Original Article

Clinical effectiveness and efficiency of a new steerable sheath technology for radiofrequency ablation in Chinese patients with atrial fibrillation: a retrospective comparative cohort study

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Background: The clinical effectiveness and efficiency of a steerable sheath for radiofrequency catheter ablation (RFCA) in Chinese patients with atrial fibrillation (AF) needs to be compared with a fixed curve sheath to optimize RFCA procedure.

Methods: This retrospective study included adult AF patients with their first RFCA that was conducted by the same electrophysiologist using a steerable sheath (VIZIGO, Biosense Webster, Inc.) or a fixed curve sheath (NaviEase, Synaptic Medical) in a Chinese tertiary care hospital from January to November 2021. The medical records kept at the hospital were the source of study data that included patient baseline characteristics and outcome measures for the clinical effectiveness and efficiency of RFCA procedure. Multivariate generalized linear regression analyses were performed to explore the impact of sheath type on clinical effectiveness and efficiency after adjustment.

Results: Fourteen patients using steerable sheath and 34 patients using fixed curve sheath for RFCA were included in the data analysis. Most of patient baseline characteristics associated with the two study groups were comparable except that the steerable sheath group had significantly higher left atrium diameter (41.9±6.5 *vs.* 38.1±3.9 mm, P=0.017) and larger left atrium volume (150.4±29.5 *vs.* 126.8±27.5 mL, P=0.017) than the fixed curve sheath group. Using steerable sheath was associated with significantly shorter total pulmonary vein isolation (PVI) fluoroscopy time and post-surgery hospital length of stay (LOS) than using fixed curve sheath in both unadjusted comparisons (PVI fluoroscopy time: 1.3±1.5 *vs.* 4.0±3.9 min, P=0.004; post-surgery LOS: 2.1±0.7 *vs.* 2.9±1.5 days, P=0.034) and multivariate generalized regression analyses (PVI fluoroscopy time: coefficient =–0.859, P=0.014; post-surgery LOS: coefficient =–0.303, P=0.018).

Conclusions: Compared to fixed curve sheath, steerable sheath used for RFAC could have the potential to shorten the PVI fluoroscopy time and reduce post-surgery LOS in a Chinese real-world hospital setting. Future real-world studies with large sample size are needed to confirm our study findings.

Keywords: Atrial fibrillation; steerable sheath; fixed curve sheath; fluoroscopy time; length of stay (LOS)

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Introduction

Atrial fibrillation (AF) affects about 2%, or nearly 10 million people, of the Chinese population (1), and this figure is expected to grow steadily with the aging population in China. AF has become a major health problem in China due to its clinical consequences, which include stroke, heart failure, and other heart-related complications and mortality (2).

Since the first catheter ablation was conducted in humans in 1981, catheter ablation has matured into a highly effective treatment that is recommended to AF patients who are not suitable for or intolerant to oral treatments (3). The fast-growing AF population in China and the instant effects of radiofrequency catheter ablation (RFCA) have greatly encouraged the uptake of catheter ablation in tertiary care hospitals across China, which is displayed by the figure accounting for over 40,000 annual AF ablation performed across the country (4). The apparent gap between the demand and capacity for AF ablation has driven Chinese interventional cardiologists to work much longer than their counterparts in western countries (5). In addition, fluoroscopy radiation is inevitable during the process of positioning a conventional ablation catheter during RFCA. The occupational hazards (such as back pain caused by lead protection or increased cancer risk associated with radiation exposure) have become the major health concern and further lowered the productivity of Chinese interventional cardiologists. More importantly, over 20% AF patients still experience disease relapse after their first RFCA likely due to insufficient efficiency of RFCA procedure (6). To mitigate such issues for interventional cardiologists and unmet medical needs of AF patients, a steerable sheath (The CARTO VIZIGO™ Bi-Directional Guiding Sheath) was introduced in China in 2018. This steerable sheath is designed to work with the CARTO® 3 System map to visualize ablation catheter without fluoroscopy and enhance performance efficiency for the navigation and positioning of ablation catheter (7). Previous randomized clinical trials from western countries demonstrated that steerable sheath could gain more clinical benefits than non-steerable sheath by increasing clinical success rate and reducing fluoroscopy time (8,9). However, these clinical benefits should be evaluated in Chinese tertiary care hospital setting before widely using steerable sheath to optimize RFCA procedure in Chinese patients with AF. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1021/rc).

Highlight box

Key findings

- Steerable sheath is preferred to fixed curve sheath for conducting radiofre-quency catheter ablation (RFCA) in atrial fibrillation (AF) patients with a large left atrium or patients requiring supplementary ablation.
- Steerable sheath is associated with significantly less fluoroscopy time and shorter length of hospital stay after ablation than fixed curve sheath for RFCA in a real-world setting.

What is known and what is new?

- Steerable sheath improves the navigation of ablation catheter for AF.
- The advantage of using steerable sheath to conduct RFCA is confirmed in re-al-world setting and the significantly shorter length of hospital stay after RFCA suggests that steerable sheath could improve clinical outcomes.

