedure time. 6) The object of study was human being, but not animal or tissue. The exclusion criteria were as follows: 1) case reports, conference abstracts, and animal experiments; 2) Studies reporting incomplete or irrelevant data; 3) Studies that didn't use SS; 4) Studies using methods other than radiofrequency ablation (such as cryoablation and pulse ablation).

Data Extraction, Results, and Quality Assessment

The standardized protocol and reporting forms was used to extract data on study characteristics (year of publication, study design, authors, year of publication), study questions (sample size, AF type, sheath type, duration, baseline characteristics) and results (outcomes, key findings). Two paired reviewers ((Jin and Zhou) independently extracted this information from each study and resolved any disagreements through discussion. The primary end points were the rate of recurrence of AF and atrial tachyarrhythmias after surgery and perioperative and FU complications. Secondary endpoints included PVs acute reconnection, ablation time, fluoroscopy time, and total procedure time. Risk bias was assessed independently by two reviewers (Jin and Zhou) using the Newcastle Ottawa scale(NOS) for the quality of the selected studies. Any disagreement was then resolved through the participation and discussion of the third reviewer (Xie).

Statistical analysis

All extracted data were summarized and analyzed by using Review Manager version 5.3 software (Copenhagen: Nordic Cochrane Centre, Cochrane Collaboration, 2014). We used odds ratio (OR) and respective 95% confidence intervals (95% CI) to compare differences for dichotomous variables and calculated weighted mean difference (WMD) or standard mean difference (SMD) and respective 95% confidence intervals (95% CI) to analyze continuous variables. A Cochrane's Q p-value < 0.05 was considered significant. With a 95% confidence interval, the statistic I2 was interpreted as follows: $\geqslant$ 50% reflectd high heterogeneity between studies, and $< 50\%$ indicated low heterogeneity. In the case of low heterogeneity, we used the fixed effects model; When heterogeneity was significant, a random effects model was used. Study possible publication bias was assessed by funnel plot.

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

Patient and public involvement

Patients were not invloved in this study.

Results

Study and Data Selection

The results of the detailed search process were shown in Figure 1, 333 potentially relevant records were obtained in our search strategy, of which 175 were excluded as duplicates. Of the remaining, 149 studies were excluded after title and abstract reviewed. After detailed assessment of the full text, further 4 studies were excluded due to the following: 2 uncontrolled trials, 1 using “VIZIGO, Biosense Webster Inc., Irvine, CA bi-directional sheath, 1 reporting duplicate date. In the end, we selected 5 studies in this meta-analysis.

Study Characteristics and Quality Assessment of Included Studies

From the selected studies, there were 518 subjects, of which 282 (54.4%) in the SS group and 236 (45.6%) in the NSS group. The characteristics of the 5 studies were summarized in Supplementary Table 1. The incidence of paroxysmal AF was 69%, and the Christopher Piorkowski et al.[13-14], Kim Rajappan et al.[15], Marc W. Deyell et al.[16] and Masaharu Masuda et al.[17] included all subtypes of AF. Steering sheaths used in selected studies included non-steerable transseptal sheath (Mullins; Cook Inc., Bloomington, IN, USA) , aconventional non-steerable sheath (Swartz SL0, St Jude Medical), controlled steerable sheath (Agilis, St. Jude Medical, St. Paul, MN, USA). The follow-up in the 3 studies was 6 months after the first surgery, but 12 ± 2 months in the study by Masaharu Masuda et al.[17], 3 months in the study by Marc W. Deyell et al.[16]. There were no significant differences between the two groups in terms of mean age, proportion of males, hypertension ratio, duration of AF, mean left atrial (LA) diameter, and proportion of underlying cardiac disease.

Main clinical outcomes

The main endpoint included in the study was the electrocardiogram recording of atrial fibrillation recurrence time ≥ 30 seconds 3 to 12 months after radiofrequency ablation. Christopher Piorkowsk et al., Kim Rajappan et al., Marc W. Deyell et al., and Masaharu Masuda et al. reported statistically significant differences in the recurrence rate of atrial tachyarrhythmia after atrial fibrillation ablation surgery. The heterogeneity test of these five studies shows that（χ2=4.04, df=4, I2=1%, P=0.4), there was no significant heterogeneity between the studies, and a fixed effects model was used for analysis. Summary analysis showed that there was a significant difference in the recurrence rate of AF after the first surgery between SS and NSS ablation treatments [OR=0.52, 95% CI (0.36, 0.76), z=3.41, P=0.0006]; (Figure 2A).

Another primary endpoint is the incidence of perioperative and follow-up complications in both groups. Among the included literature, 4 articles [13-16] reported the occurrence of complications, with 225 cases in the SS group and 203 cases in the NSS group. Heterogeneity testing showed that（ χ2=0.97, df=3, I2=0%, P=0.81), there was no significant heterogeneity between the studies, and a fixed effects model was used for analysis. There was no statistically significant difference between the two groups [OR=1.03, 95% CI (0.42, 2.56), z=0.07, P=0.94]; (Figure 2B). Inguinal and femoral vein hematoma are the most common intraoperative and postoperative complications. Christopher Piorkowsk et al. reported that one patient in the rotatable sheath group experienced a perioperative stroke during follow-up with minimal residual material; One patient had a pseudoaneurysm in the Femoral artery pathway, which must be resolved by surgery; In the NSS group, 2 patients developed

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

cardiac tamponade requiring pericardial puncture, and 1 patient developed phrenic nerve paralysis, which was relieved during follow-up.

Secondary Clinical Outcomes

Acute Pulmonary vein reconnection is one of the secondary clinical outcomes. Three of the five studies mentioned acute Pulmonary vein reconnection, and heterogeneity test showed that（χ 2=0.35, df=2, I2=0%, P=0.84), with no significant heterogeneity between studies. A fixed effects model was used for analysis, and summary analysis showed that the SS group was superior to the NSS group in reducing the risk of PV reconnection [OR=0.47, 95% CI (0.23, 0.95), z=2.10, P=0.04]; (Figure 3A). Christopher Piorkowski et al. reported that compared with the NSS group, the SS group had less acute Pulmonary vein reconnection (11.1% versus 20.0%), which was similar to the research results published by Marc W. Deyell et al. and Masaharu Masuda et al. The study by Kim Rajappan et al. did not involve a description of acute reconnection of PV.

Among the included literature, 5 articles reported ablation time and fluoroscopy time respectively, with small heterogeneity between each study. Fixed effect models were used for analysis, and after summary analysis, it was found that the SS group was not superior to the NSS group in reducing ablation time [WMD=− 3.6, 95% CI (− 9.77, 2.57), z=1.14, P=0.25] (Figure 3B); The SS group was not superior to the NSS group in reducing fluoroscopy time [WMD=− 3.32, 95% CI (-9.10, 2.47), z=1.12, P=0.26] (Figure 3C). In addition, 5 articles were included to report the total program time, and heterogeneity testing showed that（χ 2=7.44, df=4, I2=46%, P=0.11), with significant heterogeneity between studies. A random effects model was used for analysis, and summary analysis showed that there was no statistically significant difference between the two groups [WMD=− 3.11, 95% CI (− 9.63, 3.42), z=0.93, P=0.35] (Figure 3D). The results showed that the SS group was not superior to the NSS group in reducing total program time.

Risk of bias in included studies

For the analysis of AF recurrence rate, the funnel plot was symmetric, so we think there was no significant publication bias (Figure 4).

Discussion

This meta-analysis showed that there was no significant difference in clinical complications between AF ablation with SS and NSS, suggesting that both SS and NSS are safe and effective for AF ablation. There was no statistically significant difference in ablation time between SS and NSS for radiofrequency ablation of atrial fibrillation, Mhanna M et al. obtained positive results after excluding Piorkowski 2008, with a P-value less than 0.05. They believe that using the SS shortened the surgical time, which we believe is evidence of a lack of robustness in the results. Due to rigorous considerations, we still believe that using the SS does not have an advantage in shortening the surgical time of atrial fibrillation radiofrequency ablation[18]. However, in reducing the incidence of AF, rapid atrial arrhythmia and pulmonary vein connection, SS have significant advantages over fixed curved sheaths.

Radiofrequency catheter ablation (RFCA) has developed as the recommended treatment for AF, and circumferential pulmonary vein antrum isolation is considered to be the cornerstone for the treatment of paroxysmal and persistent AF[1-4]. However, similar to other long left atrial ablation lines, continuous and transmural ablation of these lesions is often difficult to achieve. Therefore, in clinical practice, due to the following reasons:1) Incomplete isolation of pulmonary veins; 2) Distant pulmonary vein isolation; 3) The occurrence of pulmonary vein reconnection lead to the occurrence

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

of AF and atrial arrhythmia in a large number of patients, which greatly reduces the success rate of radiofrequency ablation[6,19,20]. Therefore, the duration and transmural lesions of PVI are critical to reduce AF recurrence. But during actual manipulation, It is a major challenge for the interventionalist to attempt a complex 3D ablation line in the pulmonary vein vestibule in an organ which moves with the respiratory rate, requiring a stable catheter and adequate tissue contact in order to achieve the desired ablation goal (transmural ablation with long duration). In recent years, steerable transseptal sheaths and fixed curve sheaths have been widely used in clinical radiofrequency ablation. The SS is convenient to enter and contact the ablation target, which is conducive to the continuity, maintenance and transmurality of the ablation target, and has been paid more and more attention and used in clinical practice[8-12]. Studies have shown that SS used for AF ablation are more effective and have comparable safety to conventional fixed curve sheaths[13-17]. However, the SS has a higher price than the fixed curve sheath, which requires patients to bear more equipment costs and becomes the concern of clinical surgeons. Therefore, we need a meta-analysis to evaluate and clarify the clinical impact of radiofrequency ablation under SS navigation, so as to provide a basis for clinical practice.

