Clinical Benefit and Safety of Ablation Index -Guided Higher-Power Ablation Protected by Impedance Spike Cut-off in Patients with Atrial Fibrillation

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Article

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Abstract

Aims: To evaluate the procedural effectiveness, efficiency and safety outcomes when using ablation index-guided higher-power ablation protected by impedance spike cut-off for atrial fibrillation (AF) up to 12-month follow-up in China.

Methods：132 patients were consecutively enrolled. The endpoints included freedom from any atrial arrhythmia during 12-month follow-up, first-pass pulmonary vein isolation (PVI) rate, RF ablation time, procedure time and fluoroscopy time.

Results: All patients achieved acute PVI and first-pass PVI rate was 87.9%. During 12-month follow-up, the overall success rate was 82.6%. The mean procedure time, total RF ablation time, baseline impedance value and fluoroscopy time were 55.3±11.3min, 36.0±8.5min, 118.5±9.4Ω and 7.1±3.6min, respectively. The spike cut-off occurred in 72 (54.6%) subjects and mostly during PVI at the anterior carina of right pulmonary vein (RPV) (25.8%), ridge between left atrial appendage and left pulmonary vein (22.0%), and inferior of RPV (16.7%). The overall major adverse event rate was 0.8%. The result of Cox regression analysis showed that gender, baseline impedance value and contact force were independent prognostic factors for recurrence.

Conclusion: AI-guided higher-power ablation with impedance spike cut-off appears to be a safe and effective ablation technique for AF and leads to a high overall success rate at 12 months.

Introduction

Atrial fibrillation (AF) is the most common arrhythmia in elderly individuals which constitutes a significant public health problem.[1] With ageing populations, atrial fibrillation was predicted to affect 6–12 million people in the USA by 2050 and 17.9 million in Europe by 2060.[2–3] The incidence of AF is progressively increasing due to aging of the population.[3] AF is associated with increased morbidity, especially stroke and heart failure, as well as increased mortality.[1] Approximately 80–95% AF cases are recognized caused by focal electrical discharges emerging from the pulmonary veins.[5] Pulmonary vein isolation (PVI) is the cornerstone of current atrial fibrillation ablation techniques, with the greatest efficacy in patients with atrial fibrillation.[4]

Radiofrequency (RF) higher-power ablation has been identified as a novel approach for AF to improve procedure effectiveness. Previously published studies have shown that the utility of high-power and short-duration (50–80W for 5s) ablation could achieve similar lesion depth with fewer complications compared to conventional lower-power, longer-duration settings (20–30W for 30s).[6,7] Ablation index (AI) is a novel marker incorporating contact force, time, and power in a weighted formula. The latest meta-analysis[8] revealed that AI-guided procedure resulted in a significantly shorter fluoroscopy time and total ablation time, higher first-pass isolation and lower acute pulmonary vein reconnection. Another meta-analysis results also suggested that AI-guided catheter ablation is associated with increased efficacy of AF ablation, while preserving a comparable safety profile.[9] Impedance spike cut-off is an auxiliary function in some integrated RF generator systems, such as SMARTABLATE™ generator (Biosense Webster, Irvine, CA, USA). If the impedance spikes higher than the number set here in any half second interval, the RF energy will automatically shut off to avoid steam pops. To our best knowledge, there is no published research to evaluate its impact on safety during catheter ablation, including when used with AI.

The primary objective of the study is to evaluate the procedural efficiency, safety, and effectiveness outcomes associated with the use of AIHP ablation protected by impedance spike cut-off for AF in Chinese patient.

Results

Baseline characteristics

A total of 132 patients who underwent higher-power catheter ablation for AF were enrolled and evaluated. Figure 1 illustrated the patient flow through the study. Table 1 summarized patients' baseline demographical and clinical characteristics. The mean age was 60.1 ± 9.7 years and 65.9% of the patients were male. The most prevalent comorbidity was hypertension. The baseline patient characteristics were similar between PAF and PsAF patients except mean left atrial (LA) diameter and the LVEF.

