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The Impact of Steerable Sheaths on Stability of the Catheter Ablation for Paroxysmal Atrial Fibrillation, Evaluated by Contact Force

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Abstract

Background: Catheter ablation (CA) is a potentially curative method for treatment of severe symptomatic and drug-refractory atrial fibrillation (AF).
Objectives: This study aimed to evaluate the impact of steerable sheaths on catheter stability in paroxysmal AF based on contact force (CF) method.
Methods: Fifty-two patients were included in this study and they were randomly enrolled to two groups: Pulmonary vein isolation using steerable (Group 1, n=26) or fixed-curve (Group 2, n=26) sheaths employing a force-sensing ablation catheter. We analyzed the operator-blinded and unblinded CFs when the operators were satisfied with the catheter position.
Results: The average CF was 23.56±9.43 g (Group 1) vs. 22.03±10.56 g (Group 2) for the blind condition (P<0.05) and 24.61±10.46 g (Group 1) vs. 22.18± 9.84 g (Group 2) for the unblinded condition (P<0.05). There was significant heterogeneity of CFs between the segments: the CFs of the anterior-middle, anteroinferior, posterior-middle, and inferior posteroinferior segments of the right pulmonary vein (RPV), as well as of the roof, superior anterosuperior, anterior-middle, inferior anteroinferior, and inferior posteroinferior segments of the left pulmonary vein (LPV), showed significant statistical differences in the blinded condition (P<0.05). The CFs of the roof, anterosuperior, anterior-middle, and inferior anteroinferior, and posteroinferior segments of the RPV, and LPV showed statistical differences in the unblinded condition (P<0.05). The posterior and roof segments showed enhanced CFs in both groups. Generally, group one had a lower proportion of acute reconnection rate and less tendency for recurrence.
Conclusion: In conclusion, catheter stability improved with steerable sheaths owing to the potential of attaining higher CFs. This advantage was independent of CF guidance and exhibited a specific distribution pattern.

Keywords: Atrial fibrillation, Catheter stability, Contact force, Pulmonary vein isolation, Steerable sheath

1. Background

Catheter ablation (CA), commonly used to treat atrial fibrillation (AF) since Haïssaguerre *et al.* (1) identified the pulmonary veins (PV) as triggers capable of initiating AF paroxysms, is a potentially curative method for the treatment of highly symptomatic and drug-refractory AF. Successful CA for paroxysmal AF is predominantly determined by continuing circumferential PV isolation (PVI); however, many patients experience a recurrence of AF, in which the electrical reconnections of isolated PVs are believed to play a dominant role (2-8). Therefore, effective and durable ablation lesion formation is critical for positive clinical outcomes following AF ablation.

Adequate catheter tip-to-tissue contact is the primary determinant responsible for influencing lesion formation and durability, as well as improving the safety aspects (9). Based on this, a new technology including contact force (CF) catheters, as well as steerable sheaths, are being developed to improve the continuity and durability of ablation lesion formation. Traditionally, the location of ablations is displayed through annotation tags using a three-dimensional (3D) system based on predefined criteria, including local voltage and impedance, where energy is subjectively delivered and difficult to identify.

Pure tactile feedback is not reliable to ensure catheter tip-to-tissue contact, as it may be influenced by anatomical variations, the catheter shaft, deflection, torque, and the different sheaths used. A manually controlled steerable sheath for catheter navigation results in a significantly higher clinical success rate because of its reliable CF (10-11). In this study, PVIs were performed using CF-sensing catheters at predefined anatomical locations, using a combination of steerable or fixed-curve sheaths with a 3D mapping system.

We analyzed the catheter position with CF values as parameters and sought to compare the CF values using both steerable and fixed-curve sheaths when CF data were blinded and unblinded to the operators.

2. Objectives

We attempted to evaluate the impact of steerable sheaths on the maneuverability and stability of catheters in different segments of the PVs based on CF values during PVI.