The advantage of using the SS for navigation may be due to the fact that the ablation tip is passively steered relative to the sheath itself and is only pushed and retracted within the sheath based on electrogram, fluorogram, and three-dimensional tactile information, which greatly improves the stability and steerability of the ablation tip[9]. It also allows the head ablation control in the millimeter range at the preset ablation target, which greatly reduces the occurrence of leakage points during ablation (eventually leading to acute reconnection of pulmonary veins). In addition, precise navigation of the ablation head provides the basis for reliable pacer and voltage mapping to find gaps in the complex 3-D PV anatomy to improve achievement of complete PVI[21]. Second, the pressure that could be applied through the tip of the ablation catheter was higher, which makes it possible to achieve transmural ablation of thicker regions of the left atrium (usually anterior to the left and right sided PVs)[22,23]. This is also confirmed by Masaharu Masuda et al.[17], when using the SS, the CF of the ipsilateral pulmonary vein vestibule was higher than that by using the fixed curve sheath. In the same area, CF value was only 5g when using fixed sheath, but almost doubled when using SS. The stability of the target may also reduce tissue edema caused by catheter instability due to heart beating. Moreover, more stable transmural ablation reduces the incidence of acute PV reconnection, as confirmed by this meta-analysis.

Celestino Sardu et al.'s study mentioned that excessive inflammation can lead to changes in the electrolytic dissection of the atrial myocardium. [24]Sardu C et al. believed that the persistence of abnormal calcium treatment can activate Ion channel and trigger calcium dependent signaling pathways. The miR-106b-25 cluster mediated posttranscriptional regulation of ryanodine receptor type-2 is a potential molecular mechanism involved in the pathogenesis of paroxysmal atrial fibrillation. [25]Moreover, intracellular calcium treatment in patients with atrial fibrillation is related to the increased incidence of abnormal spontaneous sarcoplasmic calcium release events, which can be attributed to the imbalance of ryanodine receptor type-2, leading to the delay and trigger mechanism after Depolarization, and ultimately promoting atrial remodeling and the development of atrial fibrillation into a more lasting form.[26]The study by Kim Rajappan et al.[15] further showed that the use of the SS for right inferior pulmonary vein ablation could reduce CT registration time as well as ablation time. This may be due to the fact that the right lower pulmonary vein is relatively more difficult to place and attach by using the fixed curved sheath, while the SS

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

can use the inverted U technique to quickly attach to PVs, which can build 3D models flexibly. This also greatly reduces the impact of the learning curve and manipulation experience of young interventionalists on RF ablation.

In addition, research by Janosi K and Guo R et al. found that compared to the standard, non-visualizable SS, visualizable SS significantly not only reduces the left atrial procedure time, RF delivery and fluoroscopy exposure ,but also but also significantly improved CF and initial PVI rate [27]. This greatly improves the safety of the surgery.[28]

Access with a larger transseptal sheath and ablation with more catheter tip pressure often raise safety concerns for the interventionalist during the procedure. In complications, there is no higher overall complication rate with SS. However, thicker sheaths have a direct correlation to single complications such as femoral vein injury and hematoma. Continuous monitoring and data collection, interpretation, and alarm settings may help clinical doctors in timely treatment management and medication adjustment, as well as early detection of atrial fibrillation recurrence and timely intervention to reduce stroke and other related atrial fibrillation complications.[29]

Limitations There are some limitations to this study. Firstly, all included studies are partly retrospective or non-randomized observational cohort studies. Secondly, in these studies, the force-time index or other ablation index are not mentioned. This data is reproducible in some clinical ablation treatments and is gaining increasing acceptance. If available, it will provide a firmer basis for clinical selection of SS. Finally, our sample size was small, with a minimum follow-up of 3 months and a maximum follow-up of 12 months. Therefore, the effect of selective sheath on AF recurrence in long-term follow-up is uncertain. To confirm the findings in our study, we need more randomized studies with larger sample sizes and longer follow-up.

Conclusion Compared with traditional fixed sheath, catheter ablation of AF with SS has better efficacy, which can effectively reduce the recurrence rate of AF and the occurrence of acute PVs. However, it can't shorten the procedure time and reduce complications.

For Peer Review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

Supplementary Table 1 Baseline characteristics of included studies
Figure 1 The flowchart of the literature search process
Figure 2 Forest plot of the primary outcomes. (A) Recurrence of AF and atrial arrhythmias and (B) Complications. CI, confidence interval; SS, steerable; NSS non-steerable sheath; M--H, Mantel--Haenszel
Figure 3 Forest plot of the secondary outcomes. (A) acute pulmonary vein reconnection;(B) ablation time;(C) fluoroscopy time;(D) total procedure time. CI, confidence interval; SS, steerable; NSS non-steerable sheath; M--H, Mantel--Haenszel
Figure 4 Funnel plot of comparison: SS/NSS, outcomes: AF recurrence rate

Author contribution Xinyao Jin and Mingbin Xie designed the meta-analysis and selected studies. Yuqing Zhou and Yuanhong Wu collected and analyzed the data statistically. All authors contributed to the writing of this manuscript.

Data availability statement No new data were generated or analysed in support of this research.

Patient consent for publication
Not applicable.

Ethics approval
Not applicable.

Funding There were no sources of funding for this systematic review and meta-analysis.

Conflict of interest The authors declare no competing interests.

References
[1] Haïssaguerre M, Jaïs P, Shah DC, Takahashi A, Hocini M, QuiniouG, et al. Spontaneous initiation of atrial fibrillation by ectopic beats originating in the pulmonary veins. N Engl J Med. 1998;339:659-666.
[2] Packer D L, Mark D B, Robb R A , et al. Effect of Catheter Ablation vs Antiarrhythmic Drug Therapy on

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

Mortality, Stroke, Bleeding, and Cardiac Arrest Among Patients With Atrial Fibrillation: The CABANA Randomized Clinical Trial. JAMA. 2019 Apr 2;321(13):1261-1274.

[3] C Blomström-Lundqvist, Gizurarson S, J Schwieler, et al. Effect of Catheter Ablation vs Antiarrhythmic Medication on Quality of Life in Patients With Atrial Fibrillation: The CAPTAF Randomized Clinical Trial. JAMA. 2019 Mar 19;321(11):1059-1068.

[4] Marrouche N F, Brachmann J, Andresen D, et al. Catheter Ablation for Atrial Fibrillation with Heart Failure. N Engl J Med. 2018 Feb 1;378(5):417-427.

[5] Ouyang F, Tilz R , Chun J , et al. Long-Term Results of Catheter Ablation in Paroxysmal Atrial Fibrillation Lessons From a 5-Year Follow-Up. Circulation. 2010 Dec 7;122(23):2368-2377.

[6] Shah S, Barakat AF, Saliba WI, Abdur Rehman K, Tarakji KG, Rickard J, et al. Recurrent atrial fibrillation after initial long-term ablation success: electrophysiological findings and outcomes of repeat ablation procedures. Circ Arrhythm Electrophysiol. 2018;11(4):e005785.

[7] Macle L, Khairy P, Weerasooriya R, et al. Adenosine-guided pulmonary vein isolation for the treatment of paroxysmal atrial fibrillation: an international, multicentre, randomised superiority tria. Lancet, 2015:672-679.

[8] Hiner E, Shah DP. Choice of Steerable Sheath Impacts Contact Force Stability During Pulmonary Vein Isolation. J Innov Card Rhythm Manag. 2021 Dec 15;12(12):4790-4795.

[9] Joseph J, Wong KC, Ginks MR, Bashir Y, Betts TR, Rajappan K. Steerable sheath technology in the ablation of atrial fibrillation. Recent Pat Cardiovasc Drug Discov. 2013 Dec;8(3):171-177.

[10] Ullah W, Hunter RJ, McLean A, Dhinoja M, Earley MJ, Sporton S, Schilling RJ. Impact of steerable sheaths on contact forces and reconnection sites in ablation for persistent atrial fibrillation. J Cardiovasc Electrophysiol. 2015 Mar;26(3):266-273.

[11] Reichlin T, Michaud GF. Our approach to maximizing the durability of pulmonary vein isolation during a paroxysmal atrial fibrillation ablation procedure. J Cardiovasc Electrophysiol. 2012 Nov;23(11):1272-1276.

[12] Brunelli M, Raffa S, Große A, Wauters K, Menoni S, Schreiber M, Geller JC. Influence of the anatomic characteristics of the pulmonary vein ostium, the learning curve, and the use of a steerable sheath on success of pulmonary vein isolation with a novel multielectrode ablation catheter. Europace. 2012 Mar;14(3):331-340.

[13] Piorkowski C, Eitel C, Rolf S, et al. Steerable versus nonsteerable sheath technology in atrial fibrillation ablation: a prospective, randomized study. Circulation Arrhythmia & Electrophysiology, 2011, 4(2):157-165.

[14]PMD Christopher, KMD Hans, GMD Jin-Hong, et al. Steerable Sheath Catheter Navigation for Ablation of Atrial Fibrillation: A Case Control Study. Pacing and Clinical Electrophysiology, 2008, 31(7):863-873.