What is the implication, and what should change now?

- This study could promote more clinical applications of steerable sheath and the generation of robust real-world evidence to further prove the clinical benefits of steerable sheath.

Methods

This study was designed as a retrospective comparative cohort study to explore any differences in clinical effectiveness and efficiency between steerable sheath and fixed curve sheath in patients who underwent RFCA for AF in Xiangya Hospital, a teaching hospital of Central South University in Changsha, China. This study retrospectively reviewed all medical records associated with the cases of RFCA in a Chinese tertiary care hospital. The data were extracted and analyzed to explore the differences in measurable outcomes for clinical effectiveness and efficiency [operation efficiency, radiation exposure, surgery outcomes, and post-surgery length of hospital stay (LOS)] associated with RFCA by using either a steerable sheath or a fixed curve sheath. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional ethics committee of Xiangya Hospital (No. 202011162) and individual consent for this retrospective analysis was waived.

Patient identification

The operative notes in the electronic medical information system of the study hospital were screened to identify AF patients who underwent RFCA from October 1, 2020, to

September 30, 2021. The RFCA for the identified patients was conducted using the set ablation index (AI) values by left atrial wall (mean AI for rear wall: 383, mean AI for front wall: 468, mean AI for top: 431, mean AI for bottom: 424, mean AI for ridge: 468) and VISTAGTM module parameters which included contact force (mean: 9.9 g), ablation temperature (mean: 36.9 ℃), baseline impedance (mean: 124.7 Ω), and reduction of impedance (mean: 7.3 Ω). To minimize the potential confounding effects on the outcome measures, the patient's medical records associated with the hospital episode for RFCA were reviewed to determine the eligibility for being included according to the inclusion and exclusion criteria. This study included patients if they met all the following criteria: (I) adult AF patients (18 years or older as of the date of RFCA) who underwent RFCA using the Thermocool Smarttouch™ Surrounding Flow (STSF) radiofrequency catheter under the guidance of AI; (II) RFCA was conducted with either a steerable sheath (VIZIGO, Biosense Webster, Inc.) or a fixed curve sheath (NaviEase, Synaptic Medical) for RFCA in the study hospital; and (III) RFCA was performed by the same interventional cardiologist (the study investigator) to control the confounding effects associated with surgery skills. The exclusion criteria for this study were as follows: (I) patients underwent emergent or unscheduled RFCA due to critical conditions; (II) patients had previous treatment with any types of AF ablation; (III) AF ablation was conducted using an approach other than radiofrequency; (IV) RFCA was interrupted due to an unexpected medical circumstance; or (V) patients underwent other heart-related procedures along with RFCA. This retrospective cohort study did not take sample size calculation into account but include all eligible patients who underwent RFCA during the study period.

Data extraction

The operative notes and medical notes associated with RFCA were the main data sources for the provision of data to be applied in data analysis: (I) patient characteristics (demographics, insurance types, hospital admission diagnoses including AF type and comorbidities, heart function, stroke risk assessment by CHA2DS2-VASc), (II) pre-surgery heart assessment [aortic diameter, left atrium diameter, left atrial volume, and left ventricular ejection fraction (LVEF)], (III) RFCA procedure information [sheath information, AI information, atrial puncture time, pulmonary vein isolation (PVI) time, ablation time, and irritation fluid volume], (IV) radiation exposure information [fluoroscopy time (minutes), PVI fluoroscopy time (minutes), and radiation exposure dose (mGy)], (V) ablation outcomes (first pass isolation success, immediate postoperative heart rhythm, and perioperative complications), and (VI) post-surgery LOS.

Statistical analysis

The included patients were divided into two study groups by the type of sheath (steerable sheath *vs.* fixed curve sheath) used in the RFCA procedures for data analyses. The collected information for patient baseline characteristics associated with the two study groups were summarized using descriptive statistical methods and compared using either the Student's *t*-test for continuous variables or Fisher's exact test for categorical variables. To explore the impact of sheath types on the clinical effectiveness (ablation outcomes: first pass isolation success, immediate postoperative heart rhythm, and perioperative complications) and efficiency (atrial puncture time, PVI time, ablation time, irritation fluid volume, fluoroscopy time, PVI fluoroscopy time, radiation exposure dose, and post-surgery LOS) associated with RFCA, this study selected regression models appropriate to the nature of the outcome measures and conducted univariate regression analyses to explore any potential confounding factors from patient characteristics and the pre-surgery heart assessment. The identified confounding factors were applied as independent variables in the multivariate regression analyses for the adjusted comparisons of the outcome measures between the two sheath types. The selected regression models were the generalized linear regression model for continuous outcomes (atrial puncture time, PVI time, ablation time, irritation fluid volume, fluoroscopy time, PVI fluoroscopy time, and radiation exposure doses, and post-surgery LOS) and the logistic regression model for ablation first pass isolation success. The patients with missing information were excluded from the regression analyses described above. To guide the interpretation of the results of multivariate regression analyses, this study used the multivariate regression models and the patient characteristics (age, body weight, AF type, concurrent arrhythmia), heart characteristics (heart function and left atrium diameter), and ablation approach of all included patients to predict the outcomes for RFCA with the two types of sheaths. The predicted outcomes associated with the two sheaths were compared using either the paired

t-test for continuous outcomes or the McNemar test for categorical outcomes. To confirm the robustness of the results from the multivariate regression analyses for PVI fluoroscopy time and post-surgery LOS, probabilistic sensitivity analyses (PSA) with 10,000 Monte Carlo simulations was conducted using the multivariate regression models to estimate the median and the 95% credible intervals for the differences in the two outcomes between the types of sheaths.