3. Methods

3.1. Study population

Fifty-two consecutive patients with symptomatic paroxysmal AF who were refractory or intolerant to one or more antiarrhythmic drugs (AAD) between September 2019 and August 2020 were prospectively enrolled in this study. Inclusion criteria were as follows: 1) Receiving initial RFCA of AF at our center; 2) Informed consent could be obtained. Exclusion criteria included: 1) Left atrial anteroposterior dimension >55 mm; 2) Reversible causes for AF; 3) Severe cardiac disease (ejection fraction <35%, valvular cardiac diseases, hypertrophic cardiomyopathy); 4) Incomplete medical records; and (5) Life expectancy less than one year. All patients underwent CA for AF for the first time. Each patient required ≥1 episode of sustained AF (>30 s) was documented by 12-lead electrocardiogram and Holter monitoring. Patients were equally divided into two groups using a random number table: steerable sheaths were used in group one and fixed-curve sheaths in group two. Informed consent was obtained from all patients.

3.2. Preoperative preparation

All patients went off class I and class III AADs for more than five half-lives and had undergone transesophageal echocardiography to exclude left atrial (LA) thrombus prior to the procedure. For all patients ablation procedures was performed with continuous oral anticoagulation by warfarin with a target international normalized ratio (INR) of 2–3. Also, new oral anticoagulants. subcutaneous low molecular-weight heparin injection was used as a bridge to warfarin whenever INR was below the target. These procedures were conducted by two experienced operators.

3.3. Procedure

The procedure was performed under conscious sedation through continuous infusion of fentanyl using noninvasive monitoring of blood pressure and oxygen saturation. External midazolam was administered when cardioversion was performed to restore sinus rhythm during the procedure. All CAs were performed using a 3D electroanatomic mapping system (EnSite Velocity-3 system, St. Jude Medical, Saint Paul, MN) with a CF-sensing catheter (TactiCath Quartz, St. Jude Medical).

A 10-polar catheter was placed inside the coronary sinus via the left femoral vein. In the first group, one steerable sheath (Aglilis NxT, St. Jude Medical) and one fixed-curve sheath (Swartz SL1, St. Jude Medical) were positioned in the LA via the right femoral vein for the CF-sensing (steerable sheath) and circular PV (fixed-curve sheath) catheters. In group two, the CF-sensing and circular PV catheters were passed through two long, fixed-curve sheaths via the right femoral vein. Two separate transseptal punctures were placed. After the first trans-septal puncture, retrograde angiography of the PVs was done. The activated clotting time was measured every 20–30 min throughout the ablation procedure and was maintained at over 300 s following the intravenous administration of heparin (100 IU/kg).

In this study, PVI around the ipsilateral PVs was performed without any other stepwise ablation, unless the additional tricuspid isthmus was ablated in the presence of atrial flutter. After being aware of the CF values, PVI was conducted in a temperature-controlled mode at 43°C achieving lesion size index (LSI) of about five. The radiofrequency energy was 30 W in the anterior wall, 25 W in the posterior wall, and 35 W in the LA ridge, while the irrigation flow rate was preset at 17–30 mL/min during the ablation.

The endpoint of the procedure was bidirectional PV conduction blockage. Acute PV reconnections were defined as PV-LA reconnection took part spontaneously or in the setting of intravenous isoproterenol infusion. It conducted at rates of 5, 10, 15, and 20 µg /min for 2 minutes at each infusion rate. The isoproterenol infusion was discontinued upon induction of AF or heart rate of more than 150 bpm within 30 min following the initial completion of the PVI.

3.4. CF measurement and analysis

The circumferential lesions around the PVs were predefined into 24 segments (Figure 1). The operators who selected a sample point in each segment were blinded to the CF parameters at the initial stage of the procedure. CF values were immediately recorded once the catheter was placed, depending on the electrogram amplitude, impedance, fluoroscopy, and 3D navigation at each sample point. Subsequently, the operators had access to the CF parameters and adjusted the catheter position according to the CF values, if necessary. The CF values were recorded again. After obtaining the CF values, the procedure was guided by the CF parameters. The standardized CF value targets were 10–40 g for every lesion. The values were classified as low CF (<10 g), suitable CF (10–40 g), or high CF (≥40 g), according to the previous studies (12-14).