Table 1
Baseline characteristics

Parameter	Total Patients (N = 132)	Persistent AF (N = 67)	Paroxysmal AF (N = 65)	P-value
Age, mean ± SD, years	60.1 ± 9.7	59.6 ± 10.1	60.5 ± 9.2	0.583
BMI, mean ± SD, kg/m^2	24.5 ± 3.7	24.8 ± 4.1	24.0 ± 3.1	0.320
Male, n (%)	65.9%	65.6%	56.9%	0.050
CHA2DS2-VASc score, Mean ± SD	1.7 ± 1.6	1.6 ± 1.5	1.9 ± 1.6	0.283
HAS-BLED score, mean ± SD	1.0 ± 0.9	0.9 ± 0.8	1.1 ± 1.0	0.100
Comorbidity				0.298
Hypertension	44.7%	43.3%	46.2%	
Coronary artery disease	4.6%	3.0%	6.2%	
Stroke History	6.8%	10.5%	3.1%	
Diabetes	7.6%	9.0%	6.2%	
AF_TYPE, n (%)				
Persistent AF	50.8%	–	–	
Paroxysmal AF	49.2%	–	–	
History of AF, mean ± SD, month	35.5 ± 55.8	41.8 ± 59.0	29.1 ± 50.1	0.194
Ventricular Rate, mean ± SD, %	77.4 ± 15.3	76.6 ± 14.7	78.3 ± 15.9	0.516
QRS, mean ± SD	103.9 ± 17.4	105.0 ± 17.2	102.9 ± 17.7	0.485
LAD, Mean ± SD	41.2 ± 5.6	42.7 ± 4.6	39.7 ± 6.1	< 0.01
LVEF, Mean ± SD	64.3 ± 7.8	61.8 ± 8.8	67.0 ± 5.5	< 0.01
Anticoagulation				
Total	100.0%	110.5%	100.0%	0.938
Warfarin, n (%)	50.0%	56.7%	49.2%	
NOACs, n (%)	45.5%	49.3%	47.7%	
Enoxaparin, n (%)	14.4%	16.4%	13.9%	

Mean ± SDs are presented unless otherwise specified. BMI indicates body mass index; AF, atrial fibrillation; LAD, left atrial diameter; LVEF, left ventricular ejection fraction; NOAC, novel oral anticoagulants.

Procedural efficiency

As described in Table 2, acute PVI was achieved in all patients and first-pass PVI rate was 87.9%. Mean procedure time was 55.3 ± 11.3 minutes and mean total RF ablation time per procedure was 36.0 ± 8.5 minutes. Mean Fluoroscopy time and dose was 7.1 ± 3.6 minutes and 45.8 ± 26.6mGy, respectively. Mean baseline impedance value was set to be 118.5 ± 9.4Ω. The number of pulmonary vein application was similar between right and left circumferential lesion (39.5 ± 10.2 vs. 41.0 ± 11.4, P = 0.283). Comparing the results between PAF and PsAF subgroups, the procedure time was significantly longer (53.0 ± 10.9 vs. 57.4 ± 11.3, P = 0.024) and the fluoroscopy dose (41.4 ± 20.2 vs. 50.1 ± 27.7, P = 0.024) was significantly higher in PsAF patients. 16 patients (12.2%) had acute reconnection and gaps were most frequently happened at carina of right pulmonary vein (RPV) (n = 8) and carina of left pulmonary vein (LPV) (n = 2). Impedance spike cut-off occurred in 72 (54.6%) subjects, most commonly at anterior carina of RPV (25.8%), ridge between left atrial appendage and LPV (22.0%), and inferior of RPV (16.7%) (Table 3).

Table 2
Procedural efficiency

	Total Patients (N = 132)	**Persistent AF (N = 67)**	**Paroxysmal AF (N = 65)**	**P-value**
Number of RPV application, mean ± SD	39.5 ± 10.2	38.3 ± 10.6	40.8 ± 9.8	0.168
Number of LPV application, mean ± SD	41.0 ± 11.4	40.9 ± 12.9	41.1 ± 9.7	0.914
PVI success, n (%)	100.0%	100.0%	100.0%	
First-pass PVI, n (%)	116(87.9%)	55(82.1%)	61(93.9%)	0.072
Procedure time, mean ± SD, min	55.3 ± 11.3	57.4 ± 11.3	53.0 ± 10.9	0.024
Impedance, mean ± SD, Ω	118.5 ± 9.4	117.5 ± 9.1	119.4 ± 9.6	0.259
RF ablation time per procedure, mean ± SD, min	36.0 ± 8.5	37.3 ± 8.8	34.7 ± 8.2	0.081
Fluoroscopy time, mean ± SD, min	7.1 ± 3.6	7.3 ± 3.8	6.9 ± 3.1	0.486
Fluoroscopy dose, mean ± SD, mGy	45.8 ± 26.6	50.1 ± 27.7	41.4 ± 20.2	0.042

Mean ± SDs are presented unless otherwise specified. RPV indicates right pulmonary vein; LPV, left pulmonary vein; PVI, pulmonary vein isolation; RF, radiofrequency.

Table 3
Impedance Spike cut-off summary

Cut off positions	Total patients (N = 132)
RPV	
Anterior roof, n (%)	7 (5.3%)
Anterior carina, n (%)	34 (25.8%)
Anterior inferior, n (%)	1 (0.8%)
Posterior inferior, n (%)	1 (0.8%)
Posterior carina, n (%)	7 (5.3%)
Inferior, n (%)	22 (16.7%)
LPV	
Anterior roof, n (%)	9 (6.8%)
Roof, n (%)	2 (1.5%)
ridge, n (%)	29 (22.0%)
Anterior carina, n (%)	3 (2.3%)

RPV indicates right pulmonary vein; LPV indicates left pulmonary vein.