The statistical significance in these analyses was defined as a two-sided P value less than 0.05. All data analyses were conducted using the statistical software R or 2013 Microsoft Excel.

Results

Fifty AF patients who underwent RFCA during the study period were identified. A further assessment of the patient eligibility to be included in the study eliminated two patients—one with previous RFCA treatment and the other one patient with previous ablation using both radiofrequency and Marshall ethanol infusion. At the end, 14 patients using steerable sheath and 34 patients using fixed curve sheath met both study inclusion and exclusion criteria.

Patient characteristics and RFCA procedure associated with the two study groups

The comparison of the patient characteristics between the steerable sheath group and the fixed curve group did not identify any statistically significant differences in patient demographics (age: 60.7±8.0 *vs.* 57.7±11.0 years, P=0.375; male gender proportion: 64.3% *vs.* 70.6%, P=0.669), heart function (left ventricular ejection fraction: 61.9%±7.2% *vs.* 59.5%±9.7%, P=0.477), stroke risk (CHA2DS2-VASc: 1.3±1.1 *vs.* 1.6±1.7, P=0.860), and bleeding risk (HAS-BLED score: 0.6±0.5 *vs.* 0.9±1.1, P=0.704). However, the steerable sheath group had a slightly higher proportion of persistent AF than the fixed curve sheath group (35.7% *vs.* 17.6%, P=0.176). A further comparison of pre-surgery heart anatomic information revealed a significantly higher left atrium diameter (41.9±6.5 *vs.* 38.1±3.9 mm, P=0.017) and larger left atrium volume (150.4±29.5 *vs.* 126.8±27.5 mL, P=0.017) in the steerable sheath group. Approaches to ablation reported by the two study groups included (I) PVI only, (II) PVI plus box isolation of fibrotic areas, (III) PVI plus tricuspid isthmus ablation, (IV) PVI plus ablation of left atrium top line, and (V) PVI plus superior vena cava ablation. PVI plus supplementary ablation was more prevalent in the steerable sheath group (57.1% *vs.* 29.4%, P=0.071). Moreover, the steerable sheath group had a significantly higher rate of using ibutilide—the only antiarrhythmic drug administered during the ablation procedure—than the NaviEase group (57.1% *vs.* 5.9%, P<0.001). There was no missing information associated with the patients included in the two study groups. The patient characteristics and ablation procedure information of the two study groups are summarized in *Table 1*.

Unadjusted comparisons of ablation-related outcomes, radiation exposure, and post-surgery LOS between the two sheath groups

Although the two sheath groups had highly comparable PVI duration (the steerable sheath group *vs.* the fixed curve group: 50.5±9.0 *vs.* 48.8±11.1 min, P=0.614), the steerable sheath group was associated with a significantly shorter duration of PVI fluoroscopy time (1.3±1.5 *vs.* 4.0±3.9 min, P=0.004). Other ablation outcomes, including the ablation first pass isolation success rate, instant isolation success rate, and post-surgery AF rate, in the two study groups were highly comparable; and there were no reported complications associated with RFCA in either group. Lastly, the steerable sheath group was associated with a significantly shorter post-surgery LOS than the fixed curve group (2.1±0.7 *vs.* 2.9±1.5 days, P=0.034). The results of the unadjusted comparisons of the outcome measures between the two sheath groups are summarized in *Table 2*.

Predictors for ablation-related outcomes, fluoroscopy, and post-surgery LOS in patients who received RFCA

The multivariate regression analyses did not identify any predictors from patient characteristics, sheath type, and ablation locations for first pass isolation success, instant isolation success, PVI duration, and irritation fluid volume. Relative to the fixed curve sheath, using the steerable sheath showed a significant reduction in PVI fluoroscopy time (coefficient =–0.859, P=0.014) and in the post-surgery LOS (coefficient =–0.303, P=0.028) after the adjustment of patient characteristics in the multivariate regression analysis. Other predictors for fluoroscopy time included: (I) PVI combined with supplementary ablation (coefficient =0.790, P=0.041), (II) persistent AF (coefficient =–1.269, P=0.004), and (III) morbidities with NYHA III heart failure (coefficient