3.5. Follow-up

After ablation, the patients were followed regularly at 1, 3, 6, and 12 months and every six months after the first year. A blanking period of three months was considered for the study. The follow-up visit included intensive questioning for arrhythmia-related symptoms, ECG and 24 h Holter recordings. All documented episodes of atrial tachycardia (AT), atrial flutter (AFL) and AF lasting more than 30

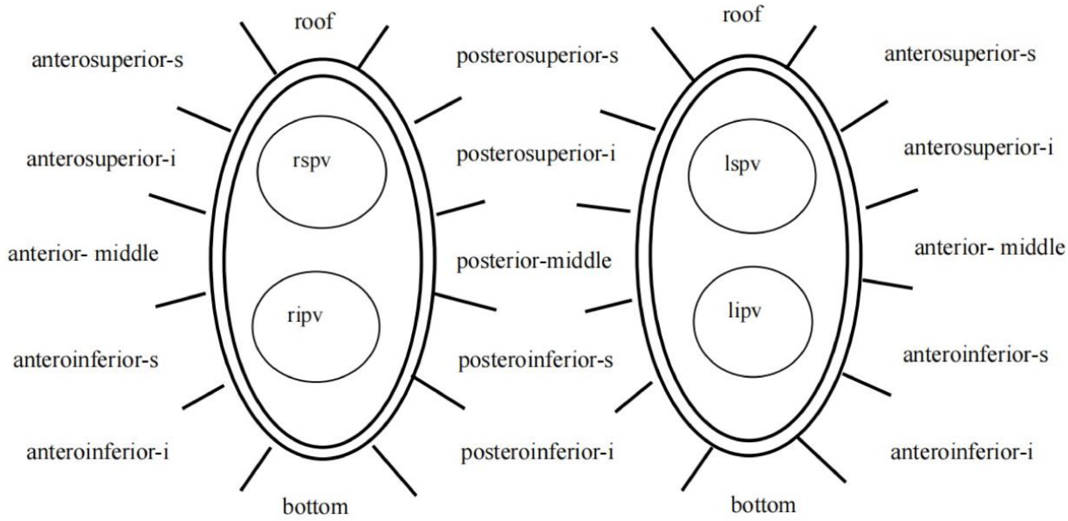

Figure 1. Pulmonary vein segments. Both the right and left pulmonary veins are divided into the following segments: roof, anterosuperior, anterior-middle, anteroinferior, bottom, posteroinferior, posterior-middle, and posterosuperior segments. Aside from the roof, middle, and bottom segments, the pulmonary vein segments are divided into two subsegments (superior (s) and inferior (i)). rpsv, right superior pulmonary vein; ripv, right inferior pulmonary vein; lspv, left superior pulmonary vein; lipv, left inferior pulmonary vein

Table 1. Patient characteristics

Characteristics	Steerable sheath (n=26)	Fixed-curve sheath (n=26)	P-value
Mean age, years (±SD)	64.4±9.4	62.8±6.4	0.43
Male sex (N)	53.8% (14)	42.2% (12)	0.58
Body mass index, Kg/M^2 (±Sd)	25.4±3.9	24.6±3	0.38
Smoking (N)	19.2% (5)	23.1% (6)	0.73
Hypertension (N)	53.8% (14)	57.7% (15)	0.78
Diabetes mellitus (N)	11.5% (3)	26.9% (7)	0.16
Previous stroke or TIA (N)	23.1% (6)	7.7% (2)	0.25
Cha$_2$ds$_2$vasc score (±Sd)	2.58±1.64	2.38±1.3	0.65
Hasbled score (±SD)	1.42±1	0.96±0.9	0.09
Lad, MM (±SD)	36.8±6.6	39.4±6.2	0.16
Lvef, % (±SD)	66.2±4.6	66.7±4.2	0.65

SD: standard deviation; TIA: transient ischemic attack; HASBLED: Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly score; CHA2DS2VASC: Congestive heart failure, Hypertension, Age, Diabetes, Stroke/transient ischemic attack, Vascular disease, Age, Sex category score; LVEF: left ventricular ejection fraction.

seconds were considered as a recurrence.

