BMJ Open

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]

To cite: Jin X, Zhou Y, Wu Y, *et al*. Safety and efficacy of steerable versus non-steerable sheaths for catheter ablation of atrial fibrillation systematic review and meta-analysis. *BMJ Open* 2023;**13**:e068350. doi:10.1136/bmjopen-2022-068350

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-068350).

Received 15 September 2022
Accepted 08 September 2023

[1]Department of Cardiology, Hangzhou Red Cross Hospital, Hangzhou, China
[2]First Clinical Medical College, Zhejiang Chinese Medical University, Hangzhou, China

Correspondence to
Mingbin Xie;
hz_xiemingbin@163.com

ABSTRACT

Objectives With the development of radiofrequency (RF) ablation technology. In recent years, more and more patients with atrial fibrillation (AF) have been treated with RF ablation. Steerable sheaths (SS) have been widely used in RF ablation of AF. The aim of this meta-analysis was to compare the efficacy and safety of AF ablation using 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 ORs and mean difference to calculate the effect. We also estimated the 95% CI.

Results Five studies of RF 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 42.8% (OR: 0.52, 95% CI 0.36, 0.76, z=3.41, p=0.0006) and acute pulmonary vein (PV) reconnection (8.7% vs 17.4%, OR: 0.47, 95% CI 0.23, 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 RF ablation of AF can effectively reduce the recurrence rate of AF and the occurrence of acute PVs reconnection events. However, there is no advantage in shortening the total RF time, fluoroscopy time, total surgical time and reducing complications.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Rigorous search strategy including grey literature and non-indexed trials.
⇒ Quality of evidence assessment using the Grading of Recommendations Assessment, Development and Evaluation framework.
⇒ 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.
⇒ The included studies are retrospective and non-randomised observational cohort study, lacking large sample, multi-centre randomised controlled trial.
⇒ 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 non-steerable sheaths guided atrial fibrillation ablation.

INTRODUCTION

Description of the condition

Since Haïssaguerre *et al* reported that the rapid impulse issued by the ectopic excitation centre in the pulmonary vein triggered and driven atrial fibrillation (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 (RF) 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 oedema 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, steerable sheaths (SS) have been widely used in RF 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 non-steerable sheaths (NSS) in RF ablation of AF has not been systematically evaluated and analysed. 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 Preferred Reporting Items for Systematic Reviews and Meta-Analyses guideline criteria. This systematic review was conducted pursuant to a forward-looking agreement and was not registered with any external entity. Two researchers (XJ and YZ) searched three 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 (eg, therapeutic studies, human cohort trials); (2) AF (eg, paroxysmal AF and persistent AF); (3) sheath (eg, SS, navigable vascular sheaths, NSS, fixed curve sheaths); (4) RF ablation (eg, pulmonary vein isolation, pulmonary vein vestibule isolation and circumferential pulmonary vein isolation). MESH and keywords were identified for each of the four 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 (XJ and YZ). The disagreement was decided by the third examiner (MX). All studies considered to meet the screening criteria for title and abstract were reviewed in full by two independent reviewers (XJ and YZ) using the same criteria. The participation of the third reviewer (MX) 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 reconnection, 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 did not use SS; (4) studies using methods other than RF ablation (such as cryoablation and pulse ablation).

Data extraction, results and quality assessment

The standardised 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 ((XJ and YZ) 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 (XJ and YZ) using the Newcastle Ottawa Scale for the quality of the selected studies. Any disagreement was then resolved through the participation and discussion of the third reviewer (MX).