Lesion analysis

As two patients' lesion records were lost for technical reasons, the lesion data of 130 patients were collected and analyzed. In total, there were 10,340 ablation lesions performed (left PV lesion, n = 5,203, right PV lesion, n = 5,137). The mean AI value, mean ablation time per lesion, mean impedance drop, and mean contact force per lesion was 442.4 ± 48.8, 17.7 ± 6.1 seconds, 6.8 ± 4.6Ω, and 10.9 ± 6.1, respectively. Table 4 summarized the mean ablation time, mean contact force, mean impedance drop, and mean AI value of lesions in nine different segments and Fig. 2 described the variability of the AI value of lesions in each segment.

Table 4
Lesion analysis

	Number of patients (N = 130)									
	LPV circle, n = 127					RPV circle, n = 130				
	LPV lesion, n = 5,203					RPV lesion, n = 5,137				
	Overall	Left Anterior	Left Posterior	Left Roof	Left Inferior	Left Ridge	Right Anterior	Right Posterior	Right Roof	Right Inferior
Lesions, n	10,340	113	1,535	1,104	785	1,666	1,715	1,513	1,136	733
Ablation time per lesion, mean ± SD, s	17.7 ± 6.7	18.0 ± 9.2	16.3 ± 5.4	17.9 ± 7.0	17.5 ± 6.8	20.1 ± 8.3	17.4 ± 6.3	16.8 ± 5.8	17.9 ± 6.4	17.2 ± 5.6
Impedance drop per lesion, mean ± SD, Ω	6.8 ± 4.6	6.0 ± 3.9	6.0 ± 3.6	8.0 ± 5.7	6.6 ± 3.9	6.8 ± 4.5	7.8 ± 4.7	5.5 ± 4.2	7.3 ± 5.0	6.3 ± 4.3
Contact force per lesion, mean ± SD, g	10.9 ± 6.1	11.5 ± 6.7	11.7 ± 6.0	11.1 ± 6.8	10.0 ± 5.6	8.0 ± 4.8	13.0 ± 5.9	10.5 ± 6.1	11.7 ± 6.4	10.8 ± 5.5
AI per lesion, mean ± SD	442.4 ± 48.8	431.3 ± 62.1	423.5 ± 34.9	436.7 ± 48.0	432.1 ± 48.1	455.9 ± 59.3	478.5 ± 38.5	418.9 ± 38.2	442.3 ± 40.9	436.6 ± 41.6

Mean ± SDs are presented unless otherwise specified. RPV indicates right pulmonary vein; LPV, left pulmonary vein; AI, ablation index.

Long-term effectiveness

The Kaplan-Meier analysis showed that at 12-month follow-up, freedom from any atrial arrhythmias lasting more than 30 seconds was 82.6% (109/132) (Fig. 3). The results in PAF and PsAF subgroup were similar (86.2% vs, 79.1%, P = 0.402). Among those patients with recurrence, six of them underwent repeat ablation. Cox regression analysis showed that female gender, procedure time, baseline impedance value and contact force were independent prognostic factors for recurrence during 12-month follow-up. (Table 5)

Table 5
Cox regression

	HR (95% CI)	P-value
Gender	2.35 (1.01–5.45)	P = 0.048
Procedure time	1.05 (1.01–1.10)	P = 0.025
Base impedance value	1.06 (1.01–1.11)	P = 0.031
Contact force	0.84 (0.71–0.98)	P = 0.029

Independent prognostic factors for recurrence during 12-month follow-up. HR, hazard ratio.

Safety analysis

During catheter ablation in 150 subjects, only two audible steam-pops without clinical sequelae occurred, which might be due to sudden higher contact force (40-45g) that happened at the anterior of LIPV and the anterior of RPV, respectively. One of the two patients had pericardial tamponade during the operation. The patient had an audible steam pop following pericardial effusion when the STSF was located at the anterior of LIPV. No spike cut-off happened while the maximum contact force achieved 45g. No other procedure/device related complications happened.

Discussion

The key findings of this study include:

AI guided higher-power short duration approach can shorten procedural and ablation time without having a negative impact on acute and 12-month success rate.

The places where spike cut-off most frequently happened (anterior carina of RPV, ridge between left atrial appendage and left pulmonary vein, and inferior of RPV), which can help to avoid incidence of steam pop in order to make sure the safety.