3.6. Statistical analysis

Normally distributed data were presented as mean±standard deviation and statistically compared using Student's t-test. Nonparametric variavbles were reported by medians. The Mann–Whitney U-test was performed to compare nonparametric data between groups. Categorical data were expressed as counts and compared using Pearson's χ^2 test. The survival analysis was conducted with a Kaplan–Meier method. In case of multiple comparisons, the Bonferroni-adjusted P-value was used. All data were analyzed using Statistical Product and Service Solutions (SPSS) version 20.0 (IBM, Armonk, NY, USA).

4. Results

All 52 patients successfully underwent PVIs. There were report of failure to achieve the bidirectional blockage, and no severe complications observed. In total, 1,248 individual radiofrequency points were included in this study. The patients demographics are described in Table 1. There were no statistical differences in the baseline characteristics between the steerable sheath and fixed-curve sheath groups.

4.1. CFs of the two conditions in each group

Generally, the CFs rates showed a specific local distribution pattern within the groups (Figure 2). The average CFs of each segment in group one ranged from 10.65±1.81 g (inferior anterosuperior (anterosuperior-i) segment of LPV) to 36.25±5.49 g (posterosuperior-i segment of RPV) in the blinded condition. When the CF data was visible to the operators, the average CFs of each segment ranged between 12.30±2.96 g (posteroinferior-i segment of RPV) and 44.95±5.86 g (roof segment of LPV). Similarly, the average CFs of each segment in group two ranged from 8.95±1.54 g (superior anteroinferior (anteroinferior-s) segment of LPV) to 36.75±7.07 g (posteroinferior-s segment of LPV) when the operators were blinded and 8.80±1.85 g

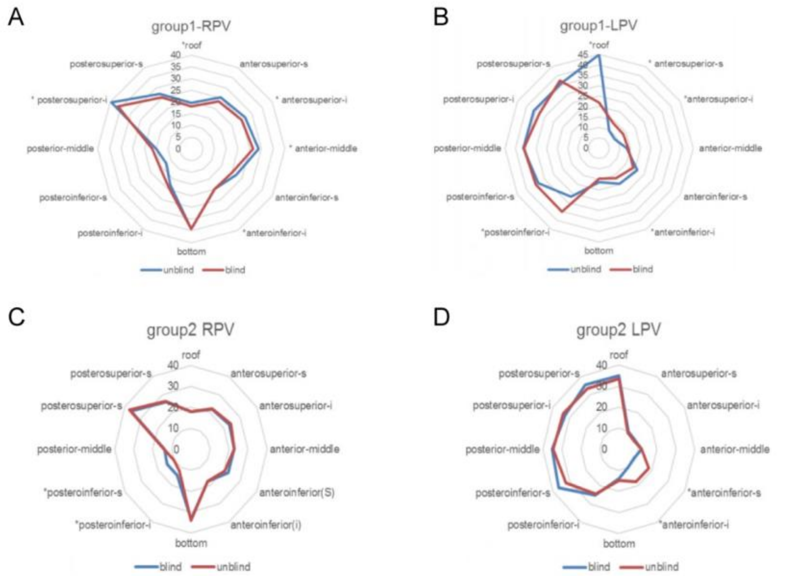

Figure 2. Comparison of average contact forces (CFs) (A) The average CFs of the right pulmonary veins (RPVs) by segments in group one when the operators are blinded and unblinded to the CF data; (B) the average CFs of the left pulmonary veins (LPVs) by segments in group one when the operators are blinded and unblinded to the CF data; (C) the average CFs of the RPVs by segments in group two when the operators are blinded and unblinded to the CF data; (D) the average CFs of the LPVs by segments in group twp when the operators are blinded and unblinded to the CF data. *Significant difference between two conditions (P<0.05).