[15] Kim R, Victoria B, Laura R, et al. A randomized trial to compare atrial fibrillation ablation using a steerable vs. a NSS. Europace, 2009(5):571-575.

[16] Deyell M W, Wen G, Laksman Z, et al. The impact of steerable sheaths on unblinded contact force during catheter ablation for atrial fibrillation. J Interv Card Electrophysiol. 2020 Apr;57(3):417-424.

[17] Masuda M, Fujita M, Iida O, et al. Steerable versus NSS during pulmonary vein isolation: impact of left atrial enlargement on the catheter–tissue contact force. J Interv Card Electrophysiol, 2016, 47(1):1-9.

[18] Mhanna M, Beran A, Al-Abdouh A, Sajdeya O, Barbarawi M, Alsaiqali M, Jabri A, Al-Aaraj A, Alharbi A, Chacko P. Steerable versus nonsteerable sheath technology in atrial fibrillation ablation: A systematic review and meta-analysis. J Arrhythm. 2022 Jun 3;38(4):570-579.

[19] Neuzil P, Reddy VY, Kautzner J, Petru J,Wichterle D, Shah D, et al. Electrical reconnection after pulmonary vein isolation is contingent on contact force during initial treatment: results from the EFFICAS I study. Circ Arrhythm Electrophysiol. 2013;6:327–333.

[20] Sotomi Y, Kikkawa T, Inoue K, Tanaka K, Toyoshima Y, Oka T, et al. Regional difference of optimal

For Peer Review Only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

contact force to prevent acute pulmonary vein reconnection during radiofrequency catheter ablation for atrial fibrillation. J Cardiovasc Electrophysiol. 2014;25:941–947.

[21] Ali A, Sakes A, Arkenbout EA, Henselmans P, van Starkenburg R, Szili-Torok T, Breedveld P. Catheter steering in interventional cardiology: Mechanical analysis and novel solution. Proc Inst Mech Eng H. 2019 Dec;233(12):1207-1218.

[22] Kautzner J, Neuzil P, Lambert H, Peichl P, Petru J, Cihak R, et al.EFFICAS II: optimization of catheter contact force improves out-come ofpulmonary vein isolation for paroxysmal atrial fibrillation.Europace. 2015;17:1229–1235.

[23] Schluermann F, Krauss T, Biermann J, Hartmann M, Trolese L, Pache G, et al. In vivo contact force measurements and correlation with left atrial anatomy during catheter ablation ofatrial fibrillation. Europace. 2015;17:1526–1532.

[24] Sardu C, Santulli G, Santamaria M, Barbieri M, Sacra C, Paolisso P, D'Amico F, Testa N, Caporaso I, Paolisso G, Marfella R, Rizzo MR. Effects of Alpha Lipoic Acid on Multiple Cytokines and Biomarkers and Recurrence of Atrial Fibrillation Within 1 Year of Catheter Ablation. Am J Cardiol. 2017 May 1;119(9):1382-1386.

[25] Sardu C, Santulli G, Guerra G, Trotta MC, Santamaria M, Sacra C, Testa N, Ducceschi V, Gatta G, Amico M, Sasso FC, Paolisso G, Marfella R. Modulation of SERCA in Patients with Persistent Atrial Fibrillation Treated by Epicardial Thoracoscopic Ablation: The CAMAF Study. J Clin Med. 2020 Feb 17;9(2):544.

[26] Sardu C, Santamaria M, Paolisso G, Marfella R. microRNA expression changes after atrial fibrillation catheter ablation. Pharmacogenomics. 2015 Nov;16(16):1863-77.

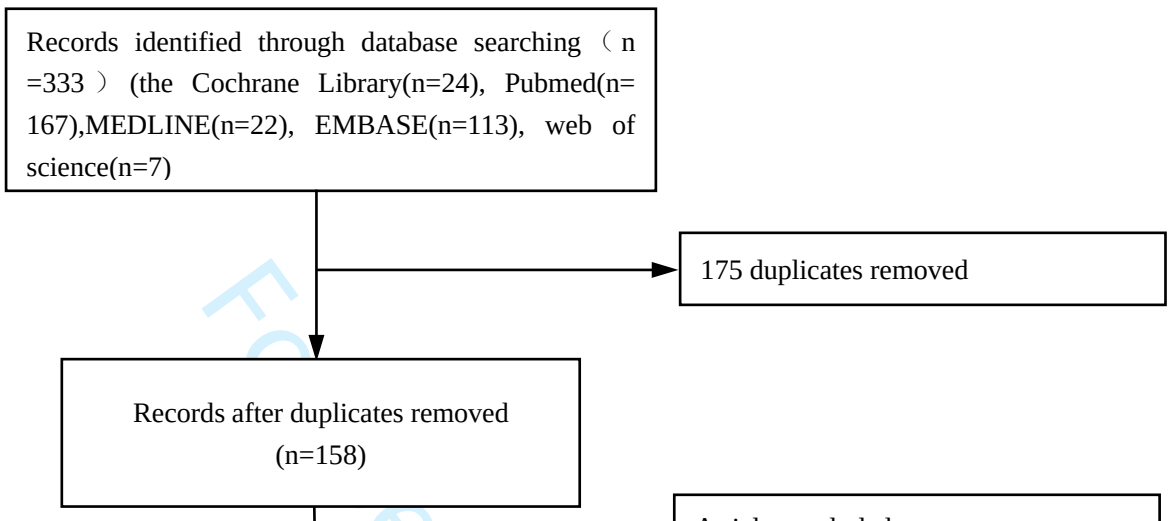
[27] Guo R, Jia R, Cen Z, Lu S, Yang C, Han S, Li D, Cui K. Effects of the visualized steerable sheath applied to catheter ablation of paroxysmal atrial fibrillation. J Interv Card Electrophysiol. 2022 Aug;64(2):511-518.

[28] Janosi K, Debreceni D, Janosa B, Bocz B, Simor T, Kupo P. Visualizable vs. standard, non-visualizable steerable sheath for pulmonary vein isolation procedures: Randomized, single-centre trial. Front Cardiovasc Med. 2022 Nov 16;9:1033755.

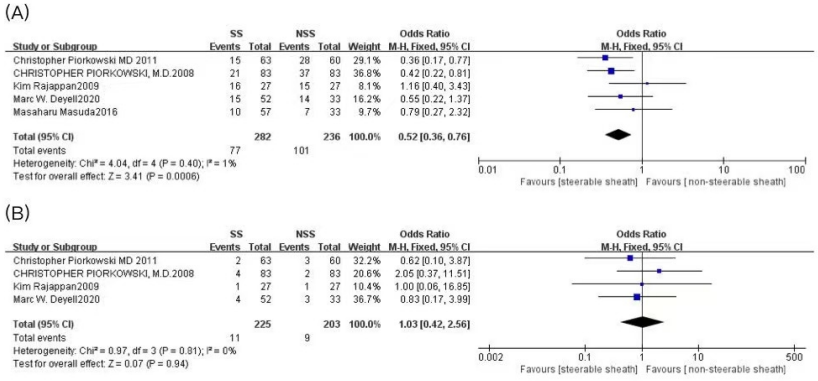
[29] Sardu C, Santamaria M, Rizzo MR, Barbieri M, di Marino M, Paolisso G, Santulli G, Marfella R. Telemonitoring in heart failure patients treated by cardiac resynchronisation therapy with defibrillator (CRT-D): the TELECART Study. Int J Clin Pract. 2016 Jul;70(7):569-76.

For Peer Review Only

Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.



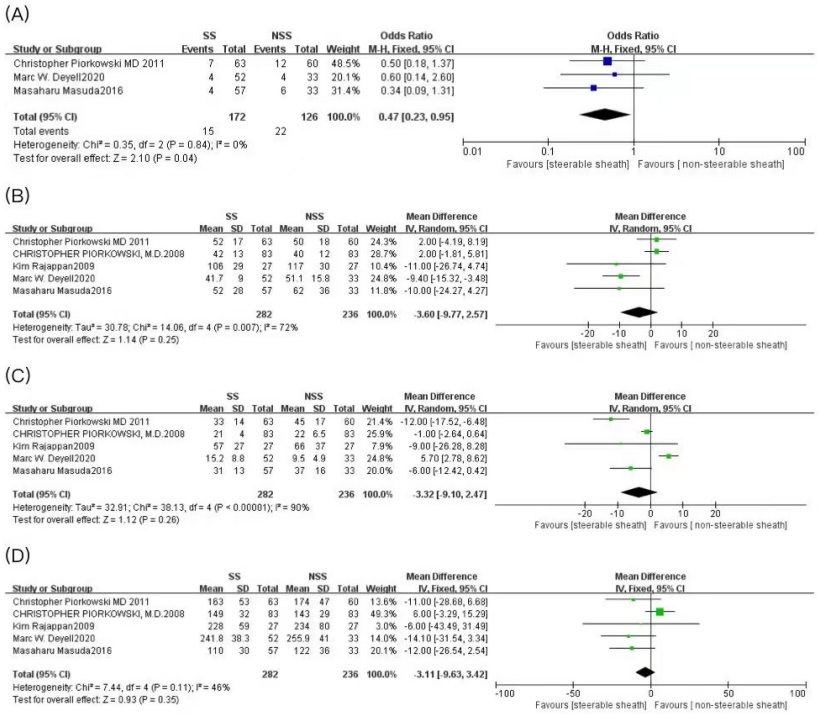
Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .



(A) Recurrence of AF and atrial arrhythmias and (B) Complications.

419x177mm (72 x 72 DPI)

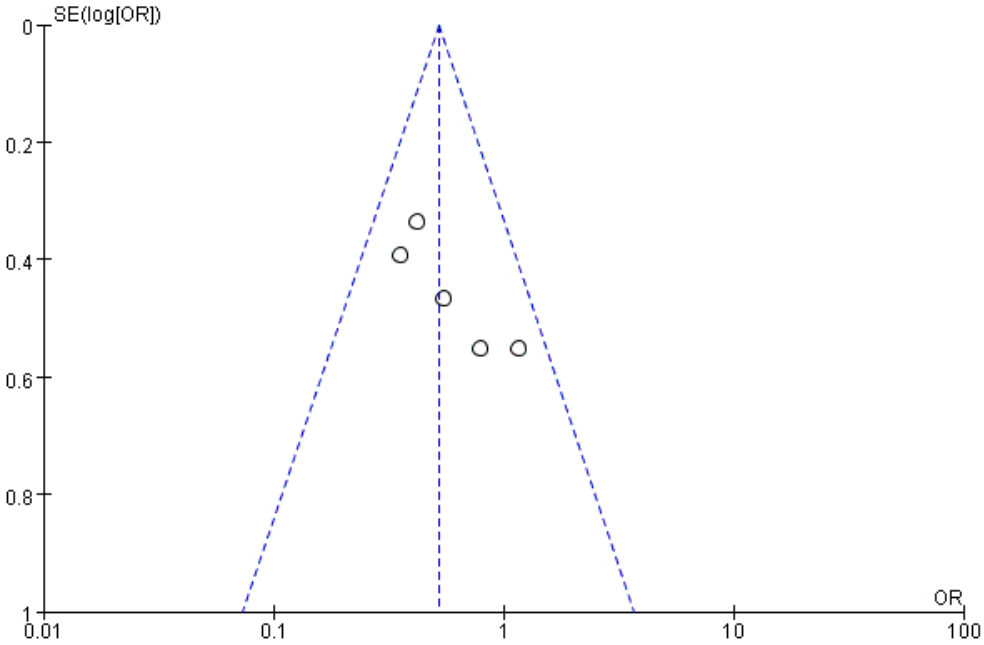
BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.



(A) acute pulmonary vein reconnection;(B) ablation time;(C) fluoroscopy time;(D) total procedure time fluoroscopy time.

419x319mm (72 x 72 DPI)

BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.



Funnel plot of comparison

211x141mm (72 x 72 DPI)

BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Table 1 Baseline characteristics of included studies

First author (year)	Study design	Sample size		Age		Male n(%)		PAF	AF duration		LA size		Hypertension n(%)		Structural heart disease n(%)		Follow-up (month)
		SS	NSS	SS	NSS	SS	NSS	(n)	SS	NSS	SS	NSS	SS	NSS	SS	NSS	
Christopher Piorkowski MD 2011[13]	Prospective observational	63	60	57±9	62±9	44 (70)	35 (58)	64%	46	55	43 ± 6	45±6	42(67)	40 (67)	16(25.4)	22(36.7)	6
Christopher Piorkowski M.D.2008[14]	Retrospective observational	83	83	55 ±9	55 ± 9	61 (73)	61 (73)	80%	52	54	36 ± 13	38 ± 8	34(41)	34 (41)	13(15.7)	13(15.7)	6
Kim Rajappan 2009[15]	Prospective observational	27	27	57±10	54±10	19	20	50%	53±31	61±41	41±6	40±8	NA	NA	10(37)	7(26)	6
Marc W. Deyell2020[16]	Retrospective observational	52	33	56.6±13.1	61.2±11.7	36	20	69.4%	NA	NA	41.8 ±6.4	40.2 ±7	21 (40.38)	16(48.48)	NA	NA	3
Masaharu Masuda2016[17]	Prospective observational	57	33	67 ± 11	66± 11	39 (68)	24 (73)	67%	29 ± 36	25± 26	40 ± 7	38± 6	33(58)	22(67)	NA	NA	12±2

SS steerable sheath, NSS non-steerable sheath, PAF paroxysmal atrial fibrillation, AF atrial fibrillation, LA left atrium, N/A not available/applicable;

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Erasmushogeschool . Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA

http://bmjopen-2022-068350 on 21 September 2023.

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	1-2
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	1-2
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	2-3
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	2
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	2-3
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	3
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	3
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	8
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	3
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	3
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	3
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	3
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	3
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	3
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	3
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	3
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	3
Certainty	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	3

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool . Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA
10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
assessment			
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	7
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	7
Study characteristics	17	Cite each included study and present its characteristics.	3
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	4
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	4、9-10
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	4、9-10
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	4、9-10
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	4、9-10
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	4、9-10
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	4、9-10
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	4、9-10
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	5-6
	23b	Discuss any limitations of the evidence included in the review.	5-6
	23c	Discuss any limitations of the review processes used.	5-6
	23d	Discuss implications of the results for practice, policy, and future research.	5-6
OTHER INFORMATION			
Registration and protocol	24a	Registration does not apply .	2
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	2
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	2
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	10
Competing interests	26	Declare any competing interests of review authors.	10
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	10

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

For peer review only

1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . cted by copyright, including for uses related to text and data mining, AI training, and similar technologies.

PRISMA 2020 Checklist

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

For peer review only

10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

BMJ Open

Safety and efficacy of steerable versus non-steerable sheaths for catheter ablation of atrial fibrillation systematic review and meta-analysis

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-068350.R2
Article Type:	Original research
Date Submitted by the Author:	30-Aug-2023
Complete List of Authors:	Jin, Xinyao; Hangzhou Red Cross Hospital, Zhou, Yuqing; Zhejiang Chinese Medical University First Clinical Medical College Wu, Yuanhong; Hangzhou Red Cross Hospital Xie, Mingbin; Hangzhou Red Cross Hospital
Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Evidence based practice, Cardiovascular medicine
Keywords:	Pacing & electrophysiology < CARDIOLOGY, Adult cardiology < CARDIOLOGY, Audit < CARDIOLOGY

SCHOLARONE™
Manuscripts

BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

Safety and efficacy of steerable versus non-steerable sheaths for catheter ablation of atrial fibrillation systematic review and meta-analysis

Xinyao Jin[1]; Yuqing Zhou[2]; Yuanhong Wu[1] ; Mingbin Xie[1*]

Department of Cardiology, Affiliated Hangzhou Chest Hospital, Zhejiang University School of Medicine (HangZhou Red Cross Hospital), Hangzhou, Zhejiang, China.
2 The First College of Clinical Medicine, Zhejiang Chinese Medical University, Hangzhou, Zhejiang, China.
*Corresponding author：Xie Mingbin ORCID：0000-0002-1875-2505
e-mail:hz_xiemingbin@163.com
Xinyao Jin and Yuqing Zhou contributed equally to this work.

Abstract

Objectives With the development of radiofrequency ablation technology. In recent years, more and more patients with atrial fibrillation(AF) have been treated with radiofrequency ablation. Steerable sheaths have been widely used in radiofrequency ablation of AF. The aim of this meta-analysis was to compare the efficacy and safety of AF ablation using steerable(SS) and non-steerable sheaths(NSS).

Methods From the beginning to March 2022, we conducted a comprehensive, systematic search of the databases Pubmed, MEDLINE, EMBASE, web of science and the Cochrane Library to finish the study. For categorical and continuous data, We used odds ratios (OR) and mean difference (MD) to calculate the effect. And we also estimated the 95% Confidence Interval (CI).

Results Five studies of radiofrequency ablation of AF were selected, three prospective and two retrospective, involving 282 SS and 236 NSS ablation patients. The rate of recurrence of AF or atrial arrhythmias was 27.3% versus 43.6% (OR: 0.50, 95% CI: 0.35 to 0.73, Z = 3.59, P = 0.00003) and acute pulmonary vein reconnection (PVs) (8.7% vs 17.4%, OR: 0.47, 95% CI: 0.23 to 0.95, Z = 2.10, P = 0.04); In the SS group and the NSS group, the total ablation time (P = 0.25), fluoroscopy time (P = 0.26) and total operative time (P = 0.35) were not significantly different.

Conclusions Compared with the use of NSS, the use of SS for radiofrequency ablation of AF can effectively reduce the recurrence rate of AF and the occurrence of acute PVs events. However, there is no advantage in shortening the total radiofrequency time, fluoroscopy time, total surgical time, and reducing complications.

Key words AF, catheter ablation, steerable sheath, non-steerable sheath, Meta-analysis

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

STRENGTHS AND LIMITATIONS OF THIS STUDY

1. Rigorous search strategy including grey literature and non-indexed trials.
2.Quality of evidence assessment using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework.
3. There is notable heterogeneity and the small number of studies limits the analyses that can be conducted to account for heterogeneity in the absence of patient-level data.
4. The included studies are retrospective and non-randomized observational Cohort study, lacking large sample, multi center Randomized controlled trial.
5.There are many clinical studies on controllable and fixed sheaths, but there is a lack of systematic analysis. We provides a homogenous evaluation of evidence by assessing the effectiveness, safety and efficiency of NSS guided AF ablation .