Table 1 Summary of the patient characteristics of the two sheath study groups

Variable	Steerable sheath group (N=14)	Fixed curve sheath group (N=34)	P value
Demographics			
Age (years), mean ± SD	60.7±8.0	57.7±11.0	0.375
Male, %	64.3	70.6	0.669
Body weight (kg), mean ± SD	67.4±11.5	68.0±9.1	0.835
AF type, %			
Persistent AF	35.7	17.6	0.176
Paroxysmal AF	64.3	82.4	0.176
AF duration			
Disease duration after AF diagnosis (years), mean ± SD	2.9±3.8	2.8±3.2	0.742
Previous drug treatment for AF, %	21.4	29.4	0.572
Heart anatomic information, mean ± SD			
Aortic diameter (mm)	29.4±1.9	28.4±2.9	0.260
Left atrium diameter (mm)	41.9±6.5	38.1±3.9	0.017
Left atrial volume (mL)	150.43±29.50	126.80±27.48	0.017
Heart function, %			
NYHA I	50.0	29.4	0.175
NYHA II	50.0	61.8	0.452
NYHA III	0.0	8.8	0.251
NYHA IV	0.0	0.0	
LVEF, mean ± SD	61.9±7.2	59.5±9.7	0.477
Stroke and bleeding risk, mean ± SD			
CHA2DS2-VASc	1.3±1.1	1.6±1.7	0.860
HAS-BLED score	0.6±0.5	0.9±1.1	0.704
Concurrent arrhythmia, %			
Atrial premature beats and atrial tachycardia	21.4	35.3	0.346
Premature ventricular contractions and ventricular tachycardia	21.4	35.3	0.346
Atrial flutter	0.0	8.8	0.251
Atrioventricular block	0.0	8.8	0.251
AF with long pause	0.0	2.9	0.517
Any type of concurrent arrhythmia	35.7	58.8	0.145

Table 1 (*continued*)

Table 1 (*continued*)

Variable	Steerable sheath group (N=14)	Fixed curve sheath group (N=34)	P value
Main comorbidities, %			
Hypertension	50.0	35.3	0.344
Coronary heart disease	21.4	35.3	0.346
Hyperlipidemia	14.3	17.6	0.776
Atrial septal defect	7.1	0.0	0.115
Valvular heart disease	7.1	0.0	0.115
Diabetes	7.1	14.7	0.471

AF, atrial fibrillation; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; CHA2DS2-VASc, Congestive heart failure, Hypertension, Age ≥75 years (doubled), Diabetes mellitus, prior Stroke or transient ischemic attack or thromboembolism (doubled), Vascular disease, Age 65 to 74 years, Sex category; HAS-BLED, Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly.

Table 2 Summary of the ablation procedures and outcomes of the two sheath study groups

Outcome measure	Steerable sheath group (N=14)	Fixed curve sheath group (N=34)	P value
Ablation approach, %			
PVI only	42.9	70.6	0.071
PVI plus box isolation of fibrotic areas	42.9	20.6	0.115
PVI plus tricuspid isthmus ablation	7.1	0.0	0.115
PVI plus ablation of left atrium top line	7.1	2.9	0.508
PVI plus superior vena cava ablation	0.0	5.9	0.354
Utilization of antiarrhythmic drug during ablation (ibutilide), %	57.1	5.9	<0.001
Ablation procedure time, mean ± SD			
Ablation time (min)	39.5±9.4	46.1±17.3	0.468
Atrial puncture time (min)	11.1±5.4	9.6±3.6	0.258
PVI time (min)	50.5±9.0	48.8±11.1	0.614
Radiation exposure, mean ± SD			
Total fluoroscopy time (min)	10.1±5.0	10.0±4.5	0.954
PVI fluoroscopy time (min)	1.3±1.5	4.0±3.9	0.004
Radiation doses associated with PVI (mGy)	21.9±21.8	32.6±27.4	0.135
Ablation outcomes			
First pass isolation success, %	85.7	79.4	0.611
Post-surgery AF, %	0.0	0.0	1.000
Post-surgery LOS (days), mean ± SD	2.1±0.7	2.9±1.5	0.034

AF, atrial fibrillation; LOS, length of stay; PVI, pulmonary vein isolation.