The quality of ablation lesion is essential to prevent PV reconnection, which is a major determining factor for AF recurrence.[10–14] The properties of the lesion during RF ablation are related to the ablation power, contact force, duration of application, catheter stability and electrode diameter of the RF catheter.[15] Compared with conventional RF ablation with moderate power (20-40w) for a relatively long duration (20-40s) at a CF of 10-20g, higher power and shortened application time can enhance catheter stability in a beating heart and result in optimal lesion formation.[16] Recently, a series of experimental and observational studies assessing the effectiveness and safety of high-power ablation have been conducted. A study using “uncontrolled” high-power ablation (50W) for PVI demonstrated a significantly shorter fluoroscopic time and LA procedural time, together with an increased risk of complications.[17] Another randomized controlled trial comparing high power with moderate power ablation showed a shorter ablation and procedure time with similar complication rate and the 12-month recurrence rate.[16] Our study found that the overall freedom from any atrial arrhythmias was 82.6% during 12-month follow-up, which was similar with that in other high-power short duration studies.[18,19] And gender (female), procedure time, baseline impedance value and contact force (CF) were independent prognostic factors for AF recurrence.

In our study, the higher-power ablation has achieved 100% acute success and first-pass PVI was 87.9% indicating a high-quality and contiguous lesion creation. As for the efficiency results, our study’s relatively short total procedure time (55min), ablation time (36min), and fluoroscopy time (7min) have marked a fast PVI procedure from traditional power ablation, which was consistent with other high-power ablation studies,[22,23] even though 50% of our patients were PsAF. Procedural efficiency can drive lab efficiency which has great impact in many large volume centers of China where each operator routinely treats 3–5 patients per day.

Our results also suggest that using impedance spike cut-off could help prevent steam-pops during catheter ablation and reduce subsequent procedural complications such as cardiac tamponade, as indicated with the low cardiac tamponade rate observed (0.8%). In our study, the cut off location were recorded and analyzed. It most frequently happened at anterior carina of RPV, ridge between left atrial appendage and left pulmonary vein, and inferior of RPV. A study reported that risk of steam pops increased with longer time of ablation and higher power of ablation.[25] As the power crucially affects local impedance drop,[26] spike cut-off, shutting off automatically if the impedance exceeds, might be a protector to avoid steam pops; In this case, we try to find locations where spike cut-off most frequently happened to prompt the places where steam pops might occur. To our knowledge, there are no studies demonstrating spike cut-off analysis, so our results could be a reference for other research. Two steam pops occurred probably because of sudden higher contact force, and cardiac tamponade was observed in one of the steam pops cases. In a prospective observational study investing the association of various catheter parameters on the audible steam pop occurrence during LA ablation, 59 audible steam pops were reported.[20] The locations of those steam pops were widely distributed without significant differences. The result of another prospective study with the sample size of 80 showed that one audible steam pop occurred during ablation of the carina between the LPV.[21] A high-power ablation study reported steam pops were perceived in 4 of 50 patients when ablating the left anterior segment.[22] It seems that the locations of steam pops were irregular. More evidence might be needed to help explore the location characteristics of steam pops. A study assessing the effect of CF, power and time on the risk of steam pop formation demonstrated that steam pops was more frequent in thinner tissue, at longer ablation times, and at higher powers.[25] In our study, both patients who had steam pops did not had spike cut-off, which suggests that besides impedance changing, other factors such as excessive CF may also be important factor. Lastly, the low complication rate reported in our study is consistent with other high/higher-power ablation studies.[22–24]

There are two main limitations to this study. First, this study was a single-arm, single-center, observational study and only 132 patients were enrolled. Further comparative, multi-center, randomized trials with larger sample size should be conducted to evaluate the clinical outcomes. Second, the locations of impedance spike cut-off and gaps were not recorded according to the nine segments in the lesion analysis, making it hard to analyze the correlation between the ablation parameters and the events. However, the exploration of locations of spike cut-off occurred was really an interesting outcome, which might help operations recognize locations where steam pops may be easy to occur.

Methods

Study design

This single-center, retrospective real-world study used the de-identified data retrieved from the electronic medical records (EMR) at the First Affiliated Hospital of University of Science and Technology of China, from June 2019 to June 2020. The study was approved by the hospital (KY 2019080). The inclusion criteria were: (1) age > 18 years old; (2) underwent primary radiofrequency catheter ablation. Patients were excluded if they met any of the following criteria: (1) left atrial (LA) diameter > 50mm, (2) uncontrolled heart failure or NYHA function class III or IV, (3) life expectancy less than 12 months. All patients were monitored for AF recurrence using Holter for 7 days at 3, 6, 9 and 12 months.