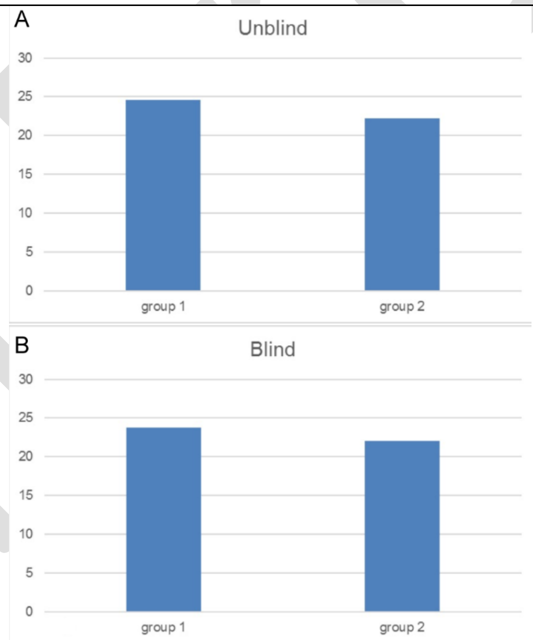

Figure 3. Comparison of average contact forces (CFs) in the steerable sheath and fixed-curve groups (A) The blinded condition (P<0.05); (B) the unblinded condition (P<0.05).

(anterosuperior-i segment of LPV) to 34.65±5.82 g (posterior-middle segment of LPV) when the operators were not blinded.

The LA ridge was contributed to the lowest CF values in LPVs, while the highest CF values were achieved in the posterosuperior regions. In RPVs, the lowest CF was found in the posteroinferior regions, while the highest CF was recorded in the posterosuperior regions.

4.2. CFs according to steerable and fixed-curve sheath usage

Group one had higher average CFs (Figure 3). The average CF of group one was 23.56±9.43 g vs. 22.03±10.58 g in (Group two) in the operator-blinded condition (P<0.05) and 24.98±10.04 g vs. 22.18±9.88

g in the operator-unblinded condition (P<0.05). The average CFs of the operator-unblinded condition were higher than those of the blinded condition in both groups; however, comparing the blinded and unblinded conditions, the proportions of CFs in each criteria range demonstrated no statistical difference (P>0.05) in both groups (Figure 4).

Meanwhile, there was a significant heterogeneity of CFs between segments (Figure 5). When comparing the CFs of the operator-blinded condition between the groups, there were statistical differences in the anterior-middle, anteroinferior, posterior-middle, and posteroinferior-i segments of the RPV, as well as in the roof, anterior-middle, anterosuperior-s, anteroinferior-i, and posteroinferior-i segments of the LPV (P<0.05). The roof, anterosuperior, anterior-middle, anteroinferior-i, and posteroinferior segments of the RPV and the roof, anterosuperior, anteroinferior-i, and posteroinferior-i segments of the LPV also showed statistical differences between groups in the operator-unblinded condition (P<0.05).

4.3. Procedural outcomes

In group one shorter total radiofrequency and fluoroscopy times were reported in comparison with group two (Table 2); however, there was no statistical difference in the total procedural time (117.62±31.04 min vs. 127.38±31.39 min, respectively; P=0.33). Group one had a lower proportion of acute reconnection rate compared with group two, although this was not statistically significant (3.8% vs. 11.5%, respectively; P=0.61).

After a median follow-up time of 18 (12, 24) months, five and nine patients survived from recurrence in group 1 and 2, respectively (P=0.13). In the Kaplan–Meier analysis, steerable sheath was associated with less recurrence rate than fixed-curve sheath (HR: 0.43, 95% CI:0.145-1.24, P=0.11) (Figure 6).