Statistical analysis

All extracted data were summarised and analysed by using Review Manager V.5.3 software (Copenhagen: Nordic Cochrane Centre, Cochrane Collaboration, 2014). We used OR and respective 95% CIs to compare differences for dichotomous variables and calculated weighted mean difference (WMD) or standard mean difference and respective 95% CIs to analyse continuous variables. A Cochrane's Q p value <0.05 was considered significant. With a 95% CI, the statistic I^2 was interpreted as follows: ≥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 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 involved 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

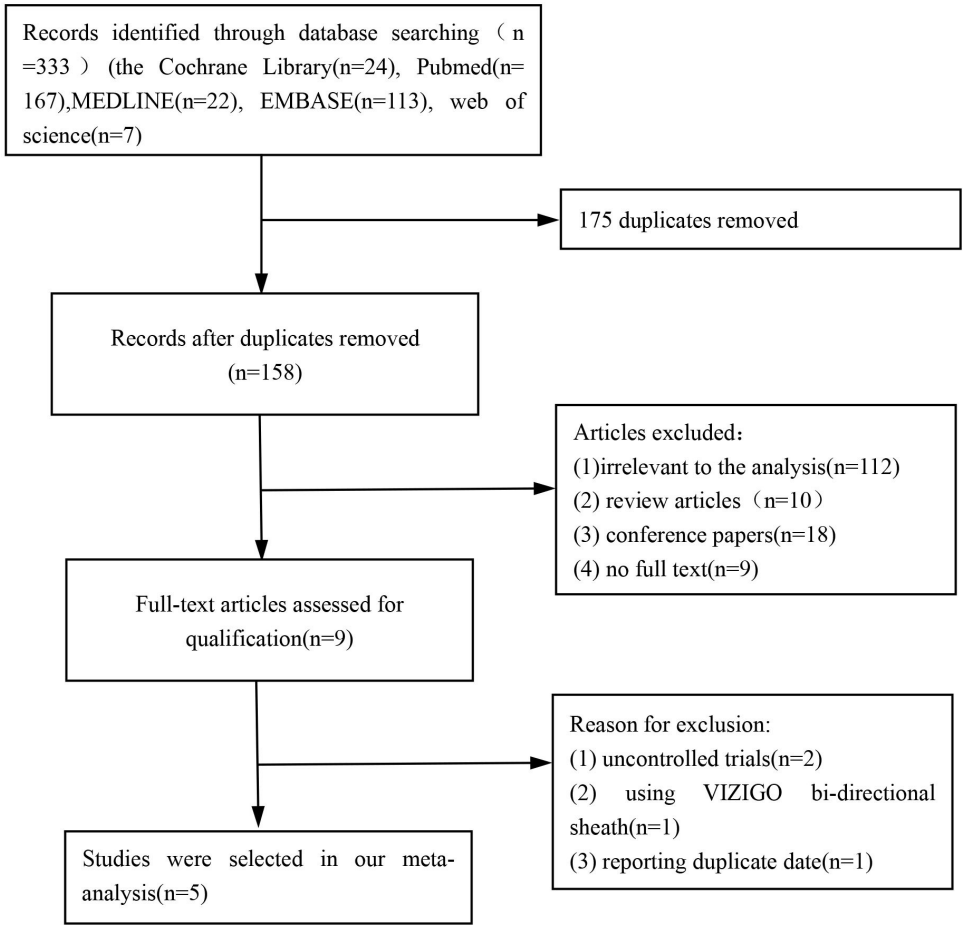

Figure 1 The flowchart of the literature search process.

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 four studies were excluded due to the following: two uncontrolled trials, one using (VIZIGO, Biosense Webster Inc, Irvine, CA, USA) bi-directional sheath, one reporting duplicate date. In the end, we selected five 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 five studies were summarised in online supplemental table 1. The incidence of paroxysmal AF was 69%, and Piorkowski *et al*,[13 14] Rajappan *et al*,[15] Deyell *et al*[16] and 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), a conventional NSS (Swartz SL0, St Jude Medical), controlled SS (Agilis, St. Jude Medical, St. Paul, MN, USA). The follow-up in the three studies was 6 months after the first surgery, but 12±2 months in the study by Masuda *et al*,[17] 3 months in the study by 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 ECG recording of AF recurrence time ≥30 s 3–12 months after RF ablation. Piorkowsk *et al*, Rajappan *et al*, Deyell *et al* and Masuda *et al* reported statistically significant differences in the recurrence rate of atrial tachyarrhythmia after AF ablation surgery. The heterogeneity test of these five studies shows that (χ^2=4.04, df=4, I^2=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, four 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 (χ^2=0.97, df=3, I^2=0%, p=0.81), there was no significant heterogeneity between the studies, and a fixed effects model was used for analysis. There was no