Ablation Procedure and follow-up

All procedures were performed under general anesthesia. Fast anatomical mapping of the left atrium was performed with the PentaRay catheter. Subsequently, all patients underwent bilateral PVI. AI-guided point-by-point ablation encircling ipsilateral pulmonary veins was performed using Thermocool SmartTouch SF (STSF) catheter. Ablation power was set to 40-50W targeting AI values (480–500 anterior, 400–420 inferior and posterior, 460–480 roof and 500–520 ridge) and interlesion distance ≤ 6mm. The segments’ structure was showed as Fig. 4. The spike cut-off on the generator was designated as 15 ~ 20% of base impedance. If the impedance spikes higher than the number set, the RF energy will automatically shut off by the RF Generator within 1 second. The Visitag Module was utilized to visualize RF applications using the following stability criteria: 2.5mm maximum range, 3s minimum time, 2 maximum point size. Additional linear ablation was performed if a left atrium indicates low voltage regions was observed. Following this, a 20-minute waiting period was observed to uncover any dormant conduction.

Outpatient clinical visits were planned at 3, 6, 9 and 12 months after the procedure. A 7-days Holter was obtained at each clinic visit. AF recurrence was defined as episodes of any atrial arrhythmias lasting ≥ 30 seconds.

Study outcomes

The following main procedural endpoints were included in the outcomes evaluation: acute PVI success rate, procedure time, total RF ablation time, fluoroscopy time and dose, first-pass PVI rate, impedance value, the number of pulmonary vein application, spike cut-off rate and segments. Ablation lesions' AI value per lesion, RF time per lesion, impedance drop per lesion and contact force per lesion were also evaluated.

The long-term effectiveness endpoint was examined by AF recurrence rate during 12-month follow-up. The safety endpoints included the incidence of acute (within 7 days of procedure) and chronic procedure/device related complications up to 1 year.

Statistical analyses

Patients were excluded from the analysis without imputation if they were lost to follow-up time or died prior to the last follow-up. Descriptive statistics and statistical comparison were used to evaluate the baseline, effectiveness, efficiency and safety endpoints. Descriptive analyses were reported as mean (standard deviation) for continuous variables, or count and percentage for categorical variables. The time to recurrence was estimated using the Kaplan-Meier method.

In addition, a subgroup analysis was also conducted in this study. The included patients were divided into two subgroups according to the patient was diagnosed as either persistent AF(PsAF) or paroxysmal AF(PAF). Baseline characteristics and all study outcomes were compared between two subgroups. The study applied the Welch's t-test when appropriate for continuous variables and the Chi-Square test for categorical variables to determine whether the differences observed across the two subgroups were significant.

Cox proportional-hazards model was used to analyze the correlation between baseline and intraoperative characteristics and recurrence during 12-month follow-up. R (version 4.0.1) software has been used to perform the statistical analyses in this study. All statistical comparisons were two-sided tests at significant level of 0.05.

Conclusion

AI-guided higher-power ablation together with spike cut-off appears to be a safe and effective ablation technique for AF and leads to a high overall success rate at 12 months in China.

Declarations

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Ethics statement

We can confirm that all methods were carried out in accordance with relevant guidelines and regulations.All procedures were approved by the Ethics Committee of The First Affiliated Hospital of USTC (Hefei, China; approval no. 2019 KY080).we can confirm that informed consent was obtained from all subjects and/or their legal guardian(s).

Author contributions

F.G. carried out the study. J.X. and F.G. substantially contributed to the concept design for the work. F.G,J.X, J.L, J.Z, H.Z, H.S., C.Z and J.X contributed to the data collection and the interpretation of data. All authors contributed to the data analysis. F.G. participated substantially in drafting the manuscript. All authors contributed substantially to critical editing and revising of the manuscript. All authors had final approval of the final version of the manuscript.

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Data availability statement

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Additional Information

Trial registration：Chinese Clinical Trial Registry ChiCTR1900026316. URL: http://www.chictr.org.cn/showproj.aspx?proj=43903.