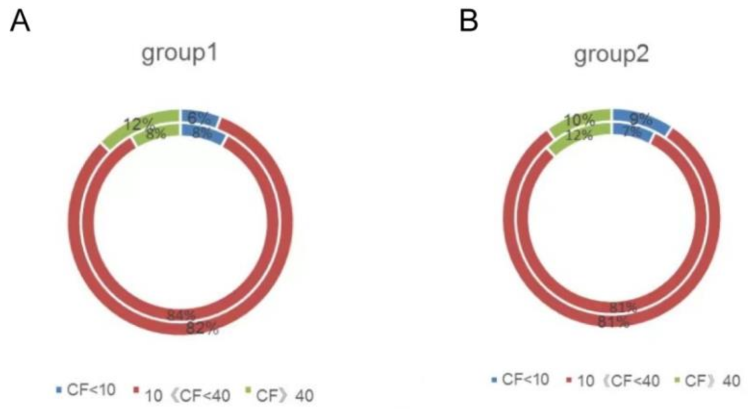

Figure 4. Proportions of each contact force range in the steerable sheath and fixed-curve groups. Inner circle, blinded; outer circle, unblinded. (A) Group 1 (P>0.05); (B) Group 2 (P>0.05).

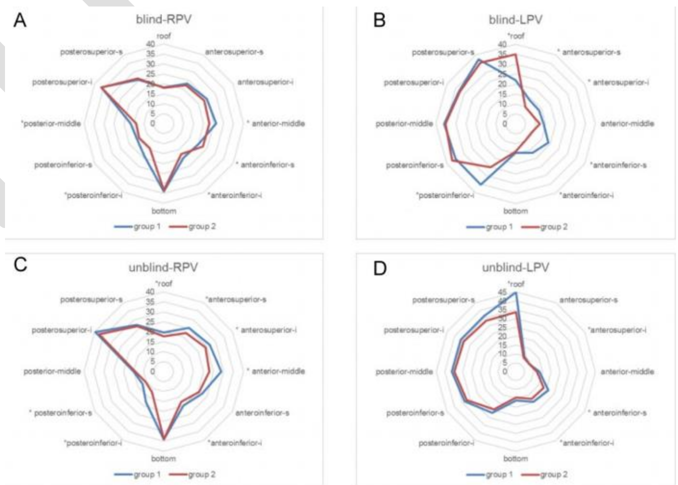

Figure 5. Comparison of average contact forces (CFs) in the steerable sheath and the fixed-curve groups (A) The average CFs of the right pulmonary veins (RPVs) by segments when the operators were blinded to the CF data; (B) the average CFs of the left pulmonary veins (LPVs) by segments when the operators were blinded to the CF data; (C) the average CFs of the RPVs by segments when the operators were unblinded to the CF data; (D) the average CFs of the LPVs by segments when the operators were unblinded to the CF data. *Significant difference between two conditions (P<0.05).

Table 2. Procedural characteristics

Characteristics	Steerable sheath (n=26)	Fixed-curve sheath (n=26)	P-value
Procedure time (min)	117.62±31.04	127.38±31.39	0.33
Total rf time (min)	42.24±10.05	49.05±11.09	0.04
Fluoroscopy time (min)	20.07±4.41	24.05±4.84	0.01
Acute reconnection, n (%)	1 (3.8)	3 (11.5)	0.61

RF: radiofrequency

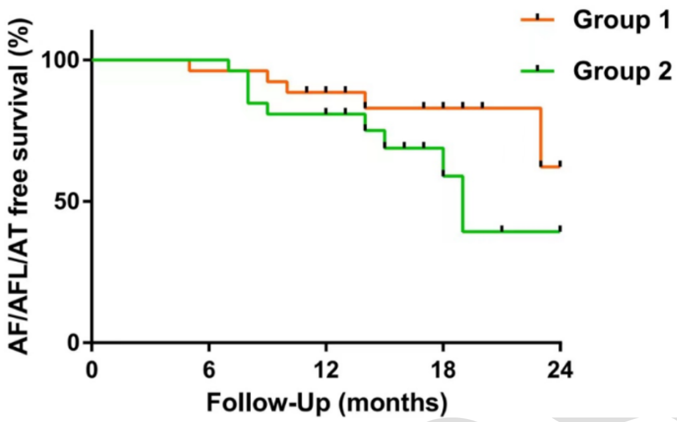

Figure 6. Comparison of recurrence after a median follow-up of 18 (12, 24) months between the steerable sheath group and the fixed-curve group (HR: 0.43, 95% CI:0.145-1.24, P=0.11).