Introduction

Discription of the Condtion

Since Haissagurer et al. Reported that the rapid impulse issued by the ectopic excitation center in the pulmonary vein triggered and driven AF through the electrical connection with the atrium[1]. Ablation of the electrical connection site was the radical treatment of AF, which laid the theoretical basis for the treatment of AF by pulmonary vein vestibular electrical isolation(PVI). With the development of technology, radiofrequency ablation is widely used in the treatment of AF, which greatly reduces the recurrence of AF, effectively prevents the occurrence of heart failure and embolism events, prolongs patients' life and improves their quality of life. [2-4]. In clinical practice, pulmonary vein reconnection still occurs in large numbers after the first ablation due to non-continuous ablation line, focal non-transmural lesions and tissue edema caused by ablation head displacement, which greatly increases the recurrence rate of AF[5-7]. Therefore, stable, repeatable and reliable attachment to the ablation target during the ablation process has become one of the keys to the success of ablation[8-12], which goes beyond the use of traditional fixed curve sheaths. In prior practice, SS have been widely used in radiofrequency ablation of AF and improved catheter navigation, catheter stability, and LA wall contact, so as to provide stable transmural ablation lesions and reduce reconnection of pulmonary veins to reduce AF recurrence[9]. However, we know that the Comparison of SS and NSS in radiofrequency ablation of AF has not been systematically evaluated and analyzed. Therefore, our meta-analysis is to compare the outcomes and safety of RF ablation of AF using SS and NSS, in order to provide reliable evidence for clinical practice.

Method

Search strategy

We conducted and reported this systematic review according to the PRISMA guideline criteria. This systematic review was conducted pursuant to a forward-looking agreement and was not registered with any external entity. Two researchers (Jin and Zhou) searched 3 databases: Pubmed, MEDLINE, EMBASE, web of science, the Cochrane Library. It was limited to English literature, and there are no specific date, sex and age restrictions. The coverage dates for this review began from each database's inception and ended on 22 March 2022. The search strategy consisted of four core components, which were linked using the AND operator: 1) clinical trials(e.g., therapeutic studies, human cohort trials); 2) AF(e.g. paroxysmal AF and persistent AF); 3) sheath(e.g., SS, navigable vascular sheaths, NSS, fixed curve sheaths); 4) Radiofrequency ablation(e.g., pulmonary vein

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

isolation, pulmonary vein vestibule isolation and circumferential pulmonary vein isolation). MESH and keywords were identified for each of the 4 keywords to complete the search and were reviewed by an independent expert (consultant) from an external institution. In addition, We manually reviewed the reference lists of previously included trials and retrieved key articles to further complete the relevant study.

Study selection

The title and abstract of the study were independently selected by two researchers (Jin and Zhou). The disagreement was decided by the third examiner (Xie). All studies considered to meet the screening criteria for title and abstract were reviewed in full by 2 independent reviewers (Jin and Zhou) using the same criteria. The participation of the third reviewer (Xie) in the discussion was used to resolve the inconsistency. Articles were filtrated and identified according to the following inclusion criteria: 1) All AF catheter ablation relevant clinical studies were original articles published in English; 2) Full text and complete data could be provided(if the data is incomplete, complete data can be provided after contacting the author); 3) Case-control study (including prospective cohort study or retrospective cohort study design); 4) The primary end points of the study were recurrence of AF and atrial arrhythmias, and surgical complications. 5) The secondary end points were acute PVs, ablation time, fluoroscopy time and total procedure time. 6) The object of study was human being, but not animal or tissue. The exclusion criteria were as follows: 1) case reports, conference abstracts, and animal experiments; 2) Studies reporting incomplete or irrelevant data; 3) Studies that didn't use SS; 4) Studies using methods other than radiofrequency ablation (such as cryoablation and pulse ablation).

Data Extraction, Results, and Quality Assessment

The standardized protocol and reporting forms was used to extract data on study characteristics (year of publication, study design, authors, year of publication), study questions (sample size, AF type, sheath type, duration, baseline characteristics) and results (outcomes, key findings). Two paired reviewers ((Jin and Zhou) independently extracted this information from each study and resolved any disagreements through discussion. The primary end points were the rate of recurrence of AF and atrial tachyarrhythmias after surgery and perioperative and FU complications. Secondary endpoints included PVs acute reconnection, ablation time, fluoroscopy time, and total procedure time. Risk bias was assessed independently by two reviewers (Jin and Zhou) using the Newcastle Ottawa scale(NOS) for the quality of the selected studies. Any disagreement was then resolved through the participation and discussion of the third reviewer (Xie).

Statistical analysis

All extracted data were summarized and analyzed by using Review Manager version 5.3 software (Copenhagen: Nordic Cochrane Centre, Cochrane Collaboration, 2014). We used odds ratio (OR) and respective 95% confidence intervals (95% CI) to compare differences for dichotomous variables and calculated weighted mean difference (WMD) or standard mean difference (SMD) and respective 95% confidence intervals (95% CI) to analyze continuous variables. A Cochrane's Q p-value < 0.05 was considered significant. With a 95% confidence interval, the statistic I2 was interpreted as follows: $\geqslant$ 50% reflectd high heterogeneity between studies, and $< 50\%$ indicated low heterogeneity. In the case of low heterogeneity, we used the fixed effects model; When heterogeneity was significant, a random effects model was used. In addition, we actively explore whether there is inherent heterogeneity potential among the included studies, and further consider the study design, population, race, age, method, and other sources of variation. When heterogeneity

For Peer Review Only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

is found in the included studies, a random effects model is selected and further subgroup analysis is conducted based on the sources of heterogeneity to explore the possibility of heterogeneity sources. Study possible publication bias was assessed by funnel plot.

Patient and public involvement

Patients were not invloved in this study.

Results

Study and Data Selection

The results of the detailed search process were shown in Figure 1, 333 potentially relevant records were obtained in our search strategy, of which 175 were excluded as duplicates. Of the remaining, 149 studies were excluded after title and abstract reviewed. After detailed assessment of the full text, further 4 studies were excluded due to the following: 2 uncontrolled trials, 1 using "VIZIGO, Biosense Webster Inc., Irvine, CA bi-directional sheath, 1 reporting duplicate date. In the end, we selected 5 studies in this meta-analysis.

Study Characteristics and Quality Assessment of Included Studies

From the selected studies, there were 518 subjects, of which 282 (54.4%) in the SS group and 236 (45.6%) in the NSS group. The characteristics of the 5 studies were summarized in Supplementary Table 1. The incidence of paroxysmal AF was 69%, and the Christopher Piorkowski et al.[13-14], Kim Rajappan et al.[15], Marc W. Deyell et al.[16] and Masaharu Masuda et al.[17] included all subtypes of AF. Steering sheaths used in selected studies included non-steerable transseptal sheath (Mullins; Cook Inc., Bloomington, IN, USA) , aconventional non-steerable sheath (Swartz SL0, St Jude Medical), controlled steerable sheath (Agilis, St. Jude Medical, St. Paul, MN, USA). The follow-up in the 3 studies was 6 months after the first surgery, but 12 ± 2 months in the study by Masaharu Masuda et al.[17], 3 months in the study by Marc W. Deyell et al.[16]. There were no significant differences between the two groups in terms of mean age, proportion of males, hypertension ratio, duration of AF, mean left atrial (LA) diameter, and proportion of underlying cardiac disease.

Main clinical outcomes

The main endpoint included in the study was the electrocardiogram recording of atrial fibrillation recurrence time ⩾ 30 seconds 3 to 12 months after radiofrequency ablation. Christopher Piorkowsk et al., Kim Rajappan et al., Marc W. Deyell et al., and Masaharu Masuda et al. reported statistically significant differences in the recurrence rate of atrial tachyarrhythmia after atrial fibrillation ablation surgery. The heterogeneity test of these five studies shows that（χ2=4.04, df=4, I2=1%, P=0.4), there was no significant heterogeneity between the studies, and a fixed effects model was used for analysis. Summary analysis showed that there was a significant difference in the recurrence rate of AF after the first surgery between SS and NSS ablation treatments [OR=0.52, 95% CI (0.36, 0.76), z=3.41, P=0.0006]; (Figure 2A).

Another primary endpoint is the incidence of perioperative and follow-up complications in both groups. Among the included literature, 4 articles [13-16] reported the occurrence of complications, with 225 cases in the SS group and 203 cases in the NSS group. Heterogeneity testing showed that（ χ2=0.97, df=3, I2=0%, P=0.81), there was no significant heterogeneity between the studies, and a fixed effects model was used for analysis. There was no statistically significant difference between the two groups [OR=1.03, 95% CI (0.42, 2.56), z=0.07, P=0.94]; (Figure 2B). Inguinal and femoral

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

vein hematoma are the most common intraoperative and postoperative complications. Christopher Piorkowsk et al. reported that one patient in the rotatable sheath group experienced a perioperative stroke during follow-up with minimal residual material; One patient had a pseudoaneurysm in the Femoral artery pathway, which must be resolved by surgery; In the NSS group, 2 patients developed cardiac tamponade requiring pericardial puncture, and 1 patient developed phrenic nerve paralysis, which was relieved during follow-up.