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Figures

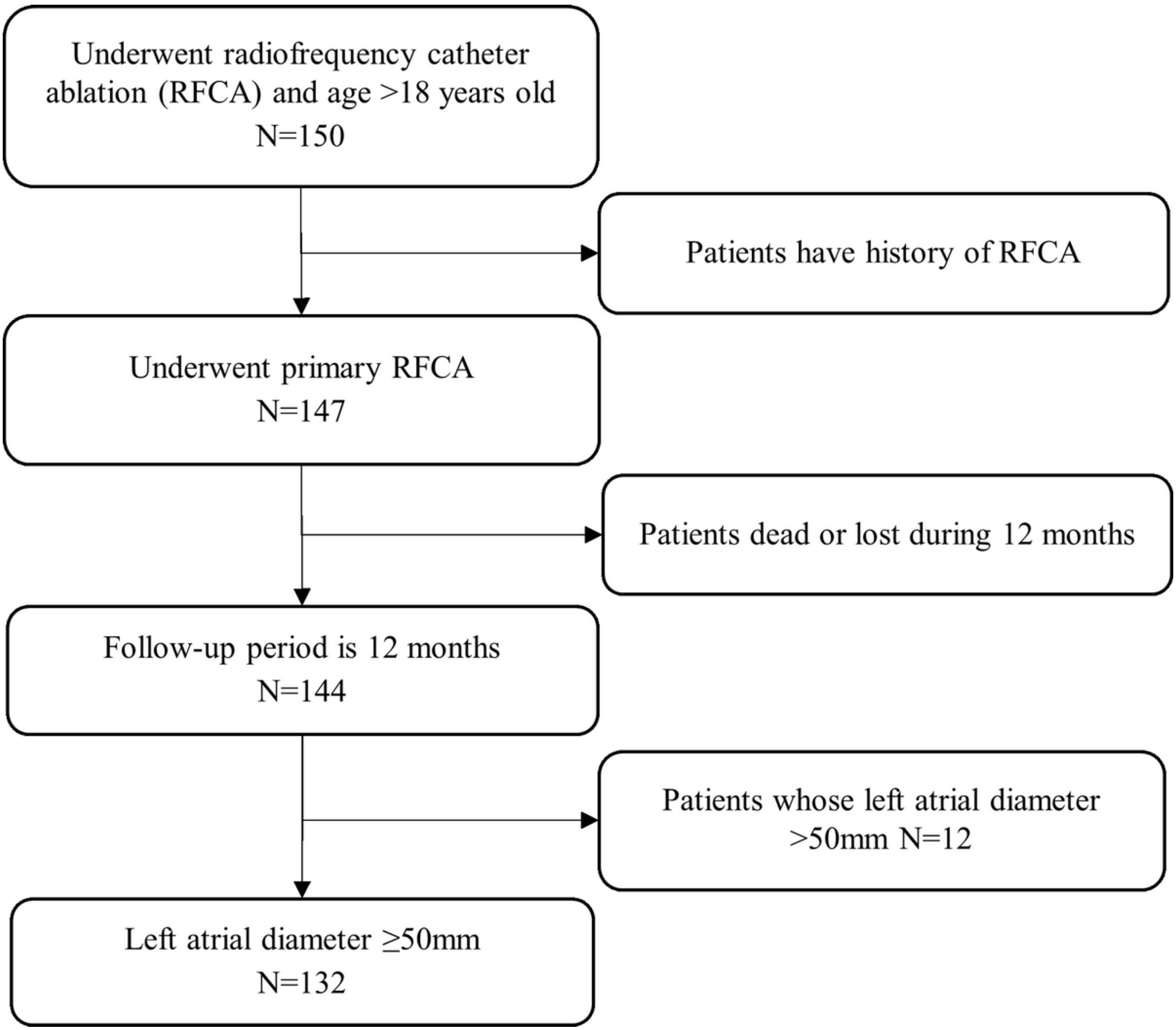

Figure 1

Patients Flow. The patient sample size included in the study under the inclusion and excluded criteria which were mentioned in the methods.