5. Discussion

In this clinical study considering the impact of catheter stability when using a steerable vs. a fixed-curve sheath in PVI for paroxysmal AF based on CF data. This study demonstrated that in some segments, the CFs were higher when using steerable sheaths compared with fixed-curve sheaths when the catheter was in place during PVI for paroxysmal AF, regardless of whether or not the operators had access to the CF data. The significance of the differences between the two groups revealed a specific anatomical distribution pattern.

Several studies had previously demonstrated that the ablation lesion size of AF was correlated well with the CF (15,16). A CF-sensing catheter was shown to reduce any residual conduction gaps, as well as the incidence of PV reconnections in AF ablation (17,18). Therefore, we believe that it is reasonable to use CF as a reference index to evaluate the position and stability of the catheters.

In this study, when the operators were satisfied with the catheter position in the blinded condition, the CF values in the steerable sheath group were differed significantly when compared with the corresponding CFs in the fixed-curve sheath group. There were six and five higher CF value segments in the LPV and RPV in the steerable sheath group, respectively. The advantage of the steerable sheath was obvious in inferior sections of the RPV and anterior sections of the LPV. The increment in CF values in the anteroinferior and posteroinferior regions of the right PV antrum might be attributable to the anatomic characteristics of RPVs. These findings were consistent with a recent study demonstrated that steerable sheath contributing better enhanced CF, and improved catheter stability, especially in posteroinferior regions of the right PV antrum (19).

Without the CF data as a guide, the contact between the catheter and tissue was dependent on indirect methods, such as the tactile sensation of the operators, local electrogram, and movement of the catheter under fluoroscopy. The stability of the catheter was primarily based on the experience of the operators. The inferior walls of the RPVs are close to the atrial septum, while the position of the catheter in these regions depends on the deflection and torque compared with the superior walls, embodying the advantage of using a steerable sheath. In addition, the anatomy of left atrium significantly influences the contact of catheter that could be minimized by a steerable sheath (10).

Catheter-tissue contact cannot be reliably ensured by pure tactile feedback, as it might be influenced by the catheter, as well as the different applied sheaths. As described earlier, there was no statistical difference in LA parasternal diameter between the two groups (36.8±6.6 mm vs. 39.4±6.2 mm; P=0.16). All procedures were performed using the same type of catheter. We demonstrated improvements in the catheter stability with steerable sheaths in a small number of patients, attributing this improvement to the increased control over catheter manipulation by steerable sheaths.

When CF parameters were unblinded to the operators, the higher CFs were observed in six LPV segments and seven RPV segments in the steerable sheath group when the operators were satisfied with the catheter position. This was consistent with the results of the operator-blinded condition, suggesting that the effect of steerable sheaths on catheter stability is independent of the CF parameter, and has the characteristics associated with anatomic location. There were no statistical differences in CFs in the posterior walls of the LPV and anterosuperior walls of the RPV between the two groups.

The anatomical differences also coincided with the blinded condition. Furthermore, posterosuperior sections and roof segments showed enhanced CFs in both groups. In contrast, the benefit of steerable sheaths with respect to enhanced CFs was not significant in the posterior walls, reflecting the safety of steerable sheaths to some extent (20). This demonstrates that achieving adequate CF is readily possible in certain anatomical locations, which are relatively easier to access regarding the positioning of the catheter with fixed-curve sheaths. It is relatively easier for the catheter to be directly placed, without requiring much rotation in the posterior and roof walls; however, operators should be vigilant in terms of enhanced CFs to prevent complications such as cardiac tamponade at these sites.