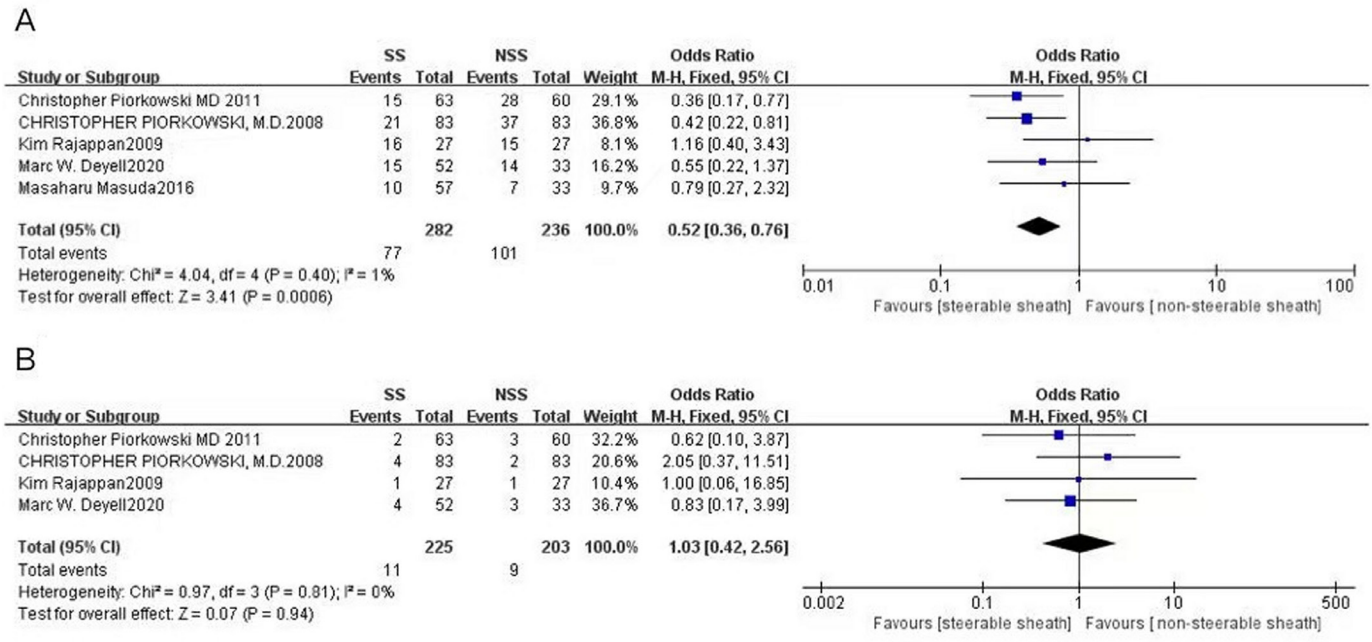

Figure 2 Forest plot of the primary outcomes. (A) Recurrence of atrial fibrillation and atrial arrhythmias and (B) complications. M-H, Mantel-Haenszel; NSS, non-steerable sheaths; SS, steerable sheaths.

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 haematoma are the most common intraoperative and postoperative complications. 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, two patients developed cardiac tamponade requiring pericardial puncture, and one 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, I^2=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). Piorkowski *et al* reported that compared with the NSS group, the SS group had less acute Pulmonary vein reconnection (11.1% vs 20.0%), which was similar to the research results published by Deyell *et al* and Masuda *et al*. The study by Rajappan *et al* did not involve a description of acute reconnection of PV.