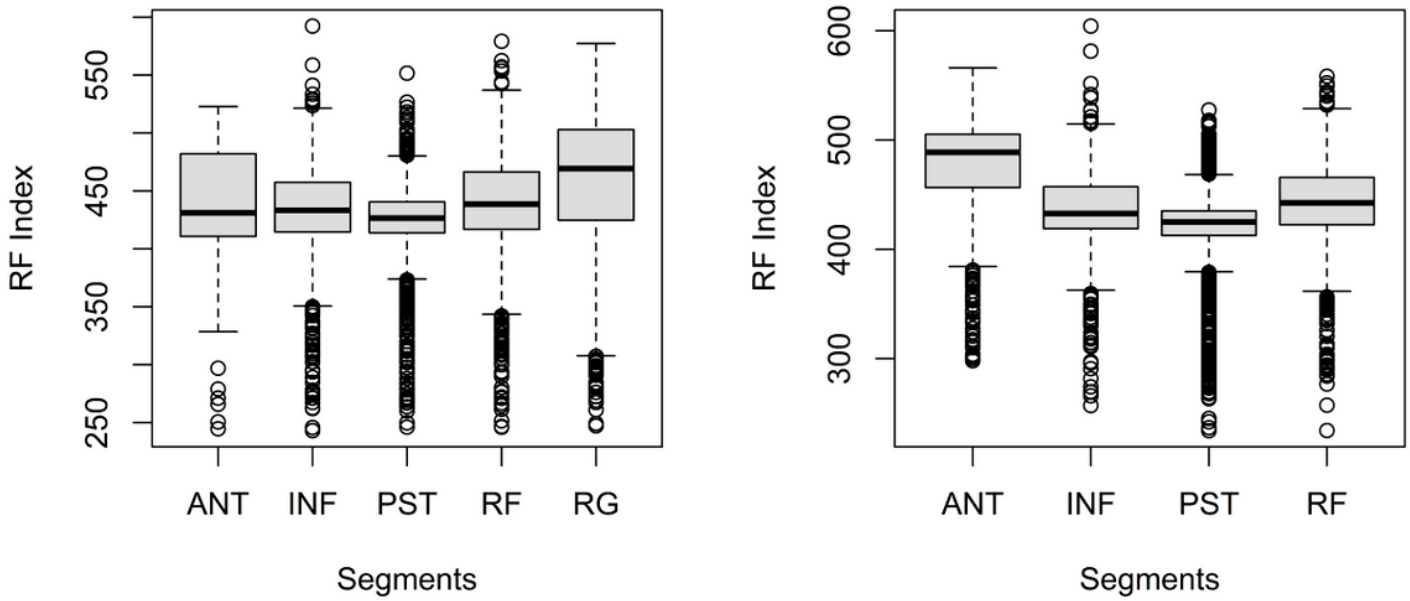

Figure 2

Box plot of ablation index (AI) values of nine segments. Box plot denotes the minimum, maximum, first quartile, third quartile, median and outliers of AI values.

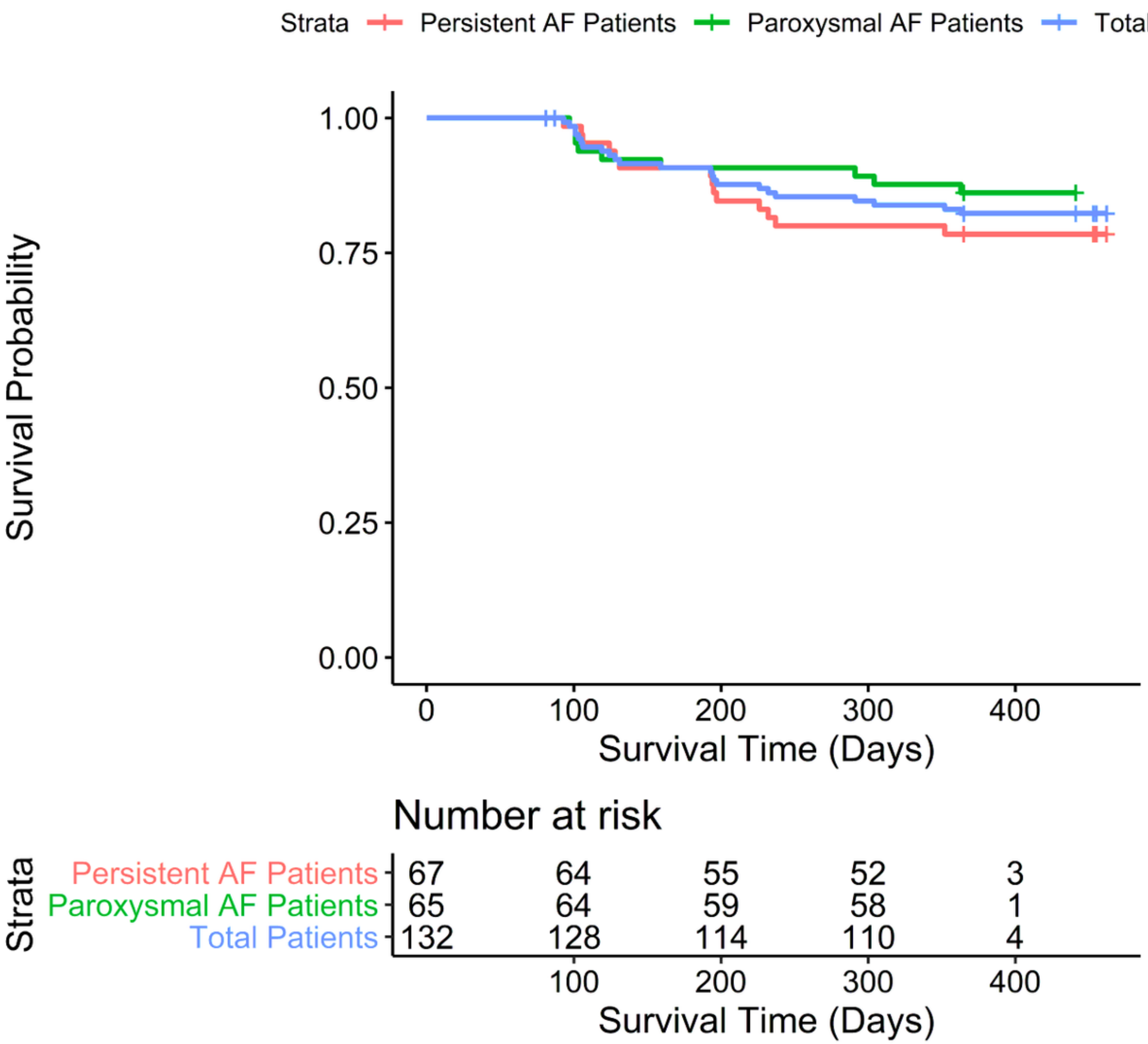

Figure 3

Kaplan−Meier survival curves. Survival rate for atrial fibrillation (AF) recurrence-free survival within 1-year after catheter ablation in overall, paroxysmal atrial fibrillation (PAF) patients and persistent atrial fibrillation (PsAF) patients.