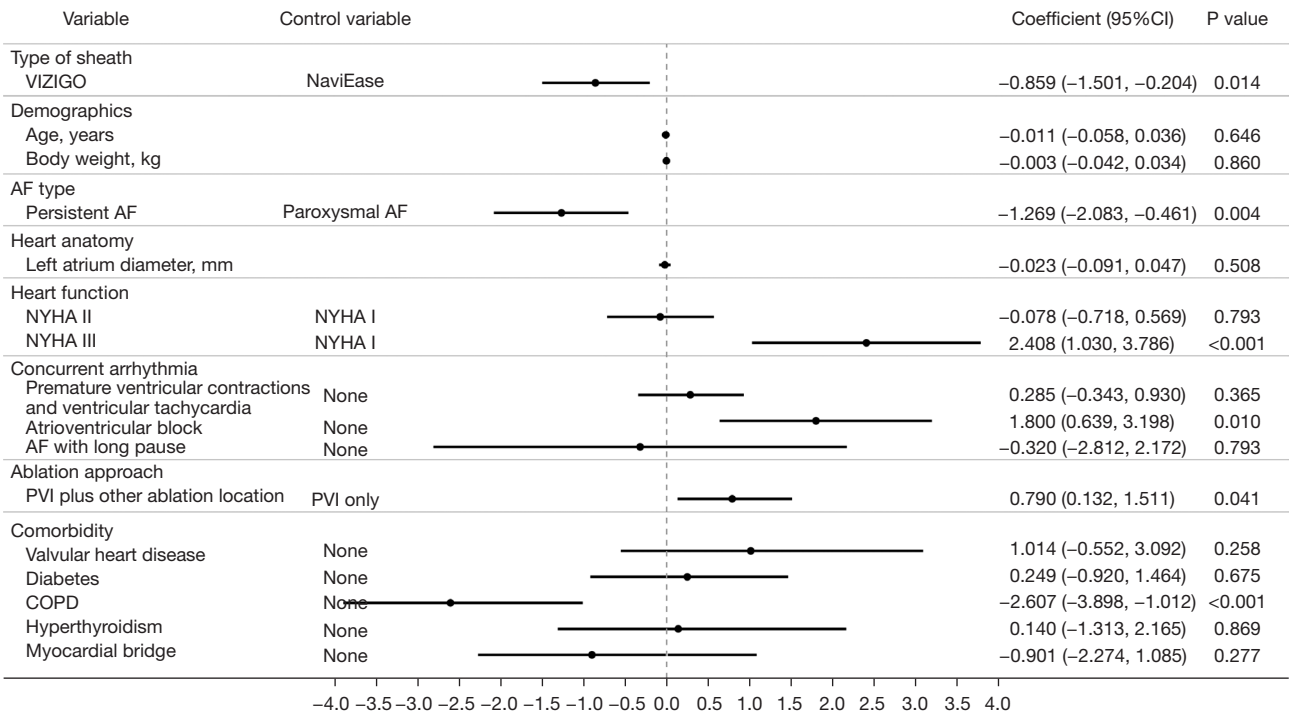

Figure 1 Results of the multivariate generalized linear regression analysis for PVI fluoroscopy time in the study cohort. AF, atrial fibrillation; COPD, chronic obstructive pulmonary disease; NYHA, New York Heart Association; PVI, pulmonary vein isolation.

=2.408, P<0.001), atrioventricular block (coefficient =1.800, P=0.010), or chronic obstructive pulmonary disease (COPD) (coefficient =−2.607, P<0.001). No patient characteristics were identified from the multivariate generalized linear regression analysis as a predictor for post-surgery LOS. The multivariate regression analyses for PVI fluoroscopy time and post-surgery LOS are illustrated in *Figure 1* and *Figure 2*, respectively.

Uncertainty associated with the differences in PVI fluoroscopy time and post-surgery LOS between the two types of sheaths

The predicted PVI fluoroscopy time and post-surgery LOS for the two types of sheaths from the multivariate regression models were compared, which confirmed the significant differences of the two outcomes between the steerable sheath and the fixed curve sheath (PVI fluoroscopy time: 1.6±1.6 *vs.* 3.9±3.8 min, P<0.001; post-surgery LOS: 2.2±0.9 *vs.* 2.9±1.2 days, P<0.001). A PSA with 10,000 Monte Carlo simulations reaffirmed the differences in fluoroscopy time in PVI (median: −1.9 min, 95% credible interval: −3.5 to −0.8 min) and post-surgery LOS (median: −0.9 days, 95% credible interval: −1.5 to −0.4 days). The simulated results for the PVI fluoroscopy time and post-surgery LOS are plotted in *Figure 3* and *Figure 4*, respectively.

Discussion

It is difficult to comprehensively measure the clinical effectiveness and efficiency of a sheath used in RFCA with a limited sample size in a retrospective study setting. Even with a meticulous review of all documented records on the RFCA procedure, the current study was unable to replicate most of previously reported advantages of the steerable sheath in comparison to a fixed curve sheath (7,10,11) but the observed significant reduction of PVI fluoroscopy time and post-surgery LOS may be considered a promising aspect of improved clinical efficiency of steerable sheath for RFCA. In addition, these study findings can encourage future research to confirm the clinical benefits of steerable sheath in reducing the risk of electrode and sheath dislocation into the right atrium which requires fluoroscopic verification during maneuvers performed with the sheath, simplifying the ablation process, and improving initial PVI success rate.