Secondary Clinical Outcomes

Acute Pulmonary vein reconnection is one of the secondary clinical outcomes. Three of the five studies mentioned acute Pulmonary vein reconnection, and heterogeneity test showed that（χ 2=0.35, df=2, I2=0%, P=0.84), with no significant heterogeneity between studies. A fixed effects model was used for analysis, and summary analysis showed that the SS group was superior to the NSS group in reducing the risk of PV reconnection [OR=0.47, 95% CI (0.23, 0.95), z=2.10, P=0.04]; (Figure 3A). Christopher Piorkowski et al. reported that compared with the NSS group, the SS group had less acute Pulmonary vein reconnection (11.1% versus 20.0%), which was similar to the research results published by Marc W. Deyell et al. and Masaharu Masuda et al. The study by Kim Rajappan et al. did not involve a description of acute reconnection of PV.

Among the included literature, 5 articles reported ablation time and fluoroscopy time respectively, with small heterogeneity between each study. Fixed effect models were used for analysis, and after summary analysis, it was found that the SS group was not superior to the NSS group in reducing ablation time [WMD=− 3.6, 95% CI (− 9.77, 2.57), z=1.14, P=0.25] (Figure 3B); The SS group was not superior to the NSS group in reducing fluoroscopy time [WMD=− 3.32, 95% CI (-9.10, 2.47), z=1.12, P=0.26] (Figure 3C). In addition, 5 articles were included to report the total program time, and heterogeneity testing showed that（χ 2=7.44, df=4, I2=46%, P=0.11), with significant heterogeneity between studies. A random effects model was used for analysis, and summary analysis showed that there was no statistically significant difference between the two groups [WMD=− 3.11, 95% CI (− 9.63, 3.42), z=0.93, P=0.35] (Figure 3D). The results showed that the SS group was not superior to the NSS group in reducing total program time.

Risk of bias in included studies

For the analysis of AF recurrence rate, the funnel plot was symmetric, so we think there was no significant publication bias (Figure 4).

Discussion

This meta-analysis showed that there was no significant difference in clinical complications between AF ablation with SS and NSS, suggesting that both SS and NSS are safe and effective for AF ablation. There was no statistically significant difference in ablation time between SS and NSS for radiofrequency ablation of atrial fibrillation, Mhanna M et al. obtained positive results after excluding Piorkowski 2008, with a P-value less than 0.05. They believe that using the SS shortened the surgical time, which we believe is evidence of a lack of robustness in the results. Due to rigorous considerations, we still believe that using the SS does not have an advantage in shortening the surgical time of atrial fibrillation radiofrequency ablation[18]. However, in reducing the incidence of AF, rapid atrial arrhythmia and pulmonary vein connection, SS have significant advantages over fixed curved sheaths.

Radiofrequency catheter ablation (RFCA) has developed as the recommended treatment for AF, and circumferential pulmonary vein antrum isolation is considered to be the cornerstone for the

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

treatment of paroxysmal and persistent AF[1-4]. However, similar to other long left atrial ablation lines, continuous and transmural ablation of these lesions is often difficult to achieve. Therefore, in clinical practice, due to the following reasons:1) Incomplete isolation of pulmonary veins; 2) Distant pulmonary vein isolation; 3) The occurrence of pulmonary vein reconnection lead to the occurrence of AF and atrial arrhythmia in a large number of patients, which greatly reduces the success rate of radiofrequency ablation[6,19,20]. Therefore, the duration and transmural lesions of PVI are critical to reduce AF recurrence. But during actual manipulation, It is a major challenge for the interventionalist to attempt a complex 3D ablation line in the pulmonary vein vestibule in an organ which moves with the respiratory rate, requiring a stable catheter and adequate tissue contact in order to achieve the desired ablation goal (transmural ablation with long duration). In recent years, steerable transseptal sheaths and fixed curve sheaths have been widely used in clinical radiofrequency ablation. The SS is convenient to enter and contact the ablation target, which is conducive to the continuity, maintenance and transmurality of the ablation target, and has been paid more and more attention and used in clinical practice[8-12]. Studies have shown that SS used for AF ablation are more effective and have comparable safety to conventional fixed curve sheaths[13-17]. However, the SS has a higher price than the fixed curve sheath, which requires patients to bear more equipment costs and becomes the concern of clinical surgeons. Therefore, we need a meta-analysis to evaluate and clarify the clinical impact of radiofrequency ablation under SS navigation, so as to provide a basis for clinical practice.

The advantage of using the SS for navigation may be due to the fact that the ablation tip is passively steered relative to the sheath itself and is only pushed and retracted within the sheath based on electrogram, fluorogram, and three-dimensional tactile information, which greatly improves the stability and steerability of the ablation tip[9]. It also allows the head ablation control in the millimeter range at the preset ablation target, which greatly reduces the occurrence of leakage points during ablation (eventually leading to acute reconnection of pulmonary veins). In addition, precise navigation of the ablation head provides the basis for reliable pacer and voltage mapping to find gaps in the complex 3-D PV anatomy to improve achievement of complete PVI[21]. Second, the pressure that could be applied through the tip of the ablation catheter was higher, which makes it possible to achieve transmural ablation of thicker regions of the left atrium (usually anterior to the left and right sided PVs)[22,23]. This is also confirmed by Masaharu Masuda et al.[17], when using the SS, the CF of the ipsilateral pulmonary vein vestibule was higher than that by using the fixed curve sheath. In the same area, CF value was only 5g when using fixed sheath, but almost doubled when using SS. The stability of the target may also reduce tissue edema caused by catheter instability due to heart beating. Moreover, more stable transmural ablation reduces the incidence of acute PV reconnection, as confirmed by this meta-analysis.

Celestino Sardu et al.'s study mentioned that excessive inflammation can lead to changes in the electrolytic dissection of the atrial myocardium. [24]Sardu C et al. believed that the persistence of abnormal calcium treatment can activate Ion channel and trigger calcium dependent signaling pathways. The miR-106b-25 cluster mediated posttranscriptional regulation of ryanodine receptor type-2 is a potential molecular mechanism involved in the pathogenesis of paroxysmal atrial fibrillation. [25]Moreover, intracellular calcium treatment in patients with atrial fibrillation is related to the increased incidence of abnormal spontaneous sarcoplasmic calcium release events, which can be attributed to the imbalance of ryanodine receptor type-2, leading to the delay and trigger mechanism after Depolarization, and ultimately promoting atrial remodeling and the

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

development of atrial fibrillation into a more lasting form.[26]The study by Kim Rajappan et al.[15] further showed that the use of the SS for right inferior pulmonary vein ablation could reduce CT registration time as well as ablation time. This may be due to the fact that the right lower pulmonary vein is relatively more difficult to place and attach by using the fixed curved sheath, while the SS can use the inverted U technique to quickly attach to PVs, which can build 3D models flexibly. This also greatly reduces the impact of the learning curve and manipulation experience of young interventionalists on RF ablation.

In addition, research by Janosi K and Guo R et al. found that compared to the standard, non-visualizable SS, visualizable SS significantly not only reduces the left atrial procedure time, RF delivery and fluoroscopy exposure ,but also but also significantly improved CF and initial PVI rate [27]. This greatly improves the safety of the surgery.[28]

Access with a larger transseptal sheath and ablation with more catheter tip pressure often raise safety concerns for the interventionalist during the procedure. In complications, there is no higher overall complication rate with SS. However, thicker sheaths have a direct correlation to single complications such as femoral vein injury and hematoma. Continuous monitoring and data collection, interpretation, and alarm settings may help clinical doctors in timely treatment management and medication adjustment, as well as early detection of atrial fibrillation recurrence and timely intervention to reduce stroke and other related atrial fibrillation complications.[29]

Limitations There are some limitations to this study. Firstly, all included studies are partly retrospective or non-randomized observational cohort studies. Secondly, in these studies, the force-time index or other ablation index are not mentioned. This data is reproducible in some clinical ablation treatments and is gaining increasing acceptance. If available, it will provide a firmer basis for clinical selection of SS. Finally, our sample size was small, with a minimum follow-up of 3 months and a maximum follow-up of 12 months. Therefore, the effect of selective sheath on AF recurrence in long-term follow-up is uncertain. To confirm the findings in our study, we need more randomized studies with larger sample sizes and longer follow-up.

Conclusion Compared with traditional fixed sheath, catheter ablation of AF with SS has better efficacy, which can effectively reduce the recurrence rate of AF and the occurrence of acute PVs. However, it can't shorten the procedure time and reduce complications.

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

Supplementary Table 1 Baseline characteristics of included studies
Figure 1 The flowchart of the literature search process
Figure 2 Forest plot of the primary outcomes. (A) Recurrence of AF and atrial arrhythmias and (B) Complications. CI, confidence interval; SS, steerable; NSS non-steerable sheath; M--H, Mantel--Haenszel
Figure 3 Forest plot of the secondary outcomes. (A) acute pulmonary vein reconnection;(B) ablation time;(C) fluoroscopy time;(D) total procedure time fluoroscopy time. CI, confidence interval; SS, steerable; NSS non-steerable sheath; M--H, Mantel--Haenszel
Figure 4 Funnel plot of comparison: SS/NSS, outcomes: AF recurrence rate

Author contribution Xinyao Jin and Mingbin Xie designed the meta-analysis and selected studies. Yuqing Zhou and Yuanhong Wu collected and analyzed the data statistically. All authors contributed to the writing of this manuscript.

Data availability statement No new data were generated or analysed in support of this research.

Patient consent for publication
Not applicable.

Ethics approval
Not applicable.

Funding There were no sources of funding for this systematic review and meta-analysis.

Conflict of interest The authors declare no competing interests.