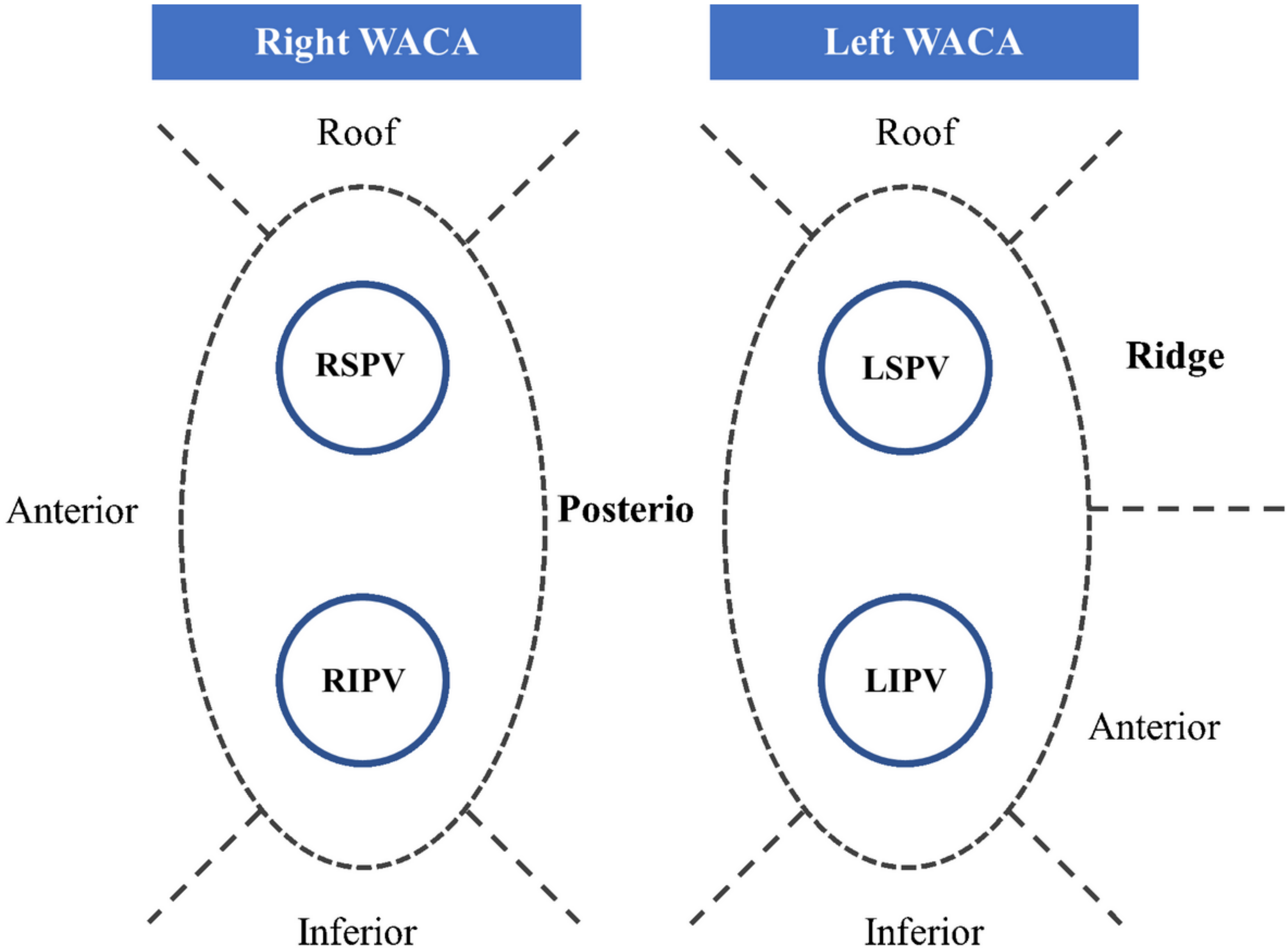

Figure 4

Nine Segments in the Radiofrequency Ablation Procedures. WACA, wide area circumferential ablation; RIPV, right inferior pulmonary vein; RSPV, right superior pulmonary vein; LIPV, left inferior pulmonary vein; LSPV, left superior pulmonary vein.