Among the included literature, five 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, five articles were included to report the total programme time, and heterogeneity testing showed that (χ^2=7.44, df=4, I^2=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 programme 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 RF ablation of AF, Mhanna *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 AF RF

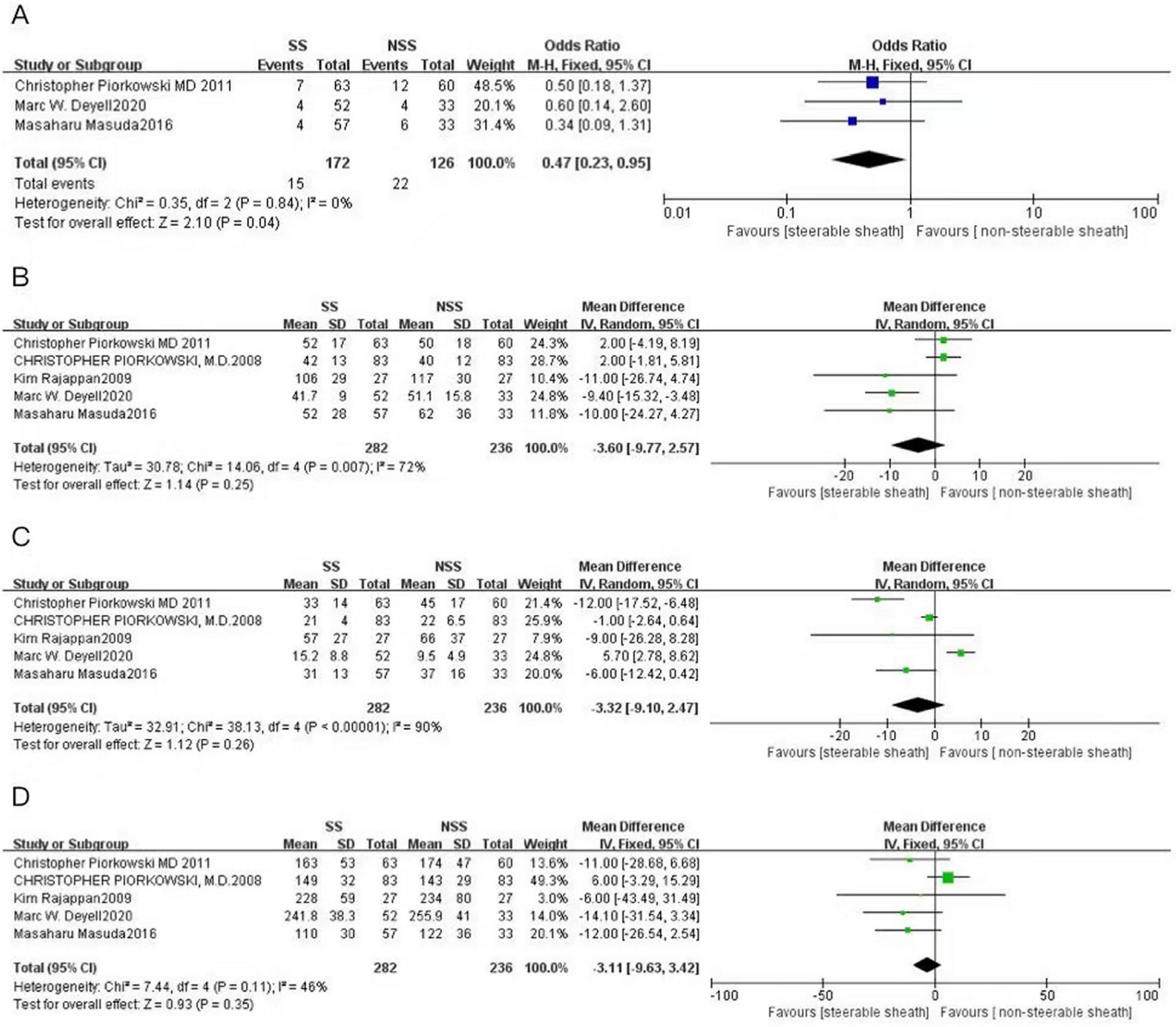

Figure 3 Forest plot of the secondary outcomes. (A) Acute pulmonary vein reconnection; (B) ablation time; (C) fluoroscopy time; (D) total procedure time fluoroscopy time. M-H, Mantel-Haenszel; NSS, non-steerable sheaths; SS, steerable sheaths.