References
[1] Haïssaguerre M, Jaïs P, Shah DC, Takahashi A, Hocini M, QuiniouG, et al. Spontaneous initiation of atrial fibrillation by ectopic beats originating in the pulmonary veins. N Engl J Med. 1998;339:659-666.
[2] Packer D L, Mark D B, Robb R A , et al. Effect of Catheter Ablation vs Antiarrhythmic Drug Therapy on

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies. Erasmushogeschool .

Mortality, Stroke, Bleeding, and Cardiac Arrest Among Patients With Atrial Fibrillation: The CABANA Randomized Clinical Trial. JAMA. 2019 Apr 2;321(13):1261-1274.

[3] C Blomström-Lundqvist, Gizurarson S, J Schwieler, et al. Effect of Catheter Ablation vs Antiarrhythmic Medication on Quality of Life in Patients With Atrial Fibrillation: The CAPTAF Randomized Clinical Trial. JAMA. 2019 Mar 19;321(11):1059-1068.

[4] Marrouche N F, Brachmann J, Andresen D, et al. Catheter Ablation for Atrial Fibrillation with Heart Failure. N Engl J Med. 2018 Feb 1;378(5):417-427.

[5] Ouyang F, Tilz R , Chun J , et al. Long-Term Results of Catheter Ablation in Paroxysmal Atrial Fibrillation Lessons From a 5-Year Follow-Up. Circulation. 2010 Dec 7;122(23):2368-2377.

[6] Shah S, Barakat AF, Saliba WI, Abdur Rehman K, Tarakji KG, Rickard J, et al. Recurrent atrial fibrillation after initial long-term ablation success: electrophysiological findings and outcomes of repeat ablation procedures. Circ Arrhythm Electrophysiol. 2018;11(4):e005785.

[7] Macle L, Khairy P, Weerasooriya R, et al. Adenosine-guided pulmonary vein isolation for the treatment of paroxysmal atrial fibrillation: an international, multicentre, randomised superiority tria. Lancet, 2015:672-679.

[8] Hiner E, Shah DP. Choice of Steerable Sheath Impacts Contact Force Stability During Pulmonary Vein Isolation. J Innov Card Rhythm Manag. 2021 Dec 15;12(12):4790-4795.

[9] Joseph J, Wong KC, Ginks MR, Bashir Y, Betts TR, Rajappan K. Steerable sheath technology in the ablation of atrial fibrillation. Recent Pat Cardiovasc Drug Discov. 2013 Dec;8(3):171-177.

[10] Ullah W, Hunter RJ, McLean A, Dhinoja M, Earley MJ, Sporton S, Schilling RJ. Impact of steerable sheaths on contact forces and reconnection sites in ablation for persistent atrial fibrillation. J Cardiovasc Electrophysiol. 2015 Mar;26(3):266-273.

[11] Reichlin T, Michaud GF. Our approach to maximizing the durability of pulmonary vein isolation during a paroxysmal atrial fibrillation ablation procedure. J Cardiovasc Electrophysiol. 2012 Nov;23(11):1272-1276.

[12] Brunelli M, Raffa S, Große A, Wauters K, Menoni S, Schreiber M, Geller JC. Influence of the anatomic characteristics of the pulmonary vein ostium, the learning curve, and the use of a steerable sheath on success of pulmonary vein isolation with a novel multielectrode ablation catheter. Europace. 2012 Mar;14(3):331-340.

[13] Piorkowski C, Eitel C, Rolf S, et al. Steerable versus nonsteerable sheath technology in atrial fibrillation ablation: a prospective, randomized study. Circulation Arrhythmia & Electrophysiology, 2011, 4(2):157-165.

[14]PMD Christopher, KMD Hans, GMD Jin-Hong, et al. Steerable Sheath Catheter Navigation for Ablation of Atrial Fibrillation: A Case Control Study. Pacing and Clinical Electrophysiology, 2008, 31(7):863-873.

[15] Kim R, Victoria B, Laura R, et al. A randomized trial to compare atrial fibrillation ablation using a steerable vs. a NSS. Europace, 2009(5):571-575.

[16] Deyell M W, Wen G, Laksman Z, et al. The impact of steerable sheaths on unblinded contact force during catheter ablation for atrial fibrillation. J Interv Card Electrophysiol. 2020 Apr;57(3):417-424.

[17] Masuda M, Fujita M, Iida O, et al. Steerable versus NSS during pulmonary vein isolation: impact of left atrial enlargement on the catheter–tissue contact force. J Interv Card Electrophysiol, 2016, 47(1):1-9.

[18] Mhanna M, Beran A, Al-Abdouh A, Sajdeya O, Barbarawi M, Alsaiqali M, Jabri A, Al-Aaraj A, Alharbi A, Chacko P. Steerable versus nonsteerable sheath technology in atrial fibrillation ablation: A systematic review and meta-analysis. J Arrhythm. 2022 Jun 3;38(4):570-579.

[19] Neuzil P, Reddy VY, Kautzner J, Petru J,Wichterle D, Shah D, et al. Electrical reconnection after pulmonary vein isolation is contingent on contact force during initial treatment: results from the EFFICAS I study. Circ Arrhythm Electrophysiol. 2013;6:327–333.

[20] Sotomi Y, Kikkawa T, Inoue K, Tanaka K, Toyoshima Y, Oka T, et al. Regional difference of optimal

For Peer Review Only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

contact force to prevent acute pulmonary vein reconnection during radiofrequency catheter ablation for atrial fibrillation. J Cardiovasc Electrophysiol. 2014;25:941–947.

[21] Ali A, Sakes A, Arkenbout EA, Henselmans P, van Starkenburg R, Szili-Torok T, Breedveld P. Catheter steering in interventional cardiology: Mechanical analysis and novel solution. Proc Inst Mech Eng H. 2019 Dec;233(12):1207-1218.

[22] Kautzner J, Neuzil P, Lambert H, Peichl P, Petru J, Cihak R, et al.EFFICAS II: optimization of catheter contact force improves out-come ofpulmonary vein isolation for paroxysmal atrial fibrillation.Europace. 2015;17:1229–1235.

[23] Schluermann F, Krauss T, Biermann J, Hartmann M, Trolese L, Pache G, et al. In vivo contact force measurements and correlation with left atrial anatomy during catheter ablation ofatrial fibrillation. Europace. 2015;17:1526–1532.

[24] Sardu C, Santulli G, Santamaria M, Barbieri M, Sacra C, Paolisso P, D'Amico F, Testa N, Caporaso I, Paolisso G, Marfella R, Rizzo MR. Effects of Alpha Lipoic Acid on Multiple Cytokines and Biomarkers and Recurrence of Atrial Fibrillation Within 1 Year of Catheter Ablation. Am J Cardiol. 2017 May 1;119(9):1382-1386.

[25] Sardu C, Santulli G, Guerra G, Trotta MC, Santamaria M, Sacra C, Testa N, Ducceschi V, Gatta G, Amico M, Sasso FC, Paolisso G, Marfella R. Modulation of SERCA in Patients with Persistent Atrial Fibrillation Treated by Epicardial Thoracoscopic Ablation: The CAMAF Study. J Clin Med. 2020 Feb 17;9(2):544.

[26] Sardu C, Santamaria M, Paolisso G, Marfella R. microRNA expression changes after atrial fibrillation catheter ablation. Pharmacogenomics. 2015 Nov;16(16):1863-77.

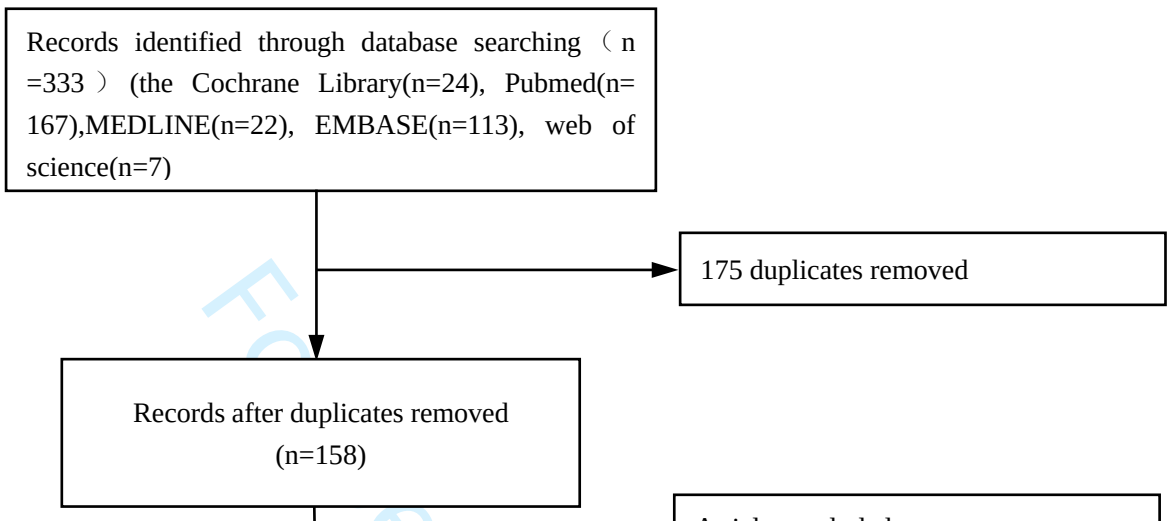
[27] Guo R, Jia R, Cen Z, Lu S, Yang C, Han S, Li D, Cui K. Effects of the visualized steerable sheath applied to catheter ablation of paroxysmal atrial fibrillation. J Interv Card Electrophysiol. 2022 Aug;64(2):511-518.