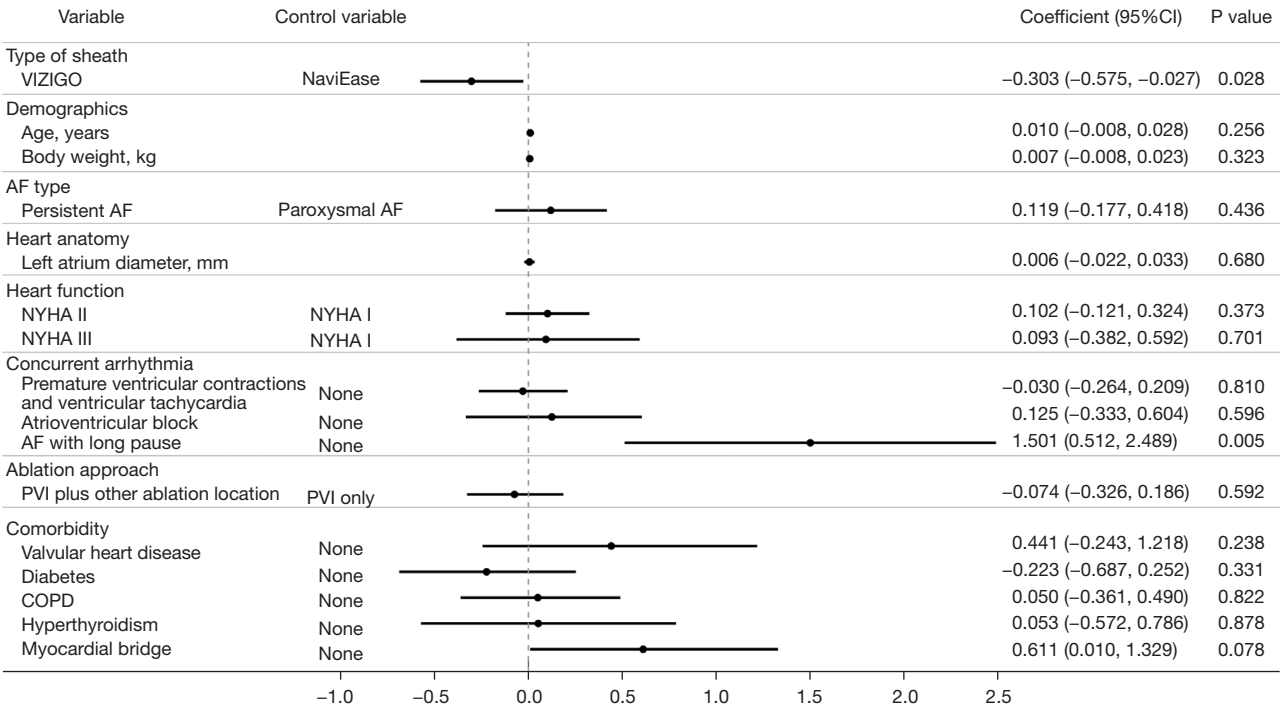

Figure 2 Results of the multivariate generalized linear regression analysis for post-surgery LOS in the study cohort. AF, atrial fibrillation; COPD, chronic obstructive pulmonary disease; NYHA, New York Heart Association; PVI, pulmonary vein isolation; LOS, length of hospital stay.

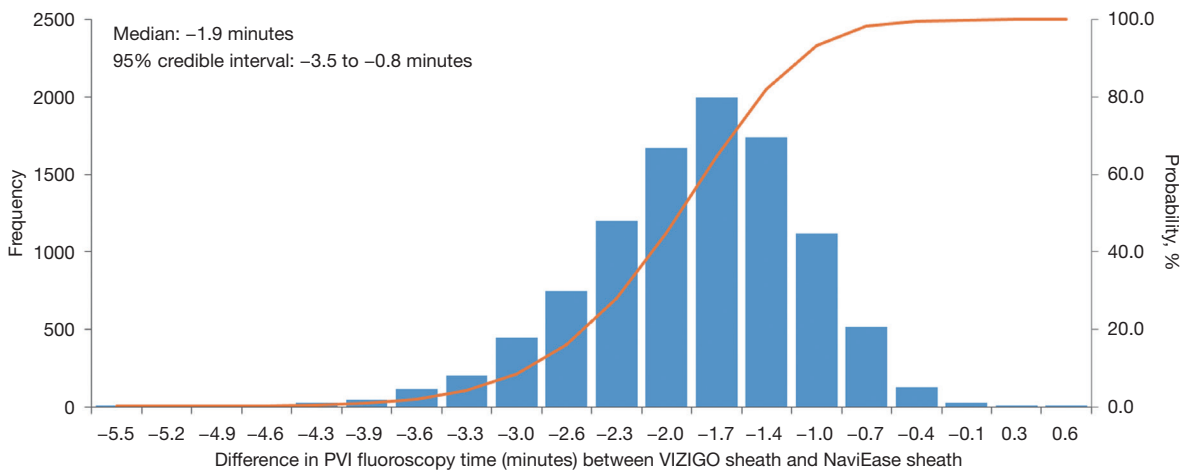

Figure 3 The distribution of the 10,000 simulated differences in PVI fluoroscopy time between the two study sheaths. PVI, pulmonary vein isolation.

