

## Peer Review File

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### Reviewer A

First, the authors emphasized that this is a real-world study but this is incorrect because of the small sample size. In general, a real-world study should be characterized with a very large sample. The title is also misleading since it did not indicate the comparisons between steerable sheath and fixed curve sheath and the clinical research design of this study, i.e., a retrospective comparative cohort study.

Reply: we have accepted this comment and changed the title of this manuscript.

Changes in text: the title has been changed to “Clinical effectiveness and efficiency of a new steerable sheath technology for radiofrequency ablation in Chinese patients with atrial fibrillation: A retrospective comparative cohort study” (Page 1, Line 2 to 4).

Second, the abstract needs some revisions. The aim did not indicate the clinical needs for this research focus. The methods need to describe the inclusion of subjects, the assessment of baseline clinical factors, follow up procedures, and measurements of efficacy and safety outcomes. The results need to first report the baseline comparability of the two groups and report the results of the adjustment analysis in terms of efficacy and safety outcomes. Due to the very small sample, the authors need to tone down the current conclusion and have comments for the clinical implications of the findings.

Reply: We have revised the abstract to address this comment.

Changes in text: we have revised the background by explaining the rationale for this study. The background has been revised as “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”(Page 2, Line 2-4). The revision for the method is to explain the collected information from the study data sources (“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”) (Page 2, Line 9-10). The results have been revised by adding the results for the comparisons of patient baseline characteristics between the two study groups [“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 mm vs. 38.1 +/-3.9 mm, p=0.017) and larger left atrium volume (150.4 +/- 29.5 ml vs. 126.8 +/- 27.5 ml, p=0.017) than the fixed curve sheath group”] (Page 2, Line 14-19). The conclusions have been revised by reducing the tone (“Compared to fixed curve sheath, steerable sheath used for RFAC could have the potential to shorten the PVI fluoroscopy time and reduce post-RA LOS in a Chinese real-world hospital setting. Future real-world studies with large sample size are needed to confirm our study findings” (Page 2, Line 26-29).

Third, in the introduction of the main text, the authors need to review what has been known on the efficacy and safety of VIZIGO sheath and analyze what the limitations and knowledge gaps are on the research focus. The current study cannot provide real-world evidence for the efficacy and safety of VIZIGO sheath.

Reply: We have added the findings of previous randomized clinical trials comparing steerable sheath and non-steerable sheath in patients who underwent radiofrequency catheter ablation and explained that these findings should be confirmed in Chinese patients to optimize RFCA procedure in Chinese tertiary care hospital settings.

Changes in text: we have revised the last sentence in the introduction as below: “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. 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.” (Page 4, Line 14 to 21)

Fourth, in the methodology of the main text, please describe the clinical research design and sample size estimation of this study, as well as the follow up procedures and details of how the outcomes were measured. In statistics, please first compare the baseline characteristics of the two groups and retrospectively calculate the statistical power of the findings. Please indicate the P value for statistical significance.

Reply: we have revised the method section according to the raised comments. However, this study didn't perform sample size calculation due to the retrospective study design. Instead, this study enrolled all eligible patients during the defined observation time.

Changes in text: We have added the information about the study design (“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”) (Page 5, Line 1-3). We further stated the outcome measures in the statistical methods. Because the original manuscript explained why the sample size calculation was not performed, there are no revisions to address the sample size calculation. In addition, the original manuscript has defined the p value for statistical significance already (Page 8, Line 10).

## **Reviewer B**

The paper titled “Real-world clinical effectiveness and efficiency of a new steerable sheath technology for radiofrequency ablation in Chinese patients with atrial fibrillation” is interesting. Relative to fixed curve sheath, steerable sheath used for RFAC could significantly shorten the PVI fluoroscopy time and reduce post-RA LOS in a Chinese real-world hospital setting. However, there are several minor issues that if addressed would significantly improve the manuscript.

- 1) In the introduction of the manuscript, it is necessary to clearly indicate the knowledge gaps and limitations of prior study and the clinical significance of this study.

Reply: Please see our Reply to the third comment of Review A.

- 2) What is the difference between this study and published study [Utilization of steerable sheath improves the efficiency of atrial fibrillation ablation guided by robotic magnetic navigation compared with fixed-curve sheath, Clin Cardiol, PMID: 35195273]? What is the innovation? These should be described in the discussion.

Reply: we want to thank the review for bring this study to our attention as the findings of the mentioned study well align with our study findings on the reduced PVI time associated with steerable sheath. We have revised the discussion to use this study to support the external validity of our study findings.

Changes in text: we have added one sentence as below: “A recent study comparing steerable sheath with fixed curve sheath guided by robotic magnetic navigation reported similar results and confirmed the external validity of our study findings.” (Page 16, Line 5-7)

- 3) How to control catheter positioning and stability? What impact will it have on the surgical results? Suggest adding relevant content.

Reply: Our study was unable to compare the two sheath types regarding their differences in positioning and stability as this retrospective study was unable to identify such information from medical records. We do think that steerable sheath could provide better positioning and stability than fixed curve sheath. Thus, we have revised the discussion by acknowledging this limitation and call future prospective studies to assess positioning and stability of two sheath types using visual approaches such as electroanatomic mapping and intracardiac echocardiography.

Changes in text: we have revised the discussion by adding “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". (Page 16, Line 12-17)

- 4) There are many uncertainties in retrospective research, which increase the deviation of research results. How to explain and solve this problem?

Reply: the original manuscript has considered the uncertainty and bias associated with our study as the major limitation already. Potential solutions to address these limitations have been discussed in the original manuscript (Page 15, Line 9-23; Page 16, Line 1-9).

- 5) The introduction part of this paper is not comprehensive enough, and the similar papers have not been cited, such as "The prognostic significance of left atrial appendage peak flow velocity in the recurrence of persistent atrial fibrillation following first radiofrequency catheter ablation, J Thorac Dis, PMID: 34795943". It is recommended to quote this article.

Reply: we have accepted this comment by citing this study in the introduction for the unmet medical needs of AF patients.

Changes in text: we have added one sentence to address this comment: "More importantly, over 20% AF patients still experience disease relapse after their first RFCA likely due to insufficient efficiency of RFCA procedure". (Page 4, Line 8-10)