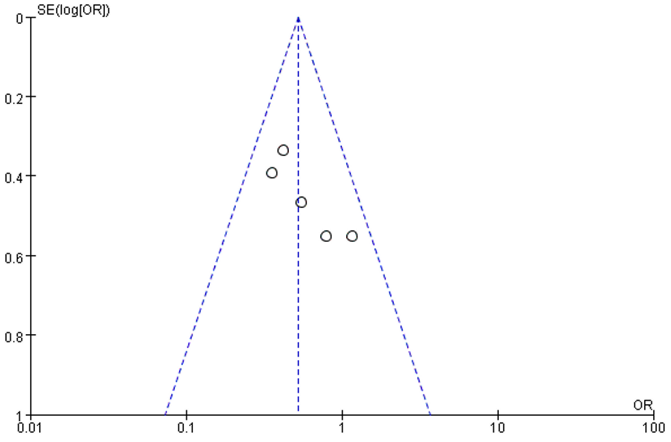

Figure 4 Funnel plot of comparison: Steerable sheaths/non-steerable sheaths, outcomes: atrial fibrillation recurrence rate.

ablation.[18] However, in reducing the incidence of AF, rapid atrial arrhythmia and pulmonary vein connection, SS have significant advantages over fixed curved sheaths.

RF catheter ablation 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 LA 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 RF 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 RF 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 RF 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 3D tactile information, which greatly improves the stability and steerability of the ablation tip.[9] It also allows the head ablation control in the millimetre 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 3D 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 Masuda *et al*,[17] when using the SS, the contact force (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 5 g when using fixed sheath, but almost doubled when using SS. The stability of the target may also reduce tissue oedema caused by catheter instability due to heartbeating. Moreover, more stable transmural ablation reduces the incidence of acute PV reconnection, as confirmed by this meta-analysis.

Sardu *et al*'s study mentioned that excessive inflammation can lead to changes in the electrolytic dissection of the atrial myocardium.[24] Sardu *et al* believed that the persistence of abnormal calcium treatment can activate ion channel and trigger calcium dependent signalling 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 AF.[25] Moreover, intracellular calcium treatment in patients with AF 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 depolarisation, and ultimately promoting atrial remodelling and the development of AF into a more lasting form.[26] The study by 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 *et al* and Guo *et al* found that compared with the standard, non-visualisable SS, visualisable SS significantly not only reduces the LA 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 haematoma. 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 AF recurrence and timely intervention to reduce stroke and other related AF complications.[29]

Limitations

There are some limitations to this study. First, all included studies are partly retrospective or non-randomised observational cohort studies. Second, 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 of our study, we need more randomised 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 reconnection. However, it cannot shorten the procedure time and reduce complications.

Contributors XJ and MX designed the meta-analysis and selected studies. MX was responsible for the revision of the manuscript and overall content as the guarantor. YZ and YW collected and analysed the data statistically. All authors contributed to the writing of this manuscript. MX was responsible for the revision of the manuscript and overall content as the guarantor.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data sharing not applicable as no datasets generated and/or analysed for this study. No new data were generated or analysed in support of this research.