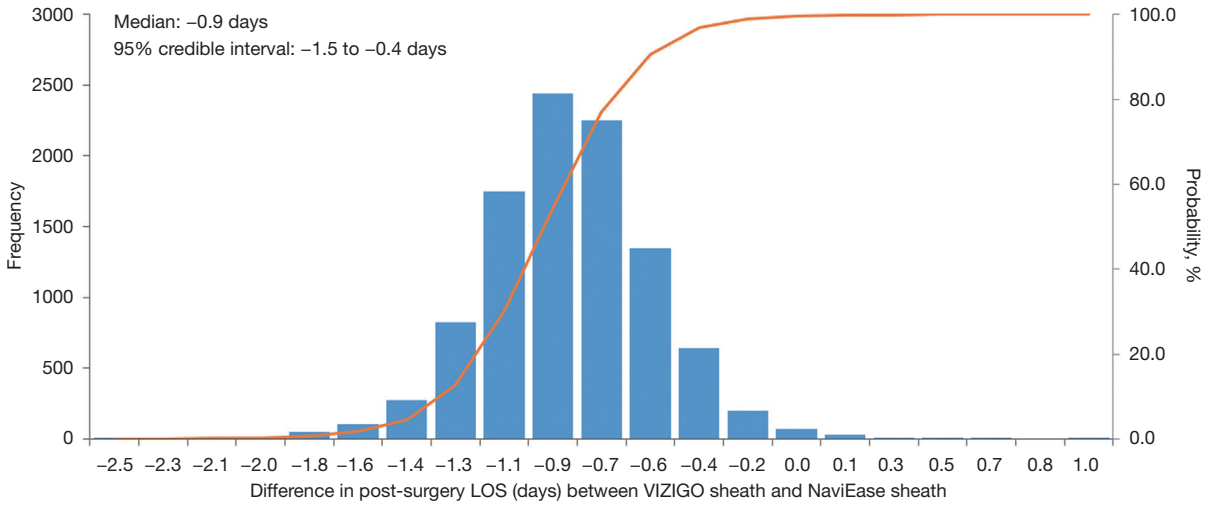

Figure 4 The distribution of the 10,000 simulated differences in post-surgery LOS between the two study sheaths. LOS, length of hospital stay.

Steerable sheath has been developed to address the limitations of using a fixed curve sheath for AF ablation. A fixed curve sheath usually requires fluoroscopy for visualization to guide the positioning of the catheter during ablation. The absence of the bi-directional deflection feature in a fixed curve sheath could pose difficulties in reaching all desired sites with a catheter for ablation. Consequently, the design of the VIZIGO sheath can be highly enticing to interventional cardiologists because of its less dependence on fluoroscopy and enhanced performance by leveraging the features of 180° bi-directional deflection and tapered distal tip for smooth transition profile between the dilator and the sheath, which promotes ease of entry into the left atrium during the transseptal access. The observed differences in the heart anatomy, ablation approach, PVI fluoroscopy time, and utilization of an antiarrhythmic drug (ibutilide) during ablation between the two sheath study groups could indicate the preference of our interventional cardiologists likely due to their experience with the features promoted for the VIZIGO sheath. Patients in the steerable sheath group had a significantly larger left atrium diameter, which is an indicator of the size of the left atrium. A larger left atrium is characterized by a thinner wall due to stretching and a higher risk of puncturing during a catheter ablation than a smaller left atrium (12). As a result, interventional cardiologists may prefer the VIZIGO sheath in their operation, which has better visualization with the CARTO® system, to reduce the risk inherent to patients with a larger left atrium. The superior visualization capabilities of VIZIGO could also improve the preciseness of catheter maneuvering on the ablation site and reduce the contact force needed for ablation. The current study found that steerable sheath was used more often in patients requiring PVI in addition to supplementary ablations on other locations, such as fibrotic areas, tricuspid isthmus, and left atrium roof, that are difficult for a fixed curve sheath to reach using a fixed curve sheath. For example, box isolation of fibrotic areas is usually implemented with PVI in patients with fibrotic atrial cardiomyopathy (FACM) to improve ablation outcomes (13). Because anterior fibrotic areas are more common and larger than posterior fibrotic areas in AF patients with FACM (14), it would be much easier for the bi-directional VIZIGO sheath to steer the catheter from the pulmonary vein entrance to the anterior wall of the left atrium. In addition, the management of persistent AF generally involves the catheter ablation of complex fractionated atrial electrograms (CFAE) (15); therefore, the bi-directional design of the VIZIGO sheath could be more attractive than a fixed curve sheath to ablators when operating on patients with persistent AF. As ibutilide is a Class III AAD that prolongs the atrial refractory period and helps with improving catheter ablation outcomes in patients with complicated AF, such as long-standing persistent AF (16), the higher rate of ibutilide use during ablation in the steerable sheath group could be an indicator for the disease complexity and also the surgeon's preference of using steerable sheath for treating complicated RFCA cases.