[28] Janosi K, Debreceni D, Janosa B, Bocz B, Simor T, Kupo P. Visualizable vs. standard, non-visualizable steerable sheath for pulmonary vein isolation procedures: Randomized, single-centre trial. Front Cardiovasc Med. 2022 Nov 16;9:1033755.

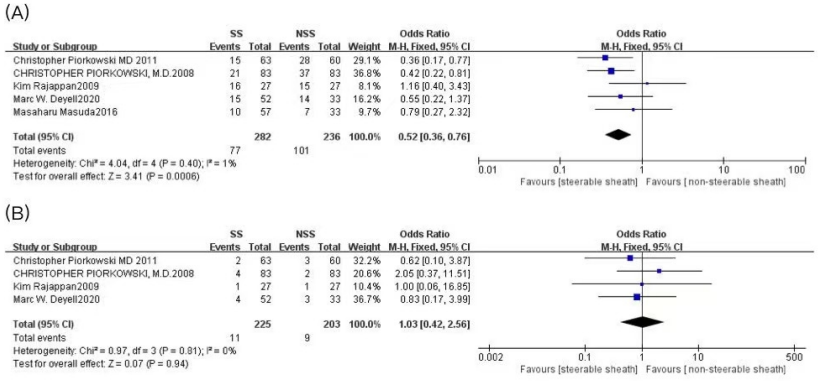
[29] Sardu C, Santamaria M, Rizzo MR, Barbieri M, di Marino M, Paolisso G, Santulli G, Marfella R. Telemonitoring in heart failure patients treated by cardiac resynchronisation therapy with defibrillator (CRT-D): the TELECART Study. Int J Clin Pract. 2016 Jul;70(7):569-76.

For Peer Review Only

Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.



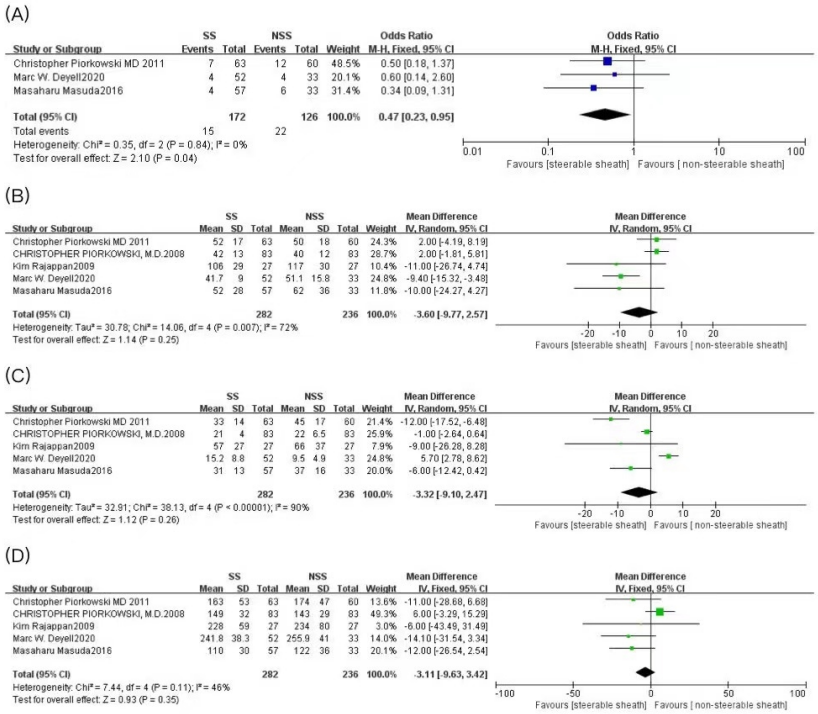
Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .



(A) Recurrence of AF and atrial arrhythmias and (B) Complications.

419x177mm (72 x 72 DPI)

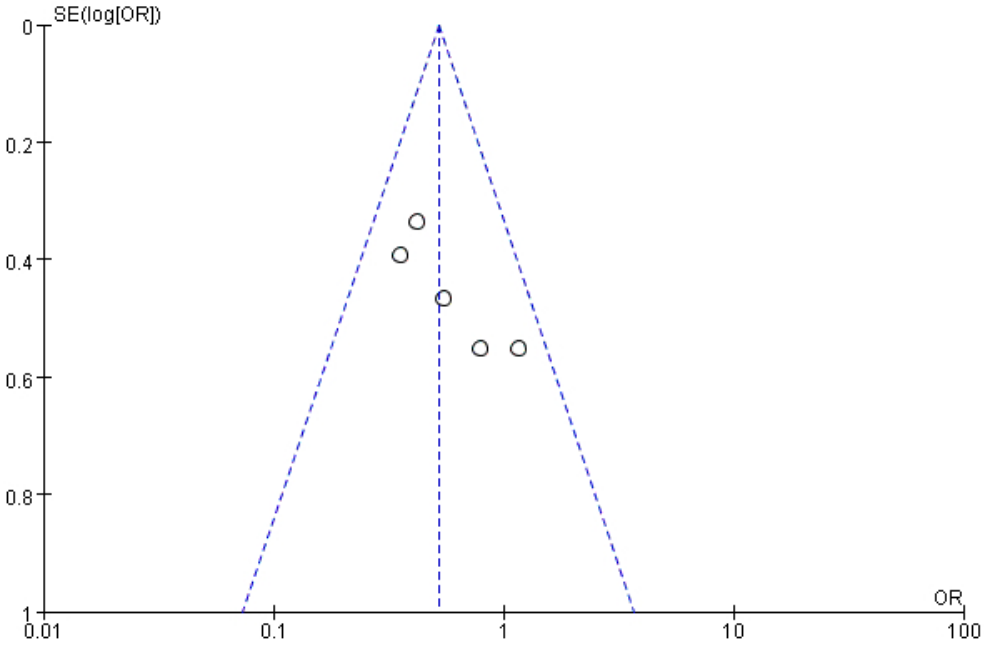
BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.



(A) acute pulmonary vein reconnection;(B) ablation time;(C) fluoroscopy time;(D) total procedure time fluoroscopy time.

419x319mm (72 x 72 DPI)

BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.



Funnel plot of comparison

211x141mm (72 x 72 DPI)

BMJ Open: first published as 10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Table 1 Baseline characteristics of included studies

First author (year)	Study design	Sample size		Age		Male n(%)		PAF	AF duration		LA size		Hypertension n(%)		Structural heart disease n(%)		Follow-up (month)
		SS	NSS	SS	NSS	SS	NSS	(n)	SS	NSS	SS	NSS	SS	NSS	SS	NSS	
Christopher Piorkowski MD 2011[13]	Prospective observational	63	60	57±9	62±9	44 (70)	35 (58)	64%	46	55	43 ± 6	45±6	42(67)	40 (67)	16(25.4)	22(36.7)	6
Christopher Piorkowski M.D.2008[14]	Retrospective observational	83	83	55 ±9	55 ± 9	61 (73)	61 (73)	80%	52	54	36 ± 13	38 ± 8	34(41)	34 (41)	13(15.7)	13(15.7)	6
Kim Rajappan 2009[15]	Prospective observational	27	27	57±10	54±10	19	20	50%	53±31	61±41	41±6	40±8	NA	NA	10(37)	7(26)	6
Marc W. Deyell2020[16]	Retrospective observational	52	33	56.6±13.1	61.2±11.7	36	20	69.4%	NA	NA	41.8 ±6.4	40.2 ±7	21 (40.38)	16(48.48)	NA	NA	3
Masaharu Masuda2016[17]	Prospective observational	57	33	67 ± 11	66± 11	39 (68)	24 (73)	67%	29 ± 36	25± 26	40 ± 7	38± 6	33(58)	22(67)	NA	NA	12±2

SS steerable sheath, NSS non-steerable sheath, PAF paroxysmal atrial fibrillation, AF atrial fibrillation, LA left atrium, N/A not available/applicable;

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

Erasmushogeschool . Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA

http://bmjopen-2022-068350 on 21 September 2023.

For peer review only

Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool .

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	1-2
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	1-2
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	2-3
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	2
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	2-3
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	3
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	3
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	8
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	3
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	3
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	3
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	3
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	3
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	3
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	3
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	3
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	3
Certainty	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	3

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.
Erasmushogeschool . Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA
10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
assessment			
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	7
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	7
Study characteristics	17	Cite each included study and present its characteristics.	3
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	4
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	4、9-10
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	4、9-10
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	4、9-10
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	4、9-10
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	4、9-10
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	4、9-10
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	4、9-10
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	5-6
	23b	Discuss any limitations of the evidence included in the review.	5-6
	23c	Discuss any limitations of the review processes used.	5-6
	23d	Discuss implications of the results for practice, policy, and future research.	5-6
OTHER INFORMATION			
Registration and protocol	24a	Registration does not apply .	2
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	2
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	2
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	10
Competing interests	26	Declare any competing interests of review authors.	10
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	10

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

For peer review only

1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . cted by copyright, including for uses related to text and data mining, AI training, and similar technologies.

PRISMA 2020 Checklist

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: http://www.prisma-statement.org/

For peer review only

10.1136/bmjopen-2022-068350 on 21 September 2023. Downloaded from http://bmjopen.bmj.com/ on June 5, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.