The average CFs of the two groups were improved in the unblinded condition compared with those in the blinded type. Meanwhile, no significant elevation occurred in the proportion of high CF values according to the preset target criteria in the unblinded condition. This advantage may be attributed to providing a true CF value in grams, which is more reliable than indirect measurements during PVI. So, the operators could adjust the position of the ablation catheter within a consensus CF range. In the condition of blindness, the steerable sheath group offered an improved proportion of CF values in the target, compared with the fixed-curve sheath group in this study; however, this difference was not statistically significant. This finding also reflects the safety of the steerable sheath, rather than blind elevations in the CFs.

Interestingly, this advantage was weakened when the operators were unblinded. It may be because the increment of steerable sheaths in CF was uneven. Moreover, the catheter was located more easily on the posterior walls, regardless of the applied sheaths while ablating, possibly contributing to the lesser stiffness of the fixed-curve sheaths and therefore resulting in a similar CF to that of steerable sheaths. In our study, all PVIs were guided by CF parameters and LSI after CF data acquisition. Steerable sheaths improved the CFs, as well as certain procedural outcomes, such as reducing the total radiofrequency and fluoroscopy times. Acute PV reconnections were lower in group one, and recurrence rate seemed to be reduced by steerable sheath. These reductions may be attributed to the improved stability of the catheter via steerable sheaths.

5.1. Limitations

This randomized controlled trial conducted on steerable sheaths for CF ablation. Most of the CF data were obtained during sinus rhythm, as the study was performed in the patients with paroxysmal AF under conscious sedation. Subsequently, the findings might be different in patients within persistent AF, or if performed under general anesthesia. In this study, we compared the CF parameters between groups, recorded immediately once the catheter was in place. We aimed to investigate the influence of steerable sheaths on catheter stability, rather than determine the outcomes of PVI. After data collection, all ablation procedures were performed under the guidance of the CF parameters; therefore, there was no additional effect of blinding on the outcomes of CA. Furthermore, the operators attempted to maintain the CF values of the preset target during the procedures. Therefore, we believe that these limitations were acceptable. It is unlikely that a learning curve influenced the findings of this study as all procedures were performed by experienced operators. This study examined a single type of steerable sheaths and ablation catheters. We acknowledged that operators may have individual preferences regarding comfort and capability of different steerable and fixed-curve sheaths; therefore, we used only one type of sheath. Finally, future studies should include larger sample sizes, as well as more types of sheaths and CF sensing catheters, to improve the reliability of the results.

6. Conclusion

In this study, steerable sheaths were associated with an increase in CF value, thus improving catheter stability during paroxysmal AF ablation. This advantage was independent of the knowledge of CF data. Additionally, this increase in CF has anatomic heterogeneity: the anterior-middle, anteroinferior, and posteroinferior segments of the RPV, and the anterosuperior and anteroinferior segments of the LPV exhibited obvious benefits when a steerable sheath was used. The posterosuperior segments of the RPV, and the posterosuperior and posterior-middle segments of the LPV showed no CF improvements when a steerable sheath was used. The advantage of steerable sheaths is particularly pronounced in areas where placement of catheters is more difficult, such as the LA ridge and the inferior regions of the RPV. Posterior and roof regions showed a trend towards higher CFs with both sheaths, suggesting the regional differences regarding the advantage of steerable sheaths. We suggest that operators should be particularly vigilant against the risk of cardiac tamponade in these regions. Overall, this study recommends the catheter stability would improve with steerable sheaths because of the potential for attaining higher CFs.

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Footnotes

Conflicts of Interest: The authors declared no conflict of interest.
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Ethical considerations: The study was approved by the ethics committee of Shaoxing People's Hospital (approval no. 2019-K-Y-128-01). All procedures performed in studies involving human participants were in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Informed consent was obtained from all participants.

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