The current study confirmed another important

advantage of steerable sheath over fixed curve sheath, which is less dependence on fluoroscopy during PVI. The PVI fluoroscopy time associated with steerable sheath was reduced by half when compared to that for a fixed curve sheath in the adjusted comparison analysis. Theoretically, using VIZIGO with the CARTO system has sufficient capacity for visualization that allow interventional cardiologists to conduct fluoroscopy-free PVI (7). Nevertheless, fluoroscopy was employed to confirm the position of the catheter in our study setting as there were limited clinical experience with the VIZIGO sheath and clinical uncertainties to conduct VIZIGO sheath-guided RFCA without fluoroscopy. However, the reduced dependence on fluoroscopy during PVI conducted with the VIZIGO sheath is an important step towards enabling RFCA that is free of radiation exposure, which is expected to address the health hazards caused by radiation exposure and wearing lead shields in interventional cardiologists (17). The rapid growth in the demand for RFCA in China has substantially increased the workload among interventional cardiologists, and back pain caused by wearing lead protection for prolonged period has become a major health hazard resulting in the deterioration in the quality of life of interventional cardiologists and even the decision of changing the career (5). Accordingly, a widespread implementation of steerable sheath in RFCA could be an effective solution to address the current challenges of RFCA increasing demands and health hazards from fluoroscopy that is inevitable during RFCA with a fixed curve sheath.

The current study additionally found that using steerable sheath for RFCA could shorten the post-surgery LOS in comparison to a fixed curve sheath. Our study did not observe any statistically significant differences in the measured ablation outcomes including the first pass isolation success rate and post-surgery AF rate. As a retrospective study with a small sample size, the current study may have been unable to detect statistical significance for the ablation outcomes that favour steerable sheath. For example, another study assessing the VIZIGO sheath for RFCA in Chinese patients with paroxysmal AF reported that the VIZIGO sheath was associated with a significantly higher initial PVI rate (76.9% *vs.* 54.7%, P<0.001) than the Swartz sheath (10), which is another brand of fixed sheath used for RFCA in China. We speculated that patients with initial PVI could have faster recovery after ablation; consequently, the higher initial PVI rate associated with the VIZIGO sheath resulted in a significantly shorter post-surgery LOS among patients in the steerable sheath group. When this potential benefit associated with steerable is confirmed, adopting steerable sheath for RFCA could help addressing the growing ablation treatment needs in China. Thus, our study has important implications for both clinical practice and research in this area. As a real-world study, it validates the anticipated advantages of using a steerable sheath to conduct RFCA in patients with AF which were not fully explored in randomized clinical trials. The encouraging results from our study may spur the future use of steerable sheaths for RFCA in actual clinical settings and generating robust real-world evidence to confirm and explain our study outcomes.

As previously mentioned, the current study has limitations that stem from the retrospective design, the use of a single setting, and the small sample size. The findings of this study must be interpreted with caution and with a consideration of uncertainties and biases. The RFCA procedures could vary substantially across facilities in China due to the differences in the operating environment and the clinical experiences of the interventional cardiologists. For example, the initial PVI rate associated with steerable sheath observed in our study was much higher than that in another Chinese setting (10). All included patients were operated by the same interventional cardiologist. This could raise the concerns on the generalizability of the generated evidence in this study. In addition, using steerable sheath did not reduce the total fluoroscopy time for RFCA, which relied heavily on fluoroscopy for catheter navigation and the heart's anatomical structure in our study setting. Combining steerable sheath and intracardiac echocardiography, a fluoroscopy-free technology providing real-time monitoring of heart's anatomical structure, could better support fluoroscopy-free RFCA (18), which has been advocated to protect interventional cardiologists from occupational hazards associated with fluoroscopy. To address the uncertainty of the findings from our study cohort, we developed a Monte Carlo simulation model to confirm the robustness of the results for the PVI fluoroscopy time and the post-surgery LOS. A recent study (19) comparing steerable sheath with fixed curve sheath guided by robotic magnetic navigation reported similar results and confirmed the external validity of our study findings. In addition, our study was unable to follow up patients to assess long-term clinical impact of the sheath types due to the limitation of our hospital information system, which mainly collects and stores the medical records of inpatients. The observed shorter LOS associated with steerable sheath after ablation suggests that our study might not detect all potential

clinical benefits of steerable sheath likely due to small sample size and limited information. For example, steerable sheath was designed to improve the positioning and stability of catheter during RFCA. Our medical records didn't contain the information that can be used to measure these two outcomes. Thus, well-designed prospective studies with a sufficient sample size, visual information regarding positioning and stability of catheter, and long-term follow up of the clinical outcomes are required to clarify the clinical and economic impact of the numerous advantages associated with the design of the VIZIGO sheath for AF ablation.

Conclusions

This real-world study examined patient records associated with RFCA at a Chinese tertiary care hospital to explore the potential benefits of using steerable sheath in AF ablation. Despite the small sample size, this study confirmed that a steerable sheath (VIZIGO) could (I) be more attractive to interventional cardiologists than fixed curve sheath when conducting RFCA in patients with a large left atrium and supplementary ablation needs, (II) reduce dependence on fluoroscopy during PVI, and (III) shorten the post-surgery LOS likely due to the improved success rate of initial PVI. Future studies with large sample size should be strongly encouraged to confirm and further unearth the clinical benefits of steerable sheath used for RFCA.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1021/rc

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional ethics committee of Xiangya Hospital (No. 202011162) and individual consent for this retrospective analysis was waived.

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