ORCID iD

Xinyao Jin http://orcid.org/0000-0002-7260-7261

REFERENCES

1 Haïssaguerre M, Jaïs P, Shah DC, *et al*. Spontaneous initiation of atrial fibrillation by ectopic beats originating in the pulmonary veins. *N Engl J Med* 1998;339:659–66.
2 Packer DL, Mark DB, Robb RA, *et al*. Effect of catheter ablation vs antiarrhythmic drug therapy on mortality, stroke, bleeding, and cardiac arrest among patients with atrial fibrillation. *JAMA* 2019;321:1261–74.
3 Blomström-Lundqvist C, Gizurarson S, Schwieler J, *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;321:1059–68.
4 Marrouche NF, Kheirkhahan M, Brachmann J. Catheter ablation for atrial fibrillation with heart failure. *N Engl J Med* 2018;379:492.
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;122:2368–77.
6 Shah S, Barakat AF, Saliba WI, *et al*. Recurrent atrial fibrillation after initial long-term ablation success: electrophysiological findings and outcomes of repeat ablation procedures. *Circ Arrhythm Electrophysiol* 2018;11: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 trial. *Lancet* 2015;386:672–9.
8 Hiner E, Shah DP. Choice of Steerable sheath impacts contact force stability during pulmonary vein isolation. *J Innov Card Rhythm Manag* 2021;12:4790–5.
9 Joseph J, Wong KCK, Ginks MR, *et al*. Steerable sheath technology in the ablation of atrial fibrillation. *Recent Pat Cardiovasc Drug Discov* 2013;8:171–7.
10 Ullah W, Hunter RJ, McLean A, *et al*. Impact of Steerable sheaths on contact forces and Reconnection sites in ablation for persistent atrial fibrillation. *J Cardiovasc Electrophysiol* 2015;26:266–73.
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;23:1272–6.
12 Brunelli M, Raffa S, Große A, *et al*. 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;14:331–40.
13 Piorkowski C, Eitel C, Rolf S, *et al*. Steerable versus nonsteerable sheath technology in atrial fibrillation ablation: a prospective, randomized study. *Circ Arrhythm* Electrophysiol 2011;4:157–65.
14 Piorkowski C, Kottkamp H, Gerds-Li J-H, *et al*. Steerable sheath catheter navigation for ablation of atrial fibrillation: a case-control study. *Pacing Clin Electrophysiol* 2008;31:863–73. Available http://blackwell-synergy.com/doi/abs/10.1111/pace.2008.31.issue-7
15 Rajappan K, Baker V, Richmond L, *et al*. A randomized trial to compare atrial fibrillation ablation using a steerable vs. a non-steerable sheath. *Europace* 2009;11:571–5.
16 Deyell MW, 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;57:417–24.
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;47:99–107.
18 Mhanna M, Beran A, Al-Abdouh A, *et al*. Steerable versus Nonsteerable sheath technology in atrial fibrillation ablation: A systematic review and meta-analysis. *J Arrhythm* 2022;38:570–9.
19 Neuzil P, Reddy VY, Kautzner J, *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;6:327–33.
20 Sotomi Y, Kikkawa T, Inoue K, *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;25:941–7.
21 Ali A, Sakes A, Arkenbout EA, *et al*. Catheter steering in Interventional cardiology: mechanical analysis and novel solution. *Proc Inst Mech Eng H* 2019;233:1207–18.
22 Kautzner J, Neuzil P, Lambert H, *et al*. EFFICAS II: optimization of catheter contact force improves outcome of pulmonary vein isolation for paroxysmal atrial fibrillation. *Europace* 2015;17:1229–35.
23 Schluermann F, Krauss T, Biermann J, *et al*. In vivo contact force measurements and correlation with left atrial anatomy during catheter ablation Ofatrial fibrillation. *Europace* 2015;17:1526–32.
24 Sardu C, Santulli G, Santamaria M, *et al*. 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;119:1382–6.
25 Sardu C, Santulli G, Guerra G, *et al*. Modulation of SERCA in patients with persistent atrial fibrillation treated by Epicardial Thoracoscopic ablation: the CAMAF study. *J Clin Med* 2020;9:544.
26 Sardu C, Santamaria M, Paolisso G, *et al*. microRNA expression changes after atrial fibrillation catheter ablation. *Pharmacogenomics* 2015;16:1863–77.
27 Guo R, Jia R, Cen Z, *et al*. Effects of the visualized Steerable sheath applied to catheter ablation of Paroxysmal atrial fibrillation. *J Interv Card Electrophysiol* 2022;64:511–8.
28 Janosi K, Debreceni D, Janosa B, *et al*. Visualizable vs. standard, non-Visualizable Steerable sheath for pulmonary vein isolation procedures: randomized, single-centre trial. *Front Cardiovasc Med* 2022;9:1033755.
29 Sardu C, Santamaria M, Rizzo MR, *et al*. Telemonitoring in heart failure patients treated by cardiac Resynchronisation therapy with Defibrillator (CRT-D): the TELECART study. *Int J Clin Pract* 2016;70:569–76.

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 ±7.0	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；